Extension Request
OMB No. 0920-0571, exp. 10/31/2015

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

Supporting Statement Part A

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- The goal of the study is to assess performance of state, tribal and territorial programs funded through the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) in providing underserved women access to timely breast and cervical cancer screening and diagnostic services.
- Data are used to assess program reach, service quality, and outcomes. The information allows CDC to provide routine feedback to grantees based on their data submissions, to tailor technical assistance as needed, report performance to stakeholders, and to support program planning, surveillance and secondary data analysis activities.
- Grantees collect data on clinical services provided through their programs, and report a de-identified standardized service-level record to CDC on each screening encounter.
- The population studied are low-income, uninsured and underinsured women receiving cancer screening clinical services through 67 NBCCEDP funded states, territories, and tribal organizations.
- Many data analysis methods are used. Data are aggregated at the grantee and national levels to assess performance in meeting program benchmarks and goals. Longitudinal data are used to assess patient rescreening and outcomes over time. Screening outcomes such as abnormal findings, diagnostic follow-up and cancer detection are assessed using logistic regression to estimate odds based on demographic characteristics such as age, race and ethnicity.

ABSTRACT

CDC is currently approved to collect performance indicator data from state, tribal and territorial programs funded through the National Breast and Cervical Cancer Early Detection Program (NBCCEDP). The information collection allows CDC to provide routine feedback to grantees based on their data submissions, to tailor technical assistance as needed, and to support program planning, surveillance and secondary data analysis activities. A three-year extension was approved by OMB in November 2012. The current request is to extend OMB approval for three years. No additional changes to the information collection instrument are proposed. There is no change to the estimated burden.

A. JUSTIFICATION

A1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) is requesting approval of a three-year extension for the Minimum Data Elements (MDEs) for the National Breast and Cervical Cancer Early Detection Program (NBCCEDP); OMB Control Number 0920-0571, Expiration date: 10/31/2015.

Breast cancer is a leading cause of cancer-related death among American women. The American Cancer Society (ACS) estimates that 231,840 new cases of invasive breast cancer will be diagnosed among women in 2015 and 40,290 women will die of breast disease. Mammography is extremely valuable as an early detection tool because it can detect breast cancer well before a lump is palpable, when the cancer is still in an early and more treatable stage. Women older than age 40 reduce their risk of breast cancer mortality and increase their treatment options when they receive annual mammography screening.

Papanicolaou (Pap) tests effectively detect both precancerous lesions and invasive cervical cancer. The detection and treatment of precancerous lesions can prevent nearly all cervical cancer-related deaths. Although the widespread use of Pap tests has contributed greatly to a decreased incidence of invasive cervical cancer in recent decades, the ACS estimates that 12,900 new cases will be diagnosed in 2015 and 4,100 women will die of this disease.

Congress established the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) in 1991 by enacting the Breast and Cervical Cancer Mortality Prevention Act of 1990, Public Law 101-354 (Attachment 1a). This legislation authorized the Centers for Disease Control and Prevention (CDC) to provide funding to states for the development and maintenance of early detection programs designed to ensure that under-served, low income, and under-insured women receive access to breast and cervical cancer screening services. The NBCCEDP has operated for 25 years and currently funds 67 programs including all 50 states, five U.S. Territories, 11 American Indian/Alaska Native organizations and the District of Columbia. The present agreement between NBCCEDP grantees and the CDC is outlined in Program

Announcement DP12-1205 effective 6/30/2012.

The Breast and Cervical Cancer Mortality Prevention Act of 1990 authorizes the CDC to ensure NBCCEDP grantees implement and maintain effective program components including screening, tracking, follow-up and patient navigation, quality assurance and improvement, public education and outreach, provider education, partnership development, evaluation and surveillance. In addition, grantees are funded to collect and maintain screening and follow-up data and to assure the completeness, timeliness and quality of information about women served through the program. Twice per year, grantees submit a de-identified subset of these data to CDC. These datasets, called the Minimum Data Elements (MDEs), contain patient demographic, screening and outcome data (Attachment 3a). No changes to the MDE dataset are proposed in this extension request.

The data collection authority for this study is Section 301 of the Public Health Service Act [42 U.S.C. 241] (Attachment 1b). A data contractor has been retained to assist with data management and analysis.

