Department of Veterans Affairs Veterans Health Administration Washington, DC 20420 VHA DIRECTIVE 1155 Transmittal Sheet November 22, 2024

TREATMENT OF ACUTE ISCHEMIC STROKE

1. SUMMARY OF MAJOR CHANGES: This directive:

- a. Replaces most references to the drug alteplase with the generic term thrombolytic throughout the directive.
- b. Updates and clearly delineates responsibilities of the Chief Officer, Specialty Care Program Office; Neurology National Program Executive Director; Veterans Integrated Services Network (VISN) Director; Department Veterans Affairs (VA) medical facility Director, VA medical facility Chief of Staff and VA health care provider (see paragraph 2).
- c. Adds a requirement for the VISN Director to submit the acute ischemic stroke (AIS) care plans for each VA medical facility in their VISN to the Neurology Program Office within 1 year of publication of this directive and to review the plan at least annually and update if required (see paragraph 2.g.(5)).
- d. Updates a requirement for Veterans Health Administration (VHA) Comprehensive Stroke Centers (CSCs), VHA Primary Stroke Centers (PSCs) and Limited Hours Stroke Facilities (LHSFs) to have a Stroke Committee that meets at least quarterly (see paragraph 3.n.). See paragraph 4 for VHA Stroke Center Designations.
- e. Adds a requirement for VHA PSCs and CSCs to have a designated Stroke Coordinator (see paragraph 3.f.).
- f. Adds a requirement for storage of thrombolytic drugs in the Emergency Department (ED) and Intensive Care Unit (ICU) as required for VHA CSCs, PSCs and LHSFs (see paragraph 3.h.).
- g. Updates a requirement for the initial designation of a VHA CSC to now require an in-person site visit or similar certification by an accreditation body (see paragraph 4.c.).
- h. Requires that clinical staff requiring stroke training be limited to full-time ED and ICU-based physicians and nurses (see paragraph 5).
 - i. Adds Appendix A, Acute Ischemic Stroke Informed Consent.
- 2. RELATED ISSUES: None.
- **3. POLICY OWNER:** The Specialty Care Program Office (11SPEC) is responsible for the content of this VHA directive. Questions may be referred to the National Neurology Program at VHA11SPEC15N2@va.gov.

- **4. LOCAL DOCUMENT REQUIREMENTS:** The VA medical facility Director is required to develop a written VA medical facility AIS management plan (see paragraph 2.h.(2)).
- **5. RESCISSION:** VHA Directive 1155(1), Treatment of Acute Ischemic Stroke, dated June 2, 2018, is rescinded.
- **6. RECERTIFICATION:** This VHA directive is scheduled for recertification on or before the last working day of November 2029. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.
- **7. IMPLEMENTATION SCHEDULE:** This directive is effective 6 months from publication. **NOTE:** The requirement for the VISN Director to submit AIS care plans is effective within 1 year of publication.

BY DIRECTION OF THE OFFICE OF THE UNDER SECRETARY FOR HEALTH:

/s/ Erica Scavella, MD, FACP, FACHE Assistant Under Secretary for Health for Clinical Services and Chief Medical Officer

NOTE: All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.

DISTRIBUTION: Emailed to the VHA Publications Distribution List on December 12, 2024.

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TREATMENT OF ACUTE ISCHEMIC STROKE

1. POLICY

It is Veterans Health Administration (VHA) policy that all Department of Veterans Affairs (VA) medical facilities providing inpatient acute medical or surgical care, or inpatient chronic care provide appropriate and timely care to patients with Acute Ischemic Stroke (AIS). This directive systematizes and standardizes care provided to Veterans who experience AIS. **AUTHORITY:** 38 U.S.C. § 7301(b).

