Enhancing Triadic Communication About Cognition for Older Adults with Alzheimer's Disease or Related Dementias Facing a Cancer Management Decision – Focus Groups
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1. PURPOSE OF STUDY

Approximately 7% of older adults diagnosed with cancer have pre-existing dementia (Alzheimer's Disease or Related Dementias [ADRD]). Despite the proven benefits of cancer treatments, patients with ADRD and cancer experience greater treatment complications and higher mortality than patients without dementia. In addition, cancer treatments can cause cognitive decline to accelerate. Nevertheless, cancer treatments can also minimize cancerrelated symptoms and morbidity, thus improving quality of life for some patients. Older adults with cognitive impairment are rarely included in oncology clinical trials; therefore, the optimal approach to treatment in these patients is unknown. Thus, cancer management decision making in this population is complex due to the need to balance potential treatment benefits with possible side effects. When data to guide recommendations are limited, decisions about cancer treatment should rely on individual patient goals and preferences. Patients with cognitive impairment have varying degrees of decisional capacity and increasingly rely on care partners as their primary decision makers for complex cancer treatment decisions. Oncologists have very little knowledge and training on how to navigate this triadic interaction. Despite these complexities, there is no standard approach to guide oncology clinicians when discussing cognitive impairment in the context of cancer treatment decisions for patients with preexisting ADRD.

Our team has developed a Geriatric Assessment (GA)-guided communication tool for increasing and improving conversations about aging-related conditions in oncology (Improving Communication in Older Cancer Patients and Their Caregivers [COACH]). In a cluster-randomized trial of 541 older adults with advanced cancer and 414 of their care partners, the GA-guided communication tool increased care partner and patient **perceptions of "autonomy support", whereby they felt that their oncology clinicians were supportive and ensured cancer care was congruent with their values, as measured by the** Health Care Climate Questionnaire (4-6 week HCCQ; care partners [17.6 vs 16.3; p=0.005]; patients [17.4 vs 16.7; p=0.03]). In a secondary analysis of patients with an impaired cognitive screen enrolled in this study (N=175), the COACH GA intervention significantly increased the number of conversations specifically about cognition (63.4% of GA intervention patients versus 12.1% of usual care; p<0.0001). However, conversations were largely physician dominated and did not provide adequate conversational space for care partner or patient cognitive-related concerns. Additionally, the COACH GA intervention was not evaluated in patients with ADRD, and adaptation of the intervention for this population is needed.

We will adapt the COACH GA intervention for older adults with ADRD who are considering a decision about cancer management (adapted intervention: COACH-Cog). COACH-Cog adaptations will include: 1) brief, focused training for oncology clinicians about dementia in the context of cancer and communication training to navigate the triadic nature of these conversations with care partners providing decisional support and input, thereby enhancing oncology clinician *knowledge* and supporting their *decision processes*; and 2) care partner and patient Communication Coaching and Question Prompt List providing *knowledge*, *skills*,

and *behavioral cueing* for discussing their cognitive concerns and cognitive-related goals with their oncology clinicians. Experts in cognition, geriatric oncology, behavioral neurology, communication science, and palliative care as well as focus groups with stakeholders (care partners, patients, clinicians, experts in geriatric oncology and cognition) will guide these adaptations.

Aim: To gather key stakeholder input for feedback on the adaption of the COACH GA intervention (i.e., develop COACH-Cog) to enhance triadic communication among oncologists, care partners and patients with ADRD.

2. BACKGROUND AND RATIONALE

Alzheimer's Disease and Related Dementias (ADRD) are prevalent aging-related conditions in older patients with cancer.[1] The proportion of patients with concurrent diagnoses of dementia and cancer varies by cancer type and age, but it is estimated in population-based analyses to be approximately 7-10% of older patients with cancer.[2,3] Preexisting diagnoses of dementia are more common in patients who are older, female, Black, unmarried, less educated, and living in areas with a higher percentage of poverty.[3] A similar prevalence of patients with co-occurring cognitive impairment and cancer has been seen at our University of Rochester Wilmot Cancer Institute.[4] Given the aging demographics of the United States, the prevalence of older patients with ADRD who are diagnosed cancer will continue to grow.[5-9]

