Do Reports That Capture the Age-Related Problems of Older Patients with Cancer Improve Doctor-Patient Conversations?—The COACH Study

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ABSTRACT

Background: Over 60% of cancers occur in older adults (aged ≥65 years), and the number of older adults with cancer is expected to grow as the population ages. Geriatric assessment (GA), which consists of a validated set of patient-centered measures that capture geriatric domains (e.g., physical function and cognition), can identify aging-related concerns important to older persons with cancer and their caregivers.

Objectives: The primary aim was to determine whether providing a web-generated GA summary with targeted recommendations to older patients with advanced cancer, their caregivers, and their oncologists could improve patient satisfaction with communication about aging-related concerns. Secondary aims were to determine whether the intervention could increase discussions about aging-related conditions during audio-recorded clinic visits, improve patient and caregiver quality of life (QOL), and improve caregiver satisfaction with communication about the patient’s aging-related conditions.

Methods: We used a cluster randomized clinical trial. Patients aged ≥70 years with advanced solid tumors or lymphoma and at least 1 impaired GA domain (captured by using GA during screening procedures) were enrolled from 31 practices affiliated with the University of Rochester Cancer Center National Cancer Institute Community Oncology Research Program. Oncology practices were randomized to intervention (GA summary plus GA-guided recommendations) or usual care (no summary or recommendations). The prespecified primary outcome was patient satisfaction with communication about aging-related concerns (measured by the modified Health Care Climate Questionnaire [HCCQ-age]; higher scores indicate greater satisfaction). The primary aim assessment was captured 7 to 14 days after the audio-recorded clinic visit by a telephone call and at 4 to 6 weeks, 3 months, and 6 months after enrollment (by paper). The first secondary outcome was the number of discussions about aging-related conditions; the clinic visit after conducting the GA was audio-recorded, transcribed, and analyzed by 2 blinded coders. Patient QOL (measured using the Functional Assessment of Cancer Therapy-General [FACT-G]), caregiver QOL (measured using the 12-item Short Form [SF-12]), and caregiver’s satisfaction with their own communication about the patient’s aging-related conditions (HCCQ-CGAGE) were captured at 4 to 6 weeks, 3 months, and 6 months from enrollment. Outcomes were analyzed using linear mixed models with study arm as the fixed effect, adjusting for the clusters (random effect).

Results: From 2014 to 2017, 541 eligible patients (293 in intervention) and 414 eligible caregivers (231 in intervention) were enrolled from 31 practice site clusters (17 intervention sites and 14 usual care sites). There were no significant differences in patient demographics by study arm (mean age, 77 years; 49% female). The mean age of the caregivers was 66.5 years; 74.9% were female, and 66.7% were a spouse or cohabitating partner. In 509 patients evaluable for the primary aim, the HCCQ-age score in the intervention arm was 1.09 points higher than that in usual care (95% CI, 0.05-2.13; *P* = .04; intraclass correlation coefficient [ICC], 0.02). In 528 evaluable patients, there was an adjusted mean of 8.02 discussions in the intervention arm, compared with 4.43 discussions in usual care (difference = 3.59 discussions; 95% CI, 2.2-5.0
discussions; \( P < .001; \) ICC = 0.14). The intervention did not improve the average change in patient QOL from baseline to 6 months (FACT-G difference = −0.23; SE, 1.03; \( P = .82 \)) or caregiver QOL (SF-12 difference = 0.59; SE, 0.82; \( P = .47 \)). Caregivers in the intervention arm were more satisfied with their communications 4 to 6 weeks after the clinical visit (HCCQ-CGAGE range, 5-20; difference = 1.05; 95% CI, 0.12-1.98; \( P = .03 \)) but not at 6 months (HCCQ-CGAGE adjusted means, 16.5 vs 15.6; adjusted difference = 0.83; 95% CI, −0.1 to 1.7; \( P = .07 \)).

**Conclusions:** This study is the first large multisite intervention study to demonstrate that providing a GA summary with GA-guided recommendations to community oncologists facilitates communication about aging-related concerns and improves patient satisfaction with communication and care. However, the intervention showed no difference on patient and caregiver QOL over the study period. This study demonstrates a practical model for implementation of the American Society of Clinical Oncology guidelines for geriatric oncology in community oncology clinics.

**Limitations:** Even though we adjusted for practice effect, there is a risk of bias inherent in cluster randomization. Other limitations are that the intervention was conducted at a single time point and not longitudinally, and only 1 visit was audio-recorded.
BACKGROUND

A growing population of older patients are at high risk for adverse outcomes from cancer treatment. Cancer is a disease of aging; approximately 60% of all cancers and 70% of cancer mortality occur in persons aged ≥65 years. The number of patients with cancer >65 years is projected to significantly increase over the next 20 years. Aging is a highly individualized process, characterized by an increased prevalence of health status conditions that can affect decision-making for cancer treatment, treatment tolerance, and, ultimately, outcomes. Older adults with cancer have a high prevalence of comorbidity, disability, and geriatric syndromes. The majority of older patients with cancer are treated based on extrapolations of evidence derived from clinical trials providing data on the safety and efficacy of treatment in younger patients or in older patients who are fit without other health status conditions. This study enrolled older cancer patients who also had other health status conditions to understand how best to improve their patient-centered outcomes.

Significance

Older adults with cancer and their caregivers are presented with complex information regarding the risks and benefits of treatment for advanced cancer, but aging-related concerns and outcomes are not usually discussed. Outcomes important to older adults with cancer include not only tumor shrinkage and progression-free survival (which are traditionally measured in clinical trials), but also the effect of treatment on quality of life (QOL) and geriatric domains (e.g., physical function, psychological status, cognitive abilities, social support). The geriatric assessment (GA), a validated mechanism to obtain patient-reported information about issues important to the older adult related to geriatric domains and the impact of medical problems on QOL, provides valuable information that could identify and help address the concerns of older patients with cancer and their caregivers (see “Components of the Comprehensive GA”). Evidence suggests that although underlying health status issues and deficits in geriatric domains correlate directly with the toxicity of chemotherapy and patient-centered outcomes, these considerations are not addressed in routine oncology clinical care. The commonly used Karnofsky Performance Status (KPS) and Eastern Cooperative Oncology
Group (ECOG) performance status (PS) measures do correlate with treatment toxicity, but these tools were validated in younger groups of patients and do not reliably predict outcomes in older adults with cancer.\textsuperscript{15-17} Additionally, these tools do not address critical domains that affect patient-centered outcomes, morbidity, and mortality in the older patient.\textsuperscript{14} GA can help define the “stage of aging by using fitness to define physiologic age (eg, fit, vulnerable, frail)”\textsuperscript{18} and better predict tolerance to treatment,\textsuperscript{19-21} adding important aging-related information that is not captured by traditional PS assessment tools used in oncology.\textsuperscript{22} A Cancer and Aging Research Group (CARG) study found that several GA variables predicted severe chemotherapy toxicities in older patients.\textsuperscript{23} It has also been shown that GA can predict overall survival in older patients with cancer.\textsuperscript{24} Studies have found that oncologists will modify treatment decisions based on GA results when information is provided to them.\textsuperscript{11,25} Recently, an American Society of Clinical Oncology (ASCO) guideline highlighted the value of GA for older patients with cancer.\textsuperscript{26}

Our research team has found that incorporating GA into the clinical decision-making process for older patients with cancer is feasible in oncology clinics and helps identify conditions (normally overlooked in routine oncology care) that are rated as very important to older patients and caregivers.\textsuperscript{10-13,23,27} We have also shown that the vast majority of older patients with advanced cancer and their caregivers want information on how cancer treatment can affect geriatric domains (eg, independence, mood, cognition).\textsuperscript{28} Unfortunately, clinical trial data that dictate evidence-based care for patients with cancer, the majority of whom are older with additional health status considerations, have not generally included GA.\textsuperscript{9}

**Gap in Knowledge**

There is a critical gap in knowledge regarding how to improve communication about aging-related concerns between older adults with cancer, their caregivers, and oncologists.\textsuperscript{27,29,30} The use of QOL assessments in clinical practice has been shown to monitor disease and treatment, improve the delivery of care, and detect physical or psychosocial problems that otherwise might be overlooked. For example, Detmar et al\textsuperscript{31} showed that providing physicians and patients with summaries of patient-reported QOL information
increased discussions and improved management of QOL issues in patients with cancer undergoing chemotherapy. Similarly, important patient-reported information obtained from GA could help oncologists address aging-related concerns of patients and their caregivers, thereby improving satisfaction with communication. Despite the fact that the majority of patients with cancer are ≥70 years, most oncologists have received little training in the care of older patients. As a result, common problems facing an aging population of patients with cancer may go unrecognized and produce serious consequences; for example, an older patient who has a history of falls is more likely to develop serious toxicity from chemotherapy.

Identification of aging-related concerns may also facilitate discussions about prognosis; this is important because many patients do not understand that cancer treatment is not curative in the setting of advanced cancer and can negatively affect QOL. Although GA predicts risk from cancer treatment and survival in older patients with cancer, before this study, there was no evidence-based approach regarding the use of GA to improve communication during the decision-making process for cancer treatment. Recently, an ASCO guideline highlighted the value of GA for older patients with cancer. However, the ASCO guideline acknowledges that there remains a critical gap in knowledge regarding how to implement GA to improve communication about aging-related conditions between older adults with cancer, their caregivers, and oncologists in community oncology practices, where the majority of older adults with cancer receive care. The hypothesis of this research proposal is that providing older patients with advanced cancer, their caregivers, and their oncologists with a summary of GA-derived information and targeted recommendations can improve communication (as assessed by patient and caregiver satisfaction with communication about aging-related health concerns and discussions about aging-related conditions captured during audio-recorded clinical encounters) and improve patient and caregiver-reported QOL.

**GA-Targeted Recommendations and Relevance to Older Patients With Cancer and Their Caregivers**

We hypothesized that providing a GA summary plus GA-guided recommendations to oncologists could improve patient-reported outcomes; this approach was similar to an early
Interventions guided by GA have positive effects on health outcomes, including prevention of disability and reduction in the risk of falls, unplanned hospitalizations, and nursing home admissions. Several studies have shown that the implementation of GA-guided recommendations into the clinical care of older patients with cancer is feasible. The ELCAPA study illustrated that providing GA information to oncology teams can influence treatment decisions, although outcomes from these interventions were not measured in this study. Another pilot study showed that GA affected the oncology treatment plan. In a study by McCorkle et al, geriatric nurse practitioners conducted GA with patients with cancer, and their intervention led to a survival advantage (a 67% rate for 2-year survival in the intervention group compared with 40% in the control group) and improved QOL. In a study by Goodwin et al, patients with breast cancer in the GA-guided recommendations group were significantly more likely to return to normal functioning than were those in the control group. Different approaches for chemotherapy selection and dosing for older and/or frail patients are supported by the literature and are incorporated as a GA-guided recommendation. For example, the FOCUS-2 trial found that chemotherapy for advanced colorectal cancer was safe and efficacious in an older and/or frail patient if started at a 20% dose reduction with escalation as tolerated. The GA and recommendations used in this proposal have been developed through preliminary work, an extensive review of the evidence, and the clinical expertise of the geriatric oncologists on the research team.

Funding Mechanisms

The study received support from PCORI under their “Communication and Dissemination” portfolio and the National Cancer Institute (NCI) through the University of Rochester NCI Community Oncology Research Program (NCORP) Research Base. The original primary aim funded by PCORI, a measure of direct communication about age-related concerns (now secondary aim 1), was highly valued by their reviewers, who agreed that the study would address a critical gap in knowledge regarding how to improve communication about aging-related concerns between older adults with cancer, their caregivers, and their oncologists. NCI valued the patient satisfaction with communication about aging-related concerns (primary
aim). In our discussions, the PCORI project oversight group agreed that communication and patient satisfaction with communication were both worthy outcomes of the study but stressed that we needed to fulfill our contractual obligations. Although we changed our primary aim to satisfaction with communication about aging-related concerns at the request of NCI, we retained the power analysis for the original primary aim in the concept, as (1) the primary aim required a similar sample size, and (2) this satisfied both NCI’s and PCORI’s priorities. This was a reasonable solution in the spirit of collaboration that adequately met the requests of both funding groups. As such, the primary end point discussed in this report is a measure of patient satisfaction with communication about aging-related concerns, and the first secondary outcome is a measure of direct communication about aging-related concerns (Appendix A).

Study Objectives

This was a cluster randomized study within the University of Rochester Cancer Center (URCC) NCORP Research Base network evaluating whether providing a GA summary plus GA-guided recommendations to patients, caregivers, and oncologists can (1) improve patient satisfaction with communication about aging-related concerns between patients, caregivers, and oncologists; (2) increase discussions about aging-related conditions during audio-recorded clinical visits between patients, caregivers, and oncologists; (3) improve patient and caregiver QOL; and (4) improve caregiver satisfaction with communication about aging-related concerns and patient and caregiver satisfaction with communication about overall health.

Primary Aim: Patient Satisfaction With Communication About Aging-Related Concerns

The primary aim was to determine whether providing a GA summary plus GA-guided recommendations to patients, their caregivers, and their oncologists would improve patient satisfaction with communication with their oncologist about aging-related concerns.

Hypothesis: Patient satisfaction with communication with the oncologist about aging-related issues will be significantly higher in the intervention arm than in the usual care (control) arm.
Secondary Aims

Secondary aim 1: direct communication about aging-related concerns. To determine whether providing a GA summary plus GA-guided recommendations to patients, their caregivers, and their oncologists increases discussions about aging-related conditions during clinic consultation.

Hypothesis: A higher number of aging-related conditions will be discussed and addressed in the intervention arm than in the usual care arm.

Secondary aim 2: patient and caregiver QOL. To determine whether initially providing patients, their caregivers, and their oncologists with a GA summary plus GA-guided recommendations before their treatment influences the QOL of older patients receiving cancer treatment and their caregivers.

Secondary aim 3: caregiver satisfaction with communication about aging-related concerns and patient and caregiver satisfaction with communication about overall health. To determine whether providing patients, their caregivers, and their oncologists with a GA summary plus GA-guided recommendations influences caregiver satisfaction with communication about aging-related concerns and patient and caregiver satisfaction with communication about overall health.
PARTICIPATION OF PATIENTS AND OTHER STAKEHOLDERS

The Communication on Aging and Cancer Health (COACH) study (URCC13070) followed a multidirectional approach with stakeholders at all levels. Stakeholders involved in this study included older patients, caregivers, geriatric oncology researchers, community oncologists (who make decisions and care for the majority of older patients with cancer), and the allied health care professionals who care for older patients with cancer (eg, nurses, nutritionists, therapists, social workers). A community-based participatory research approach was used (Figure 1); this included the development of materials through collaboration and an iterative review process that incorporated feedback from all stakeholders. These materials included research questions, policies, and programs and practices that affect the care and services that patients, families, and caregivers receive. The stakeholders were divided into the following groups: (1) Stakeholders for Care in Oncology and Research for our Elders Board (SCOREboard), an advisory board composed of older patients and caregivers; (2) the CARG; (3) NCORP, composed of community oncologists, principal investigators (PIs), and their research teams; (4) the U13 Oversight Board; and (5) the Specialized Oncology Care and Research in the Elderly (SOCARE) local partners (Figure 1, Table 1).

To maximize the engagement and participation of the stakeholders, we provided adequate time for each group to review, comprehend, and give feedback on the materials being developed. After discussions with stakeholders and the research team, all of the feedback was compiled, summarized, and reviewed by the research team to determine which ideas should be implemented. The final draft provided by the research team was reviewed by the stakeholders. Any additional changes were incorporated, and final materials were distributed and/or reviewed as a group for stakeholder approval.
Figure 1. Stakeholder Engagement Interactions, Definitions, and Process for Incorporating SCOREboard Input

Abbreviation: SCOREboard, Stakeholders for Care in Oncology and Research for our Elders Board.

- U13: U13 grant, “Geriatric Oncology Research to Improve Clinical Care”
- SOCARE: Specialized Oncology Care & Research in the Elderly
- URCC NCORP: University of Rochester Cancer Center NCI Community Oncology Research Program
### Table 1. Key Stakeholders and Responsibilities in SCOREboard’s Engagement

<table>
<thead>
<tr>
<th>Group name</th>
<th>Definitions and core responsibilities in engagement</th>
</tr>
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</table>
| **SCOREboard**     | **Definition:** “patient partners,” patients and caregivers who have either lived with the experience of being an older patient (aged ≥65 y) with cancer or caring for an older patient (aged ≥65 y) with cancer.  
 **Individuals and core responsibilities:**  
 *Entire board* – Provide feedback and make recommendations to the research team and other stakeholders based on their knowledge and personal experiences to guide the research process of the COACH trial.  
 *Chair* – Serves as the main liaison between the board and the research team; facilitates all board meetings |
| **Research team**  | **Definition:** Team of individuals at the University of Rochester NCORP Research Base working towards the successful completion of the COACH trial.  
 **Individuals and core responsibilities:**  
 *PI* – Primary person responsible for the design, conduct, and reporting of clinical trial; makes final decisions on all aspects of the study, using SCOREboard’s input to guide decisions.  
 *Project managers* – Serve as SCOREboard’s point persons on the research team; manage all SCOREboard activities and payments; compile homework assignments; organize all SCOREboard-related activities  
 *Co-investigators, technical and administrative staff, students* – implement SCOREboard’s input into the appropriate parts of the COACH trial. |
| **CARG**           | **Definition:** A group of geriatric oncology researchers dedicated to improving the care of older patients with cancer.  
 **Individuals and core responsibilities:**  
 Recommended potential SCOREboard members who met the criteria. |
| **U13 Oversight Board** | Consists of members from the National Institute on Aging, NCI, and CARG                                                                                                                                  |
| **URCC NCORP**     | Conducts multicenter nationwide cancer prevention and control, screening, and posttreatment surveillance clinical trials at community sites within the URCC NCORP Research Base network. |
| **SOCARE local partners** | Group of geriatric oncologists that runs referral-based consultative clinics that collect pilot data on patient preferences, outcomes, and GA-guided interventions in older patients with cancer. |

**Abbreviations:** CARG, Cancer and Aging Research Group; COACH, Communication on Aging and Cancer Health; NCI, National Cancer Institute; PI, principal investigator; NCORP, NCI Community Oncology Research Program; SCOREboard, Stakeholders for Care in Oncology and Research for our Elders Board; SOCARE, Specialized Oncology Care and Research in the Elderly; URCC, University of Rochester Cancer Center.
Older Patients With Cancer and Caregivers Advisory Board

The mission of SCOREboard was to provide feedback and make recommendations to the research team based on the knowledge and personal experiences of SCOREboard members, and to elevate the medical care, support services, and outcomes for patients aged ≥70 years with cancer. Therefore, SCOREboard members helped plan the study, assisted in determining the best way to approach and recruit patients, provided suggestions to members about recruiting methods, reviewed the content of the data to be collected, reviewed the method of collection (surveys and instruments), and addressed study-related issues that arose. The board is chaired by an older, experienced advocate for patients with cancer, with support from the PI and the project manager. Initially, there were 14 active participants on the board; at the end of the study, 10 active participants remained on the board. Members withdrew from participation due to declining health. The research team conducted weekly calls with the SCOREboard chair to give updates on the status of the study and to discuss the agenda items of the upcoming SCOREboard meetings. The SCOREboard chair met with the research team a minimum of twice a year in person: (1) during the annual NCORP meeting, and (2) in the spring when the chair was in town attending the annual Breast Cancer Coalition of Rochester meeting (another group with which she is actively involved). SCOREboard has met regularly almost every month to review study documents, study progress, data, and any study-related challenges.

Engagement with the research team and SCOREboard resulted in multiple benefits. Upon reflection, even though SCOREboard members were enthusiastic about engaging in the COACH trial as patient partners, many members recalled being reluctant in the past about participating in clinical trials, citing a misunderstanding of the true purpose of research as well as distrust in the researchers’ agendas (Table 2). This highlights the need for patient education as part of the clinical trial recruitment process, which can be achieved by incorporating patient partner groups into research teams beginning with the design phase of research studies. In doing so, patient partners can aid researchers in destigmatizing patients’ roles in clinical trials. As a direct result of being a SCOREboard member, all members report that, given the opportunity, they would participate in other stakeholder groups as patient partners (Table 2). Additionally, SCOREboard members who were initially reluctant to be a patient participant
stated that they would be more likely now to participate if approached because they are more comfortable asking questions about the nature of the research and their proposed responsibilities and associated risks due to participating in a previous clinical trial.

SCOREboard’s participation in the COACH trial has greatly influenced the way the research team now thinks about clinical research. Research questions are now better designed from the perspective of the patient population being studied. At the onset of every new research idea, the following questions are asked: (1) “How does this impact the patient population?” (2) “What are patients’ preferences?” and (3) “Are the questions framed in such a way that the average patient can understand?” Because of the tremendous benefit of engaging SCOREboard, all new research concepts (from the research team) are developed with detailed input from SCOREboard. The positive outcomes of actively engaging SCOREboard in the COACH trial were evidenced by researchers in the University of Rochester’s internal and external networks. SCOREboard’s input is now highly requested by researchers at the University of Rochester Medical Center during the development of research projects that focus on patients with cancer.
Table 2. Quotes from SCOREboard Members Concerning Effects of Active Engagement

<table>
<thead>
<tr>
<th>Initial reluctance to participate in clinical trials and changed attitudes</th>
</tr>
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<tbody>
<tr>
<td>• “I refused when I was approached by someone who just asked me to be in a research study when I had cancer. After being a SCOREboard member and seeing the need for clinical trials, I definitely would become a participant.”</td>
</tr>
<tr>
<td>• “I’ve been highly critical of PIs who say they have patient advocates as collaborators or partners in their study, when they’ve really only been tokens. At times I wondered if it was even possible to establish real partnerships between researchers and patients/patient advocates. Now I know it is possible.”</td>
</tr>
<tr>
<td>• “I learned of the reluctance of medical doctors to participate in research because of their time constraints even though the research may be helpful to them in the long run. I particularly appreciate the fact that questions are raised about the efficacy of treatments and then research is conducted in a fair and honest manner to ascertain answers as clearly as possible.”</td>
</tr>
<tr>
<td>• “Before participating with SCOREboard, I had the stereotypical impression that clinical trials were conducted using only new or experimental drugs. I didn’t realize that the term ‘clinical trials’ could in fact be anything that enhances people’s lives.”</td>
</tr>
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<table>
<thead>
<tr>
<th>Language and communication in study</th>
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<tbody>
<tr>
<td>• “The impact of language on the anticipated results was shown to be very important, as became evident in so many of the SCOREboard discussions. It was enlightening and rewarding to hear members of SCOREboard be so vehemently careful about the language that was to be used in the recruitment and in the study.”</td>
</tr>
<tr>
<td>• “We had lengthy discussions about words—something I think was very valuable. To deliberate on simple words, such as ‘elderly,’ and to find new ways to designate the populations with whom we were trying to communicate; would ‘older,’ or ‘senior,’ or other words be a better way to address an older population? Did we need to establish a gentler way to communicate? To help our patient population feel more at ease for participating in the clinical trial?”</td>
</tr>
<tr>
<td>• “I have found that what resonated with me perhaps more than any single part of this experience was the critical importance of authentic communication among ALL stakeholders.”</td>
</tr>
<tr>
<td>• “I have a much better understanding of the differences in the various funding NCI mechanisms and PCORI. I’ve been reminded of the importance of continuing open communication, of establishing clear guidelines, of maintaining enough of a workload to keep people engaged without overburdening them, and of assurance that people see the results of their work.”</td>
</tr>
</tbody>
</table>
Takeaways/what was learned

• “I learned how clinical trials helped in the battle against cancer. Cancer patients and their caregivers should participate in clinical trials. It would be a good way to prove that a patient with a positive attitude has a much better chance of survival.”

