Establishing Data Elements for the Paul Coverdell National Acute Stroke Registry
Part 1: Proceedings of an Expert Panel

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Background and Purpose—Stroke is the third-leading cause of death and a leading cause of disability in adults in the United States. In recent years, leaders in the stroke care community identified a national registry as a critical tool to monitor the practice of evidence-based medicine for acute stroke patients and to target areas for continuous quality of care improvements. An expert panel was convened by the Centers for Disease Control and Prevention to recommend a standard list of data elements to be considered during development of prototypes of the Paul Coverdell National Acute Stroke Registry.

Methods—A multidisciplinary panel of representatives of the Brain Attack Coalition, professional associations, nonprofit stroke organizations, and federal health agencies convened in February 2001 to recommend key data elements. Agreement was reached among all participants before an element was added to the list.

Results—The recommended elements included patient-level data to track the process of delivering stroke care from symptom onset through transport to the hospital, emergency department diagnostic evaluation, use of thrombolytic therapy when indicated, other aspects of acute care, referral to rehabilitation services, and 90-day follow-up. Hospital-level measures pertaining to stroke center guidelines were also recommended to augment patient-level data.

Conclusions—Routine monitoring of the suggested parameters could promote community awareness campaigns, support quality improvement interventions for stroke care and stroke prevention in each state, and guide professional education in hospital and emergency system settings. Such efforts would reduce disability and death among stroke patients. (Stroke. 2003;34:151-156.)

Key Words: data collection ■ registry ■ stroke assessment ■ stroke, acute ■ thrombolytic therapy

Stroke is the third-leading cause of death and a leading cause of serious, long-term disability in the United States; about 4.5 million Americans and their families live with the disabling effects of stroke.1 Aggressive treatment of patients with acute stroke could reduce disability if implemented in a timely fashion and used consistently throughout the United States. The recommended treatment of acute ischemic stroke includes the use of thrombolytic medications; tissue plasminogen activator (tPA), approved by the US Food and Drug Administration in 1996, has been shown to reverse or limit the effects of acute stroke.2 The use of tPA is low, however, in part because treatment must be administered within 3 hours of stroke onset to be effective. As such, only about 3% of patients with stroke are being treated with the appropriate thrombolytic agent,3,4 and only a fraction of stroke patients present to the hospital in time to receive a treatment that may make the difference between disability and full recovery.5

The need to coordinate and streamline the clinical evaluation process for acute stroke patients was first documented in 1989 after a review of evaluations for 20 patients enrolled in a clinical trial of a fibrinolytic agent for acute ischemic stroke.6 Since that time, clinical pathways, evidence-based practice guidelines, and significant advances in treatment and diagnostic imaging modalities have emerged to improve the quality of care delivered to victims of acute stroke.2,5,7-10 These guidelines go beyond the need to increase the appro-
Appropriate use of thrombolytic therapy for acute ischemic stroke. Stroke unit care, a major advancement in stroke management, is applicable to all stroke patients and needs to be implemented more fully in clinical practice. Despite scientific knowledge that stroke patients must be treated rapidly in a coordinated stroke program to improve patient outcome, many hospitals do not have the organization, personnel, and equipment required to triage and treat stroke patients according to current guidelines.

Established quality registers in other countries address issues similar to those addressed by the Paul Coverdell National Acute Stroke Registry. The Riks-Stroke Registry, established in Sweden in 1994, provides feedback on the quality of care and outcome of stroke to individual hospitals relative to all hospitals in the nation as an impetus for improvement in stroke management. Data from the Riks-Stroke Registry indicated that a smaller proportion of patients treated in stroke units were in long-term institutions at a 3-month follow-up than patients treated in general medical or neurological wards. The Registry of the Canadian Stroke Network, recently set up, is a national prospective clinical database that contains data about the care and treatment given to people who suffer a stroke or transient ischemic attack. The Registry of the Canadian Stroke Network will provide the information necessary for Canada to formulate recommendations for best practice in stroke management (www.canadianstrokenetwork.ca).

A recent study that focused on processes of care critical to outcome among Medicare beneficiaries indicated substantial opportunity for improvement at both the state and national levels in the United States. Recommendations from a 1998 presidential commission on quality in the healthcare industry recognized the importance of focusing on system failure rather than practitioner failure to increase the dissemination and implementation of current clinical practice guidelines.

