Information Collection Request for OMB Clearance

Assessing the Diabetes Detection Initiative for Policy Decisions

Supporting Statement Part B

Submitted by:

Ping Zhang, Ph.D.
Technical Monitor and Principal Investigator
Phone 770-488-5842
Fax 770-488-1148
Email PZhang@cdc.gov

Centers for Disease Control and Prevention
National Center for Chronic Disease Prevention and Health Promotion
Division of Diabetes Translation
Buford Highway, MS K-10
Atlanta, GA

January 4, 2008

B. Collections of Information Employing Statistical Methods

B1. Respondent Universe and Sampling Methods

Two separate data collections will be conducted: (1) the DDI Health Clinic Leadership Survey (Attachment F)—to obtain information on the cost associated with delivering medical services for diabetes screening and diagnosis among clinics that participated in the DDI; and (2) a data collection involving patients—which includes the DDI Patient Survey (Attachment G.1) and the Stated Preferences Module (Attachment G.2). The patient data collection will obtain information that will be used to estimate the out-of-pocket medical and non-medical direct health care costs such as co-payments, transportation costs, and the value of participants' time for screening. The patient data collection will also obtain information that will be used to estimate the perceived economic benefit of diabetes screening.

Estimated Size of the Respondent Universe

The universe for the DDI Health Clinic Leadership Survey includes the 43 clinics that participated in the implementation of the DDI. The survey will be sent to the Medical Director at each of the 43 clinics. The universe for the patient data collection will include patients of HRSA clinics in each of the ten communities that participated in the DDI. To be eligible for the DDI Patient Survey and the Stated Preferences Module, a patient must be at least 40 years old and have never been diagnosed with diabetes (unless it was diagnosed only during pregnancy). An estimate of the total adult patient population served by participating clinics and the estimated number who would be eligible for the patient survey, by region, are shown in Table B.1 – 1. We estimate that the approximate size of the universe for the patient survey is 218,507 patients.

Table B.1-1. Estimated Size of the Adult Patient Population Served by Participating Clinics and the Eligible Patient Population for the Survey

HHS Region	Location	Adult Patient Population	Eligible Patient Population
1	Springfield & Holyoke, MA	56,847	34,108
2	East Harlem, NY	43,717	26,230
3	Fayette and Greenbrier Counties, WV	62,634	37,580
4	Orangeburg, SC	24,140	14,484
5	Flint, MI	12,193	7,316
6	Choctaw Nation, OK	21,393	12,836
7	Wichita / Sedgwick County, KS	30,956	18,573
8	Wind River Indian Reservation, WY)	11,977	7,186
9	Oakland, CA	94,904	56,942
10	Seattle, WA	5,420	3,252

Sample Design and Estimated Sample Size

In the case of the DDI Health Clinic Leadership Survey, the survey will be administered to the universe of possible respondents. The survey will be sent to the Medical Director at each of the 43 clinics that participated in the DDI. The survey will be completed by the Medical Director or designated representative. Given the small number of participating clinics, it will be necessary to survey the universe, rather than a sample, of clinics that participated in the study.

In the case of the DDI Patient Survey and the Stated Preferences Module, Battelle survey operations staff will recruit 600 clinic patients in person—60 from each of the 10 regions in which the pilot DDI was implemented. Patients will be screened to ensure that they meet the study eligibility criteria. To be eligible for the survey a patient must be at least 40 years old and have never been diagnosed with diabetes (unless it was diagnosed only during pregnancy). Eligible patients who agree to participate in the study will be asked to sign a consent form and asked to complete a survey while they wait to see their health provider at the clinic.

Response Rate and Statistical Power

A total of 43 clinics were recruited for participation in the pilot implementation of the DDI. We anticipate that 70% of these clinics will respond to the surveys for the proposed economic evaluation. Based on the results of the pretest, we expect that approximately 60% of eligible patients will agree to participate in the survey.

The sample size of 600 patients is expected to have sufficient power to identify differences in the preference for alternative attribute levels. Under the study design, each patient is asked to select one choice from among four (where one of the choices is to do nothing). For the other three choices, the attribute levels for each dimension will be assigned randomly so that attribute levels across dimensions will be uncorrelated. This process will be repeated eight times for each person.

