Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN) Reporting System

Office of Management and Budget

Change Worksheet Supporting Statement and Attachments

Centers for Disease Control and Prevention
National Center for Chronic Disease Prevention and Health Promotion
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A. Justification

A.1 Circumstances Making the Collection of Information Necessary

The National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC) is requesting approval for a three-year extension of the data collected for the Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN) program. This request contains all of the changes in the OMB 83-C that was submitted and approved by OMB in May 2006. The changes are highlighted in the data collection instrument to assist with identifying those field descriptions that have been deleted, added or changed, since approval of the original information collection instrument, approved in November 2003. All of the other aspects of the program and clearance have remained unchanged since the last clearance.

The WISEWOMAN program was initiated in response to the Secretary of Health and Human Services' Continuous Improvement Initiative, asking for the development of programs that examine ways in which service delivery can be improved for selected population. WISEWOMAN was authorized in 1993 through a legislative supplement to the Breast and Cervical Cancer Mortality Prevention Act of 1990 (Public Law 101-354). Through additional legislative action, the CDC WISEWOMAN program was allowed to fund up to 15 projects through 2005. This extension request is to approve all 15 projects for another three years for continuous program improvement and cost-effectiveness analysis.

The WISEWOMAN program focuses on reducing cardiovascular disease (CVD) risk factors among at-risk women. CVD, which includes heart disease, myocardial infarctions, and stroke, is the leading cause of death for women in the United States. It is a primary contributor to mortality, morbidity, and decreased quality of life especially among older women in this country. Addressing such risk factors as elevated cholesterol, high blood pressure, obesity, sedentary lifestyle, diabetes, and smoking greatly reduces a woman's risk of CVD-related illness and death. Women in lower income brackets, with lower levels of education, or without health insurance have an increased risk of CVD morbidity and mortality, as they have limited access to health services and have been shown to be more likely to smoke cigarettes, engage in limited physical activity, and have poor nutrition. State, territorial, and tribal organizations awarded WISEWOMAN grants are expected to report information pertaining to the above mentioned factors for the purposes of program evaluation and cost-effectiveness analyses. Because the data collection system used by WISEWOMAN is based on the National Breast and Cervical Cancer Early Detection Program (NBCCEDP), the burden of collecting the additional information has been minimized.

A.2 Purpose and Use of Information Collection

This request continues to fulfill two purposes: 1) for continuous program improvement, and 2) use in a cost-effectiveness analysis. Ongoing evaluation, utilizing timely information, improves program performance. Moreover, performance must be assessed at least annually for compliance with the CDC's Government Performance and Results Act (GPRA) strategic plan. The minimum data elements (MDEs) allow for identifying the number of women screened over a given reporting period at a given location. Because each location has a target number of women that are expected to be screened upon full implementation, the MDEs can be used to assess whether specific locations are on track to meet their stated screening goals.

The ultimate goal of the evaluation has been to assess overall performance to determine if the program warrants expansion. The information will be used to generate cost-effectiveness analyses that can facilitate comparison of WISEWOMAN with other programs. An effective intervention is a necessary, but not sufficient, condition for justifying implementation of a demonstration program. An additional question is whether the program, even if effective, is the best use of scarce public health resources. This requires a cost-effectiveness analysis, defined as the costs required to yield a specific, comparable outcome. Cost-effectiveness analysis plays an increasingly important role in determining funding priorities. Therefore, participating WISEWOMAN programs are required to submit cost data along with the MDE data and the quarterly reports for purposes of cost-effectiveness analysis. A low cost-effectiveness ratio makes a strong case for further implementation of WISEWOMAN. However, cost-effectiveness analysis does little to identify particular strengths and weaknesses of interventions. For these reasons, the information has been used for supplemental evaluations. These evaluations provide additional details about the overall benefits of WISEWOMAN and assists in identifying improvement opportunities that may be incorporated into future programs. The information contained in the reports have been used for secondary data analyses to answer specific questions related to CVD risk among low-income at-risk women.

