

Information Collection Request

New

Costs of Implementing Community-Based Sodium Reduction Strategies

Supporting Statement: Part A

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- **Goal of the study:** CDC and RTI International propose to survey all of the partners of Sodium Reduction in Community Program (SRCP) Round 3 grantees. Respondents will report data on staff time, materials used, and activities completed to support sodium reduction efforts. These data will be used to estimate the costs to SRCP partners of implementing sodium reduction strategies.
- **Intended use of the resulting data:** The insights to be gained from this data collection will be critical to understanding the full costs of implementing community-based sodium reduction strategies. CDC will use findings for SRCP planning and technical assistance to SRCP awardees and other entities that are interested in community-based sodium reduction strategies. Findings will also be disseminated to state and local organizations to inform planning and sustainability of other community-based public health initiatives.
- **Methods to be used to collect:** Data collection will be conducted through the use of a survey, originally developed and piloted with eight partners during the evaluation of SRCP Round 2 and revised based on lessons learned from the Round 2 evaluation and consultation with CDC and other stakeholders. We are collecting only program-level cost data and no individual-level data. We are not requesting sensitive or personally identifiable information.
- **The subpopulation to be studied:** Food service partners of SRCP grantees.
- **How data will be analyzed:** We will examine the average cost per partner overall and stratified by organizational size. We will also examine the change in revenue and profit from implementing sodium reduction strategies. These analyses will provide preliminary estimates of the costs of implementing community-based sodium reduction strategies.

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

This is a new Information Collection Request (ICR). CDC's authorization to collect this information is provided by the Public Health Service Act (Attachment 1).

Background

The Centers for Disease Control and Prevention (CDC) is the primary Federal agency for protecting health and promoting quality of life through the prevention and control of disease, injury, and disability. CDC is committed to programs that reduce the health and economic consequences of the leading causes of death and disability, thereby ensuring a long, productive, healthy life for all people.

Sodium reduction is a public health imperative. Although the *2015–2020 Dietary Guidelines for Americans* (USDA/USDHHS, 2015) recommends no more than 2,300 mg/day of sodium for adults, U.S. adults consume an average of more than 3,500 mg/day (USDA, 2014). Centers for Disease Control and Prevention (CDC) National Health and Nutrition Examination Survey (NHANES) data from 2013–2014 indicate that men over the age of 20 consume an average of 4,099 mg/day of sodium (US Department of Agriculture, 2015). The significant gap between recommended intake and average intake poses a serious public health risk; high sodium intake leads to hypertension, a common and costly health risk in the United States. The number of American adults with hypertension, estimated at 77.9 million (Go et al., 2013), continues to grow. The increasing prevalence of hypertension is especially troubling because high blood pressure leads to serious health issues, including cardiovascular disease (CVD), stroke, and kidney disease. One study projected that the real direct medical costs of CVD will triple between 2010 and 2030, from \$273 billion to \$818 billion (Heidenreich et al., 2011). Recent studies have shown that even modest population-level sodium reductions can lead to significant decreases in blood pressure and to potentially enormous savings—in lives and in dollars (Aburto et al., 2013; Adler et al., 2014; Bibbins-Domingo et al., 2010; Coxson et al., 2013; He et al., 2013; Palar & Sturm, 2009; Smith-Spangler et al., 2010).

Reducing sodium levels presents a special set of challenges for public health programs because high sodium intake is largely the result of sodium found in processed foods and foods prepared in restaurants. Commonly used to enhance flavor, texture, and viscosity or to preserve foods, salt is often hidden and difficult for consumers to recognize (IOM, 2010). Past sodium reduction initiatives that focused on consumer outreach and education succeeded in creating awareness of the link between sodium and hypertension, but failed to make a significant impact on consumption levels. Although consumer outreach and education should be a part of any sodium reduction strategy, these strategies are independently insufficient (IOM, 2010). As such, multiple reports by the Institute of Medicine (IOM) and the Food and Drug Administration (FDA) have asserted the need for large-scale, population-based efforts to decrease sodium consumption.

