

Health Care Guideline

Diagnosis and Initial Treatment of Ischemic Stroke

ICSI has endorsed with qualifications the following American Heart Association (AHA)/American Stroke Association (ASA) documents:

- 2013 AHA/ASA Guidelines for the Early Management of Patients with Acute Ischemic Stroke
- 2015 AHA/ASA Focused Update of the 2013 Guidelines for the Early Management of Patients With Acute Ischemic Stroke Regarding Endovascular Treatment
- 2016 Scientific Rationale for the Inclusion and Exclusion Criteria for Intravenous Alteplase in Acute Ischemic Stroke

The AHA/ASA's original documents can be accessed at http://www.strokeassociation.org/STROKEORG/.

Using the ICSI endorsement process, this document has been reviewed by the ICSI Diagnosis and Initial Treatment of Ischemic Stroke work group: Anderson D, Larson D, Ferguson A, Klaas J, Kushner F, Peterson B, Sierzant T, Streib C, Thomson R.

The American Heart Association (AHA)/American Stroke Association (ASA) are not sponsors of, affiliated with or endorsers of ICSI or the ICSI Diagnosis and Initial Treatment of Ischemic Stroke work group. The AHA/ASA has not reviewed ICSI's processes for endorsement of guidelines. The following ICSI endorsement and conclusions are solely the consensus of the ICSI Diagnosis and Initial Treatment of Ischemic Stroke work group using the ICSI Endorsement Process.

Please note, the previous ICSI Diagnosis and Initial Treatment of Ischemic Stroke guideline from July 2012 is being retired.

Health Care Guideline:



Diagnosis and Initial Treatment of Ischemic Stroke

Acute Ischemic Stroke Algorithm

Eleventh Edition December 2016

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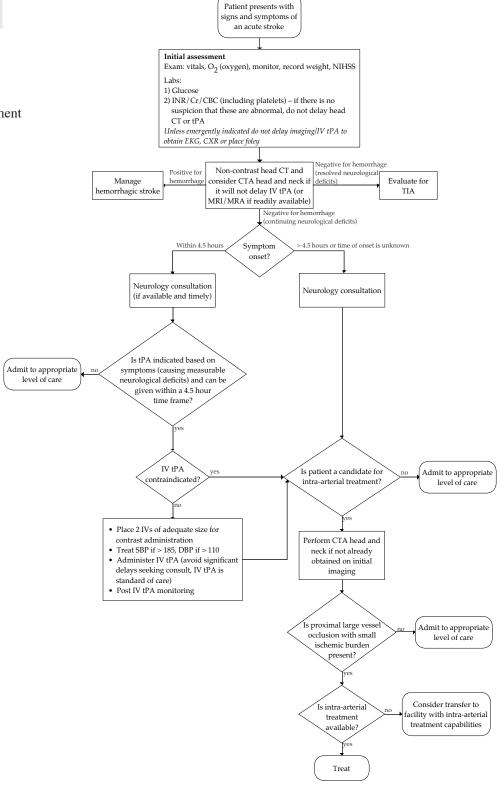


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Evidence Grading

The American Heart Association (AHA)/American Stroke Association (ASA) uses its own system for classifying recommendations and evaluating the levels of evidence. This system is explained in the AHA/ASA stroke documents. Since this is an endorsement document, ICSI did not use its own system to evaluate the levels of evidence or classify recommendations. In one instance where the level of evidence for a recommendation was upgraded, the work group used AHA/ASA's system. In all other instances, where new literature was available to support the existing recommendations or qualification statement for an existing recommendation, the new literature was cited. If there was no new literature, no literature was cited.

Foreword

The American Heart Association/American Stroke Association (AHA/ASA) is not a sponsor of or affiliated with, nor does it endorse ICSI or the ICSI Diagnosis and Initial Treatment of Ischemic Stroke work group. AHA/ASA has not reviewed ICSI's process for endorsement of guidelines. The following ICSI endorsement and conclusions are solely the consensus of the ICSI Diagnosis and Initial Treatment of Ischemic Stroke work group using the ICSI Endorsement Process.

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Introduction

Stroke is the fifth leading cause of death in the United States and a leading cause of serious long-term disability (*Mozzafarian*, 2015; *Kochanek*, 2014). Annually, approximately 800,000 people in the United States have a stroke, and 130,000 die (*Centers for Disease Control and Prevention*, 2016). Of all strokes, 87% are ischemic strokes (*Mozaffarian*, 2015). In Minnesota, ischemic stroke death rate – regardless of gender and age group – is at 19 per 100,000, compared to the national rate of 20 per 100,000, for years 2011-2013 per the Centers for Disease Control and Prevention's Interactive Atlas of Heart Disease and Stroke.

In the United States, one person dies from stroke every four minutes, on average (Mozaffarian, 2015). Therefore, time is of the essence in getting appropriate early care for persons with an onset of stroke symptoms. The recommendations in this guideline are for early management of stroke due to ischemic brain ischemia/infarction. This guideline does not address stroke prevention, transient ischemic stroke (TIA) or management of hemorrhagic stroke.

To increase access to appropriate early care for stroke, Minnesota passed legislation to authorize the Minnesota Department of Health (MDH) to designate hospitals as Acute Stroke-Ready Hospitals, Primary Stroke Centers and Comprehensive Stroke Centers. In addition to hospital designation, the legislation also included data collection and reporting, and standardization of EMS protocols. These changes have led to 91 hospitals in Minnesota getting designated as stroke hospitals as of January 1, 2016, and 87% of residents living within 30 minutes of a designated stroke center, per MDH data. MDH provides training, education and other resources to the hospitals that want to become designated as stroke centers. The ICSI Diagnosis and Initial Treatment of Ischemic Stroke guideline work group strongly encourages the hospitals to participate in this process.

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Endorsement of American Heart Association (AHA)/American Stroke Association (ASA) Stroke Documents

The ICSI Diagnosis and Initial Treatment of Ischemic Stroke guideline work group endorsed the content and recommendations from three AHA/ASA documents (see below). For detailed explanation and evidence supporting the recommendations, see the original documents. AHA/ASA provided writing group and reviewer group conflict of interest disclosures. These were reviewed and taken into consideration by the ICSI Diagnosis and Initial Treatment of Ischemic Stroke work group. The AHA/ASA's original documents can be accessed at http://www.strokeassociation.org/STROKEORG/.

1. 2013 AHA/ASA Guidelines for the Early Management of Patients with Acute Ischemic Stroke. Full citation: Jauch EC, Saver JL, Adams HP Jr, Bruno A, Connors JJ, Demaerschalk BM, Khatri P, McMullan PW Jr, Qureshi AI, Rosenfeld K, Scott PA, Summers DR, Wang DZ, Wintermark M, Yonas H; on behalf of the American Heart Association Stroke Council, Council on Cardiovascular Nursing, Council on Peripheral Vascular Disease, and Council on Clinical Cardiology. Guidelines for the early management of patients with acute ischemic stroke: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. Stroke 2013;44:870-947.

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The literature search was conducted for studies published between January 2012 and March 2016 for any new studies to update the recommendations in this document. For information on the types of studies searched and the literature search terms, please see Appendix A, "Literature Search Terms by Topic."

The following sections content and recommendations were reviewed and endorsed:

- Public Stroke Education and Prehospital Stroke Management
- Designation of Stroke Centers and Stroke Care Quality Improvement Process
- Emergency Evaluation and Diagnosis of Acute Ischemic Stroke
- Early Diagnosis: Brain and Vascular Imaging: Recommendations for Patients With Acute Cerebral Ischemic Symptoms That Have Not Yet Resolved
- General Supportive Care and Treatment of Acute Complications
- Anticoagulants
- Antiplatelet Agents
- Admission to the Hospital and General Acute Treatment (After Hospitalization)
- Treatment of Acute Neurological Complications

The following sections content and recommendations were reviewed and endorsed:

- Early Diagnosis: Brain and Vascular Imaging: Recommendations for Patients With Cerebral Ischemic Symptoms That Have Resolved
- Intravenous Fibrinolysis
- Endovascular Interventions
- Volume Expansion, Vasodilators, and Induced Hypertension
- Neuroprotective Agents
- Surgical Interventions

2. 2015 AHA/ASA Focused Update of the 2013 Guidelines for the Early Management of Patients With Acute Ischemic Stroke Regarding Endovascular Treatment.

Full citation: Powers WJ, Derdeyn CP, Biller J, Coffey CS, Hoh BL, Jauch EC, Johnston KC, Johnston SC, Khalessi AA, Kidwell CS, Meschia JF, Ovbiagele B, Yavagal DR; on behalf of the American Heart Association Stroke Council. 2015 American Heart Association/American Stroke Association focused update of the 2013 guidelines for the early management of patients with acute ischemic stroke regarding endovascular treatment: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke* 2015;46:3020-35.

ICSI did not conduct literature search on the recommendations in this guideline since AHA/ASA's update was recent. However, it was brought to the attention by work group members to include in the review two studies published in 2016 on this topic. Those studies are Goyal, 2016 and Schönenberger, 2016. Refer to the reference section for full citations on these studies.

3. **2016** Scientific Rationale for the Inclusion and Exclusion Criteria for Intravenous Alteplase in Acute Ischemic Stroke. Full citation: Demaerschalk BM, Kleindorfer DO, Adeoye OM, Demchuk AM, Fugate JE, Grotta JC, Khalessi AA, Levy EI, Palesch YY, Prabhakaran S, Saposnik G, Saver JL, Smith EE; on behalf of the American Heart Association Stroke Council and Council on Epidemiology and Prevention. Scientific rationale for the inclusion and exclusion criteria for intravenous alteplase in acute ischemic stroke: a statement for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke* 2016;47:581-641.

ICSI did not conduct literature search on the recommendations in this guideline, since AHA/ASA's update was recent.

Recommendations

Note: In this document, qualification statement signifies substantial qualification/change to the original AHA/ASA recommendation, and recommendations with qualifications statements are labeled as "agree with qualification." Statements that are comments only do not significantly change the original recommendation, and those recommendations are labeled as "agree."

Prehospital

AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus Qualification Statement/	New Literature Support
Public Stroke Education and Prehospi	 	Comment	
1. To increase both the number of patients who are treated and the quality of care, educational stroke programs for physicians, hospital personnel, and EMS personnel are recommended (Class I; Level of Evidence B). (Unchanged from the previous guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	
2. Activation of the 911 system by patients or other members of the public is strongly recommended (Class I; Level of Evidence B). 911 Dispatchers should make stroke a priority dispatch, and transport times should be minimized. (Unchanged from the previous guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree Stroke symptoms should prompt dispatchers to upgrade the response to a priority dispatch, despite what local dispatch protocols might recommend.	Ekundayo, 2013
3. Pre-hospital care providers should use prehospital stroke assessment tools, such as the Los Angeles Prehospital Stroke Screen or Cincinnati Prehospital Stroke Scale (Class I; Level of Evidence B). (Unchanged from the previous guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree Research is ongoing to establish valid and reliable pre-hospital tools to identify patients with acute large artery occlusive strokes, a subgroup that benefits from neurointerventional care offered in only some centers, as well as specialized triage paradigms that improve outcomes for such patients.	Malekzadeh, 2015; Oostema, 2015; Rudd, 2015; Brandler, 2014; Baldereschi, 2012
4. EMS personnel should begin the initial management of stroke in the field, as outlined in Table 4 (Class I; Level of Evidence B). Development of a stroke protocol to be used by EMS personnel is strongly encouraged. (Unchanged from the previous guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree Table 4 is on page 875 of 2013 AHA/ASA guidelines for the Early Management of Patients with Acute Ischemic Stroke.	

AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus Qualification Statement/ Comment	New Literature Support
5. Patients should be transported rapidly to the closest available certified PSC or CSC or, if no such centers exist, the most appropriate institution that provides emergency stroke care as described in the statement (Class I; Level of Evidence A). In some instances, this may involve air medical transport and hospital bypass. (Revised from the previous guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree Specific to Minnesota, Acute Stroke-Ready Hospital (ASRH) is a reasonable option to PSC or CSC.	Oostema, 2014; Baldereschi, 2012
6. EMS personnel should provide prehospital notification to the receiving hospital that a potential stroke patient is en route so that the appropriate hospital resources may be mobilized before patient arrival (Class I; Level of Evidence B). (Revised from the previous guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	Oostema, 2014; Baldereschi, 2012
Designation of Stroke Centers and Str	oke Care Quality Improve	ement Process	
1. The creation of PSCs is recommended (Class I; Level of Evidence B). The organization of such resources will depend on local resources. The stroke system design of regional ASRHs and PSCs that provide emergency care and that are closely associated with a CSC, which provides more extensive care, has considerable appeal. (Unchanged from the previous guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	Switzer, 2015
2. Certification of stroke centers by an independent external body, such as TJC or state health department, is recommended (Class I; Level of Evidence B). Additional medical centers should seek such certification. (Revised from the previous guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	

AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus Qualification Statement/ Comment	New Literature Support
3. Healthcare institutions should organize a multidisciplinary quality improvement committee to review and monitor stroke care quality benchmarks, indicators, evidence-based practices, and outcomes (Class I; Level of Evidence B). The formation of a clinical process improvement team and the establishment of a stroke care data bank are helpful for such quality of care assurances. The data repository can be used to identify the gaps or disparities in quality stroke care. Once the gaps have been identified, specific interventions can be initiated to address these gaps or disparities. (New recommendation)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	Power, 2014
4. For patients with suspected stroke, EMS should bypass hospitals that do not have resources to treat stroke and go to the closest facility most capable of treating acute stroke (Class I; Level of Evidence B). (Unchanged from the previous guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	
5. For sites without in-house imaging interpretation expertise, teleradiology systems approved by the Food and Drug Administration (FDA) or equivalent organization are recommended for timely review of brain CT and MRI scans in patients with suspected acute stroke (Class I; Level of Evidence B). (New recommendation)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	
6. When implemented within a telestroke network, teleradiology systems approved by the FDA (or equivalent organization) are useful in supporting rapid imaging interpretation in time for fibrinolysis decision-making (Class I; Level of Evidence B). (New recommendation)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	
7. The development of CSCs is recommended (Class I; Level of Evidence C). (Unchanged from the previous guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	Panezai, 2013

AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus Qualification Statement/ Comment	New Literature Support
8. Implementation of telestroke consultation in conjunction with stroke education and training for healthcare providers can be useful in increasing the use of intravenous rtPA at community hospitals without access to adequate onsite stroke expertise (Class IIa; Level of Evidence B). (New recommendation)	Class IIa: Benefit>>Risk IT IS REASONABLE to perform procedure/administer treatment.	Agree	Demaerschalk, 2012a; Demaerschalk, 2012b; Meyer, 2012
9. The creation of ASRHs can be useful (Class Ha; Level of Evidence C). As with PSCs, the organization of such resources will depend on local resources. The stroke system design of regional ASRHs and PSCs that provide emergency care and that are closely associated with a CSC, which provides more extensive care, has considerable appeal. (New recommendation)	Class IIa: Benefit>>Risk IT IS REASONABLE to perform procedure/administer treatment.	Agree	

Evaluation/Diagnosis

AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus Qualification Statement/ Comment	New Literature Support
Emergency Evaluation and Diagnosis	of Acute Ischemic Stroke		
1. An organized protocol for the emergency evaluation of patients with suspected stroke is recommended (Class I; Level of Evidence B). The goal is to complete an evaluation and to begin fibrinolytic treatment within 60 minutes of the patient's arrival in an ED. Designation of an acute stroke team that includes physicians, nurses, and laboratory/radiology personnel is encouraged. Patients with stroke should have a careful clinical assessment, including neurological examination. (Unchanged from the previous guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	

AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus Qualification Statement/ Comment	New Literature Support
2. The use of a stroke rating scale, preferably the NIHSS, is recommended (Class I; Level of Evidence B). (Unchanged from the previous guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	
3. A limited number of hematologic, coagulation, and biochemistry tests are recommended during the initial emergency evaluation, and only the assessment of blood glucose must precede the initiation of intravenous rtPA (Table 8) (Class I; Level of Evidence B). (Revised from the previous guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree For the list of tests, refer to Table 8 (Immediate Diagnostic Studies: Evaluation of a Patient With Suspected Acute Ischemic Stroke) on page 881 in the 2013 AHA/ASA Guidelines for the Early Management of Patients with Acute Ischemic Stroke.	
4. Baseline electrocardiogram assessment is recommended in patients presenting with acute ischemic stroke but should not delay initiation of intravenous rtPA (Class I; Level of Evidence B). (Revised from the previous guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	
5. Baseline troponin assessment is recommended in patients presenting with acute ischemic stroke but should not delay initiation of intravenous rtPA (Class I; Level of Evidence C). (Revised from the previous guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	
6. The usefulness of chest radiographs in the hyperacute stroke setting in the absence of evidence of acute pulmonary, cardiac, or pulmonary vascular disease is unclear. If obtained, they should not unnecessarily delay administration of fibrinolysis (Class IIb; Level of Evidence B). (Revised from the previous guideline)	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree	

AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus Qualification Statement/ Comment	New Literature Support
Early Diagnosis: Brain and Vascular Symptoms That Have Not Yet Resol		tions for Patients With Acut	e Cerebral Ischemic
1. Emergency imaging of the brain is recommended before initiating any specific therapy to treat acute ischemic stroke (Class I; Level of Evidence A). In most instances, NECT will provide the necessary information to make decisions about emergency management. (Unchanged from the previous guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	
2. Either NECT or MRI is recommended before intravenous rtPA administration to exclude ICH (absolute contraindication) and to determine whether CT hypodensity or MRI hyperintensity of ischemia is present (Class I; Level of Evidence A). (Revised from the 2009 imaging scientific statement)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	
3. Intravenous fibrinolytic therapy is recommended in the setting of early ischemic changes (other than frank hypodensity) on CT, regardless of their extent (Class I; Level of Evidence A). (Revised from the 2009 imaging scientific statement)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	
4. A non-invasive intracranial vascular study is strongly recommended during the initial imaging evaluation of the acute stroke patient if either intra-arterial fibrinolysis or mechanical thrombectomy is contemplated for management but should not delay intravenous rtPA if indicated (Class I; Level of Evidence A). (Revised from the 2009 imaging scientific statement)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree with qualification The ICSI work group would like to change this recommendation to add "cervical and" before intracranial vascular. Therefore, the recommendation would state the following: A non-invasive cervical and intracranial vascular study is strongly recommended during the initial imaging evaluation of the acute stroke patient if either intra-arterial fibrinolysis or mechanical thrombectomy is contemplated for management but should not delay intravenous rtPA if indicated.	Menon, 2015; van den Wijngaard, 2015; Chung, 2014

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AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus	New Literature Support
		Qualification Statement/ Comment	11
5. In intravenous fibrinolysis candidates, the brain imaging study should be interpreted within 45 minutes of patient arrival in the ED by a physician with expertise in reading CT and MRI studies of the brain parenchyma (Class I; Level of Evidence C). (Revised from the previous guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	Spokoyny, 2014; Demaerschalk, 2012b
6. CT perfusion and MRI perfusion and diffusion imaging, including measures of infarct core and penumbra, may be considered for the selection of patients for acute reperfusion therapy beyond the time windows for intravenous fibrinolysis. These techniques provide additional information that may improve diagnosis, mechanism, and severity of ischemic stroke and allow more informed clinical decision-making (Class IIb; Level of Evidence B). (Revised from the 2009 imaging scientific statement)	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED	The ICSI Diagnosis and Initial Treatment of Ischemic Stroke work group concluded that evidence of value of core/penumbra imaging remains unproven, and its use in selecting patients for treatment with IV tPA beyond recommended time window of 4.5 hours from onset is not recommended outside a clinical trial per recommendation 3 in Wake- up/Unclear Onset Time Stroke section of Intravenous Fibrinolysis recommendations table. Recommendation 3 pertains to the use of imaging criteria to determine administration of IV tPA but in the setting of "wake-up stroke" (or onset time unknown). Please also see recommendation 3 in Imaging section of Endovascular Interventions recommendations table pertaining to selection for endovascular thrombectomy beyond recommended window of 6 hours from onset.	Albers, 2015; Borst, 2015; Burton, 2015; Galinovic, 2014; Sanelli, 2014; Schroeder, 2014; Lin, 2014; Kidwell, 2013; Michel, 2012; Nagakane, 2012
7. Frank hypodensity on NECT may increase the risk of hemorrhage with fibrinolysis and should be considered in treatment decisions. If frank hypodensity involves more than one third of the MCA territory, intravenous rtPA treatment should be withheld (Class III; Level of Evidence A). (Revised from the 2009 imaging scientific statement)	Class III: Harm or No Benefit	Agree	

Acute Management

AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus Qualification Statement/ Comment	New Literature Support
General Supportive Care and Treatme	nt of Acute Complication	ons	
1. Cardiac monitoring is recommended to screen for atrial fibrillation and other potentially serious cardiac arrhythmias that would necessitate emergency cardiac interventions. Cardiac monitoring should be performed for at least the first 24 hours (Class I; Level of Evidence B). (Revised from the previous guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/ administered.	Agree Further studies are required to determine patient selection, optimal timing, method and duration of cardiac monitoring, which are important issues relevant to long-term secondary stroke prevention that is beyond the purview of this guideline.	
2. Patients who have elevated blood pressure and are otherwise eligible for treatment with intravenous rtPA should have their blood pressure carefully lowered (Table 9) so that their systolic blood pressure is <185 mmHg and their diastolic blood pressure is <110 mmHg (Class I; Level of Evidence B) before fibrinolytic therapy is initiated. If medications are given to lower blood pressure, the clinician should be sure that the blood pressure is stabilized at the lower level before beginning treatment with intravenous rtPA and maintained below 180/105 mmHg for at least the first 24 hours after intravenous rtPA treatment. (Unchanged from the previous guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/ administered.	Agree For approaches to arterial hypertension in acute ischemic stroke, refer to Table 9 (Potential Approaches to Arterial Hypertension in Acute Ischemic Stroke Patients Who are Candidates for Acute Reperfusion Therapy) on page 891 in the 2013 AHA/ASA Guidelines for the Early Management of Patients with Acute Ischemic Stroke.	Berge, 2015; Lee, 2015; Bath, 2014; He, 2014
3. Airway support and ventilatory assistance are recommended for the treatment of patients with acute stroke who have decreased consciousness or who have bulbar dysfunction that causes compromise of the airway (Class I; Level of Evidence C). (Unchanged from the previous guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	Minnerup, 2012
4. Supplemental oxygen should be provided to maintain oxygen saturation > 94% (Class I; Level of Evidence C). (Revised from the previous guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	Bennett, 2014

AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus Qualification Statement/ Comment	New Literature Support
5. Sources of hyperthermia (temperature > 38°C) should be identified and treated, and antipyretic medications should be administered to lower temperature in hyperthermic patients with stroke (Class I; Level of Evidence C). (Unchanged from the previous guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	
6. Until other data become available, consensus exists that the previously described blood pressure recommendations should be followed in patients undergoing other acute interventions to recanalize occluded vessels, including intra-arterial fibrinolysis (Class I; Level of Evidence C). (Unchanged from the previous guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree with qualification For the list of therapies, refer to Table 9 (Potential Approaches to Arterial Hypertension in Acute Ischemic Stroke Patients Who are Candidates for Acute Reperfusion Therapy) on page 891 in the 2013 AHA/ASA Guidelines for the Early Management of Patients with Acute Ischemic Stroke guideline. It is consensus of the ICSI work group to add Clevidipine to this list. Studies have been done to evaluate the effectiveness and safety of this therapy.	
7. In patients with markedly elevated blood pressure who do not receive fibrinolysis, a reasonable goal is to lower blood pressure by 15% during the first 24 hours after onset of stroke. The level of blood pressure that would mandate such treatment is not known, but consensus exists that medications should be withheld unless the systolic blood pressure is > 220 mm Hg or the diastolic blood pressure is > 120 mm Hg (Class I; Level of Evidence C). (Revised from the previous guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	He, 2014
8. Hypovolemia should be corrected with intravenous normal saline, and cardiac arrhythmias that might be reducing cardiac output should be corrected (Class I; Level of Evidence C). (Revised from the previous guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	

AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus Qualification Statement/ Comment	New Literature Support
9. Hypoglycemia (blood glucose < 60 mg/dL) should be treated in patients with acute ischemic stroke (Class I; Level of Evidence C). The goal is to achieve normoglycemia. (Revised from the previous guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	
10. Evidence from one clinical trial indicates that initiation of antihypertensive therapy within 24 hours of stroke is relatively safe. Restarting antihypertensive medications is reasonable after the first 24 hours for patients who have preexisting hypertension and are neurologically stable unless a specific contraindication to restarting treatment is known (Class IIa; Level of Evidence B). (Revised from the previous guideline)	Class IIa: Benefit>>Risk IT IS REASONABLE to perform procedure/administer treatment.	Agree As 2013 AHA/ASA guideline for the Early Management of Patients with Acute Ischemic Stroke point out on p. 891, the optimal time after onset of ischemic stroke to restart or start long-term antihypertensive therapy has not been established. The optimal time may depend on patient and stroke characteristics. It seems reasonable to initiate long-term antihypertensive therapy after the initial 24 hours from stroke onset in most patients.	
11. No data are available to guide selection of medications for the lowering of blood pressure in the setting of acute ischemic stroke. The antihypertensive medications and doses included in Table 9 are reasonable choices based on general consensus (Class IIa; Level of Evidence C). (Revised from the previous guideline)	Class IIa: Benefit>>Risk IT IS REASONABLE to perform procedure/ administer treatment.	Agree with qualification For the list of therapies, refer to Table 9 (Potential Approaches to Arterial Hypertension in Acute Ischemic Stroke Patients Who are Candidates for Acute Reperfusion Therapy) on page 891 in the 2013 AHA/ASA Guidelines for the Early Management of Patients with Acute Ischemic Stroke. It is consensus of the ICSI work group to add Clevidipine to this list. Studies have been done to evaluate the effectiveness and safety of this therapy.	

AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus Qualification Statement/ Comment	New Literature Support
12. Evidence indicates that persistent inhospital hyperglycemia during the first 24 hours after stroke is associated with worse outcomes than normoglycemia, and thus, it is reasonable to treat hyperglycemia to achieve blood glucose levels in a range of 140 to 180 mg/dL and to closely monitor to prevent hypoglycemia in patients with acute ischemic stroke (Class IIa; Level of Evidence C). (Revised from the previous guideline)	Class IIa: Benefit>>Risk IT IS REASONABLE to perform procedure/administer treatment.	Agree	Rosso, 2015
13. The management of arterial hypertension in patients not undergoing reperfusion strategies remains challenging. Data to guide recommendations for treatment are inconclusive or conflicting. Many patients have spontaneous declines in blood pressure during the first 24 hours after onset of stroke. Until more definitive data are available, the benefit of treating arterial hypertension in the setting of acute ischemic stroke is not well established (Class IIb; Level of Evidence C). Patients who have malignant hypertension or other medical indications for aggressive treatment of blood pressure should be treated accordingly. (Revised from the previous guideline)	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree	Lee, 2015; Zhao, 2015; Bath, 2014; He, 2014
14. Supplemental oxygen is not recommended in non-hypoxic patients with acute ischemic stroke (Class III; Level of Evidence B). (Unchanged from the previous guideline)	Class III: Harm or No Benefit	Agree	Bennett, 2014

AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus Qualification Statement/ Comment	New Literature Support
Intravenous Fibrinolysis (Endorsed Reand Exclusion Criteria for Intravenous			r the Inclusion
Age Issues			
1. For otherwise medically eligible patients ≥ 18 years of age, intravenous alteplase administration within 3 hours is equally recommended for patients < 80 and > 80 years of age. Older age is an adverse prognostic factor in stroke but does not modify the treatment effect of thrombolysis. Although older patients have poorer outcomes, higher mortality, and higher rates of sICH than those < 80 years of age, compared with control subjects, intravenous alteplase provides a better chance of being independent at 3 months across all age groups (Class I; Level of Evidence A).	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/ administered.	Agree	
2. The efficacy and risk of intravenous alteplase administration in the pediatric population (neonates, children, and adolescents < 18 years of age) are not well established (Class IIb; Level of Evidence B).	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree	
Stroke Severity			
1. For severe stroke symptoms, intravenous alteplase is indicated within 3 hours from symptom onset of ischemic stroke. Despite increased risk of hemorrhagic transformation, there is still proven clinical benefit for patients with severe stroke symptoms (Class I; Level of Evidence A).	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	
2. For patients with mild but disabling stroke symptoms, intravenous alteplase is indicated within 3 hours from symptom onset of ischemic stroke. There should be no exclusion for patients with mild but nonetheless disabling stroke symptoms in the opinion of the treating physician from treatment with intravenous alteplase because there is proven clinical benefit for those patients (Class I; Level of Evidence A).	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	

AHA/ASA Recommendation 3. Within 3 hours from symptom onset,	AHA/ASA Class Class IIb: Benefit ≥	ICSI Work Group Consensus Qualification Statement/ Comment	New Literature Support
treatment of patients with milder ischemic stroke symptoms that are judged as non-disabling may be considered. Treatment risks should be weighed against possible benefits; however, more study is needed to further define the risk-to-benefit ratio (Class IIb; Level of Evidence C).	Risk Procedure/Treatment MAY BE CONSIDERED.	Agree	
Rapidly Improving			
1. Intravenous alteplase treatment is reasonable for patients who present with moderate to severe ischemic stroke and demonstrate early improvement but remain moderately impaired and potentially disabled in the judgment of the examiner (Class IIa; Level of Evidence A).	Class IIa: Benefit>>Risk IT IS REASONABLE to perform procedure/administer treatment.	Agree	
2. Because time from onset of symptoms to treatment has such a powerful impact on outcome, delaying treatment with intravenous alteplase to monitor for further improvement is not recommended (Class III; Level of Evidence C).	Class III: Harm or No Benefit	Agree	
Time from Symptom Onset			
1. The time from last seen normal to treatment with intravenous alteplase should be < 3 hours for eligible patients with the use of standard eligibility criteria (Class I; Level of Evidence A).	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	
2. Intravenous alteplase treatment in the 3- to 4.5-hour time window is also recommended for those patients < 80 years of age without a history of both diabetes mellitus and prior stroke, NIHSS score < 25, not taking any OACs, and without imaging evidence of ischemic injury involving more than one third of the MCA territory (Class I; Level of Evidence B).	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree See Extended 3- to 4.5-Hour Window: Recommendations Section below for recommendations on patients > 80 years of age, patients taking warfarin with an INR < 1.7, patients with a baseline NIHSS score > 25 and patients with prior stroke and diabetes mellitus.	
3. Treatment should be initiated as quickly as possible within the above listed time frames because time to treatment is strongly associated with outcome (Class I; Level of Evidence A).	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	

AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus Qualification Statement/ Comment	New Literature Support
4. In patients in the 0- to 4.5-hour time window who meet criteria for treatment with intravenous alteplase, substantially delaying intravenous alteplase treatment to obtain penumbral imaging before treatment is not recommended (<i>Class III</i> ; <i>Level of Evidence C</i>).	Class III: Harm or No Benefit	Agree	
Extended 3- to 4.5-Hour Window			
1. Intravenous alteplase is recommended for carefully selected patients who meet ECASS III criteria and are treated in the	Class I: Benefit>>>Risk	Agree	
3- to 4.5-hour window (Class I; Level of Evidence B).	Procedure/Treatment SHOULD be performed/administered.		
2. For patients > 80 years of age presenting in the 3- to 4.5-hour window, intravenous alteplase treatment is safe	Class IIa: Benefit>>Risk	Agree	
and can be as effective as in younger patients (Class IIa; Level of Evidence B).	to perform procedure/administer treatment.		
3. For patients taking warfarin and with an INR < 1.7 who present in the 3- to 4.5-hour window, intravenous alteplase	Class IIb: Benefit ≥ Risk	Agree	
treatment appears safe and may be beneficial (Class IIb; Level of Evidence B).	Procedure/Treatment MAY BE CONSIDERED.		
4. The benefit of intravenous alteplase administration for acute stroke patients with a baseline NIHSS score > 25 and	Class IIb: Benefit ≥ Risk	Agree	
presenting in the 3- to 4.5-hour window is uncertain (<i>Class IIb</i> ; <i>Level of Evidence C</i>).	Procedure/Treatment MAY BE CONSIDERED.		
5. In acute ischemic stroke patients with prior stroke and diabetes mellitus presenting in the 3- to 4.5- hour window,	Class IIb: Benefit ≥ Risk	Agree	
intravenous alteplase may be as effective as treatment in the 0- to 3-hour window and may be a reasonable option (Class IIb; Level of Evidence B).	Procedure/Treatment MAY BE CONSIDERED.		
Acute Intracranial Hemorrhage on CT			1
1. Intravenous alteplase should not be administered to a patient whose CT reveals an acute intracranial hemorrhage (Class III; Level of Evidence C).	Class III: Harm or No Benefit	Agree	

AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus Qualification Statement/ Comment	New Literature Support
Pregnancy and Postpartum			
1. Intravenous alteplase administration for ischemic stroke may be considered in pregnancy when the anticipated benefits of treating moderate to severe stroke outweigh the anticipated increased risks of uterine bleeding (Class IIb; Level of Evidence C).	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree with qualification It is consensus of the ICSI work group to recommend consultation with a high-risk obstetrics gynecology provider in these instances.	
2. The safety and efficacy of intravenous alteplase in the early postpartum period (< 14 days after delivery) have not been well established (Class IIb; Level of Evidence C).	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree	
3. Urgent consultation with an obstetrician-gynecologist and potentially a perinatologist to assist with management of the mother and fetus is recommended (Class I; Level of Evidence C).	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	
Platelets and Coagulation Studies			
1. The safety and efficacy of intravenous alteplase for acute stroke patients with platelets < 100000/mm ³ , INR > 1.7, aPTT > 40 seconds, or PT > 15 seconds are unknown, and intravenous alteplase is not recommended (<i>Class III</i> ; <i>Level of Evidence C</i>).	Class III: Harm or No Benefit	Agree	
2. Given the extremely low risk of unsuspected abnormal platelet counts or coagulation studies in a population, it is reasonable that urgent intravenous alteplase treatment not be delayed while waiting for hematologic or coagulation testing if there is no reason to suspect an abnormal test (Class IIa; Level of Evidence B).	Class IIa: Benefit>>Risk IT IS REASONABLE to perform procedure/administer treatment.	Agree	
History of Bleeding Diathesis/Coagulopa	1	I	
1. The safety and efficacy of intravenous alteplase for acute stroke patients with a clinical history of potential bleeding diathesis or coagulopathy are unknown. Intravenous alteplase may be considered on a case-by-case basis (Class IIb; Level of Evidence C).	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree	

AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus Qualification Statement/ Comment	New Literature Support
Anticoagulant Use			
 Intravenous alteplase may be reasonable in patients who have a history of warfarin use and an INR ≤ 1.7 (Class IIb; Level of Evidence B). Intravenous alteplase in patients who have a history of warfarin use and an INR > 1.7 is not recommended (Class III; Level of Evidence B). 	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED. Class III: Harm or No Benefit	Agree	
3. Intravenous alteplase in patients who have received a dose of LMWH within the previous 24 hours is not recommended. This applies to both prophylactic doses and treatment doses (Class III; Level of Evidence B).	Class III: Harm or No Benefit	Agree Refer to Table 4 (Inclusion and Exclusion Characteristics of Patients With Ischemic Stroke Who Could Be Treated With Intravenous rTPA Within 3 Hours From Symptom Onset) on page 586 of the 2016 Scientific Rationale for the Inclusion and Exclusion Criteria for Intravenous Alteplase in Acute Ischemic Stroke. The table states that as it relates to heparin, exclusion criteria include heparin received within 48 hours resulting in abnormally elevated aPTT above the upper limit of normal.	
4. The use of intravenous alteplase in patients taking direct thrombin inhibitors or direct factor Xa inhibitors has not been firmly established but may be harmful (Class III; Level of Evidence C). The use of intravenous alteplase in patients taking direct thrombin inhibitors or direct factor Xa inhibitors is not recommended unless laboratory tests such as aPTT, INR, platelet count, ecarin clotting time, thrombin time, or appropriate direct factor Xa activity assays are normal or the patient has not received a dose of these agents for > 48 hours (assuming normal renal metabolizing function).	Class III: Harm or No Benefit	Agree Antidotes are being tested for direct factor Xa and thrombin inhibitors. At this point, no recommendation can be made about efficacy and safety of alteplase in patients taking direct facor Xa and thrombin inhibitors.	

AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus Qualification Statement/ Comment	New Literature Support	
Major Surgery Within 14 Days				
1. Use of intravenous alteplase in carefully selected patients presenting with acute ischemic stroke who have undergone a major surgery in the preceding 14 days may be considered, but the potential increased risk of surgical-site hemorrhage should be weighed against the anticipated benefits of reduced stroke-related neurological deficits (Class IIb; Level of Evidence C).	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree		
Major Trauma Within 14 days and Seven	re Head Trauma Within 3	3 Months		
1. In acute ischemic stroke patients with recent major trauma (within 14 days), intravenous alteplase may be carefully considered, with the risks of bleeding from injuries related to the trauma weighed against the severity and potential disability from the ischemic stroke (Class IIb; Level of Evidence C).	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree		
2. In acute ischemic stroke patients with recent severe head trauma (within 3 months), intravenous alteplase is contraindicated (Class III; Level of Evidence C).	Class III: Harm or No Benefit	Agree		
3. Given the possibility of bleeding complications from the underlying severe head trauma, intravenous alteplase is not recommended in posttraumatic infarction that occurs during the acute in-hospital phase (Class III; Level of Evidence C).	Class III: Harm or No Benefit	Agree		
Acute MI or History of Recent MI				
1. For patients presenting with concurrent acute ischemic stroke and acute MI, treatment with intravenous alteplase at the dose appropriate for cerebral ischemia, followed by percutaneous coronary angioplasty and stenting if indicated, is reasonable (Class IIa; Level of Evidence C).	Class IIa: Benefit>>Risk IT IS REASONABLE to perform procedure/administer treatment.	Agree		

AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group	New Literature
AHA/ASA Recommendation	Ana/asa Ciass	Consensus	Support
		Qualification Statement/	11
		Comment	
2. For patients presenting with acute	Class IIa:	Agree	
ischemic stroke and a history of recent	Benefit>>Risk		
MI in the past 3 months, treating the ischemic stroke with intravenous	IT IS REASONABLE		
alteplase is reasonable if the recent MI	to perform procedure/administer		
was non-STEMI (Class IIa; Level of	treatment.		
Evidence C), is reasonable if the recent MI was STEMI involving the right or			
inferior myocardium (Class IIa; Level of	Class IIb: Benefit ≥ Risk		
Evidence C), and may be reasonable if the			
recent MI was STEMI involving the left anterior myocardium (Class IIb; Level of	Procedure/Treatment MAY BE		
Evidence C).	CONSIDERED.		
Left-Sided Heart Thrombus			
1. For patients with major acute ischemic	Class IIb: Benefit ≥	Agree	
stroke likely to produce severe disability	Risk		
and known left atrial or ventricular thrombus, treatment with intravenous	Procedure/Treatment		
alteplase may be reasonable (Class IIb;	MAY BE CONSIDERED.		
Level of Evidence C).	CONSIDERED.		
2. For patients presenting with moderate	Class IIb: Benefit ≥	Agree	
acute ischemic stroke likely to produce mild disability and known left atrial or	Risk		
ventricular thrombus, treatment with	Procedure/Treatment MAY BE		
intravenous alteplase is of uncertain net	CONSIDERED.		
benefit (Class IIb; Level of Evidence C). Endocarditis			
	Class III: Harm or No	Agrae	
1. For patients with acute ischemic stroke and symptoms consistent with	Benefit	Agree	
infective endocarditis, treatment with			
intravenous alteplase is not recommended			
because of the increased risk of intracranial hemorrhage (Class III; Level			
of Evidence C).			
History of Intracranial/Spinal Surgery Within 3 Months			
1. For patients with acute ischemic	Class III: Harm or No	Agree	
stroke and a history of intracranial/spinal	Benefit		
surgery within the prior 3 months, intravenous alteplase is potentially			
harmful (Class III; Level of Evidence C).			
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AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus Qualification Statement/ Comment	New Literature Support	
History of Ischemic Stroke Within 3 Mon	iths			
1. Use of intravenous alteplase in patients presenting with acute ischemic stroke who have had a prior ischemic stroke within 3 months may be harmful (Class III; Level of Evidence B).	Class III: Harm or No Benefit	Agree		
2. The potential for increased risk of sICH and associated morbidity and mortality exists but is not well established (Class IIb; Level of Evidence B).	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree		
3. The potential risks should be discussed during thrombolysis eligibility deliberation and weighed against the anticipated benefits during decision-making (Class I; Level of Evidence C).	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree		
Active Internal Bleeding or History of Ga	astrointestinal/Genitourin	ary Bleeding Within 21 Days		
1. Reported literature details a low bleeding risk with intravenous alteplase administration in the setting of past gastrointestinal/genitourinary bleeding. Administration of intravenous alteplase in this patient population may be reasonable (Class IIb; Level of Evidence C).	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree		
2. Patients with a structural gastrointestinal malignancy or recent bleeding event within 21 days of their stroke event should be considered high risk, and intravenous alteplase administration is potentially harmful (Class III; Level of Evidence C).	Class III: Harm or No Benefit	Agree		
Arterial Puncture of Non-Compressible Vessels in the Preceding 7 Days				
1. The safety and efficacy of administering intravenous alteplase to acute stroke patients who have had an arterial puncture of a non-compressible blood vessel in the 7 days preceding stroke symptoms are uncertain (Class IIb; Level of Evidence C).	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree		

AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus Qualification Statement/ Comment	New Literature Support
Uncontrolled Hypertension, Severe Hype	rtension, Repeated Blood	Pressure, or Requiring Aggre	ssive Treatment
1. Intravenous alteplase is recommended in patients whose blood pressure can be lowered safely (to <185/110 mm Hg) with antihypertensive agents, with the physician assessing the stability of the blood pressure before starting intravenous alteplase (Class I; Level of Evidence B).	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	
2. If medications are given to lower blood pressure, the clinician should be sure that the blood pressure is stabilized at the lower level before beginning treatment with intravenous alteplase and maintained below 180/105 mmHg for at least the first 24 hours after intravenous alteplase treatment (Class I; Level of Evidence B).	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	
History of Intracranial Hemorrhage			
1. Intravenous alteplase has not been shown to increase sICH rates in patients with CMBs. Intravenous alteplase administration in these patients is therefore reasonable (Class IIa; Level of Evidence B).	Class IIa: Benefit>>Risk IT IS REASONABLE to perform procedure/administer treatment.	Agree CMB = Cerebral Microbleed	
2. Intravenous alteplase administration in patients who have a history of intracranial hemorrhage is potentially harmful (Class III; Level of Evidence C).	Class III: Harm or No Benefit	Agree	
Unruptured Intracranial Aneurysm			
1. For patients presenting with acute ischemic stroke who are known to harbor a small or moderate-sized (< 10 mm) unruptured and unsecured intracranial aneurysm, administration of intravenous alteplase is reasonable and probably recommended (Class IIa; Level of Evidence C).	Class IIa: Benefit>>Risk IT IS REASONABLE to perform procedure/administer treatment.	Agree	
2. Usefulness and risk of intravenous alteplase in patients with acute ischemic stroke who harbor a giant unruptured and unsecured intracranial aneurysm are not well established (Class IIb; Level of Evidence C).	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree	

AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus Qualification Statement/ Comment	New Literature Support
Intracranial Vascular Malformation			
1. For patients presenting with acute ischemic stroke who are known to harbor an unruptured and untreated intracranial vascular malformation, the usefulness and risks of administration of intravenous alteplase are not well established (Class IIb; Level of Evidence C).	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree	
2. Because of the increased risk of ICH in this population of patients, intravenous alteplase may be considered in patients with stroke with severe neurologic deficits and a high likelihood of morbidity and mortality to outweigh the anticipated risk of ICH secondary to thrombolysis (Class IIb; Level of Evidence C).	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree	
Intracranial Neoplasms			
1. Intravenous alteplase treatment is probably recommended for patients with acute ischemic stroke who harbor an extra-axial intracranial neoplasm (Class IIa; Level of Evidence C).	Class IIa: Benefit>>Risk IT IS REASONABLE to perform procedure/administer treatment.	Agree	
2. Intravenous alteplase treatment for patients with acute ischemic stroke who harbor an intra-axial intracranial neoplasm is potentially harmful (Class III; Level of Evidence C).	Class III: Harm or No Benefit	Agree	
Serious Medical Comorbid Illnesses			
1. In patients with end-stage renal disease on hemodialysis and normal aPTT, intravenous alteplase is recommended (Class I; Level of Evidence C). However, those with elevated aPTT may have elevated risk for hemorrhagic complications.	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	
2. Patients with preexisting dementia may benefit from intravenous alteplase (Class IIb; Level of Evidence B). Individual considerations such as life expectancy and premorbid level of function are important to determine whether alteplase may offer a clinically meaningful benefit.	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree	

AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus Qualification Statement/ Comment	New Literature Support
3. The safety and efficacy of alteplase in patients with current malignancy are not well established (Class IIb; Level of Evidence C). Patients with systemic malignancy and reasonable (> 6 months) life expectancy may benefit from intravenous alteplase if other contraindications such as coagulation abnormalities, recent surgery, or systemic bleeding do not coexist.	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree	
Preexisting Disability			
1. Preexisting disability does not seem to independently increase the risk of sICH after intravenous alteplase, but it may be associated with less neurological improvement and higher mortality. Thrombolytic therapy with intravenous alteplase for acute stroke patients with preexisting disability (mRS score ≥ 2) may be reasonable, but decisions should take into account relevant factors other than mRS (including quality of life, social support, place of residence, need for a caregiver after alteplase administration, patients' and families' preferences, and goals of care) (Class IIb; Level of Evidence B).	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree	
Blood Glucose			
1. Intravenous alteplase is recommended in otherwise eligible patients within initial glucose levels > 50 mg/ dL (Class I; Level of Evidence A).	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	
2. Treating clinicians should be aware that hypoglycemia and hyperglycemia may mimic acute stroke presentations and check blood glucose levels before intravenous initiation. Intravenous alteplase is not indicated for nonvascular conditions (Class III; Level of Evidence B).	Class III: Harm or No Benefit	Agree	
3. Treatment with intravenous alteplase in patients with acute ischemic stroke who present with initial glucose levels > 400 mg/dL that are subsequently normalized and who are otherwise eligible may be reasonable (Class IIb; Level of Evidence C).	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree	

AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus Qualification Statement/ Comment	New Literature Support
Seizure at Stroke Onset Syndrome			
1. Intravenous alteplase is reasonable in patients with a seizure at the time of onset of acute stroke if evidence suggests that residual impairments are secondary to stroke and not a postictal phenomenon (Class IIa; Level of Evidence C).	Class IIa: Benefit>>Risk IT IS REASONABLE to perform procedure/administer treatment.	Agree	
Early Ischemic Changes on CT			
1. Intravenous alteplase administration is recommended in the setting of EICs of mild to moderate extent (other than frank hypodensity) (Class I; Level of Evidence A).	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	
2. There remains insufficient evidence to identify a threshold of hypoattenuation severity or extent that affects treatment response to alteplase. However, administering intravenous alteplase to patients whose CT brain imaging exhibits extensive regions of clear hypoattenuation is not recommended. These patients have a poor prognosis despite intravenous alteplase, and severe hypoattenuation defined as obvious hypodensity represents irreversible injury (Class III; Level of Evidence A).	Class III: Harm or No Benefit	Agree	
Diabetic Hemorrhagic Retinopathy or Ot	ther Hemorrhagic Ophtha	almological Conditions	
1. Use of intravenous alteplase in patients presenting with acute ischemic stroke who have a history of diabetic hemorrhagic retinopathy or other hemorrhagic ophthalmic conditions is reasonable to recommend, but the potential increased risk of visual loss should be weighed against the anticipated benefits of reduced stroke-related neurological deficits (Class IIa; Level of Evidence B).	Class IIa: Benefit>>Risk IT IS REASONABLE to perform procedure/administer treatment.	Agree	
Suspicion of SAH on Pretreatment Evalu	ation		
1. Intravenous alteplase is contraindicated in patients presenting with symptoms and signs most consistent with an SAH (Class III; Level of Evidence C).	Class III: Harm or No Benefit	Agree	

AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus	New Literature
		Qualification Statement/ Comment	Support
Wake-Up/Unclear Onset Time Stroke			
1. Intravenous alteplase is not recommended in ischemic stroke patients who awoke with stroke with time last known to be at baseline state > 3 or 4.5 hours (Class III; Level of Evidence B).	Class III: Harm or No Benefit	Agree	
2. Intravenous alteplase is not recommended in ischemic stroke patients who have an unclear time and/ or unwitnessed symptom onset and in whom the time last known to be at baseline state is > 3 or 4.5 hours (Class III; Level of Evidence B).	Class III: Harm or No Benefit	Agree	
3. Use of imaging criteria to select ischemic stroke patients who awoke with stroke or have unclear time of symptom onset for treatment with intravenous alteplase is not recommended outside a clinical trial (Class III; Level of Evidence B).	Class III: Harm or No Benefit	Agree with Qualification The ICSI Diagnosis and Initial Treatment of Stroke work group agrees with this recommendation. Please also see recommendation 6 in "Early Diagnosis: Brain and Vascular Imaging: Recommendations for Patients With Acute Cerebral Ischemic Symptoms That Have Not Yet Resolved" recommendations table also pertaining to IV tPA but in the setting of patient selection for treatment beyond the recommended window of 4.5 hours from onset and recommendation 3 in "Imaging" section of "Endovascular Interventions" recommendations table pertaining to selection for endovascular thrombectomy beyond the recommended window of 6 hours from onset.	
Menstruation and Menorrhagia			
1. Intravenous alteplase is probably indicated in women who are menstruating who present with acute ischemic stroke and do not have a history of menorrhagia. However, women should be warned that alteplase treatment could increase the degree of menstrual flow (Class IIa; Level of Evidence C).	Class IIa: Benefit>>Risk IT IS REASONABLE to perform procedure/administer treatment.	Agree	

AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus Qualification Statement/	New Literature Support
2. Because the potential benefits of intravenous alteplase probably outweigh the risks of serious bleeding in patients with recent or active history of menorrhagia without clinically significant anemia or hypotension, intravenous alteplase administration may be considered (Class IIb; Level of Evidence	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree	
C). 3. When there is a history of recent or active vaginal bleeding causing clinically significant anemia, then emergent consultation with a gynecologist is probably indicated before a decision about intravenous alteplase is made (Class IIa; Level of Evidence C).	Class IIa: Benefit>>Risk IT IS REASONABLE to perform procedure/administer treatment.	Agree	
4. In patients who are menstruating or have active vaginal bleeding and are treated with alteplase, the degree of vaginal bleeding should be monitored for 24 hours after alteplase (Class I; Level of Evidence C).	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be peformed/administered.		
Intracardiac Mass			
1. For patients with major acute ischemic stroke likely to produce severe disability and cardiac myxoma, treatment with intravenous alteplase may be reasonable (Class IIb; Level of Evidence C).	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree	
2. For patients presenting with major acute ischemic stroke likely to produce severe disability and papillary fibroelastoma, treatment with intravenous alteplase may be reasonable (Class IIb; Level of Evidence C).	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree	
Aortic Arch Dissection and Cervicocephalic Arterial Dissection, Known or Suspected			
1. Intravenous alteplase in acute ischemic stroke known or suspected to be associated with aortic arch dissection is not recommended and is potentially harmful (Class III; Level of Evidence C).	Class III: Harm or No Benefit	Agree	
2. Intravenous alteplase in acute ischemic stroke known or suspected to be associated with extracranial cervical arterial dissection is reasonably safe within 4.5 hours and is probably recommended (Class IIa; Level of Evidence C).	Class IIa: Benefit>>Risk IT IS REASONABLE to perform procedure/administer treatment.	Agree	

AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus Qualification Statement/ Comment	New Literature Support
3. Intravenous alteplase usefulness and hemorrhagic risk in acute ischemic stroke known or suspected to be associated with intracranial arterial dissection remain unknown, uncertain, and not well established (Class IIb; Level of Evidence C).	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree	
Dural Puncture Within 7 Days			
1. Intravenous alteplase may be considered for patients who present with acute ischemic stroke, even in instances when they may have undergone a lumbar dural puncture in the preceding 7 days (Class IIb; Level of Evidence C).	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree	
Psychogenic/Conversion/Malingering SM			
1. The risk of symptomatic intracranial hemorrhage in the SM population is quite low; thus, starting intravenous alteplase is probably recommended in preference over delaying treatment to pursue additional diagnostic studies (Class IIa; Level of Evidence B).	Class IIa: Benefit>>Risk IT IS REASONABLE to perform procedure/administer treatment.	Agree	
Catheterization Laboratory Environmen	t/ Endovascular Complica	ations/Stroke Syndrome	
1. Intravenous alteplase is reasonable for the treatment of acute ischemic stroke complications of cardiac or cerebral angiographic procedures, depending on the usual eligibility criteria (Class IIa; Level of Evidence A).	Class IIa: Benefit>>Risk IT IS REASONABLE to perform procedure/administer treatment.	Agree	
Consent for the Incompetent Patient			
1. In an emergency, when the patient is not competent and there is no immediately available legally authorized representative to provide proxy consent, it is recommended to proceed with intravenous alteplase in an otherwise eligible patient with acute ischemic stroke (Class I; Level of Evidence C).	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	
2. Visual displays that convey the benefits and the risks of intravenous alteplase can be useful to assist with shared decision making and aid in establishing informed consent (Class IIa; Level of Evidence B).	Class IIa: Benefit>>Risk IT IS REASONABLE to perform procedure/administer treatment.	Agree	

AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus Qualification Statement/ Comment	New Literature Support
Concurrent Antiplatelet Medication			
1. The administration of aspirin (or other antiplatelet agents) as an adjunctive therapy within 24 hours of intravenous alteplase is not recommended (<i>Class III</i> ; <i>Level of Evidence C</i>).	Class III: Harm or No Benefit	Agree	
2. The concurrent administration of other intravenous antiplatelet agents that inhibit the glycoprotein IIb/ IIIa receptor is not recommended outside a clinical trial (Class III; Level of Evidence B).	Class III: Harm or No Benefit	Agree	
3. Intravenous alteplase is recommended for patients taking antiplatelet drug monotherapy before stroke on the basis of evidence that the benefit of alteplase outweighs a possible small increased risk of sICH (Class I; Level of Evidence A).	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	
4. Intravenous alteplase is recommended for patients taking antiplatelet drug combination therapy (e.g., aspirin and clopidogrel) before stroke on the basis of evidence that the benefit of alteplase outweighs a probable increased risk of sICH (Class I; Level of Evidence B).	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	
Drug Use (Cocaine)			
1. Treating clinicians should be aware that illicit drug use may be a contributing factor to incident stroke. Intravenous alteplase is reasonable in instances of illicit drug use—associated acute ischemic stroke in patients with no other exclusions (Class IIa; Level of Evidence C).	Class IIa: Benefit>>Risk IT IS REASONABLE to perform procedure/administer treatment.	Agree	
Sickle Cell Disease			
1. Acute management of ischemic stroke resulting from SCD should include optimal hydration, correction of hypoxemia, correction of systemic hypotension, and blood exchange to reduce the percentage of hemoglobin S levels (Class I; Level of Evidence B).	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	
2. Intravenous alteplase for children and adults presenting with an acute ischemic stroke with known SCD is not well established (Class IIb; Level of Evidence C).	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree	

AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus Qualification Statement/ Comment	New Literature Support
Endovascular Interventions (Recommend Association Focused Update of the 2013 C Stroke Regarding Endovascular Treatme	Guidelines for the Early N		
Endovascular Interventions			
 Patients eligible for intravenous rtPA should receive intravenous rtPA even if endovascular treatments are being considered (Class I; Level of Evidence A). (Unchanged from the 2013 guideline) Patients should receive endovascular therapy with a stent retriever if they meet all the following criteria (Class I; Level of Evidence A). (New recommendation): 	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered. Class I: Benefit>>>Risk Procedure/Treatment SHOULD be	Agree Agree The ICSI work group would like to affirm that there is NO upper age limit for	
a. Prestroke mRS score 0 to 1, b. Acute ischemic stroke receiving intravenous rtPA within 4.5 hours of onset according to guidelines from professional medical societies, c. Causative occlusion of the ICA or proximal MCA (M1), d. Age ≥18 years, e. NIHSS score of ≥6, f. ASPECTS of ≥6, and g. Treatment can be initiated (groin puncture) within 6 hours	performed/administered.	endovascular stroke treatment in acute ischemic stroke. Elderly patients benefit similarly to their younger counterparts. Age should never be solely used as exclusion criteria for endovascular stroke treatment.	
3. As with intravenous rtPA, reduced time from symptom onset to reperfusion with endovascular therapies is highly associated with better clinical outcomes. To ensure benefit, reperfusion to TICI grade 2b/3 should be achieved as early as possible and within 6 hours of stroke onset (Class I; Level of Evidence B-R). (Revised from the 2013 guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	
4. When treatment is initiated beyond 6 hours from symptom onset, the effectiveness of endovascular therapy is uncertain for patients with acute ischemic stroke who have causative occlusion of the ICA or proximal MCA (M1) (Class IIb; Level of Evidence C). Additional randomized trial data are needed. (New recommendation)	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree	

AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus	New Literature
AITA/ASA Recommendation	AHA/ASA Class	Qualification Statement/ Comment	Support
5. In carefully selected patients with anterior circulation occlusion who have contraindications to intravenous rtPA, endovascular therapy with stent retrievers completed within 6 hours of stroke onset is reasonable (Class IIa; Level of Evidence C). Inadequate data are available at this time to determine the clinical efficacy of endovascular therapy with stent retrievers for those patients whose contraindications are time based or not time based (e.g., prior stroke, serious head trauma, hemorrhagic coagulopathy, or receiving anticoagulant medications). (New recommendation)	Upgraded Class: Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree with qualification The ICSI work group recommends that based upon the most recent trial evidence, endovascular stroke treatment should be pursued even in patients with contraindications for IV tPA (Goyal, 2016). Therefore, the class and level of evidence should be upgraded to Class I, Level of Evidence A.	Goyal, 2016
6. Although the benefits are uncertain, the use of endovascular therapy with stent retrievers may be reasonable for carefully selected patients with acute ischemic stroke in whom treatment can be initiated (groin puncture) within 6 hours of symptom onset and who have causative occlusion of the M2 or M3 portion of the MCAs, anterior cerebral arteries, vertebral arteries, basilar artery, or posterior cerebral arteries (Class IIb; Level of Evidence C). (New recommendation)	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree with qualification The ICSI Diagnosis and Treatment of Ischemic Stroke guideline work group agrees that it may be reasonable to treat causative occlusions in the M2 division of the MCA, anterior cerebral artery, vertebral artery, basilar artery or posterior cerebral artery (Goyal, 2016; Lemmens, 2016; Sarraj, 2016). Endovascular treatment of more distal MCA occlusions such as the M3 or M4 division is not well studied. Interventions on very distal occlusions are less likely to result in clinical benefit than more proximal occlusion (Lemmens, 2016). It is consensus of the ICSI work group to not recommend routine endovascular intervention of occlusion more distal than the M2 division of the MCA.	Goyal, 2016; Lemmens, 2016; Sarraj, 2016
7. Endovascular therapy with stent retrievers may be reasonable for some patients < 18 years of age with acute ischemic stroke who have demonstrated large-vessel occlusion in whom treatment can be initiated (groin puncture) within 6 hours of symptom onset, but the benefits are not established in this age group (Class IIb; Level of Evidence C). (New recommendation)	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree	

AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus Qualification Statement/ Comment	New Literature Support
8. Although its benefits are uncertain, the use of endovascular therapy with stent retrievers may be reasonable for patients with acute ischemic stroke in whom treatment can be initiated (groin puncture) within 6 hours of symptom onset and who have prestroke mRS score > 1, ASPECTS < 6, or NIHSS score < 6 and causative occlusion of the ICA or proximal MCA (M1) (Class IIb; Level of Evidence B-R). Additional randomized trial data are needed. (New recommendation)	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree	
9. Observing patients after intravenous rtPA to assess for clinical response before pursuing endovascular therapy is not required to achieve beneficial outcomes and is not recommended. (Class III; Level of Evidence B-R). (New recommendation)	Class III: Harm or No Benefit	Agree	
10. Use of stent retrievers is indicated in preference to the MERCI device. (Class I; Level of Evidence A).	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	
The use of mechanical thrombectomy devices other than stent retrievers may be reasonable in some circumstances (Class IIb, Level B-NR). (New recommendation)	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.		
11. The use of a proximal balloon guide catheter or a large-bore distal-access catheter rather than a cervical guide catheter alone in conjunction with stent retrievers may be beneficial (Class IIa; Level of Evidence C). Future studies should examine which systems provide the highest recanalization rates with the lowest risk for non-target embolization. (New recommendation)	Class IIa: Benefit>>Risk IT IS REASONABLE to perform procedure/administer treatment.	Agree	

AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group	New Literature
7 TITE TO THE COMMENCE OF		Consensus	Support
		Qualification Statement/ Comment	
12. The technical goal of the thrombectomy procedure should be a TICI grade 2b/3 angiographic result to maximize the probability of a good functional clinical outcome (Class I; Level of Evidence A). Use of salvage technical adjuncts, including intra-arterial fibrinolysis, may be reasonable to achieve these angiographic results if completed within 6 hours of symptom onset (Class IIb; Level of Evidence B-R). (New recommendation) 13. Angioplasty and stenting of proximal cervical atherosclerotic stenosis or complete occlusion at the time of thrombectomy may be considered, but	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered. Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED. Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE	Agree	
the usefulness is unknown (Class IIb; Level of Evidence C). Future randomized studies are needed. (New recommendation)	CONSIDERED.		
14. Initial treatment with intra-arterial fibrinolysis is beneficial for carefully selected patients with major ischemic strokes of <6 hours' duration caused by occlusions of the MCA (Class I; Level of Evidence B-R). However, these data are derived from clinical trials that no longer reflect current practice, including the use of fibrinolytic drugs that are not available. A clinically beneficial dose of intra-arterial rtPA is not established, and rtPA does not have US Food and Drug Administration approval for intra-arterial use. As a consequence, endovascular therapy with stent retrievers is recommended over intra-arterial fibrinolysis as first-line therapy (Class I; Level of Evidence E). (Revised from the 2013 guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/ administered.	Agree	
15. Intra-arterial fibrinolysis initiated within 6 hours of stroke onset in carefully selected patients who have contraindications to the use of intravenous rtPA might be considered, but the consequences are unknown (Class IIb; Level of Evidence C). (Revised from the 2013 guideline)	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree	

AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus	New
	22224	Qualification Statement/ Comment	Literature Support
16. It might be reasonable to favor conscious sedation over general anesthesia during endovascular therapy for acute ischemic stroke. However, the ultimate selection of anesthetic technique during endovascular therapy for acute ischemic stroke should be individualized on the basis of patient risk factors, tolerance of the procedure, and other clinical characteristics. Randomized trial data are needed (Class IIb; Level of Evidence C). (New recommendation)	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree with qualification The ICSI Diagnosis and Initial Treatment of Ischemic Stroke work group would like to note that a recent randomized trial by Schönenberger 2016 compared early efficacy of endovascular thrombectomy under general anesthesia vs. conscious sedation and demonstrated no difference. This was a small study, conducted at one center, and was not powered for other secondary outcomes such as mortality and functional status. Due to these limitations, the ICSI Diagnosis and Initial Treatment of Ischemic Stroke work group would like to emphasize that the choice of intervention should be based on patient characteristics. Further research is needed.	
Imaging			
1. Emergency imaging of the brain is recommended before any specific treatment for acute stroke is initiated (Class I; Level of Evidence A). In most instances, nonenhanced CT will provide the necessary information to make decisions about emergency management. (Unchanged from the 2013 guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	
2. If endovascular therapy is contemplated, a non-invasive intracranial vascular study is strongly recommended during the initial imaging evaluation of the acute stroke patient but should not delay intravenous rtPA if indicated. For patients who qualify for intravenous rtPA according to guidelines from professional medical societies, initiating intravenous rtPA before noninvasive vascular imaging is recommended for patients who have not had noninvasive vascular imaging as part of their initial imaging assessment for stroke. Noninvasive intracranial vascular imaging should then be obtained as quickly as possible (Class I; Level of Evidence A). (New recommendation)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree with qualification The ICSI work group recognizes that clinical practice may vary. If an institution's initial imaging evaluation of an acute stroke patient routinely includes rapid, non-invasive vascular imaging that does not delay administration of IV r-tPA, then it would be reasonable to obtain vascular imaging prior to administering IV r-tPA. Conversely, there may be instances where vascular imaging is not necessary prior to initiating endovascular treatment (e.g., presence of a hyperdense vessel sign on non-contrast head CT, or clinical syndrome of large vessel occlusion stroke in the setting of a normal head CT).	