• “I am learning a great deal in several different areas. For instance, I did not know about the work required to recruit subjects for research. I did not know that people are hired and trained to recruit. It is also interesting the amount of care for the subjects that is included in the planning.”

• “I learned something about the amount of work that is required in the preparation of a research project: how the interest of each of the stakeholders—patients, doctors, staff, funders—must be respected and honored.”

Abbreviations: NCI, National Cancer Institute; PIs, principal investigators; SCOREboard, Stakeholders for Care in Oncology and Research for our Elders Board.
Cancer and Aging Research Group

The CARG is a group of geriatric oncology researchers across the nation with a collaborative effort to design and implement clinical trials to improve the care of older adults with cancer. The PI and the research team had biweekly meetings with CARG members from City of Hope Comprehensive Cancer Center and the University of Chicago. Portions of the GA-guided recommendations were presented on CARG conference calls for feedback approximately every other week during the study. After the GA-guided recommendations for each domain had been shared and reviewed by the CARG, teleconferences were held with a select number of experts in each domain to finalize the intervention recommendations used in the COACH study.

The PI and research team worked with City of Hope to develop and implement the GA intervention on their website, http://www.mycarg.org. The website, a location designated to this study, was built to include GA-specific domain scoring and subsequent GA-guided recommendation forms generated and printed per patient based on the domains found to be impaired. In addition, domain-specific handouts for physicians, patients, and patient caregivers were developed using input from CARG stakeholders. Handouts and GA-guided recommendation forms were printed from the mycarg.org website based on the patient’s impaired domains. CARG stakeholders and University of Chicago colleagues also collaborated with SCOREboard to develop a telephone call script that was used when calling study patients to assess satisfaction with communication with their oncologist about aging-related concerns after the audio-recorded baseline visit.

NCORP Oncologists and Clinical Research Staff

The URCC NCORP was used as the infrastructure for this study. The URCC NCORP network enrolls patients from community oncology practices throughout the United States (Appendix B). The URCC Research Base serves as the coordinating site. One of the important events used to promote NCORP affiliate sites’ participation (ie, oncologist engagement) in
Research Base activities is the annual URCC NCORP meeting. This 2-day meeting is held in Rochester, New York, every year in September. Members of every active NCORP affiliate are represented; this meeting encourages an open forum to discuss each individual NCORP affiliate’s interest in ongoing studies, provides updates on studies in progress, and openly discusses any study-related challenges. During the September 2013 NCORP meeting, several barriers limiting recruitment on the COACH trial were discussed openly with both study coordinators and site investigators. As a result, the study was amended to modify eligibility criteria and simplify study-related documents. In addition to the annual meetings, webinars were offered frequently by the study PI to facilitate engagement between the community sites and the Research Base; these webinars allowed the research team to receive feedback about the study and to incorporate this feedback to improve the study, increase patient and caregiver recruitment, and encourage connection and understanding between the Research Base and the clinical research staff and physicians at the community sites. Over 30 webinars were presented between 2014 and 2017, ranging from resolving issues that arose during the study, such as how to complete the prescreening log and how to submit audio recordings, to ways to remind patients that they would be receiving a study-related telephone call and sharing site tips on enrollment strategies.

Project managers at the URCC NCORP Research Base also offered regular study-specific trainings to clinical research staff and physicians; training materials, study documents, study manuals, and past webinars were made available on the URCC NCORP website. An example of study-specific training offered was how to conduct the GA via the Geriatric Assessment Procedures Manual. This manual provided in-depth instruction that could not feasibly be covered during trainings and provided guidelines for administering and scoring each assessment (Figure 2).
Figure 2. Excerpt From GA Procedures Manual

Nutritional Status Administration
Obtain patient’s current height, current weight AND past weight from the medical chart. If not in the chart, ask the patient what his/her weight was 6 months ago. You will then calculate and record % weight loss per instructions on the questionnaire.

1. Patient’s current height? _______ inches

2. Patient’s weight:
   a. Weight approximately 6 months ago? _______ pounds
   b. Current weight? _______ pounds
   c. Approximate weight loss over 6 months? _______ pounds

Use a regular calculator to complete this question.

d. Percent weight loss: _______ Percent

Use a regular calculator to complete this question.

\[ d = \left( \frac{c}{a} \right) \times 100 \]

Divide line c by line a. Then multiply the answer by 100. This is the approximate percentage lost over 6 months.

• The percent of weight lost is another score that is recorded on the GA Scoring Guide.
  • If the weight loss percentage is 10% or more, the subject met the cut-off score for impairment.

Abbreviation: GA, geriatric assessment.
U13 Oversight Board

The U13 grant “Geriatric Oncology Research to Improve Clinical Care” is a cooperative conference grant between the CARG in collaboration with the Geriatrics and Clinical Gerontology branch of the National Institute on Aging (NIA) and the NCI. The mission of this conference grant program is to provide a forum for a multidisciplinary team of investigators in geriatrics and oncology to review the present level of evidence in geriatric oncology, identify areas of highest research priority, and develop research approaches to improve clinical care for older adults with cancer within the next 10 years. The U13 oversight board includes representatives from organizations invested in improving clinical care for older adults with cancer. The oversight board has met through routine conference calls (every 6 months) and during the U13 meetings. In 2010, the CARG received a U13 grant in collaboration with the NIA and NCI, and the CARG conducted its first conference (Biological, Clinical, and Psychosocial Correlates at the Interface of Cancer and Aging Research) on September 25 and 26, 2010; the second conference (Design of Therapeutic Clinical Trials for Older and/or Frail Adults) was held on November 17 and 18, 2012; and the third conference (Design and Implementation of Intervention Studies to Maintain or Improve the Quality of Survival of Older and/or Frail Adults with Cancer) was held on May 14 and 15, 2015. Conference speakers from multiple disciplines summarized the current evidence in geriatric oncology, outlined knowledge gaps, and highlighted the strengths and limitations of proposed research study designs such that they could be addressed to improve future geriatric oncology research; the COACH study was 1 such study. These meetings provide a forum during which researchers receive feedback on ongoing research studies. The efforts from U13 have been widely disseminated in high-impact journals and at clinical conferences (ie, ASCO and American Geriatrics Society), reaching a wide audience. SCOREboard members also attended CARG/U13 conferences, and members participated in creating multiple publications that were produced from these conferences. As a next step, Dr Mohile, along with other CARG investigators (W.D. and A.H. at City of Hope), applied for and received an NIA R21/R33 grant to develop infrastructure for geriatric oncology research on behalf of the CARG. The COACH study will be shared as a resource for other
investigators in this initiative, and SCOREboard will continue to be funded as a resource for geriatric oncology investigators across the country.

**SOCARE Local Partners**

Dr. Mohile directs a referral-based consultative SOCARE clinic that has collected pilot data on patient preferences, outcomes, and GA-guided interventions in 200 older patients with cancer. All measures and the GA intervention in this research were used within the SOCARE clinic. Patients were referred to the clinic by their primary oncology team. As routine in the clinic, each patient completes the GA by pencil and paper, and summaries of the results are provided to the patient and their caregivers. Ratings of each GA domain and acceptability/understanding of the GA summaries are assessed. GA-guided interventions, developed by the SOCARE team, are provided to the referring physician, the patient, and the patient’s caregivers. The measures and GA recommendations used in this study were based on those developed and used in the SOCARE clinic; the GA was further refined by stakeholder input for this study and for a multicenter research environment. The SOCARE geriatric oncologists and SOCARE database have continued to inform our study regarding the GA. The patients and caregivers seen as part of SOCARE have continued to inform what is most important in the care of an older patient with advanced cancer.
METHODS

Study Overview

This cluster randomized study evaluated whether a standardized comprehensive GA administered through a novel web-based approach can facilitate communication of aging-related problems that could influence outcomes important to the older patient with cancer and their caregivers. Adults aged ≥70 years with an advanced solid tumor or lymphoma malignancy in the URCC NCORP network were eligible. Oncologists who practiced at sites within the URCC NCORP network were also enrolled as participants. Eligible patients from enrolled oncologists were consented, and those who agreed to participate underwent a clinical assessment consisting of collecting sociodemographic characteristics and GA. Eligible patients then chose a caregiver aged ≥21 years on whom they relied. Patients with no eligible caregivers were still permitted to enroll in the study if they received permission from the URCC NCORP Research Base before enrollment. Community oncology practices were randomized to either the intervention or usual care.

Study Design Overview

The study was designed as a cluster randomized trial (randomization unit is the community oncology practice) because a care-of-service model is applied to each patient by the oncology team (Figure 3). If a cluster randomized design was not undertaken, there could be contamination, as oncologists would be able to choose their preferred care-of-service model if exposed to patients randomly assigned to both arms. In the intervention arm, oncologists, patients, and patient caregivers were provided with the GA summary plus GA-guided recommendations. In the usual care arm, no GA summary or recommendations were provided to the oncology teams, but an alert was provided to the oncologist if the patient scored positively on tests indicating potentially clinically significant depression or cognitive impairment. Given rapid changes that can occur in oncology practice with new supportive care and treatment agents, it was important to compare outcomes in the same period as would be possible in a cluster randomized study design compared with a “pre- vs postintervention” study design.
Figure 3. Study Design for the COACH Trial

Abbreviations: COACH, Communication on Aging and Cancer Health; GA, geriatric assessment.
Study Participants and Eligibility

NCORP community oncology practices vary in their size, number of practice locations, and geographical catchment area. NCORP practice sites were randomized within a 2-arm cluster randomized design using NCORP practice sites as the unit of randomization. An NCORP practice was defined as any practice location within an overarching NCORP designation where oncologists and study staff work independently (ie, did not cross over into another practice site).

The study involved adult human participants. Study participants included oncologists, patients, and patient caregivers. Accounting for a small dropout rate of 5% (based on our observational cohort data23), the targeted accrual was 528 patient participants total. The dropout rate reflects patients who signed consent but withdrew before the audio-recorded baseline visit and the use of the modified Health Care Climate Questionnaire (HCCQ) to capture satisfaction with communication about aging-related concerns (which occurred within 7-14 days of the baseline visit). There was no limit placed on the number of oncologists enrolled in the study.

Potential participants were identified through our prescreening procedures and were tracked using a dedicated screening log, where all patients and their caregivers who were approached for the study were recorded. Patients completed GA during screening to determine eligibility (see Figure 4). The reasons why patients and caregivers who were approached but never registered at screening visit were meticulously recorded. Program managers at the URCC NCORP Research Base reviewed the screening logs on a biweekly basis and reached out to sites when there were missed opportunities (ie, if a patient was mistakenly marked as ineligible, or there was no further information on a patient who was approached). Patients who signed a consent form but were never enrolled (baseline registered) were defined as either screen failure (ie, a patient agreed to participate but could not enroll because he or she was not eligible) or screen withdrawal (ie, a patient was eligible but decided not to participate in the study). These instances were captured on the patient withdrawal form.
Figure 4. Outline for Study-Specific Procedures

**Usual Care Site (Arm 2)**

- **Oncology Physician Enrollment – Baseline survey on REDCAP**
  - Subject Identification Process

- **Screening: Visit 0**
  - Consent patient & caregiver, complete screening registration.
  - If time permits, administer GA measures (cognitive, physical performance, and nutrition) to patient.
  - Subjects (patient and caregiver) complete screening packet during visit or take the screening packet & baseline packet home with them to complete prior to the baseline visit.
  - CRA completes CRA screening study forms.
  - Confirm subjects will bring completed packets to next visit or schedule additional time if needed to complete at visit.

- **Score GA & Complete Baseline Registration**
  - When patient and CRA screening forms complete, score each GA measure as per training procedures (at screening or beginning of baseline visit prior to study visit with oncology physician).
  - Complete baseline registration for patient & caregiver if patient has 1 or more domains that meet cut-off score for impairment (other than polypharmacy).

- **Baseline: Visit 1 – Usual Care**
  - Inform oncology physician if depression (GDS) or cognition (BOMC) assessments score ≥ 11.
  - Study visit with oncology physician occurs – audio record this visit
  - Oncology physician completes forms about patient
  - Submit all materials to URCC within 7 days.

- **Baseline: Visit 1 – Intervention**
  - CRA enters GA Score on MYCARG.ORG
  - Print and provide GA summary and recommendations forms to oncology physician, patient and caregiver.
  - Information on cognitive impairment or depression is included in summary.

- **Telephone Team Call to Patient within 1 to 7 days of Baseline Visit**
  - Health Care Climate Questionnaires will be obtained via a phone call administered by trained personnel blinded to group assignment within 1 to 7 days of the baseline audio-recorded clinic consultation.

- **All Follow-up Visits: Visit 2*, Visit 3, Visit 4**
  - (Visits are 4 to 6 Weeks, 3 months, and 6 months from Baseline)
  - **Before Visit:** Confirm patient & caregiver will bring completed packets to study visit.
  - **During Visit:** Administer cognitive and physical performance measures and complete CRA study forms.
  - **After Visit:** Submit all forms to URCC Research Base within 7 days.

*Intervention Arm ONLY: CRA complete GA-driven recommendation follow-up forms at visit 2

**Abbreviations:**
- BOMC, Blessed Orientation Memory Concentration
- CRA, clinical research associate
- GA, geriatric assessment
- GDS, Geriatric Depression Scale
- REDCAP, Research Electronic Data Capture
- URCC, University of Rochester Cancer Center.
Entry Criteria for Oncologists

Oncologists must have worked at an NCORP practice site with no plans to leave that NCORP practice or retire at the time of enrollment in the study.

Entry Criteria for Patients

_Inclusion criteria._

- ≥70 years, male or female.
- Diagnosis of an advanced solid tumor malignancy (advanced cancer) or lymphoma. In most situations, this would be a stage IV cancer. A patient with a diagnosis of stage III cancer or lymphoma was eligible if a cure was not possible or anticipated. Clinical staging without pathological confirmation of advanced disease was allowed.
- Was considering or receiving any kind of cancer treatment (any line), including but not limited to hormonal treatment, chemotherapy, monoclonal antibody therapy, or targeted therapy. Patients who were considering therapy were eligible even if they ultimately chose not to receive it. Patients with a history of any previous cancer treatment, including radiation and/or surgery, were eligible. A patient could also participate in this study if they had been enrolled in a previous treatment trial if all other inclusion criteria were met and exclusion criteria were not met.
- Had at least 1 GA domain meet the cutoff score for impairment other than polypharmacy (see “Components of the Comprehensive GA”).
- Had visits planned with the oncologists for at least 3 months and was willing to come in for study visits.
- Was able to provide informed consent or, if the oncologist determined that the patient did not have decision-making capacity, a patient-designated health care proxy (per institutional policies) must have signed consent by the baseline visit.
- Had an adequate understanding of English, because not all GA measures have been validated in other languages.
Exclusion criteria.

- Had surgery planned within 3 months of consent. Patients who had previously received surgery were eligible.
- Had already made a decision to not undergo any cancer treatment (eg, being followed in best supportive care or hospice).

Entry Criteria for Caregivers

Inclusion criteria.

- Selected by the patient when asked if there is a “family member, partner, friend or caregiver [≥21 years] with whom you discuss or who can be helpful in health-related matters”; patients who could not identify such a person (“caregiver”) were eligible for the study. A caregiver did not need to be someone who lived with the patient or provided direct hands-on care. A caregiver could be any person who provided support (in any way) to the patient.
- If a health care proxy signed consent for or with a patient and wanted to participate in the caregiver portion of the study, this same person was always the caregiver selected. If a health care proxy did not want to enroll as a caregiver in the study or, if enrolled, chose to stop their own participation in the caregiver portion of the study but was able to assist the patient in completing the study, the patient could still participate. In other words, the health care proxy could have chosen NOT to participate in the caregiver portion of the study. This did not preclude the patient from participating in the patient portion of the study with the health care proxy’s assistance.

Exclusion criterion.

- Caregiver was unable to understand the consent form due to cognitive, health, or sensory impairment.
Interventions and Comparators

Because the GA is not performed by community oncologists and the COACH study allowed patients/caregivers/oncologists to choose their cancer treatments, a usual care comparator arm was appropriate and allowed for an accurate and proper assessment of how the intervention could improve communication about aging-related issues and outcomes compared with current clinical practice. This study design is similar to those of previous studies that evaluated the impact of providing summarized QOL information to patients and oncologists on communication and outcomes. Usual care was the comparator arm in these cluster randomized studies.31,46

Outcomes

Primary Outcome

Patient satisfaction with communication about aging-related concerns. The HCCQ-PTOVERALL47-50 measures patient-centered autonomy-supportive physician behaviors and satisfaction with communication, such as whether the patient and caregiver feel that the physician understands the patient’s perspective, provides choices and options, and encourages participation in decisions. The measure has been studied and validated for use with older patients.47-49 Similar to other studies that adapt satisfaction scales to capture specific clinical criteria (eg, satisfaction with the physician regarding communication about chemotherapy),51 the original HCCQ (HCCQ-PTOVERALL) was modified for this study (HCCQ-age) to specifically determine if providing a GA summary plus GA-guided recommendations to patients, patient caregivers, and oncologists improves patient satisfaction with communication with the oncologist about aging-related concerns rather than satisfaction with other aspects of cancer care (eg, communication about cancer treatment). HCCQs (both HCCQ-age and HCCQ-PTOVERALL) were administered 7 to 14 days after the baseline audio-recorded clinic visit.52-55 HCCQ-age was used for the prespecified primary aim. These measures were obtained via a phone call administered by trained personnel blinded to the study arm (or mailed if a telephone call within 12-14 days of the baseline visit was not feasible). In the cases where collection of data postvisit was not feasible, the 4- to 6-week visit HCCQ-age and HCCQ-PTOVERALL data
were used in their place. Data from measures for satisfaction with communication about aging-related concerns were also collected at the 4- to 6-week, 3-month, and 6-month follow-up visits. Both HCCQ-age and HCCQ-PTOVERALL are located in Appendix C.

Pilot data to inform this study’s analysis was gathered from Dr Epstein’s previous studies; he has extensive experience with the use of the HCCQ-PTOVERALL and has captured data from this measure in 81 patients similar to those who were recruited for the present study (ie, older patients with advanced cancer). Patients were recruited to Dr Epstein’s NCI-funded study (ie, the Valuing Opinions, Individual Communication, and Experience [VOICE] study) that evaluated a coaching intervention to improve physician communication behaviors. Because the VOICE study used a cluster randomized design, an intracluster correlation coefficient (ICC) was estimated from existing data to assist with sample size calculations for the current proposal. Ceiling effects are common with HCCQ-PTOVERALL and with patient satisfaction scales in general, although the modified version likely has less of a ceiling effect due to its focus on the specific clinical scenario (ie, aging). Despite the ceiling effects, policy makers have used patient satisfaction as a key measure for reimbursement in clinical practice, with a focus on obtaining “perfect” scores.

**Secondary Outcome 1**

*Direct communication about aging-related concerns.* This important aim was to evaluate if GA intervention increased discussions about aging-related issues between patients, caregivers, and oncologists. For this aim, the first medical consultation after GA administration was audio-recorded. Audio recordings were sent to the URCC NCORP Research Base, where they were transcribed and coded for the quantitative analysis of the communication processes, including the number of questions asked and topics discussed. The methodology was established in previous work by Dr Epstein’s group.

To ensure the rigor and reproducibility of the coding of transcripts, we undertook multiple steps. A detailed code book was developed, and all coding procedures were outlined (Appendix D). Extensive training (>40 hours) was conducted with all coders, including the PI and
co-investigators with content analysis expertise. For each transcript, coding was performed independently by 2 trained coders who were blinded to arm assignments. A consensus coding was developed for every transcript. The coding schema included definitions for each code and the specific steps the coders followed during the coding process. The coding procedures involved an initial reading of the transcript to identify specific geriatric concerns and the initiator of the concerns, followed by a second reading in which physician response quality and interventions implemented due to concerns were discussed. Five coders were involved in the coding process, and their presence remained stable throughout the study. They underwent extensive training, including practice transcripts and use of the coding manual. The PI remained involved in the coding process and provided guidance or adjudication when necessary.

In addition to double coding all transcripts, all 5 coders coded 20% of the transcripts to further maintain interrater reliability. For each transcript, whether dually coded or coded by the entire coding team, a consensus was agreed upon, and a final consensus code was recorded. Interrater percentage agreement was monitored and, if it fell below 70%, which is considered acceptable for interrater reliability on narrative coding, the coding team would require additional training; the interrater percentage agreement never fell below 70%. Interrater reliability assessment is discussed under “Data Source for Secondary Aim 1.”

Secondary Outcomes 2 and 3

Patient and caregiver QOL, caregiver satisfaction with communication about aging-related concerns, and patient and caregiver satisfaction with communication about overall health. Secondary outcomes included health-related QOL as measured by the Functional Assessment of Cancer Therapy-General (FACT-G), caregiver QOL (burden) as measured by the Caregiver Reactions Assessment (CRA), and the 12-Item Short Form (SF-12). The FACT-G, a 27-item questionnaire, was used to assess health status in terms of 4 QOL dimensions: physical well-being, emotional well-being, social well-being, and functional well-being. We hypothesized that the mean QOL for patients and caregivers at sites randomized to the intervention arm would be higher than for those in the usual care arm at 4 to 6 weeks.
following the intervention and that this increase would be both statistically significant and clinically meaningful (5%-10%). Other secondary outcomes included caregiver satisfaction with communication about the patient’s overall health (HCCQ-COVERALL), the caregiver’s views about the patient’s satisfaction with communication about aging-related health concerns (HCCQ-PTAGE), the caregiver’s satisfaction with caregiver’s communication about the patient’s aging-related health concerns (HCCQ-CGAGE), and the patient’s satisfaction with communication about overall health (HCCQ-PTOVERALL) at 4 to 6 weeks, 3 months, and 6 months after enrollment.

We conducted exploratory analyses to determine whether underlying frailty (increased GA impairment) in older patients with advanced cancer is associated with communication about aging-related concerns.

