Immunization Program Core Components and Staffing Models

OSTLTS Generic Information Collection Request
OMB No. 0920-0879

Supporting Statement – Section A

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Program Official/Project Officer
Emma Gelman, MPH
Public Health Advisor
Centers for Disease Control and Prevention (CDC)
National Center for Immunization and Respiratory Diseases
Immunization Services Division
Program Operations Branch
1600 Clifton Rd. N.E.
Mailstop: A-19
Atlanta, GA 30333
Telephone: 404-718-8772
Fax: 404-639-8615
irn7@cdc.gov

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 data collection aligns with that of the O2C2. Information will be collected from immunization program managers at the funded 64 state, local, and territorial health departments acting in their official capacities (50 states, 6 locals and 8 territories including the District of Columbia). Each health department has one immunization program manager who will be interviewed as part of this project.

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 services of: 1) linking people to needed personal health services and assure provision of health care when otherwise unavailable; and, 2) evaluating effectiveness, accessibility, and quality of personal and population-based health services.

An estimated 10 million cases of vaccine preventable diseases and 33,000 deaths are prevented each year through timely immunization. However, on the other side, for those not immunized, approximately 43,000 adults and 300 children in the United States die annually from vaccine-preventable diseases or their complications. Despite high immunization coverage levels for preschool-aged children, pockets of need remain among both children and adults. Additional doses of vaccine are needed to purchase the full series of recommended vaccines for children who are not eligible for the Vaccines for Children program and instead go to state and local public health departments for vaccinations.

Authorized under Section 317 of the Public Health Service Act, federal funding for the 317 grant program was launched in 1963. The Section 317 grant program works to ensure that children, adolescents, and adults receive appropriate immunizations by partnering with healthcare providers in the public and private sectors. Forty-two years later, in 2005, CDC awarded $431 million in federal grants to state, local, and territorial public health agencies for program operations and vaccine purchase. Currently there are 64 grantees: all 50 states, six large cities, and eight territories and former territories.

The Section 317 grant program helps assure the implementation of effective immunization practices and proper use of vaccines to achieve high immunization coverage, and supports infrastructure for essential activities such as immunization registries, outreach, disease surveillance, outbreak control, education, and service delivery. A strong immunization infrastructure ensures optimal coverage with routinely recommended vaccines. A strong immunization infrastructure is crucial, especially when public health priorities can shift rapidly in the event of an outbreak of a vaccine-preventable disease or a bioterrorism event.

Managing immunization resources to deal with urgent events or unanticipated shortages pose challenges to state programs.

Especially in an era of declining resources and competing priorities, public health agencies must make difficult decisions about which programmatic components are most likely to have the greatest public health impact. Similarly, public health agencies must make informed decisions about the most effective and efficient staffing levels and structure for their immunization program. Although the Immunization Program Operations Manual (IPOM) serves as a resource to assist immunization program managers and their staff in implementing comprehensive immunization programs, the IPOM does not provide specific guidance to immunization programs about staffing levels and structure[1]. As a result, there is wide variation across health departments in how immunization programs are staffed and structured. For example, information from the 2014 awardee funding applications indicate that the number of immunization program staff funded by the annual award ranges from 7 to 97 and the total number of staff are not strongly associated with variables that might otherwise be considered predictive of staff size (e.g., size of population served, amount of annual award).

This purpose of this project is to enhance knowledge about the variation that exists among immunization programs with regard to the staffing levels and structure essential for conducting core immunization program components and to identify scalable immunization program staffing models. The knowledge gained from this project will be used by CDC to inform decision making and guidance provided to immunization programs regarding staffing models and structure.

Overview of the Data Collection System – The information collection system consists of individual telephone interviews using a semi-structured interview guide developed in collaboration with CDC/NCIRD (see **Att. A Interview Guide**). These interviews will describe the staffing level and structure used to implement core immunization program components, identify perceived strengths and weaknesses associated with current staffing levels and structures, and identify opportunities to enhance the effectiveness and scalability of immunization program staffing models. The interview format is used to best gather the richest and most nuanced information needed for the purposes of this project, and capture variations across states and jurisdictions. The telephone interview guide was reviewed by several CDC/NCIRD staff and pilot tested in August and September of 2014 with three individuals who have extensive knowledge of the role and responsibilities of immunization program managers and formerly served as immunization program managers themselves. Feedback from this group was used to refine questions as needed and establish the estimated time required to complete the telephone interview. Interviewers are also trained and highly skilled in using the interview guide to facilitate a concise and focused conversation between the interviewer and the respondent. Qualitative data from the interviews will be imported into Dedoose® qualitative data analysis software (www.dedoose.com).

