Economic Analysis of the National Breast and Cervical Cancer Early Detection Program (NBCCEDP)

Request for OMB Clearance

Supporting Statement Part A—Justification

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A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Division of Cancer Prevention and Control (DCPC), is requesting approval to collect one year of cost data from the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) grantees using a tailored Cost Assessment Tool (CAT). The data collected will be used to conduct economic analysis and evaluation of the NBCCEDP. The cost data collection for which we are requesting approval is in accordance with the CDC's mission to conduct, support, and promote efforts to prevent cancer and to increase early detection of cancer, authorized by section 301 of the Public Health Service Act [42 USC 241] (**Attachment 1**).

The NBCCEDP is a nationwide, comprehensive, federally sponsored public health program, authorized by Public Law 101-354, the Breast and Cervical Cancer Mortality Prevention Act of 1990 (42 U.S.C. §300N-4A) (**Attachment 2**). This program assists uninsured and underserved women ages 18 to 64 to obtain cervical cancer screening and women ages 40 to 64 to obtain breast cancer screening. The NBCCEDP ensures that these priority populations gain access to screening services for the early detection of breast and cervical cancer. Screening and early detection of breast and cervical cancer have been shown to reduce death rates and greatly improve cancer patients' survival.[1-3]

The NBCCEDP is currently operating in all 50 states, the District of Columbia, 4 U.S. territories, and 13 American Indian and Alaska Native tribal organizations. From its inception in 1991 through June 2006, the NBCCEDP—through its dedicated national partners; state, tribal, and territorial health officials; community leaders; medical care providers; and others—has provided more than 7.2 million breast and cervical cancer screening and diagnostic services to over 3 million medically underserved, low-income women, and the program has diagnosed 30,963 breast and 1,934 cervical cancers and 45,632 high-grade precursor cervical lesions. The NBCCEDP provides clinical breast examinations, mammograms, and Pap tests for eligible women who participate in the program, as well as diagnostic testing for women whose screening outcome is abnormal.[4] Women diagnosed with cancer through the program are eligible for Medicaid coverage

through the Breast and Cervical Cancer Prevention and Treatment Act passed by Congress in 2000.

Detailed epidemiologic data is available on all women enrolled in the program, which facilitates analysis and evaluation of the effectiveness of the program. Each grantee submits to CDC information on demographics, types of screening and diagnostic services provided, and final diagnosis and outcomes for women enrolled in their program through the Minimum Data Elements (MDEs)/System for Technical Assistance Reporting (STAR) for the NBCCEDP (Office of Management and Budget [OMB] No. 0920-0571, expiration date: 1/31/2010). However, the true economic cost of providing these preventive screening services is not currently available. The proposed data collection effort will provide cost data to complement the information available from the MDEs and will enable CDC to conduct a systematic economic evaluation and analysis of the NBCCEDP. The potential long-term plan of the program is to incorporate economic cost data collection into the already existing MDEs' collection and submission to CDC.

A.2 Purposes and Use of the Information Collection

The NBCCEDP has an annual budget of approximately $200 million to provide breast and cervical cancer screening, program support functions, and other health intervention activities. In the NBCCEDP-enacting legislation (42 USC §300k et seq), Congress mandated that CDC award grant funds only to grantees capable of carrying out major program functions as described in the legislation and that each grantee should ensure that grant funds will be used in the most cost-efficient manner. To date, CDC has been unable to evaluate grantees on this second requirement because of a lack of true economic cost data from the program. The effectiveness of the NBCCEDP has been measured only in the quantity of women screened and the quality of the clinical services provided.

As indicated in the Federal Register Notice (**Attachment 3**), economic evaluation will provide critical information to reach informed decision making by assessing the effectiveness of the program in relation to the cost expended on program activities.[5-7] We will identify all program activities and collect activity-based costs, thereby systematically calculating all costs related to performing specific activities. In the United States, there is a long history of using the activity-based costing approach to perform cost-effectiveness evaluation of substance abuse programs.[8-11]

In addition, several recent studies have been published on the cost-effectiveness of international cervical cancer screening programs using activity-based cost collection.[12-13]

This activity-based data collection will allow CDC to perform in-depth evaluation of the NBCCEDP that has not been possible previously using budget information and federal expenditures.[14] It will allow CDC to assess the cost of the programs, identify factors that affect cost, perform cost-effectiveness analysis, and develop a resource allocation tool. Performing an assessment of the resources expended on NBCCEDP in relation to the value created will provide critical information to the CDC for improving program efficiency within the various components of the NBCCEDP, including screening, case management, outreach, and overall management. The cost data will allow CDC to utilize a more systematic process to allocate program funds based on grantees' past performance and future needs. For individual programs, the findings in this study will enable them to make changes to their business model (e.g., infrastructure, service distribution) to make use of identified cost-efficient strategies identified through these analyses. Furthermore, for those programs with identified higher-than-average fixed costs, their funding will be adjusted accordingly by CDC using the results of the analyses.