For older adults with cognitive impairment and cancer, medical decision making is more complex. Patients, care partners, and clinicians need to carefully consider competing comorbidities in the context of potential risks and benefits of treatment options.[10] Our group and others have demonstrated that advanced age and low cognitive reserve are associated with cognitive decline following exposure to cancer therapy.[11,12] Patients with pre-existing dementia at the time of cancer diagnosis have historically experienced worse cancer- related outcomes.[2,13] Patients with dementia are diagnosed at later stages of cancer and are more likely to experience side effects from cancer therapy,[3,14] although this paradigm may be shifting in the era of novel, targeted cancer treatments that have more favorable side effect profiles. For some patients, the benefits of cancer treatments outweigh the risks by minimizing the morbidity and symptoms from cancer, thereby improving quality of life. Older adults with cognitive impairment are not typically included in oncology clinical trials; thus the optimal approach to cancer treatment in these patients and how best to balance the potential risks and benefits of treatment are not well established.[10,15] When limited data exist, decisions about cancer treatment should rely largely on patient goals and preferences, as supported by care partners. Unfortunately, no standard approach has been developed for discussions about cognition among oncology clinicians, patients with pre-existing ADRD, and their care partners. Due to limited access to geriatricians and palliative care specialists, oncology clinicians are increasingly responsible for care coordination and management for older adults with ADRD and cancer.[16] An intervention for this population with a large potential to improve outcomes through better communication and more appropriate decision making for cancer treatment is highly desirable.

A Geriatric Assessment (GA) communication tool can facilitate conversations about aging-related conditions, including cognitive impairment, with older adults and their care partners.[17,18] In oncology, GA captures overall health status through patient-reported and coordinator-administered measures evaluating aging-related conditions.[19-21] Our group has developed a communication tool that integrates a GA summary with detailed care management recommendations for identified aging-related conditions. The GA communication tool increases discussions about aging-related conditions in the oncology setting.[17] Care partners and patients in the GA intervention arm perceive greater **autonomy support** and shared decision making with their oncology clinicians.[17] Autonomy support is an individual's perception of the degree to which they experience their health professionals as supporting choice and ensuring congruence with their values.[22,23] Autonomy support is based on self-determination theory, and greater autonomy support is hypothesized to lead to improved health outcomes.[24] However, our GA-based communication tool has not been studied in patients with pre-existing ADRD. Given the complex decision making as well as the unique incorporation of the care partner as a decisional support for patients with cognitive impairment and cancer, **adaptations are needed** to improve communication about cognition in the context of cancer management decision making for this population.

A critical gap in knowledge remains: How should oncology clinicians discuss cognitive impairment in the context of cancer management for patients with pre-existing ADRD who face a decision about cancer management? To address this gap in knowledge, we will extend our prior research by adapting our COACH GA communication tool (i.e., develop COACH-Cog) to enhance communication about cognitive impairment and acknowledge concerns about cognition and cognitive-related goals in the context of a cancer management decision through a multicomponent communication intervention to promote shared decisionmaking through autonomy support.

3. ADMINISTRATIVE ORGANIZATION

This study will take place through the University of Rochester Wilmot Cancer Institute.

4. STUDY DESIGN

This study will consist of focus groups to guide the adaption of a communication tool. We will collect qualitative data from the focus groups as well as socio-demographic data about subjects.

A total of 40 participants will be recruited for focus groups. Focus groups will be conducted with 2-10 participants per group. If subjects are unavailable to join a focus group meeting, they may be considered to participate in an individual interview instead of a focus group. Focus groups and interviews will be conducted via URMC's HIPAA compliant Zoom platform.

Focus groups will be conducted with the following stakeholders:
1) Medical oncologists
2) Clinicians with expertise in cognitive impairment and dementia
3) Older patients with cancer

4) Caregivers of patients with dementia or mild cognitive impairment. Of note, these caregivers are not necessarily taking part in any other aspect of the study.

