Integrated Approach to Patient and Family Engagement for Advance Care Planning for Vulnerable Older Adult within an Accountable Care Organization (ACO)

Protocol Number 9

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Study Title: Integrated Approach to Patient and Family Engagement for Advance Care Planning for Vulnerable Older Adult within an Accountable Care Organization (ACO)

Short Title: IMPACT: Integrated Multidisciplinary Patient and Family Advance Care Planning Trial

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Background, Rationale and Context

One-fifth of the total U.S. population will be over the age of 65 by 2050.[1,2] Inevitably, there will be a corresponding surge in those with multiple chronic conditions ("multimorbidity") along with an associated increase in health care expenditures.[1-6] Multimorbidity has been associated with (a) poor patient health outcomes, including depression, polypharmacy, socioeconomic deprivation, poorer quality of life, and decreased satisfaction with care; and (b) increased overall health system costs, primarily due to increased healthcare utilization and burdensome care. [7-16] [17,18] Yet multimorbidity alone does not identify the subset of older adults at greatest need of assistance with care planning.[19,20] Evidence is emerging that persons with multimorbidity plus functional and/or cognitive impairment are at the highest risk for poor outcomes with respect to disability and mortality, above and beyond the risk attributable to individual diseases.[2,18,20-24] Here, we define these patients as *"vulnerable older adults"*: adults 65 years and older who have 2 or more chronic conditions plus impairments in either physical function (e.g., mobility disability),cognition, and/or frailty.

At present, the care of vulnerable older adults is marked by fragmented health care focused on disease-based treatment, lengthy and recurrent hospital stays, and higher cost care through the end of life.[25-28] As opposed to a disease-based approach to health care, a function-based approach for subpopulations of patients will foster more focus on the importance of Advance Care Planning (ACP) in vulnerable older adults.[29] Such a focus provides a pathway to remedy poor physician-patient communication about patients' views and desires for their health care and thus a reduction in burdensome care that often does not meet these patients' health care goals. This opportunity is perhaps the greatest in primary care settings, where providers focused primarily on disease often lack the time to devote to improving discussions on ACP with their patients. The 2014 Institute of Medicine (IOM) report "Dying in America" emphasized the U.S. healthcare system's need for new models of care to promote ACP conversations.[30] Based on this report and others, changes to healthcare policy and reimbursement, and creation of novel value-based models of care, have generated opportunities to meet the needs of this growing vulnerable older adult population.

We propose to promote ACP conversations by utilizing the Electronic Health Record (EHR) to identify the most vulnerable primary care patients and then leveraging Nurse Navigators as the first point of contact for ACP discussions. Nurse Navigators already function well in engaging patients with care coordination, patient education, and connections to community-based resources. The proposed project is a natural extension of their role and empowers the nurses to use their skills more fully. To leverage these

opportunities, our research will evaluate the effectiveness of enhancing patient and family engagement in Advance Care Planning through a Nurse Navigator led pathway. Our overall hypothesis is that in a primary care setting, a coupled informatics and Nurse Navigator led ACP pathway will improve ACP documentation within the EHR as compared to usual care and will improve provider-patient communication about goals of care.

Objectives:

Primary Aim

Aim 1: To determine whether a nurse navigator led ACP pathway improves having advance care planning discussions between patients and their primary care provider along with improving documentation of these discussions utilizing an innovative outpatient ACP documentation tool in the Electronic Health Record (EHR) for vulnerable older adults.

Hypothesis:
1.0a: In a primary care, accountable care organization (ACO) setting, we hypothesize that the nurse navigator led ACP pathway will improve ACP documentation utilizing the New ACP documentation tool in the EHR compared to usual care by relative improvement of 50%.

1.0b: In a primary care, accountable care organization (ACO) setting, we hypothesize that the nurse navigator led ACP pathway will result in high quality provider-patient communication about goals of care through the use of the New ACP documentation tool in the EHR.

Secondarily Aim

Aim 2.1: To compare usage of ACP billing codes among patients for the nurse navigator led ACP pathway versus usual care.

Hypothesis: We hypothesize that the nurse navigator led ACP pathway will result in increased utilization of ACP billing codes by relative improvement of 50%.

Aim 2.2: To compare documented designated surrogate decision makers and advance directive (AD) form completion rates in the EHR for the nurse navigator led ACP pathway versus usual care.

Hypothesis: We hypothesize that the nurse navigator led ACP pathway will result in increased rate of documented designated surrogate decision makers in the EHR by a relative improvement of 25% and improved AD completion rates and documentation in the EHR by relative improvement of 10%.

Exploratory Aims:

Aim 3.1: To compare Medical Scope of Treatment (MOST) form completion rates and documentation in the EHR for the nurse navigator led ACP pathway versus usual care.

Hypothesis: We hypothesize that the nurse navigator led ACP pathway will result in improved MOST completion rates and documentation in the EHR by relative improvement of 10%.

Aim 3.2 To compare quality of end-of-life care for patients who pass away who were in the nurse navigator led ACP pathway versus usual care.

Hypothesis: We hypothesize that the nurse navigator led advance care planning (ACP) pathway will results in improved quality of end-of-life care in those who pass away.

Aim 3.3 To compare patient healthcare utilization (inpatient hospitalizations, emergency department (ED) visits, intensive care unit (ICU) admissions and length of stay, and mechanical intubations) between the nurse navigator led ACP pathway versus usual care.