Items of Information to be Collected –
The interview guide consists of sixteen (16) questions, structured as follows:

- Questions 1-9 map to Objective #1 which is to describe the staffing level and structure used to implement core immunization program components.
- Questions 10-14 map to Objective #2 which is to identify strengths and weaknesses associated with current immunization program staffing level and structure.
- Questions 15 is an open-ended question that maps to Objective #3 which is to identify opportunities to enhance the effectiveness and scalability of immunization program staffing models.
- Question 16 is a general wrap-up question that simply asks the interviewee if there are any other comments that s/he would like to provide before concluding the interview.

Prior to initiating each interview, information from the 2014 awardee funding applications will be used to pre-populate questions 1 and 2 of the interview guide. Pre-populating the first two questions of the interview guide will enable the interviewer to confirm or update information and reduce respondent burden.

2. Purpose and Use of the Information Collection

The purpose of the data collection is to enhance knowledge about the variation that exists among immunization programs with regard to the staffing levels and structure essential for conducting core immunization program components and to identify scalable immunization program staffing models. The knowledge gained from this project will be used by CDC to inform the guidance and technical assistance provided to immunization programs regarding staffing models and structure. No publication of these data is planned. This information will be for internal CDC use only, for CDC's Immunization Services Division (ISD), National Center for Infectious and Respiratory Diseases (NCIRD).

3. Use of Improved Information Technology and Burden Reduction

The interview format is used to best gather the richest and most nuanced information needed for the purposes of this initiative, and capture variations across states. Interviews will be scheduled according to each respondent's schedule, within a 2-week period. The questions are open-ended and seek input, reflections, and experiences relevant to the immunization program staffing level and structure. Interview questions do not require additional preparation or data collection prior to or after the interview on the part of respondent. Interviewers are also trained and highly skilled in using the interview guide to reduce unnecessary respondent burden associated with providing the requested information.

Qualitative data from the interviews will be imported into Dedoose® qualitative data analysis software (www.dedoose.com). The collected qualitative data will be coded and

analyzed thematically, where data analysts will identify key themes that emerged across groups of interviews by segment or other characteristics. Frequency and intensity of discussions on a specific topic will be key indicators used for extracting main themes.

4. Efforts to Identify Duplication and Use of Similar Information

Prior to initiating this project, steps were taken to ensure that this project is not duplicating efforts or collecting information that is already available elsewhere. A preliminary external literature review, environmental scan, and review of internal CDC/NCIRD reports did not identify any systematic compilations of data on immunization program staffing levels and structure by CDC, state health departments, academic researchers, or other agencies. We next explored the possibility of extracting data from the progress reports submitted to CDC by immunization program managers; however, we determined that the progress reports lack the information needed to describe the staffing level and structure used to implement core immunization program components. The progress reports also lack information about the perceived strengths and weakness associated with current staffing levels and structures. Therefore, the data we are requesting to gather is not available in any other format.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection.

6. Consequences of Collecting the Information Less Frequently

The purpose of this request is to enhance knowledge about the variation that exists among immunization programs with regard to the staffing levels and structure essential for conducting core immunization program components and to identify scalable immunization program staffing models. Specifically, without this data, there would be:

- No timely and confirmed data regarding each immunization program awardee's staffing level and structure used to implement core immunization program components;
- No opportunity to identify ways to enhance the effectiveness and scalability of immunization program staffing models;
- Funding at the state and local level potentially not being used for important immunization activities and interventions, due to potentially preventable or surmountable challenges related to program staffing level and structure; and
- Less effective public health infrastructure and capacities to address future need to scale up immunization program staffing in response to pandemics or other unexpected events.

This request is for a one time data collection. There are no legal obstacles to reduce the burden.

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

There are no special circumstances with this information 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 (OSC) – OMB No. 0920-0879. A 60-day Federal Register Notice was published in the Federal Register on October 31, 2013, Vol. 78, No. 211; pp. 653 25-26. No comments were received.

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. Assurance of Confidentiality Provided to Respondents

The Privacy Act does not apply to this data collection. Employees of state and local public health agencies will be speaking from their official roles.

This data collection is not research involving human subjects.

