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Adopted 2018 (Resolution 18)*

ACR-ASNR-SIR-SNIS PRACTICE PARAMETER FOR THE PERFORMANCE OF ENDOVASCULAR EMBOLECTOMY AND REVASCULARIZATION IN ACUTE STROKE

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care¹. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner in light of all the circumstances presented. Thus, an approach that differs from the guidance in this document, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in this document when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of this document is to assist practitioners in achieving this objective.

PRACTICE PARAMETER

^{1 &}lt;u>Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing,</u> N.W.2d (Iowa 2013) Iowa Supreme Court refuses to find that the *ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures* (Revised 2008) sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, <u>Stanley v. McCarver</u>, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

I. INTRODUCTION

This practice parameter was developed and written with the collaboration of the American College of Radiology (ACR), the American Society of Neuroradiology (ASNR), the Society of Interventional Radiology (SIR), and the Society of NeuroInterventional Surgery (SNIS). This practice parameter will focus on several areas, including: i) recent advances in endovascular stroke care, ii) qualifications and responsibilities of the endovascular stroke team, iii) recommendations regarding equipment and instrumentation, iv) technical aspects and/or recommendations regarding performance and reporting of the endovascular procedure and periprocedural care, and v) recommendations on quality control and performance improvement.

Every year in the United States, an estimated 795,000 people suffer an ischemic stroke. It is estimated that at least approximately 10%, or nearly 80,000, of these strokes will be caused by an emergent large-vessel occlusion (ELVO) affecting the intracranial internal carotid artery, the proximal middle cerebral artery, the intracranial vertebral arteries, or the basilar artery. The effect of this is devastating: ELVO strokes are associated with greater symptoms and worse outcomes, for a disease that, overall, is a leading cause of death and disability and has been associated with indirect and direct societal costs of up to \$34 billion [1].

The status of endovascular stroke therapy changed significantly in 2015 with the publication of 5 randomized controlled trials that showed a substantial benefit of mechanical thrombectomy in select patients presenting with acute neurological symptoms attributable to a large-vessel occlusion within 6 hours from time of onset [2-6]. There are an estimated 24 ELVO strokes per 100,000 people per year in the United States. Some regions in the country are performing 10 to 12 endovascular stroke procedures per 100,000 population whereas the national average is between 3 to 6 endovascular stroke interventions per 100,000 people [7]. These estimates suggest a potential for significant growth in the endovascular stroke procedure volume. Endovascular treatment of ELVO acute ischemic stroke (AIS) has evolved rapidly in the last decade. ELVO AIS has been transformed from a condition with significant morbidity and mortality to one in which lives and neurological function can be saved. New embolectomy devices, imaging techniques, and systems of care have truly revolutionized the care of the stroke patient. Within the first 6 hours after onset of symptoms, many patients can be treated safely and effectively, with good clinical outcomes being achieved in a significant number of cases. The newest clinical trial results suggest that many patients who awaken with stroke symptoms or are treated between 6 and 24 hours of symptom onset may also benefit, provided they have a favorable imaging profile (eg, DAWN or DEFUSE-3 [8,9]). Of necessity, the practice parameter outlined below will evolve based on new clinical trial results and other lines of evidence.

II. DEFINITIONS

For the purpose of this practice parameter, the following definitions apply:

Alberta Stroke Program Early Computed Tomographic Score (ASPECTS) – A method of measuring early ischemic change, originally described with noncontrast computed tomography (CT) [10] and subsequently applied to other CT modalities and to MRI [11-14], which predicts functional outcome and hemorrhage risk in patients who are candidates for intravenous thrombolysis and thrombectomy.

Class of recommendation – A *Class 1* recommendation represents a strong recommendation or indication, for which there is evidence for and/or general agreement that the procedure or treatment is useful and effective. A *Class 2a* recommendation represents a moderate level of recommendation, in which a course of action is considered reasonable or may be useful or beneficial. The weight of evidence or opinion is in favor of the procedure or treatment. A *Class 2b* recommendation represents a weaker recommendation, in which a course of action might be reasonable, may be considered, or where the usefulness/effectiveness is considered uncertain or less well established by evidence or opinion. A *Class 3* recommendation represents a course of action for which there is evidence and/or general agreement that the procedure or treatment is not useful/effective, and in some cases may be harmful [15,16].

CNS infarction – CNS infarction is brain, spinal cord, or retinal cell death attributable to ischemia, based on pathological, imaging, other objective evidence of cerebral, spinal cord, or retinal focal ischemic injury in a

defined vascular distribution, or clinical evidence of cerebral, spinal cord, or retinal focal ischemic injury based on symptoms persisting >24 hours or until death, and other etiologies excluded. (Note: CNS infarction includes hemorrhagic infarctions (HI), types I and II; see "Hemorrhagic Infarction" [15-18].)

Diagnostic catheter angiography – a minimally invasive procedure involving percutaneous catheterization of any of the arteries or veins involving the head and neck, brain, or spinal cord, performed with injection of a radiocontrast agent and digital subtraction imaging.

ELVO – Any acute occlusion of the internal carotid, proximal anterior cerebral, proximal middle cerebral (M1 and M2 segments), proximal posterior cerebral, or vertebrobasilar arteries documented by vascular imaging [19].

HI – Type I is defined by petechiae of blood along the margins of the infarction, whereas type II has confluent petechiae within the infarction but without a space-occupying effect. HI is characterized by its lack of mass effect [18].

Intracerebral hemorrhage (ICH) – A focal collection of blood within the brain parenchyma or ventricular system that is not caused by trauma (Note: ICH includes parenchymal hemorrhages after CNS infarction; see "Hemorrhagic Infarction" and "Parenchymal Infarction" [18].)

Ischemic stroke – An episode of neurological dysfunction caused by focal cerebral, spinal, or retinal infarction (Note: Evidence of CNS infarction is as defined previously [15-18].)

Level of evidence – *Level A* evidence is high-level evidence, most often derived from more than one randomized controlled trial, a meta-analysis of high-quality randomized controlled trials, or a randomized controlled trial supported by a high-quality registry. *Level B* evidence is moderate-quality evidence, which may be derived from randomized controlled trials or a well-designed nonrandomized study, or a meta-analysis of such trials. *Level C* evidence is considered limited- or lower-level evidence, based on observational trials or registries, meta-analyses of such trials, or consensus of expert opinion based on experience [15,16].

Major complication – An event that results in admission to the hospital for therapy (for outpatient procedures), an unplanned increase in the level of care, an unplanned increase in the length of hospital stay, or in permanent adverse sequelae or death (see Appendix A).

Mechanical thrombectomy – A minimally invasive procedure involving diagnostic catheter angiography followed by direct removal of a thromboembolus from a target vessel using catheter-based techniques. Examples may involve use of a stent retriever or an aspiration device, with or without maceration of the clot.

Minor complication – An event that results in no sequelae or requires minimal therapy or a short hospital stay for observation (see Appendix A).