A2. Purpose and Use of Information Collection

The CDC uses standardized reports generated from each semi-annual MDE submission to assess performance of the national program and grantees. The CDC provides routine feedback to grantees based on their data submissions and tailors technical assistance as needed. The data are also used by the CDC for national program surveillance, planning and improvement, reporting program results to Congress and other legislative authorities, and secondary analyses by CDC's Division of Cancer Prevention and Control (DCPC) scientific staff for research purposes.

The CDC reviews the quality of MDE data in each submission to ensure data are appropriate to monitor and evaluate the program. Data accuracy and management are critical to the proper tracking and follow-up of women served by the grantee programs. Edits identify incomplete information as well as improper skip patterns between data fields and patient records. The CDC expects that less than five percent of records reported in grantee data sets contain edits.

The CDC has defined a set of core program performance indicators that use MDE data to

evaluate grantee performance in meeting NBCCEDP guidelines and expectations for service delivery, to target technical assistance needs, and to influence performance-based funding decisions. Core indicators evaluate two critical categories of performance — Screening Priority and Service Delivery.

Screening Priority Indicators assess performance in directing resources to priority populations as defined by CDC evidence-based policy. For example, the CDC expects that a minimum of 75 percent of all mammography screenings funded by the NBCCEDP be provided to women age 50 and older, where mammography is proven most effective as a screening tool. For cervical screening, the CDC prioritizes screening women who have not had a Pap test in the past five years, where the majority of cervical cancers occur. The allocation of screening resources to under-served and priority populations is essential to the NBCCEDP's mission to reduce breast and cervical cancer morbidity and mortality.

Service Delivery Indicators help to ensure that women receive high quality clinical services through the program. Grantees must meet expected standards for providing appropriate and timely patient follow-up when diagnostic evaluation and treatment services are needed. The CDC monitors the percentage of records with either an abnormal screening result or a planned diagnostic procedure that indicate complete follow-up. The amount of time that passes between abnormal screening results and diagnoses is monitored, as well as the amount of time between diagnoses and the initiation of clinically recommended treatment.

The following table summarizes the core program performance indicators and standards. Program indicators may change over time to reflect program priorities and areas of concern.
Core Performance Indicators and Standards for Service Delivery Evaluation:

Screening Priority Indicators	Initial Program Pap tests; Never or Rarely Screened	A minimum of 20% of all women receiving a first funded Pap test within the NBCCEDP should either have never had a previous Pap test, or not had a previous Pap test within the last five years.
	Screening Mammograms Provided to Women ≥ 50 Years of Age	A minimum of 75% of all mammogram screenings funded by the NBCCEDP should be provided to women ≥ 50 years of age.
Cervical Cancer Service Delivery Indicators	Abnormal Screening Results with Complete Follow-up	A minimum of 90% of records with either an abnormal screening result or a diagnostic procedure planned should indicate that diagnostic evaluation has been completed.
	Abnormal Screening Results; Time from Screening to Diagnosis > 90 Days	No more than 25% of records with a diagnostic procedure planned should exceed 90 days between the screening procedure and the final diagnosis.
	Treatment Started for Diagnosis of HSIL, CIN2, CIN3, CIS, Invasive	A minimum of 90% of records with a final diagnosis of HSIL, CIN2, CIN3, CIS or invasive carcinoma should indicate that treatment has been initiated.
	HSIL, CIN2, CIN3, CIS; Time from Diagnosis to Treatment > 90 Days	No more than 20% of records with a complete final diagnosis of HSIL, CIN2, or CIN3/CIS should exceed 90 days between final diagnosis and treatment initiation.
	Invasive Carcinoma; Time from Diagnosis to Treatment > 60 Days	No more than 20% of records with a complete final diagnosis of invasive cervical carcinoma should exceed 60 days between final diagnosis and treatment initiation.

Breast Cancer Service Delivery Indicators	Abnormal Screening Results with Complete Follow-up	A minimum of 90% of records with either an abnormal screening result or a diagnostic procedure planned should indicate that diagnostic evaluation has been completed.
	Abnormal Screening Results; Time from Screening to Diagnosis > 60 Days	No more than 25% of records with a diagnostic procedure planned should exceed 60 days between the screening procedure and the final diagnosis.
	Treatment Started for Breast Cancer	A minimum of 90% of records with a final diagnosis of invasive breast cancer should indicate that treatment has been initiated.
	Breast Cancer; Time from Diagnosis to Treatment > 60 Days	No more than 20% of records with a complete final diagnosis of invasive breast cancer should exceed 60 days between final diagnosis and treatment initiation.

