Information Collection Request

New

Formative Evaluation, Implementation and Rapid Evaluation (FIRE) of Diabetes Self-Management in Disproportionately Affected Populations (DAPs) Provider Listening Sessions (Phase I)

Submitted Under

CDC/ATSDR Formative Research and Tool Development

0920-1154

Supporting Statement A

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Goal of Project: To collect information from up to 60 professionals and organization representatives that provide diabetes self-management education and support services (DSMES). These professionals and organizations serve disproportionately affected populations (DAPs) impacted by type 2 diabetes, such as minority women (e.g., African American, Hispanic/Latino, American Indian/Alaska Native, Asian American/Pacific Islander), people with learning disabilities, and people with mental health disorders.

The project aims to understand and address opportunities to reach and improve health outcomes for DAPs. CDC seeks approval to conduct listening sessions with DSMES service organizations serving DAPs as a first phase of this project. A second phase (under a separate OMB approval request) will include listening sessions with persons with diabetes. Following the listening sessions, CDC will use the findings to inform the development of diabetes self-management materials and resources.

Intended Use of Resulting Data: The project aims to address opportunities to reach and improve health outcomes for DAPs, as they are highly impacted by diabetes. Findings also will provide the opportunity to make appropriate adjustments in activities and resources needed as they relate to program development, implementation, and evaluation of DSMES services. Findings from the project also will be used to identify alternative, gender-sensitive and culturally tailored interventions to prevent and manage diabetes in DAPs.

Methods to be used to collect data: Information will be collected through 12 listening sessions with providers and representatives from organizations that provide DSMES services that serve six DAP audiences. The sessions will be conducted on Zoom or a similar videoconferencing platform, with 4-5 participants per session. The discussions will be facilitated by an experienced moderator, based on a semi-structured discussion guide.

How data will be analyzed: Information collected during the listening sessions will be recorded, then organized and analyzed using a qualitative table analysis method. A list of codes will be developed based on the questions in the semi-structured discussion guide used for each session and applied to the data collected.

JUSTIFICATION

A1. Circumstances Making the Collection of Information Necessary

To address opportunities to reach and improve health outcomes for disproportionately affected populations (DAPs) impacted by type 2 diabetes, CDC seeks approval to conduct listening sessions with staff representatives of relevant DSMES service provider organizations. (Listening sessions with DAP consumers will be submitted in a separate OMB package).

Diabetes self-management education and support (DSMES) services are critical elements of care for people managing diabetes to improve patient outcomes.[i] While it is well established that DSMES, a complex health intervention, is generally effective at enhancing self-care behaviors, improving glycemic control, lowering health care costs, and improving quality of life, the specific impact of DSMES features on outcomes have not been thoroughly evaluated for specific cultural and gendered populations.[ii] DSMES programs are structured to provide content that is all-inclusive. Although content in these programs may provide valuable information, the programs are not structured to meet the needs of higher burden populations, such as minority women, people with learning disabilities, and people with mental health disorders, among others.[iii]

There is an urgency to reduce and prevent diabetes-related complications among DAPs, including women, racial and ethnic minority populations, people with learning disabilities, and people with mental health disorders, and identifying social determinants of health (SDoH) that impact successful DSMES in these communities. Organizations that serve these communities engage in many essential aspects of management of type 2 diabetes. However, more information is required to understand the strategies used by these organizations to reach DAP communities and to discover the needs and barriers faced by them to manage diabetes and prevent complications.

Qualitative data collection (i.e., listening sessions) can be used to collect formative data to improve the capacity of organizations, uncover the needs of these communities, and to develop or enhance culturally responsive services, resources, and outreach messages for DSMES providers to apply to improve their efforts to support diabetes self-management to prevent diabetes-related complications within the DAP communities they serve. The information gathered can be applied to diabetes self-management education and support strategies, campaigns, or programs (e.g., through CDC interventions, grants/contracts, and programs) that reach these DAPs. CDC also may apply the results to make the appropriate adjustments in activities and resources needed related to program development, implementation, and evaluation of DSMES programs.