Subsequently, leaders in the stroke care community identified a national stroke registry as a critical tool to document treatment pathways, procedures, and use of resources in the delivery of stroke care to objectively guide improvements in the quality of care. The registry recommendations focus on acute care, an emphasis different from that of traditional stroke registries, which focused on the epidemiology and etiology of stroke. Accordingly, case ascertainment and data collection must be real time or at least fairly current to ensure the ability to monitor current trends and measure changes fairly rapidly.

In response to this urgent public health need, Congress appropriated $4.5 million for fiscal year 2001 to the Centers for Disease Control and Prevention (CDC) for the development of a national acute stroke registry to track and improve the delivery of care to stroke patients. Congress further directed that the registry be named after US Senator Paul Coverdell of Georgia, who suffered a fatal stroke in 2000. The congressional language directed CDC to (1) consult with a panel from the Brain Attack Coalition and professional and nonprofit organizations in developing registry data elements and (2) design and test registry prototypes. We present here the methods for developing the list of recommended data elements and the resulting initial list of data elements recommended by the panel for the Paul Coverdell National Acute Stroke Registry prototypes. The panel recognizes that the data elements presented here represent a global perspective and that not all elements would be feasible in all settings with varying resources. Prototype development workshops will serve to establish a consensus on case definition, inclusion criteria, refinement of data elements, expansion of data elements, and development of concise data definitions. A committee comprised representatives for each prototype award recipient and CDC will oversee the publication of standards, description, and rationale for data elements to be collected by registry prototypes in the pilot phase.

Methods

A preliminary list of data elements was produced by CDC in accordance with professionally developed, widely accepted clinical practice guidelines, which were reviewed to identify relevant measures and data elements. Resources included journal articles, scientific statements, and educational materials from major professional organizations involved with improving the delivery of stroke care. CDC convened a national multidisciplinary panel of experts in February 2001 to review and revise the initial list of measures and reach consensus on measurements necessary to improve the quality of stroke treatment. The expert panel comprised representatives of the Brain Attack Coalition and several of its member organizations, including the American Academy of Neurology, American Association of Neuroscience Nurses, American Stroke Association division of the American Heart Association, and the National Stroke Association. Representatives of federal health agencies (the National Institute for Neurologic Disorders and Stroke, Centers for Medicare and Medicaid Services [formerly the Health Care Financing Administration], Veterans Administration, and CDC) were also included. The panel reviewed and discussed established stroke registry parameters before making recommendations. Agreement shown either verbally or by raising of hands was reached among all participants before an element was added to the list. The list of data elements presented here will serve to guide postaward workshops to refine and expand data elements and to develop concise data definitions for implementation of the prototype registries.

Results

Data elements recommended by the expert panel included patient-level information organized in domains that reflect the entire timeframe of the acute stroke episode from onset through treatment to follow-up (Table 1). These can be generally categorized as (1) prehospital, (2) emergency evaluation and treatment, (3) in-hospital evaluation and treatment, and (4) discharge information and postdischarge follow-up.

The prehospital data elements include items that may be related to treatment delay such as patient demographic characteristics and details about prehospital transport (Table 1). Excessive delays in time from onset of signs and symptoms to arrival at an emergency department (ED) may make the difference between disability and full recovery. The public needs to recognize the signs and symptoms of stroke and to treat stroke as a medical emergency. Delays in transport may also signal needed improvements in the way an emergency medical system (EMS) handles acute stroke patients.

The emergency evaluation and treatment data elements address patient care activities that occur during the first few hours after arrival at the hospital. The rapid diagnosis of stroke subtype and possible contraindications to thrombolytic
### TABLE 1. Patient-Level Data Elements Recommended for the Paul Coverdell National Acute Stroke Registry Prototypes

#### I: Prehospital
- Patient demographics
  - Age
  - Gender
  - Race
  - Hispanic origin
  - Zip code of residence
  - Health insurance status
  - Contact information for 90-day follow-up

- Transport and EMS care
  - Arrival mode
  - Data and time of call to EMS
  - Date and time of EMS dispatch
  - Date and time of EMS scene arrival
  - Date and time of EMS scene departure
  - Blood pressure measurement
  - Heart rate measurement
  - EMS Stroke Scale recorded
  - Pre-arrival notification to receiving hospital of stroke victim en route

