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WILMOT CANCER INSTITUTE

A patient-centered communication tool (UR-GOAL) for older patients with acute myeloid leukemia, their caregivers, and their oncologists

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1.0 Background

1.1. Acute myeloid leukemia is a disease of the aging

Nearly 60% of acute myeloid leukemia (AML) diagnoses are in adults aged ≥ 60 years.[1] For fit older patients with AML (i.e., without significant comorbidities or disabilities), the standard first-line treatment consists of intensive inpatient chemotherapy. Intensive chemotherapy provides the best chance for durable remission, but it is associated with a high treatment-related mortality (60-day mortality: 15-20%).[2,3] Intensive therapy is utilized in <1% of older patients with AML seen in the community oncology setting, due to various reasons such as distance to tertiary centers and need for hospitalizations.[6] In the last decade, low-intensity outpatient treatments (e.g., azacitidine, decitabine, venetoclax, ivosidenib, enasidenib) with reduced treatment-related mortality rates have become available.[4-9] These treatments have permitted more older patients with AML, including those with comorbidities and disabilities, to receive leukemia-directed therapy.[10] Despite these treatment options, 40-50% of diagnosed individuals do not undergo leukemia-directed therapies.[11]

1.2. There is substantial heterogeneity in the health status of older patients, making treatment selection challenging

In a prospective study of 74 older patients with AML receiving intensive induction therapy, up to 69% had physical impairments, 42% had significant comorbidities, 29% had impaired cognition, and 40% were depressed.[12] The effect these fitness-related factors have on disease progression, treatment tolerance, and response is not well understood, in part due to an underrepresentation of older patients in clinical trials. This is especially true regarding older patients with comorbidities and poor performance status.[1] It is often challenging for oncologists to identify older patients with AML who are fit enough for intensive treatment, or fit enough to receive treatment at all. Practice patterns therefore vary.

1.3. Older patients with AML often do not feel informed of their disease and treatment options.

We have previously conducted a qualitative study of 15 older patients with AML and 15 oncologists to better understand their experience during the initial AML diagnosis and treatment decision-making.[13] Many older patients did not feel that they were adequately informed of their treatment options (Patient quote: *"The only option I had was going through this. It's do or die."*)[14] Patients and oncologists perceived fitness-related factors such as physical function, comorbidities, psychological health, and cognition as important for initial treatment decision-making.[13] Therefore, incorporating patient preferences and fitness-related factors into AML treatment decisions may facilitate communication and shared decision-making, leading to increased patient satisfaction.[15-18]

1.4. Best worst scaling to elicit patient preferences

Best-worst scaling (BWS) is a technique that assesses the relative importance that patients place on different aspects or attributes of care. BWS consists of choice tasks, with a minimum of three attributes (e.g., daily activities, quality of life, location of treatment, survival), in which a patient

is asked to indicate the best and worst options. The overall aim is to obtain a ranking of the attributes. This methodology is a reliable and valid technique that can help patients to consider the risks and benefits of treatment as well as to clarify and reveal their values to their oncologists, ultimately improving shared decision making.[19,20]

1.5. Information preferences vary among patients, and accurate prognostic awareness is an important component of shared decision-making.

In a multicenter prospective cohort study, we have found that older patients were less likely to prefer treatment success rates presented in percentages. We also found that over half of patients with hematologic malignancies overestimate their prognosis compared to their oncologists.[21] Among older adults with AML, >90% thought that they could be cured, compared to 30% of oncologists.[22] Patients with poor prognostic awareness are more likely to opt for aggressive chemotherapy[23,24] and less likely to utilize palliative and hospice services at the end-of-life.[25,26] Older patients have lower awareness of their prognosis than younger adults.[27-29] Therefore, prognostic discussion with oncologists can facilitate accurate prognostic awareness among older patients with AML (who are often incurable). We have shown that among older adults with cancer referred to geriatric oncology clinics at our center, almost 60% stated that a frank conversation about their prognosis would be helpful to them.

1.5. Caregivers play an essential role in decision-making

Caregivers (generally family members or friends) play an integral role in the care of older adults,[30], and many assist patients with treatment decision-making and participate in prognostic discussions and.[31,32] Effective communication between older patients and caregivers is associated with patient and caregiver satisfaction with care, treatment adherence, and improved health outcomes.[33,34] In addition, clear communication between patients and caregivers can ensure that the needs of both are met.[35] 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.[36-39] Disagreement between patient and caregiver is associated with negative outcomes such as increased patient depression[36] as well increased caregiver anxiety, distress, depression, and burden (i.e., the latter refers to stress experienced by caregivers from providing care for patients).[39-42]

1.6. Overall goal

Older adults with AML may benefit from help and support in understanding their treatment options. This pilot study seeks to develop and adapt a patient-centered communication tool (University of Rochester-Geriatric Oncology Assessment for acute myeloid Leukemia or UR-GOAL) and then evaluate the usability and feasibility of this tool. The UR-GOAL tool will incorporate BWS to elicit patient preferences as well as assessments of fitness and prognostic awareness. We hypothesize that this tool will be usable and feasible in this population. Once we have shown usability and feasibility, we will assess whether the UR-GOAL tool improves shared decision-making, communication, and prognostic awareness. Given that caregivers are closely involved in the care of older adults with cancer, we also seek to obtain feedback from caregivers. In addition, we will also obtain feedback from oncologists.

