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

Request for OMB Clearance

Extension

Supporting Statement Part A—Justification

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Attachment 4. NBCCEDP Cost Assessment Tool and User's Manual

Summary

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 currently approved to collect two years of information about activity-based economic costs incurred by the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) during the period fiscal years 2009 and 2010 (OMB No. 0920-0776, exp. 03/31/2011). CDC is requesting OMB approval for a six-month extension to complete the FY09-10 data collection. Based on our experience with previous cycles of data collection, 20 of the 68 respondents (30%) will not be able to meet the deadline of 3/31/2011. These grantees will complete their fiscal year (FY 10) closeout in April or May 2011. As a result, these grantees will not be prepared to submit data to CDC until their FY is complete and records have been reconciled. The requested six-month extension will provide the time these grantees need to complete their FY10 closeout and conduct data quality checks before submitting information to CDC. The requested six-month extension will improve the quality and completeness of information used for planned data analysis, and ensure CDC's authority to receive late submissions.

In this request, there are no proposed changes to the data collection instrument, data collection methodology, or the estimated burden per response. The only changes are a decrease in the estimated number of respondents (allowing for late submissions) and a six-month extension of the data collection period.

A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

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 National Breast and Cervical Cancer Early Detection Program (NBCCEDP) is a nationwide, comprehensive, federally sponsored public health program that makes important cancer screening services available to uninsured and underserved women. Through the NBCCEDP, eligible women ages 18 to 64 may obtain cervical cancer screening and eligible women ages 40 to 64 may obtain clinical breast exams and breast cancer screening. The NBCCEDP also provides diagnostic testing for women

whose screening outcome is abnormal.[4] The NBCCEDP is the largest organized cancer screening program in the United States, with an annual budget of approximately $200 million.

The NBCCEDP currently operates in all 50 states, the District of Columbia, five U.S. territories, and 12 American Indian and Alaska Native tribal organizations. From its inception in 1991 through June 2010, the NBCCEDP—through its dedicated national partners; state, tribal, and territorial health officials; community leaders; medical care providers; and others—has provided more than 9.2 million breast and cervical cancer screening services to over 3.7 million medically underserved, low-income women, and the program has diagnosed 44,855 breast and 2,554 cervical cancers and 123,563 high-grade precursor cervical lesions. 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.

The NBCCEDP was authorized by Public Law 101-354, the Breast and Cervical Cancer Mortality Prevention Act of 1990 (42 U.S.C. §300N-4A) (**Attachment 1a**). In the enacting legislation, Congress mandated that (1) CDC award grant funds only to grantees capable of carrying out major program functions as described in the legislation, and (2) that each grantee should ensure that grant funds will be used in the most cost-efficient manner. However, to date, CDC has been unable to systematically 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.

In accordance with the CDC's mission to conduct, support, and promote efforts to prevent cancer and to increase early detection of cancer (see Section 301 of the Public Health Service Act [42 USC 241] (**Attachment 1b**), in 2008 CDC obtained a one-year OMB approval to collect information about activity-based costs from NBCCEDP grantees, followed in 2009 by a Revision request authorizing the collection of two additional years of information (OMB No. 0920-0776, exp. 3/31/2011). At this time, due to the importance of the NBCCEDP and the availability of additional resources to support its evaluation, CDC is requesting OMB approval to extend data collection for an additional six months. Based on our experience with previous cycles of data collection, 20 of the 68 respondents (30%) will not be able to meet the deadline of 3/31/2011, when the current OMB approval is scheduled to expire. These grantees will complete their fiscal year (FY) closeout in April or May 2011. As a result, these grantees will not be prepared to submit data to CDC until their FY is complete and records have been reconciled. The requested

extension will provide the time these grantees need to complete their FY10 closeout and conduct data quality checks before submitting information to CDC. The requested six-month extension will improve the quality and completeness of information used for planned data analysis, and ensure CDC's authority to receive late submissions.

The activity-based cost information collected for economic analysis of the NBCCEDP is unique and does not duplicate information reported to CDC about other aspects of the program. Detailed epidemiologic data about all women enrolled in the program is available to facilitate analysis and evaluation of the effectiveness of the program. Each NBCCEDP 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) for the NBCCEDP (OMB no. 0920-0571, expiration date 11/30/2012). 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 and comprehensive economic evaluation and analysis of the NBCCEDP.