#### II: ED evaluation and treatment
- ED triage
  - Date and time of arrival in ED
  - Date and time examined by ED medical doctor
  - ED admitting diagnoses (primary, 2nd, 3rd)
  - Whether stroke was any one of the admitting diagnoses
  - Neurologist consulted
  - Date and time of neurological consult
  - Neurosurgical consult
  - Data and time of neurosurgical consult

- Initial brain imaging
  - Type of image
  - Date and time of image
  - Data and time image results to treating physician
  - Image findings
  - Type of stroke
  - Stroke mechanism
  - Location of stroke
  - Side of stroke

- Onset of symptoms (weakness/numbness, dimness or loss of vision, speech, headache, and/or dizziness)
  - Presence of each symptom
  - Date and time of onset for each symptom
  - Whether patient awoke with each symptom
  - Duration of symptoms <8 hours

- NIHSS score

- Current risk factors
  - Obesity
  - High cholesterol/lipids or dyslipidemia
  - Smoking
  - Medications (3–4 categories that address tPA treatment issues)
  - Alcohol use in the past 30 days
  - Cocaine/crack use in the past 30 days
  - Diet pill use in the past 30 days

- Thrombolytic treatment
  - Whether thrombolytic therapy was given

#### III: In-hospital evaluation and treatment
- Other diagnostic or surgical procedures
  - Electrocardiogram
  - Lumbar puncture
  - Carotid endarterectomy
  - Stent
  - Angioplasty

- Consultations during hospitalization
  - Speech
  - Physical medicine and rehabilitation
  - Occupational therapy
  - Primary doctor
  - Cardiologist
  - Home health
  - Rehabilitation coordinator
  - Neuropsychiatry
  - Vascular surgery

#### IV: Discharge information and postdischarge follow-up
- Discharge information
  - Date of hospital discharge
  - Attending physician’s area of specialty
  - Whether a stroke pathway was used
  - Did the patient have access to an acute stroke team?
  - Discharge status
  - Barthel Index at discharge
  - Discharge plan

- Medical history at discharge (ever and active treatment in the past 6 months)
  - Stroke/transient ischemic attack/VBI
  - Myocardial infarction
  - Atrial fibrillation
  - Congestive heart failure
  - Head/neck trauma
  - Valve prosthesis
  - Hypertension
  - Dyslipidemia
  - Diabetes mellitus
  - Peripheral vascular disease
  - Asthma/chronic obstructive pulmonary disease
  - Subacute bacterial endocarditis
  - Migraine headache
  - Obesity
  - Cocaine/crack use
  - Smoking

- 90-day follow-up
  - Barthel Index
  - Medications
  - Place of residence (eg, nursing home, assisted living facility, patient’s home)

NIHSS indicates National Institutes of Health Stroke Scale; VBI, vertebro-basilar insufficiency.

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therapy needs to occur within 3 hours of stroke onset for tPA to be a potential viable option. As such, other patient-level domains were recommended to track the process through the ED that would ultimately lead to a timely evaluation, diagnosis, and treatment for ischemic stroke (Table 1). These elements included information on the ED triage, diagnostic evaluation (particularly the initial brain imaging, documentation of the onset of symptoms, National Institutes of Health Stroke Scale score, presence of current risk factors, and use of current medications that might serve as contraindications to thrombolytic treatment), and the delivery of thrombolytic treatment. Tracking these elements may lead to streamlining of key care processes that might otherwise delay the initiation of thrombolytic therapy to the point at which it is not optimally beneficial to the patient.

The in-hospital evaluation and treatment data elements address aspects of care that occur between the emergency management of the patient and hospital discharge. This additional patient-level information would allow monitoring of the quality of care during the hospitalization for stroke, including the use of other diagnostic or surgical procedures and the use of physician specialist or allied health consultation during the hospitalization. These elements would indicate the comprehensiveness of stroke care delivered to the patient during the hospital stay.

Discharge information and postdischarge follow-up data elements include a summary of the patient’s medical and functional status at the time of hospital discharge, as well as summary elements of the patient’s overall management while in the hospital. They also include an assessment at 90 days after discharge about the patient’s function, medication being used, and setting of the patient’s residence (e.g., nursing facility, personal residence). These elements provide a summary of the patient’s status after the emergency and inpatient care that was provided.

