

Racial and Ethnic Approaches to Community Health across the U.S. (REACH US) Evaluation

Supporting Statement Part A

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Project Officer: Youlian Liao, MD
Division of Adult and Community Health (DACH)
National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP)
Centers for Disease Control and Prevention (CDC)
Atlanta, GA 30341
Telephone: (770) 488-5299
Fax: (770) 488-5974
Email: Youlian.Liao@cdc.hhs.gov

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A. Justification

1. Circumstances Making the Collection of Information Necessary

In 1999, the Centers for Disease Control and Prevention (CDC) launched the Racial and Ethnic Approaches to Community Health (REACH) 2010 demonstration project as authorized by Public Health Service Act, Title 42 United States Code, Chapter 6A - Public Health Service, Subchapter II - General Powers and Duties, Section 241 Research and Investigation (42USC241) (**Attachment 1**). This was a community intervention program targeting six health priority areas: cardiovascular disease, diabetes, improving breast and cervical cancer screening and management, improving adult or childhood immunizations, infant mortality, and HIV/AIDS. The funded communities targeted at least one of the following six racial/ethnic groups: African Americans, Alaska Natives, American Indians, Asian Americans, Hispanic Americans, or Pacific Islanders. Evaluation is of critical importance in documenting and assessing the reduction of health disparities among racial and ethnic populations. CDC conducted the REACH 2010 Risk Factor Survey from 2001 through 2006 in the residents of 27 communities focusing on cardiovascular disease, diabetes, and deficits in breast and cervical cancer screening and treatment (OMB number 0920-0502). The results from the survey have provided valuable information regarding efforts by the REACH 2010 communities to reduce health disparities.

CDC is to continue the program in eliminating the health disparities in minority communities. Starting September 30, 2007, a similar program, “Racial and Ethnic Approaches to Community Health across the U.S.” (REACH US) further moves into establishing a national multilevel program that approaches the elimination of racial and ethnic health disparities through the application, synthesis, and dissemination of promising practices within public health practice. Consequently, two levels of interlinked 5-year funding are supported 1) 18 Centers of Excellence in the Elimination of Disparities serving as expert centers by providing the infrastructure to coordinate, refine, and disseminate programmatic activities within specified racial and ethnic group(s) and along selected health priority areas, and 2) 22 Action Communities that implement practice-based or evidence-based practice/programs within a minority community, also along selected health priority areas. The priority areas are cardiovascular disease (heart disease and stroke), diabetes, breast and cervical cancer, adult/older adult immunization and infectious disease [limited to hepatitis B and tuberculosis], respiratory (limited to asthma), and infant mortality. This new intervention program includes some communities that previously participated in REACH 2010 and some new communities.

CDC requests OMB approval to continue the valuation of the program through a similar annual survey in 29 communities focusing on cardiovascular disease, diabetes, and deficits in breast and cervical cancer screening and treatment over 5 years. Within each community a total of 900 persons will be surveyed each year (26,100 respondents each year). Respondents will be persons over the age of 18 years who are within the race and ethnic group targeted by the specific REACH community. The methodologies will be similar to those used in the previously approved REACH 2010 evaluation instrument. The REACH US questionnaire will have minor changes tailored to the new features of the program (see **Attachment 3a for the Introductory Screening Interview** and **Attachment 3b for the detailed Household Member Interview**).

The survey focuses on the following areas: socio-demography, health-related quality of life, access to health care, physical activity, fruits and vegetables intake, cigarette smoking, diabetes, hypertension, cholesterol and cardiovascular disease screening and intervention, mammography and cervical cancer screening, and adult immunizations. The questionnaire in Attachment 3b includes some modules that may be used in selected communities targeting a specific health priority area (e.g., cardiovascular disease) and in communities implementing a specific intervention (e.g., weight control).

2. Purposes and Use of Information Collection

The purpose of this data collection will be to assess the prevalence and changes of self-reported risk behaviors associated with cardiovascular disease, diabetes, deficits in breast and cervical cancer screening, and other preventive services. Data will be collected on a yearly basis enabling investigators to assess changes in the performance measures during the intervention and will assess community progress towards meeting performance objectives. While state-based risk factor data exist from the Behavioral Risk Factor Surveillance System, these data do not reflect the level of health behaviors within local communities. This necessitates the collection of data within local communities.

The results of previous REACH 2010 Risk Factor Surveys have served multiple purposes. First, the data gathered have been utilized to determine the extent of health disparities across the racial and ethnic groups served by the REACH communities. Second, the communities and CDC have used these data to track progress in reducing and eliminating disparities. Third, the information has provided a scientific basis to assist CDC and other governmental agencies in determining the need and direction of additional programs and served as a model for potential future assessments. The annual data collected in the survey were sent to grantees of the surveyed communities with support documentation (e.g., methodology, data tables, data format, and data use instruction). These data have been used in numerous community newsletters, flyers, reports, briefings to local government and congress persons, conferences, as well as publications in scientific journals. CDC has used these data in CDC publications, websites, congressional briefing, national conferences, and scientific journals. The data to be collected in the proposed REACH US evaluation survey will serve similar purposes.

