Information Collection Request

New

The Centers for Disease Control and Prevention (CDC) Study on Disparities in Distress Screening among Lung and Ovarian Cancer Survivors

Supporting Statement: Part A

Program Official/Contact
Elizabeth A. Rohan, PhD, MSW
Division of Cancer Prevention and Control
Centers for Disease Control and Prevention
Atlanta, GA

Telephone: (770) 488-3053
Fax: (770) 488-4760
E-mail: erohan@cdc.gov

May 16, 2019

TABLE OF CONTENTS

- **Goal of the study:** 1) To assess the rates at which distress screening practices are implemented in healthcare facilities across the U.S. 2) To determine factors that influence whether ovarian and lung cancer patients receive distress screening. 3) To understand facilitators and barriers to implementation of distress screening.

- **Intended use of the resulting data:** Data will provide information to CDC's National Comprehensive Cancer Control Program (NCCCP) for the development of information, resources and technical assistance to support screening and intervention efforts in healthcare systems.

- **Methods to be used to collect data:** A one-time extraction/abstraction of existing data from patient electronic health records collected as a part of normal operations of the health care facilities, key informant interviews and focus group interviews

- **The subpopulation to be studied**: Ovarian and lung cancer survivors

- **How data will be analyzed:** Descriptive analysis of distress screening rates by age, cancer type, and race/ethnicity; logistic regression of factors/covariates that may influence the receipt of distress screening; and thematic qualitative analysis based on and grounded theory approaches.

This is a request for OMB to approve the new submission titled, "Disparities in Distress Screening among Ovarian and Lung Cancer Survivors." The purpose of this study is to examine the extent to which disparities exist in distress screening and follow-up care among cancer treatment facilities and programs across the country. CDC believes that it is imperative to develop a greater understanding about the types of services for lung and ovarian cancer survivors because they experience high levels of distress and are among those that experience the lowest 5-year survival rates.

This study will includes a quantitative review of existing patient medical records from 50 facilities and examine information related to their distress screening and follow-up services, relative to their cancer diagnosis and sociodemographic information. Qualitative interviews and focus groups with healthcare practitioners will be conducted at twelve facilities to understand the processes of distress screening, patterns of follow-up care, and the related challenges and facilitators. This evaluation will provide CDC's National Comprehensive Cancer Control Program (NCCCP) information to be used for the development of information, resources and technical assistance to support screening, as well as intervention efforts in healthcare systems.

A. JUSTIFICATION

A1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) is supporting a one-year study to examine the extent to which disparities exist in distress screening and follow-up among cancer treatment facilities and programs across the country. The CDC, Division of Cancer Prevention and Control (DCPC) is requesting approval from OMB for data collection activities to examine

disparities in distress screening among ovarian and lung cancer survivors. This is a new data collection request for one year, which is how long we anticipate data collection itself will take.

Section 301 of the Public Health Service Act (42 U.S.C.241) authorizes the collection of these data.

One of the strategic priorities of CDC's DCPC is to improve health and health outcomes for cancer survivors so that they live longer, healthier lives. To support these priorities, DCPC has to focus on improving the integration of clinical and public health data to support data-driven decisions by providers and state health departments. Within the cancer treatment community, interest in the psychosocial impacts of cancer diagnosis and treatment is increasing. These psychosocial impacts are wide ranging and include not only anxiety related to the illness and treatment side effects such as pain, fatigue and cognition, but also stress related to nonmedical issues such as family relationships, financial hardship, social stressors (e.g., transportation), and stigmatization. There is growing evidence that addressing the psychosocial stresses of cancer survivors increases both their longevity and quality of life.[1-4]

Since 2015, the American College of Surgeons' Commission on Cancer (CoC) has required accredited facilities to routinely screen for distress in cancer patients a minimum of one time at a pivotal medical visit.[1] Examples of a pivotal medical visit may include medical visits at times of greatest risk for distress, such as time of diagnosis, transitions during treatment, or transitions off treatment. Approximately one-third of cancer survivors experience psychosocial distress during their cancer treatment experience.[2-4] Prevalence of distress vary by cancer type and may be correlated with poor prognosis.[5] Ovarian and lung cancer have relatively low 5-year survival rates (45% and 17%, respectively),[6] thus it is prudent to focus on these groups.

