Clinical Interventional Study Protocol Template

PREFACE

The Clinical Intervention Study Protocol Template is a suggested format for clinical trials sponsored by the National Institute on Aging (NIA). Investigators are encouraged to use this format, as appropriate, when developing protocols for their studies. Large multi-site observational studies will also benefit from this protocol template.

Note that instructions and explanatory text are indicated by italics and should be replaced in your protocol with appropriate text. Section headings and template text formatted in regular type should be included in your protocol document as provided in the template.

The goal of this template is to provide a general format applicable to all single- and multicenter clinical intervention trials (e.g., drug, surgery, behavioral, nutritional, device, etc.).

As you can see the version number and date are on the bottom of each page. When making changes to an approved and "final" protocol, please provide a summary of the changes, with the date, at the front of the protocol.

EFFECT OF AN ADVANCE CARE PLANNING INTERVENTION ON DOCUMENTATION OF ADVANCE DIRECTIVE ORDERS

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Study Title

Effect of an Advance Care Planning Intervention on Documentation of Advance Directive Orders

Objectives

The primary objective of this embedded, pragmatic, cluster-randomized trial (ePCT) is to test the effects of an advance care planning (ACP) intervention on documentation of do-not-resuscitate (DNR) orders in a target cohort of assisted living community (ALC) residents with dementia from 160 ALCs in FL, MN, and WI.

We will also be conducting semi-structured interviews with Bluestone clinicians and staff from 18 ALCs, to describe: (1) the ACP process with ALC patients and their families, and how changes in advance directives are communicated to ALC staff; (2) impressions of the ACP intervention; and (3) challenges to honoring resident advance directives in the ALC setting

Design and Outcomes

ALC residents who are "full code" or do not have a documented code status in their electronic health record (EHR) at baseline will be randomly assigned to Usual care or ACP informational packet and video sent electronically to resident or proxy.

The primary clinical outcome will be the proportion of residents with DNR orders in the EHR at the end of four months followup. Secondary clinical outcomes will be: proportion of residents with do-not-hospitalize (DNH) orders in the EHR at the end of four months followup; proportion of residents with Medicare CPT billing code for ACP during the four months followup; and proportion of enrolled residents with any hospitalizations over four months (outcome available for FL ALCs only). Implementation outcomes include counts of emails sent and video views.

Interventions and Duration

ALCs recruited for the study share a common clinician service group, Bluestone Physician Services (Bluestone). Bluestone delivers 800-900 physician visits per day, including urgent care and COVID-19 testing. Delivery of the intervention leverages a component of Bluestone's EHR infrastructure, an online portal used to share resident clinical updates with family members, ALC staff, and other members of the resident's care team (hospice, home health, etc.). This ePCT has two arms: usual care or ACP information .

ACP Information:
Patient centered medical home (PCMH) specialists at Bluestone will determine who is the correct person to receive the informational materials. If the patient is the correct recipient, Bluestone will deliver the informational materials to the resident at the ALC. If

the proxy is the correct recipient, the PCMH specialist will determine whether or not the proxy is using the existing online portal. If the proxy is using the portal, the informational materials will be sent electronically. If the proxy does not access the portal, the informational materials will be sent to their residences.

The informational materials include an email with a link to a video highlighting the goals of care and their relationship to common treatment decisions including resuscitation, hospitalization, antibiotic use, and feeding tubes. For patients and proxies who are not using the online portal, a cover letter and brochure with the same information contained in the video will be mailed. Materials will be available in English and Spanish.

Usual Care: ALC patients and proxies randomized to the usual care arm have ACP discussions with a clinician at admission, annually, and sometimes with a hospitalization or other change in condition. There is no standardized decision- or conversation-support tools used to have these discussions.

Sample Size and Population

Based on baseline Bluestone data, for the 100 already randomized facilities, we expect 54% of residents in the control arm will have a DNR order at the end of 4-months followup. Based on the same data, we estimated an ICC of 0.012. Assuming a conservative ICC of .02, to achieve a power of .80, we need 71 ALCs per arm with 10 PLWD in each to demonstrate an 8-percentage point increase in DNR orders, such that information outreach would result in 62% of these residents having a DNR order at the end of 4-month follow-up.

For the additional 60 facilities, we expect only 26% of the residents in the control arm will have DNR order at the end of 4-months follow-up based on baseline Bluestone data (similar ICC to previously randomized facilities). Assuming a conservative ICC of .02, to achieve a power of .80, we need 79 ALCs per arm with 10 PLWD in each to demonstrate a 7-percentage point increase in DNR orders, such that information outreach would result in 33% of these residents having a DNR order at the end of 4-month follow-up.

We will add 30 ALCs to the existing 50 ALCs per arm, resulting in 80 ALCs per arm. We will be able to detect between a 7- and 8-percentage point change in documentation of DNR orders in the EMR. Our primary approach will be an intention-to-treat (ITT) analysis.

STUDY TEAM ROSTER

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1 STUDY OBJECTIVES

1.1 Primary Objective

The primary objective of this embedded, pragmatic, cluster-randomized trial (ePCT) is to test the effects of an advance care planning (ACP) intervention on documentation of do-not-resuscitate (DNR) orders in a target cohort of assisted living community (ALC) residents with dementia from 160 ALCs in FL, MN, and WI.

1.2 Secondary Objectives

The secondary objective is to use semi-structured interviews with Bluestone clinicians and staff from 18 ALCs to describe: 1) the virtual ACP process with ALC residents and their families, and how changes in advance directives are communicated to ALC staff; (2) impressions of COVID-specific ACP intervention; and (3) challenges to honoring resident advance directives during the coronavirus pandemic.

2 BACKGROUND AND RATIONALE

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

Assisted living communities (ALCs) serve over 800,000 vulnerable older adults at high risk of developing complications and dying from COVID-19. Most ALC residents are 85 years of age or older and require assistance with bathing and dressing. Over 80% of ALC residents have three or more chronic conditions, and ALC and long-stay nursing (NH) residents have similar rates of diabetes, chronic obstructive pulmonary disease (COPD), and heart failure. Up to 70% of ALC residents have Alzheimer's Disease and Related Dementias (ADRD). In normal times, 43% of ALC residents are transferred in the last 30 days of life and 16% die in hospital. However, ALC residents with dementia and other comorbid conditions are especially susceptible to the most serious respiratory complications of COVID-19, and the least likely to benefit from hospital level care.

Unlike nursing homes, ALC residents contract separately for most medical services, which are delivered by external provider groups. Bluestone Physician Services, an existing partner under the National Institute on Aging IMPACT Collaboratory (U54AG063546), provides medical services in approximately 1,000 ALCs across three states (MN, WI, and FL). In the face of the coronavirus pandemic, Bluestone has rapidly transitioned from an on-site population health management model to remote care delivery. Bluestone is delivering 800-900 virtual physician visits per day, including urgent care and COVID-19 testing.

Documenting preferences in the form of an advance directive or medical order, reduces receipt of unwanted care. In the face of the current pandemic, it is critically important to optimize advance care planning (ACP) and documentation of advance directives. ALC residents and their proxies must understand the course of COVID-19, treatment options if complications develop, and potential outcomes of these treatment options to make informed choices about their advance directives, particular as they relate to their preferences for hospital transfer and artificial ventilation.

2.2 Study Rationale

A major long-term care priority in response to COVID-19 is increased use of resident advance directives. Despite an overwhelming patient and caregiver preference for comfort-focused end-of-life care, 43% of ALC residents are transferred in the last 30 days of life and 16% die in hospital. In the face of COVID-19, Bluestone understands the urgent need to increase advance directive ascertainment and documentation in their ALCs, particularly for their most vulnerable residents, such as the 69% of their residents with dementia. Bluestone is unique among ALF providers in that it has an integrated electronic health record (EHR) with a HIPAA-compliant feature that allows its physicians to communicate information about residents to family members, ALC staff, and other members of the resident's care team. Bluestone's EHR data contain detailed information on resident physical and cognitive function, chronic conditions (including dementia diagnoses), and documentation of advance directives. We will leverage this infrastructure to conduct a 1-year trial of an ACP intervention directed toward residents and families of ALC residents with dementia.