Modified Rankin Scale (\underline{mRS}) – A 7-point ordinal scale for measuring the degree of disability or dependence of patients who have suffered a stroke. It is a measure of overall functional outcome, rather than specific symptom severity. The scale ranges from 0 (no symptoms) to 6 (dead) (see Appendix).

Modified thrombolysis in cerebral infarction (mTICI) score – A scale ranging from 0 to 3 that describes the degree of (re)perfusion of an artery past its initial occlusion and into its distal branches. A score of 0 indicates no perfusion, whereas a score of 3 indicates full reperfusion with filling of all the distal branches, including M3 and M4 (see Appendix).

National Institutes of Health Stroke Scale (NIHSS) – A 42-point scale used to objectively and reproducibly quantify the severity of select symptoms caused by a stroke. The NIHSS is composed of 11 items, each of which scores a specific area of neurological function from 0 (not present) up to 4 (most severe). In the case of coma, certain scores (eg, those for ataxia) default to 0, so the maximum score in a comatose patient is 39 [20] (see Appendix).

Parenchymal hemorrhage (PH)— Type I is a confluent hemorrhage limited to <30% of the infarcted area with only mild space-occupying effect, and type II is >30% of the infarcted area and/or exerts a significant space-occupying effect. PH is characterized by the presence of mass effect, similar to the ICH definition of a focal collection of blood. PH should be considered ICHs [18].

Stent retriever – A stent-like device that is used to remove a thromboembolus from an occluded vessel.

Stroke caused by ICH – Rapidly developing clinical signs of neurological dysfunction attributable to a focal collection of blood within the brain parenchyma or ventricular system that is not caused by trauma [18].

Subarachnoid hemorrhage – Bleeding into the subarachnoid space (the space between the arachnoid membrane and the pia matter of the brain or spinal cord) [18].

Threshold – A specific level of an indicator that should prompt the performance of a review

Thrombolysis – A method of dissolving a thromboembolus within an occluded vessel using a fibrinolytic medication, such as alteplase. At this time, alteplase is the only FDA-approved medication for use for acute stroke patients and is only FDA-approved for intravenous use within 3 hours from time of onset or last known well. Per AHA/ASA guidelines, intravenous alteplase may be used up to 4.5 hours from onset or last known well in select, eligible patients. The intra-arterial administration of thrombolytics is well described, though considered "off-label" for acute stroke patients [16].

III. INDICATIONS AND CONTRAINDICATIONS

A. Summary

- 1. Class 1 recommendations based on Level A indications for endovascular revascularization include, but are not limited to:
 - a. Treatment of adult patients with major stroke symptoms (NIHSS >6) caused by large-vessel occlusion (ICA or M1 segment of the middle cerebral artery).
 - b. Endovascular treatment, which can be initiated within 6 hours of symptom onset.
- 2. Current contraindications for endovascular intervention based on a consensus of expert opinion include, but are not limited to:
 - a. Evidence of a large irreversible infarction (>1/3 of the middle cerebral artery territory or ASPECTS <6) in the territory of the index vessel.
 - b. Severe baseline functional (cognitive and/or medical) disability that would render the potential benefits of revascularization negligible.
 - c. Presence of intraparenchymal hemorrhage at the time of imaging evaluation.
 - 3. There is mounting evidence that suggests that some patients not meeting Class 1 Level A eligibility criteria may also benefit from treatment. Thus, it may be reasonable to treat some patients outside Class 1 recommendations.

B. Discussion

This section of the Practice Parameter concerns the clinical indications for endovascular revascularization in patients with acute arterial ischemic stroke. Guidelines concerning the technical aspects of revascularization are covered elsewhere.

The indications and contraindications described above have been endorsed by numerous professional societies focused on cerebrovascular diseases that include physicians in the fields of neuroradiology, interventional

radiology, neurointerventional surgery, neurosurgery, and neurology. While these standards are the current Class 1 recommendations, some publications indicate that up to 40% to 50% of the patients treated are outside of the Class 1 recommendations of the AHA [21].

The inclusion and exclusion criteria are based on the following concepts:

- Patient selection for interventional stroke treatment requires the potential morbidity and mortality of the
 untreated stroke to be greater than the risk of intervention. For example, a minor stroke that is unlikely to
 cause significant long-term disability does not generally justify an invasive procedure that may be more likely
 to cause greater harm than the stroke itself.
- NIHSS is the widely accepted clinical means of quantifying stroke severity. Current definition of severe stroke is NIHSS ≥6.
- Likelihood of a good clinical outcome in stroke depends on the timeliness of cerebral reperfusion.

1. Patient Characteristics

a. Stroke Severity

The NIHSS cutoff determining "major stroke symptoms" has evolved over time with a general trend toward treating lower NIHSS. Early interventional stroke trials that focused on intra-arterial thrombolysis defined major stroke as having an NIHSS ≥ 10 [22]. This threshold was based on the low likelihood of a good clinical outcome when patients at or above the threshold stroke severity were not treated. Subsequent trials lowered the definition of major stroke to any stroke having an NIHSS ≥ 8 . This change was also based on the observation that patients with strokes less severe than the selected severity threshold had a reasonably good chance of a good clinical outcome if left untreated.

• Most recently, the definition of major stroke for the purposes of endovascular therapy selection has been lowered to NIHSS ≥6 [3,5,23]. The presumption is that patients with minor strokes defined as NIHSS ≤5 are less likely to have a poor neurological outcome than if they undergo an interventional procedure.

Although this guideline is well founded in principle, there are some patients who present with minor stroke symptoms due a large-vessel occlusion that clinically worsen late in the course of their stroke because of collateral failure. While such patients may have benefited from early treatment, they are often not eligible for treatment when their symptoms worsen late in their clinical course because they fall outside currently established temporal windows for therapeutic opportunity.

• Another category of patients with minor stroke symptoms who may benefit from endovascular revascularization are those patients in whom intravenous thrombolysis is contraindicated. Given the absence of any treatment options, such patients could reasonably be offered interventional therapy. Unfortunately, it is not clear whether the risks of interventional treatment are less than the risks of disease natural history in such patients.

Although further research is needed to determine when interventional therapy should be considered for patients presenting with minor stroke symptoms, preliminary data suggest that patients with minor stroke symptoms and large-vessel occlusion may benefit from mechanical thrombectomy [24]. As the risk and benefit of treatment evolve, so might the pool of patients for whom thrombectomy may be considered reasonable. For example, patients with isolated aphasia or hemianopia may be reasonable for treatment despite lower NIH stroke scale scores [15].

• Select patients with large-vessel occlusion and an NIHSS <5 may still benefit from endovascular therapy.

b. Age

All clinical trials of endovascular therapy for acute stroke have been conducted in adult patients at least 18 years of age. On the other end of the age spectrum, 3 of the 5 landmark IA versus IV therapy randomized trials published in 2015 did not exclude elderly patients (MR CLEAN, ESCAPE IA, EXTEND-IA). We do not advocate for intra-arterial therapy being withheld from patients based on advanced age alone, and additional study is required to determine the clinical efficacy of endovascular revascularization in the very elderly (>80 years) population.

