

Assessment of Colorectal Cancer Control Program Implementation at Health System Clinic Sites

CSTLTS Generic Information Collection Request
OMB No. 0920-0879

Supporting Statement – Section A

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Program Official/Project Officer

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- **Purpose of the data collection:** The purpose of this data collection is to assess how individual Colorectal Cancer Control Program (CRCCP) health system clinics implement the program, including evidence-based interventions (EBIs).
- **Intended use of the resulting data:** The information collection will allow CDC CRCCP to better describe CRCCP implementation within clinic sites, including the factors that contribute to or hinder EBI implementation. The information collection will inform guidance, resource development, and technical assistance activities the CDC CRCCP conducts in support of its goal to increase CRC screening rates. Dissemination of results will inform both funded and non-funded primary care clinics in implementing and sustaining EBIs.
- **Methods to be used to collect data:** Data will be collected using a one-time, web-based information collection instrument.
- **Respondent Universe:** Data will be collected from representatives of 393 health system clinics implementing the CRCCP on behalf of 15 awardees. One individual per health system clinic will complete the survey.
- **How data will be analyzed:** Data will be analyzed using STATA to calculate descriptive statistics. Qualitative responses will be analyzed to identify emerging themes across clinics.

Section A – Justification

1. Circumstances Making the Collection of Information Necessary

Background

This information collection is being conducted using OMB No. 0920-0879 “Information Collections to Advance State, Tribal, Local and Territorial Governmental Agency System Performance, Capacity, and Program Delivery” nicknamed the “CSTLTS Generic.” The respondent universe for this information collection aligns with that of the CSTLTS Generic. Data will be collected from a total of 393 respondents across participating health system clinics, including 278 Community Health Centers or Federally Qualified Health Centers; 3 health department clinics; 48 health systems or hospital owned clinics; 16 other primary care facilities; 41 private or physician owned clinics; and 7 tribal health clinics (see **Attachment A – List of CRCCP Clinics**). These 393 health system clinics are delegated to implement evidence-based interventions (EBIs) on behalf of 15 Colorectal Cancer Control Program (CRCCP) awardees (see **Attachment B – List of CRCCP Awardees**). Awardees include 15 State health departments (including the District of Columbia Department of Health). Respondents acting in their official capacities include one clinic representative per health system clinic. Every health system clinic is located within the geographic jurisdiction covered by the 15 CRCCP awardees.

Because CRCCP awardees are not health systems and lack the capacity to unilaterally implement the program among the large number of healthcare clinics, awardees rely on health system clinics to implement CRCCP EBIs to effectively reach the eligible patient population and achieve the primary program outcome of increased clinic-level CRC screening rates. In addition to EBI implementation, health system clinic staff measure and report progress towards achieving the primary program outcome and report data to the grantee for submission to CDC.

This information collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241). This information collection falls under the essential public health service(s) of

- 1. Monitoring health status to identify community health problems
- 2. Diagnosing and investigating health problems and health hazards in the community
- 3. Informing, educating, and empowering people about health issues
- 4. Mobilizing community partnerships to identify and solve health problems
- 5. Development of policies and plans that support individual and community health efforts
- 6. Enforcement of laws and regulations that protect health and ensure safety
- 7. Linking people to needed personal health services and assure the provision of health care when otherwise unavailable
- 8. Assuring a competent public health and personal health care workforce
- 9. Evaluating effectiveness, accessibility, and quality of personal and population-based health services
- 10. Research for new insights and innovative solutions to health problems ¹

¹In 2016, colorectal cancer (CRC) was the second highest cause of cancer-related incidence (37.4 per 100,000) and mortality (13.7 per 100,000) among cancers affecting both men and women in the United States (U.S.).² An estimated 52,286 people died from colorectal cancer in 2016.²

CRC screening reduces morbidity and mortality. The United States Preventive Services Task Force (USPSTF) currently recommends CRC screening among average-risk, asymptomatic adults ages 50-75.³ However, despite several tests proven effective at reducing CRC morbidity and mortality,³ nearly one third of adults ages 50-75 were not up-to-date with CRC screening recommendations in 2016.⁴ The National Colorectal Cancer Round Table (NCCRT) has set the ambitious target of having 80% of adults in every community up-to-date with CRC screening (<http://nccrt.org>).