3 STUDY DESIGN

This is a one year, embedded, pragmatic cluster-randomized trial (ePCT). ALCs will be randomly assigned to Usual care or ACP informational website and video sent electronically to family members. Stratifying by state and balancing on baseline use of DNR orders, number of Bluestone residents in the ALC, and resident clinical characteristics, a Brown statistician will randomize 160 ALCs to the intervention or control study arms (80 ALCs per arm).

Information materials include an email (Appendix A) with a link to a video describing resident goals of care and instructions for documenting treatment preferences in the form of advance directives or medical orders (Appendix B). When patients or proxies are not using the online portal, a letter and brochure reflecting the same content as the video will be sent to their residences. The materials were developed by Susan Hickman, Kathleen Unroe and colleagues at Indiana University. Dr. Hickman has agreed to modify their materials for the purposes of the study.In addition, all Bluestone clinicians will receive training (Appendix C) and a tailored conversation guide to help structure conversations with patients or proxies, when appropriate (Appendix D).

Residents and family members of eligible residents in ALCs randomized to the usual care arm have ACP discussions with a clinician at admission, annually, and sometimes with a hospitalization or other change in condition. There is no standardized decision- or conversation-support tools used to have these discussions. Clinicians will engage PLWD in advance care planning discussions as they would in usual care.

The primary clinical outcome will be the proportion of residents with DNR orders in the EHR at the end of four months followup. Secondary clinical outcomes will be: proportion of residents with do-not-hospitalize (DNH) orders in the EHR at the end of four months followup; proportion of residents with Medicare CPT billing code for ACP during the four months followup; and proportion of enrolled residents with any hospitalizations over

four months (outcome available for FL ALCs only). Implementation outcomes include counts of physician calls with family members and counts of website and video views. We plan to enroll approximately 3,000 patients and/or their proxies.

Our partner health care systems will know which ALCs are randomized to each arm. Brown University statistician and data management staff will present aggregated post-random assignment comparisons of intervention and control facilities' baseline characteristics, but these preliminary analyses will be not generated at the individual facility level. Drs. Mitchell and McCreedy will be blinded. ALC assignment will be unblinded to the DSMB members at their request.

We will also be conducting semi-structured interviews with Bluestone clinicians and staff from 16 ALCs, to describe: 1) the ACP process with ALC patients and their families, and how changes in advance directives are communicated to ALC staff; (2) impressions of the ACP intervention; and (3) challenges to honoring resident advance directives in the ALC setting

4 SELECTION AND ENROLLMENT OF PARTICIPANTS

4.1 Inclusion Criteria

The unit of random assignment will be the ALC and the unit of analysis the resident, clustered within the ALC. We will use Bluestone's EHR data to identify eligible ALCs. Eligible ALCs will have at least 10 patients with a dementia diagnosis (ICD-10) who are not on hospice and do not have orders for comfort care or DNH at baseline.

4.2 Exclusion Criteria

ALCs with less than 10 patients with a dementia diagnosis (ICD-10) who are not on hospice and do not have orders for comfort care only or DNH baseline will be excluded from the study. Further, Bluestone may exclude ALCs prior to randomization based on knowledge of competing ACP initiatives or any other concerns about their relationship with the ALC.

4.3 Study Enrollment Procedures

This is an ePCT in which Bluestone will be responsible for enrolling participants. We are asking for a waiver of informed consent on Bluestone's behalf. Per 45 CFR §46.116 f 3 (i-v), we believe that:

(i) The research involves no more than minimal risk to the subjects; The only risk to the broad group of individuals for whom we are requesting the EHR data is the risk of breach of confidentiality and we have described our security procedures for minimizing this risk. We also believe there is minimal risk to the subset of individuals who will be subjected to the intervention itself. The intervention will consist of three arms - a control arm (usual care); treatment arm 1 where eligible residents in ALCs randomized to the information arm will receive a letter from their Bluestone physician with links to an informational website and advanced care planning (ACP) video sent through the online portal; and treatment arm 2 where eligible residents will receive the same outreach letter from their Bluestone physician with links to the informational website and video in addition to a follow-up phone call by their Bluestone physician to have a structured conversation about

ACP with families. ACP is something that is routinely discussed between physicians and patients and their caregivers. This intervention, which examines the effectiveness of two modes of delivery for the discussion compared to usual care, does not increase the level of risk beyond what an individual would encounter in usual care.

(ii) The research could not practicably be carried out without the requested waiver or alteration; There is no need for the research team to have contact with study subjects for this study. Recruitment and selection can be done passively through the use of EHR and the physician offices will be sending the letters and making the clinical phone calls in the two treatment arms directly. It would not be practicable to contact individuals for informed consent.

(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 data could not practicably be sent to the research team without identifiers because we will be following individuals over time and must be able to link their information longitudinally. In addition, we must be able to identify EHR records within specific locations in order to recruit facilities as well as tell physicians which patients to include in the intervention.

(iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and We do not believe the waiver or alteration will adversely affect the rights and welfare of the subjects. The physicians who will be involved in the intervention already have access to the patients' EHR for routine clinical care purposes and will be reaching out to them as they would in regular practice. Patients are free to ignore the informational letter and not engage with the physician in an ACP discussion. The EHR data used will be will be securely stored and kept confidential. Direct identifiers will be removed by Brown Center for Gerontology and Health Care Research IT Director and replaced with study IDs prior to release to the study team for analysis. All results will be presented in aggregate. No individual information will be released.

(v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation. We will provide Bluestone with copies of reports and manuscripts that result from this project. they are free to share information with their clinicians and facilities. The clinicians and facilities are free to share the information with interested families and patients.

For the process evaluation, will ask Bluestone leadership to nominate eight physicians to participate in semi-structured interviews. The research assistant will contact the physicians recommended by corporate leadership, explain the study, and provide an opt-out for participation. We will use the baseline EHR data to identify eight ACLs (one for each physician interviewed) with varying baseline AD use. Bluestone leadership and/or the physician working in the ALC will approach the director to ask if s/he would participate in an interview. The director will nominate a member of the direct care staff for interview.

5 STUDY INTERVENTIONS

5.1 Interventions, Administration, and Duration

Delivery of the intervention leverages a component of Bluestone's EHR infrastructure, an online portal used to share resident clinical updates with family members, ALC staff, and other members of the resident's care team (hospice, home health, etc.). This ePCT has two arms: usual care and ACP information.

Information Only:
Patient centered medical home specialists at Bluestone will determine who is the correct person to receive the informational materials. If the patient is the correct recipient, Bluestone will send the informational materials to the resident at the ALC. If the proxy is the correct recipient, the clinical assistant will determine whether or not the proxy is using the existing online portal. If the proxy is using the portal, the informational materials will be sent electronically. If the proxy does not access the portal, the informational materials will be sent to their residences.

The informational materials include an email with a link to a video highlighting the goals of care and their relationship to common treatment decisions including resuscitation, hospitalization, antibiotic use, and feeding tubes. For patients and proxies who are not using the online portal, a cover letter and brochure with the same information contained in the video will be mailed. Materials will be available in English and Spanish.

Usual Care: ALC patients and proxies randomized to the usual care arm have ACP discussions with a clinician at admission, annually, and sometimes with a hospitalization or other change in condition. There is no standardized decision- or conversation-support tools used to have these discussions.

5.2 Handling of Study Interventions

Our partner, Bluestone, will know which ALCs are randomized to each arm. Brown University statistician and data management staff will present aggregated post-random assignment comparisons of intervention and control facilities' baseline characteristics, but these preliminary analyses will be not generated at the individual facility level. Drs. Mitchell and McCreedy will be blinded. ALC assignment will be unblinded to the DSMB members at their request.

5.3 Concomitant Interventions

This is a pragmatic study. It is possible that ALCs enrolled in this study may be participating in other ACP interventions. We do not expect participation in competing interventions will differ between treatments and control arms. When Bluestone is aware of such interventions, they may choose to exclude ALCs prior to randomization. It is also possible that Bluestone physicians may work in ALFs randomized to different study arms. We will work to limit this contamination through the randomization process. We expect the effect of this potential contamination to be limited as clinical assistants will

only send informational materials to patients randomized to the information only arm and physicians will only call patients / proxies whom they are instructed to call.

5.4 Adherence Assessment

Adherence outcomes include number of emails sent to patients / proxies and the number of clicks to follow links for informational website or video, and number of patients / proxies.

6 STUDY PROCEDURES

There will be 80 ALCs in each study arm. The outcome follow-up time for this intervention is four months. If the outreach intervention works, we expect orders to change shortly after the physician and patients or proxies have a discussion.