Recognizing the importance of population-based approaches, CDC launched the first round of the Sodium Reduction in Communities Program (SRCP) in 2010 to reduce sodium intake by helping to create healthier food environments (Mugavero et al., 2012) and a second round in 2013 to reduce sodium intake in food environments through population-based sodium reduction strategies. SRCP's project goals include increasing access to and availability of lower-sodium food options. The long-term goal of the initiative is to reduce sodium intake to within the recommended levels in the *Dietary Guidelines for Americans*. The 2010 SRCP awardees implemented strategies in a variety of venues, including worksites, schools, independent restaurants, grocery and convenience stores, hospitals, and venues serving meals for older adults (e.g., senior and congregate meal sites). RTI International led the cross-site evaluation for these communities and found that achievements at the community level have the potential to bolster ongoing efforts at the individual, organizational, and national levels, and vice versa. Thus, community-based sodium reduction strategies play an important role in supporting broader changes and individual behavior changes. RTI is currently wrapping up the evaluation of the second round of SRCP, and preliminary findings demonstrate a strong impact of the program on availability, accessibility, and purchase of lower sodium options. RTI in collaboration with CDC will publish final results from the evaluation in 2019.

In 2016, CDC funded eight grantees (SRCP Round 3) to continue improving community and environmental supports for sodium reduction and to build practice-based evidence around effective population-based strategies to reduce sodium consumption. Grantees included state and local health departments and one university medical center. These communities are partnering with organizations to implement sodium reduction strategies in their food service venues. By creating a healthier environment, CDC seeks to decrease the population-wide burden of sodium intake. A list of grantees from each SRCP funding opportunity announcement is provided in Attachment 5.

Overview of the Proposed Assessment

CDC and RTI International propose to collect information from all partners of SRCP grantees that are willing to participate in order to estimate the costs to SRCP partners of implementing sodium reduction strategies. Partner organizations are those that work to implement the sodium reduction strategies in their food services and can include worksites, schools, universities, hospitals, senior meal programs, food banks, and restaurants. The information collection will occur via a cost data collection survey (Attachment 2), in which respondents will be asked about a key set of sodium reduction activities that were developed based on a pilot study with 8 partners during the evaluation of SRCP Round 2. Activities include: establishing nutrition guidelines, developing lower sodium products or recipes, preparing lower-sodium food, promoting lower-sodium foods, and attending additional meetings. Respondents are asked to report on all costs since beginning work on sodium reduction strategies as part of SRCP. While grantees began work on SRCP in 2016, partners began work at different

times, so the time period of costs will vary by partner. Therefore, we also ask how long they have been working on sodium reduction. For each activity, respondents will be asked the number and types of staff that worked on the activity, the average monthly number of hours worked on that activity for each staff member, the number of months worked by each staff member, and how long the activity will continue. Additionally, for each activity, respondents will be asked to report any non-labor expenditures on materials or supplies. RTI will work with CDC and grantees to reach out to partners and request their participation in the survey.

We will analyze partner cost data to assess the implementation costs incurred by partners for sodium reduction activities to date. These costs will be divided into startup and ongoing costs. It is important to understand this distinction because, while startup costs are generally only incurred once, ongoing costs are those required for program sustainability. Analyzing startup and ongoing costs will inform CDC, recipients, and future partners' budgets and will better enable them to plan for future sodium reduction activities. Additionally, partners will likely be at different stages of implementation since they started work at different times, so categorizing costs into startup and ongoing, will help to explain potential differences in costs between partners. We will examine per capita costs by dividing total implementation costs by the number of people reached by the partner. The insights to be gained from this data collection will be critical to understanding the full costs of implementing SRCP. Estimates will be considered preliminary and not externally generalizable, but can provide a basis for future planning and evaluation. Understanding the costs to partners is important for program planning to support program longevity and sustainability. For example, CDC can use the estimate to provide guidance or technical assistance to entities that are interested in population-based strategies for reducing sodium consumption. Results will also be disseminated to other state and local organizations to inform planning and sustainability of other community-based public health initiatives.

OMB approval is requested for one year.

