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CIRCULAR LETTER: DHCQ 04-4-440

TO: Chief Executive Officers
Acute Care Hospitals

FROM: Paul I. Dreyer, Ph.D.
Director

DATE: April 13, 2004

RE: Advisory Bulletin: Primary Stroke Services

Introduction

The Department of Public Health recently promulgated hospital licensure regulations for Primary Stroke Services (see Attachment A). Under the new regulations, which became effective on March 12, 2004, a hospital may request voluntary designation as a provider of primary stroke services. Full implementation of the new regulations is contingent on development of the service by the hospital, designation of the service by the Department, and implementation of point-of-entry plans for primary stroke services by the Emergency Medical Services (EMS) regions. To assist hospitals in developing a primary stroke service that meets the regulatory requirements for designation, the Department offers this Advisory Bulletin which includes information about the application process for designation as a primary stroke service, data collection and submission, and guidance regarding time to treatment (referred to as Time Targets in the regulations). A provider education session will be scheduled in late spring to assist providers with development of a primary stroke service and application for designation under the new regulations.

The Department's goal is to improve stroke care in Massachusetts, which will include but is not limited to increasing the number of ischemic stroke patients arriving through the Emergency Department (ED) who receive FDA approved thrombolytic treatment (currently only intravenous t-PA is approved for this purpose) within the appropriate clinical time frame. Consistent with clinical standards of practice, the total time from patient symptom onset to

treatment of acute ischemic stroke with IV t-PA should be within three hours¹. No ischemic stroke patient should be treated with IV t-PA after three hours from symptom onset or ‘last seen well time’, unless the IV t-PA is administered under an Institutional Review Board approved protocol.

In its effort to evaluate and improve stroke care, the Department’s goal is to work with the hospitals to ensure that:

1. Symptom onset or ‘last seen well time’ will be documented in the patient’s medical record in all cases (100%) of suspected ischemic stroke, regardless of time of ED arrival.
2. All patients (100%) with suspected ischemic stroke who present within 3 hours of symptom onset will be considered and evaluated for eligibility to receive IV t-PA, and either receive it or have a documented contraindication or rationale for non-treatment with IV t-PA that is consistent with clinical standards of practice. Rationale for non-treatment would include situations where there is insufficient time to adequately evaluate and treat a potentially eligible patient within the three-hour window.
3. All ischemic stroke patients who receive IV t-PA are treated as rapidly as is safe and feasible, with the goal of treating patients within 60 minutes of ED arrival.

We have included suggested time intervals for several intermediate process measures (see Attachment B) to assist hospitals in analyzing the efficiency of acute stroke patient evaluation for patients arriving through the Emergency Department. Hospitals that consistently meet these time targets may be more successful in minimizing time to treatment.

Data Elements for Collection and Submission to Vendor

The Department has issued a Request for Response to select a vendor to perform acute ischemic stroke data management services for the Department and hospitals with a designated primary stroke service. The estimated cost for the data management services is less than \$500 per year per hospital.

The data elements listed below will be collected for all patients presenting to the Emergency Department (ED) with symptoms of acute stroke who arrive within three hours of symptom onset and are discharged with a diagnosis of ischemic stroke. Data items 1-8 will be documented on these patients as they are assessed in the ED. The de-identified data will be submitted at least monthly to the vendor. Data collected on patients determined to be experiencing a condition other than ischemic stroke will not be submitted to the vendor.

¹ Tissue plasminogen activator for acute ischemic stroke. The National Institute of Neurological Disorders and Stroke rt-PA Stroke Study Group. N Engl J Med 1995; 333:1581-1587

- 1) Age
- 2) Gender
- 3) Race
- 4) Date and Time (military) of patient arrival at ED
- 5) Date and Time (military) of symptom onset (or 'time last seen well')
- 6) Date and Time (military) of completion of initial brain imaging (CT or MRI)
- 7) Date and Time (military) of initiation of IV thrombolytic (t-PA) bolus
- 8) If t-PA not administered, reason(s) documented as contraindications or rationale under accepted clinical standards of practice
- 9) Hospital discharge destination (UB-92, 837 or JCAHO discharge code)

Because de-identified patient data will be submitted to the vendor, hospitals should maintain a readily retrievable file code that unlocks the identity of patients.

