A Telehealth Advance Care Planning Intervention in those with Mild Cognitive Impairment or Unrecognized Dementia

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1. **FULL PROTOCOL TITLE**

A Telehealth Advance Care Planning Intervention in those with Mild Cognitive Impairment or Unrecognized Dementia
(Tele-Voice Study)

Principal Investigator:

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Study Intervention Provided by:

Wake Forest School of Medicine

Version 2
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(Any modification to the protocol should be annotated on the coversheet or in an appendix. The annotation should note the exact words that are changed, the location in the protocol, the date the modification was approved by the Executive Committee, and the date it became effective.)

2. **TABLE OF CONTENTS**

3. PRÉCIS

There are approximately 46.8 million people worldwide affected by dementia with this number expected to double in the next 20 years.[1] Dementia, the sixth leading cause of death within the United States, is a progressive and incurable condition that, unlike most other terminal illnesses, can have a disease course spanning several years.[2] Unfortunately most persons living with dementia (PLWD) and their caregivers lack prognostic awareness coupled with the fact that capacity becomes compromised as the disease progresses results in these patients being at high risk for receiving aggressive and burdensome treatments at the end-of-life without clear associated improvements in quality of life or survival.[3-6] Documented ACP can lead to increased treatment concordance with patient's wishes, as well as decreased hospitalization rates, in-hospital deaths, and overall healthcare costs.[7-13] Despite these well-documented benefits, ACP has not been incorporated consistently into the care of community-dwelling older adults, particularly for PLWD. Most research on ACP has either excluded PLWD or has focused within the nursing home setting or in patients with advance stages of dementia; where most patients have limited capacity.[14] Thus there is a critical need for ACP interventions that target PLWD early in the disease course and that involve their surrogate decision maker/caregiver to enhance goal-concordant care.

Past ACP interventions have primarily focused on the completion of advance directives. While completion of advanced directives may reduce over-treatment, it likely does not have a substantial impact on patient-centered care or satisfaction with care.[10] In a recent consensus statement on ACP, experts highlighted the identification and documentation of a surrogate decision-maker, discussion of values and care preferences with this surrogate, and documentation of these wishes in the EHR as the top 5 ACP patient-centered outcomes.[15] ACP interventions that include a focus on the communication of goals, values, and beliefs result in an increased receipt of goal-concordant care.[11]

Studies have shown that PLWD who complete ACP are less likely to want or receive aggressive interventions at the end of life.[16] But possibly since dementia is under-recognized as a terminal condition and since capacity becomes compromised as the dementia progress, the rates of ACP completion remain low in this population.[2,17] This is problematic since the lack of ACP is associated with increased rates of hospitalization, higher rates of tube feed insertions, higher healthcare cost, lower family satisfaction, and lower rates of hospice enrollment.[18-24] Thus, there is growing recognition that improving goal-directed care in PLWD will require a greater focus on ACP early in the disease course for PLWD.[25,26] Telehealth could play an integral role in promoting ACP implementation in PLWD and their caregivers but has been understudied in this population.

Telehealth has the potential to overcome barriers related to timing and travel restraints and to provide patients and their caregivers with an opportunity to discuss their goals, values, and priorities for their healthcare within their home setting. Recent studies have demonstrated patients' willingness to use telehealth and have shown that it can play an integral role in dementia care management.[27-32] However, the use of telehealth to conduct ACP has been understudied.[31]

The purpose of this study is to test a telehealth ACP intervention among patient-care partner dyads in those with either mild cognitive impairment (MCI), mild dementia, or unrecognized dementia. The goal is to evaluate the reach and adoption of ACP Telehealth intervention among those with either mild cognitive impairment, mild dementia, or unrecognized dementia.

3.1 Study Title

A Telehealth Advance Care Planning Intervention in those Patients with Mild Cognitive Impairment or Unrecognized Dementia.

3.2 Objectives/Aims

Aim 1: Evaluate the reach and adoption of a telehealth ACP intervention among patients with either mild cognitive impairment, mild dementia, or unrecognized dementia.

Aim 2: To evaluate the implementation of a telehealth ACP intervention by tracking the quality of ACP discussions documented within the EHR.

3.3 Design

This is a pragmatic pilot study where 300 patients with recognized or probable MCI or mild dementia and their care partner (if available) will be approached to participate in a telehealth ACP visit with a member of the patient's primary care team.

3.4 Interventions and Duration

One-time telehealth ACP visit with a primary care provider team member, the patient, and their care partner (optional). The visit will focus on disease understanding, prognosis (if appropriate), eliciting overall health-related goals and values, identification of meaning in life, unacceptable care states, the role of surrogate decision-maker, and end-of-life wishes.

3.5 Sample Size and Population

A sample size of 300 patients and their care partner (optional) with recognized or probable MCI or mild dementia.
In addition, up to 50 primary care providers who participated in our intervention will be approached to complete a RedCap survey at the end of the intervention.

4. STUDY TEAM ROSTER

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6. STUDY OBJECTIVES

6.1 Primary Objective

Evaluate the reach and adoption of a telehealth ACP intervention among patients with either mild cognitive impairment, mild dementia, or unrecognized dementia.

H1: We hypothesize that at least 50% of 300 participants (N=100) will agree to participate and at least 90% of those who agree to participate (N=80) will complete the telehealth ACP intervention.

6.2 Secondary Objectives

To evaluate the implementation of the telehealth ACP intervention by tracking the quality of ACP discussions using an embedded EHR tool.

H2: We hypothesize that at least 80% of the completed telehealth ACP visits will be high-quality in nature. Discussion quality will be operationalized using a scoring system derived from the ACPWise documentation program.[36] High-quality ACP discussions will be defined as addressing ≥4 of the 9 core components in the ACP discussion: Disease understanding, health-related goals, what matters most in their life, important milestones, health-related worries, named surrogate decision-maker, unacceptable states at the end-of-life (e.g. being in a coma, etc.), goals if their health was to worsen, and documentation of code status.

7. BACKGROUND AND RATIONALE

7.1 Background on Condition, Disease, or Other Primary Study Focus

Dementia is a prevalent cause of death, despite low recognition as a terminal disease, is characterized by its indolent course.[6] Given the limited prognostic awareness and compromised capacity that occurs as the disease progresses, persons living with dementia (PLWD) often undergo aggressive and burdensome treatments at the end of life.[7-13] This makes PLWD an ideal population for early participation in Advance Care Planning (ACP).[17] Documented ACP can lead to decreased hospitalization rates and in-hospital deaths, decreased overall healthcare cost, and increases the likelihood of patients receiving medical care that is consistent with their overall goals, values, and health care preferences, i.e. goal-concordant care. [7-13] Despite these well-documented benefits, ACP has not been incorporated consistently into the care of community-dwelling older adults, particularly for PLWD. Most research on ACP has excluded PLWD or has focused within the nursing home setting, where most patients have limited capacity.[14] Thus there is a critical need for ACP interventions that target PLWD early in the disease course and that involve their surrogate decision-maker/caregiver to enhance goal-concordant care.

7.2 Rationale:

The COVID-19 pandemic has brought to the forefront the importance of ACP and the potential for coupling ACP with the use of telehealth to foster this important aspect of dementia care.[27-31] Telehealth has the potential to overcome barriers related to timing and travel restraints and to provide patients and their caregivers with an opportunity to discuss their goals, values, and priorities for their healthcare within their home setting; prioritizing "aging in place".[33] Telehealth has been proven to improve patient safety through the use of medication reminders, caregiver education support, and wandering-prevention tracking; and has led to decrease caregiver burden.[33-37] This highlighting the amenability of providing dementia care and management through telehealth.[38] The COVID-19 pandemic also has addressed prior barriers related to reimbursement for telehealth services[39], however, the use of telehealth for the purposes of ACP has been understudied.[31] The purpose of this study is to test a telehealth ACP intervention among patient-care partner dyads in those with either mild cognitive impairment (MCI) or unrecognized dementia. The goal is to evaluate the reach and adoption of ACP Telehealth intervention among those with either mild cognitive impairment, mild dementia, or unrecognized dementia.

8. STUDY DESIGN

8.1 Design:

This is a pragmatic pilot study where 300 patients with either mild cognitive impairment, mild dementia, or unrecognized dementia and their care partner will be approached to participate in a telehealth ACP visit with a member of their primary care team. Patients are still eligible to participate in the study even if a care partner/loved one does not attend the ACP visit with them. Our goal is to pilot-test and evaluate a pragmatic Telehealth ACP intervention among patients with either unrecognized dementia or with the diagnosis of mild cognitive impairment (MCI) or mild dementia.

8.2 Outcomes:

Primary outcomes: will be reach and adoption.

1. **Reach** will be defined as the proportion of eligible patient or patient-care partner dyads who agree

to participate.

2. **Adoption** will be defined as the proportion of patients or patient-care partner dyads who complete the ACP telehealth intervention.

Secondary outcomes:

1) **Documented advance care planning discussion rates**
   a) Documented in the ACPwise documentation template within the electronic health record.
   b) Reported as the number of discussed documented within the electronic health record. Completed determines better outcome.

2) **Advance Care Planning Billing code usage**
   a) ACP billing codes: 99497 and 99498 usages will be recorded.
   b) Usage of ACP Billing codes determines better outcome.

3) **Quality of APC documentation**
   a) Documented in the ACPwise documentation template within the electronic health record.
   b) Score of 0 (indicates no advance care planning questions answered) to 9 (indicates nine advance care planning questions answered)
   c) High-quality ACP discussions will be defined as addressing ≥4 of the 9 core components in the ACP discussion, with 1 point assigned if the following factors were addressed as part of the ACP discussion: Disease understanding, health-related goals, what matters most in their life, important milestones, health-related worries, named surrogate decision-maker, unacceptable states at the end-of-life (e.g. being in a coma, etc.), goals if their health was to worsen, and documentation of code status.