2. Purposes and Use of the Information Collection

The purpose of the assessment is to estimate the actual partner costs of implementing sodium reduction strategies as part of SRCP. The information collection will occur via a cost data collection survey, in which respondents will be asked about costs incurred on a key set of sodium reduction activities

The goal of the information collection is to provide CDC, grantees, and their partners with the ability to analyze data related to the partner costs associated with the implementation of sodium reduction strategies. These data collected by RTI International will be used to conduct a series of economic analyses assessing the costs of implementing the program to inform future program planning and cost-effectiveness analysis of the current program.

Cost data are currently limited for implementation of sodium reduction strategies at the community level. Economic analysis will provide critical information for decision making by assessing the actual costs of implementing sodium reduction strategies. The literature contains numerous examples of using costing methodologies to obtain detailed cost data to perform economic evaluations of health programs in the United States and internationally. In the United States, there is a long history of using an activity-based costing approach to perform cost-effectiveness evaluations of substance abuse programs, which recently has been extended to cancer interventions and a significant proportion of costs are shared by program partners.

3. Use of Improved Information Technology and Burden Reduction

All cost data will be collected electronically via email using an electronic survey instrument to reduce respondent burden, data collection errors, and delays in receiving data. The survey will be provided via email as an attachment and will be sent and received on RTI's secure servers. No sensitive information will be collected. The survey includes 13 items and can be completed at the convenience of the respondent. A Microsoft Word-based draft version of the cost survey was pilot tested during the evaluation of SRCP Round 2 to assess its ability to provide requested data and identify approaches to minimize burden. The tool has been revised to only include the most important questions to inform the relevant evaluation questions; therefore, no extraneous information will be collected. The survey will also include detailed instructions for completion, which have been revised based on feedback from the pilot test.

RTI will collect and tabulate the data provided by program partners. We expect to collect minimum information necessary to address the project's evaluation questions. Efforts have been made to design the instrument to be brief, easy to use, and understandable. The study investigators have carefully considered the content, appropriateness, and phrasing of the questions.

4. Efforts to Identify Duplication and Use of Similar Information

During the evaluation of SRCP Round 2, RTI developed a partner cost data collection survey based on interviews with SRCP partners. The survey was piloted to eight SRCP partners. None of these eight partners will be surveyed again as part of this data collection. The survey has been revised to reflect lessons learned and consultation with CDC and other stakeholders, such as grantees and key partner contacts.

While the SRCP has existed since 2010, the goal and mission of the program has evolved with each funding cycle. The 2016-2021 funding cycle (Round 3) is the first such initiative to include as a focus the cost of implementing sodium reduction strategies on partner organizations. The evaluation of SRCP Round 2 did include a small pilot study on partner costs, but this is the first large-scale effort to collect these costs. The proposed information collection is unique in that

there are no other surveys administered to partners of SRCP funded grantees that assess the partner costs associated with implementing sodium reduction strategies. This is the first data collection effort to assess an initiative of this nature. In addition, the partner cost data will provide complementary information that is not obtained through regular grantee progress reporting to CDC. The partner cost data collection instrument was developed by a panel of evaluators from RTI and CDC to ensure that the most useful questions were being asked and to minimize redundancy. Content was informed by a series of structured interviews with partners conducted by RTI during the evaluation of SRCP Round 2. The tool was piloted with a small group of Round 2 partner organizations, and modified based on lessons learned and discussions with CDC and other stakeholders.

CDC project officers communicate with SRCP grantees on an ongoing basis, including thorough monthly conference calls. However, routine calls and progress reports do not provide a systematic overview of the costs realized by partner organizations during the implementation of sodium reduction strategies. Similarly, the financial reporting required of grantees, the Federal Financial Report (FFRs) and program budgets, do not include detailed information of the true program costs, including partner cost contributions.

5. Impact on Small Businesses or Other Small Entities

Small businesses and other small entities will not be specifically targeted to participate in this assessment. Recruited participants will be organizations partnering with SRCP grantees. It is possible that some partners who will be recruited to complete the cost survey may be representatives of a small business. However, there are no specific requirements for small businesses.