The CDC also uses the MDE data to monitor grantee performance in meeting projected screening volume, to assess fiscal management and realistic goals for service delivery.

MDE data are used to report results to CDC officials, Congress, and the Office of Management and Budget. CDC's National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) has developed performance measures for the Government Performance Reporting Act (GPRA) and the Program Assessment Rating Tool (PART) that use MDE data to evaluate NBCCEDP program outcomes to include in annual reports to the Office of Management and Budget (OMB) used for budget formulation. These measures require credible data sources. The NBCCEDP measures evaluate trends in the number of women screened for breast and cervical cancer and cancers detected, and the timeliness and completeness of follow-up to diagnosis and treatment.

The data collection methodology has been successful with no problems reported by the NBCCEDP grantees. The continuation of data collection is imperative for future monitoring and evaluation of the NBCCEDP. Finally, subsets of MDE data are available to internal and external investigators, on a limited basis and with appropriate security controls, for research purposes.

A3. Use of Improved Information Technology and Burden Reduction

The CDC requires grantees to electronically report a minimum set of screening and follow-up data. The data definitions and record layouts for this file were designed by the Program Services Branch of the Division of Cancer Prevention and Control and are detailed in Attachment 3a. Grantees submit the MDE data as an electronic fixed-length text file using a secure submission web site, which simplifies the data reporting process for grantees and organizes the receipt of grantee text files by the CDC. The CDC developed and maintains a patient tracking data management software package for optional use by grantees to manage local program data and facilitate the extraction of the minimum data set. The system is a Windows-based desktop application currently used by approximately one-half of the NBCCEDP grantee programs. CDC provides any necessary technical support to grantees that use the data management system.

A4. Efforts to Identify Duplication and Use of Similar Information

There are no existing, comparable data sources available for the collection of this information. The reported screening and follow-up data provide information about women specifically enrolled and screened in the NBCCEDP and are available exclusively from NBCCEDP grantees. The consistent reporting of screening, final diagnosis, and treatment initiation data to the CDC promotes assurances that grantee programs provide appropriate and timely clinical services to women who utilize the NBCCEDP, a requirement of the law establishing the program.

The Annual Survey of the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) Grantees' Program Implementation (OMB No. 0920-1046 exp. 1/31/2018) collects standardized data on grantee activities within an evolving healthcare context. The information is used to assess the use of evidence-based interventions and non-screening partnerships to implement systems changes within health systems and communities to improve access, quality and adherence to cancer screening across a broader population than individuals receiving direct clinical services. The implementation activity data complement the MDE clinical service data to

describe different program components and assess training and technical assistance needs.

The National Program of Cancer Registries (NPCR; OMB No. 0920-0469, exp. 5/31/2016) collects data on all women diagnosed with cancer. However, NPCR data are collected and verified through medical record confirmation several months after a final diagnosis is made. The data aggregated by the NPCR do not include screening and tracking information nor do they allow for assurances that women receive appropriate and timely care prior to and following final diagnosis. The NPCR data complement the NBCCEDP by providing national population-based rates of disease for which to compare and evaluate the outcomes of a cancer screening program. The NBCCEDP data collection is unique in providing a national data set that assists the CDC in the ongoing development and maintenance of an early detection program designed to ensure access to breast and cervical cancer screening services for under-served women.

A5. Impact on Small Businesses or Other Small Entities

No small businesses are involved in this study.

A6. Consequences of Collecting the Information Less Frequently

The CDC aggregates screening and follow-up data from grantees semi-annually. This allows the CDC to regularly evaluate the overall performance of the NBCCEDP, to make adjustments toward improved effectiveness and to identify new goals as part of on-going planning efforts. It also allows the CDC to effectively monitor grantee performance and provide constructive guidance to them on a consistent basis. In addition, the semi-annual review of the screening and follow-up data enables the CDC to identify problems with timely and complete follow-up for women with abnormal screening results or diagnoses of cancer or pre-cancer. The collection of these data less frequently would compromise the ability of the CDC to perform this surveillance. The CDC is also obligated to provide annual status reports on the NBCCEDP to Congress and other CDC officials. There are no legal obstacles to reduce the burden.

A7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

These data are collected in a manner consistent with the guidelines in 5 CFR 1320.5. There are no special circumstances contained within this application.

A8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside

the Agency

A. Notice of this study was published in the Federal Register on June 25, 2015, Vol. 80, No. 122, pages 36539-36540 (Attachment 2a). One comment was received (Attachment 2b).

