

Information Collection Request

New

Understanding the Needs of Ovarian Cancer Survivors

Supporting Statement: Part A

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LIST OF ATTACHMENTS

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Attachment 2 – Attachment 2– 60-Day FRN

Attachment 3a – Mail-in Questionnaire

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Attachment 4b – Mailed Frequently Asked Question Insert for State Cancer Registry Recruitment

Attachment 4c –Mailed Initial Questionnaire Reminder for State Cancer Registry Recruitment

Attachment 4d –Mailed Final Questionnaire Reminder for State Cancer Registry Recruitment

Attachment 5- Web-based Frequently Asked Question Insert for State Cancer Registry

Attachment 6a – NORC IRB Approval Letter

Attachment 6b – CDC IRB Approval Letter

- **Goal of the study:** To further the understanding of the experiences and needs of ovarian cancer survivors.
- **Intended use of the resulting data:** Results will add to the existing knowledge base to benefit future public health programs and interventions to improve the health of ovarian cancer survivors.
- **Methods to be used to collect:** A web-based questionnaire or self-administered mail questionnaire will be administered to eligible respondents recruited via state cancer registries.
- **The subpopulation to be studied:** 1,500 ovarian cancer survivors, consisting of 500 interviews in each of the following categories: Hispanic, Non-Hispanic African American, Other (including Non-Hispanic White).
- **How data will be analyzed:** Statistical analysis of quantitative questionnaire data and operational data.

SECTION A - JUSTIFICATION

A.1. Circumstances Making the Collection of Information Necessary

The proposed project, “Understanding the Needs of Ovarian Cancer Survivors (OCS),” is a new Information Collection Request (ICR) and OMB approval is requested for one year. The Centers for Disease Control and Prevention (CDC) is requesting Office of Management and Budget (OMB) approval to conduct a study to collect information from ovarian cancer survivors, a group whose needs are unique compared with other cancer survivor groups due to a variety of factors, including a lack of screening options, typical late stage diagnosis, and lower survival rates. CDC is authorized to conduct this information collection by section 301 of the Public Health Service Act (**Attachment 1**). This project will gather information on the needs of ovarian cancer survivors in order to help public health programs develop and implement interventions aimed at improving survivor health.

Background

With over 20,000 women diagnosed each year, ovarian cancer is the ninth most common cancer and fifth leading cause of death among women in the United States. Without a recommended screening test, ovarian cancer is often diagnosed at a late stage, resulting in low five-year survival rates (Danforth, Im, & Whitlock, 2012). While previous studies identified some of the needs of ovarian cancer survivors, particularly related to physical complications and side effects, additional research is needed to understand the psychosocial challenges and needs of survivors to inform future public health interventions.

Ovarian cancer survivors include women who are newly diagnosed, those undergoing treatment, and those in remission (National Academies of Sciences, Engineering, and Medicine, 2016). A March 2016 report released by the National Academies of Sciences, Engineering, and Medicine identified key priorities for researchers. This report, *Ovarian Cancers: Evolving Paradigms in Research and Care*, highlighted the need for research into the needs of ovarian cancer survivors throughout the entire course of the disease.

Following diagnosis and treatment, cancer survivors can experience disabilities, functional loss, and morbidities that influence many aspects of daily living (Yabroff et al., 2007; Silver et al., 2015). Because of the consequences of their disease and treatment, survivors are more likely to experience unemployment or reduced employment, as well as higher medical costs (Torp et al., 2017; Fuerstein et al., 2010; de Boer et al., 2009; Ekweume et al., 2014). Because a return to work is seen by cancer survivors as a return to normal life and by society as an economic benefit, identifying factors that predict employment assume great importance given the increasing numbers of cancer survivors (de Boer et al., 2009). These outcomes highlight important unmet needs of cancer survivors such as reducing disability and maximizing independence and quality of life (Stout et al., 2016). The results from this questionnaire will identify key areas of unmet needs related to employment and financial stress for ovarian cancer survivors. This in turn will support the ongoing efforts to integrate rehabilitative services into optimal cancer care and to develop workplace accommodations that enable survivors to return to work (Stout et al., 2016; de Boer 2008).

Symptoms of ovarian cancer can often be mistaken for other conditions, which can lead to a delay in the diagnosis of ovarian cancer and subsequent lower survival. Additionally, because symptoms of ovarian cancer are often nonspecific, women initially seek medical services from primary care providers and gynecologists rather than a cancer specialist (such as a gynecologic oncologist) (Wynn et al, 2007; Ryerson et al. 2007). Referral to an oncology specialist then becomes an important step for optimal diagnosis and treatment. Identifying which providers ultimately diagnose their cancer can be used to

inform improved diagnosis and treatment of ovarian cancer (National Academies of Sciences, Engineering, and Medicine, 2016).

