CDC Newborn Screening Quality Assurance Program – Spinal Muscular Atrophy (SMA) Proficiency Testing (PT) Pilot
OSTLTS Generic Information Collection Request
OMB No. 0920-0879

Supporting Statement – Section A

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- **Purpose of the data collection**
  To strengthen the capacity of state public health laboratories (PHL) to incorporate screening for spinal muscular atrophy (SMA) into their newborn screening programs. CDC will assess the ability of PHL to utilize new protocols for analyzing reference blood spot samples and report data to CDC's Newborn Screening Quality Assurance Program (NSQAP). The overall goal is to establish an SMA proficiency testing (PT) program that will support state-based efforts aiding early identification and treatment of newborns with SMA.
- **Intended use of the resulting data**
  The lab data reporting form will allow CDC to assess 1) the types of lab tests used by PHL, and 2) the accuracy of SMA test results produced by PHL. The accompanying feedback survey will allow CDC and PHL to identify opportunities for improving the DBS panel, protocols and guidance for SMA testing, or procedures for submitting SMA PT data to CDC. All findings will be used to improve program services and performance.
- **Methods to be used to collect data**
  CDC will distribute pilot proficiency testing specimens (dried blood spots) to participating PHL along with instructions. Labs will analyze the specimens and report results to CDC. Data collection instruments consist of 2 Excel spreadsheets: a lab reporting form and a customer feedback form. Once completed these are to be returned to NSMBB via email.
- **Respondent Universe**
  Approximately 40 state public health labs have contacted CDC in the past 12 months inquiring about a SMA proficiency testing (PT) service. These labs will be invited to participate in the assessment.
- **How data will be analyzed**
  Data analysis will involve simple as well as categorical statistics. Individual respondents will receive an evaluation of their performance (actual versus expected outcome per PT specimen). This evaluation will not be shared with any other participant. All participants will receive an event summary report containing aggregate data. The use of custom Lab IDs known only to CDC and respondent maintains confidentiality of the data.

Section A – Justification

1. Circumstances Making the Collection of Information Necessary

Background

This information collection is being conducted using OMB No. 0920-0879 "Information Collections to Advance State, Tribal, Local and Territorial Governmental Agency System Performance, Capacity, and Program Delivery" nicknamed the "CSTLTS Generic." The respondent universe for this information collection aligns with that of the CSTLTS Generic. Data will be collected from a total of 40 respondents across 40 public health departments. Respondents acting in their official capacities include clinical laboratory technologists and technicians.

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
☒ 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
☐ 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
☒ 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 [1]

Spinal muscular atrophy (SMA) is a genetic disorder that affects motor neurons in the spinal cord and causes progressive muscle degeneration. Infants born with infantile or type 1 SMA become incapacitated and typically die within 2 to 4 years of life. However, if SMA is diagnosed and treated prior to onset of symptoms with an FDA approved drug, children with Type 1 SMA can avoid severe, deleterious effects of the disease and may retain the ability to live relatively normal lives. Newborn screening for SMA allows for early detection of affected infants that may appear normal at birth and early treatment can halt irreversible neuronal damage. In 2018, SMA was added by the HHS Secretary to the recommended uniform screening panel (RUSP) for newborn screening and a number of domestic public health programs have begun routine screening. It is expected that all U.S. newborn screening laboratories will adopt SMA screening in the next few years.

The Newborn Screening Saves Lives Reauthorization Act (P.L 113 - 240) mandates that CDC provide quality assurance to newborn screening state labs and in addition provide "quality control and other performance test material." Proficiency testing (PT) is an integral component of a robust quality assurance program. During proficiency testing, a lab conducts blinded analysis of reference specimens of known diagnosis. The lab's findings are then assessed for accuracy. Public health programs rely on PT challenges conducted by CDC to comply with their clinical testing regulatory requirements (e.g. CLIA).

CDC's Newborn Screening and Molecular Biology Branch (NSMBB), a unit within the Division of Laboratory Sciences, is responsible for meeting the mandate of the Newborn Screening Saves Lives Reauthorization Act. The NSMBB's Newborn Screening Quality Assurance Program (NSQAP) has developed reference dried blood spot samples (DBS) and will develop guidance for assays to detect SMA.