**Data Sources and Measures Collected**

**Components of the Comprehensive GA**

The comprehensive GA includes 8 domains (ie, physical performance, functional status, cognition, psychological status, nutrition, comorbidity, social support, and polypharmacy) captured in 17 assessments (see Appendix E). The assessment tools comprising the comprehensive GA are listed in Table 3. The various assessment tools were selected based upon extensive data in the geriatric literature demonstrating predictive value, as well as feasibility data, in multiple studies of older adult patients with cancer. Other than the cognitive and physical performance measures, the assessments were self-administered. Patients who could not complete the assessment on their own received assistance from study personnel or from a caregiver. The GA was performed before baseline registration, and follow-up GA measures were collected at 4 to 6 weeks, 3 months, and 6 months. The GA was performed with patients in both study arms.
<table>
<thead>
<tr>
<th>Domain</th>
<th>Tool(s)</th>
<th>Score signifying impairment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical function</td>
<td>• ADLs</td>
<td>• Any ADL deficit</td>
</tr>
<tr>
<td></td>
<td>• IADLs</td>
<td>• Any IADL deficit</td>
</tr>
<tr>
<td></td>
<td>• Fall history</td>
<td>• Any history of falls</td>
</tr>
<tr>
<td></td>
<td>• OARS physical health</td>
<td>• A lot of difficulty with any task</td>
</tr>
<tr>
<td>Objective physical performance</td>
<td>• Short Physical Performance Battery</td>
<td>• ≤9 points</td>
</tr>
<tr>
<td></td>
<td>• Timed “Up and Go”</td>
<td>• &gt;13.5 seconds</td>
</tr>
<tr>
<td>Comorbidity</td>
<td>• OARS comorbidity</td>
<td>• Patient answered “yes” to ≥3 chronic illnesses</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 1 illness interferes “a great deal” with QOL</td>
</tr>
<tr>
<td>Nutrition</td>
<td>• BMI</td>
<td>• &lt;21</td>
</tr>
<tr>
<td></td>
<td>• Mini Nutritional Status</td>
<td>• ≤11 points</td>
</tr>
<tr>
<td></td>
<td>• Weight loss</td>
<td>• &gt;10% from baseline weight</td>
</tr>
<tr>
<td>Social support</td>
<td>• OARS Medical Social Support</td>
<td>• Patient answers 1 of the social support questions indicating less-than-adequate support for care</td>
</tr>
<tr>
<td>Polypharmacy</td>
<td>• Polypharmacy</td>
<td>• ≥5 regularly scheduled prescription medications OR</td>
</tr>
<tr>
<td></td>
<td>• Lab</td>
<td>• Any high-risk medication OR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Creatinine clearance &lt;60 ml/min</td>
</tr>
<tr>
<td>Psychological</td>
<td>• GAD-7</td>
<td>• ≥10 points</td>
</tr>
<tr>
<td></td>
<td>• Geriatric Depression Scale</td>
<td>• ≥5 points</td>
</tr>
<tr>
<td>Cognition</td>
<td>• BOMC test</td>
<td>• ≥11 points</td>
</tr>
<tr>
<td></td>
<td>• Mini-Cog</td>
<td>• 0 words recalled OR 1-2 words recalled + abnormal clock drawing test</td>
</tr>
</tbody>
</table>

Abbreviations: ADLs, activities of daily living; BMI, body mass index; BOMC, Blessed Orientation Memory Concentration; GAD-7, 7-item Generalized Anxiety Disorder; IADLs, instrumental activities of daily living; OARS, Older Americans Resources and Services; QOL, quality of life.
**Patient Measures for Primary Aim**

Patients received a call from the telephone team that orally administered both HCCQs (HCCQ-PTOVERALL and HCCQ-age) within 7 to 14 days of the baseline visit by trained personnel blinded to the study arm (or mailed if a telephone call within 2 weeks of the baseline visit was not feasible). In cases where obtaining postvisit data was not feasible, the 4- to 6-week visit HCCQ-PTOVERALL and HCCQ-age data were used in their place. The HCCQ-PTOVERALL\textsuperscript{47-50} measures patient-centered autonomy-supportive physician behaviors and satisfaction with communication, such as whether the patient and caregiver feel that the physician understands their perspective, provides choices and options, and encourages participation in decisions (Appendix C). Similar to other studies that adapt satisfaction scales to capture specific clinical criteria (eg, satisfaction with the physician regarding communication about chemotherapy),\textsuperscript{51} the HCCQ-PTOVERALL was modified for this study (HCCQ-age; score 0-28, with higher scores signifying higher satisfaction with communication about aging-related concerns) to specifically address patient satisfaction with oncologist behaviors and communication regarding aging-related concerns (Appendix C). We describe how missing data were handled under “Changes to Study Protocol” as well as the protocol itself and the statistical analysis plan.

**Data Source for Secondary Aim 1**

As part of baseline procedures, the baseline clinic visit was audio-recorded after the GA was performed in both arms and after the GA summary and GA-guided recommendations were generated via \url{http://www.mycarg.org} for the intervention arm. All enrolled patients (intervention arm and usual care arm) had 1 office visit (baseline visit) with their caregiver and participating oncologist audio-recorded. All parties present for recorded office visits, including enrolled patients, any accompanying caregivers, family or friends, the oncologist, and any other physicians or health care providers not participating in the study, were fully aware that the conversation was going to be audio-recorded and provided their consent. The audio recordings were transcribed and deidentified, and coding was performed independently by 2 trained coders who were blinded to the arm assignment.
**COACH coder interrater reliability.** To establish interrater reliability between coders, all 5 coders coded 20% of all transcripts. These transcripts were allocated over the entire duration of time that coding was conducted to monitor ongoing agreement among all coders. Transcripts were randomly assigned to each coder. Every fifth transcript was coded by all coders, and to prevent coding drift, the teams of coders alternated. Table 4 explains the coding strategy.

**Table 4. Coding Strategy**

<table>
<thead>
<tr>
<th>Transcript No.</th>
<th>Coder 1</th>
<th>Coder 2</th>
<th>Coder 3</th>
<th>Coder 4</th>
<th>Coder 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>X</td>
<td>X</td>
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<td>3</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
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<td>4</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
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<td>5</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>6</td>
<td>X</td>
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<td>X</td>
</tr>
</tbody>
</table>

Percentage agreement was used to compute interrater reliability. The coding schema involved a conditional coding structure, a process where each coder read through the transcript to code for any mention of an aging-related domain. If an aging-related domain was mentioned, coders then read through again to code more specifically which aging-related concern was discussed and the quality of the response to this concern (ie, acknowledged, addressed, or dismissed). Then, if the response quality was coded as addressed, the coders read through to code for any specific recommendations used to address the concern. As a result of this conditional coding structure, interrater reliability involved percentage agreement in 3 coding areas: (1) number of aging-related concerns, (2) a composite GA communication score that included the physician’s response quality, and (3) the physician’s recommendations.

All 5 coders met to establish consensus for the transcript. The percentage agreement was calculated using the difference or variance between each individual coder and the final consensus code. To calculate the variance for each coder from the consensus, the difference
between the agreed consensus and individual coder was divided by the agreed consensus. The percentage difference scores for the 5 coders were then averaged to calculate the final percentage agreement. In Appendix D, there are 2 representations of transcripts coded by all 5 individuals.

The interrater agreement percentage never fell below 70%; therefore, the coding team never required additional training. A further summary of the coding procedures, including assessment of interrater reliability and resolution procedures for disagreement, is included in Appendix D.

Data Sources for Secondary Aims 2 and 3

Measures for secondary aims 2 and 3: caregiver satisfaction with communication about aging-related concerns and patient and caregiver satisfaction with communication about overall care and patient and caregiver health-related QOL.

- **Satisfaction.** Caregivers completed the surveys at the same time points as patients (see Table 5); surveys were provided to the caregivers by the clinical research associates and were completed on paper. However, caregivers did not receive the telephone team call or complete a baseline visit HCCQ. Caregivers completed 3 different versions of the HCCQ (higher scores indicate greater satisfaction) at similar time points to assess satisfaction with (1) a caregiver’s views about the patient’s satisfaction with communication about aging-related concerns (HCCQ-PTAGE; score 0-28); (2) a caregiver’s satisfaction with their own communication about the patient’s aging-related conditions (HCCQ-CGAGE; score 0-20); and (3) caregiver satisfaction with communication about overall care (HCCQ-CGOVERALL; score 0-20). The caregiver HCCQ was included in the 4- to 6-week, 3-month, and 6-month assessment packets (Table 5). Patients also completed a measure of their satisfaction with communication about overall care (HCCQ-PTOVERALL; score 0-20) (Appendix E).

- **Health-related QOL.** QOL measures included assessments of distress and accompanying symptoms (Table 5). QOL and symptoms were measured using validated assessments.
Caregivers completed validated measures to assess the impact of caregiving on their QOL (ie, caregiver reaction and SF-12). Caregiver economic burden was assessed, including the time required to give care (Appendix E).

Other measures (patient and caregiver).

- **Sociodemographic** (patient and caregiver): Data on age, race and ethnicity, sex, highest level of education achieved, employment status, marital status, and with whom patients live were captured. We also assessed financial concerns and understanding of disease (Appendix E).

- **Tumor and treatment characteristics** (patient): The tumor stage, previous surgery or radiation, previous cancer treatment, and current cancer treatment plan (if any) were captured by the clinical research associate (Appendix E).
### Table 5. Patient and Caregiver Measures and Time Points Collected

<table>
<thead>
<tr>
<th>Aim(s)</th>
<th>Measures</th>
<th>Time(s) collected</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td>Demographics and baseline characteristics (patient and caregiver)</td>
<td>Baseline</td>
</tr>
<tr>
<td>S1 and S2</td>
<td>Medical characteristics and treatment (patient)</td>
<td>Baseline</td>
</tr>
<tr>
<td>GA</td>
<td>Concomitant-medications/polypharmacy/baseline laboratory tests (patient)</td>
<td>Baseline</td>
</tr>
<tr>
<td>GA</td>
<td>Physical performance (patient) — fall history/Short Physical Performance Battery/ Timed “Up and Go”/OARS Physical Health</td>
<td>Baseline</td>
</tr>
<tr>
<td>GA</td>
<td>Functional status (patient) — ADLs/IADLs</td>
<td>Baseline</td>
</tr>
<tr>
<td>GA</td>
<td>Comorbidity (patient) — OARS Comorbidity</td>
<td>Baseline</td>
</tr>
<tr>
<td>GA</td>
<td>Cognition (patient) — Mini-Cog/BOMC test</td>
<td>Baseline</td>
</tr>
<tr>
<td>GA</td>
<td>Nutrition (patient) — Nutritional Status and Mini Nutritional Assessment</td>
<td>Baseline</td>
</tr>
<tr>
<td>GA</td>
<td>Social support (patient) — OARS Medical Social Support</td>
<td>Baseline</td>
</tr>
<tr>
<td>GA</td>
<td>Psychological health — Geriatric Depression Scale (patient)/GAD-7 scale (patient and caregiver)</td>
<td>Baseline</td>
</tr>
<tr>
<td>S1</td>
<td>Direct communication (patient and caregiver) — audio-recorded baseline visit</td>
<td>Baseline</td>
</tr>
<tr>
<td>P1 and S3</td>
<td>Satisfaction (patient and caregiver) — HCCQ-age/HCCQ-PTAGE/HCCQ-CGAGE/HCCQ-CGOVERALL/HCCQ-PTOVERALL</td>
<td>Baseline, 4-6 wk, 3 mo, 6 mo</td>
</tr>
<tr>
<td>S2</td>
<td>QOL — FACT-G (patient)/SF-12 (caregiver)</td>
<td>Baseline, 4-6 wk, 3 mo, 6 mo</td>
</tr>
<tr>
<td>S2</td>
<td>Caregiver health and economic burden (caregiver)</td>
<td>Baseline, 4-6 wk, 3 mo, 6 mo</td>
</tr>
</tbody>
</table>

Abbreviations: ADLs, activities of daily living; BOMC, Blessed Orientation Memory Concentration; FACT-G, Functional Assessment of Cancer-General; GA, geriatric assessment; GAD-7, 7-item Generalized Anxiety Disorder; HCCQ, Health Care Climate Questionnaire; IADLs, instrumental activities of daily living; N/A, not applicable; OARS, Older Americans Resources and Services; P1, primary aim; QOL, quality of life; S1, secondary aim 1; S2, secondary aim 2; S3, secondary aim 3; SF-12, 12-item Short Form.
Oncology Physician Surveys

Oncologists completed a baseline survey before or when their first patient consented to the study and a brief follow-up survey at the end of the study. For each patient, after the audio-recorded baseline clinic visit, oncologists were asked about potentially important covariates or moderators, including disease and treatment characteristics, using 2 measures, the Treatment Decision Making form, and the Understanding of Disease-Physician form (Appendix E).

Medical Record Abstraction and Claims: Exploratory Aims

We obtained medical records to verify information about disease location, pathology, stage, metastases, and survival status. We also requested information from the clinical research staff on the recommendations that were made and implemented. To assess health care use (eg, adverse events, such as hospitalizations) for future work on examining the cost-effectiveness of the intervention, we asked permission to obtain Medicare claims on the patient consent form. We will obtain claims data in the future for all patients who consented to this. All consent and research procedures for obtaining Medicare claims will be followed at https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Privacy

Statistical Plan

Statistical Considerations

This was a cluster randomized trial with NCORP practice sites used as the clusters. Because of the cluster randomized study design, we applied a linear mixed-model methodology. The dependent variable was the study’s outcomes (eg, the satisfaction score for the primary aim and number of communications for the secondary aim), and the fixed effect was the study arm. NCORP practice sites were entered as a random effect independent of residual error. Estimation was performed using restricted maximum likelihood (REML), and the null hypothesis of zero mean difference between arms was tested using an F test. The specific NCORP practice site differences were assessed graphically using best linear unbiased predictors (BLUPs) of the mean response for each NCORP site. Besides the primary model with study arm
as a fixed effect and practice site as a random effect as outlined previously, an additional prespecified regression analysis, controlling for clinically important socioeconomic variables (eg, patient sex, age, race/ethnicity, cancer type, chemotherapy treatment status, monoclonal antibody treatment status) as fixed effects was conducted. Interactions between statistically significant covariates and the treatment arm were evaluated. No a priori sub-arm analysis was specified.

**Sample Size for Primary Aim: Patient Satisfaction With Communication About Aging-Related Concerns**

We used the HCCQ-age to address patient satisfaction with communication about aging-related issues. Based on an analysis of the VOICE study (PI: R.E.), the standard deviation estimate of HCCQ (HCCQ-PTOVERALL) was 2.1. In addition, analysis of the VOICE study data revealed that the ICC was 0.14, with a 95% CI from 0.01 to 0.51. Because of the large amount of uncertainty in the ICC, we calculated power curves for ICC = \{0.01, 0.14, 0.51\}, with an ICC of 0.51 being the most conservative. This design (8 sites per arm and 31 participants per site) had 80% power at the $\alpha = 0.05$ significance level to detect a change in HCCQ-age of 0.6, 1.3, and 2.3 for ICC = \{0.01, 0.14, 0.51\}, respectively. Because the best estimate of the ICC was 0.14, the expected detectable difference was 1.3. This corresponds to an effect size of 0.62. The range of the HCCQ-age scores was 0 (worst possible) to 28 (best possible). Figure 5 shows the power for a range of detectable differences for ICC = \{0.01, 0.14, 0.51\}. 
Small changes in satisfaction scores have been interpreted in other studies to be meaningful given a focus on achievement of high satisfaction scores and the link with financial reimbursement.\textsuperscript{50} To our knowledge, there is no research that defines clinically meaningful satisfaction scores for either communication or care. Ceiling effects are common, and this is true also for the HCCQ measures used in this study; 1 study showed that patient ratings on the HCCQ-PTOVERALL were significantly higher than the standardized patient ratings of the same physician.\textsuperscript{50} Studies evaluating satisfaction as an outcome, including HCCQ (HCCQ-PTOVERALL),\textsuperscript{71,72} discuss the positive effects of interventions on satisfaction with mean scores of $<1$ point and with changes in summed scores of $\leq 3$ points.\textsuperscript{52,73-77}

Accounting for a small dropout rate of 5% (based on our observational cohort data\textsuperscript{23}), the targeted accrual was 528 total patient participants. The dropout rate reflects patients who signed consent but withdrew before the audio-recorded baseline visit and capture of the HCCQ-age data (which occurred within 7-14 days of the baseline visit).
During NCORP site recruitment, we aimed for at least 16 NCORP sites to participate. Because recruitment was slower than anticipated, we allowed more sites to participate to meet our targeted accrual. The total patient sample size (N = 528) was the same, and accrual ceased when our target was met.

Sample Size for Secondary Aim 1: Direct Communication About Aging-Related Concerns

This aim evaluated the number of discussions related to geriatric domains, as measured by the GA, brought up during the audio-recorded baseline visit. In our preliminary data from a multicenter study, the median number of discussions was 1 in 32 audio-recorded conversations between older patients, patient caregivers, and oncologists. This preliminary work allowed us to calculate the ICC among 8 different sites for the assessment of the secondary outcome, the number of discussions related to geriatric domains. The ICC was 0.122, with a 95% CI of 0.008 to 0.659. Because of the large amount of uncertainty in the ICC, we calculated power curves for ICC = {0.008, 0.122, 0.659}, with an ICC of 0.659 being the most conservative. This design (with 8 NCORP sites per arm and 31 evaluable participants per NCORP site) had 80% power at the $\alpha = 0.05$ significance level to detect a change of 0.235, 0.456, and 0.962 in the mean number of discussions for ICC = {0.008, 0.122, 0.659}, respectively, assuming an SD of 0.78 (Figure 6). Because the best estimate of the ICC was 0.122, the expected detectable difference was 0.456. This corresponded to an effect size of 0.59. The analysis for this aim was the same as patient satisfaction with communication about aging-related concerns but used the number of discussions of aging-related concerns as the response.
Secondary Aim 2: Influence of GA Summary and GA-Guided Recommendations on Patient and Caregiver Health-Related QOL

To assess the effect of the intervention on QOL, we used a conditional mixed-effects model (mixed-effects analysis of covariance) structured as follows. The T2 and T3 outcomes were the response. The baseline (T1) level was included as a fixed effect, as well as arm, time, and arm × time interaction. An “unstructured” correlation matrix was used for the repeated measures from the same participant. The model was adjusted for practice site clusters using a random effect independent of the within-participant random effects. The model was fit using REML. We also compared whether the uptake of GA recommendations influenced patient-reported QOL and caregiver burden. Data from the intervention arm were fit to a linear mixed model with FACT or CRA as the outcome, number and percentage of implemented interventions (number implemented/number recommended) as the fixed effect, and NCORP site as a random effect independent of residual error. Analyses were adjusted for treatment status.
Secondary Aim 3: Caregiver Satisfaction With Communication About Aging-Related Concerns and Patient and Caregiver Satisfaction With Communication About Overall Care

We compared the effect of the intervention on caregiver satisfaction with communication about the patient’s overall care (HCCQ-CGOVERALL), the caregiver’s views of the patient’s satisfaction with communication about aging-related concerns (HCCQ-PTAGE), the caregiver’s satisfaction with their own communication about the patient’s aging-related conditions (HCCQ-CGAGE), and the patient’s satisfaction with communication about overall care (HCCQ-PTOVERALL), using a similar linear mixed-model methodology. The mixed-effects model was structured as follows. The T1, T2, and T3 outcomes were the response. The arm–time main effects and arm × time interaction were included as fixed effects. An unstructured correlation matrix was assumed for the repeated measures from the same participant. The model was adjusted for practice site clusters using a random effect independent of the within-participant random effects and fit via REML. The overall difference between arms as well as time-specific differences were evaluated using marginal means estimates.

Exploratory Aims

We conducted analyses to determine whether increasing GA impairments (ie, frailty) in older patients with advanced cancer was associated with intervention effects on satisfaction with communication about aging-related concerns and with direct communication about aging-related concerns. We found increased GA impairment (ie, frailty) to be negatively associated with satisfaction with communication at baseline ($\beta = -3.2$), at 4 to 6 weeks ($\beta = -6.2$), and at 3 months ($\beta = -5.7$; all $P < .01$). In the GA intervention arm vs the usual care arm, we found that for each frailty status group, there was an increased average number of aging-related conversations (robust, 6.8 vs 3.3 conversations; prefrail, 7.9 vs 4.2 conversations; and frail, 9.0 vs 5.2 conversations, respectively; all $P < .01$). These results show that there are interactions between GA impairments by frailty status (robust vs prefrail vs frail) and outcomes.
Missing Data

Every effort was made to encourage and facilitate participants’ completion of questionnaires. However, baseline data from some participants were missing, and there was dropout postintervention (see Figure 7 for details). Under missing at random (MAR) assumptions, we evaluated the influence of missing data on the study results via multiple imputation (MI). We used the Markov chain Monte Carlo (MCMC) method (SAS PROC MI: MCMC, multiple chains, EM posterior model), with 100 imputations, and the estimands were combined using PROC MIANALYZE. We evaluated the reasons for missing data. The most common reasons for dropout were patients being too sick due to cancer to fill out surveys, entry into hospice care, and death. The examination of the reasons for missingness did not reveal any reason to suspect a missing not at random (MNAR) mechanism. We also employed additional sensitivity analysis using pattern mixture models (Appendix F, Supplementary Table 1). The main analysis results are reported based on complete cases.
Abbreviations: COACH, Communication on Aging and Cancer Health; GA, geriatric assessment; HCCQ, Health Care Climate Questionnaire; NCORP, NCI Community Oncology Research Program; Pts, patients.

1Sites no longer associated with their respective NCORP affiliate or with the URCC Research Base.

2Clusters that maintained IRB approval but never actually enrolled any participants.

3Discussions about aging-related concerns during clinic consultation assessed using audio-recordings of baseline visit with physician.
Satisfaction with communication regarding aging-related concerns assessed using HCCQ-age collected data at baseline.

Irretrievable, site miscommunication, technical difficulty, or protocol violation.

*Screen enrolled.

*Only enrolled physicians of evaluable patients are included in the diagram. If patient dropout resulted in a physician having no evaluable patients, the physician was also excluded.
Changes to Study Protocol

At the activation of the study, recruitment was slower than anticipated. We reached out to community sites at our annual meeting and through targeted surveys to determine the reasons. As a result of feedback from sites and stakeholders, we made minimal but necessary changes to the eligibility requirements. This feedback in addition to the transition from Cancer Control Oncology Program to NCORP (which had more sites) also allowed more sites to participate so that we could recruit the planned number of patients. The statistical analysis plan did not change otherwise. Sites and stakeholders notified us that trying to recruit and enroll a vulnerable older patient population before starting first-line chemotherapy for advanced cancer is logistically very difficult. Often, these patients were new to the clinic and felt overwhelmed. We adjusted eligibility so that any patient aged ≥70 years being followed in oncology clinical practice with advanced cancer who was considering treatment or receiving treatment for cancer was eligible. Because aging-related issues are common for all older patients with cancer, this modification also made the study more generalizable by allowing GA information to be used for patients with advanced cancer in any treatment situation. The University of Rochester’s IRB and the NCORP practice sites’ IRBs approved this amendment. All changes to the initial protocol are detailed in Appendix A.
RESULTS

Overview of Participant Flow

In this cluster randomized trial, individual practice components were grouped into practice site clusters, based on where oncologists and study staff worked independently (eg, did not cross over into another practice site). Eighty-five practice site clusters obtained the appropriate IRB approval and were randomized to either the intervention (GA summary plus GA-guided recommendations) or usual care arm (no GA summary or recommendations provided to the oncology teams). From 2014 to 2017, 31 practice sites (17 intervention and 14 usual care) enrolled participants (patients, physicians, and caregivers); 610 patients completed screening procedures, and of those, 546 patients were enrolled, along with 417 caregivers and 132 physicians. From screening to enrollment, patient attrition was caused by 31 screen failures (ie, a patient agreed to participate but could not enroll because they were ineligible) and 33 screen withdrawals (ie, a patient was eligible but decided not to participate in the study during the screening period).