Health outcome measures assessed include systolic and diastolic blood pressure, total and HDL cholesterol, body mass index (BMI), smoking rates, and project-specific nutrition and physical activity variables. WISEWOMAN MDEs were also purposely chosen so that they could be combined into a summary measure that assesses overall CVD risk. This measure was chosen because it provides an assessment of the overall reduction in CVD among WISEWOMAN participants and can be easily implemented based on existing risk scoring algorithms. The summary measure is important because it allows for assessing the benefits using a single, comparable metric that can be conveyed to policy makers. To determine which of the existing CVD risk estimators should be used for our analysis, we assessed the power of 11 CVD risk estimators that could be used with WISEWOMAN data to detect changes in risk due to changes

in select inputs. We simulated various combinations of improvements in blood pressure, cholesterol, and smoking status for a random subset of women and identified two estimators that are most appropriate for evaluating the effectiveness of risk reduction programs. The two estimators are an algorithm for 10-year risk of coronary heart disease (CHD) developed by Anderson et al (1991) and a scoring sheet predicting 5-year probability of cardiovascular disease (CVD) developed by Jackson (2000). Both estimators were derived based on the data from the Framingham Heart Study and both include age, systolic blood pressure, total and HDL cholesterol, and smoking status as input risk factors. Jackson (2000) also accounts for diastolic blood pressure. Anderson's estimator consists of a set of formulas that calculate risk as a continuous variable. Jackson's estimator, on the other hand, is a color-keyed chart used to place individuals into one of the 8 risk categories (<2.5%; 2.5 – 5%, 5-10%, 10-15%, 15-20%, 20-25%, 25-30%, and >30%). We have used both of these estimators to assess changes in CVD risk among WISEWOMAN participants from baseline to follow-up.

The primary purpose of the MDEs is to assess effectiveness of the WISEWOMAN program. The methods used in the various effectiveness analyses depend on the individual projects' design. For two group pretest posttest designs, we assess effectiveness of providing an enhanced intervention (screening plus intervention) versus a minimum intervention (screening only). For one group pretest posttest designs, we assess effectiveness of program participation (screening plus intervention) versus the absence of program participation (no screening, no intervention).

Effectiveness Analysis

1.1. Two group pretest posttest designs

We assess effectiveness of two group pretest posttest designs by comparing baseline and follow-up data of the treatment group (those that receive the intervention) to baseline and follow-up data of the control group (screenings only). We first assess whether changes in individual risk factors (including systolic and diastolic blood pressure, total and HDL cholesterol, body weight, BMI, smoking rates, nutrition and physical activity) are statistically significantly different among enhanced intervention participants than among minimum intervention participants. Next, we combine the risk factors into a summary measure that assesses overall CVD risk and examine differences in CVD risk changes between intervention and control groups. We estimate changes in CVD risk using two methods: an algorithm for 10-year risk of coronary heart disease (CHD) developed by Anderson et al (1991) and a scoring sheet predicting 5-year probability of cardiovascular disease (CVD) developed by Jackson (2000). In the simulation analysis described above, we found that these two estimators have more power to detect reductions in CVD risk as a result of improvements in input factors. The results of this analysis allow for a determination of whether screenings plus interventions are more effective, and/or more cost-effective, than screenings alone in reducing CVD risk among WISEWOMAN participants.

1.2. One group pretest posttest designs

Effectiveness analyses for the one group pretest posttest designs consist of two analyses. In the first analysis, we conservatively assume that in the absence of WISEWOMAN, participants' risk factors would remain unchanged. Therefore, for each project we test whether changes in risk factors are statistically significantly different from zero. We will assess changes in individual risk factors (including systolic and diastolic blood pressure, total and HDL cholesterol, body weight, BMI, smoking rates, nutrition, and physical activity) and changes in the overall measure of CVD risk using Anderson's and Jackson's estimators. In the second analysis, we plot the baseline values and follow-up values for each woman and create a regression line over time for each type of value. The regression line for the baseline values provides the best estimate of the trends occurring in our population given the fact that women entering the program at baseline are directly from the population without the effects of the program.

A.3 Use of Improved Information Technology and Burden Reduction

All data continues to be submitted electronically by grantees to reduce the respondent burden and speed delivery. The MDE data are transmitted as electronic fixed-length text files consistent with the file formats located within attachment 2. To ensure that the reporting burden is minimized, CDC and the contractor provide in-person and/or remote technical assistance to grantees upon request.

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

These data are available exclusively from the WISEWOMAN grantees, and no other source of data exists that would allow for determining whether or not to expand the WISEWOMAN demonstration to other locations. Although data-sets with questions related to cardiovascular disease currently exist [e.g., the state-based Behavioral Risk Factor Surveillance System (BRFSS)], these data do not include participants enrolled in the WISEWOMAN program. All WISEWOMAN participants also participate in the NBCCEDP program. Rather than require participants to provide duplicative information, WISEWOMAN relies on the NBCCEDP reporting system to provide demographic characteristics of participants, including age, race, gender, and education. This reduces participant's response burden and streamlines the data reporting process.

