A Comprehensive Assessment of the National Program to Eliminate Diabetes Related Health Disparities in Vulnerable Populations

New

Supporting Statement: Part A

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March 2, 2015

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- Goal of the study: to collect information about how 6 CDC-funded national organizations, working with 18 selected communities, are implementing strategies to eliminate diabetes disparities in communities with vulnerable populations; factors that are facilitating implementation; challenges encountered and addressed; and lessons learned. Activities are conducted through the National Program to Eliminate Diabetes Related Health Disparities in Vulnerable Populations (hereafter referred to as the VP Program), which is administered by CDC's Division of Diabetes Translation (DDT).

- Data collection methods: Information will be collected through 48 semi-structured interviews: 12 interviews with respondents who are employed by the 6 national organizations (2 per organization), and 36 respondents who are affiliated with the 18 community coalitions (2 per community).

- Analysis plan: Information collected during the interviews will be organized and analyzed using a qualitative table analysis method. A list of codes will be developed based on the prioritized assessment questions and applied to the data collected.

- Intended use of findings: to explore significant factors related to the implementation of evidence–based interventions in communities with vulnerable populations; to better understand the relevance of community partnerships in support of diabetes prevention and control activities; and to inform and enhance the level of technical assistance provided by CDC. Findings will have long-term implications for DDT's work in health disparities.

- The VP cooperative agreement program ends in August 2015. CDC's contract with the information collection contractor ends September 1, 2015. In order to complete the assessment,

OMB approval is requested no later than June 1, 2015.

A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

Diabetes affects over 29 million people in the United States, is the sixth leading cause of death in the country, and can cause serious health complications, including heart disease, blindness, kidney failure, and lower-extremity amputations. The overall prevalence of diabetes in the U.S. is over 9%. However, higher rates of type 2 diabetes and its complications exist across particular groups of the population such as older adults (> 60 years) racial and ethnic minority groups (e.g., African Americans, Hispanic/ Latino Americans, American Indians, Native Hawaiians and Other Pacific Islanders, and some Asian Americans), people with low socioeconomic status (SES), and rural populations. These groups are considered vulnerable populations. Vulnerable populations are groups that are not well integrated into the health care system because of ethnic, cultural, economic, geographic, or health characteristics. This isolation puts members of these groups at risk for not obtaining necessary medical care, and thus constitutes a potential threat to their health.

In an effort to reduce diabetes-related disparities, CDC's Division of Diabetes Translation (DDT) aims to concentrate efforts where the greatest impact can be achieved for populations with the greatest burden or risk. In August 2010, DDT published a funding opportunity announcement for the National Program to Eliminate Diabetes Related Health Disparities in Vulnerable Populations (hereafter referred to as the VP Program). Six national organizations (hereafter referred to as VP grantees) received cooperative agreement funding to identify and mobilize three local community sites (a total of 18 sites). Each site is implementing community-based interventions to address risk factors that influence the burden of diabetes in their communities. The 5-year program has created a platform for coordination and integration of efforts between CDC, national organizations, and community partners to focus on health disparities and diabetes at the community level.

Using the community change approach, the VP grantees have identified a local partner in each of the selected communities. In collaboration with the local partners they convened or re-established a diabetes coalition in each community, worked with local partners and coalition members to conduct a community needs assessment by gathering local level data, assisted with strategic planning and the development of a community-driven action plan, identified appropriate evidence-based interventions, and provided training and technical assistance with the implementation and evaluation of selected interventions.

CDC proposes to collect information that will assess the overall implementation of the VP program by conducting in-depth telephone interviews with VP grantees, site coordinators and coalition members. The information collected will address how the community change approach worked to address diabetes management and control within the context of communities that are significantly impacted by social determinants of health (e.g., low income, limited access to healthy food options, challenges with built environment, and limited access to health care). Additionally, the information collection will focus on how each grantee and community have implemented the strategies they selected, the challenges encountered and addressed, and what changes have occurred as a result of their activities. OMB approval is requested for one year.