Exploratory Outcomes will include the estimated cost of delivering the intervention, the number of ACP visits completed with a care partner/loved one vs those without a care partner/loved one, the number of advance directives (AD) completed and uploaded into the EHR, and the rates of emergency room and inpatient hospitalizations. We will also survey PCPs and patient adopters to assess acceptability, appropriateness, and satisfaction with the intervention. Fidelity to the model will also be assessed by the number of times a patient had to be contacted prior to agreeing to participate, number of patients or patient-care partner dyads who do not show up to their Telehealth visit, the number of visits completed by telephone, and by video, the number of patients or patient-care partner dyads who have technological difficulty and are unable to be contacted for the visit via video, number of visits in which the ACPWise documentation tool was used by the PCP, and time lag between agreeing to participate and actually conducting their telehealth ACP visit. We will also examine the percentage that eRADAR identifies patients within the EHR who do or do not also have diagnostic codes for cognitive impairment.

8.3 Sample:

300 patients and their care partners (if available) will be approached for the study.

In addition, up to 50 primary care providers who participated in the study will be approached to complete a RedCap survey at the end of the intervention.

8.4 Setting:

Wake Forest Baptist Health, in collaboration with a physician-led group focused on value-based care

(CHESS Health Solutions), is affiliated with an ACO program that incorporates more than 150 primary care and multi-specialty practices with more than 330 physicians and Advanced Practice Providers in 80 locations in communities throughout central North Carolina. For this pilot project, participants will be recruited from 7 primary care clinics and an additional clinic will be added if needed to meet recruitment numbers

8.5 Study Duration:

One-time telehealth ACP visit with a member of the patient's primary care team.

8.6 Intervention and Interactions

Patients

This is a pragmatic pilot study where 300 patients with either mild cognitive impairment, mild dementia, or unrecognized dementia and their care partners (if available) will be approached to participate in a telehealth ACP visit with a member of the patient's primary care team. Patients without willing or available care partners are still eligible to participate in the study. A list of eligible patients will be identified from the EHR using a combination of diagnosis codes and a novel risk prediction model for unrecognized dementia. The list will be provided to each corresponding site for the primary care physician to advise on the patient's capacity. Patients in which PCPs confirmed capacity will be approached first by the research team to gauge their interest in participating in the telehealth ACP visit. Patients will be asked if they have a care partner to join them in the visit. Depending on the patients' response, care partners' will be approached for participation. For patients and care partners that agree to participate, a dyad telehealth ACP visit will be scheduled. For patients who agree to participate but their care partners refused or patients who cannot identify a care partner to participate in the telehealth ACP visit, the visit will be scheduled only with the patient. Appointment information and reminders will be provided to the patient and care partner by mail, email, portal, telephone, and/or text messaging. Patients will be either be mailed (if we don't have a current email address or if patients prefer mail) or sent via email through RedCap an after-visit survey to assess patient's acceptability and appropriateness using the validated Acceptability of Intervention Measure (AIM)[40] and Intervention Appropriateness Measure (IAM)[40], and overall satisfaction with the intervention. For patients who either don't have current email address or prefer mail, a self-addressed stamped envelope will be provided for patients to mail back their survey. All patients who complete the survey will be entered into a raffle for a $100 gift card.

Providers

Once telehealth ACP visits are completed, we will reach out up to 50 providers via email who participated in the intervention and invite them to complete a one-time RedCap survey that assesses acceptability and appropriateness using the validated Acceptability of Intervention Measure (AIM)[40] and Intervention Appropriateness Measure (IAM)[40], and overall satisfaction with the intervention. Providers will receive an email with a link to complete the survey. Completion of the survey will signify consent. If incomplete, providers will be sent a reminder email 2 weeks later to complete the survey. If still incomplete, providers will be contacted by telephone 2 weeks later. All providers who complete the survey will be entered into a raffle for a $200 gift card.

9. SELECTION AND ENROLLMENT OF PARTICIPANTS

Patients must reside in the state of NC and have seen their primary care provider within the past 12

months. In addition, patients must have recognized or probable MCI or mild dementia AND retain the decisional capacity to complete ACP. Patients will be identified through the EHR in one of two ways: (a) diagnosis codes (ICD-10) for MCI/Dementia or (b) the EHR Risk of Alzheimer's and Dementia Assessment Rule (eRADAR[41]) prediction model. The use of eRADAR will help to circumvent the reality that diagnostic codes for cognitive impairment are vastly underutilized;[42] eRADAR utilizes dementia-related symptoms and risk factors as well as healthcare utilization from the EHR to identify patients with probable unrecognized dementia (a high likelihood of dementia/cognitive impairment in the absence of diagnosis codes).[41] The research team will send PCPs the list of eligible patients before outreach to confirm that individuals still have capacity for decision-making.

9.1 Inclusion Criteria

1. Age 65 years and older and residing in NC
2. Diagnosis of recognized or probable MCI or mild dementia
3. Have decisional capacity according to their PCP to complete ACP
4. Completed visit with their PCP within the past 12 months
5. Affiliated with an Accountable Care Organization.
6. English-speaking

9.2 Exclusion Criteria

1. Moderate to severe hearing loss that would preclude participating in a video or telephone intervention
2. No phone number available for patient.
3. Lives in a long-term care facility

9.3 Study Enrollment Procedures

Patients

A full waiver of consent is requested for identifying participants using the EHR algorithm. In the clinic environment, ACP is part of the standard of care. However, we are modifying this process by implementing a telehealth option to enhance documentation of the ACP visit. Therefore, we will obtain clinical consent for the telehealth visit from patients and care partners; patients and care partners are free to decline a telehealth visit for an ACP discussion.
A list of eligible patients at participating sites will be generated and will be distributed to each patient's PCP to advise on the patient's decision-making capacity.

If lack of capacity is assessed when patients are approached or after consent, we will call the patient back and use the following language: "when talking with your primary care provider, they thought actually it would be best to discuss advance care planning at your upcoming in-person visit instead of through an extra telehealth visit."

A recruitment letter/postcard will be sent to patients whose PCPs confirm capacity. The research team will approach patients via telephone for participation with a waiver of informed consent. Patients will be asked if they have a care partner/loved one to join them in the visit. Depending on the patients' response, care partners/loved ones' will be approached for participation. Upon participant agreement, a telehealth

ACP visit will be scheduled. For patients whose care partner/loved one agrees to participate, a dyad telehealth ACP visit will be scheduled. For patients who agreed to participate but care partner/loved one refuses or patients who cannot identify a care partner/loved one to participate in the telehealth ACP visit, the visit will be scheduled only with the patient. Appointment information will be sent to patients and care partners through a variety of communication channels per patient's preference (email, mailing, portal, telephone, and/or text messaging). The research staff will give a telephone call reminder and ensure understanding on how to set up the telehealth visit to the patient and care partner/loved one day before the appointment (except for Monday appointments and then the reminder call will occur the Friday prior to the appointment) in addition to sending reminders through a variety of communication channels per patient's preference (email, mailing, portal, and/or text messaging). We will document reasons for ineligibility and non-participation of eligible candidates in a study tracking log. We will also record the date of acceptance or non-acceptance for the telehealth ACP visit participation. Participants will not be compensated for participating in the telehealth ACP visit. After completion of the visit, patients will be either be mailed (if we don't have a current email address or if patients prefer mail) or sent via email through RedCap an after-visit survey to assess patient's acceptability and appropriateness using the validated Acceptability of Intervention Measure (AIM)[40] and Intervention Appropriateness Measure (IAM)[40], and overall satisfaction with the intervention. For patients who either don't have current email address or prefer USPS mail, a self-addressed, stamped envelope will be provided for patients to mail back their survey. All patients who complete the survey will be entered into a raffle for a $100 gift card.

There are special informed consent considerations for individuals in this pragmatic study. We will seek a waiver of individual informed consent as set forth by criteria found in HHS 45 CFR 46:116:

(i) the research involves no more than minimal risk to the subjects;
(ii) the research could not practicably be carried out without the requested waiver or alteration;
(iii) if the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
(iv) (the waiver or alteration will not adversely affect the rights and welfare of the subjects; and
(v) whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

We will also request a full <u>HIPAA waiver</u> of individual authorization as set forth by the following conditions:

(1) Use or disclosure involves no more than minimal risk to the privacy of individuals because of the presence of at least the following elements:

- An adequate plan to protect health information identifiers from improper use or disclosure,
- An adequate plan to destroy identifiers at the earliest opportunity absent a health or research justification or legal requirement to retain them, and
- Adequate written assurances that the PHI will not be used or disclosed to a third party except as required by law, for authorized oversight of the research study, or for other research uses and disclosures permitted by the Privacy Rule;

(2) Research could not practicably be conducted without the waiver or alteration; and

(3) Research could not practicably be conducted without access to and use of PHI.

To justify items 2 and 3 above, the data to be used for this study is currently and regularly collected for non-research purposes. We are seeking a waiver of informed consent from study participants and so it would not be practical to request direct HIPAA authorization. Research staff will contact study participants for clinical consent. As part of the pragmatic nature of the study, sample eligibility relies on a review of the PHI, and study outcomes will be retrieved from electronic health records as well.