2.0 Aim and Hypothesis

2.1 Primary Aim

Develop and adapt a communication tool (UR-GOAL) for 10 older patients with AML.

2.2 Secondary Aim

Evaluate the usability and feasibility of the UR-GOAL communication tool among 15 older patients with AML, their caregivers, and oncologists.

2.3 Exploratory Aim

To assess change in priorities longitudinally among 15 older patients with AML.

2.4 Overall Hypothesis

The UR-GOAL will be usable and feasible.

2.5 Usability and feasibility metrics

The usability and feasibility of the UR-GOAL communication tool will be evaluated based on the following:

a) Recruitment rates (percentage of patients who are approached and agree to enroll)
b) System Usability Scale (score on 10-item scale, ranging 0-100; higher score corresponds to greater usability)
c) Semi-structured interviews (audio-recorded/transcribed interviews exploring perceived usefulness, barriers, and facilitators)

3.0. Study Design and Population

3.1. Study Settings
Wilmot Cancer Institute (WCI), University of Rochester Medical Center (URMC) and its affiliated centers

3.2. Study Type
Aim 1: Qualitative study

Aim 2 and Exploratory Aim: Single-arm pilot study

3.3. Study Population
Aim 1: We will gather feedback from 20 older patients with AML. We anticipate thematic saturation will be reached with this number of participants based on past similar research.[43,44] We will consent up to 30 patients to account for screen fail or withdrawal.

Aim 2 and Exploratory Aim: We will recruit 15 older patients with AML (and their caregivers if available) to evaluate the usability and feasibility. We will consent up to 20 patients to account for screen fail or withdrawal. We will also interview their oncologists.

3.4. Inclusion and Exclusion Criteria for Patients

Inclusion criteria:

Aim 1

- Age ≥60 years (conventional definition of older age in AML)
- Established AML diagnosis (within 1 year)
- Able to provide informed consent
- English-speaking

Aim 2

- Age ≥60 years (conventional definition of older age in AML)
- Newly diagnosed AML
- Able to provide informed consent
- English-speaking

Exclusion criteria

- None

3.5. Inclusion and Exclusion Criteria for Caregivers (Aim 2 only)

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 (Aim 2 only)

Inclusion criteria:
- A practicing oncologist
- At least one of their patients are recruited to the study
- English-speaking

Exclusion criteria
- None

3.7. Number of Subjects

Aim 1: We plan to enroll 20 patients in 6 months. Two previous qualitative studies conducted in this population showed a recruitment of 75%-100%. Annually, from 2012-2018, WCI saw 60-70 patients aged ≥60 years with AML.

Aim 2 and Exploratory Aim: We plan to enroll 15 patients (and their caregivers if available) in 12 months. We will be recruiting patients from WCI and WCI-affiliated sites. The WCI inpatient malignant hematology service will also be screened. We plan recruit at least 3 oncologists and up to 15 oncologists (assuming 1 patient per oncologist is enrolled).

3.8. Gender of 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).[45]

3.9. Age of 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

Recruitment will exclude vulnerable populations such as fetuses, neonates, children, pregnant woman, prisoners, and institutionalized individuals. We will also exclude adults who are deemed to not have decisional capacity and those who lost their consent capacity during the study period, as per their treating oncologist.

4.0 Recruitment and Consent

Subjects will be enrolled at the URMC WCI.

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

Patients will be identified by treating physicians at WCI and WCI-affiliated sites, nurses of these physicians, and the study coordinator. The study coordinator will work closely with physicians and nurses to identify patients who have an established AML diagnosis (Aim 1) or have been newly diagnosed with AML (Aim 2). Given permission from the oncologist, the study team will screen clinic schedules of these oncology providers. The study coordinator will contact the physician (or designee) and inform them of patient eligibility and ask permission to approach the patient. The principal investigator will address any eligibility questions that may arise.

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

1. Physician/Study Investigator makes the initial contact and provides consent form, and patient signs consent with the physician on the same day: After confirming with the physician (or their designee) that a patient is a potential candidate for the study, the study staff will provide a consent form to the treating physician/study investigator so he/she can provide it to the patient during an in-person clinic visit. The physician/study investigator will go over every detail of the study during the clinic visit with patient. If agrees, the patient will sign the consent form with the physician/study investigator during the same in-person visit.