CDC's general authority to collect information is provided by Section 301 of the Public Health Service Act (see 42 USC 241, **Attachment 1**).

A.2. Purpose and Use of Information Collection

The purpose of this data collection is to learn more about both CDC's and VP grantees' performance and capacity building efforts to support diabetes management and control interventions in vulnerable populations. Additionally, the information collected will highlight the progress made in achieving the VP program goals and contribution to reducing diabetes and health disparities.

Semi-structured interviews will be used to improve understanding of the relevance of community partnerships in support of diabetes activities, to inform and enhance the level of technical assistance provided to cooperative agreement recipients, to explore significant factors related to the implementation of evidence-based interventions in vulnerable communities, and to articulate meaningful outcomes of this national program to key stakeholders.

A.3. Use of Improved Information Technology and Burden Reduction

The proposed information collection is based on qualitative methods, primarily semi-structured individual interviews. While several efforts are being made to reduce burden on respondents, electronic information collection methods have limited utility for this type of qualitative inquiry. Interviews will be facilitated by an interview guide that is customized based upon the role of each participant. To expedite and streamline the interviews, CDC will prepare interviewers by summarizing information from existing, publicly available sources. For example, information from the applicable community action plan will ensure that the interviewer is familiar with the specific activities of each site in advance of the interviews. Only the minimum information necessary for the purposes of this project will be collected.

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

There are no similar data available that meet the needs of this proposed assessment. This is the first time that information will be collected on facilitators and barriers relevant to the activities implemented by the six VP grantees and their community partners. The proposed information collection does not duplicate any information currently being collected.

A.5 Impact on Small Businesses or Other Entities

The primary respondents for the VP program interviews are grantee organization staff, representatives of community agencies and coalition members. Participation in the interviews is voluntary and does not impose a data collection or record-keeping requirement for small business.

A.6 Consequences of Collecting the Information Less Frequently

This information collection is critical to the overall assessment of the VP initiative and essential for future program planning. Without this information collection, CDC will not be able to conduct an adequate assessment of the program's function, identify and understand factors that affect the implementation process, assess efficiencies for different strategies, or identify implications of targeting vulnerable populations.

The proposed information collection will allow CDC to effectively develop and provide technical assistance for work being conducted in relationship to vulnerable populations at the state, national and community levels. Consequences of not collecting the information would include an inability for CDC to describe VP program implementation, decreased ability to disseminate information on VP efforts that effectively decrease diabetes burden, inability to build on the success of the VP program, or inability to apply program knowledge to program improvements. In sum, not collecting the information would hinder CDC's efforts to aid state diabetes and community-based programs in effective delivery and implementation of diabetes activities in vulnerable communities. The semi-structured interviews will be conducted at one point in time over a period of 2 months.

There are no legal obstacles to reducing the burden.

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 with the regulation.

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

A. A notice for the proposed information collection was published in the Federal Register on October 7, 2014, Vol. 79, No. 194, pp. 60471-60472. One public comment was received and acknowledged **(**see **Attachment 3).**

B. The interview protocols have been developed and reviewed by members of the Vulnerable Populations Evaluation Workgroup (see Table A.8-B).

Table A.8 –B Efforts to Consult Outside of the Agency

Consultant	Title	Affiliation	Phone Number	Contribution to Project
Ronnie Bell, PhD	Professor	Wake Forest University	336-716-9736	Reviewed data collection materials
Pam Yankeelov, PhD	Professor	University of Louisville	502-852-0426	Reviewed data collection materials
Sheila Castaneda, PhD	Professor	San Diego State University	619-594-2395	Reviewed data collection materials
Regina Tipton	Program Coordinator	Center for Appalachian Philanthropy	740-876-4262	Reviewed data collection materials
Melinda Martin	Project Director	AAPCHO	510-272-9536	Reviewed data collection materials
Charlene Cole	Program Coordinator	National Kidney Foundation of Michigan	313- 259-1574	Reviewed data collection materials

A.9 Explanation of Any Payment or Gift to Respondents

Respondents will not receive any payments or gifts for their participation.

