OMB Clearance Request

Minimum Data Elements (MDEs)/System for Technical Assistance Reporting (STAR) for the National Breast and Cervical Cancer Early Detection Program (NBCCEDP)

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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) and System for Technical Assistance Reporting (STAR) for the National Breast and Cervical Cancer Early Detection Program (NBCCEDP); OMB Control Number 0920-0571, Expiration date: 11/30/2006. State, territorial, and American Indian/Alaska Native organizations report breast and cervical cancer screening data to the CDC in a minimum data format. Infrastructure data is reported to the CDC via STAR.

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 1). 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 initially funded four state programs and has expanded to currently fund 68 total programs including all 50 states, four U.S Territories, 13 American

Indian/Alaska Native organizations and the District of Columbia. The present agreement between NBCCEDP grantees and the CDC is outlined in Program Announcement 02060.

Breast cancer is a leading cause of cancer-related death among American women. The American Cancer Society (ACS) estimated that 211,240 new cases of invasive breast cancer would be diagnosed among women in 2005, and 40,410 women would 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 estimated that 10,370 new cases would be diagnosed in 2005 and 3,710 women would die of this disease.

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 its completeness, timeliness and quality. The CDC requires that grantees report these data to the CDC for formatting and analysis to ensure an effective method of evaluating their performance, and to facilitate the continuing surveillance of a national screening and tracking program for the early detection of breast and cervical cancer. The data collection authority for this study is Section 301 of the Public Health Service Act [42 U.S.C. 241] (Attachment 2).

A2. Purpose and Use of Information Collection

The NBCCEDP is designed to ensure that breast and cervical cancer screening services are available for under-served, low income, and under-insured women through grantee programs. The CDC aggregates data about grantee infrastructure annually, and data about grantee screening and tracking performance semi-annually. Attachment 3 provides a list of the data items the CDC currently requires, which have not changed since receiving current OMB

approval in 2003. These data include the Minimum Data Elements or MDEs, and infrastructure data collected through the System for Technical Assistance Reporting (STAR). A data contractor, Information Management Services, Inc. (IMS) has been retained to assist with data management and analysis. Based on the semi-annual MDE submissions, standardized reports are generated by IMS for the grantees and the CDC. These reports allow regular data reviews for surveillance, completeness, timeliness and quality as part of program monitoring and evaluation. The data are also regularly used by the CDC for program planning and program improvement. The CDC provides regular feedback to grantees based on their data submissions and tailors technical assistance as needed. The MDE data set also allows for secondary analyses by Division of Cancer Prevention and Control epidemiologists for research purposes.

IMS also processes the STAR data that are reviewed annually to assess the status of program infrastructure. Again, IMS produces regular STAR reports for the grantees and the CDC to review for program monitoring.

In addition, the CDC has developed a set of program performance indicators that are assessed annually. Data from the MDEs and STAR are reflected in three categories of performance indicators:

Program and Fiscal Management, Infrastructure, and Service Delivery.

Program and Fiscal Management indicators reflect the ability of grantees to plan and implement ongoing program management. For example, the CDC reviews the allocation of funds, expecting that a minimum of 60% of funds expended by a grantee program are used to pay for screening and diagnostic services, lab fees and support services directly related to screening services such as patient tracking and case management. This 60% requirement is a stipulation of the Breast and Cervical Cancer Mortality Prevention Act of 1990, Public Law 101-354 (Attachment 1).

The CDC also monitors the ability of each grantee to reach a self-projected screening level, reflecting the ability of the grantee program to set and reach realistic goals for service delivery. The CDC has set a target for grantee programs to reach at least 90% of their projected screening numbers, but not to exceed 100% of their projection. Exceeding targeted screening levels may put grantees at risk for budget shortfalls. The CDC also monitors the difference between the funds awarded to a grantee and the funds spent by the grantee. The CDC expects that grantees should spend between 75 - 100% of their annual awards. This measure reflects the ability of grantees to spend their

award and reduce the level of carry-over funds.

Infrastructure indicators monitor the ability of grantees to effectively maintain the staff necessary for program management. Frequent staff turnover or persistent vacancies may indicate a problem with program systems or management. The CDC expects 80% of key staff positions to be continually filled by the grantee program. Non-staffed positions are defined by the CDC as a vacancy of six months or more.

