Case Investigation of Cervical Cancer (CICC) Study

Supporting Statement – Section A

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- **Goal of the study:** To understand screening and care histories of women with invasive cervical cancer, which can be prevented by a vaccine and timely screening tests.

- **Intended use of the resulting data:** This study will provide data on the facilitators or barriers to cervical cancer screening and follow-up to develop interventions targeted to reach never or rarely screened women, and to understand missed opportunities for treatment of precancer.

- **Methods to be used to collect:** Self-administered mailed surveys and medical chart abstraction will be used to collect data on invasive cervical cancer cases identified by 3 state-based central cancer registries.

- **The subpopulation to be studied:** Women aged 21 and older who were diagnosed with invasive cervical cancer from January 2014 and December 2016 in Louisiana, Michigan, and New Jersey.

- **How data will be analyzed:** Descriptive statistics and logistic regressions to understand the facilitators and barriers to appropriate screening and follow-up for cervical cancer.

Section A – Justification

A.1. Circumstances Making the Collection of Information Necessary

The proposed project, "Case Investigation of Cervical Cancer (CICC) Study," is a new Information Collection Request (ICR) and OMB approval is requested for two years.

Background

Invasive cervical cancer occurs when cervical cancer spreads from the surface of the cervix to deeper cervical tissue or to other parts of the body. Cervical cancer in the United States is largely preventable because a vaccine to prevent human papillomavirus (HPV) infections and screening tests are available. Over 80% of cervical cancers are associated with HPV types that can be prevented with the HPV vaccine (Benard et al., 2014a). Timely cervical cancer screening and appropriate follow-up allow for detection and treatment of cervical precancers (Schiffman et al., 2013). Despite evidence that vaccination and screening save lives and that all or most cervical cancers can be avoided, each year in the U.S. more than 12,000 women are diagnosed with cervical cancer, and more than 4,000 die from the disease. When a woman develops cervical cancer, it represents a potential missed opportunity for vaccination, screening or appropriate follow-up.

A previous study has shown that half of the women who developed cervical cancer in the U.S. were not adequately screened (Leyden et al., 2005). A more recent study showed that there were still approximately 8,000,000 women in the U.S. who had not been screened for cervical cancer in the previous five years (Benard et al., 2014a). As such, cervical cancer incidence and death rates remain substantial, especially among populations with limited access to care (Freeman and Wingrove, 2005).

To reduce the cervical cancer burden, it is essential to understand the facilitators of or barriers to screening for women who are rarely or never screened. Previous case investigations in managed care environments have identified points of programmatic interventions (Leyden et al., 2005; Sung et al., 2000) and findings may not be the same for the general population, who would have access to a variety of health care settings.

In accordance with the CDC's mission to conduct, support, and promote efforts to prevent cancer and to increase early detection of cancer (see Section 301 of the Public Health Service Act [42 USC 241] **(Attachment 1)**, the Division of Cancer Prevention and Control is funding a retrospective study aimed to address this research gap and understand the facilitators and barriers of screening and care among women who are survivors of invasive cervical cancer. This study, also known as the Case Investigation of Cervical Cancer (CICC), will answer the following research questions: (1) Did women who were diagnosed with invasive cervical cancer get screened at any time during the five years prior to their cervical cancer diagnosis? (2) What were the facilitators or barriers to getting screened? (3) Did cervical cancer survivors get the recommended follow-up for an abnormal test in a timely manner? (4) What were the facilitators or barriers to getting follow-up for an abnormal test? (5) What were the women's patterns of seeking medical care (i.e. routine medical care or care for symptoms)?

To answer these questions, CDC will collect and analyze information from three sources, in collaboration with central cancer registries and a contract research organization.

1. Information about tumor characteristics, diagnosis, and cancer stage that is maintained by the registries.
2. Survey assessing facilitators and barriers to screening and follow-up for abnormal results.
3. Medical chart history of screening and treatment received in the 5 years prior to diagnosis with invasive cervical cancer.