The 2016 Institute of Medicine report on ovarian cancer, funded by CDC, called for increased study of the psychosocial needs of ovarian cancer survivors[7], recognizing the high rates of depression, anxiety, and distress.[8] Lung cancer survivors, too, experience high levels of distress[9]; up to 60% of these survivors experience distress.[10] Positive social support and good mental health is associated with longer survival among ovarian and lung cancer patients.[11-12]

Despite this interest in distress screening, there is a dearth of literature exploring the facilitators and barriers to implementing routine distress screening, as well as the utility of distress screening in improving patient outcomes. To address this, the primary objectives of the study are to:

1. Determine the percentage of patients screened for distress (for a given facility), and whether the percentage of patients screened differs by diagnosis (lung or ovarian) and sociodemographic factors such as race, ethnicity, sex, age
2. Understand how screening is accomplished and the patterns of care following distress screening, including referrals to psychosocial assessments and intervention services
3. Understand the challenges and facilitators in meeting the needs of distressed patients
4. Assess the extent to which routine distress screening and appropriate follow-up/treatment are associated with positive health outcomes

This evaluation will provide information to CDC's National Comprehensive Cancer Control Program (NCCCP) that will be used for the development of information, resources and technical

assistance to support screening as well as intervention efforts in healthcare systems. Furthermore, findings will be used to evaluate the need to help with policy, systems and/or environmental changes that may enhance the landscape of quality of life services for cancer survivors in communities at large. Published manuscripts will add depth to the peer-reviewed scientific literature with regard to facilitators and barriers to implementing distress screening practices and best practices that are successfully integrated into routine cancer care.

A2. Purpose and Use of the Information Collection

This study will implement a mixed-method study design that includes a quantitative review of existing patient medical records and qualitative interviews and focus groups with healthcare practitioners about the facilitators and barriers to routine distress screening.

Site Selection. Westat, the contractor for this study, will recruit a minimum of 50 sites from states with the highest reported incidence rates for lung and ovarian cancers. A purposive sampling strategy will be employed to identify the sampling frame, which will consist of cancer healthcare facilities (hereafter, referred to as facility) within these states that have fully adopted the use of electronic health records (EHRs). These facilities will be stratified by CoC-accreditation status, geographic urbanicity, and other facility demographic information. Furthermore, the recruitment team will solicit participation from facilities affiliated with study partner organizations (described in section A.8) who have the mechanisms to promote the study's visibility through organization dissemination channels such as the organization's listserv, Web site etc.

Westat will first contact facilities with an email to all identified facilities. The email will be sent from a project mailbox and contain a brief description of the study, highlight benefits of participation, and study contact information. Westat will also recruit facilities through professional organization contacts or listservs. Project staff will review facilities that express interest in the study and conduct follow-up phone calls to determine the facility's eligibility, confirm their participation in the study, and identify a facility point of contact (POC) for the study. Subsequent phone calls will be scheduled to review the study FAQs, IRB application information, and a data security fact sheet.

EHR Data. The study team will work with each of the 50 facilities to determine parameters for a one-time release of data from existing patient electronic health records that are collected as a part of normal operations of the healthcare facilities. The records will be selected based on primary cancer site (lung or ovary) and year of diagnosis (within calendar year 2017). Data elements that will be collected include a patient's cancer information, information related to their distress screening, and follow-up services. Facilities will provide these data to Westat via a secure file transfer protocol (SFTP). Personal identifiers including patient name, address, birth date, and social security number will not be collected.

The study builds on the literature that examines the procedures that facilities use for administering distress screening, including tools used and pivotal time points at which patients are screened[12-14], and one known evaluation to assess the adherence to screening guidelines, and medical service utilization outcomes related to distress screening.[15]

Qualitative Interviews and Focus Groups. Researchers will select a subset of 12 facilities (again stratified by CoC-accreditation status, geographic urbanicity, and other facility demographic information) from the original 50 to participate in qualitative interviews to understand the processes of distress screening and patterns of follow-up care and the related challenges and facilitators. All interviews will be conducted through an online web conferencing platform, such as WebEx. For each selected facility, this will include one key informant interview with a facility administrator, and one focus group with 4-8 facility staff members who have direct experience with the implementation of distress screening and/or follow-up procedures. Pilot testing of these instruments will be conducted both individually and using a focus group format consisting of nine or fewer individuals in total.