Service Delivery indicators help to ensure that grantees provide complete and timely screening and follow-up services to women in priority populations. The CDC monitors the percentage of records with either an abnormal screening result or a planned diagnostic procedure that contain complete follow-up information. The amount of time that passes between abnormal screening results and their diagnoses is monitored, as well as the amount of time between diagnoses and the initiation of treatment, as clinically recommended. The following table provides the performance indicators and standards that are utilized for service delivery evaluation. These program indicators may change over time to more accurately reflect program priorities and areas of concern.

Performance Indicators and Standards for Service Delivery Evaluation:

Screening Indicators	Initial Program Pap tests; Never of 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 Diagnostic 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 Diagnostic 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 monitors the percentage of records with one or more errors in grantee data submissions. Data accuracy and management are critical to the proper tracking and follow-up of women served by the grantee programs. Errors include incomplete information as well as improper skip patterns between data fields and patient records. The CDC expects that ≤ 5% of records reported in grantee data sets contain errors.

In addition, the Division of Cancer Prevention and Control has developed specific measures for the Government Performance Results Act, or GPRA. We are required by the Act to develop and assess performance measures for the NBCCEDP and report them to

the Office of Management and Budget (OMB). Data, whether MDE, STAR, GPRA indicators or program performance indicators, are also used for reporting to CDC officials, Congress, and other national stakeholders.

Since receiving OMB approval in September 2002, the CDC has used the MDE and STAR data for program monitoring and surveillance purposes. The data provide valuable information to monitor program performance, in particular, to assure that women receive timely and appropriate diagnostic and treatment services through the NBCCEDP. In addition, the MDE and STAR data allow the CDC to monitor data and program quality and provide meaningful technical assistance to grantee programs. The data collection methodology has been successful with no problems reported by the NBCCEDP grantee programs. The continuation of data collection is imperative for future monitoring and evaluation of the NBCCEDP. In addition, the data are used to report to other departments within the CDC, Congress, and the Office of Management and Budget.

A3. Use of Improved Information Technology and Burden Reduction

Grantees report infrastructure data using a secure, web-based system developed and maintained by the CDC (Attachment 4). The web-based system facilitates data entry by allowing grantees

access to the system at any location with an internet connection, and by permitting multiple users at a grantee program to access and enter data into the system simultaneously. The system eliminates software installation and upgrades by grantees and provides a secure archive location for their data. The system features a dynamic, online help file that is kept current by the CDC and allows for concurrent access to the data files if grantees require technical assistance from the CDC. In addition, the system allows grantees to import their infrastructure data from the previous year to use as a template for their next annual data submission.

The CDC also requires grantees to electronically report a minimum set of screening and follow-up data. The CDC developed and maintains a data management software package designed to facilitate the data entry, quality assurance, and reporting of the minimum data set. The system is a Windows-based application currently used by approximately one-half of the NBCCEDP grantee programs. The CDC provides any necessary technical assistance to grantees that use the data management system. Grantees report the data set as an electronic, fixed-length text file. 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. The CDC has developed

and supports a new, secure, password-protected submission web page where grantees now post their text files once prepared. This submission web site simplifies the process of reporting screening and follow-up data for grantees, and organizes the receipt of grantee text files by CDC; but does not reduce grantee burden of reporting screening and follow-up data.

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 the infrastructure data 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 National Program of Cancer Registries (NPCR) 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 does not include screening and tracking

information nor does it 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 workable for the NBCCEDP to wait until the NPCR provides their 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 infrastructure data from grantees annually and 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 adequate 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 3/29/2006, Vol. 71, No. 60, pages 15748-15749. The burden hours were incorrectly reported in the FRN and are corrected in subsequent reports. No public comments were 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 21 members. This committee is formally sanctioned by the CDC and meets semi-annually to review relevant issues, including data issues. The formal advisory committee last convened on December 6-7, 2005, and met previously in May 2005 at an annual business meeting for NBCCEDP grantee Program Directors. A list of the Committee members and their contact information is provided in Attachment 6.

In addition to the formal advisory committee, Data Managers and other key employees within each NBCCEDP grantee program participate in an annual conference for grantee Data Managers and on semi-annual National Data Conference Calls. Both 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. Both forums also provide excellent networking opportunities for grantee staff to share their data management experiences and ideas among associates.

The CDC maintains a working group to review and discuss data issues once each month. This work 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 2005, the CDC convened two expert panels, breast and cervical, to address new technology in cancer detection, recommend changes to program policies for reimbursement of new clinical procedures, and evaluate the impact of policy changes on program components including data management. Another workgroup that included representatives from grantee programs convened in 2005 to evaluate algorithms used to assess NBCCEDP program performance.

