

SUPPORTING STATEMENT A
FOR
NATIONAL DIABETES EDUCATION PROGRAM
SURVEY OF THE PUBLIC

June, 2012

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

National Institutes of Health/NIDDK Project Officer: Joanne Gallivan, M.S., R.D.

Building 31, Room 9A04

31 Center Drive, MSC 2560

Bethesda, MD 20892

Phone: 301-496-6110

Fax: 301-496-7422

E-mail: joanne_gallivan@nih.gov

Contents

Part A: JUSTIFICATION.....	3
A.1. Circumstances Making the Collection of Information Necessary.....	3
A.2. Purpose and Use of the Information.....	6
A.3. Use of Information Technology and Burden Reduction.....	8
A.4. Efforts to Identify Duplication and Use of Similar Information.....	9
A.5. Impact on Small Businesses or Other Small Entities.....	9
A.6. Consequences of Collecting the Information Less Frequently.....	9
A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5.....	10
A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency.....	10
A.9. Explanation of Any Payment or Gift to Respondents.....	10
A.10. Assurance of Confidentiality Provided to Respondents.....	10
A.11. Justification for Sensitive Questions.....	11
A.12. Estimates of Hour Burden Including Annualized Hourly Costs.....	12
A.13. Estimate of Other Total Annual Cost Burden to Respondents or Recordkeepers.....	13
A.14. Annualized Cost to the Federal Government.....	13
A.15. Explanation for Program Changes or Adjustments.....	13
A.16. Plans for Tabulation and Publication and Project Time Schedule.....	13
A.17. Reason(s) Display of OMB Expiration Date is Inappropriate.....	14
A.18. Exceptions to Certification for Paperwork Reduction Act Submissions.....	14

Attachments for Supporting Statement A:

Attachment A: Survey of the Public’s Knowledge, Attitudes and Practices Questionnaire

Attachment B: NDEP National Diabetes Survey: Initial Results: Trends from Three Rounds
(2006, 2008, 2011) For Respondents Ages 45+, May 15, 2012

SUPPORTING STATEMENT

Part A: JUSTIFICATION

A.1. Circumstances Making the Collection of Information Necessary

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) requests that the Office of Management and Budget (OMB) review and approve the reinstatement without change for the approved information collection (OMB No. 0925-0552), under the *Paperwork Reduction Act of 1995*. This collection is for NIDDK to conduct a survey of the public to support program planning activities of the National Diabetes Education Program (NDEP).

The National Diabetes Research and Education Act, Public Law 93-354, amended the Public Health Service Act to provide greater and more effective efforts in research and public education with regard to diabetes. Current authorization for NIDDK's research and information dissemination activities is contained in 42 USC 285c. The Act authorizes the establishment of the Diabetes Mellitus Interagency Coordinating Committee to coordinate the activities of National Institutes of Health (NIH) and other agencies related to diabetes and its complications. The Diabetes Mellitus Interagency Coordinating Committee launched the National Diabetes Education Program (NDEP) in 1997, in response to scientific evidence that improved management of diabetes can significantly reduce morbidity and mortality related to the disease.

NDEP is a partnership of the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) and more than 200 public and private organizations. The long-term goal of the NDEP is to reduce the burden of diabetes and pre-diabetes in the United States, and its territories, by facilitating the adoption of proven strategies to prevent or delay the onset of diabetes and its complications. The program audiences include the public, people at risk for diabetes, people with diabetes and their families, with special emphasis on racial/ethnic populations; health care providers; and payers and purchasers of health care and health care system policy makers. The NDEP objectives are:

- (1) Increase awareness and knowledge of the seriousness of diabetes, its risk factors, and effective strategies for preventing type 2 diabetes and complications associated with diabetes
- (2) Increase the number of people who live well with diabetes and effectively manage their disease to prevent or delay complications and improve quality of life
- (3) Decrease the number of Americans with undiagnosed diabetes
- (4) Among people at risk for type 2 diabetes, increase the number who make and sustain effective lifestyle changes to prevent diabetes
- (5) Facilitate efforts to improve diabetes-related health care and education, as well as systems for delivering care
- (6) Reduce health disparities in populations disproportionately burdened by diabetes
- (7) Facilitate the incorporation of evidence-based research findings into health care practices

An integral part of the NDEP strategic plan is evaluation. The program evaluation documents the extent to which the NDEP program has been implemented and how successful it has been in meeting the program objectives.