Additionally, cancer survivors who have other chronic diseases, experience more limitations in daily functions, lower quality of life, and higher levels of disease burden overall. However, we know little about which chronic diseases and comorbidities represent the highest burden for ovarian cancer survivors or how these survivors manage their comorbidities.

In order to address these research gaps and supplement current knowledge of the ongoing needs of survivors, including how to implement programs and interventions to improve their health, CDC is seeking to better understand the experiences and needs of ovarian cancer survivors. The goal of this project is assess the health, treatment, and health care access of ovarian cancer survivors to more effectively develop interventions targeted to this population. To achieve this goal, CDC has designed a questionnaire-based research study with four key aims:

1. Describe and assess the physical and mental health of ovarian cancer survivors;
2. Understand the medical and non-medical interventions ovarian cancer survivors may use to manage their condition, including late and long-term effects;
3. Explore barriers and facilitators in accessing and receiving appropriate diagnostic care, cancer treatment, and follow-up care;
4. Assess access to and use of cancer survivorship programs that address the varying needs (psychological, medical, and informational) of ovarian cancer survivors.

A.2. Purpose and Use of the Information Collection

The purpose of this one-time data collection is to better understand and describe the needs and experiences of ovarian cancer survivors in order to develop more effective interventions targeted to this population. To do this, the project will survey ovarian cancer survivors on their experiences throughout their diagnosis and treatment (**Attachment 3a-b**). Survivors will be recruited via state cancer registries. The project may also reach out to national cancer organizations for recruitment, such as Facing Our Risk of Cancer Empowered (FORCE) or state-specific cancer groups.

Overview of the data collection procedures

State cancer registry recruitment and data collection

NORC will work with CDC to identify states to assist with this study. The states will be selected based on the accessibility of the data from their state cancer registry and the states own availability to provide assistance for data collection. NORC will reach out to the selected states to provide an overview of the study, discuss logistics, and gauge interest in assisting with recruitment efforts. NORC will work with those states who are interested and willing to identify eligible women to contact for participation.

Data collection will involve a series of mailings and nonresponse follow-up activities. The methods proposed are adapted from those outlined in Dillman's Tailored Design Method and considered best practices for multi-mode surveys (Dillman, Smyth, & Christian, 2014). All selected sample members from the state cancer registries will be mailed an initial invitation with a web address and unique login (**Attachment 4a**). The initial mailing will also contain a frequently asked questions (FAQ) document to provide additional information on the study itself (**Attachment 4b**). A web-based version of the FAQ also be available via a link from the web-based questionnaire (**Attachment 5**). All questionnaires will

include a study ID to track responses.

NORC will focus its initial contact attempts on encouraging respondents to complete the questionnaire online (**Attachment 3b**). However, approximately one month after the invitation mailing, NORC will begin implementation of a mail questionnaire option. Eligible women who did not complete the questionnaire during the first month will be mailed a personalized self-administered questionnaire packet. Each packet will include a questionnaire (**Attachment 3a**), a cover letter addressed to the respondent (**Attachment 4c**), and a business reply envelope. Seven weeks after the initial questionnaire mailing, NORC will send a second hardcopy of the questionnaire (**Attachment 3a**) to all non-responders with another personalized cover letter (**Attachment 4d**). Respondents who complete the hardcopy questionnaire will be sent the \$10 Amazon gift code when their questionnaire has been received.

Study Purpose

The project will evaluate the needs of ovarian cancer survivors during their disease trajectory. Specifically this study seeks to: 1) describe the physical and mental health of ovarian cancer survivors; 2) understand the medical and non-medical interventions ovarian cancer survivors may use to manage their condition, including late and long-term effects; 3) explore barriers and facilitators in accessing and receiving appropriate diagnostic care, cancer treatment, and follow-up care; and 4) describe access to and utilization of cancer survivorship programs that address the psychological, medical, informational, needs of ovarian cancer survivors. To achieve the goals of the questionnaire, CDC will develop a questionnaire that addresses these aims.