2. Study staff makes the initial contact and provides consent form, and patient signs consent with the study staff on the same day: After confirming with the physician (or their designee) that a patient is a potential candidate for the study, the patient will be provided with an informed consent form 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 agrees, the patient will sign the consent form with the study staff during the same in- person visit with the study staff.

For **verbal consent with patients**, below are the possible scenarios for obtaining consent.

1. Physician/Study Investigator makes the initial contact, study staff follows up with the patient on the phone, and patient provides verbal consent on

the phone: After confirming with the physician (or their designee) that a patient is a potential candidate for the study, the physician/study investigator confirms with the patient that he/she is willing to speak with the study staff about the study. The study staff will then call the patient via phone. The study coordinator 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 he/she followed the script and the patient agrees to participate in the study. An information sheet summarizing the study and patient' s involvement will be mailed /emailed to the patient for their records.

2. Physician/Study Investigator makes the initial contact and provides consent form, study staff follows up with the patient on the phone, and patient provides verbal consent on the phone: After confirming with the physician (or their designee) that a patient is a potential candidate for the study, the study staff will provide a consent form to the treating physician/study investigator so he/she can provide it to the patient during an in-person clinic visit. If the patient is interested but does not want to consent on the same day, the patient will bring the consent form home. The study staff will then call the patient via phone. The study coordinator 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 he/she followed the script and the patient agrees to participate in the study. An information sheet summarizing the study and patient's involvement will be mailed/emailed to the patient for their records.

3. Study staff makes the initial contact and provides consent form, study staff follows up with the patient on the phone, and patient provides verbal consent on the phone: After confirming with the physician (or their designee) that a patient is willing to speak with the study coordinator about the study, the patient will be provided with an informed consent form by the study staff when they come in for an in-person clinic visit. If the patient is interested but does not want to consent on the same day, the patient will bring the consent form home. The study staff will then call the patient via phone. The study coordinator 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 he/she followed the script and the patient agrees to participate in the study. An information sheet summarizing the study and patient's involvement will be mailed/emailed to the patient for their records.

For caregivers, we will obtain verbal consent. They will be provided with an information sheet. 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 coordinator about the study, the study staff then call the caregiver via phone. The study coordinator 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 he/she followed the script and the patient agrees to participate in the study. An information sheet summarizing the study and caregiver's involvement will be provided/mailed/emailed to the caregiver for their records.

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

4.1.1. Informed Consent

Informed consent will be obtained from the patient by the study investigators or coordinators. Consent documents will be signed by the patient and maintained in the patient record with copies provided to the patient. For verbal consent, documents will be maintained in the patient record with copies provided to the patient. Verbal consent documents with caregivers and oncologists will also be maintained in separate records with copies provided to caregivers and oncologists.

Waiver of documentation of consent:
We are requesting for waiver of documentation of consent as the research involves no more than minimal risk to the subjects and involves procedures for which written consent is normally not required outside the research context. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.

Alteration of HIPAA Authorization:
We are requesting an alteration of HIPAA authorization. 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 record. 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.

We are requesting an alteration of HIPAA authorization for enrollment of caregivers and oncologists. We will provide an information sheet to these participants who provided verbal consent. Verbal consent will allow for reduction of in-person visits, thus maximizing the safety of both patients and study staff. We are not collecting protected health information (PHI) from Oncologists or Caregivers.

4.1.2. 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.

4.1.3. Participation

Regulations at the state, federal, and institutional level 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 personnel if it is determined that it is not favorable for the patient. All information regarding consent and withdrawal will be kept confidential.

4.1.4. Duration

Aim 1: The qualitative section of this study involves interviewing consented patients for 30-60 minutes. They will watch an education video and use the UR-GOAL tool and feedback can be provided during the interview. Study participants will be interviewed by the study team either in-person (in a private space) or via phone/zoom. Interviews will be audio-recorded, uploaded to Box, and subsequently deleted from the audio-recorder.

Aim 2 and Exploratory Aim: After completing baseline measures, watching an education video, and completing the UR-GOAL tool, study participants will participate in a semi-structured interview with the study team for 30-60 minutes either in-person or via phone/zoom. The post-intervention measures will be completed within 1-2 weeks of the patient's encounter with the primary oncologist either in-person or via phone/zoom. Caregivers will complete baseline measures and watch an education video. They will participate in a separate semi-structured interview with the study team for 30-60 minutes either in-person or via phone/zoom. The post-intervention measures will be completed within 1-2 weeks of the patient's encounter with the primary oncologist either in-person or via phone/zoom. 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 1-2 weeks of the patients encounter. 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 have 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 personnel 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 Eligibility verification
- 5.1.5 Verification that consent form has been signed and who signed by (patient and/or health care proxy) and date signed
- 5.1.6 Treatment facility (WCI vs. Other)
- 5.1.7 Participant's identification
  - 5.1.7.a First and last names
  - 5.1.7.b Birth date (MM/DD/YEAR)
  - 5.1.7.c Gender
  - 5.1.7.d Race
  - 5.1.7.e Five-digit zip code
  - 5.1.7.f Medical Record Number
  - 5.1.7.g Ethnicity
  - 5.1.7.h Patient's preferred and alternate phone numbers (and email address if patients consent to be contacted via email)
  - 5.1.7.i Date of baseline visit