Patient after-visit survey

A waiver of signed informed consent is also requested for adopters, those patients who complete the telemedicine ACP visit with a member of their primary care team since the survey poses no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context, we are requesting a waiver of informed consent. After a patient completes their telehealth ACP visit, they will be asked to complete a one-time survey to assess acceptability and appropriateness using 2 validated surveys, the Acceptability of Intervention Measure (AIM)[40] and the Intervention Appropriateness Measure (IAM)[40], as well as overall satisfaction with the intervention. Patients will be either be mailed (if we don't have a current email address or if patients prefer mail) or sent via email through RedCap the survey. For patients who are mailed the survey, a self-addressed, stamped envelope will be provided for patients to mail back their survey. All patients who complete the survey will be entered into a raffle for a $100 gift card.

We will seek a waiver of signed informed consent as set forth by criteria found in HHS 45 CFR 46:116: (i) the research involves no more than minimal risk to the subjects; (ii) the research could not practicably be carried out without the requested waiver or alteration; (iii) if the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format; (iv) the waiver or alteration will not adversely affect the rights and welfare of the subjects; and (v) whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Providers

A waiver of signed informed consent is also requested for primary care providers facilitating the intervention. Once the telehealth ACP visits are completed, PCPs will be asked to complete a one-time REDCap survey to assess acceptability and appropriateness using 2 validated surveys, the Acceptability of Intervention Measure (AIM)[40] and the Intervention Appropriateness Measure (IAM)[40], as well as overall satisfaction with the intervention. Providers will receive an email with a link to complete the survey. Completion of the survey will signify consent. If incomplete, providers will be sent a reminder email 2 weeks later to complete the survey. If still incomplete, providers will be contacted by telephone 2 weeks later. All providers who complete the survey will be entered into a raffle for a $200 gift card.

We will seek a waiver of signed informed consent as set forth by criteria found in HHS 45 CFR 46:116: (i) the research involves no more than minimal risk to the subjects; (ii) the research could not practicably be carried out without the requested waiver or alteration; (iii) if the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format; (iv) the waiver or alteration will not adversely affect the rights and welfare of the subjects; and (v) whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

10. **STUDY INTERVENTIONS**

10.1 Interventions, Administration, and Duration

Patients and Care Partners

A list of eligible patients at participating sites will be generated and will be distributed to each patient's PCP to advise on the patient's decision-making capacity. A recruitment postcard will be sent to patients whose PCPs confirm capacity. The research team will approach patients via telephone using a script to describe the purpose of the ACP visit and inquire about their willingness to participate. Patients will be asked if they have a care partner/loved one to join them in the visit. Depending on the patients' response, care partners/loved ones' will be approached for participation. Upon participant agreement, a telehealth ACP visit will be scheduled. For patients whose care partner/loved one agrees to participate, a dyad telehealth ACP visit will be scheduled. For patients who agreed to participate but care partner/loved ones refuse or patients who cannot identify a care partner/loved one to participate in the telehealth ACP visit, the visit will be scheduled only with the patient.

We will send the patient and care partner/loved one appointment information through a variety of communication channels per the patient's preference (email, mailing, or portal/mychart) that will include the date of the visit and what to expect during the visit. Patients and care partners will receive a telephone call to reminder them of the appointment and to ensure understanding on how to set up the telehealth visit to the patient and care partner/loved one day before the appointment (except for Monday appointments and then the reminder call will occur the Friday prior to the appointment). In addition, we will text patients a reminder message if they have phone with texting capabilities. The telehealth ACP visit will consist of a member from the patient's primary care team (physician assistant, nurse practitioner, physician) discussing ACP with the patient and if they have one, their care partner/loved one. The visit will focus on disease understanding, prognosis (if appropriate), eliciting overall health-related goals and values, identification of meaning in life, unacceptable care states, the role of surrogate decision-maker, and end-of-life wishes. The sites will utilize our ACPWise documentation tool to help facilitate, document, and bill for these visits. The primary care provider team will use clinical judgment to determine capacity to make clinical decisions, and if they feel the patient lacks capacity, they will rely on the patient's care partner/loved one for any clinical decisions. Participants will not be compensated for participation in the telehealth ACP visit. After a patient completes their telehealth ACP visit, they will be asked to complete a one-time survey to assess acceptability and appropriateness using 2 validated surveys, the Acceptability of Intervention Measure (AIM)[40] and the Intervention Appropriateness Measure (IAM)[40], as well as overall satisfaction with the intervention. Patients will be either be mailed (if we don't have a current email address or if patients prefer mail) or sent via email through RedCap the survey. For patients who are mailed the survey, a self-addressed, stamped envelope will be provided for patients to mail back their survey. All patients who complete the survey will be entered into a raffle for a $100 gift card.

Providers

Once the Telehealth ACP visits are completed, we will reach out via email to all the providers who participated in the intervention and invite them to complete a one-time RedCap survey that assesses acceptability, appropriateness, and overall satisfaction with the intervention. Completion of the survey will signify consent. If incomplete, providers will be sent a reminder email 2 weeks later to complete the survey. If still incomplete, providers will be contacted by telephone 2 weeks later. All providers who complete the survey will be entered into a raffle for a $200 gift card.

11. HANDLING OF STUDY INTERVENTION

All providers from participating sites will be trained on how to use the ACPWise documentation tool and on the study protocol.

All sites will have a manual describing visit procedure and documentation. The manual will also have a sample of the ACPWise tool and instructions for front desk personnel on how to check in a patient for a Telehealth ACP visit.

Providers that have facilitated the intervention will be asked to complete a REDCap survey and patient adopters will be asked to complete a survey to assess acceptability and appropriateness using 2 validated surveys: Acceptability of Intervention Measure (AIM) and Intervention Appropriateness Measure (IAM) along with overall satisfaction with the intervention.

12. SAFETY ASSESSMENTS

Potential risks include that some individuals may find ACP discussion to be uncomfortable, stressful, and/or depressing. This is expected to be temporary. All study staff and providers will be trained to deal with these situations and every effort will be made to address each participant's concerns or problems in the most supportive, empathic, and therapeutic manner. The potential benefits of this intervention may include overcoming barriers to ACP related to timing and travel restraints and providing patients and their care partners with an expanded opportunity to discuss their goals, values, and priorities for healthcare at the comfort of their home. We foresee that the potential benefits outweigh the potential risks of the intervention.

All study staff and/or providers will be trained to identify cues for discomfort, stress, and anxiety during the discussion of advance care planning, paying special attention to body language. Once cues have been identified, staff and/or providers will point out discomfort and ask the participant if they do not feel comfortable pursuing the discussion any longer and that they have the right to skip or end the advance care planning discussion at any time. We will make every effort to address each participant's concerns or problems in the most supportive, empathic, and therapeutic manner. If the participant wishes to skip or discontinue the advance care planning discussion, the staff and/or provider will send a message describing the event to the PI for documentation. However, we do not foresee having AEs and SAEs as this study presents no more than minimal risk of harm.

12.1 Adverse Events and Serious Adverse Events

We do not foresee having SAEs as this study presents no more than minimal risk of harm.

Definitions for adverse events (AEs) and serious adverse events (SAEs) to be used for this trial:
AE Definition: AE is any untoward or unfavorable medical occurrence in a human study participant, including any abnormal sign of increased stress/anxiety or discomfort, temporally associated with the participants' involvement in the research, whether or not considered related to participation in the research.

AEs for this study include: Discomfort with ACP discussion, increased stress/anxiety. These events are no more than minimal risk of harm.

SAE Definition: SAEs consist of any adverse event that results in death; is life-threatening or places the participant at immediate risk of death from the event as it occurred; requires or prolongs hospitalization; causes persistent or significant disability or incapacity; results in congenital anomalies or birth defects; is another condition which investigators judge to represent significant hazards

SAEs for this pilot study include: We do not foresee having SAEs as this study presents no more than minimal risk of harm.

12.2 Reporting Procedures

Any unanticipated problems, serious and unexpected adverse events, deviations, or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the IRB and sponsor or appropriate government agency if appropriate. In the case of a serious adverse event, the Wake Forest Institutional Review Board and the appropriate Program Officer at NIA IMPACT Collaboratory will be notified within 24 hours.

12.3 Safety Monitoring

The Principal Investigator (PI) will be responsible for ensuring participants' safety daily. In addition, the NIA IMPACT Collaboratory has assigned a Project Safety Officer to oversee all data and safety monitoring activities for this study. The Project Safety Officer will act in an advisory capacity to the NIA Director to monitor participant safety, evaluate the progress of the study, and review procedures for maintaining the confidentiality of data, the quality of data collection, management, and analyses. Refer to the NIA IMPACT Collaboratory Omnibus DSMB Charter for details.

13. STATISTICAL CONSIDERATIONS

13.1 Sample Size and Randomization

Two hundred individuals with either mild cognitive impairment (MCI), mild dementia, or unrecognized dementia will be approached to participate in a Telehealth ACP visit. In addition, if eligible patients have a care partner, we will approach them for participation in a dyad ACP visit (patient + care partner). In our previous randomized trial of a nurse-navigator ACP pathway (IMPACT),[43] 139 of 294 patients consented and completed the ACP intervention. If we assume a conservative Beta((139/10)+0.5,(155/10)+0.5) prior distribution for this rate, this presumes a prior mean rate of adoption = 47% (min=17%, 25th percentile=41%, 75th percentile = 53%, max=83%). Based on simulations, <u>if we approach 300 eligible patients</u>, we expect that a median of 94 participants will consent to participate and complete the telehealth intervention (25th percentile = 81, 75th percentile = 108). In >70% of our simulations, the posterior probability that the estimated intervention completion (adoption) rate is ≥40% was >0.70, thus we believe our proposed sample size will be adequate to judge whether an appropriate number of persons with unrecognized dementia or MCI will complete the ACP telehealth intervention. We do plan to oversample to have at least 20% of our population from racial/ethnic minority population. If we have issues obtaining 20%, we will try and use the area deprivation index to target at least 20% from a socioeconomic disadvantage group.