The listening sessions will focus on hearing from providers who have experience providing tailored resources and services to the identified DAPs.

Populations to be included: A summary of participants for the listening sessions is included in Table A1-1.

Table A1-1. Summary of Qualitative Research Segmentation and Participants

Research	Audience	# of	# of Participants

Activity	Segment	Sessions	
Listening Sessions with Providers	DSMES providers that support African American women	2	4-5
	DSMES providers that support Hispanic women	2	4-5
	DSMES providers that support AA/PI women	2	4-5
	DSMES providers that support AI/AN women	2	4-5
	DSMES providers that support people with learning disabilities	2	4-5
	DSMES providers that support people with mental health disorders	2	4-5
	TOTAL	**12**	**60** (no more than 60 across all groups)

A2. Purpose and Use of the Information Collection

CDC is seeking OMB approval to conduct listening sessions with DSMES service providers serving DAPs impacted by type 2 diabetes. (Listening sessions with DAP consumers will be submitted in a separate OMB package).

The objective of the listening sessions with providers is to explore the sociocultural, environmental, and life stage factors that impact diabetes self-management and participation in DSMES services among racial and ethnic minority women, people with learning disabilities, and people with mental health disorders and understand the services and resources that will be most helpful for providers to effectively serve these DAP communities. The qualitative data collection will assess the capacity and needs of DSMES provider organizations serving DAPs and their understanding of the unique needs and drivers of the priority audience groups. The data collected will guide the development and testing of materials to improve efforts to support diabetes self-management programs and services in their provision of culturally appropriate interventions, messages, and materials related to diabetes self-management for DAP communities. CDC may submit additional information collection requests to OMB if materials and messages require testing prior to release.

Recruitment for Service Provider Listening Sessions*:* The contractor will work with an advisory committee and other partners and use the DSMES locator tool linked from the CDC website to identify and conduct outreach to potential participants for the listening sessions.

Conduct of Service Provider Listening Sessions: The contractor will conduct 12 listening sessions with 4-5 DSMES service providers per session, for a maximum of 60 participants, representing the six DAP audiences.

Generalizability and Applicability of Findings: The data collection is qualitative in nature, and therefore not generalizable to the full population of DSMES providers nationwide or to all Americans with diabetes who receive DSMES services. However, the data collection will yield valuable insights and direction because it incorporates feedback and expertise of organizations currently working to provide DSMES services for consumers disproportionately affected by type 2 diabetes.

Role of CDC: CDC's role in this project includes questionnaire design, data collection, data entry, analysis, writing reports, and preparing dissemination materials.

A3. Use of Improved Information Technology and Burden Reduction

The proposed data collection will be conducted entirely online, which negates the need for travel to and from listening session facilities, thereby reducing costs and burden for participants.

A4. Efforts to Identify Duplication and Use of Similar Information

The project builds on a previously conducted literature review, which demonstrated that while DSMES services are generally effective at enhancing self-care behaviors, improving glycemic control, lowering health care costs, and improving quality of life, DSMES services are underutilized by DAP audiences. Therefore, the project is needed to address the specific needs of DAP audiences, including African American, Hispanic, Asian American/Pacific Islander (AA/PI), and American Indian/Alaska Native (AI/AN) women; people with learning disabilities; and those with mental health disorders.

A5. Impact on Small Businesses or Other Small Entities

Some of the organizations to be included in the data collection are small entities. The project team has limited the burden on these organizations by gathering their feedback via a remote listening session. Each participant will receive an incentive of $150 for their time to participate in a listening session.

A6. Consequences of Collecting the Information Less Frequently

The data collection is needed to guide the development and testing of materials for DSMES providers that will be developed by the end of 2024. Without insights and feedback from the data collection, materials cannot be developed effectively.

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

This request fully complies with regulation 5 CFR 1320.5.

