Assess Breast and Cervical Cancer Screening Program Activities to Expand Access to Screening

OSTLTS Generic Information Collection Request
OMB No. 0920-0879

Supporting Statement – Section A

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Section A – Justification

1. Circumstances Making the Collection of Information Necessary

Background

This data collection is being conducted using the Generic Information Collection mechanism of the OSTLTS Survey Center (OSC) – OMB No. 0920-0879. The respondent universe for this data collection aligns with that of the OSC. Data will be collected from State, Tribal and Territory health department professionals acting in their official capacities. This data collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241).

To improve access to cancer screening, Congress passed the Breast and Cervical Cancer Mortality Prevention Act of 1990 (Public Law 101-354) which directed CDC to create the National Breast and Cervical Cancer Early Detection Program (NBCCEDP). Currently, the NBCCEDP funds 67 grantees including all 50 states, the District of Columbia, 5 U.S. territories, and 11 American Indian/Alaska Native tribes or tribal organizations. Grantees provide screening services for breast and cervical cancer to low-income, uninsured, and underinsured women who otherwise would not have access to screening.

Since 1991, NBCCEDP-funded grantees have served more than 4.3 million women, provided more than 10.7 million breast and cervical cancer screening examinations, and diagnosed more than 56,662 breast cancers, 3,206 invasive cervical cancers, and 152,470 premalignant cervical lesions, of which 41% were high-grade (**see Attachment A – About the National Breast and Cervical Cancer Early Detection Program).**

As a comprehensive, organized screening program, the NBCCEDP supports activities including program management, partnership development, public education and targeted outreach, screening and diagnostic services, patient navigation, quality assurance and quality improvement, professional development, data management and utilization, and program monitoring and evaluation (**see Attachment B – NBCCEDP Framework**). For clinical service delivery, grantees fund health care providers in their state/territory/tribe to deliver breast and cervical cancer screening, diagnostic evaluation, and treatment referrals for women diagnosed with cancer.

CDC issued a new Funding Opportunity Announcement (FOA) to support a new 5-year cooperative agreement for the NBCCEDP effective July 2012 (CDC-RFA-DP12-1205). This new FOA begins to shift the NBCCEDP from a focus on direct service provision to implementation of expanded evidence-based activities intended to increase rates of breast and cervical cancer screening at the population level. Though NBCCEDP grantees continue to provide breast and cervical cancer screening for un- and underinsured women, CDC is encouraging the implementation of strategies to increase screening rates beyond that of program-eligible women. This data collection is being proposed in order to assess program implementation, particularly related to these expanded population-based efforts.

Privacy Impact Assessment

Overview of the Data Collection System – The data collection system consists of a web-based questionnaire designed to collect information from Program Directors of the state, tribal and territorial grantees of the NBCCEDP about their program implementation (**see Attachment C – Data Collection Instrument: Web version and Attachment D – Data Collection Instrument: MS Word version**). The data collection instrument will be web-based. The instrument was pilot tested by 11 public health professionals in two phases. In the first phase, 8 public health professionals tested a paper-version of the instrument to assess the clarity of the questions and response categories. The instrument was then tested with 3 public health professionals. The average time required to complete the responses during pilot testing was 28 minutes.

Items of Information to be Collected – The instrument consists of 67 questions, including 3 questions on respondent background, 36 questions on program activities, 12 questions on clinical service delivery, 1 question on monitoring, 3 questions on non-screening partnerships, 3 questions on data use, 1 question on training and technical assistance, and 8 questions on program management. Questions are of various types including dichotomous and multiple response. An effort was made to limit questions requiring open-ended or narrative responses and skip patterns are included where possible. CDC investigators will collect data focusing on NBCCEDP program activities, clinical service delivery, non-screening partnerships, data use, training and technical assistance, and program management

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age – The data collection system involves using a web-based instrument. Respondents will be sent a link directing them to the online instrument only (i.e., not a website). No website content will be directed at children.

2. Purpose and Use of the Information Collection

The purpose of this data collection is to assess state, tribal and territorial health department implementation of programs to increase breast and cervical cancer screening within an expanded target population and an evolving healthcare context. CDC investigators will collect data focusing on NBCCEDP program activities, clinical service delivery, non-screening partnerships, data use, training and technical assistance, and program management.

This assessment will enable CDC to identify implementation activities and assess alignment with NBCCEDP goals and objectives, monitor program transition to efforts aimed at impacting population-based screening, identify technical assistance needs of state, tribe and territorial health department cancer control programs, and identify implementation models with potential to expand and transition to new settings to increase program impact and reach. The proposed data collection activity will allow CDC to gauge its progress in meeting NBCCEDP program goals. The assessment will provide insight into areas that need improvement and identify successful activities that should be maintained, replicated, or expanded. Specifically, the activities to be assessed include (1) program activities (2) clinical service delivery (3) evaluation (4) non-screening partnerships (5) data use (6) training and technical assistance and (7) program management.

The proposed data collection activities will contribute to a more effective NBCCEDP and strengthen CDC's ability to demonstrate program results. The scope of data collection is limited to the activities and experiences of NBCCEDP grantees acting in their official capacity. As such, this data collection will not require IRB review. Collection of these data will not yield data that can be generalized. CDC expects to use these findings to better understand the range of experiences among state, tribal and territorial governmental grantees and as one of many inputs into decision-making and/or program management or assessment. In addition, the findings will be reported to the grantees to help them identify successful implementation models and focus networking for shared experiences, lessons learned, and best practices.

3. Use of Improved Information Technology and Burden Reduction

Data will be collected via a web-based questionnaire allowing respondents to complete and submit their responses electronically. This method was chosen to reduce the overall burden on respondents. The instrument was designed to collect the minimum information necessary for the purposes of this project (i.e., limited to 67 questions).