A.2. Purpose and Use of the Information Collection

The purpose of this one-time data collection is to conduct a case investigation on women affiliated with three state cancer registries (i.e., New Jersey, Michigan, Louisiana) who were diagnosed with invasive cervical cancers to identify potential missed opportunities for proven public health interventions and determine the barriers and facilitators to screening and recommended follow-up of abnormal screening tests. This study will provide actionable information on how to reach underserved women who are never or rarely screened or who receive inadequate follow-up care. The proposed project will identify women recently diagnosed with invasive cervical cancer (2014-2016) through cancer registries in three states: Louisiana, Michigan, and New Jersey. Each registry

will enroll cancer survivors within that state who consent to participate in the study. Three types of data will be collected. (1) Existing cancer registry data will provide information on tumor characteristics, diagnosis, and stage of cancer. This will be used to describe the characteristics of the sample of survivors. (2) Participants will be asked to complete a questionnaire. The purpose of the survey is to identify self-reported barriers and facilitators to screening and care, and to examine recall of screening tests. (3) Participants will also be asked to provide consent for a medical chart abstraction. The purpose of the medical chart abstraction is to obtain detailed clinical information about all screening and treatment prior to diagnosis.

This 3-part data collection will enhance the data that is currently collected by the cancer registry with additional data from the perspective of the woman and the information from the medical chart abstraction on actual practice to help better understand the factors associated with why women continue to get a preventable disease. Together this information will identify opportunities for intervention to reach women and their providers to increase screening and appropriate follow-up care.

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

We use technological information where possible to reduce respondent burden.

(1) Information on tumor characteristics, diagnosis, and stage of cancer is already maintained in an electronic database by the cancer registries. Respondent burden is reduced by eliminating contacts with patients who are ineligible for the study and keeps the survey questions to a minimum.

(2) The same data collection instrument will be used by all cancer registries and the questions were adapted from surveys developed for studies addressing barriers to screening (Benard et al., 2014b). The purpose of the survey is to identify self-reported barriers and facilitators to screening and care. We also ask minimal information to examine recall of basic screening tests. The preferred method for completing the survey in English or Spanish would be self-administered by paper with follow-up phone calls (**Attachment 4a and 4b**). Previous research completed by the selected cancer registries found that the majority of cancer survivors have responded to mailed surveys. Respondents can also complete the self-administered surveys when it is most convenient for them. To maximize study response rates, a mixed-mode data collection method (i.e., self-administered mail-in survey plus telephone interview) is proposed. However, telephone interviewers will ask the same survey questions using the paper survey and phone script.

(3) In order to reduce the burden to participants, we propose to abstract their detailed clinical information about screening and treatment prior to diagnosis from their medical records, using electronic records where available.

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

Following consultation with medical care providers, researchers and a review of the literature, it was determined that while there have been studies conducted to evaluate barriers to screening and medical chart information in relation to cervical cancer prevention and diagnosis---the planned data collection efforts do not duplicate any other current or previous data collection efforts. Other studies have examined medical chart data of cervical cancer patients in managed care environments (Leyden et al., 2005; Sung et al., 2000), but no study has addressed this across different health care settings. Additionally, other studies have conducted surveys with women about barriers to screening (Benard et al., 2014b); however, no study has combined the patient self-reported answers with the medical chart verification among cervical cancer survivors.

A.5. Impact on Small Businesses or Other Small Entities

The consent process was designed to minimize burden to all physicians contacted, while meeting cancer registry and human subject requirements. Cancer registries staff will identify potential participants who were diagnosed with cervical cancer and mail letters to the physicians on record who made the diagnosis (**Attachment 3**). The letter will inform them about the study and indicate the name(s) and date(s) of birth of the patient(s) selected for recruitment. The letter will explain that physicians have two weeks from receipt of the letter to give permission for patient contact or decline. Permission is presumed ("passive permission") if physicians do not respond, and physicians only need to take action if recruitment of their patient(s) would be inappropriate or inadvisable. Contact information for each registry will be clearly labeled in the letter. This procedure for physician permission is recommended and approved by the selected cancer registries in this study to minimize physician burden.

After participants have been contacted, agree to participate in the study, and provide medical information for services five years prior to and including the date of the cancer diagnosis, providers who are identified will be contacted about obtaining medical records for the specific event or

service (i.e. Pap test or other procedure for screening or follow-up associated with any cervical abnormalities). It is estimated that the provider would take less than 5 minutes per case to gather and send the information to the cancer registry, which will be abstracted by trained medical abstractors at the cancer registries. The burden on the provider is estimated in Section A12.

