Department of Veterans Affairs
Office of Inspector General

Report No. 15-03803-26

Combined Assessment Program Summary Report

Evaluation of Acute Ischemic Stroke Care in Veterans Health Administration Facilities

December 3, 2015

Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections completed an evaluation of acute ischemic stroke care in Veterans Health Administration facilities. The purpose of the review was to determine the extent to which Veterans Health Administration facilities complied with selected requirements for the assessment and treatment of patients who had acute ischemic stroke symptoms.

We conducted this review at 50 Veterans Health Administration medical facilities during Combined Assessment Program reviews performed across the country from April 1, 2014, through March 31, 2015.

Although we observed many positive practices, we identified several opportunities for Veterans Health Administration facilities to improve. Discussion with managers at several levels of the Veterans Health Administration indicated that considerable activity is underway to reassess the requirements for stroke care and make improvements across the system.

We recommended that the Under Secretary for Health improve the availability of expertise in stroke treatment across the system. We also recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensure compliance with stroke care requirements, including prompt and thorough assessment, treatment, and patient education, and ensure the gathering and reporting of required stroke data elements.

Comments

The Under Secretary for Health concurred with the findings and recommendations. (See Appendix A, pages 10–12, for the full text of the comments.) The implementation plans are acceptable, and we will follow up until all actions are completed.

JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections completed an evaluation of acute ischemic stroke (AIS) care in Veterans Health Administration (VHA) facilities. The purpose of the review was to determine the extent to which VHA facilities complied with selected requirements for the assessment and treatment of patients who had AIS symptoms.

Background

Stroke is the fifth leading cause of death in the United States, accounting for about one of every 20 deaths. Strokes are classified as either hemorrhagic or ischemic. AIS is a stroke caused by thrombosis or embolism and accounts for 87 percent of all strokes. Approximately 795,000 people experience a new or recurrent stroke each year,[1] 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. About 15,000 veterans are hospitalized at VHA facilities 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 in the first 6 months post-stroke.[2]

In November 2011, VHA implemented a policy intended to standardize the care and treatment of AIS at VHA facilities. The policy is based upon the American Heart Association/American Stroke Association Guidelines. 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.

By June 1, 2012, VHA required facilities with inpatient acute medical or surgical beds to implement a written policy to provide appropriate care to patients with AIS.[3] Veterans Integrated Service Networks are to assign each facility an appropriate designation for stroke care—Primary Stroke Center (PSC), Limited Hours Stroke Facility (LHSF), Supporting Stroke Facility (SSF), or None of these. Facilities' policies and practices must meet the requirements for their designation.

In our review, 12 facilities had the PSC designation, 12 other facilities had the LHSF designation, and 26 facilities had the SSF designation. Six facilities' designation was 'None,' and we excluded them from this review. One of these facilities had inappropriately selected 'None' even though it has inpatient medical beds (Tomah). Some large, complex facilities that had the capabilities to provide PSC service had chosen LHSF or SSF (San Antonio, Dallas, Long Beach). We suggest that the program office, in collaboration with Veterans Integrated Service Networks, review facility

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[1] American Heart Association. Heart Disease and Stroke Statistics—2015 Update. *Circulation* 2015; 131: e29-e322. Chapter 14. Published online before print December 17, 2014. doi: 10.1161/CIR.0000000000000152.

[2] VA Office of Research and Development, Health Services Research and Development Service. *Quality Enhancement Research Initiative Fact Sheet*. June 2013.

[3] VHA Directive 2011-038, *Treatment of Acute Ischemic Stroke*, November 2, 2011.

capabilities versus selected designation and ensure provision of the highest level of care.

The LHSF designation allows a facility to provide PSC care during administrative hours (generally Monday–Friday, 8 a.m. to 5 p.m.) and SSF care after administrative hours. We asked LHSF facilities whether their community lists them as a PSC during administrative hours so that the facility is not bypassed by the Emergency Management System, and below are some of the themes in their responses:

- Their state, county, or community Emergency Management System only recognizes a stroke center that functions 24 hours per day.
- They have not informed the local Emergency Management System of their limited PSC status because they thought it would be too confusing to clarify what time the status changes.
- They have had several meetings to help the Emergency Management System understand the limited hours concept.

While we understand that some facilities will not be able to provide PSC care around the clock due to limited resources, we think this designation is confusing to staff, patients, and community Emergency Management Systems. We suggest that the program office consider eliminating the LHSF designation.

