

November 2, 2011

TREATMENT OF ACUTE ISCHEMIC STROKE (AIS)

1. PURPOSE: This Veterans Health Administration (VHA) Directive provides policy for the management of acute ischemic stroke (AIS) in VHA medical facilities.

2. BACKGROUND

a. Stroke is the third leading cause of death in the United States, accounting for more than one of every fifteen deaths. Strokes are classified as either hemorrhagic or ischemic. AIS is a stroke caused by thrombosis or embolism and accounts for 85 percent of all strokes. More than 700,000 persons experience a new or recurrent stroke each year, resulting in an approximate cost of \$58.6 billion. Strokes are also one of the major causes of long-term disability among adults, and their prevalence will continue to increase as the population ages. VHA estimates that 15,000 Veterans are hospitalized for strokes each year, with new strokes costing an estimated \$111 million for acute inpatient care, \$75 million for post-acute inpatient care, and \$88 million for follow-up care over 6 months post-stroke according to the VHA Quality Enhancement Research Initiative (QUERI). Forty percent of these stroke survivors are left with moderate functional impairments with an additional 15 to 30 percent with severe disability.

b. VHA is committed to providing Veterans with access to emergency care that is prompt, safe, appropriate, and cost effective. Veterans need to be able to obtain emergency care that meets a single standard of care for similar VHA facilities nationally. Prompt access to care is crucial to limiting damage done by a stroke.

c. In Fiscal Year (FY) 2009, the Department of Veterans Affairs (VA) initiated an Office of Quality and Performance (OQP) study to systematically evaluate indicators of acute stroke care quality. This study along with the 2009 VHA Emergency Department (ED) and Urgent Care Clinic (UCC) Stroke Survey provided information on the emergency service support structure for stroke treatment in VHA facilities and gave a picture of current stroke care in VA, identifying factors that affected practice patterns. These data are valuable in the ongoing assessment and enhancement of VHA processes with respect to emergent stroke treatment and care. This VHA policy will standardize the care and treatment of AIS at VHA facilities.

d. Policy based upon the American Heart Association (AHA)–American Stroke Association (ASA) Guidelines and the National Institute of Neurologic Disorders and Stroke (NINDS) Thrombolytic Therapy with Tissue Plasminogen Activator (r-tPA) Stroke Study will systematize and standardize care provided to stroke victims. Stroke systems of care can address differences in site capabilities and improve the quality of care for Veterans, with the ultimate goal of reducing the morbidity and mortality associated with stroke.

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e. Definitions

(1) **VHA Primary Stroke Center (PSC).** A VHA PSC is a facility or system with the necessary personnel, infrastructure, expertise, and programs to diagnose and treat stroke patients emergently 24 hours a day, 7 days a week (24/7), 365 days a year in the ED or in the medical facility. The VHA PSC must have a stroke unit, or other designated location within the medical facility where stroke patients are admitted, staffed by medical personnel who have additional training and expertise in stroke care.

(2) **VHA Limited Hours Stroke Facility (LHSF).** VHA LHSF is a facility or system with the necessary personnel, infrastructure, expertise, and programs to diagnose and treat stroke patients emergently, including the administration of r-tPA to appropriate candidates, only during normal business hours, as defined by local policy. Acute patients presenting outside these hours must be referred or diverted to a Stroke Centers designated by local policy.

(3) **VHA Supporting Stroke Facility (SSF).** A VHA SSF is a facility with limited capabilities related to staffing, technician coverage, study interpretation, or appropriate numbers and types of beds that does not allow for consistent care of patients presenting with acute stroke. Robust transfer agreements for in-hospital stroke and protocols, including Emergency Medical Services (EMS) diversion, must be in place to triage or transfer acute stroke patients to facilities offering a higher level of stroke care. Generally, these are either VHA PSCs, non-VA Joint Commission (JC), or state designated PSCs. VHA SSFs can, however, provide post-stroke medical care (excluding thrombolytic therapy), rehabilitation and follow-up care.