Items of information to be collected

The instrument solicits information about ovarian cancer diagnosis, type of medical services or treatment received, satisfaction with medical care, and medications taken. The questionnaire also asks about physical or psychological symptoms or side effects of ovarian cancer diagnosis and treatment as well as medical system or family support available to cancer survivors. Experiences with employment, health insurance coverage and health care access, and the financial impact of cancer are also covered (**Attachments 3a-3b**). To minimize burden, there are no questions that require only open-ended or narrative responses. However, there are a few questions with space to provide narrative responses only if the respondent wants to provide additional information or wants to provide a response outside of the response set.

Data collected from this project will add to the existing ovarian cancer survivor knowledge base to the benefit of future programs and interventions. The data collection instrument for this submission is included in this submission as **Attachment3a-3b**.

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

The questionnaire will be offered through a multi-mode approach using both computer-assisted web interviewing (CAWI) and a mailed questionnaire. Both modes of questionnaire administration will include skip logic patterns to reduce overall respondent burden. Offering women the opportunity to complete the questionnaire over the web or by mail reduces respondent burden because it allows the respondent to respond in a way that is most convenient for her.

The web-based questionnaire will be programmed in Voxco, a computer aided interviewing (CAI) system that can administer the web questionnaire with minimal user-errors such as missing data or incorrect skip patterns. Use of a web questionnaire will also increase the convenience of completing the questionnaire

for participants by allowing multiple methods of completion. Transfer of data collected electronically will eliminate the need for data entry.

The Voxco system produces fully responsive, 508-compliant web pages capable of being comfortably viewed on a PC or Mac, tablet, or smartphone. It can be viewed through most modern browsers (including Internet Explorer, Chrome, Firefox, and Safari). Each questionnaire is programmed to create visual consistency across questions, examine potential user proficiency and technology limitations, and accommodate multiple technology platforms. Questionnaires are formatted to maximize readability, including appropriate question spacing, pixilation, font type and size, and properly programmed branching patterns. Questionnaire formatting considerations also include the use of color, diagrams, and pictures to enhance respondent comprehension. Screenshots of the formatted questionnaire can be found in **Attachment 3b**.

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

Based on a division- and federal-wide review, CDC has determined that the planned data collection efforts do not duplicate any other current or previous data collection efforts related to ovarian cancer survivors. A recent NASEM report on ovarian cancer indicated a need for this research and also informed the questionnaire content (National Academies of Sciences, Engineering, and Medicine, 2016). Additionally, the project team consulted with the Ovarian Cancer Research Fund Alliance (OCRFA) to ensure the content was relevant and there were not similar efforts already in place.

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

This data collection effort does not involve any small businesses or other small entities.

A.6. Consequences of Collecting the Information Less Frequently

This is a one-time data collection. A one-time largescale, comprehensive questionnaire describing the medical, financial, and psychosocial needs of ovarian cancer survivors has not been conducted previously and is needed because the needs of ovarian cancer survivors are different from other cancer survivors, leaving a gap in the existing knowledge base. Therefore, if data are not collected, an opportunity to assess the needs of this population and inform future public health efforts will have been missed. Only key questions and topics are included in the questionnaire in order to respect respondent burden, by keeping the questionnaire administration time as short as possible.

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

In accordance with 5 CFR 1320.8(d), [7/5/2019], a 60-day notice for public comment was published in the *Federal Register*. (Volume 84, Number 129, pages 32187-32189). No public comments were received.

B. Efforts to Consult Outside the Agency

The study protocol, data collection plan, data collection instrument, and analysis plan have been discussed with individuals inside and outside the study team. The project team consulted with leading ovarian cancer support organization, such as OCRFA to ensure the content was relevant and not duplicated elsewhere. In addition, the project has benefited from input from Dr. Lila Rutten at the Mayo Clinic and Dr. Helen Parsons at the University of Minnesota for this project.

Dr. Rutten was consulted on the development of the questionnaire including content, formatting, and organization. Dr. Parsons' experience and expertise with cancer registries was used in identifying points of contact within various state cancer registries as well as identifying any barriers to participation.

Contact information for both is listed below.

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

We will provide all respondents who complete the questionnaire with a \$10 Amazon gift code to encourage their participation and convey appreciation for contributing to this important study. Numerous studies have shown that tokens of appreciation can significantly increase response rates and the use of modest tokens of appreciation is expected to enhance questionnaire response rates without biasing responses (Abreru & Winters, 1999; Shettle & Mooney, 1999; Göritz, 2006).