For the intention-to-treat analysis, 541 patients (293 intervention, 248 usual care), 414 caregivers (231 intervention, 183 usual care), and 131 physicians (63 intervention, 68 usual care) were included. In the intervention arm, 3 patients and 2 caregivers were excluded due to protocol violations, that is, a divergence from the protocol that materially (1) reduced the quality or completeness of the data; (2) made the informed consent form inaccurate; or (3) impacted a participant’s safety, rights, or welfare. In the usual care arm, 1 patient and 1 caregiver were excluded as a result of a protocol violation; 1 patient was registered and later found to be ineligible.

For the primary aim (patient satisfaction with communication about aging-related concerns), we included 509 patients (271 intervention, 238 usual care); 388 caregivers (211 intervention, 177 usual care); and 130 physicians (63 intervention, 67 usual care). For secondary aim 1, (direct communication about aging-related concerns), we included 528 patients (284 intervention, 244 usual care); 405 caregivers (225 intervention, 180 usual care); and 130 physicians (62 intervention, 68 usual care). The reasons for attrition are documented in Figure
7. For the satisfaction with communication about aging-related concerns aim, the most common reasons for missing data were an inability to contact the patient by phone within the allotted time and the survey not being returned by mail (per protocol).

Patient Characteristics

There were no differences in demographic (mean age 77 years; 49% female), clinical, or disease characteristics by arm except for monoclonal antibody treatment status (Table 6). As a result, monoclonal antibody treatment status was included as an important socioeconomic variable controlled for in subsequent analyses (see “Statistical Plan”). The patients in this study were frail, with the majority having 2 or more GA impairments (Figure 8); most were impaired in physical function (93.7%, Figure 9). Comparing the individual GA impairments by arm, there were no significant differences in any of the domains except for physical performance and social support. More patients in the usual care arm had impaired physical performance (96% vs 92%, respectively; \( P = .03 \)) and social support (33% vs 25%, respectively; \( P = .05 \); Figure 10) than patients in the intervention arm.

Table 6. Patient Demographic, Clinical, and Disease Characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Usual care arm (n = 248)</th>
<th>Intervention arm (n = 293)</th>
<th>( P ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD), y</td>
<td>76.4 (5.3)</td>
<td>76.7 (5.2)</td>
<td>.50</td>
</tr>
<tr>
<td>Sex, No. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>127 (51.2)</td>
<td>137 (46.9)</td>
<td>.32</td>
</tr>
<tr>
<td>Race/ethnicity, No. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-Hispanic White</td>
<td>219 (88.3)</td>
<td>263 (90.1)</td>
<td>.68</td>
</tr>
<tr>
<td>African American</td>
<td>21 (8.5)</td>
<td>19 (6.5)</td>
<td></td>
</tr>
<tr>
<td>GI or lung, No. (%)</td>
<td>128 (51.6)</td>
<td>150 (51.4)</td>
<td>.84</td>
</tr>
<tr>
<td>Stage IV, No. (%)</td>
<td>219 (88.3)</td>
<td>261 (89.4)</td>
<td>.69</td>
</tr>
<tr>
<td>Cancer treatments, No. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chemotherapy</td>
<td>164 (65.9)</td>
<td>205 (70.5)</td>
<td>.28</td>
</tr>
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<td>Variable</td>
<td>Usual care arm (n = 248)</td>
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<td>------------------------</td>
<td>--------------------------</td>
<td>-----------------------------</td>
<td>---------</td>
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<tr>
<td>Monoclonal antibodies</td>
<td>49 (20.1)</td>
<td>94 (32.2)</td>
<td>.001</td>
</tr>
<tr>
<td>Hormonal treatment</td>
<td>53 (21.3)</td>
<td>44 (15.1)</td>
<td>.06</td>
</tr>
</tbody>
</table>

Abbreviation: GI, gastrointestinal.

*Note that 1 patient had missing demographic variables; the difference between arms for age, a continuous variable, was tested by a 2-sample t test and by chi-square test for categorical variables.

**Figure 8. Number of GA Impairments**

Abbreviation: GA, geriatric assessment.
Figure 9. Prevalence of GA Impairments by GA Domain

- Psychological Status: 25.1%
- Cognition: 28.8%
- Social Support: 33.3%
- Function Status: 59.0%
- Nutrition: 60.3%
- Comorbidity: 63.8%
- Polypharmacy: 83.7%
- Physical Performance: 93.7%

Abbreviation: GA, geriatric assessment.

Figure 10. Prevalence of GA Domain Impairments by Study Arm

- Physical Performance
- Polypharmacy
- Comorbidity
- Function Status
- Nutrition
- Social Support
- Cognition
- Psychological Status

Abbreviation: GA, geriatric assessment.
Caregiver Characteristics

Caregivers (mean age, 66.5 years; range, 26-92 years) were more likely to be non-Hispanic White vs other races and to be the patient’s spouse vs another relationship (Table 7). Caregivers tended to have multiple impairments, including comorbidities (39%), anxiety (23%), distress (43%), and depression (18%) (Table 7).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>All caregivers (N = 414)</th>
<th>Intervention arm (n = 231)</th>
<th>Usual care arm (n = 183)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD), y</td>
<td>66.5 (12.5)</td>
<td>66.2 (12.5)</td>
<td>66.9 (12.5)</td>
<td>.57</td>
</tr>
<tr>
<td>&lt;70</td>
<td>210 (50.7)</td>
<td>121 (52.4)</td>
<td>89 (48.6)</td>
<td>.73</td>
</tr>
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<td>70-79</td>
<td>151 (36.5)</td>
<td>81 (35.1)</td>
<td>70 (38.3)</td>
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<td>≥80</td>
<td>50 (12.1)</td>
<td>27 (11.7)</td>
<td>23 (12.6)</td>
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<td>Sex, No. (%)</td>
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<td>.32</td>
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<td>Female</td>
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<td>Male</td>
<td>101 (24.4)</td>
<td>52 (22.5)</td>
<td>49 (26.8)</td>
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<tr>
<td>Education, No. (%)</td>
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<td>.26</td>
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<td>Less than high school</td>
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<td>15 (6.5)</td>
<td>15 (8.2)</td>
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<td>High school graduate</td>
<td>118 (28.5)</td>
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<td>45 (24.6)</td>
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<td>Some college or above</td>
<td>263 (63.5)</td>
<td>141 (61.0)</td>
<td>122 (66.7)</td>
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<tr>
<td>Race, No. (%)</td>
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<td>.98</td>
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<tr>
<td>Non-Hispanic White</td>
<td>369 (89.1)</td>
<td>206 (89.2)</td>
<td>163 (89.1)</td>
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</tr>
<tr>
<td>African American</td>
<td>27 (6.5)</td>
<td>15 (6.5)</td>
<td>12 (6.6)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>15 (3.6)</td>
<td>8 (3.5)</td>
<td>7 (3.8)</td>
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<tr>
<td>Relationship, No. (%)</td>
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<td></td>
<td>.04</td>
</tr>
<tr>
<td>Spouse/cohabiting partner</td>
<td>276 (66.7)</td>
<td>151 (65.4)</td>
<td>125 (68.3)</td>
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</tr>
<tr>
<td>Characteristic</td>
<td>All caregivers (N = 414)</td>
<td>Intervention arm (n = 231)</td>
<td>Usual care arm (n = 183)</td>
<td>P value</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>--------------------------</td>
<td>-----------------------------</td>
<td>--------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Son/daughter</td>
<td>94 (22.7)</td>
<td>61 (26.4)</td>
<td>33 (18.0)</td>
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<tr>
<td>Other</td>
<td>41 (9.9)</td>
<td>17 (7.4)</td>
<td>24 (13.1)</td>
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<tr>
<td>Annual income, No. (%), $</td>
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<td>.54</td>
</tr>
<tr>
<td>≤50 000</td>
<td>151 (36.5)</td>
<td>80 (34.6)</td>
<td>71 (38.8)</td>
<td></td>
</tr>
<tr>
<td>&gt;50 000</td>
<td>178 (43.0)</td>
<td>100 (43.3)</td>
<td>78 (42.6)</td>
<td></td>
</tr>
<tr>
<td>Declined to answer</td>
<td>81 (19.6)</td>
<td>49 (21.2)</td>
<td>32 (17.5)</td>
<td></td>
</tr>
<tr>
<td>Living arrangement, No. (%)</td>
<td></td>
<td></td>
<td></td>
<td>1.00</td>
</tr>
<tr>
<td>Independent living, &gt;1 story</td>
<td>188 (45.4)</td>
<td>105 (45.5)</td>
<td>83 (45.4)</td>
<td></td>
</tr>
<tr>
<td>Independent living, 1 story</td>
<td>215 (51.9)</td>
<td>120 (51.9)</td>
<td>95 (51.9)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>7 (1.7)</td>
<td>4 (1.7)</td>
<td>3 (1.6)</td>
<td></td>
</tr>
<tr>
<td>Comorbidity, No. (%)</td>
<td></td>
<td></td>
<td></td>
<td>.88</td>
</tr>
<tr>
<td>Yes</td>
<td>162 (39.1)</td>
<td>91 (39.4)</td>
<td>71 (38.8)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>249 (60.1)</td>
<td>138 (59.7)</td>
<td>111 (60.7)</td>
<td></td>
</tr>
<tr>
<td>Anxiety (GAD-7 score ≥5), No. (%)</td>
<td></td>
<td></td>
<td></td>
<td>.86</td>
</tr>
<tr>
<td>Yes</td>
<td>97 (23.4)</td>
<td>53 (22.9)</td>
<td>44 (24.0)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>300 (72.5)</td>
<td>167 (72.3)</td>
<td>133 (72.7)</td>
<td></td>
</tr>
<tr>
<td>Distress (score ≥4), No. (%)</td>
<td></td>
<td></td>
<td></td>
<td>.82</td>
</tr>
<tr>
<td>Yes</td>
<td>177 (42.8)</td>
<td>98 (42.4)</td>
<td>79 (43.2)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>230 (55.6)</td>
<td>130 (56.3)</td>
<td>100 (54.6)</td>
<td></td>
</tr>
<tr>
<td>Depression (PHQ-2 score ≥2), No. (%)</td>
<td></td>
<td></td>
<td></td>
<td>.69</td>
</tr>
<tr>
<td>Yes</td>
<td>75 (18.1)</td>
<td>40 (17.3)</td>
<td>35 (19.1)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>322 (77.8)</td>
<td>180 (77.9)</td>
<td>142 (77.6)</td>
<td></td>
</tr>
<tr>
<td>SF-12 score, mean (SD)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Primary Aim: Patient Satisfaction With Communication About Aging-Related Concerns

Patient satisfaction with communication about aging-related concerns was measured using the HCCQ-age (7 questions, scale, 0-28). In 509 evaluable patients, the adjusted mean satisfaction score with communication about aging-related concerns was 22.8 (SE, 0.27; range, 5-28 for the HCCQ-age) postclinic visit. The score in the intervention arm was 1.09 points higher than that in the usual care arm (95% CI, 0.05-2.13; \( P = .04 \); ICC = 0.02; Figure 1). Graphical examination suggested nonnormality, so we used an alternate analytical approach to examine sensitivity to nonnormality. The satisfaction score was dichotomized at the median, and a generalized linear mixed model with a logit link was used. The results from this analysis were consistent with the previous findings (odds ratio [OR] for score above the median comparing the intervention arm vs usual care, 1.60 [95% CI, 1.09-2.38]).
Telephone-collected HCCQ-age data about patients’ aging-related concerns at the postbaseline visit were not available for 60 patients who had 4- to 6-week data (Appendix C). Per protocol, 4- to 6-week data for these 60 patients were used in place of the telephone-collected data, allowing for more complete analysis (N = 509). To evaluate the impact of using these data on the results, we used information from patients who provided both sets of HCCQ-age data (telephone collected and 4-6 weeks, n = 410). Among these 410 patients, the HCCQ-age values for aging-related conversations decreased from the telephone call to 4 to 6 weeks after baseline. The between-arm difference in the decrease was not statistically significant (intervention arm compared with usual care, −0.64 [95% CI, −1.16 to −0.13] vs −0.33 [95% CI, −0.98 to 0.33], respectively; P = .45).

**Differences in Patient Satisfaction With Communication About Aging-Related Concerns Across NCORP Practice Sites**

In this cluster randomized controlled trial (RCT), when we examined the difference in the practice site clusters, we found that heterogeneity between site clusters for patient satisfaction with communication about aging-related concerns was small (ICC = 0.02; Figure 12).
Secondary Aim 1: Direct Communication About Aging-Related Concerns

Using an open coding approach of themes and subthemes, we quantified the number of aging-related conversations (“discussions”), number of aging-related discussions with high-quality communication (“acknowledged”), and number of discussions addressed that “led to interventions” defined as resulting in GA-guided recommendations prescribed to patients by oncologists.

In 528 evaluable patients, the adjusted mean (SE) number of discussions about aging-related concerns during the oncology clinic visit was 6.34 (0.48). Of note, we noticed that there was a difference in the SD between our pilot data (SD, 0.78) and the actual data from our COACH study (SD, 4.02). This is most likely due to the increased rigor related to the
development of the coding book for the COACH study as a result of increased resources (PCORI funding). Quantifying aging-related discussions per the coding schema showed that the number of discussions in the first clinical encounter with the physician after the GA was performed ranged from 0 to 18. There was an adjusted mean of 8.02 discussions in the intervention arm compared with 4.43 discussions in usual care (adjusted difference = 3.59; 95% CI, 2.2-5.0; \( P < 0.001 \); ICC = 0.14; Figure 13). The intervention arm had an adjusted mean of 4.60 high-quality discussions per clinic visit, compared with 2.59 discussions in usual care (adjusted difference = 1.99; 95% CI, 1.20-2.77; \( P < .001 \); ICC = 0.06; Figure 13). There was an adjusted mean of 3.20 discussions about GA-guided recommendations in the intervention arm compared with 1.14 discussions in usual care (adjusted difference = 2.06; 95% CI, 0.99-3.12; \( P < .001 \); ICC = 0.30; Figure 13). The intervention arm had significantly more discussions for all GA domains than the usual care arm (Table 8).

**Figure 13. Direct Communication About Aging-Related Concerns**

![Bar chart showing the number of conversations for all, higher quality, and recommendations domains for intervention vs. usual care groups.](chart.png)
Table 8. Discussions of the GA Domains by Study Arm (Per Clinic Visit)

<table>
<thead>
<tr>
<th>GA domain</th>
<th>No. of discussions</th>
<th>Intervention arm</th>
<th>Usual care arm</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical performance</td>
<td>1.87</td>
<td>0.75</td>
<td></td>
<td>&lt;.01</td>
</tr>
<tr>
<td>Functional status</td>
<td>0.58</td>
<td>0.36</td>
<td></td>
<td>&lt;.01</td>
</tr>
<tr>
<td>Comorbidity</td>
<td>0.67</td>
<td>0.41</td>
<td></td>
<td>&lt;.01</td>
</tr>
<tr>
<td>Cognition</td>
<td>0.45</td>
<td>0.12</td>
<td></td>
<td>&lt;.01</td>
</tr>
<tr>
<td>Nutrition</td>
<td>1.71</td>
<td>1.26</td>
<td></td>
<td>&lt;.01</td>
</tr>
<tr>
<td>Social support</td>
<td>0.75</td>
<td>0.22</td>
<td></td>
<td>&lt;.01</td>
</tr>
<tr>
<td>Polypharmacy</td>
<td>1.59</td>
<td>1.00</td>
<td></td>
<td>&lt;.01</td>
</tr>
<tr>
<td>Psychological health</td>
<td>0.36</td>
<td>0.11</td>
<td></td>
<td>&lt;.01</td>
</tr>
</tbody>
</table>

Abbreviation: GA, geriatric assessment.

**Differences in Direct Communication Across NCORP Practice Sites**

In this cluster RCT, when we examined the difference in the practice site clusters for the direct communication about aging-related concerns aim, we found heterogeneity between site clusters (ICC = 0.14; Figure 14).
Missing Data for Primary Aim and Secondary Aim 1

Every effort was made to encourage and facilitate participants’ completion of the questionnaires, but some dropout occurred postintervention, and some baseline data were also missing. For the direct communication outcome, only a small proportion (2.4%) had missing data. Because the between-arm difference in the outcome was substantial (average number of discussions, 8.0 intervention arm vs 4.4 usual care arm; \( P < .0001 \)), and examination of the reasons for missingness did not reveal any concerning pattern that might influence the results, we report the complete-case analysis. For the patients’ satisfaction with communication about aging-related concerns outcome, 5.7% had missing data. We conducted additional analysis via MI with the fully conditional specification (FCS) method (SAS PROC MI: FCS, 100 imputations) using study arm, patient age, GA score, and number of communications as ancillary variables, assuming data were MAR. The parameter estimates (between-arm difference in satisfaction...
with communication score) from the MI analysis (1.07; 95% CI, 0.02-2.13; \( P = .046 \)) were similar to those of the complete-case analysis (1.09; 95% CI, 0.05-2.13; \( P = .041 \)).

To assess the sensitivity of the results to missing data analytical methods and assumptions, we also conducted MI using the MCMC method (SAS PROC MI; multiple chains, EM posterior mode, 100 imputations) and received results similar to those from the complete-case analysis. We also employed additional sensitivity analysis to MNAR using a pattern mixture model.\(^{79,80,83}\) The examination of the reasons for missingness did not reveal any reason to suspect an MNAR mechanism.\(^{84}\) Given the small proportion of missing data, the fact that there was no reason to expect violation of the MAR assumption, and the stability of the results under different imputation methods, the results can be considered robust.

**Adjusting for Covariates**

For both the primary outcome (patient satisfaction with communication about aging-related concerns) and secondary aim 1 (direct communication about aging-related concerns), we also executed additional linear mixed models (Appendix F, Supplementary Tables 2A and B) with key clinical and demographic covariates (age, sex, race/ethnicity, tumor type, chemotherapy) added as fixed effects to the study arm and a random effect to the practice site. The only statistically significant association (\( P < .05 \)) of these covariates was found for the communication outcomes. Patients with lung cancer had more communication about aging-related concerns than did patients with other types of cancer (\( P < .01 \)), and patients treated with monoclonal antibodies also had more communication about aging-related concerns than did those without that treatment (\( P = .01 \)).

**Secondary Aim 2: Influence of GA Summary and GA-Guided Recommendations on Patient and Caregiver Health-Related QOL From Baseline to 6 Months**

Patients’ health-related QOL was assessed using the FACT-G total score. We did not observe any effect of the intervention on QOL (range, 23-108; adjusted difference = −0.23; SE, 1.03; \( P = .82 \)) for the between-arm difference in average change from baseline to 6 months (Figure 15). Similarly, we did not detect any impact of uptake of GA recommendations on changes in QOL (number of addressed conversations: \( \hat{\beta} = −.19 \); SE, 0.23; \( P = .42 \); proportion of
addressed conversations: $\beta = -0.83; \text{SE}, 2.38; P = .73$). The intervention did not affect QOL of caregivers as assessed by the following items on the CRA:

1. Finance: adjusted difference = $-0.07; \text{SE}, 0.06; P = .23$;
2. Health problems: adjusted difference = $-0.05; \text{SE}, 0.05; P = .35$;
3. Disturbed schedule: adjusted difference = $-0.01; \text{SE}, 0.08, P = .86$;
4. Self-esteem: adjusted difference = $0.03; \text{SE}, 0.04; P = .36$; or
5. Lack of social support: adjusted difference = $-0.04; \text{SE}, 0.05; P = .48$; or as assessed using the SF-12 (total score: adjusted difference = 0.59; SE, 0.82; $P = .47$; Figure 16).

**Figure 15. QOL of Older Patients as Assessed Using the FACT-G**

Abbreviations: FACT-G, Functional Assessment of Cancer-General; QOL, quality of life.
Secondary Aim 3: Caregiver Satisfaction With Communication Regarding the Patient’s Aging-Related Conditions and Patient and Caregiver Satisfaction With Communication About Overall Care

Secondary outcomes included caregiver satisfaction with communication about the patient’s aging-related conditions and patient and caregiver satisfaction with communication about overall care. Caregivers completed 3 different versions of the HCCQ (where higher scores indicate greater satisfaction with communication) at 4 to 6 weeks, 3 months, and 6 months to assess (1) caregiver views of the patient’s satisfaction with communication about aging-related concerns (HCCQ-PTAGE; score 0-28); (2) caregiver satisfaction with their own communication regarding the patient’s aging-related conditions (HCCQ-CGAGE; score 0-20); and (3) caregiver satisfaction with communication about the patient’s overall care (HCCQ-CGOVERALL; score 0-20). Patients also completed a measure of their satisfaction with communication about overall care (HCCQ-PTOVERALL; score, 0-20).

Secondary analysis of the 4- to 6-week data showed that caregivers in the intervention arm were more satisfied with their own communication with oncologists regarding the patient’s overall care (HCCQ-CGOVERALL: range, 2-20; difference = 1.34; 95% CI, 0.50-2.18; \( P = .004 \); Figure 17); were more satisfied with their communication about the patient’s aging-related conditions (HCCQ-CGAGE: range, 5-20; difference = 1.05; 95% CI, 0.12-1.98; \( P = .03 \);
Figure 18); and were more positive about their view about the patient’s satisfaction with communication about aging-related health concerns (HCCQ-PTAGE: range, 6-28; difference = 1.6; 95% CI, 0.29-2.9; P = .02; Figure 19) than patients in the usual care arm.

Additional secondary analysis of the 3-month data showed that caregivers were more positive about their view of the patient’s satisfaction with communication about aging-related concerns (HCCQ-PTAGE: range, 0-28; difference = 1.3; 95% CI, 0.02-2.6; P = .05; Figure 19). Over the study period of 6 months, for the HCCQ-CGOVERALL, the overall study arm effect was in favor of the GA intervention (adjusted difference = 0.8; 95% CI, 0.0-1.6; P = .05); the adjusted mean GA intervention score was 17.4, compared with 16.6 in the usual care arm (Figure 17). There was no statistical difference in caregivers’ views about patients’ satisfaction with communication about aging-related concerns (HCCQ-PTAGE: adjusted means, 23.4 vs 22.3; adjusted difference = 1.1; 95% CI, −0.2-2.4; P = .08; Figure 19) or with the caregivers’ own communication about the patient’s aging-related conditions (HCCQ-CGAGE: adjusted means, 16.5 vs 15.6; adjusted difference = 0.83; 95% CI, −0.1 to 1.7; P = .07; Figure 18). Patients in the intervention arm reported significantly greater satisfaction with communication about overall care over 6 months than did those in the usual care arm (HCCQ-PTOVERALL: adjusted means 17.5 vs 16.8, respectively; adjusted difference = 0.7; 95% CI, 0.06-1.25; P = .03; Figure 20).
Figure 17. Caregiver Satisfaction With Communication About the Patient’s Overall Care (HCCQ-CGOVERALL)

![Graph showing caregiver satisfaction with communication about the patient's overall care.](image)

Abbreviation: GA, geriatric assessment.

Figure 18. Caregiver Satisfaction With Their Own Communication About the Patient’s Aging-Related Health Conditions (HCCQ-CGAGE)

![Graph showing caregiver satisfaction with their own communication about the patient's aging-related health conditions.](image)

Abbreviation: GA, geriatric assessment.
Figure 19. Caregiver’s View of Patient’s Satisfaction With Communication About Aging-Related Concerns (HCCQ-PTAGE)

![Graph showing Adjusted Mean (Standard Error) of GA Arm and Control over time (4-6 weeks, 3 months, 6 months). Study Arm: p=0.08]

Abbreviation: GA, geriatric assessment.