3. POLICY: It is VHA policy that all medical facilities with inpatient acute care medical or surgical beds must have a written policy to provide appropriate care to patients with AIS in place by January 1, 2012, and implemented no later than June 1, 2012.

4. ACTION

a. National Director for Neurology and National Director for Emergency Medicine.

The National Director for Neurology and National Director for Emergency Medicine are responsible for:

(1) Providing national guidance to ensure a standardized approach for the evaluation and management of patients presenting to the ED or UCC with AIS.

(2) Drafting policy and identifying appropriate measures to monitor compliance and quantify improvements in care after policy implementation.

b. Veterans Integrated Service Network (VISN) Director. Each VISN Director is responsible for:

(1) Assessing the capability of each facility in the VISN and assigning an appropriate designation for stroke care to each. The appropriate designations include:

- (a) VHA Primary Stroke Center,
- b) VHA Limited Hours Stroke Facility;
- (c) VHA Supporting Stroke Facility; or
- (d) None of these.

(2) Ensuring that all facilities with inpatient acute care beds within the VISN have policies that define and establish the provision of care to patients with AIS.

(3) Submitting a copy of the VISN plans for stroke care to the Chief Consultant, Specialty Care Services or their designee within 90 days of the publication for review and concurrence.

c. **Facility Director.** Each Facility Director is responsible for ensuring:

(1) That local policy, for the management of patients with AIS, is developed by January 1, 2012, and implemented no later than June 1, 2012. This policy must include the following elements:

(a) Clinical protocols or pathways for the rapid identification, evaluation, and treatment of patients presenting with symptoms and signs consistent with AIS. These protocols or pathways may be paper-based tools initially with subsequent development of computer-based products (recommended), and must include plans for managing patients with AIS presenting within 120 minutes of stroke symptom onset (r-tPA eligible patients), and for those presenting after 120 minutes (r-tPA ineligible patients) (see Att. A).

NOTE: A recent randomized, double-blind clinical trial found r-tPA to be effective and relatively safe when used up to 4.5 hours from symptoms onset. This has led some stroke specialists and at least one major guideline to endorse r-tPA use with this longer time window for a carefully-selected subset of patients who may benefit. However the Food and Drug Administration (FDA) has not yet approved the administration of r-tPA beyond 3 hours. It is recommended that VHA medical facilities follow FDA-approved administration of r-tPA, unless the facility has approved protocols and resources to support treatment in the extended 4.5 hour time frame.

(b) Sites designated as a VHA PSC or a VHA LHSF must organize a formal stroke team that is available during operational hours and able to respond in person within 30 minutes of a call.

(c) In-house radiology technician coverage and radiology attending physician's privileged to complete and interpret non-contrast Computed Tomography (CT) scans must be available within 45 minutes of patient arrival and must be available at VHA PSC and VHA LHSF during designated hours of operation. Availability of competent experienced neurologists, neurosurgeons, or other designated members of the Stroke Team, as defined by local policy to read scans, would be an acceptable alternative to staffing with trained and experienced radiologist attending coverage.

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(d) r-tPA must be readily available for use in the ED and Intensive Care Unit (ICU) at every VHA PSC and VHA LHSF for use when needed. If these drugs are not stocked in the ED or the ICU, pharmacy must be able to deliver this drug to the patient location within 15 minutes of the request at VHA PSC and VHA LHSF sites. The protocol or pathway must delineate strict inclusion and exclusion criteria that must be followed for the administration of r-tPA (see Att. B).

(e) A valid iMEDConsent™ form must be completed prior to administration of r-tPA. When iMEDConsent™ is not used because of issues outlined in Handbook 1004.05, signature consent must be documented on the appropriate printed VA Form 10-0431a, Consent for Clinical Treatment/Procedure or VA Form 10-0431b, Consent for Transfusion of Blood Products. Patients not willing to consent to treatment with r-tPA must have documentation in the medical record indicating the reasons for not consenting to r-tPA administration.

