Information Collection Request

New

Evaluation of the Chronic Disease Self-Management Program in the US Affiliated Pacific Islands

Supporting Statement: Part A

Program Official/Contact

Stacy De Jesus, MPH

National Center for Chronic Disease Prevention and Health Promotion, Office of Public Health Practice

Centers for Disease Control and Prevention

Atlanta, Georgia

770-488-6393 (office)

770-488-488-5973 (fax)

SVL9@cdc.gov

May 28, 2019

TABLE OF CONTENTS

- **Goal of the study:** CDSMP is a 6-week group-based educational workshop aimed to improve eligible participants' knowledge and ability to self-manage chronic disease. The goal of this study is to evaluate the implementation of Stanford University's Chronic Disease Self-Management Program (CDSMP) in the US Affiliated Pacific Islands. The purpose of this evaluation is examine if this program can be effective for people in the USAPIs to better manage their chronic conditions.
- **Intended use of the resulting data:** To document the implementation of and adaptation to CDSMP in the US Affiliated Pacific Islands. If the evaluation demonstrates that CDSMP is feasible and has similar outcomes, then CDC will continue to promote its implementation as effective self-management program for people in the USAPIs. This would also probably result in a paper highlighting that it can be applied in remote and resource poor settings.
- **Methods to be used to collect data:** Prospective cohort design
- **The subpopulation to be studied:** Adults attending CDSMP workshops in 6 US Affiliated Pacific Islands
- **How data will be analyzed:** Descriptive statistics will be used for quantitative data and content analysis will be used for qualitative data.

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) at the Centers for Disease Control and Prevention (CDC) is requesting OMB approval for a new information collection request. Six in 10 adults live with at least one chronic disease (Centers for Disease Control and Prevention, 2019). Stanford University's Chronic Disease Self-Management Program (CDSMP) is a 6-week series of workshops for people with arthritis, diabetes, lung disease, cancer, and other health problems. The workshops focus on helping participants learn strategies to manage chronic disease, including techniques to deal with problems such as frustration, fatigue, pain and isolation; appropriate exercise for maintaining and improving strength, flexibility, and endurance; and appropriate use of medications among others. Proven benefits of CDSMP include decreased pain and health distress, increased energy and fatigue, increased physical activity, better communication with health care providers, and increased confidence in managing chronic disease (Ory, Smith, Ahn, Jiang, Lorig, Whitelaw, 2014).
The program will be offered repeatedly over the course of three years. This new request is for 2 years, which will cover repeated data collection planned to occur over 21 months. NCCDPHP plans to evaluate the first ever implementation of CDSMP in the US Affiliated Pacific Islands (USAPIs). These jurisdictions include American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, the Republic of Palau, the Republic of the Marshall Islands, and the Federated States of Micronesia. Eligible participants include any person living in USAPIs with chronic health problems. USAPIs recruit participants through a variety of methods, including word of mouth and NCD clinic referrals.

CDSMP has never been implemented in the USAPIs The purpose of this evaluation is to know if this program can be effective for people in the USAPIs to better manage their chronic conditions. If the evaluation demonstrates that CDSMP is feasible and has similar outcomes, then CDC will continue to promote its implementation as effective self-management program for people in the USAPIs.

Because this is the first time CDSMP is being implemented in the USAPIs, we do not know if the intervention, which has proven to improve health outcomes in many ethnic groups within the United States, will lead to improved health outcomes for these communities. (Lorig, Sobel, Stewart, Brown, Ritter, González, Lauren, Homan, 1999) We have not found evidence that the CDSMP is ineffective with particular ethnic groups; however, the literature on CDSMP covers only implementations in the United States and Japan (Yukawa, Yamazaki, Yonekura, Togari, Abbott, Homma, 2010). We are unaware of CDSMP use and evaluations from less developed nations or those where lifestyles are more similar to those of the USAPIs. We also do not know if the way the intervention as delivered will be effective. For example, CDSMP requires implementers to use an English manual and to deliver the training in English. The material has been translated into several other languages, but only one Pacific Island language (Samoan). The CDSMP questionnaire will be implemented in English across all other DP19-1901 cooperative agreement recipients. All of the implementation areas are officially English-speaking, but actual fluency in English varies across individuals. Many CDSMP leaders believe it may be difficult to administer the program in English because the communities they want to reach do not all speak English.