Facility-level Administrative Information. To inform the collection of existing EHR data and qualitative interviews, each participating facility will provide the study team with administrative data on cancer caseloads, existing documentation on distress screening implementation and reporting practices.

Westat will work with the POC in each facility to identify and contact individuals for the qualitative interviewers (and focus group, for selected sites). The facility POC will send an email (composed by Westat) to facilitate scheduling an agreed upon time for the focus groups. Once participants are confirmed for the interviews, Westat will provide log in instructions to the video conferencing platform.

Trained interviewers from Westat will read the informed consent and obtain verbal consent from all interviewees prior to both key informant and focus group interviews. The study has obtained the Westat IRB approval statement and waiver of written consent. CDC is not engaged in collecting data; therefore, we have applied for reliance on Westat's IRB approval.

Research Questions

This study will use a multi-level, mixed methods approach to examine the rates at which lung and ovarian cancer survivors are receiving distress screening and the extent to which adequate support is given to patients who receive screening and meet distress thresholds. The design of the study and the data collection process described here is formulated to address the research questions efficiently and to explore critical factors that affect psychological distress screening, types of assessments, referrals, and follow-up procedures across a diverse set of facilities. The collection of both quantitative and qualitative data will allow for the triangulation of findings across multiple sources of data and facilitate the detection of gaps and alignment of data from administrator, clinician, and the patient. Table A2.1.a provides an overview of the levels of data collection and type of data for each of the research questions that we will address in this study.

Table A2.1.a: Overview of Research Questions, by Study Level and Method

Level		Method	Research Question
	Program-level	Quantitative	1. Are cancer care facilities currently providing mandated routine distress screening for every lung and ovarian cancer patient?
Ind	Program-level	Quantitative	a. What is the percentage of patients screened for distress (for a given facility)?

ividual-level		Quantitative	2. Does the percentage of patients screened differ by type of cancer diagnosis (lung or ovarian, or cancer stage at diagnosis), race, ethnicity, sex, age, smoking status, or other sociodemographic factors?
		Both	3. What are the patterns of care following distress screening?
		Both	a. How is screening and assessment accomplished? Who conducts the screening and assessments (i.e. physician, nurse, social worker, mental health professional)?
		Both	b. What types of referrals/interventions are made following an assessment? Are they referred to an oncology social worker or other mental health professional for a full psychosocial assessment?
		Both	c. Does this staff provide care? Referral only?
	Program-level	Qualitative	4. What are the barriers and facilitators associated with implementing routine distress screening?
		Qualitative	5. What are the challenges and facilitators in meeting the needs of distressed patients?
		Qualitative	a. How can NCCCP help with reducing barriers and supporting facilitators?

We will use facility databases in conjunction with key informant interviews and focus groups to obtain information on the policies, administration, and perceptions related to the implementation of distress screening protocols. At the individual-level, we will use non-identifying data that are digitally extracted and manually abstracted from existing EHRs of lung and ovarian cancer survivors. The purposively selected facilities will provide standardized EHR data fields as well as manually abstracted data on psychosocial distress. Findings from these data will allow for examination of screening rates (in aggregate) by program and potential disparities in screening rates by sociodemographic characteristics and cancer status.

Audiences for Data and Results

Findings will provide facility administrators and clinical staff with essential program management, development, and implementation information on best practices in distress screening. Findings will inform researchers about the extent to which distress screening practices and sufficient implementation of these best practices are associated with patient health outcomes. Summary reports to each participating facility will be disseminated through multiple methods (See Section A.16 for more detail). The data may be used as self-assessments for each facility to use for quality improvement purposes. Facilities will also see how they scored compared to other participating facilities. Scientific publications and presentations will inform the oncology community about the implementation of distress screening processes, as well as the impact of distress screening (and subsequent treatment for distress) on patient outcomes.

Evaluation findings will be of use to both CDC and NCCCP through:

- Showing whether there are observable differences in distress screening practices by cancer type and by patient demographic characteristics;
- Providing further evidence on the association between distress screening implementation and positive health outcomes, including whether these differ across groups;
- Identifying best practices and effective strategies for distress screening;
- Describing the range of experiences and practices in distress screening; and
- Understanding barriers and facilitators to successful implementation.

Facilities and cancer treatment programs can use evaluation findings to:

- Improve the implementation and documentation of distress screening practices;
- Improve the quality and standards of the psychosocial services they provide; and
- Learn about the barriers to treatment and services that are provided to lung and ovarian cancer patients.