In addition, because the survey is voluntary and each recruited participant will indicate their desire to participate at the start of the survey, we anticipate that the impact of the information collection on respondents will be minimal. The administration of the survey will allow respondents to complete the survey in multiple sessions at their convenience over several weeks, which will also minimize the burden on small employers. Furthermore, we will provide \$50 gift cards as incentives for completing the survey.

6. Consequences of Collecting the Information Less Frequently

Without these cost data, CDC will not be able to assess the cost burden associated with the implementation of sodium reduction strategies. This economic analysis will provide critical information to inform decision making and future resource allocation by assessing the actual costs of SRCP grantees and their partners. This information is vital to the overall evaluation of the SRCP program and essential for future, successful program planning, implementation, and

sustainability. It is anticipated that over the two-year evaluation period, program partners will collect and report these cost data once, in Spring 2019.

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.

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

A 60-day Federal Register Notice was published in the *Federal Register* on June 1, 2018, Vol. 83, No. 106, pp. 25458-25460 (see Attachment 3a). CDC received two non-substantive comments (see Attachment 3b).

There were no additional efforts to consult outside the agency.

9. Explanation of Any Payment or Gift to Respondents

Participating SRCP partners will be provided \$50 gift cards as incentives for completing the survey. It is essential to incentivize participation from partners, because they are busy organizations that may be reluctant to devote the time to participate. Incentives have been shown to significantly increase participation rates and \$50 has been shown as an important threshold to achieve with one study estimating a 30% increase in response with incentives \$50 or greater compared to incentives less than \$50 (Goritz 2006, Asire 2017)

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

The CDC Privacy Office has reviewed this submission and determined that the Privacy Act does not apply. Although a primary contact person will be identified for each organization, the contact person will be speaking from their role as a representative of the responding SRCP partner's organization. The information collection does not involve collection of sensitive or personal information.

Respondents are organizations partnering with SRCP grantees that are providing information on their staff time costs and non-labor expenditures on materials or supplies. Minimum information in identifiable form (IIF) is being collected. Information collection is for the purpose of assessing CDC-funded programs' activities at the partner organizational level.

Privacy

The proposed study involves a minimum amount of IIF, and includes only business contact information for each respondent (i.e., name, telephone number, and email address). The information to be obtained through surveys concerns organizational activities and costs rather than personal matters and is not considered highly sensitive. Within surveys, respondents will be asked to identify the number and types of staff involved in the implementation of sodium reduction strategies, but they will not be asked to provide specific names or information about individual program staff or partners. The cost information collected will focus on programmatic spending; the survey will not ask respondents to input any information about themselves.

Survey responses from partner organizations will be linked to the SRCP that the organization partners with to ensure that findings can be linked to other existing organizational data from SRCP grantees. RTI, the data collection contractor, will have access to IIF for program leadership and staff recruited for participation. No other personal identifiers will be collected.

Contact information will be stored separately from response data. A linking file will be created and available only to project management at RTI International. This information will only be used to ensure completeness of the data files. The linking file will include the role of the respondent and their organization (and will not include the individual's name or contact information), the date of survey/interview completion, and the code assigned to the data file. This will ensure that no IIF outside of the individual's role and organization is re-linkable. All data files will be stored in a secure electronic folder on a password-protected shared computer drive that is only accessible by authorized project staff.

- A. Safeguards. Data collection will be conducted via email using an electronic survey document. Data will be submitted to CDC according to approved Internet-based communication protocols. Identifiable partner data will not be shared with grantees. Grantees will only receive data in aggregate. The systems to be put in place will ensure that stored information is accessible to authorized users yet secure. Study information and data, including contact information for respondents, linking identifiers, and responses, will be destroyed within 3 years of the project end date. All electronic data files will be stored at RTI on a project shared drive on RTI's secure network servers; only project staff who have been authorized by the project manager can access the shared drive.
- B. Consent. An informed consent statement will be included on the cover page of the survey instrument prior to the instrument questions.

The consent statement informs respondents of how the data will be used and that their participation in the survey is voluntary. They can choose not to answer individual questions, end the survey or interview at any time, or decline participation without penalty. Whether or not individuals choose to participate will not impact current or

future funding. Respondents will be required to either agree to or decline participation prior to completing the survey.