6.1 Schedule of Evaluations

Table 1. Project Timeline

		2021												2022		
Workgroup	**Task**	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**	**Jan**	**Feb**	**Mar**
Data	Ongoing transfers of EHR data to Brown	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Data	ALC eligibility and randomization	X	X	X							X					
Data	Ongoing eligibility list transfer from Brown to Bluestone	X	X	X	X	X	X	X	X	X	X					
Aim 1	Finalize intervention materials	X	X	X												
Aim 2	Finalize interview guides				X	X										
Aim 2	Identification of providers and AL staff for interviews					X	X									
Aim 1	Intervention roll-out: rolling study enrollment, 4-month follow-up			X	X	X	X	X	X	X	X	*	*			
Aim 1	Intervention roll-out to newly added facilites, 4-month follow-up										X	*	*	*	*	
Aim 2	Process evaluation interviews							X	X	X						
Aim 2	Transcribe interviews									X	X	X				
Aim 2	Analyze interviews											X	X			
Aim 1	Unblinding and evaluation of study primary & secondary outcomes											X	X	X	X	
Aim 1 & 2	Dissemination of results														X	X

6.2 Description of Evaluations

6.2.1 Screening Evaluation

Consenting Procedure

We are requesting a waiver of informed consent per 45 CFR §46.116 f 3 (i-v). Please see section 4.3 for details.

6.2.2 Enrollment, Baseline, and/or Randomization

Enrollment

This is a pragmatic trial. Using Bluestone's EHR, research staff will identify potentially eligible ALCs which have at least 10 residents with a dementia diagnosis (ICD-10) who are full code or missing code status at baseline. Bluestone will enroll ALCs. Bluestone will have discretion to exclude potentially eligible ALCs prior to randomization based on information on competing interventions or other relationship characteristics with ALC.

Randomization

Stratifying by state and balancing on baseline use of advance directives, number of Bluestone residents in the ALC, and resident clinical characteristics, a Brown statistician will randomize 160 ALCs to the intervention or control study arms (80 ALCs per arm).

6.2.3 Follow-up Visits

There will be no direct follow-up for residents / proxies in ALCs randomized to usual care or information only study arms.

6.2.4 Completion/Final Evaluation

There are no completion, final evaluations. Outcomes will be evaluated using EHR data

7 SAFETY ASSESSMENTS

7.1 Adverse Events and Serious Adverse Events

Adverse Event (AE) Definition: AE is any untoward or unfavorable medical occurrence in a human study participant, including any abnormal sign (e.g. abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the participants' involvement in the research, whether or not considered related to participation in the research.

AEs for this study include:

The potential AEs that could occur during this trial are negative emotional reactions when patients or family members watch ACP video or talk to a clinician about resident care preferences. Negative emotional reactions may include feelings of anxiety, worry or sadness. Negative emotional reactions resulting from watching the ACP video or talking to a clinician about resident care preferences would be classified as mild because the distress is easily tolerated and/or remediated, requires no medical evaluation, and has signs and symptoms that are transient. An immediate, negative reaction to watching the video or having a conversation with a clinician would fit the study relatedness category "Definitely Related." AEs resulting from negative emotional reactions to the intervention are expected but likely rare. Our prior testing of a similar ACP video in a nursing home population with dementia demonstrated high user acceptability and few negative emotional responses. We believe the intervention does not incur any greater distress than usual ACP practices.

Serious Adverse Events (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:

No serious adverse events (SAEs) are expected, as this intervention does not contain any components with the potential to be life threatening, require or prolong hospitalization, cause persistent or significant disability or incapacity, or result in congenital anomalies or birth defects.

7.1.1 Reporting Procedures

Process for identifying AEs and SAEs:

As part of Bluestone clinician training, instructions will be given as to what constitutes an AE / UP and how to report potential AEs / UPs to study staff. Bluestone clinicians will be instructed to offer to end a conversation, or have a conversation at another time, if a resident or proxy seems to be experiencing emotional distress as a result of their discussion. The Bluestone staff should report any potential AEs / UPs to the study project manager within one day of the event by calling or emailing the study project manager

(contact information provided during training). All potential AEs / UPs will be investigated and a Event Reporting Form will be completed and submitted to the PI via email within 24 hours of the project manager becoming aware of the event. Similarly, contact information for the study project manager will be provided at the end of the outreach letter. All potential AEs / UPs reported by study participants will be investigated and a Event Reporting Form will be completed and submitted to the PI via email within 24 hours of the project manager becoming aware of the event.

7.1.2 Follow-up for Adverse Events

Upon receipt of the Event Reporting Form, the PI and Dr. Sandra Shi complete the Event Verification Form. Dr. Shi is a co-investigator on the project and a board-certified geriatrician with ACP experience. Specifically, the PI and Dr. Shi will review the details of the event, confirm that the event meets criteria for a true AE / UP, and classify the severity, expectedness, and relatedness of the event.

During verification, if it is determined that the event does not meet the criteria for a true AE / UP, the Event Reporting Form and the Event Verification Form will be retained by the study team, and no further action will be taken. During verification, if it is determined that the event meets the criteria for a true AE / UP, we will follow the reporting schedule detailed below.

During verification, if it is determined that the event is a true AE, the Event Reporting Form and the Event Verification Form will be retained for quarterly reporting of AEs to the Safety Officer (SO), the NIA Program Officer, and the IRB. A summary of AEs will be included in the annual DSMB report.

During verification, if it is determined that the event is a true UP, the PI will notify the safety officer, the SO, the NIA Program Officer, the Office for Human Research Protections, and the IRB within 24 hours of the research team becoming aware of the event (within 48 hours of the event occurring). The Event Verification Form will also be used to capture the follow-up status of a resident who has experienced a UP. The Event Reporting Form and the Event Verification Form will be retained and a summary of UPs will be included in the annual DSMB report.

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7.2 Safety Monitoring

8 INTERVENTION DISCONTINUATION

We do not include stopping rules for two reasons. First, this is a minimal risk study for which AEs will be rare. Second, a stopping rule would not be very feasible since the implementation period is less than one year– which means that interim data analyses will be difficult, if not impossible, to perform until the intervention is nearly complete.

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9 STATISTICAL CONSIDERATIONS

9.1 General Design Issues

The primary objective of this embedded, pragmatic, cluster-randomized trial (ePCT) is to test the effects of a COVID-specific, advance care planning (ACP) intervention on documentation of do-not-resuscitate (DNR) orders in a target cohort of assisted living community (ALC) residents with dementia from 160 ALCs in FL, MN and WI.

ALC residents with dementia who are full code or missing code status at baseline will be randomly assigned to usual care or to receive ACP informational website and video sent electronically to patients / proxies .

The primary clinical outcome will be the proportion of residents with DNR orders in the EHR at the end of four months followup. Secondary clinical outcomes will be: proportion of residents with do-not-hospitalize (DNH) orders in the EHR at the end of four months followup; proportion of residents with Medicare CPT billing code for ACP during the four months followup; and proportion of enrolled residents with any hospitalizations over four months (outcome available for FL ALCs only). Implementation outcomes include counts of emails and video views.

9.2 Sample Size and Randomization

Table 2 presents the number of ALCs per study arm required to detect varying levels of prevalence of DNR orders in the treatment arm for the 100 ALCs already randomized to the Information Only or Control study arms, assuming α=.05, β=.20, and several values of the intra-class correlation coefficient (ICC). Based on baseline Bluestone data, we expect 54% of residents in the control arm will have a DNR order at the end of 4-months followup. Based on the same data, we estimated an ICC of 0.012 from the random intercept logistic model.[4] Assuming a conservative ICC of .02, to achieve a power of .80, we need 71 ALCs per arm with 10 PLWD in each to demonstrate an 8-percentage point increase in DNR orders, such that information outreach would result in 62% of these residents having a DNR order at the end of 4-month follow-up.

Table 1. Number of ALCs required per study arm at varying effect sizes and values of the intra-class correlation coefficient (10 residents per cluster, **54% DNR among controls**)

	Intraclass Correlation Coefficient (ICC)				
Effect in Treated	0.010	0.015	0.020	0.025	0.030
0.60	117	121	126	131	136
0.61	85	89	92	96	99
0.62	65	68	71	73	76
0.63	51	53	56	58	60
0.64	41	43	45	47	48

In the additional 60 facilities, we expect only 26% of the residents in the control arm will have DNR order at the end of 4-months follow-up based on baseline Bluestone data (similar ICC to previously randomized facilities). Assuming a conservative ICC of .02, to achieve a power of .80, we need 79 ALCs per arm with 10 PLWD in each to demonstrate a 7-percentage point increase in DNR orders, such that information outreach would result in 33% of these residents having a DNR order at the end of 4-month follow-up (Table 3).