2. RESPONSIBILITIES

- a. <u>Under Secretary for Health.</u> The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.
- b. <u>Assistant Under Secretary for Health for Clinical Services.</u> The Assistant Under Secretary for Health for Clinical Services is responsible for supporting the Chief Officer, Specialty Care Program Office (SCPO) with implementation and oversight of this directive and collaborating with the Assistant Under Secretary for Health for Patient Care Services to support implementation of this directive.
- c. <u>Assistant Under Secretary for Health for Patient Care Services/Chief Nursing Officer.</u> The Assistant Under Secretary for Health for Patient Care Services/Chief Nursing Officer (CNO) is responsible for supporting the program offices within Patient Care Services and collaborating with the Assistant Under Secretary for Health for Clinical Services to support implementation of this directive.
 - d. **Chief Operating Officer.** The Chief Operating Officer is responsible for:
- (1) Communicating the contents of this directive to each of the Veterans Integrated Service Network (VISNs).
- (2) Assisting VISN Directors to resolve implementation and compliance challenges in all VA medical facilities within that VISN.
- (3) Providing oversight of VISNs to ensure compliance with this directive and its effectiveness.
- e. <u>Chief Officer, Specialty Care Program Office.</u> The Chief Officer, SCPO is responsible for supporting the Neurology National Program Executive Director (NPED) in executing their responsibilities as outlined in this directive.
- f. <u>Neurology National Program Executive Director.</u> The Neurology NPED is responsible for:
- (1) Developing and providing national guidance to VISNs and VA medical facilities to ensure standardized evaluation and management of patients with AIS who present to the Emergency Department (ED), Level 1 Urgent Care or in-hospital.

- (2) Identifying appropriate measures to assess quality of stroke care and to quantify improvements in care, and to monitor compliance with this directive and reporting of quality indicators related to AIS care.
 - (3) Reviewing and concurring on AIS care plans submitted by VISNs.
- (4) Supporting VISN Directors in designation of VA medical facilities as a VHA Comprehensive Stroke Center (CSC), VHA Primary Stroke Center (PSC), VHA Limited Hours Stroke Facility (LHSF) and VHA Supporting Stroke Facility (SSF). **NOTE:** For further information on these designations, see paragraph 4.
- g. <u>Veterans Integrated Services Network Director</u>. The VISN Director is responsible for:
- (1) Ensuring that all VA medical facilities within the VISN comply with this directive, and informing leadership when barriers to compliance are identified.
- (2) Assessing the capability of each VA medical facility in the VISN and assigning an appropriate designation no less than every 5 years or at VA medical facility request. Designations include VHA CSC, VHA PSC, VHA LHSF and VHA SSF. **NOTE:** For further information on these designations, see paragraph 4.
- (3) Ensuring that all VA medical facilities with an ED or Level 1 Urgent Care within the VISN have AIS management plans that define and establish the provision of care to patients with AIS and are consistent with this directive. For details, see paragraph 3.
- (4) Ensuring that all VA medical facilities providing AIS care in the VISN are submitting monthly quality indicator data as defined in paragraph 3.j.
- (5) Ensuring AIS care plans for each VA medical facility in their VISN are uploaded to the National Neurology Program website for review and concurrence within 1 year of publication and by the end of each fiscal year thereafter. The website is located at https://rebrand.ly/NPO-Stroke. **NOTE:** This is an internal VA website that is not available to the public.
 - h. **VA Medical Facility Director.** The VA medical facility Director is responsible for:
- (1) Ensuring overall VA medical facility compliance with this directive and appropriate corrective action is taken if non-compliance is identified.
- (2) Developing a written VA medical facility AIS management plan, and ensuring it is reviewed and updated at least annually. See paragraph 3.
- (3) Reporting to the VISN Director upon publication of the VA medical facility AIS management plan and upon any substantive change.
- (4) Submitting monthly quality indicator data used to monitor progress in stroke care, which includes the measures tracked by the Inpatient Evaluation Center (IPEC), located

at https://dvagov.sharepoint.com/sites/VHAIPEC/SitePages/Home.aspx. **NOTE:** This is an internal VA website that is not available to the public.

