Pre-Hospital Stroke Systems of Care: Emergency Medical Service System (EMSS) Implementation Assessment

OSTLTS Generic Information Collection Request OMB No. 0920-0879

Supporting Statement – Section A

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- **Purpose of the data collection** To identify effective strategies and potential challenges associated with the implementation of emergency medical service system (EMSS) based activities to enhance stroke systems of care. These EMSS based activities are coordinated by state agencies, including state health departments, and involve the pre-notification, triage, transport, and transfer of stroke patients to the most appropriate stroke facility.
- **Intended use of the resulting data** Data will be used to inform CDC about issues related to implementation of EMSS based activities to enhance stroke systems of care and to examine these issues to develop technical assistance material for state health departments and EMSS coordinators. The information will be disseminated to the intended audiences via conference presentations, webinars, fact sheets and implementation guides.
- **Methods to be used to collect data** Information will be collected via informant interviews conducted by telephone.
- **Respondent Universe** 48 state government staff and their delegates involved in stroke systems of care in 6 selected states (Georgia, Louisiana, Missouri, Rhode Island, South Carolina and Wyoming).
- How data will be analyzed Qualitative thematic analysis will be conducted.

Section A – Justification

1. Circumstances Making the Collection of Information Necessary

Background

This information collection is being conducted using the Generic Information Collection mechanism of the OSTLTS OMB Clearance Center (O2C2) – OMB No. 0920-0879. The respondent universe for this information collection aligns with that of the O2C2. The respondent universe for this information collection consists of a total of 48 state government staff and their delegates in 6 selected states (Georgia, Louisiana, Missouri, Rhode Island, South Carolina and Wyoming). Respondents acting in their official capacities include 6 State Health Department staff (one from each selected state), 6 state EMS Task Force Directors, 6 state EMS data managers, 12 state EMS/Stroke Task Force Members, and 18 delegates. The delegates included in this information collection consist of EMS/Stroke Task Force members directed by the state health or safety departments (through state law and/or formal endorsement) to act on behalf of the STLT government agency staff involved in the provision of essential public health services to most effectively implement stroke systems of care in that jurisdiction.¹ Specific delegates vary depending on the state, but may include EMS- Related Task Force Members, Rural Health Task Force Members, and Healthcare Task Force Members (**Please see Attachment A: Respondent Breakdown**).

This information collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241). This information collection falls under the essential public health service(s) of

- 1. Monitoring health status to identify community health problems
- \Box 2. Diagnosing and investigating health problems and health hazards in the community
- 3. Informing, educating, and empowering people about health issues
- 4. Mobilizing community partnerships to identify and solve health problems
- \boxtimes 5. Development of policies and plans that support individual and community health efforts
- 6. Enforcement of laws and regulations that protect health and ensure safety
- 7. Linking people to needed personal health services and assure the provision of health care when otherwise unavailable
- \boxtimes 8. Assuring a competent public health and personal health care workforce
- 9. Evaluating effectiveness, accessibility, and quality of personal and population-based health services
- 10. Research for new insights and innovative solutions to health problems ²

Every year, approximately 795,000 people have a stroke. About 610,000 of these are first or new strokes; 185,000 are recurrent strokes.³ Stroke is the fifth leading cause of death in the United States and an important cause of disability.⁴ There are life-saving treatments for stroke, but patients must receive them quickly, often within hours of stroke onset. State-level interventions to enhance pre-notification, triage, transport, and transfer of patients to the most appropriate stroke facility could help increase the reach, consistency, coordination, and quality of pre-hospital/ emergency medical service systems (EMSS) stroke care.

Stroke systems of care at state and local levels work to coordinate the full range of activities and services associated with stroke prevention, treatment, and rehabilitation to promote timely, effective care.⁵ In stroke systems of care, EMSS and EMS providers are essential in the recognition of suspected strokes and providing timely transport and pre-hospital care for patients. State-level interventions to require or otherwise encourage evidence-supported pre-hospital/EMSS activities related to stroke pre-notification, triage, transport, and transfer of patients to the most appropriate stroke facility can reduce time to treatment and subsequently improve health outcomes.