In addition to the patient-level data elements described above, the panel recommended a number of hospital-level measures pertaining to stroke center guidelines to augment the patient-level data (Table 2). Basic hospital-level domains included characteristics about the hospital and availability of a hospital diagnostic laboratory. Domains relevant to stroke center guidelines included availability of current head imaging technology and rapid interpretation, an acute stroke team, treatment protocols, monitoring capabilities, a stroke unit, and essential diagnostic equipment for stroke evaluation (Table 2). Other important hospital-level elements that could affect the quality of care for stroke patients included the presence of neurosurgical capabilities and the availability of rehabilitation therapy, an extant research program in stroke prevention and treatment, and stroke education and training programs. The presence of an existing stroke registry and consistent tracking of stroke patient outcome measures were also considered important data elements for the national registry.

**Discussion**

The CDC stroke registry project parallels efforts by other national organizations, federal health agencies, and health professionals who champion the same cause, improving the

<table>
<thead>
<tr>
<th>TABLE 2. Hospital-Level Data Elements Recommended for the Paul Coverdell National Acute Stroke Registry Prototypes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hospital characteristics</strong></td>
</tr>
<tr>
<td>No. of staffed beds</td>
</tr>
<tr>
<td>No. of acute care beds</td>
</tr>
<tr>
<td>Estimated No. of acute stroke patients per month</td>
</tr>
<tr>
<td>Academic/nonacademic</td>
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<tr>
<td>Private/public</td>
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<tr>
<td>Urban/semirural/rural</td>
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<tr>
<td>Hospital lab availability</td>
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<tr>
<td>CT scan</td>
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<tr>
<td>CT scan availability</td>
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<tr>
<td>Availability of CT reader with experience in identifying early stroke</td>
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<tr>
<td>ED</td>
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<tr>
<td>ED physicians trained to rapidly diagnose and treat acute stroke</td>
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<tr>
<td>ED staffing/personnel—acute stroke nurse/team?</td>
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<tr>
<td>ED interaction with EMS for prehospital notification</td>
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<tr>
<td>Treatment protocol</td>
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<tr>
<td>Does hospital have written guidelines for emergency treatment of stroke patients?</td>
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<tr>
<td>Is a tPA protocol in place?</td>
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<tr>
<td>Physician experienced in thrombolytic therapy for stroke</td>
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<tr>
<td>Trained in use of the NIHSS</td>
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<td>Is tPA available 24 hours/day, 7 days/week within 1 hour of physician order?</td>
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<tr>
<td>Monitoring capability (in stroke unit, ICU, stepdown unit)</td>
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<tr>
<td>Cardiac: rhythm</td>
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<tr>
<td>Blood pressure</td>
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<tr>
<td>O₂ saturation</td>
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<tr>
<td>Neurological checks, NIHSS</td>
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<tr>
<td>Stroke unit availability</td>
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<tr>
<td>Diagnostic equipment availability</td>
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<tr>
<td>MRI/MRA</td>
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<tr>
<td>Ultrasound: carotid duplex / transcranial Doppler</td>
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<tr>
<td>Echocardiography: transthoracic + transesophageal</td>
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<tr>
<td>Cerebral, angiography</td>
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<tr>
<td>Testing for hypercoagulable states</td>
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<tr>
<td>Surgery capabilities</td>
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<tr>
<td>Carotid endarterectomy</td>
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<tr>
<td>Hematoma evacuation</td>
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<tr>
<td>Aneurysm clipping treatment of vasospasm</td>
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<tr>
<td>Other</td>
</tr>
<tr>
<td>Rehabilitation therapies availability</td>
</tr>
<tr>
<td>Speech therapy + videofluoroscopy of swallowing or modified barium swallow</td>
</tr>
<tr>
<td>Physical therapy</td>
</tr>
<tr>
<td>Occupational therapy</td>
</tr>
<tr>
<td>Social worker, discharge planner</td>
</tr>
<tr>
<td>Case manager nurse practitioner or clinical nurse specialist</td>
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<tr>
<td>Research programs in stroke prevention and treatment</td>
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<tr>
<td>Professional stroke education and training programs</td>
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<tr>
<td>Pre-existing stroke registry that monitors the performance of stroke care</td>
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<tr>
<td>Availability and type of commercial software used</td>
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<tr>
<td>Chart abstraction is the primary data source</td>
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<tr>
<td>In-hospital data collection</td>
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<tr>
<td>Tracking of stroke patient outcomes by the hospital</td>
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</table>