A8. Comments in Response to the FRN and Efforts to Consult Outside the Agency

A *Federal Register* notice was published for this generic information collection request on July 22, 2022, Vol. 87, No. 140, pp. 43860-3861. No public comments were received. No additional comment periods are required for project-specific requests submitted under this generic.

Part B: CONSULTATION

Table 1. External Consultations

Name	Title	Affiliation	Phone	Email	Role
OUTSIDE CONSULTANTS					
Eileen Hanlon	Associate Director, Communications	FHI 360 (research contractor)	202-884-8914	ehanlon@fhi360.org	Project manager
Julie Bromberg	Associate Director, Research	FHI 360 (research contractor)	202-884-8025	jbromberg@fhi360.org	Research manager
Yalonda Lewis	Research Associate	FHI 360 (research contractor)	202-884-8185	ylewis@fhi360.org	Moderator
Mary-Esther Gourdin	Research Associate	FHI 360 (research contractor)	202-884-8821	mgourdin@fhi360.org	Research associate
Morgan Barnes	Subject Matter Expert	Center for Black Women's Wellness	404-539-8733	mbarnes@cbww.org	Advisory Committee Member
Michele Smith	Subject Matter Expert	Indian Health Service	402-878-2231 x1205	michele.smith@ihs.gov	Advisory Committee Member

Chihiro Sato	Subject Matter Expert	Asian American Diabetes Initiative - Joslin Diabetes Center	617-939-7112	Chihiro.Sato@joslin.harvard.edu	Advisory Committee Member
Nia Aitaoto	Subject Matter Expert	Pacific Islander Center of Primary Care Excellence (PI-CoPCE)	808-222-8043	nia.aitaoto@gmail.com	Advisory Committee Member
Diana Echenique	Subject Matter Expert	Office of Minority Health Resource Center	(202) 460-2228	diana.echenique@gmail.com	Advisory Committee Member
Anna Norton	Subject Matter Expert	DiabetesSisters	201-233-0002	anna@diabetessisters.org	Advisory Committee Member
Suzan Guzman	Subject Matter Expert	Behavioral Diabetes Institute	858-336-7097	sjg@behavioraldiabetes.org	Advisory Committee Member
Chris Mackey	Subject Matter Expert	Lakeshore Foundation	205-403-5449	chrism@lakeshore.org	Advisory Committee Member

Table 2. Consultations within CDC

Name	Title	Affiliation	Phone	Email	Role
Jennifer Morgan, MSPH	Health Scientist	National Center for Chronic Disease Prevention and Health Promotion	-	hdv1@cdc.gov	Technical Monitor
Kimberly D. Farris, PhD, MPH, MSW	Lead Health Scientist	National Center for Chronic Disease Prevention and Health Promotion	-	yey5@cdc.gov	Subject Matter Expert
Sarah Jean Jacques, MPH	Health Scientist	National Center for Chronic Disease Prevention and Health Promotion	-	ugt3@cdc.gov	Subject Matter Expert
Joshua Petty, MBA	Health Communications Specialist	National Center for Chronic Disease	-	ftk1@cdc.gov	Contract Officer Representative

		Prevention and Health Promotion			

A9. Explanation of Any Payment or Gift to Respondents

Appropriate incentives are key to the success of research efforts and to prevent overburdening the public. Even when individuals initially agree to participate, an incentive that is perceived as “insufficient” (e.g., too little money) may result in a greater likelihood of people who opt not to proceed.

While DSMES providers can have a variety of professional backgrounds, they often are healthcare providers or people with advanced degrees, and participation in the listening sessions will require 1 hour of their time. Therefore, service providers who participate in the listening sessions will receive an incentive of $150.00.

This incentive amount is used in market research for professional audiences and the contractor has used these amounts in other CDC projects. Lower amounts result in lower participation rates and higher recruitment costs. The lower participation rates lead to delays in data collection and in providing timely results. The higher recruitment costs can outweigh cost savings from reduced incentives.