In his memorandum for the President's management council dated January 20, 2006, the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget wrote, "Incentives are most appropriately used in Federal statistical surveys with hard-to-find populations or respondents whose failure to participate would jeopardize the quality of the survey data (e.g., in panel surveys experiencing high attrition), or in studies that impose exceptional burden on respondents, such as those asking highly sensitive questions..." Offering tokens of appreciation is considered necessary to recruit minorities and historically underrepresented groups in to research studies. This project aims to recruit a diverse sample in terms of race/ethnicity while also targeting hard-to-reach populations (ovarian cancer survivors); given these goals, this study will especially benefit from tokens of appreciation. In addition, the questionnaires ask about sensitive topics that justify the use of incentives. Topics such as family history of cancer, personal history of cancer, genetic testing, and utilization of medical services are generally found to be sensitive in nature for respondents.

By using an Amazon gift code, the code will be automatically assigned upon completion of the questionnaire when completing over the web. This code will be displayed on the screen and can also be emailed to the respondent if she chooses. Respondents completing the questionnaire will receive the token of appreciation regardless of whether they skip any questions. Respondents who mail in a completed questionnaire will also receive the incentive, either via an email from the project with the gift code or via an incentive letter with the assigned gift code printed inside.

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

CDC's Privacy Office has reviewed this submission and determined that the Privacy Act does not apply. CDC is contracting with NORC at the University of Chicago to collect and analyze the questionnaire data. NORC will have access to personally identifiable information, which is necessary in order to contact women for participation. State cancer registries will provide NORC with a dataset that contains name, basic demographics, and contact information for women who meet the study inclusion criteria and have agreed to be contacted. NORC will assign these women a case identification number that will be stored within the dataset. The questionnaire instrument is designed to minimize the collection of personal identifier information and contain only information necessary to conduct the study.

To maintain the confidentiality of the participants, any data files shared with CDC will be stripped of any personally identifiable information. At the conclusion of the study, the final dataset will be delivered to CDC at the end of the study in de-identified format. Additionally, data files will be delivered using a secure file transfer protocol (SFTP) site. When reporting data from this study, only aggregate data will be used to report study results.

Key safeguards have been put in place to assure respondents that their responses will be treated in a secure and private manner. Prior to the start of the questionnaire, the prospective respondent will be shown a landing page with informed consent text and eligibility screener (**Attachment 3c**). The informed consent language is written in simple language (grade 7.5 Flesch-Kincaid reading level). Consent includes a brief description of the study and contains the following key points:

- Purpose of the study
- Study procedures
- Question topics
- Estimated time required to participate
- Disclosure of incentive
- Potential risks and benefits
- Statement that participation is voluntary
- Telephone numbers of persons they may contact with further questions
- Authority for the data collection

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

IRB Approval

NORC submitted the initial study protocol for approval to conduct cognitive interviews; the cognitive interview protocol was approved in July 2018. An amendment for the main data collection effort was submitted in December 2018; the main data collection was approved by NORC's IRB (**Attachment 6a**) in 2/23/2019. The IRB protocol is currently under review by CDC's IRB (**Attachment 6b**). NORC will also work with the selected state registries on any IRB approvals for this study.

Sensitive Questions

The proposed data collection includes sensitive information related to the respondent's personal and family history of cancer, and their use of medical services, medication, and providers during or after cancer treatment. In addition, questions concerning education level or income may be viewed as sensitive by a portion of respondents. We will also be asking participants about their race and ethnicity. Race as

well as income and medical care access will be important control variables in multivariate analyses. The sensitivity of the data to be collected necessitates the privacy protection.

To minimize psychological distress, participants will be informed that they may skip over any questions that they do not want to answer for any reason and that they may stop participating at any time. Participants will be given the toll-free telephone numbers of the project COR at CDC to answer questions pertaining to the study or their rights as a research volunteer. The web and print version of the questionnaire and are entirely self-administered and maximize respondent privacy without the need to verbalize responses.

A.12. Estimates of Annualized Burden Hours and Costs

The estimate of burden for the instruments is based on cognitive interviews with nine respondents. A variety of instruments and platforms will be used to collect information from respondents. The annual burden hours requested (1,254) are based on the number of completed responses we expect to collect over the requested period for this clearance.

The questionnaire, which will only be administered once, is estimated at no longer than 50 minutes per respondent. We anticipate that we will need to draw a sample of 4,800 individuals from the state cancer registries in order to meet our target (n=1,200) for the registry sample.

Tables 1 and 2 display the annualized estimated hour and cost estimates for data collection. The annualized wages are based on data from the United States Department of Labor, Bureau of Labor Statistics (2015) for state, local, and private industry earning and assumes an average hourly wage rate for respondents who work an estimated 40-hour work week and usual hourly earnings of \$23.23.