Recent CDC assessments completed by the Division for Heart Disease and Stroke Prevention (DHDSP) in 2018 identified early evidence related to state-level pre-hospital stroke systems of care interventions in the published and gray literatures¹ and examined existing enacted state laws (statutes, legislation, and regulations) in the 50 states and DC intended to enhance stroke systems of care.⁶ The findings identified large variability across states, with few having a comprehensive approach that aligned with early evidence. This information along with the identified technical assistance needs of CDC grantees demonstrated a gap in information about effective implementation strategies and challenges associated with state-level actions to improve prehospital stroke systems of care.

The purpose of this information collection is to fill this gap by assessing effective development and implementation strategies for EMSS based activities to enhance stroke systems of care including stroke pre-notification, triage, transport, and transfer of patients to the most appropriate stroke facility.

To do this, CDC is partnering with the Association of State and Territorial Health Officials (ASTHO). ASTHO, a national nonprofit organization representing public health agencies in the United States, the U.S. Territories, and the District of Columbia, will conduct this information collection through a cooperative agreement that seeks to capture information on processes, roles, facilitators and barriers to state-level EMSS based activities to enhance pre-hospital stroke system of care. ASTHO is responsible for developing the information collection instrument, leading data collection, analyzing qualitative data and preparing an aggregated data summary for CDC.

Data will be used to inform CDC about issues related to implementation of stroke systems of care and to examine these issues to develop technical assistance material for state health departments and EMSS coordinators. The information will be disseminated to the intended audiences via conference presentations, webinars, fact sheets and implementation guides.

Overview of the Information Collection System

Data will be collected from a total of 48 respondents via telephone informant interviews (**see Attachment B: Telephone Interview Guide**). The instrument will be used to gather information from state health department staff and their delegates regarding effective strategies and potential challenges associated with the implementation of EMSS based activities to enhance stroke systems of care.

The information collection instrument was pilot tested by three public health professionals. Feedback from these individuals was used to refine questions as needed and establish the estimated time required to complete the information collection instrument.

Items of Information to be Collected

The data collection instrument consists of a total of 29 open-ended questions. The instrument will capture information on the following:

- Development roles, processes, facilitators and barriers for state-level EMSS based interventions to enhance pre-hospital stroke system of care (9 questions)
- Implementation stakeholders, challenges, and potential solutions for state-level EMSS based interventions to enhance pre-hospital stroke system of care (4 questions)
- EMS system structure, protocols, communication and supervision related to prehospital stroke system of care (4 questions)
- Program improvement, outcomes, and sustainability of state-level EMSS based interventions to enhance pre-hospital stroke system of care (12 questions).

2. Purpose and Use of the Information Collection

The purpose of this information collection is to identify effective strategies and potential challenges associated with developing and implementing EMSS based activities to enhance pre-hospital stroke systems of care including pre-notification, triage, transport, and transfer of patients to the most appropriate stroke facility.

Data will be used to inform CDC about issues related to implementation of EMSS based activities to enhance stroke systems of care and to examine these issues to develop technical assistance material for state health departments and EMSS coordinators. The information will be disseminated to the intended audiences via conference presentations, webinars, fact sheets and implementation guides.

3. Use of Improved Information Technology and Burden Reduction

Data will be collected via telephone informant interviews. This method was chosen to reduce the overall burden on respondents by focusing the discussion on the most pertinent issues specific to each respondent. Telephone interviews will also help to minimize the burden on respondents and project staff by reducing the time required for follow-up—teams can verify responses and request clarification as needed during the information collection process. The data collection instrument was designed to allow for skipping based on responses to role and previous questions and to collect the minimum information necessary for the purposes of this project (i.e., limited to 29 questions).

