

Information Collection Request

Reinstatement

Paul Coverdell National Acute Stroke Program

(PCNASP) Reporting System

OMB No. 0920-1108

Supporting Statement Part B

Program Official/Contact

Sallyann Coleman King, MD, MSc

Medical Officer

Division for Heart Disease and Stroke Prevention

National Center for Chronic Disease Prevention and Health Promotion

Centers for Disease Control and Prevention

Atlanta, GA 30341

Telephone: (770) 488-5892

Fax: (770) 488-8334

Email: FJQ9@cdc.gov

April 23, 2019

Table of Contents

B. Statistical Methods

1. Respondent Universe and Sampling Methods
2. Procedures for the Collection of Information
3. Methods to Maximize Response Rates and Deal with Nonresponse
4. Test of Procedures or Methods to be Undertaken
5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

List of Attachments

- 1: 2015-2020 PCNASP Awardees
- 2: Section 317 of the Public Health Service Act [42 U.S.C. 247b(k)(2)]
- 3a: Crosswalk between program aims and short/intermediate/long term outcomes
- 3b: Crosswalk between short/intermediate/long term outcomes, performance measures, and data sources
- 4a: Pre-hospital care data elements
- 4b: In-hospital care data elements
- 4c: Post-hospital quality of care data elements
- 5a: Template of hospital inventory data elements for hospitals
- 5b: Template of hospital inventory data elements for awardees
- 6: 60-day Federal Register Notice (FRN)
- 7: IRB approval letter
- 8: Screenshot of Secure Access Management Services (SAMS) web portal
- 9: Information collection and transmission flow diagram
- 10a: Crosswalk of pre-hospital care data element changes
- 10b: Crosswalk of in-hospital care data element changes
- 10c: Crosswalk of post-hospital care data element changes
- 10d: Crosswalk of hospital inventory data element changes
- 11: Example table shells of performance measure summary reports
- 12: Data burden excerpt from PCNASP Reference Guide

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 establish/maintain a steering committee that serves to advise and help establish program partnerships. Awardees 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.

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	Awardees (9) in coordination with hospital and EMS partners
In-hospital quality of care data	Awardees (9) in coordination with hospital partners
Post-hospital quality of care data	Awardees (9) in coordination with hospitals and post-hospital care providers
Hospital inventory data	Hospitals (378)
	Awardees (9)

**Note: burden is not assessed for the hospital's collection or transmission of in-hospital data. Burden is also not assessed for the collection or transmission of pre-hospital or post-hospital data when existing data systems are used. 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 acute 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.

PCNASP receives data from all 9 awardees under the cooperative agreement (CDC-RFA-DP15-1514). Neither hospital nor direct patient identifiers are included in the data sent to CDC. Awardees are not required to develop a sampling plan for the selection of hospitals. However, 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 & Medicaid 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 9** describes the flow of this information collection and transmission. The pre-, in-, and post-hospital care data elements are defined with national partner organizations to align data standards and collection methods when possible. Awardees choose their own data sources/systems to collect the data. The data system chosen by awardees depends on the availability of the data and their access to it. For example, pre-hospital care data can be collected by awardees from their partner hospitals or in partnership with their state office of EMS. Post-hospital care data can be collected by awardees from their partner hospitals or other healthcare facilities (e.g., stroke rehabilitation facilities). Awardees send compiled data to CDC through secure access management services (SAMS) web portal quarterly (**Attachment 8**). 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.

CDC will aggregate data from all awardees. The data will reside in a secured file location on CDC servers, which is only accessible by the PCNASP data analyst and statistician.

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 Notice of Funding Opportunity 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.

Sallyann Coleman King, MD, MSc
PCNASP Director & Medical Officer
fjq9@cdc.gov
770-488-5892

Lisa Cooper
Project Officer
las0@cdc.gov
404-498-0393

Xin Tong, MPH
Statistician
fvx4@cdc.gov
770-488-4551

Xiaoping Yin, MS
Data Analyst
yxq9@cdc.gov
404-718-6612

Epidemiology and Surveillance Team
Division for Heart Disease and Stroke Prevention
Centers for Disease Control and Prevention
4770 Buford Hwy NE, MS F-77

Atlanta, GA 30341-3717
770-488-8080 / 770-488-8334 Fax