A.10 Assurance of Confidentiality Provided to Respondents

Information in identifiable form (IIF) will be collected in order to schedule interviews. Respondents will be speaking from their roles as participants in activities related to the implementation of the Vulnerable Populations program and will not provide any personal

information to CDC or CDC's contractor. Only aggregated data will be provided in summary reports to CDC.

Privacy Impact Assessment Information

The following items are described below: 1) an overview of the information collection; 2) a delineation of the items of information to be collected; 3) a description of how the information will be shared and for what purpose; 4) a statement detailing the impact the proposed collection will have on the respondent's privacy; 5) opportunities to consent, and whether individuals are informed that providing the information is voluntary or mandatory; 6) how the information will be secured; and 7) if a system of records is being created under the Privacy Act.

1. Overview of the Information Collection

Information will be gathered over a 2-month period from the 6 VP grantees and respondents in each of their 3 community sites. Semi-structured interviews will be conducted with a total 48 participants distributed as follows: one project coordinator and one consultant from each of the 6 VP grantee organizations (n=12); one community partner or one coalition member from each of the 3 local community sites (per grantee organization) (n=18); and one site coordinator from each of the 3 local community sites (per grantee organization) (n=18). The VP grantees will provide contact information for potential respondents to the contractor. CDC's contractor will conduct interviews, and manage recruitment and supporting communication. To reduce burden and ensure that questions are tailored to each respondent type, separate interview guides have been created for Project Coordinators and Consultants (see **Attachment 4**), Community Partners/Coalition Members (see **Attachment 5**) and Site Coordinators (see **Attachment 6**).

2. Delineation of the items of information to be collected

The Grantee Interview Guide covers topics related to the grantee staff experience working across 3 selected communities, involvement in the planning process, training and technical assistance provided, capacity building, facilitation of interventions, perspectives on impact of the project and expectation of future impact based on lessons learned. The Community Partner/Coalition Member Guide covers topics related to community partners/coalition members role and perspectives about the project, involvement and experience with the planning process, barriers and facilitators associated with interventions, key outcomes, lessons learned and recommendations for grantee and CDC regarding vulnerable population funding. Lastly, the Site Coordinator Guide covers topics related to site coordinators perspectives about the project, involvement and experience with the planning process, barriers and facilitators associated with interventions, key outcomes, lessons learned and recommendations for the grantee and CDC regarding vulnerable population funding.

3. Description of how information will be shared and for what purpose

The unit of analysis is the site or grantee organization. Contact information collected for respondents will be used by the contractor to schedule interviews. Only the individual's role, organization, community and date of interview will be recorded with the responses. Interviews will be coded prior to data entry by the contractor and then entered into the project database or qualitative analysis software for further analysis. Only senior project management with the contractor will have access to the linking file. Outside of that file, no personal identifiers will be maintained that would allow contractor team members or CDC staff to link a participant's responses to his or her name. After conducting the interviews the contractor will prepare an aggregate summary report for CDC. The interview data will be used to better understand the relevance of community partnerships in support of diabetes activities, to inform and enhance the level of technical assistance provided to cooperative agreement recipients, to explore significant factors related to the implementation of evidence-based interventions in vulnerable communities, as well as to be better able to articulate meaningful outcomes of this national program to key stakeholders.

4. Impact the proposed collection will have on respondent's privacy

For the interviews, CDC is primarily interested in the organizational partners involved in implementing activities and the roles of the individuals within those organizations who are involved, not the individual in that role. As a result, collection of names is not necessary. The information being collected pertains to the organization and site and not to the specific respondent; hence the proposed data collection will have little or no effect on the respondent's privacy.