- (a) Percentage of eligible patients who receive timely thrombolytic therapy.
- (b) Percentage of patients with symptoms of AIS that have the National Institutes of Health Stroke Scale completed:
- <u>1.</u> Prior to treatment or acute transfer for patients eligible for thrombolytic or endovascular thrombectomy.
- <u>2.</u> Within 12 hours of admission for patients presenting outside of the window for thrombolytic administration.
 - (c) Percentage of patients being screened for dysphagia before oral intake.
- (d) Percentage of eligible patients who receive either timely endovascular clot retrieval on site (at a VHA CSC) or timely transfer for endovascular clot retrieval.
- (5) Ensuring appropriate, detailed, and current transfer agreements and protocols are in place in compliance with VHA Directive 1094(1), Inter-Facility Transfer Policy, dated January 11, 2017, and 38 U.S.C. § 1784A.
- (a) For VA medical facilities that are a VHA LHSF, having protocols in place with Emergency Medical Services to bypass the facility outside of the specified hours acute stroke care is provided, and when large vessel occlusion is suspected; and having detailed and current transfer agreements that incorporate the principles of 38 U.S.C. § 1784A for transfer of acute stroke patients to facilities offering an appropriate level of stroke care. The goal of transfer is to get Veterans appropriate acute stroke care as quickly as possible when indicated, to a hospital capable of providing the appropriate acute stroke interventions.
- (b) For VA medical facilities that are a VHA SSF, having protocols in place with Emergency Medical Services to bypass the facility when acute stroke is suspected; and having detailed and current transfer agreements that incorporate the principles of 38 U.S.C. § 1784A for transfer of acute stroke patients to VA medical facilities offering a higher level of stroke care. The goal of transfer is to get Veterans appropriate acute stroke care as quickly as possible when indicated, to a hospital capable of providing the appropriate acute stroke interventions. VHA SSFs can provide post-stroke medical care as well as inpatient or outpatient rehabilitation and follow-up care.
- (c) For all VA medical facilities except VHA CSCs, having detailed and current transfer agreements that incorporate the principles of 38 U.S.C. § 1784A for patients requiring surgical and interventional procedures (e.g., mechanical thrombectomy). In general, transfer will be to a VHA CSC or a nationally or State-designated CSC, as clinically indicated.

i. VA Medical Facility Chief of Staff and Associate Director for Patient Care

<u>Services.</u> The VA medical facility Chief of Staff (CoS) and Associate Director for Patient Care Services (ADPCS) are responsible for:

- (1) Reviewing the VA medical facility AIS management plan at least annually and updating it as necessary.
- (2) Appointing the Stroke Committee Chair for a VHA CSC, PSC or LHSF and responding to the issues raised by the committee.
- (3) Monitoring and evaluating transfers to ensure compliance with VHA Directive 1094(1) and 38 U.S.C. § 1784A.
- j. VA Medical Facility Stroke Committee Chair. NOTE: The VA medical facility Stroke Committee Chair is appointed by the VA medical facility CoS and ADPCS and must be filled by a clinician leading stroke care at the VA medical facility with substantial experience and expertise in stroke (e.g., a neurologist or board-eligible specialist in emergency medicine or critical care). Nurses with expertise in acute stroke treatment can chair the Stroke Committee. These clinicians can serve the VA medical facility through a part-time or full-time appointment consistent with VHA Directive 1065(1), Productivity and Staffing Guidance for Specialty Provider Group Practice, dated December 22, 2020. The VA medical facility Stroke Committee Chair is responsible for:
- (1) Leading a chartered Stroke Committee that meets at least quarterly to review facility stroke care quality data and address any care issues and report to the Medical Executive Committee. Members must include representatives from all relevant stakeholders in code stroke process (e.g., Stroke Coordinator, ED/Level 1 Urgent Care director and nurse manager, ICU director and nurse manager, hospitalist, chief nurse of acute or surgical care, lab representative, radiology representative, pharmacy representative, quality management consultant). Additional personnel can include Education or Simulation coordinator, National Telestroke Program representative, acute care nurse managers, facility telehealth coordinator and union representative.
- (2) Ensuring that the committee's recommendations for stroke care align with VISN and VHA policies and requirements, as well as regulations of relevant outside survey bodies.
- (3) Establishing, monitoring, and providing trainings regarding backup and Continuity of Operations Plan and Disaster Recovery plan for informatics systems degradations or complete system failures that are designed to maintain an adequate level of system performance in providing safe patient care services for treatment of Acute Ischemic Stroke. See VHA Directive 0320(1), VHA Comprehensive Emergency Management Program, dated July 6, 2020.
- k. <u>VA Medical Facility Stroke Coordinator.</u> *NOTE:* The position of the VA medical facility Stroke Coordinator is appointed by the VA medical facility Director in collaboration with the CoS and ADPCS; and must be filled by a non-physician health care provider (e.g., Certified Nurse Practitioner, Certified Nurse Specialist, Registered Nurse, Physician Assistant, Advanced Practice Registered Nurse) with expertise in

