

Information Collection Request

Revision

Minimum Data Elements (MDEs) for the National Breast and Cervical Cancer Early Detection Program (NBCCEDP)

OMB Control No. 0920-0571

Supporting Statement: PART A

Program Official/Contact

Dara Schlueter, MPH

Health Scientist

Division of Cancer Prevention and Control

National Center for Chronic Disease Prevention and Health Promotion

Centers for Disease Control and Prevention

Atlanta, GA 30341

Phone: 404-498-1782

Fax: 770-488-3230

Sax9@cdc.gov

December 18, 2018

TABLE OF CONTENTS

A. JUSTIFICATION

- A1. Circumstances Making the Collection of Information Necessary
- A2. Purpose and Use of the Information Collection
- A3. Use of Improved Information Technology and Burden Reduction
- A4. Efforts to Identify Duplication and Use of Similar Information
- A5. Impact on Small Businesses or Other Small Entities
- A6. Consequences of Collecting the Information Less Frequently
- A7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
- A8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency
- A9. Explanation of Any Payment or Gift to Respondents
- A10. Protection of the Privacy and Confidentiality of Information Provided by Respondents
- A11. Institutional Review Board (IRB) and Justification for Sensitive Questions
- A12. Estimates of Annualized Burden Hours and Costs
- A13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers
- A14. Annualized Cost to the Federal Government
- A15. Explanation for Program Changes or Adjustments
- A16. Plans for Tabulation and Publication and Project Time Schedule
- A17. Reason(s) Display of OMB Expiration Date is Inappropriate
- A18. Exceptions to Certification for Paperwork Reduction Act Submissions

REFERENCES

ATTACHMENTS

- ATT 1. Authorizing Legislation
- ATT 2. The Breast and Cervical Cancer Mortality Prevention Act of 1990
- ATT 3. NBCCEDP Logic Model
- ATT 4. NBCCEDP Evaluation Question Matrix
- ATT 5. MDE Data Definitions
- ATT 6. Proposed Changes to the Currently-Approved MDE Data Variables
- ATT 7. 60-Day Federal Register Announcement
- ATT 8. Institutional Review Board Approval
- ATT 9. Privacy Impact Assessment



- Goal of the study: The goal of this information collection is to systematically collect information about delivery of screening and follow-up clinical services under the NBCCEDP, a program including 70 grantees.
- Intended use of the resulting data: CDC will use resulting information to monitor processes and outcomes associated with NBCCEDP activities.
- Methods to be used to collect data: CDC will collect revised MDEs on a semi-annual basis from all grantee programs.
- The subpopulation to be studied: The subpopulation for the MDEs is the 70 NBCCEDP Data Managers.
- How data will be analyzed: CDC will use descriptive statistics to produce reports for CDC program management and NBCCEDP grantees.

ABSTRACT

CDC is requesting a Revision to OMB No. 0920-0571, an information collection for the National Breast and Cervical Cancer Early Detection Program (NBCCEDP). The currently approved information collection is based on a program requirement that NBCCEDP-funded grantees must report clinical data on breast and cervical cancer screening services to the CDC in a minimum data elements (MDEs) format semiannually. Based on assessments of the previous cooperative agreement (DP12-1205), CDC determined that several data variables were no longer relevant to CDC and did not effectively serve the program monitoring and evaluation purposes for which they were intended. We are planning to remove, collapse, or revise variables in the proposed information collection. CDC anticipates that these changes will reduce burden to grantees. The revised information collection will continue to allow CDC to provide routine monitoring feedback to grantees based on their semiannual MDE data submissions, tailor technical assistance as needed, support program planning, and assess program outcomes. OMB approval is requested for three years.

A. Justification

1. Circumstances Making the Collection of Information Necessary

CDC is requesting a Revision to OMB No. 0920-0571 for the information collection titled, “Minimum Data Elements (MDEs) for the National Breast and Cervical Cancer Early Detection Program (NBCCEDP).” The proposed changes include modifying the content of the MDE

information collection to remove variables no longer relevant for monitoring and evaluation purposes, realign variables with updated clinical reporting guidelines, and collapse some variables to simplify responses. The overall length of the MDE data collection is decreasing from 99 variables to 67 variables. The number of grantees increased from 67 to 70 in July 2017 with the funding of a new five-year cooperative agreement. The estimated annualized burden is expected to decrease. OMB approval is requested for three years.

