

**Extension Request**  
**OMB No. 0920-0571, exp. 1/31/2010**

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

**Supporting Statement Part A**

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- Attachment 1b: Section 301 of the Public Health Service Act [42 U.S.C. 241]
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## **ABSTRACT**

CDC is currently approved to collect performance indicator data from state 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 modification to the content of the information collection was approved by OMB in June 2008. The current request is to extend OMB approval for three years. No additional changes to the information collection instrument or the burden estimate are proposed.

### **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: 01/31/2010.

Breast cancer is a leading cause of cancer-related death among American women. The American Cancer Society (ACS) estimates that 192,370 new cases of invasive breast cancer will be diagnosed among women in 2009 and 40,170 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 11,270 new cases will be diagnosed in 2009 and 4,070 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 19 years and currently funds 68 programs including all 50 states, five U.S. Territories, 12 American Indian/Alaska Native organizations and the District of Columbia. The present agreement between NBCCEDP grantees and the CDC is outlined in Program Announcement DP07-703.

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 case management, 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 (see Attachment 3). The current set of MDEs reflects changes approved by OMB in June 2008 and fully implemented with the 2009 data transmissions.. The changes included minor modifications of some MDE data elements as well as discontinuation of underutilized infrastructure elements (System for Technical Assistance Reporting, “STAR”). No additional changes 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 $\geq$ 50 Years of Age	A minimum of 75% of all mammogram screenings funded by the NBCCEDP should be provided to women $\geq$ 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 > 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 Diagnosis of HSIL, CIN II, CIN III, CIS, Invasive	A minimum of 90% of records with a final diagnosis of HSIL, CIN II, CIN III, CIS or invasive carcinoma should indicate that treatment has been initiated.

	HSIL, CIN II, CIN III, CIS; Time from Diagnosis to Treatment > 90 Days	No more than 20% of records with a complete final diagnosis of HSIL, CIN II, or CIN III/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 Program Rating Assessment Tool (PART) that use MDE data to evaluate NBCCEDP program outcomes in annual reports to the Office of Management and Budget (OMB). PART measures require credible data sources. The NBCCEDP PART measure evaluates trends in cervical cancer incidence among women receiving Pap tests through the program. In 2008, MDE data were also used to report program

performance and outcome data to a comprehensive Government Accounting Office (GAO) study of the Medicaid Treatment Act and the NBCCEDP.

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 3. 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 Economic Analysis of the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) (OMB No. 0920-0776 exp. 3/31/2011) collects activity-based cost information from NBCCEDP grantees to support analysis of the costs and cost-effectiveness of the NBCCEDP. The information will be used to assess the costs of various program components, identify factors that impact average cost, perform cost-effectiveness analysis, and to develop a resource allocation tool for ensuring the most appropriate use of limited program resources. The MDE data complement the cost data collection by providing the effectiveness measure for the cost-effectiveness analyses of the program.

The National Program of Cancer Registries (NPCR; OMB No. 0920-0469, exp. 1/31/2010) 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. Because it is imperative that the CDC monitor the timely and appropriate delivery of diagnostic and treatment services, it is not feasible for the NBCCEDP to wait until the NPCR provides its end-result data. 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 4/22/2009, Vol. 74, No. 76, pages 18384-18385 (Attachment 2). [No public comments have been received.](#)
- 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 22 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 June 16-17, 2009, and met previously in March 2008. 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 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 2008 the CDC convened a workgroup to address new imaging technology for breast cancer detection, to evaluate program impact and make recommendations for changes to program policies. Another workgroup in 2008 addressed the impact of updated consensus guidelines for the management of women with abnormal cervical cancer screening tests and recommended corresponding changes to MDE algorithms that evaluate adequacy of clinical follow-up within the program.

#### **A9. Explanation of Any Payment or Gift to Respondents**

Not Applicable.

#### **A10. Assurance of Confidentiality Provided to Respondents**

Staff in the CDC Information Collection Review Office have reviewed this application and have determined that the Privacy Act does not apply. Although grantees have access to personally identifiable information, only de-identified data records are transmitted to CDC. Additional information on privacy safeguards applicable to data collection, de-identification, coding, transmission, storage, and reporting appears below.

Confidentiality is of the utmost importance to the CDC. The NBCCEDP grantees collect personally identifiable information on each woman served (e.g., name, address, social security number, age, race/ethnicity) along with information about each woman's screening history, the screening and diagnostic procedures provided, and the results of those procedures. If cancer or pre-cancer is diagnosed, then information about treatment initiation and stage of disease is also collected. Although the variables and data collection instruments vary among grantees, the grantees standardize the data format before reporting them. Grantees remove most personal identifiers and assign a unique code for each woman in the database prior to the electronic transfer of a data file to the data contractor. The unique patient ID number is created by each grantee and most use a sequential number so that patients are identified as patient #1, #2, etc. Each grantee maintains the linkage information between the unique codes and the personal identifiers in their local database in order to respond to and follow-up with specific providers about an individual woman or to respond to data queries from the CDC. The unique method of record identification allows the CDC to anonymously track each woman served throughout her involvement with the NBCCEDP. The identifying data provided to the data contractor include

patient ID number, county of residence, state of residence, zip code of residence, race, date of birth, and Hispanic origin. The linkage information is never provided to the data contractor or the CDC, nor is identifying information on women beyond the variables noted above. 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, 2010. (Attachment 5).