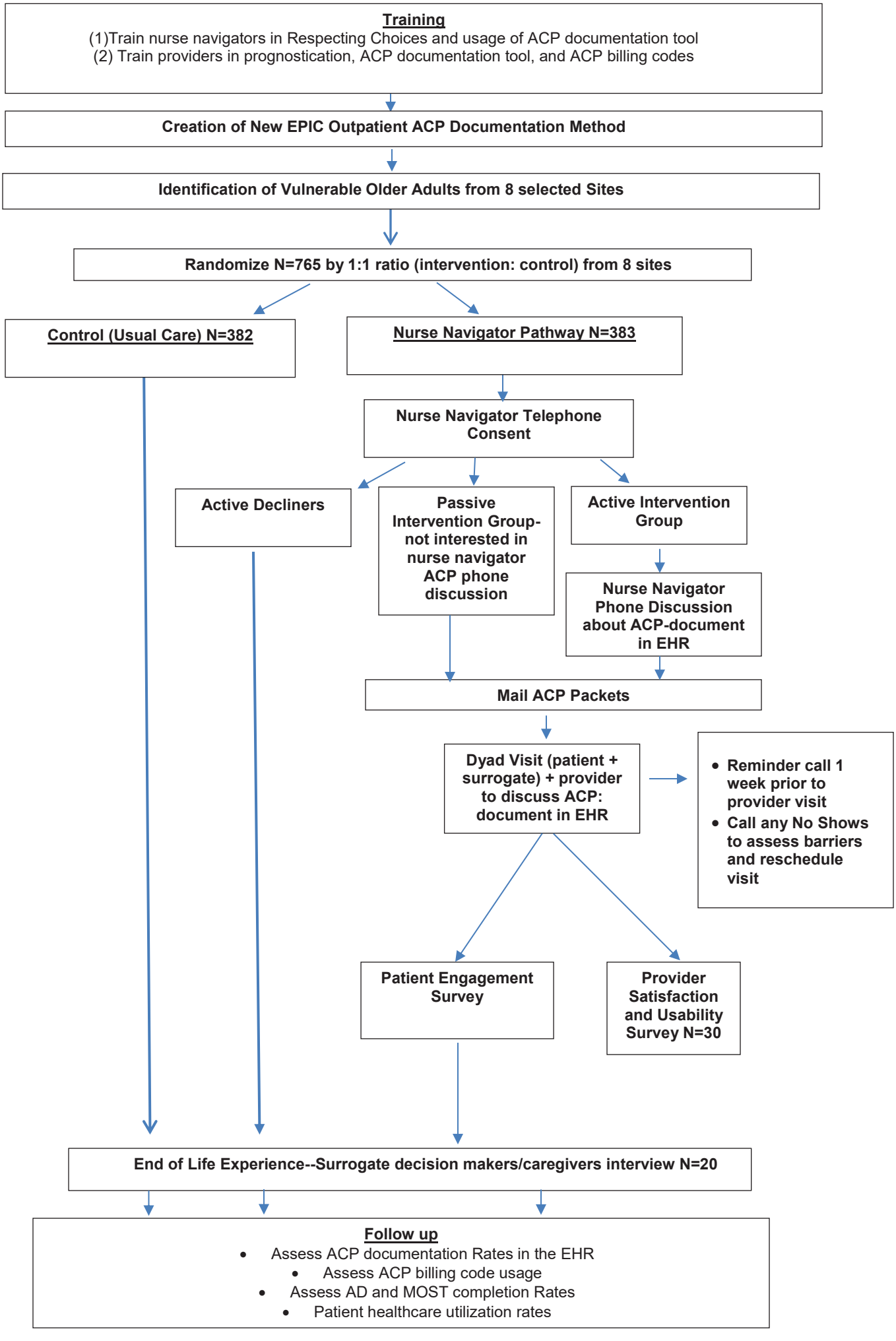
> Hypothesis: We hypothesize that the nurse navigator led ACP pathway will lead to improvements in healthcare utilization (lower rates of inpatient hospitalization, ED visits, and ICU admissions, shorter ICU length of stay, and lower rates of intubations and CPR) versus usual care.

Methods and Measures

Design

This study is a randomized, pragmatic, comparative effectiveness trial for determining better ways to engage multimorbid patients and their family members in Advance Care Planning through a Nurse Navigator led pathway versus usual care. We propose to utilize Zelen's design [31-35](a more recent label/generalization for this type of design is the cohort multiple randomized controlled trial (cmRCT),[36] a pragmatic clinical trial design whereby all participants are randomized prior to informed consent, and then only patients randomized to the interventional arm are approached for consent and subsequently enrolled in the intervention group. Note that patients that do not consent to the intervention are still counted as part of the intervention group under an intent-to-treat paradigm, which necessitates passive ascertainment mechanisms for outcomes (i.e. administrative claims or the EHR). One appealing aspect of Zelen's design is that it facilitates estimating real-world effectiveness, as we will be able to estimate the rate at which patients decline to consent/refuse the nurse navigator intervention, which then factors into overall estimates of effectiveness. In addition, others have pointed out that the Zelen's design is ethical and particularly useful within the context of trials of screening interventions, where the desire is to estimate an effect on the entire population of eligible patients. [32,33]

The flow of the project is illustrated in the diagram below:


Training
(1)Train nurse navigators in Respecting Choices and usage of ACP documentation tool
(2) Train providers in prognostication, ACP documentation tool, and ACP billing codes
Creation of New EPIC Outpatient ACP Documentation Method
Identification of Vulnerable Older Adults from 8 selected Sites
Randomize N=765 by 1:1 ratio (intervention: control) from 8 sites
Control (Usual Care) N=382
Nurse Navigator Pathway N=383
Nurse Navigator Telephone Consent
Active Decliners
Passive Intervention Group- not interested in nurse navigator ACP phone discussion
Active Intervention Group
Nurse Navigator Phone Discussion about ACP-document in EHR
Mail ACP Packets
Dyad Visit (patient + surrogate) + provider to discuss ACP: document in EHR
Reminder call 1 week prior to provider visit
Call any No Shows to assess barriers and reschedule visit
Patient Engagement Survey
Provider Satisfaction and Usability Survey N=30
End of Life Experience--Surrogate decision makers/caregivers interview N=20
Follow up
Assess ACP documentation Rates in the EHR
Assess ACP billing code usage
Assess AD and MOST completion Rates
Patient healthcare utilization rates