Both breast and cervical cancers are prevalent among U.S. women. In 2014, more than 236,000 women were diagnosed with breast cancer, and more than 12,000 women were diagnosed with cervical cancer.¹ Evidence shows that deaths from both breast and cervical cancers can be avoided by increasing screening services – mammography and Pap tests – among women. However, screening is typically under-utilized among women who are under- or uninsured, have no regular source of healthcare, or who recently immigrated to the U.S.²

To improve access to cancer screening, Congress passed the Breast and Cervical Cancer Mortality Prevention Act of 1990 (Attachment 2 - Breast and Cervical Cancer Mortality Prevention Act of 1990) which directed CDC to create the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) and to conduct program monitoring and evaluation activities. NBCCEDP currently funds 70 grantees including all 50 states and the District of Columbia (D.C.); U.S. territories; and tribes or tribal organizations.

An important purpose of the NBCCEDP is to decrease breast and cervical cancer incidence, morbidity, and mortality by funding grantees to provide breast and cervical cancer screening and diagnostic services to eligible women. Priority populations for the NBCCEDP include women residing within defined geographical locations (as determined by the funded program) who are (1) at or below 250% of the federal poverty level, (2) aged 40-64 years for breast cancer services, and aged 21-64 years for cervical cancer services, and (3) under- or uninsured. The Breast and Cervical Cancer Mortality Prevention Act of 1990 (heretofore, referred to as the ‘Act’) also authorizes the CDC to ensure that NBCCEDP grantees effectively implement and maintain the

¹ Centers for Disease Control and Prevention (2017). *Cancer*. Retrieved on 2 August 2017 from <https://www.cdc.gov/cancer/index.htm>.

² Centers for Disease Control and Prevention. Cancer screening test use—United States, 2015. *MMWR* 2012;66(8):201-206.

program management components for which they are funded including the collection and maintenance of screening and follow-up data for women served; and the completeness and quality of the data.

In 2017, CDC issued a new Funding Opportunity Announcement to support a 5-year cooperative agreement for the NBCCEDP (CDC-RFA-DP17-1701). As in the past, grantees are required under the new FOA to report MDEs to CDC in order to ensure an effective method of monitoring and evaluating grantees' performance and to assure that all women served receive screening and, if indicated, complete and timely diagnostic services. Based on current evaluation needs and recommendations from subject matter experts, CDC determined that some MDE variables previously collected are no longer relevant or are outdated, and can be eliminated. Furthermore, CDC identified the need to revise several variables (e.g., cancer stage) so that they are consistent with current professional standards. And finally, CDC is proposing to collapse some variables in order to simplify data reporting and reduce burden. CDC is responsible for continually reevaluating the appropriateness of the MDE data reporting. The data collection authority for this study is the Public Health Service Act (Attachment 1 – Authorizing Legislation)

2. Purpose and Use of the Information Collection

CDC is required to monitor and evaluate both processes and outcomes related to the NBCCEDP. CDC developed a logic model to reflect the strategies and expected outcomes associated with the NBCCEDP over time (Attachment 3 – NBCCEDP Logic Model). This logic model guided the development of evaluation questions designed to monitor grantees' strategies and activities, and evaluate program outcomes (Attachment 4 – NBCCEDP Evaluation Question Matrix).

The MDEs provide patient-level data to monitor the delivery of screening and diagnostic clinical services, which is critical for evaluating grantee performance (Attachment 5 – MDE Data Definitions). Several changes will be made to the MDE data to remove, revise, and collapse variables in order to increase the usefulness of the MDE data and reduce grantee burden. Also, several existing data elements were repositioned in the MDE file format to improve the logical flow of the record. Attachment 6 – Proposed Changes to the Currently-Approved MDE Data Variables provides a list of specific changes to the MDEs and rationale for each change.

Together, the proposed revisions are expected to increase efficiency of MDE data reporting by limiting data variables to only those that are critical to adequately monitor program performance and evaluate processes and outcomes of interest. In addition, this Revision will reduce burden by eliminating data variables no longer needed by CDC.

The scope of information collection is limited to monitoring the public health activities and experiences of NBCCEDP grantees acting in their official capacity, and the information collection will not yield information that can be generalized. As such, this information collection will not require IRB review. CDC will use this information to better understand the range of experiences among grantees and as one of many inputs into decision-making and/or program management. In addition, after each data submission, reports will be produced and reviewed with individual grantees to help identify data quality issues and to use for making program improvements.

3. Use of Improved Information Technology and Burden Reduction

As stated in the currently approved information collection, the CDC developed and maintains a data management software package designed to facilitate the data entry, editing, quality assurance, and reporting of the MDE dataset. The system is a Windows-based application currently used by approximately one-half of the NBCCEDP grantees. This system minimizes burden among grantees by providing a standardized reporting system and making the data submission process more efficient. The CDC provides technical assistance to grantees using the data management system. Grantees report the dataset as an electronic, fixed-length text file to a secure, password-protected submission Web site where grantees post their text files once prepared (www.nbccedp.org). This submission Web site simplifies the process of reporting MDE data for grantees, and organizes the receipt of grantee text files by the CDC. A data contractor, Information Management Services, Inc. (IMS), is retained to assist with data management and analysis of the MDE submissions, which includes generating standardized reports for the grantees and the CDC.

