

**Paul Coverdell National Acute Stroke Program
(PCNASP) Reporting System**

New Request

Supporting Statement Part A: Justification

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Goal of the Study

The CDC's Paul Coverdell National Acute Stroke Program (PCNASP) seeks to improve quality of care for acute stroke patients through systematic approaches to quality improvement activities. PCNASP works with nine state health departments to focus on improving quality of care throughout the stroke continuum of care. To improve quality of care, information will be collected during 3 phases of care: (i) pre-hospital care provided by emergency services, (ii) in-hospital care provided by a variety of units, and (iii) post-discharge care provided by rehabilitation facilities, primary care physicians, and others.

Intended Use of the Resulting Data

Data reporting will allow for continuous program monitoring, identification of successes and challenges for awardees, and assessment of the overall effectiveness and influence of PCNASP. Specifically, resulting data will be used to monitor and improve the quality of care for acute stroke patients, improve recovery, improve adherence to post-stroke guidelines, and reduce complications, readmissions, and early mortality for acute stroke patients. Lessons learned from the awardees will also help inform stroke care in settings outside of PCNASP.

Methods to be Used to Collect

Partner hospitals selected by awardees (state health departments) will electronically transmit data files to PCNASP awardees. PCNASP awardees will then transmit de-identified files to CDC.

The Subpopulation to be Studied

PCNASP-funded awardees will report all cases of acute hemorrhagic stroke (subarachnoid hemorrhage and intracerebral hemorrhage), acute ischemic stroke, acute ill-defined stroke, and transient ischemic attack (TIA) among patients age 18 and over from participating hospitals.

How Data will be Analyzed

CDC will perform annual data validation of select and highly important data elements, as well as quarterly data quality review and performance monitoring.

A. Justification

A.1 Circumstances Making the Collection of Information Necessary

The National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC) is submitting a new information collection request for OMB approval for three years to collect information from awardees funded through the Paul Coverdell National Acute Stroke Program (PCNASP). Awardees are state departments of health that will work with selected partners to improve systems of acute stroke care in their respective jurisdictions (**Attachment 1**). PCNASP is authorized under Section 317 of the Public Health Service Act (PHSA), 42 U.S.C. 247b(k)(2) as amended (**Attachment 2**).

Stroke is largely preventable, yet nearly 800,000 strokes and transient ischemic attacks (TIAs) occur each year, leading to ~130,000 deaths annually, and significant morbidity in survivors. In conjunction with scientific advances to prevent and treat strokes, there has been increased recognition in the importance of establishing integrated stroke systems of care that link care coordination and access to primary stroke prevention and community education, pre-hospital care, acute stroke treatment, secondary prevention, rehabilitation, and quality improvement activities. To address the public health burden of stroke, CDC has initiated and progressively expanded PCNASP from 2001 to the present to conduct organized quality improvement activities for acute stroke patients from stroke onset through hospital discharge. During previous funding cycles, initial PCNASP efforts focused on improving in-hospital stroke care, with awardees additionally individually piloting pre-hospital and post-hospital information collection methods.

For PCNASP's 2015-2020 funding cycle (June 30, 2015-June 29, 2020) 9 awardees were selected through a competitive Funding Opportunity Announcement (FOA) that was conducted through an external review panel. These awardees were selected because they demonstrated through pre-specified criteria that they have the most comprehensive plans and capacity to execute and implement programmatic activities that align with PCNASP program aims. All PCNASP awardees are working with selected partners in their jurisdictions to collect information for the following three phases of stroke care: pre-hospital, in-hospital, and post-hospital care. Since acute stroke patient outcomes are influenced by rapid initiation of appropriate care in the pre-hospital setting, followed by effective communication and coordination during transitions to in-hospital and post-hospital care, a systems approach that addresses the entire continuum of care is needed to improve outcomes for patients. PCNASP will use quality improvement and systems analysis techniques to add value to information routinely collected for patient care.

The standardized set of common data elements in the pre-hospital, in-hospital, and post-hospital phases of care are used for PCNASP performance measures. Each of these measures are directly tied to program short-term, intermediate, and long-term outcome measures (**Attachment 3b**), which are linked to program aims (**Attachment 3a**).