Figure 20. Patient Satisfaction With Communication About the Patient’s Overall Care (HCCQ-PTOVERALL)

![Graph showing Adjusted Mean (Standard Error) of GA Arm and Control over time (Telephone, 4-6 weeks, 3 months, 6 months). Study Arm: p=0.03]

Abbreviation: GA, geriatric assessment.
DISCUSSION

Context for Study Results

This study tested whether GA information provided to community oncologists improves patient satisfaction with communication about aging-related concerns and facilitates direct communication about aging-related concerns measured by audio-recording of clinical encounters. This study enrolled patients aged ≥70 years with advanced solid tumors or lymphoma who had other significant aging-related health conditions (eligibility criteria included at least 1 GA domain impairment [e.g., physical function, comorbidity, cognition], excluding polypharmacy). These were frail patients for whom treatment decisions were not evidence based due to exclusion of this group from clinical trials, yet such patients represent the majority of those receiving care in community oncology clinics. This study is the first large multisite intervention trial to demonstrate that providing a GA summary with GA-guided recommendations to community oncologists facilitates communication about aging-related concerns and improves patient satisfaction with communication and care. Also, the GA intervention significantly increased the number and quality of conversations about aging-related concerns. This study showed that GA improves the patient-centered outcomes of older patients with cancer. Secondary analysis also showed improvements at 4 to 6 weeks with caregivers’ satisfaction with their own communication about patients’ aging-related conditions. However, this benefit did not persist at the 6-month time point. In addition, the intervention did not improve QOL.

GA consists of a compilation of validated tools that assess specific domains (e.g., physical function, cognition) known to be associated with adverse outcomes in older patients; evidence has been increasing for the use of GA for evaluation and management of vulnerabilities in older patients with cancer to help guide shared decision-making between patients, caregivers, and oncologists.\textsuperscript{66,85} In patients aged ≥70 years receiving cancer treatment, GA should be used to identify vulnerabilities or geriatric impairments that are not routinely captured in oncology assessments. GA identifies clinically significant aging-related problems, such as risk for falls and cognitive impairment, that are not detected during a routine oncology history and physical
examination. In addition, GA provides information regarding geriatric-specific domains beyond those captured by standard oncology assessment tools, KPS, and the ECOG PS. For example, Repetto and colleagues found that GA added substantial information regarding the functional status of older patients with cancer, including those with good PS. Similarly, Serraino and colleagues found that GA “can help to better identify the specific needs of each patient with a poor [performance status] among the whole set of functional status parameters.” GA can identify other health problems that may not be detected during a routine history and physical examination, such as the need for assistance with daily function, malnutrition, and comorbidities. Kenis and colleagues showed that GA detected unknown geriatric problems in 51.2% (n = 931) of 1820 patients, most commonly related to function (40.1%) and nutrition (37.6%). Similarly to the results from previous studies, the results of our study show that there are significant domain impairments on GA in older patients with advanced cancer being cared for in the community, ranging from >90% for impaired physical performance to about 30% for impaired psychological status; our higher prevalence may reflect the finding that the patients being seen in the community are more ill than are patients enrolled in studies in academic centers but also may reflect that multiple tools were used in this study to evaluate each domain.

This study shows that providing older patients with cancer and their caregivers and oncologists with a GA summary improves communication about aging-related health concerns and satisfaction with communication about such concerns; before this study, there was no evidence-based approach for the use of GA to improve communication about aging-related concerns in oncology clinics. Older patients with advanced cancer and their caregivers must understand how cancer treatment (specifically chemotherapy) can affect QOL in light of underlying health status. Assessing the values and preferences of older patients with cancer is critical to informed treatment decision-making. Older adults with cancer and their caregivers are presented with complex information, but aging-related concerns and outcomes are not usually discussed. In 2007, the NCI published a monograph, coauthored by Dr Epstein, Patient-Centered Communication in Cancer Care, which reviewed 2200 communication studies in the setting of advanced cancer. The monograph highlighted the importance of patient-centered
care in effective communication. In health care settings\textsuperscript{,91} effective communication is characterized by (1) informed, activated, participatory, and communicative patients and caregivers; (2) informed, receptive, patient-centered, and communicative clinicians; and (3) a health care system that provides accessible, well-organized, and responsive health services that are tailored to the patient’s needs. This study is the first to show that a GA model of care can help facilitate communication about the high-priority aging-related concerns of older patients with cancer and their caregivers.

Several recent systematic reviews and prospective observational studies have demonstrated that GA results can influence cancer treatment decision-making. Problems identified by GA can impact decision-making for cancer treatment.\textsuperscript{85} In a systematic review by Hamaker et al\textsuperscript{,92} the initial cancer treatment plan was modified in 39% of patients based on GA evaluation. Two-thirds of these modifications resulted in less intensive treatment, likely an attempt to adjust treatment in patients who have GA impairments.\textsuperscript{6} In another large study by Kenis et al\textsuperscript{,89} the authors reported that GA influenced the treatment decision in 25.3% of older patients. In 2 hospitals, Decoster et al\textsuperscript{,93} found that physicians consulted the GA for 56% of patients (N = 902), and in these patients, the GA influenced treatment decisions in 44.2%. In large cohorts of older patients with cancer who undergo GA, the assessment influences cancer treatment decisions 20% to 47% of the time, primarily toward less intensive therapy. In the only RCT of GA being used to guide management, Corre et al\textsuperscript{,94} randomly assigned 494 older patients with non–small cell lung cancer to an experimental strategy on the basis of GA vs a standard strategy of chemotherapy allocation. Patients in the GA-guided treatment arm, compared with standard care arm patients, experienced significantly less all-grade toxicity (85.6% vs 93.4%, respectively; \( P = .015 \)) and fewer treatment failures as a result of toxicity (4.8% vs 11.8%, respectively; \( P = .007 \)), with no differences in survival.\textsuperscript{94} While the current study showed that GA improves patient-centered outcomes, future research with the data collected in this study as well as other ongoing RCTs will show how GA influences decision-making and other clinical outcomes.
Two studies of experts using Delphi consensus methodology have described interventions that could be used for each impaired domain on GA, and this information can guide clinical care. Partnering with caregivers to ensure the safety and well-being of older patients with cancer, especially those with significant functional and cognitive impairment, should be done when conducting research in this population. The uptake of GA-guided interventions by the oncologic team can vary depending on the infrastructure available to implement the intervention. For example, 1 study identified that >50% of patients had an impairment identified by GA; however, only 26% of patients received the recommended intervention when implementation depended on the treating oncologist. On the other hand, some studies have shown a higher intervention implementation rate based on the GA results when an infrastructure is in place to execute the interventions. Our future work will examine the relationship between adherence to GA-recommended interventions and outcomes.

Generalizability of the Findings

Patients and their caregivers were recruited from the outpatient community oncology practices affiliated with the URCC NCORP Research Base network. The results of this study are generalizable to the majority of older adults with cancer and their caregivers because the study included older patients with cancer and their caregivers from diverse backgrounds and with varying health statuses seen at a wide range of community oncology practices across the United States. The data may not be generalizable to older adults who identify as Black, Hispanic, or other non-White races/ethnicities due to the low recruitment of patients from these underrepresented backgrounds.

Implementation of Study Results

ASCO established a geriatric oncology task force. Through this mechanism, the findings of the COACH study will be disseminated to oncologists around the world. In addition, the first ASCO guidelines for geriatric oncology were published on May 21, 2018, to provide guidance regarding the practical assessment and management of vulnerabilities in older patients undergoing chemotherapy. An expert panel was convened to develop clinical practice guideline recommendations based on a systematic review of the medical literature. A total of 68 studies
that met the eligibility criteria form the evidentiary basis for the recommendations. The recommendation is that in patients ≥65 years receiving chemotherapy, GA should be used to identify vulnerabilities that are not routinely captured in oncology assessments. Evidence supports, at a minimum, an assessment of function, comorbidity, falls, depression, cognition, and nutrition. The panel recommended that IADLs be assessed to screen for issues with function, a thorough history or validated tool to assess comorbidity, a single question for falls, the Geriatric Depression Scale to screen for depression, the Mini-Cog or the BOMC test to screen for cognitive impairment, and an assessment of unintentional weight loss to evaluate nutrition. The COACH study demonstrates that implementing the above-mentioned guidelines in community oncology clinics is feasible, because all recommended assessment tools were included as part of the study. Future research will examine the optimal approaches to dissemination and implementation of GA in community oncology practices.

Subpopulation Considerations

With respect to older persons with cancer, in particular, there is a clear need for research on interventions to optimize the health of older patients with cancer, especially those who have medical problems other than cancer or are in the “older-old” (aged 70-80 years) and “oldest-old” (≥80 years) subgroups. Our results showed that there is an interaction between GA impairments by frailty status (robust vs prefrail vs frail) and outcomes; specifically, the frailest patients were not as satisfied with the GA process as were those who were less frail. It may be that for frail older adults, the summary and recommendations were too lengthy to review during 1 clinic visit. Patients with lung cancer and those treated with monoclonal antibodies had more communication about aging-related concerns during the clinic visit; this may be because patients with lung cancer may have more aging-related conditions that influence cancer care, and that patients who receive monoclonal antibodies are more susceptible to chemotherapy toxicities. Practices demonstrated heterogeneity in communication (both in satisfaction scores of patients and in communication about aging-related concerns during the clinic visit); further research should investigate if this is the result of oncologist-, patient-, or system-level factors.
Study Limitations

For this study, only 1 clinic visit was audio-recorded and analyzed; therefore, we were not able to assess communication in a more comprehensive manner. One visit may not be representative of other visits. Future work should measure direct communication over time. Another limitation was the small number of non-White participants enrolled in the COACH trial. We will continue to work with our community stakeholders to identify and address barriers to non-White participation in clinical trials. We recognize the underrepresentation of non-White patients in clinical trials including the present COACH trial and worked with our community site stakeholders to address the recruitment of these populations. To elucidate the difficulties sites have enrolling older non-White patients in clinical trials, we asked what barriers these clinics face when it comes to enrolling underserved patients. Clinics cited multiple reasons for barriers to recruitment, including, but not limited to, language barriers, mistrust of the health care system, participant burden of studies, and lack of knowledge. Future studies should work with patient and caregiver advocates to provide a unique perspective about recruiting older adults from non-White races/ethnicities for clinical trials.

Future Research

Using the data collected from this trial, we will examine the quality of communication about aging-related conditions in community oncology visits using a mixed-methods intervention design. We will look quantitatively at patient and caregiver satisfaction with communication and conduct further analyses of the transcribed audio recordings of the clinic visits to examine and capture the quality of the conversations to (1) evaluate concordant and discordant themes and perform comparative analysis across groups, and (2) evaluate differences in satisfaction with communication between high- and low-quality conversations.

Using the data collected from this trial, we will also conduct research to improve our understanding of financial toxicity in both patients and caregivers, patient preferences, the caregiver experience, and missed opportunities in oncology settings. Using data science methods, we will evaluate the conversations in the transcripts of audio-recorded visits between
patients and physicians to more precisely evaluate the quality of the conversations via machine learning.
CONCLUSIONS

The COACH study is the first study to demonstrate the utility of GA to improve patient-centered outcomes (specifically satisfaction) of older patients with cancer. In addition, this study demonstrated that GA can be integrated into routine oncology care; oncologists used GA during a clinic visit with older patients and their caregivers to guide discussions about aging-related concerns. This study demonstrates that ASCO guidelines are feasible to implement in community oncology practices. The COACH study demonstrated that a web-based GA summary with recommendations for GA-guided interventions improves patient-centered outcomes, including direct communication about aging-related concerns and patient satisfaction with communication; however, in this study, GA did not improve the QOL of older patients. This study was the first to evaluate GA in a cluster randomized trial for older patients with advanced cancer. These analyses also show that providing a GA summary with GA-guided recommendations to community oncologists improved caregiver satisfaction with communication about the patient’s overall care within 4 to 6 weeks after the intervention; caregiver satisfaction with their own communication about the patient’s aging-related conditions; and caregiver views of the patient’s satisfaction with communication about aging-related concerns up to 3 months after the intervention. However, benefits to caregiver satisfaction were not found at 6 months, and there was no significant improvement in caregiver QOL.

GA identifies risk factors for adverse outcomes in older patients and adds information to standard oncology performance measures.\(^{19}\) Well-designed prospective observational studies have found that items included in a GA summary can identify older patients at greatest risk for chemotherapy toxicity and mortality.\(^{23,26,82,96,97}\) We have also shown that GA improves the quantity and quality of aging-related discussions in patients with advanced cancer and improves patient and caregiver satisfaction with their communication with the oncologists. Studies have shown that GA is feasible for use in community oncology clinics.\(^{13,23,27}\) Consensus panels of geriatric oncology experts have recommended several validated tools that identify older patients receiving chemotherapy at highest risk of adverse outcomes and that are practical for
use, even in busy oncology clinics. These results are consistent with the growing geriatric oncology literature and other expert guideline panels recommending that oncologists use GA in the care of older patients with cancer. Our study also demonstrates the feasibility of conducting the GA in busy community oncology clinics in patients with advanced cancer who are largely excluded from clinical trials. Ultimately, the choice of which GA tools to use depends on the questions being asked, how GA results will be used, and the resources available for implementation. In the new ASCO guideline, the expert panel proposed that at a minimum, measurements of IADLs, comorbidity, depression, and nutrition; record of fall history; and cognitive screening should be administered for all patients aged ≥65 years (see “Implementation of Study Results” for more details). The COACH study included all the ASCO guideline-recommended tools and demonstrates their feasibility for community oncology clinics. The tools recommended by the ASCO guidelines were used in our study to capture GA domain impairments. In addition, more conversations in the intervention arm led to GA-guided recommendations than did those in the control arm.

The results from the study demonstrate the need for further research to examine whether providing a GA summary and recommendations for interventions to community oncologists can improve other clinical outcomes. In addition, more research is needed to identify ways to support caregivers who care for older patients with advanced cancer. Our next steps will be to further investigate ways to disseminate and implement GA for community oncology clinics as well as improve caregiver outcomes.
REFERENCES


ACKNOWLEDGMENTS

Coauthor Arti Hurria, MD, died November 7, 2018.
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Appendix A
Letters and Protocol Changes
Protocol Changes after receiving University of Rochester Institutional Review Board (IRB) Approval:

1. Response letter to National Cancer Institute (NCI) explaining protocol changes as part of new dual funding mechanism----------------------------------------------- Page 5-12

2. Protocol Amendment changes----------------------------------------------------------------------------------- Page 13-16
Dear Cancer Prevention and Control Concept Review Committee:

Thank you for the thorough review of our study “URCC13070: Improving Communications for Cancer Treatment: Addressing Concerns of Older Cancer Patients and Caregivers.” This Phase III randomized trial was submitted as a trial to be funded by the Patient Centered Outcomes Research Institute (PCORI) and the NCI through the University of Rochester CCOP Research Base. It was approved by PCORI in April, 2013 with funding starting July 1, 2013. We agree with the Committee regarding the importance of this PCORI supported study for assessing communication between older patients, their physicians, and caregivers. We also appreciate the need for the study to be acceptable to both PCORI and NCI. Your review asks us to exchange the primary aim with one of the secondary aims and for minor clarifications in the concept. We believe we have fully addressed all of the recommendations.

PCORI expressed understanding for the delays caused by the government shutdown and NCI’s required review. Despite that, since we are funded by a contract, PCORI is unable to provide any no-cost extensions. Due to the above, we are already behind in some of our contract milestones.

Therefore, we really need to start study procedures as soon as possible and would greatly appreciate anything the NCI can do or we can do to speed up the review process, now that the main scientific item requested (e.g., primary endpoint modification) has been met.

The revised concept contains additional information to address the requested clarifications. The purpose of this intervention is to provide clinically important geriatric assessment information reported by patients along with recommendations derived from the geriatrics literature to oncology physicians so that they can address these concerns with the older patient and his/her caregiver. We have added background information on geriatric assessment (section 2.4), relevance of recommendations from geriatric assessment for older adults with cancer (2.5), relevance to communication and patient-centered care (2.6), and qualitative preliminary data on concerns that patients and caregivers deem as very important that can be captured from geriatric assessment (2.7.5 and Table 1). Further pilot data supporting the aims, outcomes, and sample size for the study is provided.

The concept is well-developed; it contains all of the information present in the protocol except for recruitment, registration, and data management procedures. If the submitted concept is acceptable, we could quickly make revisions before submitting a final protocol. If helpful, we could submit the protocol to the NCI within a few days turn around to help streamline the process. Please advise us.

We understand this is an evolving new prototype for future collaborations, and are very willing and able to work with both NCI and PCORI to help the synergy work and ensure this is a successful study. We believe that this study is an important example of how this type of collaboration can facilitate important cancer care delivery research that might not otherwise be able to be funded. The reviews of the project by the PCORI committees specifically praised the synergy of the two funding sources working in concert.
Below are our responses to the changes requested and the clarifications sought in the NCI review.

1. **Review:** “The hypothesis and primary objective are not only difficult to define, but will not provide data that can be utilized to improve patient care. One can assume that the group of oncologists with easy access to the patients’ geriatric related concerns and recommendations will be able to address them or respond to them with the patient; however, the control group will know the nature of the study and may perform better than usual in their geriatric assessment. Both groups will be biased.

The Review Committee believes that the secondary objectives of patient/caregiver satisfaction or patient quality of life or other measures of improvement in care would be more useful primary endpoints, as it is difficult to relate the number of items addressed in an office visit with the delivery of care to the patient.”

**Response:** PCORI funded us through the “Communication and Dissemination” portfolio of the Patient Centered Outcomes Institute and our original primary aim (now secondary aim 1) was highly valued by their reviewers, who agreed the study would address a critical gap in the knowledge regarding how to improve communication about age-related concerns between older adults with cancer, their caregivers, and oncologists.\(^1\)\(^3\) In our discussions, the PCORI project oversight group agreed that both communication and patient satisfaction with communication were both worthy outcomes of the study, but stressed that we needed to fulfill our contractual obligations. Although we changed our primary aim to satisfaction, we have retained the power analysis for the original primary aim in the concept since 1. the new primary aim requires a similar sample size, and 2. this satisfies both NCI’s and PCORI’s concerns. It is important to remain as close to the purpose of the funded contract as possible and be able to report something meaningful about this aim. We feel this is a very reasonable solution in the spirit of collaboration that adequately meets the requests of both funding groups.

As mentioned above, the new primary endpoint will be a measure of patient satisfaction with communication. We were luckily able to quickly access pilot data from Dr. Epstein’s NCI-funded VOICE study.\(^4\) This pilot data supports the use of the Health Care Climate Questionnaire (HCCQ) as the primary aim for this study and provided us with the data to estimate an intracluster correlation coefficient (ICC) required for sample size calculation for a cluster randomized study. Similar to other studies which adapt satisfaction scales to capture specific clinical criteria (e.g., satisfaction with physician regarding communication about chemotherapy),\(^5\) the HCCQ has been modified for this study to specifically address patient satisfaction with physician behaviors and communication regarding age-related issues and concerns in order to specifically address satisfaction with the intervention (geriatric assessment summary and recommendations) rather than satisfaction with other aspects of cancer care (e.g., communication about cancer treatment). As is done with satisfaction with care surveys in other research and in clinical settings, the HCCQ (both modified and original) will be administered within 1 week after the audio-taped clinic visit.\(^6\)\(^9\) Please refer to Section 4.1 and 9 in the
concepts for further information on HCCQ and sample size calculation. The HCCQ measures are included with the submission.

In answer to the first part of this concern, we do not agree that any bias from knowing a group assignment will significantly bias the study. Although the control arm is aware of the study purpose, previous studies of geriatric assessment (see Sections 2.4 and 2.7) conducted with cancer patients have demonstrated that there is still a significant lack of understanding on what to do or how to respond clinically to this information.

2. **Review:** “In the concept especially sections 4.1 and 5.3.2 are references to physician explanations of prognosis, physician responses to patients’ emotional concerns, and physician decision making (5.3.2 and 7) regarding cancer therapy choices for their patients. Please clarify how this will assessed and what this information will be used for. Is this part of the secondary aims?

**Response:** Re: Clarification re: sections 4.1 and 5.3.2. which refer to explanations of prognosis and physician responses to patients’ emotional concerns. When the directly observed communication outcome was our primary outcome, we intended to also utilize the audiotapes to evaluate physician communication behaviors. This work is derived from Ron Epstein, a co-investigator on the study, and is used as the primary outcome for his NCI-funded study, R01CA140419. These outcomes are derived from the actual audiotapes and coders address communication behaviors of engaging and responding to concerns as well as how they inform and frame information. The protocol for how to code and analyze physician communication behaviors is well-developed by Dr. Epstein’s team as demonstrated by his previous work in this area.  

Although this work may be able to provide information on how physicians communicate cancer treatment options to older patients with other significant medical problems, it is not essential to the current study after it has been re-designed (since patient satisfaction with communication is now the primary aim) and therefore these exploratory analyses have been eliminated. We will explore these analyses as the basis for future work in this area.

Re: Clarification of physician decision making regarding cancer therapy choices for their patients (sections 5.3.2 and 7) and what physician baseline forms questions section 4.3.3 are addressing. This study recruits an older patient population with advanced cancer and other medical or geriatric problems (having at least one impaired geriatric domain is part of the eligibility requirement). This study, therefore, gives us an opportunity to understand how treatment decisions are made for older patients with advanced cancer and other medical or geriatric problems. This is a complex clinical situation with uncertainty regarding risks and benefits of different treatment options. We therefore added an exploratory aim which is to describe how patients, caregivers, and oncologists make decisions for cancer treatment. Sections 4.3.3 and 5.3.2 refer to a baseline survey from physicians that will obtain a brief amount of information regarding their background and decision-making preferences. At baseline, one situational vignette will also be given to each physician that assesses how the physician
approaches cancer treatment in older patients with advanced cancer. Baseline surveys can be completed through an email link using REDCap or on paper, whichever the physician prefers. We have pilot tested the survey and it takes less than 10 minutes to complete. After the audi-taped clinic visit, the physician will complete one brief form (< 5 min to complete), which captures the factors that influenced the final treatment decision. Because this study is about communication, we feel that it is important to collect information about the physician and how the physician approaches treatment decisions for this population. We will submit the physician forms with the full protocol.

Section 7 in the concept refers to the intervention and what the physicians will do as part of the intervention. The physicians will have a 20 minute training phone call with the PI or senior study staff to provide training on how to utilize the geriatric assessment information in clinical practice. This procedure is part of the intervention. Based on our IRB requirements, physicians will be informed about these procedures prior to enrollment with a document that outlines all the required procedures, but do not need to provide a formal consent. We will submit these documents and outline this plan in the full protocol.

**Re:** In section 4.3.5 is all of this data necessary to obtain from time-consuming chart review. In summary, please explain what will be done with the large amount of information that is to be collected. Because we are evaluating treatment choices and outcomes from treatment in an older patient population with advanced cancer, we had originally thought to gather information on adverse outcomes (e.g., hospitalizations) and health care utilization. However, we agree with the reviewers that this chart review is time-consuming and have eliminated it. We will ask CRAs at the sites to report what the final treatment plan is after the audiotaped visit in order to evaluate how treatment decisions are made, but will not require extensive chart review or laboratory and medical records. In order to allow us to conduct future work in examining cost-effectiveness and impact of geriatric assessment on health care utilization, we will ask patients in their consent forms for permission to obtain their Medicare claims for future work. This will not be done in this study but will set up the opportunity to conduct future cancer care delivery projects. Patients will still be able to participate in this study if they choose not to give permission to obtain their claims for future studies. We have revised section 4.3.5 accordingly.