A.5 Impact on Small Businesses or Other Small Entities

No small businesses will be adversely impacted by this study.

A.6 Consequences of Collecting the Information Less Frequently

Ongoing evaluation is a necessary component of the program and the evaluation cannot be completed without the requisite data. The reporting periods established for WISEWOMAN are identical to those established for NBCCEDP and are frequent enough to allow for ongoing evaluation, but not too frequent to be overly burdensome. The current reporting periods allow CDC and grantees to assess performance at regular intervals, and to make adjustments as necessary. Less frequent data collection would compromise the ability to successfully conduct the evaluation.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The data collection described in this request for extension is consistent with the guidelines in 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. Notice of this study was published in the *Federal Register* on September 29, 2006 in Volume 71, No. 189, pgs. 57512-57513. Attachment 1 contains a copy of the 60-day notice, public comments and the program's response to the public comments.

B. The WISEWOMAN data collection and reporting infrastructure is based on the NBCCEDP data collection and reporting infrastructure. The NBCCEDP data collection was developed by the Division of Cancer Prevention and Control (DCPC) in collaboration with an outside contractor (IMS) and a formal advisory committee consisting of key stakeholders. The WISEWOMAN data collection was developed and is continually reviewed by the Division of Heart Disease and Stroke Prevention, an outside contractor (RTI), and a formal advisory committee consisting of representatives from all WISEWOMAN grantees (MDE subcommittee). WISEWOMAN also hosts an annual conference in which the stakeholders mentioned above can review data issues. WISEWOMAN also hosts quarterly conference calls with WISEWOMAN grantees (part of the MDE subcommittee) and RTI (the data contractor) to address specific issues. Additionally, WISEWOMAN and RTI staff participate in NBCCEDP data conference calls to ensure collaboration across programs. Primary contact information for the stakeholders mentioned above are listed below:

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These activities allow direct discussion of data issues between the CDC and key stakeholders. When data issues arise that cannot be resolved during the meetings, CDC confers with the data contractors RTI International, solicits continued feedback from grantees via the MDE subcommittee, and contacts other experts both within and outside the Agency prior to making changes to the reporting infrastructure.

A.9 Explanation of Any Payment or Gift to Respondents

No payment will be provided to respondents.

A.10 Assurance of Confidentiality Provided to Respondents

The CDC Privacy Act Officer has reviewed this request for OMB Clearance and has determined that the Privacy Act is not applicable.

Ensuring that the data are kept secure is of utmost importance to CDC and the grantees. The WISEWOMAN grantees collect personal identifiers on each woman served (e.g., name, address, social security number, age, race/ethnicity) along with information about the woman's medical history, results of the screening exam, and intervention participation. Although names, social security numbers, and other identifying information are collected by grantees, grantees will strip identifiers before sending data to RTI and will maintain the unique list linking ID and name at each site. The grantees will maintain this identifiable information in their own already established record systems; therefore, the Privacy Act does not apply.

The unique method of record identification allows each woman served to be tracked throughout their involvement with WISEWOMAN without using names or other identifying information. The identifying data provided to the contractor include an encoded patient ID number, county of residence, state of residence, zip code of residence, Hispanic origin, race, date of birth, and other risk factor data. (see attachment 2 in the Data User's Manuel). All grantees, CDC, and RTI received approval from both internal and external Institutional Review Boards authorizing collection and analysis of this information (**Attachment 3**).

The CDC does not anticipate the development of a public use data set using WISEWOMAN data. Based on the WISEWOMAN data, formal reports are developed for publication both biennially and periodically. Reports never include personal identifiers nor are they presented in a manner that allows for identification of individual participants. The reports are disseminated to the public through the CDC Internet web site, peer-reviewed journals, and publications. CDC may allow secondary analysis of WISEWOMAN data for relevant research purposes. If granted permission to use the data by CDC, external researchers will be required to sign a Data Use Agreement form indicating that they agree to comply with the provisions outlined for data release. No identifying information will ever be granted to external researchers.

A.11 Justification for Sensitive Questions

No information of a sensitive nature, such as religious beliefs or sexual behavior and attitudes, will be collected.

A.12 Estimates of Annualized Burden Hours and Costs

A. The estimated annual burden hours has not changed. The estimated annual respondent burden across all 15 proposed grantees is 2,160 hours. Because much of the data are collected and maintained by WISEWOMAN grantee programs as part of their internal evaluation, the additional burden for data reporting is small and only entails the time needed to generate and submit electronic data files and write brief responses for the quarterly reports. The respondent burden is further reduced by the electronic data submission, the consistent reporting schedule, and the similarity of WISEWOMAN and NBCCEDP data requirements. Table A.12-1 summarizes the proposed number of respondents and estimated burden hours.