Awardees will work directly with their partners to place evidence based quality improvement activities in the context of their state’s capabilities, health care structure, and needs. Thus, the specific quality improvement activities implemented will vary depending on the awardees’ programmatic goals. Examples of activities include awardees directly targeting stroke quality improve activities in rural areas, and awardees working with local EMS systems to launch pilot programs for linking pre-hospital and in-hospital data. Specific activities that are implemented may be influenced by the current capacity of hospitals in stroke care; thus this information collection request includes the collection of hospital inventory data that is important to improving the quality of stroke care within states.

Pre-hospital data will focus on improving pre-hospital care for acute stroke by working with EMS agencies to develop pre-hospital data collection systems. Linking this pre-hospital and in-hospital data will enable EMS and emergency department hospital staff to collaboratively improve early acute stroke care transitions. This is particularly important to ensure that patients who are eligible to receive time-sensitive therapies, such as tissue plasminogen activator (tPA), receive appropriate care within a timely manner. The post-hospital transition of care (TOC) data will help identify opportunities to improve the transition from hospital to the next care setting, patient education, access to community resources post-discharge, re-integration with primary care providers, and prevention of early complications after hospital discharge. Although PCNASP information collection will be across three different phases, it is significant and vital that PCNASP will be using an integrated approach to stroke care by developing state-based stroke systems of care that link patient data across the phases to examine care for the entire care continuum. To supplement patient data collected across the continuum, hospital inventory data will help to understand hospitals’ capacity for delivering stroke care. This data is not routinely collected outside of PCNASP.

A.2 Purpose and Use of the Information Collection

PCNASP has 5 program aims that are listed in Attachment 3a. Progress is assessed based on a variety of information sources that include both process performance measures and patient-level quality of care performance measures. **Attachment 3a** provides an overview of program aims and their relationship to short-, intermediate-, and long-term measures. **Attachment 3b** provides a detailed summary of information sources for these measures. Overall, information that will be collected will assess whether short-term and intermediate-term project activities are leading to intended long-term outcomes, as well as the reach and impact of the program; these are critical to enabling CDC to work with awardees to ensure appropriate dissemination of program impact and lessons learned. More specifically, data that is collected on quality improvement activities will help identify gaps, challenges, and successes in providing high quality care to improve patient outcomes. This resulting data and lessons learned will help drive performance measure development and improvement and the use of evidence-based stroke care on a broader national level.

Process performance measures include information on partnerships between awardees and stroke-related entities, recruitment of hospital and EMS agencies, interventions implemented as a result of data reports, and quality improvement efforts. Process-related measures are principally addressed by awardees through annual reports of activities which are not part of this information collection request. However, some process-related measures will be derived from quality of care data described in the current information collection request.

This information collection request focuses on the patient-level quality of care performance measures that are derived from pre-hospital care data elements (**Attachment 4a**), in-hospital data elements (**Attachment 4b**), and post-hospital transition of care data elements (**Attachment 4c**). Pre-hospital quality of care information will support analysis and performance on metrics measuring adherence to guidelines for early management of potential stroke patients, identify gaps in care, and drive improvement in care as needed. In-hospital quality of care information will be used to support identification of opportunities for improvement in acute care. Post-hospital transition of care information will identify opportunities to improve the prevention of complications, readmissions, and recurrent stroke as well as improve recovery, access to community services, and reintegration with primary care providers. Together, information obtained from pre-, in-, and post-hospital data elements will reflect the full continuum of care for stroke patients and provides an opportunity to assess quality and opportunities for improvement across this entire continuum. Thus, the collection of this information is a critical component to track the progress and completion of meeting essential program aims and outcomes. Additionally, the collection of this patient-level quality of care information is vital to assessing some of the process performance measures that help determine success of the program and inform lessons learned.

CDC also requests OMB approval to collect information through a hospital inventory survey (**Attachments 5a and 5b**). Many of the hospital inventory data elements are not routinely collected by hospitals and/or EMS systems, and are thus included in this information collection request. Data captured in the hospital inventory survey, such as facility size and capacity, will be used in data analysis to stratify patient-level quality improvement performance measures.