stroke, who can serve the VA medical facility through a part-time or full-time appointment consistent with VHA Directive 1065(1). The VA medical facility Stroke Coordinator in PSCs and CSCs is responsible for:

- (1) Ensuring efficient and clear patient flow and safe transitions of stroke care.
- (2) Assisting with discharge planning and organization of outpatient stroke care.
- (3) Ensuring completion and documentation of required stroke training for full-time ED and ICU physicians and Certified Nurse Practitioners, Certified Nurse Specialists and Registered Nurses providing care at VHA CSCs and PSCs (see paragraph 5).
- I. <u>VA Health Care Provider.</u> The VA health care provider is responsible for following the informed consent process for thrombolytics as specified in VHA Directive 1004.01(3), Informed Consent for Clinical Treatments and Procedures, dated December 12, 2023. See Appendix A for additional details.

3. REQUIREMENTS FOR THE VA MEDICAL FACILITY ACUTE ISCHEMIC STROKE MANAGEMENT PLAN

The VA medical facility AIS management plan must include the following:

- a. Clinical plans for the rapid identification, evaluation, and treatment of patients presenting with symptoms and signs consistent with AIS. The protocol must include plans for managing patients with AIS symptoms who are eligible for thrombolytic therapy or endovascular thrombectomy, as well as those not eligible for acute stroke treatment. *NOTE:* Thrombolytic therapy may include alteplase or tenecteplase. It is recommended that VA medical facilities follow American Heart Association/American Stroke Association Acute Stroke Treatment guidelines. Guideline-concordant therapies that are not Food and Drug Administration-approved may be presented to your local pharmacy and therapeutics committee along with the relevant clinical practice guidelines for approval.
- b. VA medical facilities with the capacity to provide endovascular thrombectomy for acute stroke treatment must include this therapy in their stroke plans. At all other VA medical facilities, plans must be developed or modified to identify and transfer patients potentially benefitting from endovascular thrombectomy to a CSC designated by The Joint Commission or other entity able to provide endovascular thrombectomy at all times.
- c. VA medical facilities that are a VHA CSC or VHA PSC must have a stroke unit or other designated location (i.e., Intensive Care Unit (ICU)) within the VA medical facility, where stroke patients are admitted. VA health care providers with additional training and expertise in stroke care must staff the unit. An exception is that a PSC may elect not to admit stroke patients after thrombolysis, in which case it must have the ability to complete a timely transfer to an admitting hospital (2 hours maximum).
 - d. Identification of a formal stroke team at those sites designated as VHA CSC,

PSC, or LHSF. The team must be available during operational hours and be able to respond in person or via tele-medicine within 30 minutes of a call.

