CONNECT

Caregiver Oncology Needs Evaluation Tool

Practice Survey for Multi-Site Community Oncology Planning for the CONNECT Intervention Targeting Lung Cancer Caregivers (WF-2300CD)

Why are we requesting this survey?

This survey is being conducted as part of an NCI-funded U34 Planning Grant in collaboration with the Wake Forest NCI Community Oncology Research Program Research Base (WF NCORP RB). For this grant, we will pilot test an intervention as a separate CCDR study/protocol (WF-2301CD). Data collected in this survey will be used to plan a future Phase III randomized clinical trial to test the efficacy of a caregiver intervention within NCORP.

What is the purpose of this survey?

The purpose of this CCDR Study Survey is to understand your practice's potential interest in and capacity to participate in the future caregiver trial. We are specifically interested in interest and capacity in the outpatient setting at your practice.

Who should respond to this survey?

This survey should be completed by an NCORP staff member such as an NCORP Administrator, CCDR Lead, or lead study coordinator who will confer with key personnel (practice clinical staff, NCORP PI, other staff within practice) to complete the survey on behalf of the practice. We define a practice as one or more affiliate/sub-affiliate sites that share providers and supportive care services available to caregivers and would be willing to participate as a single unit in the future clinical trial.

How long will this survey take?

This survey will take about 15-20 minutes to complete once the data have been collected. If your practice participated in the 2022 Landscape Assessment, it may be helpful to consult with your practice's representative for the Landscape Survey to obtain those data for questions 14-17 below.

Date Completed: _____

Here is a PDF fill-in or printable form that may be helpful for collecting data or circulating the form to other practice personnel [attach here].

Practice ID: _____

What is your role at your institution? (check all that apply)

- NCORP Administrator/ Director
- Project/ Research Coordinator
- CCDR Lead
- Clinical Research Nurse
- Data Manager
- CRA
- Oncologist
- PI
- Protocol Specialist
- Regulatory Coordinator
- Other: _____

Please provide your email address: _____

Please complete the following brief survey to indicate your practice's interest and provide information to allow us to assess the capacity at your practice to participate in the future clinical trial.

Future Trial Description: The future clinical trial will test the Caregiver Oncology Needs Evaluation Tool (CONNECT) designed to connect lung cancer caregivers (i.e., family or family-like members providing unpaid care to a care-recipient with lung cancer) with existing supportive care resources (e.g., mental health services, financial navigation, cancer education) at the practice, local community, and nationwide. Importantly, practices will **not** be asked to develop or offer new supportive care resources; rather, CONNECT is focused on connecting caregivers with existing resources that may or may not be at your practice. CONNECT is low burden for caregivers and includes a 1.5-minute animated video, a brief survey to identify their service interests, a tailored list of supportive care resources, and navigation services provided by a Wake Forest University School of Medicine navigator by telephone. CONNECT can be completed at home or using a study tablet in the clinic.

Participants: We anticipate enrolling approximately 314 lung caregiver-patient dyads (i.e., caregiver + their care-recipient) to participate in one of 2-3 study arms. Caregiver inclusion criteria includes: (1) Provides the majority of the unpaid care during cancer treatment for a patient meeting the criteria below; and (2) ≥18 years of age. Caregivers will be excluded if they are: (1) currently receiving cancer treatment; or (2) unable to read and communicate in English.

Patient inclusion criteria includes: (1) Must have a current diagnosis of new or recurrent stage II-IV lung cancer and must be enrolled in the study after the start of anticancer systemic therapy (+/- radiation therapy) with at least 9 weeks of any planned anticancer treatment remaining and (2) Patients must be ambulatory and up (i.e., not bedridden) more than 50% of waking hours. Patients will be excluded if they: (1) are post-treatment survivors at the time of study enrollment; (2) enrolled in hospice care; or (3) unable to read and communicate in English.

Comparison Groups: The future trial may include a Usual Care (that is, care that the caregivers would be expected to receive at your practice as part of normal care) comparison group and/or a group that receives a generic, non-tailored resource list (no access to video, survey to identify interests, or navigation services).

What we will ask practices to do: Practice staff would be responsible for identifying and enrolling eligible caregiver-patient dyads. Our primary source of data collection will be REDCap (and managed by Wake Forest); however, practice staff will be responsible for following up with dyads in the case of missing data. Data collection will occur at three time points including before randomization (baseline), at 12-weeks, and at 24 weeks. Site staff would be responsible for minimal data abstraction from the patient's electronic health record. Other data collection is self-report from caregivers and patients. Practice staff may also be responsible for overseeing study tablets when in use at the clinic.

Local Practice Referral Coordinator: Each participating practice will identify a Local Practice Referral Coordinator defined as a staff member from the NCORP practice site who is knowledgeable (or able and willing to learn) about available local supportive care resources and referral processes for caregivers at their practice (e.g., social worker, navigator, therapist, nurse). This local practice staff member will add local resource information to a CONNECT resource database (may enlist support from other local staff) and facilitate referrals to link caregivers participating in the CONNECT Intervention arm with services. They will also interface with the Central Caregiver Navigator (see description below) for caregivers randomized to the CONNECT Intervention arm and report on training and participation metrics and details and suggestions to improve the future trial.

Study Champions: Each participating practice may also be asked to identify a research or clinical champion, separate from the Local Practice Referral Coordinator. These roles are defined as research or clinical personnel with high interest and agency to support the project and able to communicate its importance to various stakeholders.

Practice staff may also be responsible for overseeing study tablets when in use at the clinic.