13.2 Outcomes

<u>Primary outcomes</u>: will be reach and adoption.

1. **<u>Reach</u>** will be defined as the proportion of eligible patient or patient-care partner dyads who agree to participate.

2. **<u>Adoption</u>** will be defined as the proportion of patients or patient-care partner dyads who complete the

ACP telehealth intervention.

Secondary outcomes:

1) **Documented advance care planning discussion rates**
   a) Documented in the ACPwise documentation template within the electronic health record.
   b) Reported as the number of discussed documented within the electronic health record. Completed determines better outcome.

2) **Advance Care Planning Billing code usage**
   a) ACP billing codes: 99497 and 99498 usages will be recorded.
   b) Usage of ACP Billing codes determines better outcome.

3) **Quality of APC documentation**
   a) Documented in the ACPwise documentation template within the electronic health record.
   b) Score of 0 (indicates no advance care planning questions answered) to 9 (indicates nine advance care planning questions answered)
   c) High-quality ACP discussions will be defined as addressing ≥4 of the 9 core components in the ACP discussion, with 1 point assigned if the following factors were addressed as part of the ACP discussion: Disease understanding, health-related goals, what matters most in their life, important milestones, health-related worries, named surrogate decision-maker, unacceptable states at the end-of-life (e.g. being in a coma, etc.), goals if their health was to worsen, and documentation of code status.

Exploratory Outcomes will include the estimated cost of delivering the intervention, the number of ACP visits completed with a care partner/loved one vs those without a care partner/loved one, the number of advance directives (AD) completed and uploaded into the EHR, and the rates of emergency room and inpatient hospitalizations. We will also survey PCPs and patient adopters to assess acceptability, appropriateness, and satisfaction with the intervention. Fidelity to the model will also be assessed by the number of times a patient had to be contacted prior to agreeing to participate, number of patients or patient-care partner dyads who do not show up to their Telehealth visit, the number of visits completed by telephone, and by video, the number of patients or patient-care partner dyads who have technological difficulty and are unable to be contacted for the visit via video, number of visits in which the ACPWise documentation tool was used by the PCP, and time lag between agreeing to participate and actually conducting their telehealth ACP visit. We will also examine the percentage that eRADAR identifies patients within the EHR who also have diagnostic codes for cognitive impairment.

13.3 Data Analyses

The statistical approach for this project will be largely descriptive and focus on the estimation of key parameters for designing a subsequent embedded pragmatic clinical trial (ePCT). We've chosen to approach the primary outcomes for the pilot from a Bayesian paradigm, as it more naturally permits making probability statements concerning our criteria for adoption and the quality of ACP discussions (i.e. that at least 40% of approached patients will complete the telehealth ACP intervention, and that ≥80% of ACP discussion will be of high quality). Given that the primary endpoints are binary outcomes, we plan to use a standard conjugate Beta-Binomial hierarchical regression framework, which can accommodate covariates as needed. We expect that we will minimally evaluate variability in adoption by age, primary care practice / primary care provider, and by whether the patient was identified as having unrecognized dementia by the EHR Risk of Alzheimer's and Dementia Assessment Rule (eRADAR)[41] or via diagnosis codes for MCI/ADRD.

We hypothesize that at least 80% of the completed telehealth ACP visits will be high-quality in nature. Discussion quality will be operationalized using a scoring system derived from the ACPWise documentation program.[43] High-quality ACP discussions will be defined as addressing ≥4 of the 9 core components in the ACP discussion: Disease understanding, health-related goals, what matters most in their life, important milestones, health-related worries, named surrogate decision-maker, unacceptable states at the end-of-life (e.g. being in a coma, etc.), goals if their health was to worsen, and documentation of code status. Analyses of the use of ACP billing codes and ACP documentation scanned into the EHR will be based on Generalized Linear Mixed Model (GLMM) approaches to binary outcomes. A focus of these models, beyond estimating event frequencies, will be the estimation of intraclass correlation coefficients (ICC) by primary care practice/primary care provider.[44] For the incidence of healthcare utilization and burdensome treatment, the primary goal will similarly be the estimation of event rates and ICCs that could inform a future cluster-randomized ePCT. In order to obtain reliable estimates,[45] note that analyses of utilization and burdensome treatment will be based on the entire population of individuals within Accountable Care Organizations affiliated with our health system identified by either eRADAR or diagnosis codes for MCI. Data on emergency department visits and inpatient hospitalizations from the EHR will be supplemented with admission, discharge, and transfer data from a national transitional care network (PatientPing, www.patientping.com) in order to capture utilization outside of our health system. Analyses will utilize time-to-event approaches that can accommodate recurrent events and the competing risk of death.[46,47] Simplifications to fully parametric models will likely be necessary to estimate ICCs within the context of time-to-event data.[48]

14. DATA COLLECTION AND QUALITY ASSURANCE

14.1 Data Collection Forms

Research staff will use the study tracking log to document reasons for ineligibility and non-participation of eligible candidates and note the date of acceptance or non-acceptance for the telehealth ACP visit participation.

The sites will utilize our ACPWise documentation tool to help facilitate, document, and bill for these visits.

15. PARTICIPANT RIGHTS AND CONFIDENTIALITY

15.1 Institutional Review Board (IRB) Review

This protocol and any subsequent modifications will be reviewed and approved by the IRB or ethics committee responsible for oversight of the study.

15.2 Informed Consent Forms

Patients and Care Partners

This intervention will be enhancing standard of care by having ACP visits completed via telehealth instead of in-person. We are interested in determining how well this telehealth option will be accepted in practice and request a waiver of informed consent for research purposes, noting that a waiver of individual informed consent is set forth by criteria found in HHS 45 CFR 46:116:

(i) the research involves no more than minimal risk to the subjects;

the activities in our protocol involve subjects meeting with their PCP through Telehealth to discuss

advance care planning, subjects are not required to travel nor to do anything clinical other than to have a conversation with their PCP in the comfort of their home, therefore, our research involves no more than minimal risk to subjects; ACP, in general, is standard of care and the addition of a Telehealth option does not increase risk;

(ii) the research could not practicably be carried out without the requested waiver or alteration;

we are modifying a standard of care process. This is a pragmatic trial aimed primarily at determining reach and adoption of a telehealth approach to ACP in a real-world setting. Requiring informed consent for research purposes would undermine this goal as the process must stay as close to the standard process as possible and could introduce important selection biases greatly reducing the knowledge generated;

(iii) if the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

the research has access to identifiable information through the electronic medical record for identifying eligible patients. The study cannot be carried out without suing such information;

(iv) the waiver or alteration will not adversely affect the rights and welfare of the subjects;

being that we also will be getting clinical consent for the Telehealth visits for subjects (patients and their care partners (if they have one) are free to decline a Telehealth visit for an ACP discussion), we do not consider the waiver to adversely affect the rights and welfare of the subjects;

(v) whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation; an effort will be made to share results of the study (such as published manuscripts) with the clinicians that have facilitated the intervention that could then share with their patients.

Although a waiver of individual informed consent will be requested for those who will be participating in the telehealth ACP visits, we will obtain clinical consent for the telehealth visits as would occur as part of the standard of care—patients and care partners are free to decline a Telehealth visit for an ACP discussion. The study staff will verbally explain the purpose and what will take place in a Telehealth ACP visit to prospective participants in simple and easy to understand language. The potential participant will be asked if they have any questions. Study staff will make note of the date and decision of patient and care partner participation in the study tracking log. Once the patient agrees to participate in the Telehealth ACP visit, the visit will be scheduled.

This process of the waiver of inform consent and clinical consent also applies to patients who are unable to consent on their own behalf. The surrogate decision maker will be reached to provide participation for themselves and the patient in the Telehealth ACP visit.

<u>Patient after-visit survey</u>

A waiver of signed informed consent is also requested for adopters, those patients who complete the telemedicine ACP visit with a member of their primary care team. Since the survey poses no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context, we are requesting a waiver of informed consent. After a patient completes their telehealth ACP visit, they will be asked to complete a one-time survey to assess acceptability and appropriateness using 2 validated surveys, the Acceptability of Intervention Measure (AIM)[40] and the Intervention Appropriateness Measure (IAM)[40], as well as overall satisfaction with the intervention. Patients will be either be mailed (if we don't have a current email address or if patients prefer mail) or sent via email through RedCap the survey. For patients who are mailed the survey, a self-

addressed, stamped envelope will be provided for patients to mail back their survey. All patients who complete the survey will be entered into a raffle for a $100 gift card.

We will seek a waiver of signed informed consent as set forth by criteria found in HHS 45 CFR 46:116: (i) the research involves no more than minimal risk to the subjects; (ii) the research could not practicably be carried out without the requested waiver or alteration; (iii) if the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format; (iv) the waiver or alteration will not adversely affect the rights and welfare of the subjects; and (v) whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Providers

In addition, a waiver of sign consent is requested for primary care providers that have participated in the intervention. Providers will be asked to complete a one-time REDCap survey to assess acceptability and appropriateness using 2 validated surveys: Acceptability of Intervention Measure (AIM) and Intervention Appropriateness Measure (IAM) and overall satisfaction with the intervention.

15.3 Participant Confidentiality

Patients and Care Partners

We will also request for a full HIPAA waiver of individual authorization as set forth by the following conditions:

(1) Use or disclosure involves no more than minimal risk to the privacy of individuals because of the presence of at least the following elements:

- An adequate plan to protect health information identifiers from improper use or disclosure,
- An adequate plan to destroy identifiers at the earliest opportunity absent a health or research justification or legal requirement to retain them, and
- Adequate written assurances that the PHI will not be used or disclosed to a third party except as required by law, for authorized oversight of the research study, or for other research uses and disclosures permitted by the Privacy Rule;

(2) Research could not practicably be conducted without the waiver or alteration; and

(3) Research could not practicably be conducted without access to and use of PHI.