The Islands program would like to examine whether the CDSMP can have direct applicability in the USAPI's and the extent to which local adaptations are required to ensure applicability. This evaluation data collection is part and parcel with the CDSMP, and evaluation questionnaires were provided from the CSMP website. We plan to examine CDSMP over several years, taking a controlled approach to adapt one aspect of the program at a time (e.g. language, examples). This evaluation is a baseline data collection effort and findings will be used to inform program adaptations, including language delivery method or cultural appropriateness of program phrasing. Future CDSMP implementation and corresponding data collect efforts may change language delivery method or slightly alter program phrasing to ensure clear communication and cultural appropriateness with the intended audience. If there are challenges with administering the data collection questionnaire due to cultural or language differences, we will ask CDSMP master trainers to account for and report any challenges. This would also probably result in a paper highlighting that it can be applied in remote and resource poor settings.

As a new initiative, no data exist to assess CDSMP implementation in the USAPIs. Collecting this data will help us understand if CDSMP, an evidence-based intervention, has the same effect in the US Affiliated Pacific Islands as it has in multiple ethnic groups within the United States.

This new ICR is authorized under Section 301(a) of the PHS Act, 42 U.S.C. 241(a). This authority authorizes NCCDPHP to collect data for this project to improve health among these communities.

2. Purpose and Use of the Information Collection

The purpose of the data collection effort is to understand how CDSMP is being implemented in the region, to identify barriers and facilitators to implementation and to understand the self-reported effects of the program on program participants. As a new initiative, no data exist to assess CDSMP implementation in the USAPIs. The data collected will be used to understand if CDSMP, an evidence-based intervention, has the same effect in the US Affiliated Pacific Islands as it has in multiple ethnic groups within the United States.

We will be using two data collection instruments: Chronic Disease Self-Management Workshop Evaluation Form and Chronic Disease Self-Management Questionnaire. More information on each instrument is provided below:

Chronic Disease Self-Management Workshop Evaluation Form: This is a questionnaire to assess program participant satisfaction with CDSMP. A paper questionnaire will be administered at the end of the 6 week workshop. Results will be used to assess satisfaction with the delivery of CDSMP and to identify ways to improve the delivery of CDSMP.

Chronic Disease Self-Management Questionnaire: This is a pre- and post-test for CDSMP program participants. It will assess chronic disease related symptoms and health behaviors before CDSMP and at the end of the 6 week workshop. A paper questionnaire will be administered at the start of and at the end of the 6 week workshop. Identifying information includes the participant name, which is collected to compare the two questionnaires to each other. However, the CDSMP workshop leaders, who administer the questionnaire, will also assign a number to each participant and replace the names on the questionnaires with the numbers. Administrators will have the name alone on a cover sheet that can be torn off after the number is written on the questionnaire (and double-checked). A scanned copy of the questionnaire will be electronically submitted to CDC using the Citrix Sharefile drobox and will be de-identified, including only the participants' assigned number. CDC will use the assigned number to match pre- and post-tests in the data analysis. Names will not be used in the data analysis or report. Results will be used to compare changes in health behavior and chronic disease related symptoms from the start of the workshop to the end of the workshop.

3. Use of Improved Information Technology and Burden Reduction

Responses from program participants will be reported on paper, scanned, and submitted to the CDC via Citrix ShareFile dropbox. We are hesitant to administer an online questionnaire to program participants because they may not have access to the internet or computers, in addition to unreliable internet connectivity in these jurisdictions. We do not anticipate the

Pacific Islands improving their internet connectivity during the data collection, but if they do so sufficiently, we will work towards electronic data collection.

4. Efforts to Identify Duplication and Use of Similar Information

Data are not already available on CDSMP in Pacific Island jurisdictions. These jurisdictions began implementing CDSMP in the fall and winter of 2016 and do not consistently and uniformly collect data from program participants.

5. Impact on Small Business or Other Small Entities

This data collection will not involve small businesses because small businesses are not conducting the program and are not involved in the program we are collecting data from.

6. Consequences of Collecting the Information Less Frequently

Information will be collected from respondents twice: at the start of the CDSMP workshop and at the end of the CDSMP workshop. Data are collected this way to ensure we can compare pre-workshop data with post-workshop data. If data were collected less frequently, we will not be able to assess the effect of the program on participants and we will not be able to compare program effects in the Pacific Islands to program effects in the Continental U.S. and Hawaii. In addition, participants will only complete 1 six week workshop. Therefore, the only opportunity to collect data from each participant is pre-post workshop.