4. Efforts to Identify Duplication and Use of Similar Information

As stated in the currently approved information collection, there are no existing, comparable data sources available for the collection of this information. The MDE data provide information about

women who are specifically served in the NBCCEDP. The consistent reporting of these data to the CDC remains critical and promotes assurances that the grantees provide appropriate and timely clinical services to women who utilize the NBCCEDP, a requirement of the law establishing the program. The MDE dataset is unique in providing a national dataset that assists the CDC in the ongoing development and management of a cancer screening program designed to provide under-served women with access to breast and cervical cancer screening and diagnostic services.

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

As stated in the currently approved information collection request, the CDC aggregates MDE data from grantees semiannually. This allows for consistent program monitoring and evaluation, facilitates grantee oversight and delivery of technical assistance, and informs CDC planning. The collection of these MDE data less frequently would compromise the ability of the CDC to perform the needed monitoring and evaluation, including required reporting to other Federal agencies. The CDC is obligated to provide annual status reports on the NBCCEDP to Congress, Office of Management and Budget, and other CDC officials. 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

A. PUBLIC NOTICE

Notice of this project was published in the Federal Register on March 5, 2018 in Vol. 83, No 43, pages 9320-9321. (See Attachment 7 – 60-Day Federal Register Notice).

No public comments were received.

B. CONSULTATION

In spring 2017, grantees were invited to provide feedback on the revised MDE data variables. A total of 6 grantee programs provided substantive written feedback on the revised MDEs. A list of those individuals is included in Table 8.1.

Table 8.1. Individuals Who Have Provided Consultation on the Project

Consultant	Title	Affiliation	Email	Phone	Year of Consult
Emily Kinsella	Program Director	Colorado Department of Public Health and Environment	Emily.Kinsella@state.co.us	303-692-2511	2017
Cynthia Snyder	Data Manager	Kansas Department of Health and Environment	Cynthia.snyder@ks.gov	785-296-2923	2017
Maryann Zaremba	Program Director	Maine Center for Disease Control and Prevention	Maryann.M.Zaremba@Maine.gov	207- 287-3262	2017
Libby Bruggeman	Data Manager	New Mexico Department of Health	Libby.Bruggeman@state.nm.us	505-841-5835	2017
John Veazey	Data Manager	Rhode Island Department of Health	john.veazey@health.ri.gov	401-222-5960	2017
Michael Mosley	Data Manager	Southeast Alaska Regional Health Consortium (SEARHC)	mmosley@searhc.org	907-463-4000	2017

9. Explanation of Any Payment or Gift to Respondents

CDC will not provide payments or gifts to respondents.

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

This submission has been reviewed by CDC's Information System Security Office, who determined that the Privacy Act does not apply because CDC only receives de-identified patient demographic data (i.e., date of birth [month and year only]; race/ethnicity; and county, state, and zip code). These variables are routinely collected when medical services are provided. The new variables added to the MDE dataset were reviewed and found to be consistent with the previous ruling.

Overview of the Information Collection System

CDC proposes to collect revised minimum data elements (MDEs) from NBCCEDP grantees, who include 70 grantees (all State health departments, D.C., U.S. territories, and tribes or tribal organizations). The information collection will support monitoring and evaluation of program implementation \grantees to report MDE data.

The MDEs consist of an electronic submission of de-identified patient-level data from all 70 NBCCEDP grantees. CDC proposes use of updated MDE variables to reflect current needs of the NBCCEDP (Attachment 5). The revised MDEs eliminate several variables no longer used by CDC, as well as revises or collapses several variables (Attachment 6). The data manager within each grantee program will serve as the respondent. Approximately half of all grantees use the CDC-developed Windows-based application for data collection; remaining grantees use their approved data management and reporting systems. All grantees submit their data electronically through a secure, password protected program web site.

Grantees will continue to submit MDEs semi-annually in April and October of each program year, which runs from July-June. All MDE data submissions are reported via an electronic, fixed-length text file to a secure, password-protected submission Web site on nbccedp.org. The CDC contactor will manage, aggregate, and validate the MDE data for quality and completeness, and prepare an analysis file and reports for delivery to CDC.

