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Multisociety Consensus Quality Improvement Revised Consensus Statement for Endovascular Therapy of Acute Ischemic Stroke

From the American Association of Neurological Surgeons (AANS), American Society of Neuroradiology (ASNR), Cardiovascular and Interventional Radiology Society of Europe (CIRSE), Canadian Interventional Radiology Association (CIRA), Congress of Neurological Surgeons (CNS), European Society of Minimally Invasive Neurological Therapy (ESMINT), European Society of Neuroradiology (ESNR), European Stroke Organization (ESO), Society for Cardiovascular Angiography and Interventions (SCAI), Society of Interventional Radiology (SIR), Society of NeuroInterventional Surgery (SNIS), and World Stroke Organization (WSO), D. Sacks, B. Baxter, B.C.V. Campbell, J.S. Carpenter, C. Cognard, D. Dippel, M. Eesa, U. Fischer, K. Hausegger, J.A. Hirsch, M.S. Hussain, O. Jansen, M.V. Jayaraman, A.A. Khalessi, B.W. Kluck, S. Lavine, P.M. Meyers, S. Ramee, D.A. Rüfenacht, C.M. Schirmer and D. Vorwerk

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ABBREVIATIONS: ASPECTS = Alberta Stroke Program Early Computed Tomography Score; EVT = endovascular therapy; mRS = modified Rankin Scale; mTICI = modified thrombolysis in cerebral infarction; NIHSS = National Institutes of Health Stroke Scale; QI = quality improvement; SAH = subarachnoid hemorrhage; SICH = symptomatic intracranial hemorrhage; SITS-MOST = Safe Implementation of Thrombolysis in Stroke Monitoring Study; TICI = thrombolysis in cerebral infarction; TIMI = thrombolysis in myocardial infarction; TPA = tissue plasminogen activator

Endovascular therapy (EVT) for acute ischemic stroke in selected patients has recently been proved effective in several clinical trials, and the widespread adoption of thrombectomy into routine clinical practice has begun. However, these acute stroke services are resource-intensive, including advanced cerebral im-

aging and highly trained multidisciplinary hospital teams rapidly responding to emergency activation. Despite the previous acceptance of intravenous fibrinolysis for acute ischemic stroke and the development of designated stroke centers,¹ ischemic stroke remains a leading cause of adult death and disability.² Many patients are not candidates for fibrinolysis, and intravenous therapy is relatively ineffective for severe strokes as a result of large cerebral artery occlusions. Moreover, it is uncertain if the benefits of endovascular stroke treatment in the trial setting can be generalized to clinical care provided by hospitals and teams of varying training, experience, and case volume. In other medical disciplines, rapid technologic advancement required guidelines to utilize these tools effectively and responsibly.³ Quality-improvement (QI) metrics for the outcomes of endovascular ischemic stroke treatment were published by a multisociety, multispecialty, international consensus group in 2013.⁴ These QI metrics have been accepted at a national level in Great Britain and Ireland⁵ but have yet to be included into stroke center accreditation requirements in the United States. Subsequent to the publication of the prior QI guidelines, eight randomized trials and several meta-analyses of EVT have been published.^{6–20} These randomized trials have established EVT as standard of care when available,^{5,21–23} and provide additional data on which to update the metrics and bench-

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Table E1 is available online at www.jvir.org/cms/attachment/2119125784/2089482678/mmcl.xlsx.

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Table 1: mTICI revascularization scale scores^{30,31,113}

Score	Description
0	No perfusion, complete obstruction; no flow past occlusion of “major” vessel
1	Perfusion past initial obstruction but limited distal branch filling with little/slow distal perfusion
2a	Partial perfusion: <50% of “major” vascular territory perfused (eg, filling and complete perfusion through one M2 division)
2b	Partial perfusion: ≥50% of major vascular territory is filled, but there is not complete and normal perfusion of entire territory
3	Complete or full perfusion with filling of all distal branches

Note:—mTICI indicates modified thrombolysis in cerebral infarction.

marks of the previous paper.⁴ Therefore, it is now appropriate to revise the prior QI document based on new evidence.

Revision of this QI consensus statement remains focused on processes of care and patient outcomes. Other documents address standards for physician training^{24,25} and recommendations for patient selection and treatment methods.^{5,23} As in the previous guidelines, it is intended that these benchmarks be used in a quality-improvement program to assess and improve processes and outcomes in acute stroke revascularization. The benchmarks provide the consensus process and outcome consensus measures called for by the Stroke Treatment Academic Industry Roundtable (STAIR) IX for the next generation of endovascular trials.²⁶ The benchmarks may also be suitable for accreditation of stroke intervention programs. Most of the metrics apply to the role of the interventional physician, regardless of specialty or particular board certification, but comprehensive stroke care requires a broad multidisciplinary process involving care that ranges from emergency dispatch of paramedics through acute hospital care and posttreatment subacute rehabilitation. Therefore, although it is not the intention of this document to assess in detail the quality of facilities, some of the metrics also apply to institutional policies and procedures for stroke care.

MATERIALS AND METHODS

A literature search was conducted by using Ovid and EMBASE from 2012 (from the last date of the literature search for the first publication of these metrics)⁴ to October 2015 by using article titles that included the following: (acute ischemic stroke OR cerebrovascular accident OR stroke) AND (intra-arterial OR intra-arterial OR endovascular OR angioplasty OR stent OR stent retriever OR mechanical thrombectomy OR thrombolysis OR tissue plasminogen activator [TPA] OR TPA OR urokinase OR streptokinase OR TPA OR urokinaseR alteplase OR tenecteplase). Additional articles were then solicited from writing group members. An evidence table (Table E1, available on-line at www.jvir.org/cms/attachment/2119125784/2089482678/mmcl.xlsx) was constructed by using articles that were randomized controlled trials, registries, or case series of at least 100 patients, and some case series of less than 100 patients were included if the series provided uniquely useful data. From the evidence table, metrics were chosen that were believed to be important markers of quality of care. Thresholds for metrics were then chosen by consensus of the writing group based on review of the evidence table. Consensus was defined as 80% of the writing group. If consensus was not achieved during discussion, a modified Delphi process was used to obtain consensus.²⁷ If consensus was not achieved after the modified Delphi process, a threshold was not chosen. The evidence table was then updated by using the same search terms in February 2017 at the time of completion of

the draft of the document to allow updating of the metrics if appropriate.

Standards for developing clinical practice guidelines were reviewed.²⁸ It was determined that most of these standards were not applicable for this document that updates quality benchmarks for processes and outcomes of care rather than creating recommendations for types of patient care. For this reason, this revision has been changed to a consensus statement rather than a guideline.

DEFINITIONS

Measures and metrics will depend on the definition of a good outcome or a complication and the time at which patients are assessed for these outcomes, as many patients show gradual improvement following an ischemic stroke. Numerous trials have used varying definitions for similar concepts. The definitions used in this document were derived from review of these trials and then consensus of the writing group.

Ischemic Central Nervous System Infarction. A uniformly accepted simple definition of central nervous system infarction remains elusive. A successful multidisciplinary attempt arrived at a definition as follows²⁹:

Central nervous system infarction is defined as brain, spinal cord, or retinal cell death due to ischemia, based on:

1. Pathological, imaging, or other objective evidence of cerebral, spinal cord, or retinal focal ischemic injury in a defined vascular distribution; or
2. Clinical evidence of cerebral, spinal cord, or retinal focal ischemic injury based on symptoms persisting at least 24 hours or until death, and other etiologies excluded.