5. Opportunities for Consent

The CDC's data collection contractor will explain the nature of the data collection to each interview respondent. The interview will include an oral consent process that indicates the voluntary nature of participation as well as the purposes and uses of the information collection **(see Attachment 4, 5, 6)**. The oral consent process will include the statement:

> "Please know that your name will not be used in any reports, and we will not quote you directly without asking for your permission first. Your participation is completely voluntary, you may end the interview at any time, and if we ask a question that you would prefer not to answer, just tell us, and we'll skip over it."

Additionally, the oral consent process states that notes will be taken to accurately capture the interview and the interviews will be recorded to be sure that responses are correctly and completely captured. Permission to be recorded will be requested by the contractor during the oral consent process.

6. Safeguards

CDC's contractor will have direct access to the data collected through semi-structured interviews. CDC's contractor will safeguard the responses and will not release any identifying information. Project reports and manuscripts will contain aggregated data only; results will not be associated with any individual respondent. Any information sent to CDC will not be associated with any individual identifiers. All handwritten notes, typed notes, and audio recordings from interviews will be maintained in a secure manner. Hard copies of these materials will be stored in a locking filing cabinet. The interview notes and any other materials produced from the interviews will be handled or viewed only by CDC's contractor staff members who are directly responsible for data collection and analysis. Digital audio recordings will be stored on password-protected file servers and deleted upon study completion.

7. Privacy Act Determination

This information has been reviewed by NCCDPHP which determined that the Privacy Act does not apply. CDC will not receive any identifiable response data from the interview participants. The interviewer will know the names of the interview participants; however response information will not be linked to the names of participants or retrieved by name.

A.11 Justification for Sensitive Questions

Participants will be asked to discuss implementation barriers and technical assistance needs, which could be considered sensitive in nature. This information will help CDC to understand how they might provide improved technical assistance to programs in the future. The information to be collected is not personal in nature.

A.12 Estimate of Annualized Burden Hours and Costs

Three Interview Guide instruments have been developed to facilitate interviews with the three major groups of respondents. The instruments are based on a unified assessment scheme, but have been tailored to target different respondent groups for information about specific issues and experiences. This strategy supports the collection of all information needed for the assessment, but minimizes burden to respondents and avoids overlap in questions for respondent groups except in circumstances where a variety of perspectives are needed to fully address an evaluation question. All of the respondents are from the private non-profit sector.

The Interview Guide for Grantee Staff (see **Attachment 4**) will be used to facilitate interviews with two members of the management team from each of the 6 VP grantee organizations (N=12). The estimated burden is 1.5 hours per response.

The Interview Guide for Community Partners/Coalition Members (see **Attachment 5**) will be used to facilitate interviews with one respondent at each of the 18 local community sites. To obtain a variety of perspectives, approximately one community partner representative or coalition member will be drawn from each site (N=18). The estimated burden is 1.5 hours per response.

Similarly, the Interview Guide for Site Coordinators (see **Attachment 6**) will be used to facilitate interviews with one respondent at each site (N=18). The estimated burden is 1.5 hours per response.

To schedule and conduct an approximately 48 interviews, the total estimated burden to respondents is 72 hours, as summarized in **Table A.12-1.**

Table A.12-1. Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in Hours)	Total Burden (in Hours)
Grantee (staff designee)	Grantee Interview Guide	12	1	1.5	18
Community Partner/Coalition Member	Community Partner/ Coalition Member Interview Guide	18	1	1.5	27
Site Coordinator	Site Coordinator Interview Guide	18	1	1.5	27
				Total	72

Table A.12-2 presents the calculations for cost of annualized burden hours. The participants' wages may vary significantly depending on respondent employment status and the state, tribe, or territory in which they reside. Therefore, the average hourly wage data below are based on the average estimated hourly wage (See http://www.bls.gov/oes/current/oes_nat.htm).

Table A.12-2. Estimated Annualized Cost to Respondents

Type of Respondent	Form Name	Number of Respondents	Total Burden (in Hours)	Average Hourly Wage	Total Cost
Grantee (staff designee)	Grantee Interview Guide	12	18	$25	$450
Community Partner/Coalition Member	Community Partner/ Coalition Member Interview Guide	18	27	$20	$540
Site Coordinator	Site Coordinator Interview Guide	18	27	$15	$405
				Total	$1,395

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

There are no costs to respondents other than their time.