3. **Review:** “Clarify the importance of obtaining a “partial response” is in section 5.3.3. Are the physicians being assessed on number and quality of domains discussed? The quality of communication would be a separate objective, as the number of domains is stated to be the first aim.”

**Response:** We agree and assessment of quality of communication has been eliminated as noted in 2 above.
4. **Review:** “The number of visits required on page 10 may interfere with accrual, as the baseline visits may possibly be performed as inpatient consultation or patients may receive treatment immediately after their first consultation”

**Response:** The vast majority of oncology care occurs in the outpatient setting and it is rare that patients start treatment immediately after their first clinic consultation. The CCOP community physicians at our September, 2013 meeting evaluated the procedures and helped us refine them so they would work within their clinical practices. The study procedures, therefore, are in line with how oncology consultations work the vast majority of time: patients with advanced cancer see the oncologist to discuss either a new diagnosis or progression of disease (e.g., s/p surgery or adjuvant treatment), treatment options are discussed, the patient and caregiver/family are provided with opportunity to discuss options at home and/or make a treatment decision in the office, and then another visit is scheduled with a treatment time in infusion center or for after approvals for oral treatments are obtained. There is generally another visit with the oncology team before treatment is initiated to go over procedures for treatment including a review of side effects. For patients who decline treatment, follow-up visits are scheduled where symptoms or a palliative care plan are discussed after the initial visit.

As part of the study, we do require that the physician have just one visit with the patient after consent and before treatment is initiated (Visit 1). It was confirmed by the CCOP community physicians that this commonly happens and that they were willing to have one study visit with the patient. They mentioned that the therapeutic trials they work with in the community usually have many more visits that are required for eligibility and baseline procedures.

In the rare situation that a patient is treated in the hospital urgently or receives chemotherapy immediately after their visit, the patient will not be able to participate in this trial. These patients are not usually able to enter into any clinical trials, ours or others, due to the need for urgent treatment. The study is able to accommodate patients starting treatment the next day after the consent is obtained as long as the physician is willing to have a visit with the patient because all baseline procedures can occur in a one day period of time (see response to 8). Therapeutic trials often require a significantly higher number of tests and procedures for eligibility requirements and the CCOP community physicians and staff felt that this study was feasible and seemed much easier to carry through then other studies they have worked with.

5. **Review:** “List all secondary aims in section 2.2 (as mentioned in section 4.2).”

**Response:** We have clarified the aims (which have moved to section 1) and they now match with section 4.2.

6. **Review:** “Changing the primary objective may drive down the number of participants required, and thus aid with finishing the study over 3 years per the PCORI grant. Already collected data from the geriatric R01 study may allow elimination of the first phase of the study.”
Response: Please refer to the response for 1. Calculating power for the new primary aim led to a very similar sample size as the new secondary aim. We agree that we could eliminate the first phase of the study for sites that have completed procedures for the R01 study and have included this in this study’s procedures.

7. Review: “Please clarify table 1. Are all non-starred items to be assessed at any later time points – is the GA being used to predict prognosis or to follow patients or both?”

Response: The Table 1 the reviewer is referring to is now Table 2 in the concept. Table 2 describes the baseline geriatric assessment and what is used as a cut-off for impairment on each domain. Only patients who have at least 1 impaired domain will be eligible for the study. We will follow a few of the geriatric assessment measures over time (e.g., function, cognition, physical performance, and depression) as these are highly correlated with HRQoL. A Table that summarizes the measures has been provided.

8. Review: “Please clarify the procedures on page 10, especially for visit 0; it is unclear as to how many tests will be administered, whether they are outside of the geriatric assessment, and who will administer the test. This information would be helpful in a table format. Please revise the footer that may be obstructing part of page 10.”

Response: All measures have been piloted in our geriatric oncology clinics (Mohile, Dale, Hurria) and through preliminary data now described in the concept (Section 2.7). We have outlined the measures that will be completed by the physician, CRA, patient, and caregiver in the Outline of Procedures and fixed the formatting issue. We also included a summary of measures and a Table of measures that describes all the measures for the physician, patient, and caregiver.

Visit 0 refers to the day that the consent is obtained. Because we understand that patients and caregivers will be presented with a large amount of information on the day they provide consent, we have incorporated flexibility into the protocol so that patients and caregivers can choose when they want to complete the baseline surveys and procedures with the CRA. We allow patients and caregivers to complete the surveys at Visit 0, take the surveys home and bring to Visit 1, or complete before Visit 1 in the office. We also allow the CRA to complete baseline geriatric assessment procedures (physical performance and cognitive tests) on either Visit 0 or Visit 1. In our geriatric oncology clinic, we mail a close replica of the surveys incorporated in this study to the homes of patients a week before their new patient visits. Over 90% of patients bring the surveys to their first visits. Patients and caregivers have expressed appreciation with this process as they prefer to complete surveys on their own time at home rather than in the office. We will collect information on who completes the surveys (patient, caregiver, or patient with assistance from caregiver/CRA). Visit 1 should occur within 2 weeks of Visit 0.
9. Review: “Statistical analysis will be re-assessed with the changing of the primary endpoint”

Response: Please refer to Section 9 in the concept for an overview of the statistical analysis.


Sincerely,

Supriya Mohile

Supriya Mohile, MD, MS
Associate Professor of Medicine
Director, Geriatric Oncology Program
James Wilmot Cancer Center
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University of Rochester CCOP Research Base
Summary of Protocol Changes throughout Study

2/24/2014 to University of Rochester RSRB

1. Throughout the protocol – Modified primary and secondary aims and hypotheses, added to study procedures, and changed study design at NCI’s request to reflect the following: The primary outcome, patient satisfaction regarding communication about age-related issues as measured by a modified Health Care Climate Questionnaire (HCCQ), will be obtained via a phone call administered by trained personnel, the Telephone Team, who are blinded to group assignment within 1 to 7 days of the baseline audio-recorded clinic consultation, hereby referred to as the Telephone Team Call. Caregivers will complete measures of satisfaction, and caregiver burden (both health and economic) at the same time points. However, caregivers will not receive the Telephone Team Call. Throughout the protocol, language was added to describe the procedures for completing the primary aim.

2. Throughout the protocol: Added language on research findings that support further research on primary and secondary aims.

3. We have included a “version date” in the protocol footer and have updated the dates on the consent form.

4. Throughout the protocol, we clarified names for study visits, arms and sites.

5. We modified ‘chemotherapy’ to say ‘cancer treatment’ throughout the protocol.

6. Throughout the sections on study design and eligibility (Sections, 1,3,4) we clarified the eligibility criteria: Adults, age ≥70 with an advanced solid tumor malignancy, who have not received systemic cancer treatment (e.g., chemotherapy, monoclonal antibodies, or targeted therapies) for the current diagnosis of advanced cancer in the University of Rochester Cancer Center Community Clinical Oncology Program (UR CCOP) network, will be eligible. Physicians who practice at sites within the URCC CCOP network are eligible to participate in the study and will be enrolled.

7. Throughout the sections on study design (Sections 1 & 3) - Clarified criteria for completing the observational phase of the study to say: An interested practice site will be able to participate in the next phase of the study, if the practice site has met one of the following criteria: enrolled 2 patients in the lead-in period, underwent geriatric assessment training procedures for another study, or 3 months have passed from the time of the first practice site IRB approval. Practice sites that do not enroll patients during the 3 month “lead-in” period, will enroll all future eligible patients according to the randomized treatment group assigned to that practice site. Clarified throughout the protocol that there will be a maximum of 2 patients per CCOP for completing the observational period.

8. Clarified number of participants: A total of 578 patients and 578 caregivers (maximum) will be enrolled in the study; 50 during the observation period and 528 during the cluster randomized period. (page 5).

9. Sections on Study Design, eligibility were clarified to reflect the following inclusion criteria: Must be undergoing the decision for first line treatment with chemotherapy and/or monoclonal antibody therapy and/or targeted therapy for the current diagnosis with their primary oncologists. Patients for whom radiation is being considered are eligible as long as radiation is being considered for non-curative (i.e., palliative) purposes. Patients are not required to ultimately receive these therapies.

10. Section on exclusion criteria for physicians was clarified: Plans to leave CCOP practice or retire at time of enrollment into study.

11. Section on eligibility - “a cancer that is IV” has been changed to “a stage IV cancer”.

12. Sections for study summary and eligibility included definition for GA and Caregiver.
13. Section on procedures added language: “audiotapes will be labeled and stored using the patient’s initials and date.”

14. Changed eligibility for patients to say that patients must have at least one score within GA indicating impairment other than polypharmacy.

15. Modified Table 2: Components of the Comprehensive Geriatric Assessment.

16. Section on Outcomes updated to reflect: We will obtain information about disease location, pathology, stage, and metastases from CRA surveys and will request information from the CRA on the final treatment recommendations made and implemented. We will utilize medical information to verify eligibility and in our exploratory aim to understand how communication about age-related issues is related to decision-making for cancer treatment.

17. Study Procedures section and outline of study-specific procedures updated to reflect telephone team call, clarification that materials will be submitted within 7 days, clarification on physician procedures for REDCap, clarification on registration procedures and edits for improved readability. All edits to eligibility criteria are also included in the Study Procedures section.

18. Clarified that ONLY serious adverse events related to the study procedures need to be reported for data and safety monitoring purposes and that AEs and SAEs related to routine oncology treatment and care DO NOT need to be reported, but will be collected on outcomes forms as per Appendix X-2.

19. Section on Statistical Plan was updated to address the changes in primary and secondary aims.

20. Marie Flannery PhD, NP and Rita Gowara-Bhat have been added as co-investigators on the study.

21. Data Management Section updated: data submission should now be mailed to Libby Nagalski.

22. A follow-up physician survey on REDCap has been added collecting data on physician’s confidence in geriatrics and opinion of the geriatric assessment. The latter for only intervention practice site physicians.

23. Surveys on HCCQ and HCCQ-communication have been added to collect the primary aim.

3/26/2014 to NCI

1. As suggested by the NCI, we removed the “lead-in period.” The schema was changed as a result and all language related to the “lead-in period” in the protocol and consents were removed.

2. As suggested by the NCI, we clarified that a caregiver should be recruited with the patient as much as possible. We did allow patients who do not have a willing caregiver to participate as we would want to include these vulnerable older adults in the study. We will require sites to specify reasons behind lack of participation by a caregiver during the registration process. These clarifications along with our training will hopefully create an expectation for caregiver recruitment.

3. We reorganized the document as much as possible so that it is clearer. We also reviewed and clarified the schemas and tables so that they are accurate. We moved the Table of Measures to Appendix 1 so it is easier to find.

4. We clarified that scoring of the GA would occur in both of the arms.

5. Statistical comments: We conducted a thorough review of the statistics section and corrected all inconsistencies and typos.

6. Screening log updated to reflect patients, caregivers, and physicians and language in protocol reflects updated screening log as requested by the NCI.

7. Typos were corrected.
8. Clarified eligibility and requirements for contact information.
9. Clarified that future research activities will consist of “future research activities on health care utilization and costs of cancer care delivery.”
10. Provided language on confidentiality of audiorecordings.
11. Added language to clarify caregiver’s participation in the study.
12. Study population was updated to reflect 528 people with each patient encouraged to have one caregiver participate.
13. The term ‘oncology physician’ is used for consistency and replaced the terms, doctor, oncologist, and physician.
14. Added language to clarify the timing of caergiver enrollment. “Caregivers must enroll in the study before or on the baseline visit because they will accompany the patients during the clinic consultation that will be audio-recorded (baseline) and complete surveys.”
15. Clarified health care proxy participation as caregiver with the following language: “The health care proxy should agree to participate in the study as the caregiver. If a health care proxy chooses to stop their own participation in the study, but is able to assist the patient in completing the study, the patient can still participate.”
16. Registration procedures and eligibility criteria updated to reduce redundancy.
17. Registration information and time allotted for visits updated for accuracy.
18. Language added to clarify on procedures for telephone team call.
19. Language on procedures for the cognition and depression assessments added: “Prior to the study visit with the oncology physician, if depression (GDS) or cognition (BOMC) assessments score ≥ 11, inform patient’s oncology physician as follows:
   ▪ Usual Care arm -- inform oncology physician with template as per training.
   ▪ Intervention arm -- information on cognitive impairment or depression is included in summary (see section 10.3.3, Intervention Procedures).”

11/1/2014 to NCI

1. Included minor grammatical changes, changed “CCOP” to “NCORP”, made terms consistent, and deleted repetitive sections.
2. Revised eligibility requirements in response to feedback from community sites; verified that our power and statistical plan would not change as a result of these changes.

   Our primary aim for this study is to evaluate whether the geriatric assessment (GA) with geriatric assessment-driven interventions can improve communication with regards to age-related concerns of older patients and caregivers in oncology clinical practice.

   Our current eligibility requires patients to be considering first line chemotherapy. But sites have communicated that trying to recruit, screen with the GA, and enroll a vulnerable older patient population in a short period of time prior to starting first line chemotherapy for advanced cancer is logistically very difficult. Often these patients are new patients to the clinic, they are overwhelmed, and treatment needs to start in a short period of time for advanced cancer.

   In our pilot data, derived from Dr. Epstein’s NCI-funded VOICE study, patients were included in any stage of the cancer care continuum (from diagnosis to end of life). We found there was “room to improve” with regards to patient satisfaction about communication and with oncology teams addressing patient and caregiver age-related concerns for all older patients in that data.

   Therefore we are comfortable in amending the protocol so it is similar to the pilot study; that any patient aged 70 and over being followed in oncology clinical practice with advanced cancer who is either undergoing a decision to receive treatment or who is receiving treatment for cancer will be eligible. We have added language to specify that patients receiving any kind of cancer treatment are eligible. Patients who have already made a decision to not receive cancer treatment (e.g., in best supportive care or hospice) will be excluded.

   Since age-related issues are common for all older patients with cancer, this modification will also make the study more generalizable by allowing geriatric assessment information to be utilized for patients with advanced cancer in any treatment situation or in best supportive care and from a larger proportion of patients in clinical practice. Patients starting new treatments for cancer are still eligible
for this study, and subset analyses can evaluate how age-related issues impact the decision to start treatment.

3. Provided additional options for oncology physician intervention training to add flexibility when scheduling training can be difficult (e.g. individual phone call with the PI, webinar, reviewing the slides and attestation). Provided further clarification that office staff (research or clinical staff) can be trained to complete the geriatric assessment. Provided suggestions on how to implement the geriatric assessment into clinical practice.

11/1/14 to University of Rochester RSRB
1. Revised eligibility requirements in response to feedback from NCI and community sites; verified that our power and statistical plan would not change as a result of these changes.

Any patient aged 70 and over being followed in oncology clinical practice with advanced cancer who is either undergoing a decision to receive treatment or who is receiving treatment for cancer will be eligible. We have added language to specify that patients receiving any kind of cancer treatment are eligible. Patients who have already made a decision to not receive cancer treatment (e.g., in best supportive care or hospice) will be excluded.

For a detailed list of the changes, please see below.

Section ‘4.2.1b. Inclusion Criteria for Patients Changed to:

4.2.1b. Diagnosis of an advanced solid tumor malignancy (advanced cancer) or lymphoma. In most situations, this would be a stage IV cancer. A patient with a diagnosis of stage III cancer or lymphoma is eligible if cure is not possible or anticipated. Clinical staging without pathological confirmation of advanced disease is allowed.

Must be considering or currently receiving any kind of cancer treatment (any line), including but not limited to hormonal treatment, chemotherapy, monoclonal antibody therapy, or targeted therapy. Patients who are considering therapy are eligible even if they ultimately choose not to be on therapy. Patients with a history of any previous cancer treatment, including radiation and/or surgery are eligible. A patient may also be enrolled on a treatment trial and participate in this study, if all other inclusion and exclusion criteria are met.

Section ‘4.2.2b. Exclusion Criteria for Patients Added:

4.2.2b. Have already made a decision to not undergo any cancer treatment (e.g., being followed in best supportive care or hospice).

4/25/17 to NCI
1. Clarified and outlined the statistical analysis in greater detail in the protocol. No changes were made to outcomes or statistical plans, rather clarifications and more detail regarding randomization and planned analyses were added. These revisions were incorporated after NCORP statisticians review of the statistical analyses procedures in preparation for analyses to be conducted after the study accrual is complete and data on the primary aim is collected.

Summary of significant changes (pages refer to the tracked version of the protocol):
A. Language was included to clarify aims specified by the funding agencies, NCI and PCORI. The aims themselves are not changed. (section 2, page 14)
B. Exploratory aims were clarified. These clarifications build on coding procedures that were finalized after the protocol was approved as well as include survival as an exploratory aim (survival data is already being collected as part of study procedures) (section 2.3, page 15)
C. Updated coding procedures and survival data collection procedures were included in the Outcomes section. (section 7.2 page 21-22)
D. More detail was added to describe the cluster randomization process. (section 9, page 25)
E. Minor edits were made to the statistical plan to provide clarity. No changes to the plan (power, analyses) were made. (section 15, pages 34-37
Appendix B
NCORP Affiliate Map
Appendix C

Primary Aim: Patient Satisfaction with Communication about Age-related Concerns: Telephone HCCQ
The below page captures the modified Health Care Climate Questionnaire (HCCQ-Age) which was used for the primary aim of the study. The modified HCCQ-Age specifically addresses patient satisfaction with their oncology physician’s behavior and communication regarding age-related issues and concerns.
Satisfaction with Communication About Other Medical Issues and Aging Concerns

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neutral</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Your cancer doctor encouraged you to ask questions about your other medical issues in addition to the cancer and/or any health concerns that could be from aging.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>2.</td>
<td>Your cancer doctor was willing to discuss your other medical issues in addition to the cancer and/or any health concerns that could be from aging.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>3.</td>
<td>Your cancer doctor gave you information you could understand about your other medical issues in addition to the cancer and/or any health concerns that could be from aging.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>4.</td>
<td>Your cancer doctor helped you to feel comfortable discussing how cancer treatment could affect your other medical issues in addition to the cancer and/or any health concerns that could be from aging.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>5.</td>
<td>You feel your cancer doctor understood your overall health, including your other medical issues in addition to the cancer and/or any health concerns that could be from aging.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>6.</td>
<td>I understand why my cancer doctor suggested my treatment plan because he/she talked with me about my medical tests and procedures and how it led to my current diagnosis.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>7.</td>
<td>You feel your cancer doctor understood you as a person, including values and beliefs important to you.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
The below page is captures the original Health Care Climate Questionnaire (HCCQ) which measures patient satisfaction with physician behaviors regarding their care.
### Satisfactory with Overall Communication About Overall Health

<table>
<thead>
<tr>
<th>Satisfactory with Overall Communication About Overall Health</th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neutral</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Your cancer doctor encouraged you to ask questions.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Your cancer doctor was willing to discuss any topic of importance to you.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Your cancer doctor gave you information you could understand.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Your cancer doctor helped you to feel comfortable discussing what to expect in the future.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. You feel understood by your cancer doctor.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix D
Secondary Aim 1: Direct Communication about Age-related Concerns: Coding Procedures and Manual
The present manual is a proposal for a coding system of clinical encounters between oncologists, patients, and caregivers regarding discussions around aging related concerns. In general we are coding for explicit behavior versus implicit behavior as it relates to aging, symptoms, or uncertainty, unless otherwise outlined. Explicit is defined as the concern being specifically stated; the geriatric domain is specifically mention and addressed it is not implied or indirect. For example, I am worried that you have had 3 recent falls; I am concerned that you have recently lost 20 lbs., or I am worried that the medicines you prescribed will interact with my diabetes medications. (Implicit reference to a geriatric domain means the concern is obliquely or indirectly mentioned; it is implied and not directly stated. Implicit reference to the cognitive domain is present in the example transcript. The provider refers 3 different times in the conversations to aspects related to the patient’s cognitive status – twice by asking the patient and once by asking the family member. If you identify an implicit referral to a domain other than cognitive bring to a consensus meeting with the PI or designee.)

GENERAL COMMENTS
In developing this coding manual, we utilized aspects of other coding schemes.

- VERONA coding scheme differentiates between cues and concerns. A “cue” often is vague and requires clarification from the healthcare provider. In contrast, a “concern” is clear and does not need clarification from the healthcare provider.
- The Motivational Interviewing Treatment Integrity scale codes for specific behavior counts that are associated with behaviors that are in line with motivational interviewing.

CODING

Coding Principles
- Discussions related to one domain can stop and start again at a different point in the transcript. This would be coded as one age related discussion. For example, if a patient starts talking about being confused, and then moves onto talking about feeling nauseous and then later in the visit the caregiver brings up the confusion again, this would all be coded as a single age related discussion regarding confusion and as a symptom of nausea separately. One would not code that there were two age related discussions regarding confusion.
- Any age related discussion will be coded with the following information.
  - Coding “who” initiated the discussion regarding an age related concern.
  - Coding which “Geriatric Assessment” Domain is discussed.
  - Coding the “discussion quality” of the age related concern.
- Symptoms will also be coded. Transcripts will be coded to document any discussion regarding symptoms. Each symptom will be identified and who initiated the symptom discussion will be coded.
- Uncertainty will also be coded.
Inter-rater Reliability
- Inter-rater reliability will be established during training for all coders.
- During training, team coding will be done. Inter-rater reliability will be assessed until 70% agreement is reached for a minimum of five transcripts.
- To ensure ongoing inter-rater agreement, inter-rater reliability will be assessed. If 70% agreement is not achieved, additional training will be conducted.
- Overall, a minimum of 20% of transcripts will be assessed for inter-rater agreement.
- The percent agreement will be calculated using the difference or variance between each individual coder and the final consensus code, to calculate the variance for each coder from the consensus, the difference between the agreed consensus and individual coder will be divided by the agreed consensus. The average will then be calculated as a final percent agreement. If 70% inter-rater reliability is not reached at any time the PI will be notified and ongoing training implemented until 70% agreement is reestablished.

Overall Coding Scheme

Step by Step: Coding Procedure and Data Entry
1. During the first read through, begin coding for the geriatric domains. All coders will code using the transcript in Atlas.ti. All coders will have an Atlas entry for each transcript he or she completes.
2. Identify the specific concern and who initiated it. Also, identify if the geriatric assessment was mentioned and if there are any actions under the general domain.
3. During the second read through, identify the response quality of the specific age related concern as defined by the Response Quality Classifications listed below.
4. Identify the specific care process or intervention concerning the response quality as defined by the Coding Data Dictionary listed below. Record all interventions whether or not there was a previous GA concern mentioned.
5. During the third read through, symptoms and uncertainty as defined by the Coding Data Dictionary and instructions listed below.
6. Identify the specific symptom/uncertainty and who initiated it.
7. Once coding is complete, the coder will submit their codes to REDCAP.
8. If a coder is unsure of any codes, he or she will speak with the PI to gain understanding and clarification. If there is a change, modification, or clarification made, all coders should be identified.

