**Paul Coverdell National Acute Stroke Program**

**(PCNASP) Reporting System**

**New Request**

**Supporting Statement Part B: Statistical Methods**

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**List of Attachments**

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Attachment 2: Section 317 of the Public Health Service Act [42 U.S.C. 247b(k)(2)]

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## **B: Statistical Methods**

## **B.1 Respondent Universe and Sampling Methods**

The PCNASP is funded to improve quality of care for acute stroke patients from stroke onset through hospital discharge through organized quality improvement activities. During this cooperative agreement, PCNASP funds 9 awardees (**Attachment 1**), who are state departments of health. As detailed in the funding opportunity announcement (FOA), awardees will establish/maintain a steering committee that serves to advise and help establish program partnerships. Awardees will work directly with their selected partners, which includes, but is not limited to, local/regional EMS systems and hospitals, state/regional EMS Directors, hospitals, integrated healthcare systems, and post-hospital care providers.

Each awardee has different strategies for the recruitment of partners in the pre-hospital, in-hospital, and post-hospital phases. These strategies vary based on the awardee’s programmatic goals, infrastructure, existing partnerships, state regulations, and awardee infrastructure and capabilities. Some examples of recruitment strategies include: recruiting hospitals that are located in areas with high stroke mortality and hospitalization rates, targeted recruitment of hospitals in both urban and rural areas, recruiting hospitals who have the staffing and infrastructure capabilities for PCNASP data collection, and partnering with pre- and post-hospital care providers in regions with existing partnerships with in-hospital partners. CDC does not dictate specific characteristics of hospitals that have to be recruited. However, this type of resulting information from recruitment can be determined through responses collected in the PCNASP hospital inventory survey.

**Table B.1.a Respondent and Associated Partners for the Collection and Transmission of Information**

|  |  |
| --- | --- |
| **Information** | **Respondent and Associated Partners (N)** |
| Pre-hospital quality of care data | Hospitals in coordination with local/regional EMS systems (78) |
| Awardees (9)\* |
| In-hospital quality of care data | Hospitals\*\* (315) |
| Awardees (9) |
| Post-hospital quality of care data | Hospitals in coordination with post-hospital care providers (20) |
| Awardees (9) |
| Hospital inventory data | Hospitals (315) |
| Awardees (9) |

*\*The 9 awardees are California, Georgia, Massachusetts, Michigan, Minnesota, New York, Ohio, Washington, and Wisconsin*

*\*\*Note: burden is not assessed for the hospital’s collection or transmission of in-hospital data. Please reference section A.12 in Supporting Statement A for further details about this.*

The target populations include acute stroke patients (intracerebral hemorrhage, ischemic stroke, potential acute stroke patients, and patients presenting with a transient ischemic attack (TIA)). The inclusion criteria can be defined as all individuals diagnosed with an acute stroke (ischemic stroke or intracerebral hemorrhage) or transient ischemic attack (TIA) presenting to acuAte care hospitals or emergency departments, and all individuals presenting to EMS with a potential acute stroke or TIA. CDC encourages but does not require the inclusion of patients presenting with stroke in pregnancy (including peripartum stroke). CDC encourages the inclusion of patients with acute stroke or TIA that are in ED boarding. CDC strongly encourages the inclusion of patients presenting with subarachnoid hemorrhage. These patients that are included in PCNASP are the basis of which programmatic aims are carried out and measured. Through data that is collected on this patient population, PCNASP measures improvements in the quality of systems of stroke care through data-driven activities across the care continuum.

PCNASP will receive data from all 9 awardees under the cooperative agreement. Hospital names will not be included in the data sent to CDC. Hospitals are given the option to abstract all stroke cases or to use the sampling strategy developed by The Joint Commission and Centers for Medicare & Medical Services (CMS) for reporting of stroke quality of care data to those two entities.

## **B.2 Procedures for the Collection of Information**

Quality of care information collection includes data from 3 different phases: pre-hospital (**Attachment 4a**), in-hospital (**Attachment 4b**), and post-hospital (**Attachment 4c**). **Attachment 6** describes the flow of this information collection and transmission. All awardees collect a common set of core data elements, with the ability to also collect optional data elements based on the needs and goals of their individual programmatic plans that fit within the broader goals of PCNASP. The in-hospital care data elements are defined with national partner organizations and collected from patients’ medical records. The awardees electronically pull the in-hospital data from their respective hospitals, so the transmission process occurs on the awardees’ end. In contrast, hospitals transmit pre-hospital and post-hospital quality of care data on a quarterly basis to their awardee. Subsequently, the awardees will link the data from EMS (pre-hospital care data), in-hospital care, and post-hospital transition of care and send it to CDC through secure access management services (SAMS) web portal quarterly (**Attachment 8**). The mechanism used by grantees to link data across the stroke continuum will depend on the infrastructure that they develop. Some examples of these strategies include implementing a unique ID into pre-hospital data systems that exists in the in-hospital patient record and entering post-hospital transition of care data into the same data platform as the in-hospital patient record. Information is transmitted as a SAS (Statistical Analysis System) data set. All the information is de-identified.

Additionally, hospital inventory data will be collected by hospitals on an annual basis (**Attachment 5a**) and transmitted to the hospitals’ awardee either electronically or on a paper form. The awardee then compiles all hospital responses into a single Excel file to submit to CDC annually (**Attachment 5b**). Without PCNASP, this data is not systematically or routinely collected by hospitals and sent to their respective awardee. The hospital inventory data can be linked to in-hospital data through a unique de-identified hospital ID common to both sources.

Awardees utilize the data to help drive decisions on specific quality improvement activities that they want to focus on to provide high quality care to improve outcomes. These activities fit within the scope of the PCNASP aims. Awardees send their data to CDC to aggregate data from all awardees. Data are used to track the overall progress of the program and quality improvement efforts CDC also provides feedback to awardees on any data errors or missing data that is identified. Additionally, aggregated data from PCNASP can be used more broadly to drive developments in evidence-based stroke care and formulate national performance metrics.

The data will reside in a secured file location on CDC servers.

## **B.3 Methods to Maximize Response Rates and Deal with Nonresponse**

All PCNASP awardees are expected to report data in a timely manner. CDC requires data submission as a stipulation of the Funding Opportunity Announcement and the cooperative agreement notice of grant award. Awardees that have difficulty with data submission will be provided technical assistance by the PCNASP Health Scientist, the PCNASP Project Officers, and/or the data contractor. If necessary, short extensions will be provided to give the awardees additional time to report. The schedule for data reporting will remain consistent.

The use of existing data dictionary (**Attachments 4a, 4b, 4c, 5a, 5b**) and data abstraction guidelines for electronic submission of data makes it easy for awardees to comply with the request. In addition, CDC’s PCNASP team will provide a detailed assessment of data quality to all awardees after each data submission.

## **B.4 Test of Procedures or Methods to be Undertaken**

The data uploading systems developed and maintained by CDC have been tested by PCNASP staff. SAMS is used by states for a variety of purposes and is a familiar process to them.

## **B.5 Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data**

CDC staff from the PCNASP program were consulted about the substantive, methodological, and statistical aspects of the study.

## All of the data analyses will be done on site at CDC in the Division for Heart Disease and Stroke Prevention. CDC investigators will collaborate with the awardees and their partners on ideas for analyses, development of analytic plans for each study, interpretation of the data and manuscript preparation. The following is a list of PCNASP staff at CDC who work on the oversight, development, methodology, and statistical design of data that is collected.

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