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AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus Qualification Statement/ Comment	New Literature Support
3. The benefits of additional imaging beyond CT and CTA or MRI and MRA such as CT perfusion or diffusion- and perfusion-weighted imaging for selecting patients for endovascular therapy are unknown (Class IIb; Level of Evidence C). Further randomized, controlled trials may be helpful to determine whether advanced imaging paradigms using CT perfusion, CTA, and MRI perfusion and diffusion imaging, including measures of infarct core, collateral flow status, and penumbra, are beneficial for selecting patients for acute reperfusion therapy who are within 6 hours of symptom onset and have an ASPECTS < 6. Further randomized, controlled trials should be done to determine whether advanced imaging paradigms with CT perfusion, MRI perfusion, CTA, and diffusion imaging, including measures of infarct core, collateral flow status, and penumbra, are beneficial for selecting patients for acute reperfusion therapy who are beyond 6 hours from symptom onset. (New recommendation)	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree with qualifications The ICSI Diagnosis and Treatment of Ischemic Stroke work group agrees with this recommendation. Please also see recommendation 6 from Early Diagnosis: Brain and Vascular Imaging: Recommendations for Patients With Acute Cerebral Ischemic Symptoms That Have Not Yet Resolved recommendations table pertaining to administration of IV tPA in setting of patient selection for treatment outside the recommended window of 4.5 hours from onset and recommendation 3 in Wake- up/Unclear Onset Time section of Intravenous Fibrinolysis recommendations table also pertaining to administration of IV tPA but in the setting of "wake-up stroke" (unclear time onset of stroke).	
Stroke Systems of Care			
1. Patients should be transported rapidly to the closest available certified primary stroke center or comprehensive stroke center or, if no such centers exist, the most appropriate institution that provides emergency stroke care as described in the 2013 guidelines (Class I; Level of Evidence A). In some instances, this may involve air medical transport and hospital bypass. (Unchanged from the 2013 guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/ administered.	Agree The ICSI work group notes that local practice should account for the presence of Acute Stroke-Ready Hospitals in the state of Minnesota. Patients should be rapidly transported to the nearest Acute Stroke-Ready Hospital, which may include hospital bypass. It is reasonable to consider transporting patients with suspected large vessel occlusion stroke directly to comprehensive stroke centers if they are a similar distance to other Acute Stroke-Ready	

AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus Qualification Statement/ Comment	New Literature Support
2. Regional systems of stroke care should be developed. These should consist of the following: a. Healthcare facilities that provide initial emergency care, including administration of intravenous rtPA, such as primary stroke centers, comprehensive stroke centers, and other facilities, and b. Centers capable of performing endovascular stroke treatment with comprehensive periprocedural care, including comprehensive stroke centers and other healthcare facilities, to which rapid transport can be arranged when appropriate (Class I; Level of Evidence A). (Revised from the 2013 guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/ administered.	Agree	
3. It may be useful for primary stroke centers and other health care facilities that provide initial emergency care, including administration of intravenous rtPA, to develop the capability of performing emergency noninvasive intracranial vascular imaging to most appropriately select patients for transfer for endovascular intervention and to reduce the time to endovascular treatment (Class IIb; Level of Evidence C). (Revised from the 2013 guideline)	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree	
4. Endovascular therapy requires the patient to be at an experienced stroke center with rapid access to cerebral angiography and qualified neurointerventionalists. Systems should be designed, executed, and monitored to emphasize expeditious assessment and treatment. Outcomes for all patients should be tracked. Facilities are encouraged to define criteria that can be used to credential individuals who can perform safe and timely intra-arterial revascularization procedures (Class I; Level of Evidence E). (Revised from the 2013 guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/ administered.	Agree	

AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus Qualification Statement/ Comment	New Literature Support
Anticoagulants			
1. At present, the usefulness of argatroban or other thrombin inhibitors for treatment of patients with acute ischemic stroke is not well established (Class IIb; Level of Evidence B). These agents should be used in the setting of clinical trials. (New recommendation)	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree	Wang, 2012
2. The usefulness of urgent anticoagulation in patients with severe stenosis of an internal carotid artery ipsilateral to an ischemic stroke is not well established (Class IIb; Level of Evidence B). (New recommendation)	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree	Wang, 2012
3. Urgent anticoagulation, with the goal of preventing early recurrent stroke, halting neurological worsening, or improving outcomes after acute ischemic stroke, is not recommended for treatment of patients with acute ischemic stroke (Class III; Level of Evidence A). (Unchanged from the previous guideline)	Class III: Harm or No Benefit	Agree	Paciaroni, 2015
4. Urgent anticoagulation for the management of non- cerebrovascular conditions is not recommended for patients with moderate-to-severe strokes because of an increased risk of serious intracranial hemorrhagic complications (Class III; Level of Evidence A). (Unchanged from the previous guideline)	Class III: Harm or No Benefit	Agree	
5. Initiation of anticoagulant therapy within 24 hours of treatment with intravenous rtPA is not recommended (Class III; Level of Evidence B). (Unchanged from the previous guideline)	Class III: Harm or No Benefit	Agree	
Antiplatelet Agents			
1. Oral administration of aspirin (initial dose is 325 mg) within 24 to 48 hours after stroke onset is recommended for treatment of most patients (Class I; Level of Evidence A). (Unchanged from the previous guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree with qualification Earliest safe administration of aspirin is important for secondary stroke prevention. (Rothwell, 2016) Detailed discussion of secondary prevention is beyond the purview of this guideline.	Rothwell, 2016

AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus Qualification Statement/ Comment	New Literature Support	
2. The usefulness of clopidogrel for the treatment of acute ischemic stroke is not well established (Class IIb; Level of Evidence C). Further research testing the usefulness of the emergency administration of clopidogrel in the treatment of patients with acute stroke is required. (Revised from the previous guideline)	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree		
3. The efficacy of intravenous tirofiban and eptifibatide is not well established, and these agents should be used only in the setting of clinical trials (Class IIb; Level of Evidence C). (New recommendation)	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree		
4. Aspirin is not recommended as a substitute for other acute interventions for treatment of stroke, including intravenous rtPA (Class III; Level of Evidence B). (Unchanged from the previous guideline)	Class III: Harm or No Benefit	Agree		
5. The administration of other intravenous antiplatelet agents that inhibit the glycoprotein IIb/IIIa receptor is not recommended (Class III; Level of Evidence B). (Revised from the previous guideline) Further research testing the usefulness of emergency administration of these medications as a treatment option in patients with acute ischemic stroke is required.	Class III: Harm or No Benefit	Agree		
6. The administration of aspirin (or other antiplatelet agents) as an adjunctive therapy within 24 hours of intravenous fibrinolysis is not recommended (Class III; Level of Evidence C). (Revised from the previous guideline)	Class III: Harm or No Benefit	Agree		
Admission to the Hospital and General Acute Treatment (After Hospitalization)				
1. The use of comprehensive specialized stroke care (stroke units) that incorporates rehabilitation is recommended (Class I; Level of Evidence A). (Unchanged from the previous guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/ administered.	Agree		

AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus Qualification Statement/ Comment	New Literature Support
2. Patients with suspected pneumonia or UTIs should be treated with appropriate	Class I: Benefit>>>Risk	Agree	
antibiotics (Class I; Level of Evidence A). (Revised from the previous guideline)	Procedure/Treatment SHOULD be performed/administered.		
3. Subcutaneous administration of anticoagulants is recommended for	Class I: Benefit>>>Risk	Agree	
treatment of immobilized patients to prevent DVT (Class I; Level of Evidence A). (Unchanged from the previous guideline)	Procedure/Treatment SHOULD be performed/administered.		
4. The use of standardized stroke care order sets is recommended to improve	Class I: Benefit>>>Risk	Agree	
general management (Class I; Level of Evidence B). (Unchanged from the previous guideline)	Procedure/Treatment SHOULD be performed/administered.		
5. Assessment of swallowing before the patient begins eating, drinking, or	Class I: Benefit>>>Risk	Agree	
receiving oral medications is recommended (Class I; Level of Evidence B). (Unchanged from the previous guideline)	Procedure/Treatment SHOULD be performed/administered.		
6. Patients who cannot take solid food and liquids orally should receive NG, nasoduodenal, or PEG tube feedings to maintain hydration and nutrition while undergoing efforts to restore swallowing	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree with qualification The consensus of the ICSI work group is to add the following: "provided artificial nutrition and hydration are in	
(Class I; Level of Evidence B). (Revised from the previous guideline)	performed/administered.	accordance with the patient's wishes and goals of care."	
		Therefore the recommendation would state the following:	
		Patients who cannot take solid food and liquids orally should receive NG, nasoduodenal or PEG tube	
		feedings to maintain hydration and nutrition while undergoing efforts to restore swallowing provided artificial nutrition and hydration are in accordance	
		with the patient's wishes and goals of care.	

AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus Qualification Statement/ Comment	New Literature Support
7. Early mobilization of less severely affected patients and measures to prevent subacute complications of stroke are recommended (Class I; Level of Evidence C). (Unchanged from the previous guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree with qualification AVERT 2015 study "Efficacy and safety of very early mobilization within 24 hours of stroke onset (AVERT): a randomized controlled trial" found that very early mobilization may not be associated with favorable outcomes at 3 months (AVERT, 2015). Further research is needed on this topic to determine the efficacy and safety of early mobilization.	AVERT, 2015
8. Treatment of concomitant medical diseases is recommended (Class I; Level of Evidence C). (Unchanged from the previous guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	
9. Early institution of interventions to prevent recurrent stroke is recommended (Class I; Level of Evidence C). (Unchanged from the previous guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	
10. The use of aspirin is reasonable for treatment of patients who cannot receive anticoagulants for DVT prophylaxis (Class IIa; Level of Evidence A). (Revised from the previous guideline)	Class IIa: Benefit>>Risk IT IS REASONABLE to perform procedure/administer treatment.	Agree	
11. In selecting between NG and PEG tube routes of feeding in patients who cannot take solid food or liquids orally, it is reasonable to prefer NG tube feeding until 2 to 3 weeks after stroke onset (Class IIa; Level of Evidence B). (Revised from the previous guideline)	Class IIa: Benefit>>Risk IT IS REASONABLE to perform procedure/administer treatment.	Agree	
12. The use of intermittent external compression devices is reasonable for treatment of patients who cannot receive anticoagulants (Class IIa; Level of Evidence B). (Revised from the previous guideline)	Class IIa: Benefit>>Risk IT IS REASONABLE to perform procedure/administer treatment.	Agree	

AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus Qualification Statement/ Comment	New Literature Support
13. Routine use of nutritional supplements has not been shown to be beneficial (Class III; Level of Evidence B). (Revised from the previous guideline)	Class III: No Benefit	Agree	
14. Routine use of prophylactic antibiotics has not been shown to be beneficial (Class III; Level of Evidence B). (Revised from the previous guideline)	Class III: No Benefit	Agree	
15. Routine placement of indwelling bladder catheters is not recommended because of the associated risk of catheterassociated UTIs (Class III; Level of Evidence C). (Unchanged from the previous guideline)	Class III: Harm or No Benefit	Agree	
Treatment of Acute Neurological Compli	cations		
1. Patients with major infarctions are at high risk for complicating brain edema and increased ICP. Measures to lessen the risk of edema and close monitoring of the patient for signs of neurological worsening during the first days after stroke are recommended (Class I; Level of Evidence A). Early transfer of patients at risk for malignant brain edema to an institution with neurosurgical expertise should be considered. (Revised from the previous guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	
2. Decompressive surgical evacuation of a space-occupying cerebellar infarction is effective in preventing and treating herniation and brain stem compression (Class I; Level of Evidence B). (Revised from the previous guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	

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AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus	New Literature Support
		Qualification Statement/ Comment	
3. Decompressive surgery for malignant edema of the cerebral hemisphere is effective and potentially lifesaving (Class I; Level of Evidence B). Advanced patient age and patient/family valuations of achievable outcome states may affect decisions regarding surgery. (Revised from the previous guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree with qualification Decompressive surgery for malignant cerebral infarction leads to improved mortality and morbidity when performed within 48 hours of stroke onset. However, in spite of improved outcome, survivors often have significant disability secondary to their underlying stroke. It is essential to determine whether the expected range of functional outcomes post-decompressive craniectomy is consistent with patient and family goals of care. Clinical trials have also specifically studied the benefit of decompressive craniectomy for patients > 60 years old. In this patient population, outcomes were still improved with decompressive craniectomy, though functional outcomes were worse in comparison to their younger counterparts (Streib, 2016).	Streib, 2016
4. Recurrent seizures after stroke should be treated in a manner similar to other acute neurological conditions, and antiepileptic agents should be selected by specific patient characteristics (Class I; Level of Evidence B). (Unchanged from the previous guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	
5. Placement of a ventricular drain is useful in patients with acute hydrocephalus secondary to ischemic stroke (Class I; Level of Evidence C). (Revised from the previous guideline)	Class I: Benefit>>>Risk Procedure/Treatment SHOULD be performed/administered.	Agree	
6. Although aggressive medical measures have been recommended for treatment of deteriorating patients with malignant brain edema after large cerebral infarction, the usefulness of these measures is not well established (Class IIb; Level of Evidence C). (Revised from the previous guideline)	Class IIb: Benefit ≥ Risk Procedure/Treatment MAY BE CONSIDERED.	Agree	

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AHA/ASA Recommendation	AHA/ASA Class	ICSI Work Group Consensus Qualification Statement/ Comment	New Literature Support
7. Because of lack of evidence of efficacy and the potential to increase the risk of infectious complications, corticosteroids (in conventional or large doses) are not recommended for treatment of cerebral edema and increased ICP complicating ischemic stroke (Class III; Level of Evidence A). (Unchanged from the previous guideline)	Class III: Harm or No Benefit	Agree	
8. Prophylactic use of anticonvulsants is not recommended (Class III; Level of Evidence C). (Unchanged from the previous guideline)	Class III: Harm or No Benefit	Agree	



Quality Improvement Support:

Diagnosis and Initial Treatment of Ischemic Stroke

The Aims and Measures section is intended to provide protocol users with a menu of measures for multiple purposes that may include the following:

- population health improvement measures,
- quality improvement measures for delivery systems,
- measures from regulatory organizations such as Joint Commission,
- measures that are currently required for public reporting,
- measures that are part of Center for Medicare Services Physician Quality Reporting initiative, and
- other measures from local and national organizations aimed at measuring population health and improvement of care delivery.