The grantee programs also maintain the encryption scheme between their unique codes in the MDE data and the personal identifiers in their database. Neither the encryption scheme nor identifying information on women, other than the variables noted, will ever be provided to the CDC or the data contractor.

The CDC does not anticipate the development of a public-use data set using the NBCCEDP data. Formal reports will be developed for publication both semi-annually and periodically. These reports will present results from the program based upon demographic information such as age and race, and reported as national aggregate data rather than grantee-specific. A limited set of grantee-specific data reported in a five-year aggregate are available to the public on the CDC Web site. Reports do not include record identifiers. Reports are disseminated to the public through the CDC public web site, peer review journals, and publications. Secondary analysis of data for the purposes of research is conducted to address specific research questions concerning breast and cervical cancer screening.

Investigators outside of the agency are permitted to submit a proposal to the CDC requesting use of the national data set. Each proposal is reviewed internally by a committee comprised of designated representatives from each Branch in the DCPC who are knowledgeable about the data set, its uses, and limitations. Upon review by the committee, each proposal is approved, denied, or the investigator is asked to provide additional information. Investigators who submit successful proposals to the CDC are required to sign a Data Sharing Agreement for Special Usage Form (Attachment 6) indicating they agree to comply with the provisions outlined for data use. Successful applicants do not gain access to the entire data set. The CDC develops and provides to each successful applicant a custom data set that meets the minimum needs of their proposal. The CDC replaces all encrypted identifiers in custom data sets with randomly generated record identifiers that cannot be linked back to the CDC database or to any of the identifying information maintained in the grantee databases.

#### **A11. Justification for Sensitive Questions**

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 544 hours across all 68 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 544.

Table A12A. Number of Respondents and Estimated Burden Hours:

Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
NBCCEDP Grantees	68	2	4	544

- 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 cost to respondents is \$17,658.

Table A12B. Estimated Annualized Cost to Respondents:

Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Average Hourly Wage	Total Cost
NBCCEDP Grantees	68	2	4	\$32.46	\$17,658

**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 \$1,372,335 for a five-year total of \$6,861,673. Data contractor MDE-related activities, included in the table below, are estimated at

\$850,848 annually for 6.5 full time employees. MDE activities include data processing, data analysis and data systems maintenance. Data contractor NBCCEDP program administration activities are estimated at \$521,487 annually for 4.0 full time employees. Data contractor NBCCEDP program administration activities include administration, technical support, training, and other direct costs. CDC personnel costs are estimated at \$170,258 annually for 1.3 full time data managers and 0.2 public health analyst. The following table summarizes the estimated Federal Government cost distribution.

**Estimated Annualized Federal Government Cost Distribution:**

	Annualized Cost
CDC Personnel Subtotal	\$170,258
Data Contractor Subtotal	\$850,848
Total	\$1,021,106

**A15. Explanation for Program Changes or Adjustments**

There are no changes to the number of respondents, the average burden per response, or the total estimated annualized burden hours since approval of the Change Request in June 2008.

**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 of each year
Raw data reviewed	30 working days after data submission
Data analysis file created	40 working days after data submission
Standardized surveillance reports generated	60 working days after data submission
Screening and tracking data reported	October 15 of each year
Raw data reviewed	30 working days after data submission
Data analysis file created	40 working days after data submission

Standardized surveillance reports generated	60 working days after 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 will 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 [1991–2002 National Report](#), summarizing the first 12 years of the National Breast and Cervical Cancer Early Detection Program, with a 5-year update projected for publication in 2009. This report provided 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.

Special Research Projects will be reports on topics of interest to CDC researchers that are for publication in peer reviewed journals. The CDC expects these projects to be developed periodically. Two publications in 2008 led by CDC health economists examined the costs of screening: *Estimating Personal Costs Incurred by a Woman Participating in Mammography Screening in the NBCCEDP*, Ekweume et al; and *Identifying and controlling for program-level differences in comparative costs analysis: Lessons from the economic evaluation of the NBCCEDP*, Subramaniam, et al. A 2006 publication on breast cancer screening, and a companion manuscript currently in peer-review on cervical cancer screening, estimate the eligible population and reach of the program to medically underserved women in this country: *Meeting the mammography screening needs of underserved women: the performance of the National Breast and Cervical Cancer Early Detection Program in 2002–2003 (United States)*, Tangka, et al.

#### **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.