4. Efforts to Identify Duplication and Use of Similar Information

Although recent CDC assessments completed in 2018 by DHDSP examined early evidence related to pre-hospital stroke systems of care interventions in the published and gray literatures¹ and examined enacted state laws using the legal search engine, Westlaw (Thomson Reuters, Eagan, Minnesota)⁶, neither assessment directly examined the steps needed to develop and implement state-level EMSS based activities to improve stroke systems of care. The previous assessments identified gaps in comprehensive approaches to state-level pre-hospital stroke systems of care but did not provide tangible steps state health departments and EMSS coordinators could take to address the gap. This study will provide information about the effective strategies and potential challenges associated with developing and implementing EMSS based activities to improve prehospital stroke systems of care.

The information that will be collected through this project is not available from other data sources or through other means. During the concept development and planning phases, the project team met with subject matter experts from CDC's Paul Coverdell National Acute Stroke Program and several national partners engaged in stroke systems of care to ensure that there are no similar information sources available to meet the needs of the proposed information collection. Additionally, the 2018 detailed early evidence review of stroke systems of care literature demonstrated that no one has collected this information in the past.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

This request is for a one-time data collection. There are no legal obstacles to reduce the burden. If no data are collected, CDC will be unable to:

- Capture in-depth information about best practices in developing and implementing state-level interventions to enhance pre-hospital stroke systems of care
- Provide information to state health department grantees and EMSS coordinators about the common facilitators and barriers to this work that may impede uptake of evidence-based practice
- Understand the program improvement processes, outcomes, and sustainability of statelevel interventions to enhance pre-hospital stroke systems of care

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

There are no special circumstances with this data collection package. This request fully complies with the regulation 5 CFR 1320.5 and will be voluntary.

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

This data collection is being conducted using the Generic Information Collection mechanism of the OSTLTS OMB Clearance Center (O2C2) – OMB No. 0920-0879. A 60-day Federal Register Notice was published in the Federal Register on April 27, 2017, Vol. 82, No. 80, pp 19371-19373. One non-substantive comment was received. CDC sent forward the standard CDC response.

CDC partners with professional STLT organizations, such as the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), and the National Association of Local Boards of Health (NALBOH) along with the National Center for Health Statistics (NCHS) to ensure that the collection requests under individual ICs are not in conflict with collections they have or will have in the field within the same timeframe.

9. Explanation of Any Payment or Gift to Respondents

CDC will not provide payments or gifts to respondents.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The Privacy Act does not apply to this data collection. STLT governmental staff and delegates will be speaking from their official roles.

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

No information will be collected that are of sensitive nature. This data collection is not research involving human subjects.

12. Estimates of Annualized Burden Hours and Costs

The estimate for burden hours is based on a pilot test of the data collection instrument by three public health professionals. In the pilot test, the average time to complete the instrument including time for reviewing instructions, gathering needed information and completing the instrument, was approximately 70 minutes (range: 60–90). For the purposes of estimating burden hours, the upper limit of this range (i.e., 90 minutes) is used.

Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) Bureau of Labor Statistics for occupational employment for Top Executives http://www.bls.gov/oes/current/oes_nat.htm. Based on DOL data, an average hourly wage of \$61.55 is estimated for all 48 respondents. Table A-12 shows estimated burden and cost information.

There will be a total of 48 respondents and 48 responses.

Data collection Instrument : Form Name	Type of Respondent	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Telephone Interview Guide	Senior state health department and EMS executive staff	30	1	90 / 60	45	\$61.55	\$2,770
	State delegates implementing stroke systems of care	18	1	90 / 60	27	\$61.55	\$1,662

Table A-12: Estimated Annualized Burden Hours and Costs to Respondents

TOTALS 48 1	72	\$4,432
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13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There will be no direct costs to the respondents other than their time to participate in each data collection.

14. Annualized Cost to the Government

There are no equipment or overhead costs. The only cost to the federal government would be the salary of CDC staff and cooperative agreement partner, ASTHO, to develop the data collection instrument, collect data, and perform data analysis. The total estimated cost to the federal government is \$19,813.12. Table A-14 describes how this cost estimate was calculated.