Table 1. Estimated annualized burden hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs)	Total Burden (in hrs)
Ovarian cancer survivors—state cancer registries	Mail in or web-based questionnaire [Attachment 3a]	1,200	1	50/60	1000
TOTAL		1,200			1000

Table 2. Estimated annualized burden costs

Type of Respondents	Form Name	No. of Respondents	Total Burden (in hrs.)	Hourly Wage Rate	Total Cost
Ovarian cancer survivors—state cancer registries	Mail in or web-based questionnaire [Attachment 3a]	1,200	1000	\$23.23	\$23,230
TOTAL		1,200	1000		\$23,230

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 questionnaire.

A.14. Annualized Cost to the Government

The estimated average annual cost to the Federal government for the proposed data collection activities is \$308,752.46. This figure encompasses the salaries of federal employees to oversee the data collection and contractor fees for questionnaire development, recruitment, and questionnaire administration:

Table A14-A. Estimated Annualized Cost to the Government

Estimated Annualized Cost to the Government	
Cost Category	Estimated Annualized Cost
Federal employee costs	\$25,706.43
5% FTE of 1 GS-14 @ \$140,765/yr = \$7,038.50	
5% FTE of 2 GS-13 @ \$106,903/yr = \$10,690.30	
5% FTE of 1 O-4 @ \$102,953/year = \$5,147.63	
Fellow cost	
5% FTE of 1 GS-9 @ 56,680/year= \$2830.00	
Contractual costs for questionnaire development, recruitment, and questionnaire administration. (\$849,138.10/3 years)	\$283,046.03
Total	\$308,752.46

A.15. Explanation for Program Changes or Adjustments

This is a new information collection request (ICR).

A.16. Plans for Tabulation and Publication and Project Time Schedule

Project Time Schedule

Table A16-1 presents the estimated timeline for conducting data collection following receipt of OMB clearance. Information will be collected over approximately a 6 month time period and will not exceed the approved expiration date.

Table A16-A: Estimated schedule for questionnaire recruitment, administration, data analysis, and publication.

Activity	Time Schedule
Questionnaire recruitment	July-November 2021
Questionnaire administration	July-November 2021
Analysis of questionnaire results (topline reports)	November 2021-February 2022
Report Writing/Recommendations to CDC based on Findings	February-September 2022

Questionnaire findings will inform comprehensive cancer control planning efforts and provide guidance on efforts to support ovarian cancer survivors. Additionally, findings will be disseminated through presentations and/or posters at meetings and publications in peer-reviewed journals. All abstracts, poster presentations, and manuscripts will undergo CDC clearance review prior to submission to conferences or journals. In addition to standard peer-reviewed publications and conference presentation, reports of results for the public will be developed and posted on the CDC website. These brief results synopses for the lay public will focus on the aims of this study and the gaps and issues identified in the National Academies report on Ovarian Cancers. These include: 1) physical and mental health experienced by ovarian cancer survivors; 2) the kinds of interventions ovarian cancer survivors use to manage their conditions and improve their quality of life; 3) barriers in access to care and support services; and 4) unmet need and concerns of ovarian cancer survivors. These descriptions will focus heavily on data visualizations to ease interpretation of results and will be developed with health literacy and numeracy needs of the public in mind. These results briefs will also be shared with partner organizations in ovarian cancer for dissemination and use in decision-making and priority setting. Additional briefs may be developed based on feedback from partner organizations or based on interesting results.

Specific planned manuscripts for peer-reviewed publication and dissemination are detailed below. We first will use descriptive statistics to summarize the characteristics of the study sample and examine the distribution of individual variables. For scales that were drawn from the literature and are being used as they were originally designed, scale scores will be calculated as described by the instruments' developers. Means and standard deviations will be calculated for the scale items and where possible, compared to scores reported in the literature. We will conduct a series of analyses employing descriptive statistics (means, medians, t-tests, and chi-square tests), linear and logistic regression, and other multivariate techniques to address the research questions outlined below. These research questions were based on the specific aims of this study, as well as the identification of gaps in the literature identified by previous CDC work in ovarian cancer survivorship, and the National Academies report on Ovarian Cancers.

While the initial analysis plan for this data collection effort will focus on the manuscripts listed below, as well as our public facing data briefs, several additional analyses could be conducted using data collected from these questionnaires.

1. What is the impact of non-response and sampling bias in a study of ovarian cancer survivors?

One of the key benefits of using population based data sources for research recruitment, like cancer registries, is the opportunity to assess non-response bias. Since cancer registries collect demographic and

cancer-related data on all cancer patients, we are able to compare cancer survivors who agree to participate in research to those who do not to assess if the extent of non-response bias in the sample.

