SUPPORTING STATEMENT B

FOR

NATIONAL DIABETES EDUCATION PROGRAM

COMMUNITY EVALUATION OF

THE NATIONAL DIABETES EDUCATION PROGRAM'S

DIABETES HEALTHSENSE WEBSITE

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

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B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

B.1. Respondent Universe and Sampling Methods

The respondent universe, sample size, and expected number of completed surveys are summarized in Table B. 1-1.

Table B. 1-1 -- Summary of Respondent Universe, Sample Size, and Number of Expected Completed Surveys

Survey	Universe	Sample	Expected Completed
Educator Pre Interview	5	5	5
Educator Post Interview	5	5	5
Intervention Participant Recruitment Guide	5	5	10
Comparison Participant Recruitment Guide	10	10	10
Participant Pretests	200	200	200
Participant Posttests	200	200	150
Participant Exit Satisfaction Survey	200	200	150
Participant Follow-up Interview	10	10	10
Comparison Pretests	250	250	250
Comparison Posttests	250	250	150

For the Community Evaluation of Diabetes HealthSense, sites will be recruited to conduct a total of 10 Diabetes HealthSense Education sessions (two sessions per site). Each

session will have 20 participants. Therefore, the final respondent universe of participants in the evaluation of Diabetes HealthSense will be 200. As participants will be asked to complete the pretest upon entry into the program, we expect a 100% response rate for the pretest instrument. Based on a similar evaluation effort in the literature,[1] we expect about a 67% response rate for the posttest instrument.[2]

Because Exit Satisfaction Surveys will be completed prior to leaving the session, we expect a 100% response rate for this instrument. One participant from each of the 10 groups will be randomly selected to participate in the Participant Follow-up Interview. If that participant is unwilling or unable to participate in the interview, another will be randomly selected until a participant is successfully selected. Because of this methodology, we expect a 100% response rate for these interviews.

The respondent universe for the comparison group will be all those who agree to participate. We anticipate a 100% response rate on the pretest questionnaire and a 60% response rate on the posttest questionnaire.

In order to ensure that sites are recruiting participants that fit program inclusion criteria, site leaders will be asked to complete one recruitment guide for each intervention group or comparison group. The respondent universe for these recruitment guides will be one site leader from each of the 5 intervention and 10 comparison sites. We expect a 100% response rate for these guides.

To recruit evaluation sites, the NDEP plans to work with a partner organization whose members are diabetes educators across the United States. The organization will work with its

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[1] Ramadas, A, Quek, KF, Chan, CKY, Oldenburg, B and Hussein, Z (2011) Randomized-controlled trial of a web-based dietary intervention for patients with type 2 diabetes mellitus: Study protocol of my DIDeA. BMC Public Health. 2011, 11:359.

[2] 67% (300/450) is the average response rate among intervention participants (150/200 = 75%) and comparison participants (150/250 = 60%).

members to identify 15 geographically dispersed sites capable of recruiting sufficient numbers of people at risk of and with diabetes. These sites will be randomized into intervention (n=5) and comparison (n=10) sites. Intervention sites will receive up to $8,000 to complete up to 2 separate Diabetes HealthSense education programs as well as facilitate the evaluation process. The funding covers program costs (such as trainers, facilities, and supplies) as well as costs associated with the evaluation (such as copying and mailing). Comparison sites will receive $1,000 to recruit and facilitate the collection of evaluation data with one group of participants.

Items will be included on the pretest for both the intervention and comparison group members that assess demographic information, prior health resource experience, and motivation to change personal diabetes health habits (See Table B. 1-2). Inclusion of these items will allow for statistical controlling of the data as needed to ensure meaningful comparisons.

Table B. 1-2 -- Questions Used to Ensure Comparison and Intervention Group Similarity

Construct	Pretest Questions
Demographic Information	Q30-Q40
Prior Resource Experience	Q1-5
Motivation to Change	Q21a-i; Q22

Sample size and power were assessed for cluster-level trials with person-level repeated measures outcomes using Optimal Design Plus Empirical Evidence (Version 3.01, 2005-2011 HLM Software). A sample size of 300 people completing pre- and post-questionnaires within 20

clusters will allow detection of medium effects ($d \geq .33$) at alpha = .05, power=.80, and intraclass correlation coefficient, rho = .018.[3]

B.2. <u>Procedures for the Collection of Information</u>

Key leaders at each intervention site will participate in a training session that will detail all responsibilities and tasks. Participants in the Community Evaluation of Diabetes HealthSense will be informed during recruitment about the evaluation and their responsibilities will be outlined. Participants will sign forms consenting to participate in the education program and all aspects of the evaluation. Included on this form will be email contact information for each participant. Following receipt of the consent form, evaluation staff will send a link to the online pretest via email to each participant. Each participant will then complete the online pretest following recruitment and consent procedures but before participating in the educational session. At the conclusion of the educational session, trainers will allow time for and ensure the completion of the Participant Exit Survey. All participants will then receive a link to the online posttest survey via email 4 weeks following their educational program. Follow-up emails will be sent as needed to encourage completion of the posttest survey. Honest answers will be encouraged prior to all survey completion. Following the receipt of each group's posttest surveys, one participant from each group will be randomly selected to participate in the Follow-up Interview. This participant will then be contacted via email, participation in the interview will be confirmed, and the interview will be scheduled and conducted via phone.

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[3] Littenburg, B & Maclean, CD. Intra-cluster correlation coefficients in adults with diabetes in primary care practices: The Vermont diabetes information system field survey. *BMC Medical Research Methodology*. 2006, 6:20.

Soon after sites are selected and randomized, Educator Pre Interviews with one key educator at each intervention site will be conducted via phone. Educator Post Interviews will be conducted with the same key partner at each intervention site after all other data has been collected from that site. This interview will also be conducted via phone.

B.3. <u>Methods to Maximize Response Rates and Deal with Nonresponse</u>

Educators and participants in the Community Evaluation of Diabetes HealthSense will be informed during recruitment about the evaluation and the responsibilities of all will be outlined. The Participant Pretest will be collected immediately after the recruitment process ensuring completion by all participants. The Participant Exit Satisfaction Survey will be collected at the end of the education session. By asking the respondents to complete the online questionnaires prior to leaving the session, we anticipate a higher response rate. In addition, email notifications will be sent to all participants 2 weeks prior to receiving the link to remind them to expect the posttest survey link and again 2 weeks after the link is sent to remind them to complete the posttest survey. In addition, a small acknowledgement of time and trouble in the form of a monetary incentive ($25) will be given to participants when they complete all questionnaires in an effort to maximize response rates.

Efforts to maximize response rates for comparison group participants will include the use of a monetary incentive ($40 distributed after the pretest), an email thanking them for their pretest, an email notification to expect the posttest survey link 2 weeks prior to receiving the link, and an email notification after the link is sent to remind them to complete the posttest survey. Any expected email address changes will be solicited from participants in each data collection email.

B.4. <u>Test of Procedures or Methods to be Undertaken</u>

Cognitive testing will be conducted with educators, people with diabetes, and people at risk of diabetes (n<10) for each data collection instrument. Feedback from this cognitive testing will be incorporated into the survey instruments.

B.5. <u>Individuals Consulted on Statistical Aspects and Individuals Collecting and/or</u>

<u>Analyzing Data</u>

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[2] Littenburg, B & MacLean, C.D. (2006). Intra-cluster correlation coefficients in adults with diabetes in primary care practices: the Vermont Diabetes Information System field survey. *BMC Med Res Methodol* , 6, 20. doi: 10.1186/1471-2288-6-20.