A.6. Consequences of Collecting the Information Less Frequently

This survey will be administered one time. A single telephone interview will be offered as an alternative for those who do not respond to the survey. Without this data there would be no information to inform interventions targeted at understanding the facilitators and barriers to reach never or rarely screened women, or women who do not obtain appropriate precancer follow up and treatment, so that cervical cancer burden can be reduced. The one time medical chart abstraction is necessary to help determine the type of care that was provided to each woman in the five years prior to her diagnosis. This information will be used to verify and supplement the responses that are given by participants in the survey.

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

There are no special circumstances with this information collection package. This request fully complies with the regulation 5 CFR 1320.5.

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

A. Federal Register Notice

A 60-day Federal Register Notice was published in the Federal Register on March 24, 2016, Vol. 81, No. 57, pp. 15724-5 (**Attachment 2**). No public comments were received.

B. Efforts to Consult Outside the Agency

The study protocol, data collection plan, identification of state cancer registries, data collection instrument, and analysis plan have been discussed with individuals inside and outside the study team. The project has benefited from input from individuals with varying expertise. Several consultants outside the core study team are listed below.

Other Consultants					
Name	**Degree**	**Position**	**Institution**	**Phone**	**E-mail**
Glenn Copeland	MBA	Director	Michigan Cancer Surveillance System	(517) 335-8677	copelandg@michigan.gov
Wu Xiang-Cheng	MD, PhD	Director	Louisiana Tumor Registry	(504) 568-5763	xwu@lsuhsc.edu
Eduardo Franco	PhD, MPH	Professor	Montreal Cancer Center	(514) 398-6032	eduardo.franco@mcgill.ca
Warner Huh	MD	Gynecologic Oncologist	University of Birmingham AL	(205) 934-9999	whuh@uabmc.edu
Antoinette Stroup	PhD	Director	New Jersey State Cancer Registry	(732) 235-7422	ams722@sph.rutgers.edu
Sarah Temkin	MD	Gynecologic Oncologist	Johns Hopkins University & National Cancer Institute	(240) 2765865	temkinsm@mail.nih.gov

A.9. Explanation of Any Payment or Gift to Respondents

Cervical cancer survivors may feel stigmatized since cervical cancer is a gynecologic cancer or because it is associated with a sexually-transmitted virus. Therefore, we will offer an incentive in order to encourage the participation of this hard to reach population. When the materials (surveys, medical release form and healthcare source form) are received at the cancer registry, a $25 incentive will be mailed to the participant after receipt of the completed survey to CDC. This incentive is meant to encourage the completion of the study materials and to acknowledge the time and effort involved in study participation. A systematic review of multiple studies has shown that larger incentives amounts (when compared to no incentive or a smaller incentive amount) significantly increases survey response rates. (Singer et al., 2012) The cover letter (**Attachment 5a and 5b)** and the Research Participant Information Sheet (**Attachment 6a and 6b**) state that participation in the study is voluntary.

The IMPACT (Improving Patient Access to Quality Cancer Treatment) study is a pilot project examining barriers in access to care, treatment, and outcomes among cancer patients in New Jersey. Compared to respondents for breast, colorectal, and prostate surveys, significantly lower response rates for cervical cancer surveys was observed during the initial

recruitment period. The investigators changed the recruitment protocol to increase the incentive for completing the cervical cancer surveys from $15 to $25 and doubled their response rates (Herman et al, 2017) Many cervical cancer survivors in the previous study were socioeconomically disadvantaged and younger than survivors of other cancers (mean age is 40 years old). Participants will also be asked to complete a Medical Release and Healthcare Source forms (**Attachment 7a and 7b**) that lists the contact information for locations where they received health care for the five years prior to diagnosis.

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

CDC has engaged a contractor, Battelle, to assist with information collection and analysis. Relevant contract documentation was reviewed by CDC's Office of the Chief Information Security Officer (OCISO) for IT security. OCISO determined that the Privacy Act does not apply. Although state cancer registries and health care providers maintain personally identifiable information (PII) in their existing records systems, PII will not be disclosed to CDC. The data set used for analysis will be organized by a unique patient-level ID assigned by the contractor.

Data collection will be completed by three state cancer registries. These central, population-based registries are mandated by state law to maintain personally identifiable information for all persons who were diagnosed with cancer in their state. No additional personal identifiers will be collected and data collection does not involve sensitive information. All personal identifier information will remain at the cancer registry and will not be shared with Battelle or CDC. The information will be maintained in a secure manner. Each cancer registry has standard protocols in place for the protection of personal identifier information that is part of their state mandate. Data that is shared with Battelle and CDC will contain only the de-identified, randomized study ID.