Socio-demographic factors, such as age, and cancer-related factors, such as age at diagnosis, stage, and first course of treatment will be compared. Cross-tabulations with chi-squares will be used to make bivariate comparisons. Comparisons will occur within each cancer registry used for recruitment and pooled across all state cancer registry samples. In addition, a logistic regression model will be run to identify factors associated with greatest odds of responding or participating.

In addition, the particular design of this study will allow us to examine sampling bias by comparing ovarian cancer survivors recruited through a state cancer registry to those recruited through alternative means key demographic and cancer-related characteristics. Also, these groups can also be compared on key outcomes, such as use of health care services and patient-reported outcomes such as pain, depression, or quality of life.

Bi-variate associations will be examined using cross-tabulations and chi-square tests. In addition, logistic regression models will estimate the odds of being in the registry sample vs. being in the online sample for selected demographic and medical variable of interest. This will help us determine which variables may be driving sampling bias between the samples. In addition, it also allows us to make important inferences about any associations or results uncovered in analyses where the two datasets are pooled.

2. What are the prognostic factors for continued employment among ovarian cancer survivors?

Descriptive analyses will be conducted on the pre-cancer employment status and any transitions in employment status post-cancer. We will describe changes in percent of women employed at at diagnosis, and 'currently' (at the time of the interview) as well as reported changes in type of work or change in hours of work following treatment. Using multivariable logistic regression we will examine predictors of returning vs. not returning to full or part-time work. These will include age, income, race/ethnicity, education, marital status, general health, material and psychological social support during treatment, ability to carry out daily activities, cancer stage at diagnosis, change in co-morbid conditions after treatment, type of treatment, treatment effects such as lymphedema, memory loss, fatigue or neuropathy, sick leave, and health insurance status.

3. What has been the impact of ovarian cancer diagnosis and treatment on financial well-being of ovarian cancer survivors?

The outcomes of interest in this analysis are financial hardship, bankruptcy, inability to pay medical bills, worry about medical bills, and having to make financial sacrifices. We will tabulate response to these questions separately, and conduct correlational analysis for this set of variables. Using factor analysis we may examine these as a composite of financial hardship. We will consider the following variables as predictors of the financial hardship due to cancer: current employment status, type of health insurance coverage, having insurance to cover cancer treatment, sick leave, general health, income, age, education, marital status, continued late-term effects of treatment, and recurrence of cancer.

4. What comorbidities and chronic diseases do ovarian cancer survivors face before and after treatment for ovarian cancer?

Descriptive analyses will be conducted on the comorbidities and other chronic diseases faced by ovarian cancer survivors both before and after treatment. Specifically, we will describe percentages of ovarian cancer survivors who also have 1) hypertension, 2) high cholesterol, 3) heart problems, 4) stroke, 5) diabetes, 6) arthritis, 7) osteoporosis or osteopenia, 8) asthma, 9) emphysema, chronic bronchitis, or chronic obstructive pulmonary disease (COPD), 10) kidney disease, 11) stomach and/or intestinal

problems, 12) anemia, and 13) others and the percentages of each that were diagnosed before or after their ovarian cancer diagnosis.

5. What medications do ovarian cancer survivors use to manage their comorbidities and other chronic diseases?

Descriptive analyses will be conducted on the number of ovarian cancer survivors taking medications for depression and/or anxiety and the percentages of women that were prescribed the medication(s) before or after ovarian cancer treatment, whether or not they are currently taking medication for depression and/or anxiety, and what type of doctor prescribed the medication(s). We will also analyze percentages of women ever taking medication for 1) blood pressure, 2) diabetes, and 3) sleep, whether these medications were taken before, after, or during treatment, and whether or not they are currently being taken.

6. What symptoms did ovarian cancer survivors experience prior to their cancer diagnosis?

Descriptive analyses will be conducted on the symptoms experienced by ovarian cancer survivors and duration of symptoms prior to their diagnosis of ovarian cancer. We will describe percentages of ovarian cancer survivors experiencing symptoms related to ovarian cancer including 1) vaginal bleeding or discharge that was not normal for them, 2) pain or pressure in the pelvic or abdominal area, 3) lower back pain, 4) bloating or stomach swelling, 5) feeling full quickly or difficulty eating, and 6) change in bathroom habits. We will also describe percentages of how long survivors were experiencing symptoms prior to receiving a diagnosis of ovarian cancer, ranging from 2 weeks to greater than 6 months, and at what stage their cancer was ultimately diagnosed.