A.3 Use of Improved Information Technology and Burden Reduction

All data that will be submitted to CDC for PCNASP will be electronically reported. Burden will be reduced by the allowed use of data uploads by electronic health record (EHR) adapters that can automatically extract data from EHRs for transmission to CDC.

A.4 Efforts to Identify Duplication and Use of Similar Information

In-hospital quality data and quality indicators are based on standards and recommendations set forth by national partner organizations to reflect evidence-based stroke care strategies. PCNASP quality indicators will align closely with these recommendations.

PCNASP pre-hospital data elements are currently collected by EMS providers for the National Emergency Medical Services Information System (NEMESIS). Additionally, awardees may be utilizing other programs and/or methods that currently collect pre-hospital data elements that will overlap with those collected by PCNASP. Methods to utilize existing data collection systems for PCNASP are discussed with awardees to avoid data duplication.

The hospital inventory data that PCNASP will collect is unique to PCNASP and is not available through alternative programs or databases. This information is important to collect to inform if and how certain elements of stroke capacity influence quality of care and outcomes. To our knowledge, similar information about hospital stroke capacity is not captured by partner organizations.

Occasionally, PCNASP data elements may need to be updated to maintain alignment with research findings, guidelines, or recommendations from partner organizations. CDC anticipates that technical adjustments will be consistent with currently defined PCNASP objectives, burden estimates, and information collection methods. CDC will submit Change Requests to obtain OMB approval of updates to the data elements. If substantive changes are needed, CDC will submit a Revision.

A.5 Impact on Small Businesses or Other Small Entities

This data collection will not involve small businesses.

A.6 Consequences of Collecting the Information Less Frequently

Awardees will transmit patient quality data to CDC quarterly and hospital inventory data annually. Improvements in quality of care will be measured by adherence to established guidelines for care and quality metrics. Thus, the ability of CDC to monitor and improve quality of care would be compromised if data were collected less frequently.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A 60-day Notice was published in the *Federal Register* on July 20, 2015, Vol. 80, No.138, pp.42820-22 (see **Attachment 5**). No public comments were received.

A.9 Explanation of Any Payments or Gifts to Respondents

PCNASP will not provide any payments or gifts to individuals.

A.10 Protection of the Privacy and Confidentiality of Information Provided to Respondents

The PCNASP data collection will be conducted primarily for continuous quality improvement of patient care, evaluation, and assessment of short-term patient health outcomes and transition of care from hospital to home. CDC will not collect direct patient identifiers or hospital identifiers, but will collect a limited dataset. The Privacy Act does not apply. Information transmitted to CDC will be managed according to an approved security plan.

A.11 Institutional Review Board (IRB) and Justification for Sensitive Questions

The primary intent of the cooperative agreement and information collection is quality improvement. However, PCNASP data does provide opportunities for research as a secondary use. CDC has obtained IRB approval for secondary research uses of the information collection (**Attachment 8**).

PCNASP, along with national partner organizations, collects patient data about race and ethnicity (**Attachment 4b**). The collection of this information for acute stroke patients is important to assessing disparities in access to care across the care continuum as well as quality of care. The American Heart Association/American Stroke Association released a Scientific Statement in 2011 which stated the importance of understanding features of the health care system that affect existing racial-ethnic disparities in stroke care. Thus, the recognition of these disparities are an essential component of improving the quality of stroke care. PCNASP does not have any other potentially sensitive questions incorporated into the program.

A.12 Estimates of Annualized Burden Hours and Costs

OMB approval is requested for three years.

There are four categories of information collection tools: pre-hospital (**Attachment 4a**), in-hospital (**Attachment 4b**), post-hospital (**Attachment 4c**), and hospital inventory (**Attachments 5a and 5b**). Based on awardees' prior experiences in establishing partnerships, the number of hospitals that will collect information is estimated to be a mean of 35. Therefore, across the 9 awardees, there will be approximately 315 total hospitals. Based on discussions with awardees, we estimate that there will be fewer partners transmitting pre-hospital quality of care data (78 total) as well as post-hospital quality of care data (20 total).