Confidentiality will be protected by collecting only information needed to assess study outcomes, minimizing to the fullest extent possible the collection of any information that could directly identify subjects, and maintaining all study information in a secure manner. To help ensure subject privacy and confidentiality, only a unique study identifier will appear on the data collection form. Any collected patient identifying information corresponding to the unique study identifier will be maintained on a linkage file, store separately from the data. The linkage file will be kept secure, with access limited to designated study personnel. Following data collection subject identifying information will be destroyed three years after closure of the study, consistent with data validation and study design, producing an anonymous analytical data set. Data access will be limited to study staff. Data and records will be kept locked and secured, with any computer data password protected. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study.

Patient after-visit survey

A waiver of signed informed consent is also requested for adopters, those patients who complete the telemedicine ACP visit with a member of their primary care team. Since the survey poses no more than

minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context, we are requesting a waiver of informed consent. After a patient completes their telehealth ACP visit, they will be asked to complete a one-time survey to assess acceptability and appropriateness using 2 validated surveys, the Acceptability of Intervention Measure (AIM)[40] and the Intervention Appropriateness Measure (IAM)[40], as well as overall satisfaction with the intervention. Patients will be mailed the survey with a self-addressed, stamped envelope. Completion of the survey will signify consent.

Providers

We are only requesting a waiver of sign consent for providers that have facilitated the intervention. Providers will be asked to complete a one-time REDCap survey to assess acceptability and appropriateness using 2 validated surveys: Acceptability of Intervention Measure (AIM) and Intervention Appropriateness Measure (IAM) and overall satisfaction. A HIPAA waiver is not necessary as we will not collect any provider specific information other than acceptability and appropriateness of the intervention.

16. **PUBLICATION OF RESEARCH FINDINGS**

Publication of the results of this trial will be governed by the policies and procedures developed by the Steering Committee. Any presentation, abstract, or manuscript will be made available for review by the sponsor and the NIA prior to submission.

17. **APPENDICES/SUPPLEMENTAL**

17.1 Clinical Telephone Script—Patient

Hello, my name is_____. I am a calling from Wake Forest Baptist Health. I am trying to reach [patient's name]. Are you [patient's name]? Thank you for taking my call. We are calling because [provider's name] would like to schedule a visit with you to further discuss your current health-related goals and medical preferences. Is this a good time for us to talk? It will take about 10 minutes. If it isn't, I can call you at another time. If yes, proceeded below. If no, asked when would be a good time to call back.

Is there a loved one or care partner at home with you that you would like to hear this call? If yes, ask if they can put the call on speaker so that they both can hear.

We are in the process of scheduling visits for [provider's name] to talk with his/her patients about their current health-related goals and medical preferences. Specifically, [provider's name] wants to talk with you about your current health-related goals, any worries you may have about your health, and about any future medical preferences related to the type of care you would or would not want to receive. This type of visit is called an Advance Care Planning visit. This visit can help your provider and others be aware of what matters most to you and helps them better align care to your goals. Our goal is to really empower patients to have a voice in what matters most to them to ensure they receive the type of care they want and deserve.

This visit typically takes about 30 minutes and can be done either by telephone or video. You may have already had a video or telephone visit with [provider's name] or one of your other providers. We are doing these visits this way to make it easier on patients and their loved ones since the visits can be done in the comfort of their home.

This Advance Care Planning visit is optional. You may choose not to schedule this visit and it will NOT affect the care you get from [provider's name]. This type of visit will have the normal co-pay that you would have when you see your primary care provider. (The co-pay is the same whether the visit is in person or by video or telephone.) Is this something you would be interested in doing with [provider's name]?

- If no—thank the patient, please ask reason for decline. Annotate in the tracking log and end the call
- If yes—continue below

Great-thank you for agreeing to meet with [provider's name]. The visit should take about 30 minutes. If you choose a video visit, we can send you a link that you would need to click on to connect to that visit either via email or through your MyChart (mywakehealth) account. If you choose to have the visit over the phone instead of video, your provider will call you at your appointment time. If you have a significant other/loved one or a care partner, they may attend the visit with you. We will also send you instructions prior to your visit.

Would you prefer to schedule this visit as a video visit or a telephone visit? Annotate in tracking log.

If the patient is going to be doing the visit via video:
Thank you so much, do you prefer us to send you visit information and the video visit link by email or to your mychart (mywakehealth) account [if they have one] ? Annotate answer and confirm email address if doing via email and Annotate the information in the tracking log.

All you would need to do is click on the link that we send you during your appointment time. The link will take you to a virtual waiting room until the provider enters the virtual room. If you are having someone else joining you during your visit, they do not need to be present with you as we can also send them a link to join the visit.

If the patient is going to be doing the visit via telephone:
Thank you so much, what would be the best phone number for the provider to call you at the time of the appointment, is it this number? Thank you so much. Confirm contact information. Annotate the information in the tracking log.

Do you prefer us to send you visit information by email, mail, or to your mychart (mywakehealth) account [if they have one] ? Annotate answer and confirm contact information based on preference and Annotate the information in the tracking log.

Your provider will call you on the date and time of your appointment. If you are having someone else join you during your visit, please have them with you in the same room at the time of the appointment and place the call on speaker.

Scheduling:
If the clinic has asked us to schedule the visits for them say:
In looking at the clinic schedule, here are a couple of days and times available (provide days and times). Are any of these days and times good for you? Schedule appointment according to patient's preferences and annotate in the tracking log.

Wonderful, your Advance Care Planning visit has been scheduled with [provider's name] for [date] at [time] by [video or telephone].

If the clinic is going to schedule the visit then say:
Someone from [provider's name] office will be in contact with you shortly to schedule the visit.

Care Partner participation if not already involved in the call:
We also recommend for a care partner or loved one to join this visit with you.
Do you have a care partner/loved one that you would like to join you during the visit?

- If no—Annotate in the tracking log and move to the scheduling section
- If yes—Is your loved one there with you?
    - If no--what is the name and contact information of the person you would like to join you during the visit? Thank you for this. We will contact [care partner's name] to give them this appointment information. We will let you know if [care partner's name] decides that they do not want to attend the visit. Annotate the information in the tracking log and continue with scheduling.
    - If yes—move on to the care partner script.

Final steps:

If doing via video
We will call and text you (if have phone with texting abilities) one day prior to your visit unless you have an appointment on Monday and then we will call you the Friday prior to your appointment to remind you of your visit. When we call you, we will also ensure you have received the video link, if not, then we can resend it to you at that time either via email or text.

Do you have a phone with texting abilities?
If no: Annotate in tracking log
If yes: Is the number I called you the number we should text? If no please obtain the correct number and annotate in the tracking log.

If doing via telephone
We will call one day prior to your visit unless you have an appointment on Monday and then we will call you the Friday prior to your appointment to reminder you of your visit.

Do you have any questions for me? If no questions continue.

Thank you so much. Please call [research staff name and number] or the clinic in case you need to cancel or re-schedule your Advance Care Planning visit.

Thank patient and end call

17.2 Clinical Telephone Script—Care Partner/Loved One

Hello, my name is_____. I am a calling from Wake Forest Baptist Health. I am trying to reach [care partner/loved one's name]. Are you [care partner/loved one's name]? Thank you for taking my call. We are calling because your loved one [name of patient] would like you to join [him/her] in a Telehealth Advance care planning visit with [provider's name] to further discuss [patient's name] current health-related goals and medical preferences. Is this a good time for us to talk? It will take about 10 minutes. If it isn't, I can call you at another time. If yes, proceeded below. If no, asked when would be a good time to call back.

We have scheduled a visit for [patient's name] to talk with [provider's name] about their current health-related goals and medical preferences. Specifically, the visit allows for conversations about [patient's name] current health-related goals, any worries [patient's name] may have about his/her health, and any future medical preferences related to the type of care [patient's name] would or would not want to receive. This type of visit is called an Advance Care Planning visit.
This visit can help [provider's name] and others be aware of what matters most to [patient's name] and helps them better align care to their goals. Our goal is to really empower patients to have a voice in what matters most to them to ensure they receive the type of care they want and deserve.

This visit should take about 30 minutes and [patient's name] has decided they would like to do this visit by [state how the patient want to do the visit: telephone or video]. We are doing these visits this way to make it easier on patients and their loved ones since the visits can be done in the comfort of their home.

Participation in this visit with [patient's name] is optional. You may choose not to participate in this visit. Is this something you would be interested in doing with [patient's name] and his/her provider?
If no—thank the care partner, please ask reason for decline. Annotate in the tracking log and end the call
If yes—continue below

Thank you for your interest. [patient's name] has chosen to schedule the visit on [date & time patient chose]. Is that a good time and day for you to participate?

- If no—coordinate scheduling between patient and caregiver and schedule it in WakeOne.
- If yes—ask below

If patient chose to do the visit via video:
Your loved one [name of patient] would like to do the advance care planning visit via video, so we would need to send you a link to access the visit via video. We will need your email address so that we can send you the visit information and video link. Annotate care partner/loved ones email address and document in the tracking log. If they don't have an email address, we can text them the link and mail them the visit information – Annotate in tracking log if they don't have email address and preferred number to text and preferred address to send visit information.

