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

Request for OMB Clearance

Revision

Supporting Statement Part A—Justification

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LIST OF ATTACHMENTS

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- Attachment 1b. Authorizing Legislation: Section 301 of the Public Health Service Act [42 USC 241]
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Attachment 4. Participants Providing Feedback on Study Design and Survey

Attachment 5a. Current NBCCEDP Cost Assessment Tool and User's Manual

Attachment 5b. Proposed Changes to the Cost Assessment Tool

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 one year of information about activity-based economic costs incurred by the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) during the period 07/01/2005 – 06/30/2006 (OMB No. 0920-0776, exp. 04/30/2009). With this Revision request, CDC seeks to obtain OMB approval to collect two additional, consecutive years of economic data pertaining to the period 07/01/2007 – 06/30/2009. Minor changes to the data collection instrument are proposed to collect supplementary information about activities supported by respondent organizations through the use of non-federal funds.

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 is currently operating in all 50 states, the District of Columbia, 5 U.S. territories, and 12 American Indian and Alaska Native tribal organizations. From its inception in 1991 through June 2008, the NBCCEDP—through its dedicated national partners; state, tribal, and territorial health officials; community leaders; medical care providers; and others—has provided more than 7.8 million breast and cervical cancer screening services to over 3.2 million medically underserved, low-income women, and the program has diagnosed 35,090 breast and 2,161 cervical cancers and 55,612 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**), CDC obtained a one-year OMB approval in 2008 to collect information about activity-based costs from NBCCEDP grantees (OMB No. 0920-0776, exp. 04/30/2009). 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 two additional, consecutive years, with minor modifications to the data collection instrument (the Cost Allocation Tool, or CAT).

The primary reasons for the additional years of data collection and minor changes to the CAT are as follows: First, additional years of data are needed to account for year-to-year variation in program expenditures. For instance, a program site may expend a large amount of money in one year in outreach for recruitment of eligible women and then spend very little the following year. Without multiple years of program data, such fluctuations in expenditures may erroneously give the appearance that a specific category of activities at a program site is less or more expensive than comparable activities at another NBCCEDP site. By collecting a total of three consecutive years of cost data for each site, the average expenditure across the three years can be derived for each program activity to avoid these fluctuations. It is therefore methodologically desirable to have at least three years of data.

We also propose to implement a minor but important modification to the CAT. NBCCEDP funded programs may use non-CDC funds to provide screening services to certain groups of women, for example, state funding may be used to provide mammograms to women younger than 50 years of age. However, this information is not currently reported to CDC, and negatively affects our ability to evaluate the NBCCEDP and to establish valid cost and cost-effectiveness

estimates. We propose to begin collecting the total number of screens performed by the programs (i.e., both CDC and non-CDC funded screens), and the total cost expended by the programs regardless of the funding source. To minimize burden to respondents, we will not require respondents to identify the specific source of funding for the numerous activities performed by the programs.

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 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 and comprehensive 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 current activity-based data collection and the proposed two-year extension 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 3a) 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 activitybased 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 additional two years of cost information to be collected will improve CDC's ability 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 will thus provide additional insights about the 15 WISEWOMAN programs that overlap with the NBCCEDP.

Specifically, the additional data to be collected in this two-year 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 costeffectiveness and cost-efficiency.

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

During the course of the past 18 months, 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. 1/31/2010). 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 inkind 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 an additional two years of cost data, 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 November 6, 2008 (Volume 73, Number 216, pages 66048-66049), (**Attachment 2**). No public comments have been 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. 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 1b**).

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 3 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 is 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 revised survey.

Estimates of Annualized Burden Hours and Costs A.12

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 5a** includes the current CAT and a user's manual, which contains the CAT as well as additional instructions and clarifications for completing the entries.

Minor changes to the CAT (see Attachment 5b) will be implemented to provide enhanced information about screening and diagnostic activities supported through the use of non-federal funds. The burden to respondents in this minor change to CAT is considered acceptable since respondents have already been trained to use the CAT and have completed and submitted cost data for the period 07/01/2006 - 06/30/2007. Therefore, the original overall estimated burden of 22 hours to attend training sessions, gather the required data, and enter the information into the Webbased system remains the same as presented in Table A12.1. 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 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.