It is essential that valid epidemiological studies be performed on representative samples from varying racial and ethnic groups with collection of data from appropriate comparison populations. This study within the REACH communities represents the only epidemiologic study of a random sample of adults utilizing a detailed telephone assessment of health behaviors. Since the questions are derived from performance measures widely employed in public health and the data collection methods will be similar to those conducted in the state-based Behavioral Risk Factor Surveillance System (BRFSS), CDC will be able to use data from the BRFSS as a control for the REACH communities and minimize the burden of data collection. In addition, since each community questionnaire is identical, the REACH communities will also serve as control communities for each other, further minimizing the data collection burden.

This study is essential to the evaluation of the REACH program. If this study is not conducted, knowledge regarding the health disparities within and among the REACH

communities will be limited and CDC will not be able to assess progress towards the national objectives including the goal of eliminating health disparities in the REACH communities. Without this information CDC's ability to evaluate each community's progress in eliminating disparities in health will be greatly hampered.

3. Use of Improved Information Technology and Burden Reduction

In order to increase efficiency and consequently decrease respondent burden, participants will be interviewed utilizing Computer Assisted Telephone Interview (CATI) methodology. The telephone survey will be administered by a contractor. All data collection tools, including the subject interview, interview guide and script have been adapted from established performance measures and from existing surveys. Only those items which are essential in determining the previous and present health behaviors of the interviewee or to validate the responses are included.

4. Efforts to Identify Duplication and Use of Similar Information

An extensive review of scientific literature, medical journals, and governmental publications has been conducted to locate other studies regarding racial and ethnic disparities in health. Most of the current knowledge comes from epidemiologic studies in selected local areas in a small scale. These data did not reflect the prevalence of health behaviors in the REACH communities.

The concept of the study during initial planning of REACH 2010 was presented in 1998 to the Surgeon General, the Assistant Secretary for Program Evaluation, the Office of Minority Health DHHS, and the REACH 2010 Investigators. In addition there were presentations to a working group of subject matter experts that assisted the REACH 2010 grantees, the Cardiovascular Health Program, Division of Adult and Community Health, CDC, Division of Cancer Prevention and Control, CDC, Division of Diabetes Translation, CDC, and the National Immunization Program, CDC. As a result of these interactions and ongoing communications, it has been determined that no other epidemiologically valid study which assesses the pre- and post intervention health effects within the REACH communities has been conducted. In addition, morbidity and mortality data which may be available to some REACH communities are not appropriate for evaluation of intervention change given the short duration of intervention. Therefore data on health risk behaviors which are more likely to respond to intervention effects will be collected within the intervention community.

5. Impact on Small Businesses or Other Small Entities

The data to be collected in this study will be obtained from individual study subjects. No data will be collected from small businesses.

6. Consequences of Collecting the Information Less Frequently

The data collection in this study will consist of yearly surveys in the communities. If the information were collected on a less frequent basis, we would run the risk of missing changes in several performance measures. This would greatly increase the likelihood of not demonstrating statistically significant improvements in health disparities. Each year a random sample of the residents in the community is selected. Given the size and population of most of the communities, it is very unlikely that the same resident will be surveyed more than once over the years.

There are no legal obstacles to reduce the burden.

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

This data collection will not involve any of the special circumstances relating to the guidelines of 5 CFR 1320.5.

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

A 60-day Federal Register Notice was published in the Federal Register on November 16, 2007 (volume 72, number 221, pp. 64652-64653) (see **Attachment 2a**). CDC received one public comment and provided a response (see **Attachment 2b**).

In the past 5 years, we obtained consultations and input from academic scientists in the fields of epidemiology, biostatistics, survey design, and the evaluation of intervention studies. Our contractors have performed two site visits to every surveyed community and two environmental scan interviews with grantees and have received input on the study design, data collection procedure, instrument, as well as data usage. The surveyed communities also provided comments on the Vietnamese and Khmer versions of the questionnaire.

9. Explanation of Any Payment or Gift to Respondents

No payments or gifts will be offered to respondents.

10. Assurance of Confidentiality Provided to Respondents

This information collection request has been reviewed by Privacy staff who determined that the Privacy Act is not applicable. The data collection contractor will purchase lists of telephone numbers that are associated with names, however, names will be removed from the call lists provided to the interviewer, and names of participating respondents will not be collected by the interviewer. In limited situations, the interviewer may have temporary access to a potential respondent's first name or initials, such as when it is necessary to schedule a call-back to conduct the complete interview. In these situations, the first name or initials will be deleted from the interviewer's scheduling notes as soon as the interview has been completed. Response data will be identified and retrieved by a unique identification number assigned to each respondent. Neither the names nor any other information by which respondents could be individually identified will be recorded. Therefore, answers cannot be linked to individual respondents. Only aggregate data will be analyzed and reported.