The web-based data collection instrument software has been developed using an open-source product called Lime Survey (limesurvey.org). This reduced development cost and provided for maximum control of the collection instrument and these data.

The data contractor will host the collection instrument and data using a secure submission web site. Users will be provided with a unique 'token' that will enable them access to view and enter their data. The data collected will be archived on secure network servers with user ID and password restricted access at the location of the data contractor and at the CDC. Networked systems are maintained in a locked room with access strictly limited to essential employees. The contractor aggregates and validates the data for quality and completeness and prepares an analysis file for delivery to CDC. All data will be maintained for restricted access on CDC's secure LAN server.

4. Efforts to Identify Duplication and Use of Similar Information

The data to be collected are unique to the implementation of the provisions related to the NBCCEDP in Program Announcement CDC-RFA-DP12-1205, and are therefore not duplicative of other efforts. The RFA requires that Health Departments funded under the NBCCEDP report semi-annually to the Procurement and Grants Office (PGO). Grantees are responsible for submitting programmatic information including a list of staff, a delineation of program objectives, a progress report on performance measures, a program work plan, and a listing of accomplishments. While information collected through these reports identifies program activities, it does not provide any systematic information specific to the implementation of these activities or describe the relationship with implementation partners. Thus, this new information collection will fill a gap in allowing CDC to systematically assess these aspects of the NBCCEDP across all grantees.

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 ensure collection of data that is not otherwise available in a current, time sensitive, or standardized format to specific or emergent priorities of HHS and CDC. Specifically, without this data there would be:

- No systematic collection regarding the implementation of year 1 program activities as specified in the CDC-RFA-DP12-1205.
- No systematic assessment of training and technical assistance needs.
- Less effective and timely assessment of implementation partners of program activities.
- Fewer resources from which to make data-driven decisions that are often required of CDC and state, tribal, and territorial governmental health agencies.

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 Survey Center (OSC) – OMB No. 0920-0879. A 60-day Federal Register Notice was published in the Federal Register on October 22, 2010, Vol. 75, No. 204; pp. 65353-54. Two comments were received, one from the Association of State and Territorial Health Officials (ASTHO) and another from the National Association of County and City Health Officials (NACCHO).

CDC partners with professional organizations such as ASTHO, NACCHO, the National Association of Local Boards of Health, as well as 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, tribal, and territorial public health agencies will be speaking from their official roles and will not be asked, nor will they provide, individually identifiable information.

This data collection is not research involving human subjects.

11. Justification for Sensitive Questions

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

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 3 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 28 minutes.

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 67 number respondents. Table A-12 shows estimated burden and cost information.

Table A-12: Estimated Annualized Burden Hours and Costs to Respondents - Assessing Breast and Cervical Cancer Screening Programs' Activities

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
Breast and Cervical Cancer Program Directors	67	1	28/60	31	$57.11	$1,770.41
TOTALS	**67**	**1**		**31**		$1,770.41

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 funding for the data contractor, Information Management Services (IMS), to support the development of the web-based application, data collection, and associated tasks.

Questions have been prepared by CDC staff (FTE) and the web-based instrument will be programmed by data contractor staff. Two senior level FTEs will conduct all related activities. A senior FTE manager at CDC will oversee all related activities. A data contractor will program, field, and analyze the results of the web-based data collection. The estimated cost to the federal government is $82,502.40. Table A-14.1 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
Health Scientist (GS-13) Overall lead for development of instrument, pilot testing, OMB package preparation, data collection, , quality control, data analysis, report preparation	800	53.26	$42,608.00
Health Scientist (GS-13) Consultation with staff lead on instrument development, OMB package preparation, data collection, quality control, data analysis, report preparation	320	53.26	$17,043.20
Lead Health Scientist (GS-14) Management oversight for instrument development, pilot testing, OMB package preparation, data collection and analysis, report preparation	160	62.93	$10,068.80
Contractor Costs			
Annualized Cost of Contract with Data Contractor Responsible for building web-based application, data collection, data coding and entry, quality control, data analysis, report preparation (GS-13 equivalent)	240	53.26	$12,782.40
Estimated Total Cost of Information Collection			$82,502.40

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

The results of this data collection, individual and aggregate, will be published in the form of a grantee report. The results will be used to support individual grantees in the state, tribe and territory health departments and to provide CDC management a snapshot of how the NBCCEDP is being implemented as a whole. Within 150 days following OMB approval, respondents will receive a report summarizing findings (**see Attachment E – Sample Grantee Report**). Reports which will be generated for internal CDC use will also be produced (**see Attachment F – Sample Management Report**) and will be completed within 150 days following OMB approval. A summary of this timeline is provided below:

Estimated Project Time Schedule

- ✓ Design questionnaire..... (COMPLETE)
- ✓ Pilot test questionnaire..... (COMPLETE)
- ✓ Enter questions into [Lime Survey]..... (COMPLETE)
- ✓ Prepare OMB package..... (COMPLETE)
- ✓ Submit OMB package..... (COMPLETE)
- ❑ OMB approval..... (TBD)
- ❑ Conduct data collection (includes reminders)..... (Open 3 weeks)
- ❑ Collect, code, enter, quality control, and analyze data..... (3 weeks)
- ❑ Prepare report..... (3 weeks)
- ❑ Disseminate results/reports…….…… (Date TBD)

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 – Supporting Statement A

Note: Attachments are included as separate files as instructed.

- **Attachment A** – About the National Breast and Cervical Cancer Early Detection Program website
- **Attachment B**– NBCCEDP Framework
- **Attachment C** – Data Collection Instrument: Web version
- **Attachment D**– Data Collection Instrument: MS Word version
- **Attachment E** – Sample Grantee Report
- **Attachment F** – Sample Management Report