“Who” Initiated
- When a discussion about an age related concern, symptom or uncertainty is mentioned, code who started the conversation. Coders should code whether initiation of concern was by oncologist, patient, caregiver, other health care provider, or other family member/friend.

Age Related Concern
- Identifying the aging concern.
  - Categorize the age related discussion into any one of the GA domains.
  - Multiple age related concerns could be mentioned in a single conversation. Examples are provided in the example coded transcripts.
  - Each topic within a domain would be counted separately. A discussion may mention a decrease in appetite and decrease in weight. These would be coded as 2 separate discussions. The nutrition code would be used twice in this situation because appetite and decrease in weight are two separate topics.

Response Quality Classifications
Determining whether the age related concern was just a simple ask, not addressed, or was acknowledged, and/or appropriately addressed:
- Not Addressed/Dismissed: Examples of how the concern was not addressed. The following examples are not codes to be used.
  - Ignoring is when the provider makes no reference to either the content or the emotion of the concern.
  - Shutting down or denying is when the provider actively shuts down or moves away from the concern expressed, without making specific reference to it.
  - Minimizing is when the provider makes light of the concern expressed or normalizes the concern.
- Acknowledged: A provider could have discussions that are included in the GA Recommendation forms. These discussions are included in the Table in this coding manual as a reference. The oncologist may demonstrate other types of acknowledgements. Examples or types of acknowledgements that are not on the GA Recommendation forms are listed below.
  - Follow-up question regarding the concern.
  - Simple reflection or restating the concern.
- Complex reflection or rewording the concern to try to put meaning to the statement.
- Validation or praise.
- Implicit empathy is any response which allows for further disclosure through having an empathic function without asking explicitly for further clarification or specifically mentioning the nature or the emotion of the concern.

- ** Appropriately Addressed**: Aging related concerns are considered appropriately addressed when there is a care process implemented that comes from the GA Recommendation forms. If there is a care process that a coder believes should be included, the coder will bring it to the weekly meeting to discuss. These will be reviewed by the PI or designee and will be added to the list as a subcode.

### Symptoms
- All transcripts will be coded for symptoms.
- Code for actual presence of symptom (i.e.: patient reports symptom, physician or family member discuss patient symptom). Do not code for teaching about possible symptom in the future and do not code if a symptom is assessed but not present (i.e. Are you having any pain? , No , I don’t have pain)

**What is a symptom?**
- “a symptom is a departure from normal function or feeling which is noticed by the patient, reflecting the presence of an unusual feeling or state. A symptom is subjectively perceived by the patient. A symptom is generally perceived as change from normal and a possible indicator of disease”
- There are many symptoms that may be either physical or psychological. Some common examples are: pain, nausea, worried, sad, dizzy...... If in doubt – highlight as a symptom in Atlas on the transcript.

### Identification
- Code for whether or not a symptom is reported in the transcript (Occurrence)
  - No (0)
  - Yes (1)
- Identify the symptom(s) reported. If more than one symptom is reported list each. The symptom(s) will be recorded in REDCAP; a comprehensive list of symptoms has been created - as the possible list of symptoms is many – enter the first few letters and a pop –up list of options to choose will be provided. If the symptom is not listed, there is an OTHER option, just type in the symptom (as a string variable).

### Uncertainty

**Definition**
Uncertainty is a state of mind – a lack of knowledge about some aspect of reality and an associated awareness of one’s lack of knowledge. Medical uncertainty can be present in the discussion of symptoms, diagnosis, treatment (benefit and toxicity) and prognosis. For this project, we will only be coding explicitly stated expressions of uncertainty. Quotes should be coded to include entire dialogue around uncertainty.

**Step 1**
Code for person starting conversation about uncertainty.
Step 2
Code for topic/issue of uncertainty.
There are four possible categories:

1. **Scientific Uncertainty** – this encompasses any statements about diagnosis, treatment and prognosis. Codes do not have to specify which aspect is being addressed since these often overlap. Examples:
   - “We are not sure what is causing you to have palpitations – it could be a number of factors…”
   - “Doctor, I still don’t know why I developed this cancer. I have always led a healthy lifestyle.”
   - “This chemotherapy has a 40% chance of causing tumor shrinkage, provided of course you tolerate it well.”
   - “So there is no way of knowing for sure whether this treatment will work for me?”
   - “It’s hard to say...it could be months to 1 year for you. But this could go quickly too.”
   - “I read somewhere she has 3-6 months to live, which is it?”

**Discussion about potential treatment toxicities in general should not be coded – only include if discussion is tailored specifically to patient situation.**

2. **Practical Uncertainty** – this encompasses any statements about the structure and process of care. Examples:
   - “We will have to check to see if your insurance covers this anti-nausea medication otherwise we may have to use an alternative.”
   - “I don’t think one of us will always be able to come with Dad for his treatments but we will try.”

3. **Personal Uncertainty** – this encompasses any statements pertaining to psychosocial and existential issues surrounding illness. Examples:
   - “This treatment may buy you some more time. For some patients, that matters a lot but for others, it is more important to know whether they will feel better on chemotherapy.”
   - “A big what if for you to think about is what if things start to get really bad, should we shock your heart and do CPR? Would you want to be on life support?”
   - “I am looking for directions. Not knowing what is going to happen to me is tough.”

4. **Other/Miscellaneous** – this can include any statements that do not fit into the other categories.

Note: Statements can be coded for more than one category, e.g. discussion about prognosis may qualify for both Scientific and Personal uncertainty.

**Coding Data Dictionary**
The different domains, codes, and subcodes are outlined in the below table for aging discussions, symptoms, and uncertainty.
<table>
<thead>
<tr>
<th>Code</th>
<th>Definition</th>
<th>Subcode</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oncologist</td>
<td>The oncologist will be denoted with a “D” in the transcript.</td>
<td></td>
</tr>
<tr>
<td>Patient</td>
<td>The patient will be denoted with a “P” in the transcript.</td>
<td></td>
</tr>
<tr>
<td>Caregiver</td>
<td>The caregiver will be denoted with a “C” in the transcript.</td>
<td></td>
</tr>
<tr>
<td>Other healthcare provider</td>
<td>This could be denoted by the nurse practitioner, physician assistant, nurse..</td>
<td></td>
</tr>
<tr>
<td>Other family member/friend</td>
<td>Other individuals in the room will be denoted as a female voice # and/or male voice #</td>
<td></td>
</tr>
</tbody>
</table>

**Domain: Age Related Concern**

Description: Any discussion that fits into one of the GA domains will be considered an “aging” issue. Can use the domain code if a concern that was mentioned does not fit into a specific age related domain.

<table>
<thead>
<tr>
<th>Code</th>
<th>Definition</th>
<th>Subcode</th>
</tr>
</thead>
<tbody>
<tr>
<td>Geriatric Assessment</td>
<td>Any mention of the geriatric assessment. For instance if the oncologist says “They did the geriatric assessment...”</td>
<td></td>
</tr>
<tr>
<td>Handouts</td>
<td>Any mention of handouts without a reference to a specific domain impairment.</td>
<td></td>
</tr>
<tr>
<td>General Intervention</td>
<td>Any age related concern that is not classified under the following domains</td>
<td>Mention of Geriatric Assessment Assess values and goals for treatment outcome Elicit caregiver perspective/input Discussed health care proxy Goals of care preferences Confirm health care proxy in chart List emergency contacts in chart Confirm completed Advanced Directives in chart Discuss advanced directive Change chemo regimen Gave handouts Discuss treatment goals</td>
</tr>
<tr>
<td>Physical Performance</td>
<td>Any discussion regarding the patient’s mobility.</td>
<td>Ability to stand for long periods Ability to Exercise Walk any distance Getting up or sitting down form a chair Balance/Unsteadiness Hearing Vision Falls Strength/Weakness Difficulty with stairs Unspecified</td>
</tr>
<tr>
<td>Code</td>
<td>Definition</td>
<td>Subcode</td>
</tr>
<tr>
<td>------------------</td>
<td>---------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| **Functional Status** | Any discussion regarding the patient’s ability to do any daily activities independently. | Bathing  
Getting dressed  
Eating  
Getting out of bed/chairs  
Walking  
Using the toilet  
Using the telephone  
Going shopping (clothes/groceries)  
Taking medication  
Managing finances  
Driving  
Activities of daily living  
Unspecified |
| **Cognitive/Explicit** | Any discussion where memory loss or confusion is mentioned, indicating that there was a change from a previous state. The discussion around cognitive concerns can be explicit or implicit. If it is explicit code as “Cognitive/Explicit.” If it is implicit, code as “Cognitive/Implicit.” | Memory  
Confusion  
Concentration  
Comprehension  
Delirium  
Orientation  
Unspecified |
| **Cognitive/Implicit** | Any discussion where memory loss or confusion is mentioned, indicating that there was a change from a previous state. The discussion around cognitive concerns can be explicit or implicit. If it is explicit code as “Cognitive/Explicit.” If it is implicit, code as “Cognitive/Implicit.” | Memory  
Confusion  
Concentration  
Comprehension  
Delirium  
Orientation  
Unspecified |
| **Comorbidity** | Any age related concern related to non-cancer disease or illness. | Diabetes  
Cardiovascular disease  
Hypertension  
Arthritis or rheumatism  
Lung disease (emphysema or chronic bronchitis)  
Chronic liver or kidney disease  
Other cancer or leukemia  
Glaucoma  
Circulation trouble in arms or legs  
Stomach or intestinal disorders  
Osteoporosis  
Depression  
Stroke  
Other |
| **Polypharmacy** | Any age related concern that mentions drugs/medication in terms of the number of medications, safety of the medication, or interaction with other medications. | Drug/drug interaction  
Number of meds  
Medications/Medication management  
Supportive meds  
High-risk drug  
Age-related side effect (unsteadiness, confusion, etc)  
Unspecified |
<table>
<thead>
<tr>
<th>Code</th>
<th>Definition</th>
<th>Subcode</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nutritional Status</td>
<td>Any age related discussion addressing problems with eating or weight issues.</td>
<td>Weight</td>
</tr>
<tr>
<td>Psychological Status</td>
<td>Any discussion where there is a mention of psychological health.</td>
<td>Sadness</td>
</tr>
<tr>
<td>Social Support</td>
<td>Any discussion where there is a mention of having a support to complete daily living activities, assistance to getting to medical visits, or any mention of having friends or caregivers for support.</td>
<td>Medical social support</td>
</tr>
</tbody>
</table>

**Domain: Quality of Age Related Discussion**

Description: The quality of age related discussion is coded to differentiate between just asking about the concern, dismissing it, acknowledging it, or implementing appropriate interventions/care processes. These codes are not mutually exclusive. The quality of the conversion can be coded with “Asked,” “Acknowledged,” and “Appropriately Addressed.”

<table>
<thead>
<tr>
<th>Code</th>
<th>Definition</th>
<th>Subcode</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asked/General</td>
<td>This code would be used if the physician asks about an age related concern. For example, if a physician says: “Are you having more falls?” but does not follow-up with anything else.</td>
<td>Ability to stand for long periods</td>
</tr>
</tbody>
</table>
| Asked/Physical Performance | The oncologists asked about the patient’s mobility. | }
<table>
<thead>
<tr>
<th>DOMAIN</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Asked/Functional Status</strong></td>
<td>Oncologists asked about the patient’s ability to do any daily activities independently.</td>
</tr>
<tr>
<td><strong>Asked/Cognitive Explicit</strong></td>
<td>Oncologists explicitly asked about the patient’s cognitive status. OR It appears that the oncologist is attempting to determine the patient’s cognitive status without explicitly asking about memory, confusion, concentration, or comprehension.</td>
</tr>
<tr>
<td><strong>Asked/Cognitive Implicit</strong></td>
<td>Oncologists asked the patient and/or caregiver about any pre-existing non-cancer disease or illness.</td>
</tr>
<tr>
<td><strong>Asked/Comorbidity</strong></td>
<td>Oncologists asked about non-cancer medications or supplements that the patient may be taking.</td>
</tr>
<tr>
<td><strong>Asked/Polypharmacy</strong></td>
<td>Oncologists asked about the patient’s nutritional status.</td>
</tr>
<tr>
<td><strong>Asked/Psych</strong></td>
<td>Oncologists asked about the patient’s mental health status.</td>
</tr>
<tr>
<td><strong>Asked/Social Support</strong></td>
<td>Any discussion where there is a mention of having a support to complete daily living activities, assistance to getting to medical visits, or any mention of having friends or caregivers for support.</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Not Addressed/General</td>
<td>The oncologist makes no attempt to comment on the concern mentioned or does not follow-up on the initial “ask.”</td>
</tr>
</tbody>
</table>
| Not Addressed/Physical      | The oncologist makes no attempt to comment on the physical performance concern mentioned or does not follow-up on the initial “ask.” | ✓ Ability to stand for long periods  
✓ Ability to Exercise  
✓ Walk any distance  
✓ Getting up or sitting down form a chair  
✓ Balance  
✓ Hearing  
✓ Vision  
✓ Falls |
| Performance                 |                                                                                                                                         |                                                                                                                                     |
| Not Addressed/Functional    | The oncologist makes no attempt to comment on the functional status concern mentioned or does not follow-up on the initial “ask.” | ✓ Bathing  
✓ Getting dressed  
✓ Eating  
✓ Getting out of bed/chairs  
✓ Walking  
✓ Using the toilet  
✓ Using the telephone  
✓ Going shopping (clothes/groceries)  
✓ Taking medication  
✓ Managing finances  
✓ Driving |
| Status                      |                                                                                                                                         |                                                                                                                                     |
| Not Addressed/Cognitive     | The oncologist makes no attempt to comment on the cognitive status concern mentioned or does not follow-up on the initial “ask.” | ✓ Memory  
✓ Confusion  
✓ Concentration  
✓ Comprehension |
| Explicit                    |                                                                                                                                         |                                                                                                                                     |
| Not Addressed/Cognitive     | The oncologist makes no attempt to comment on the comorbidity concern mentioned or does not follow-up on the initial “ask.” | ✓ Diabetes  
✓ Cardiovascular disease  
✓ Hypertension  
✓ Mental Health Issue (pre-existing) |
| Implicit                    |                                                                                                                                         |                                                                                                                                     |
| Not Addressed/Polypharmacy  | The oncologist makes no attempt to comment on the polypharmacy concern mentioned or does not follow-up on the initial “ask.” | ✓ Drug/drug interaction  
✓ Number of meds  
✓ Medications |
| Not Addressed/Nutrition     | The oncologist makes no attempt to comment on the nutrition concern mentioned or does not follow-up on the initial “ask.” | ✓ Weight loss  
✓ Weight gain  
✓ Taste change  
✓ Lack of appetite  
✓ Dietary restriction  
✓ Decrease BMI  
✓ Problems with speech/swallowing  
✓ Decreased food/fluid intake |
| Not Addressed/Psych         | The oncologist makes no attempt to comment on the mental health concern mentioned or does not follow-up on the initial “ask.” | ✓ Sadness  
✓ Depression  
✓ Feeling anxious  
✓ Sense of helplessness |
<table>
<thead>
<tr>
<th>DOMAIN</th>
<th>Description</th>
</tr>
</thead>
</table>
| Not Addressed/Social Support | The oncologist makes no attempt to comment on the comorbidity concern mentioned or does not follow-up on the initial “ask.” | ✓ Medical social support  
✓ Instrumental support  
✓ Emotional social support  
✓ Companionship support  
✓ Informational support |
| Acknowledged/General | The oncologists acknowledged the concern by exploring the issues but did not implement any care processes. | ✓ Assess patient’s value and goals for outcomes from cancer and cancer treatment.  
✓ Elicit caregiver input and perspective.  
✓ Discuss health care proxy.  
✓ Elicit goals of care preferences. |
| Acknowledged/Physical Performance | The oncologists acknowledged the physical performance concern by exploring the issues but did not implement any care processes. | ✓ Weigh risks and benefits of treatment options incorporating information about the patient’s physical performance.  
✓ Address possible impact of treatment on falls and physical performance. |
| Acknowledged/Functional Status | The oncologists acknowledged the functional status concern by exploring the issues but did not implement any care processes. | ✓ Weigh risks and benefits of treatment options incorporating information about the patient’s functional status.  
✓ Address impact of treatment on function and independence. |
| Acknowledged/Cognitive Explicit | The oncologists acknowledged the cognitive concern by exploring the issues but did not implement any care processes. | ✓ Discuss patient’s concerns about cognition.  
✓ Elicit input and perspectives from caregiver(s) about the patient’s cognition.  
✓ Assess decision-making capacity.  
✓ Elicit health care proxy information and input if the patient lacks decision-making capacity.  
✓ Carefully weigh risks and benefits given limited data and potential for further cognitive impairment and functional impairment. |
<table>
<thead>
<tr>
<th>Code</th>
<th>Definition</th>
<th>Subcode</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acknowledged/Comorbidity</td>
<td>The oncologists acknowledged the comorbidity concern by exploring the issues but did not implement any care processes.</td>
<td>✓ Discuss how comorbidities affect risks and benefits of treatment choices including chemotherapy, monoclonal antibodies or tyrosine kinase inhibitors. ✓ Discuss modifications of treatment options and plan based on specific comorbidities or comorbidity burden. ✓ Discuss how cancer treatment could affect other comorbidities. ✓ Discuss how information about their cancer treatment plan will be communicated to other physicians involved in their care. ✓ Discuss how other physicians can contact the oncology team with any questions about the cancer treatment plan.</td>
</tr>
<tr>
<td>Acknowledged/Polypharmacy</td>
<td>The oncologists acknowledged the polypharmacy concern by exploring the issues but did not implement any care processes.</td>
<td>✓ Evaluate drug/drug interactions. ✓ Review and optimize non-cancer medications. ✓ Take into consideration cost of the medication including insurance coverage and out-of-pocket costs. ✓ Assess if there are any barriers to acquiring medications. ✓ Prepare the patient regarding anticipated side effects to avoid inappropriate medication and discontinuation. ✓ Have patient/caregiver repeat back his/her understanding of how to take the medication, common side effects, and “when to worry” and “what to do if worried” for oral oncology drugs or supportive care drugs. ✓ Engage family/other caregivers and interdisciplinary team in the medication management process.</td>
</tr>
<tr>
<td>Acknowledged/Nutrition</td>
<td>The oncologists acknowledged the nutrition related concern by exploring the issues but did not implement any care processes.</td>
<td>✓ Discuss concerns related to nutrition. ✓ Discuss how treatment may impact nutrition. ✓ Make recommendations for nutritional supplements, small frequent meals, high protein/high calorie snacks. ✓ Make recommendation for increased fluid intake</td>
</tr>
<tr>
<td>Code</td>
<td>Definition</td>
<td>Subcode</td>
</tr>
<tr>
<td>-----------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Acknowledged/Psych</td>
<td>The oncologists acknowledged the mental health concern by exploring the issues but did not implement any care processes.</td>
<td>✓ Evaluate for symptoms of major depressive disorder. ✓ Elicit the caregiver perspective. ✓ Assess support at home. ✓ Discuss history of mood issues and treatment history. ✓ Discuss patient’s perspective and willingness to engage with community resources, psychotherapy, and/or spiritual counseling. ✓ Assess suicide risk if appropriate. ✓ Assess elder abuse if appropriate.</td>
</tr>
<tr>
<td>Acknowledged/Social Support</td>
<td>The oncologists acknowledged the social support concern by exploring the issues but did not implement any care processes.</td>
<td>✓ Discuss who the patient can call in case of an emergency. ✓ Discuss adequacy of social support at home. ✓ Elicit caregiver input. ✓ Discuss safety and/or risk/benefit of treatment options for a patient with decreased social support.</td>
</tr>
<tr>
<td>Appropriately Addressed/General</td>
<td>This code would be used when appropriate care processes were implemented at the visit according to the GA Recommendation forms.</td>
<td>✓ Confirm health care proxy is in medical record. ✓ List emergency contacts in medical record. ✓ Confirm that completed Advanced Directives is in medical record.</td>
</tr>
<tr>
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<td>Subcode</td>
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| Appropriately Addressed/Physical Performance | The oncologist implemented appropriate care processes to address the physical performance concern. | ✓ Referred physical therapy  
✓ Referred occupational therapy  
✓ Referred aide services  
✓ Referred personal emergency response (PERS) information  
✓ Referred to vision specialist  
✓ Referred to home nursing services  
✓ Referred to hearing specialist  
✓ Requested gait/assistive device evaluation, strength and balance training  
✓ Performed a physical examination  
✓ Reviewed medication to minimize psychoactive and duplicative medications  
✓ Modified treatment dosage  
✓ Modified treatment choice  
✓ Considered single agent rather than doublet therapy  
✓ Modified treatment regimen  
✓ Choose non-neurotoxic regimen for cancer treatment over a neurotoxic regimen (if available)  
✓ Conducted toxicity check  
✓ Gave fall counseling handout  
✓ Gave energy conservation handout  
✓ Gave information on exercise/exercise prescription |
| Appropriately Addressed/Functional Status | The oncologist implemented care processes to address the functional status concern. | ✓ Recommended Aide Services  
✓ Recommended OT  
✓ Recommended Personal Emergency Response Information  
✓ Recommended Home nursing services  
✓ Patients orthostatic blood pressure was checked  
✓ Psychoactive medications were minimized  
✓ Duplicate medications were minimized  
✓ Modified treatment dosage or regimen  
✓ Conducted frequent toxicity checks  
✓ Gave patient fall counseling handout  
✓ Gave patient energy counseling handout  
✓ Gave patient exercise/exercise prescription |
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<tr>
<td>Appropriately Addressed/Cognitive Explicit</td>
<td>The oncologist implemented care processes that addressed the cognitive concern.</td>
<td>✓ Confirmed and complete health care proxy (if patient has impaired capacity)</td>
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<td>Appropriately/Addressed Cognitive Implicit</td>
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<td>✓ Recommended TSH if dementia was suspected</td>
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<td>✓ Recommended B12 if dementia was suspected</td>
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<td></td>
<td>✓ Recommended brain imaging</td>
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<td>✓ Referred to clinician experienced in cognitive evaluation (Geriatrician, Neurologist or Geriatric Psychiatrist)</td>
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<td>✓ Referred to a social worker</td>
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<td></td>
<td>✓ Referred palliative care</td>
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<td>✓ Performed neuropsychological testing if dementia was suspected</td>
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<td></td>
<td></td>
<td>✓ Provided information on cognitive rehabilitation or memory care programs</td>
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<tr>
<td></td>
<td></td>
<td>✓ Confirmed that patient had assistance with filling pill box</td>
</tr>
<tr>
<td></td>
<td></td>
<td>✓ Did medication review to minimize psychoactive and high risk medication</td>
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<td>✓ Modified cancer treatment dosage</td>
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<tr>
<td></td>
<td></td>
<td>✓ Modified cancer treatment choice</td>
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<tr>
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<td></td>
<td>✓ Modified cancer treatment regimen</td>
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<td></td>
<td>✓ Gave patient/family member handout on delirium risk counseling</td>
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<tr>
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<td>✓ Gave explicit and written instructions for calendar, medications to be given, cancer treatment plan</td>
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</table>