5.2. Registration Information for Caregivers

- 5.2.1 Participant's identification
  - 5.2.1.a First and last names
  - 5.2.1.b Birth date (MM/DD/YEAR)
  - 5.2.1.c Gender
  - 5.2.1.d Race
  - 5.2.1.e Five-digit zip code
  - 5.2.1.f Ethnicity
  - 5.2.1.g Caregiver's preferred and alternate phone numbers (and email address if patients consent to be contacted via email)

5.3. Registration Information for Oncologists

- 5.3.1 Participant's identification
  - 5.3.1.a First and last names
  - 5.3.1.b Birth date (MM/DD/YEAR)
  - 5.3.1.c Gender
  - 5.3.1.d Race
  - 5.3.1.e Five-digit zip code
  - 5.3.1.f Ethnicity

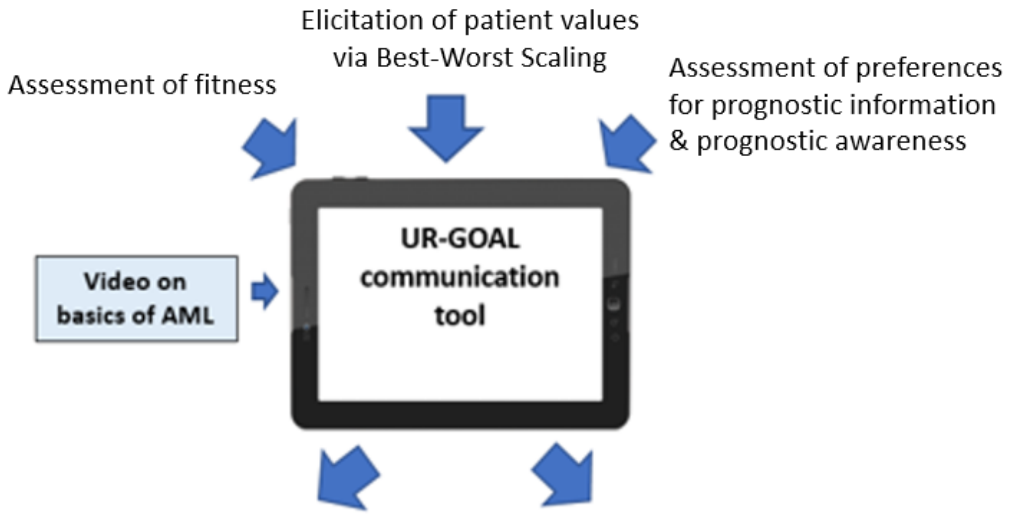
5.4. Initial Assessment

In Aim 1, study patients will complete demographics and a 30-60 minutes interview in which they will watch an education video and complete the UR-GOAL tool and provide feedback. Patients in Aim 2 will complete baseline assessments with the study coordinator, watch an education video, and complete the UR-GOAL tool. Caregivers in Aim 2 will complete baseline assessments with the study coordinator and watch an education video.

6.0. UR-GOAL Intervention Tool

The proposed tool consists of three components: BWS to elicit patient preferences, fitness assessment, and prognostic awareness assessment (Figure 1). In addition, an education video will also be included. The education tool provides information on the diagnosis, epidemiology, symptoms, risk factors, and prognosis of AML, as well as goals of AML treatment and treatment approaches.