Another potential benefit of this study is the linkage to CDC's Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN) program (OMB No. 0920-0612, expiration date: 1/31/2010). This program serves the same NBCCEDP population but focuses on chronic diseases such as heart disease, stroke, diabetes, and other serious health problems. Because WISEWOMAN is coordinated through the NBCCEDP, it offers low-income women "one-stop shopping" so they can be screened for breast and cervical cancer, high blood pressure, high cholesterol, and other diseases. The CAT developed in this study can be used to collect cost data on the 15 WISEWOMAN programs that overlap with the NBCCEDP.

Specifically, data collected in this study will be used to

- conduct economic analyses and evaluation of the NBCCEDP's major program functions, as described in 42 USC §300k(a);
- explain factors contributing to the variation in the average cost per woman screened or served in the NBCCEDP; and
- develop a method for allocating program resources that incorporates the effectiveness and efficiency of programs.

In addition, this cost collection will enable CDC to directly address recommendations from the OMB's Program Assessment Rating Tool (PART) evaluation, which recommends that federal programs develop procedures to measure and achieve efficiencies and cost-effectiveness in their program execution. The cost data collected will also be used by the grantees themselves to achieve efficiencies within their programs. The service delivery structure used by the grantees differs and there is wide variation in the cost per woman screened or served. Detailed activity-based costs collected using the CAT will enable the grantees to evaluate their programs and identify areas for improvement.

A.3 Use of Improved Information Technology and Burden Reduction

The CAT will be completed by all respondents via the Web. All data will be collected via this Web-based tool to reduce respondent burden, data collection errors, and delays in receiving data. The tool will include several features to specifically reduce burden and collect high-quality data. For example, the tool will include automated data checks so that it can be used by grantees to perform self-directed quality checks on the data as they input the information. In addition, the list of NBCCEDP activities will be provided in drop-down boxes to eliminate time spent typing in text, and the tool will also contain an interactive user's guide that will provide variable definitions and instructions. The tool will be easily accessible through the Web, and all grantees will be provided with detailed instructions and training to input the required data. RTI International, the contractor for this project, will collect and tabulate the data provided by the grantees. All grantees have the capacity to transmit data electronically.

A.4 Efforts to Identify Duplication and Use of Similar Information

During the course of the past 12 months, CDC has initiated a thorough review of available data sources to assess whether the sources can provide the data required for a systematic cost analysis. We reviewed the STAR database, through which infrastructure data regarding the NBCCEDP-funded grantees have been reported to CDC. Overall, STAR focuses on infrastructure issues, and the data collected do not provide information for estimating activity-based program costs.

The Financial Status Report (FSR) submitted by grantees was also reviewed; this document provides information about total federal dollars spent during the fiscal year, but there are no details

on activities performed. As a result, component or activity costs cannot be identified or allocated to breast versus cervical cancer screening services. Neither the FSR nor STAR provided details on in-kind contributions, which were reported to be a significant proportion of the total outlays of the grantees.

A.5 Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this study.

A.6 Consequences of Collecting the Information Less Frequently

Without this cost data, CDC will not be able to perform an assessment of the factors that affect the cost of providing screening services or a systematic study of the cost-effectiveness of the program. This information is critical to the overall evaluation of the NBCCEDP and essential for future program planning. CDC will collect one year of cost data from all grantees funded by the NBCCEDP to estimate activity-based costs. Funding is received on an annual basis, and budgeting is designed on an annual basis. Therefore, the cost data will also be annual to be consistent and complete.

There are no legal obstacles to reduce the burden.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR1320.5

This project fully complies with all guidelines of 5 CFR 1320.5. There are no special circumstances.

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

As required by 5 CFR 1320.8(d), a notice of this data collection was published in the Federal Register on April 4, 2007 (Volume 72, Number 64, pages 16368-16369), (**Attachment 3**). One comment was received and our response is provided in **Attachment 4**.