CT indicates computed tomographic; ICU, intensive care unit; MRI, magnetic resonance imaging; MRA, magnetic resonance angiography.
quality of care for stroke. Measuring performance parameters that reflect adherence to recommendations for rapid and efficient stroke treatment can identify areas for improvement. In recent years, there has been increased recognition that performance measures should exist in all domains of hospital-based stroke care and should be linked to clinical guidelines.6,20 The data elements recommended by the expert panel include patient demographics, which may be associated with treatment delay, and additional patient-level data that track the process from the onset of symptoms through EMS and ED evaluation, use of thrombolytic therapy when indicated, other aspects of acute care, rehabilitation services, and 90-day follow-up. Organized inpatient care (stroke unit), characterized by coordinated multidisciplinary rehabilitation, education programs and training in stroke, and specialization of medical and nursing staff, has been shown to be effective in reducing death, dependency, and institutionalization after stroke.11,12 As such, hospital-level measures pertaining to stroke center guidelines were also recommended to augment patient-level data.

Unlike traditional disease registries, which focus on the epidemiology and etiology of a disease, most contemporary stroke registry programs aim to provide a monitoring system for measures of clinical performance that support quality improvements in the delivery of care. These hospital-based registries do not provide data generalizable to a general population on stroke or stroke subtype incidence, prognosis, risk factors, and survival patterns. A program announcement for applications for the development of prototypes for the Paul Coverdell National Acute Stroke Registry was published in the Federal Register on May 17, 2001. After a competitive process, 4 sites were funded to design and test prototypes. Each prototype will be tested in a statewide sample of hospitals that represent the diversity of facilities that offer acute care to stroke victims throughout the state. Each registry prototype will collect a standard list of data elements but may also incorporate other distinct components. The evaluation of these prototypes will determine the feasibility of collecting the data elements and the availability and accessibility of the recommended elements. The evaluation will also assess what components of each registry system work best and in what type of environment. The 4 sites funded in federal fiscal year 2001 include (1) the Emory University School of Medicine in Georgia, (2) the Massachusetts Peer Review Organization, Inc, (3) the Michigan State University Department of Epidemiology, and (4) the University of Cincinnati Department of Neurology in Ohio. The Research Triangle Institute was funded to evaluate the prototypes. Postaward workshops have been held since the program began about October 1, 2001, and have served to establish a consensus on case definition, inclusion criteria, refinement of data elements, expansion of data elements (including measures of secondary prevention), and development of concise data definitions. A committee will oversee the publication of standards, description, and rationale for data elements to be collected by all registry prototypes in the pilot phase.

The short-term goal of the expert panel was to recommend a set of valid clinical parameters that could serve to guide hospital and community interventions to improve quality of care and reduce disability in stroke patients. It is recognized that a more efficient care delivery system, one that decreases complications and improves patient outcomes, will also lessen the fiscal burden to the acute and long-term healthcare systems as the elderly US population increases. The Paul Coverdell National Acute Stroke Registry project will need to continue prototype testing and refinement and conduct quality of care improvement programs in participating hospitals. The long-term goal of this CDC project is to establish statewide registries nationally, similar to the CDC National Program of Cancer Registries21 and Traumatic Brain Injury Surveillance Program.22 Ongoing population-based stroke registries for planning and evaluating prevention, acute care, and rehabilitation for stroke sufferers will ultimately reduce death and disability and improve the quality of life among persons with stroke. A national stroke registry could provide important, consistently available data to monitor progress in reducing the incidence of stroke and associated disabilities and mortality. A major challenge in establishing a national registry is the associated costs of collecting, storing, maintaining, and analyzing data. Optimal improvements in stroke care will require a synthesis of improvements in (1) community education programs for early recognition of stroke symptoms and the importance of treating stroke as a medical emergency, (2) EMS evaluation of patients for suspected stroke and prehospital notification, (3) effective triage for the most appropriate emergency care, (4) establishment of a systematic national program for monitoring the quality of medical stroke care, and (5) national and local collaborative efforts to guide continuous improvements in the delivery of stroke care and stroke prevention.

References


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