The survey protocol for the contractor will utilize widely accepted practices to treat data in a confidential manner ensuring that the integrity of the survey will not be jeopardized by careless or inappropriate use of the data. All staff members are trained in and clearly understand the need to uphold confidentiality rules. Should a contractor staff member violate confidentiality and privacy procedures at any time, they will be removed from the project or reprimanded, as appropriate.

The data collection contractor will observe information management practices established by the National Institute of Standards and Technology (NIST), as specified in the *Guide for Developing Security Plans for Information Technology Systems* (special publication 800-18), *An Introduction to Computer Security: The NIST Handbook* (special publication 800-12), and *Generally Accepted Principles and Practices for Securing Information Technology Systems* (special publication 800-14). Security methodologies include physical access control; logical control of access to the IT environment as a whole; specific authorization and logical control of access rights to data and programs, based upon specific need for access; extensive network and Internet security control; management and operational controls; and monitoring, audit and variance detection. The data collection contractor will be selected no later than August 2008 through an open competitive process.

The IRB approval letter for this information collection is included as Attachment 6.

11. Justification for Sensitive Questions

Questions relating to race/ethnicity and income can be considered of a sensitive nature. However, these questions are important and are necessary in order to reach the intended audience for the REACH US program. The evaluation (survey) component needs to be consistent with the intervention program. Collection of income data will enable investigators to determine whether improvements in health status have occurred within certain segments of the community including those with low socioeconomic status. The privacy safeguards above are being implemented in recognition of the potentially sensitive nature of some questions in this information collection.

12. Estimates of Annualized Burden Hours and Costs

Random samples of community residents will be selected. The introductory call (Attachment 3a) will screen for eligibility by geographic, race/ethnicity, and age criteria. The average burden per respondent will be approximately two minutes. If the respondent is eligible and willing to participate, it will take an average of 15 minutes to complete the household member questionnaire interview (Attachment 3b). Based on experience from the REACH 2010 information collection, approximately 100,500 persons will need to be screened in order to obtain 26,100 completed interviews (900 respondents in each of the 29 REACH US communities). The estimated screening response rate is 69% and the estimated response rate for the household member interview is 61%. The estimated annualized burden hours are 9,875.

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Adults ages 18 and older who live in communities participating in the REACH US program	Introductory Screening Interview	100,500	1	2/60	3,350
	Household Member Interview	26,100	1	15/60	6,525
Total					9,875

Based on a mean hourly wage rate of \$11, the estimates of annualized costs to respondents are as follows in Table A.12-2. Eleven dollars/hour was used since the survey will be administered in minority populations with moderate to low income levels. The total estimated annualized cost to respondents is \$108,625.

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Total Burden in Hours	Average Hourly Wage Rate	Respondent Cost
Adults ages 18 and older who live in communities participating in the REACH US program	Introductory Screening Interview	100,500	1	3,350	\$11	\$ 36,850
	Household Member Interview	26,100	1	6,525	\$11	\$ 71,775
Total						\$108,625

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

There are no additional costs to respondents.

14. Annualized Cost to the Government

The annual cost to the government includes the costs for contracted data collection and the personnel costs of federal employees involved in oversight and data analysis. We will select a contractor through open competition to perform the survey. The contractor's responsibilities include: identify appropriate geographic areas of the surveyed community; identify a sampling frame from which to select households; instrument refinement; sampling plan, design, and selection; training of interviewers; administration of the appropriate survey; data management; and transfer data to CDC. Based on the experience and the costs in the previous surveys, the annual contract cost is estimated as \$5,000,000. The personnel costs of federal employees are about \$100,000 per year, based on 100% of an FTE at GS-14. Hence, the total annual cost to the Government is about \$5,100,000.

15. Explanation for Program Changes or Adjustments

The REACH US program is replacing the REACH 2010 program which was discontinued in September 2007. The OMB clearance for the information collection under the REACH 2010 program (0920-0502) will be discontinued upon receipt of OMB approval for the proposed new information collection for REACH US. The burden estimate for each respondent participating in an interview has not changed. However, the revised burden estimate reflects an increased number of survey communities (29) compared to REACH 2010 (27 communities).

16. Plans for Tabulation and Publication and Project Time Schedule

Data collection for this study is scheduled to begin four weeks after OMB approval, and to continue on an annual basis. A three-year approval period is being requested for this information collection. During the third year another application for OMB approval will be submitted in order to continue data collection for another two years.

As in the REACH 2010 clearance, the actual data collection will take 6-8 months each year. Data will be cleaned within a month. Raw data, tabulation of data, as well as supporting documentation will be sent to each community within two months after completion of data collection. CDC and the communities will use these data, including data analysis for presentation and publication, immediately after the data are available. When the subsequent year's data are available, analysis will include multiple years of data. CDC will analyze aggregated data by priority area and by racial/ethnic group. Secular trend analyses have been performed in the past and will be continued.

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

Display of the OMB Expiration date is reasonable and will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exemptions to the certification are requested.