Data is harvested from the pre-, in- and post-hospital setting and transferred from partners, to the state departments of health and then to CDC. Burden is not assessed for:

- the primary collection of pre-hospital, in-hospital, and post-hospital data by hospitals

because they are routine but strengthened through PCNASP funding.

- the transmission of in-hospital data from partners to their awardee, because this is a process that awardees undertake. Awardees use their selected data system to electronically pull in-hospital data from their partners. Hospital data collection systems being used to collect and transfer data to grantees for in-hospital data are preexisting.

Therefore, at the hospital level, we will only be accounting for the burden of primary data collection of hospital inventory data and the burden of transmitting pre-hospital quality of care, post-hospital quality of care, and hospital inventory data.

- The average burden per response is 15 minutes for the quarterly transmission of pre-hospital data from hospitals to their respective awardee.
- Additionally, the average burden per response is 15 minutes for the quarterly transmission of post-hospital data to the awardees.
- For the hospital inventory data, burden is assessed for the primary collection and transmission of the data from the hospital to their awardee, which occurs on an annual basis. Information collection of this inventory data has an average burden per response of 15 minutes and transmission from hospitals to their awardee has an average burden per response of 15 minutes (30 minutes total).

Multiple avenues decrease burden within the Coverdell program as well as moreover benefits the hospitals for other required reporting. Coverdell program measures have been developed and harmonized with other national organizations and agencies working in this arena in order to minimize burden. Also, benefit of hospital participation in the PCNASP is stroke coordinator support with measures abstraction and data quality and improvement in quality measures reported to monitoring agencies. The current proposal includes measures that are based on a history of stroke technical assistance quality improvement activities as well as health department selected measures. These measures will continued to be harmonized through collaboration and mutual work with the American Heart Association via a pre-existing Memorandum of Understanding, with The Joint Commission via CDC representation on their Technical Advisory Panels, and through collaboration across CDC via continued conversations with other divisions collecting hospital based data as well as via a CDC Office of the Director initiative with representatives from every center providing recommendations on a surveillance platform of shared services.

Pre-hospital, in-hospital, and post-hospital quality of care data will be transmitted by awardees to CDC on a quarterly schedule. This has an average burden per response of 30 minutes per file. The file(s) will be in the form of a SAS (Statistical Analysis System) data set. The transmission will occur through the Secure Access Management Services (SAMS) web portal (**Attachment 9**). SAMS is operating under an approved security plan. Additionally, burden is assessed for each PCNASP awardee to annually compile the hospital inventory information for its jurisdiction and transmit its aggregate file to CDC. Awardees then transmit a

de-identified file to CDC (**Attachment 5b**). The estimated burden per response for a PCNASP awardee is 8 hours. Data will be submitted as an Excel file through the SAMS web portal. **Attachment 6** has a diagram of the collection and transmission process.

Thus, the total estimated annualized burden to respondents is 382 hours.

Table A.12.a. Estimated Annualized Burden Hours

| Type of Respondent | Form Name | Number Of Respondents | Number of Responses per Respondent | Average Burden per Response (in hours) | Total Burden Hours |
|--------------------------|------------------------------------|-----------------------|------------------------------------|--|--------------------|
| PCNASP Hospital Partners | Pre-hospital quality of care data | 78 | 4 | 15/60 | 78 |
| | Post-hospital quality of care data | 20 | 4 | 15/60 | 20 |
| | Hospital inventory data | 315 | 1 | 30/60 | 158 |
| PCNASP Awardee | Pre-hospital quality of care data | 9 | 4 | 30/60 | 18 |
| | In-hospital quality of care data | 9 | 4 | 30/60 | 18 |
| | Post-hospital quality of care data | 9 | 4 | 30/60 | 18 |
| | Hospital inventory data | 9 | 1 | 8 | 72 |
| Total | | | | | 382 |

The total estimated annualized cost to respondents is \$10,426. This estimate is based on data from the Bureau of Labor Statistics. The estimate of costs to awardees' partners is \$8,589, and is based on an average hourly wage of \$33.55 for staff to transmit pre-hospital, post-hospital, and hospital inventory data, and collect hospital inventory data. Additionally, the estimate of costs to awardees is \$4,488, and is based on an average hourly wage of \$35.63 for awardee staff to compile pre-hospital, in-hospital, post-hospital, and hospital inventory data received from hospitals and transmit the information to CDC. Costs to awardees are paid under terms of the cooperative agreement.