VHA's AIS policy does not address the use of telemedicine for stroke care (real-time two-way audio and visual communication between a PSC and other centers). Telemedicine can serve as a way to provide acute stroke expertise to facilities without full-time neurological services thereby maximizing the use of tissue plasminogen activator (tPA) and decreasing the time to initiate tPA.[4] In a recent review of stroke care at the Tomah facility, we recommended that VHA assess the use of telehealth evaluation in patients presenting to rural and/or low complexity VHA facilities with signs and symptoms of an acute stroke.[5]

In addition to looking at initial evaluation and treatment of patients presenting with AIS symptoms, we also reviewed certain aspects of stroke care that are recommended but not required. For 97 percent of sampled patients, we found that clinicians either ordered medication to prevent venous thrombosis or documented a contraindication. At the time of discharge, clinicians had ordered statin medications[6] for 90 percent of patients and antiplatelet medications for 96 percent of patients.

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[4] American Heart Association/American Stroke Association. Guidelines for the Early Management of Patients With Acute Ischemic Stroke: Executive Summary: A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association, *Stroke*. March 2013; 44(3): 870–947. Published online before print January 31, 2013. doi: 10.1161/STR.0b013e318284056a.

[5] *Healthcare Inspection – Care of an Urgent Care Clinic Patient, Tomah VA Medical Center, Tomah, Wisconsin*, Report No. 15-02456-396, June 18, 2015.

[6] Statins are a class of drugs that lower the level of cholesterol in the blood by reducing the production of cholesterol by the liver. American Heart Association/American Stroke Association guidelines recommend statin medication for patients for secondary stroke prevention.

Patients experiencing stroke symptoms ideally call 911 for transportation to the nearest VA or non-VA PSC facility. To obtain the most expedient care, patients should not travel on their own to LHSF or SSF sites after administrative hours. We asked LHSF and SSF managers whether they provided this instruction to patients, and they said they did—LHSF 75 percent and SSF 83 percent. The ways they did this included community outreach through stroke fairs, handouts available in primary care clinics, and post-stroke educational materials.

Scope and Methodology

We performed this review in conjunction with 50 Combined Assessment Program (CAP) reviews conducted from April 1, 2014, through March 31, 2015. The facilities we visited were a stratified random sample of all VHA facilities and represented a mix of facility size, affiliation, geographic location, and Veterans Integrated Service Networks. OIG generated an individual CAP report for each facility. For this report, we summarized the data collected from the individual facility CAP reviews.

We reviewed facility policies and conversed with applicable managers and employees. Additionally, we reviewed 1,487 patient electronic health records and 557 employee training files. The requirements that relate to this review have been in place since 2011, and we used 90 percent as our expectation for compliance. The patient samples within each facility were probability samples and thus represent the entire patient population of that facility.

Patient Selection. We selected all records of patients who had stroke visit or admission dates from January 1 through December 31, 2013. We used fiscal years 2013 and 2014 outpatient and inpatient (main and bed section) datasets to capture patient visits or admissions for stroke in calendar year 2013.

The outpatients selected had a primary International Classification of Diseases-9 (ICD-9) diagnosis code of 434.91 (cerebral infarction due to unspecified occlusion or stenosis of unspecified cerebral artery) during an Emergency Department (ED) or urgent care visit. The inpatients selected had a principal admission diagnosis or primary diagnosis for the full stay of International Classification of Diseases-9 diagnosis code 434.91 or bed section code 19 (stroke).

Sampling. We used a two-stage, complex probability sample design to select patients from the study population. In the first stage of sampling, we randomly selected the 50 VHA facilities that had acute inpatient beds and were scheduled for CAP visits, which we had stratified by the 12 catchment areas of the OIG's Office of Healthcare Inspections regional offices. In the second stage of sampling, we statistically randomly selected patients according to the type of facility. For PSC and LHSF, we randomly selected 45 patients for each facility with more than 45 patients. We included all patients for facilities with 45 or fewer stroke patients. For SSF, we randomly selected 60 patients for each facility with more than 60. We included all patients for facilities with 60 or fewer stroke patients.

<u>Statistical Data Analysis</u>. We estimated percentages according to our complex, multi-stage sample design. We used Horvitz-Thompson sampling weights (reciprocal of sampling probabilities) to account for unequal probability sampling and the Taylor expansion method to obtain the sampling errors for the estimates.

We presented 95 percent confidence intervals (CI) for the estimates of the true values (parameters) of the study population. A CI gives an estimated range of values (being calculated from a given set of sample data) that is likely to include an unknown population parameter. The 95 percent CI indicates that among all possible samples we could have selected of the same size and design, 95 percent of the time the population parameter would have been included in the computed intervals.