All you would need to do is click on the link we send you during the appointment time. The link will take you to a virtual waiting room until the provider enters the virtual room. You do not need to be present with [patient's name] as we have also sent them a link to join the visit. We will call you and send a text (if you have a phone with texting abilities) one day prior to the video visit, unless the visit is scheduled on a Monday and then we will call you the Friday prior to the visit, to ensure you have received the video link, if not, then we can resend it to you at that time. Do you have a phone with texting abilities?

If no: Annotate in Tracking log

If yes: Is the number I called you the number we should text? If no please obtain the correct number and annotate in the tracking log.

Do you have any question for me so far? Thank you so much.

If patient chose to do the visit via telephone:
Your loved one [name of patient] would like to do the advance care planning visit via telephone. At [date & time patient chose] of the appointment, you will need to be in the same room as the patient. The doctor will call the patient at the scheduled date and time and you will need to place the telephone on speaker so that both of you can hear the doctor.

Do you prefer us to send you the visit information via email or mail? Annotate answer and obtain the care partner/loved ones email address or mailing address and document in the tracking log.

We will call you one day prior to the visit, unless the visit is scheduled on a Monday and then we will call you the Friday prior to the visit to remind you of your visit.

Do you have any question for me so far? If no questions continue.

Thank you so much. Please call [research staff name and number] or the clinic in case you need to cancel or re-schedule your Advance Care Planning visit.

Thank caregiver and end call

17.3 Suggested Communication Scripts and Templates

17.3.1 Recruitment Postcard for Patients

THE TELE VOICE INITIATIVE

Every Person should have a VOICE in What Matters Most to Them

Wake Forest® Baptist Health

This is to let you know that we will be reaching out to you by phone in the next couple of days to schedule a visit with your primary care provider to review your current health related goals and future medical preferences.

This type of visit is called an Advance Care Planning Visit. This visit will help your medical providers and others be aware of what matters most to you and helps them better align care to your goals.

Our goal is to empower every person to have a voice in what matters most to them to ensure they receive the type of care they want and deserve!

We will reach out to you shortly to discuss further.

Sincerely,

Wake Forest® Baptist Health

17.3.2 Appointment Information Template with Link for Video Visits

Email, MyChart/Portal Message, Mail

Dear [Patient Name/Caregiver Name]

Thank you again for agreeing to participate in an Advance Care Planning visit with your [name of provider].

The visit is scheduled for [date] at [time].

You should receive an email with the video link.

Once you click on the link you will be placed in a virtual waiting room. Sometimes the doctor may be running late. We ask that you wait in the virtual waiting room until the doctor enters the room. If for any reason the link does not work at the time of your appointment, the doctor will call the number listed in the patient's chart to conduct the visit by phone. If for some reason, the provider is not able to contact you, we will call back to re-schedule the visit at a later time.

We will give you a reminder call a day before the scheduled visit.

Please call us at [research staff number] if you have any questions about the study or if you need to cancel or reschedule your appointment.

We greatly appreciate your participation.

Text Messaging

WFBH: Join your Video Visit on [date] @ [time]: [link]

17.3.3 Appointment Information Template for Telephone Visits

Email, Portal or Letter

Dear [Patient Name/Care partner Name]

Thank you for agreeing to participate in the Advance Care Planning visit with [name of provider] and your loved-one or [name of patient].

The visit is scheduled for [date] at [time].

For patients: [Name of Primary care Provider] will call you on the date and time of your appointment. If you are having someone else join you during your visit, please have them with you in the same room at the time of the appointment and place the phone on speaker.

For care partners: [Name of Primary care Provider] will call your loved one on the date and time of the appointment. If you are joining your loved one during the visit, please be with them in the same room at the time of the appointment and place the phone on speaker.

We will give you a reminder call 1 day before the scheduled visit unless your visit is scheduled on Monday and then we will give you a call the Friday prior to your appointment.

Please call us at [research name/ number] if you have any questions about the study or if you need to cancel or reschedule your Telehealth appointment.

We greatly appreciate your participation.

17.3.4 Appointment Reminder Telephone Script for Video Visits

Hello, my name is_____. I am a (student/faculty member/staff member) from Wake Forest Baptist Medical Center and I am contacting you to remind you of the Telehealth Advance Care Planning visit with [name of provider] and your loved-one or [name of patient].

The Telehealth Advance Care planning visit is scheduled for [date] at [time] via video.

I wanted to quickly check if you still have the email or mychart message that we have sent you with the link to join the Telehealth visit? If not, I can resend it or text you the information now. (if they did not receive, please ask their preference for resending the information (email, mychart, or text) and do accordingly)

Once you click the link you will be placed in a virtual waiting room. Sometimes the provider may be running late. We ask that you wait in the virtual waiting room until the provider enters the room. If for any reason the link does not work at the time of your appointment, the provider will call the number listed in the patient's chart to conduct the visit by phone. If for some reason, the provider is not able to contact you, we will call back to reschedule the visit at a later time.

Do you have any questions on how to use the email link?
If not—great, you can always reach out to us in case you have any questions.
If yes—walk with the patient/care partner over the process again.

Is there anything else I can do for you today?

Please give us a call at [clinic number] if you have any issues connecting to your video visit.

Thank you. End Call

17.3.5 Appointment Reminder Telephone Script for Telephone Visits

Hello, my name is_____. I am a (student/faculty member/staff member) from Wake Forest Baptist Medical Center and I am contacting you to remind you of the Telehealth Advance Care Planning visit with [name of provider] and your loved one or [name of patient].

The Telehealth Advance Care planning visit is scheduled for [date] at [time] as a telephone visit.

For patients: [Name of Primary care Provider] will call you on the date and time of your appointment. If you are having someone else join you during your visit, please have them with you in the same room at the time of the appointment and place the phone on speaker.

For care partners: [Name of Primary care Provider] will call [Name of Patient] on the date and time of the appointment. If you are joining your loved one during the visit, please be with them in the same room at the time of the appointment and place the phone on speaker.

If for some reason, the provider is not able to contact you, we will call back to reschedule the visit at a later time.

Do you have any questions?
If not—great, you can always reach out to us in case you have any questions
If yes—walk with the patient/care partner over the process again.

Is there anything else I can do for you today?

Please give us a call at [research staff name/number] if you have any questions or need any help

Thank you. End Call

17.3.6 Text Message Reminder For Video Appointment

WFBH: Join your Video Visit on [date] @ [time]: [link]

17.3.7 Video Visit Instructions for Patient doing video visits

Video Visit Instructions for Patient and Care Partner

Instructions to log in for a Video Visit.

There are three ways in which you can log in for a video visit on the day of your scheduled visit:

1. **Email Link**--the clinic sends you a link to your email. ***(this is the easiest way)***
2. **MyChart**--if you have a mychart (mywakehealth account), you can do the video visit through your account. You can access your MyChart (mywakehealth account) either through a Mobile device (i.e smartphone) or a Computer.
3. Use the link provided to you through **text messaging**. ***(this is also very easy)***

Sometimes the provider may be running late. Please wait in the virtual waiting room until the provider enters the virtual room.

If for any reason the link does not work at the time of your appointment, the doctor will call the number listed in the patient's chart to conduct the visit by telephone.

If for some reason, the provider is not able to contact you, we will call back to reschedule the visit at a later time.

Please read the instructions below to help you log in for a video visit whichever is easier for you.

On the day of your scheduled video visit

How to log in for your Video Visit: Email Link

1. Please open up your email account and access the email that was sent to you from the clinic about your appointment.
2. Please click on the link that was provided in the email.
3. Once you click the link, you will be placed in a virtual waiting room until your provider joins.

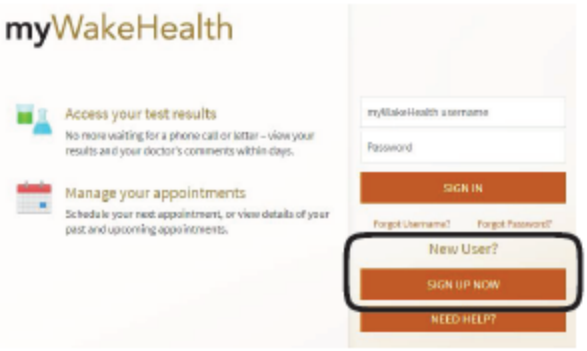
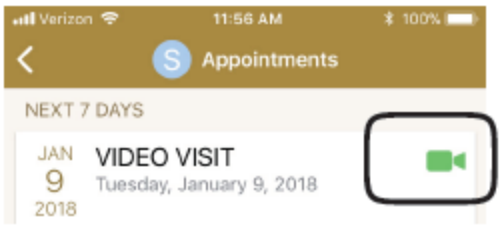
How to log in for your Video Visit: Text Message link

1. Please click on the link that was provided to you on your text message.
2. Once you click the link, you will be placed in a virtual waiting room until your provider joins.

How to log in for your Video Visit: using Mychart (Mywakehealth)

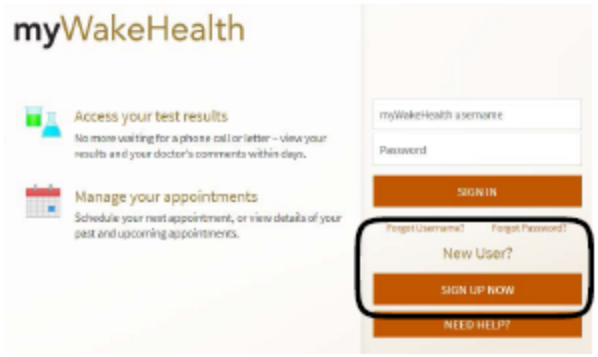
Please follow the instructions below.

