Document Type: Study Protocol and Statistical Analysis Plan

Title: A pilot randomized controlled trial of a patient-centered communication tool (UR-GOAL) for older patients with acute myeloid leukemia, their caregivers, and their oncologists

NCT number: NCT05335369

Document Date: January 15, 2026

UNIVERSITY OF ROCHESTER MEDICAL CENTER

WILMOT CANCER INSTITUTE

A pilot randomized controlled trial of a patient-centered communication tool (UR-GOAL) for older patients with acute myeloid leukemia, their caregivers, and their oncologists

January 15th, 2026

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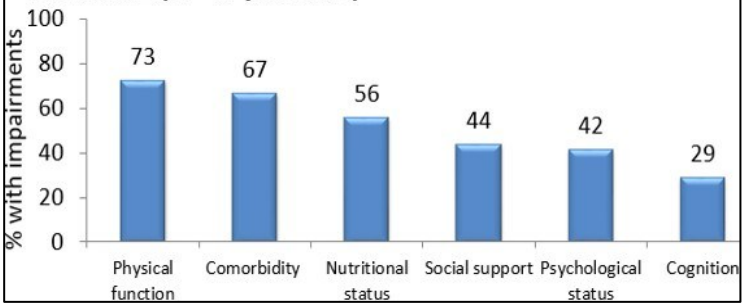
1.0. Background

1.1. Substantial heterogeneity in the health status of older patients with AML makes treatment selection challenging.

Approximately 70% of AML cases are diagnosed in adults aged ≥60 years.[1] In the last decade, an increasing number of treatment options have become available to older patients with AML, even to those who have significant comorbidities or disabilities.[2-5] In older patients with AML receiving chemotherapy, we have demonstrated that 73% had impairments in physical function, 67% had significant comorbidities, and 29% had impairments in cognition (**Figure 1**).[6,7] The effects of these fitness-related factors on disease progression, treatment tolerance, and response are not well understood, in part due to an underrepresentation of older patients in clinical trials. This is especially true for older patients with comorbidities and poor performance status.[8] Oncologists often have difficulty identifying older patients with AML who may benefit from treatment or who may experience excessive treatment toxicities. Practice patterns, therefore, vary, which may potentially lead to overtreatment, undertreatment, and poor outcomes in this population (2-year survival<20%).[9-12]

Figure 1: Age-related vulnerabilities in older adults with AML (N=40 patients)



1.2. Shared decision-making (SDM) is a key component of patient-centered care.[13]

Many patients want to be involved in medical decisions, and SDM is associated with greater patient-rated quality of care, satisfaction with physician communication, and patient-reported outcomes. SDM may also lead to a reduction in overtreatment, undertreatment, and in healthcare utilization. To achieve SDM, treatment teams must ensure that 1) patients are informed about the nature of the disease and its treatment options (including their risks and benefits), 2) patient values are incorporated into treatment decisions, and 3) patients are aware of their prognosis.[14]

1.3. Older patients with AML often believe they are not well informed about their disease and its treatment options.

Table 1: Representative quotes

Interviewer: *"Was there any discussion about any Other treatment options?* Patient 07: *"No. Not that I know of. Anyway."*
Patient 09: *"I guess sometimes doctors think patients know more than they actually do.", "I think that maybe a better explanation, whether you're 40 or 70, of AML because people off the street don't know what it is, so an explanation of what it is and why treatment needs to be aggressive and it needs to happen right away. And then be told what the options are at this time."*

We conducted a qualitative study of 15 older patients with AML and 15 oncologists to better understand their experiences during the initial diagnosis and treatment decision-making period.[15] Patients believed that they were not well informed about their disease and treatment options (**Table 1**).[15] Patients and oncologists perceived fitness-related factors such as physical function and cognition as important for initial treatment decision-making, although these factors were not systematically or formally assessed.[16] Fitness-related factors can affect the risks and benefits of treatment in AML.[17,18] Integrating fitness-related factors into AML treatment selection will likely facilitate SDM and improve communication.[19-22]

1.4. Best-Worst Scaling (BWS) can reliably elicit patient values.

BWS is a reliable and valid technique[23] that originated in marketing and has been increasingly used in health care.[20,24-27] BWS assesses the relative importance that patients place on various aspects or attributes of care. BWS consists of choice tasks, with a minimum of three attributes (e.g., daily activities, quality of life, response to treatment, survival), for which a patient is asked to indicate the best and worst options. The overall aim is to obtain a ranking of attributes. BWS can help patients with AML consider the risks and benefits of treatment and clarify and reveal their values to their oncologists.[28,29] Incorporating BWS into a communication tool might empower and prompt patients to communicate better with their oncologists. In addition, a better understanding of patient values should allow oncologists to tailor communication about treatments and ultimately promote SDM.

1.5. Preferences for prognostic information vary among patients, and accurate prognostic awareness is an important component of SDM.

Among older adults with cancer referred to the geriatric oncology clinic at our center, approximately 60% stated that a frank conversation about their prognosis would be helpful to them. Poor prognostic awareness is common among patients with cancer.[30-32] In a prior study, we found that over half of patients with hematologic malignancies overestimated their prognosis compared to their oncologists.[33] Among 100 older adults with AML, 90% perceived that they were likely to be cured of their AML, whereas their oncologists estimated only 31% were likely to be cured.[30] Older patients have a lower awareness of their prognosis than younger adults.[34-36] Patients with poor prognostic awareness are more likely to opt for aggressive chemotherapy.[37,38] A communication

tool that elicits preferences for prognostic information and prognostic awareness might help tailor communication about treatment decision-making between older patients with AML and their oncologists.

1.6. Patient decision aids have been evaluated for cancer care.

A systematic review of decision tools, aids, and programs (e.g., question prompt sheets, decision coaching) in oncology found 46 randomized trials, 12 of which were for cancer treatment, primarily focusing on solid tumors.[39] The trials mostly focused on proximal outcomes which included patients' knowledge of decisions, accurate risk perception, value-choice congruency, decisional conflict, participation in decision-making, feeling undecided, patient satisfaction, choice, and consultation. Meta-analysis has shown that patient decision aids improved patient knowledge, accurate risk perception, and value-choice agreement. In addition, patient decision aids reduced decisional conflict, clinician-controlled decision-making, and patient indecision. No trials have measured the effect of these decision aids on patient-clinician communication, distal outcomes such as decisional regret, and distant outcome such as healthcare utilization.[39] One study utilized adaptive conjoint analyses (ACA; BWS and ACA are techniques to elicit patient preferences in real-time). To our knowledge, BWS has not been incorporated into any decision aids.[40] A better understanding of the effects of decision tools on proximal, distal, and distant outcomes may guide future implementation, which we will assess in this proposal.[41]

1.7. There is a lack of decision tools, aids, and programs to facilitate SDM in older patients with AML.

To better understand the landscape in hematologic malignancies, we conducted a systematic review of decision aids in hematologic malignancies and included all development studies and clinical trials.[42] Two studies included patients with AML,[43,44] and two studies included a mixed cancer population including AML.[45,46] Interventions included trained facilitators who provided treatment decision support, a web-based tool, nurse-delivered telephone support, actual patient videos sharing experiences and reflections, and AML educational videos. These interventions were found to be feasible, and proximal outcomes included improved AML knowledge, reduced decisional conflict, and greater patient confidence in communicating with their oncologists.[43-46] None of the tools collected information about patient fitness levels, personal values, and prognostic awareness. While interventions to facilitate advance care planning (ACP)/serious illness conversation and prognostic understanding have been developed for patients with cancer,[47-51] few have improved prognostic understanding,[47,49] and none were adapted for the specific needs of older patients with AML.[52] Controversy surrounds the impact of ACP, particularly on the effects of ACP and completion of advance directives on end-of-life care, as well as the distinction between ACP (used in stable chronic illness) and serious illness communication (used in acute or decompensated illness). Our intervention is broader than ACP or serious illness conversation, and it addresses several components (fitness level, patient values, and prognostic awareness) that are important for treatment decision-making in older adults, thereby improving patient outcomes before the end of life. Our proposal fills an important gap by utilizing an

innovative communication tool to improve SDM and communication between older patients with AML and their oncologists, as well as prognostic awareness in this population.