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

This request fully complies with the regulation 5 CFR 1320.5.

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

Part A: PUBLIC NOTICE

A 60-day Federal Register notice was published in the Federal Register on February *2, 2018, vol. 83, No. 23, pg.4917- pg.4918* (see Att. 2). CDC did not receive public comments related to this notice.

Part B: CONSULTATION

Consultations outside of CDC did not occur. CDC is supporting the implementation of CDSMP through its cooperative agreement with the US Affiliated Pacific Islands. CDC is interested in documenting the effects of CDSMP in the USAPIs. This is critical because it is the first time that CDSMP is being implemented in this region and CDSMP is potentially a strategy to improve community clinical linkages and if effective, CDC will continue to encourage CDSMP in the region.

9. Explanation of Any Payment or Gift to respondents

Gifts (financial and non-financial) will not be provided to respondents.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

CDC's Chief Privacy Officer and NCCDPHP's Information Systems Security Officer (ISSO) have reviewed this submission, and determined that the Privacy Act does not apply. While the Privacy Act is not applicable, given the sensitivity of information collected, all appropriate security controls and rules of behavior will be incorporated to protect the privacy of information obtained. Personally identifiable information (PII) will not be transmitted to CDC. CDC will only include aggregate and summary information in reports and will not include information that may identify respondents.

A. Data will be secured by physical, technical, and administrative safeguards as outlined below:

Physical

- Questionnaires will be stored in locked cabinets only accessible by the questionnaire administrator (CDSMP Leader).
- Physical copies of questionnaires will be destroyed the CDC evaluator alerts the participant that the scanned questionnaire files have been received by CDC.
- CDC will maintain electronically scanned copies on CDC's secure share drive accessible by DP19-1901 staff, including Elizabeth Adams (evaluator), Madalena Soares (program manager), Stacy DeJesus (program COR).

Technical

- Questionnaires will be scanned by CDSMP leaders and maintained in a secure location on a dedicated server only accessible by the questionnaire administrator (CDSMP leader) and DP19-1901 cooperative agreement recipient staff. The server will have a firewall.
- The questionnaire administrators will submit electronic copies of the questionnaire to the CDC using the Citrix Sharefile dropbox. CDC will maintain the questionnaires and abstracted data in a secure location on a dedicated server only accessible by evaluation staff, the program coordinator, and the program assistant. The server will have a firewall.

Data Management

- Each participating jurisdiction will develop a data management plan and submit it to CDC. CDC will provide model language that can be tailored by each participating jurisdiction based on capacity and infrastructure. We will instruct all DP19-1901 cooperative agreement recipients to enter data in Microsoft Excel on a security protected computer. No respondent identifiers will be used in the

course evaluation questionnaire. Administrators will have the name alone on a cover sheet that can be torn off after the number is written on the questionnaire (and double-checked). A scanned copy of the questionnaire will be electronically submitted to CDC using the Citrix Sharefile drobox and will be de-identified, including only the participants' assigned number. The scanned de-identified questionnaires and corresponding Excel file will be housed on the DP19-1901 cooperative agreement recipients secure server and will be password protected. . We will periodically review and update these security processes when needed.

B. The data collected is not considered research with human subjects; however, we will be providing a consent form to sign for those that volunteer to participate.

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

This project was determined to be Non-Research, since it is public health practice and program evaluation. However, we will ensure that participants are well aware their participation is voluntary and they will not lose access to CDSMP if they refuse.

The following types of sensitive questions will be asked in the CDSMP Questionnaire: chronic disease status, age range (e.g. 30-39), race and/or ethnicity, education, language, and marital status. We are collecting this information to understand participant characteristics and to assess similarities and differences in outcomes based on characteristics. Language and race/ethnicity are especially important to this data collection because this is the first time the intervention is being implemented among the US Affiliated Pacific Islands. The languages and race/ethnicities are unique to this area and we would like to assess intervention outcomes among these communities compared to previously studied communities. We are also assessing the ability for leaders to deliver training in English, which is not the primary language for many of the anticipated participants. Individual data, however, will not be reported. This information will be aggregated.

We are also collecting their names in order to match pre and post- questionnaires, which will help us assess how the intervention affects health symptoms, health behavior, and self-efficacy. The participant names, however, will be on a cover sheet and removed from the pre and post questionnaires. Survey administrators will assign the questionnairesa number and keep a log of participant names and numbers. The name log and surveys will be safely secured in two separate locations. CDC will receive a scan copy of the questionnaires; we will not receive names.