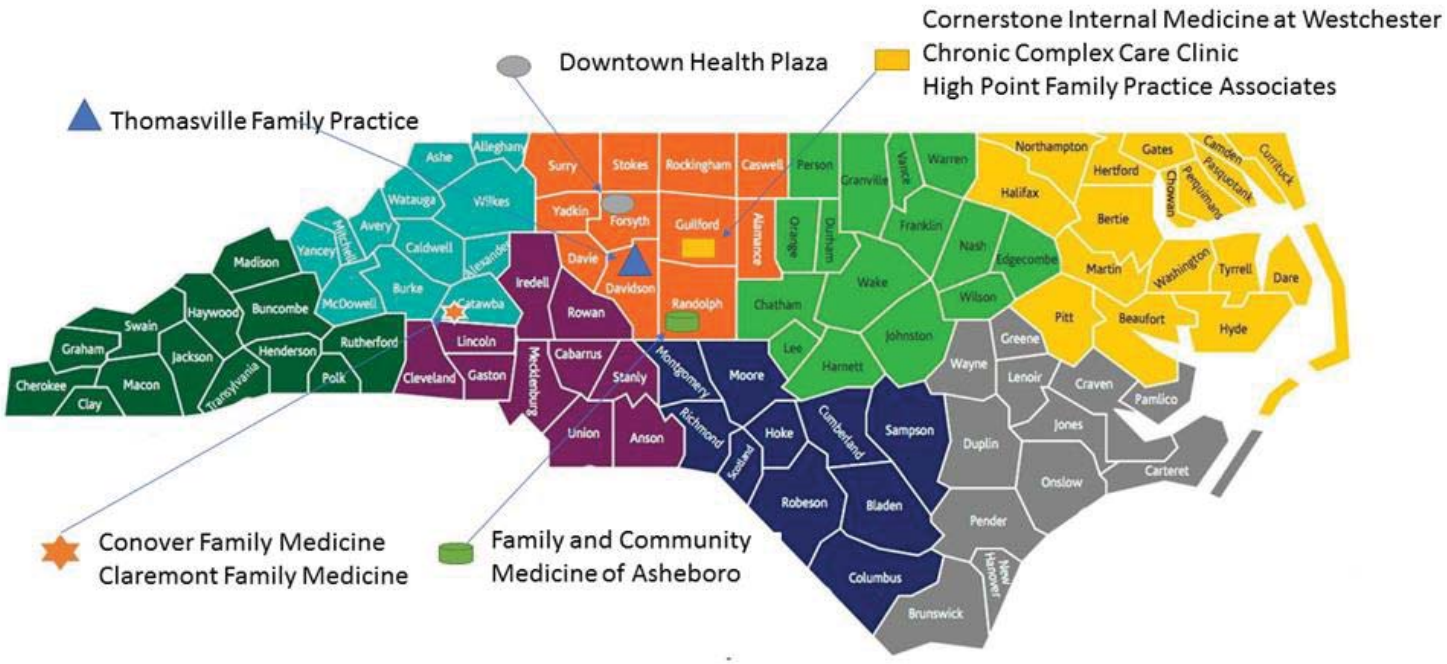
Setting: Wake Forest Baptist Health (WFBH) and Cornerstone HealthCare are a single clinical enterprise, with a Next Generation Accountable Care Organization (ACO) program, incorporating more than 150 primary care and multi-specialty practices with more than 330 physicians and advanced practice providers in 80 locations in communities throughout central North Carolina. Each primary care and many specialty care practices have dedicated Nurse Navigators and patient care advocates to aid in care transitions, promote patient-centered care and identify gaps in care. Through its position as a Next Generation ACO, Cornerstone has a robust informatics platform to drive data collection to enable directed focus on quality of care, patient experience, and optimal patient outcomes. This organizational commitment serves as an accelerant to systemic change, furthermore, the many providers and geographic area covered would enable wide dissemination throughout our region. Our study will focus on the following sites within Cornerstone and Wake Forest Baptist Health with a large proportion of vulnerable older adults:

1. Thomasville Family Practice Associates, Thomasville
2. Cornerstone Internal Medicine at Westchester, High Point
3. Family and Community Medicine, Asheboro
4. Claremont Family Medicine, Claremont
5. Conover Family Medicine, Conover
6. Chronic Complex Care Clinic, High Point
7. High Point Family Practice Associates, High Point
8. Downtown Health Plaza, Winston Salem

Our plan is to reach the sites in 2 tiers. Our first tier will start with sites 1-2 the first month and will expand to sites 3-7 in the second month. Our second tier will start at about four months in, which we will expand to Downtown Health Plaza, site number 8. We have included Downtown Health Plaza due to the rich diversity in patient population. Having Downtown Health Plaza as a site will be beneficial to allow us reach our recruitment numbers with a diverse population.

Below is a map with the participating sites.

IMPACT STUDY SITES



The following sites are participating sites for the IMPACT Study

Subject Selection Criteria:

Patient Eligibility Criteria

Inclusion Criteria:

1. Aged 65 or older patient within the Wake Forest Baptist Health ACO.
2. Have seen their primary care provider within the Wake Forest/Cornerstone network in the past 12 months.
3. Charlson Comorbidity Index (CCI) of 3 or higher.
4. Impairments in either physical function, cognition, and/or frailty defined by:
    a. Impairments in physical function
        i. ICD-10 Codes:
            1. Falls = V00.141A, V00.312A, W01.110A, W01.198A, W03.XXXA, W05.0XXA, W05.1XXA, W05.2XXA, W06.XXXA, W07.XXXA, W08.XXXA, W10.1XXA, W10.8XXA, W17.81XA, W17.89XA, W18.11XA, W18.30XA, W19.XXXA, R29.6,z91.81
            2. Muscular Deconditioning R29.898
            3. Physical Deconditioning R53.81
            4. Gait Abnormality R26.9, 26.89
            5. Impaired physical mobility Z74.09
            6. Difficulty walking R26.2
            7. Debility R53.81, R54,
            8. Wheelchair bound Z99.3
        ii. Annual Wellness Visit:
            1. Positive Falls Assessment
            2. Impairments in Activities of Daily Living, answer of yes needing assistance with any of the following:
                a. Feeding self, bathing self, dressing self, use of toilet, needing assistive device for walking or cannot walk.
    b. Impairments in Cognition:
        i. ICD-10 Codes:
            1. Impaired cognition R41.89
            2. Dementia F01.50, F02.81, G30.9, F02.80, G20, G31.83, G31.09, G30.0, G30.1, G30.8, G31.01, G31.09, F03.90
            3. Memory Change: R41.3, F06.8
            4. MCI (mild cognitive impairment): G31.84
            5. History of memory loss Z86.59
            6. History of short-term memory loss Z87.898
        ii. *Annual Wellness Visit*:
            1. Answer of yes to either “has a diagnosis of dementia or cognitive impairment?” And/or “are there any memory concerns by the patient, others, or providers?”

c. Frailty:
    i. EHR Frailty Index (eFI) score >0.21. Frailty Indices (FIs) based on the accumulated deficits model of frailty[37,38] have shown efficacy in predicting health outcomes of interest for at-risk older adults across multiple environments.[37,39-48] In the United Kingdom, researchers have developed an eFI using routine primary care data in the EHR which has been incorporated into National Health Service and British Geriatrics Society guidelines.[49,50]. Their EHR-based frailty index (eFI)[51] primarily uses diagnostic codes to identify and stage frailty. As part of a separate project, Drs. Pajewski and Callahan have adapted the eFI for use in the Wake Forest EHR, applying it to patients enrolled in the Wake Forest Medicare Shared Savings Plan. We will utilize this work in the present project as a screening measure to identify patients that are likely to be frail. The underlying data and scoring definitions used in calculating the eFI are described in a separate document that has been provided as an appendix to this protocol.

5. English speaking.
6. No documented Advance Directive in the EHR.

Exclusion Criteria:

1. Moderate to severe hearing loss (due to phone interventions).
    a. ICD10 code: H91.90, H91.91, H91.93, H91.92
2. Non-English speaking (not all navigators speak a second language; subtleties may not be conveyed effectively).
    a. ICD10 Code: Z78.9
3. No phone number available for patient.
4. Short Portable Mental Status Questionnaire (SPMSQ) score of ≥ 5 or score of ≥ 6 or more for those with only a grade school education.

