

Extension Request
OMB No. 0920-0571, exp. 11/30/2012

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

Supporting Statement Part B

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LIST OF ATTACHMENTS

- Attachment 1a: Public Law 101-354, The Breast and Cervical Cancer Mortality Prevention Act of 1990
- Attachment 1b: Section 301 of the Public Health Service Act [42 U.S.C. 241]
- Attachment 2a: Federal Register Notice
- Attachment 2b: Summary of Public Comments and CDC Response
- Attachment 3a: MDE Data Items and Definitions Required for Reporting
- Attachment 3b: Web-based Portal for MDE Submission
- Attachment 4: Participants in Consultation Outside of the Agency
- Attachment 5: CDC Institutional Review Board - Approval Notification
- Attachment 6: Data Sharing Agreement Form
- Attachment 7: Map of National Breast and Cervical Cancer Early Detection Program Grantees
- Attachment 8: Estimated Data Reporting
- Attachment 9: Data Collection and Processing Flowchart
- Attachment 10: Data Surveillance Reports

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

B1. Respondent Universe and Sampling Methods

The respondents are the 67 NBCCEDP grantees that currently receive CDC funds to develop and maintain comprehensive breast and cervical cancer screening and tracking programs (Attachment 7). The CDC expects a continued response rate of 100% for data reporting since an established working relationship currently exists between the NBCCEDP grantees and the CDC. In addition, the CDC requires the data submissions as a stipulation of the NBCCEDP Program Announcement and the cooperative agreement notice of grant awards to all grantees.

Sampling methods are not employed. Screening and follow-up data collection is performed at the grantee level on every woman enrolled in the NBCCEDP and is reported to the CDC semi-annually. The CDC estimates that the funding currently available to the NBCCEDP enables it to reach 13.2% of women aged 40-64 eligible for breast cancer screening and 8.7% of women aged 18-64 eligible for cervical cancer screening through the program. Grantees will report cumulative data sets dating back to the establishment of their original cooperative agreement with the NBCCEDP. To date, over 4 million women have received breast and cervical screening services through the NBCCEDP. The plot provided in Attachment 8 lists the number of women served collectively by grantee programs in each program year of the NBCCEDP from 1991 - 2011.

B2. Procedures for the Collection of Information

NBCCEDP grantees are funded to aggregate screening and follow-up data for the breast and cervical services they provide. The Data Collection and Processing Flowchart provided in Attachment 9 indicates that data collection begins at a grantee (program) site where clients are enrolled in the program and screening procedures are provided. The data are entered into the grantee's data management system used to track patients and services. A subset of these data are exported to a standard MDE file. The MDE file is electronically submitted to the data contractor (IMS) on the semi-annual reporting dates using a secure submission web site. A submission narrative document that briefly summarizes any known data issues at the time of MDE file submission accompanies the MDE file.

The data contractor logs and archives each MDE file received from the grantees. A preliminary review validates expected format and record counts and, if necessary, clarification is requested from grantees. The data are then used to generate grantee-specific reports that identify blank, invalid and illogical values across all data fields.

After preliminary data quality checks are completed, the data contractor creates an aggregate analysis file for generating standardized NBCCEDP surveillance reports and special CDC requests. The analysis file is also used to generate grantee-specific reports about the quality, completeness and timeliness of clinical data. The Management Report provides feedback on data quality and completeness within the most recent 18 months of data reporting using tables and record audits. Plots and graphs provide program year data for age and race demographics, counts of women served, procedures performed and cancer incidence. The Data Quality

Indicator Guide Report (DQIG) provides a five-year trend of record counts, percentages and expected ranges for specific data quality items. In addition, a Core Indicator Report assesses the program performance indicators and standards for service delivery evaluation provided in Section A2 of the Supporting Statement. Attachment 10 provides an example of each feedback report discussed above. Once the feedback reports are provided to the grantees, they are given the opportunity to discuss the reports and their methods of data management with the CDC and the data contractor.

The CDC acknowledges the potential delay between screening services and data entry. Thus, grantees are expected to report complete demographic and screening data for all records with a procedure date more than 3.5 months prior to the reporting date; and they are expected to report complete final diagnosis and treatment initiation data for all records with a procedure date more than 9.5 months prior to the reporting date. The following table provides examples of the cutoff dates for complete data reporting.

Cutoff Dates for Complete Data Reporting by Grantees:

Semi-annual Reporting date	Screening cutoff date for providing complete demographic and screening data	Screening cutoff date for providing complete final diagnosis and treatment initiation data
April 15, 2012	December 31, 2011	June 30, 2011
October 15, 2012	June 30, 2012	December 31, 2011

B3. Methods to Maximize Response Rates and Deal with Non-response

As an established program, the CDC expects that all NBCCEDP grantees will continue to report data in a timely manner with OMB approval of the requested extension. In addition, the CDC requires the data submissions as a stipulation of the Program Announcement and the cooperative agreement notice of grant award. Respondents that have difficulty with a data submission are provided technical assistance by the CDC Project Officer and/or the data contractor. The schedule for data reporting remains consistent each year as presented in Section A16 of the Supporting Statement. The current use, by some grantees, of a data management system developed and maintained by the CDC facilitates their ability to comply with the request for reporting screening and follow-up data. Grantees using an alternate data management system should also find little difficulty in the request for the continued reporting of screening and follow-up data because it is transmitted electronically as an ASCII text file, which is a common format for data interchange. The data definitions for the text file are provided in Attachment 3a.

Professional training in the use of the data reporting system is available for grantee Program Directors and Data Managers at the NBCCEDP annual business meeting as well as in live and recorded webinars. On-site training is also available from the data contractor as needed. Grantees receive an independent and detailed assessment of their data quality and completeness from the data contractor, providing an additional incentive for reporting the requested data. Data reporting benefits each grantee program by aiding their patient tracking and data collection methods.

Grantees also receive a Data User's Manual that provides complete written instruction regarding data submission requirements, data variables, data field descriptions, report descriptions, etc. The manual supports consistent submissions across grantee programs. The manual is accessible through a secure, password-protected web site for NBCCEDP data managers and program directors maintained by the data contractor.

B4. Tests of Procedures or Methods to be Undertaken

The data management and reporting systems developed and maintained by the CDC have been internally tested by NBCCEDP staff and the data contractor. From 2005-2007, CDC conducted a comprehensive evaluation of the accuracy of the national MDE dataset to assess the correlation between data in the MDE database and the patient medical records to inform data collection and usage. Overall, results indicated that measures of program outcomes reported using the MDE data are accurate and reflect the true number of cancers detected by the NBCCEDP. Based on the results from this evaluation, recommendations were developed for additional clarification of some data items and changes in data collection for others to improve the consistency of data collected across programs. A number of issues identified were addressed through changes to the MDE data definitions and data collection approved by OMB on 6/7/2008.

B5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The data collection was designed by the Division of Cancer Prevention and Control, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway NE, Mail Stop K-52, Atlanta, GA 30341-3717.

The CDC Project Officer for the data management contract is Janet Royalty, MS (770-488-3085), Data Manager at the Program Services Branch, Division of Cancer Prevention and Control, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway NE, Mail Stop K-57, Atlanta, GA 30341-3717.

Data analysis is performed by the data contractor, Information Management Services, Inc. (IMS), under the direction of Mr. David Roney, Corporate Officer (301-680-9770), 12501 Prosperity Drive, Suite 200, Silver Spring, MD 20904. NBCCEDP data collection and data quality standards are formulated and recommended by the Program Services Branch of the Division of Cancer Prevention and Control and the Division's NBCCEDP data working group.