A3. Use of Improved Information Technology and Burden Reduction

In compliance with the Certification for Paperwork Reduction Act Submissions--5 CFR 1320.9, data from facility EHR systems will be transferred from the facilities to Westat via a web-based SFTP. The doc server uses Advanced Encryption Standard (AES) 256-bit Transport Layer Security (TLS) to secure all communications so that the data transmitted between the user and the server is strongly encrypted.

Limited EHR and distress screening data will be transmitted from the facilities via Westat's SFTP, providing a secure data transfer service that meets CDC policies for data transmission via the Internet. If the facility agrees, Westat will access existing EHR distress screening data remotely using Westat's remote abstraction security requirements that meet the Federal Information Security Management Act (FISMA), encryption, and FedRAMP requirements.

A Microsoft Access data collection tool will be designed to accommodate a one to many (1:m) relationship between patient information, screenings, and interventions, respectively, where one patient case may be linked to multiple screenings, and each screening may be linked to multiple interventions. By allowing direct digital transmission of data, this significantly reduces burden on facilities as compared to alternate paper-based methods. Respondents can enter and submit the data at a time and location that is convenient for them. In addition, the data entry and quality control mechanisms built into the MS Access database are designed to reduce errors that might otherwise require follow-up, thus reducing burden, improve data quality and data security. Westat will download the files from the doc server and will review the data to verify that all data are formatted correctly.

A4. Efforts to Identify Duplication and Use of Similar Information

This evaluation will provide information specific to the Disparities in Distress Screening among Lung and Ovarian Cancer Survivors study. One prior study conducted in 2013 (Zebrack, 2017) examined distress screening rates and medical utilization across a broad range of cancer types. Since the establishment of distress screening practices as a standard for accreditation by the American College of Surgeons' (ACS) Commission on Cancer (CoC), no similar studies have been conducted to assess the impact of these standards on distress screening implementation. A search of federal websites (including CDC.gov, Cancer.gov, Reginfo.gov, Regulations.gov, and Healthdata.gov) revealed there are no current federal data collection efforts such as this. This current study will provide updated findings on the current state of the science by examining distress screening practices, the documentation of screening, referral and assessments in facility EHR systems, specifically among lung and ovarian cancer survivors. Furthermore, we intend to capture data through qualitative interviews to assess processes, facilitators, and barriers to distress screening implementation. Data collected will serve as a primary mechanism through which to understand distress screening practices, administrative processes, impact on patients, and to ultimately inform how CDC's NCCCP can provide resources to improve and sustain these practices. The data are not collected through any other mechanism.

Currently, the study has been approved to meet compliance for Standard 4.7 (Study of Quality) by the ACS CoC. The study team has formed official collaborative partnerships with the CoC and the Patient Centered Research Collaborative (PCRC). These partners will provide existing archival and administrative data (as available) to the study team, which we will use to inform our data collection process. In particular, we will use these data sources from our partners to identify facilities and facility staff to contact about participating in this study. Similar information about a facility's distress screening protocols will be used to tailor interview questions to maximize returns from the qualitative data collection.

A5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in the evaluation. All respondents will be individuals who participate voluntarily.

A6. Consequences of Collecting the Information Less Frequently

This is a one-time collection.

A7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The data collection efforts will be in full compliance with all guidelines of 5 CFR 1320.5.

A8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

As required by 5 CFR 1320.8(d), the 60-Day Federal Register Notice soliciting comments on this study prior to initial submission to OMB was published on March 6, 2019 (FR Doc. 2019–04068). No comments from the public were received.

Study partners were consulted in 2017 and 2018 on the development of the evaluation design, data collection methodology, and associated burden. Members of the Patient Centered Research Collaborative (PCRC), and PCRC chair Bradley Zebrack provided consultation on the clarity of instructions, data elements to request, feasibility of data collection approach, and estimated burden on facility staff to extract existing EHR data elements for the study. Nina Miller, Cancer Liaison Initiatives Manager of the ACS CoC provided overall consultation on study design, recruitment strategy, and use of CoC accreditation standard as incentive for facilities to participate.