Patients who become Ineligible:
Patients who transfer care outside of Wake Forest or go to hospice, Long Term Acute Care facility or Skilled Nursing Facility are ineligible to participate in the study.

Caregiver Eligibility Criteria
Exclusion Criteria:
Caregivers of patients who were randomized to the intervention arm but were either ineligible, declined to participate or withdrew from the study and expired, will be ineligible to participate in the Bereavement Interview.

Sample Size:

Intervention and Control groups
Patients will be randomized using a 1:1 ratio to either the nurse led ACP pathway or usual care. Only those who were randomized to the Nurse Navigator led pathway (intervention arm) will be contacted for participation and informed consent. Outcomes for all randomized patients will be accessed passively via the EHR. Randomization will take effect in two tiers. The first tier of randomization will be for sites 1-7, the second tier of randomization will be for Downtown Health Plaza due to the rollout of the study at different sites.

Providers
Up to 30 providers who agreed to conduct ACP discussions will be recruited to complete a RedCAP survey.

Surrogate decision makers/caregivers
Up to 20 surrogate decision makers/caregivers of patients who passed away in the intervention and control groups, 10 from each group, will be recruited to complete the Bereavement Interview.

Interventions and Interactions

Healthcare Providers and Research team training prior to recruitment

Nurse Navigators, trained in Respecting Choices, will be part of the research team to ensure successful recruitment and interaction with patients. Respecting Choices (RC) is an internationally recognized, evidence-based model of advance care planning (ACP) that creates a healthcare culture of person-centered care; care that honors an individual's goals and values for current and future healthcare.[52,53] In addition, Nurse Navigators will receive training in the Collaborative Institutional Training Initiative (CITI) and the protocol. Nurse Navigators are employees of Wake Forest Baptist Medical Center. Nurse Navigators already function well in engaging patients with care coordination, patient education, and connections to community-based resources. They already have an established relationship with the target population in our proposed project, therefore, this project is a natural extension of their role and empowers the nurses to use their skills more fully.

Providers (MD, NP, PAs, or Social Worker) at identified Wake Forest/Cornerstone sites, who work along these Nurse Navigators, will receive training in (a) prognostication for multimorbid older adults using a validated, standardized prognostication tool (ePrognosis)[54]; (b) document ACP discussion using a new ACP documentation tab in the EHR, and (c) bill using the new ACP codes (99497, 99498) to make ACP visits economically viable. These trainings are necessary for the successful implementation of ACP visits.

A notary is required in North Carolina for completion of an Advance Directive. One staff member at each site will be identified to become a public notary if one isn't already available at that site.

To ensure the fidelity of the study, site visits may be conducted during the study to evaluate study conduct. Sites will be monitored by the Principal Investigator and/or Research Manager for patient enrollment, compliance with protocol procedures, and troubleshoot any study related challenges.

Usual Care

In the Usual Care arm, there is no approach by nurse navigators to initiate advance care planning discussions and it does not have a structure advance care planning visit. Providers may conduct advance care planning conversations only when deemed necessary by the provider, usually very close to the end-of-life without a structure format. Therefore, no further action is required for the patients who were randomly assigned to the usual care arm.

Nurse Navigator Pathway

The Nurse Navigator Pathway is a structured format of conducting advance care planning discussions. Nurse navigators are being used as leverage to: approach qualified patients to initiate (prime for) advance care planning discussions using the New ACP note template in the Electronic Health Record (EHR) and documenting these discussions in the New ACP note template in the EHR, schedule advance care planning visit with patients' primary care provider to further discuss advance care planning and to mail advance care planning resources to patients after their initial advance care

planning discussion. Providers will then have advance care planning visits to discuss advance care planning with patients and will document these visits in a structured format using the New ACP note template in the EHR.

Nurse Navigator Telephone Encounters

The goal of "reach" is to determine similarities and differences in those who agree to participate and complete all aspects of the study (active participants), those who initially agree to participate, but then later do not come to their in-person appointment to discuss ACP (passive decliners), and those who do not express interest in participating at all (active decliners). For all three groups, we will look at demographic characteristics to provide information about the population subgroups that are more or less likely to participate (e.g., age, marital status, adult children (# and proximity to participant), race/ethnicity, and socioeconomic status. For those who decline (both passive and active decliners), we will have the nurse navigators ask:

1) Reasons for not participating, such as time, transportation, lack of interest, perceived not important, etc.
2) Provide feedback on ways the study can be more appealing/of interest to them.

We will also assess the total number of participants reached by nurse navigator and number reached per week. We will assess how many times the nurse navigator needed to reach out to the participants before completion of ACP telephone visit and the time it took to complete each visit.

Nurse Navigators already function well in engaging patients with care coordination, patient education, and connections to community-based resources. The proposed project is a natural extension of their role and empowers the nurses to use their skills more fully. Therefore, the calls that Nurse Navigators will be making will not be "cold calls" since they already have an established relationship with these patients. Nurse Navigators will initiate ACP discussions over the phone with qualified participants who were consented. An ACP Discussion Telephone Script will be created for them to follow along with a New ACP note template to document these discussions within the EHR. They will answer any questions patients may have about ACP and will schedule a visit with the patient's primary care provider, using the New ACP Visit type built in the Epic system, to further discuss ACP. This will be linked with their upcoming Medicare Annual Wellness Visit (AWV) or as ACP visit alone (if they have already completed their AWV visit). Navigators will also mention that the patient should bring a family member or surrogate person with them to their ACP visit and that they will need to complete a Patient Engagement Survey at the end of their visit.

They will route their telephone note to the patient's primary care provider and the research manager to let them know they had this ACP telephone encounter and that they have scheduled an ACP visit.

If the patient refuses to participate in the ACP discussion with the nurse navigator but is willing to participate in the study, we will allow them to continue to participate. The nurse navigators will not have an ACP discussion, as per the patient request, and will schedule an ACP visit with the patient's PCP.

The research team will send a Thank You Postcard to patients who agreed to participate to thank them for their participation. Also, the research staff will send patients a Reminder Postcard half way before their visit appointment to keep them engage in the study. See Addendum.

Within a week of the telephone encounter, the Navigators or Ancillary staff will mail these patients an ACP Packet, which will include information about ACP, NC advance directive, a self-addressed stamped envelope to mail the advance directive, copy of the Post-intervention survey, and a copy of

the Study Information Sheet, a copy of the verbal consent form, a compensation letter, and a W9 form. See Addendum.

