

Attachment 3d: Healthcare Facility IRB information

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

Healthcare Facility IRB Information

(Suggested for use in healthcare facility IRB submission package)

Healthcare facilities engaged in research involving human subjects usually have their own IRBs to oversee research conducted within the institution or by the staff of the institution. To assist in the IRB process for this study, Westat, CDC's contractor, has provided information that can be adapted to your healthcare facility's IRB for participation in this research project. Westat is not acting as an external IRB agent for healthcare facilities, but only providing information to streamline the participating healthcare facilities' IRB process. Below are components for this project that each healthcare facility can adapt to their IRB application.

TITLE OF RESEARCH PROJECT

Disparities in Distress Screening among Lung and Ovarian Cancer Survivors

AGENCY

The Centers for Disease Control and Prevention (CDC), and Westat, CDC's contractor

ESTIMATED PROJECT START DATE AND KEY MILESTONES

Start Date: Fall of 2018

Data collection: Spring-Fall of 2019

End Date: Fall of 2020

PROJECT SUMMARY

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.^{1,2,3,4}With the transition to 'patient-centered care' by the American College of Surgeons, Commission on Cancer (CoC) in 2015 came the mandate to provide Psychosocial Distress Screening for all cancer patients. The distress screening is addressed in Standard 3.2 of the 2015 and 2016 Cancer Program Standards of the CoC. Specifically stated: Each calendar year, the cancer committee develops and implements a process to integrate and monitor onsite psychosocial distress screening and referral for the provision of psychosocial care. With this standard, it is required that all cancer patients must be screened for distress a minimum of one time at a pivotal medical visit as determined by the program. The cancer committee defines one or more medical visits that are part of a pivotal time for the distress screening process. Examples of a pivotal medical visit may include postsurgical visits, first visit with a medical oncologist to discuss chemotherapy, routine visit with a radiation oncologist, or a post chemotherapy follow-up visit. Preference should be given to pivotal medical visits at times of greatest risk for distress, such as time of diagnosis, transitions during treatment, or transitions off treatment.⁵

Now that several years have transpired since the CoC mandate, it is important for the CDC to evaluate whether cancer survivors are receiving the mandated distress screening and whether or not facilities are providing adequate support for those patients who show signs of distress. Because ovarian and lung cancer patients have relatively low five year survival rates,⁶ it is prudent to focus the evaluation on them. This project will examine the extent to which disparities exist in distress screening and follow-up among cancer treatment facilities and programs (both CoC-accredited and non-CoC-accredited) across the country. The proposed project seeks to understand the facilitators and barriers to the process of incorporating distress screening and follow-up treatment in the care of ovarian and lung cancer survivors.

^{1,1} Adler, N., Page, A. eds. (2008) "Cancer Care for the Whole Patient: Meeting Psychosocial Healthcare Needs." Institute of Medicine,

Washington, DC.

^{2,2} Hodgkinson, K., Butow, P., Fuchs, A., Hunt, G.E., Stenlake, A., Hobbs, K.M., Brand, A. Wain, G. (2007). "Long-term survival from gynecological cancer: Psychosocial outcomes, supportive care needs and positive outcomes." *Gynecologic Oncology*, Volume 104, Issue 2: 381-389.

^{3,3} Lutengendorf, S.K., De Geest, K., Bender, D., Ahmed, A., et. al., (2012). "Social influences on clinical outcomes of patients with ovarian cancer." *Journal of Clinical Oncology*, Volume 30, Number 23: 2885-2890.

^{4,4} Rohan, E.A., Boehm, J., Gabuten, A., 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*, Volume 34, Issue 3: 169-183.

^{5,5} American College of Surgeons Commission on Cancer (2016). *Cancer Program Standards: Ensuring Patient-Centered Care*. Retrieved 6/6/2017 from <https://www.facs.org/quality-programs/cancer/coc/standards>

^{6,6} US Cancer Statistics Working Group (2016). *United States Cancer Statistics: 1999-2012 Incidence and Mortality Web-based Report*. Available at www.cdc.gov/uscs

Results will provide valuable information on addressing the psychosocial needs of these survivors. Results will assist the CDC’s National Comprehensive Cancer Control Program (NCCCP) with the development of information, resources and technical assistance to support screening and intervention efforts in healthcare systems, and to evaluate the need for policy, systems and/or environmental change to enhance the landscape of quality of life services for cancer survivors in communities. The project aims to evaluate ovarian and lung cancer survivors receiving psychosocial distress screening to determine whether adequate support is given and to identify any disparities in receipt of mandated care.

