Information Collection Request for OMB Clearance

Assessing the Diabetes Detection Initiative for Policy Decisions

Supporting Statement Part A

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Table of Contents

List of Tables

List of Attachments

A. Justification

A1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests the approval by the Office of Management and Budget (OMB) of a new information collection for the economic assessment of diabetes screening of low-income patients by health clinics. Type 2 diabetes is a chronic disease that affects more than 18 million Americans and their families but 5 million may be undiagnosed (1). As the disease progresses, it often causes severe complications—including heart disease, blindness, lower extremity arterial disease, and kidney failure—that can ultimately damage every organ in the body and lead to premature death. In many states, half of all people with diabetes do not receive recommended preventive care services that are known to reduce the risk of diabetes complications (2). The direct health costs of diabetes in the US were estimated to be nearly $132 billion in 2002 (3). This figure does not take into account the indirect health costs or value of potential work loss attributable to diabetes-related illness or premature death.

The prevalence of diagnosed Type 2 diabetes increased six-fold in the latter half of the last century (4). Diabetes risk factors such as obesity and physical inactivity have played a major role in the dramatic increase in rates of Type 2 diabetes in recent years. Age, race, and ethnicity are also important risk factors. The prevalence of diabetes increases with age in all racial and ethnic groups. Whereas 8.6% of Americans over age 20 have diabetes, 20.1% of Americans over age 65 have diabetes. Far fewer Americans younger than age 20 have diabetes, but the prevalence of diabetes in this age group appears to be rising considerably. The rising prevalence of diabetes in this age group, as in other age groups, is attributed to increases in physical inactivity and obesity.

American Indians, African Americans, Latino Americans, and some Asian Americans and Pacific Islanders are disproportionately affected by diabetes. For example, African and Hispanic Americans are almost twice as likely to have diabetes as non-Hispanic white Americans of similar age, and American Indians are almost three times as likely to have diabetes as non-Hispanic whites of similar age. As the prevalence of obesity and sedentary lifestyles increases and the U.S. population becomes older and more ethnically diverse, the prevalence of diabetes is expected to continue to rise (5).

Socioeconomic and environmental factors may also play a role in a person's risk of developing diabetes and in the course of diabetes once it has developed. People with Type 2 diabetes are more likely to have less education and lower incomes than people without diabetes (6). Elderly minority women, who are more likely to live alone and to have lower socioeconomic status, are also more likely to have diabetes and to lack resources to adequately manage their disease (7).

The Diabetes Detection Initiative (DDI) was launched in November of 2003 as a national pilot to mobilize community-based efforts targeted toward identifying a portion of the overall population with undiagnosed Type 2 diabetes, especially low-income patients,

refer them for diagnostic testing and, if appropriate, follow-up treatment (8). The implementation of the DDI was the result of an extensive partnership among federal agencies, and, within each region, a number of public, community-based, and private partners which came together to tailor the general DDI approach to specific local circumstances. The Office of the Secretary was centrally involved, and, in addition to CDC, collaborating federal agencies included the Health Resources and Services Administration (HRSA), the Agency for Healthcare Research and Quality (AHRQ), the Indian Health Service (IHS), Centers for Medicare and Medicaid Services (CMMS), the Food and Drug Administration (FDA), and the National Institutes of Health (NIH). Ten pilot locations were involved in the pilot implementation, one in each federal administrative region. Five of the pilot locales began their efforts in November 2003 (Fayette/Greenbrier, WV; Wichita and Sedgwick County KS; Flint, MI; Choctaw Nation, OK; and East Harlem, NY). Five of the pilot locales began their efforts in March-April 2004 (Orangeburg County; SC; Oakland, CA; the Wind River Reservation, WY; Springfield-Holyoke, MA; and Seattle, WA).