Future plans for economic analysis of the NBCCEDP include the collection and analysis of additional years of cost data. After completing the analysis of the information collected during the initial three years of approval (0920-0776, 2008-2011), CDC may request reinstatement of data collection in 2012. Any future data collection cycles will reflect lessons learned in the initial data collection period, and could result in changes to the CAT. The potential long-term plan is to incorporate economic cost data collection into the approved MDE collection.

Privacy Impact Assessment

The economic cost of the NBCCEDP data collection has not been previously assessed. An overview of the data collection system and a listing of the items of information to be collected are provided in the subsequent sections.

Overview of the Data Collection System

NBCCEDP-funded grantees, which are state, territorial and tribal governments or bona-fide agents, collect data to manage their screening programs and retain primary responsibility for information collection procedures. They collect activity-based cost data, which are used to

estimate the cost of delivering screening, diagnostic, and other health-related services in the program. A subset of data on program resources and expenditures will be reported annually to CDC electronically using a web-based Cost Assessment Tool (CAT) system. All grantees receive annual training on use of the web-based CAT. Automated data checks will be incorporated into the tool and this will allow the grantees to review and check data prior to transmission. The CAT will only be accessible to program staff who is assigned a userid and password to access the site.

Items of information to be collected

NBCCEDP grantees maintain fiscal data to manage program resources. The following cost data will be collected from each grantee (see **Attachment 4** for specific data items):

- Funding received and sources
- In-kind contributions
- Labor activities and cost
- Consultant cost
- Cost of Screening and diagnostic tests
- Administrative cost
- Total number of individuals screened/served by the program

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

The cost data compiled at the grantee level are transmitted to the contractor via a password-protected secure website and are encrypted during transmission. The encryption is accomplished via Secure Sockets Layer (SSL) strong encryption, the same level of protection used by e-commerce sites to protect financial transactions.

The cost data reporting websites do not have content directed at children under 13 years of age.

A.2 Purposes and Use of the Information Collection

A six-month extension of the currently approved two-year data collection period will allow CDC to complete three complete sets of FY data collection and will allow CDC to perform in-depth evaluation of the NBCCEDP that has not been possible previously using budget information

and federal expenditures.[14] Because the NBCCEDP is extremely important in serving women who have no other source of preventive health care, policy makers are demanding greater value and better outcomes in the program. On January 29, 2008, the Committee on Oversight and Government Reform of the U.S. Congress held a hearing to address screening gaps and to discuss progress to date and challenges facing the NBCCEDP. The ongoing economic cost study was one of the issues discussed at this hearing and the Congressional Committee members echoed the importance of this cost study to efforts aimed at improving program performance. 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.

NBCCEDP grantees also recognize the importance of the economic cost study as a necessary step to justify funding and improve program administration over the long run. 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, identify areas for improvement, and achieve better efficiencies within their programs. Some programs have commented that "participating in the CDC's economic cost study will help them to be more efficient and better maximize their resources to get all the work done that needs to get done."

Economic evaluation is providing 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] The Cost Assessment Tool already in use (see Attachment 4) identifies all program activities and collects 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]

The cost information to be collected will improve CDC's ability to assess the cost of the NBCCEDP 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: 03/31/2013). 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 will thus provide additional insights about the 21 WISEWOMAN programs that overlap with the NBCCEDP.

Specifically, the additional data to be collected in this six-month extension will be used to

- improve 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 an improved method for allocating program resources that incorporates the effectiveness and efficiency of programs.

The collection of activity-based cost information for economic analysis is thus essential for ensuring that CDC meets its fiscal responsibility for appropriate use of funds as appropriated by Congress; for assessing how well the NBCCEDP is performing nationally and in individual grantee programs; and for informing future program planning and policy decisions. The collection of two additional years of cost data will substantially improve the estimates of cost-effectiveness and cost-efficiency.