Consent and advisement language for study participants can be found in **Attachments 5a and 5b** (cover letter), Attachments 6a and 6b (research participant information sheet), **Attachments 7a and 7b** (medical release and healthcare source forms), and **Attachments 8a and 8b** (phone follow-up script).

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

IRB Approval

This study was approved by Battelle's and all cancer registries (LA, MI, NJ) IRB (**Attachment 10**).

Sensitive Questions

This survey collects information on procedures conducted before a diagnosis of cervical cancer. Potentially sensitive data elements include race/ethnicity, insurance status, income, information about their screening and follow-up procedures as well as previous chronic conditions. These data elements may be sensitive to the respondents and have been limited to the minimum required to adequately address the objectives of this study. Finally, participants may experience some psychological stress as they are reminded of past or present health issues while answering the questions. However, the survey is completely voluntary and respondents do not have to answer questions that make them feel uncomfortable.

A.12. Estimates of Annualized Burden Hours and Costs

Data will be collected from three sources. Tables 1 & 2 provide the annualized burden estimates by type of respondent based on two years of data collection.

(1) Data maintained by cancer registries will provide information on tumor characteristics, diagnosis, and stage of cancer and will be used to identify the eligible sample. These data are already maintained by the cancer registries as part of their state mandate to provide cancer surveillance. Burden is not assessed for the registry's and the contractor's participation in patient recruitment because these activities are reflected as study costs.

(2) Based on preliminary data provided by the state cancer registries, we expect to have 836 eligible cervical cancer survivors per year over two years. On an annual basis, we anticipate collecting completed surveys (**Attachments 4a and 4b**) from 418 cancer survivors, a 50% response rate. The estimated burden per response is 15 minutes. The estimate for burden hours is based on a pilot test of the data collection instrument with nine cervical cancer survivors. In the pilot test, the average time to complete the survey was approximately 15 minutes, including time for reviewing instructions. The questionnaire can be completed in English or Spanish, using a mail-in format.

(3) Burden for chart abstraction is based on two sources: (a) cancer survivors, and (b) office assistants at healthcare locations.

(3a) Approximately 80% of survey respondents (n=334) will also complete the Medical Release and Healthcare Source Forms (**Attachments 7a and 7b**). The estimated burden per response is 5 minutes.

(3b) On average, each patient is expected to identify 3 medical providers (range of 1-5). CDC's contractor will conduct a review of each chart authorized by one of the study participants (334 patients x 3 chart reviews per patient = 1002 chart reviews; see **Attachment 9**). Burden is not assessed for medical chart abstraction, per se, since the contractor's effort is included as a study cost. However, the medical chart abstraction process will require support from an office assistant employed by each health care office. Burden is assessed for the office assistant's support. The estimated burden is 5 minutes for each chart.

The total annual estimated burden for data collection is 217 hours (see **Table 1**).

Table 1: Estimated Annualized Burden Hours*

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Invasive cervical cancer survivors	Case Investigation of Cervical Cancer Study Survey	418	1	15/60	105
	Medical Release and Healthcare Source Forms	334	1	5/60	28
Health care office assistant	Support for medical record abstraction	3 x 334 = 1002**	1	5/60	84
				Total	217

*Annualized over 2 years.

**It is anticipated the number of providers a woman would have seen in the prior 5 years will range from 1 to 5; we selected the average of 3 providers per woman for this table.

Type of Respondent	No. of Respondents by Form	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Invasive cervical cancer survivors	418 (Survey) 334 (Medical Release & Healthcare Source Forms)	1 1	15 / 60 5/60	105 28	$23	$2,415 $644
Health care office assistant	3 x 334 = 1002**	1	5 / 60	84	$23	$1,932
					Total	**$4,991**

The estimated cost of the time devoted to this information collection by respondents is $4,991 as summarized in Table 2. To calculate this cost, we used the mean hourly wage of $23, which represents the Department of Labor estimated mean for state, local, and private industry earnings (U.S. Bureau of Labor Statistics, 2015). There are no direct costs to respondents associated with this information collection.

Table 2. Estimated Response Burden Table (Annualized Wages)*

*Annualized over 2 years

**It is anticipated the number of providers a woman would have seen in the prior 5 years will range from 1 to 5; we selected the average of 3 providers per woman for this table.

A.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 complete the survey.

A.14. Annualized Cost to the Government

There are no equipment or overhead costs. The only cost to the federal government will be the salary of CDC staff and funding for the contractor, Battelle, to support the development of the study design, data collection, and associated tasks.