- While patients <18 years of age were not included in these clinical trials, endovascular stroke therapy is considered reasonable in this population on a case-by-case basis according to expert consensus [25].
- Endovascular therapy should not be withheld based on advanced age alone.

c. Time

It is clear from all clinical stroke trials conducted to date that the likelihood of a good clinical outcome depends on the timeliness of cerebral reperfusion. Data acquired from large populations of stroke patients that have not been selected or stratified on the basis of cerebral perfusion imaging or collateral status have shown that revascularization becomes futile if reperfusion is not achieved within 6 hours of symptom onset.

 More recently, combined data from multiple randomized controlled stent retriever trials have suggested that improved clinical outcomes are possible if cerebral reperfusion is achieved within 7.3 hours of symptom onset [26].

This futility threshold is considered by many to represent the time at which an intervention in progress may be reasonably aborted, because the likelihood of harm exceeds the likelihood of benefit if reperfusion is established beyond that temporal boundary. In such cases, reperfusion of irreversible infarction may result in hemorrhage that contributes to a worsening of the patient's clinical outcome. One notable exception to this rule concerns the use of intra-arterial thrombolytic drugs as a component of the endovascular intervention. Prior studies have not established the safety of intra-arterial thrombolytic administration to stroke patients who are more than 6 hours from last seen normal [27].

Looking forward, there is mounting evidence that imaging, as opposed to time of symptom onset, can be used to determine which patients are most likely to benefit from intervention [28,29]. The DAWN trial, for example, recently demonstrated that patients with a clinical deficit that is disproportionately severe compared to small infarct volume on initial imaging benefit from mechanical thrombectomy between 6 and 24 hours after last seen well [9]. Initial infarct volumes were assessed by DWI MRI or perfusion CT and measured with automated software. Additional clinical trials are likely to further refine patient triage in the near future.

• Imaging biomarkers of cerebral physiology may identify patients who may benefit from endovascular therapy beyond 6 hours.

2. Imaging Characteristics

The goal of imaging in the setting of acute stroke is to: (a) differentiate those with hemorrhage from those with true acute ischemic presentations; (b) identify those with a small- to moderate-sized ischemic core; (c) and assess for a proximal occlusion of an intracranial artery thought to be amenable to endovascular therapy. Inclusion of the aortic arch and extracranial vasculature in the vascular assessment allows for identification of additional arterial findings relevant to mechanical thrombectomy, such as anatomy for endovascular access (including variants or other findings posing technical challenges), or potential for carotid or vertebral arteria

disease, either as a cause for the proximal intracranial arterial occlusion or requiring consideration in the technical aspects of successful recanalization (eg, carotid stenosis or carotid occlusion).

• Brain and vascular imaging should be performed at the time of the patient's first scan.

Although MRI/MRA and CT/CTA can both be used for this assessment, most centers will likely perform CT/CTA because of the ubiquitous nature of this technology, ease of performing brain and vascular imaging, and the relative lack of contraindications to imaging, as can occur with MR-based protocols [30].

It is well recognized that, although CTA does add time to the imaging protocol, the benefits of this vascular imaging for clinical decision making outweigh potential risks and reduce overall time from imaging to decision making for endovascular management. All efforts should be made to minimize the delay in performing this vascular imaging. Thrombolytic therapy can be started immediately following the noncontrast CT, if the patient is determined eligible, while the CTA is being planned. In centers with appropriate safety protocols in place, this can be done with the patient remaining in the CT scanner. Sites without immediate access to CTA should perform a noncontrast CT to ensure that IV tPA decision making is not unduly delayed and should not delay appropriate care in order to complete the CTA.

1. Infarct Size

Large irreversible infarction in territory of the index vessel is widely regarded as a contraindication to endovascular revascularization. In such cases, there is no expected benefit of revascularization, and the likelihood of procedure-related harm due to reperfusion resulting in hemorrhagic transformation is high. Although diffusion-weighted MR imaging sequences are considered most accurate for quantifying cerebral infarction, many factors continue to limit the widespread use of MR imaging to evaluate acute stroke patients in clinical practice. Infarction involving ≥1/3 of the middle cerebral artery territory has been considered a contraindication to interventional treatment based on this principle. In an effort to standardize imaging criteria to support this guideline, the ASPECT score was developed. Although an ASPECT score <6 or other evidence of a large core infarction at presentation is generally considered a contraindication to endovascular revascularization, there is increasing controversy regarding the reliability of CT-based ASPECT score to determine the extent of irreversible infarction [31-33]. While there may be a treatment benefit from endovascular revascularization in patients with lower ASPECT scores, this effect may not translate into higher rates of functional independence (mRS ≤2) after treatment.

Significant subacute infarction or hemorrhage within the territory of an occluded target artery due to a prior event predating the index presentation should be considered a contraindication to revascularization of the occluded vessel. In such cases, reperfusion of an affected brain may precipitate lethal or severely disabling cerebral hemorrhage within the territory of the index vessel, negating any benefit of revascularization.

2. Vascular Imaging

Vascular imaging should be performed at the same time as the initial brain imaging. This should include assessment of the intracranial and extracranial arteries, including the aortic arch, and can be done using single-phase technique. CT perfusion or multiphase CT angiography may form part of the initial cross-sectional imaging work-up of a stroke patient. CT perfusion and multiphase CTA were used to identify patients with large irreversible infarction for exclusion in randomized trials [3,4,34]. There are differing methods and grading scales for multiphase CTA, with emphasis on determining the presence and robustness of pial-to-pial collaterals. There is also recognized variation in CT perfusion map outputs among different vendor software packages. The optimal use of these advanced imaging techniques is not established by *Level I*, Class A evidence. Based on currently published data, performing multiphase CTA and/or CT perfusion is not required to identify the criteria for inclusion or exclusion of a patient from

thrombectomy in current clinical practice, although these may be helpful in some situations, such as for those patients being considered for transfer to a center capable of performing endovascular therapy.

- Large core infarct (as defined by >1/3 of MCA territory already infarcted, or ASPECTS <6) is a strong relative contraindication to endovascular revascularization, whether assessed by CT- or MR-based techniques.
- Any hemorrhage is a contraindication for administration of thrombolytic medications.
- Intracranial hemorrhage is also generally considered to be a contraindication for mechanical thrombectomy except in selected patients in whom the potential benefit of intervention outweighs the risk of revascularization.

3. Occlusion Location

As noted above, currently supported indications for interventional stroke therapy endorse specific anatomical criteria involving large artery occlusions within the anterior circulation. These anatomical criteria have been derived from a synthesis of data from large randomized clinical trials subjected to rigorous peer review. There have not been large trials directed at AIS within the posterior circulations (occlusion of basilar or vertebral artery), and *Level A* evidence for endovascular treatment does not exist. However, treatment of these potentially devastating strokes is commonly performed and should be considered on a case-by-case basis. Consequently, the authors of this document feel that posterior circulation arterial ischemic stroke should be considered separately.