A9. Explanation of Any Payment or Gift to Respondents

Not Applicable.

A10. Assurance of Confidentiality Provided to Respondents

The CDC Privacy Act Officer has reviewed this application and has 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 personal identifiers 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, the results of those procedures; and if cancer or pre-cancer is diagnosed, then information about treatment initiation and stage of disease. Although the variables and data collection instruments vary among grantees, the grantees standardize the data categories before reporting them. Grantees remove personal identifiers and assign a unique code for each woman in the database prior to the electronic transfer of a data file to IMS. 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 program maintains the linkage information between the unique codes and the personal identifiers in their database in order to respond to and follow-up with specific providers about an individual woman or 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 IMS 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 IMS or the CDC, nor is identifying information on women beyond the variables noted above given to IMS or the CDC. 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 13, 2007. (Attachment 7).

The grantee programs maintain the encryption information between their unique codes 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 IMS.

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 biennially 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 will be available on the CDC public web site. Reports will not include record identifiers. The reports will be 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 that submit successful proposals to the CDC are required to sign a Data Sharing Agreement Form (Attachment 8) 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. Grantees report the requested infrastructure data to the CDC annually. The total estimated respondent burden across all 68 grantees is 1,700 hours for reporting infrastructure data. This estimate is based upon internal testing of the CDC's web-based system developed for the exact purpose of reporting this information. In addition, the CDC received voluntary consultation from six respondents regarding the

estimated burden of reporting this data. The burden of reporting infrastructure data to the CDC is reduced by the web-based system features detailed in section A3 of the Supporting Statement. The burden is further reduced by a consistent annual reporting schedule. Table A12A summarizes the number of respondents and estimated burden hours.

Table A12A. Number of Respondents and Estimated Burden Hours:

Report	Number of Respondents	Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Infrastructure Report (STAR)	68	1	25	1,700
Screening and Follow-up (MDE)	68	2	4	544
Total	68	3	33	2,244

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. This burden has been further reduced by the development of the submission web page noted in Section A3. 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 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 this data.

B. The estimated annualized cost to respondents for the hour burden of reporting infrastructure, screening and follow-up information 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 $25.21 plus a 25% allowance of $6.31 for benefits, for an estimated hourly wage plus benefits of $31.52. As indicated in Table A12A,

the estimated annualized hour burden for each Data Manager to report infrastructure, screening and follow-up data is 33 hours. Therefore, the annualized cost for each grantee Data Manager to report the STAR and MDE data, provided in Table A12B, is estimated as $1,040.16.

Table A12B. Estimated Annualized Cost to Respondents:

	Mean Hourly Wage Plus Benefits	Total Annualized Hours	Total Annualized Cost to Respondents
Each Grantee Data Manager	$31.52	33	$1,040.16
Total: (68 Grantee Data Managers)	$31.52	2,244	$70,730.88

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, Information Management Services, Inc. (IMS) and CDC personnel. IMS is funded at an annual cost of $1,372,335 for a five-year total of $6,861,673. IMS MDE/STAR related activities, included in the table below, are estimated at

$782,231 annually for 6.0 full time employees. MDE/STAR activities include data processing, data analysis and data systems maintenance. IMS NBCCEDP program administration activities are estimated at $590,104 annually for 4.5 full time employees. IMS NBCCEDP program administration activities include administration, technical support, training, and other direct costs. CDC personnel costs are estimated at $209,520 annually for 1.8 full time data managers and 0.2 public health advisor. The following table summarizes the estimated Federal Government cost distribution.

Estimated Annualized Federal Government Cost Distribution:

A15. Explanation for Program Changes or Adjustments

The total annualized burden decreased from 2,343 hours to 2,244 hours due to a decrease in the number of respondents from 71 to 68. However, the annualized burden in hours per respondent did not change; nor did the reporting requirements.

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 date for the reporting of infrastructure data is October 31 annually. The following table summarizes the time schedule for data reporting, analysis and publication.

Time Schedule for Data Reporting, Analysis and Publication:

The CDC plans to use 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 will be standardized, biennial reports that include basic statistics and outcome variables by race and age. These reports will include formal reports for use by CDC staff and internet publications posted to the CDC web site for dissemination to the public.