Door-to-Event Time. The term “door” is used to determine the time of onset of medical care, as in “door to time of CT imaging.” It is defined as the time of arrival in the emergency department for an outpatient or the time first discovered to have a stroke for an inpatient. When patients are transferred, “door” refers to the arrival (ie, registration) time at the receiving facility.

Time to Thrombus. Time to thrombus is considered to represent the start of endovascular lytic infusion or first placement of a mechanical device in the target vessel.

Successful Revascularization. Successful revascularization is considered to represent modified thrombolysis in cerebral infarction (mTICI)^{30,31} grade 2b or 3 flow through the previously occluded vessel segment (Table 1).

Symptomatic Intracranial Hemorrhage. Symptomatic intracranial hemorrhage (SICH) is a parenchymal hematoma type II (per the Safe Implementation of Thrombolysis in Stroke Monitoring Study [SITS-MOST] definition)³² or subarachnoid hemorrhage

Table 2: mRS Scores³⁵

Score	Description
0	No symptoms
1	No significant disability: able to carry out all usual activities despite some symptoms
2	Slight disability: able to look after own affairs without assistance but unable to carry out all previous activities
3	Moderate disability: requires some help but able to walk unassisted
4	Moderately severe disability: unable to attend to own bodily needs without assistance and unable to walk unassisted
5	Severe disability: requires constant nursing care and attention, bedridden, incontinent
6	Dead

Note:—mRS indicates modified Rankin Scale.

(SAH) with neurologic deterioration leading to an increase in National Institutes of Health Stroke Scale (NIHSS) score >4 or leading to death within 36 hours of treatment. Because of the risk of vessel perforation during endovascular procedures, SAH has been added as a cause of intracranial hemorrhage to the SITS-MOST SICH definition.³³

This definition is similar to that used in the recent randomized trials of EVT.^{7,11,15} Several of the authors of those trials have joined others in proposing a new definition of SICH.³⁴ These new definitions have not yet been validated on a larger scale, adopted in stroke trials, or applied to the outcomes of the recent randomized trials. Therefore, the original definition of SICH is maintained in the present revision of the consensus statement and modified to include any intracranial hemorrhage associated with a decrease in NIHSS score >4 or death within 24 hours of the end of the revascularization procedure.²⁰

Good Clinical Outcome. A good clinical outcome is a measure of neurologic functional with a score of 0–2 on the modified Rankin Scale (mRS; Table 2)³⁵ assessed 90 days after treatment. This does not exclude clinically significant benefit in patients in whom an mRS score of 2 is not achieved.

INDICATIONS AND CONTRAINDICATIONS

EVT for acute ischemic stroke with large vessel occlusion is established in guidelines as the standard of care.^{22,36} If the patient is also eligible for intravenous TPA, this drug should be administered as a “bridging” strategy in parallel without delaying thrombectomy. Waiting to assess “response” to TPA is strongly discouraged,²² as clinical improvement may not indicate recanalization. The rate of TPA-induced recanalization before thrombectomy (performed without delay) was $<10\%$ in recent randomized trials.^{11,13,20} Proceeding directly to thrombectomy (ie, direct thrombectomy) should be performed in appropriate candidates with a contraindication to TPA, including risk of hemorrhage or when >4.5 hours have elapsed since stroke onset.

Indications and contraindications for EVT are based on subgroup analyses of randomized trials and case series. Clinical trials tend to have more restrictive criteria, whereas case series represent more of a “real-world” experience. Potential selection criteria are based on stroke severity, time (ie, duration of symptoms), imaging, clot location, age, and comorbidities.

Stroke Severity. Clinical trials have set variable NIHSS score limits for eligibility, often requiring ≥ 6 , 8, or 10 points. The Multi-center Randomized Clinical Trial of Endovascular Treatment for Acute Ischemic Stroke in the Netherlands (MR CLEAN) trial had a minimum NIHSS score of 2 and Extending the Time for Thrombolysis in Emergency Neurologic Deficits-Intra-Arte-

rial (EXTEND-IA) had no NIHSS score limits, but, given the requirement for large vessel occlusion, few patients with NIHSS scores <6 were enrolled.³⁷ Individual patient data meta-analysis of five positive randomized trials¹⁴ demonstrated highly consistent treatment effects across the NIHSS score spectrum, at least for NIHSS scores ≥ 6 . Data from observational studies have demonstrated an important incidence of large vessel occlusion in patients with clinically mild stroke and a propensity for these patients to later experience neurologic deterioration.³⁸ The risk/benefit in patients with low NIHSS scores therefore needs to be carefully considered, and future studies have to address whether endovascular procedures are beneficial in patients with mild symptoms and proximal vessel occlusion. There are no data supporting an upper limit on stroke severity.

Time. Most trials of intra-arterial lytic agents and mechanical revascularization devices have historically required start of treatment within 6 or 8 hours^{39–42} for anterior-circulation strokes. The strongest evidence for EVT is for treatment commenced within 6 hours.^{14,43} More rapid time to reperfusion has been linked to improved clinical outcomes and is therefore an important consideration in patient selection.^{43–45} A few patients in recent trials were treated at 6–8 hours in the Randomized Trial of Revascularization with Solitaire FR Device versus Best Medical Therapy in the Treatment of Acute Stroke Due to Anterior Circulation Large Vessel Occlusion Presenting within Eight Hours of Symptom Onset (REVASCAT) trial¹⁵ and at 6–12 hours in the Endovascular Treatment for Small Core and Anterior Circulation Proximal Occlusion with Emphasis on Minimizing CT to Recanalization Times (ESCAPE) trial.¹³ Individual patient data meta-analysis suggests significant benefit to at least 7 hours, 18 minutes.⁴⁶ Observational studies have suggested that patients presenting at later time points with favorable imaging findings still benefit from reperfusion,⁴⁷ and this was confirmed in the DWI or CTP Assessment with Clinical Mismatch in the Triage of Wake-Up and Late Presenting Strokes Undergoing Neurointervention with Trevo (DAWN) trial,⁴⁸ which used clinical-core mismatch criteria to select patients 6–24 hours after the “last known well” time. In the DAWN trial,⁴⁸ independent functional outcome occurred in 48.6% of patients who underwent endovascular treatment versus 13.1% of control patients ($P < .0001$) with similar revascularization success as 0–6-hour thrombectomy trials and no variation in treatment effect between the 6- to 12-hour and 12- to 24-hour treatment windows. Other randomized trials in extended time windows are ongoing.^{49,50} Vertebrobasilar occlusions have been treated at extended times, sometimes more than 24–48 hours after symptom onset.^{51,52} This is partly because of the traditional definition of onset as the last known well time. Patients with basi-

lar artery occlusion may have prodromal mild symptoms in 60% of cases before the development of severe deficits.⁵³ The Basilar Artery International Cooperation Study (BASICS) registry⁵³ advocated using time of severe deficit (ie, likely moment of occlusion) and found that good outcome with reperfusion beyond 9 hours of that time was extraordinarily rare.⁵³ Randomized trials in patients with basilar artery occlusion are ongoing.^{54,55}

Imaging. Noncontrast CT has been an essential component of patient selection in randomized trials of intravenous and endovascular revascularization for treatment of acute stroke.^{1,7,11,13,15,20,39–41,56} Absolute noncontrast CT contraindications to endovascular treatment are similar to those for intravenous thrombolytic agents and include the presence of acute intracranial hemorrhage or a significant established infarct.¹