- There is consensus that patients with intracranial ICA or M1 segment MCA occlusion are appropriate for endovascular treatment. However, it has been proposed that treatment of smaller vessels located more distally in the anterior circulation should be considered reasonable, but there is significant variability of opinion as to which vessels constitute reasonable targets for interventional therapy.
- Some arterial segments may be regarded as controversial. For example, *Level A* evidence currently suggests that M2 lesions do not benefit in aggregate from treatment [29,35]. However, some post hoc analyses suggest that there may be certain subgroups of patients with M2 occlusions that may benefit from treatment. There is mounting evidence that the proximal M2 segments of the middle cerebral arteries are suitable targets for endovascular revascularization [36-39].

One of the difficulties encountered in analysis of modern clinical trial data concerns the inconsistent definition of proximal M2 occlusion. Case series and post hoc analyses of randomized clinical trial data inconsistently show improved clinical outcomes in successfully revascularized M2 occlusions depending on the size of the affected vascular territory. Nonetheless, there is an absence of Class I evidence supporting the practice of M2 revascularization owing to the small number of patients with isolated M2 occlusions in recent positive clinical trials for interventional stroke therapy. However, consensus of expert opinion increasingly supports the indication for interventional revascularization of a proximal M2 occlusion affecting perfusion of an entire frontal lobe, parietal lobe, and/or temporal lobe equivalent. Post hoc analysis of IMS III data shows that M2 division occlusions affecting a cortical lobar equivalent probably benefit from reperfusion therapy, but that smaller middle cerebral artery branch occlusions do not [39]. Interventional treatment for occlusions of the anterior cerebral artery, posterior cerebral artery and distal middle cerebral artery (M3 or M4 segments) would be considered controversial by many who believe there is an insufficient added clinical benefit to justify the risk of an invasive intervention.

• The presumption is that many of these occlusions will recanalize either because of the effects of intravenous thrombolytics or the body's natural thrombolytic process. In addition, the risk of endovascular instrumentation increases as the cerebral artery becomes smaller, more distal, and thinner walled [35].

For the pregnant or potentially pregnant patient, see the <u>ACR-SPR Practice Parameter for Imaging Pregnant or</u> Potentially Pregnant Adolescents and Women with Ionizing Radiation [40].

IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the <u>ACR-ASNR-SIR-SNIS Practice Parameter for the Performance of Diagnostic Cervicocerebral Catheter</u> Angiography in Adults [41].

A. Physician

Physicians providing emergent intra-arterial intervention for AIS are required to have appropriate training and experience for the performance of neuroangiography and neuroendovascular therapy, which are essential for safe and efficient stroke patient management. While the physician qualifications below are tailored toward new practitioners, it should be recognized that there are current practitioners (who may be board certified or board eligible in either radiology, neurology, or neurosurgery) having trained prior to, or outside of, established formal neuroendovascular training programs, and having acquired the necessary skills listed below to perform safe and effective intra-arterial stroke treatment. Nonetheless, all neuroendovascular specialists are required to participate in maintenance of certification and maintenance of qualification requirements, as listed below.

Endovascular embolectomy and revascularization in acute stroke examinations must be performed by or under the supervision of and interpreted by a physician who has met the following qualifications <u>ACR-ASNR-SIR-SNIS</u> <u>Practice Parameter for the Performance of Diagnostic Cervicocerebral Catheter Angiography in Adults [41] as well as the qualifications below:</u>

 Accreditation Council for Graduate Medicine Education (ACGME) or Royal College of Physicians and Surgeons of Canada (RCPSC) accredited residency or fellowship training (in radiology, neurology, or neurosurgery), which should include documented training in the diagnosis and management of acute stroke. Those physicians who did not have adequate such training during their residencies must spend an additional period (to complete at least one year) of training in clinical neurosciences and neuroimaging, focusing on the diagnosis and management of acute stroke, the interpretation of cerebral arteriography, and neuroimaging.

or

- 2. Dedicated training in Interventional Neuroradiology (also termed Endovascular Neurosurgery or Interventional Neurology) under the direction of a Neurointerventionalist (with neuroradiology, neurology, or neurosurgical training background) at a high-volume center. It is preferred that this is a dedicated time (minimum of one year), which occurs after graduating from residency (ie, a fellowship). A training program accredited by a national accrediting body is also strongly preferred but not required. Within these programs, specific training for intra-arterial therapy for AIS should be performed, including obtaining appropriate access even in challenging anatomy, microcatheter navigation in the cerebral circulation, knowledge and training of the use of stroke-specific devices, and complication avoidance and management. While various national standards will have differing procedure requirements, we encourage practitioners to meet their national minimum procedural and training standards. Nonaccredited fellowships are also expected to have adequate training to meet minimum procedure requirements.
- 3. Physicians meeting all of the qualifications in 1 or 2 above must have the following:

Documentation of competency in all aspects of the procedure and pre- and postprocedure care by the use of objective outcome-based tools related to angiographic experience is necessary. Attestation of competency by a qualified neurointerventionalist who has observed the physician during the performance of thrombectomy procedures is required.

For previously credentialed physicians who perform intra-arterial catheter-directed stroke procedures at their local institutions, they should have documented procedural and clinical outcomes that meet national standards and published evidence-based guidelines.

The written substantiation should come from the chief of interventional radiology, the chief of neuroradiology, the chief of interventional neuroradiology, or the chair of the department of the institution

in which the physician will be providing these services². Substantiation could also come from a prior institution in which the physician provided the services, but only at the discretion of the current interventional, neurointerventional, or neuroradiology chief or of the chair who solicits the additional input.

Maintenance of Competence

Physicians must perform a sufficient number of endovascular embolectomy and revascularization in acute stroke procedures to maintain their skills, with acceptable success and complication rates according to this parameter. Individual physician outcomes should conform to national standards and institutional requirements. In addition, the physician should participate in an ongoing quality assurance and improvement program. The goals of this quality assurance program for stroke therapy would be to monitor outcomes both in the periprocedural period and at 90 days. The quality assurance program must review all emergency interventional stroke therapy patients. In addition, physicians and facilities should participate in a quality improvement registry. Participation in a national registry is encouraged. Outcomes should be tracked and recorded. Threshold levels for recanalization and complication rates have been established by society consensus [42,43]. Based on these references we suggest the following as a minimum, but the indicators and thresholds are currently being revised and will replace the current thresholds.

- 1. Successful recanalization (modified TICI 2b or 3) in at least 60% of cases.
- 2. Embolization to new territory of <15%.
- 3. Symptomatic intracranial hemorrhage (ie, Parenchymal Hematoma on imaging with clinical deterioration) rate <12% [43,44].