Percentages can only take non-negative values from 0 to 100, but their logits can have unrestricted range so that the normal approximation can be used. Thus, we calculated the CIs for percentages on the logit scale and then transformed them back to the original scale to ensure that the calculated CIs contained only the proper range of 0 to 100 percent. All data analyses were performed using SAS statistical software, version 9.4 (TS1M0), SAS Institute, Inc. (Cary, NC).

Inspectors conducted the reviews in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

Inspection Results

Issue 1:   Patient Assessment and Treatment

Patients may exhibit stroke symptoms upon presentation to a facility at a clinic visit, in the ED, or during an inpatient stay for an unrelated condition. VHA requires that all facilities with inpatient acute care medical or surgical beds have a written policy to provide timely care to patients with AIS.[7] There should be two different protocols—one for patient arrival at the facility in less than 120 minutes from the onset of symptoms and one for arrival in more than 120 minutes. Clinicians decide on treatment based on the timeframe from onset of symptoms. If patients present with AIS within 120 minutes of the onset of symptoms, clinicians may consider treatment with tPA (alteplase).

Facilities' policies generally included stroke clinical pathways or protocols. Additionally, facilities' policies generally required the performance of appropriate tests during an AIS evaluation, and facilities generally completed these.

Non-contrast computed tomography (CT) scans or magnetic resonance imaging (MRI) must be available to make a prompt diagnosis of AIS. VHA requires PSC and LHSF sites to have in-house radiology technician coverage and radiology attending physicians privileged to complete and interpret non-contrast CT scans within 45 minutes of patient arrival during administrative hours of operation. Availability of experienced neurologists, neurosurgeons, or other designated clinicians as defined by local policy would be an acceptable alternative to staffing with experienced radiologist coverage. When facilities completed CTs or MRIs, they did not always make results available to clinicians within 45 minutes of patient arrival. See Table 1 below for the results.

Table 1. CT or MRI results not made available to clinicians within 45 minutes of patient arrival.

	PSC		LHSF	
	Estimated percent	95 percent CI	Estimated percent	95 percent CI
CT or MRI results not made available to clinicians within 45 minutes of patient arrival	21.3	13.66–31.60	25.7	13.66–31.60

Source: VA OIG

The National Institutes of Health (NIH) has published a stroke scale to assist with categorizing stroke symptoms. VHA requires clinicians to complete the NIH stroke scale for all patients with AIS symptoms. Stroke scale completion timing depends on the onset of symptoms. Clinicians are to complete the scale within 45 minutes of arrival for those patients presenting within the timeframe for tPA and within 24 hours for those

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[7] VHA Directive 2011-038.

presenting outside the timeframe for tPA. See Table 2 below for the estimated results regarding clinicians not completing NIH stroke scales for patients who presented within and outside the timeframe for tPA.

Table 2.   Patients presenting with AIS symptoms who did not have the NIH stroke scale completed.

	PSC		LHSF		SSF	
	Estimated percent	95 percent CI	Estimated percent	95 percent CI	Estimated percent	95 percent CI
Within timeframe for tPA	25.4	13.53–42.57	32.8	17.96–52.13	46.2	31.41–61.69
Outside timeframe for tPA	41.9	27.81–57.43	56.2	43.50–68.18	65.4	47.70–79.67
Overall percent not completed	40.4	27.11–55.31	53.3	40.51–65.50	62.7	46.70–76.39

Source: VA OIG

Patients with new AIS symptoms who receive intravenous tPA experience improved outcomes.[8]   PSC and LHSF sites have the capability, knowledge, and monitoring resources to administer tPA. Of 1,488 total patients whose electronic health records we reviewed, we estimated that 10.9 percent arrived at the ED within the timeframe for tPA administration (95 percent CI: 9.35–12.65). Of these, we estimated that 69.5 percent did not receive tPA (95 percent CI: 57.63–79.19). We attempted to identify the reasons that clinicians did not administer tPA to eligible patients and found either that too much time elapsed before the neurologist saw the patient or that clinicians did not document a reason. PSC and LHSF clinicians need to promptly treat patients who are eligible for tPA.