Nurse Navigators will remind participants of their scheduled ACP visit one week prior to their visit. Navigators will also remind participants of the types of documents they need to bring to the visit and that they are free to bring a family member or surrogate person with them. In addition, the Nurse Navigators will remind participants that they will need to complete a Patient Engagement Survey at the end of their visit.

Nurse Navigators will explain to participants that they will have access to the survey in three ways:

- By email containing a link to a RedCap survey to complete over the internet.
- By using the RedCap link provided in the Patient Engagement Information Sheet found in their ACP Packet.
- By completing the hard copy survey found in their ACP packet and mail back to the research team.

Nurse Navigators will reach out via telephone to participants who were NO shows or cancelations within a week of their missed scheduled visit to assess barriers and reason for no show. They will create a telephone encounter to document their discussion. They will ask them if they would like the visit rescheduled and if yes, they will have that visit rescheduled for them and alert their primary care provider. Any participants who NO shows or cancelations for the provider visit were, the nurse navigator will ask the following question:

1. "Could you please tell us a little bit more about why you were not able to attend the provider visit?" -Was it lack of time? Lack of interest? Lack of transportation? Or another reason.

Nurse Navigators will attempt to call NO shows or cancelations every week up to 3 times, if after the 3rd time the patient is still not able to be reached, the research team will send the patient a Missed Clinic Appointment Postcard for patients to call back to reschedule their appointment if interested. If patients do not respond within 3 weeks, the patient will be lost to follow up. See Addendum.

Provider Visits

The providers will receive the forwarded ACP telephone encounter that occurred by the nurse navigator along with alert that an ACP visit was scheduled for their patient. The providers will know this is an ACP visit since the Nurse Navigators will be scheduling these visits using the new ACP visit type.

The providers will then have a group dyad visit with the patient and their family member (or desired surrogate/caregiver).

The provider will discuss ACP, patient's goals and values, along with their estimated prognosis (if appropriate). They will complete an Advance Directive and/or Medical Scope of Treatment (MOST) form if appropriate during that visit. The providers will use a SmartText template to help direct and document these discussions within EHR. They will use the ACP billing codes for billing these encounters. They will also show the patients how to have online access to the providers' notes through the EHR (mywakehhealth) and provide an access code to anyone who doesn't already have access. If, during the visit, the patient is ready to complete an Advance Directive, the provider will contact the staff member that became a notary to complete an Advance Directive right away. If, during the visit, the patient or their surrogate are not ready to fill out an Advance Directive, the provider will make a follow up visit with the patient, or if they would like to complete the document

outside of the provider's office, then information will be provided in the after visit summary (AVS) about the North Carolina Partnership for Compassionate Care who provides free notary for patients and their family members through the "GOTPLANS123" program.[57]

After the ACP visit, providers will remind participants that they will receive an email after the visit to complete the Patient engagement survey or they can complete the hard copy of the survey and mail back the survey to the research team.

Providers will complete a RedCap survey for process measures 3 to 9 months after an initial patient visit was completed. The survey will assess what is going well, what is not going well and identify any barriers (e.g. lack of confidence, lack of time, uncertainty about prognosis, fear of taking away patient's hope, impacts negatively on clinical practice/workflow) and satisfaction.

To assess adoption, we will assess what percentage of patients completed nurse navigator led pathway. We will assess what percentage of patients and their chosen decision maker (MPOA) completed a provider visit. We will assess if there were any locational differences between participants and decliners (e.g. rural vs urban)

ACP Visit scheduling and payment

The preferred method to schedule visits is to have the Nurse Navigator schedule the visits using the new visit type called Advance Care Planning. We would like this visit to be linked to the patient's Annual Wellness Visit (AWV) where providers will discuss Advance Care Planning with the patient and their family member at the beginning of the visit. There is no copay for the patient to have this type of visit.

In case the patient already had an AWV, the Nurse Navigator will schedule a separate visit with the patient's PCP to only discuss Advance Care Planning. ACP visits will require a standard copayment as per the patients' insurance requirements.

The provider will bill for the services using the new ACP codes (99497, 99498) to make these visits economically viable.

We estimate that Advance Care Planning discussions will take approximately 30-45 minutes.

Patient engagement survey

The Patient engagement survey will provide feedback about the participant's experience and level of engagement during the ACP visit. It will assess whether the patient was accompanied by their chosen decision maker and reasons why if the patient came to the visit alone, their knowledge about medical decision makers, determining the patient's goals and values, considering the type of care they would want at the end of life, the quality of the ACP visit and provider/patient communication. See Addendum.

The Patient engagement survey will be created in RedCap. Only the participants that have completed the ACP visit will need to complete the survey. Participants will have access to the survey in three ways:

- We will use a Patient engagement Email Template that will be released automatically 48 hours from the scheduled ACP visit. The email template will contain a link to the RedCap Survey. If for some reason the ACP visit was not completed, the email template will contain information for participants to disregard the email. The research staff will then update the release date in RedCap to resend the survey automatically 48 hours after the rescheduled visit. See Addendum.

- Participants can use the Patient engagement survey Information Sheet, found in their ACP Packet, with a link to the survey to complete it as soon as they get home. See Addendum.
- If a participant does not have internet access, a hard copy of the Patient engagement survey will be provide along with self-addressed stamped envelope for them to fill out and mail back to the research team.

For participants that complete the Patient engagement survey before their visit, the research staff will send them a letter explaining that the survey needs to be completed after their ACP visit with their primary care provider. The survey and a self-addressed envelope will be provided with the letter for participants to re-send the survey after their ACP visit. See Addendum for cover letter example.

If participants did not complete the Patient engagement survey two weeks from their completed ACP visit, the research staff will call the participant up to 3 times using the Patient Engagement Scrip Follow Up to see if the participant would like to complete the survey over the phone or send a hard copy of the survey by mail. If the participant cannot be reached, the research staff will send them a letter to remind patients to complete their survey. The survey and a self-addressed envelope will be provided with the letter for participants mail back. If the participants do not respond to the letter after 3 weeks, the research staff will call participants one more time to remind to complete the survey. If participants do not respond to the last call within a week, participants will be lost to follow up. See Addendum.

Participants will receive a $25 gift card after completion of their patient engagement survey, which will be mailed to them.

Provider Satisfaction

Providers that have agreed to facilitate ACP conversations with patients in the intervention group will receive a survey 3 to 9 months after an initial visit was completed to measure satisfaction and quality improvement of the intervention.

Providers will also receive a usability survey to assess usability of the New ACP Documentation tool.