1.8. Caregivers play an essential role in decision-making

Caregivers (generally family members or friends) play an integral role in the care of older adults,[53], and many assist patients with treatment decision-making and participate in prognostic discussions and.[54,55] Effective communication between older patients and caregivers are associated with patient and caregiver satisfaction with care, treatment adherence, and improved health outcomes.[56,57] In addition, clear communication between patients and caregivers can ensure that the needs of both are met.[58] Studies have shown that disagreements between patients and caregivers in the reporting of symptoms, description of treatment side effects and benefits, and estimates of prognosis are common.[59-62] Disagreement between patient and caregiver is associated with negative outcomes such as increased patient depression[59] as well increased caregiver anxiety, distress, depression, and burden (i.e., the latter refers to the stress experienced by caregivers from providing care for patients).[62-65]

1.9. Overall goal

We have developed a patient-centered communication tool (University of Rochester-Geriatric Oncology assessment for Acute myeloid Leukemia or UR-GOAL) that 1) conducts assessments of fitness, 2) elicits patient values via BWS, and 3) elicits preferences for prognostic information and assesses prognostic awareness. The tool includes an AML educational video. We have refined the tool based on feedback from stakeholders consisting of older patients with cancer (including AML), caregivers, and oncologists. This was further adapted in a qualitative study of 15 older patients with AML. A single-arm pilot study is currently ongoing, and we have demonstrated the feasibility of recruiting older patients with newly diagnosed AML.

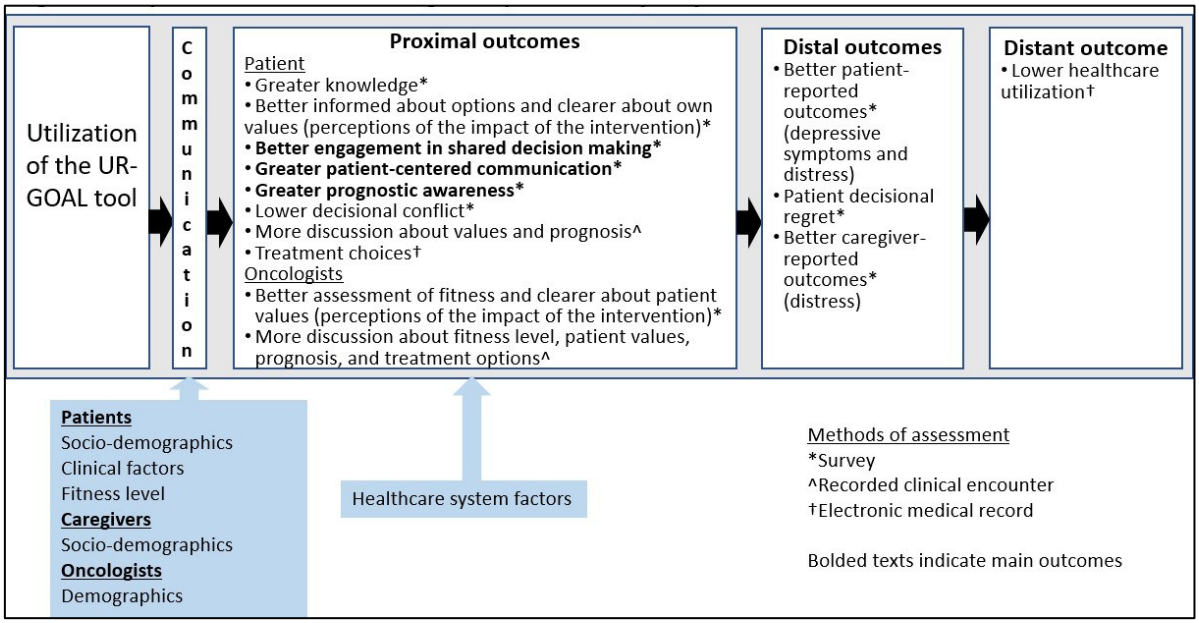
The objective of this study is to conduct a pilot randomized trial to evaluate the preliminary efficacy of the UR-GOAL tool in improving SDM and communication between 100 older patients with AML and their oncologists. We hypothesize that compared to usual care, the UR- GOAL tool will improve SDM and communication between older patients with AML and their oncologists. Incorporating patient values into SDM is a key priority of the Patient-Centered Outcomes Research Institute (PCORI) and National Cancer Institute.[66,67]

1.10. Conceptual model

We adapted the SDM conceptual model proposed by Elwyn et al (Figure 2).[68] The model classifies outcomes into proximal, distal, and distant, without imposing definitive time limits as divisions will not be precise. Proximal outcomes occur as a direct result of using SDM (e.g., perceived impact, treatment choice, SDM), distal outcomes occur

after a clinical encounter (e.g., decisional regret), and distant outcomes occur in the longer term (e.g., healthcare utilization) after a treatment has been initiated. We selected our assessments guided by this model (Figure 2). Factors related to the patient, caregiver, oncologist, and healthcare system influence SDM. In this pilot RCT, we will collect patients, caregivers, and oncologist factors.

Figure 2: Adapted shared decision-making conceptual model by Elwyn et al.



2.0. Aim and Hypothesis

2.1. Primary Aim

To assess the preliminary efficacy of the UR-GOAL communication tool versus usual care in improving shared decision-making [9-item Shared Decision-Making Questionnaire (SDM-9)].

2.2. Secondary Aim

To assess the preliminary efficacy of the UR-GOAL communication tool versus usual care in improving communication [Patient-Centered Communication Cancer Care-36 (PCC-Ca-36 form)] between older patients with AML and their oncologists.

2.3. Exploratory Aim

To assess the preliminary efficacy of the UR-GOAL communication tool versus usual care in improving prognostic awareness in older patients with AML.

2.4. Overall Hypothesis

Compared to usual care, the UR-GOAL communication tool will improve shared decision-making and communication between older patients with AML and their oncologists.

3.0. Study Design and Population

3.1. Study Settings
Wilmot Cancer Institute (WCI), University of Rochester Medical Center (including WCI-affiliated community practices in Geneva, Greece, Sands/Canandaigua, and Strong West/Brockport – the latter 4 practices are also Interlakes Oncology).

3.2. Study Type
Pilot randomized trial

3.3. Study Population
We will recruit 100 older patients with AML (and their caregivers if available). We will consent up to 150 patients to account for screen fail or withdrawal. We will also recruit their oncologists.

3.4. Inclusion and Exclusion Criteria for Patients

Inclusion criteria:
- Age ≥60 years
- Newly diagnosed AML or being worked up for possible AML
- Able to provide informed consent
- Agreement of their oncologist to participate in the study
- English-speaking

  If patients screen positive for cognitive impairment on the Mini-Cog test performed as part of the baseline assessment, they can still enroll if they can provide informed consent and have decision-making capacity as determined by their treating oncologist.

Exclusion criteria
- None

3.5. Inclusion and Exclusion Criteria for Caregivers

Inclusion criteria:
- Selected by the patient when asked if there is a "*family member, partner, friend or caregiver [age 21 or older] with whom you discuss or who can be helpful in health- related matters;"* patients who cannot identify such a person ("caregiver") *can* be eligible for the study. A caregiver need not be someone who lives with the patient or provides direct hands-on care. A caregiver can be any person who provides support (in any way) to the patient
- Able to provide informed consent
- English-speaking

3.6. Inclusion and Exclusion Criteria for Oncologists

Inclusion criteria:

- A practicing oncologist
- At least one of their patients is recruited for the study
- English-speaking

Exclusion criteria

- None

3.7. Number of Subjects

We plan to enroll 100 patients (and their caregivers if available) in 2 years. We will be recruiting patients from WCI and Interlakes Oncology. The WCI inpatient malignant hematology service will also be screened. We plan recruit at least 5 oncologists.

3.8. Gender of Patient Subjects

The gender ratio of enrolled patients will be similar to that of the gender ratio of AML in older adults (approximately 1.2:1 male to female ratio).[69]

3.9. Age of Patient Subjects

We will recruit patients with AML aged 60 and above (from date of consent, confirmed on electronic medical record).

3.10. Racial and Ethnic Origin

The Caucasian to Non-Caucasian ratio of individuals with AML is 5:1. In Rochester, New York, Whites, African Americans, and Hispanics make up approximately 65%, 30%, and 5% of the population (Race and Ethnicity in Rochester, NY statistical atlas). As enrollment is limited to English-speaking patients, we predict a higher percentage of whites. The study does not restrict enrollment based on race or ethnicity.

3.11. Vulnerable Subjects

No special classes of subjects such as fetuses, neonates, children, pregnant women, prisoners, institutionalized individuals or other vulnerable populations will be recruited.