There may be some subjects that fall into more than one of these groups and may be able to provided perspectives in one or more groups. If subjects identify as having perspectives from two or more groups (e.g. clinicians that are both oncologists but also have formal training in caring for older adults with cognitive impairment, such as clinicians dual trained in geriatrics and oncology), then we will count that individual as providing perspectives in both categories though they will be registered only once with the category they primarily identify with.

5. SUBJECT POPULATION

Participants for the focus groups will be drawn from the following stakeholders:
1) Medical oncologists
2) Clinicians with expertise in cognitive impairment and dementia
3) Older patients with cancer
4) Caregivers of patients with dementia

There may be some subjects that fall into more than one of these groups and may be able to provided perspectives in one or more groups.

The total number of participants enrolled will be 40 participants.

If thematic saturation is reached with subjects that completed the focus groups, we will not replace any subjects that withdrew from the study. During the conduct of the study, if thematic saturation is reached earlier than 40 participants, we will stop conducting focus groups/interviews earlier than 40 participants.

Inclusion of Vulnerable Populations:

☐☐This study does not involve adults with decisional impairments.

6. INCLUSION AND EXCLUSION CRITERIA

The inclusion and exclusion criteria for all participants are that they must be able to consent for themselves and must speak English.

The focus groups will be conducted in English and thus participants will need to be able to speak English to participate.

- For the medical oncologist focus group, participants must be a medical oncologist.
- For the clinicians with expertise in cognitive impairment and dementia focus group, participants must be a clinician that treats patients with cognitive impairment and dementia.
- For the older patients with cancer focus group, participants must be older than 65 years of age and have or had cancer.

- For the caregivers of patients with dementia focus group, participants must be caregivers of patients with dementia or mild cognitive impairment.

7. RECRUITMENT METHODS

Focus Group subjects will be recruited through several existing networks including:

- The Cancer and Aging Research Group (CARG)
- Community oncologists affiliated with UR NCORP
- Network of clinicians affiliated with the Roybal Center
- Clinicians affiliated with the Division of Geriatric Medicine at the University of Rochester
- Member of the Stakeholders for Care in Oncology and Research for our Elders (SCOREBoard), a patient advocacy group with longstanding ties to the geriatric oncology group at University of Rochester, including the PI[25]
- Wilmot Community Outreach and Engagement Office
- Caregivers of patients with MCI or dementia will be identified a few specific ways: 1) We will work with clinicians affiliated with the Division of Geriatric Medicine as noted above to help identify potential caregivers and with clinicians support and permission will approach potentially eligible caregivers. We will also work with clinicians at Wilmot Cancer Institute that would not be eligible to participate in subsequent phases of this study to identify potential caregivers and with clinicians support and permission will approach potentially eligible caregivers. 2) If necessary, we will also consider presenting our study at aging research support networks for clinical trials focused on dementia populations, such as the Recruitment Accelerator for Diversity in Aging Research (RADAR-CLD; this is an NIA funded network to support aging and dementia focused studies) or the University of Rochester Roybal Center. The Roybal center uses the HARP database project (STUDY00001252, PI: Heffner), which is a research registry by the current study's investigators, which affords direct contact with older caregivers who have previously agreed to be contacted for future research study participation. Contact information is collected and maintained via the IRB approved HARP database study. Registry participants are contacted by phone, email or letter and invited to be screened when new HARP studies become available. Dr. Kathi Heffner, a Co-Investigator, is a HARP database investigator. Presenting at these networks can facilitate recruitment of potential participants through disseminating knowledge about the study participation opportunity.

The study coordinator will meet with the potential subject in person or via phone and explain the purpose of the study.

8. CONSENT PROCESS

This research is no greater than minimal risk and involves focus groups for which written consent is normally *not* required outside the research context. We are requesting for waiver of documentation of consent as the research involves no more than minimal risk to the subjects. The only record linking the subject and the research would be the consent document and the

principal risk would be potential harm resulting from a breach of confidentiality. For this reason, we will use a verbal consent. A member of the study team will use the verbal consent script, then sign and date it to confirm that s/he followed the script and the subject agreed to participate in the study. Following the completion of verbal consent with the subject, the member of the study team will mail or email the subject a study information sheet that summarizes what the study entails and the subject's involvement in it.

9. STUDY PROCEDURES

Focus groups will be performed to adapt the intervention.