SSF sites should have stroke policies that specify a plan for timely stabilization and transfer of patients who arrive within the timeframe for tPA administration. Of the patients who presented to SSF sites within the timeframe for tPA, we estimated that 39.4 percent (95 percent CI: 29.98–46.63) were not transferred to a PSC. Some of the reasons for not transferring these patients were that they had a contraindication for tPA or that the symptoms were resolving. Several patients were not transferred because by the time the work-up was done, the patient was no longer within the timeframe for tPA. SSF sites generally do not have the capability, knowledge, or monitoring resources to administer tPA and should not administer tPA; however, two sites had administered tPA prior to transfer to PSCs.

VHA requires every PSC and LHSF site to have tPA readily available for use when needed in the ED and intensive care unit.[9]   If the ED or intensive care unit does not stock this drug, pharmacy staff must be able to deliver it to the patient location within 15 minutes of the request. PSC and LHSF sites generally had tPA readily available.

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[8] American Heart Association/American Stroke Association. Guidelines for the Early Management of Patients With Acute Ischemic Stroke: Executive Summary: A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association.

[9] VHA Directive 2011-038.

VHA requires that clinicians screen patients for difficulty swallowing (also known as dysphagia, a common AIS symptom) before oral intake. Oral intake by patients with dysphagia can result in choking and aspiration. See Table 3 below for the results regarding clinicians not screening applicable patients.

Table 3. Admitted patients who did not have a dysphagia screen prior to oral intake.

	PSC		LHSF		SSF	
	Estimated percent	95 percent CI	Estimated percent	95 percent CI	Estimated percent	95 percent CI
Within timeframe for tPA	24.4	10.63–46.57	34.9	14.41–61.17	45.6	25.72–67.04
Outside timeframe for tPA	24.1	16.82–33.43	31.7	22.10–43.17	24.2	16.82–33.43
Total	24.1	13.75–38.70	32.1	21.47–44.90	25.6	17.46–35.77

Source: VA OIG

Issue 2:   Employee and Patient Education

VHA does not have specific AIS education requirements for employees but does require that facilities have an "extensive web-based training program available for staff."[10]

Thirty-seven facilities required stroke training for some of their employees (10 PSC, 10 LHSF, 17 SSF). For those sites with a local requirement, 49 percent did not document the training they required (5 PSC, 5 LHSF, 7 SSF). In the absence of a national requirement, those facilities that require training should ensure employees receive it. We suggest that VHA consider mandating a specific training course for certain relevant employees, such as ED and intensive care unit employees.

VHA requires that stroke guidelines be posted in the ED and urgent care center and at inpatient unit nursing stations so that employees are easily able to refer to them should a patient present with stroke symptoms.[11] We inspected these areas and found that overall, 33 percent of sampled facilities did not post stroke guidelines.

VHA requires that employees provide stroke education to patients and that patient education include printed resources.[12] We estimated that facilities did not have printed educational information available for patients 14.5 percent of the time (95 percent CI: 6.70–28.48). Additionally, clinicians did not always document that they provided printed stroke education to patients. See Table 4 on the next page for the results.

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[10] VHA Directive 2011-038.
[11] VHA Directive 2011-038.
[12] VHA Directive 2011-038.

Table 4. Noncompliance with requirement to document patient stroke education.

	PSC		LHSF		SSF	
	Estimated percent	95 percent CI	Estimated percent	95 percent CI	Estimated percent	95 percent CI
Patients' electronic health records that did not contain documented evidence that clinicians provided patient stroke education	45.8	31.95–60.35	50.7	29.62–71.54	71.0	50.55–85.44

Source: VA OIG

Issue 3:   AIS Data Gathering and Reporting

VHA requires facilities designated as PSC, LHF, or SSF sites to gather data related to patients who exhibit AIS symptoms.[13] See Table 5 below for the required data elements and the results.

Table 5. AIS data elements required and noncompliance with gathering and reporting them.

	PSC		LHSF		SSF	
	Estimated percent	95 percent CI	Estimated percent	95 percent CI	Estimated percent	95 percent CI
Percent of eligible patients given tPA therapy	33.3	11.61–65.11	35.2	13.16–66.11	60.6	39.42–78.40
Percent of patients with symptoms for AIS who had the NIH stroke scale completed	35.2	13.16–66.11	33.3	11.61–65.55	NA	NA
Percent of patients screened for difficulty swallowing before oral intake	33.3	11.61–65.11	35.2	13.16–66.11	60.3	41.24–76.62

Source: VA OIG

Conclusions

We observed many positive practices during our review, including facilities' policies, which generally included stroke clinical pathways or protocols; completion of appropriate tests during an AIS evaluation; and ordering discharge medications to prevent future venous thrombosis.