Privacy Impact Assessment Information

The current activity-based cost data collection will allow CDC to perform an in-depth evaluation of the NBCCEDP. The economic evaluation will be performed to address key questions that will guide the future direction of breast and cervical cancer screening programs. The following questions will be addressed:

1. How much funding is required annually by each program? What funding sources are used by each program (i.e., CDC, state funds, in-kind funds)? What is the level of in-kind contributions received by each program? What are the primary sources of in-kind contributions?
2. What is the distribution of costs among the key program components (e.g., recruitment, service delivery, patient support) for each program?
3. What is the average and incremental non-clinical cost per person screened for each program? Does average and incremental cost change across the years for each program? Are the programs cost-effective? What is the cost per cancer detected (or cancers prevented if are cervical lesions are removed)?
4. What is the average clinical cost (screening and diagnostic testing) for each program (includes only individuals who receive direct service delivery)?
5. What is the average cost per number of screens performed due to specific recruitment activities? What type of recruitment efforts are the most cost-effective (assessed separately for the insured and uninsured population if possible)?
6. What is the average cost of enrolling individuals in insurance programs (Medicaid)?

The collection of activity-based cost information for economic analysis is essential for ensuring that CDC meets its fiscal responsibility for appropriate use of funds as appropriated by the United States Congress; assessing how well the NBCCEDP is performing nationally and in individual grantee programs; and informing future program planning and policy decisions. The data collected will be analyzed and used by CDC and individual programs to improve program operations to make more efficient use of funding received. CDC will publish relevant findings in the peer-reviewed literature to assist other cancer screening programs to design efficient programs. The CAT collects only the information that is needed for addressing defined cost analysis objectives. No IIF is being collected in the CAT.

A.3 Use of Improved Information Technology and Burden Reduction

Currently, the CAT is being completed by all respondents via the Web. All data are collected via this Web-based tool to reduce respondent burden, data collection errors, and delays in receiving data. The tool includes several features to specifically reduce burden and collect high-quality data. For example, the tool includes 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 lists of NBCCEDP activities are provided in drop-down boxes to eliminate time spent typing in text. The tool also contains an interactive user's guide that provides variable definitions and instructions. The tool is easily accessible through the Web, and all grantees are provided with detailed instructions and training to input the required data. RTI International, the contractor for this project, collects and tabulates 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

Prior to initiating this project, CDC conducted a thorough review of available data sources to assess whether the sources could provide the data required for a systematic cost analysis. We reviewed the MDE/STAR database, through which infrastructure data regarding the NBCCEDP-funded grantees has been reported to CDC (OMB No. 0920-0571, exp. 11/30/2012). The STAR component of the database focused on infrastructure issues and has since been discontinued. The MDE data collection does 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. There are no alternative sources of the information being collected.

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 completing the approved three years of cost data collection, CDC will not be able to fully perform an assessment of the long-term factors that may 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 and decision making. As stated above, CDC plans to collect an additional two years 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 collected on an annual basis 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

A.8.a. Federal Register Notice.

As required by 5 CFR 1320.8(d), a notice of the revised data collection plan was published in the Federal Register on October 13, 2010 (Volume 75, Number 197, pages 62835-62836), (**Attachment 2**). No public comments were received.

A.8.b. 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 (see **Attachment 3**), authorized under section 301 of the Public Health Service Act [42 USC 241] (**Attachment 1b**). These key stakeholders endorsed the CAT as an efficient cost data collection instrument.

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

Respondents are the NBCCEDP grantees. The data collection contractor, Research Triangle Institute (RTI), is responsible for initial screening contacts with respondents and for collecting response data on behalf of CDC. All data are been 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. The cost data collection (CAT) has no IIF.

Data will be treated in a secure 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 does not require IRB review and approval under 45 CFR 46.

Privacy Impact Assessment Information

A. This submission has been reviewed by staff in CDC's Information Collection Review Office, who determined that the Privacy Act does not apply. Although we have been working with one or more contact persons in each program, these individuals have not provided any identifiable personal or sensitive information. Rather, they have provided us with aggregate information about their respective programs. The contact person's name and contact information (IIF) will be destroyed after data collection is completed.
B. The NBCCEDP economic cost data are secured by technical, physical and administrative safeguards as outlined below.

   Technical

   - The NBCCEDP cost data collected via CAT reside on a dedicated server that

resides on the contractor's local area network behind the contractor's firewall and is password protected on its own security domain. Access to the server is limited to the contractor's authorized project staff. No non-project staff are allowed access to the data. All of the contractor's project staff are required to sign a non-disclosure agreement before passwords and keys are assigned.

- The NBCCEDP cost data that are submitted electronically are encrypted during transmission from the grantees and arrive on a server behind the data collection contractor's firewall. Each grantee has its own directory location so no grantee has access to another grantee's data.