This section provides resources, strategies and measurement for use in closing the gap between current clinical practice and the recommendations set forth in the guideline.

The subdivisions of this section are:

Aims and Measures

Aims and Measures

1. Increase the percentage of patient's age 18 years and over receiving appropriate thrombolytic and appropriate antithrombotic therapy for ischemic stroke (tPA and aspirin, other antiplatelet agents, or an anticoagulant).

Measure for accomplishing this aim:

- a. Percentage of eligible patients with ischemic stroke treated with tPA.
- 2. Increase the percentage of stroke patients age 18 years and over who receive appropriate medical management within the initial 24-48 hours of diagnosis for prevention of complications such as:
 - Aspiration
 - Deep vein thrombosis
 - Nutritional status decline

Measures for accomplishing this aim:

- a. Percentage of ischemic stroke patients with paralysis or other reason for immobility who receive appropriate prevention for venous thromboembolism (subcutaneous heparin or pneumatic compression device).
- b. Percentage of ischemic stroke patients who are assessed with a swallow screening test before receiving food, fluids or medications by mouth.

Measurement Specifications

Measurement #1a

Percentage of eligible patients with ischemic stroke treated with tPA.

Population Definition

Patients age 18 years and older initially presenting with acute symptoms of ischemic stroke who are eligible for tPA.

Data of Interest

of patients treated with tPA

of patients eligible for tPA

Numerator/Denominator Definitions

Numerator: Number of patients who were treated with tPA.

Denominator: Number of patients eligible for tPA treatment.

Method/Source of Data Collection

Review EHR for patients meeting criteria under population definition and determine the number of patients treated with tPA.

Time Frame Pertaining to Data Collection

Monthly.

Notes

This is a process measure, and improvement is noted as an increase in the rate.

Measurement #2a

Percentage of patients with ischemic stroke with paralysis or other reason for immobility receiving appropriate prevention for venous thromboembolism (subcutaneous heparin or pneumatic compression device).

Population Definition

Patients age 18 years and older initially presenting with acute symptoms of ischemic stroke with paralysis or other reason for immobility.

Data of Interest

of patients who have appropriate prevention for VTE

of patients who present with acute symptoms of ischemic stroke and paralysis or other reason for immobility

Numerator and Denominator Definitions

Numerator: Number of patients who have appropriate prevention for VTE such as subcutaneous heparin

or pneumatic compression device.

Denominator: Number of patients presenting with acute symptoms of ischemic stroke and paralysis or

other reason for immobility.

Method/Source of Data Collection

Review EHR for patients meeting criteria under population definition and determine the number of patients who have appropriate prevention for VTE.

Time Frame Pertaining to Data Collection

Monthly.

Notes

This is a process measure, and improvement is noted as an increase in the rate.

Measurement #2b

Percentage of ischemic stroke patients who are assessed with a swallow screening test before receiving food, fluids or medications by mouth.

Population Definition

Patients age 18 years and older initially presenting with acute symptoms of ischemic stroke.

Data of Interest

of patients who receive an early swallow evaluation

of patients who present with acute ischemic stroke

Numerator and Denominator Definitions

Numerator: Number of patients who were screened for dysphagia before taking any food, fluids or

medication (including aspirin) by mouth.

Denominator: Number of all patients presenting with symptoms of acute ischemic stroke.

Method/Source of Data Collection

Review EHR for patients meeting criteria under Population Definition and determine the number of patients who have an early swallow evaluation.

Time Frame Pertaining to Data Collection

Monthly.

Notes

This is a process measure, and improvement is noted as an increase in the rate.



Supporting Evidence:

Diagnosis and Initial Treatment of Ischemic Stroke

The subdivisions of this section are:

- References
- Appendices

References

Links are provided for those new references added to this edition (author name is highlighted in blue).

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Appendix A – Literature Search Terms by Topic

Public Stroke Education and Prehospital Stroke Management

Educational stroke programs for physicians, hospital personnel and EMS personnel, 911 activation for stroke patients, prehospital stroke assessment tools, Los Angeles Prehospital Stroke Screen, Cincinnati Prehospital Stroke Scale, stroke protocol for EMS personnel, EMS transportation for stroke patients, prehospital notification for stroke patients.

Designation of Stroke Centers and Stroke Care Quality Improvement Process

Primary stroke center, acute stroke-ready hospital, comprehensive stroke center, certification of stroke centers, multidisciplinary quality improvement committee for stroke, data repository for stroke care, teleradiology for acute stroke, telestroke network, telestroke and tPA, telestroke and community hospitals.

Emergency Evaluation and Diagnosis of Acute Ischemic Stroke

ER protocol for stroke, fibrinolytic treatment for stroke in the ER, acute stroke team in the ER, stroke rating scale, NIH Stroke Scale/Score, laboratory tests for stroke patients, laboratory tests and rtPA administration, blood glucose and rtPA, baseline electrocardiogram assessment in acute ischemic stroke patients, baseline troponin assessment in acute ischemic stroke patients.

Early Diagnosis: Brain and Vascular Imaging: Recommendations for Patients With Acute Cerebral Ischemic Symptoms That Have Not Yet Resolved

Brain imaging for acute ischemic stroke, non-contrast-enhanced computed tomography in acute ischemic stroke patients, NECT and rtPA administration, MRI and rTPA administration, exclusion of intracranial hemorrhage in stroke patients, intravenous fibrinolytic therapy for early ischemic changes on CT, non-invasive intracranial vascular study and imaging for acute stroke patients, non-invasive intracranial study and intra-arterial fibrinolysis, non-invasive intracranial study and mechanical thrombectomy, What is the time frame for the brain imaging study interpretation in intravenous fibrinolysis candidates?, perfusion CT, perfusion MRI, wake-up stroke, penumbra imaging, frank hypodensity on NECT.

General Supportive Care and Treatment of Acute Complications

What cardiac monitoring should be done for ischemic stroke patients?, How should blood pressure be controlled prior to initiating fibrinolytic therapy?, What should blood pressure be after giving fibrinolytic therapy?, airway support and ventilator assistance for ischemic stroke, When should you give supplemental oxygen to an ischemic stroke patient?, hyperthermia and ischemic stroke, blood pressure control and intra-arterial fibrinolysis, blood pressure control for ischemic stroke patients who do not receive fibrinolysis, management of hypovolemia in acute ischemic stroke, management of hypoglycemia in acute ischemic stroke, When to start antihypertensive therapy after stroke in patients without preexisting hypertension and in patients with preexisting hypertension?, blood pressure medications to use for acute ischemic stroke patients, hyperglycemia and acute ischemic stroke, management of arterial hypertension in patients with acute ischemic stroke. Use of supplemental oxygen in non-hypoxic patients with acute ischemic stroke.

Admission to the Hospital and General Acute Treatment (After Hospitalization)

Comprehensive stroke care with rehabilitation, suspected pneumonia in patients with acute ischemic stroke, suspected urinary tract infection in patients with acute ischemic stroke, DVT prophylaxis in immobilized patients with acute ischemic stroke, standardized stroke care order sets for management of acute ischemic stroke, assessment of swallowing for stroke patients, feeding stroke patients unable to take food orally, early mobilization in stroke patients, treatment on concomitant medical diseases for patients with acute ischemic

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stroke, prevention of recurrent stroke in the acute ischemic stroke patient, aspirin for DVT prophylaxis for stroke patients unable to receive anticoagulants, nasogastric (NG) versus percutaneous endoscopic gastrostomy (PEG) tube feeding after stroke onset, intermittent external compression device for DVT prophylaxis in stroke patients unable to take anticoagulants, nutritional supplements in acute stroke patients, prophylactic antibiotics in acute stroke patients, indwelling bladder catheter in acute stroke patients.

Treatment of Acute Neurological Complications

ICP management, management of increased intercranial pressure in stroke, decompressive surgical evacuation of a space-occupying cerebral infarction, decompressive surgery for malignant edema of the cerebral hemisphere, treatment of recurrent seizures after stroke, treatment of acute hydrocephalus secondary to ischemic stroke, ventricular drain for acute hydrocephalus secondary to ischemic stroke, use of corticosteroids to treat cerebral edema and increased intracranial pressure from ischemic stroke, prophylactic use of anticonvulsants for stroke patient.



Appendix B – ICSI Shared Decision-Making Model

ICSI Institute for Clinical Systems Improvement

The Collaborative Conversation™ Shared Decision-Making and the Translation of Evidence into Practice

A consistent finding from clinical and health services research is the failure to translate research into practice. The translation of evidence into practice can be advanced through the use of shared decision-making since shared decision-making results in evidence being incorporated into patient and clinician consultations.

Shared decision-making (SDM) is a process in which patient and clinicians collaborate to clarify all acceptable options, ensure that the patient is well-informed and chose a course of care consistent with patient values and preferences and the best available medical evidence. (Minnesota Shared Decision-Making Collaborative [MSDMC], 2011).

Evidence-based guidelines may recommend the use of shared decision-making for decisions in instances where the evidence is equivocal, when patient action or inaction (such as medication adherence or lifestyle changes) can impact the potential outcome, or when the evidence does not indicate a single best recommendation.

SDM is a patient-centered approach that involves a conversation between the patient and the clinician. It is ideal to involve caregivers and family members in these conversations, as well. Family members and caregivers can participate in discussions, ask questions, hear content the patient may miss and provide invaluable support in decision follow-through. Although only patients and clinicians are specifically mentioned throughout this document for brevity purposes, this does not diminish the importance of caregivers and families in patient-centered care.

Both the patient and the clinician bring expertise to the shared decision-making conversation. Clinicians' expertise includes disease etiology, prognosis, options for treatment including the burden and benefit to the patient, and outcome probabilities. Patients' expertise lies in their knowledge of their risk tolerance, body, priorities, family and financial issues, as well as their daily experience with the condition (adapted from Making Shared Decision-Making a Reality. No decision about me, without me. Coulter, A., Collins, A., The King's Fund 2011).

Treatment options vary in their burden on a patient. SDM offers an opportunity to help the patient select a treatment to which they can adhere. When conversations discussing options occurs, patients and clinicians are actively engaged while considering the attributes and issues of the available options. This empathic approach results in the clinician and patient co-creating a decision and a plan of care (adapted from Montori, V., the Mayo Clinic KER UNIT, April 2015). Decision aids can be supportive of this conversation when they communicate the best available evidence to inform the patient and clinician discussion.

Without a conversation, clinicians may make assumptions about what the patient prefers. This creates the potential for discrepancies between what clinicians assume and what patients want, resulting in a "preference misdiagnosis" (adapted from Health Policy Publishing, LLC, May 2013).

Difficulty in initiating a conversation is cited by patients and clinicians as one of the barriers to shared decision-making. To address this impediment, ICSI worked with patients, practicing clinicians, and other stakeholders to develop the Collaborative ConversationTM model for use across the care continuum.

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Collaborative ConversationTM

A collaborative approach towards decision-making is a fundamental tenet of Shared Decision-Making (SDM). The Collaborative ConversationTM is an inter professional approach that nurtures relationships; enhances patients' knowledge, skills and confidence as vital participants in their health; and encourages them to manage their health care. Within a Collaborative ConversationTM, the perspective is that the patient, rather than the clinician, knows which course of action is most consistent with the patient's values and preferences.

Use of Collaborative Conversation™ elements and tools is even more necessary to support patient, care clinician and team relationships when patients and families are dealing with high stakes or highly charged issues. A diagnosis of a life-limiting illness is one example of such a circumstance.

The overall objective for the Collaborative Conversation[™] approach is to create an environment in which the patient, family and care team work collaboratively to reach and carry out a decision that is consistent with the patient's values and preferences, along with the best available evidence. A rote script, completed form or checklist does not constitute this approach. Rather it is a set of skills employed appropriately for the specific situation. These skills need to be used artfully to address all aspects of the person involved in making a decision: cognitive, affective, social and spiritual.

Key communication skills help build the collaborative conversation approach. These skills include (Adapted from O'Connor, Jacobsen Decisional Conflict: Supporting People Experiencing Uncertainty about Options Affecting their Health [2007], and Bunn H, O'Connor AM, Jacobsen MJ Analyzing decision support and related communication [1998, 2003])

1. Listening skills

Encourage patient to talk by providing prompts to continue such as *go on, and then? and uh huh* or by repeating the last thing a person said, *It's confusing*.

Paraphrase content of messages shared by patient to promote exploration, clarify content and to communicate that the person's unique perspective has been heard. The clinician should use their own words rather than just parroting what they heard.