10.1 Privacy Impact Assessment Information

No individually identifiable information (IIF) will be collected.

11. Justification for Sensitive Questions

No information will be collected that are of personal or sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

The estimate for burden hours is based on the results of the pilot test of the interview guide with three former immunization program managers. The average time to complete the telephone interview including time for reviewing instructions, gathering needed information and completing the interview is estimated an average of 45 minutes and no more than 60 minutes. For the purpose of estimating burden hours, the upper limit of this range (i.e., 60 minutes) is used.

Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) National Compensation Survey estimate for management occupations – medical and health services managers in state government (http://www.bls.gov/ncs/ocs/sp/nctb1349.pdf). Based on DOL data, an average hourly wage of $57.11 is estimated for all 64 number respondents. Table A-12 shows estimated burden and cost information.

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
Telephone Interview Guide	Immunization Program Managers	64	1	1.0	64	$57.11	$3,655.04
	TOTALS	**64**	**1**		**64**		$3,655.04

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 the data collection (i.e., telephone interview).

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 contractors and sub-contractors supporting the data collection activities and associated tasks.

The data collection tool will be prepared by contractors and sub-contractors to CDC. A senior level sub-contractor will oversee data collection and manage all aspects of the process including data collection via telephone interviews. The estimated cost to the federal government for the entire data collection period is $13,111. 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	Average Cost
CDC Project Officer, GS -13	25	$46.43	$1,161
Director of Research and Assessment (Contractor to CDC)	10	$60	$600
Project Manager (Contractor to CDC)	50	$35	$1,750
Interviewers (Contractors to ASTHO/Sub-Contractors to CDC) Consultation on data collection interviews and quality control	192	$50	$9,600
Estimated Total Cost of Information Collection			**$13,111**

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Project Time Schedule

Upon receipt of OMB approval, telephone interviews will be scheduled and completed with all 64 immunization program managers. Upon completion of all the telephone interviews, data will be cleaned, coded and analyzed, and a final report will be developed and disseminated to CDC.

Table A-16: Project Time Schedule

Task	Timeline
✓ Design interview guide tool	COMPLETE
✓ Pilot test interview guide	COMPLETE
✓ Develop data collection protocol, instructions, and analysis plan	COMPLETE
✓ Prepare OMB package	COMPLETE
✓ Submit OMB package	COMPLETE
❑ OMB approval	TBD
❑ Conduct telephone interviews	Within 4 weeks of OMB approval
❑ Code, quality control, and analyze qualitative data from interviews	Within 3 weeks of completing interviews
❑ Prepare report	Within 5 weeks of completing analysis
❑ Disseminate report	Within 2 weeks of finalizing the report

Analysis Plan

The data collection from the telephone interviews aim to answer the following questions:

1. How are CDC-funded immunization programs staffed and structured?
2. What opportunities exist to enhance the ways in which immunization programs are staffed and structured?
3. What opportunities exist to enhance the effectiveness and scalability of immunization program staffing models?

All data from the telephone interviews will be imported into Dedoose® qualitative data analysis software (www.dedoose.com). The collected qualitative data will be coded and analyzed thematically, where data analysts will identify key themes that emerged across groups of interviews by segment or other characteristics. Frequency and intensity of discussions on a specific topic will be key indicators used for extracting main themes.

The results of the review of existing data and the telephone interviews will be used for quality improvement purposes, to help guide CDC's NCIRD enhancements, and to improve the communication, technical assistance, and other resources provided to state, local, and territorial health departments receiving federal immunization funding in the future. The goal is to better understand the variation that exists among immunization programs with regard to staffing level and structure and to identify scalable immunization staffing models.

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

Att. A Interview Guide

REFERENCES

1. Department of Health and Human Services. Centers for Disease Control and Prevention (CDC). The 2013-2017 Immunization Program Operations Manual (IPOM).
2. Department of Health and Human Services. Centers for Disease Control and Prevention (CDC). "Program in Brief: Immunization Grant Program (Section 317)." Available at http://www.317coalition.org/documents/programinbrief.pdf. Accessed on 9/21/14.
3. National Vaccine Advisory Committee. Protecting the public's health: critical functions of the section 317 immunization program -- a report to the National Vaccine Advisory Committee. *Public Health Reports*. 2013: 128(2): 78-95.
4. Jarris P, Dolen V. Section 317 immunization program: protecting a national asset. *Public Health Reports*. 2013: 128(2):96-98.