A.14 Annualized Cost to the Federal Government

The total estimated annualized cost to the government is $77,750. It includes the cost of government personnel and the cost of an information collection and management contractor.

Government personnel – Governmental costs for this project include personnel costs for federal staff involved in planning and designing the qualitative assessment, data collection instruments and OMB materials, collecting and analyzing the data, and reporting, which includes approximately 5% of one GS-14 lead health communication specialist at $100,000 annual salary, 10% of one GS-13 health education specialist and 5% of one GS-13 public health advisor at $85,000 annual salary.

Contracted data collection –The project design and data collection is being conducted under a contract with CDC's data collection contractor. The contract for implementation of the efforts described here totals $60,000 and includes costs for planning, conducting, and analyzing data from the interviews. The entirety of this amount is dedicated to semi-structured interviews, communications, analysis of findings and report writing.

Table A.14-1. Estimated Annualized Cost to the Federal Government

Labor:	
5% of one GS-14 lead Health Communication Specialist's time for project planning, management, OMB review, analysis of findings, and report writing	$5,000
10% of one GS-13 Health Education Specialist's time for project planning, management, OMB review	$8,500
5% of one GS-13 Public Health Advisor's time for project planning, management, OMB review, analysis of findings, and report writing	$4,250
Contractor: in-depth interviews, transcription, analysis of findings, and report writing	$60,000
Total	$77,750

A15. Explanation for Program Changes or Adjustments

This is a new data collection effort.

A16. Plans for Tabulation and Publication and Project Time Schedule

Qualitative data collected from the interviews will be organized and analyzed using a qualitative table analysis method. A list of codes will be developed based on the prioritized assessment questions and applied to the data collected. Once codes are developed and all coders are in agreement on what each means, additional steps will be taken to ensure consistent coding and to enhance reliability including: limited pilot-testing of codes and double-coding.

CDC will develop a variety of products (i.e., reports, conference presentations, publications, training materials) to ensure dissemination of the interview findings to the grantees and other key stakeholders. These reports will summarize findings for the grantee organizations and across the respondent types. CDC will also oversee the development of several manuscripts over the course of the evaluation. The topics to be addressed and publications to be targeted will be developed once findings are available to ensure that they focus on the issues most salient to the grantees and program stakeholders at that time.

CDC's preferred timeline is outlined below. The VP cooperative agreement program ends in August 2015 and CDC's contract with the information collection contractor ends September 1, 2015. In order to complete the assessment, OMB approval must be obtained no later than June 1, 2015 (sooner would be preferable).

Task	**Time Schedule**
ICF will work with grantees to develop interview list 4/1/2015	April 2015
Interview list finalized 4/30/2015	April 2015-May 2015
ICF send out introductory email to interview participants, summary of topics to be covered, and obtain participant availability 5/1/2015	May 2015 4 weeks in advance of interview start
Interviews scheduled and confirmed by calendar invite with bridge line number 5/30/2015	May 15, 2015 3 weeks in advance of interviews
Data Collection Open-Interviews start 6/1/2015	
ICF will send reminder email to interview participants 1 week before scheduled interviews	1 week in advance of interview start
ICF will send reminder email 2 days before scheduled interview	2 days before scheduled interview

Data Collection Closed-Interviews will end 7/15/2015	
Interviews should be transcribed as interviews occur and finalized by	June 1-July 15, 2015
Top line summary (with code definition sheet) no more than 5 pages	July 30, 2015
Data analysis completed	August 15, 2015
Draft summary report submitted to CDC for review	August 30, 2015
CDC will provide feedback on draft summary report	7-10 business days (September 10, 2015)
Final Summary Report submitted to CDC	September 20, 2015 2015 by noon

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

The OMB 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

There are no exceptions to this certification.