Table A.12-1 Number of Respondents and Estimated Burden Hours

Report	Number of Respondents	Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Screening MDE Report	15	2	16	480
Intervention MDE Report	15	2	8	240
Cost Report	15	2	16	480
Quarterly Report	15	4	16	960
Total				2,160

B. The estimated annual cost to respondents for the burden of reporting the information is calculated by multiplying the respondent burden hours for each data manager by their average hourly wage (including fringe benefits). Based on information contained in the grant application, Grantee Data Managers earn a mean hourly wage of $27.10. As indicated in Table A.12-2, the estimated annual burden for each Data Manager to report the WISEWOMAN data is 144 hours. Therefore, the estimated annual cost, as reported in Table A.12-2, for each grantee Data Manager to report all necessary information is $3,902. The estimated total annual cost is $58,530.

Table A.12-2 Estimated Annualized Cost to Respondents

	Mean Hourly Wage Plus Benefits	Total Annualized Hours	Total Annualized Cost to Respondents
Each Grantee Data Manager	$27.10	144	$3,902
Total (15 Grantee Data Managers)	$27.10	2,160	$58,530

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

Respondents will incur no capital or maintenance costs to complete this data collection.

A.14 Annualized Cost to the Federal Government

The annualized cost to the federal government described in this request for extension is slightly higher than the annualized cost to the federal government described in the currently approved ICR. Total operation and maintenance costs include work performed by the data contractor, RTI International, and CDC personnel. RTI has a contract of $350,000 with CDC for information collection and analysis. CDC personnel costs are estimated at $10,000. Table A.14-1 summarizes the estimated federal government cost distribution.

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

	Annualized Cost
Data Contractor Total	**$350,000**
Data Collection	$88,000
Data Analysis	$122,000
Data Reporting	$85,000
Data Training	$55,000
CDC - GS 13 Technical Monitor at 10% FTE	**$10,000**
Total	**$360,000**

A.15 Explanation for Program Changes or Adjustments

Although changes were made to the attached forms via an 83-C approval in May 2006, these changes did not affect the overall burden. The burden remains the same.

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

CDC will continue to use the screening and intervention data reported by grantees to produce three categories of publications: Primary Summary Reports, Planned Publications, and Special Research Projects. The Primary Summary Reports are standardized, biennial reports that include basic statistics summarizing risk factor variables for each grantee. These reports are produced within 60 working days of receipt of the information. Planned Publications are formal reports that include cost-effectiveness analyses, multivariate analyses of the MDEs, and an examination of specific hypotheses. These reports are produced annually for inclusion in publications and presentations at conferences. These publications are also posted to the CDC web site and included in peer-reviewed journals. Special Research Projects include topics of interest to CDC and other researchers that are for publication in peer-reviewed journals. These projects are developed periodically with input and collaboration from grantees and outside researchers.

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

There is no request for an exemption from displaying the expiration date for OMB approval.

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.

ATTACHMENTS

Please Note: OMB approved the changes identified within the attachments via an 83-C request in May 2006. Changes are identified by a vertical line in the margin of the respective attachment. The changes are identified is to show the changes that have occurred since the collection was approved in November 2003.

- **Attachment 1 60-Day Federal Register Notice**
- **Attachment 2 WISEWOMAN Data User's Manual: Version 6.2 (and attachments)**
  - **Attachment 1: Standard Screening MDE Field Descriptions**
  - **Attachment 2: Standard Intervention MDE Field Descriptions**
  - **Attachment 3: Examples of Project-Specific MDEs for the Screening MDE File**
  - **Attachment 4: WISEWOMAN Data Submission Form**
  - **Attachment 5: Standard Screening MDE Errors**
  - **Attachment 6: Standard Intervention MDE Errors**
  - **Attachment 7: Validation of the Alert Follow-up Data**
  - **Attachment 8: Sample Baseline and 1-Year Change MDE Charts Data from All Projects Combined**
  - **Attachment 9: Validation of Out-of-Range Values**
  - **Attachment 10: Project Specific Definitions of Intervention Completion**
  - **Attachment 11: New/Revised Minimum Data Elements for the April 2008 and April 2009 Submissions**
- **Attachment 3 IRB Letter**