How to log in for your Video Visit: **Mobile Devices**

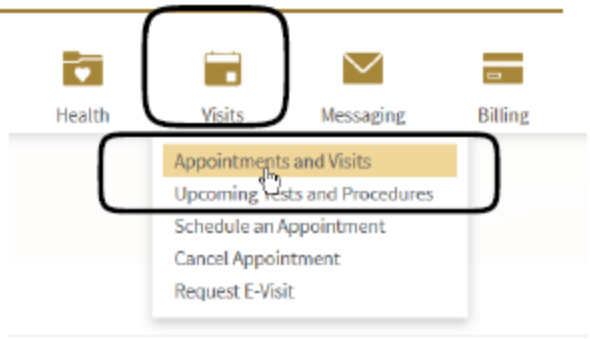
Download the **MyChart by Epic** app from your app store. If first time using the **MyChart** app, select **Wake Forest Baptist Health** as your health care organization. Log in using your **myWakeHealth** username and password.	
This step is **only** necessary if you **do not** already have a **myWakeHealth** account. If you do not yet have a **myWakeHealth** account, you will need to create one by visiting **myWakeHealth.org**. (use the Sign Up Now option)	
On the Activities screen, click on **Appointments**	
On the Appointments screen, click the **green camera icon** next to your scheduled Video Visit	
Click **Begin Visit**.	

How to log in for your Video Visit: Computer

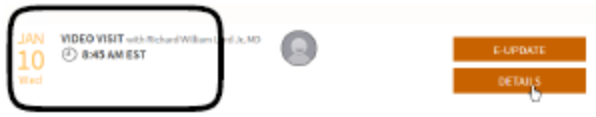
Log in to **myWakeHealth.org**
Note: You **must** use **Google Chrome, Firefox,** or **Safari** browsers.
If you do not yet have a **myWakeHealth** account, you will need to create one by visiting **myWakeHealth.org**. (use the Sign Up Now option).



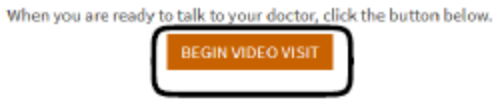
After logging in, go to **Visits** > **Appointments and Visits**



Select the appointment corresponding to your **Video Visit**.



Review the information regarding your appointment.
Once you have reviewed the information, choose **Begin Video Visit**.
The Video Visit will open in a new browser window.



17.4 Provider Email

Thank you for your participating in the Tele-Voice Study.

We ask that you complete the following survey to share with us your experience with the study.

The survey should take less than 5 minutes to complete.

The providers who complete the survey will be entered into a raffle for a chance to win a $200 gift card.

Responding to this survey is voluntary; you are not required to participate. However, if you choose to complete and return this survey, you are consenting to participate in a research study. The information collected from this survey will be used for research purposes only. You are not expected to receive any direct benefit from taking part in this research study. We hope the information learned from this study will benefit other people in the future. The information will be confidential. Thank you in advance for your time and input.

If you have any questions or concerns about this survey, you may contact myself, the Study Principal Investigator—Dr. Jennifer Gabbard at 336-716-8028. If you have a question about your rights as a research participant, or have questions or want to offer input, you should contact the Chairman of the IRB at (336) 716-4542 or the Research Subject Advocate at (336) 716-8372. The Institutional Review Board (IRB) is a group of people who review the research to protect your rights.

If you have questions, please contact Dr. Jennifer Gabbard.

Thank you for your participation in this study!

The Tele-Voice Study Team

Please complete the survey through the link below:

<< redcap survey link will be created>>>>>

17.5 Provider RedCap Survey

Thank you for your participating in the Tele-Voice Study.

We ask that you complete the following survey to share with us your experience with the study.

The survey should take less than 5 minutes to complete.

The providers who complete the survey will be entered into a raffle for a chance to win a $200 gift card.

Responding to this survey is voluntary; you are not required to participate. However, if you choose to complete and return this survey, you are consenting to participate in a research study. The information collected from this survey will be used for research purposes only. The only alternative is to not participate in this survey. You may choose to not participate or you may withdraw from the survey for any reason without penalty or loss of benefits to which you are otherwise entitled.

You might have discomforts that are not listed in this form. Tell the investigator or study staff right away if you have any problems.

We hope the information learned from this study will benefit other people in the future. The information will be confidential except when sharing the information is required by law or as described in this form. The Investigator, the sponsor or persons working on behalf of the sponsor, and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed.

Thank you in advance for your time and input.

Whom to contact about this study
During the study, if you have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed above.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact:

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00050987.

Please provide your email address at the end of the survey to be entered into the $200 gift card raffle

Provider Survey:

1. **What is your title:**
   a. Physician (1)
   b. NP (2)
   c. PA (3)
   d. Social worker (4)

The following questions refer to your satisfaction doing Advance Care Planning (ACP) through Telehealth (either telephone or video)

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2. **How comfortable did you feel discussing Advance care Planning (ACP) through telehealth (either telephone or video) with the patient and/or their loved one?**
   a. Very comfortable (5)
   b. Comfortable (4)
   c. Not Sure (3)
   d. Uncomfortable (2)
   e. Very Uncomfortable (1)

3. **Do you feel the design of doing ACP through Telehealth is a helpful way for more patients to have ACP discussions with providers and loved ones?**
   a. Strongly Agree (5)
   b. Agree (4)
   c. Undecided (3)
   d. Disagree (2)
   e. Strongly Disagree (1)
4. **How satisfied were you with doing ACP through Telehealth?**
   a. Very Satisfied (5)
   b. Satisfied (4)
   c. Neutral (3)
   d. Dissatisfied (2)
   e. Very dissatisfied (1)

	1 = Completely disagree	2 = Disagree	3 = Neither agree nor disagree	4 = Agree	5 = Completely agree
5. The telemedicine ACP intervention met my approval					
6. The telemedicine ACP intervention was appealing to me.					
7. I liked the telemedicine ACP intervention					
8. I welcomed the telemedicine ACP intervention					

9. The telemedicine ACP intervention seemed fitting					
10. The telemedicine ACP intervention was suitable/acceptable to me					
11. The telemedicine ACP intervention was applicable/relevant					
12. The telemedicine ACP intervention seemed like a good match					

13. Do you have a preference either telephone or video to do Telemedicine ACP visits?

a. I prefer Telephone
b. I prefer Video
c. I have no preference, either Telephone or Video is fine

14. Do you have any recommendations on how we can improve this project going forward?

The following questions refer on the usage of the new ACP documentation tool

15. How easy was the new ACP documentation tool to use and document ACP discussions in the electronic health record?

a. Very easy (5)
b. Easy (4)
c. Neutral (3)
d. Difficult (2)
e. Very Difficult (1)

16. How often do you think you would use the new ACP documentation tool to have ACP discussions with your patients in the future?

a. Every time (5)
b. Almost Every time (4)
c. Occasionally/sometimes (3)
d. Almost never (2)
e. Never (1)

17. Do you have any recommendation on how we can improve the ACP documentation tool?

The following questions refers to your workload and priorities as a provider

18. Where do you see ACP in regard to your priorities at work?

a. High priority (5)

b. Moderate Priority (4)
c. Neutral (3)
d. Somewhat priority (2)
e. Low priority (1)

19. If we can continue the Telehealth ACP intervention going forward, how likely would you use this model for ACP in your practice?

a. Always (5)
b. Very Often (4)
c. Fairly Many Times (3)
d. Occasionally (2)
e. Never (1)

20. How much of an increase on your workload has this ACP study created for you?

a. None (4)
b. Some (3)
c. Quite a bit (2)
d. An extreme amount (1)

21. Do you have any additional feedback?

22. Please provide your email address to be entered into a $200 raffle for completing this survey: _____

Thank you so much for your participation and time!!!!

Sincerely
The Tele-Voice Study Team

17.6 Provider Telephone Script

Hello, is this [name of provider]? Hi, this is [name of research staff] calling you about the Tele-Voice study you have participated on.

The reason for my call is that we have not received your survey. We would love to have your feedback about the study to make sure we can improve future interventions like this. The providers that complete the survey are automatically entered into a drawing for a chance to win a $200 gift card. The survey is completely voluntary to participate and it will only take about 5 minutes to complete. If you choose to complete the survey, you are consenting to participate in a research study. The information collected from this survey will be used for research purposes only.

We hope the information learned from this study will benefit other people in the future. The information will be confidential. Thank you in advance for your time and input.

If you have time, would you like to do the survey over the phone with me?

If yes—open redcap survey and proceed

If no—I completely understand, would you like me to send you a hard copy of the survey or send you the email with the survey link? Do as asked.

Thank you so much for your time, we greatly appreciate your participation in the Tele-Voice study.

17.7 Patient After Visit survey Mail Version

Patient Survey

Dear <Participant Name>

Thank you for completing either a telephone or video Advance Care Planning visit with your member of your primary care team.

We would love to learn a little bit more about your experience and want to see if you would be willing to complete the following brief survey attached about your experience.

The survey should take <u>less than 5 minutes</u> to complete.

Those who complete the survey will be entered into a raffle for a chance to win a <u>$100 gift card</u>.

Responding to this survey is voluntary; you are not required to participate. However, if you choose to complete and return this survey, you are consenting to participate in a research study. The information collected from this survey will be used for research purposes **only.** The only alternative is to not participate in this survey. You may choose to not participate or you may withdraw from the survey for any reason without penalty or loss of benefits to which you are otherwise entitled.

Responding to this survey is voluntary; you are not required to participate. However, if you choose to complete and return this survey, you are consenting to participate in a research study. The information collected from this survey will be used for research purposes **only.** The only alternative is to not participate in this survey. You may choose to not participate or you may withdraw from the survey

for any reason without penalty or loss of benefits to which you are otherwise entitled.