Table 3. Number of ALCs required per study arm at varying effect sizes and values of the intra-class correlation coefficient (10 residents per cluster, **26% DNR among controls**)

	Intraclass Correlation Coefficient (ICC)				
Effect in Treated	0.010	0.015	0.020	0.025	0.030
0.32	98	102	106	110	114
0.33	73	76	79	82	85
0.34	56	59	61	63	65
0.35	45	47	49	50	52
0.36	37	38	40	41	43

We will add 30 ALCs to the existing 50 ALCs per arm, resulting in 80 ALCs per arm. We will be able to detect between a 7- and 8-percentage point change in documentation of DNR orders in the EMR.

9.2.1 Treatment Assignment Procedures

Stratifying by state and balancing on baseline use of advance directives, number of Bluestone residents in the ALC, and resident clinical characteristics, a Brown statistician will randomize 160 ALCs to the intervention or control study arms (80 ALCs per arm).

9.3 Interim analyses and Stopping Rules

There will be no interim analysis and we do not include stopping rules for two reasons. First, this is a minimal risk study for which AEs will be rare. Second, a stopping rule would not be very feasible since the implementation period is less than one year– which means that interim data analyses will be difficult, if not impossible, to perform until the intervention is nearly complete.

9.4 Outcomes

9.4.1 Primary outcome

The primary clinical outcome will be the proportion of residents with DNR orders in the EHR at the end of four months followup.

9.4.2 Secondary outcomes

Secondary clinical outcomes will be: proportion of residents with do-not-hospitalize (DNH) orders in the EHR at the end of four months followup; proportion of residents with Medicare CPT billing code for ACP during the four months followup; and proportion of enrolled residents with any hospitalizations over four months (outcome available for FL ALCs only).

Implementation outcomes include counts of emails sent to patients/proxies and counts of website and video views.

9.5 Data Analyses

Our primary approach will be an intention-to-treat (ITT) analysis. Last observed advance directive status will be used for residents who are censored due to death or discharge after 2 months followup. Model specifications are based on Donner & Klar for cluster randomized controlled trials where Y_{ij} is the advance directive status for resident i from ALC j, and $logit(P(Y_{ij} = 1)) = \mu_{ij}$, where $\mu_{ij} = \mu + \alpha I_{ij} + \sum_{l=1}^{L} \gamma_{ijl} X_{ijl} + u_j$. We define $u_j \sim N(0, \sigma_u^2)$ as the conditional effect of ALC j on the logit scale, X_{ijl} are individual-level covariates, γ_{ijl} are unknown parameters, I_{ij} is an indicator for intervention arm membership, and α is the conditional treatment effect.

10 DATA COLLECTION AND QUALITY ASSURANCE

10.1 Data Collection Forms

We will be receiving data from three pieces of Bluestone's integrated health information system: the primary EHR; the specialized Bridge interface with families and the care team; and the individual level capture of hospitalizations (FL ALCs only). Brown has an existing partnership with Bluestone [U54AG063546], for which we developed a Data Use Agreement. As we have done in previous trials, Bluestone IT staff will place a new copy of the data package in a SharePoint location each month. Brown IT staff will download the data into our secure environment, apply study identifiers, and create analytic data sets.

Specific data elements available from the EHR include:

- Resident and ALC identifiers
- Active diagnosis codes (ICD-10)
- Functional and cognitive status assessments
- Physician orders (treatments, diagnostic tests, etc.)
- Medication orders
- Advance directives / code status (full code, DNR, DNH, DNI, preference for comfort care)
- COVID testing results
- Hospitalizations (emergency department, ED, and observation stays, inpatient)

10.2 Data Management

Brown University's Center for Gerontology and Health Care Research (CGHCR) will serve as the Data Management/Statistical Center for the study. The CGHCR will be responsible for: receiving all person-level data from NHs, linking all data sources, creating analysis files, and conducting analyses.

The CGHCR will receive person-level data from Bluestone's EHR. To protect resident confidentiality, the corporation will place their data in a SSH secure server and will provide login information to the CGHCR. Data transfer to CGHCR secure servers will be via SFTP protocol with password protection. Once the files have been uploaded to the CGHCR servers, they will be stored, unmodified, in a secure file location specific to these uploads. They will then be read into SAS datasets, one per file type. The CGHCR will then notify the ALC system that the data were successfully downloaded and extracted, at which point the ALC systems will remove the data from their servers. All data files will be accompanied by a manifest detailing the number of distinct persons and records expected in them. The CGHCR will connect to the corporation servers on a monthly basis. The CGHCR's information systems manager will be in charge of the data transfer, and he will replace the HICs and SSNs fields with a Brown University-generated identification number (throughout our different data sources) to allow linkage of data for analytic purposes.

We maintain numerous confidential databases and have a high level of security built into our computing system. The computing infrastructure consists of a VMS cluster, which houses all substantial data, a group of Windows servers that provide computing services and infrastructure support for client systems, and client Windows PCs through which all users access our systems. Network security is provided by a combination of firewalls, local network access controls, and continuous auditing and monitoring for security breaches. All access from systems external to the LAN is limited to encrypted channels (e.g., SSL for VMS terminal sessions or VPN connections for LAN file sharing access). Unencrypted access is provided only for the CGHCR external Web site and general e-mail support functions. The VMS cluster acts as a file server for Windows clients, and file access controls are consistently applied whether access is from the VMS or Windows environment.

Security within the system is applied via Access Controlled Entries (ACEs) attached to all files on all systems. Security is applied uniformly to all files within a subtree of any file system, with the general rule that groups of users sharing a common task may read each other's files but, in most cases, not write to each other's files. VMS provides a highly-secure programming environment with ACEs applied to all objects and extremely controlled access to the larger system for individual users, as well as a versioning file system, secure batch queues and distributed processing, and efficient backup and recovery procedures. Windows clients are limited to a subset of these services (e.g., there is no way for file version information to be shown to Windows clients), but otherwise access is secured as for any other method of accessing data.

Personally- and partially-de-identified data are housed in files that are restricted to systems management or to programmers who have been identified as custodians. No data are ever moved to more "public" spaces without identification information being stripped

or non-reversibly encoded. Encoding is generally done via fairly large Roman cyphers applied iteratively to the original character string. No reverse encoding is ever generated nor maintained. Any matching between personally-identified data sources is done within a secured area prior to any data being exported. Windows servers that house partially de-identified data have matching ACEs applied so that access restrictions are applied consistently with VMS-based data.

Since we use demographic covariates for many of our analyses, even the encoded data are best considered partially de-identified. ACEs restrict access to all data housed by CGHCR, such that access to any data elements on the servers is limited to those staff authorized to make such access. Authorizations are, in turn, granted by the core system's support staff upon request from a PI or other appropriate data owner. All users authorized to access CGHCR systems have access to some storage that is considered "general file sharing" but, by convention and policy, all individual or otherwise restricted data is prohibited from being stored on such space. Desktop systems are authorized to specific users, and it is assumed that they will store data they are authorized to work with on such local systems. The LAN is switched, yielding a reasonable amount of security between clients and servers within the LAN. Desktop systems are required to run current anti-virus software and are prohibited from running local file-sharing software. External analyses are run periodically to verify the security of systems within the LAN.

Similarly, the Windows servers which support the LAN are configured as a local, isolated, secure, collapsed AD forest local to our LAN. DNS, DHCP, and other critical services are secured within the context of the local forest and are not accessible externally (with the exception, of course, of VPN or RDP access from authorized client systems). Extensive monitoring is done from the VMS cluster to ensure the health and stability of the Windows forest structure, and the individual servers within it.

In summary, CGHCR’s VMS computer system is highly secure and accessible only to authorized users. Within the group of authorized users, access to project data is restricted to individuals who are authorized to work on that specific research project. Access to identifiers is further restricted to the systems manager alone. Furthermore, CGHCR employees have signed an oath of confidentiality, and its violation is sufficient grounds for immediate termination.