The oncologist implemented care processes that addressed the cognitive concern.
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<tr>
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<th>Definition</th>
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</table>
| Appropriately Addressed/Comorbidity | The oncologist implemented care processes to address the comorbidity concern. | ✓ Initiate direct communication (written/electronic, or phone) with patient’s primary care physician about the plan for the patient’s cancer.  
✓ Treatment modification: history of diabetes-avoid neurotoxic agents if another options is equivalent.  
✓ Treatment modification: history of heart failure-minimize volume of agents and/or administer treatments at slower infusion rate.  
✓ Treatment modification: history of renal impairment-avoid nephrotoxic agents if another option is available and/or adjust dose appropriately.  
✓ Treatment modification: modify dosage or schedule if there is concern about how the patient will tolerate therapy or if there is a concern about worsening of comorbidities.  
✓ Provide smoking cessation counseling if the patient currently smokes. |
<table>
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<td>Appropriately Addressed/Polypharmacy</td>
<td>The oncologist implemented appropriate care processes to address the polypharmacy concern.</td>
<td>✓ Recommended/Prescribed /Clarified RX&lt;br&gt;✓ Recommended pillbox and/or medication calendar&lt;br&gt;✓ Had patient/caregiver repeat back his/her understanding of how to take the medication, common side effects, and &quot;when to worry&quot; and &quot;what to do if worried&quot; for oral oncology drugs or supportive care drugs&lt;br&gt;✓ Asked patient to bring in all medications and supplements to review at the next visit&lt;br&gt;✓ Contacted PCP to help reduce regimen complexity&lt;br&gt;✓ Reduced medications solely used for hypertension or diabetes (including dose and number of medications)&lt;br&gt;✓ Consulted pharmacist that fills the patient's scripts to synchronize medication refills&lt;br&gt;✓ Had pharmacist meet patient to evaluate drug interactions and provide medication counseling&lt;br&gt;✓ Provided easily understandable written instruction to patient/caregiver for taking new medications&lt;br&gt;✓ Provided handout about up to date counseling&lt;br&gt;✓ BP medications were decreased or eliminated if BP was low or normal</td>
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<tr>
<td>Appropriately Addressed/Nutrition</td>
<td>The oncologist implemented appropriate care processes to address the nutrition concern.</td>
<td>✓ Recommended nutritional supplement, small frequent meals, high protein/high calorie snacks.&lt;br&gt;✓ Recommended meals on wheels&lt;br&gt;✓ Recommended saline mouthwash 3 or 4 times per day (if treatment has high risk of mucositis)&lt;br&gt;✓ Referred to Dentist&lt;br&gt;✓ Referred to Nutritionist/Dietician&lt;br&gt;✓ Referred to Speech and Swallow&lt;br&gt;✓ Scheduled frequent toxicity checks&lt;br&gt;✓ Utilized aggressive anti-emetic therapy&lt;br&gt;✓ Used another cancer treatment option if appropriate&lt;br&gt;✓ Gave nutritional handout&lt;br&gt;✓ Gave mucositis handout</td>
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<tr>
<td>Appropriately Addressed/Psych</td>
<td>The oncologist implemented appropriate care processes to address the mental health concern.</td>
<td>✓ Evaluate for symptoms of major depressive disorder</td>
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<td>✓ Elicit the caregiver perspective</td>
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<td>✓ Assess support at home</td>
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<td>✓ Discuss history of mood issues and treatment history</td>
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<td>✓ Discuss patient’s perspective and willingness to engage with community resources, psychotherapy, and/or spiritual counseling</td>
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<td>✓ Assess suicide risk if appropriate</td>
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<td>✓ Assess elder abuse if appropriate</td>
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<td>✓ Provide written or verbal communication with primary physician about psychological distress</td>
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<td>✓ Refer to counseling/psychotherapy, social work, spiritual counseling, chaplaincy services, psychiatry, or palliative care.</td>
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<td>✓ Initiate pharmacologic therapy if appropriate in conjunction with PCP</td>
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<td>✓ Provide linkage to community resources (such as support groups and local/national buddy or volunteer programs)</td>
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</table>
| Appropriately Addressed/Social Support | The oncologist implemented appropriate care processes to address the social support concern. | ✓ Referred social worker  
✓ Referred visiting nurse aide or home health aide  
✓ Referred to alternative living environments e.g. assisted living  
✓ Referred assistance programs (food stamps, meal delivery, energy assistance, cash assistance)  
✓ Referred medical insurance advising (Medicaid), advocacy and negotiation  
✓ Referred legal assistance for economic or social needs  
✓ Referred community resource mobilization and linkage programs that provide case monitoring, care planning, pharmaceutical assistance, and or local resource support (volunteers, patient navigator, American cancer society)  
✓ Confirmed that a health care proxy is documented in medical record  
✓ Modified treatment choice and dosage  
✓ Provided information about ride assistance program  
✓ Assisted with set up of ride assistance program |
Training
All coders will need to practice coding on a minimum of 5 standard transcripts to ensure that coding is consistent.

1. A new coder will be trained on how to code and enter the data into the REDCap database, starting with 2 transcripts. These 2 transcripts will then be compared to the standard transcripts for agreement.

2. If 90% inter-rater reliability is attained for the relevant domains and codes, the coder will be given the other 3 standard protocols. After these are coded, they will be compared to the partner 3 transcripts. The inter-rater reliability needs to be at 90%.

Appendix

Symptom Inventory
Pain, Fatigue / tiredness, Nausea, Disturbed sleep, Distressed/ upset. Shortness of breath, Problem remembering things, Lack of appetite, Drowsy /sleepy, Dry mouth, Sad, Vomiting, Numbness and tingling, Constipation, Diarrhea, Weakness, Difficulty concentrating, Confusion, Other cognitive issues, Irritable, Anxiety/ nervousness, Worry, Depression, Feeling sick, Headache, Myalgia/Arthralgia (muscle or joint aches), Backache, Muscle spasms, Abdominal pain, Sexuality issues/ dysfunction, Body image changes, Hair loss, Menopausal symptoms (hot flashes), Gait disturbance/difficulty walking, Poor coordination, Altered mental states/confusion, Dizziness/light headedness/fainting, Seizure, Speech changes, Vision changes, Skin breakdown, Rash, Pruritus (itching), Fever/chills, Sweating, Bleeding/bruising, Flu-like symptoms, Lump/bump, Anemia , Allergic Reaction/ Allergy Symptoms (itchy eyes/runny nose/sinus), Jaundice, Dysphagia (difficulty swallowing/sore throat), Mucositis (sore mouth), Esophagitis (sore swallowing/heartburn), Heartburn, Taste alterations, Weight loss, Weight gain, Nocturia (getting up at night to void), Incontinence, Urinary changes (pain/frequency), Hematuria (blood in urine), Hemorrhoids/blood in stool/rectal pressure, Cough (phlegm/sputum), Wheezing, Hiccups, Lymphedema, Bloating, Swelling (any location), Ascites (swelling abdomen), Swelling Lower extremities

Example Coded Transcripts
Following this document

Geriatric Assessment Tool
Following this document
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The table shows the percent agreement among different variables and concerns across Lee, Teraisa, Jen, Lisa, Patrick, and Consensus. The data is categorized under different domains such as Geriatric Domain Mention, Functional Status, Nutritional Status, Cognition, Physical Performance, and more. Each domain lists the number of concerns mentioned, the response, quality, and acknowledgment status, with percentages indicating the level of agreement.
Appendix E
Measures
MEASURES TO BE COLLECTED

Collection Time-points are Screening/Baseline, Telephone Team Call to patient within 1 to 7 days from baseline to assess patient satisfaction, 4-6 weeks, 10-14 weeks (3 months) and 20-24 weeks (6 months). Measures signified by *** are only collected at screening/baseline and not at follow-up visits. Measures signified by (Follow-up) are collected only at follow-up visits.

We have piloted all measures. In total, geriatric assessment measures that are filled out by the patient require approximately 20 minutes of time. The additional measures (quality of life, symptoms, communication, decision-making) captured at baseline require an additional 30 minutes of time. The follow-up questionnaires require about 30 minutes of time in total. Caregiver assessments require about 30 minutes of time.

We have incorporated flexibility with timing in order to reduce patient burden. Patients and caregivers may complete geriatric assessment at clinic at time of consent or before next visit. They may choose to complete measures at home in between visits. We have found that 90% of patients complete measures at home if allowed to do so. The geriatric oncology clinic at the University of Rochester routinely captures these measures as part of clinical care.

The telephone call that will capture the patient satisfaction measures (based on the Health Care Climate Questionnaire, HCCQ) will take <10 minutes and will occur within 1 to 7 days of the baseline audiotaped visit. The assessments performed by the Clinical Research Associate take about 30 to 45 minutes of time in total (including physical performance and cognitive tests). Any person at the practice site can be trained by Research Base staff to do the assessments. The assessments do not need to be performed by the physician.

The physician assessments will be done either on paper or through REDCap, whichever the physician prefers. The baseline assessments take no longer than 10 minutes and after each patient visit, the decision-making form (to assess factors that influenced decisions) is less than one-page long (2 minutes to complete).

1. **Patient Surveys**

1.1. **Demographics***: Age, race and ethnicity, gender, highest level of education achieved, employment status, marital status, living situation, and presence of a living companion will be captured. We will also assess financial concerns, understanding of disease, self-rated health, and subjective age.

1.2. **Geriatric assessment**: Assessment tools comprising the comprehensive geriatric assessment are discussed below. The various assessment tools were selected based upon extensive data in the geriatric literature demonstrating predictive value as well as feasibility data in multiple studies of elderly patients with cancer. Other than the cognitive and physical performance measures, the assessments are self-administered. Patients who cannot complete the assessment on their own can receive assistance from the study personnel or caregiver. The comprehensive assessment is performed first prior to treatment and brief follow-up GA measures are collected at 4-6 weeks, 3 months, and 6 months. Measures collected only at baseline are noted with ***.

1.2.1. **Activities of daily living (ADL):** ADLs are measures of self-care. ADL independence will be assessed using the Katz Index of Independence in Activities of Daily Living, commonly referred to as the Katz ADL. The Katz ADL is the most appropriate instrument to assess functional status as a measurement of the patient’s ability to perform activities of daily living independently. Clinicians typically use the tool to detect problems in performing activities of daily living and to plan care accordingly. The Index ranks adequacy of performance in the six functions of bathing, dressing, toileting, transferring, continence, and feeding. Patients are scored yes/no for independence in each of the six functions. A score of
6 indicates full function, 4 indicates moderate impairment, and 2 or less indicates severe functional impairment.

1.2.2. Instrumental Activities of Daily Living (IADL): Self-reported functional status will be assessed using the IADL subscale of the Multidimensional Functional Assessment Questionnaire: Older American Resources and Services (OARS). The IADL subscale consists of seven questions rated on a three-point Likert scale. It measures the degree to which an activity can be performed independently.

1.2.3. Fall History: A self-reported history of falls in the past six months will be recorded. A history of a recent fall has been demonstrated to be independently predictive of increased risk for chemotherapy toxicity in older cancer patients.

1.2.4. OARS Physical Health: Self-reported questions that assess the degree of difficulty with physical tasks such as walking, climbing stairs, stooping, and reaching. This measure correlates with disability and comorbidity.

1.2.5. OARS Comorbidity: Patients self-report their coexisting medical conditions and also rate the degree to which their illness causes impairment in daily activities. The OARS Physical Health Section has been shown to correlate significantly with health professional ratings of comorbidity as well.

1.2.6. OARS Medical Social Support and Social Activities: A 13-question survey asking patients to identify the number of support persons involved in their medical care as well as the degree to which they felt supported in a variety of situations. A follow-up question will be used to assess how much a patient’s physical or emotional health interfered with social activities.

1.2.7. Generalized Anxiety Disorder 7 (GAD-7): The GAD-7 is a self-administered patient questionnaire used as a screening tool and severity measure for generalized anxiety disorder. The GAD-7 score is calculated by assigning scores of 0, 1, 2, and 3, to the response categories of “hardly ever,” “several days,” “more than half the days,” and “nearly every day,” respectively, and adding together the scores for the seven questions. Scores of 5, 10, and 15 are taken as the cut off points for mild, moderate, and severe anxiety, respectively. When used as a screening tool, further evaluation is recommended when the score is 10 or greater. Using the threshold score of 10, the GAD-7 has a sensitivity of 89% and a specificity of 82% for generalized anxiety disorder. It is moderately good at screening three other common anxiety disorders – panic disorder (sensitivity 74%, specificity 81%), social anxiety disorder (sensitivity 72%, specificity 80%), and post-traumatic stress disorder (sensitivity 66%, specificity 81%).

1.2.8. Geriatric Depression Scale (GDS): Patients will be screened with the Geriatric Depression Scale (GDS). The GDS contains questions that are intended to screen elderly patients for depression, while parsing out complaints related to advanced age.

1.3. Satisfaction, Quality of Life, and Symptoms:

1.3.1. Health Care Climate Questionnaire (HCCQ) (Follow-up) measures patient- centered autonomy-supportive physician behaviors such as whether the patient and caregiver feels that the physician understands his/her perspective, provides choices and options, and encourages participation in decisions. The measure has been studied and validated in older patients. Similar to other studies which adapt satisfaction scales to capture specific clinical criteria (e.g., satisfaction with physician regarding communication about chemotherapy), the HCCQ has been modified for this study to specifically address patient satisfaction with physician behaviors and communication regarding age-related issues and concerns in order to specifically address satisfaction with the intervention (geriatric assessment summary) rather than satisfaction with other aspects of cancer care (e.g., communication about cancer treatment)(HCCQ-age). As is done with satisfaction with care surveys in other research and
in clinical settings, the HCCQ (both modified and original) will be administered within 1 week after the audio-taped clinic visit. Our University of Chicago collaborators (Dale and Gorawara-Bhatt) have experience with the conduct of such assessments over the phone and this minimizes perceived or real influence from the physician or team. The University of Chicago collaborators and research staff, who are subcontracted through a PCORI contract with the University of Chicago, will be blinded to group assignment. The HCCQ will also be completed as part of the patient and caregiver packets in follow up time points for comparison.

1.3.2. FACT: Quality of life will be measured using the Functional Assessment of Chronic Illness Therapy tool. Although there are several validated tools for QoL, the FACT has been validated in the geriatric population. It is a subset of a larger group of FACT scales that assess health-related quality of life measures. It has demonstrated high internal validity and high test-retest reliability.

2. CRA Packet (CRA fills out at visits)
2.1. Tumor and Treatment Characteristics: The tumor stage, previous surgery or radiation, chemotherapy type, dosing, and schedule (intended and received), other cancer treatments, and supportive care medications will be captured by the CRA. Survival status at 12 months from study entry will be captured on the withdrawal form or survival status form, once available.

2.1.1. Cancer Treatment History will be used to collect the patient’s previous treatments for his/her advanced cancer.

2.2. Geriatric Assessment
2.2.1. Timed Up and Go***, The Timed Up & Go is a performance based test of functional status, measuring how many seconds it takes to stand up from a standard armchair, walk 3 meters (10 feet), turn, walk back to the chair, and sit down again. In community dwelling older adults, there was inter-rater and intra-rater reliability (intraclass correlation coefficient 0.99 for both).

2.2.2. Mini-Cog: A tool that is validated in the geriatric population to quickly assess cognitive impairment. The Mini-Cog takes approximately 3 minutes to administer. It has minimal language content, which reduces cultural and educational bias. It combines a 3-item recall component with a Clock Drawing Test.

2.2.3. Short Blessed Orientation-Memory-Concentration (BOMC) Test ***: A six-question evaluation that screens for cognitive impairment. Studies have shown its validity as a screening instrument and the correlation of its results with those of more extensive mental status tests.

2.2.4. Nutritional Status and Mini Nutrition Assessment (MNA): Screening for nutritional deficit will be performed with body mass index (BMI) evaluation and self-reported weight loss. Further nutritional evaluation will be performed with the Mini-Nutritional Assessment*** (MNA), a well validated screening measure for nutritional deficiency which has shown to be prognostic of survival in older patients with cancer. Weight will be assessed at each time point. Height will be measured at baseline.
2.2.5. **Short Physical Performance Battery**: Physical performance measures objectively evaluate mobility and fall risk. Falls are common in older cancer patients and predictive of adverse outcomes.

2.2.6. **Labs**: CRA will send results of baseline tests collected including hemoglobin, liver function tests, and renal function.

2.2.7. **Polypharmacy** will be ascertained from the medical record after patients have been asked to review their medication list on file for any changes in the Polypharmacy Log and Polypharmacy High Risk Drug Review.

3. **Caregiver Packet**

3.1. **Demographics***: Age, race and ethnicity, gender, highest level of education achieved, employment status, marital status, and presence of a living companion will be captured. Additionally, we will collect information on underlying health conditions (Physical Health).

3.2. **Caregiver Reaction Assessment (CRA)** is designed to measure the reactions of family members to caring for elderly relatives. The instrument consists of five dimensions (caregiver’s esteem, lack of family support, finances, schedule, and health). Items are rated on a 5-point scale (from "strongly agree" to "strongly disagree"). The CRA allows for measurement of positive and negative reactions to caregiving.

3.3. **The 12-Item Short Form Health Survey (SF-12)**: This measure was developed for the Medical Outcomes Study (MOS), a multi-year study of patients with chronic conditions. The measure assesses functional health and well-being.

4. **Physician Assessment**

4.1. **Physician Baseline Demographics and Treatment Preferences***: Age, race and ethnicity, gender, and details on medical practice will be captured. We will also capture patient volume, and specify years of training after fellowship. We will assess comfort with shared decision making in the baseline survey. The goal of shared decision-making is to make decisions in a manner consistent with the patient's wishes. The patient drives the process. Determining where on the shared decision-making continuum the patient feels most comfortable requires clear communication and dedicated time from the physician. Several studies have utilized the proposed measure for assessing the relationship between physician decision-making styles on clinical outcomes.

4.2. **Situational Vignettes***: Physicians will be presented with one of eight clinical scenarios of an elderly cancer patient with a variety of geriatric-related impairments (i.e. physical frailty, cognitive impairment). A series of questions will follow each vignette inquiring about the likelihood of the physician to offer chemotherapy in the scenario and details regarding the regimen that would be considered (i.e. chemotherapy type, dosing, etc.). Only one vignette will be provided to each physician. The survey will not be repeated with each subsequent patient.

*Treatment Decision-Making Form (after each audiotaped visit):* Physicians will complete a short (<10 questions) follow-up survey requesting information on the treatment plan for the patient and factors that influenced how the decision was made. This follow-up survey is adapted from work by Dr. Dale and Dr. Mobile evaluating how decisions are made for starting hormonal treatment for prostate cancer. Physicians will be asked to identify factors that influenced their decision in developing a treatment plan for each specific patient (i.e., age, stage of disease, performance status, geriatric measures). Physicians will rank each factor to determine which are most influential in their decision making process. Physicians will also be asked if results of geriatric assessment influenced their decision-making. If physicians have multiple patients enrolled on study, this survey will be completed for each individual patient.
4.3. *Physician Follow-up Survey (follow-up)*: Physicians will complete a brief survey on REDCap, which will ask them about confidence in geriatrics and their opinion on the usefulness of the Geriatric Assessment (for intervention arm). Some questions asked at baseline will be repeated at study completion.


5. **Audio-recordings of oncologist-patient visit**

A CRA will audio-record the patient-oncologist consultation. This visit must occur after the geriatric assessment is completed and before treatment initiation. A medical consultation should be scheduled prior to start of cancer treatment (if planned). We will assess the number of age-related concerns brought up by patients and caregivers. We will also assess how the physician addresses these concerns. Our team has experience with all of the study measures.

**Transcriptionists** will transcribe all audio-recorded visits and will be blinded to study condition. **Coders** will undergo extensive training and supervision by developers of the scales. Transcriptionists and coders will not be part of the study team or involved in any other aspects of the study, and will be blinded to study hypotheses and site assignments to intervention or control. Further, during analysis, study team members will be blinded to site assignments of intervention or control.
TABLES OF DATA TO BE KEPT

Table 1: Patient Measures

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<thead>
<tr>
<th>Measure</th>
<th>Aim</th>
<th>Screening Visit 00</th>
<th>Baseline Visit 01</th>
<th>Telephone Team Call</th>
<th>4-6 Weeks Visit 02</th>
<th>3 Months Visit 03</th>
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Note: Screening and baseline can be combined. A research staff member from the Telephone Team will call the patient within 1 to 7 days after the baseline audiorecorded visit.

Abbreviations: Pt (Patient); Phys (Physician); GA (Geriatric Assessment); P1 (Primary Aim 1); S2 (Secondary Aim 2); ADL (Activities of Daily Living); IADL (Instrumental Activities of Daily Living); GAD (Generalized Anxiety Disorder 7-Item Scale); Geriatric Depression Scale (GDS); FACTF (Functional Assessment of Chronic Illness Therapy)
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**Note:** Screening and baseline can be combined. * A research staff member from the Telephone Team will call the patient within 1 to 7 days after the baseline audiorecorded visit.

**Abbreviations:** C (Caregiver); S2 (Secondary Aim 2); S3 (Secondary Aim 3); SF-12 (12-Item Short Form Health Survey); HCCQ (Health Care Climate Questionnaire)
Table 3: Clinical Research Associate & Physician Measures

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**Note:** Screening and baseline can be combined. The measures/forms are not listed in the order of administration. <sup>a</sup>A research staff member from the Telephone Team will call the patient within 1 to 7 days after the baseline audiorecorded visit. <sup>b</sup>The Screening Coversheet page 2 collects patient information that will be used to establish survival status. <sup>c</sup>The Physician Baseline Survey will be administered via REDCap or paper form and the situational vignettes are collected as part of the Physician Baseline Survey. <sup>d</sup>The physician follow-up survey will be administered at the end of the study period. <sup>e</sup>These forms will be used for study documentation purposes. <sup>f</sup>Collected at one year.

**Abbreviations:** CRA (Clinical Research Associate); Phys (Physician); GA (geriatric assessment); E (Exploratory Aim); S1 (Secondary Aim 1); BOMC (Blessed-Orientation Memory Concentration Test); SPPB (Short Physical Performance Battery)
MEASURES REFERENCES:
Appendix F
Statistical Supplementary Documents
Supplementary Table 1.
Multiple imputations for Primary Aim:
Patient Satisfaction with Communication about Age-related Concerns

<table>
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<th>Analysis Type</th>
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<th>95% Confidence Interval</th>
<th>P-value</th>
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</table>

Abbreviations: MI: Multiple imputations; MCMC: Markov Chain Monte Carlo; FCS: Fully Conditional Specification; NMAR: Missing Not at Random - The Pattern Mixture Model assumed 1) no different pattern among patients with missing data (shift=0); 2) Assumes that patient with missing values in the intervention arm had mean score by 0.4 worse (shift=−0.4) with no difference for patients in control arm; 3) Similarly with shift=1.0.

Supplementary Table 2A: Patient Satisfaction with Communication about Age-related Concerns

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Model was adjusted for practices (random effect)
### Supplementary Table 2B: Communication about Age-related Concerns

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Models were adjusted for practices (random effect)
Disclaimer:
The [views, statements, opinions] presented in this report are solely the responsibility of the author(s) and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute® (PCORI®), its Board of Governors or Methodology Committee.

Acknowledgment:
Research reported in this report was funded through a Patient-Centered Outcomes Research Institute® (PCORI®) Award (#CD-12-11-4634). Further information available at: https://www.pcori.org/research-results/2013/do-reports-capture-age-related-problems-older-patients-cancer-improve-doctor