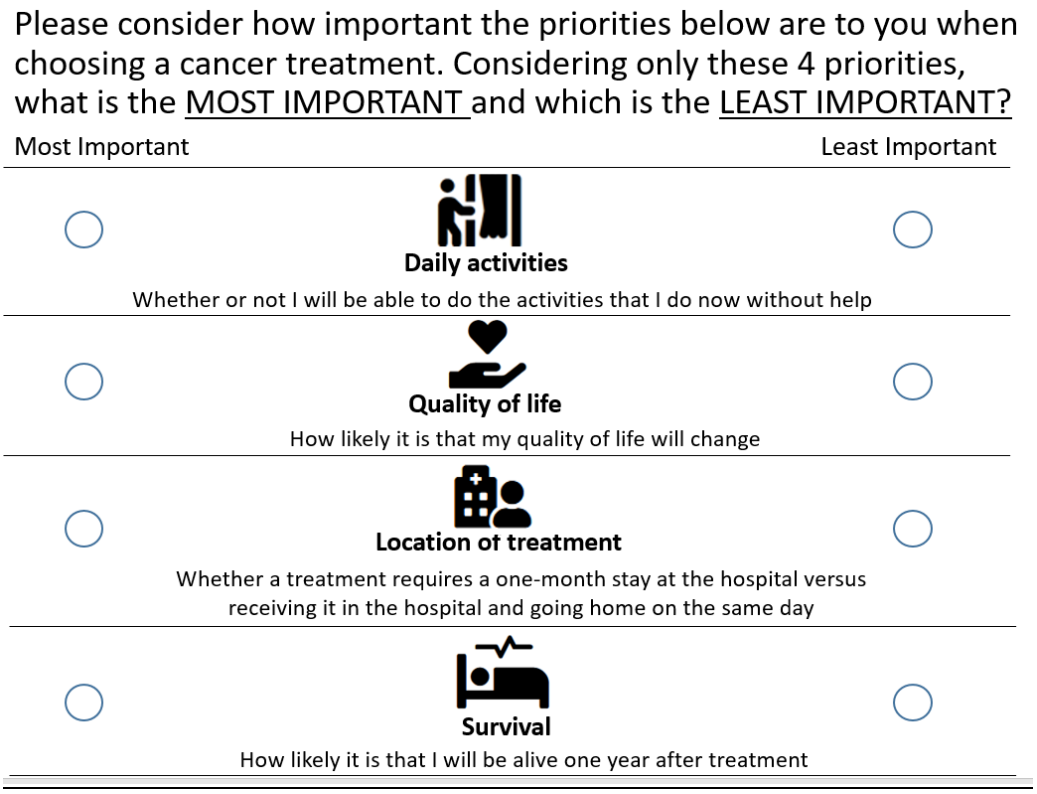
Figure 1: Components of the UR-GOAL communication tool



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 2**). This process then repeats 10 times until all attributes are evaluated. Based on our qualitative study of older patients with AML and oncologists,[43] 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 2: Best-Worst Scaling showing 4 options



6.2. Fitness Assessment:

We will include assessments (e.g., physical function, nutritional status; Table 1) that evaluate fitness and are important in decision-making for both patient and oncologist.[13] At completion, a summary containing the patient's fitness level will be provided to the oncologists.

Table 1: Questionnaires that will be included in the tool

Fitness domain	**Assessments**
Physical function	Activities of daily living, instrumental activities of daily living, number of falls, Short Physical Performance Battery
Nutritional status	Weight loss in the prior 6 months
Comorbidity	Hearing and eyesight
Psychological health	Geriatric Depression scale
Social support	Patient's social support Living situation
Medications	Number of medications
Cognition	Mini-Cog

6.3. Prognostic Awareness Assessment:

We will incorporate assessment of prognostic awareness (i.e., 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 physician treated), and whether conversation about prognosis would be helpful to them. At completion, a summary contacting 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 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 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 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 standard of care. We developed this video based on feedback from the leukemia and bone marrow transplant and geriatric oncology groups at WCI.

The video is available for view using this link:
https://rochester.box.com/s/m25aidirevgzaeumgvnpxmd3mck1lxhy

7.0. Treatment Protocol

7.1. Study Outline

We will screen and consent eligible patients of treating physicians at WCI and WCI-affiliated centers.

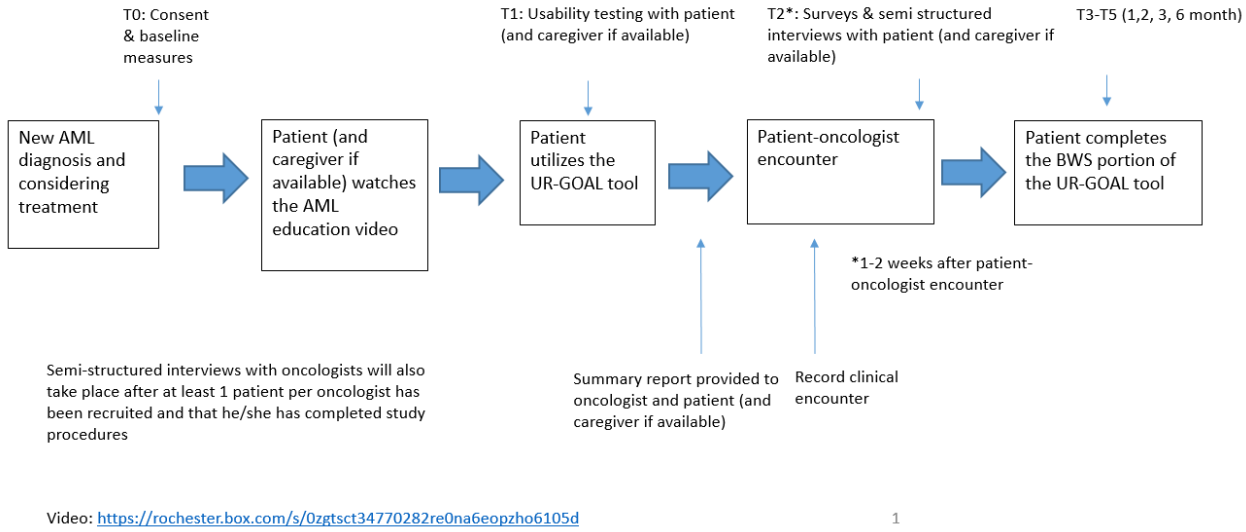
For Aim 1, the study team will conduct an in-person or zoom/phone interview for 30-60 minutes. First, we will explain the rationale of the study. Second, patients will use the communication tool. Third, we will conduct an interview to elicit feedback about the communication tool. This feedback will be used to adapt the tool for Aim 2.