End-of-life experiences

Telephone Interviews will be conducted with surrogate decision makers/caregivers of patients who passed away in the intervention and control groups. We estimated about 40 patients will pass away during our intervention phase and that only about 50% of surrogates/caregivers will agree to participate. Thus we plan to recruit up to 20 individual surrogates/caregivers whose loved one participated in the IMPACT study; up to 10 from surrogates/caregivers whose loved one completed the nurse navigator led pathway who passed away and up to 10 family members whose loved one was assigned to the "usual care" group who passed away. We will be measuring quality of end-of-life care by using the Bereavement Telephone Interview Template.[58] Surrogate decision makers/caregivers will be consented over the phone by the research staff using the Bereavement Telephone Interview Consent. Research staff will schedule telephone interviews with the Q-PRO group at Wake Forest. The Q-PRO team will use the Bereavement Telephone Interview Template to conduct interviews over the phone. Should a bereaved surrogate/caregiver become so upset during the consent or interview process, the Q-PRO team and research staff will use a Bereavement Response Statement document to mitigate the situation and will referred the participant to speak to the Research Subject Advocate if requested. Please see Addendum.

Study Timeline (see attachment)

We will roll out the study in 2 tiers. Our first tier will start with 2 sites the first month and will expand to 5 more sites the second month. Our second tier will start at about four months in, which we will expand to Downtown Health Plaza. The following table contains the time-points for administrating the study at various sites.

SITES 1 & 7*								
Measures	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7-12	Month 13-24
Consent	X	X	X	X	X	X	X	
Initial ACP discussion	X	X	X	X	X	X	X	
Schedule PCP ACP visit		X	X	X	X	X	X	
PCP ACP visits		X	X	X	X	X	X	
Patient engagement survey		X	X	X	X	X	X	
PCP RedCap Survey (2)			X	x	x	X	x	
Bereavement Survey		X	X	X	X	X	X	X
SITE 8*								
Measures	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10-12	Month 13-24
Consent	X	X	X					
Initial ACP discussion	X	X	X					
Schedule PCP ACP visit		X	X	X	X	X	X	
PCP ACP visits		X	X	X	X	X	X	
Patient engagement survey		X	X	X	X	X	X	
PCP RedCap Survey (2)			X					
Bereavement Survey		X	X	X	X	X	X	X

*Sites

1=Thomasville Family Practice Associates, Thomasville
2=Cornerstone Internal Medicine at Westchester, High Point
3=Family and Community Medicine, Asheboro
4=Claremont Family Medicine, Claremont
5=Conover Family Medicine, Conover
6=Chronic Complex Care Clinic, High Point
7=High Point Family Practice Associates, High Point
8=Downtown Health Plaza

Outcome Measure(s)

Primary Outcomes

1. **Patients' documented advance care planning discussion**
    a. Nurse Navigator-Patient telephone advance care planning discussion
        i. Documented in the newly created ACP telephone note template.
        ii. Reported as the number of discussion completed or not. Completed determines better outcome.
    b. Provider-Patient advance care planning discussion
        i. Documented in the newly created ACP note template.
        ii. Reported as the number of discussion completed or not. Completed determines better outcome.

2. **Quality of advance care planning discussions from Nurse Navigator and Provider's perspective.**
    a. Nurse Navigator and participant discussions
        i. Documented in the newly created ACP note template.
        ii. A scoring mechanism was created to measure quality of ACP discussions documented in the newly created ACP note template. Measured by score ranging from 0-8; Score of 5 or higher indicating better quality of ACP discussion and decision making.
    b. Provider and participant discussions
        i. Documented in the newly created ACP note template.
        ii. A scoring mechanism was created to measure quality of ACP discussions documented in the newly created ACP note template. Measured by score ranging from 0-15; Score of 8 or higher indicating better quality of ACP discussion and decision making.
3. **Quality of advance care planning discussions from Patient's perspective.**
    a. Measured by Quality about EOL Communication (QOC).[59]
        1. 13-item instrument with an overall score and 2 subscale scores for "general communication skills" and "communication about end-of-life care."[59] scores range from 0 ("poor") to 10 ("absolutely perfect"). Higher scores determine better outcomes.

Secondary Outcomes

1. **Advance care planning billing code usage**
    a. ACP billing codes: 99497 and 99498 usages will be recorded.

2. **Documented Designated Surrogate Decision Maker**
    a. Documented in the newly created ACP note template
    b. Measured by number of designated surrogate decision makers documented in the EHR. Documented surrogate decision maker determines better outcome.
3. **Advance Directive completion rates**
    a. Documented in an Advance Directive form.

i. Reported as the number of completed and scanned advance directive documents in the EHR. Scanned documents determine better outcome.

Exploratory Outcomes

1. **Medical Scope of Treatment (MOST) completion rates**
    a. Documented MOST form discussions
        i. Reported as the number of completed MOST discussion within the new ACP template and/or completed and scanned MOST forms into the EHR. Documented discussion in the EHR and/or Scanned forms determine better outcome.

2. **Quality of end-of life care**
    a. Measured by After-death bereaved family member interview[58]
        i. A structured interview with the caregivers of those subjects that die during the study will be conducted between 2-6 months following the study subject's death using the After-Death Bereaved Family Member Interview. The interview provides an assessment of patient-focused, family-centered care and assesses overall quality of care received. An overall rating is derived from the ratings questions, with higher score indicating best possible care

3. **Patient healthcare utilization rates and cost**
    a. Measured by the number of events: inpatient hospitalizations, emergency department (ED) visits, intensive care unit (ICU) admissions and length of stay, mechanical intubations rates, and in-hospital CPR rates measured in the EHR.
    b. Measure cost by healthcare expenditures for hospitalization and emergency room visits.
    c. Lower healthcare utilization rates and cost determine better outcome.

4. **Provider satisfaction with the intervention**
    a. Measured by the Provider satisfaction survey via Redcap.
        i. Measured by Likert scale of very satisfied, satisfied, neutral, dissatisfied, very dissatisfied; very comfortable, comfortable, not sure, uncomfortable, very uncomfortable; strongly agree, agree, undecided, disagree, strongly disagree; definitely, very probably, probably, probably not, definitely not; high priority, moderate priority, neutral, somewhat priority, low priority; always, very often, fairly many times, occasionally, never; none some quite a bit, an extreme amount. Very satisfied, satisfied; very comfortable, comfortable; strongly agree, agree; definitely, very probably; high priority, moderate priority; always, very often; none, some, determines better satisfaction.

5. **Fidelity of IMPACT study implementation**
    a. Assessed by fidelity to the model, measured by the number of protocol deviations.
    b. Less number of protocol deviations determine better outcome.
    c. We will also look at process measures to help impact future studies.
    d. Cost of IMPACT study implementation will also be measured by overall budget.