Efforts to Consult Outside the Agency

In developing the survey instruments, CDC and RTI consulted widely with NBCCEDP directors, managers, and the NBCCEDP Federal Advisory Committee. In 2004, CDC staff conducted site visits in four state programs (Florida, Kansas, New Hampshire, and Oregon) to

interview program directors and data managers about their ability to understand the data elements to be collected and their ability to complete the questionnaire within a reasonable time frame. The programs were able to understand and complete the questionnaire with the instructions provided. These interviews led to the conclusion that collecting activity-based information through the survey questionnaire was feasible.

We consulted with nine programs to pilot test the survey instruments. In this additional consultation, we asked participating programs to help identify other cost information that we may have missed in the draft survey and to identify the person best suited to provide this information.

We also conducted two workshops, one in Washington, D.C., in July 2006 and the other in Atlanta in August 2007. The workshop provided direct feedback on the program directors and their data managers' acceptability of this project. The workshop also provided feedback on how to improve the draft survey instruments. All 68 program directors and data managers participated in the Washington, D.C., workshop. We incorporated the comments from the Washington, D.C., workshop and presented the revised and improved draft version of the CAT to the 68 program directors and data managers in the Atlanta workshop.

Finally, in February 2007, we consulted with the NBCCEDP's Federal Advisory Committee on this project. The NBCCEDP's Federal Advisory Committee was authorized under section 301 of the Public Health Service Act [42 USC 241] (**Attachment 5**).

The committee provided helpful comments on how to improve CAT. Specifically, the committee suggested the following:

- DCPC should redesign the CAT to only collect new rather than the existing data. This approach would minimize the burden placed on grantees of entering existing information in the CAT.
- DCPC should ensure that program grantees have personnel with appropriate knowledge and skills to manage the CAT. This effort should be included in technical support and education provided by CDC and RTI to grantees during the course of this study.

Attachment 6 provides the names and telephone numbers of the points of contact at each site visit, location and, the nine programs that participated in the pilot test of the survey instruments.

As a result of these consultations, we elected to simplify the survey and were able to obtain an estimate of respondent burden.

A.9 Explanation of Any Payment or Gift to Respondents

Respondents do not receive payments or gifts for participating in this data collection.

A.10 Assurance of Confidentiality Provided to Respondents

The CDC Privacy Act Officer has reviewed this application and has determined that the Privacy Act is not applicable because respondents are the NBCCEDP grantees. Although one or more contact persons will be identified for each program, the contact person will not provide any identifiable information about him or herself. The contact person will provide aggregate information about the respondent. The contact person's name and contact information will be destroyed after data collection is completed.

RTI will be responsible for initial screening contacts with respondents and for collecting response data on behalf of CDC. All data will be collected via the Web-based data collection method using the CAT. The electronic data files containing the response data will be submitted via the Web to RTI. The data transmitted to CDC will contain only the de-identified program codes, not the program names. Program data will be in aggregate form; patient-level data will not be collected.

Data will be treated in a confidential manner and will not be disclosed, unless disclosure is otherwise compelled by law. Neither the names of respondents nor the programs they represent will be identified in published reports or publicly available data. Respondents will not, however, receive a guarantee of confidentiality.

The Institutional Review Board (IRB) of RTI has determined that this data collection is exempt from IRB review and approval under 45 CFR 46.

A.11 Justification for Sensitive Questions

We are collecting program-level cost data, but not at the individual patient level. No sensitive questions will be asked in this survey.

A.12 Estimates of Annualized Burden Hours and Costs

Each of the 68 NBCCEDP programs will be asked to complete one set of data for their program via the NBCCEDP Cost Assessment Tool (CAT), requiring only one response per respondent program. **Attachment 7** includes both the CAT, and a user's manual which contains the CAT as well as additional instructions and clarifications for completing the entries. The data collection process will be a one-time effort. As discussed earlier, based on the feedback provided from the nine grantees during the pilot phase of this project, we estimate that each grantee will require a total of approximately 22 hours to attend training sessions, gather the required data, and enter the information into the Web-based system. We anticipate a 100% response rate, since grantees are required to participate in all data collection activities related to the program. Table A12-1 summarizes the annualized burden hours.

Exhibit A12-1. Estimated Annualized Burden Hours

Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden (in hrs)	Total Burden (in hrs)
NBCCEDP grantee	68	1	22	1,496

The program director, the business manager, and the data manager will all be required to contribute information to complete the CAT. On average, data collection will require 4 hours each from the director and the business manager, and 14 hours from the data manager, for a total of 22 hours per grantee. The estimated cost to respondents is $34,004, which is included in their grant awards. This annualized cost to respondents is based on the average wages provided to us during pilot testing of our data collection questionnaire with the nine grantees. The average hourly wage rate reported in Table A12-2 is a weighted average based on the program director spending 4 hours with an hourly wage of $30, the business manager spending 4 hours with an hourly wage of $25, and a data manager spending 14 hours with a wage of $20.