Items of information to be collected

The revised MDEs consist of seven sections. The number of items completed by a respondent will vary due to skip logic. Sections include:

1. Patient demographics
2. Breast cancer screening

3. Cervical cancer screening
4. Breast and cervical cancer diagnoses
5. Breast and cervical cancer treatment
6. Cancer registry data
7. Patient navigation

How information is shared and for what purpose

Grantee respondents will receive customized feedback using MDE data from their program. Grantees will not have access to other grantees' submissions or individualized reports. Program summary information and NBCCEDP aggregate results (e.g., performance ranges) will be shared across programs for grantees to compare performance to the NBCCEDP as a whole.

Information will be used by CDC to monitor and evaluate the NBCCEDP, provide feedback to grantees for program improvement, provide summary data to stakeholders on program processes and outcomes, and inform program planning. CDC investigators will prepare formal reports periodically for Congress and the public. CDC does not plan to create a public use dataset given the programmatic nature of the information and its strict application for monitoring the 70 NBCCEDP grantees. Program Announcement CDC-RFA-DP17-1701, the current NBCCEDP funding announcement, requires that CDC monitor and evaluate NBCCEDP processes and outcomes.

Statement of impact on the respondent's privacy

The MDEs include sensitive information about patient demographics (e.g., race/ethnicity, birthdate), cancer diagnosis, and treatment initiation, which is central to the purposes of CDC's program evaluation and oversight activities. All MDE data submissions are reported by grantees via an electronic, fixed-length text file to a secure, password-protected submission Web site on www.nbccedp.org. All data submissions are maintained in a secure data management system with access limited to the data contractor and CDC staff. Patient-level data are de-identified before submission to CDC (with the exception of birth date to establish patient age), and CDC is unable to identify individual participants from the data received.

Opportunities to consent to sharing and submission of information

Participation in screening and follow-up, and providing information to do so, is voluntary; therefore, those patients who wish to opt out may do so. Grantees are notified that their information will be maintained in a secure manner and that they will receive individualized feedback reports to inform future MDE submissions and programmatic decision-making. There are no advisements that relate to data sharing since CDC has no plans to share information or develop a public-use dataset. There is no impact on the respondent's privacy.

How information is secured

This information collection is secured by technical, physical, and administrative safeguards as outlined below.

Technical

- All data reside on a dedicated server on the contractor's local area network behind the contractor's firewall and is password protected on its own security domain. Access to the server is limited to the contractor's authorized project staff. No non-project staff is allowed access to the data. All of the contractor's project staff is required to sign a confidentiality agreement before passwords and keys are assigned.
- Access to the NBCCEDP program website is restricted via a password-protected secure website. Access to grantee submissions are further restricted within the website. Each grantee has its own directory location, so no grantee has access to another grantee's information. The NBCCEDP program website utilizes the Hypertext Transfer Protocol Secure (HTTPS) to ensure secure connections. In addition, the website will enable Strict Transport Security (HSTS), which is in compliance with OMB memorandum M-15-13, Policy to Require Secure Connections across Federal Websites and Web Services.
- Once information has been compiled by the contractor and delivered to CDC using IMS' secure file transfer system, all data are maintained for restricted access on CDC's secure LAN server with access permission grantee by the CDC NBCCEDP data manager.

Physical

- The contractor's server is housed in a secure facility with restricted access.

- Receipt and processing logs are maintained to document data receipt, file processing and report production. All reports and electronic storage media containing grantee information are stored under lock and key when not in use and will be destroyed when no longer needed.
- Once data have been compiled by the contractor and delivered to CDC, all datasets are maintained for restricted access on a secure LAN server, which is housed in a secure facility. All CDC staff are issued identification badges and access to the building is controlled by key cards.

Administrative

- CDC and contract staff have developed and implemented an information system security plan to ensure that the information is kept secure. Periodic review and update of the contractor's security processes is conducted to adjust for needed changes and will be amended as needed to maintain the continued security of the information.
- The contractual agreement between CDC and the contractor includes non-disclosure terms. The contractor's project security team oversees operations to prevent unauthorized disclosure of the NBCCEDP data.
- Once the information have been delivered to CDC, data are housed on CDC's secure LAN server and restricted access is controlled by the NBCCEDP data manager.

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

Both the currently approved and proposed MDE datasets include sensitive information about cancer diagnosis and treatment initiation, which is central to the purposes of program evaluation and oversight. In addition, race and ethnicity data are collected per the Department of Health and Human Services guidelines and for use in data analyses.

12. Estimates of Annualized Burden Hours and Costs

The total number of grantees increased from 67 grantees under DP12-1205 to 70 grantees under DP17-1701. Grantees report the MDE data to the CDC semi-annually.