Infarct size can be approximated on noncontrast CT by using the Alberta Stroke Program Early CT Score (ASPECTS).^{57,58} However, the score is not closely related to infarct volume or functional eloquence and has variable interrater agreement, particularly early after stroke onset. In recent randomized trials, there was clear benefit in patients with ASPECTS 6–8 and 9/10. Relatively few patients with ASPECTS 0–5 were included in the trials. The benefit in this group appeared to be of lesser magnitude, but a clinically meaningful benefit could not be excluded.¹⁴ Patients with ASPECTS 3–5 will be evaluated in a randomized trial.⁵⁹

The hyperdense middle cerebral artery sign can alert clinicians to the presence of a large vessel occlusion. This sign has a high degree of sensitivity if thin (~1-mm) slices are reconstructed and good specificity if clearly asymmetric compared with the contralateral artery.⁶⁰ Clot length on noncontrast CT of more than 8 mm has been associated with lower recanalization rates after intravenous TPA,⁶¹ but this is not absolute,⁶² and none of the positive randomized trials considered clot length in determining eligibility. The Randomized, Concurrent Controlled Trial to Assess the Penumbra System's Safety and Effectiveness in the Treatment of Acute Stroke (THERAPY) trial that used this criterion was neutral.¹⁸ There is evidence that occult anterograde flow can be associated with TPA-induced recanalization even in the presence of a long thrombus.⁶³

The target vessel occlusion should be established by using noninvasive angiography (CT or MR imaging), as practiced in all the positive randomized trials. This also provides information on proximal arterial pathology and catheter access. CT angiography has also been used to grade the quality of collateral flow. However, there is potential for standard single early-phase acquisitions to underestimate late-arriving collateral flow and therefore exclude patients who may benefit. Dynamic angiography derived from CT perfusion or multiphase CT angiography acquisitions avoids this pitfall.⁶⁴

Many centers use CT perfusion to improve diagnostic sensitivity and provide an estimate of tissue viability, which is closely related to the quality of collateral blood flow. A large volume of ischemic core (eg, >70 mL) on CT perfusion is certainly associated with a worse prognosis, but whether this alters treatment effect within 6 hours of stroke onset is yet to be clarified. Some case series have suggested a benefit of reperfusion even in patients with a large ischemic core >100 mL.⁶⁵ Analysis of the MR CLEAN

trial did not reveal treatment effect heterogeneity between cases of <70 and >70-mL core, although the absolute probability of independent functional outcome in those with a core >70 mL was only 8%.⁶⁶ Rather than excluding patients from treatment as a result of a large ischemic core, the presence of favorable imaging may be useful in deciding to pursue treatment in patients with otherwise less favorable clinical characteristics. Estimation of ischemic core volume by using CT perfusion combined with age and NIHSS score in clinical-core mismatch was shown to identify patients who benefit from thrombectomy in the extended time window of 6–24 hours in the DAWN trial.⁴⁸

MR imaging with diffusion imaging, with or without perfusion imaging, is increasingly used in some centers. There are some logistic challenges of safety screening and rapid access to MR scanners that have to be overcome to avoid relevant delays in treatment. However, in the high-performing centers in the Solitaire With the Intention For Thrombectomy as PRiMary Endovascular treatment (SWIFT PRIME trial),⁴⁴ there was no significant difference in arrival to randomization time according to image technique (ie, CT versus MR imaging), suggesting that MR-related delay is not inevitable. Uncertainties regarding whether core volume is truly treatment effect-modifying or simply prognostic apply, as discussed with CT perfusion.⁶⁵ It is also important to note that measured perfusion lesion volumes vary between processing software programs and the thresholds used to estimate ischemic core may vary with time.⁶⁷

Clot Location. The randomized trials demonstrated clear benefit in internal carotid artery terminus and M1 (ie, first segment of middle cerebral artery) occlusion, with or without tandem occlusion in the cervical carotid artery.^{10,14} Arterial occlusions arising more proximally are associated with poorer outcomes. Most notably, “T-lesions” have the poorest outcomes among anterior-circulation strokes.^{68,69} Proximal M1 occlusions have worse outcomes than distal M1 occlusions as a result of occlusion of lenticulostriate arteries and basal ganglia infarction, with an increased risk of reperfusion hemorrhage.⁷⁰ More distal M2 occlusions were less common among trial patients, and a clear benefit was not demonstrated, although there was no significant heterogeneity in treatment effect observed. Many patients with M2 occlusions were assessed as having M1 occlusions at the site and reclassified as having M2 occlusions by the core laboratory, leading to a predominance of larger, more proximal occlusions. Some case-control studies have suggested that benefit persists in M2 occlusions, with similar safety as M1 occlusions.⁷¹ Basilar artery occlusion was not included in the recent trials, in some cases because of perceived lack of equipoise and in others because of concerns regarding excessive heterogeneity. The BASICS trial⁵⁴ is ongoing, but many sites regard the dismal prognosis if untreated and the clear improvement associated with recanalization as sufficient grounds to treat. EVT for occlusions in the anterior cerebral artery, M3/4 segments, and posterior cerebral artery has not been systematically studied. More distal vessels are smaller and more tortuous, which potentially increases procedural risk, and the smaller territory at risk and increased efficacy of TPA reduces the benefit. Further device development may alter this balance in the future.

Age. Although increased age is associated with a worse prognosis after stroke in general, the recent trials have clearly demonstrated a treatment effect in patients aged >80 years of at least the same magnitude as in younger patients. Indeed, there is a significant mortality benefit in elderly patients, with 20% absolute risk reduction (number needed to treat = 5).^{10,14} Importantly, the trials included only patients with independent premorbid function, regardless of age, and the potential quality-of-life benefit for patients with significant comorbidities needs to be weighed in clinical practice. Prestroke dementia before endovascular reperfusion has been linked with a low probability of achieving a good clinical outcome.⁷² Some trials have therefore excluded patients aged >80 years.⁷³ Older patients may also have tortuous arterial access, which can complicate the procedure.

Medical Comorbidities. Most contraindications to intravenous thrombolysis do not apply to EVT. Overall, mechanical thrombectomy (with or without intravenous TPA) has a similar risk of SICH compared with TPA alone.^{10,14} There are relatively limited data on the safety of EVT in patients with markedly abnormal coagulation (eg, International Normalized Ratio >3.0 or current use of novel or direct oral anticoagulant agents), and risks and benefits need to be considered on an individual basis.

The criteria chosen to select patients for treatment will affect outcomes. Patients at higher risk are more likely to do poorly with or without treatment, but selection of only patients at low risk will deny clinical benefit to a large number of severely ill patients. Because published selection criteria vary, there is no single “correct” list of inclusion and exclusion criteria. The American Heart Association has published class I recommendations for EVT patient selection,²² but 40%–50% of patients are now being treated outside of these class I recommendations.^{74,75} Based on published data and the desired ratio of benefit to risk, each institution will need to create and follow its own indications and contraindications.

Metric 1: At least 90% of patients who meet the institutional selection criteria (ie, indications/contraindications) should be treated with endovascular therapy.

PROCESS AND OUTCOMES METRICS

In general, previously published endovascular stroke therapy metrics⁷⁶ were designed to measure aggregate performance of hospital or clinical outcomes. They were neither designed nor intended to define individual physician performance. In contrast, this document provides requirements for performance criteria for the individual practitioner and the facility. The purpose of these metrics is to define the minimum standards for EVT in acute ischemic stroke patients. It is recognized that a concerted team effort is required to ensure efficient workflow, timely EVT, and safe, effective care.