Once participants are identified and consented, the study coordinator will interface with participant as needed by email or phone to schedule focus group and other information needs. A Zoom link for the focus group will be sent out individually to participants by email.

Prior to or at the beginning of the focus group or up to one week after completion of the focus group, a brief questionnaire for socio-demographic data will be administered via RedCap. Following informed consent, the focus group participant will be sent a link to complete the questions via RedCap. If a participant prefers, the study coordinator can also verbally ask the survey questions to them via phone as an alternative method of administration. This form will gather participants name, age, race, ethnicity, gender, sex at birth, sexual orientation, marital status, living situation, education level, household income, employment status, primary language, insurance status, zip code, and information about the perspective that they are offering during the focus group. For clinicians this will include details about the number of years in practice and the approximate number of patients they see weekly. For caregivers, this will include information about the number of years in the caregiving role. For cancer survivors, this will include information about the time since their cancer diagnosis and general information about the type of treatment they previously received (e.g. surgery, radiation, chemotherapy, other). The PI or other trained study staff will conduct focus groups (2-10 participants per group) with the following stakeholders: 1) Medical oncologists, 2) Clinicians with expertise in cognitive impairment and dementia, 3) Older patients with cancer, and 4) Caregivers of patients with dementia. Field notes will be taken by a research coordinator observing and not moderating the discussion. A total of 40 participants will be recruited for focus groups. If subjects are unavailable to join a focus group meeting, they may be considered to participate in an individual interview instead of a focus group.

Focus groups and interviews will be conducted via URMC's HIPAA compliant Zoom platform. During the focus groups, the study team will screen share materials to prompt discussion and elicit feedback from focus group participants (see "other subject materials" submission for images that will be screen shared). Focus groups will last approximately one hour. These focus groups will be audio-recorded and transcribed into deidentified transcripts. Audio files and transcripts will be stored in a secure Box folder. After preliminary analysis of focus group transcripts, individual semi-structured interviews may be used to follow up on themes needing further elucidation if necessary.

10. AUDIO RECORDINGS

Audio recordings will be generated during focus groups by recording through the URMC HIPAA-compliant Zoom platform. Recordings will be used for data analysis. Recordings will be stored directly on HIPAA compliant URMC Box. Within the Box drive, data will be stored in a password protected folder with access restricted to the PI and a subset of study team members.

Audio recordings will be transcribed by a HIPAA compliant medical transcription company (Execuscribe, Inc) in a de-identified manner. All personal identifiers will be deleted (e.g. deidentified) from the transcriptions of the audio-recordings. Audio-recordings and transcripts will be stored on URMC Box and will be accessible only by the PI and relevant study staff. Audio recordings will be stored until 1 year after completion of all study procedures, and then destroyed. De-identified transcripts may be made available to other researchers per NIH/NIA guidelines.

11. RISKS TO SUBJECTS

An anticipated risk to subjects is loss of privacy/breach of confidentiality. All efforts have been made to mitigate loss of privacy. We are using URMC's HIPAA-compliant Zoom platform. Subjects will provide their email address in order to be sent a zoom link for the focus group. The Zoom link for focus group participation will be individually emailed to each participant and there will be no sharing of emails of other focus group participants.

During the course of the focus group, the subjects may self-disclose information about their

own experiences to the other subjects in the focus group. By agreeing to participate in a focus group, subjects are agreeing to share their experiences with other focus group participants. If patients are concerned about a privacy aspect from participating in a focus group, we could do an individual interview with them.

Another anticipated risk to subjects is potential distress resulting from topics discussed in the focus group. In the event of distress, the PI would be available to speak with subjects and provide a referral to social work and other support resources as needed.

12. POTENTIAL BENEFITS TO SUBJECTS

There are no anticipated potential benefits to individual participants from taking part in the research.

13. COSTS FOR PARTICIPATION

There are no costs that participants would be responsible for because of participation in this research.

14. PAYMENT FOR PARTICIPATION

We will compensate all subjects for their time with a gift card for $75 using the University of Rochester Advarra system. Payment will be provided after completion of the focus group. If a participant withdraws from the study before joining a focus group, they will not be

provided with payment. If a participant withdraws from the study before finishing (in the middle of a focus group), they will still be provided with the full payment.