In March 2006, NDEP launched a national probability telephone survey (OMB No. 0925-0552) on the public's knowledge, attitudes and practices related to diabetes. This survey was repeated in 2008 and again in 2011. The surveys are designed to collect information on key target audiences of NDEP – people with diabetes and their families, people with pre-diabetes, people at risk for developing diabetes and the public. To improve estimates of minorities, a stratified sample design was used that oversamples African American and Hispanic households. These surveys have been funded by the NIH One Percent Evaluation Set-Aside Program administered by the Office of Program Evaluation and Performance (OPEP) within the Office of the Director (OD) and by NIDDK/NDEP funding.

The Department of Health and Human Services (DHHS) is authorized, under the Public Health Service (PHS) Act, to allocate up to one percent of appropriations for PHS programs for the evaluation of their effectiveness. In addition to assessing the effectiveness of federal health programs, the purpose of the One Percent Evaluation Set-Aside is to identify ways to improve their implementation and effectiveness. The One Percent Evaluation Set-Aside provides a critical funding mechanism by which NIH and other public health service agencies can evaluate program performance.

Approval is requested for the reinstatement without change for the data collection approved by OMB (OMB No. 0925-0552/ Exp. 01/31/2012). Procedures for this data collection are described in Supporting Statement B. The 2011 survey questionnaire is included in Attachment A.

A.2. Purpose and Use of the Information

The purpose of this clearance request is to further collect data that supports the program planning and evaluation activities of the National Diabetes Education Program (NDEP). The lead agency for implementation and evaluation of NDEP is the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). As noted earlier, the NIDDK is specifically mandated to “conduct and support research, training, health information dissemination, and other programs with respect to diabetes” To that end, the National Diabetes Education Program conducts diabetes awareness and education activities, develops and disseminates education tools and resources, and promotes initiatives to improve the quality of and access to diabetes care.

Multiple strategies have been devised to address the NDEP objectives. These have been described in the NDEP Strategic Plan and include: (1) promoting and implementing culturally and linguistically-appropriate diabetes awareness and education campaigns for a wide variety of audiences; (2) identifying, disseminating, and supporting the adoption of evidence-based, culturally and linguistically-appropriate tools and resources that support behavior change, improved quality of life, and better diabetes outcomes; (3) expanding NDEP reach and visibility through collaborations with public, private, and nontraditional partners, and use of national, state, and local media, traditional and social media, and other relevant channels.; and

(4) conducting and supporting the evaluation of NDEP resources, promotions, and other activities to improve future NDEP initiatives.

An integral part of the National Diabetes Education Program's strategic plan continues to be an evaluation plan that is a comprehensive strategy for process and impact evaluation. The process evaluation monitors program implementation, demonstrates progress toward achievement of objectives, and identifies areas in need of mid-course correction or continuation.

The process evaluation indicators on audience reach and access, for example, are measured in the following ways:

- Television, radio and print public service advertising placements are tracked and the reach and frequency of TV messages, for example, are reported as the number of plays (frequency) and estimated number of listeners (reach).
- Results of press releases are tracked by a clipping service and the number of news stories and the number of publications that pick up the story and their circulation (reach) are reported.
- Publications ordered from the National Diabetes Information Clearinghouse and public inquiries to CDC's Division of Diabetes Translation are tracked as well as website statistics tracking visitors, page views, duration on page, and other standard measures.