The recent endovascular trials have reiterated the importance of appropriate patient selection and procedural performance such as timely and more complete revascularization to improve the likelihood of achieving a good clinical outcome. This paradigm is based on selecting patients with potentially salvageable ischemic penumbra. A noncontrast head CT/MR study and vascular imaging such as CT/MR angiography will demonstrate areas of estab-

lished infarct and presence of a proximal large vessel occlusion, respectively, and provide vital information to select patients for endovascular therapy.

Data Collection

From a quality-assurance perspective, endovascular therapy for acute ischemic stroke differs slightly from other areas in which quality initiatives, morbidity, and mortality discussions focus on specific events in which errors in care or complications occurred. The measure of benefit from endovascular stroke therapy is not based on single or isolated cases, but rather is expressed as a percentage of aggregated patients treated who can function independently at 3 months. This has also been measured by using shift analysis in the recent endovascular trials.⁷⁷ As demonstrated in those trials, clinical benefit from EVT is dependent on delivery of high-quality care in a timely manner at the institutional level by a dedicated team.

As such, performance metrics from large aggregates of patients treated by endovascular means are compared versus performance standards in clinical trials in which benefits were demonstrated, recognizing that patients may be treated outside trial inclusion criteria on a case-by-case basis. This requires all patients’ procedural, process, and clinical outcomes to be entered into a data base, trial, or registry.^{24,76,78–80} Without the denominator of “all patients,” measures of success and percentage descriptors are meaningless. These data allow comparison of metrics against benchmarks for individual operator performance, risk-adjusted clinical outcomes, and individual and institutional process measures.

As stated in a prior document concerning Comprehensive Stroke Centers,⁷⁶ it is advantageous to collect data in a standardized fashion to avoid redundant efforts. Data collection tools such as multicenter registries will serve as useful benchmarks and will facilitate an ongoing process of constant evaluation. Multicenter registries are recommended over institutional registries because of the ability to serve as a benchmark against other institutions. There are numerous examples of such data-collection tools for treatment of acute ischemic stroke.^{78,80–82} A recent publication looking at trends in endovascular therapy and clinical outcomes within the Get With The Guidelines–Stroke registry⁸³ demonstrates the utility of strict data collection within well-maintained nationwide data base systems.

Data collection for EVT is closely tied in with the process already in place for patients who are eligible for intravenous thrombolytic therapy and starts with documentation of time of onset and the time the patient arrives at the “door.” This could mean (i) the door of a primary stroke center, where data collection should ideally start, or, (ii) in cases being transferred to an endovascular center, the time of registration at the center that receives the patient. The detailed time metrics will be discussed in the next section. Data collection, especially time points, should be as inclusive as possible, with subsequent metrics being reported by combining multiple elements. The mandatory threshold for collection of the minimum defined elements is 100%.

Data concerning demographic characteristics are used to identify various patient subgroups, whereas other data points are pertinent for risk adjustment and are necessary for evaluation of pro-

cedural and clinical outcomes. These would include factors specific to the individual case, such as location of occlusion and time from onset, as well as demographic factors specific to patient subgroups, such as age, race, and sex. Ancillary data such as prognostic factors pertaining to comorbidity, stroke severity, and imaging parameters may help in risk- and severity-adjusted analysis to adjust for variability in case mix. Collection of these data points is necessary for an appropriate evaluation of patient risk factors and also for study of institutional factors that could influence overall patient outcomes and have a bearing on evaluation of operator performance.

At a minimum, these data should include age, sex, premorbid mRS score, NIHSS score, location of occlusion, various time points and intervals described in the subsequent sections, blood pressure, blood glucose level at presentation, and presence of atrial fibrillation. Specific data-collection metrics for EVT have already been included in national guidelines.^{22,23,36} Other data elements may be helpful and may become evident with further research, such as radiation exposure and contrast agent dose.

Metric 2: 100% of patients have the required minimum process and outcomes data entered into an institutional or national data base, trial, or registry.

Time Intervals

Emergency endovascular stroke treatment is one of the most complex multidisciplinary functions a medical institution chooses to undertake. Reperfusion treatment (intravenous or endovascular) achieved within the shortest period of time is widely accepted as a prerequisite for optimal clinical outcomes.^{45,84,85}

Subgroup analyses from several trials^{43,86,87} have shown that treatment delays resulted in significant decrease in the likelihood of a good outcome of endovascular stroke therapy. Analysis of the pooled data of 5 endovascular trials⁴⁶ confirmed this: every 1-hour delay in time from onset to arterial puncture results in a 5.3% shift in the direction of more disability on the mRS.

There are many steps from stroke onset to completion of treatment, and optimal and timely execution of each of these steps is necessary to achieve the stated goal. Numerous opportunities exist to minimize the time needed for each step from the time of the acute stroke to patient arrival to the hospital and then until reperfusion is achieved.

Process improvement for emergency stroke treatment should be an ongoing component of all stroke systems of care and should focus on all the tasks and activities in this complex sequence of events. These data are then used for quality assessment/assurance and process improvement and therefore directly relate to the eventual clinical outcome of the patients being treated by the team. To judge satisfaction of these performance goals in regard to expeditious delivery of care, time points and intervals are the units of measurement.

At a minimum, the time points and intervals specified in this document should be tracked in all cases. Institutions may choose to measure additional time points. The more time points that are recorded, the more exactly deficiencies might be identified; however, this may prove onerous to document from a resource perspective. For instance, delays in obtaining a CT scan may result from delay in ordering the study, delay in response by CT staff (eg,

multiple other procedures being requested at the same time), or delay related to transportation.

Acknowledgment of the critical importance of time to reperfusion for obtaining favorable outcomes in myocardial reperfusion treatments has led to the formation of initiatives such as “Door to Balloon: An Alliance of Quality” for patients with ST-segment elevation myocardial infarction. The key was achievement of a door-to-balloon time of <90 minutes for at least 75% of patients presenting directly to the treating hospital by using various strategies identified through research, resulting in dramatic reductions in times.^{88,89}

The impressive results in shortening the time to myocardial reperfusion for acute myocardial infarction obtained by such initiatives provided an impetus for launching similar initiatives related to intravenous TPA for stroke.⁹⁰ The Joint Commission has set a more ambitious goal of 80% of patients treated within 1 hour for primary stroke centers.⁹¹ The experience in reducing door-to-needle times reported by the group from Helsinki⁹² suggests that, with simple strategies, median door-to-needle times of 30 minutes or even less can be achieved. Because of the need for neurologic assessment and imaging in addition to the emergency medicine and interventional components, acute stroke patients referred for EVT require more time for initiation of treatment than patients with ST-segment elevation myocardial infarction. Although rapid-response mechanisms aiming to result in initiation of revascularization therapies within the minimum amount of time can be modeled according to the myocardial infarction experience, it should be recognized that acute stroke treatment, especially EVT, requires a far more complex infrastructure. Notwithstanding that, it is clear that, similar to the cardiology model, major improvements in door-to-treatment time need to take place to increase the proportion of favorable outcomes for patients treated with EVT for acute stroke.⁹³

Since the early years of endovascular stroke treatment, various time metrics have been reported, with a trend toward overall improvement in times. These were initially reported on the basis of case series,^{94,95} with newer metrics from registries,^{96,97} earlier device trials,^{98,99} and recent randomized controlled trials.¹⁰ These reports focused on median onset-to-groin puncture times ranging from 200 minutes in the latest randomized trials¹⁰ to 277 minutes in registry data.⁹⁷ Recent trial data¹⁰ have also reported various components of these times, breaking them down into intervals that include patient arrival times and imaging times. In the ESCAPE trial,¹³ the authors reported a median time from imaging to arterial puncture of 51 minutes and a median time from imaging to reperfusion of 84 minutes. The median imaging-to-puncture time in the SWIFT PRIME trial²⁰ was 57 minutes. The Highly Effective Reperfusion evaluated in Multiple Endovascular Stroke trials (HERMES) meta-analysis of treatment times from five recent large endovascular trials⁴⁶ reported better clinical outcomes with faster treatment times, with median door-to-imaging time of 19 minutes, imaging-to-puncture time of 76 minutes, and puncture-to-reperfusion time of 44 minutes in the entire cohort.