Continuing Medical Education

The physician's continuing education should be in accordance with the <u>ACR Practice Parameter for Continuing Medical Education (CME) [45].</u>

B. Qualified Medical Physicist

A Qualified Medical Physicist is an individual who is competent to practice independently in one or more of the subfields in medical physics. The American College of Radiology considers certification, continuing education, and experience in the appropriate subfield(s) to demonstrate that an individual is competent to practice in one or more of the subfields in medical physics, and to be a Qualified Medical Physicist. The ACR strongly recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR), the Canadian College of Physics in Medicine, or by the American Board of Medical Physics (ABMP).

A Qualified Medical Physicist should meet the <u>ACR Practice Parameter for Continuing Medical Education</u> (CME). (ACR Resolution 17, 1996 – revised in 2012, Resolution 42) [45]

The appropriate subfield of medical physics for this parameter is Diagnostic Medical Physics. (Previous medical physics certification categories including Radiological Physics, Diagnostic Radiological Physics, and Diagnostic Imaging Physics are also acceptable.)

C. Registered Radiologist Assistant

A registered radiologist assistant is an advanced level radiographer who is certified and registered as a radiologist assistant by the American Registry of Radiologic Technologists (ARRT) after having successfully completed an advanced academic program encompassing an ACR/ASRT (American Society of Radiologic Technologists)

²At institutions in which there is joint (dual) credentialing across departments doing like procedures, this substantiation of experience should be done by the chairs of both departments to ensure equity of experience among practitioners when their training backgrounds differ.

radiologist assistant curriculum and a radiologist-directed clinical preceptorship. Under radiologist supervision, the radiologist assistant may perform patient assessment, patient management, and selected examinations as delineated in the Joint Policy Statement of the ACR and the ASRT titled "Radiologist Assistant: Roles and Responsibilities" and as allowed by state law. The radiologist assistant transmits to the supervising radiologists those observations that have a bearing on diagnosis. Performance of diagnostic interpretations remains outside the scope of practice of the radiologist assistant. (ACR Resolution 34, adopted in 2006 – revised in 2016, Resolution 1-c)

D. Radiologic Technologist

- 1. The technologist, together with the physician and nursing personnel, should be responsible for patient comfort and safety. The technologist should be able to prepare and position3 the patient for the arteriographic procedure and, together with the nurse, monitor the patient during the procedure. The technologist should obtain the imaging data in a manner prescribed by the supervising physician. The technologist should also perform regular quality control testing of the equipment under supervision of the physicist.
- 2. Technologists should be properly trained in the use of the arteriographic equipment and endovascular devices employed in the institution. They should demonstrate appropriate knowledge of patient positioning, endovascular devices, angiographic imaging and archiving, radiation protection angiographic contrast injectors, angiographic supplies, and physiologic monitoring equipment. Certification as a vascular and interventional radiologic technologist is one measure of appropriate training. The technologists should be trained in cardiopulmonary resuscitation and in the location and function of the resuscitation equipment.
- 3. Technologists should be certified by the American Registry of Radiologic Technologists (ARRT) or have an unrestricted state license and documented training and experience in catheter cerebral arteriography.

E. Sedation and Analgesia Services

If the patient is to undergo procedural sedation, a licensed provider must monitor the patient as his/her primary responsibility and in accordance with the ACR-SIR Practice Parameter for Sedation/Analgesia [46]. Individuals should be trained in the location of and the use of the facility's resuscitation equipment and in institutional protocols for code team alerts. Licensed providers must be privileged by the institution to administer sedation.

F. Nursing Services

Nursing services are necessary for monitoring the patient during the procedure in cases in which a qualified anesthesiologist is not involved.

V. SPECIFICATIONS OF THE EXAMINATION

A. Facilities and Resources

Endovascular therapy requires the patient to be at an experienced stroke center with rapid access to cerebral angiography and qualified neurointerventionalists. Although complications of endovascular stroke intervention rarely require urgent surgery, angiographic procedures should be performed in an environment where necessary

³The American College of Radiology approves of the practice of certified and/or licensed radiologic technologists performing fluoroscopy in a facility or department as a positioning or localizing procedure only, and then only if monitored by a supervising physician who is personally and immediately available*. There must be a written policy or process for the positioning or localizing procedure that is approved by the medical director of the facility or department/service and that includes written authority or policies and processes for designating radiologic technologists who may perform such procedures. (ACR Resolution 26, 1987 – revised in 2007, Resolution 12m)

^{*}For the purposes of this parameter, "personally and immediately available" is defined in manner of the "personal supervision" provision of CMS—a physician must be in attendance in the room during the performance of the procedure. Program Memorandum Carriers, DHHS, HCFA, Transmittal B-01-28, April 19, 2001.

surgical intervention can be instituted promptly. This would be an acute-care hospital with adequate neurointerventional, neurosurgery, vascular surgery, anesthesiology, and ancillary support [42].

B. Preprocedure Care

a. Clinical Evaluation

- i. Clinical evaluation necessary for therapeutic decision making in the acute phase should be performed as appropriate, including, but not necessarily limited to, the following:
 - 1. Relevant history of present illness, including time that the patient was last known to be well
 - 2. Pertinent comorbidities and recent medications
 - 3. Assessment of premorbid functioning including determination of mRS
 - 4. Assessment of neurological impairment, including determination of NIHSS
 - 5. Assessment of hemodynamic and airway stability, including basic vital signs
- ii. Clinical evaluation in the acute phase should be performed expediently. Any clinical evaluation that is not necessary for decision making in the acute phase but would delay acute therapies should be deferred.

b. Serological Evaluation

- i. Serological evaluation has traditionally been considered in the therapeutic decision making. This may no longer be relevant when performing a mechanical thrombectomy and should not delay acute therapy.
- ii. Serological evaluation in the acute phase should be performed expediently. Any serological tests that are not necessary for decision making in the acute phase but would delay acute therapies should be deferred.

c. Radiological Evaluation

- i. Neurological imaging may be reasonably performed using CT/CTA or MRI/MRA, as dictated by institutional protocol, resource availability, and patient condition.
- ii. At a minimum, neurological imaging should be sufficient to allow identification of intracranial hemorrhage, extent of completed infarction, and location of vessel occlusion.
- iii. Additional neurological imaging for assessment of ischemic penumbra, such as perfusion imaging or multiphase CT angiography, may be performed as necessary.
- iv. Neurological imaging necessary for therapeutic decision making in the acute phase should be performed expediently. To the extent possible, effort should made to minimize the time elapsed between patient arrival and completion of neurological imaging. Any radiological studies that are not necessary for decision making in the acute phase but would delay acute therapies should be deferred.
- v. Administration of iodinated contrast should not be delayed on account of unavailable serum creatinine result [47].

d. Informed Consent

i. Informed consent must be in compliance with all state or federal laws, as appropriate, and the <u>ACR</u>–<u>SIR</u>–<u>SPR Practice Parameter on Informed Consent for Image-Guided Procedures</u> [48].

e. Transpor

i. Once the decision has been made to perform endovascular treatment of AIS, transport of the patient to an appropriately equipped procedure room should be performed expediently. To the extent possible, effort should be taken to minimize the time elapsed between patient arrival and arterial puncture.