10.3 Quality Assurance

10.3.1 Training

Clinicians will receive training (Appendix C) and a tailored conversation guide to help structure conversations with patients or proxies, when appropriate (Appendix D).

10.3.2 Monitoring

The NIA IMPACT Collaboratory DSMB will oversee all data and safety monitoring activities for this study. The number of DSMB members will be determined by NIA, and one will be designated the Chairperson. DSMB members will be appointed by the NIA Director. This DSMB will act in an advisory capacity to the NIA Director to monitor participant safety, to evaluate the progress of the study, and to review

procedures for maintaining the confidentiality of data, the quality of data collection, management, and analyses. Advarra IRB will conduct the ethical review required for the protection of human subjects or else make an exempt determination. NIA PO, in consultation with DSMB chair, will make a determination regarding the level and format of data and safety monitoring this study requires, i.e., full DSMB oversight or monitoring by an independent SO. Lynn Mcnicoll, MD, has agreed to serve as the SO for this study.

The facility level randomized clinical trial will be operating under the direction of Drs. Susan Mitchell and Ellen McCreedy, in conjunction with the trial statistician Roee Gutman, Ph.D. Bluestone Physician Services, under the direction of Todd Stivland, MD, will be recruiting, introducing the intervention and training local staff. Mr. Jeff Hiris (systems manager) and Ms. Laura Dionne (database manger) will be responsible for extracting the necessary data from the participating facilities' EMR in order to construct the outcome variable as well as all relevant independent variables and to integrate into the analysis data base the implementation monitoring data. Once the data files have been properly prepared, Ms. Annie Yang (analyst) will conduct outcome analyses according to pre-specified analysis plan. The study PI and the MPIs of the IMPACT Collaboratory will remain blind throughout this process.

11 PARTICIPANT RIGHTS AND CONFIDENTIALITY

11.1 Institutional Review Board (IRB) Review

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

11.2 Informed Consent Forms

This is an ePCT in which Bluestone will be responsible for enrolling participants. We are asking for a waiver of informed consent on Bluestone's behalf. Per 45 CFR §46.116 f 3 (i-v), we believe that:

(i) The research involves no more than minimal risk to the subjects; The only risk to the broad group of individuals for whom we are requesting the EHR data is the risk of breach of confidentiality and we have described our security procedures for minimizing this risk. We also believe there is minimal risk to the subset of individuals who will be subjected to the intervention itself. The intervention will consist of three arms - a control arm (usual care); treatment arm 1 where eligible residents in ALCs randomized to the information arm will receive a letter from their Bluestone physician with links to an informational website and advanced care planning (ACP) video sent through the online portal; and treatment arm 2 where eligible residents will receive the same outreach letter from their Bluestone physician with links to the informational website and video in addition to a follow-up phone call by their Bluestone physician to have a structured conversation about ACP. ACP is something that is routinely discussed between physicians and patients and

their caregivers. This intervention, which examines the effectiveness of two modes of delivery for the discussion compared to usual care, does not increase the level of risk beyond what an individual would encounter in usual care.

(ii) The research could not practicably be carried out without the requested waiver or alteration; There is no need for the research team to have contact with study subjects for this study. Recruitment and selection can be done passively through the use of EHR and the physician offices will be sending the letters and making the clinical phone calls in the two treatment arms directly. It would not be practicable to contact individuals for informed consent.

(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 data could not practicably be sent to the research team without identifiers because we will be following individuals over time and must be able to link their information longitudinally. In addition, we must be able to identify EHR records within specific locations in order to recruit facilities as well as tell physicians which patients to include in the intervention.

(iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and We do not believe the waiver or alteration will adversely affect the rights and welfare of the subjects. The physicians who will be involved in the intervention already have access to the patients' EHR for routine clinical care purposes and will be reaching out to them as they would in regular practice. Patients are free to ignore the informational letter and not engage with the physician in an ACP discussion. The EHR data used will be will be securely stored and kept confidential. Direct identifiers will be removed by Brown Center for Gerontology and Health Care Research IT Director and replaced with study IDs prior to release to the study team for analysis. All results will be presented in aggregate. No individual information will be released.

(v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation. We will provide Bluestone with copies of reports and manuscripts that result from this project. they are free to share information with their clinicians and facilities. The clinicians and facilities are free to share the information with interested families and patients. ALCs with less than 20 residents with a dementia diagnosis (ICD-10) who are not on hospice and do not have orders for comfort care only or DNH baseline will be excluded from the study.

11.3 Participant Confidentiality

To protect resident confidentiality, the corporation will place their data in a SSH secure server and will provide login information to the CGHCR. Data transfer to CGHCR secure servers will be via SFTP protocol with password protection. Once the files have been uploaded to the CGHCR servers, they will be stored, unmodified, in a secure file location specific to these uploads. They will then be read into SAS datasets, one per file type. The CGHCR will then notify the ALC system that the data were successfully downloaded and extracted, at which point the ALC systems will remove the data from their servers. All data files will be accompanied by a manifest detailing the number of distinct persons and

records expected in them. The CGHCR will connect to the corporation servers on a monthly basis. The CGHCR's information systems manager will be in charge of the data transfer, and he will replace the HICs and SSNs fields with a Brown University-generated identification number (throughout our different data sources) to allow linkage of data for analytic purposes.

11.4 Study Discontinuation

The study may be discontinued at any time by the IRB, the NIA, the OHRP, the FDA, or other government agencies as part of their duties to ensure that research participants are protected.

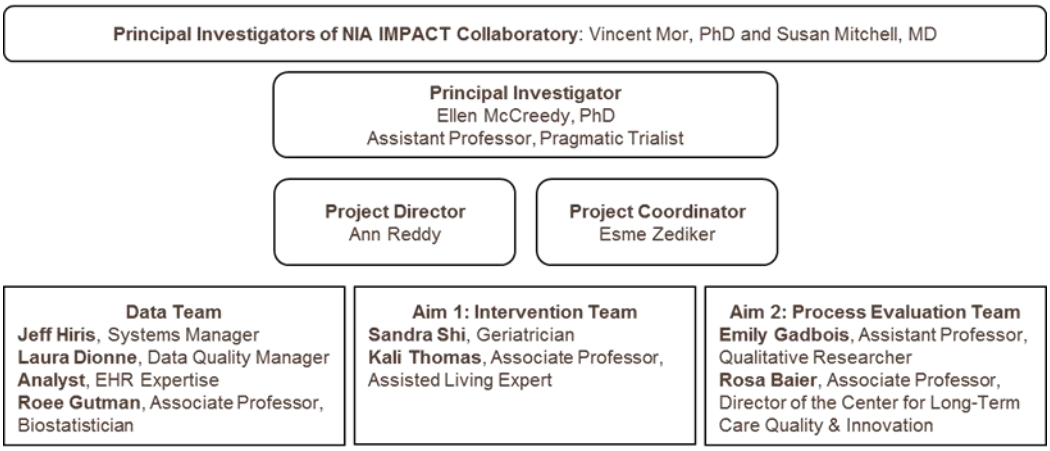
12 ETHICAL CONSIDERATIONS

Ethical consideration for the trial will be in accordance with the Federal Policy for the Protection of Human Subjects (HHS Human Subjects Research 45 Code of Federal Regulations (CFR) 46).

13 COMMITTEES

The study uses a concurrent, embedded mixed methods design in which qualitative data is used to capture impressions of implementation and help explain quantitative results. To accomplish this, the project team is split in half and Aim 1 and Aim 2 tasks are carried out simultaneously. Weekly meetings will be held for Aim1 and Aim 2 teams, with a biweekly meeting for the study leadership. We will also hold weekly meetings with Bluestone leadership. The PI (EM) has served as co-Investigator on three embedded pragmatic trials of institutionalized older adults, one of which she directs. The PI (EM) will lead full team meetings, oversee overall project direction, ensure timely submission of all requested project materials, ensure project milestones are met, and review and approve all publications. She will be assisted by the Project Manager (AR) and Project Coordinator (EZ). The Aim 1 team will be led by PI (SM) and Co-I (SS), geriatricians with expertise in testing physician support tools for the NH and ALC settings, and Co-I (KT), a nationally recognized expert on assisted living. The Aim 2 team will be led by Co-I (RB) and Co-I (EG). Co-I (RB) is the Director of the Center for Long-Term Care Quality & Innovation, which has conducted several similar process evaluations to the one proposed. Co-I (EG) is a qualitative researcher with experience conducting and analyzing interviews with clinicians and long-term care staff. The team also includes an experienced data manager and an analyst with experience using EHR physician orders to establish code status. As a supplement, the study also benefits from the oversight of the NIA IMPACT Collaboratory (U54AG063546). Figure 1 describes organizational structure and leadership of work teams.