The endovascular trials represent optimal results based on study site and patient selection. Many of the endovascular trials included only study sites with a proved ability to respond rapidly,

excluded patients with carotid dissections or internal carotid artery–origin occlusions, and excluded patients who could not be treated rapidly. However, the reported times in recent trials did include time taken for patient randomization. These rapid responses have not been uniformly achieved in other trials, registries, or case series.^{18,100–102} Nevertheless, the time intervals in this consensus statement are intended to be achievable with good practice as centers become proficient at routinely performing endovascular therapies, and provide a benchmark for QI in current clinical practice. Moreover, many of the conditions and findings that, in the past, could have complicated decision-making, such as older age, extracranial carotid obstruction, vessel tortuosity, requirement for penumbral imaging, and requirement for general anesthesia, did not negatively influence treatment effect and should not delay the decision for treatment. The treatment of more complex cases than were included in the trials may prolong treatment times but should not prolong the time to arterial puncture.

As a general approach to setting metrics for care processes, we used data from the HERMES collaboration.⁴⁶ The 75th-percentile times (ie, slowest quartile) are considered minimum benchmarks, and the 25th-percentile times (ie, fastest quartile) from that study are considered achievable by the best centers with high volumes and good resource infrastructure. The metrics are intended to be used for measurements such that centers will progressively become faster and improve times from minimum acceptable to ideal.

The times reported in the following sections apply to anterior circulation occlusions, as vertebrobasilar occlusions were excluded in the recent randomized trials. These metrics should be applicable regardless of the time of the day and regardless of whether the patient presents on a weekday versus a weekend.¹⁰³ These metrics represent maximum recommended times. Because of ample evidence that, the shorter the time to reperfusion, the higher the likelihood of a favorable outcome, all centers should strive to initiate endovascular therapy within the shortest possible time frame. Although intravenous TPA administration should not represent a justification for excessive delays in initiation of endovascular therapy, it is acknowledged that intravenous thrombolysis may be associated with some delays in initiation of endovascular therapy.

Door to Imaging. Most hospitals will use CT-based imaging, but some hospital protocols may use MR imaging as the first imaging study. The use of CT angiography or MR angiography for vascular imaging is considered the standard of care for endovascular treatment based on recent trials and should be incorporated into the imaging protocol. Indeed, previously published guidelines on imaging in acute stroke patients¹⁰⁴ recommend that noninvasive vascular imaging be routinely performed, and it is recognized that the use of advanced multimodal imaging does not delay treatment times.¹⁰⁵ Regardless of the choice of technique based on institutional preferences, imaging should be started as quickly as feasible. Because of the difficulty in defining exactly when an order might have been entered in the system, this document is in agreement with the American Stroke Association recommendations that these time intervals be measured from arrival to start of imaging, which will also include vascular imaging. Interpretation of imaging is done in parallel and usually at the scanner by the treat-

ing team, and the time needed to interpret the scans and make a decision will be part of the overall time from the start of imaging to arterial puncture. In the HERMES meta-analysis,⁴⁶ the fastest 25% of cases had imaging initiated by 12 minutes, and 75% of patients had imaging initiated within 30 minutes.

Metric 3: 75% of patients being evaluated for revascularization should have imaging initiated within 30 minutes from time of arrival. At the best of centers with high volumes and an established resource infrastructure, this is expected to be achieved in 12 minutes.

Imaging to Puncture. The largest amount of time from door to revascularization comes from the steps from door to puncture rather than puncture to revascularization, and most endovascular treatment decisions are made after imaging. Therefore, the largest opportunities to reduce delays and improve outcomes will come from reducing imaging-to-puncture times. The recommended time from start of imaging to arterial puncture is 50 minutes or less. This is in keeping with the time intervals reported in the recent endovascular trials, which had a fastest 25th percentile of 51 minutes,⁴⁶ and it is the consensus of the writing group that this time metric is necessary, achievable, and consistent with the improvement in door-to-balloon times that have been achieved for acute myocardial infarction. The recent trials also reported that 75% of patients had an imaging-to-puncture time of no more than 110 minutes. For patients transferred from another site whose imaging does not need to be repeated, it is expected that door-to-puncture times can be reduced by 30 minutes.

Metric 4: 75% of patients treated with endovascular therapy should have an imaging-to-puncture time of 110 minutes or less. At the best of centers with high volumes and an established resource infrastructure, this is expected to be achieved in 50 minutes or less.

Metric 5: For patients transferred from another site in whom imaging is not repeated, 75% of patients being treated should have a door-to-puncture time of 80 minutes or less.

Imaging-to-Thrombus Time. Previous versions of this document have included imaging-to-thrombus time as a metric. This is no longer believed to be a necessary time point for measurement as a result of inaccuracies of measurement and inconsistent practice in documenting the same.

Puncture Time to Reperfusion. This metric assesses the efficiency of the interventional physician and team. Given the rapid advancements in endovascular treatment modalities, these recommendations are likely to change. In the Mechanical Embolus Removal in Cerebral Ischemia registry,⁴¹ the largest prospective endovascular data base to date reflecting procedural outcomes across a large variety of stroke centers in the United States, the median time from groin puncture to the end of the procedure was 90 minutes. Newer technologies such as “stentrievors” have been noted to achieve significantly shorter procedural times (median of approximately 50 minutes).⁴⁶

Although time to final angiography is easily measured, it may be variable depending on the need to perform thrombolysis of peripheral-branch occlusions after recanalization of the proximal occlusion, as more complete revascularization is likely to lead to

improved clinical outcomes, albeit at some increased procedural risk. The time metric described here for successful reperfusion represents the time to first reach an mTICI grade $\geq 2b$. Additional time, if required to achieve complete revascularization, ie, mTICI grade 3, is not reflected in this metric. Recent trials have published their time intervals, and, by doing so, set new expectations. Median time from groin puncture to reperfusion in the SWIFT PRIME trial²⁰ was 24 minutes (interquartile range, 18–33 minutes). The median puncture-to-reperfusion time in the HERMES collaboration⁴⁶ was 44 minutes (interquartile range, 27–64.5 minutes). Generally, we recommend that procedure times not exceed 60 minutes as in the recent trials, and the reperfusion target should be to reach mTICI grade $\geq 2b$.²⁰ This threshold is further clarified in the following section on recanalization/reperfusion.

Metric 6: In 70% of patients, mTICI grade $\geq 2b$ should be reached ideally within 60 minutes of arterial puncture.

Recanalization/Reperfusion

Revascularization is key to improving outcomes with endovascular stroke therapy. Recanalization of the occluded vessel and reperfusion of the distal capillary bed are measures of revascularization, and, although intimately linked, are not necessarily interchangeable. Of the two measures, reperfusion of the distal capillary bed is most linked with clinical outcome.¹⁰⁶ Reperfusion can be assessed by using CT or MR perfusion imaging. On angiography, crude assessment of reperfusion can be made by assessing blood flow into the distal bed, but this does not necessarily correlate with reperfusion on a microcirculatory level.¹⁰⁶ Although advances have been made in perfusion assessment in the angiographic suite,¹⁰⁷ this assessment is not readily available at the present time. Therefore, most interventionalists will rely on a combination of recanalization and reperfusion to assess revascularization.