- C. Nature of Response. Participation in the survey is voluntary for all participants; respondents who decline participation will not face penalty of any kind.

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

We are collecting program-level cost implementation data. We are not collecting individual-level data. This information collection does not request sensitive or personal information.

The Institutional Review Board (IRB) of CDC's information collection contractor determined that this project does not constitute research with human subjects as defined by the US Code of Federal Regulations (45 CFR 46.102) (see Attachment 6).

12. Estimates of Annualized Burden Hours and Costs

12.a Estimated Annualized Burden Hours

OMB approval is requested for one year. Annualized estimates of the number of respondents involved in the information collection activities are provided below.

The estimated burden per response for the SRCP Partner Cost Survey is 1 hour. There are 88 partner organizations across all SRCP grantees and we assume a 50% response rate so the total estimated annualized number of respondents is 44 and the total estimated annualized burden is 44 hours.

Table A12a. Estimated Annualized Burden to Respondents

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
SRCP Partner Program Manager	SRCP Partner Cost Survey	44	1	1	44
Total:					44

12b. Annualized Cost to Respondents

Average hourly wage estimates were obtained from the U.S. Department of Labor, Bureau of Labor Statistics. The estimated annualized cost to respondents is \$4,958.80, as summarized below in Table A.12-B.

- The average annual salary of \$117,200 for general and operational managers was used to calculate the hourly wage of \$56.35 for program managers.

Table A12b. Annualized cost to Respondents

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Average Hourly Wage Rate	Total Cost
SRCP Partner Program Manager	SRCP Partner Cost Survey	44	1	1	\$56.35	\$2,479.40
Total						\$2,479.40

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

No costs other than those described in A.12 will be incurred by the respondents to complete this data collection.

14. Annualized Cost to the Federal Government

Table A14. presents the two types of costs to the government that will be incurred: (1) external contracted data collection and analyses and (2) government personnel.

1. The project is being conducted under a contract that was awarded on September 17, 2017. The contract is for a total of 2 years. The annualized cost for the cost data collection task for the data contractor is estimated at \$39,190.

2. Governmental costs for this project include personnel costs for federal staff involved in providing oversight and guidance for the planning and design of the assessment, refinement of the data collection tools, development of OMB materials, collection and analysis of the data, and reporting. These activities involve approximately 5% of a GS-12 health scientist and 5% of a GS-13 health scientist. The total cost of federal staff to the federal government is \$8,886. The total annualized cost to the federal government for the duration of this data collection is \$48,076.

Table A14. Estimated Annualized Federal Government Cost Distribution

Type of Government Cost	Annualized Cost
Data Contractor	\$39,190
Federal Staff	\$8,886
GS-12 health scientist at 5% FTE	\$ 3,785
GS-13 health scientist at 5% FTE	\$5,101
Total	\$48,076

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

16A. Publication Plan

Estimates of the average startup and ongoing cost of implementing sodium reduction strategies by organization type will be disseminated to grantees and other stakeholders through reports, briefings, presentations at professional meetings, and publication of manuscripts in peer-reviewed journals. Table A16-A is an example shell of the presentations of results. It is anticipated that the results of this project will be developed into several scientific and nonscientific reports.

Table A16-A. Example Table Shell for Dissemination of Results

Type of Organization	Average Total Startup Cost	Average Monthly Ongoing Cost
Restaurant		
Cafeteria (worksite or hospital)		
School		
Congregate Meal		
Food bank		

16B. Project Time Schedule

The expected time schedule for project activities is presented in Table A16-B.

Table A16-B. Estimated Time Schedule for Project Activities

Activity	Expected Timeline
Development of final version of the cost survey	November 2017 – December 2017
Receive OMB Approval	Winter 2018
Recruitment emails sent to partners	Spring 2019
Technical assistance for cost collection tool	Spring 2019
Data collection	Spring 2019
Cost analyses	Summer 2019

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

The OMB expiration date will be displayed on all information collection instruments. No request for an exemption from displaying the expiration date for OMB approval is being sought.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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