Application for Designation as a Primary Stroke Service

Application forms for Designation as a Primary Stroke Service and instructions for submission of an application will be available on the Department's website on April 30 (see <http://www.state.ma.us/dph/dhcq/hcqskel.htm>). In late spring, the Department and the Massachusetts Hospital Association will sponsor an educational session to assist hospitals in the development of a primary stroke service and completion of the application for designation. Applications will be accepted by the Department beginning June 1, 2004. Applications that meet the regulatory requirements will be approved subject to receipt of a signed contract with the data management vendor. Details regarding the data management vendor contract will be available once a vendor is selected.

Office of Emergency Medical Services Point-of-Entry Plans

In October 2004, the Emergency Medical Services Regions will begin implementing point-of-entry plans for primary stroke services that have been designated by the Department. Under these plans, ambulances with patients experiencing acute stroke symptoms will be directed to hospitals with designated primary stroke services. The plans will be revised as more primary stroke services are designated. The Office of Emergency Medical Services will develop an algorithm to be used by emergency transport services in areas where there is no designated primary stroke service or the travel time is greater than 20 minutes to that service.

Public Education Information

Any hospital seeking technical assistance regarding the primary stroke services community education requirement (105 CMR 130.1412) should contact Kathy Foell, in the Department's Center for Community Health, Cardiovascular Health Initiative Program. Ms. Foell can be reached at 617-624-5469 or at kathy.foell@state.ma.us

Attachment A: 105 CMR 130.1400 through 1413

Also available at <http://www.state.ma.us/dph/dhcq/hcqskel.htm>

Attachment B: Emergency Department Process Measure Assessment Tool

Attachment A
Amendments to the Hospital Licensure Regulations (105 CMR 130.000)
105 CMR 130.1400 Primary Stroke Service Licensure Regulations
(The official document in its entirety is available from the Secretary of State's Office)

1) Add a new section (H) to 105 CMR 130.020 Definitions, Essential Health Service, Excluded Services List:

(H) Primary Stroke Service.

2) Add a new section (AA) to 105 CMR 130.020 Definitions, Service:

(AA) Primary Stroke Service. Emergency diagnostic and therapeutic services provided by a multidisciplinary team and available 24 hours per day, seven days per week to patients presenting with symptoms of acute stroke.

3) Add following new sections 105 CMR 130.1400 through 1413:

130.1400: Purpose

The purpose of 105 CMR 130.1400 through 105 CMR 130.1413 is to establish standards for the designation of a Primary Stroke Service in a hospital with licensed Emergency Services.

130.1401: Definitions

Acute Hemorrhagic Stroke (a subtype of Acute Stroke) means the relatively rapid onset of a focal neurological deficit with signs or symptoms persisting longer than 24 hours and not attributable to another disease process. Initial CT/MRI may show evidence of acute brain hemorrhage (either intracerebral or subarachnoid blood) or no evidence of blood on imaging in the presence of blood in the subarachnoid space by lumbar puncture.

Acute Ischemic Stroke (a subtype of Acute Stroke) means the relatively rapid onset of a focal neurological deficit with signs or symptoms persisting longer than 24 hours and not attributable to another disease process. Initial CT/MRI may show evidence of acute ischemic changes or no evidence of stroke.

Acute Stroke means the relatively rapid onset of a focal neurological deficit with signs or symptoms persisting longer than 24 hours and not attributable to another disease process. Acute stroke includes both ischemic and hemorrhagic stroke, and requires brain imaging to define the stroke subtype.