In each pilot locale, a regional Department of Health and Human Services (HHS) representative helped convene a local implementation team, whose members included representatives from the relevant state Diabetes Control Program, at least one primary care association, HRSA- or IHS-funded health centers, and other community-based organizational partners. These clinics were selected because they serve disadvantage populations that were both disproportionately poor and uninsured. Populations targeted varied by pilot locale. Latinos received considerable attention in East Harlem and Oakland, while outreach to Native Americans was the main focus of the Wind River and Choctaw Nation's efforts. The populations receiving the greatest attention in Flint, Orangeburg, Wichita, and Springfield were African American residents, while Fayette/Greenbrier and Seattle targeted a diverse mix of populations at risk. Although DDI has ended, the need for diabetes screening remains even in areas that participated in DDI.

The proposed economic assessment will address three questions: (1) What types of activities are being used to screen for diabetes and what is the distribution of overall costs by type of activity by the type of clinics that participated in DDI?; (2) What is the average economic cost per person screened for diabetes and per person diagnosed?; and (3) What is the perceived economic benefit of diabetes screening to individuals targeted by the DDI? The results of the study will help the CDC and other policymakers in deciding how to design future screening programs that also target similar disadvantaged populations.

This study is authorized by Section 301 of the PHS Act (42 U.S.C. 241). A copy of the legislation is included as **Attachment A**. Data will be collected by a contractor, Battelle Centers for Public Health Research and Evaluation.

A2. Purpose and Use of the Information Collection

The objective of the proposed study is to design, conduct and analyze the results of two separate, but related, data collections. These include:

- The **DDI Health Clinic Leadership Survey** will be administered to the clinics that participated in the DDI to obtain information regarding the clinic's current activities in the areas of diabetes awareness and screening, including the resources used in delivering the medical services required in diabetes screening and diagnosis, as well as staff time associated with patient outreach activities.
- The **DDI Patient Survey**, which includes a **Stated Preferences Module,** will be administered to a sample of patients at the clinics that participated in the DDI to obtain two different types of information: (1) data from which to estimate the out-of-pocket medical and non-medical direct health care costs such as copayments, transportation costs, and the value of participants' time for screening; and (2) data needed to estimate the perceived economic benefits of diabetes screening.

Data from these surveys will address three questions: (1) What types of activities are being used to screen for diabetes and what is the distribution of overall costs by type of activity?; (2) What is the average economic cost per person screened for diabetes and per person diagnosed; and (3) What is the perceived economic benefit of diabetes screening to individuals targeted by the DDI? The answers to these questions will be critical for making a number of public health policy decisions related to screening for undiagnosed diabetes. First, by providing information regarding resource use and the cost per case of diagnosed diabetes, the results of the study will provide information for designing diabetes screening programs and for conducting a more complete cost-effectiveness analysis of screening for undiagnosed diabetes. Second, the information on perceived benefits will be used to derive consumer demand for screening services so that the response of participants to various fee schedules can be predicted. Participant demand for screening services along with information on resource use and cost per case of newly diagnosed diabetes will provide CDC with critical information needed to make policy decisions regarding diabetes screening programs. Finally, results of the proposed economic assessment could also be used to predict the degree of participation if a diabetes screening program were offered on a large scale at different fee schedules.

A3. Use of Improved Information Technology and Burden Reduction

The Stated Preferences Module – a component of the DDI Patient Survey - will be administered as a computer-assisted in-person interview (CAPI). A primary advantage of using CAPI for this module is that the specific features of the various diabetes programs to be evaluated will be randomly selected for each respondent. Other advantages include ease of response for the survey respondent, which may increase the response rate, and ease of survey administration and data entry.

In the case of the DDI Health Clinic Leadership Survey, an electronic management information system (MIS) will be used to monitor data collection activities. The MIS, which will store all background data known about each respondent, will also contain the dates of advance and reminder e-mail messages, the dates that questionnaires were

mailed, and the dates that completed questionnaires (or refusals) were received. Mailing labels and personalized letters will be generated from this system. Follow-up e-mail dates will then be computed by the tracking system to ensure timely reminders to non-respondents. The MIS will be used to generate weekly status reports throughout the data collection period. This system will reduce respondent burden by ensuring that respondents are contacted at appropriate times and are not sent e-mail reminders if a completed survey (or refusal) has been received.