Brad Zebrack, PhD, MSW, MPH, FAPOS
Professor
University of Michigan School of Social Work
University of Michigan Comprehensive Cancer Center
Health Behaviors and Outcomes Research Program
(734) 615-5940

Nina Miller, MSSW, OSW-C
Cancer Liaison Initiatives Manager
American College of Surgeons
Commission on Cancer
Office: 312-202-5592
Mobile: 312-339-2411

A9. Explanation of Any Payment or Gift to Respondents

We will conduct one key informant interview and one focus group from 12 of the 50 participating facilities. The key informant interview will take place with a facility administrator, and will last for approximately 60 minutes. The focus group, consisting of a mix of medical providers, social workers, and consult staff who are involved in distress screening, will last for approximately 90 minutes. Interviews and focus groups will take place through a video call and will be recorded audio with consent. A verbal informed consent to be interviewed will be obtained over the phone.

Interview and focus group respondents will receive a monetary thank you for their participation, $100 and $60 respectively. The incentive amounts are based on Department of Labor, Bureau of Labor Statistics occupational employment wage estimates and are commensurate with prior studies of facility administrators and medical staff. Studies have shown that incentives significantly improve participation of overloaded facility staff and scheduling challenges for activities beyond the scope of patient care duties.[16,17] Payment for participating in interviews or surveys is standard practice when seeking participation of professionals such as physicians and allied health providers due to their demanding schedules and limited time for activities beyond their scope of responsibility.[16,17] The incentive payment is an effective method of drawing attention to the study and gaining cooperation for completing the interview.[16-21] An incentive of $100 for a 60-minute interview with high-ranking health administrators is modest, when compared with current incentives offered by the data collection contractor to senior healthcare professionals (the market rate for this population typically range from $100 to $200). A $60

incentive for clinicians and health care providers to participate in a 90-minute interview is modest, yet shown to be necessary to attain high levels of participation.[16, 19, 20, 21]

Inappropriateness of other forms of incentives

Other forms of incentives that have been considered include: gas cards, debit and credit cards, gift cards or coupons (i.e. to a grocery store) or other types of in-kind gifts. There is theoretical support for offering cash incentives to healthcare professionals, especially when efforts and costs of their participation might be measured relative to the perceived value of their time, as in an economic exchange.[22] Cash incentives offer the greatest flexibility, convenience to the recipient, and carry the lowest administrative costs.

Several meta-analysis studies have shown that monetary incentives have a greater effect than non-monetary incentives.[23,24] Cash has a more universally understood value, whereas many potential respondents may not realize the monetary value of an in-kind incentive such as passes to regional parks. On the contrary, respondents may perceive gifts as having less value than cash, and may vary in their interests or likelihoods to make use of the gift.

A10. Protection of the Privacy and Confidentiality of Information Provided to Respondents

CDC/NCCDPHP's Information Systems Security Officer has reviewed this submission and determined that the Privacy Act is not applicable. Westat, the contractor for the CDC Disparities in Distress Screening among Lung and Ovarian Cancer Survivors project uses guidelines established by the National Institute of Standards and Technology (NIST; 800-series) for meeting the requirements of FISMA. Westat complies with all relevant laws, regulations, and policies governing the security of data and the protection of confidentiality. The datasets created will contain no means of identifying individual respondents. Security protocols will be implemented to ensure that all data are recorded and stored in such a manner that individual research subjects cannot be identified directly or through identifiers. EHR entries will include a unique ID number for each respondent generated and assigned by Westat. The unique ID number will consist of a two-character/digit hospital code followed by three-digit patient code (ex.01-001). Electronic data will be password protected and stored by the data management contractor and will be destroyed at the end of the contract period.

All components of this project adhere to legal requirements for safeguarding electronic health information and qualitative data are governed by the following standards in the HIPAA Privacy Rule 45 CFR 164.514(e)(3)(ii) for limited datasets. All participating facilities are expected to request review and approval from their facility's Institutional Review Boards (IRB) or sign a Business Associates Agreement (BAA) with Westat, acting as the covered entity to ensure protections of personally identifiable information (PII), prior to beginning any data collection for this project. Westat has already obtained IRB approval of all data collection instruments and has approval to conduct the evaluation.