Acute Stroke Expertise means any of the following: (1) completion of a stroke fellowship, (2) participation (as an attendee or faculty) in at least two regional, national, or international stroke courses or conferences each year, (3) five or more peer-reviewed publications on stroke, (4) eight or more continuing medical education (CME) credits each year in the area of cerebrovascular disease, or (5) other criteria approved by the governing body of the hospital.

Acute Stroke Team means physician(s) and other health care professionals, e.g., nurse, physician's assistant, or nurse practitioner, with acute stroke expertise available for prompt consultation consistent with time targets acceptable to the Department.

Primary Stroke Service means emergency diagnostic and therapeutic services provided by a multidisciplinary team and available 24 hours per day, seven days per week to patients presenting with symptoms of acute stroke.

Time Targets means time frames established by the Department in an advisory bulletin regarding Primary Stroke Services.

130.1402: Application to Provide Primary Stroke Service

Each hospital seeking designation as a provider of a Primary Stroke Service shall submit an application to the Department, on forms prescribed by the Department, documenting how the hospital will meet the standards in 105 CMR 130.1400 through 130.1413.

130.1403: Evaluation of an Application

The Department shall designate a Primary Stroke Service upon demonstration satisfactory to the Department that the hospital meets the criteria in 105 CMR 130.1400 through 130.1413.

130.1404: Stroke Service Director or Coordinator

The hospital shall designate a licensed physician with acute stroke expertise, who can represent the Primary Stroke Service and evaluate the hospital's capabilities to provide the required services, as the Stroke Service Director or Coordinator.

130.1405: Written Care Protocols

(A) The hospital shall develop and implement written care protocols for acute stroke. Such protocols shall include both the emergency and post-admission care of acute stroke patients by a multidisciplinary team. The hospital shall treat eligible patients according to its written care protocols consistent with time targets acceptable to the Department. These protocols shall address issues such as stabilization of vital functions, initial diagnostic tests, and use of medications (including but not limited to intravenous tissue-type plasminogen activator (t-PA) treatment), as applicable. These protocols shall be based on previously published guidelines or developed by a multidisciplinary team organized by the Stroke Service. Written care protocols for acute stroke shall be available in the Emergency Department (ED) and other areas likely to evaluate and treat patients with acute stroke.

(B) Emergency Department (ED) Stroke Protocols

1. The hospital shall develop and implement written protocols for triage and treatment of patients presenting with symptoms of acute stroke in the Emergency Department (e.g., use of thrombolytic therapy, management of increased intracranial pressure and blood pressure and post-thrombolysis management plan, as applicable).
2. The protocols shall include a method for communicating effectively with Emergency Medical Service (EMS) personnel in the pre-hospital setting during transportation of a patient with symptoms of acute stroke. The ED must be able to efficiently prepare for the arrival, to receive, and to triage patients with symptoms of acute stroke arriving via EMS transportation.
3. The hospital shall develop and implement a specific, well-organized system for promptly notifying and activating the Acute Stroke Team to evaluate patients presenting with symptoms of acute stroke.

(C) Post-Admission Care Protocols

The hospital shall develop and implement written protocols for the post-admission care of acute stroke patients.

130.1406: Neuroimaging Services

(A) The hospital shall have the ability to promptly perform brain computed tomography (CT) or magnetic resonance imaging (MRI) scans consistent with time targets acceptable to the Department.

(B) The hospital shall provide prompt interpretation after study completion by a physician with experience in acute stroke neuroimaging, consistent with time targets acceptable to the Department. Neuroimaging interpretation may be provided directly by a staff physician at the hospital or by contractual arrangement with consultant physician(s). Physicians providing neuroimaging interpretation shall be available in the hospital or through remote access (e.g., teleradiology).

130.1407: Other Imaging and Electrocardiogram Services

The hospital shall have the ability to promptly perform and evaluate chest x-rays and electrocardiograms consistent with time targets acceptable to the Department.