PROCEDURES AND POPULATIONS INVOLVED

As a participating organization, [HEALTHCARE FACILITY NAME] will contribute to the quantitative and qualitative data collection for this study.

Quantitative Data Collection: [HEALTHCARE FACILITY NAME] will provide Westat, CDC’s contractor, a Limited Dataset with information from adult (age 18 and older) lung and ovarian cancer patients related to patient demographics, cancer diagnosis, and treatment, and receipt of distress screening. Data will be extracted either by healthcare facility IT staff, onsite study partner abstractors, onsite healthcare facility abstractors, or through remote abstraction by study staff abstractors. Table 1 contains a preliminary list of data elements that will be sent to Westat.

Table 1. Example of data elements to be collected from EHRs

Data Element	Description
Patient characteristics	<ul style="list-style-type: none"> • Age at diagnosis, gender, race, ethnicity • Postal code • Primary Payor
Cancer description	<ul style="list-style-type: none"> • Date of diagnosis • Primary site/Histology • Stage of disease at diagnosis (clinical and/or pathologic)
Distress screening*	<ul style="list-style-type: none"> • Number of days since diagnosis • Type and date of “pivotal visit” (if available) • Distress screening tool used • Distress threshold score (if available) • Distress reason • Title of staff administering the screening/or denote if self-administered • Location and/or setting at which screening took place (i.e. check-in at out-patient visit, waiting room, during chemotherapy) • Any change in psychological distress noted
Interventions and Referrals	<p>For patients with distress scores greater than threshold cutoff:</p> <ul style="list-style-type: none"> • Referral for assessment (yes/no) and Number of days since diagnosis <ul style="list-style-type: none"> o Type of assessment (i.e. social worker, palliative care, dietician, other) • Referral for intervention/services (yes/no) and Number of days since diagnosis

Data Element	Description
	<ul style="list-style-type: none"> • Description of recommended follow-up <ul style="list-style-type: none"> o Provider type o Intervention type o Number of visits
Medical Service Utilization	<ul style="list-style-type: none"> • Number of emergency department visits • Number of healthcare facilityizations
Other	<ul style="list-style-type: none"> • Health indicators (smoking status); history of mental health (e.g., depression, anxiety, post-traumatic stress, etc.) • Any change in psychological distress noted (may be abstracted from data on multiple screening events) • Physician or Nursing notes (i.e. change in diagnosis) • Social worker/other mental health professional notes • Vital status

*Obtained for each administration of distress screening, as available in the EHR.

For each data element collected, Westat will enter the healthcare facility data into a data extraction tool. Some data may not be in a standardized format within specific fields in the EHR, such as screening instruments or physician notes that are scanned and uploaded in a PDF format. The data from the EHR extraction will be transferred from the facilities to Westat via a Secure File Transfer Protocol (SFTP). If EHR is remotely accessed, study staff will follow strict security requirements, including FISMA, encryption, and FedRAMP.

Qualitative Data Collection: [HEALTHCARE FACILITY NAME] will provide names and contact information (e.g. email addresses) to Westat of healthcare facility administrators, providers, and staff for qualitative data collection for the purposes of understanding [HEALTHCARE FACILITY NAME]'s cancer distress screening program. Upon recruitment of healthcare facility administrators, Westat will conduct one 60-minute key informant interview by telephone about the administrative decisions related to the implementation of the distress screening policies. In addition, Westat will conduct one 90-minute focus group consisting of a mix of medical providers, social workers, and consult staff who are involved in one or more stages of the screening.

Confidentiality, Data Security and Data Destruction

[HEALTHCARE FACILITY NAME] may require Westat to sign a Business Associates Agreement (BAA) with [HEALTHCARE FACILITY NAME], acting as the covered entity to ensure protections of PHI.