15. SUBJECT WITHDRAWALS

There are not any anticipated circumstances under which participants would be withdrawn from the study without their consent. If a subject withdraws from the study at any point, we will retain and use data collected up until the moment of withdrawing from the study. If thematic saturation is reached with subjects that completed the focus groups, we will not replace any subjects that withdrew from the study.

16. PRIVACY AND CONFIDENTIALITY OF SUBJECTS AND RESEARCH DATA

All efforts have been made to mitigate loss of privacy. Subjects will provide their email address in order to be sent a zoom link for the focus group. The Zoom link for focus group participation will be individually emailed to each participant and there will be no sharing of emails of other focus group participants. We are using URMC's HIPAA-compliant Zoom platform.

During the course of the focus group, the subjects may self-disclose information about their own experiences to the other subjects in the focus group. By agreeing to participate in a focus group, subjects are agreeing to share their experiences with other focus group participants. Focus groups will be used to allow for exchange of viewpoints given the heterogeneity of the experiences in this population. Collective sharing may draw out richer insights regarding the intervention being adapted. If patients are concerned about a privacy aspect from participating in a focus group, we could do an individual interview with them.

Audio recordings of interviews will be stored directly on HIPAA compliant URMC Box. Within the Box drive, data will be stored in a password protected folder with access restricted to the PI and a subset of study team members. Audio recordings will be transcribed by a HIPAA compliant medical transcription company (Execuscribe, Inc) in a de-identified manner. All personal identifiers will be deleted (e.g. de-identified) from the transcriptions of the audio-recordings. Audio-recordings and transcripts will be stored on URMC Box and will be accessible only by the PI and relevant study staff. Audio recordings will be stored until 1 year after completion of all study procedures, and then destroyed.

Data will also be collected and managed by the research team at University of Rochester Medical Center using REDCap electronic data capture tools hosted at URMC. We will collect sociodemographic data about subjects and we will utilize REDCap to collect and manage this information. NIH (National Institutes of Health) is one of the organizations that may look at or receive copies of information in participants study records. As required by NIH, we will report participant demographic data to NIA CROMS (National Institute on Aging Clinical Research Operations & Management System).

URMC provides the following information on the REDCap program: "Vanderbilt University, in collaboration with a consortium of institutional partners, has developed a software toolset and workflow methodology for electronic collection and management of research and clinical

trial data, called REDCap (Research Electronic Data Capture). The REDCap system is a secure, web- based application that is flexible enough to be used for a variety of types of research. It provides an intuitive interface for users to enter data and real time validation rules (with automated data type and range checks) at the time of data entry. REDCap offers easy data manipulation with audit trails and functionality for reporting, monitoring and querying patient records, as well as an automated export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus). Through the REDCap Consortium, Vanderbilt has disseminated REDCap for use around the world. Currently, over 240 academic and nonprofit consortium partners on six continents with over 26,000 research end-users use REDCap."

De-identified transcripts may be made available to other researchers per NIH/NIA guidelines.

15. DATA / SAMPLE STORAGE FOR FUTURE USE

Once the focus group session is transcribed, the audio-recording of the session will be deleted within one year. Transcriptions of the focus group sessions will be deidentified and kept indefinitely on URMC Box accessible only by the PI and relevant research staff. Deidentified transcripts may be made available to other researchers per NIH/NIA guidelines.

16. DATA AND SAFETY MONITORING PLAN

Subjects will not be followed longitudinally. These participants will not be followed longitudinally. We will collect data on any adverse events that occur during the focus group that are attributable to the focus group. We do not anticipate any adverse events.

17. DATA ANALYSIS PLAN

Focus groups will be audio-recorded, transcribed, and imported to MAXQDA software for sorting, coding, and analysis. Focus groups transcripts will be supplemented by the transcript from the chat in Zoom and field notes taken by a research coordinator observing and not moderating the discussion.[26] Inductive content analysis will use a systematic classification process of coding to extract themes.[27] The PI (Magnuson) will train coders and guide the process.

18. REFERENCES

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