Finally, the survey instruments were designed to minimize respondent burden. Only that information which is necessary to achieve the objectives of the proposed study is being collected.

A4. Efforts to Identify Duplication and Use of Similar Information

During implementation of the DDI, Battelle conducted a formative evaluation of the DDI implementation for the Agency for Healthcare Research and Quality. The quantitative evaluation collected data from all participating health clinics concerning the number of finger sticks for random blood glucose performed each month from November 2003 through August 2004, the number of patient visits each month from November 2003 through August 2004; and the size of the adult population served by the clinic in calendar year 2003. In addition, the 16 clinics with diabetes registries reported the number of people with newly diagnosed diabetes by month from November 2003 through August 2004. A second element of the evaluation involved an extensive qualitative examination of the range of pilot implementation experiences, including some of the key implementation challenges faced in the early stages of the DDI, pilot strategies that were successful in meeting these challenges in distinct community settings, and specific activities that were shown to be particularly effective.

The prior DDI evaluation collected information to assess the effectiveness of the DDI; however, no information was collected regarding the cost of resources used in delivering the medical services required in diabetes screening and diagnosis, the staff time associated with patient outreach activities, or the perceived benefit of a diabetes screening program to DDI participants. The results of the proposed new data collection will provide valuable information regarding the resources used, cost per case of diabetes detected, and perceived benefit of a diabetes screening program to participants and will help policymakers in designing future diabetes screening programs.

A5. Impact on Small Businesses or Other Small Entities

Participating clinics will meet the definition of a small business. Every effort has been made to minimize the burden of the survey on small businesses. The survey will be completed only one time. In addition, in designing the survey instrument, the number of questions has been held to the minimum necessary for addressing the objectives of the proposed study.

A6. Consequences of Collecting the Information Less Frequently

The proposed survey will be conducted only once. No follow-on data collection is planned. No legal obstacles exist to reducing the data collection burden.

A7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances related to this data collection. The request fully complies with the regulation.

A8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. Comments in Response to the Federal Register Notice

As required by 5 CFR 1320.8(d), a notice of this data collection was published in the *Federal Register* on February 27, 2007 (Volume 72, Number 38, pages 8737-8738). A copy of the *Federal Register* notice is included as **Attachment B**. No public comments were received.

B. Efforts to Consult Outside the Agency

An advisory panel of economists provided input to CDC and Battelle in the development of the survey instruments and survey protocol. The Expert Panel also provided the study team with input regarding our proposed approach for estimating the perceived economic benefit of the DDI to participants. An Expert Panel meeting was held in Philadelphia, Pennsylvania, on January 6, 2005. The purpose of the meeting was to obtain input regarding: (1) a draft survey instrument—both the general attributes to be evaluated, as well as the specific alternatives associated with each attribute; (2) the proposed data collection procedures; (3) the methodology for data analysis; and (4) the specific population to be targeted with the survey. The names, telephone numbers, and e-mail addresses of the outside participants in Expert Panel meeting are provided in Table A.8 – 1.

Table A.8-1. Diabetes Detection Initiative Evaluation—Expert Panel Meeting: Philadelphia, Pennsylvania, January 6, 2005

Name, title, phone number, email address	Agency
Peter Boxall, PhD Professor, Environmental and Resource Economics (780) 492-4603 peter.boxall@ualberta.ca	University of Alberta, Edmonton, AB CANADA T6G 2H1
Kevin Boyle, PhD Department Head, Agricultural & Applied Economics (540) 231-6301 kjboyle@vt.edu	Virginia Tech Blacksburg, VA 24061
Jeffery Englin, PhD Professor and Chair, Department of Resource Economics (702) 784-4411 englin@unr.edu	University of Nevada Reno, NV 89557
Thomas P. Holmes, Ph.D. Research Forester/Economist (919) 549-4031 tholmes@fs.fed.us	USDA Forest Service Research Triangle Park, NC 27709

A9. Explanation of Any Payment or Gift to Respondents

We understand that high response rates are critical to ensure valid and precise survey estimates and reduce potential for bias. As described in section B3, several approaches will be used in an effort to maximize the response rate to the survey. Among these, we plan to offer clinic patients $5 as an incentive to participate in the survey.