B. The Division of Cancer Prevention and Control has employed several methods of consultation with individuals outside of the agency regarding the proposed data collection. The NBCCEDP has a formal advisory committee, the Breast and Cervical Cancer Early Detection and Control Advisory Committee, which is comprised of 21 members. This committee is formally sanctioned by the CDC and meets annually to review relevant issues, including data issues. The formal advisory committee last convened on November 6-7, 2014, and the next meeting is scheduled for November 9, 2015. A list of the Committee members and their contact information is provided in Attachment 4.

In addition to the formal advisory committee, Program Directors, Data Managers, Quality Assurance Coordinators, and other key employees within each NBCCEDP grantee program participate in an annual conference, quarterly calls, and periodic webinars and trainings. These contacts provide an extended forum for the direct discussion of data issues between the CDC and grantee programs and an opportunity for the CDC to solicit consultation from grantee staff members. These forums also provide excellent networking opportunities for grantee staff to share their data management experiences and ideas among associates.

The CDC maintains an internal working group to review and discuss data issues as needed. This working group includes program staff, epidemiologists, medical professionals, and social scientists. Based on the issues reviewed, the work group makes related recommendations for data changes, data analyses, and other program improvements.

Finally, when specific NBCCEDP data issues and concerns arise, the CDC typically convenes a special workgroup that includes representatives from outside of the agency to

discuss the issues and develop recommendations. For example, in 2010-2011 a study to estimate the impact of implementing digital vs. film mammography in the NBCCEDP and make recommendations for changes to program policies was conducted through a collaborative modeling analysis using two Cancer Intervention and Surveillance Modeling Network (CISNET) breast cancer models from Georgetown University and Erasmus Medical Center in the Netherlands. In 2011 and 2014, the CDC and the American Cancer Society sponsored a study by George Washington University to analyze the effects of the Patient Protection and Affordable Care Act on breast, cervical and colorectal cancer screening and treatment services to understand the potential impact of the law on the population and identify gaps and barriers remaining after implementation of the new law. In both studies, MDE data were used in part to model impact.

A9. Explanation of Any Payment or Gift to Respondents

Not Applicable.

A10. Protection of the 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. Although grantees have access to personally identifiable information in order to deliver services, only de-identified records are transmitted to CDC and the data management contractor.

The risk of direct identification of an individual in the MDE is remote because personally identifying information (name, SSN, address) data is not reported to CDC. However, a unique identifier assigned by the grantee to each client screened is reported to CDC. While each record constitutes a single screening test cycle, it is necessary to identify multiple screenings provided to the client to track appropriate re-screening over time and to track the number of unique individuals served by the program. The grantees maintain the linkage information between the identification codes and the personal identifiers in their database in order to respond and follow-up on quality assurance data queries from the CDC.

Additional information can be found in Attachment 11: Supplemental Grantee Data Collection and Privacy Information.

A11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

The study protocol for the collection of this information, CDC Protocol #1976, received approval of continuation from the CDC Institutional Review Board (IRB) through May 17, 2016, (Attachment 5).

This data collection includes sensitive information about cancer diagnosis and treatment, which is central to the purposes of the program evaluation and oversight and to ensure timely and adequate clinical follow-up of women screened through the program. In addition, race and ethnicity data are collected per HHS guidelines and for use in epidemiologic analyses.

A12. Estimates of Annualized Burden Hours and Costs

A. The requested screening and follow-up data are already collected and maintained by NBCCEDP grantee programs. Therefore, the additional burden for data reporting is small and only entails the time needed to generate and submit an electronic data file. Grantees report the screening and follow-up data to the CDC on a semi-annual basis. The estimated respondent burden of 536 hours across all 67 grantees for generating and reporting this information is based upon use of the data management system and submission web site developed and maintained by the CDC to perform these exact functions. The CDC also received voluntary consultation from not more than six respondents regarding the estimated burden of reporting these data. The total estimated annualized burden hours are 536.

Table A12A. Number of Respondents and Estimated Burden Hours:

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
NBCCEDP Grantees	Minimum Data Elements	67	2	4	536

B. The estimated annualized cost to respondents is based upon the mean hourly wage plus benefits of grantee Data Managers as reported in NBCCEDP cooperative agreement awards. Grantee Data Managers are estimated to earn a mean hourly wage of $25.97 plus a 25 percent allowance of $6.49 for benefits, for an estimated hourly wage plus benefits of $32.46. The estimated annualized cost for each grantee Data Manager to report the MDE data is estimated as $259.68. The total estimated annualized cost to respondents is $17,398.