Table 3 presents the costs to the CDC. These include the collaboration with study team including state cancer registries, review of survey questions, review of chart abstraction form, the research plan and analysis plan by CDC staff. CDC staff will also discuss analytic

approach, review initial findings, and result dissemination reports. Three senior level FTEs will conduct all related activities.

Table 4 shows the contractor costs associated with these data collection forms. These costs include contractor's efforts to work with CDC to develop the study methodology, survey, and chart abstraction tool, to prepare and obtain IRB approval, to select cancer registries and establish subcontracts, to oversee data collection, to perform quality control checks and to prepare and deliver data to CDC. The Battelle contract also includes the costs associated with subcontracts with cancer registries to identify and recruit study population, to collect survey and chart review data, to perform quality control checks and to prepare and deliver data and documentation to Battelle.

The support contract includes activities that will be conducted over 3 years. The total 3-year contract costs have been annualized over the requested 2-year period of OMB approval. However, some project-related activities (and costs) will actually occur before the OMB approval period (eg, project planning), or after the OMB approval period (eg, data analysis and report writing).

Table 3. Costs to the Federal Government: CDC*

Task	Total Hours per Staff	Number of Staff	Total Hours	Total Cost	Cost Description
Review survey questions, chart abstraction, research and sample analysis plans	**7**	**3**	**21**	**$1054.83**	GS-13 staff:14 hrs x 2x $47.36 [1] GS-14 staff:7 hrs x $55.97[2]
Discuss analytic approach, review findings and dissemination reports	**6.65**	**3**	**19.95**	**$1002.09**	GS-13staff: 13.3 hrs x 2 x $47.36[2] GS-14 staff: 6.65hrs x$55.97[3]
Total Costs	**13.65**	**3**	**40.95**	**$2056.92**	

[1]*Total cost annualized over 2 years.
Used the Federal Pay Table for Atlanta and used Grade 13, step 5 salary amounts effective January 2015.
[2] Used the Federal Pay Table for Atlanta and used Grade 14, step 5 salary amounts effective January 2015.

Table 4. Costs to the Federal Government: Contractor*

Agency	Task	Total Cost Amount
Contractor	Development methodology, survey, and chart abstraction tool; select cancer registries; data collection; delivery of data and documentation	$432,899
Contractor	**TOTAL**	**$432,899**

*Annualized over 2 years

A.15. Explanation for Program Changes or Adjustments

This is a new data collection.

A.16. Plans for Tabulation and Publication and Project Timeline

16.1 Time Schedule

OMB approval is requested for two years. All cervical cancer cases beginning January 2014 to December 2016 will be invited to the study. The timeline for data collection and reporting is included in Table 5.

Table 5: Project Timeline

Data Collection Activity	Timeline
Identify study participants	January - July 2017
Contact provider associated with diagnosis for each participant	January - July 2017
Update Contact Information	January - July 2017
First mailing with survey instructions and incentive (passive consent)	January - July 2017
Phone follow-up	January - October 2017
Medical chart abstraction	April 2017 - March 2018
Cancer Registries deliver final data and documentation to Battelle	June 2018
Battelle delivers final data and documentation to CDC	September 2018

16.2 Publication Plan

The results of this data collection will be presented as PowerPoint presentations, research posters, one-page summaries, and peer-reviewed manuscripts. Also, Battelle will prepare and submit a final report for CDC review. The report will include a brief summary of activities performed during the

project period, including interpretations and commentary on the methods and results of the analyses.

16.3 Tabulation Plan

Battelle will prepare the draft analyses, tables, and figures for scientific articles and study report that address the study research questions. Results will present descriptive statistics and logistic regressions to understand the factors associated with guideline consistent screening and follow-up care based on variables collected in the survey and chart abstraction. These analyses will help identify opportunities for intervention to reach women and their providers to increase screening and appropriate follow-up care. As a result of the sampling frame employed in this collection (see supporting statement Part B), which collects data from cancer survivors in three state cancer registries, outcomes may not be representative of the entire population of women diagnosed with cervical cancer in the United States and are thus not intended to be generalized to broader populations. Any limitations posed by the sampling methodology and frame employed in this study with regard to the non-generalizability of the data to broader populations will be clearly described in any presentations, publications, or communications associated with this collection.

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

We are requesting no exemption.

A.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.

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