Figure 1. Project Organization and Leadership



14 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.

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16 SUPPLEMENTS/APPENDICES

Appendix A. Letter to Bluestone Families

Appendix B. Educational Video for Patients / Proxies

Appendix C. Provider Training Video

Appendix D. Provider ACP Discussion Guide

Appendix A. Outreach Email / Letter

At Bluestone we believe that our patients deserve a customized approach to all aspects of their care. As your provider team, we are reaching out to all our patients and families to introduce our Advance Care Planning process. Talking with your loved ones and your provider team about values, goals, and treatment preferences ahead of time is called Advance Care Planning.

Advance Care Planning is important because it is easier to make decisions when things are stable and calm. This gives you time to reflect, talk with family, and get more information. We have learned from the COVID-19 pandemic that decision making ahead of time will help ensure medical preferences will be honored.

Every year we discuss with our patients their medical preferences. This year we are also sharing a booklet and video with our patients and family members. The booklet and video provide more information about what Advance Care Planning is, the questions you may be asked, and the benefits of Advance Care Planning. Please look through the booklet and access the video here: link to the video.

As always, if you have any questions please reach out to your Bluestone provider team through the Bridge.

Thank you

Appendix B. Educational video for patients / proxies

Overall Goals of Care

What overall goal of care fits best right now?
Identifying the goal will help guide treatment decisions.

Key Treatment Decisions and Goals of Care

What is Cardiopulmonary Resuscitation (CPR)?

CPR involves firm chest compressions administered when a person's heart and breathing stop. The goal is to restart cardiopulmonary functioning.

In many assisted living centers, staff call 911 and wait for emergency medical responders to start CPR.

Note: can you access the image below?
https://www.123rf.com/photo_143763574_cpr-cardiopulmonary-resuscitation-to-senior-elder-old-man-having-chest-pain-or-heart-attack-at-home-.html

CPR Outcomes

- People who are older and who have one or more chronic medical conditions are less likely to survive CPR, even in the hospital.
- Less than 3 out of 100 long-term care residents will survive CPR. This means that they are still alive after resuscitation and time in the intensive care unit.
- People who survive CPR may experience:
  - brain damage
  - broken ribs
  - organ damage
- It is unlikely the resident will be able to return to his/her current quality of life.

Cardiopulmonary Resuscitation (CPR) and Your Goals of Care

CPR can be attempted if a person's heart and breathing stops

CPR should not be attempted

Hospitalizations

Hospitalization involves hospital care for evaluation, stabilization of medical conditions, or treatment intended to prolong life.

Hospitalization has risks and benefits.

Decisions about Hospitalizations and Goals of Care

Prolonging Life

Hospitalization
Intensive care
Intubation
Ventilation

Maintaining Function

Hospitalization
Selective treatments

Comfort Care

Comfort-focused care
Avoid hospitalization

Decisions about the Management of Infection and Goals of Care

Prolonging Life OR **Maintaining Function**

Use antibiotics for all infections if medically indicated

Comfort Care

Do not use antibiotics unless needed to enhance comfort.

Decisions about Feeding Tubes and Goals of Care

Prolonging Life

Trial of a feeding tube.

Note: Feeding tubes do not help patients with advanced dementia live longer.

Maintaining Function

OR

Comfort Care

Assisted oral feeding

Hand feeding

No feeding tube

Documenting preferences

Documentation of goals of care and treatment preferences is important.

This helps ensure the health care providers can access information about goals of care and treatment preferences in an emergency.

Surrogates should keep a copy of key documents on hand.

Advance Care Planning Documentation Tools

There are two kinds of advance care planning documentation tools:

Advance Directives

Legal documents that include:

- Living will = end-of-life treatment preferences
- Health care proxy appointment = person authorized to make decisions for patient if patient is unable.

Medical Orders

Orders reflecting current treatment preferences that are in effect/active right now.

- Resuscitation
- Hospitalization
- POLST (Physician Orders for Life-Sustaining Treatment) *recognized in some states*

Should people with dementia participate in ACP?

People with mild or early stage dementia may be able to participate in ACP conversations with the support of family.

Surrogate decision-makers

A surrogate decision-maker is someone who makes decisions on behalf of a patient who lacks capacity.

The surrogate should make decisions based on the patient's prior preferences and choices when possible.

If the patient's preferences are unknown, the surrogate should choose what they think the resident would want if he or she could speak.

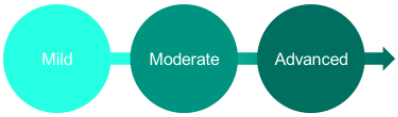
If surrogate does not know what the patient would want, they should decide what's in the patient's best interest.

ACP is critically important for people with dementia because:

- Preparation will help ensure that medical decisions are consistent with patient goals of care
- Medical decisions will need to be made when complications occur
- Dementia is a terminal diagnosis

Stages of dementia

Dementia is a progressive disease that worsens over time.

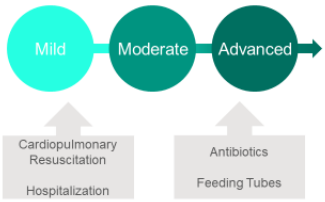


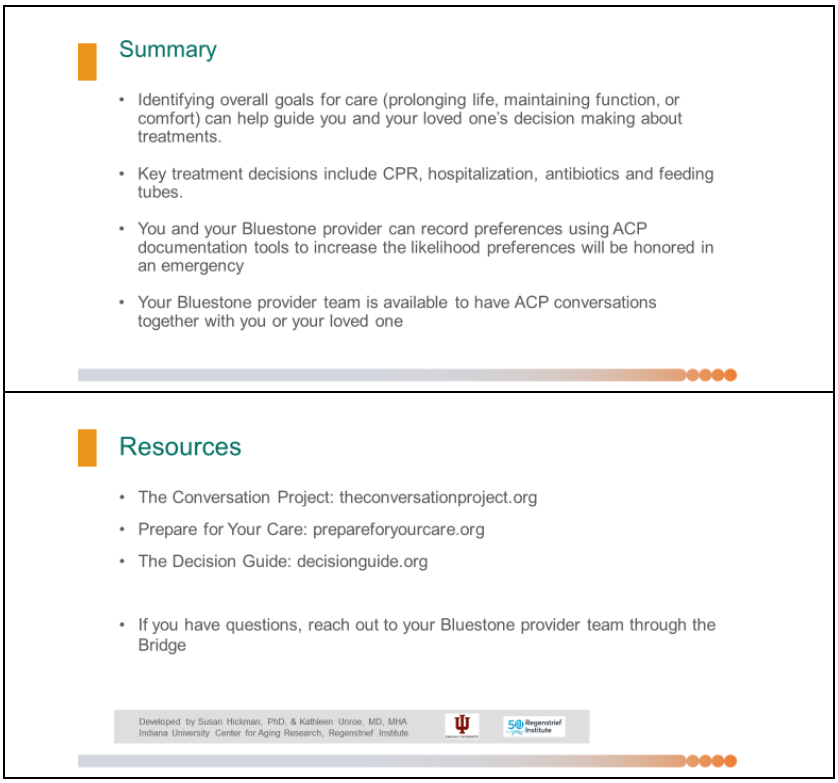
Features of advanced dementia include:

• profound memory deficits • inability to recognize family members
• limited ability to speak • inability to walk • incontinence
• total functional dependence

Treatment Decisions and Stages of Dementia

The types of treatment decisions that comes up may differ depending on the stage of dementia.




Summary
• Identifying overall goals for care (prolonging life, maintaining function, or comfort) can help guide you and your loved one's decision making about treatments.
• Key treatment decisions include CPR, hospitalization, antibiotics and feeding tubes.
• You and your Bluestone provider can record preferences using ACP documentation tools to increase the likelihood preferences will be honored in an emergency
• Your Bluestone provider team is available to have ACP conversations together with you or your loved one
Resources
• The Conversation Project: theconversationproject.org
• Prepare for Your Care: prepareforyourcare.org
• The Decision Guide: decisionguide.org
• If you have questions, reach out to your Bluestone provider team through the Bridge
Developed by Susan Hickman, PhD, & Kathleen Unroe, MD, MHA
Indiana University Center for Aging Research, Regenstrief Institute
Regenstrief Institute

Appendix C. Provider Training Video

Step 1 – Prepare for the Conversation

Review the patient's medical record.
Look for information about his or her medical condition, family situation, and any prior documentation about preferences.