Revascularization can be assessed in a number of ways, including the thrombolysis in cerebral infarction (TICI) scale,¹⁰⁸ the thrombolysis in myocardial infarction (TIMI) scale,^{109,110} the Mori reperfusion scale,¹¹¹ the Qureshi scale,¹¹² and the Arterial Occlusive Lesion score,¹¹³ among others. No direct comparisons of the revascularization scales in terms of their predictive ability for final infarct volume exist, but, through expert comparison of scales, the stroke and interventional community favors the use of the TICI scale.^{114,115} In a comparison of TIMI versus TICI scales, TICI was found to be superior to TIMI. The mTICI scale (Table 1) shifted the definition of a grade of 2b to reperfusion of $>50\%$ rather than $>66\%$ of the distal territory,³¹ and mTICI grade 2b/3 was used as the definition of procedural success in most successful endovascular trials. This is the scale recommended for future studies.³⁰ A further refinement to the TICI scale introduced a new category of 2c to define angiographic revascularization of $>90\%$ and $<100\%$ of the distal territory.¹¹⁶ However, the clinical applicability of TICI grade 2c has not been validated in larger prospective trials. Nevertheless, the higher the recanalization and reperfusion grade, the better the outcome, with particularly improved outcomes seen with grades of 2b or higher¹¹⁶ and the best outcomes seen with TICI grade 3 revascularization.¹¹⁷

Compared with earlier studies,^{9,17} the positive clinical trials of endovascular stroke therapy showed vastly improved revascular-

ization rates, with mTICI grade 2b/3 rates ranging from 58.7% to 88.0%,^{7,11,13,15,20} and the HERMES meta-analysis¹⁴ found an mTICI grade 2b/3 rate of 71%. The THERAPY trial¹⁸ reported an mTICI grade 2b/3 rate of 73%. This was assessed with the use of core laboratory adjudication in most studies, and it has been shown that local sites tend to overestimate the degree of reperfusion compared with a core laboratory.⁹⁹ Postmarket registries have found mTICI grade $\geq 2b$ rates of 70.9%–73.9%, but no central adjudication was performed.^{97,118,119} Based on this, an mTICI grade $\geq 2b$ rate of 70% seems a reasonable number for all acute ischemic strokes treated. Only moderate agreement exists between raters for the TICI scale, even though agreement is substantial when the scale is dichotomized into successful (ie, TICI grade 2b/3) or unsuccessful outcomes (ie, TICI grade 0, 1, or 2a).¹²⁰

In terms of technical success of procedures, it is also important to note the presence of distal embolization and embolization to new territory.³¹ The ultimate goal of revascularization is to improve patient outcomes. However, there is a risk that persistent attempts to recanalize an occlusion may lead to more complications. The combined metrics for SICH, revascularization, and mRS scores of 0–2 measure these risks and benefits.

Metric 7: The mTICI scale should be the primary scale used to assess angiographic reperfusion.

Metric 8: At least 70% of patients should have mTICI grade 2b/3 (ie, $>50\%$) reperfusion for all clot locations.

Postprocedural CT/MR Imaging

Postprocedural imaging is necessary to identify acute SAH or parenchymal hematoma, differentiate intraparenchymal hemorrhage from contrast staining, define the overall extent of new stroke, and identify other findings. Although there is no evidence that this improves clinical outcomes, there is consensus based on European guidelines that postprocedural imaging is required.¹²¹ CT or MR imaging within 36 hours after intervention should be performed in all stroke patients.^{7,11,15,20} Although some patients may receive CT or MR imaging immediately after the procedure, imaging performed the next day provides additional valuable information. It is recognized that there are certain circumstances that might render follow-up imaging difficult or impossible to perform. Therefore, the threshold for this imaging is 90%, acknowledging that a goal of 100% is desired.

Metric 9: At least 90% of patients should have a brain CT or MR imaging examination within 36 hours of the end of the procedure.

SICH

The most common major risk of endovascular treatment of acute ischemic stroke is SICH. As defined by individual studies, the incidences of SICH following endovascular revascularization range from 2% to 10% for combined intravenous and intra-arterial thrombolytic trials^{9,12,39,122} and from 1% to 8% for EVT trials.^{7,11,13,20,121} Several definitions have been used, as described in the National Institute of Neurological Disorders and Stroke trial,¹ the SITS-MOST³³ and INSTOR registries,⁷⁸ and European regis-

tries such as SITS-Thrombectomy,^{32,81} MR CLEAN⁸² (Netherlands), and the Heidelberg Bleeding Classification.³⁴

SAH is a unique complication of endovascular therapy and is not typically seen with intravenous therapy with TPA alone. Intraprocedural SAH caused by arterial perforation can be rapidly fatal, but has been described as being asymptomatic in as many as 16% of patients treated with mechanical thrombectomy without perforation.¹²³

The definition chosen for SICH in this document is based on that used by the SWIFT PRIME trial²⁰ and includes any intracranial hemorrhage with neurologic deterioration leading to an increase in NIHSS score >4 or leading to death within 24 hours of treatment.

SICH is not only an “end-result” evaluation of clinical judgment in the realm of patient selection and technical skill, but also a reflection of timing, procedural execution, and expeditious completion of the task. For these reasons, tracking of SICH is mandatory.

Metric 10: 100% of cases with SICH are reviewed (see “Quality Improvement”).

Metric 11: No more than 10% of treated patients should develop SICH.

Embolization of New Territory

Embolization of previously unaffected territories and embolization as a result of clot fragmentation within the treated territory can occur during endovascular treatment. Distal embolization within the treated territory is different from embolization of new territory and has been reported in 16% of patients treated with endovascular thrombolysis and 35% of patients treated with thrombectomy, without decreasing the likelihood of a favorable outcome.^{124,125} Embolization of new territory has been reported in 5%–9% of patients treated in the recent EVT trials^{7,13,20} and may cause new areas of symptomatic infarct or require additional treatment of previously unaffected vessels.

Metric 12: No more than 10% of patients should have embolization of new territory.

Death within 72 Hours of Treatment

Death within 72 hours of stroke is typically not a result of the stroke itself. The authors clearly acknowledge that every case is unique and that each instance needs to be reviewed in its entirety with the understanding that there are circumstances (eg, myocardial infarction) that lead to death in the short term and are unrelated to operator factors. Death soon after a procedure in and of itself does not imply or indicate a quality problem. However, all deaths within 72 hours are a trigger for review.

Metric 13: 100% of cases of death within 72 hours of the end of the procedure are reviewed.

Clinical Outcomes

Ultimately, the goal of endovascular stroke therapy is to limit the size and extent (ie, severity) of stroke, improve the clinical outcome of the patient, and prevent long-term disability. By convention, these outcomes are commonly assessed by using various functional grading systems: during initial hospitalization, stroke

is commonly assessed based on changes in the NIHSS score, and then, often at 90 days, by using the mRS. Clinical outcomes of stroke revascularization are multifactorial, depending on factors intrinsic to the patient such as pre-existing cerebral artery collateral vessels, procedural factors such as time to revascularization and completeness of revascularization, as well as the patient's response to a host of interventions in intensive care and then rehabilitation. Among specific patient factors, higher admission NIHSS scores and age were shown in the HERMES meta-analysis¹⁴ to portend worse outcomes with medical or endovascular therapy. Other medical comorbidities such as underlying cardiac disease, hypertension, and diabetes mellitus all play a role in outcomes. From a procedural standpoint, higher rates of recanalization are associated with improved outcomes. A key component of any interventional stroke program is tracking of clinical outcomes. To that end, we propose that a discharge NIHSS score be documented on all patients, and that all patients are contacted and evaluated to obtain an mRS score at 90 days. Early improvement in NIHSS score may function as a surrogate marker of outcome in situations in which an mRS score cannot be obtained.^{126,127} Although it is ideal to assess the patient in person, this may not always be possible, and telephone assessment of mRS score is a reasonable alternative that is well validated.¹²⁸ We understand that some patients may be lost to follow-up by 90 days.