There is clear and consistent evidence that monetary remuneration significantly increases response rates to mail, telephone and face-to-face surveys, and experts on survey methods recommend their use (9,10). Church (11) and Singer and colleagues (12) have published meta analyses comparing the response rates of mail and interviewer-mediated surveys with and without monetary incentives. These studies have shown that even a nominal gratuity increases response rates, and the amount of the incentive is positively correlated with response rate (13-16). Furthermore, combining other measures to increase response (e.g., advance letters, repeated follow-up with non-respondents) with monetary payments has been shown to produce higher response rates than payments alone or other types of incentives without payments (17, 18).

Previous research suggests that monetary incentives may be especially effective in recruiting into the sample low-income and minority respondents. For example, analyses by Singer, Van Hoewyk, and Maher (19) indicate that a $5 incentive paid to a random half of households brought a higher percentage of low-education respondents into the sample. Because the DDI targeted communities with minority populations (e.g., African Americans, Native Americans, Hispanics) and those without health insurance, we feel

that it will be particularly important to provide an incentive to obtain a high response rate from these minority populations.

Finally, in addition to increasing survey response rates, a few studies have examined the impact of incentives on data quality (19-21). For example, experiments reported by Singer, Van Hoewyk and Maher (19) indicate that promised and prepaid incentives reduce the tendency of older people and nonwhites to have more item missing data, resulting in a net reduction in item nonresponse. These studies suggest that offering an incentive may improve data quality in the sense that respondents who were provided incentives had less item-missing data and provided longer open-ended responses compared with respondents who were not provided incentives.

The CDC and Battelle Institutional Review Boards have reviewed the study protocol and concluded that the incentive is sufficient to compensate respondents for the inconvenience of completing the survey, but does not represent a coercive inducement to participate.

A10. Assurance of Privacy Provided to Respondents

This submission has been reviewed by staff in the CDC Information Collection Review Office (ICRO), who determined that the Privacy Act does not apply. Information provided by the clinic staff, their names and clinic addresses, are public information. No personal information will be collected on clinic staff and staff will be speaking from their roles.

For the purposes of the DDI Health Clinic Leadership Survey (Attachment F), the respondent is an organizational entity, not an individual. Although a contact person completes the clinic survey on behalf of the respondent organization, the contact person is speaking from their role as an employee, and does not report personal information. The name of the contact person is not linked to the study analysis data files and only maintained temporarily during data collection. To facilitate reminder notifications and follow-up necessary for quality control purposes, each pre-printed survey includes a clinic identification code. The information linking the clinic ID code to clinic name will be deleted from the final analysis dataset at the end of the study. The data collection contractor, Battelle, will provide only the de-identified dataset to CDC.

Battelle representatives will also be responsible for collecting information from patients recruited for participation in the DDI Patient Survey, which consists of a paper form (Attachment G.1) and a CAPI module (Attachment G.2). Recruitment will be conducted in a clinic setting and respondents' names will be recorded when they sign the informed consent form required by Battelle's IRB. However, response data from the surveys will not be identifiable by name. Response data will be retrieved by a patient ID code and clinic ID code, which will be used for both the DDI Patient Survey and the Stated Preferences Module. The coding system will allow the contractor to link information collected in the paper-based portion of the patient data collection to information collected in the CAPI portion of the patient data collection. The contractor will submit only de-

identified data to CDC. There will be no list of both patient ID codes and patient names created so that individual names from the consent forms cannot be linked to response data.

All project staff will be trained to understand the purpose, sponsorship, background, objectives, and importance of the project, as well as their specific role and activities on the study. In training project staff, we will emphasize the steps that will be taken to safeguard the data that are collected. Completed paper surveys (for both clinic respondents and patient respondents) will be stored in locked file cabinets in Battelle offices. All electronic files will be password protected and access to the files will be limited to authorized project staff. The steps that will be taken to protect the confidentiality of the data will be emphasized in written and verbal training procedures for project personnel.