Physical

- The contractor's server is housed in a secure facility with restricted access.
- Receipt and processing logs are maintained to document data receipt, file processing and report production. All reports and electronic storage media containing NBCCEDP cost data are stored under lock and key when not in use and will be destroyed when no longer needed.
- Once data have been compiled by the data contractor and delivered to CDC, all NBCCEDP cost datasets are maintained for restricted access on a secure LAN server, which is housed in a secure facility. All CDC staff are issued identification badges and access to the building is controlled by key cards.

Administrative

- CDC and contract staff have developed and implemented an information system security plan to ensure that the data are kept secure. Periodic review and update of the data contractor's security processes is conducted to adjust for needed changes and will be amended as needed to maintain the continued security of the data.
- The contractual agreements between CDC and both contractors include non-disclosure terms. The contractor's project security team oversees operations to prevent unauthorized disclosure of the NBCCEDP cost data.
- Once the data have been delivered to CDC, access to these datasets will be overseen by the NBCCEDP data manager as appropriate.

C. Patient consent is not needed in collecting NBCCEDP economic cost data. This is because

we are only collecting program (administrative) level data.

D. Participation in the CAT data collection is required for NBCCEDP awardees.

A.11 Justification for Sensitive Questions

The CAT does not collect personally identifiable or sensitive information. We are collecting program-level cost data, but not at the individual patient level.

A.12 Estimates of Annualized Burden Hours and Costs

A.12-1. Estimated Annualized Burden to Respondents

Respondents will be 20 of the 68 funded NBCCEDP grantees. Each respondent 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 annually. All information is reported electronically. **Attachment 4** includes the current CAT and a user's manual, which contains the CAT as well as additional instructions and clarifications for completing the entries. This Extension request does not include changes to the CAT instrument or the estimated burden per response.

The original estimated burden of 22 hours per response to attend training sessions, gather the required data, and enter the information into the Web-based system remains the same as presented in Exhibit A.12.1. The responses we have received from the programs since the CAT was implemented have been positive. We have provided technical assistance to a few programs that have had difficulty completing the CAT. We have a 100% response rate, since grantees are required to participate in all data collection activities related to the program. Table A.12-1 summarizes the annualized burden hours for the estimated 20 programs (30%) that will not be able to submit their data before the expiration of the previously approved deadline of 3/31/2011.

The total annualized burden to respondents is 440 hours.

Exhibit A.12-1. 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	20	1	22	440

A.12-2. Estimated Annualized Cost to Respondents

The program director, the business manager, and the data manager all are 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 total estimated annualized cost to respondents is $10,001, 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 Exhibit 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 A.12-2. 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	20	1	22	$22.73	$10,001

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

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

A.14 Annualized Cost to the Federal Government

The total annualized cost to the government is estimated at $75,652. Total operation and maintenance costs include work performed by the data contractor, RTI, and CDC personnel. RTI has a 36-month contract with CDC for information collection and analysis. The annualized cost of the data collection contractor for the duration of the contract is $69,702. CDC personnel costs are estimated at $5,950 annually. Exhibit A.14-1 summarizes the estimated federal government cost distribution.

Exhibit A.14-1. Estimated Annualized Federal Government Cost Distribution

	Annualized cost
Data Contractor	**$69,702**
Incremental changes to the already built data collection tool	$10,500
Additional technical assistance	$5,500
Collect data and create analytic file	$53,702
CDC Technical Monitor at 5% FTE, GS 13	**$4,250**
CDC Co-Technical Monitor at 2% FTE, GS 13	**$1,700**
Total	**$75,652**

FTE = full-time equivalent.

A.15 Explanation for Program Changes or Adjustments

As stated earlier, this request is for a six-month extension to give CDC an authority to receive late data submissions from 20 programs that are not expected to meet the March 31, 2011 deadline established by the previous OMB approval.

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

A.16.1 Plans for Tabulation

After the cost data have been entered into the CAT 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 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 are as follows: 1) we will start collecting FY10 data on November/December 2010. We expect this process to continue until all the 68 programs submit their data to CDC; 2) we request a six-month extension from OMB to ensure CDC's authority to receive data beyond the currently scheduled expiration date of OMB approval on 03/31/2011; 3) After we complete data collection, we estimate four months for the validation of data collected; 4) we estimate six months for data analysis; and 5) we estimate six months for the final report and publication.

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.

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