Metric 14: All treated patients have a documented NIHSS score 20–36 hours after treatment and at discharge. Attempts are made to contact and document a follow-up mRS score at 90 days (evaluated in person or via telephone) on all treated patients. At least 90% of treated patients have documented 90-day mRS score.

Determining a single threshold level of “good clinical outcome” for all patient populations is difficult because of the heterogeneity of treated patients and the absence of comprehensive data. Individual centers, for example, may have a more elderly patient population or patients with later presentations. The incidences of patients with an mRS score of 0–2 at 90 days in the recent randomized controlled endovascular trials ranged from 33% (MR CLEAN)⁷ to 71% (EXTEND-IA),¹¹ with an overall aggregate rate of 46% in the HERMES trial.¹⁴ Similarly, the THERAPY¹⁸ and Trial and Cost Effectiveness Evaluation of Intra-arterial Thrombectomy in Acute Ischemic Stroke (THRACE)⁸ trials reported 38% and 53% rates of mRS score 0–2 at 90 days, respectively, and, in the per-protocol population of the Pragmatic Ischemic Thrombectomy Evaluation (PISTE) trial,¹²⁹ 57% of the endovascular group reached an mRS score of 0–2 at 90 days.

The major trials focused on stroke patients with large artery occlusions, specifically internal carotid terminus or proximal middle cerebral (ie, M1) arteries. However, some patients with severe stroke have occlusions at other locations. Patients with isolated M2 branch occlusions may be reasonable candidates for EVT, but, in general, the natural history of stroke in these patients is better than those with more proximal occlusions.¹³⁰ Although there are no randomized data showing a benefit for thrombectomy in basilar artery occlusions, these are often treated at many centers.¹³¹ Several studies have specifically reported worse outcomes for patients who did not meet the trial inclusion criteria or

the current American Heart Association level IA recommendations.²² Gratz et al¹¹⁹ reported 30% versus 57% incidences of mRS score of 0–2 for high-risk patients versus standard-risk patients. Similarly, Goyal et al⁷⁵ reported 39% versus 47% incidences of mRS score of 0–2 for patients not meeting versus meeting AHA level I recommendations.

One must take prestroke functional status into account when setting a threshold for 90-day mRS score for good outcome. Most patients in the recent randomized trials had an mRS score of 0/1 at baseline. As described in the “Indications” section, this is not to imply that EVT be withheld for those who do not have an mRS score of 0/1, but that any outcome threshold needs to account for prestroke functional status.

Multicenter registries have reported results with modern thrombectomy in more heterogeneous groups of patients, including patients with vertebrobasilar and M2 clot locations as well as tandem lesions. The registries include the German Register on Revascularization in Ischemic Stroke Patients (REVASK) registry ($n = 1,107$ patients, 40% mRS score 0–2 at 90 days),¹³² the Catalonia stroke registry ($n = 536$ patients, 43% mRS score 0–2 at 90 days),¹¹⁸ the North American Solitaire registry ($n = 354$ patients, 42% mRS score 0–2 at 90 days),¹³³ and the Madrid registry ($n = 479$, 54% mRS score 0–2 at 90 days).¹³¹ The Dutch MR CLEAN registry¹³⁴ reported a 41% incidence of mRS score 0–2 at 90 days in a group of 1,321 patients. Compared with the randomized trials, the registries will include some patients at higher risk (ie, basilar occlusions), some at lower risk (ie, M2 occlusions), and some biased data, as the data are not adjudicated, likely leading to better reported outcomes. However, this is likely to be similar to the experiences of hospitals using the metrics of this document.

Clinical acumen is needed to determine the risk versus benefit of treatment based on published trial and registry data and personal experience. The AHA has created level I recommendations²² for patient selection based on current randomized trials. However, we expect these recommendations to evolve as results from trials address “wake-up” strokes, prolonged time from symptom onset, basilar artery occlusions, large infarct size, and “mothership” versus “drip-and-ship” cases.^{48,49,54,55,59,135}

We propose a single threshold for clinical outcomes for all treated patients regardless of whether they would have been candidates for most recent trials or meet the AHA level I recommendations. This is consistent with the heterogeneity of current clinical practice in which nearly half of treated patients do not meet the AHA recommendations.⁷⁵ This document does not advocate for or against treating patients outside of the randomized trial or AHA level I recommendations, but suggests a threshold that recognizes the common practice of treating such patients. The threshold of a 30% incidence of mRS score of 0–2 at 90 days is lower than those of the recent randomized trials and registries based on the experience that “off-trial” patients are more likely to be at higher risk for poor outcomes^{75,119} and the belief that the published registry results may not reflect the most current trends in patient selection. It is important to note that, although achieving an mRS score of 0–2 is an important goal, it is not the only marker of a favorable outcome after endovascular therapy. Some patients may have important clinical benefit with an mRS score shift from 4/5 down to 3. However, mRS score shift analysis re-

quires a control group comparison, which is not useful as a quality metric. This suggested threshold should not dissuade centers from treating individual patients if they believe there is a potential benefit from the procedure. Given the multiple factors that influence outcomes, centers are encouraged to benchmark their outcomes against those from a similar patient population.

The clinical outcome threshold of this document is intended to prompt internal review of the endovascular stroke program. It is not designed to constitute a standard for reimbursement from payers, or for accreditation purposes. Local patient factors such as overall medical comorbidities and time from symptom onset to treatment should be taken into account when reviewing any single institution’s performance. This is especially true in those patients who have a greater degree of prestroke disability or other comorbidities that may have excluded them from the recent randomized trials, but for whom treatment may be warranted.

Metric 15: Of all treated patients, at least 30% are independent (ie, mRS score 0–2) at 90 days after treatment.

QUALITY IMPROVEMENT

Ongoing Quality Improvement

As EVT of acute ischemic stroke becomes a mainstream offering at many centers, an endovascular-specific multidisciplinary QI process should be established in all programs offering this treatment.^{24,25} These endovascular cases, similar to trauma cases, require complex processes of care. These processes go beyond the clinical and technical skills of the operators themselves and should be monitored in a continuous and ongoing fashion.

A peer-review committee at the local hospital should be formed that involves personnel from the several backgrounds that have expertise in stroke care as well as a vested interest in quality of care and outcomes. This committee should provide an open and transparent forum for process and case review. Transparency will optimize confidence in the process, which should have a positive impact on patient care. Although there may be potential for conflict or disagreement among various participants, it is vital that the process be viewed as a nonpolitical, nonpunitive instrument for care process improvement.

Specifically within the United States, in keeping with standards established under the Health Care Quality Improvement Act of 1986 (42 USC §11101 et seq.), peer-review meetings and minutes are generally protected from legal inquiry in most states as long as the review is conducted under the auspices of the facility QI program. The Health Care Quality Improvement Act established standards for professional review actions. Although this protection is not absolute, if a professional review body meets these standards, neither the professional review body nor any person acting as a member or staff to the body will be liable for damages under most federal or state laws with respect to the action.^{136–139} All associated QI documents should include routine annotation that establishes the purpose of the document and that its content is protected under applicable federal or state law. The program should operate under the local facility umbrella established for all facility QI and peer-review initiatives.