4.0. Recruitment and Consent

Subjects will be enrolled at the URMC WCI and Interlakes Oncology. Patients will be recruited from the inpatient malignant hematology service, hematology clinics at WCI, and general oncology clinics at Interlakes Oncology.

To ensure appropriate safety precautions when conducting in-person study procedures, the process for conducting in-person visits outlined in the Guidance for Human Subject Research will be followed.

4.1. Identification of Study Subjects, Recruitment, and Consent Procedures

Patient subjects will be identified in multiple ways. First, patients will be identified by their treating oncologist, advanced practitioners (APPs), the nurses that work with the oncologists, and the study staff. The study staff will work closely with cancer team to identify patients. Second, with permission from oncologists (or their designee), we will screen for eligible patients from clinic schedules and inpatient malignant hematology services. The study staff contacts the oncologists (or their designee) and informs them that a patient may be eligible for the study. If there is a question about eligibility, the principal investigator will be contacted and will meet with the patient, review the medical records, and/or perform an assessment of eligibility if necessary.

4.1.1. Patients

For **in-person consent with patients (Figure 3)**, below are the possible scenarios for obtaining consent.

1) The treating oncologist /study investigator approaches and consents the patient: After confirming with the oncologist (or their designee) that a patient is a potential candidate for the study, the study staff will provide two versions of the consent form, the informed consent (two copies) and the watermarked “info only- do not sign” informed consent (one copy), to the treating oncologist/study investigator (or their designee) so they can provide it to the patient during an in-person clinic visit. The oncologist/study investigator (or their designee) will go over every detail of the study during the clinic visit with the patient. If they agree to participate at the same in-person or at a subsequent visit, the patient will sign both copies of the informed consent document and the oncologist/study investigator (or their designee) will sign both copies as well. The patient will retain one copy and the oncologist/study investigator (or their designee) will retain the other copy to provide to the study staff for the patient's research file. If the patient wants more information or wants to think about the study, the oncologist/study investigator (or their designee) will provide the patient with the “info only- do not sign” version of the consent document for the patient review.

2) The study staff approaches and consents the patient: After confirming with the oncologist (or their designee) that a patient is a potential candidate for

the study, the study staff will approach the patient with two versions of the consent form, the informed consent (two copies) and the watermarked “info only- do not sign” informed consent (one copy). The study staff will introduce the study to the patients and go over every detail of the study. If the patient agrees to participate, they will sign both copies of the informed consent document and the study staff will sign both copies as well. The patient will retain one copy and the study staff will retain the other for the patient’s research file. If the patient wants more information or wants to think about the study, the study staff will provide the patient with the “info only- do not sign” version of the consent document for the patient review. The study staff will let the patient know that they will be following up with the patient either over the phone or at a subsequent scheduled in-person appointment.

For **verbal consent with patients (Figure 3)**, we will use the following procedures.

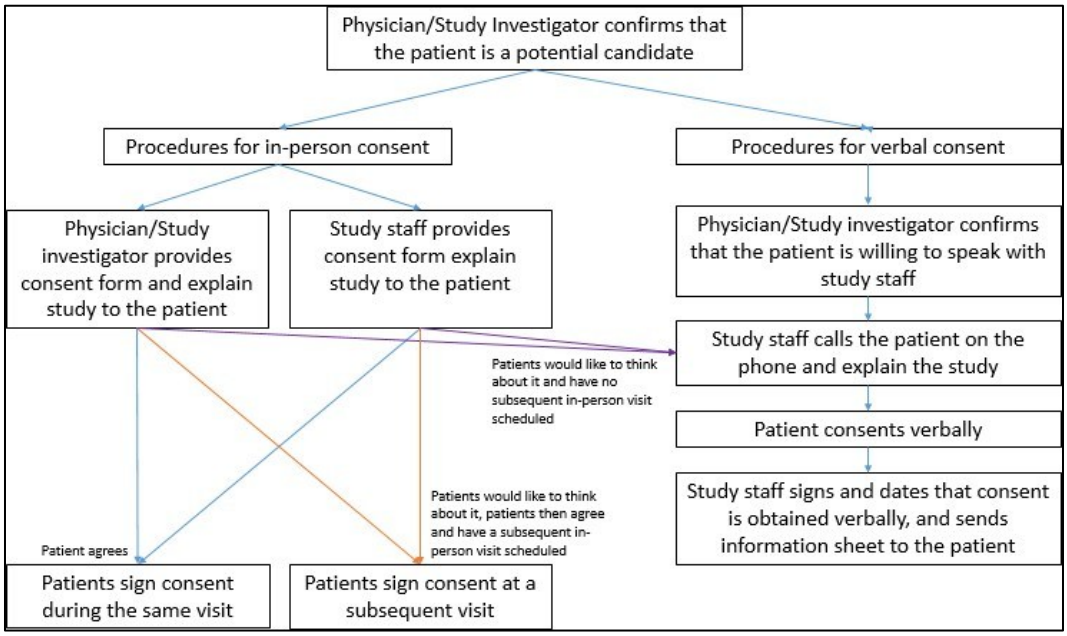
1) <u>The oncologist/study investigator (or their designee) confirms that the patient is eligible and can be approached, and the patient provides verbal consent on the phone:</u> After confirming with the oncologist (or their designee) that a patient is a potential candidate for the study, the physician/study investigator (or their designee) will confirm that the patient is willing to speak with the study staff about the study. The study staff will then call the patient via phone. The study staff will use the verbal consent script as a written aid and will go over every detail of the study with the patient to recruit them for the study. Study staff will sign and date it to confirm that they followed the script and the patient agrees to participate in the study. A copy of the verbal consent and the verbal consent information sheet summarizing the study and the patient's involvement will be mailed or emailed to the patient for their records. If the patient wants more information or wants to think about the study, the study staff will send an email to the patient with the “info only- do not sign” version of the consent document attached for the patient's review. The study staff will inform the patient they will be following up either at an in-person visit or over the phone.

2) <u>Oncologist/Study Investigator (or their designee) approaches the patient in person but they would like to think about, the study staff follows up with the patient on the phone, and the patient provides verbal consent on the phone:</u> After confirming with the oncologist (or their designee) that a patient is a potential candidate for the study, the study staff will provide an "info only” consent document to the oncologist/study investigator so they can provide it to the patient during an in-person clinic visit. The oncologist/study investigator will go over every detail of the study during the clinic visit with the patient. If they would like to think about it and do not have an upcoming in-person appointments scheduled, the study staff will follow-up with the patient via phone. The study staff will use the verbal consent script as a written aid and will go over every detail of the study with the patient to recruit them for the study. Study staff will sign and date it to confirm that they followed the script and the patient agrees to participate in the study. A copy of the verbal

consent and the verbal consent information sheet summarizing the study and the patient's involvement will be mailed or emailed to the patient for their records.

3) Study staff approaches the patient in person but they would like to think about, study staff follows up with the patient on the phone, and the patient provides verbal consent on the phone: After confirming with the oncologist (or their designee) that a patient is a potential candidate for the study, the patient will be provided with an “info only” consent document by the study staff when they come in for an in-person clinic visit. The study staff will introduce the study to the patients and go over every detail of the study. If they would like to think about it and do not have upcoming in-person appointments scheduled, the study staff will follow-up with the patient via phone. The study staff will use the verbal consent script as a written aid and will go over every detail of the study with the patient to recruit them for the study. Study staff will sign and date it to confirm that they followed the script and the patient agrees to participate in the study. A copy of the verbal consent and the verbal consent information sheet summarizing the study and the patient's involvement will be mailed or emailed to the patient for their records.

Figure 3: Consent procedures for patients



4.1.2.Caregivers

For **in-person consent with caregivers**: The patient will identify a caregiver to participate. For in-person consent, this is typically the caregiver who accompanies the patient to a clinic visit. The study staff will go over every detail of the study with the caregiver. If the caregiver agrees, the caregiver will sign the

consent with the study staff during the same in-person visit. If the caregiver wants more information or wants to think about the study, the study staff will provide the patient with the "info only-do not sign" version of the consent document for the caregiver to review.