C. Intraprocedure Care

As with all aspects of patient care in acute stroke, patient safety and time to recanalization are the primary goals. Controversy continues with regard to the appropriate approach to sedation and anesthesia with respect to the acute stroke patient. We recommend that the choice and level of sedation/anesthesia be guided by the patient's condition and resources available. Furthermore, patients undergoing endovascular intervention for AIS should be monitored and managed in accordance with the Society for Neuroscience in Anesthesiology and Critical Care Expert Consensus Statement [49]. If the patient is to undergo procedural sedation, a licensed provider must monitor the patient as his/her primary responsibility. This person must maintain an appropriate record of intraprocedural monitoring and care, as described in the ACR-SIR Practice Parameter for Sedation/Analgesia [46].

The team required to safely and expeditiously perform cerebrovascular recanalization should be qualified and experienced as outlined in section IV.A. Members of this team should assist in performing, imaging, and archiving the procedure as needed.

To expedite recanalization, all nursing, technologist, sedation provider, and interventionalist duties that can be completed prior to patient arrival should be performed. In addition, we recommend that each member of the team familiarize themselves with the patient's medical history (including advanced directives), the patient's presentation, and the patient's current condition prior to the patient arriving in the angiography suite.

Upon patient arrival in the angiography suite, we recommend clear delegation of responsibilities to team members to allow parallel systems processes and reduce procedure time. In addition to documentation of patient vital signs and medications during the procedure, intraprocedural documentation should include, at a minimum: angiography suite arrival time, arterial access time, time of first access to the site of occlusion, number of passes required to achieve recanalization, and time to recanalization with the corresponding mTICI score. Documentation should meet the requirements of the quality improvement program described in section X and comprehensive stroke center requirements.

The choice of access, guiding catheter, use of aspiration, and embolic retrieval device are left to the interventionalist's clinical judgment and personal preference. The use of intra-arterial fibrinolysis should be reserved for specific patient populations; however, these data are derived from clinical trials that no longer reflect current practice. In addition, a clinically beneficial dose of intra-arterial r-tPA is not established, and r-tPA does not have US FDA approval for intra-arterial use. Intra-arterial fibrinolysis should not be performed as an alternative to thrombectomy in patients who are candidates for primary mechanical thrombectomy [42]. The effectiveness and utility of additional intra-arterial medications, such as antiplatelet medications, has not been established. We recommend avoiding the use of cervicocerebral stents in the acute setting unless deemed absolutely necessary because of the hemorrhagic risks of antiplatelet medications in the setting of the AIS.

D. Postprocedure Care

There is no definitive guideline for postprocedural care after endovascular treatment of acute stroke due to ELVO. Despite that, patients who undergo endovascular treatment, in general, require special postprocedural attention other than the expected access site and lower or upper extremity (depending on the access: femoral, radial, brachial, carotid) checks. This is usually accomplished in a multidisciplinary team approach, along with neurologists, intensive care physicians, and other specialties (hospitalist, cardiologist if needed). Ideally these patients should be admitted to a Neuro Intensive Care Unit (NeuroICU) or to a dedicated Stroke Unit where vital signs and neurological examination can be performed every 1 h. It is a reasonable approach to keep these patients in NeuroICU/Stroke Unit care level for 24 h. Some patients with rapid neurological improvement and minor residual deficits postmechanical thrombectomy may be transferred to the stroke floor to continue stroke work up, and physical and occupational therapy. Patients with severe strokes may have decreased levels of consciousness and may require (if not already) endotracheal intubation for airway protection. In these cases, neurological examinations are limited and serial imaging may be necessary within the first 12 to 72 h to assess stroke extension, mass effect, and the need for decompressive craniectomy.

Blood pressure (BP) control after endovascular treatment is important; however, the ideal numbers are still a matter of debate. Higher BP may increase the risk of hemorrhagic conversion and lower BP may increase the risk of infarct expansion in hypoperfusion states [50-52]. The existing data regarding BP parameters in acute stroke derives from the guidelines for IV thrombolytic therapy. According to AHA/ASA guidelines [15], the recommended BP target post-IV tPA is SBP < 180 mmHg and DBP < 105 mmHg for 24 h. However, it is questionable if these parameters should be applied after successful endovascular treatment (mTICI 2b and 3) because the complete or near-complete reperfusion of the cerebral tissue associated with higher BP parameters may increase the theoretical risk of hemorrhage. In these cases, it seems reasonable to consider lower BP parameters despite the lack of evidence.

A significant number of patients with acute stroke from ELVO have a cardioembolic source, such as atrial fibrillation. In these patients, anticoagulation should be started as soon as possible [53]. The timing of when to restart or start these medications is controversial because of the risk of hemorrhagic transformation inherent to infarcted brain parenchyma. Evidence is lacking in this aspect; however, based on expert opinion, a common rule is to start anticoagulation in 72 h after small infarcts, and 7 days and 14 days after moderate- and large-size infarcts, respectively [53].

In regards to postprocedural laboratory results, patients with acute stroke benefit from tight glycemic control. The Glycemia in Acute Stroke study showed that hyperglycemia (>155 mg/dL) was associated with increased odds of poor outcome and death at 3 months [54]. The goal of glycemic control should be normoglycemia (80–120 mg/dL). The AHA/ASA guidelines recommend treatment of hypoglycemia (<60 mg/dL). For patients with hyperglycemia, it is recommended to achieve blood glucose levels in a range of 140 to 180 mg/dL [15]. Another aspect to be aware of is the risk of contrast-induced nephropathy since many of these patients are elderly and some patients may already present with decreased renal function. Temperature control is also important and sources of hyperthermia (t > 38C) should be identified and treated [15]. Postprocedural lab work in general demonstrates some degree of hemodilution; however, since most of the endovascular stroke treatments performed currently require the use of large sheaths and may have been performed in patients that have received thrombolytic therapy or anticoagulation, one should be attentive to signs of possible access site or retroperitoneal hematoma. Despite the lack of evidence specifically in acute stroke patients treated with endovascular techniques, a systematic review of blood transfusions in neurocritical care patients found that hemoglobin concentrations as low as 7 g/dL are generally well tolerated [55,56].

VI. DOCUMENTATION

Reporting should be in accordance with the <u>ACR-SIR-SPR Practice Parameter for the Reporting and Archiving</u> of Interventional Radiology Procedures [57].

Specific preprocedure information that should be available in the medical record includes clinically significant history, including indications for the procedure; premorbid functioning, ideally using mRS; degree of neurological impairment and other pertinent physical examination findings prior to treatment, including determination of NIHSS; and findings of pertinent diagnostic imaging studies. Specific postprocedure information that should be available within the medical record includes extent of angiographic recanalization, ideally using mTICI score, and degree of neurological impairment following treatment, including determination of NIHSS within 24 hours of treatment and mRS at 90 days after treatment, when possible. Documentation should meet the requirements of the quality improvement program described in section X.