6. **Usability of the ACP Documentation Tool (ACPSmart Tool)**
    a. Measured by the System Usability Scale (SUS) survey.

i. Measured by Likert Scale of strongly disagree, disagree, neutral, agree, and strongly agree.
ii. Higher score equates higher usability.

Statistical Analyses

The primary statistical aim is the comparison of rate at which ACP discussions are documented with the EHR between the nurse-navigator and usual-care groups. We will use regression techniques for censored time-to-event outcomes to compare the time to documentation of an ACP discussion, including a frailty term (i.e. random effect, different from the clinical concept of frailty) to account for correlations between patients with the same primary care physician.[60] The advantage of a time-to-event analytic framework, versus treating documentation of an ACP discussion as a binary outcome, is that it can account for variable lengths of follow-up and account for the competing risk of death using extensions such as the popular proportional model of Fine and Gray.[61] Follow-up time for patients without documentation of an ACP discussion will be defined either as of the date of the last in-person encounter with the health system (outpatient, inpatient, or emergency department visit) or as the date of death. Analyses of secondary endpoints (completion of advanced directives, completion of Medical Orders of Scope treatment forms, utilization of ACP billing codes, and healthcare utilization) will similarly utilize a time-to-event analytic framework. One additional statistical nuance, primarily with healthcare utilization, is the potential for recurrent events, i.e. a patient with multiple ED visits. We will use extensions for time-to-event analyses that can accommodate recurrent events, such as the Mean Cumulative Count estimator [62]and the regression approach of Prentice, Williams, and Peterson. [63]

Subgroup Analysis:
We will do subset analysis looking if there are differences between those who have cognitive impairment, those of have frailty and/or functional impairments and those who have both. We will also look at differences between rural and urban setting looking at zip codes. We will also look to see if there are any differences between different racial/ethnicity groups, between gender, education, and socioeconomic status to assess any healthcare disparities. We will look at the difference between those with different co-morbidities (e.g CHF vs COPD). In addition, we will look at any differences between providers (MD, NP, PA, and Social worker) in those who completed ACP visits with the patients.

Healthcare Utilization Data
We will be using PatientPing.org to assist in getting healthcare utilization rates, particular outside of the Wake Forest Baptist Health Network for patients enrolled in the IMPACT Study. PatientPing.org is already utilized here at Wake Forest in obtaining healthcare utilization rates for patients within the ACO. This data is already being collected and a contract already exist in population health to allow for the use of this data.

Power and Sample Size Considerations

Below we present power estimates based on standard calculations for time-to-event analyses.[64] The primary nuance for estimating statistical power is the use of Zelen's pre-randomization design, whereby only patients randomized to the nurse-navigator group will be approached for consent. This naturally attenuates any presumed effect of the intervention, as a proportion of patients will not consent to receive it.[65] Since patients will be randomized prior to consent to the intervention arm, we estimated about 20%of patients will be found ineligible. Then based on a previous randomized trial of ACP strategies conducted within the Veterans Affairs system, we have assumed that 44% of patients randomized to the nurse navigator group will consent to participate.[66] Furthermore, we have assumed that the incidence of ACP discussions for patients that do not consent or those randomized to usual care will be 25%. Finally, we have assumed a follow-up period of 1 year; a) 10% of patients would be lost to follow-up b) an alpha-

level of 0.05. Based on these assumptions, with 383 patients randomized to each group, 20% of patients in the intervention arm will be found ineligible (implying an expectation that n=153 of those randomized will consent to the nurse-navigator intervention). We will have >80% power provided that the rate of documented ACP discussions is at least 60% for participants that consent to the nurse-navigator intervention (which implies an overall rate of ACP discussions of 40% in the nurse-navigator arm). If the rate of documented ACP discussions is 30% in patients that do not consent or are randomized to usual care, then at least 65% of participants that consent to the nurse navigator intervention will need to have an ACP discussion documented to have >80% power (implies an overall rate of ACP discussions of ~45% in patients randomized to the nurse-navigator arm).

Human Subjects Protection

Subject Recruitment Methods

Usual Care
No further action is required for the patients who were randomly assigned to the usual care arm.

Nurse Navigator Pathway
Nurse Navigators will receive a report of patients who were randomly assigned to the Nurse Navigator arm. The report will include: first name, last name, MRN, location, provider, payor, phone, address, city, state, zip code and whether the patient has an impairment in cognition. **The Nurse Navigators are part of the research team and they are employees of Wake Forest Baptist Medical Center, they will have access to the research team's shared drive. We will submit a request to IT so that the Nurse Navigators have clearance and access to the study drive in which reports will be uploaded. Report access will be limited to research staff only. These reports will be kept in secured computers in the secure network at Wake Forest School of Medicine and they will be password protected. In addition, Nurse Navigators already work with sensitive information in which PHI should be treated with the upmost confidentiality.**

We define impairment in cognition as patients who have one or more of the following diagnostic ICD-10 codes: Impaired cognition R41.89; Dementia F01.50, F02.81, F03.90, F02.80, G20, G31.83, G31.09, G30.0, G30.1, G30.8, G31.01, G31.09; F03.90; Memory Change: R41.3, F06.8; MCI (mild cognitive impairment) G31.84; History of memory loss Z86.59; History of short-term memory loss Z87.898. The list of patients will be divided among three Nurse Navigators to call each week.

The Nurse Navigator will call patients to discuss the study and if they are interested in participating, patients will be consented over the phone. All interested participants will go through a consent process but will not sign a form since the only contact with participants will be through the phone. Nurse Navigators will use the Nurse Navigator ACP Discussion Telephone Script to recruit and consent patients.

Of the patients who have agreed to participate and have an impairment in cognition, Nurse Navigators will perform a modified Short Portable Mental Status Questionnaire (SPMSQ)[67,68] over the phone to rule out patients with moderate to severe dementia. Patients with scores of ≥ 5 will be excluded but, unless patients had only a grade school education, then patients with ≥ 6 will be excluded.

If a patient is not able to be reached, the Nurse Navigators will attempt to call the patient every week up to 3 times, if after the 3rd time the patient is still not able to be reached, the patient will be excluded from the study and an additional patient will be recruited in their place. If the patient becomes tired during the telephone visit or doesn't have time to discuss ACP, Nurse Navigators can call them back to answer the

rest of the questions. A study information sheet and a copy of the Nurse Navigator ACP Discussion Telephone Script will be mail to consented participants with their ACP packets. See Addendum.

For those who decline to participate, we will have the nurse navigators ask:

1) Reasons for not participating, such as time, transportation, lack of interest, perceived not important, etc.
2) We will also ask them to tell us ways that would have made the study more appealing/of interest to them.