This project aims to provide 40 state public health labs the opportunity to test newly developed spinal muscular atrophy (SMA) quality assurance products and provide the NSQAP with feedback (including results and raw data) associated with the proficiency testing (PT) materials tested. NSQAP intends to analyze this feedback to confirm that CDC is ready to provide the proposed new PT service and make any necessary changes to the planned PT program if warranted by the feedback. The testing data submitted will be analyzed by CDC and used to generate example PHL evaluations as well as an event summary for distribution to respondents. Based on the results of this pilot, the CDC will finalize its SMA PT program's standard operating procedures (SOPs) and data collection instruments ensuring state's capacity to accurately diagnose babies affected by SMA.

Overview of the Information Collection System

Data will be collected from up to 40 state public health labs via email of 2 electronic spreadsheets (see **Attachment A — Pilot SMA PT Data Reporting Form** and **Attachment B – Pilot SMA PT Feedback Form**). These instruments will be used to gather information from public health labs regarding test results demonstrating the utility of SMA PT materials aimed at improving the quality of testing and the ease of use of the data collection form.

The information collection instruments were pilot tested by 2 public health professionals. Feedback from this group was used to refine questions as needed, ensure accurate programming and establish the estimated time required to complete the information collection instrument.

Items of Information to be Collected

The testing data collection instrument (see **Attachment A** – Pilot SMA PT Data Reporting Form) consists of 19 main questions of various types, including multiple choice and open-ended. The instrument will collect data on the following:

- SMA Method (rows 14 – 17)
- SMN1 primer and probe information (rows 19 - 21)
- Reference gene primer and probe information (rows 23 – 27)
- Clinical assessment of specimens (rows 33 – 37)

The feedback data collection instrument (see **Attachment B** – Pilot SMA PT Feedback Form) consists of 5 main questions of various types, including interval (rating scales) and open-ended. The instrument will collect data on the following:

- Satisfaction with Pilot SMA PT Instructions (Question 1)
- Satisfaction with Pilot SMA Data Reporting Form (Question 2)
- Satisfaction with the data reporting process (Question 3)
- Satisfaction with the DBS panel provided (Question 4)

2. Purpose and Use of the Information Collection

This project aims to provide 40 state public health labs the opportunity to test newly developed spinal muscular atrophy (SMA) quality assurance products and provide CDC's Newborn Screening Quality Assurance Program (NSQAP) with feedback (including results and raw data) associated with the proficiency testing (PT) reporting materials (see **Attachment A – Pilot SMA PT Data Reporting Form**) and PT materials tested so that CDC can evaluate its readiness to offer SMA PT as a service to its more than 400 enrolled labs.

CDC's NSQAP intends to analyze this feedback and make any necessary changes to the planned PT program if warranted by the feedback. The testing data submitted using the Pilot SMA PT Data Reporting Form (see Attachment A) will be analyzed by CDC and used to generate example PHL evaluations as well as an event summary for distribution to respondents. Data collected will not be used for publication.

3. Use of Improved Information Technology and Burden Reduction

Testing data will be collected via emailed electronic spreadsheets. This method was chosen to reduce the overall burden on respondents by including drop-down options and/or check boxes for most fields. The data collection instruments were designed to collect the minimum information necessary for the purposes of this project (i.e., limited to 19 questions and 5 questions respectively by instrument).

4. Efforts to Identify Duplication and Use of Similar Information

The Newborn Screening Saves Lives Reauthorization Act (P.L 113 - 240) mandates that CDC provide quality assurance to newborn screening state labs and in addition provides "quality control and other performance test material". Under this mandate, CDC's Newborn Screening and Molecular Biology Branch is the only producer of this type of material and service. Additionally, communication from PHLs has confirmed that there are no commercially available options for SMA PT.