- e. An organized and consistent protocol for obtaining emergent stroke consultation should be created and widely disseminated amongst the different areas of the hospital (ED, Urgent Care Center, clinics and all inpatient unit nursing stations). The designated team or service must have a clear understanding of who is tasked to respond to such emergencies, and in what timeframe.
- f. VHA PSCs and CSCs must have a designated Stroke Coordinator who is responsible for ensuring efficient and clear patient flow and safe transitions of care, and who can assist with discharge planning and organization of outpatient care.
- g. All VHA CSCs, PSCs and LHSFs during designated hours of operation must have radiology technologists in the VA medical facility to perform non-contrast computed tomography (CT) scans. Radiologists privileged to interpret non-contrast CT scans must also be available to provide interpretation of the CT scan within 15 minutes of image completion and within 45 minutes of CT scan order entry, either in-person or via teleradiology services. In lieu of attending radiology review, experienced stroke clinicians who are available may interpret imaging studies for the purpose of informing acute treatment decisions.
- h. Readily available thrombolytic drug stored and available for use in the ED and ICU at every VHA CSC, PSC and LHSF. The plan must delineate inclusion and exclusion criteria consistent with American Heart Association/American Stroke Association Acute Stroke Treatment guidelines that must be considered for the administration of thrombolytic drug.
- i. The informed consent process for thrombolytics must adhere to the requirements (as specified in VHA Directive 1004.01(3)) so that the patient or surrogate understands the potential risks and benefits from thrombolytic treatment while expediting intervention to preserve life or avert serious impairment of the health of the patient. Timely thrombolytic administration maximizes stroke outcomes and minimizes disability. The potential risks must be discussed during thrombolytic eligibility deliberation and weighed against the anticipated benefits during decision-making, accommodating patients who may have limited ability to participate in education or are incapacitated and lack surrogate decision makers. The informed consent process must be documented in the electronic health record, and documentation must explicitly include whether AIS treatments or procedures were provided emergently without completing the written consent process per the emergency exception. *NOTE:* Refer to Appendix A, AIS Informed Consent.
- j. Plans for emergent transfer to the nearest VHA or non-VHA CSC or PSC capable of providing AIS care must be in place at all times for VHA LHSFs and SSFs.
- k. Methods to capture the quality indicators used to monitor progress and improvements in AIS care, as outlined in paragraph 2.h (4).

- I. VA medical facility plans for the management of AIS must be available in the ED, Level 1 Urgent Care, and at the nursing stations on the units in all VA medical facilities.
- m. VHA PSCs and LHSFs may use tele-medicine services as well as in-person VHA health care providers to deliver required care, including tele-stroke consultation for acute stroke care, tele-radiology for image interpretation and tele-critical care services for post-thrombolytic inpatient care.
- n. <u>Identification of a Formal Stroke Committee at Sites Designated as VHA CSC, PSC or LHSF.</u> VHA CSCs, PSCs and LHSFs are required to have a Stroke Committee that meets on at least a quarterly basis to review site stroke care quality data and address any care issues (see paragraph 2.j.).

4. VHA STROKE CENTER DESIGNATIONS

- a. VA medical facilities may be designated as:
- (1) VHA Comprehensive Stroke Center. A VHA CSC is a VA medical facility with the necessary personnel, infrastructure, expertise, and programs to diagnose and treat stroke patients emergently, including the administration of intravenous thrombolytic agents and performance of surgical and interventional (endovascular thrombectomy) procedures, 24 hours a day, 7 days a week, 365 days a year.
- (2) **VHA Primary Stroke Center.** A VHA PSC is a VA medical facility with the necessary personnel, infrastructure, expertise, and programs to diagnose and treat stroke patients emergently, including the administration of intravenous thrombolytics to appropriate candidates, 24 hours a day, 7 days a week, 365 days a year.
- (3) VHA Limited Hours Stroke Facility. A VHA LHSF is a VA medical facility with the necessary personnel, infrastructure, expertise, and programs to diagnose and treat stroke patients emergently, including the administration of intravenous thrombolytics to appropriate candidates during specified hours.
- (4) **VHA Supporting Stroke Facility.** A VHA SSF is a VA medical facility with limited capacity to deliver consistent care of patients presenting with AIS, based on staffing, diagnostic services, or numbers/types of beds.
- b. Designation of VA medical facilities as a VHA PSC, LHSF or SSF are supported by the Neurology NPED after submission of stroke protocols and available stroke services, as attested by signature of the VA medical facility Director and VISN Director.
- c. Initial designation of a VHA CSC also requires a site visit and data review conducted by appropriately trained personnel. This may include CSC or equivalent certification from an external accreditation body if an on-site survey is conducted as part of that certification process. Alternatively, appropriately trained VHA personnel designated by the Neurology Program Office may conduct an on-site survey. Travel expenses for this survey are borne by the VA medical facility seeking CSC designation.