Planned Publications will be formal reports that include multi-variate analyses of the minimum data set and an examination of test characteristics. These reports will be 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 will be produced every 2-3 years. Significant publications in 2005 included the 1991–2002 National Report, summarizing the first 12 years of the National Breast and Cervical Cancer Early Detection Program. 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. Also in 2005, the program initiated a web-based report on the CDC public website to report grantee-specific results from 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. A recent publication under peer-review estimates the eligible population and reach of the program to medically underserved women in this country.

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 identified in Item 19 "Certification for Paperwork Reduction Act Submissions" of OMB Form 83-I. No exceptions are requested.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

B1. Respondent Universe and Sampling Methods

The respondents are the 68 NBCCEDP grantees that currently receive CDC funds to develop and maintain comprehensive breast and cervical cancer screening and tracking programs (Attachment 9). The CDC expects a continued response rate of 100% for data reporting since an established working relationship currently exists between the NBCCEDP grantee programs 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 only enables it to reach 12-16 % of the eligible population aged 40-64. Grantees will report cumulative data sets dating back each year to the establishment of their original cooperative agreement with the NBCCEDP. To date, over 2.6 women have received breast and cervical screening services through the NBCCEDP. The plot provided in Attachment 10 lists the number of women served collectively by grantee programs in each program year of the NBCCEDP from 1991 - 2005.

B2. Procedures for the Collection of Information

The Program Director for each grantee program is responsible for aggregating the infrastructure data necessary for annual reporting. The web-based system allows the grantees to enter or update information as needed throughout the year, and then use a feature of the web-based system to submit the final infrastructure data electronically.

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 11 indicates that data collection begins at a local site where screening procedures are performed. Once the data collection forms are reviewed for completeness by a local site coordinator, the data are entered into the grantee program's data management system. Once data entry of the forms is completed, the grantee program reviews the data for errors and completeness, and queries the local site for any necessary clarification. The grantee program then reexamines the data, formats it according to the data definitions provided in Attachment 3, and forwards the file electronically to the CDC and the NBCCEDP data contractor on the semi-annual reporting dates. The reporting schedule remains consistent each year.

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	Cutoff date for providing complete demographic and screening data	Cutoff date for providing complete final diagnosis and treatment initiation data
April 15, 2006	December 31, 2005	June 30, 2005
October 15, 2006	June 30, 2006	December 31, 2005

Once the data are reported to the data contractor, they are logged and archived. The data sets are reviewed for completeness and preliminary issues, and if necessary, clarification is

requested from grantees. A file is created and used to generate grantee-specific Error Summary Reports that contain counts and associated percentages for blank field errors, inter-field relationship errors and inter-record relationship errors in each data set.

The data contractor then creates an aggregated analysis file for generating standardized, NBCCEDP surveillance reports and special CDC requests. The analysis file is also used to generate grantee-specific reports for feedback to grantees about the quality, completeness and timeliness of their data. These reports include the performance indicators and standards utilized for service delivery evaluation, provided in Section A2 of the Supporting Statement.

Management Reports provide feedback on data quality and completeness within the most recent 18 months of data reporting using tables and record audits. Plots or graphs are generated to 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 record counts and percentages for performance indicators identified by the CDC. Attachment 12 provides an example of each feedback report discussed above. Once the feedback reports are distributed to

the grantee programs, they are given the opportunity to discuss the reports and their methods of data management with the CDC and the data contractor.

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

As an established program, the CDC expects that all NBCCEDP grantees report data in a timely manner. 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 use of a web-based system developed and maintained by the CDC simplifies the process required for all grantees to comply with the request for reporting infrastructure data. 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 3.

Professional training in the use of both data reporting systems is available for grantee Program Directors and Data Managers at their respective annual conferences, and periodic training is available from the CDC 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. The data reported benefits the efforts of each grantee program with their patient tracking and data collection methods.

Grantees also receive a Data Users Manual and a STAR Users Manual that provides complete written instruction regarding data submission requirements, data variables, data field descriptions, report descriptions, etc. These documents support consistent submissions across grantee programs. The manuals are 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 web-based reporting systems developed and maintained by the CDC have been internally tested by NBCCEDP

staff and the data contractor. Each system has been voluntarily pilot tested by not more than six grantee programs. Only minor changes were effected in response to the pilot testing. The processes of developing the master and analysis files, editing and formatting the reported data, and generating the standardized reports have also been thoroughly tested by the CDC and the data contractor. If they wish, grantee programs that use an alternate data management system may submit a test file to the CDC and the data contractor to confirm the accuracy of their data reporting.

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 Information Management Services, Inc. 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.

LIST OF ATTACHMENTS