Schedule a meeting
Include the patient, surrogate, and other key family members. Use ACP documentation and chart information to identify legally appointed representative and family members.

Find a private, quiet space
Ideally use a room with a door that shuts so no one can overhear. Try to make sure there is a box of tissues just in case.

Allow for at least 30 minutes.
These conversations take time as the patient and/or surrogate reflects and shares about goals, values, and preferences.

Step 2: Introduce the Topic and Frame the Discussion

- Ask about their understanding of ACP. Describe ACP as discussions about goals, values, and preferences.
- Emphasize that ACP is a part of providing patients with good care.
- Normalize the conversation.
- Reassure patients and surrogates that preferences will be reviewed periodically and can be revisited at any time

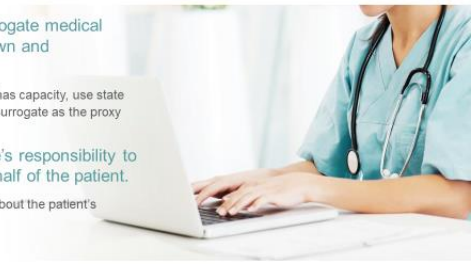
Step 3: Identify Surrogate and Clarify the Role of the Surrogate & Family

Clarify the correct surrogate medical decision-maker is known and documented.

If time allows and the patient has capacity, use state forms to formally appoint the surrogate as the proxy decision-maker.

Describe the surrogate's responsibility to make decisions on behalf of the patient.

Review prior documentation about the patient's preferences (if any).

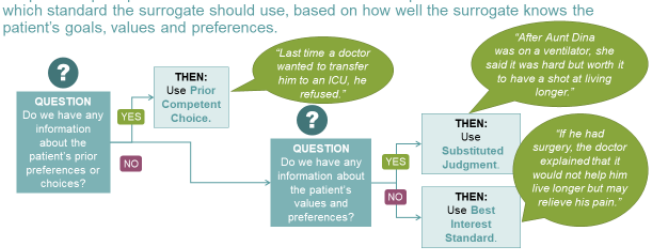


Standards for Surrogate Decision-Making

Prior competent choice	Substituted judgment	Best interest standard
Decisions are based on the patient's prior choices	Decisions are based on surrogate's understanding of the older adult's values and priorities	Objective assessment of the burdens and benefits of a particular treatment or course of action
"Last time a doctor wanted to transfer him to an ICU, he refused."	*"After Aunt Dina was on a ventilator, she said it was hard but worth it to have a shot at living longer."*	*"If he had the surgery, the doctor explained that it would not help him live longer but may relieve his pain."*

Identifying the Right Standard for Decision-Making

Ethically, a surrogate decision-maker's responsibility is to make decisions based on the patient's prior preferences and choices. The flow chart provides information about which standard the surrogate should use, based on how well the surrogate knows the patient's goals, values and preferences.



When can patients with dementia appoint a surrogate?

A lower level of capacity is required to appoint a surrogate than to make more complex clinical decisions. Studies suggest that patients with even moderate cognitive impairment can name a surrogate.

In order to evaluate whether the patient can make this decision, the patient should be approached when he/she is rested, alert, and calm. Consider the following questions:

- Does the patient demonstrate a basic understanding of what it means to have another individual make his/her health care decisions?
- Is the patient's choice of surrogate decision-maker consistent over time?
- Is the potential surrogate decision-maker identified by the patient appropriate (i.e., someone who knows the patient well)?

Step 4: Discuss the Patient's Current Health Status

Understanding the patient's current health is important to supporting informed decision-making. It can be important in identifying which treatment decisions are most likely to arise.

The patient may already have experience with these treatments that can be explored to understand preferences for the future. Some questions to consider include:

- What is your understanding of the patient's health status, diagnoses, and care needs?
- What do you expect will happen in the future?
- What do you understand about the diagnosis and trajectory of dementia (for patients with dementia)?

Asking these questions can identify gaps in knowledge and provide a starting point for discussion.

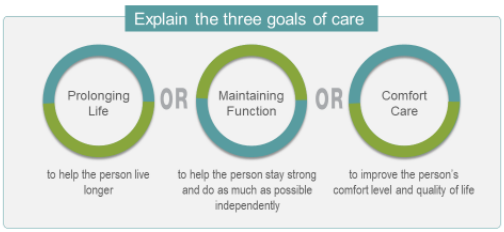
Step 5: Explore personal goals

Explore the things that matter most to the patient. Discussing past experiences, statements, or preferences can help identify current goals.

Some questions to consider include:

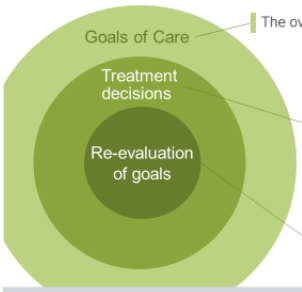
- What makes the patient unhappy, distressed, or fearful?
- What does he or she enjoy? What makes him or her happy or satisfied?
- What do you hope will happen in the coming months?
- What do you fear will happen in the coming months?
- What is the main goal of care?
- Do you have any concerns about this goal of care?

Identify Current Goal of Care



What are the patient's goals? Or the surrogate's goals for the patient? Why?

Step 6: Link Goals and Treatment Preferences



The overall Goals of Care should guide treatment decisions

Once you identify the goals, talk about goals and specific treatment decisions that are particularly relevant for older adults with serious illness

Discussing how the goals affect treatment decisions sometimes results in a re-evaluation of goals

Key Treatment Decisions

Provide information about key treatment decisions including:

- Cardiopulmonary Resuscitation
- Hospitalization
- Comfort Care
- Management of infections
- Artificial Nutrition
- Hospice