Table 3: Endovascular therapy quality improvement case review triggers and process metrics

Indications for Endovascular Treatment <ul style="list-style-type: none">● Metric 1: At least 90% of patients who meet the institution selection criteria (indications/contraindications) should be treated with endovascular therapy.
Data Collection <ul style="list-style-type: none">● Metric 2: 100% of patients have the required minimum process and outcomes data entered into an institutional or national data base, trial, or registry.
Key Time Intervals
<i>Door to imaging</i> <ul style="list-style-type: none">● Metric 3: 75% of patients being evaluated for revascularization should have imaging initiated within 30 minutes from time of arrival. At the best of centers with high volumes and an established resource infrastructure, this is expected to be achieved in 12 minutes.
<i>Imaging to puncture</i> <ul style="list-style-type: none">● Metric 4: 75% of patients treated with endovascular therapy should have an imaging-to-puncture time of 110 minutes or less. At the best of centers with high volumes and an established resource infrastructure, this is expected to be achieved in 50 minutes or less.● Metric 5: For patients transferred from another site and in whom imaging is not repeated, 75% of patients being treated should have a door-to-puncture time of 80 minutes or less.
<i>Puncture to revascularization</i> <ul style="list-style-type: none">● Metric 6: In 70% of patients, mTICI score $\geq 2b$ should be reached ideally within 60 minutes of arterial puncture.
Outcome Metrics
<i>Recanalization/reperfusion</i> <ul style="list-style-type: none">● Metric 7: The mTICI scale should be the primary scale used to assess angiographic reperfusion.● Metric 8: At least 70% of patients should have an mTICI score $\geq 2b/3$ ($>50\%$ reperfusion) for all clot locations.
Postprocedure CT/MR Imaging <ul style="list-style-type: none">● Metric 9: At least 90% of patients should have a brain CT or MR imaging within 36 hours of the end of the procedure.
<i>SICH</i> <ul style="list-style-type: none">● Metric 10: 100% of cases with SICH are reviewed.● Metric 11: No more than 10% of treated patients should develop SICH.
<i>Embolization of new territory</i> <ul style="list-style-type: none">● Metric 12: No more than 10% of patients should have embolization of new territory.
<i>Death within 72 hours of treatment</i> <ul style="list-style-type: none">● Metric 13: 100% of cases of death within 72 hours of the end of the procedure are reviewed.
Clinical Outcomes <ul style="list-style-type: none">● Metric 14: All treated patients have a documented NIHSS score at discharge. Attempts are made to contact and document a follow-up mRS score at 90 days (evaluated in person or via telephone) on all treated patients. At least 90% of treated patients have a documented 90-day mRS score.● Metric 15: Of all treated patients, at least 30% are independent (ie, mRS score 0–2) at 90 days after treatment.

Note:—mRS indicates modified Rankin Scale; mTICI, modified thrombolysis in cerebral infarction; NIHSS, National Institutes of Health Stroke Scale; SICH, symptomatic intracranial hemorrhage.

Peer Review Team

It is recommended that, under the oversight of the stroke team medical director, a predetermined multidisciplinary subgroup consisting of medical personnel with familiarity and expertise in endovascular therapy be established to address issues specifically relating to endovascular treatment. Although a stroke neurologist is generally in the best overall position to objectively assess overall process deficiencies and outcomes, for technical and procedural issues, an interventionalist perspective must be considered. Ideally, the endovascular oversight team should be directed by a highly qualified and unbiased physician such as a noninterventional vascular neurologist. Depending on the institution, the endovascular QI peer group could include a variable combination of interventionalists, vascular neurologists, cerebrovascular neurosurgeons, intensivists, and diagnostic neuroradiologists. Additional members might include hospital representative(s) from the quality assurance/improvement or risk management departments, as well as possibly the stroke coordinator or other data personnel and secretarial support staff.

Review Process

The endovascular QI meeting should occur at least quarterly, and, depending on volume, may need to occur more frequently to provide adequate assessment and review. There should be review of every case in centers with volumes <50 cases per year and

review of every case in which the parameters are outside the benchmarks (eg, prolonged time to puncture, failure of reperfusion, prolonged time to reperfusion) or in which a complication occurs (eg, SICH, embolization of new territory, or death within 72 hours). As noted earlier in the section on data collection, all cases should be entered into a trial, data base, or registry with national participation.^{24,25,76} In the United States, Medicare is functioning under the Medicare Access and Children's Health Insurance Program Reauthorization Act of 2015,¹⁴⁰ which seeks to align disparate quality programs through Qualified Clinical Data Registries. This approach is in keeping with our aforementioned recommendation for data collection and quality control.^{141,142}

The interventionalist who performed the specific case under review should be present to offer his/her observations and perspective. The focused endovascular peer review should routinely include assessment of technical factors such as device choice, supplemental lytic agent infusion, and equipment inventory assessment. Process elements such as on-call notification, timing (ie, door-to-imaging and imaging-to-arterial puncture times), procedure table setup, and overall communication should also receive routine attention. Performance review is not limited to the treating endovascular physician, but should also include the emergency department, neurology and neurointensive care personnel,

interventional technologists, nursing staff, and other related service areas as indicated. Information concerning transfer from and communication with referring primary stroke centers before and after return to the primary center, complications, and 90-day functional outcome should also be routinely discussed and benchmarked.

Triggers for Review

Any event that might affect quality should be reviewed. Specific triggers for endovascular review include unmet process benchmarks, death, and symptomatic postprocedural hemorrhage. Some complications or process delays may be unavoidable, whereas others may reflect significant errors in judgment or process deficiencies. A determination must be made if the patient was harmed. Process problems such as delays or inadequate communication increase the risk of harm. Therefore, complications and events that increase the risk of poor outcomes need to be reviewed as a means of improving quality. There must also be differentiation between clearly procedure-related complications (eg, perforation and/or dissection, distal dislodgment of thrombus that remains unreachable, embolization of new territory, and immediate SICH following the procedure) and those that might be related to the primary ischemic event itself (eg, infarction, cerebral edema, and hemorrhagic transformation). Predisposing underlying vascular disease and comorbidities must also be considered.

Physicians who choose to treat sicker patients may have poorer outcomes and may not meet established benchmarks. These cases should not be considered in isolation, as a poor outcome does not necessarily indicate that such physicians are providing a lower quality of care, but rather that they have a different patient mix than the trials that were used to create the benchmarks.^{7,8,10,11,13–15,18,20,143–145} Adjusting for risk and severity may be helpful in assessing local outcomes compared with other institutions and benchmarks. Endovascular QI case review triggers and key process metrics are summarized in Table 3.

In addition to these morbidity and mortality markers, it is incumbent on the institution and the quality-assurance/improvement and peer-review committee to also assess the “good outcomes.” A certain percentage of good outcomes are necessary for there to be sufficient benefit to the overall patient population. This document also defines minimal recanalization rates as well as improved clinical outcomes that should be attained.

Performance and Process Improvement

The committee should be equipped to deal with poor performance in a supportive, constructive, and collegial manner. In cases in which negative trends and deficiencies become apparent, improvement may require individual mentoring, additional education, or supplemental training. Endovascular stroke QI review of problematic cases should generate a specific course of action to remedy recognized problems and prevent future occurrences. Individual assignments should be tracked, with accountability reports scheduled for subsequent meetings. Further, process improvement is a continuing activity that, along with individual performance improvement, will significantly impact clinical outcomes.¹⁴⁶

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