Limited EHR and distress screening data will be transmitted from the facilities via Westat's Secure File Transfer System (SFTP) that provides a secure data transfer service that meets CDC policies for data transmission via the Internet. If the facility agrees, Westat will access EHR data

remotely using Westat's remote abstraction security requirements that meet FISMA, encryption, and FedRAMP requirements. The SFTP provides the secure data network and transmission mechanism needed to receive and store data files from participating facilities. All files sent via the SFTP are securely stored and transferred using Federal Information Processing Standard (FIPS) 140-2 validated Advanced Encryption Standard (AES) encryption. Data are encrypted both during transmission and when stored on the Westat server. Login and password is required to access the SFTP server.

The study team will safeguard the names of respondents, all information or opinions collected in the course of interviews, and any information about respondents learned incidentally during the project. All interview respondents will be required to provide verbal informed consent and will be assured that all collected information will be kept private and not disclosed in any identifiable form to anyone but the researcher conducting this study, except as otherwise required by law.

Hard copies of study data will be kept separate from personal identifiers (for the qualitative respondents) and will be kept in locked containers or in a locked room when not being used. Reasonable caution will be used in limiting access to data to only those persons who are working on the project and who have been instructed in appropriate Human Subjects requirements for the project. All study data, notes, recordings, etc. will be destroyed at the end of the contract period.

Electronic files and audio files will be accessible only to project staff and under password protection. Access to network-based data files is controlled through the use of Access Control Lists or directory- and file-access rights based on user account ID and the associated user group designation. Staff are instructed on the proper use of PCs for the storage, transfer, and use of sensitive information and the tools available such as encryption.

A11. Institutional Review Board (IRB) and Justification for Sensitive Questions

Westat has already obtained IRB approval of all data collection instruments and has approval to conduct the evaluation .

There are no questions of a particularly sensitive nature included in the evaluation.

A limited dataset for extracted data, not containing names, addresses, birth dates, or Social Security Numbers, will be transmitted to Westat via a SFTP. In addition, participating facilities may sign a business associate agreement (BAA) that protects the confidentiality of the facility's EHR data and the identity of the facility. The BAA will also provide guidance on how the data will be used in the study.

A12. Estimates of Annualized Burden Hours and Costs

Table A12.a shows the estimated annualized burden hours for the healthcare professional (e.g., Psychosocial Service Coordinator, Oncology Social Worker) who will serve as the point of contact (POC), the Health IT staff, and the qualitative interview and focus group respondents (various health care professionals). This includes an estimated one POC for recruitment and scheduling activities for each facility. An estimated one facility information technology staff will

prepare and complete the submission of the EHR data. Twelve of the 50 facilities will participate in the qualitative interviews. POCs from these 12 facilities contact participants for one individual key informant interview and one focus group of on average, six participants. The burden estimates including total estimated burden are summarized in Table A12.a. The estimated annualized burden hours are 512 hours.

Table A12.a. Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hr)	Total Burden (in hr)
Quantitative					
Healthcare Professionals (POC)	Survey	50	1	20/60	17
IT Staff	EHR data	50	1	7.5	375
Qualitative					
Healthcare Professionals	Key Informant Interview	12	1	1	12
	Focus Groups	72	1	1.5	108
TOTALS		**184**	**1**	**2.78**	**512**

Table A12.b shows the estimated annualized cost burden based on the respondents' time to participate in the study. The cost burden is estimated to be $20,434.55.

Table A12.b. Annualized Cost to Respondents

Estimated annualized cost burden							
Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hr)	Total Burden (in hr)	Hourly Wage Rate* (in $)	Total Respondent Costs (in $)
Quantitative							
Healthcare Professionals	Survey	50	1	20/60	17	$44.65	$759.05
IT Staff	EHR data	50	1	7.5	375	$38.18	$14,317.50
Qualitative							
Healthcare Professionals	Key Informant Interview	12	1	1	12	$44.65	$535.80
	Focus Groups	72	1	1.5	108	$44.65	$4,822.20
TOTAL		**184**			**512**		**$20,434.55**

*Wage rates were calculated using the mean hourly wage based on occupational employment and wage estimates from the Dept of Labor, Bureau of Labor Statistics' May 2016 National Industry-Specific Occupational Employment and Wage Estimates NAICS 622000 – Facilities, located at http://www.bls.gov/oes/current/naics3_622000.htm; Wage rates for all healthcare professionals were averaged to estimate a single hourly wage rate

A13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

Record keeper costs include the purchase of equipment, computers or computer software or services, or storage facilities for records as a result of complying with this data collection. There are no direct costs to respondents other than their time to participate in the study.