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:

- Determine if the SMA-like PT samples are appropriate for more than 80% of public health labs
- Provide public health labs with a PT program that allows them to meet requirements of CLIA
- Ensure the quality of newborn screening for SMA

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 CSTLTS Generic Information Collection Service (CSTLTS Generic) – 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 / or 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 personal or sensitive nature. This data collection is not research involving human subjects (see **Attachment E: Pilot SMA PT Research Determination**).

12. Estimates of Annualized Burden Hours and Costs

Pilot SMA PT Data Collection Form

The estimate for burden hours is based on a pilot test of the data collection instrument (see **Attachment A – Pilot SMA PT Data Reporting Form**)) by 2 of 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 8.6 minutes (range: 7 –10). For the purposes of estimating burden hours, the upper limit of this range (i.e., 10 minutes) is used.

Pilot SMA PT Feedback Form

The estimate for burden hours is based on a pilot test of the data collection instrument (see **Attachment B – Pilot SMA PT Feedback Form**) by 2 of 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 2.5 minutes (range: 2–3). For the purposes of estimating burden hours, the upper limit of this range (i.e., 3 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 Clinical Laboratory Technologists and Technicians http://www.bls.gov/oes/current/oes_nat.htm. Based on DOL data, an average hourly wage of $26.34 is estimated for all 40 respondents.

To account for potential increases due to the COVID-19 response, the hourly wage rate has been doubled to $52.68 to account for fringe benefits and overhead (https://aspe.hhs.gov/pdf-report/guidelines-regulatory-impact-analysis).Table A-12 shows estimated burden and cost information.

There will be a total of 40 respondents and 80 responses.

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

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
Pilot SMA PT Data	Clinical Laboratory	40	1	10 / 60	7	$52.68	$369

Reporting Form	Technologist or Technician						
Pilot SMA PT Feedback Form	Clinical Laboratory Technologist or Technician	40	1	3 / 60	2	$52.68	$105
	TOTALS	**80**	**1**		**9**		**$474**

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 to develop the data collection instrument, collect data, and perform data analysis. The total estimated cost to the federal government is $4658.86. Table A-14 describes how this cost estimate was calculated.

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

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Total Average Cost
Biologist – GS-12, Step 1; Data analysis and report generation	16	$38.73 /hour	$619.68
Quality Manager – GS-12, Step 9; Develop the OMB package	24	$49.22 /hour	$1181.28
Research Biologist – GS-12, Step 10; Data Analysis	2	$50.35 / hour	$100.70
Lab Chief – GS-14, Step 9; Plan and implement data collection; develop summary report	40	$68.93 /hour	$2757.20
Estimated Total Cost of Information Collection			**$4658.86**

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

As resources and respondents may be impacted by the COVID-19 pandemic, we propose that data collection begin in June 2020. Data analysis will involve simple as well as categorical statistics. Individual respondents will receive an evaluation of their performance (actual versus expected outcome per PT specimen). This evaluation will not be shared with any other participant. All participants will receive an event summary report containing aggregate data. The use of custom Lab IDs known only to CDC and respondent maintains confidentiality of the data.

Project Time Schedule

- ✓ Design instrument ..... (COMPLETE)
- ✓ Develop protocol, instructions, and analysis plan ..... (COMPLETE)
- ✓ Pilot test instrument ..... (COMPLETE)
- ✓ Prepare OMB package ..... (COMPLETE)
- ✓ Submit OMB package ..... (COMPLETE)
- ❑ OMB approval ..... (TBD)
- ❑ Recruit volunteers ..... (Open 2 weeks)
- ❑ Conduct data collection ..... (Open 4 weeks)
- ❑ Code data, conduct quality control, and analyze data..... (2 weeks)
- ❑ Prepare summary report(s) ..... (2 weeks)
- ❑ Disseminate results/reports ..... (1 day)

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

Note: Attachments are included as separate files as instructed.

1) **Attachment A – Pilot SMA PT Data Reporting Form**
2) **Attachment B – Pilot SMA PT Feedback Form**
3) **Attachment E – Pilot SMA PT Research Determination**

REFERENCE LIST

1. 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.
2. R.U.S.P. Available at https://www.hrsa.gov/advisory-committees/heritable-disorders/rusp/index.html. Accessed on 6/3/20.