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Total Average Cost
Health Scientist, GS 13-Tool development and	37	\$49.76/hour	\$1841.12
OMB package preparation			
Health Scientist, GS 13-Data analysis, report	55	\$46.83/hour	\$2575.65
development and dissemination			
Senior Analyst/ASTHO-Development of	150		\$6,505.50
interview guide, informant interviews, data			
analysis, informant interviews, report			
development and dissemination.			
Research Analyst/ASTHO- Informant	110		\$3,549.70
interviews, data analysis, report development			
and dissemination			
Research Analyst/ASTHO-Data analysis,	75		\$2662.50
informant interviews, report development			
Research Director/ASTHO- informant	30		\$1607.19
interviews, data analysis, report development			
and dissemination			
Chronic Disease Director/ASTHO-informant	20		\$1071.46
interviews and dissemination			
Estimated To	ion Collection	\$19,813.12	

Table A-14: Estimated Annualized Cost to the Federal Government

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

All information will be kept on secure, password protected servers accessible only to ASTHO project team members. Data collected during the assessment will be shared only in aggregate form. Using the thematic analysis and having access only to the fully coded, aggregate information provided by ASTHO, CDC will contribute to interpretation of findings and the creation of a summary report. The report will conclude with an overview of lessons learned regarding facilitators and barriers to implementing state-level EMSS based activities to enhance stroke systems of care. Using summary findings, CDC will also contribute to the development of complementary, technical assistance material for state health departments and EMSS coordinators that will be disseminated via conference presentations, webinars, fact sheets, implementation guides, and peer reviewed manuscripts.

Project Time Schedule

\checkmark	Design instrument	(COMPLETE)
\checkmark	Develop protocol, instructions, and analysis plan	(COMPLETE)
\checkmark	Pilot test instrument	(COMPLETE)
\checkmark	Prepare OMB package	(COMPLETE)
\checkmark	Submit OMB package	(COMPLETE)
	OMB approval	(TBD)
	Conduct data collection	(Open 8 weeks)
	Code data, conduct quality control, and analyze data	(8 weeks)
	Prepare summary report(s)	(4 weeks)
	Disseminate results/reports	(4 weeks)

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

We are requesting no exemption.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

LIST OF ATTACHMENTS – Section A

Attachment A: Respondent Breakdown Attachment B: Telephone Interview Guide

REFERENCE LIST

1. Centers for Disease Control and Prevention (CDC). Division for Heart Disease and Stroke Prevention. What is the Evidence for Existing State Laws to Enhance Pre-hospital Stroke Care? Atlanta, GA: Centers for Disease Control and Prevention; 2017.

- 2. Centers for Disease Control and Prevention (CDC). "National Public Health Performance Standards Program (NPHPSP): 10 Essential Public Health Services." Available at http://www.cdc.gov/nphpsp/essentialservices.html. Accessed on 8/14/14.
- Benjamin EJ, Blaha MJ, Chiuve SE, et al. on behalf of the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics -2017 update: a report from the American Heart Association. Circulation. 2017;135:e229e445.
- **4.** Vital Signs: Recent trends in stroke death rates United States, 2000-2015. MMWR 2017;66.
- 5. Schwamm LH, Pancioli A, Acker JE, et al. Recommendations for the establishment of stroke systems of care. Recommendations from the American Stroke Association's Task Force on the Development of Stroke Systems. Stroke. 2005;36(3):690-703.
- **6.** Centers for Disease Control and Prevention (CDC). Division for Heart Disease and Stroke Prevention. Stroke Systems of Care State Law Overview. Unpublished report; 2018.
- General Assembly Report from the State Legislated Stroke Task Force. Available at: <u>http://www.health.ri.gov/publications/generalassemblyreports/2008StateLegislatedStrokeTaskFor</u> <u>ce.pdf</u>. Accessed May 3, 2019.
- **8.** Louisiana Emergency Response Task Force. Available at: <u>http://lern.la.gov/</u>. Accessed May 3, 2019.