Data will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law. Neither the names of respondents nor the institutions they represent will be identified in published reports or publicly available data. Respondents will not, however, receive a formal guarantee of confidentiality.

The survey instruments and study protocol have been reviewed and approved by the Institutional Review Boards of CDC and Battelle. Documentation of IRB approval is provided in **Attachments C and D**.

A11. Justification for Sensitive Questions

The DDI Patient Survey involves the collection of information that may be considered sensitive by a portion of respondents, such as data concerning race, ethnicity, diagnosis of diabetes, family history of diabetes, income level, and medical expenses. Since the prevalence of both diagnosed and undiagnosed diabetes is higher among racial and ethnic minorities, many programs target these groups for treatment or prevention. If these groups also experience different levels of out-of-pocket medical or non-medical costs associated with utilizing their respective health clinics and different perceived economic benefits of diabetes screening, this information may be important in the design of programs that target these groups. Thus, although some information may be considered sensitive by a portion of respondents, the information is required for the planned analysis and use of survey results. As described in Section A.10, appropriate measures to safeguard respondent privacy have been instituted.

A12. Estimates of Annualized Burden Hours and Costs

Estimated Burden Hours

Forty-three clinics participated in the DDI and are eligible to participate in the proposed DDI Health Clinic Leadership Survey (Attachment F). We estimate a response rate of 70% (30 clinics) for this component of the proposed data collection. The average burden per response is estimated to be one hour, based on a pre-test of 2 respondents.

Data collection from patients will include Screening Questions for the DDI Patient Survey (Attachment G.3), the DDI Patient Survey (a paper form, Attachment G.1), and the Stated Preferences Module of the DDI Patient Survey (CAPI, Attachment G.2). Burden estimates are based on a pre-test of data collection instruments involving 9 respondents at a DDI clinic. The burden estimate of 20 minutes for the DDI Patient Survey includes burden for both the paper portion of the data collection and the CAPI module. Based on an estimated response rate of 60%, 1,000 patients will be screened for eligibility and interest in order to yield 600 completed responses.

The total estimated burden hours are 263, described in table A.12-1 below.

TABLE A.12-1. ESTIMATED ANNUALIZED BURDEN HOURS

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden (in hours)	Total Burden (in hours)
DDI Clinic Representatives	DDI Health Clinic Leadership Survey	30	1	1	30
Patients at DDI Clinics	Screening Questions for the DDI Patient Survey	1,000	1	2/60	33
	DDI Patient Survey	600	1	20/60	200
				Total	263

Estimated Cost to Respondents

The cost to respondents for the study is shown in Table A.12 – 2. Estimates assumed an hourly wage rate of $40 for clinic staff (an hourly rate equivalent to a registered nurse) and $6 for clinic patients (an average hourly wage rate that is slightly above the federal minimum wage). The annualized cost to respondents is $2,600.

TABLE A.12-1. ESTIMATED ANNUALIZED COST TO RESPONDENTS						
Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Total Burden (in hours)	Average Hourly Wage Rate	Total Cost
DDI Clinic Representatives	DDI Health Clinic Leadership Survey	30	1	30	$40	$1,200
Patients at DDI Clinics	Screening Questions for the DDI Patient Survey	1,000	1	33	$6	$200
	DDI Patient Survey	600	1	200	$6	$1,200
					Total	$2,600

A13. Estimate of Other Total Annual Cost Burden to Respondents or Recordkeepers

This proposed data collection entails no additional cost to respondents or record keepers.

A14. Annualized Cost to the Government

The project will take one year to complete. The total annualized costs to the government will be $176,628 (see Table A.14 - 1). This includes $150,328 in contract costs to Battelle for data collection and $26,300 in costs to the federal government. The federal costs include employee's salary and expenses related to travel and other supplies for managing the project. Ping Zhang is the principal investigator and the CDC technical monitor and will devote 0.1 FTE to the project.

