Assessing the needs and capacity of state newborn screening programs and laboratories

OSTLTS Generic Information Collection Request
OMB No. 0920-0879

Supporting Statement – Section B

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Section B – Data Collection Procedures

1. Respondent Universe and Sampling Methods

The target audiences for the two survey instruments are directors of state newborn screening programs and directors of state newborn screening laboratories.

All 50 states have a public health newborn screening program. All newborn screening programs have a director responsible for all facets of the state newborn screening program. State program directors will be asked for the year statewide newborn screening began and number of identified babies in 2009, 2010, and 2011 for each newborn screening condition identified on the current Recommended Universal Screening Panel. These data will demonstrate the impact and capacity of past and current state newborn screening programs and will inform CDC NSMBB activities, which provided critical technical support and quality assurance to all state newborn screening programs for the past 35 years.

Thirty-three of the 50 states use a state-based public health newborn screening laboratory that only serves their state population. The remaining 17 states combined use 5 state newborn screening laboratories for their newborn screening activities--Wyoming uses the Colorado newborn screening laboratory; Mississippi uses the Nebraska newborn screening laboratory; North Dakota and South Dakota use the Iowa newborn screening laboratory; Alaska, Idaho, Nevada, and New Mexico use the Oregon newborn screening laboratory; New Hampshire, Rhode Island, Vermont, and Maine use the Massachusetts newborn screening laboratory. Thus, the 50 state newborn screening programs are served by 38 newborn screening laboratories. All 38 newborn screening laboratories are affiliated with at least one state-based newborn screening program.

All 38 newborn screening laboratories have a state-based public health laboratory director responsible for all facets of the newborn screening laboratory. Laboratory directors will be asked questions to determine the needs of state newborn screening laboratories and to identify strategies for CDC NSMBB to best support state newborn screening laboratories. Together, answers to these questions will help the CDC NSMBB identify areas for program improvement, recognize opportunities for program growth, and support prioritization of funding opportunity announcements.

Information will be requested from all 50 Newborn Screening Program Directors and all 38 Newborn Screening Laboratory Directors.

Table B-1: Potential Respondent Universe

Entity	Potential Respondent	N
State Newborn Screening Programs	State Newborn Screening Program Director or designee	50
State Newborn Screening Laboratories	Newborn Screening Laboratory Director or designee	38
	Total Universe of Potential Respondents	**88**

2. Procedures for the Collection of Information

Newborn screening program directors and newborn screening laboratory directors will be sent an email inviting them, or their designee, to reply to a data collection instrument, with a link to the questions that are posted on Survey Monkey (**Attachment J—e-mail letter of invitation for PROGRAM directors & Attachment K—e-mail letter of invitation for LABORATORY directors**). In the introductory email letters, the importance of their response will be described in a letter signed by the CDC NSMBB Branch Chief. The letter will explain that the information collected will be used for continuous program improvement for CDC NSMBB. The letter will also indicate that much of the data will be disseminated as part of the 2013 50 Years of Newborn Screening awareness campaign. Responses to the data collection instruments will be requested within 30 days of sending the invitation e-mails.

Follow up on the initial invitation e-mail will occur in collaboration with the Association of Public Health Laboratories, which has long standing relationships with the state newborn screening laboratories and state newborn screening programs. An article describing the purpose and importance of these data collection instruments will be published in the Association of Public Health Laboratories (APHL) weekly e-Update, which is widely read by APHL members, including newborn screening laboratory directors and newborn screening program directors. (**Attachment L—APHL Notice**). Furthermore, APHL will send reminder announcement one week prior to the end of the data collection period (**Attachment M—APHL Reminder**). One week after the due date, the CDC NSMBB Branch Chief will send an additional e-mail encouraging participation and alerting potential respondents about the importance of the information (**Attachment N—Reminder e-mail for PROGRAM non-responders & Attachment O—Reminder e-mail for LABORATORY non-responders**).

The information will be collected using the Survey Monkey website. The link to data collection instruments will be emailed to the 50 newborn screening program directors and 38 newborn screening laboratory directors serving all 50 states. Answers to all questions will be captured in an excel database and transformed into a SAS dataset for analyses.

Information reported by newborn screening laboratories and programs will be aggregated and summarized by CDC NSMBB activities to appreciate the needs of state newborn screening laboratories and recognize the capacity and impact of state newborn screening programs.

3. Methods to Maximize Response Rates Deal with Nonresponse

One email reminder will be sent to each non-responder. The response for this survey can be maximized through the support of the Association of Public Health Laboratories that communicates with the state public health labs on a regular basis and is very supportive of this effort. A general notice will be published in the APHL weekly e-Update reminding laboratories to complete their survey (**Attachment L**). The APHL weekly e-Update article will not cite individual laboratory directors who have not submitted their survey; it will be directed to the membership at large.

4. Test of Procedures or Methods to be Undertaken

This survey was initially conceptualized by staff within the CDC NSMBB. Prior to developing the survey instruments, preliminary input was solicited from the Chief Evaluation Officer, Office of the Associate Director for Program, Centers for Disease Control and Prevention and the Associate Director for Policy, Laboratory Science, Policy, and Practice Program Office, Office of Surveillance, Epidemiology, and Laboratory Services, Centers for Disease Control and Prevention. The Association for Public Health Laboratories was consulted for examples of survey questions previously requested from state newborn screening laboratories.

A first draft of each survey instrument was created by staff within CDC NSMBB. Survey questions were reviewed and refined by senior CDC staff scientists engaged with state newborn screening laboratories. The surveys were further reviewed by the Associate Director for Science and additional leadership from the Division of Laboratory Services. The survey instruments were reviewed by the Acting Human Subjects Coordinator, Office of Science, National Center for Environmental Health for research determination, and this activity was deemed to be non-research. The program and laboratory survey instruments were then piloted by 3 representative state newborn screening program directors and 3 newborn screening laboratory directors, respectively. Feedback from newborn screening program directors showed the minimum time to complete the program survey was 25 minutes, the maximum time was 38 minutes, and the median time was 35 minutes. Feedback from the newborn screening laboratory directors showed the minimum time to

complete the laboratory survey was 10 minutes, the maximum time was 20 minutes, and the median time was 15 minutes.

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

   Data collected from these short surveys will be presented descriptively. Daniel Mandel, Ph.D., Health Scientist, Newborn Screening and Molecular Biology Branch, ibt7@cdc.gov, 770-488-7967 will be charged with validating and analyzing the data. Carla Cuthbert, Ph.D., Chief, Newborn Screening and Molecular Biology Branch, ijz6@cdc.gov, 770-488-7571 will provide oversight of this initiative.

LIST OF ATTACHMENTS – Section B

Note: Attachments are included as separate files as instructed.

Attachment J – E-mail letter of invitation for newborn screening PROGRAM directors

Attachment K – E-mail letter of invitation for newborn screening LABORATORY directors

Attachment L- APHL notice

Attachment M- APHL reminder

Attachment N–Reminder e-mail for PROGRAM nonresponders

Attachment O—Reminder e-mail for LABORATORY nonresponders