For Aim 2 and Exploratory Aim (Figure 3), the study subject will complete baseline measures and utilize the UR-GOAL communication tool either in-person or via zoom/phone. Following this, patients will complete the usability testing form. 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 physician for in-person or phone visits, and the zoom recording feature will be used for 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 consent of enrolled patients. Patients, caregivers and oncology physicians may receive copies of these recordings at their request.

The post-intervention measures, including the qualitative interviews, for patients and caregivers will be completed within 1-2 weeks of the patient's encounter with the primary oncologist either in-person or via phone/zoom. The interviews will be conducted separately. Patients will participate in a semi-structured interview for 30-60 minutes during which feedback will be elicited. Enrolled caregivers will also participate in a separate semi-structured interview for 30-60 minutes during which feedback will be elicited. Oncologist will also complete the post-intervention assessments (surveys) within 1-2 weeks of the patients encounter. The semi-structured interviews with oncologists will be conducted at any time during the study, after at least one of their patients have completed the study procedures.

To assess priorities longitudinally, patients will complete the BWS on the tool at 1, 2, 3, and 6 months.

Figure 3: Study Procedures (Aim 2 and Exploratory Aim)



7.2. Assessments of the Participants

Demographic, clinical, and cancer characteristics will be collected**.**

7.2.1. Demographics – Patient, Caregiver, and Oncologist

Patient and caregiver's age, date of birth, race, ethnicity, gender, highest level of education achieved, employment status, and marital status. This will only be collected at baseline.

Oncologist's name, date of birth, race, five-digit zip code, ethnicity, and gender will be collected.

7.2.2. Clinical and Cancer Characteristics - Patient

ECOG performance status, diagnosis, prior hematologic malignancies, cytogenetic risk group and treatment regimen will be abstracted from the medical records. This information will only be collected at baseline.

7.2.3. Measures

Measures will be collected via the UR-GOAL tool, done in person, or mailed to the participants.

7.2.2.1. 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. It is comprised of a 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.[46] If in-person SPPB cannot be performed, we will

perform the virtual SPPB via the phone/zoom, which evaluates the participants' perceived ability to perform above tests (walking, repeated chair stands, and balance).[47]

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 client'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.* Clients 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.[48]

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.[49]

Fall History: A self-reported history of falls in the past three 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.[50]

7.2.2.2. Nutritional Status (Baseline Only - Patient)

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

7.2.2.3. Comorbidity (Baseline Only - Patient and Caregiver)

OARS Comorbidity: Patients and caregivers report coexisting illnesses and indicate the degree to which these comorbidities interfere with their daily activities.[51]

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

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

General Anxiety Disorder-7: A 7-item screening tool for anxiety.[52]

Geriatric Depression Scale-15: A 15-item valid and reliable screening tool for depression in older adults.[53] 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.[54] This will be used for caregivers.

7.2.2.5. Social Support (Baseline Only - Patient)

OARS Medical Social Support: A 13-item questionnaire for patients regarding persons involved in medical social support as well as perception of overall support.[51,55]

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

7.2.2.6. 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.

7.2.2.7. Cognition (Baseline Only - Patient)

Mini-Cog (baseline only): A 3-item screening tool for cognitive impairment in older adults.[56]

7.2.2.8. Communication Self-Efficacy (Baseline and Post-intervention – Patient and Caregiver)

Perceived Efficacy in Patient-Physician Interactions (PEPPI): A valid and reliable assessment of perceived self-efficacy of older patients interacting with physicians.[57]

Perceived Efficacy in Caregiver-Physician Interactions (PECPI): A valid and reliable assessment of perceived self-efficacy of caregivers interacting with physicians.[58]

7.2.2.9. 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.[59]We will adapt the PCC-Ca-6 for caregivers.

7.2.2.10. Shared Decision-Making (Post-Intervention Only – Patient, Caregiver, and Physician)

Shared Decision-Making Questionnaire (SDM-Q-9): A 9-item reliable questionnaire assessing patient satisfaction with the medical decision-making process.[60]

Shared Decision-Making Questionnaire (SDM-Q-Doc): A 9-item reliable questionnaire assessing physician satisfaction with the medical decision-making process.[61]

CollaboRATE Measure: A 3-item questionnaire assessing patient, caregiver, and

physician shared decision-making.[62]

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.[63]

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

Disease Knowledge: A 14-item questionnaire assessing patients and caregivers' understanding of AML.