[HEALTHCARE FACILITY NAME] will release the Limited Dataset containing the extracted and abstracted EHR data to Westat via Westat's SFTP server or allow remote extraction of the EHR by project study staff. Data will never be submitted through email or any other platform. Westat's SFTP 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. Login and password is required to access the SFTP. Westat will download the files from the SFTP server and will review the data to verify that the correct variables are included before inputting the data into a web-based data abstraction tool. The data tables associated with the tool are stored on Westat's secure servers and will only be accessed by study staff at Westat.

Additionally, Westat will comply with all data destruction requirements as specified in Westat's contract with CDC for collected data that include:

- Digital EHR records transmitted from healthcare facilities
- Coded EHR distress screening and follow-up care data
- Audio recordings of key informant interviews and focus groups
- Interviewer notes from key informant interviews and focus groups

HIPAA Authorization and Informed Consent for EHR Extraction

The HIPAA Privacy Rule allows [HEALTHCARE FACILITY NAME], a covered entity, to share a Limited Dataset with an external entity for research purposes without obtaining an individual's authorization, or a waiver of authorization.

In addition, we request a waiver of informed consent under 45 CFR 46 as this retrospective study involves no more than minimal risk to patients, and it could not be practicably carried out without the waiver⁷⁷.

IRB Review and Informed Consent for Qualitative Data Collection

[HEALTHCARE FACILITY NAME] will inform employees whose contact information is shared for the qualitative data collection, that the results of the results from the interviews and focus groups will not contain any identifiable information and that the results will be used for research purposes only. The qualitative component of the study will be carried out by Westat, and will be overseen by the Westat IRB. Since these interviews and focus groups will not be completed in-person, Westat has requested from its IRB a waiver of written informed consent, and built the informed consent into the interview and focus group protocols. All participants will be given the opportunity to provide or decline consent to the interview or focus group, as well as the audio recording of the interview.

⁷⁷ U.S. Department of Health & Human Services. <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>

Risks

The use or disclosure of protected health information from the healthcare facility EHR data elements used in this study involves no more than a minimal risk to the individuals. The main risk is inadvertent disclosure of patient information. This risk will be minimized by excluding patient names and addresses from the Limited Dataset, as well as by the data security protections described above. Once Westat receives [insert healthcare facility name]'s dataset, through their secured FTP Web site, Westat will store the data on a secure network folder where only designated project staff have access. Upon completion of the study, Westat will destroy all EHR data used for this research.

Similarly, participating in the key informant and focus group interviews will pose no risks to the healthcare facility staff of personal, physical injury or emotional/psychological harm or discomfort. Individuals who participate in either key informant interview or focus group interview will not be at risk of financial loss or loss of employment or positions.

Benefits

There is no benefit to the patients or healthcare facility staff from having their data included in the study. However, participation in this study will add to the body of knowledge regarding distress screening for cancer patients that will ultimately improve the quality of life of cancer survivors. For each participating healthcare facility, CDC will develop an individual healthcare facility feedback report that allows study sites to compare their results to other participating healthcare facilities with regard to distress screening. In addition, this study has been approved by the American College of Surgeons (ACS) Commission on Cancer (CoC) as fulfilling requirements for *Standard 4.7 Studies of Quality*. Participating CoC-accredited healthcare facilities may apply for credit as appropriate.

For the qualitative part of the study, each interviewee who completes the key informant interview will receive an incentive of \$100 in the form of an electronic gift card or a check, in acknowledgement of the contribution of their time. Each focus group participant will receive \$60 in the form of an electronic gift card or a check, as acknowledgement of their time.

ATTACHMENTS

- Attachment A: EHR Data Dictionary
- Attachment B: EHR Data Extraction Instructions for Healthcare facility IT staff
- Attachment C: Data security fact sheet
- Attachment D: EHR abstraction tool
- Attachment E: Key Informant Interview Guide
- Attachment F: Focus Group Guide
- Attachment G: Informed consent for key informant interviews
- Attachment H: Informed consent for focus group interviews