Exhibit A12-2. Estimated Annualized Cost to Respondents

Type of Respondents	Number of Respondents	Number of Responses per Respondent	Response burden per respondent (hrs)	Weighted average hourly wage rate	Respondent cost
NBCCEDP grantees	68	1	22	$22.73	$34,004

A.13 Estimates of Other Total Annual Cost Burden to Respondents or Recordkeepers

No cost other than those described in Table A.12-2 will be incurred by respondents.

A.14 Annualized Cost to the Federal Government

Total operation and maintenance costs include work performed by the data contractor, RTI, and CDC personnel. RTI has a 24-month contract with CDC for information collection and analysis of $203,339. CDC personnel costs are estimated at $5,950. Table A14-1 summarizes the estimated federal government cost distribution.

Exhibit A14-1. Estimated Annualized Federal Government Cost Distribution

	Annualized cost
Data Contractor	**$203,339**
Build data collection tool	$98,686
Pilot test tool	$40,191
Train grantees	$10,760
Collect data and create analytic file	$53,702
Technical Monitor at 5% FTE, GS 13	**$4,250**
Co-Technical Monitor at 2% FTE, GS 13	**$1,700**
Total	**$209,289**

FTE = full-time equivalent.

A.15 Explanation for Program Changes or Adjustments

This request is for a new, one-time data collection.

A.16 Plans for Tabulation and Publication and Project Time Schedule

A.16.1 Plans for Tabulation

Once the cost data are entered by the grantees, we will perform a range of tasks including data validation, generation of descriptive statistics on the activity-based cost estimates, analyses of the variation in average cost among grantees, and systematic cost-effectiveness assessment of the program. These tasks are described in detail below.

Thorough data validation will be performed to assess the quality of the data available to perform the planned analysis. All data collected in the CAT (**Attachment 7**) will be assessed for missing information (i.e., percentage of fields with missing data) and incorrect data (i.e., percentage of data elements with formats that are not recognized; percentage with inappropriate range of values). We will also review whether the subcategories sum to the expected total costs. Discrepancies between the total amount of funds expended annually and the total itemized costs will be identified and clarified with the grantees. The findings from the data validation will be reviewed to identify whether any statistical or other corrections are required to generate unbiased cost estimates.

In-kind contributions will also be reviewed to ensure that only those contributions that represent true opportunity cost are included. Opportunity cost is defined as the advantage forgone as the result of the acceptance of an alternative. An example of a permissible opportunity cost is the value of volunteer effort. A person who volunteers his or her time to the NBCCEDP will not be able to devote that time to other activities for which he or she might be compensated, thus the volunteer's effort represents true opportunity cost to the volunteer. Therefore that time should be valued at the market rate and included as a cost to the program. An example of a "cost" that would not qualify as an in-kind contribution is the difference between what a provider is paid for services by the NBCCEDP program and what the provider may charge. This difference does not represent opportunity cost because it is not usual and customary to pay the amount charged (generally paid at a negotiated lower rate) for medical services in the United States.

Using the data collected in the CAT, we will generate activity-based cost estimates. For instance, using staff salary and proportion of time reported on specific activities, we will allocate staff cost to each of the NBCCEDP components. The cost generated at the activity level will be assessed to ensure that these costs sum to the total expenditure reported by the programs as a

validation check. Detailed assessment of these activity-based costs will be performed and summary statistics will be generated for costs associated with each NBCCEDP activity. We will show the possible range of values and generate univariate statistics (e.g., mean, standard deviation, median, interquartile range). We will also report the costs associated with screening for breast and cervical cancer separately. Total cost and cost for the individual components, as applicable, will be compared among the grantees. These costs will be categorized into clinical and nonclinical costs. Clinical costs will include the cost of screening and diagnostic services, and patient support/case management. Nonclinical costs will include the cost of program management, data management, tracking and follow-up, quality assurance/quality improvement, professional development, partnerships, recruitment, and evaluation. We will develop histograms to compare the distribution of costs across the program components for each grantee.