Reflection of feelings usually can be done effectively once trust has been established. Until the clinician feels that trust has been established, short reflections at the same level of intensity expressed by the patient without omitting any of the message's meaning are appropriate. Reflection in this manner communicates that the clinician understands the patient's feelings and may work as a catalyst for further problem solving. For example, the clinician identifies what the person is feeling and responds back in his or her own words like this: "So, you're unsure which choice is the best for you."

Summarize the person's key comments and reflect them back to the patient. The clinician should condense several key comments made by the patient and provide a summary of the situation. This assists the patient in gaining a broader understanding of the situation rather than getting mired down in the details. The most effective times to do this are midway through and at the end of the conversation. An example of this is "You and your family have read the information together, discussed the pros and cons, but are having a hard time making a decision because of the risks."

Perception checks ensure that the clinician accurately understands a patient or family member perspective, and may be used as a summary or reflection. They are used to verify that the clinician is interpreting the message correctly. The clinician can say, "So you are saying that you're not ready to make a decision at this time. Am I understanding you correctly?"

2. Questioning Skills

Open and closed questions are both used, with the emphasis on open questions. Open questions ask for clarification or elaboration and cannot have a yes or no answer. An example would be, "What else would influence you to choose this?" Closed questions are appropriate if specific information is required, such as "Does your daughter support your decision?"

Other skills such as summarizing, paraphrasing, and reflection of feeling can be used in the questioning process so that the patient doesn't feel pressured by questions.

Verbal tracking, referring back to a topic the patient mentioned earlier, is an important foundational skill (Ivey & Bradford-Ivey). An example of this is the clinician saying, "You mentioned earlier..."

3. Information-Giving Skills

Providing information and **providing feedback** are two methods of information giving. The distinction between providing information and giving advice is important. Information giving allows a clinician to supplement his or her knowledge and helps to keep the conversation patient centered. Giving advice, on the other hand, takes the attention away from the patient's unique goals and values, and places it on those of the clinician.

Providing information can be sharing facts or responding to questions. An example is "If we look at the evidence, the risk is..." **Providing feedback** gives the patient the clinician's view of the patient's reaction. For instance, the clinician can say, "You seem to understand the facts and value your daughter's advice."

When to Initiate a Collaborative Conversation™

Certain seminal events occur along the care continuum, creating especially opportune times for collaborative conversations. More than one of these opportunities may present at a time, and they will occur in no specific order.

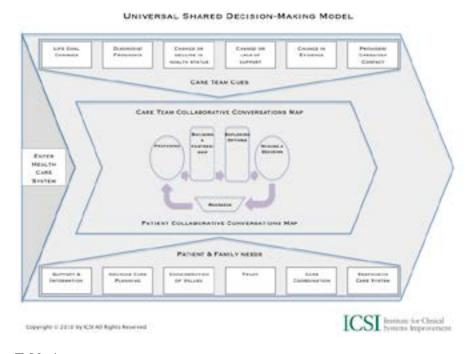


Table 1

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Cues for the Care Team to Initiate a Collaborative Conversation™:

- Life goal changes: Patient's priorities change related to things the patient values such as activities, relationships, possessions, goals and hopes, or things that contribute to the patient's emotional and spiritual well-being.
- Diagnosis/prognosis changes: Additional diagnoses, improved or worsening prognosis.
- Change or decline in health status: *Improving or worsening symptoms, change in performance status or psychological distress.*
- Change or lack of support: Increase or decrease in caregiver support, change in caregiver, change in caregiver status, change in financial standing, difference between patient and family wishes.
- Disease progression: Change in physical or psychological status as a result of the disease progression.
- Clinician/caregiver contact: Each contact between the clinician/ caregiver presents an opportunity to reaffirm with the patient that the care plan and the care he or she is receiving are consistent with his or her values.

Patient and Family Needs within a Collaborative Conversation™

- Request for support and information: Decisional conflict is indicated by, among other things, the patient verbalizing uncertainty or concern about undesired outcomes, expressing concern about choice consistency with personal values, or exhibiting behavior such as wavering, delay, preoccupation, distress or tension. Support resources may include health care professionals, family, friends, support groups, clergy and social workers. When patient expresses a need for information regarding options and their potential outcomes, the patient should understand the key facts about the options, risks and benefits, and have realistic expectations. The method and pace with which this information is provided to the patient should be appropriate for the patient's capacity at that moment.
- Advance Care Planning: With the diagnosis of a life-limiting illness, conversations around advance care planning open up. This is an opportune time to expand the scope of the conversation to other types of decisions that will need to be made as a consequence of the diagnosis of a life-limiting illness.
- Consideration of Values: The personal importance a patient assigns potential outcomes must be respected. If the patient is unclear how to prioritize his or her preferences, value clarification can be achieved through the use of decision aids, detailing the benefits and harms of potential outcomes in terms of how they will directly affect the patient, and through collaborative conversations with the clinician.
- Trust: The patient must feel confident that his or her preferences will be communicated to and respected by all caregivers.
- Care Coordination: Should the patient require care coordination, this is an opportune time to discuss the other types of care-related decisions that need to be made. These decisions will most likely need to be revisited often. Further, the care delivery system must be capable of delivering coordinated care throughout the continuum of care.
- Responsive Care System: The care system needs to support the components of patient- and family-centered care so the patient's values and preferences are incorporated into the care he or she receives throughout the care continuum.

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The Collaborative Conversation™ Map is the heart of this process. The Collaborative Conversation Map™ can be used as a stand-alone tool that is equally applicable to clinicians and patients, as shown in Table 2. Clinicians use the map as a clinical workflow. It helps get the shared decision-making process initiated and provides navigation for the process. Care teams can use the Collaborative Conversation™ to document team best practices and to formalize a common lexicon. Organizations can build fields from the Collaborative Conversation™ Map in electronic medical records to encourage process normalization. Patients use the map to prepare for decision-making, to help guide them through the process and to share critical information with their loved ones.

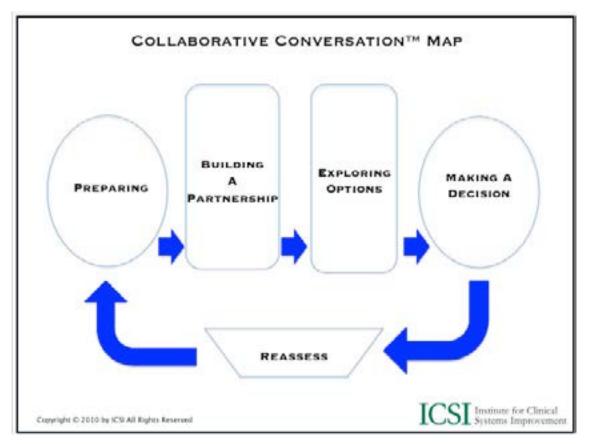


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Evaluating Shared Decision-Making

It has proven challenging to assess shared decision-making. Measuring shared decision-making remains important for continued adoption of shared decision-making as a mechanism for translating evidence into practice; promoting patient-centered care; and understanding the impact of shared decision-making on patient experience, outcomes and revenues. Many assessments exist, but they are often proxy measures.

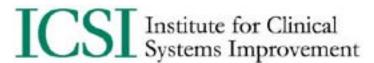
Two suggested methods for measuring shared decision-making are the CollaboRATE tool and the SURE Test. These two tools measure different aspects of shared decision-making, as described below.

The CollaboRATE tool measures the level of shared decision-making in the clinical encounter from the patient's perspective. It is a brief patient-reported measure of shared decision-making. The tools and guidance on their use can be found at http://www.collaboratescore.org/.

The SURE Test is a brief screening questionnaire the patient uses to access his or her readiness and capacity to make a decision or to determine whether he or she is comfortable with the choice that was made. In other words, it provides information on how likely a patient may be experiencing decisional conflict. If the SURE Test indicates decisional conflict may exist, the Decisional Conflict Scale should be completed in order to assess clinically significant decisional conflict.

Shared decision-making is a useful mechanism for translating evidence into practice. While research on the impacts of shared decision-making continues to grow, there is mounting evidence that both patients and clinicians benefit from SDM. Shared decision-making offers the opportunity to bring evidence and the patient's values into the patient/clinician discussion of health choices.

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Disclosure of Potential Conflicts of Interest:

Diagnosis and Initial Treatment of Ischemic Stroke

ICSI has long had a policy of transparency in declaring potential conflicting and competing interests of all individuals who participate in the development, revision and approval of ICSI guidelines and protocols.

In 2010, the ICSI Conflict of Interest Review Committee was established by the Board of Directors to review all disclosures and make recommendations to the board when steps should be taken to mitigate potential conflicts of interest, including recommendations regarding removal of work group members. This committee has adopted the Institute of Medicine Conflict of Interest standards as outlined in the report, Clinical Practice Guidelines We Can Trust (2011).

Where there are work group members with identified potential conflicts, these are disclosed and discussed at the initial work group meeting. These members are expected to recuse themselves from related discussions or authorship of related recommendations, as directed by the Conflict of Interest committee or requested by the work group.

The complete ICSI policy regarding Conflicts of Interest is available at http://bit.ly/ICSICOI.

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The only exception to this, patient and public members of a work group, are provided with a small stipend to cover meeting attendance.

ICSI facilitates and coordinates the guideline development and revision process. ICSI, member medical groups and sponsoring health plans review and provide feedback but do not have editorial control over the work group. All recommendations are based on the work group's independent evaluation of the evidence.

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Diagnosis and Initial Treatment of Ischemic Stroke

ICSI seeks review from members and the public during the revision process.

Member Review

All ICSI documents are available for member review at two points in the ICSI revision process. The ICSI Response Report is sent to members at the beginning of a document revision. The goal of this report is to solicit feedback about the guideline, including but not limited to the algorithm, content, recommendations, and implementation. Members are also welcome to participate in the public comment period (see below).

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• Hudson Physicians

Invited Reviews

For some guidelines, ICSI will invite experts in the community to comment on a guideline draft prior to finalization. This is done during the public comment period.

No invited review was done for the Diagnosis and Initial Treatment of Ischemic Stroke guideline.

ICSI Patient Advisory Council (PAC)

The ICSI Patient Advisory Council responds to any guideline review requests put forth by ICSI facilitators and work groups. The PAC members may be involved at the beginning, middle, and/or end of the revision process. Patient advisors who serve on the council consistently share their experiences and perspectives in either a comprehensive or partial review of a document.

The ICSI Patient Advisory Council did not review the Diagnosis and Initial Treatment of Ischemic Stroke guideline.



Document History and Development:

Diagnosis and Initial Treatment of Ischemic Stroke

Document Drafted		
Jan -	Jun 2	2000

First Edition Oct 2001

Second Edition Nov 2002

Third Edition Nov 2003

Fourth Edition Feb 2005

Fifth Edition Mar 2006

Sixth Edition Begins March 2007

Seventh Edition Jul 2008

Eighth Edition Jul 2009

Ninth Edition Jul 2010

Tenth Edition Aug 2012

Eleventh Edition Begins Dec 2016

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The next revision will be no later than December 2021.

Document History

- 2012 implemented the GRADE methodology to identify and evaluate recommendations.
- 2016: Original content was discontinued.

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ICSI Document Development and Revision Process

Overview

Since 1993, the Institute for Clinical Systems Improvement (ICSI) has developed more than 60 evidence-based health care documents that support best practices for the prevention, diagnosis, treatment or management of a given symptom, disease or condition for patients.

Audience and Intended Use

The information contained in this ICSI health care guideline is intended primarily for health professionals and other expert audiences.

This ICSI health care guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients and families are urged to consult a health care professional regarding their own situation and any specific medical questions they may have. In addition, they should seek assistance from a health care professional in interpreting this ICSI health care guideline and applying it in their individual case.

This ICSI health care guideline is designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and is not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition.

Document Development and Revision Process

The development process is based on a number of long-proven approaches and is continually being revised based on changing community standards. The ICSI staff, in consultation with the work group and a medical librarian, conduct a literature search to identify systematic reviews, randomized clinical trials, meta-analysis, other guidelines, regulatory statements and other pertinent literature. This literature is evaluated based on the GRADE methodology by work group members. When needed, an outside methodologist is consulted.

The work group uses this information to develop or revise clinical flows and algorithms, write recommendations, and identify gaps in the literature. The work group gives consideration to the importance of many issues as they develop the guideline. These considerations include the systems of care in our community and how resources vary, the balance between benefits and harms of interventions, patient and community values, the autonomy of clinicians and patients and more. All decisions made by the work group are done using a consensus process.

ICSI's medical group members and sponsors review each guideline as part of the revision process. They provide comment on the scientific content, recommendations and implementation strategies. This feedback is used by and responded to by the work group as part of their revision work. Final review and approval of the guideline is done by ICSI's Committee on Evidence-Based Practice. This committee is made up of practicing clinicians and nurses, drawn from ICSI member medical groups.

Implementation Recommendations and Measures

These are provided to assist medical groups and others to implement the recommendations in the guidelines. Where possible, implementation strategies are included that have been formally evaluated and tested. Measures are included that may be used for quality improvement as well as for outcome reporting. When available, regulatory or publicly reported measures are included.

Document Revision Cycle

Scientific documents are revised as indicated by changes in clinical practice and literature. ICSI staff monitors major peer-reviewed journals for any pertinent evidence that would affect a particular guideline and recommendation.