In response to this public health need, the Centers for Disease Control and Prevention (CDC), Division of Cancer Prevention and Control (DCPC) funded the Colorectal Cancer Control Program in 2009 (DP09-903) to increase CRC screening rates in 29 U.S. States.⁵ In 2015, CDC funded the CRCCP for a new five-year period under DP15 -1502, *Organized Approaches to Increase Colorectal Cancer Screening*. This cooperative agreement funds 30 awardees, including 23 State health departments, including the District of Columbia, one Tribal

organization, and six universities to implement the CRCCP. Hereafter, any reference to the 'CRCCP' refers to DP15-1502.)

This newest iteration of the CRCCP utilizes a public health model to increase clinic-level CRC screening rates through health systems change activities. CRCCP awardees work with health system clinics to implement evidence-based interventions (EBIs) proven effective at increasing CRC screening rates and recommended by *The Community Guide* (<http://www.thecommunityguide.org>).⁶ EBIs are implemented within CRCCP health system clinics with CRCCP awardees providing fiscal, technical, and other supporting assistance. To assess effectiveness, the CRCCP measures clinic-level CRC screening rates. Awardees report a standardized clinic-level data record at baseline and annually thereafter for each clinic. This data collection has OMB approval (0920-1074). While CDC is able to measure clinic-level CRC screening rates using the existing clinic data collection, we lack important information about how the CRCCP is implemented within clinics, including factors that may contribute to or hinder EBI implementation, to better inform future implementation of the CRCCP within primary care settings.

The purpose of this data collection is to assess how individual CRCCP health system clinics implement the CRCCP, including EBIs. CDC will use these data to better describe implementation sites; understand EBI implementation (including the factors that contribute to or hinder EBI implementation); inform the development of CDC guidance, resource tools, and tailored technical assistance activities; and inform both funded and non-funded primary care clinics in implementing and sustaining EBIs.

Overview of the Information Collection System

Data will be collected from 393 CRCCP health system clinics implementing EBIs on behalf of 15 CRCCP awardees via a one-time web-based assessment allowing respondents to complete and submit their responses electronically (**see Attachment C – CDC Colorectal Cancer Control Clinic Survey-Word Version and Attachment D- CDC Colorectal Cancer Control Clinic Survey-Web Version**). The instrument will be used to gather information from one clinic representative per CRCCP health system clinic regarding how individual CRCCP health system clinics implement the program, including EBIs. Clinic representatives will be able to answer the assessment questions quickly and submit their responses to the University of Washington with ease. This method was chosen to reduce the overall burden on respondents. Respondents may stop taking the assessment and finish it at a later time.

The information collection instrument was pilot tested by nine health professionals. Feedback from this group was used to refine questions as needed, ensure accurate programming and skip patterns and establish the estimated time required to complete the information collection instrument.

Items of Information to be Collected

The web-based survey consists of 24 main questions of various types, including dichotomous (yes/no), multiple response, interval (rating scales), ordinal (Likert) and open-ended. The exact number of questions each respondent will receive will be dependent on branching logic. To reduce participant burden, branching logic and skip patterns have been designed so respondents will only see relevant questions. In addition, the web-based survey has been limited to one open-ended question to minimize burden on respondents. The instrument will collect data on the following:

- Policy, Leadership, and Quality Improvement
- Clinic Resources to Improve CRC Screening
- CRC Screening Practice Improvement Implementation and Support
- Sustainability of CRC Screening Practice Improvements
- Integration (*of CRC screening practice improvements*)
- Spill-Over Effects and Unintended Consequences of the CRC Screening Initiative
- Health Information Technology

2. Purpose and Use of the Information Collection

The purpose of this data collection is to assess how individual CRCCP health system clinics implement the CRCCP, including EBIs. CDC will use these data to better describe implementation sites; understand EBI implementation (including the factors that contribute to or hinder EBI implementation); inform the development of CDC guidance, resource tools, and tailored technical assistance activities; and inform both funded and non-funded primary care clinics in implementing and sustaining EBIs.