Table A12B. Estimated Annualized Cost to Respondents:

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Average Hourly Wage	Total Cost
NBCCEDP Grantees	Minimum Data Elements	67	2	4	$32.46	$17,398

A13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

None.

A14. Annualized Cost to the Federal Government

Total operation and maintenance costs include work performed by the data contractor and CDC personnel. The data contractor is funded at an annual cost of $1,108,487 for data management support for the NBCCEDP. Data contractor MDE-related activities, included in the table below, are estimated at $720,517 annually for 4.5 full time employees. MDE activities include data processing, data analysis and data systems maintenance. Data contractor NBCCEDP program administration activities are estimated at $387,970 annually for 2.4 full time employees. Data contractor NBCCEDP program administration activities include administration, technical support, training, and other direct costs. CDC personnel costs are estimated at $218,901 annually for 1.4 full time data managers and 0.5 program analyst. The following table summarizes the estimated Federal Government cost distribution.

Estimated Annualized Federal Government Cost Distribution:

	Annualized Cost
CDC Personnel Subtotal	$218.901
Data Contractor Subtotal	$720,517
Total	$939,418

A15. Explanation for Program Changes or Adjustments

There is no change to the total estimated annualized burden hours or average burden per response since the previous extension request was approved by OMB in November 2012.

A16. Plans for Tabulation and Publication and Project Time Schedule

The CDC requests a 3-year extension for this recurring data collection. The screening and tracking data sets are reported by grantees in April and October of each year. The data files include cumulative data from the beginning date of each grantee's funded screening services up to the current reporting date. The data are formatted and analyzed within 40 working days of reporting, and analysis reports are developed within 60 working days of the reporting date. The following table summarizes the time schedule for data reporting, analysis and publication.

Time Schedule for Data Reporting, Analysis and Publication:

Tasks	Schedule
Screening and tracking data reported	April 15 and October 15 of each year
Raw data reviewed	30 working days after each data submission
Data analysis file created	40 working days after each data submission
Standardized surveillance reports generated	60 working days after each data submission
Primary Statistical Reports	Produced semi-annually for publication
Planned Publications	Produced every 2-3 years for publication
Special Research Projects	Produced periodically for publication

The CDC uses the screening and tracking data reported by grantees to produce three categories of publications: Primary Statistical Reports, Planned Publications, and Special Research Projects.

The Primary Statistical Reports are standardized, semi-annual reports that include basic statistics

and outcome variables by race and age. These are formal reports for use by CDC staff. In addition, the program maintains a web-based report on the CDC public website to report grantee-specific and national aggregate program performance to the public.

Planned Publications are formal reports that include multi-variate analyses of the minimum data set and an examination of test characteristics. These reports are reserved for inclusion in publications such as Morbidity and Mortality Weekly Report (MMWR) and presentations at conferences. These publications are also be posted to the CDC web site and included in peer review journals. The CDC expects these publications to be produced every 2-3 years. Significant publications include the 2003-2012 National Report scheduled for publication in 2015 as a supplement to the *1991–2002 National Report, Summarizing the first 12 years of the National Breast and Cervical Cancer Early Detection Program*. This report provides information on the program's framework, history, and future direction in addition to data on breast and cervical cancer screening outcomes for women served through the program. A monograph, *National Breast and Cervical Cancer Early Detection Program: Two Decades of Service to Underserved Women*, was published in a 2014 Supplement to CANCER, providing a 20 year retrospective of NBCCEDP services and impact and included several manuscripts detailing the importance and use of the MDE data within the program. Another collection of manuscripts describing the reach and health impacts of the program was published in 2015 in Cancer Causes & Control, *Special Issue: Breast and Cervical Cancer Early Detection Program*. These publications utilized the MDEs to assess program clinical outcomes, the implementation of a performance management system for the program, trends in the size and reach of the program's eligible population, and the effectiveness of targeting program priority populations.

A17. Reason(s) Display of OMB Expiration Date is Inappropriate

There is no request for an exemption from displaying the expiration date for OMB approval.

A18. Exceptions to Certification for Paperwork Reduction Act Submissions

These data are collected in a manner consistent with the certification statement. No exceptions are requested.