VII. EQUIPMENT SPECIFICATION

There are multiple technical requirements that are necessary to ensure safe and successful endovascular treatment of AIS. These include adequate arteriographic and interventional equipment and institutional facilities, physiologic monitoring equipment, and support personnel.

A. Procedural Equipment and Facilities

The following are considered the minimum equipment requirements for performing endovascular treatment of AIS. In planning facilities for these procedures, equipment and facilities more advanced than those outlined below may be desired to improve outcomes and reduce duration of the procedures. In general, at a minimum, the facility should include:

1. A high-resolution flat panel detector (preferred) or image intensifier and image monitor with digital subtraction angiographic and roadmapping capabilities. Biplane capability is desirable to guide interventions and to reduce contrast injections. Equipment requirements are more stringent than those for the performance of diagnostic cervicocerebral angiography due to the higher complexity and risk of interventional procedures. Digital angiographic systems without subtraction and roadmapping capability and older film-based systems are therefore unacceptable for these procedures, except in the rare event that

transfer to another system or institution with such capabilities would severely delay care. If such a system is employed as a back-up for a more capable system, the actual use for endovascular treatment of AIS should be monitored with the expectation that this should be very rare. Imaging data should be acquired and permanently recorded on an archival digital storage medium that allows retrieval and review. It is highly desirable to be able to record and archive images used for guidance and decision making during the procedure, including last-image-hold images and fluoroscopy loops. Imaging, image recording, and archiving must be consistent with the ALARA radiation safety philosophy. Use of last image hold, fluoroscopy loops, and pulsed fluoroscopy are recommended for dose reduction. Small focal spots for high-resolution imaging and adjustable frame rates are necessary. The available field of view should be able to fit the whole head in frontal and lateral projections, with acknowledgement that some biplane neuroangiography systems employ a slightly smaller lateral detector to facilitate multiangle oblique imaging. Modern low-dose DSA settings should be applied when possible, but high-dose settings should be available for situations that require increased diagnostic sensitivity. Rotational angiography and flat panel detector CT imaging are desirable to facilitate interventions and identify intraprocedural cerebral hemorrhage, respectively.

- 2. Adequate interventional and angiographic supplies such as embolectomy devices (eg, stent retrievers and aspiration catheters), vascular stents, embolic protection devices, angioplasty balloons, catheters, guidewires, needles, flush systems, hemostatic devices, introducer sheaths, and biohazard disposal systems.
- 3. An angiographic injector capable of varying injection volumes and rates with appropriate safety mechanisms (pressure monitoring) to prevent overinjection.
- 4. An angiography suite large enough to allow uncomplicated patient transfer from the bed to table and to allow room for the procedure table, monitoring equipment, and other hardware such as intravenous pumps, respirators, anesthesia team and equipment, oxygen tanks, suction, and gases. There should be adequate space for the operating team to work unencumbered on either side of the patient and for the circulation of other technical staff in the room without contaminating the sterile conditions.
- 5. An area within the institution appropriate for patient evaluation and preparation prior to the procedure. Appropriate emergency equipment and medications must be immediately available to treat adverse reactions associated with administered medications and/or procedural complications. Immediate access to a CT scanner is necessary to evaluate for potential cerebral hemorrhage, edema, and hydrocephalus. The equipment should be monitored and medications inventoried for drug expiration dates on a regular basis. The equipment, medications, and other emergency support must also be appropriate for the range of ages and sizes in the patient population.

B. Physiologic Monitoring and Resuscitation Equipment

- 1. Appropriate equipment should be present in the angiography suite to allow for monitoring the patient's heart rate, cardiac rhythm, and blood pressure. For facilities using sedation, a pulse oximeter must be available (see the <u>ACR-SIR Practice Parameter for Sedation/Analgesia</u> [46]). Appropriate equipment and supplies to support the safe performance of general anesthesia should be available.
- 2. Emergency resuscitation equipment and drugs should be immediately available and include the following: a defibrillator, oxygen supply and appropriate tubing and delivery systems, suction equipment, tubes for endotracheal intubation, laryngoscope, ventilation bag-valve-mask apparatus, and central venous line sets. Drugs for treating cardiopulmonary arrest, contrast reaction, vasovagal reactions, and ventricular arrhythmias, as well as drugs for narcotic or benzodiazepine reversal, and protamine if heparin is administered. Resuscitation equipment should be monitored and checked routinely in compliance with institutional policies.

VIII. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, registered radiologist assistants, radiologic technologists, and all supervising physicians have a responsibility for safety in the workplace by keeping radiation exposure to staff, and to society as a whole, "as low as reasonably achievable" (ALARA) and to assure that radiation doses to individual patients are appropriate, taking into account the possible risk from radiation exposure and the diagnostic image quality necessary to achieve the clinical objective. All personnel that work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection and application of dose limits) and the principles of proper management of radiation dose to patients (justification, optimization and the use of dose reference levels)

http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1578 web-57265295.pdf.

Nationally developed guidelines, such as the ACR's <u>Appropriateness Criteria</u>®, should be used to help choose the most appropriate imaging procedures to prevent unwarranted radiation exposure.

Facilities should have and adhere to policies and procedures that require varying ionizing radiation examination protocols (plain radiography, fluoroscopy, interventional radiology, CT) to take into account patient body habitus (such as patient dimensions, weight, or body mass index) to optimize the relationship between minimal radiation dose and adequate image quality. Automated dose reduction technologies available on imaging equipment should be used whenever appropriate. If such technology is not available, appropriate manual techniques should be used.

Additional information regarding patient radiation safety in imaging is available at the Image Gently[®] for children (www.imagegently.org) and Image Wisely[®] for adults (www.imagewisely.org) websites. These advocacy and awareness campaigns provide free educational materials for all stakeholders involved in imaging (patients, technologists, referring providers, medical physicists, and radiologists).

Radiation exposures or other dose indices should be measured and patient radiation dose estimated for representative examinations and types of patients by a Qualified Medical Physicist in accordance with the applicable ACR Technical Standards. Regular auditing of patient dose indices should be performed by comparing the facility's dose information with national benchmarks, such as the ACR Dose Index Registry, the NCRP Report No. 172, Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States or the Conference of Radiation Control Program Director's National Evaluation of X-ray Trends. (ACR Resolution 17 adopted in 2006 – revised in 2009, 2013, Resolution 52).

IX. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading *Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education* on the ACR website (https://www.acr.org/Clinical-Resources/Practice-Parameters-and-Technical-Standards).

The data developed through these policies and procedures should be used in conjunction with the thresholds described in section X below to assess diagnostic cervicocerebral catheter angiographic procedural efficacy and complication rates and, as defined in those sections, to trigger institutional review when the thresholds defined in those sections are exceeded.