Nurse Navigator will reach out via telephone to participants who were NO shows within a week of their missed scheduled visit to assess barriers and reason for no show. They will create a telephone encounter to document their discussion. They will ask them if they would like the visit rescheduled and if yes, they will have that visit rescheduled for them and alert their primary care provider. Any participants who were NO shows for the provider visit, the nurse navigator will ask the following question:

1. "Could you please tell us a little bit more about why you were not able to attend the provider visit?" -Was it lack of time? Lack of interest? Lack of transportation? Or another reason.

Nurse Navigators will attempt to call NO shows every week up to 3 times, if after the 3rd time the patient is still not able to be reached, the patient will be lost to follow up.

Patients without willing or available caregivers/loved one are still eligible to participate in the study.

All participants (excluding caregivers/loved one) in the intervention arm will received a $25 gift card for their participation.

Provider Satisfaction

We will email out a RedCap survey up to 30 providers that have agreed to facilitated ACP conversations with patients in the intervention group. Surveys will be sent 3 to 9 months after an initial visit was completed to measure satisfaction and quality improvement. The providers that agree to complete the survey also agree to participate in the research. We will follow up with providers who have not completed the survey by mailing them a copy of the survey with a return envelope. If providers still do not complete the survey, we will follow up with a phone call.

Providers that complete the Provider RedCap Survey will be entered in a raffle for a chance to win a $100 gift card.

Providers will also receive a Usability survey via RedCap to assess the usability of the new ACP documentation tool. We will follow up with providers who have not completed the survey by mailing them a copy of the survey with a return envelope. Providers that complete the survey will enter into a raffle for a chance to win a $50 gift card.

End-of-life experiences

We will access the North Carolina Death Index to see which patients passed away between February 2019 to December 2020 for both the intervention arm (nurse navigator led pathway) and the control arm (usual care). We will identify a contact person (surrogate decision makers/caregivers) for the patients who passed away for both the intervention arm (nurse navigator led pathway) and the control arm (usual care). We will send a Bereavement Card as a recruitment strategies for caregivers that qualify to participate in the bereavement interview. Then we will reach out to them via telephone using the Bereavement

Telephone Interview Consent and will recruit up to 10 surrogate decision makers/caregivers whose loved one completed the nurse navigator led pathway and up to 10 surrogate decision makers/caregivers whose loved one was from the "usual care" group to be interviewed. All interested participants will go through a consent process over the phone but will not sign a form since the only contact with participants will be through the phone. Either the research assistant (TBT) or research manager (Keren Ferris) will complete the consent. Once consent is completed, research staff will schedule interviews to be conducted between the participants and the Q-PRO staff (Shannon Golden). The Q-PRO staff will use the Bereavement Telephone Interview Template to complete these interviews over the phone. Should a bereaved surrogate/caregiver become so upset during the consenting or interview process, the Q-PRO team and research staff will use a Bereavement Response Statement document to mitigate the situation and will referred the participant to speak to the Research Subject Advocate if requested. See addendum.

For the timing of the telephone interview, we will try and complete between two to six months after the patient has passed way. We want the loved one's death to be a recent experience, but we do not want to disturb the close relatives in the most acute mourning process. We feel that 2 to 6 months after the loved one's death the participants will of course be sad due to their loss but not in the acute mourning phase and the death will be recent enough that they will remember their end-of-life experiences.

All participants who complete the interview will receive a $50 gift card for participating.

Informed Consent

Intervention Arm
A waiver of the requirements for signed informed consent is requested for the intervention arm of the study. A telephone script will be used to consent over the phone prior to initiating an ACP discussion over the phone. A study information sheet will be mail to participants along with ACP packets. The principal risk would be potential harm resulting from a breach of confidentiality; also the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. Please see addendum for copies of the telephone script and study information sheet.

Control Arm
A full waiver of consent is requested for the control arm of the study. Patients who were randomized to the control arm of the study will not be contacted and will not participate in any study related activity. The principal risk would be potential harm resulting from a breach of confidentiality. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Providers and Surrogate decision makers/caregivers
A waiver of the requirements for signed informed consent is requested for the providers and surrogate decision makers/caregivers participants.

The email containing the link to the RedCAP survey and the RedCap survey for providers will contain consent language. The providers that agreed to complete the survey also agree to participate in the research. A provider information sheet will be attached to the email sent to providers. See addendum for copies of the provider email and provider information sheet. The principal risk would be potential harm resulting from a breach of confidentiality; also the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

A Bereavement Telephone Interview Consent will be used to consent surrogate decision makers/caregivers over the phone. Surrogate decision makers/caregivers that agreed to participate in the bereavement interview are consenting to participate in the research. Please see addendum for copies of the Bereavement Telephone Interview Consent and Bereavement Telephone Interview Template. The principal risk would be potential harm resulting from a breach of confidentiality; also the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Confidentiality and Privacy

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 1 year 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.

Data and Safety Monitoring

The principal investigator will be responsible for the overall monitoring of the data and safety of study participants. The principal investigator will be assisted by other members of the study staff.

Reporting of Unanticipated Problems, Adverse Events or Deviations

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.

Appendix

A. Short Portable Mental Status Questionnaire (SPMSQ)
B. Nurse Navigator ACP Discussion Telephone Script
C. Nurse Navigator Telephone Script Reminder No-Show Calls
D. New ACP note template for Nurse Navigators
E. New ACP note template for Providers
F. Study Information Sheet-Intervention
G. Study Information Sheet-Provider
H. Provider RedCAP email
I. Provider RedCAP Survey
J. ACP Packets includes the following
    a. Copy of the North Carolina Advance Directive
    b. Copy of the Patient engagement survey
    c. Copy of Study Information Sheet-Intervention
    d. Copy of the Nurse Navigator Verbal Consent
    e. Compensation Letter
    f. W9 form
    g. Self-addressed stamped envelope to mail the advance directive and Patient engagement survey
K. Patient engagement survey, including Quality of EOL communication (QOC)
L. Patient engagement survey Information Sheet
M. Patient engagement Email Template
N. Patient engagement Telephone Script Follow Up
O. Bereavement Telephone Interview Consent
P. Bereavement Telephone Interview Template, including After-death bereaved family member interview.
Q. Bereavement Response Statement
R. eFI
S. Scoring Sheet for measuring quality of advance care planning discussions from Nurse Navigator and Provider's perspective.
T. Patient engagement survey letter—before visit
U. Patient engagement survey letter—after visit
V. Appointment Reminder postcard
W. Missed Clinic Appointment postcard
X. Thank You for your Participation postcard
Y. Usability Survey
Z. Bereavement Card

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