However, VHA could improve AIS care by increasing the availability of clinicians with stroke expertise across the system. Discussion at several levels of VHA indicated that

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[13] VHA Directive 2011-038.

considerable activity is underway to reassess the requirements for stroke care and make improvements across the system. In the meantime, VHA should ensure compliance with current requirements at each facility's designated level. Specifically, facilities need to provide CT or MRI results to clinicians timely, provide printed educational materials to patients, post stroke guidelines in key locations, and gather and report stroke data elements. Facilities need to ensure clinicians complete NIH stroke scales, provide prompt stroke treatment, complete dysphagia screens for all patients with stroke symptoms, and document they provided printed stroke education to patients.

Recommendations

1. We recommended that the Under Secretary for Health improve the availability of expertise in stroke treatment across the system.

2. We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensure compliance with stroke care requirements, including prompt and thorough assessment, treatment, and patient education, and ensure the gathering and reporting of required stroke data elements.

Under Secretary for Health Comments

Department of Veterans Affairs

Memorandum

Date: October 19, 2015

From: Under Secretary for Health (10)

Subject: **Office of Inspector General (OIG) Draft Report, Combined Assessment Program (CAP) Summary Report: Evaluation of Acute Ischemic Stroke Care in Veterans Health Administration Facilities (Project No. 2015-03803-HI-0611) (VAIQ 7638528)**

To: Assistant Inspector General for Healthcare Inspections (54)

1. Thank you for the opportunity to review the draft OIG CAP Summary Report: Evaluation of Acute Ischemic Stroke Care in VHA Facilities.

2. I concur with the report and the recommendations. Attached is VHA's corrective action plan for recommendations 1 and 2.

3. Should you have any questions, please contact Karen M. Rasmussen, MD, Director, Management Review Service (10AR) at VHA10ARMRS2@va.gov.

David J. Shulkin, M.D.

Attachment

VETERANS HEALTH ADMINISTRATION (VHA)

Action Plan

OIG Draft Report, CAP Summary Report – Evaluation of Acute Ischemic Stroke Care in VHA Facilities

Date of Draft Report: September 9, 2015

Recommendations/ Actions	Status	Completion Date

OIG Recommendations

Recommendation 1. We recommended that the Under Secretary for Health improve the availability of expertise in stroke treatment across the system.

VHA Comments: Concur

VHA Assistant Deputy Under Secretary for Health for Patient Care Services (ADUSH PCS) believes that providing access to expert stroke care across the system is vital to optimizing the care provided and outcomes achieved following acute ischemic stroke. Efforts to improve stroke expertise and care in VHA are presently being assessed and evaluated for enhancement and implementation. To achieve this, PCS will develop a plan for phased implementation of the telestroke program to link stroke specialists with Emergency Departments and include identification of patients that may benefit from endovascular therapies. Additionally, PCS will collaborate with experts in Tele-ICU regarding on-call resources and assistance with the care of Veterans admitted following stroke therapy.

To complete this action, VHA will provide documentation of:
1. The plan for phased implementation of the telestroke program; and
2. Collaboration with experts in Tele-ICU services.

Status: Target Completion Date:
In Process   April 2016

Recommendation 2. We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensure compliance with stroke care requirements, including prompt and thorough assessment, treatment, and patient education, and ensure the gathering and reporting of required stroke data elements.

VHA Comments: Concur

PCS believes that building a process to ensure appropriate care is provided within VHA facilities is critical to the health and well-being of each Veteran diagnosed with acute

ischemic stroke. PCS will reinforce expectations regarding assessment, treatment, education, and reporting of stroke data to the field by a memo from the Deputy Under Secretary for Health for Operations and Management (DUSHOM). These expectations will include performance and documentation of: NIH stroke scales, prompt stroke treatment, dysphagia screens, and printed stroke education materials to patients and families.

VHA facilities will be required to update stroke data elements and any non-compliant facilities will be required to submit an action plan for review and follow-up to VA Central Office through their respective VISN office.

To complete this action, VHA will provide documentation of:
1. The DUSHOM memorandum or equivalent guidance;
2. Distribution to relevant stakeholders, e.g., presentation of materials to Chief Medical Officers and Quality Management Officers on national calls;
3. Two quarters of facility-level results for the required elements related to stroke care compliance; and
4. A roll-up of VISN compliance results to include any action plans for facilities found to be in non-compliance.

<table>
<tr><td>Status:</td><td>Target Completion Date:</td></tr>
<tr><td>In Process</td><td>July 2016</td></tr>
</table>

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