7.2.2.12. 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 assess patient and caregivers' preferred roles in treatment decisions.[64]

7.2.2.13. Disease Understanding (Patient, Caregiver, and Physician)

Disease Understanding – Patient (baseline and post-intervention): A questionnaire assessing patient's prognostic understanding of illness and preferences regarding life expectancy discussions.

Disease Understanding – Caregiver (baseline and post-intervention): A questionnaire assessing caregiver's prognostic understanding of illness and preferences regarding life expectancy discussions.

Disease Understanding – Physician (post-intervention only): A physician-facing questionnaire assessing patient prognosis.

7.2.2.14 Decisional conflict and regret (post-intervention for decisional conflict and 1, 2, 3, and 6 month for decisional regret at)

Decisional conflict scale – A questionnaires that measures personal perceptions of uncertainty in choosing options, modifiable factors contributing to uncertainty, and effective decision making.[65]

Decisional regret scale – A questionnaire that measures distress or remorse after a healthcare decision.[66]

Was it worth it questionnaire – A questionnaires that assesses satisfaction with decision made.[67]

7.2.2.15 Health-related quality of life (Post-Intervention and 1, 2, 3, and 6 month)

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.[68]

7.2.2.16. Usability (Post-Intervention Only)

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

7.2.2.17. 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.[70]

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. Patients will fill out forms generated from RedCap and this information will be entered into RedCap (Section 9.5). Study personnel will perform SPPB and the scores will be entered into RedCap.

8.1.2. It is anticipated that allowing for the appropriate number of evaluable participants and by checking self-report measures 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. In the event that 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. The reasons for missing data will be documented. Missing questionnaire items will be treated in accordance with the documented scoring procedures. Although it is very unlikely that missing values will not occur randomly, we will confirm their randomness. Multiple imputation[71] will be applied to (1) give more accurate statistical tests and standard errors for key treatment effect parameters and to (2) give some indication of the sensitivity of the analyses to missing data. The causes and pattern of the missing data will be examined and taken into consideration in the design of future studies.

8.1.3. Data collected via the UR-GOAL communication tool will only be accessed by the following: 1) The research team and 2) The treating physician and their designee.

8.2. Data Analysis and Sample Size:

8.2.1. Analysis Plan for Aim 1

We anticipate thematic saturation will be reached with this number of participants (N=20) based on past similar research.[43,44] We will conduct and audio-record all interviews, which will be transcribed by a professional transcription service. We will analyze the qualitative data using grounded theory and constant comparative methods, with coding to structure data into categories and create groups according to the broader issues or themes.[72] An audit trail of the coding activity will be kept. We will critically examine the data collection and analysis process and reach consensus on key themes from patient feedback to be used to adapt the intervention in preparation for Aim 2.

8.2.2. Analysis Plan for Aim 2

We anticipate that our proposed sample size will be sufficient based on prior research[73] and also published guidance on usability study.[74,75] The feasibility of the UR-GOAL tool

will be evaluated based on the percentage of patients consented to the study ultimately completing all study components.

Recruitment rate (percentage of patients who are approached and agree to enroll) will also be described. Other feasibility metrics include retention rate (percentage of patients who were enrolled and completed the intervention and assessments). The usability of the UR-GOAL tool will be evaluated using the SUS score.

We will consider the UR-GOAL study feasible if >50% of consented patients ultimately complete all study components. We chose 50% based on our prior behavioral intervention study in this population and published studies that utilize similar tools (e.g., value elicitation tool).[73,76,77] We will use descriptive statistics to describe the measures. If we do not meet our usability and feasibility goals, we will further adapt the study and tool.

For other measures, these are being collected in preparation for a larger clinical trial in the future. As exploratory analyses, paired t-tests or McNemar's test will be used to evaluate change in measures from baseline to post-intervention. Linear mixed models will be used to assess change in measures over several time points.

Qualitative data from the semi-structured interviews will be analyzed as per Aim 1. Interviews will be conducted, audio-recorded, and transcribed. We will analyze the qualitative data using grounded theory and constant comparative methods, with coding to structure data into categories and create groups according to the broader issues or themes.[72] An audit trail of the coding activity will be kept. We will critically examine the data collection and analysis process and reach consensus on key themes from patient feedback to be used to further adapt the tool.

For audio-recorded clinic encounters, we will use published shared decision-making coding schemes to assess quality of shared decision making.[78,79] Coders will undergo extensive training and supervision by study investigators.