(f) Plans for emergent transfer on a 24/7 basis to the nearest VA or non-VA Primary Stroke Center capable of providing AIS care must be in place at VHA LHSF and VHA SSF.

(g) Methods to capture the quality indicators used to monitor progress and improvement in AIS care. These quality indicators include:

1. Percentage of eligible patients given thrombolytic therapy (r-tPA).
2. Percentage of patients with symptoms of AIS that have the NIH Stroke Scale completed,
 - a. Within 45 minutes of arrival for patients within the 120 minute window for r-tPA administration, or
 - b. Within 24 hours of admission for patients presenting outside of the window for r-tPA administration.
3. Percentage of patients being screened for dysphagia before oral intake.

(h) An extensive education program must be available for patients and staff. This education program must include web-based training for providers and print resources for patients. **NOTE:** *The Employment Education System (EES) Office provides these in addition to information on registration for the web-based product, and for ordering additional copies of print materials if needed.*

(i) Guidelines for the management of AIS must be posted in the ED, the UCC, and at the nursing stations on the units in all VHA facilities. **NOTE:** *Algorithms provided by the EES Office are available for posting in appropriate VHA facility locations.*

d. **Chief Consultant, Specialty Care Services.** The Chief Consultant, Specialty Care Services (10P4E), Patient Care Services is responsible for providing technical review to ensure adequacy of the VISN plans.

5. REFERENCES

a. VHA Emergency Department and Urgent Care Clinic Stroke Treatment Capability Survey FY 2009, Department of Veterans Affairs, Office of the Assistant Deputy Under Secretary for Health for Policy and Planning, Washington, D.C.

b. Adams, H., P., Del Zoppo, G., Alberts, M., J. Buhatt, D., L., Brass, L., Furlan, A., Grubb, R., L., Higashida, R., T., Jauch, E., C., Kidwell, Ch., Lyden, P., D., Morgenstern, L., B., Qureshi, A., I., Rosenwasser, R., H., Scott, P., A., & Wijidicks, F., M. (2007). Guidelines for the early management of adults with ischemic stroke. A guideline from the American Heart Association/American Stroke Association Stroke Council, Clinical Cardiology Council, Cardiovascular Radiology and Intervention Council, and the Atherosclerotic Peripheral Vascular Disease and Quality of Care Outcomes in Research Interdisciplinary Working Groups. Stroke 38, 1655-1711.

c. American Heart Association. (2005). Part 9: Adult stroke. American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Circulation 112(24 (Supplement)): IV-111-IV-120.

d. Alberts, M., J., Latchaw, R., E., Selman, W., R., Shephard, T., Hadley, M., N., Brass, L., M., et al. (2005). Recommendations for comprehensive stroke centers: a consensus statement from the Brain Attack Coalition. Stroke 2005; 36(7):1597-1616.

e. Schwamm, L., H., Pancioli, A., Acker, J., E., III, Goldstein, L.,B., Zorowitz, R.,D., Shephard, T., J. et al. (2005). Recommendations for the establishment of stroke systems of care: recommendations from the American Stroke Association's Task Force on the Development of Stroke Systems. Stroke 36(3): 690-703.

f. VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures.

g. VHA Handbook 1004.05, iMEDConsentTM.

6. FOLLOW-UP RESPONSIBILITY: The Office of Patient Care Services (10P4) is responsible for the contents of this Directive. Questions may be referred to the National Director for Emergency Medicine and/or the National Director for Neurology (10P4E) at (202) 461-7120.

7. RESCISSIONS: None. This VHA Directive expires November 30, 2016

Robert A. Petzel, M.D.
Under Secretary for Health

DISTRIBUTION: E-mailed to the VHA Publications Distribution List 11/4/2011

ATTACHMENT A

EXAMPLE OF ACUTE ISCHEMIC STROKE (AIS) CLINICAL PATHWAY



Example of AIS
Clinical Pathway.pdf

ATTACHMENT B

MAPPING OF TISSUE PLASMINOGEN ACTIVATOR (r-tPA) CHECKLIST



Mapping of r-TPA
Checklist.pdf