For **verbal consent with caregivers**: The patient will identify a caregiver and makes the initial contact. After confirming with the patient that a caregiver is willing to speak with the study staff about the study, the study staff then calls the caregiver via phone. The study staff will use the verbal consent script as a written aid and will go over every detail of the study with the caregiver to recruit them for the study. Study staff will sign and date it to confirm that they followed the script and the caregiver agrees to participate in the study. A copy of the verbal consent and the verbal consent information sheet summarizing the study and the caregiver's involvement will be mailed or emailed to the caregiver for their records. If the caregiver wants more information or wants to think about the study, the study staff will provide the caregiver with the "info only – do not sign" version of the consent document for the caregiver to review."

4.1.3. Oncologists

For oncologists, we will obtain verbal consent and they will be provided with an information sheet.

For implied consent with oncologists, study staff will contact oncologists via email. In the email, study staff will include a link to a REDCap survey for oncologists. The survey will include the same information that can be found on the RSRB approved oncologist information sheet. Therefore, when oncologists click the REDCap link, they will see the oncologist information sheet. Oncologists will review the information sheet and click "I agree" at the end of the study if they would like to consent and enroll. If the oncologist does not want to participate in the study, there will be an option for "I do not agree" at the bottom of the REDCap survey.

4.2. Informed Consent

4.2.1. Informed Consent for Patients

Informed consent will be obtained from patients by study staff. Consent documents will be signed by patients and maintained in the patient subject record with copies provided to them.

Waiver of documentation of consent for Patients:

For verbal consent with patients, we are requesting for waiver of documentation of consent as the research involves no more than minimal risk to patients and involves procedures for which written consent is normally not required outside the research context.

Alteration of Health Insurance Portability and Accountability Act (HIPAA) Authorization for Patients:

We are requesting an alteration of HIPAA authorization for patients. We will provide an information sheet to patients who provided verbal consent. Verbal consent will allow for

reduction of in-person visits, thus maximizing the safety of both patients and study staff. Nonetheless, when possible and if we are able to coordinate study and clinic visits, we will obtain written informed consent.

The study cannot be conducted without the use of protected health information (PHI) as we have to link patient reported data with medical history collected on electronic medical records. We have adequate plans to protect the PHI from improper use and disclosure. We will destroy identifiers after completion of the study for 7 years. We will not reuse or disclose the PHI to another person or entity other than the study investigators. The waiver will not adversely affect the privacy rights of the individual and the research cannot be practicably done without access to the use of the PHI.

In MOD00020056: Modification/Update #12, we proposed to access electronic medical records for up to 7 years after enrollment. At that time, subjects who were still actively on study were notified and reconsented using the updated consent form. For subjects who completed participation prior to the approval of MOD00020056, we are requesting a waiver of informed consent and a waiver of HIPAA authorization to access their electronic medical records.

Waiver of informed consent: Written informed consent cannot practicably be obtained from these subjects because many have since died, and contacting family members or legally authorized representatives solely to obtain consent for retrospective medical record review would be inappropriate and burdensome. For surviving subjects, locating and recontacting individuals years after study completion would be impracticable (at least two years have passed since study completion) and would introduce bias and incomplete data capture. The research could not practicably be carried out without the waiver and the use of identifiable information, as longitudinal clinical outcomes (e.g., healthcare utilization and survival) require accurate linkage to individual medical records. The waiver will not adversely affect the rights or welfare of subjects, as the data are limited to information already collected during routine clinical care, pose minimal risk, and will not influence subjects' current or future medical care.

Waiver of HIPAA authorization: Written HIPAA authorization cannot practicably be obtained for the same reasons described above, including subject death and the infeasibility of recontacting former participants. Access to PHI is necessary as outcomes of interest can only be ascertained through review of identifiable electronic medical records. See above regarding the plans to protect the PHI.

4.2.2. Informed Consent for Caregivers

Informed consent will be obtained from caregivers by study staff. Consent documents will be signed by caregivers and maintained in the caregiver subject record with copies provided to them.

Waiver of documentation of consent for Caregivers:

For verbal consent with caregivers, we are requesting for waiver of documentation of consent as the research involves no more than minimal risk to caregivers and involves procedures for which written consent is normally not required outside the research context.

Alteration of HIPAA Authorization for Caregivers:
We are requesting an alteration of HIPAA authorization for caregivers. We will provide an information sheet to caregivers who provided verbal consent. Verbal consent will allow for reduction of in-person visits, thus maximizing the safety of both patients and study staff. Nonetheless, when possible, we will obtain written informed consent.

The study cannot be conducted without the use of PHI because we are describing caregivers' health. We will not link caregiver reported data to their electronic medical records. We have adequate plans to protect the PHI from improper use and disclosure. We will destroy identifiers after completion of the study for 7 years. We will not reuse or disclose the PHI to another person or entity other than the study investigators. The waiver will not adversely affect the privacy rights of the individual and the research cannot be practicably done without access to the use of the PHI.

4.2.3. Informed Consent for Oncologists
Verbal consent documents with oncologists will be maintained in separate records with copies provided to them.

Waiver of documentation of consent for Oncologists:
For verbal consent with oncologists, we are requesting for waiver of documentation of consent as the research involves no more than minimal risk to oncologists and involves procedures for which written consent is normally not required outside the research context.

We will not link personal identifiable information to their electronic medical records.

4.3. Human Subject Protection

The University of Rochester Research Subject Review Board Investigator Guidance policy will be used to ensure that ethical standards for human subjects are upheld.

4.4. Participation

Regulations at the state, federal, and institutional levels will be adhered to in regards to informed consent. Study participation is completely voluntary. After consenting, participants may withdraw from the study at any time for any reason, and they may do so without any repercussions. Participants may also be withdrawn by study staff if it is determined that it is not favorable for the patient. All information regarding consent and withdrawal will be kept confidential.

4.5. Duration

In the intervention arm, after completing baseline assessments, watching an education video, and completing the UR-GOAL tool, study patients will meet with the oncology team. These clinic visits that involve treatment decision-making will be recorded. The post-intervention assessments will be completed within 4 weeks after treatment initiation. Patients will participate in a semi-structured interview with the study team for

30-60 minutes. In the usual care arm, procedures will be similar except those patients do not watch an education video. They complete the UR-GOAL tool without the BWS component.

In the intervention arm, caregivers will complete baseline assessments and watch an education video if they prefer (same video as patient). The post-intervention assessments will be completed within 4 weeks after treatment initiation either in-person or via phone/zoom. They will participate in a separate semi-structured interview with the study team for 30-60 minutes either in-person or via phone/zoom. In the usual care arm, procedures will be similar except those caregivers do not watch an education video.

At months 3 and 6, all patients will complete a brief survey. Those in the intervention arm also complete BWS only component of the tool. After the study is completed, participant data will be maintained for 7 years at URMC and will be kept in a password-protected database.

Oncologist will also complete the post-intervention assessments (surveys) within 4 weeks after treatment initiation. Oncologists will participate in a semi-structured interview with the study team for 30-60 minutes either in-person or via phone/zoom after at least one of their patients has completed the tool. The semi-structured interviews with oncologists will be conducted at any time during the study. After the study is completed, participant data will be maintained for 7 years at URMC and will be kept in a password-protected database.

5.0. Registration

If patients, caregivers, and oncologists meet eligibility criteria and have provided informed consent, the study staff will enter the following information into the OnCore Database:

5.1. Registration Information for Patients

- 5.1.1 Site
- 5.1.2 Most recent IRB approval date
- 5.1.3 Name of person registering study participant
- 5.1.4 Date of informed consent
- 5.1.5 Eligibility verification
- 5.1.6 On study date
- 5.1.7 Participant's identification
  - 5.1.7.a First and last names, middle initial
  - 5.1.7.b Birth date (MM/DD/YEAR)
  - 5.1.7.c Biological sex
  - 5.1.7.d Race
  - 5.1.7.e Medical Record Number
  - 5.1.7.f Ethnicity
  - 5.1.7.g Address
  - 5.1.7.h Five-digit zip code
  - 5.1.7.i Phone number
  - 5.1.7.j Email address (if applicable)

5.2. Registration Information for Caregivers

- 5.2.1 Site
- 5.2.2 Most recent IRB approval date
- 5.2.3 Name of person registering study participant
- 5.2.4 Date of informed consent
- 5.2.5 Eligibility verification
- 5.2.6 On study date
- 5.2.7 Participant's identification
  - 5.2.7.a First and last names, middle initial
  - 5.2.7.b Birth date (MM/DD/YEAR)
  - 5.2.7.c Biological sex
  - 5.2.7.d Race
  - 5.2.7.e Ethnicity
  - 5.2.7.f Address
  - 5.2.7.g Five-digit zip code
  - 5.2.7.h Phone number
  - 5.2.7.i Email address (if applicable)