What are the risks of the study?
The potential risks of this study are minimal in that there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. All information that we receive from you will be strictly confidential and will be kept in secure locations with password protected computers and lock offices. All your information, like your name and answers to the survey, will be kept confidential and be seen only by the study team.

You might have discomforts that are not listed in this form. Tell us right away if you have any problems, by calling the primary investigator, Jennifer Gabbard, at 336-716-8028.

We hope the information learned about your experience that will benefit other people in the future. The information will be confidential except when sharing the information is required by law or as described in this form. The Investigator, the sponsor or persons working on behalf of the sponsor, and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed.

Thank you in advance for your time and input.

Whom to contact about this study
If you have questions, concerns or complaints, please contact the primary investigator, Jennifer Gabbard, at 336-716-8028.
An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your

rights as a research subject, and/or concerns or complaints regarding this research study, contact:

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00050987.

<Participant Name>

Please complete the following questions after you have completed your telehealth (either telephone or video) Advance Care Planning visit.

Please circle or check your answer:

23. What mode, either telephone or video, did you use when having your Advance Care Planning visit with a member from your primary care team?

Telephone	Video
☐	☐

24. How comfortable did you feel discussing advance care planning through telehealth with a member from your primary care team? Please circle or check one of the following:

Very Comfortable (5)	Comfortable (4)	Neither (3)	Uncomfortable (2)	Very Uncomfortable (1)
☐	☐	☐	☐	☐

25. How satisfied were you with your Advance Care Planning telehealth visit? Please circle or check one of the following:

Very Satisfied (5)	Satisfied (4)	Neither (3)	Dissatisfied (2)	Very Dissatisfied (1)
☐	☐	☐	☐	☐

26. My Advance Care Planning telemedicine visit met my approval.

Completely Agree (5)	Agree (4)	Neither (3)	Disagree (2)	Completely Disagree (1)
☐	☐	☐	☐	☐

27. My Advance Care Planning telemedicine visit was appealing to me.

Completely Agree (5)	Agree (4)	Neither (3)	Disagree (2)	Completely Disagree (1)
☐	☐	☐	☐	☐

28. I liked my Advance Care Planning telemedicine visit.

Completely Agree (5)	Agree (4)	Neither (3)	Disagree (2)	Completely Disagree (1)
☐	☐	☐	☐	☐

29. I welcomed my Advance Care Planning telemedicine visit.

Completely Agree (5)	Agree (4)	Neither (3)	Disagree (2)	Completely Disagree (1)
☐	☐	☐	☐	☐

30. Discussing Advance Care Planning through telemedicine seems fitting to me.

Completely Agree (5)	Agree (4)	Neither (3)	Disagree (2)	Completely Disagree (1)
☐	☐	☐	☐	☐

31. My Advance Care Planning telemedicine visit was suitable/acceptable to me.

Completely Agree (5)	Agree (4)	Neither (3)	Disagree (2)	Completely Disagree (1)
☐	☐	☐	☐	☐

32. Discussing Advance Care Planning through telemedicine seems relevant/applicable.

Completely Agree (5)	Agree (4)	Neither (3)	Disagree (2)	Completely Disagree (1)
☐	☐	☐	☐	☐

33. Discussing Advance Care Planning through telemedicine seems like a <u>good match</u>.

Completely Agree (5)	Agree (4)	Neither (3)	Disagree (2)	Completely Disagree (1)
☐	☐	☐	☐	☐

34. Overall, how would you rate your provider's <u>communication</u> with you during your Advance Care Planning telemedicine visit? On the scale below, 5= "Excellent" and 1= "Very poor"

Excellent (5)	Good (4)	Neutral (3)	Poor (2)	Very Poor (1)
☐	☐	☐	☐	☐

35. If your primary care provider wanted to discuss advance care planning with you again using telemedicine (either telephone or video) in the future, would you participate?

Yes	No
☐	☐

If no, do you mind saying why?

36. How likely would you <u>recommend</u> discussing advance care planning to a friend or family member?

Definitely (5)	Very Proba-bly (4)	Probably (3)	Probably Not (2)	Definitely No (1)
☐	☐	☐	☐	☐

37. Do you have any <u>recommendations</u> on how we can <u>improve</u> doing advance care planning through telemedicine (either video or telephone) going forward? Just type either n/a or no, if no recommendations

ust type either n/a or no, if no additional comments.

Please mail back in the self-address stamped envelope after you complete the survey.

Thank you so much for your feedback and time!!!!

Sincerely
The Tele-Voice Study Team

17.8 Patient After Visit survey Redcap Version

Patient Survey

Dear <Participant Name>

Thank you for completing either a telephone or video Advance Care Planning visit with your member of your primary care team.

We would love to learn a little bit more about your experience and want to see if you would be willing to complete the following brief survey about your experience.

The survey should take <u>less than 5 minutes</u> to complete.

Those who complete the survey will be entered into a raffle for a chance to win a <u>$100 gift card</u>.

Please complete the survey through the link below:

<< redcap survey link will be created>>>>>

Responding to this survey is voluntary; you are not required to participate. However, if you choose to complete and return this survey, you are consenting to participate in a research study. The information collected from this survey will be used for research purposes **only.** The only alternative is to not participate in this survey. You may choose to not participate or you may withdraw from the survey

for any reason without penalty or loss of benefits to which you are otherwise entitled.

What are the risks of the study?
The potential risks of this study are minimal in that there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. All information that we receive from you will be strictly confidential and will be kept in secure locations with password protected computers and lock offices. All your information, like your name and answers to the survey, will be kept confidential and be seen only by the study team.

You might have discomforts that are not listed in this form. Tell us right away if you have any problems, by calling the primary investigator, Jennifer Gabbard, at 336-716-8028.

We hope the information learned about your experience that will benefit other people in the future. The information will be confidential except when sharing the information is required by law or as described in this form. The Investigator, the sponsor or persons working on behalf of the sponsor, and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed.

Thank you in advance for your time and input.

Whom to contact about this study
If you have questions, concerns or complaints, please contact the primary investigator, Jennifer Gabbard, at 336-716-8028.
An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your

rights as a research subject, and/or concerns or complaints regarding this research study, contact:

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00050987.

<Participant Name>

Please complete the following questions after you have completed your telehealth (either telephone or video) Advance Care Planning visit.

Please circle or check your answer:

39. What mode, either telephone or video, did you use when having your Advance Care Planning visit with a member from your primary care team?

Telephone	Video
☐	☐

40. How comfortable did you feel discussing advance care planning through telehealth with a member from your primary care team? Please circle or check one of the following:

Very Comfortable (5)	Comfortable (4)	Neither (3)	Uncomfortable (2)	Very Uncomfortable (1)
☐	☐	☐	☐	☐

41. How satisfied were you with your Advance Care Planning telehealth visit? Please circle or check one of the following:

Very Satisfied (5)	Satisfied (4)	Neither (3)	Dissatisfied (2)	Very Dissatisfied (1)
☐	☐	☐	☐	☐

42. My Advance Care Planning telemedicine visit met my approval.

Completely Agree (5)	Agree (4)	Neither (3)	Disagree (2)	Completely Disagree (1)
☐	☐	☐	☐	☐

43. My Advance Care Planning telemedicine visit was appealing to me.

Completely Agree (5)	Agree (4)	Neither (3)	Disagree (2)	Completely Disagree (1)
☐	☐	☐	☐	☐

44. I liked my Advance Care Planning telemedicine visit.

Completely Agree (5)	Agree (4)	Neither (3)	Disagree (2)	Completely Disagree (1)
☐	☐	☐	☐	☐

45. I welcomed my Advance Care Planning telemedicine visit.

Completely Agree (5)	Agree (4)	Neither (3)	Disagree (2)	Completely Disagree (1)
☐	☐	☐	☐	☐

46. Discussing Advance Care Planning through telemedicine seems fitting to me.

Completely Agree (5)	Agree (4)	Neither (3)	Disagree (2)	Completely Disagree (1)
☐	☐	☐	☐	☐

47. My Advance Care Planning telemedicine visit was suitable/acceptable to me.

Completely Agree (5)	Agree (4)	Neither (3)	Disagree (2)	Completely Disagree (1)
☐	☐	☐	☐	☐

48. Discussing Advance Care Planning through telemedicine seems relevant/applicable.

Completely Agree (5)	Agree (4)	Neither (3)	Disagree (2)	Completely Disagree (1)
☐	☐	☐	☐	☐

49. Discussing Advance Care Planning through telemedicine seems like a good match.

Completely Agree (5)	Agree (4)	Neither (3)	Disagree (2)	Completely Disagree (1)
☐	☐	☐	☐	☐

50. Overall, how would you rate your provider's communication with you during your Advance Care Planning telemedicine visit? On the scale below, 5= "Excellent" and 1= "Very poor"

Excellent (5)	Good (4)	Neutral (3)	Poor (2)	Very Poor (1)
☐	☐	☐	☐	☐

51. If your primary care provider wanted to discuss advance care planning with you again using telemedicine (either telephone or video) in the future, would you participate?

Yes	No

☐	☐

If no, do you mind saying why?

52. How likely would you <u>recommend</u> discussing advance care planning to a friend or family member?

Definitely (5)	Very Proba-bly (4)	Probably (3)	Probably Not (2)	Definitely No (1)
☐	☐	☐	☐	☐

53. Do you have any <u>recommendations</u> on how we can <u>improve</u> doing advance care planning through telemedicine (either video or telephone) going forward? Just type either n/a or no, if no recommendations

ust type either n/a or no, if no additional comments.

Thank you so much for your feedback and time!!!!

Sincerely
The Tele-Voice Study Team

18. REFERENCES

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