		Number of		
Type of Respondents	Number of Respondents	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.

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

Exhibit A12-2. Estimated Annualized Cost to Respondents

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

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 proposed two-year extension is \$69,702. CDC personnel costs are estimated at \$5,950 annually. Table A14-1 summarizes the estimated federal government cost distribution.

Exhibit A14-1. Estimated Annualized Federal	Government Cost Distribution
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	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 a revision to collect additional two years of data and a minor change to CAT. The explanations for the request to collect additional two years of data and a minor change to the CAT were provided in section A.1 of this document.

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 5a**) 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 grantees.

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 will be as follows: 1) Inform grantees that CDC has received clearance from OMB to collect additional two years of data; 2) data collection are conducted annually in the fall; 3) we estimate 4 months for the validation of data collected; 4) we estimate 6 months for data analysis; and 5) we estimate 6 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.

REFERENCES

- 1. American Cancer Society. 2004. *Cancer Facts and Figures*. Atlanta, GA: American Cancer Society.
- 2. Centers for Disease Control and Prevention (CDC). National Report. http://www.cdc.gov/cancer/nbccedp/bccpdfs/national_report.pdf
- 3. US Preventive Services Task Force (USPSTF). 1996. *Guide to Clinical Preventive Services, 2nd ed* (pp. 105-117). Washington, DC: U.S. Department of Health and Human Services, Office of Public Health and Science.
- 4. Centers for Disease Control and Prevention (CDC). http://www.cdc.gov/cancer/nbccedp/about.htm
- 5. Drummond, M.F., B. O'Brien, G.L. Stoddart, G.W. Torrance. 1997. *Methods for the Economic Evaluation of Health Care Programs*, 2nd ed. Oxford: Oxford University Press.
- 6. Gold, M.R., J.E. Siegel, L.B. Russell, and M.C. Weinstein. 2003. *Cost-Effectiveness in Health and Medicine*. New York: Oxford University Press.
- 7. Haddix, A.C., S.M. Teutsch, P.A. Corso, and D.O. Dunet. 2003. *A Guide to Decision Analysis and Economic Evaluation*. New York: Oxford University Press.
- 8. French, M.T., L.J. Dunlap, G.A. Zarkin, K.A. McGeary, and A.T. McLellan. 1997. "A Structured Instrument for Estimating the Economic Cost of Drug Abuse Treatment. The Drug Abuse Treatment Cost Analysis Program (DATCAP)." *Journal of Substance Abuse Treatment* 14(5):445-455
- 9. French, M.T., M.C. Roebuck, and A.T. McLellan. 2004. "Cost Estimation When Time and Resources are Limited: the Brief DATCAP." *Journal of Substance Abuse Treatment* 27(3):187-193.
- 10. Salome, H.J., and M.T. French. 2001. "Using Cost and Financing Instruments for Economic Evaluation of Substance Abuse Treatment Services." *Recent Developments in Alcoholism* 15:253-269.
- 11. Zarkin, G.A., R.C. Lindrooth, B. Demiralp, and W. Wechsberg. 2001. "The Cost and Cost-Effectiveness of an Enhanced Intervention for People with Substance Abuse Problems at Risk for HIV." *Health Services Research* 36(2):335-355.
- 12. Legood, R., A.M. Gray, C. Mahe, J. Wolstenholme, K. Jayant, B.M. Nene, et al. 2005. "Screening for Cervical Cancer in India: How Much Will it Cost? A Trial Based Analysis of the Cost Per Case Detected." *International Journal of Cancer* 117(6):981.

- Goldie, S.J., L. Gaffikin, J.D. Goldhaber-Fiebert, A. Gordillo-Tobar, C. Levin, C. Mahe, et al. 2005. "Alliance for Cervical Cancer Prevention Cost Working Group. Cost-Effectiveness of Cervical-Cancer Screening in Five Developing Countries." *New England Journal of Medicine* 353(20):2158-2168.
- 14. Mansley, E.C., D.O. Dunet, D.S. May, S.K. Chattopadhaya, and M.T. McKenna. 2002. "Variations in Average Costs Among Federally Sponsored State-Organized Cancer Detection Programs: Economics of Scale?" *Medical Decision Making*, 22 (Supplement):S67-S79.