5.3. Registration Information for Oncologists

5.3.1 Participant's identification

5.3.1.a First and last names, middle initial

5.3.1.b Birth date (MM/DD/YEAR)

5.3.1.c Biological sex

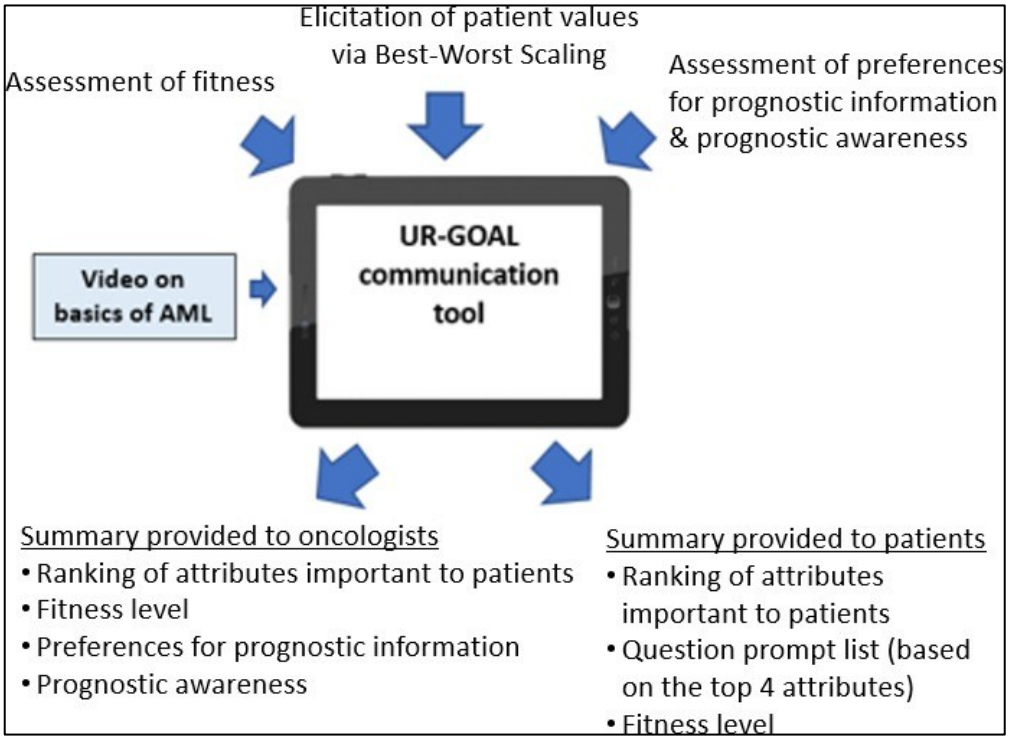
5.3.1.d Race

5.3.1.e Ethnicity

6.0. UR-GOAL Tool

The UR-GOAL tool consists of three components: BWS to elicit patient preferences, fitness assessment, and prognostic awareness assessment (Figure 4). In addition, an education video will also be included for patients in the intervention arm. The education video provides information on the diagnosis, epidemiology, symptoms, risk factors, and prognosis of AML, as well as goals of AML treatment and treatment approaches.

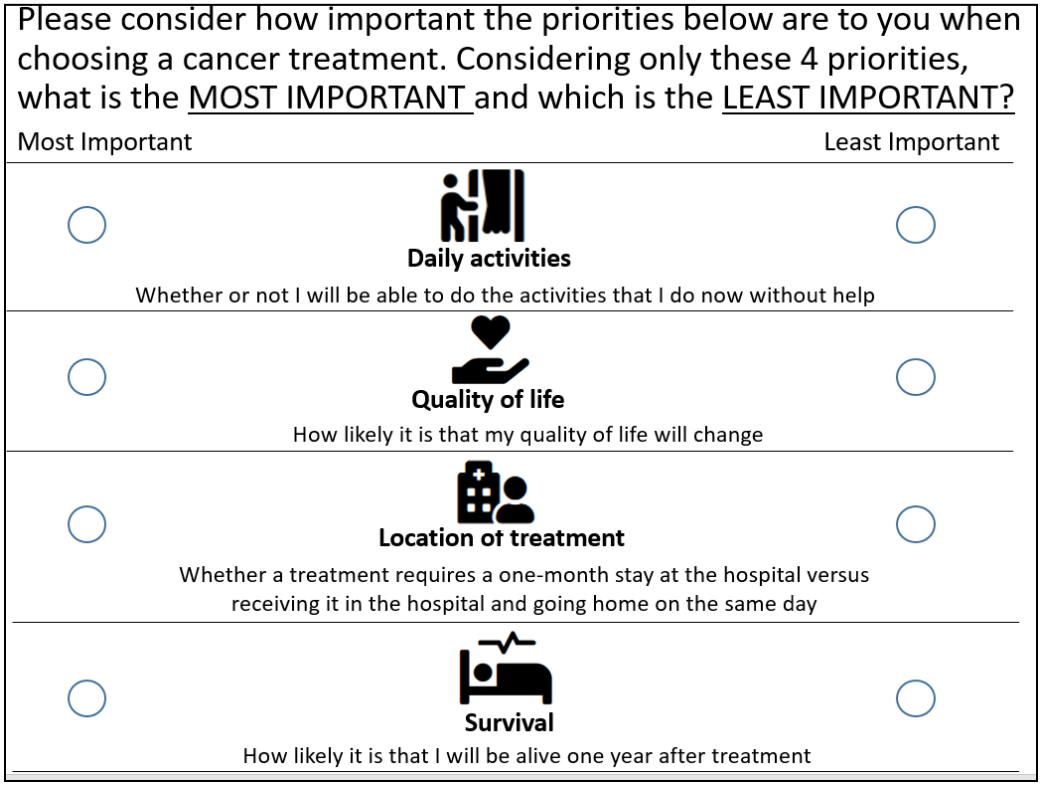
Figure 4: Components of the UR-GOAL communication tool



6.1. Best-worst scaling

BWS consists of 10 choice tasks, with 4 attributes per task. Patients will be presented with 4 attributes at a time, in which a patient is asked to rank the most and least important attribute when choosing a treatment (**Figure 5**). This process then repeats 10 times until all attributes are evaluated. Based on our qualitative study of older patients with AML and oncologists,[15] we selected eight attributes that are important in treatment decision making. At completion, a summary containing the ranking of the attributes will be provided to the patient and oncologist. The patient summary also includes a question prompt list (based on their top four attributes).

Figure 5: Best-Worst Scaling showing 4 options



6.2. Fitness Assessment:

Assessments (e.g., physical function, nutritional status; Table 1) that evaluate fitness and are important in decision-making for both patient and oncologist are included.[70] At completion, a summary containing the patient's fitness level will be provided to the oncologists.

Table 2: Assessments included in the tool

Fitness domain	Assessments
Physical function	- Activities of daily living - Instrumental activities of daily living - Fall history - Short Physical Performance Battery (performed by the study staff and entered into the tool)
Nutritional status	- Unintentional weight loss in the prior 6 months
Comorbidity	- Hearing and eyesight
Psychological health	- Geriatric Depression scale - Geriatric Anxiety scale - Distress Thermometer
Social support	- Patient's social support - Living situation
Medications	- Number of medications

Cognition	- Mini-Cog (performed by the study staff and entered into the tool)
Other	- Self-reported age - Health status

6.3. Prognostic Awareness Assessment:

Assessment of prognostic awareness (i.e., the chance of cure and survival estimates, their information preference (i.e., do they prefer treatment success rate presented in percentages, words, fractions, or they wanted to hear about a previous patient that the oncologist treated), and whether the conversation about prognosis would be helpful to them are incorporated. At completion, a summary containing this information will be provided to the oncologists.

As described above, the generated summaries are tailored and intended to improve communication between the patient and the oncologist during the decision-making process.

6.4. Education Video

As the overall goal of the study is to improve patient-physician communication, we created an education video for patients. The video contains basic information about the diagnosis, epidemiology, symptoms, risk factors, and prognosis of AML, as well as the goals of AML treatment and treatment approaches. We created this video because of two main reasons: 1) Our preliminary data suggest that many older patients may not understand the AML diagnosis and treatment approaches given the acuity, 2) The video provides an overview of AML which will help patients complete the tool subsequently (e.g., the tool will ask patients if they are willing to trade quality of life for higher remission, and the education video provides information on what remission means in the context of the different treatments). The video is not part of the standard of care. We developed this video based on feedback from leukemia and bone marrow transplant and geriatric oncology groups at WCI.