Since each person makes a selection eight times and this is the maximum number of attribute levels, each person is likely to see each attribute level at least once. With 600 people, we will be able to detect a preference for one attribute level versus another if it is selected at least 10% more often. The difference will be significant at the 5% level and the test will have 90% power.

Because each person will make multiple selections, there will be intra-person correlation in the choices. The statistical methods will take this correlation into consideration as part of the analysis. In calculating the power analysis, we assumed there is only one selection per person because the magnitude of the correlation is not known at this time. Thus, the power analysis is conservative and we expect that the study design will be able to detect smaller differences.

B2. Procedures for the Collection of Information

Stratification and Sample Selection

The numbers of facilities to be sampled in each cell were described in Section B.1.

Data Collection Procedures

Administration of the DDI Health Clinic Leadership Survey. The clinic leadership survey will be conducted by mail. Prior to mailing the survey, an email message (see **Attachment F.1**) will be sent to each respondent emphasizing the importance of the study and requesting their participation in completing the survey. A survey packet will then be sent to each respondent via express mail. The survey packet will include:

- A personal cover letter emphasizing the importance of the study,
- The survey questionnaire with an ID number pre-printed on it, and
- A postage-paid return envelope addressed to Battelle.

The letter will provide respondents with the name and telephone number of a Battelle staff member to call if they have technical questions regarding the survey. The letter will also include the name and telephone number of a person to call with questions regarding Human Subjects protection. Copies of the cover letters are provided in **Attachment F.2**. A copy of the clinic leadership survey is provided in **Attachment F**.

Respondents will be given two weeks to return the completed survey. An email reminder will be sent to non-respondents if a completed survey has not been returned within three weeks of the initial mailing. A second email message will be sent to non-respondents two weeks after the first e-mail reminder. Once a completed questionnaire has been received, the respondent will be sent an email message thanking him or her for participating in the survey. Copies of the e-email reminders to non-respondents are included in **Attachment F.3**. A copy of the thank you email message is included in **Attachment F.4**.

A management information system will be developed and used to monitor administration of the mail surveys. The management information system will contain the dates of the initial email messages, the dates that surveys are mailed, the dates that completed questionnaires are received. Mailing labels and personalized letters will be generated from this system. Dates of follow-up e-mail reminders computed by the tracking system to ensure timely mailing of necessary and appropriate follow-up materials. The management information system will also be used to generate weekly reports summarizing the status of the data collection activity throughout the data collection period.

Administration of the DDI Patient Survey. A Battelle interviewer will contact patients who visit the clinics that participated in the DDI. The patients at the clinics will be

recruited while they are waiting to see their health care provider at the clinic. Patients will be asked a series of screening questions to determine that they are eligible for the survey (see **Attachment G.3**). Patients will be eligible for the survey if they are 40 years of age or older and have never been diagnosed with diabetes (unless it was diagnosed only during pregnancy). If the respondent is eligible for inclusion in the study, he or she will be asked to provide written consent to participate in the survey. A copy of the patient consent form in provided in **Attachment G.4**.

The patient data collection will be administered in two parts. The first part is the written DDI Patient Survey with questions about the respondent's background and health history. This part will be administered as a self-administered paper survey. The second part is the Stated Preferences Module, which will assess the respondent's preferences among types diabetes screening alternatives. The Stated Preferences Module will be administered as a computer-assisted in-person interview (CAPI)—with the specific features of the various diabetes screening programs randomly selected for each respondent. Once the respondent has signed the consent form, the interviewer will provide the respondent with the paper survey and will then help the respondent complete the CAPI data collection on a laptop computer. A copy of the paper DDI Patient Survey is included in **Attachment G.1**. A screen shot of the CAPI Stated Preferences Module, along with an attribute matrix from which screening options will be randomly selected, is included in **Attachment G.2**.