5. TRAINING

- a. The following training is *required:* Stroke training must be provided, completed, and documented for full-time ED and ICU physicians and Certified Nurse Practitioners, Certified Nurse Specialists and Registered Nurses providing care at VHA CSCs and PSCs. This requirement can be fulfilled through in-person or virtual lectures or through completion of online training. Information about the National Institute of Neurological Disorders and Stroke, Stroke Scale, including options for certification, can be found at https://www.ninds.nih.gov/health-information/stroke.
- b. Accepted VA-accredited training modules are posted on the Neurology Program Stroke SharePoint located at https://rebrand.ly/NPO-Stroke. NOTE: This is an internal VA website that is not available to the public. Equivalent training is also acceptable if accredited for continuing medical education or continuing education unit credits.

6. RECORDS MANAGEMENT

All records regardless of format (for example, paper, electronic, electronic systems) created by this directive must be managed as required by the National Archives and Records Administration (NARA) approved records schedules found in VHA Records Control Schedule 10-1. Questions regarding any aspect of records management can be addressed to the appropriate Records Officer.

7. BACKGROUND

- a. Stroke is a leading cause of death or disability in the United States, and its prevalence is projected to increase as the population ages. Strokes are classified as either hemorrhagic or ischemic. AIS is caused by thrombosis or embolism and accounts for 85% of all strokes.
- b. VHA is committed to providing Veterans with access to emergency care that is prompt, safe, appropriate, equitable and cost effective. Prompt access to care is crucial to limiting permanent neurological disability following stroke. Based upon the American Heart Association (AHA)/American Stroke Association (ASA) Guidelines (https://professional.heart.org/en/guidelines-and-statements) and supported by randomized controlled trial data, this directive systematizes and standardizes care provided to Veterans who experience an acute ischemic stroke. Stroke systems of care can address differences in site capabilities and improve the quality of care for Veterans, with the goal of reducing the morbidity and mortality associated with stroke.

8. REFERENCES

- a. 38 U.S.C. §§ 1784A, 7301(b).
- b. 42 C.F.R. §§ 489.20, 489.24.
- c. VHA Directive 0320(1), VHA Comprehensive Emergency Management Program, dated July 6, 2020.

- d. VHA Directive 1004.01(3), Informed Consent for Clinical Treatments and Procedures, dated December 12, 2023.
- e. VHA Directive 1065(1), Productivity and Staffing Guidance for Specialty Provider Group Practice, dated December 22, 2020.
 - f. VHA Directive 1094(1), Inter-Facility Transfer Policy, dated January 11, 2017.
- g. Acute Ischemic Stroke Consent Process Flow Chart. https://rebrand.ly/NPO-Stroke. NOTE: This is an internal VA website that is not available to the public.
- h. VA National Telestroke Program SharePoint site. https://dvagov.sharepoint.com/sites/vanationaltelestrokeprogram. NOTE: This is an internal VA website that is not available to the public.
- i. National Neurology Program SharePoint site: https://dvagov.sharepoint.com/sites/vhannpo.
- j. IPEC SharePoint site: https://dvagov.sharepoint.com/sites/VHAIPEC/SitePages/Home.aspx. **NOTE:** This is an internal VA website that is not available to the public.
- k. Ability of patients with acute ischemic stroke to recall given information on intravenous thrombolysis: Results of a prospective multicenter study, 2023 located at https://pubmed.ncbi.nlm.nih.gov/37021170/.
- I. AHA/ASA Guidelines, Guidelines for the Early Management of Patients with Acute Ischemic Stroke: 2019 Update to the 2018 Guidelines for the Early Management of Acute Ischemic Stroke: A Guideline for Healthcare Professionals from the American Heart Association/American Stroke Association, 2019 located at https://www.ahajournals.org/doi/10.1161/STR.00000000000000011.
- m. AHA/ASA Guidelines: https://professional.heart.org/en/guidelines-and-statements.
- n. Consent Issues in the Management of Acute Ischemic Stroke: AAN Position Statement, 2022 located at https://pubmed.ncbi.nlm.nih.gov/35312627/.
- o. Effect of treatment delay, age, and stoke severity on the effects of intravenous thrombosis with alteplase for acute ischemic stroke: a meta-analysis of individual patient data from randomized trials, 2014 located at https://pmc.ncbi.nlm.nih.gov/articles/PMC4441266/.
- p. National Institutes of Health Stroke Scale. https://www.ninds.nih.gov/health-information/stroke/assess-and-treat/nih-stroke-scale.