The video is available for view using this link:
https://youtu.be/759f1o_xaGs

7.0. Study Procedures

7.1. Study Outline (see Figure 6 for Study Schema)

We will screen and consent eligible patients of treating oncologists at WCI and Interlakes Oncology. Patients and caregivers will complete baseline assessments.

Randomization will occur at the end of the baseline assessments and be revealed to the patients before the start of the intervention. We will employ two treatment arms in a 1:1 allocation ratio. Consented patients will be randomized with a computer-generated random numbers table with varying block sizes. The random numbers tables will be generated centrally using software provided by Dr. Michael Sohn, the project biostatistician. Patients randomized to the intervention arm will use the UR-GOAL communication tool either in-person or via zoom/phone. They can also receive a link via their email to complete it on their own electronic device. Patients randomized to the usual care arm will receive standard of care.

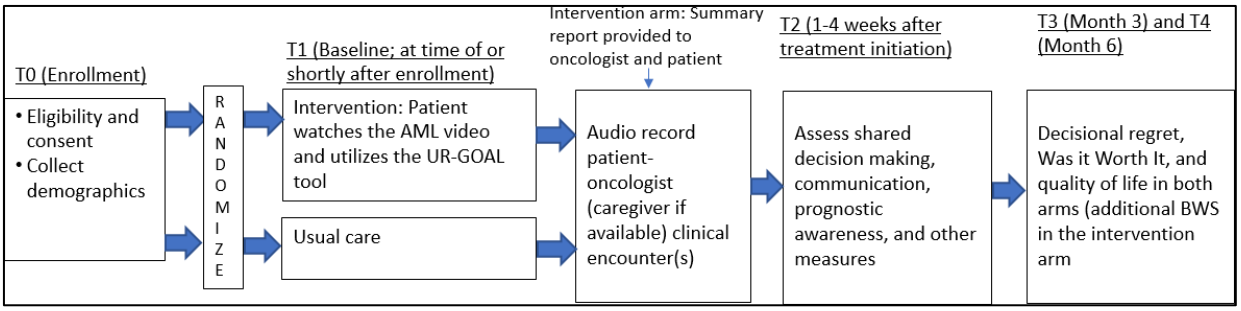
The patient (and caregiver if available) will have a visit with their primary oncologist and the clinical encounter will be audio-recorded. The study staff will provide an audio recorder to the oncologist for in-person, phone, or zoom visits. All parties present for recorded visits, including enrolled patients, any accompanying caregivers, family or friends, the oncologist, and any other physicians or health care providers not participating in the study will be fully aware that the conversation is being audio-recorded before any recording begins, in addition to the prior written or verbal consent of enrolled patients. Patients, caregivers, and oncologists may receive copies of these recordings at their request.

The post-intervention assessments, including the qualitative interviews, for patients and caregivers, will be completed within 4 weeks after treatment initiation. Qualitative interviews can be conducted either in-person or via phone/zoom. A semi-structured interview will last approximately 30-60 minutes during which feedback will be elicited. Enrolled caregivers will also participate in a semi-structured interview for 30-60 minutes during which feedback will be elicited. Oncologists will also complete the post-intervention assessments (surveys) within 4 weeks of treatment initiation. Semi-structured interviews with oncologists will be conducted at any time during the study after at least one of their patients has completed the study procedures.

To assess priorities longitudinally in the intervention arm, patients will complete the BWS on the tool at 3 and 6 months. All patients will also complete a brief survey at 3 and 6 months.

Throughout the study, if the patient/caregiver does not have access to an electronic device to complete study procedures, the study team will provide them with a tablet with internet access (wifi- or data-enabled). They will be asked to mail back the tablet or return the tablet in the next in-person visit.

Figure 6: Study Schema



7.2. Assessments of the Participants

Assessments will be collected via the UR-GOAL tool, obtained by staff on the phone, done in person, done on redcap as a survey option, or mailed to the participants. Any information required from medical records may be collected from enrollment and up to 7 years after the patient completes the study. Additional assessments not specified in the aims are collected to inform future larger clinical trials because this is a pilot study.

A subject contact form will be used to capture first and last name, middle initial, mailing address, preferred method of communication, and email address (when appropriate). This will be provided to patients and caregivers.

7.2.1. Demographics – Patient, Caregiver, and Oncologist

Patient age, race, ethnicity, gender, the highest level of education achieved, employment status, and marital status at enrollment will be collected. Patient age and gender are collected in the UR-GOAL tool. Any missing information may be abstracted from medical records.

Caregiver age, date of birth, race, ethnicity, gender, the highest level of education achieved, employment status, marital status at enrollment, living situation, and relationship to the patient will be collected.

The oncologist's date of birth, race, ethnicity, and gender will be collected.

7.2.2. Clinical, Cancer Characteristics, Healthcare Utilization, and Death – Patient

ECOG performance status, diagnosis, prior hematologic malignancies, and cytogenetic risk group at enrollment will be abstracted from the medical records.

We will collect treatment choice, number of hospitalizations, days in the hospital, intensive care unit admission, life-sustaining treatment, and use of palliative care and hospice within 1 year of diagnosis, all obtained from the medical records. We will collect disease information and outcomes for 7 years, as well as date of death.

All of the above information will be collected if they are present in the medical records.

7.2.3. Other Assessments

7.2.3.1. Physical Function and Functional Status (Baseline Only - Patient)

Short Physical Performance Battery (SPPB; baseline only): The SPPB is an objective physical assessment evaluating lower extremity physical function.[120] It is comprised of a three or four-meter walk, repeated chair stands, and a balance test. Impairment on SPPB testing has been shown to be predictive of short-term mortality and nursing home admission in community-dwelling older adults. When possible, we will also perform the virtual SPPB, which evaluates the patient's perceived ability to perform above tests (walking, repeated chair stands, and balance). Virtual SPPB rely on patients to indicate whether they can perform these tests after being shown several videos. The videos can be accessed via http://wfuhs-mat-vsppb.s3-website-us-east-1.amazonaws.com/. Patients may be directed to the website via email or the phone by study staff, or are shown these videos in-person or via zoom by study staff. Patients then indicate to study staff whether they are able to perform these tests as shown on the videos.

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.[73]

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.[74]

Fall History: A self-reported history of falls as well as number of falls 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.[75]

7.2.3.2 Nutritional Status (Baseline Only - Patient)

Screenings for nutritional deficit will be performed with body mass index (BMI) evaluation and self-reported weight loss.

7.2.3.3. Comorbidity including Hearing and Eyesight (Baseline Only - Patient and Caregiver)

Patients self-report their perceived levels of eyesight and hearing.

OARS Physical Health Section: Caregivers self-report their coexisting medical conditions and also rate the degree to which their illness causes impairment in daily activities. They also self-report their perceived levels of eyesight and hearing.

7.2.3.4. Psychological Health (Baseline and Post-Intervention – Patient and Caregiver)

General Anxiety Disorder-7: A 7-item screening tool for anxiety.[76]

Geriatric Depression Scale-15: A 15-item valid and reliable screening tool for depression in older adults.[77] This will be used for patients.

Patient Health Questionnaire-2 (PHQ-2): A 2-item valid and reliable screening tool depression in the general population.[78] This will be used for caregivers.

National Comprehensive Cancer Network Distress Thermometer: A visual analog scale for rating distress on a 0 to 10 scale and indicating problems on a checklist that may be contributing to distress.[79]

7.2.3.5. Social Support (Baseline Only - Patient)

Patients will self-report their living situation and their main social support.

7.2.3.6. Medications (Baseline Only - Patient)

Medications: We will record all prescription and non-prescription medications, dosage, and frequencies from the medical records. Polypharmacy is defined as the use of 5 or more medications.

7.2.3.7. Cognition (Baseline Only - Patient)

Mini-Cog: A 3-item screening tool for cognitive impairment in older adults.[80]

7.2.3.8. Patient-Centered Communication (Post-Intervention Only – Patient and Caregiver)

Patient-Centered Communication in Cancer Care (PCC-Ca-36): A questionnaire assessing patient-centered communication in six domains: exchanging information, making decisions, fostering healing relationships, enabling patient self-management, managing uncertainty, and responding to emotions.[81] We will adapt the PCC-Ca-6 for caregivers.