1. Based on the study description, how likely is your practice to participate in this CCDR study?
    - Very likely
    - Somewhat likely
    - Neutral
    - Somewhat unlikely
    - Very unlikely

    Comments: _____

2. We are considering different comparison group options and study design options.

    a. Would the inclusion of a usual care (that is, care that the caregivers would be expected to receive at your practice as part of normal care) comparison group make your practice unwilling to participate?
        - Yes
        - No
        - Not sure

        If yes, please explain: _____

    b. Would a change from individual level randomization to practice level randomization (in which some practices receive the CONNECT intervention and others are assigned Usual Care or a generic, non-tailored resource list) make your practice unwilling to participate?
        - Yes
        - No
        - Not sure

        If yes, please explain: _____

3. Considering eligibility criteria for caregiver-patient dyads provided above in the study description, what is the estimated number of **eligible** caregiver-patient dyads per **quarter** at your practice: _____

    a. What information was used to inform the estimate provided (select all that apply):
        - Electronic health record, navigation records, or other data sources in which caregiver identification is recorded
        - Appointment/ scheduling data
        - Cancer registry data
        - Consultation with the thoracic clinical oncology team
        - Consultation with psychosocial services, social work, and/or navigation services
        - Other, please explain: _____

    b. Of the eligible dyads provided above, what are the estimated number of dyad **accruals** per **quarter** at your practice: _____

    c. Please list any concerns you may have about the eligibility criteria: _____

4. Does your practice have experience recruiting caregivers for research studies?
    - Yes
    - No
    - Not sure

5. Does your practice have experience recruiting dyads for research studies?
    - Yes
    - No
    - Not sure

6. Do you foresee recruiting dyads to be a barrier to successfully participating at your practice?
    - Yes
    - No
    - Not sure

    If yes, how much of a barrier is this?
    - Minor
    - Moderate
    - Major

    If yes, please explain: _____

7. How would study feasibility at your practice be impacted if the study focused solely on caregivers and did not recruit their patient counterparts?
    - No improvement in feasibility
    - Minor improvement in feasibility
    - Moderate improvement in feasibility
    - Significant improvement in feasibility

8. What resources or training would be helpful to build your practice capacity to recruit dyads? _____

9. Is there at least one person at your practice who could fulfill the Local Practice Referral Coordinator role, as described above in the study description?
    - Yes
    - No
    - Not sure

    If yes, how many different people fit this description? _____

    If yes, what is the current position(s) for this person (people) at your institution? Check all that apply.

    - Social Worker
    - Mental Health Counselor
    - Nurse
    - Navigator
    - Survivorship Coordinator
    - Other, please list: _____

10. Each participating practice may be asked to identify a research **or** clinical champion who is distinct from the Local Practice Referral Coordinator described in the study description above.

a. Is there someone at your practice who could serve as a **research champion** (i.e., research personnel with high interest and agency to support the project and able to communicate its importance to various stakeholders) for this study?
   - Yes
   - No
   - Not sure

   If Yes, what position does this person hold (select one option)?

   - CCDR Lead
   - Lead Study Coordinator
   - Clinical Research Associate
   - Research Nurse
   - Other, please describe: _____

b. Is there someone at your practice who could serve as a **clinical champion** (i.e., clinical personnel with high interest and agency to support the project and able to communicate its importance to various stakeholders) for this study?
   - Yes
   - No
   - Not sure

   If Yes, what position does this person hold (select one option)?

   - Nurse
   - Advanced Practice Provider
   - Medical Oncologist
   - Radiation Oncologist
   - Surgical Oncologist
   - Other, please describe: _____

11. Has your practice successfully used study-provided tablets in the clinical setting as part of a research study?
    - Yes
    - No
    - Not sure

12. What potential barriers do you foresee at your practice to successfully participate in the study? (Response options: Not a barrier; Minor Barrier; Major Barrier)

    - Eligibility criteria are not a good fit for our patient population
    - Topic is not of a significant interest at our practice
    - Insufficient staff to successfully carry out study
    - Other, please describe: _____

13. What factors at your practice might enhance successful participation in this study? _____

Practice Group Characteristics

Please consult with other staff, as needed, to complete the questions below. For example, a CCDR Lead, practice administrator, and/or someone who oversees the cancer registry may assist with providing accurate information. Responses should represent the practice as a group.

If your practice participated in the 2022 Landscape Assessment and rostered with the same affiliates/sub-affiliates that would roster together for the future clinical trial, it may be helpful to consult with your practice's representative for the Landscape Survey to obtain those data for questions 14-17 below.

14. Is your cancer program a designated Critical Access hospital (as designated by CMS: https://www.cms.gov/medicare/provider-enrollment-and-certification/certificationandcomplianc/cahs). If participating as a practice group with more than one distinct location and at least one location is considered a Critical Access Hospital, respond "Yes".
    - Yes
    - No

15. Enter the estimated number of new analytic oncology cases/ year at your practice for the most recent year available: _____

16. Estimated proportion of new analytic oncology cases at your practice that are members of the following ethnic groups (Numbers should total 100%):
    - % Hispanic
    - % Non-Hispanic
    - % Unknown

17. Estimated proportion of new analytic oncology cases at your practice that are members of the following racial groups (Numbers should total 100%):
    - % White
    - % Black/ African American
    - % Asian
    - % Native Hawaiian/ Other Pacific Islander
    - % American Indian/ Alaskan Native
    - % More than one race
    - % Unknown

Thank you for completing this CCDR Study Survey!

Next Steps:

You have completed the WF-2300CD CONNECT Practice Survey study for your practice. We hope that this study has made you excited about the possibility of participating in the CONNECT study (WF-2301CD) to pilot test CONNECT with an anticipated activation in Spring 2024 and the future Phase III efficacy trial. We may be in contact with your practice about participation in the CONNECT Intervention Study.