There is little evidence to suggest negative effects of incentives on data quality, sample composition, and response distribution.[iv] For these reasons and because of the large body of evidence supporting these findings, incentives have been supported in many OMB-approved information collection efforts.

Ref: OMB No. 0920-0572, Expiration Date 08/31/2021

A10. Protection of the Privacy and Confidentiality of Information Provided by Respondent

Personally identifiable information (PII), including individual names, will be collected from the DSMES service organizations by FHI 360 (the research contractor) for recruitment purposes and to provide the incentives only. The CDC project team will receive records that contain only the first name of participants, not the full name or any contact information. None of the files or documents received or developed by the CDC project team will include PII. For example, no individual’s full name will appear in project documents or reports.

Participants will be informed about the security measures for privacy protections during the consent process at the beginning of each listening session. (See Attachments B, C, and D.) Before beginning the discussion, participants will be asked for verbal consent to participate in the listening sessions and to be recorded. Participants who do not consent will not continue with the discussion.

A11. Institutional Review Board (IRB) and Justification for Sensitive Questions

FHI 360’s Institutional Review Board (IRB) has reviewed the study protocol and instruments. FHI 360 has a Federal Wide Assurance, which meets all federal requirements specified in 45 C.F.R. 46. The IRB has determined that this project does not meet the regulatory definition of research as defined under 45 CFR 46.102(d)(f). Given this determination, further IRB review and approval of this project is not required.

A12. Estimates of Annualized Burden Hours and Costs

Table A.12-1. Estimated Annualized Burden Hours

Activity	Form Name	Number of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Listening Sessions W/ DSMES providers that support African American Women	Screener Script and Guidelines	15	1	5/60	1.25
	Discussion Guide for Providers Who Support Minority Women	10	1	1	10
Listening Sessions W/ DSMES providers that support Hispanic women	Screener Script and Guidelines	15	1	5/60	1.25
	Discussion Guide for Providers Who Support Minority Women	10	1	1	10
Listening Sessions W/ DSMES providers that support AA/PI Women	Screener Script and Guidelines	15	1	5/60	1.25
	Discussion Guide for	10	1	1	10

	Providers Who Support Minority Women				
Listening Sessions W/ DSMES providers that support AI/AN women	Screener Script and Guidelines	15	1	5/60	1.25
	Discussion Guide for Providers Who Support Minority Women	10	1	1	10
Listening Sessions W/ DSMES providers that support people with learning disabilities	Screener Script and Guidelines	15	1	5/60	1.25
	Discussion Guide for Providers Who Support People with Learning Disabilities	10	1	1	10
Listening Sessions W/ DSMES providers that support people with mental health disorders	Screener Script and Guidelines	15	1	5/60	1.25
	Discussion Guide for Providers Who Support People with Mental Health Disorders	10	1	1	10
Total	**150**				67.5

Table A.12-2. Estimated Annualized Burden Cost

Activity	Form Name	Number of Respondents	No. of Responses per Respondent	Average Hourly Wage	Total Burden (in hours)	Total Burden Cost
Listening Sessions W/ DSMES providers that support African American Women	Screener Script and Guidelines	15	1	$32.06	1.25	$40.07
	Discussion Guide for Providers Who Support Minority Women	10	1	$32.06	10	$320.60
Listening Sessions W/ DSMES providers	Screener Script and Guidelines	15	1	$32.06	1.25	$40.07