7.2.3.9. Shared Decision-Making (Post-Intervention Only – Patient, Caregiver, and Oncologist)

Shared Decision-Making Questionnaire (SDM-Q-9): A 9-item reliable questionnaire assessing **patient** satisfaction with the medical decision-making process.[82]

Shared Decision-Making Questionnaire (SDM-Q-Doc): A 9-item reliable

questionnaire assessing **physician** satisfaction with the medical decision-making process.[83]

Preparation for Decision-Making Scale: A 10-item questionnaire assessing patients' and caregivers' perception of how useful the communication tool is in preparing them to communicate with their physician at a consultation focused on making a health decision.[84] This is for intervention arm only.

7.2.3.10. Disease Knowledge (Baseline and Post-intervention – Patient and Caregiver)

Disease Knowledge: A questionnaire assessing patients' and caregivers' understanding of AML.

7.2.3.11. Information and Decision-Making Preferences (Baseline Only – Patient and Caregiver)

Information Preferences: A questionnaire assessing patient and caregiver preferences regarding treatment information.

Decision-Making Preferences: The Control Preference Scale assesses patients' and caregivers' preferred roles in treatment decisions.[85]

7.2.3.12. Disease Understanding (Baseline and Post-Intervention – Patient and Caregiver, Post-intervention Only – Oncologist)

Disease Understanding – Patient: A questionnaire assessing patient's prognostic understanding of illness and preferences regarding life expectancy discussions.

Disease Understanding – Caregiver: A questionnaire assessing caregiver's prognostic understanding of illness and preferences regarding life expectancy discussions.

Disease Understanding – Physician: A physician-facing questionnaire assessing patient prognosis.

7.2.3.13. Decisional conflict and regret (Post-intervention for decisional conflict; month 3, and month 6 for decisional regret – Patient only)

Decisional conflict scale – A questionnaire that measures personal perceptions of uncertainty in choosing options, modifiable factors contributing to uncertainty, and effective decision-making.[86]

Decisional regret scale – A questionnaire that measures distress or remorse after a healthcare decision.[87]

Was it worth it questionnaire – A questionnaire that assesses satisfaction with the

decision that was made.[88]

7.2.3.14. Expectations about future physical function (Post-Intervention – Patient and Oncologist)

Expectations about future physical function: We will ask the patient and their oncologist to report whether they expect the patient's physical function will worsen, stay the same, or improve over time. We will additionally ask patients how they expect this to impact their ability to live independently.

7.2.3.15. Health-related quality of life (Post-Intervention, month 3, and month 6 – Patient only)

EQ-5D-5L: A health-related quality of life questionnaire that consists of five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems, and extreme problems. The patient is asked to indicate his/her health state by ticking the box next to the most appropriate statement in each of the five dimensions. This decision results in a 1-digit number that expresses the level selected for that dimension. The digits for the five dimensions can be combined into a 5-digit number that describes the patient's health state.[89]

7.2.3.16. Usability (intervention arm only – Patient; Oncologist will complete at the end of the study)

Usability questions: Questions to assess the usability of the tool and/or summary.

7.2.3.17. Environmental Mastery (Baseline and Post-Intervention - Caregiver)

Ryff's Environmental Mastery: A 7-item questionnaire measuring whether the respondent makes effective use of opportunities and has a sense of mastery in managing environmental factors and activities, including managing everyday affairs and creating situations to benefit personal needs.[90]

8.0. Data Handling and Statistical Considerations

8.1. Data Handling

8.1.1. The same protocols and procedures for data quality and control that are readily used for the NCI Community Oncology Research Program (NCORP) Research Base protocols currently being overseen by our office (which have accrued over 1,000 patients in the previous year) will be used for this study.

8.1.2. It is anticipated that by allowing for the appropriate number of evaluable participants and by checking self-report assessments for completeness, we will have a full complement of data. Every effort will be made to encourage and facilitate participants' completion of all questionnaires and all items on the questionnaires for each study assessment. If missing data occur, every effort will be made to contact participants via phone and obtain the data or to find out why the questionnaires or items are missing. Missing questionnaire items will be treated in accordance with the documented scoring procedures.

8.1.3. Data collected via the UR-GOAL communication tool will only be accessed by the following: 1) The research team; 2) The treating oncologist and their designee; and 3) Sawtooth (see Data Security Form).

8.2. Data Analysis and Sample Size:

8.2.1. Sample Size Calculation

A 15-point difference on the SDM-Q-9 is considered clinically meaningful.[92] Assuming a standard deviation of 25 points, a sample size of 45 participants per group (90 total) will provide 80% power to detect a 15-point mean difference on SDM-Q-9 between the intervention and usual care, using a t-test with a two-tailed significance level of 0.05. To account for attrition (10%), 10 additional patients will be enrolled, increasing the total number of participants to 100.

8.2.2. Analysis Plan

Quantitative analyses*:* We will use descriptive statistics to summarize all measures. The primary outcome variable (Aim 1) will be SDM-Q-9 at post-intervention (T2). The primary analysis will involve fitting an analysis of the variance model with the study arm as a factor. A 95% confidence interval for the effect of the intervention (i.e., a difference in group means) will be computed using this model. If clinically important differences are found between the groups, particularly concerning potentially important variables (e.g., age, sex, race, ethnicity, education, and presence of the caregiver in the visit), the primary analysis will be repeated after statistically adjusting for these differences using a linear regression model. We will also investigate the interaction between the study arm and a potential effect modifier (covariate) by including the covariate

(e.g., age, sex, race, ethnicity, education, health literacy, and presence of the caregiver in the visit) and the appropriate interaction term in linear regression models. Since the power to detect interactions will be limited, the magnitudes of intervention effects in the relevant subgroups will be examined. Findings will serve as sample size justification and hypothesis generation for a future RCT. For intervention effects on PCC-Ca-36 (Aim 2), prognostic awareness (Exploratory Aim) and other exploratory outcomes (e.g., healthcare utilization, health-related quality of life), we will use similar analysis strategies. We will also perform additional exploratory analyses to assess intervention effects on caregiver-adapted PCC-Ca-6 and other caregiver outcomes.

Qualitative analyses and mixed-method integration: Similar to other studies from our group,[93-95] interviews will be conducted and audio-recorded by study staff and transcribed. We will purposefully sample 40 transcripts based on the SDM-Q-9 (20 highest and 20 lowest scores). Two trained staff ("coders") will use the OPTION scale to code for 12 items related to treatment decision-making in patients and caregivers.[96] Directed content analysis will be used. We will keep an audit trail to establish trustworthiness. We will compare mean OPTION scores in the high vs. low SDM group.

Missing data: Efforts will be made to prevent missing data. Missing data will be addressed using regression-based multiple imputation methods that assume missing at random (MAR; i.e., the probability of being missing is the same only within groups defined by the observed data). As the MAR assumption is not easily verifiable, we will perform a sensitivity analysis to explore the result of the analysis under alternative scenarios for the missing data.[97] We will perform additional sensitivity analysis including provider as a covariate.

9.0. Data Management

9.1. Data Collection Table

a) Patients

PATIENT SCHEDULE OF DATA COLLECTION				
	Eligibility and Consent Form	**Baseline Assessment (week 0±1 week)**	**Post-Intervention Assessment (within 4 weeks)***	**Month 3 and 6 (±1 week)**
Intervention and usual care				
Informed Consent	X			
Demographics		X^		
Clinical and Cancer Characteristics, Healthcare Utilization, and Death	Following enrollment and up to 7 years after the patient completes the study			
Qualitative Interview			X	
Short Physical Performance Battery/Virtual Short Physical Performance Battery, Activities of Daily Living, Instrumental Activities of Daily Living, Fall History		X (ADL, IADL, Fall history in the tool)		
Nutritional Status		X#		
Hearing and Eyesight		X#		
Geriatric Depression Scale-15 (GDS-15), Generalized Anxiety Disorder-7 (GAD-7), Distress Thermometer		X#	X	
Social Support		X#		
Medications at enrollment	Following enrollment and up to 7 years after the patient completes the study			
Mini-Cog		X		
Patient-Centered Communication in Cancer Care (PCC-Ca-36)			X	
Shared Decision-Making (SDM-Q-9)			X	
Patient Disease Knowledge		X	X	
Information and Decision-Making Preferences - Patient		X#		
Disease Understanding - Patient		X	X	
Decisional Conflict Scale			X	
Decisional Regret Scale and Was it Worth It Questionnaire				X
Expectations about Future Physical Function			X	
EQ-5D-5L			X	X
Intervention arm only				
BWS component of the UR-GOAL tool				X