3. Use of Improved Information Technology and Burden Reduction

Data will be collected via a one-time web-based survey. This method was chosen to reduce the overall burden on respondents by allowing them to electronically type and submit their answers. The web-based survey was designed to collect the minimum information necessary for the purpose of this project (i.e., limited to no more than 24 main questions).

4. Efforts to Identify Duplication and Use of Similar Information

DCPC currently collects limited health system clinic level data to monitor and evaluate CRCCP outcomes (OMB #0920-1074). However, existing health system clinic level data collection instruments do not collect data on EBI implementation or measure how CRCCP implementation efforts have been integrated with other clinic activities and initiatives. Because the CRCCP represents a new public health model and is administered solely by DCPC, these data are not available in any publicly accessible resource database.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

This request is for a one-time data collection. There are no legal obstacles to reduce the burden. If no data are collected, CDC will be unable to:

- Learn how the CRCCP is implemented in individual health system clinic sites, including EBI implementation
- Learn how EBI implementation varies across CRCCP health system clinics
- Explore the extent to which EBIs have been integrated into routine clinic practices, which may support sustainability post-CRCCP

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

There are no special circumstances with this data collection package. This request fully complies with the regulation 5 CFR 1320.5 and will be voluntary.

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

This data collection is being conducted using the Generic Information Collection mechanism of the CSTLTS Generic Information Collection Service (CSTLTS Generic) – OMB No. 0920-0879. A 60-day Federal Register Notice was published in the Federal Register on April 27, 2017, Vol. 82, No. 80, pp 19371-19373. One non-substantive comment was received. CDC sent forward the standard CDC response.

CDC partners with professional STLT organizations, such as the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), and the National Association of Local Boards of Health (NALBOH) along with the National Center for Health Statistics (NCHS) to ensure that the collection requests under individual ICs are not in conflict with collections they have or will have in the field within the same timeframe.

9. Explanation of Any Payment or Gift to Respondents

CDC will not provide payments or gifts to respondents.

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

The Privacy Act does not apply to this data collection. Respondents from health system clinics will be speaking from their official roles. Business contact information (e.g., business email address) may be collected if the individual who initially receives the invitation to participate in the survey recommends another staff person within his/her clinic would be more appropriate to respond. Business contact information collected is publicly available and will be used solely for the purpose of identifying the most appropriate respondents. It will be stored separately from survey responses and destroyed after survey administration. All business contact information will be collected and stored securely using REDCap. For additional security, only research staff affiliated with the project will have access to the data in REDCap. In addition, access to the business contact information in REDCap will be limited only to those staff responsible for administering the survey to the appropriate respondents. Settings within REDCap will restrict download of any business contact information.

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

No information will be collected that are of personal or sensitive nature.

This data collection is not research involving human subjects.

12. Estimates of Annualized Burden Hours and Costs

The estimate for burden hours is based on a pilot test of the data collection instrument by 9 public health professionals. In the pilot test, the average time to complete the instrument including time for reviewing instructions, gathering needed information and completing the instrument, was approximately 20 minutes (range: 10-50). However, the majority of pilot testers (6 out of 9) completed the survey in 10-15 minutes, with the remaining pilot testers completing the survey in 20, 30, and 50 minutes, respectively. For the purposes of estimating burden hours, the average time needed to complete the survey (i.e., 20 minutes) is used.

The person expected to complete the survey at each clinic serves the role of clinic liaison for the CRCCP program, but may hold one of many job titles. Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) Bureau of Labor Statistics for occupational employment (http://www.bls.gov/oes/current/oes_nat.htm) for “healthcare practitioners and technical workers, all other” in two general settings: (1) outpatient care centers (to include community health centers and federally qualified health centers; health department clinics; health system or hospital-owned clinics; other primary care facilities; and tribal health clinics) and offices of physicians (to include private or physician-owned clinics). This job title and these settings were selected to encompass the range of positions and setting types the clinic liaison may hold. Based on DOL data, an average hourly wage of \$27.76 (outpatient care centers) is estimated for 352 respondents, and \$28.73 (offices of physicians) is

estimated for 41 respondents. To account for potential increases due to the COVID-19 response, the hourly wage rates have been doubled to \$55.52 and \$57.46 respectively to account for fringe benefits and overhead (<https://aspe.hhs.gov/pdf-report/guidelines-regulatory-impact-analysis>).