Quality Control Procedures

Beginning with study initiation and continuing through all phases of data collection and analysis, steps will be taken to ensure that the data collected are of the highest quality possible. Experienced Battelle survey operations staff have formatted the surveys for ease of completion, as well as to facilitate coding and data entry. Electronic data cleaning will be used to detect errors not identified and resolved during the data entry process (e.g., out of range values, proper skip patterns, logical consistency checks to identify inconsistencies between variables). Errors will be corrected by referring to the survey questionnaire. A limited number of telephone follow-up calls to respondents to the clinic leadership survey will be made to clarify inconsistent responses to key questions.

B3. Methods to Maximize Response Rates and Deal with Nonresponse

In the DDI Health Clinic Leadership Survey, the survey packet will be personally addressed to the respondents. To insure fast delivery, and to emphasize the importance of the study, the forms will be sent by express mail directly to the respondent. Respondents will be given the name and toll-free telephone number to call if they have questions regarding the study. Finally, e-mail reminders will be used to encourage non-respondents to complete and return the survey. In the patient data collection, respondents will be provided with a $5 incentive to participate.

B4. Tests of Procedures or Methods to be Undertaken

The data collection instruments were pre-tested over nine individuals and two health clinics for the patient and health clinic surveys, respectively. The purpose of the pretest was to obtain an estimate of respondent burden (See Section A12), as well as to obtain comments and advice about the format, appropriateness, and relevance of survey questions.

The pre-test of the instruments for the patient data collection was conducted with nine patients at two clinics in Seattle. The pre-test respondents included 4 males and 5 females. Pre-test subjects ranged from 40 to 87 years of age. The purpose of the pre-test was to obtain an estimate of respondent burden, as well as to obtain comments and advice about the format, appropriateness and relevance of survey questions. In addition, we tabulated the answers to each question and changed the response categories in some cases. For example, we divided the lowest income level into two categories and collapsed the highest income level at a lower income because this would increase detail where it would be useful while reducing detail where it was unnecessary for this population. Most patients were able to complete both portions of the data collection in 20 minutes. The pre-test of the clinic leadership survey indicated that the survey required approximately 1 hour to complete.

Minor modifications to the survey questions and response categories were made based on the results of the pre-tests. For example, following the pretest, the font size of the patient survey was increased—to make it easier to read by elderly patients.

B5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Ping Zhang, PhD [770-488-5842] of the Division of Diabetes Translation is the Principal Investigator and Technical Monitor for the study. He has overall responsibility for overseeing the design, conduct, and analysis of the study. Dr. Zhang will also approve and receive all contract deliverables.

The survey instruments, sampling and data collection procedures, and analysis plan were designed in collaboration with researchers at Battelle Centers for Public Health Research and Evaluation (CPHRE) under contract No. 200-2001-00121, Task order No. 0014 with the Center for Disease Control and Prevention. Battelle will conduct data collection and will perform data analysis, in consultation with CDC.

Diane L. Manninen, PhD. [206-528-3140] has overall technical and financial responsibility for the study at Battelle and led the Battelle effort to design this protocol. Dr. Manninen will direct the overall data collection and analysis effort. She will also be responsible for writing the project reports.

Other personnel involved in design of the protocol and data collection instruments are:

Fred Dong, AM, MBA
Economist and statistician
Battelle Centers for Public Health Research and Evaluation
Development of data collection materials, development of analysis plan
206-528-3120

Glenna Redmond
Survey leader
Battelle Centers for Public Health Research and Evaluation
Development of data collection materials
206-528-3141

Jeffrey Englin, PhD
Economist
Development of data collection materials, development of analysis plan
Professor and Chair, Department of Resource Economics, University of Nevada at Reno
702-784-4411

References

1. Centers for Disease Control and Prevention. National Diabetes Fact Sheet: National Estimates and General Information on Diabetes in the United States, Revised edition. Atlanta, GA: U.S. Department of Health and Human Services, 2002.

2. Centers for Disease Control and Prevention. Levels of diabetes-related preventive-care practices—United States, 1997–1999. MMWR Morb Mortal Wkly Rep 2000;49(42):954-8.

3. Hogan P, Dall T, Nikolov P. Economic consequences of diabetes mellitus in the U.S. in 1997. Diabetes Care 2003;26(3):917-32.