Preparation for Decision-Making Scale			X	
Usability questions			X	

*Within 4 weeks after treatment initiation. In the case of no treatment, it will be from the clinical encounter where decision about no treatment has been made

#Assessments are within the UR-GOAL tool

^Partially within the UR-GOAL tool

b) Caregivers

CAREGIVER SCHEDULE OF DATA COLLECTION			
	Eligibility and Consent Form	**Baseline Assessment (week 0±1 week)**	**Post-Intervention Assessment (within 4 weeks)***
Informed Consent	X		
Demographics		X	
Qualitative Interview			X
Comorbidity (including hearing and eyesight)		X	
Patient Health Questionnaire-2 (PHQ-2), Generalized Anxiety Disorder-7 (GAD-7), Distress Thermometer		X	X
Patient-Centered Communication in Cancer Care (PCC-Ca-6) – adapted caregiver version			X
Ryff's Environmental Mastery		X	X
Preparation for Decision-Making Scale (**intervention arm ONLY**)			X
Caregiver Disease Knowledge		X	X
Information and Decision-Making PreferencesCaregiver		X	
Disease Understanding– Caregiver		X	X
*Within 4 weeks after treatment initiation. In the case of no treatment, it will be from the clinical encounter where a decision about no treatment has been made			

c) Oncologists

	ONCOLOGIST SCHEDULE OF DATA COLLECTION			
	Eligibility and Consent Form	**Baseline Assessment (week 0±1 week)**	**Post-intervention Assessment (within 4 weeks)***	**At the end of the study**
Informed Consent	X			
Demographics		X		
Shared Decision-Making (SQM-Q-Doc, oncologist version)			X	
Disease Understanding – Oncologist			X	
Expectations about Future Physical Function			X	
Usability questions				X
Qualitative Interview		After at least 1 patient per oncologist completed study procedures, can be done at any point during the study		
*Within 4 weeks after treatment initiation. In the case of no treatment, it will be from the clinical encounter where a decision about no treatment has been made				

9.2. All hardcopy research records will be stored onsite in the URMC, in locked research files at the WCI or our offsite location at 211 White Spruce Blvd, Rochester NY, 14623. The Cancer Center and White Spruce facilities are secured with electronic key cards or fobs. Offices within the Cancer Center and White Spruce facilities are again secured by key and data is kept in locked file cabinets. Electronic research records are stored on the URMC's password-secured and firewall-protected networks. These are the same methods of security used for patient medical records. Audio recordings will be uploaded to Box within a week of the interview and deleted from the audio recorded. All study data will be kept for a period of 7 years after the study and all reports and publications are complete.

9.3. All data collected for the current study will be used in post hoc analyses as appropriate. Data will not be used for future studies without the prior consent of the patient. The patient's research record will not be shared with their treating oncologist (unless otherwise stated), unless they provide consent or the patient's treating oncologist is a study investigator, in which case they will have access to study data. Study results will be presented at professional meetings and published.

9.4. The study staff will assign a numerical study ID to each participant once they have signed the consent form (chronologically based on the data they signed consent i.e., 001, 002, 003…). Study assessments will use this number and the participant's first, middle, and last initials as identifiers. Other identifiers as specified in the protocol will be collected and entered into REDCap.

9.5. Assessments at stated above will be collected and managed by the research teams at URMC using REDCap electronic data capture tools hosted at URMC. We will also evaluate the medical records and utilize REDCap to collect and manage this information.

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

9.5.2. According to the Clinical and Translational Science Institute (CTSI), REDCap is supported with the following means. "The *CTSI Informatics Core*, a unit of the SMD *Academic Information Technology (AIT) Group,* will serve as a central facilitator for data processing and management. REDCap data collection projects rely on a thorough study- specific data dictionary defined in an iterative self-documenting process by all members of the research team, with planning assistance from the *AIT-CTSI Informatics Core*. The iterative development and testing process results in a well-planned data collection strategy for individual studies."

9.5.3 The CTSI states that regarding security, "REDCap servers are housed in a local data center at the University of Rochester and all web-based information transmission is encrypted. REDCap was developed in a manner consistent with HIPAA security requirements and is recommended to University of Rochester researchers by the URMC Research Privacy Officer and Office for Human Subject Protection.

10.0. Risks/Benefits

10.1. Risks

There is a potential loss of confidentially associated with participation in the proposed study. In terms of loss of confidentiality, quantitative data from participants will need to be stored. Though rigorous and well-tested data safety and security guidelines will be observed, there is still a chance that confidentiality could be breached and sensitive medical information could become known to persons outside the research team.

There is still a risk that a third party could gain access to any Information provided to or collected through this site. To mitigate these risks, any data breaches and, potential identification of the subjects, Participant Payments has security measures in place to protect electronically transmitted information. They are frequently reviewing and consistently trying to improve the security of the site. They do not collect and subjects will not be asked to submit any “protected health information” as defined in HIPAA.

10.2. Benefits

There are no anticipated benefits to the participants

10.3. Payments and Costs

There is no cost to the subjects for participating. Patients will be paid $50.00 after completing the audio-recorded interview. Caregivers and oncologists will not be paid for their participation.

For this study we will use a subject payment system called Participant Payments. The system allows three ways to provide payment. Patients can choose: a reloadable debit card; direct deposit; or mailed paper checks. The study team will help create a “subject profile” in the system. In order to provide payment, the subject will need to enter their name and date of birth into their subject profile. Depending on which payment method they choose, they may also need to enter their email address and banking information. If the subject already has a Participant Payments account (because of another study that uses this system), the existing profile will be used to provide payment.

11.0. Data Safety and Monitoring

Only adverse events (AEs) related to the study intervention or procedures will be reported. In other words, AEs related to cancer treatment will not be reported.

11.1. Adverse Event Reporting Requirements

11.1.1. Adverse events will be reported using the URCC Adverse Event form and/or as required by the Cancer Center Clinical Trials Office.

	Grade 1	Grade 2			Grade 3				Grade 4		Grade 5	
		Unexpected		Expected	Unexpected		Expected		Unexpected	Expected	Unexpected	Expected
	Unexpected and Expected	with hospitalization	without hospital-ization		with hospitalization	without hospitalization	with hospitalization	without hospitalization				
Unrelated Unlikely	Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	10 Calendar Days	Not Required	10 Calendar Days	10 Calendar Days
Possible Probable Definite	Not Required	10 Calendar Days	Not Required	Not Required	10 Calendar Days	10 Calendar Days	Not Required	Not Required	5 Calendar Days	10 Calendar Days	5 Calendar Days	10 Calendar Days
Hospitalization is defined as initial hospitalization or prolongation of hospitalization for ≥ 24 hours, due to adverse event.												

11.1.2. Adverse events will be reported in accordance with the following guidelines:

11.1.3. Adverse event reports will be submitted in one of the following ways:

(1) By email: (pdf)

(2) By mail:

(3) By fax:

11.1.4. An unexpected adverse event is defined as any adverse experience, the specificity or severity of which is not consistent with the risk information. This is a minimal-risk study.

11.1.5. A serious event refers to any event in which the outcome results in any of the following: death, a life-threatening adverse experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability, incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. We anticipate that any serious events will be related to the standard of care for cancer treatments and not due to the intervention. We

will not collect adverse events related to cancer treatments.

11.1.6. Adverse events will be reported per institutional policies (University of Rochester, Research Subject Review Board, local IRB, URCC CCOP, CTO, and DSMB) as per their requirements.

11.2. Data Safety Monitoring

11.2.1. All adverse events requiring reporting will be submitted to the current Project Coordinator as described in Section 11.1. Serious adverse event reports will be forwarded to the study chair and the Data Safety and Monitoring Committee (DSMC). Adverse events are entered into a protocol-specific spreadsheet.

11.2.2. Adverse event rates are monitored utilizing the spreadsheet. If a serious adverse event is reported frequently, the study chair will conduct a detailed review. The DSMC Committee Chair will be notified and will determine if further action is required.

11.2.3. The Data Safety Monitoring Committee (DSMC) will review the study progress and cumulative reports of adverse events every year and as needed. An overall assessment of accrual and adverse events will enable the committee members to assess whether significant benefits or risks are occurring that would warrant study closure..

12.0. References

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