130.1408: Laboratory Services

The hospital shall have the ability to promptly perform and evaluate routine serum chemistry, hematology and coagulation studies for acute stroke patients, consistent with time targets acceptable to the Department.

130.1409: Neurosurgical Services

(A) The hospital shall develop and implement written protocols for patient access to neurosurgical evaluation and/or intervention within a reasonable period of time, which may include transfer to another hospital, consistent with time targets acceptable to the Department.

(B) If the written protocol includes the transfer of patients to another hospital, the hospital shall maintain a transfer agreement that describes the responsibilities of each hospital and is signed by the Stroke Service Director, the Medical Director of each hospital or his/her designee, and the Chief Executive Officer of each hospital or his/her designee.

130.1410: Quality Improvement

(A) The hospital shall implement and maintain an effective, data-driven quality assessment and performance improvement program for the Primary Stroke Service.

(B) The hospital shall collect and analyze data, as defined by the Department, on patients presenting to the ED with acute ischemic stroke who arrived within three hours of symptom onset, to identify opportunities for improvement in the service.

(C) The hospital shall submit data in a manner defined by the Department and in accordance with protocols established by the Department in an advisory bulletin.

130.1411: Continuing Health Professional Education

The hospital shall provide hospital-based staff education that addresses the needs of physicians, nurses, allied health professionals, and Emergency Medical Services (EMS) personnel. The program shall include ongoing formal training of ED and EMS system personnel in acute stroke prevention, diagnosis and treatment.

130.1412: Community Education

The hospital shall offer community education that provides information to the public regarding prevention of stroke, recognition of stroke symptoms, and/or treatment of stroke.

130.1413: Primary Stroke Service Review

The Primary Stroke Service protocols referenced in 105 CMR 130.1405 shall be reviewed and revised as necessary and at least annually by a committee designated by the governing body of the hospital and including the Stroke Service Director or Coordinator. The review must incorporate at a minimum the number of stroke patients, types of stroke evaluated, nature of any complications of thrombolytic therapy, and compliance with 105 CMR 130.1400 through 130.1413, including adherence to the time targets.

Attachment B

The following chart, which outlines the Time Targets mentioned in the Primary Stroke Service Regulations, is included to help hospitals assess the timeliness of activities related to stroke evaluation and diagnosis. Some of the activities listed below will occur concurrently, and the Department recognizes actual individual timeframes may vary, however the goal for the initiation of IV t-PA remains at one hour from the time of patient arrival in the ED.

Emergency Department Process Measure Assessment Tool

<u>Activity</u>	<u>Time Targets</u> ²
Time from patient arrival at ED to notification of Acute Stroke Team (AST), i.e., making the call to the team	within 15 minutes of arrival ³
Time from notification of AST to response of team member by phone, video or at patient bedside to assess patient as appropriate	within 15 minutes of being called
Time from order of CT scan or MRI scan to performance	within 25 minutes of order being written
Time from completion of CT scan or MRI scan to interpretation by physician	within 20 minutes of completion of scan
Time from order of chest X-Ray, if indicated, to performance through completion of chest X-Ray and interpretation	within 45 minutes of being ordered
Time from order of ECG to performance through completion of ECG and interpretation	within 45 minutes of being ordered
Time from order of lab tests to completion of tests, report of results, and interpretation	within 45 minutes of being ordered
ED door-to-needle time for IV thrombolytic (t-PA) treatment	within 60 minutes of patient arrival in ED
Time from order of neurosurgical evaluation to <i>start</i> of evaluation; includes transfer to another hospital for such evaluation, if applicable	within 2 hours of being deemed clinically necessary
Neurosurgical intervention	as needed urgently

² Source of all time targets, unless otherwise noted, is “Recommendations for the Establishment of Primary Stroke Centers”, JAMA 2000; 283:3102-3109.

³ NINDS proceedings of national symposium on Rapid Identification and Treatment of Acute Stroke, August 1997