The impact evaluation of for NDEP relies primarily on secondary data from a variety of national sources such as the National Health and Nutrition Examination Survey (NHANES OMB No. 0920-0237/ Exp. 11/30/2012), the National Health Interview Survey (NHIS OMB No. 0920-0214/ Exp. 08/31/2014), and the Behavioral Risk Factor Surveillance System (BRFSS). Data

will be drawn from sources such as the National Committee for Quality Assurance's Diabetes Physician Recognition Program and Healthcare Effectiveness Data and Information Set (HEDIS®) and relevant professional associations. The NDEP identified the need for additional information for future program planning and outreach efforts for which there is no existing relevant data source and developed a population-based survey specifically focused on diabetes.

This public survey, now called the NDEP National Diabetes Survey, has been conducted 3 times already (2006, 2008, 2011), and results from each round have been very important for NDEP to use in program planning and program development. In the last few years—partly as result of the first two surveys showing high knowledge but not high levels of behavior changes—NDEP has added a focus on changing behavior – not just what to change but also on how to change. This included developing tools to support people in their efforts rather than focusing solely increasing knowledge. The 2011 survey results and the trend comparisons documented improvements in knowledge and strategies for taking action to prevent or control diabetes since 2006 while activities around self-management of diabetes are stagnant.

The results of the 2006 and 2008 public surveys were published in an article in 2009¹ as well as disseminated at various conferences such as the American Diabetes Association, the American Association of Diabetes Educators and the CDC Division of Diabetes Translation Annual Meeting. The 2011 results and the trend comparisons have been presented at various NDEP stakeholder meetings such as the mid-May meeting of the NDEP Operations Committee.

Dissemination activities including additional presentations and a journal article will be forthcoming throughout 2012.

¹ Gallivan J, Brown C, Greenberg R, and Clark C. Predictors of Perceived Risk of the Development of Diabetes. *Diabetes Spectrum* June 20, 2009 vol. 22 no. 3 163-169

The primary data collected in this study will supplement available secondary data to provide information for NDEP to focus and refine their program strategies to reach NDEP's target audiences and to help shape NDEP's future initiatives. In addition, the survey report will provide an additional set of data points to continue the trend results demonstrating the effectiveness of NDEP's efforts over time.

A.3. Use of Information Technology and Burden Reduction

The survey will be conducted using Computer-Assisted Telephone Interviewing, or CATI. This technology has several advantages over the traditional pen and paper method. First, data are available sooner because data entry and most manual editing and data cleaning steps are eliminated. Data cleaning is more efficient because potential interviewer errors, such as missed questions or inappropriate skips, are practically eliminated. Also, any discrepancies between responses are automatically identified for probing during the course of the interview. The overall result is a lower response burden for participants.

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

After conducting a thorough assessment of available data sources, NDEP determined that primary data was needed to effectively assess outreach efforts of the National Diabetes

Education Program. As the Program evolves, NDEP will continue to review existing literature and databases and work with outside consultants to search for compatible secondary data sources. The evaluation currently relies on a variety of data sources including NHANES, NHIS, and BRFSS. Also, wherever appropriate, NDEP/NIDDK works with survey designers to piggy-back questions onto other national surveys. For example, when the National Center for Health Statistics invited agencies to submit research proposals for questionnaire material, laboratory assessments, and examination components to the NHANES survey for 2005-2006, NIDDK responded with their intent to continue to fund the NHANES questionnaire administered to persons with diabetes, which queries individuals about diagnosis of diabetes, age of diagnosis, glycemic treatment, and diagnosis of retinopathy.

A.5. Impact on Small Businesses or Other Small Entities

This data collection effort is not expected to have any impact on small businesses or other small entities.

A.6. Consequences of Collecting the Information Less Frequently

Respondents will only be contacted once.

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

There are no special circumstances relating to the guidelines of 5 CFR 1320.5 and the project fully complies.

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

A 60- Day Federal Register Notice was published on January 25, 2012 (Vol. 77, No. 16) on pages 3783-3784. There were no public comments.