that support Hispanic women	Discussion Guide for Providers Who Support Minority Women	10	1	$32.06	10	$320.60
Listening Sessions W/ DSMES providers that support AA/PI Women	Screener Script and Guidelines	15	1	$32.06	1.25	$40.07
	Discussion Guide for Providers Who Support Minority Women	10	1	$32.06	10	$320.60
Listening Sessions W/ DSMES providers that support AI/AN women	Screener Script and Guidelines	15	1	$32.06	1.25	$40.07
	Discussion Guide for Providers Who Support Minority Women	10	1	$32.06	10	$320.60
Listening Sessions W/ DSMES providers that support people with learning disabilities	Screener Script and Guidelines	15	1	$32.06	1.25	$40.07
	Discussion Guide for Providers Who Support People with Learning Disabilities	10	1	$32.06	10	$320.60
Listening Sessions W/ DSMES providers that support people with mental health disorders	Screener Script and Guidelines	15	1	$32.06	1.25	$40.07
	Discussion Guide for Providers Who Support People with Mental Health Disorders	10	1	$32.06	10	$320.60
	Total					$2,164.02

The average hourly wage of $32.06 for health and education positions in the U.S. was obtained from the U.S. Department of Labor, Bureau of Labor Statistics.

The total cost to respondents is $2164.02, based on a total burden of 66 hours.

A13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no other costs. The collection tool requires no special hardware or software and is free for participants to use.

A14. Annualized Cost to the Federal Government

The average estimated annual cost to the Federal government for conducting the data collection activities proposed is $151,500. This total cost includes approximately $135,000 for contractual costs (e.g., research planning, instrument development, expert advisors, IRB review, data collection, and analysis), and $16,500 for personnel costs for Federal employees involved in project oversight activities (5% FTE of one GS-14 employee, 10% of one GS-13 employee, and 10% of one GS-12 employee).

DDT manages a contract in which data collection activities of similar scope have been conducted; these estimates reflect typical costs for such activities based on that contract**.**

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

Labor:	
5% of one GS-14 lead Health Scientist time for project planning, management, OMB review	$5,000
10% of one GS-13 Health Scientist time for project planning, management, OMB review	$8,500
10% of one GS-12 Health Scientist time for project planning, management, OMB review	$3,000
Contractor cost for survey development, evaluation design, analysis of findings, report writing, and manuscript development	$135,000
Total estimated cost	$151,500

A15. Explanation for Program Changes or Adjustments

The information collection request (ICR) is new.

A16. Plans for Tabulation and Publication and Project Time Schedule

Data will be analyzed to identify emerging themes related to the capacity of organizations to inform interventions in support of DSMES, uncover the needs of DAP communities, and to develop and/or enhance culturally responsive materials and tools, for diabetes self-management and prevention of diabetes related complications.

The data will be used within CDC to develop and/or enhance culturally responsive materials, tools, for diabetes self-management and prevention of diabetes related complications. Reports of the listening sessions will be shared with DSMES service organizations partnering in the project and may also be shared at relevant conferences.

Table A.16. Estimated Time Schedule for Project Activities

Activity	Timeline
Invitations and coordination for Listening Sessions with providers	1 month after OMB approval
Listening Sessions conducted	2 months after OMB approval
Data analysis and reporting of Listening Sessions	4 months after OMB approval

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

The display of the OMB expiration date is appropriate.

A18. Exceptions to Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification.

REFERENCES

[i] Davis J, Fischl AH, Beck J, et al. 2022 National standards for diabetes self-management education and support. *Diabetes Care*. 2022;45 (2):484-494. https://doi.org/10.2337/dc21-2396

[ii] Gucciardi E, Wing-Sheung Chan V, et al. A systematic literature review of diabetes self-management education features to improve diabetes education in women of Black African/Caribbean and Hispanic/Latin American ethnicity. *Patient Education and Counseling*. 2013;92(2):235-245. https://doi.org/10.1016/j.pec.2013.03.007.

[iii] Skelly AH, Leeman J, Carlson J, et al. Conceptual model of symptom-focused diabetes care for African Americans. *Journal of Nursing Scholarship*. 2008;40(3):261-7. doi: 10.1111/j.1547-5069.

[iv] Singer, E and C. Ye. (2013). The use and effects of incentives in surveys. *The Annals of the American Academy of Political and Social Science*, 645(1):112–141.