4. Centers for Disease Control and Prevention. Diabetes: A Serious Public Health Problem. Atlanta: U.S. Department of Health and Human Services, 2001.

5. Boyle JP, Narayan V, Thompson TJ, Geiss LS. Projection of diabetes burden and cost through 2050: impact of changing demography and disease prevalence in the U.S. Diabetes 2001;50(S2):A206.

6. Engelgau MM, Geiss LS. The burden of diabetes mellitus. In: Leahy JL, Clark NG, Cefalu WT, editors. Medical Management of Diabetes Mellitus. New York: Marcel Dekker, 2000.

7. Centers for Disease Control and Prevention. Socioeconomic status of women with diabetes—United States, 2000. MMWR Morb Mortal Wkly Rep 2002;51(7):147-8.

8. Lanza A, Albright A, Zucker H, Martin M., The Diabetes Detection Initiative: a pilot program of selective screening. Am J Health Behav. 2007 Nov-Dec;31(6):632-42.

9. Dillman, DA. 2000. *Mail and Internet Surveys: The Tailored Design*. New York, NY: John Wiley & Sons.

10. Dillman, DA. 1978. Mail and Telephone Surveys. New York, NY: John Wiley & Sons.

11. Church, AH. 1993. Estimating the effect of incentives on mail survey response rates: a meta-analysis. Public Opinion Quarterly, 57:62-79.

12. Singer, E, Gebler, N, Raghunathan, T, Van Hoewyk, J, McGonagle, K. 1999. The effect of incentives on response rates in interviewer-mediated surveys. Journal of Official Statistics, 15: 217-230.

13. Kropf, ME, Scheib, J, Blair, J. 1999. The effect of alternative incentives on cooperation and refusal conversion in a telephone survey. Presented at the 54th

Annual Meeting of the American Association for Public Opinion Research, St. Petersburg, Florida, May 13-16, 1999.

14. Hopkins, KD, Gullikson, AR. 1992. Response rates in survey research: a meta-analysis of monetary gratuities. Journal of Experimental Education, 61:52-56.

15. Fox, RJ, Crask, MR, Kim, J. 1988. Mail survey response rate: A meta-analysis of selected techniques for inducing response. Public Opinion Quarterly, 52:467-491.

16. Harvey, L. Factors affecting response rates to mailed questionnaires: A comprehensive literature review. 1987. Journal of Marketing Research, 29(3):341-353.

17. Collins, RL, Ellickson, PL, Hays, RD, McCaffrey, DF. 2000. Effects of incentive size and timing on response rates to a follow-up wave of a longitudinal mailed survey. Evaluation Review, 24(4):347-63.

18. Yammarino, FJ, Skinner, SJ, Childers, TL. 1991. Understanding mail survey response behavior: A meta-analysis. Public Opinion Quarterly, 55:613-619.

19. Singer, E, Van Hoewyk, J, Maher, MP. 2000. Experiments with incentives in telephone surveys. Public Opinion Quarterly, 64(2):171-88.

20. Shaw, MJ, Beebe, TJ, Jensen, HL, Adlis, SA. 2001. The use of monetary incentives in a community survey: impact on response rates, data quality, and cost. Health Services Research, 35(6):1339-1346.

21. Shettle, C, Mooney, G. 1999. Monetary incentive in government surveys. Journal of Official Statistics, 15: 231-250.

22. Hanemann, W.M. and B. Kanninen (1999): "The Statistical Analysis of Discrete-Response CV Data", in I.J. Bateman and K.G. Willis (1999).

23. Heckman, J. J., and R. J. Willis. 1975. Estimation of a stochastic model of reproduction: An econometric approach. In N. Terleckyj (Ed.), Household production and consumption. New York: Columbia University Press.

24. Guilkey, D.K. and Murphy, J.L. (1993) - `Estimation and testing in the random effects probit model', Journal of Econometrics, 59, 301-317.

25. Butler, J.S. & Moffit, R. (1982). Notes and comments: A computationally efficient quadrature procedure for the one-factor multinomial probit model.