Table A.14-1. Estimates of Total Cost – Government

Types of Cost	Amount
Contractual Costs (Battelle)	$150,328.00
Federal Employee Salaries	$9,500.00
Federal Employee Travel	$1,800.00
Federal General and Administrative Support	$15,000.00
Total Annualized Cost to the Government	$176,628.00

A15. Explanation for Program Changes or Adjustments

This is a new, one-time data collection.

A16. Plans for Tabulation and Publication and Project Time Schedule

Time Schedule

The time schedule for remaining project activities is presented in Table A.16 - 1. Within the first month after receiving OMB clearance of the survey instrument and protocol, we will make preparations for data collection (including contacting clinics to schedule the recruitment of patients for the patient survey). Data collection will be completed within five months of receiving OMB clearance.

Table A.16-1. Project Time Schedule

Activity	**Schedule (months after OMB clearance)**
Preparation for data collection	Month 1
Data collection	Months 2-5
Data coding, entry, and cleaning	Months 5-6
Data analysis	Months 7-8
Draft final report	Month 8
Final report	Month 9-12

Data coding, entry and cleaning will begin as soon as completed surveys are returned and will be completed within six months of receiving OMB clearance. Data analysis and preparation of the final report will be completed 12 months after receiving OMB clearance.

Publication Plan

The results of the study will be disseminated to various stakeholders through the publication of manuscripts in peer-reviewed journals and through presentations at professional meetings.

Analysis Plan

The analysis will address three research questions: (1) What types of activities are being used to screen for diabetes and what is the distribution of overall costs by type of activity?; (2) What is the average economic cost per person screened for diabetes and per person diagnosed?; and (3) What is the perceived economic benefit of diabetes screening to individuals targeted by the DDI? The analysis will be based on the data provided by the participating clinics and patients at clinics that participated in the DDI.

Calculation of total screening costs and the average cost per case of diabetes detected

We will begin by estimating the total cost associated with each clinic's current activities related to diabetes awareness and screening, as well as the cost by type of activity. The three main components of costs include:

1. medical costs of providing diabetes screening and diagnostic services in the clinic;

2. staff time associated with in-person patient outreach activities (e.g., participation in diabetes screening at shopping malls, senior housing, work sites, health fairs and other community events); and

3. staff time and other costs devoted to indirect patient outreach activities including mass media campaigns or distribution of brochures to promote diabetes education and awareness.

The total labor cost of diabetes screening and patient outreach activities will be computed by multiplying staff hours for a particular labor category by the average hourly rate for the category. The total cost associated with diabetes outreach and screening—which is the total labor costs for all labor categories plus the cost of materials for diabetes education and outreach—will then be divided by the number of patients screened and the number of cases of diabetes diagnosed to obtain the average economic cost per person screened for diabetes and per person diagnosed.

Methodology for conducting the perceived benefits analysis

The perceived economic benefit of the diabetes screening will be analyzed using a random utility framework. In the data collection involving patients as respondents, we will vary the attributes of hypothetical diabetes screening programs across questions and respondents throughout the survey, thereby creating a data set that allows for the

estimation of a random utility model that incorporates the marginal impact of each attribute. Behaviorally, the model is based on a utility difference equation where the chosen alternative must generate higher utility than the alternative not chosen. Econometrically, the model is estimated using a discrete choice procedure such as a probit model. The dependent variable is whether an alternative is chosen (zero or one). The independent variables include the attributes of the various alternatives. Respondent-specific attributes (such as age or gender) will also be included in the analysis. A more detailed description of the methodology for conducting the perceived benefits analysis is included in **Attachment E**.

Statistical methods

Analysis to estimate the cost per case diagnosed will be performed using SAS. Stata will be used for the estimation of the stated preference models because it has procedures for both probit and logit, as well as options that adjust for random effects or fixed effects.

A17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB expiration date will be included on the cover of all survey instruments.

A18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions to certification are sought.