A.9. Explanation of Any Payment or Gift to Respondents

There are no payments to respondents anticipated.

A.10. Assurance of Privacy Provided to Respondents

This study provides assurance of privacy to respondents, as required by the Privacy Act of 1974 (P.L. 93-579), section 301 (g) of the Public Health Service Act, as amended, and P.L. 93-218, as amended. Prior to any data collection, individuals will be advised of the following: the nature of the activity; the purpose and use of the data collection, NIDDK sponsorship, and the fact that participation is voluntary at all times. Since responses are voluntary, respondents will be assured that there will be no penalties if they decide not to respond, either to the information collection as a whole or to any particular questions.

As a further guarantee of privacy, all presentation of data in reports will be in aggregate form, with no links to individuals being preserved. Reports will only be used by project staff for research purposes and for development of specific communication messages and educational materials.

A.11. Justification for Sensitive Questions

To reach NDEP target audiences, questions regarding race/ethnicity, income, and /or health status are necessary. Individual respondents will be informed that this information is important to discovering whether NDEP is reaching the people for whom the educational messages are intended. Information will be collected directly from respondents, who will be assured that this information is voluntary and will be treated as private to the extent provided by law. Questions on race/ethnicity are in compliance with OMB Directive No. 15.

Some surveys may include questions regarding how one perceives his/her own risk for diabetes and its complications. This information is needed to gain a better understanding of the target audience so that messages, strategies and materials designed will be appropriate and sensitive. Questions of this nature require sensitivity in how they are worded and approached. As noted in section A.10., participants are informed up front about the nature of their participation.

Raw data from data collections that include sensitive information are not retained once the data has been extracted and aggregated nor does the information become part of record containing permanent identifiers that can be used for retrieval.

A.12. Estimates of Hour Burden Including Annualized Hourly Costs

A.12 – 1: ESTIMATES OF HOUR BURDEN				
Type of Respondents	Number of Respondents	Frequency of Response	Average Time per Response	Total Hour Burden
Screening interview with ineligible persons	1659	1	.03	50
Eligible respondents	2100	1	.33	693
Total	3759			743

A.12 – 2: COST TO RESPONDENTS				
Type of Respondents	Number of Respondents	Frequency of Response	Hourly Wage Rate	Respondent Cost
Public including patients and their family members	2100	1	\$20.00	\$13,860
Total				\$13,860.00

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

There will be no capital, operating, or maintenance costs to the respondents.

A.14. Annualized Cost to the Federal Government

The approximate annual cost to the government for this study is \$250,000. This cost is based on costs for research design, pretesting, development of the Office of Management and Budget clearance package, programming for data collection, data analyses, and reporting and presenting the findings to the NDEP senior management after the survey analyses and results are completed. This survey will be funded by the Evaluation Set-Aside legislative authority, which is provided for in Section 241 of the Public Health Service (PHS) Act.

A.15. Explanation for Program Changes or Adjustments

This is a request for a reinstatement without change for a data collection currently approved by OMB. We request an increase in the burden amount from the previously approved 525 hours to 699.3 hours which is an increase of 5 minutes per participant and an additional 174.3 hours overall.

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

This survey will be conducted by Social & Scientific Systems (SSS), NIDDK's contractor supporting the evaluation activities of the National Diabetes Education Program. SSS will be responsible for working with the NDEP senior management in all aspects including planning, data collection, analysis, and report writing.

A.16 -1: Survey Time Schedule	
Activity	Time Schedule
Questionnaire and sampling plan development and approval	OMB approval
Begin CATI interviews	Within 2 months after OMB approval
Completed field work	7 months after OMB approval
Analyses completed	9-10 months after OMB approval
Report on survey results and trend results and presentation of relevant results to the NDEP senior management	12-15 months after OMB approval

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

No exemption is requested. The OMB control number and expiration date will be displayed in the upper right hand corner of all data collection instruments.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

This data collection has been designed in accordance with the requirements specified in Item 19 of the OMB 83-I. No exceptions to certification are required.