9.0. Data Management

9.1. Data Collection Table

9.1.1. Aim 1

	Eligibility and Consent Form	**Assessment**
Informed Consent	X	
Demographics		X
Clinical and Cancer Characteristics		X
Qualitative Interview		X
Short Physical Performance Battery/Virtual Short Physical Performance Battery, Activities of Daily Living, Instrumental Activities of Daily Living, Fall History		X
Nutritional Status		X
Comorbidity		X
Geriatric Depression Scale-15 (GDS-15), Generalized Anxiety Disorder-7 (GAD-7)		X
Social Support		X
Medications		X
Mini-Cog		X
Information and Decision-Making Preferences		X
Disease Understanding - Patient		X

9.1.2. Aim 2

a) Patients

	SCHEDULE OF DATA COLLECTION			
	Eligibility and Consent Form	**Baseline Assessment (week 0)**	**Post-intervention Assessment (week 1-2)**	**Month 1, 2, 3, and 6**
Informed Consent	X			
Demographics		X		
Clinical and Cancer Characteristics		X		
Qualitative Interview			X	
Short Physical Performance Battery/Virtual Short Physical Performance Battery, Activities of Daily Living, Instrumental Activities of Daily Living, Fall History		X		
Nutritional Status		X		
Comorbidity		X		
Geriatric Depression Scale-15 (GDS-15), Generalized Anxiety Disorder-7 (GAD-7)		X	X	
Social Support		X		
Medications		X		
Mini-Cog		X		
Perceived Efficacy in Patient-Physician Interactions (PEPPI)		X	X	
Patient-Centered Communication in Cancer Care (PCC-Ca-36)			X	
Shared Decision-Making (SDM-Q-9)[a]			X	
CollaboRATE Measure			X	
Preparation for Decision Making Scale			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
BWS component only of the tool				X
EQ-5D-5L			X	X
Usability (Usability questions)			X	

b) Caregivers

	SCHEDULE OF DATA COLLECTION		
	Eligibility and Consent Form	**Baseline Assessment (week 0)**	**Post-intervention Assessment (week 1-2)**
Informed Consent	X		
Demographics		X	
Qualitative Interview			X
Comorbidity		X	
Patient Health Questionnaire-2 (PHQ-2), Generalized Anxiety Disorder-7 (GAD-7)		X	X
Perceived Efficacy in Caregiver-Physician Interactions (PECPI)		X	X
Patient-Centered Communication in Cancer Care (PCC-Ca-6) – adapted caregiver version			X
Ryff's Environmental Mastery		X	X
CollaboRATE Measure			X
Preparation for Decision Making Scale			X
Caregiver Disease Knowledge		X	X
Information and Decision-Making Preferences – Caregiver		X	
Disease Understanding – Caregiver		X	X

c) Oncologists

	SCHEDULE OF DATA COLLECTION		
	Eligibility and Consent Form	**Baseline Assessment (week 0)**	**Post-intervention Assessment (week 1-2)**
Informed Consent	X		
Demographics		X	
Shared Decision-Making (SQM-Q-Doc, physician version)			X
Disease Understanding – Physician			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

9.2. All hardcopy research records will be stored onsite in the URMC, in locked research files at the WCI. The Cancer Center is secured with electronic key cards. Offices within the Cancer Center 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. For audio-recordings, these 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 prior consent of the patient. The patient's individual research record will not be shared with their treating physician, unless they provide consent or the patient's treating physician is a study physician, in which case they will have access to study data as a study co-investigator. Overall study results will be presented to participants, faculty and staff at the URMC after completion of the study. Study results will be presented at professional meetings and published.

9.4. The study coordinator 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…). All study forms and questionnaires will use this number and the participant's first, middle, and last initials as identifiers, to ensure data integrity. Other identifying information will not exist on these forms. A complete list of study participants with study ID, name, and contact information will be maintained separately. This linkage information will only be accessible to the study coordinator, study investigators, and the individuals responsible for maintaining the database.

9.5. Additionally, data on the socio-demographics, clinical, and cancer and treatment characteristics will be collected and managed by the research teams at URMC using REDCap electronic data capture tools hosted at URMC.[80] We will also evaluate the medical records for clinical characteristics and outcomes, and utilize REDCap to collect and manage this information.

9.5a. 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.[81]

9.5b. 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."[72]

9.5c. 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.[81]

10.0 Risks/Benefits

10.1. Risks

There is 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.

10.2. Benefits

There are no anticipated benefits to the participants.

10.3 Payments and Costs

Patients participating in the first aim will be paid $30 and those participating in the second aim will be paid $50 for their participation in the form of gift cards. For Aim 1, participants will receive the gift cards immediately following the interviews. For Aim 2, participants will be paid for completion of the post-intervention assessment. Oncologists will not be reimbursed for their participation.

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 as both exercise and mobile app-driven interventions have been shown to improve outcomes in community-dwelling older adults.

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 standard of care 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 in accordance with 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 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.

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