Table A.12.b. Estimated Annualized Burden Costs

| Type of Respondent | Form Name | Mean Hourly Wage (dollars) | Total Burden (in hours) | Total Annualized Cost to Respondents |
|---------------------------|------------------------------------|-----------------------------------|--------------------------------|---|
| PCNASP Awardee's Partners | Pre-hospital quality of care data | \$33.55 | 78 | \$2,617 |
| | Post-hospital quality of care data | \$33.55 | 20 | \$671 |
| | Hospital inventory data | \$33.55 | 158 | \$5,301 |
| PCNASP Awardee | Pre-hospital quality of care data | \$35.63 | 18 | \$641 |
| | In-hospital quality of care data | \$35.63 | 18 | \$641 |
| | Post-hospital quality of care data | \$35.63 | 18 | \$641 |
| | Hospital inventory data | \$35.63 | 72 | \$2,565 |
| Total | | | | \$10,426 |

A.13 Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

The computer hardware and software needed for an electronic data submission of information to awardees and CDC are readily available to hospitals and awardees since they collect and distribute this data for state and other purposes. Hence, no additional capital or maintenance costs are anticipated.

A.14 Annualized Cost to the Government

The data collection will be funded under cooperative agreements to each of the states and Funding Opportunity Announcement No. CDC-RFA-DP15-1514 (Paul Coverdell National Acute Stroke Prevention). The annualized cost of the cooperative agreement is \$6.74 million. The total estimated annualized cost to the federal government includes CDC personnel costs for a statistician/data manager. This estimated annualized cost is \$20,878.00 for a GS-12 data statistician at 25% FTE, \$5,867.00 for a GS-14 at 5% FTE, and \$4,965.00 for a GS-13 at 5% FTE. Thus the total annualized cost is \$6,771,710.00.

A.15 Explanation for Program Changes or Adjustments

This is a new data/information collection.

A.16 Plans for Tabulation and Publication and Project Time Schedule

Pre-hospital, in-hospital, and post-hospital transition of care data will be transmitted to CDC quarterly. Awardees work with their partners to assure that data is transmitted to them in a timely manner to meet CDC deadlines. This information will be submitted from awardees to CDC within 2 weeks of the quarter ending; PCNASP staff will then clean the data and provide feedback necessary to ensure that the data is of high-quality. Within 3 months of the quarter ending, CDC will provide a data cleaning report back to awardees. There is a total of a 6 month lag between the awardee's quarterly data submission and CDC's performance measure summary reports (see **Attachment 10** for example table shells) to allow for data to be aggregated across an appropriate amount of time. Performance measures will be assessed over time to detect trends in improvement in quality of stroke care within states; additionally data across all awardee states will be aggregated to present national-level estimates.

For example, quarter 1 2016 data (January 1, 2016-March 31, 2016) will be submitted by awardees within 2 weeks of quarter 1 2016 ending. A data cleaning report for this quarter will be provided by CDC to the awardees by the end of quarter 2 2016 (June 30, 2016), and the performance measure summary report will be provided by the end of quarter 3 2016 (September 30, 2016).

Hospital inventory data will be submitted annually. Aggregated reports on performance measures will be displayed on the CDC website. Other publications occur on an ad-hoc basis.

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB expiration date and burden statement are displayed on data dictionaries provided to respondents (**Attachments 4a, 4b, 4c, 5a, 5b**) as well as the PCNASP Reference Guide (**Attachment 11**). Awardees use the Secure Access Management Services (SAMS) web portal to securely upload data to the CDC. The SAMS portal is used by other data collection programs within the CDC, so the display of the burden statement is not possible and would become confusing to other users. PCNASP does provide the burden statement in the Data Collection section of the PCNASP Reference Guide, which is provided to all awardees (**Attachment 11**).

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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