Variation in these costs by grantee screening delivery structure (i.e., centralized, decentralized and mixed) and size of grantee program (by total number of women screened) will be assessed. We will generate univariate statistics stratified by structure and program size to identify potential differences. To assess potential economies of scale (that is, the projected cost for future programs with differing screening volumes), costs that are fixed versus variable will be identified for each grantee. Fixed costs when amortized across a large number of screens could decrease cost and make the program more efficient. It will also be important to consider diseconomies of scale because potentially larger programs may result in reduced quality of care provided. In addition, the factors that affect average cost will be evaluated using regression analysis. We propose using log-log models to identify the key factors that affect average cost (e.g., the number of women screened, screening delivery structure, proportion of breast versus cervical screens, price differences as indicated by the regional Consumer Price Index (CPI), presence of rural areas in the region served). Using log transformation of cost helps correct for skewness that is generally present in cost estimates. Also, the log-log model will help us estimate the elasticity of average cost with respect to the key factors (regressors such as the ones listed above), or, in other words, the model will provide the percentage change in average cost given a percentage change in a key factor. We will perform these analyses both including and excluding in-kind contributions to identify the impact of these contributions to program operation.

We will also perform a systematic cost-effectiveness assessment and identify incremental cost-effectiveness based on grantee screening delivery structure. The effectiveness measures used

will include the number of screens performed and the total number of cancers detected. We will calculate the cost per screen performed and the cost per cancer detected. For example, the cost per cancer detected will be obtained using the following calculation:

Cost per cancer detected = Annual total program cost / number of cancers detected.

The two ratios described above will be derived for the entire program and separately for breast and cervical cancer screening. We will perform nonparametric bootstrapping to evaluate the uncertainty of the results from the cost-effectiveness calculations to generate 95% confidence intervals. We will compare the results derived from this study with other cost-effectiveness evaluations of cancer screening programs to compare the cost-effectiveness ratios derived from the program.

Finally, we will use all the above information to create a resource allocation model that will guide future program funding decisions and provide incentives to operate the programs more efficiently. This allocation model will be based on the factors that impact the cost of individual grantee programs, the adjustment for program past performance, and the findings from the activity-based cost assessment regarding approaches to improve overall program efficiency.

A.16.2 Plans for Publication

Results of the study will be disseminated to various grantees and other stakeholders through reports, Web conferences, presentations at professional meetings, and publication of manuscripts in peer-reviewed journals. It is anticipated that the results of this project will be developed into several scientific and nonscientific reports. These reports will include the following:

- **Economic Analysis of the National Breast and Cervical Cancer Early Detection Program**

  The data collected via activity-based costing will be used to perform a systematic economic evaluation of the NBCCEDP. We will report the total cost associated with specific components of the program, the average cost per women screened/served, and the incremental cost-effectiveness of the programs, as appropriate. We will also provide the cost per screens performed and the cost per cancer detected for all grantees services combined together and separated into cervical and breast cancer screening. The

assessment will be stratified both by grantee structure and by volume of screens performed to identify potential areas for improving program efficiency.

- **Explaining State Variations in the Average Cost per Woman Served in the National Breast and Cervical Cancer Early Detection Program—United States**

  We will perform an evaluation of the factors that affect cost across the programs to identify the magnitude of the effect of each of these factors. The factors include the number of women screened, screening delivery structure, proportion of breast versus cervical screens, price differences as indicated by regional CPI, and presence of rural areas in the region served.

- **Estimating Resource Requirements Needed to Increase the Coverage of the Eligible Women to the National Breast and Cervical Cancer Early Detection Program—United States**

  Policy makers need information on the amount of resources required to increase the coverage of the women eligible for the program. At the present time, there is no accurate national estimate of the amount of resources needed to achieve high levels of screening coverage through the program. This report will describe the costs associated with specific program activities, including the clinical (e.g., screening and diagnostic tests for breast and cervical cancer and case management) and nonclinical (e.g., management, data collection, outreach activities) costs of the programs.

A.16.3 Project Timeline

The time schedule for remaining project activities is presented in Table A16-1. Within the first month after receiving OMB clearance, we will train the grantees and initiate data collection. We will complete all analysis and reporting within 12 months of receiving OMB clearance.

Exhibit A16-1. Project Time Schedule

Activity	Time schedule (months after OMB approval)
Hold orientation/training meeting	1 month
Initiate data collection	2 months
Close data submission	4 months

Validation	5-6 months
Analysis	7-9 months
Final report and publication	10-12 months

A.17 Reason(s) Display of OMB Expiration Date Is Inappropriate

No request for an exemption from displaying the expiration date for OMB approval is being sought.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

These data will be 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