X. QUALITY IMPROVEMENT

Clinical outcomes for endovascular AIS interventions depend on both individual and facility performance. A quality improvement program is necessary to identify performance results and opportunities for improvement to reduce treatment times and improve revascularization rates. A multisociety and multispecialty consensus paper provides indicators and thresholds for performance [43]. Physicians and facilities that provide these stroke

interventions should meet these thresholds. These indicators and thresholds are being revised to include the most recent trial results.

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^{*}Practice parameters and technical standards are published annually with an effective date of October 1 in the year in which amended, revised, or approved by the ACR Council. For practice parameters and technical standards published before 1999, the effective date was January 1 following the year in which the practice parameter or technical standard was amended, revised, or approved by the ACR Council.

Appendix A

Society of Interventional Radiology Standards of Practice Committee Classification of Complications by Outcome

Minor Complications

- A. No therapy, no consequence
- B. Nominal therapy, no consequence; includes overnight admission for observation only

Major Complications

- C. Require therapy, minor hospitalization (<48 hours)
- D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 hours)
- E. Permanent adverse sequelae
- F. Death

Appendix B

modified Rankin Scale [58]

- 0 =Grade 0: No signs or symptoms
- 1 = Grade 1: No significant disability; able to carry out all the usual activities of daily living without assistance. NOTE: This does not preclude the presence of weakness, sensory loss, language disturbance, etc, but implies that these are mild and do not or have not caused patient to limit his/her activities (eg, if employed before, is still employed at the same job).
- 2 = Grade 2: Slight disability; unable to carry out some previous activities but able to look after own affairs without much assistance (eg, unable to return to prior job, unable to do some household chores, but able to get along without daily supervision or help)
- 3 = Grade 3: Moderate disability requiring some help but able to walk without assistance (eg, needs daily supervision; needs assistance with small aspects of dressing, hygiene; unable to read or communicate clearly). NOTE: Use of ankle-foot orthotic or cane does not imply that the patient needs assistance.
- 4 = Grade 4: Moderately severe disability; unable to walk without assistance and unable to attend bodily needs without assistance (eg, needs 24-hour supervision and moderate to maximum assistance on several activities of daily living but still able to do some activities by self or with minimal assistance)
- 5 = Grade 5: Severe disability; bedridden, incontinent, and requiring constant nursing care and attention
- 6 =Stroke death
- 9 = Unknown (not obtainable from history or no follow-up)

Appendix C

National Institutes of Health Stroke Scale Worksheet for Scoring Stroke Symptoms [59]

STROKE CENTER STROKE SCALE FLOWSHEET National Institute of Health Stroke Scale (NIHSS)

National Institute of Health Stroke Scale (NIHSS)		
NIH aste addi	mplete NIH Stroke score consists of all 11 elements of the Stroke Scale, A modified NIH Stroke scale consists of risk (*) Items 1, 4, 5, 6. Pupil exam may be ordered in tion to the NIH Stroke scale, but is not included in the score. is NOT included on the flowsheet, but ordered separately.	Enter Stroke Scale scores for each item in the space provided. TIME NT denotes non-testable.
LEVEL OF NSCIOUSNESS	*1a. Level of consciousness	O = alert 1 = drowsy but arousable 2 = stuporous 3 = coma 0 = answers both correctly
	*1b. Level of consciousness questions (month, age) *1c. Level of consciousness commands	answers one correctly 1 = answers one correctly 2 = both incorrect 0 = performs both correctly
ŝ	(1. open, then close eyes 2. make fist, then let go) 2. Best gaze	1 = performs one correctly 2 = both incorrect 0 = norms!
VISION	(ability to follow examiner's finger across horizontal plane) 3. Visual	1 = partial gaze palsy 2 = forced deviation 0 = no visual loss
	(visual stimulus to patient's visual field quadrants - see diagram on back of form)	1 = partial hemianopsia 2 = complete hemienopsia 3 = bitateral hemianopsia (blind)
MOVEMENT	*4. Facial palsy (shows teeth, raise eyebrows, squeeze eyes shut)	0 = normal 1 minor asymmetry upon smillng, flattened nesolabial fold 2 = partial (total or near total paralysis of lower face) 3 = complete absence of movement in upper and lower face (of one or both sides)
	*5a. Motor arm - LEFT *5b. Motor arm - RIGHT (extends arms with palms DOWN to 90 degrees if sitting 45 degrees if supine and hold for 10 seconds - score	0 = no drift for 10 seconds 1 = drift, does NOT hit bed 2 = some effort against gravity, fimb falls to bed, same movement 3 = no effort against gravity, fimb falls to
	drift/movement)	bed, some movement 4 = no movement NT = amputation, joint fusion (explain) Right
	*6a. Motor leg - LEFT *6b. Motor leg - RIGHT (while supine, hold leg at 30 degrees for 5 seconds - score drift/movement)	0 = no drift for 5 seconds
	,	bed, some movement 4 = no movement NT = amputation, joint fusion (explain) Right
	Limb ataxia (finger to nose, heel down shin)	0 = absent or affected kmb too weak to perform exam 1 = present in one limb 2 = present in two limbs
SENSORY	Sensory (pin prick to face, arm, trunk and leg - compare side to side)	0 = normal = milit to moderate loss "not as sharp" 2 = severe loss, total sensory loss, patient unaware of being touched
ANGUAGE	Best language (name items, describe a picture and read sentences - see reverse side for use of words and pictures to aide in assessment)	0 = no ophasia 1 = mild to moderate aphasia, examiner can identity picture from patient response 2 = severe aphasia, examiner CANNOT identify pictures from patient response 3 = mute, no useable specoch 3 = mute, no useable specoch
ZANG	Dysarthria (evaluate speech clarity by patient repeating listed words- see reverse side for use of words to aide in assessment)	O = normal 1 = milit, sturs some words 2 = severe, sturred speech, unintelligible or mute NT = intubated or or other physical barrier (explain)
	Extinction and inattention (use information from prior testing to identify neglect or double simultaneous stimuli testing - modality; visual, tactile/auditory, spacial)	0 = normal 1 = inattention or extinction in one modelity 2 = profound hemi-inattention or hemi-inattention in more than one modelity
EYES	Pupil exam (see reverse side for diagram of mm) Not included in NIHSS Stroke Scale score Reactive = R Nonreactive = N	Size Left Reaction Left Size Right Reaction Right
Initi	als/Signatures:	Total MODIFED NIH Stroke Scale Score: Total COMPLETE NIH
		Stroke Scale Score: Initials:

Patient Name

STROKE CENTER STROKE SCALE FLOWSHEET

Appendix D

Modified Thrombolysis in Cerebral Ischemia (mTICI) Scale [60]

Grade Definitions

- 0 No perfusion
- Antegrade reperfusion past the initial occlusion, but limited distal branch filling with little or slow distal reperfusion
- 2a Antegrade reperfusion of less than half of the occluded target artery previously ischemic territory
- 2b Antegrade reperfusion of more than half of the previously occluded target artery ischemic territory
- 3 Complete antegrade reperfusion of the previously occluded target artery ischemic territory, with absence of visualized occlusion in all distal branches