There will be a total of 393 respondents and 393 responses.

Table A-12: Estimated Annualized Burden Hours and Costs to Respondents

Data collection Instrument: Form Name	Type of Respondent	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
CDC Colorectal Cancer Control Program Clinic Survey	Health System Partner Representative (outpatient care centers)	352	1	20/60	117	\$55.52	\$6,496
	Health System Partner Representative (offices of physicians)	41	1	20/60	14	\$57.46	\$804
	TOTALS	393	1		131		\$7,300

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

There will be no direct costs to the respondents other than their time to participate in each data collection.

14. Annualized Cost to the Government

There are no equipment or overhead costs. The only cost to the federal government would be the salary of CDC staff and contractors to develop the web-based survey, collect data, perform data analysis, and disseminate findings. Contractors are being used to support the following tasks: (1) develop, pilot, and administer the web-based survey, (2) conduct analysis, and (3) report and disseminate findings to CDC and other stakeholders. The total estimated cost to the federal government is \$116,447. Table A-14 describes how this cost estimate was calculated.

Table A-14: Estimated Annualized Cost to the Federal Government

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Total Average Cost
Public Health Program Specialist (GS-13, Step 1): Support for the development of the instrument, pilot testing, and review and oversee OMB package preparation	80	\$50.66	\$4,053
General Health Scientist (GS-14, Step 1): Generalized support to develop the OMB package, feedback and guidance on web-based survey, data analysis, and collaboration for report preparation	40	\$59.86	\$2,394
Health Promotion Research Center (x2) – University of Washington: Develop, pilot, and administer web-based survey, conduct analysis, disseminate results to CDC and other relevant stakeholders			\$110,000
Estimated Total Cost of Information Collection			\$116,447

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

As resources and respondents may be impacted by the COVID-19 pandemic, we propose that data collection begin in September 2020. The web-based survey will be administered to 393 health system clinic representatives in clinics implementing EBIs on behalf of 15 CRCCP awardees. Respondents will have approximately 6 weeks to complete the web-based survey. Data will be cleaned and analyzed by University of Washington using appropriate statistical software (e.g., STATA, SPSS). Data will be analyzed by jurisdiction (state and tribal area) and clinic type (e.g., FQHC) and in aggregate. Findings will be used to describe implementation sites and understand EBI implementation across clinic sites. Information collection will inform the development of CDC guidance and resource tools, as well as tailored technical assistance activities, to support future CRCCP implementation with the goal of increasing CRC screening rates over time. Dissemination of results will inform both funded and non-funded primary care clinics in implementing and sustaining EBIs.

All information will be stored on secure, password protected servers accessible only to project team members. Respondents and clinics will not be identified in any publications or reports about the survey, nor will CDC have access to any individual identifiers. These data will also be linked to clinic data collected as part of other CRCCP activities. Data collected during the assessment will be presented only in aggregate form.

Project Time Schedule

- ✓ Design instrument (COMPLETE)
- ✓ Develop protocol, instructions, and analysis plan (COMPLETE)
- ✓ Pilot test instrument (COMPLETE)
- ✓ Prepare OMB package (COMPLETE)
- ✓ Submit OMB package (COMPLETE)
- OMB approval (TBD)
- Conduct data collection (Open 6 weeks)
- Code data, conduct quality control, and analyze data..... (8 weeks)
- Prepare summary report(s) (6 weeks)
- Disseminate results/reports (4 weeks)

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

We are requesting no exemption.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

LIST OF ATTACHMENTS – Section A

Note: Attachments are included as separate files as instructed.

- Attachment A: List of CRCCP Clinics
- Attachment B: List of CRCCP Awardees
- Attachment C: CDC Colorectal Cancer Control Clinic Survey-Word Version
- Attachment D: CDC Colorectal Cancer Control Clinic Survey-Web Version

REFERENCE LIST

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