7. What interactions did ovarian cancer survivors have with the medical community related to their cancer symptoms prior to and leading up to diagnosis?

Descriptive analyses will be conducted on the number and types of physicians seen prior to and for diagnosis, referral to gynecologic oncologist for treatment, and treatments received. We will describe the mean number and standard deviation of providers seen by ovarian cancer survivors leading up to their diagnosis and percentage of survivors who sought a second opinion after receiving a diagnosis of ovarian cancer, including reasons for seeking a second opinion. We will also describe the percentages of survivors that were diagnosed with their ovarian cancer by the following types of providers: 1) gynecological oncologist (specialty oncologist), 2) surgeon, 3) primary care or Internal medicine doctor, 4) gynecologist, 5) ER doctor, and 6) other, and the percentages of survivors that ever saw a gynecologic oncologist as part of their care. To better understand how diagnosing physician and referral to a gynecologic oncologist affects treatment decisions and outcomes, we will also assess the percentages of survivors who received surgery and/or chemotherapy (including the specific chemotherapy agent used) as part of their cancer treatment. We will also perform logistic regression and correlation analyses to assess the associations of pathway to diagnosis variables with treatments received.

8. What proportion of survivors participated in clinical trials? What are the reasons for non-participation?

Descriptive statistics will be examined on various aspects of the treatment experience including participation in clinical trials. For example, we will describe proportion of survivors who were offered and/or participated in clinical trials and describe reasons for non-participation.

9. Did side effects of treatment differ by type of treatment received? And what is the frequency of use of supplements (i.e. alternative medicine, for example) for symptom management or treatment-related side effects?

Descriptive and analytic statistics will be examined on type of treatment received (both use of conventional and alternative medicines) and patient experiences with side effects of treatment. We will examine associations of use of medication for a) symptom management and b) treatment-related side effects and outcomes of patient satisfaction and quality of life measures.

10. What factors are associated with the utilization of genetic counseling and genetic testing among women with ovarian cancer?

This paper will explore factors associated with utilization of genetic counseling and testing among women diagnosed with ovarian cancer. Based on screening recommendations from the National Comprehensive Cancer Network recommend that all women diagnosed with ovarian cancer received genetic testing for the potential identification of a BRCA 1/2 mutation (Capoluongo et al. 2017). Previous research has indicated that genetic counseling and testing is being under-utilized (Madlensky et al 2017). Given the potential for specialized treatment (Hoskins et al 2017) and opportunities for cancer prevention and risk mitigation in the individual and among family members (Hoskins et al 2017), research seeking to understand factors associated with utilization of genetic counseling and testing could be used to inform the development of interventions and inform public health programs for ovarian cancer patients, providers, and/or health systems.

This analysis has four aims:

1. Describe patterns of utilization and referral to genetic counseling and testing services.
2. Assess factors associated with utilization of genetic counseling and testing
3. Describe reasons for lack of utilization of cancer genetic services
4. Describe the role of genetic counseling and genetic testing in treatment decision making

Describe patterns of utilization and referral to genetic counseling and testing services

This analysis will describe the number and percentage of individuals who spoke to their providers prior to their cancer diagnosis about their risk of cancer due to their family history, and the number who had genetic counseling and/or testing before and after their cancer diagnosis. Objective level of cancer risk will be determined using family history information reported in the questionnaire. Objective cancer-risk level will be compared between ovarian cancer survivors who received and did not receive cancer genetic services. Referring provider and utilization of genetic services by other family members will also be explored.

Assess factors associated with utilization of genetic counseling and testing

A logistic regression model will be used to assess factors associated with utilization of genetic counseling and testing. Demographic variables, such as age, income, education, marital status, and health insurance status, treatment related variables, such as stage, type of treatment received, and time since diagnosis, and risk variables, such as objective risk level, and receipt of a provider recommendation or referral, will be used as predictors. The binary outcome of the model will be use of genetic counseling and/testing compared to receipt of not cancer genetic services.

Describe reasons for lack of utilization of cancer genetic services

Reasons for not receiving genetic testing will be explored using percentages to indicate the most common reasons for not pursuing genetic testing. In addition, demographic and cancer-related characteristics will be explored among the most commonly reported reasons.

Describe the role of genetic counseling and genetic testing in treatment decision making

The number and percentage of ovarian cancer survivors who have received BRCA testing and reported taking a PARP inhibitor will be explored using cross-tabulations. In addition, the role of BRCA testing in surgical decision-making, specifically whether ovaries or breasts were removed prophylactically, will also be explored using cross-tabulations.