A14. Annualized Cost to the Federal Government

CDC has planned and allocated resources for the management, processing, and use of the collected information in a manner that will enhance its utility to federal agencies. The contract award to cover this evaluation is $298,386 over a 36-month period, but data collection will only last 12 months. Thus, the annualized contract cost is $99,462. This is based on an estimate of 2,568 hours for salaried labor (salary range from $26-53 per hour), the total cost of which is $111,348 prior to overhead and other expenses. In addition the contractor estimates other direct costs of $13,998 for computing, copying, supplies, postage/shipping, miscellaneous items, and incentives. Finally, the contractor has additional fees for overhead (100%), general/administration (16.7%) and fixed fees (6.0%).

It is estimated that three CDC employees will be involved as follows: Lead PI @ 20% time, 2 Co-PIs @ 10% time, at an estimated annualized cost of $42,615 to the government. These expenses are related to directing contractors, overseeing and solving problems as they arise, and supervising data collection.

In summary, based on the current budget, the estimated overall cost to the Federal Government for data collection is $142,077.00 for 12 months.

Table 14a. Annual Cost to the Federal Government

Average Annual Costs to Federal Government			
Staff	Total (in $)	Years Covered	Average Annual Cost (in $)
Contractor	$99,462	1	$99,462
CDC*	$42,615	1	$42,615
TOTAL	**$142,077**	**1**	**$142,077.00**

*It is estimated that three CDC employees will be involved as follows: Lead PI @ 20% time, 2 Co-PIs @ 10% time.

A15. Explanation for Program Changes or Adjustments

This is a new information collection.

A16. Plans for Tabulation and Publication and Project Time Schedule

The study will begin within 1 month of obtaining OMB approval. The contract period will include recruitment of 50 cancer programs to be included in the study, collecting EHR data from programs/facilities that agree to participate, conducting key informant and focus group interviews with health professionals within 12 of the 50 facilities, preparing an analytic dataset, data analysis, and dissemination of findings from the study.

The contractor will be responsible for all data collection activities, preparation of the analytic databases, and conducting preliminary analysis. The timetable for the study is shown below, in Table A16.a.

Table A16.a. Project time schedule

Activity	**Months after OMB approval**
Westat to email recruitment letters	month 1 - 2
Westat to conduct telephone screening	months 2 - 4
Collect facility-level information from participating facilities and establish parameters for sharing data	months 3- 5
Begin EHR data collection	months 4 - 9
Begin qualitative interviews and focus groups	months 5 - 10
End data collection	month 11
Data processing and analysis	months 11 - 15
Develop and complete summary report	months 16 - 22
Develop manuscript for publication	months 23- 28

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

The Distress Screening Study will not require exemption from displaying the expiration date of OMB approval. Any reproduction of the data collection instrument will prominently display the OMB approval number and expiration date.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

The Distress Screening Study does not require any exceptions to the Certificate for Paperwork Reduction Act (5 CFR 1320.9).

References

1 American College of Surgeons Commission on Cancer. (2012). Cancer Program Standards 2012: Ensuring Patient-Centered Care Retrieved 2/26/2012, 2012, from http://www.facs.org/cancer/coc/programstandards2012.html

2 Zabora, J. (2012). The History of Psychosocial Screening Among Cancer Patients. Journal of Psychosocial Oncology(Special Issue): 625-635.

3 Zabora, J., BrintzenhofeSzoc, K., Curbow, B., Hooker, C., & Piantadosi, S. (2001). The prevalence of psychological distress by cancer site. Psychooncology, 10(1): 19-28.

4 Zabora, J., Diaz, L., & Loscalzo, M. (2003). Psychosocial screening goes mainstream: A prospective problem-solving system as an essential element of comprehensive cancer care: background and rationale. Psycho-Oncology, 12 (Suppl. 4), S71.

5 Krebber, A.M.H., Buffart, L.M., Kleijn, G., et al., (2014).Prevalence of depression in cancer patients: a meta-analysis of diagnostic interviews and self-report instruments. Psycho-Oncology, 23(2): 1099-1611.

6 U.S. Cancer Statistics Working Group. (2016). United States Cancer Statistics: 1999–2012 Incidence and Mortality Web-based Report. Available at: www.cdc.gov/uscs.