A. Estimated burden is based on previous MDE reporting experience and the specific features of the data management system developed and maintained by CDC to perform these exact functions. While the data management system will be updated to accommodate the proposed reporting changes, the process of generating the electronic data file will not change. Prior to submitting the enclosed change application, the CDC received voluntary consultation from six respondents regarding the impact that the changes to the MDE data reporting requirements are estimated to have upon the average burden per response. Based upon the consultation, it is estimated that the changes to the MDE dataset, which include the removal of data elements no longer needed, will decrease the average burden per response. The estimated annualized burden is 350 hours.

Table 12.A. Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hr)	Total Burden (in hr)
NBCCEDP Grantees	MDEs	70	2	2.50	350
				Total	350

B. Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) National Compensation Survey estimate for database administrators in state government (<http://www.bls.gov/ncs/ocs/sp/nctb1349.pdf>). Based on DOL data, an average hourly wage of \$31.20 is estimated for all respondents.

Table 12.B. Estimated Annualized Burden Costs

Type of Respondent	Form Name	Number of Respondents	Total Burden Hours	Hourly Wage Rate	Total Cost
NBCCEDP Grantees	MDEs	70	350	\$31.20	\$10,920

Total					\$10,920
-------	--	--	--	--	----------

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 information collection.

14. Annualized Cost to the Government

Total operations and maintenance costs includes work performed by both the contractor and CDC personnel. Salary cost of CDC staff include an FTE (GS-13) to lead the project and coordinate all related activities of each information collection and two FTEs (GS-14) to serve as subject matter experts and oversee reporting requirements. Four hundred and eighty hours of staff time was estimated for each FTE annually for this information collection. Cost of the contractor represents an estimated 35% (\$463,152) of total annual contract funds (\$1,323,293) allocated for NBCCEDP data management activities. The estimated cost to the federal government is \$531,164. Table 14-A describes how the cost estimate was calculated.

Table A14-A. Estimated Annualized Cost to the Federal Government

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Average Cost
Health Scientist (GS-13) Lead health scientist to prepare OMB package; overall coordination; and consult on information collection, analysis, report preparation	480	\$40.50	\$22,066
Health Scientist (GS-14) Subject matter expertise, reporting oversight	480	\$47.86	\$22,973
Health Scientist (GS-14) Subject matter expertise, reporting oversight	480	\$47.86	\$22,973
Contractor Costs			
Annualized Cost of Contract with			

Information Management Services Responsible for building web-based application, information collection, coding and entry, quality control, analysis, report preparation			\$463,152
Estimated Total Cost of Information Collection			\$531,164

Table 14-B. Estimated Annualized Federal Government Operational and Maintenance Costs

The majority of data collection and management tasks will be the responsibility of the CDC contractor, and will not require additional operational or maintenance costs to the Federal government. CDC personnel will oversee the project, and provide leadership and coordination which will not require additional costs beyond individual employees' salaries. Therefore, there are no additional operational or maintenance costs associated with this information collection.

Table A14-B. Total Cost to the Federal Government

Operational and Maintenance Costs	Estimated Annualized Federal Government Costs	Total Cost
\$0.00	\$531,164	\$531,164

15. Explanation for Program Changes or Adjustments

Despite an increase in the number of grantees (67 to 70), the total annualized burden decreased from 536 hours to 350 hours due to the removal and revision of several data variables.

Attachment 6 provides a detailed list of each changed data variable as well as the rationale for each change.

Table A15. Changes in Information Collection

	Previous Approval		Proposed Changes for Current Revision			
	No. Respondents	No. Burden Hrs.	No. Respondents	No. Burden Hrs.	Change in Respondents	Change in Burden
Information Collection Instrument						

						Hrs.
MDEs	67	536	70	350	+3	-186
Total:						-186

16. Plans for Tabulation and Publication and Project Time Schedule

CDC proposes a revision to MDE variables that grantees are required to report. However, there are no changes relating to the time schedule for data reporting, analysis and publication that is detailed in the currently approved information collection. Grantees will report MDEs semiannually during each program year (October, April). Data validation, analysis, and report preparation and dissemination will follow. A summary timeline is provided below:

Table A16-A. Project Time Schedule

Activity	Time Schedule
Grantees submit MDE file and submission narrative on nbccedp.org	Semi-annual: April and October
Data validation, aggregation and analysis file creation sent to CDC from data contractor	2 months after MDE submission
Grantee feedback report preparation and dissemination	3 months after MDE submission
Data reviews held with grantee, CDC and data contractor	4-5 months after MDE submission
Action items generated for response in next submission (feedback loop informs the next submission)	5 months after MDE submission

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.