ACUTE ISCHEMIC STROKE INFORMED CONSENT

- 1. Acute ischemic stroke (AIS) is a medical emergency caused by a blood clot restricting blood flow to a region of the brain. Unless blood flow is restored quickly, brain cells in the affected region will die. AIS treatments that can restore blood flow to the affected brain region include administration of thrombolytic medications and, in some cases, mechanical thrombectomy (the latter performed at the Department of Veterans Affairs (VA) Comprehensive Stroke Centers and thrombectomy-capable community hospitals).
- 2. Treatments for AIS have better outcomes the sooner they are given, however the treatments can also carry risk of harm. The degree of harm versus benefit varies based on patient characteristics and can be substantial, so careful individualized discussion of the anticipated harms and benefits is imperative to informed decision-making. Patients with AIS can have impaired decision-making capacity thus, limiting their ability to participate in the informed consent discussion. Strokes are more common in older patients who can have pre-existing cognitive impairment. In addition, the stroke itself can limit the ability to independently weigh and reason about harms and benefits (e.g., patients with strokes affecting the right parietal region can be unaware of their deficits; strokes affecting language areas can impair patient understanding and or/communication). Despite these potential limitations, patients must be included in the harm and benefit discussion to the extent feasible.
- **3.** Except as otherwise stated in VA policy, all treatments and procedures require the prior, voluntary informed consent of the patient, or if the patient lacks decision-making capacity, the patient's authorized surrogate. Completing the informed consent process for AIS treatments must adhere to the requirements specified in VHA Directive 1004.01(3), Informed Consent for Clinical Treatments and Procedures, dated December 12, 2023. The practitioner must engage the patient or surrogate in an informed consent discussion about any proposed thrombolytic treatment and obtain their signature.
- **4.** The responsible practitioner can provide necessary medical care in emergency situations without the patient's express consent when all of the following apply:
- a. Immediate medical care is necessary to preserve life or prevent serious impairment of the health of the patient,
 - b. The patient is unable to consent and
- c. The VA practitioner determines that the patient has no surrogate or that waiting to obtain consent from the patient's surrogate would increase hazard to the life or health of the patient.
- **5.** Documentation and other processes for consent in medical emergencies must follow the steps outlined in VHA Directive 1004.01(3), paragraph 5.a.

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6. Additionally, if obtaining the patient's or surrogate's signature on the consent form would delay the patient's emergency care and increase the hazard to the life or health of the patient, the practitioner should ensure provision of any necessary medical care and follow the documentation procedures for consent in a medical emergency outlined in VHA Directive 1004.01(3) paragraph 5.a.(4) and (5). In these cases, the documentation should also include that the patient or surrogate consented, but the treatment team was not able to obtain their consent signature prior to the treatment either on VHA Consent for Clinical Treatment/Procedure Form 10-0431a or in the Electronic Signature Informed Consent software (i.e., iMedConsent). AIS Process Flow Chart located at

https://dvagov.sharepoint.com/sites/vhannpo/Shared%20Documents/Forms/AllItems.as px?csf=1&web=1&e=dBlkpr&CID=ea5273ac%2D7381%2D4927%2D87ac%2Dc5e766b66add&FolderCTID=0x0120003614A0EF29AFE44A878154BD3EF8A0F1&id=%2Fsites%2Fvhannpo%2FShared%20Documents%2FConsent. *NOTE:* This is an internal VA website that is not available to the public.