7 Hodgkinson, K., Butow, P., Fuchs, A., et al. (2007). Long-term survival from gynecologic cancer: Psychosocial outcomes, supportive care needs and positive outcomes. Gynecologic Oncology, 104: 381-389.

8 Rohan, E.A., Boehm, J., Allen, K., Poehlman, J. (2016). In their own words: A qualitative study of the psychosocial concerns of posttreatment and long-term lung cancer survivors. Journal of Psychosocial Oncology, 34(3): 169-183.

9 Graves, K. D., Arnold, S. M., Love, C. L., Kirsh, K. L., Moore, P. G., & Passik, S. D. (2007). Distress screening in a multidisciplinary lung cancer clinic: prevalence and predictors of clinically significant distress. Lung Cancer, 55(2): 215-224.

10 Lutgendorf, S., De Geest, K., Bender, D., et al. Social influences on clinical outcomes of patients with ovarian cancer. Journal of Clinical Oncology, 30(23): 2885-2890.

11 Temel, J., Greer, J., Muzikansky, A., Gallagher, E.R., et al. (2010). Early Palliative Care for Patients with Metastatic Non–Small-Cell Lung Cancer. New England Journal of Medicine, 363:733-742.

12 Pirl, W. F., Fann, J. R., Greer, J. A., Braun, I., Deshields, T., Fulcher, C. & Wagner, L. (2014). Recommendations for the implementation of distress screening programs in cancer

centers: report from the American Psychosocial Oncology Society (APOS), Association of Oncology Social Work (AOSW), and Oncology Nursing Society (ONS) joint task force. *Cancer*, *120*(19), 2946-2954.

13 Jacobsen, P. B., & Ransom, S. (2007). Implementation of NCCN distress management guidelines by member institutions. Journal of the National Comprehensive Cancer Network, 5(1), 99-103.

14 Rohan, E. A. (2012). Removing the stress from selecting instruments: arming social workers to take leadership in routine distress screening implementation. Journal of psychosocial oncology, 30(6), 667-678.

15 Zebrack, B., Kayser, K., Bybee, D., Padgett, L., Sundstrom, L., Jobin, C., & Oktay, J. (2017). A practice-based evaluation of distress screening protocol adherence and medical service utilization. Journal of the National Comprehensive Cancer Network, 15(7), 903-912.

16 Deehan, A., Templeton, L., Taylor, C., Drummond, C., and Strang, J. (1997). The effect of cash and other financial inducements on the response rate of general practitioners in a national postal study. British Journal of General Practice, 47, 87-90.

17 Dykema, J., Stevenson, J., Day, B., Sellers, S.L., and Bonham, V.L. (2011). Effects of incentives and prenotification on response rates and costs in a national web survey of physicians. Evaluation and the Health Professions, 34(4), 434-447. DOI: 10.1177/0163278711406113.

18 Gunn, W.J., and Rhodes, I.N. (1981). Physician response rates to a telephone survey: Effects of monetary incentive level. Public Opinion Quarterly, 45(1), 109-115.

19 Keating, N.L., Zaslavsky, A.M., Goldstein, J., West, D.W., and Ayanian, J.Z. (2008). Randomized trial of $20 versus $50 incentives to increase physician survey response rates. Medical Care, 46(8), 878-881.

20 Tambor, E.S., Chase, G.A., Faden, R.R., Geller, G., Hofinan, K.J., and Holtzman, N.A. (1993). Improving response rates through incentive and follow-up: The effect on a survey of physicians' knowledge of genetics. American Journal of Public Health, 83(11), 1599-1603.

21 Ziegenfuss, J.Y., Burmeister, K., James, K.M., Haas, L., Tilburt, J.C., and Beebe, T.J. (2012). Getting physicians to open the survey: Little evidence that an envelope teaser increases response rates. BMC Medical Research Methodology, 12(41).

22 Ryu, E., Couper, M. P., & Marans, R. W. (2005). Survey incentives: Cash vs. in-kind; face-to-face vs. mail; response rate vs. nonresponse error. International Journal of Public Opinion Research, 18(1), 89-106.

23 Church, A. H. (1993). Estimating the effect of incentives on mail survey response rates:A meta-analysis. Public Opinion Quarterly, 57, 62–79.

24 Singer, E., Van Hoewyk, J., Gebler, N., Raghunathan, T., & McGonagle, K. (1999).The effect of incentives in telephone and face-to-face surveys. Journal of Official Statistics,15, 217–230