12. Estimates of Annualized Burden Hours and Costs

The following table represents the estimated annual burden hours across respondents. The estimated annual burden hours are 95, with an estimated 190 respondents per year.

Table 12a. Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in Hours)	Total Burden Hours
Program Participants	Chronic Disease Self-Management Workshop Evaluation	190	1	10/60	32
Program Participants	Chronic Disease Self-Management Questionnaire (Pre-Post Test)	190	2	10/60	63

The following table (12b) provides the estimated annual cost to respondents. The average wage rate of $6/hour, is estimated based on consulting with jurisdictions and territories and by using the jurisdictions' and territories' cost when they submitted their cooperative agreement salary budgets for the designated respondents.

Table 12b. Annualized Cost to Respondents

Type of Respondents	Form Name	Number of respondents	Total Burden (in Hours)	Average Hourly Wage	Total Cost (# respondents by response time
Program Participants	Chronic Disease Self-Management Workshop Evaluation	190	32	$6	$192
Program Participants	Chronic Disease Self-Management Questionnaire (Pre- Post Test)	190	63	$6	$378

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

The primary cost burden to records keepers will be collecting and entering data. Based on the average salary of program coordinators, the primary leads engaged in data collection, we

estimate a burden of $95 ($15/hr X 6 hrs) across all DP19-1901 cooperative agreement recipients.

14. Annualized Cost to the Federal Government

The average annual contractor cost for this data collection is $7,800 per year. Additional annual costs include personnel costs of federal employees involved in oversight and analysis. The annual staff cost is estimated at $11,701 (.10 Program Coordinator/Public Health Advisor).

Table A14-A. Estimated Annualized Federal Government Cost Distribution

	Annualized Cost
CDC Personnel Subtotal	$11,701
Data Contractor Subtotal	$7,800
Total	$19,501

Table A14-B.

Equipment	Printing	Postage	Software Purchases	Licensing Costs	Other	total
$0	$45	$0	$0	$0	$25	$70

Table A14-C. Total Cost to the federal Government

Operational and Maintenance Costs	Estimated Annualized Federal Government Cost	Total Cost (O&M Costs + Labor Costs)
$70	$19,501	$19,571

15. Explanation of Program Changes or Adjustments

N/A. This is a new collection with a new associated burden.

16. Plans for Tabulation and Publication and Project Time Schedule

Results of the information collected will be published as a HHS/CDC publication and will be shared internally and externally with stakeholder organizations. We may seek publication to the Hawai'i Journal of Public Health and other journal venues as appropriate.

Table A16-A. Project Time Schedule

Project Time Schedule	
Activity	Time Schedule
Letters sent to respondents	1-2 months after OMB approval
Data / Information Collection	3-24 months after OMB approval
Complete Field Work	24-25 months after OMP approval
Validation	25-26 months after OMP approval

Analyses	26-32 months after OMP approval
Publication	32 months after OMB approval

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

The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification.

References

Ahn SN, Basu R, Lee Smith M, Jiang L, Lorig K, Whitelaw N, Ory MG. The impact of chronic disease self-management programs: healthcare savings through a community-based intervention (2013). *BMC Public Health*, 13:1141.
Lorig KR, Sobel DS, Stewart AL, Brown Jr BW, Ritter PL, González WV, Laurent DD, Homan HR. Evidently suggesting that a chronic disease self-management program can improve health status while reducing utilization and costs. A randomized trial. *Medical Care*, 37(1):5-14.1999.

Ory, M., Smith, M.L., Ahn, S. Jiang, L., Lorig, K., Whitelaw, N. (2014) National Study of Chronic Disease Self-Management: Age Comparison of Outcome Findings. *Health Behavior and Education*, 41, 1.

Tomioka M, Braun KL, Compton M, Tanoue L. Adapting Stanford's Chronic Disease Self-Management Program to Hawaii's Multicultural Population (2011). *The Gerontologist* 52:1, 121-132.

Yukawa K, Yamazaki Y, Yonekura Y, Togari T, Abbott FK, Homma M, et al.Effectiveness of Chronic Disease Self-Management Program in Japan: preliminary report of a longitudinal study. Nurs Health Sci2010;12(4):456–63 10.1111/j.1442-2018.2010.00559