11. What factors are associated with the utilization of medication and other support services to treat depression and anxiety among women with ovarian cancer?

Several reports and publications have highlighted the importance of treating psychological distress, like anxiety and depression, in cancer survivors (Piet et al 2012, Yi and Syrjala 2017).). This analysis seeks to understand:

1. The use of medication to treat anxiety and depression
2. The use of support services to cope with psychological or emotional distress
3. The kind of material and emotional support patients received and lacked during their cancer experience.

The use of medication to treat anxiety and depression will be analyzed both as separate outcomes and as a combined single outcome, given that the medications are often prescribed in tandem. Factors associated with medication usage, such as who prescribed the medication, when it was prescribed, and its current use, will be described. Bivariate analyses will examine socio-demographic and cancer-related characteristics associated with the use of these medications. In addition, logistic regression models will be used to identify characteristics associated with the highest vs. the lowest odds of medication utilization.

The use of support services to cope with the psychological and emotional distress due to a cancer diagnosis and treatment will be explored descriptively. Cross-tabulations and chi-square tests will be run to examine socio-demographic and cancer-related characteristics associated with utilization of support services. Socio-demographic, cancer-related, and patient reported outcomes will be used as predictors of support services use in these logistic regression models.

The types of material and emotional social support received during cancer diagnosis and treatment will be analyzed descriptively. Bivariate analyses will be conducted to assess factors associated with receiving material and emotional social support. Sociodemographic factors and characteristics associated with their cancer diagnosis and treatment will be explored as predictors or co-variates of interest. Linear regression models will be used to model factors associated with receiving social support. Three regression models will be run in order to assess potential differences in predictors of material support, emotional support, and overall social support.

In addition, the prevalence of psychological and emotional distress will be reported, as will factors associated with being diagnosed with or reporting feelings of distress.

12. What factors are associated with quality of life among ovarian cancer survivors?

Quality of life after cancer is an important component of subjective well-being and health of patients. While a patient may not have active disease, they may symptoms or treatment sequela that prevent them from living their lives the way they did prior to their cancer diagnosis. Identifying characteristics that are

associated with a good quality of life allows public health programs in cancer survivors to address active concerns of cancer survivors.

The quality of life scale included in the study questionnaire measures 6 facets of quality of life: overall health status, physical functioning, emotional functioning, cognitive functioning, and social functioning. Scores from each of these scales will be calculated and used as an outcome in a linear regression model. These regression models will assess factors associated with higher quality of life per subscale. Results will be presented as estimated marginal means to ease interpretation of estimates.

In addition, logistic regression models will be run per subscale. The standard deviation of each subscale will be explored and those who report quality of life 2 or more standard deviation lower than the mean will be classified as having poor quality of life. This method has been commonly used in the published literature (Weaver et al 2012). Models will include socio-demographic and cancer-related factors that may be driving poor quality of life.

Finally, symptomology that may be impacting quality of life, such as fatigue, pain, insomnia, or dyspnea, will be explored. The prevalence of these symptoms among those with poor quality of life will be explored, as will the overall impact of experiencing multiple symptoms.

13. What factors are associated with cognitive impairment after treatment for ovarian cancer?

Cognitive impairment or cognitive difficulties during and after cancer treatment are fairly common (Vitali et al, 2017). Colloquially, these symptoms are often referred to as ‘chemo-brain’, or ‘chemo-fog’, and most often occur among patients going through chemotherapy. These symptoms usually consist of poor short-term memory, difficulty with concentration, and difficulty in managing daily activities. The purpose of this analysis is to: 1) describe the prevalence of cognitive impairment among women with ovarian cancer, 2) describe severity of these symptoms in inter their day to day lives, and 3) identify factors associated with reporting cognitive impairment.

The types and frequency of cognitive impairment symptoms ovarian cancer survivors are experiencing will be presented descriptively. Bivariate analyses will be conducted on the association between symptoms and socio-demographic and cancer-related characteristics. Women who were experiencing these symptoms before their cancer diagnosis will be excluded from the analysis. The co-presentation of cognitive impairment symptoms with other co-morbid conditions that could cause these effects will also be explored. Socio-demographic, psychological, and cancer-related factors will be explored as potential co-variates in linear regression models of cognitive impairment.

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

The display of the OMB expiration date is not inappropriate. We are not requesting an exemption.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

No certification exemption is being sought. These activities comply with the requirements in 5 CFR 1320.9.