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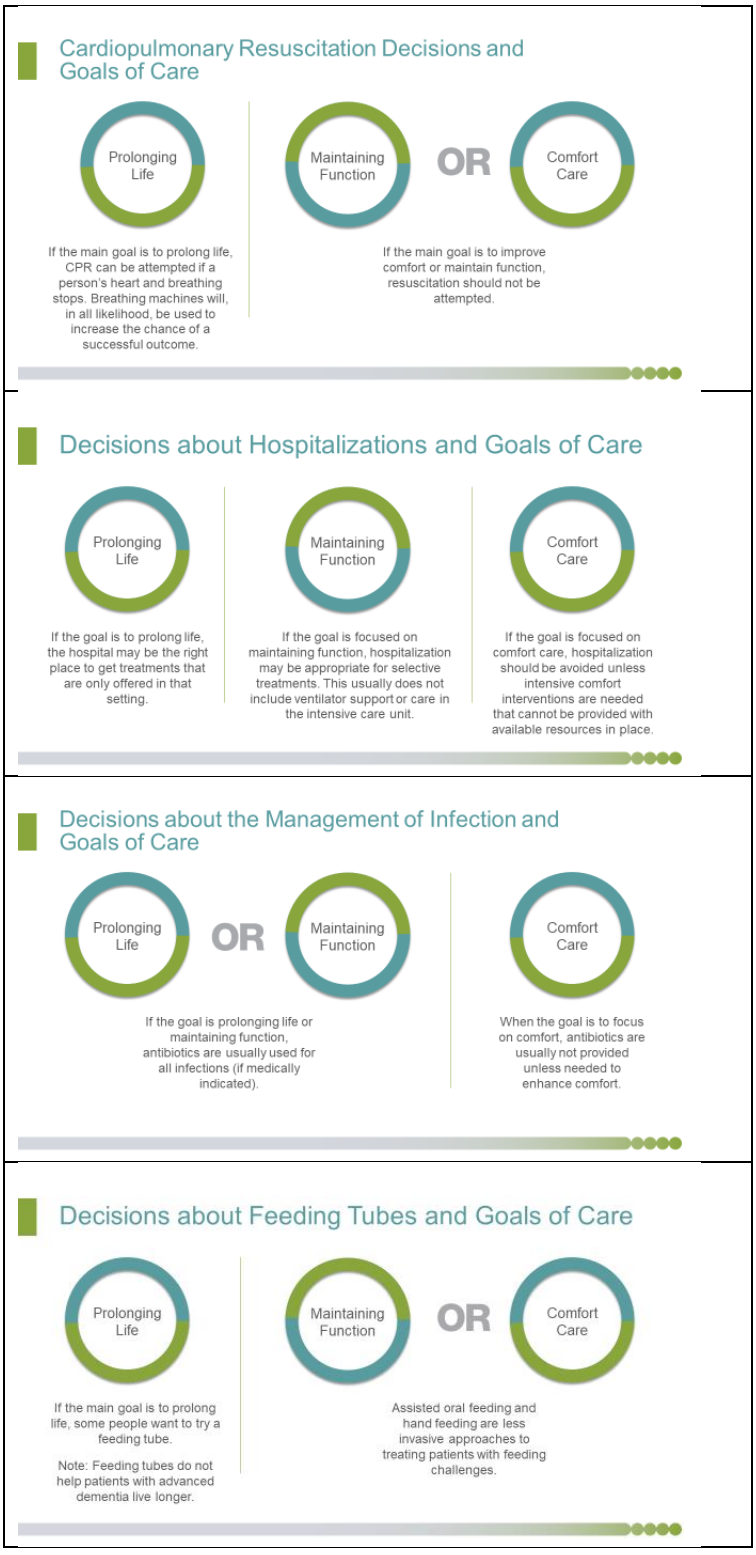
Cardiopulmonary Resuscitation Decisions and Goals of Care
Prolonging Life
If the main goal is to prolong life, CPR can be attempted if a person's heart and breathing stops. Breathing machines will, in all likelihood, be used to increase the chance of a successful outcome.
Maintaining Function
OR
Comfort Care
If the main goal is to improve comfort or maintain function, resuscitation should not be attempted.
Decisions about Hospitalizations and Goals of Care
Prolonging Life
If the goal is to prolong life, the hospital may be the right place to get treatments that are only offered in that setting.
Maintaining Function
If the goal is focused on maintaining function, hospitalization may be appropriate for selective treatments. This usually does not include ventilator support or care in the intensive care unit.
Comfort Care
If the goal is focused on comfort care, hospitalization should be avoided unless intensive comfort interventions are needed that cannot be provided with available resources in place.
Decisions about the Management of Infection and Goals of Care
Prolonging Life
OR
Maintaining Function
If the goal is prolonging life or maintaining function, antibiotics are usually used for all infections (if medically indicated).
Comfort Care
When the goal is to focus on comfort, antibiotics are usually not provided unless needed to enhance comfort.
Decisions about Feeding Tubes and Goals of Care
Prolonging Life
If the main goal is to prolong life, some people want to try a feeding tube.
Note: Feeding tubes do not help patients with advanced dementia live longer.
Maintaining Function
OR
Comfort Care
Assisted oral feeding and hand feeding are less invasive approaches to treating patients with feeding challenges.

Decisions about Hospice and Goals of Care

Prolonging Life **OR** Maintaining Function

If the goal is prolonging life or maintaining function, hospice care is not appropriate.

Comfort Care

If the goal is comfort care, hospice may be appropriate.

Note: Not every patient desiring comfort care needs to be enrolled in hospice. To receive hospice care under the Medicare benefit, a patient must meet certain criteria including less than 6 months life expectancy.

Step 7: Explain Next Steps

At the end of the ACP discussion:

- Give participants one last opportunity to ask questions. Offer a follow-up meeting if needed and review any questions you will pass on to the medical provider if requested.
- Reassure the patient and family that they are always welcome to revisit the decisions made or change their minds at any time.
- Document decisions on ACP Documentation Tools
- Thank everyone for participating!

Documentation is important to help ensure the care team can access information about the patient's goals of care and treatment preferences.

If a patient transfers out and EMS or emergency department providers cannot find the patient'2 advance care planning documents, **the patient's preferences may not be honored.**

Advance Care Planning Documentation Tools

There are two kinds of advance care planning documentation tools:

Advance Directives
Legal documents that provide information about the patient's preferences and who is authorized to make decisions if the patient loses capacity.

- Living will (end-of-life treatment preferences)
- Health care proxy/legal representative/POA

Medical Orders
Orders reflecting current treatment preferences that are in effect/active right now.

- Resuscitation
- Hospitalization
- Comfort Care
- POLST (Physician Orders for Life-Sustaining Treatment) *recognized in some states*

The POLST Program

POLST is used to document treatment preferences as medical orders. Key features include:

- Records treatment preferences as actionable medical orders that EMS can follow
- Permits documentation of preferences to have or decline treatments
- Transfers across treatment settings with patient

*See www.polst.org for more information.

Susan H please review – 16 minutes? Face to face with patients only?

Medicare Billing Codes for ACP

Physicians or other qualified health professionals can bill Medicare for ACP discussions. This includes the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed) as well as POLST and orders reflecting treatment preferences. Discussions must be face-to-face with the patient, family member(s) and/or surrogate.

99497—first 30 minutes
99498—each additional 30 minutes

Bluestone Advance Care Planning

- Advance care planning is important to patients, families, and the care team
- Use the ACP Facilitation Steps and communication skills to engage in positive, meaningful discussions about values, goal, and preferences.
- Document the outcomes of ACP discussions on advance care planning tools like POLST or medical orders.

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Appendix D. Provider ACP Discussion Guide

DISCUSSION TOPIC	KEY QUESTIONS AND PROMPTS	SUPPORTIVE INFORMATION AND GUIDANCE
Introduce the topic and frame the conversation	What is your understanding of Advance Care Planning? OR What have you heard of Advance Care Planning? Provide support: "It can be easier to make these types of decisions when things are stable and calm. This gives you time to reflect, talk with your family, and get more information." "The goal of Advance Care Planning is to make sure you receive the care you want."	Describe ACP as discussions about goals, values, and preferences about what kind of medical treatments are wanted. Emphasize that ACP is a part of providing residents with good care. Explain that it can be easier to think, reflect, and decide in advance of a crisis. Normalize the conversation. Explain that we have these discussions with all our residents. Reassure patient that preferences will be reviewed periodically and can be revisited anytime.
Describe the role of surrogate and family	Who is the patient's legal health care decision-maker? **If speaking to the patient:** If you become very sick and unable to make your own care decisions, someone else will need to make medical decisions for you. This is called a surrogate decision-maker or health care proxy. Who would you like to be your health care proxy?	Identify / appoint legal surrogate, if appropriate. Verify you have the correct surrogate decision-maker. Review any prior documentation about the patient's preferences to inform the discussion. Remind patient to have a conversation with their chosen health care proxy. Describe the surrogate's role and responsibility to make

	Direct next steps: "You should have a conversation with your health care proxy about the type of care you would want if you became very sick." **If speaking to the surrogate decision-maker:** (Patient name) has chosen you to be their surrogate/health care proxy, which means if there comes a time that (patient name) cannot tell the medical team what they would want, you would responsible for making medical decisions for them. How do you feel about that?	decisions on the resident's behalf when the resident is unable to do so. A surrogate decision-maker should make decisions based on the patient's prior preferences and choices, when available. If not, the surrogate should choose what they think the patient would want if they could be a voice in the room. If surrogate does not know what the patient would want, they should decide what's in the patient's best interest.
Discuss the patient's current health status	What is your understanding of your (the patient's) current health, medical problems, and care needs? What do you expect will happen in the future?	Explore understanding, identify gaps in knowledge and provide information as appropriate. For patients with dementia, explore understanding of trajectory of dementia and common complications.
Explore personal goals	Tell me a little bit about what is important to you (the patient) right now. What makes you (the patient) happy or satisfied? What makes you (the patient) unhappy, distressed, or fearful?	Discuss past experiences, statements, or preferences to help identify what is important to the patient.

	What do you hope, or fear, will happen in the coming months?	
Explore goals of care	When people have a serious illness, like dementia, it is important to think about the most important goal you want for your healthcare. This helps us choose treatments that are best for you and fit with your values. What questions do you have? What is the main goal of care for (patient name) at this time? Do you have any concerns about this goal?	Describe the three goals of care using the goals of care framework. Explain goals framework. The goal of ***prolonging life*** is to help the patient live longer The goal of ***maintaining function*** is to help the person stay strong and do as much as possible independently The goal of ***comfort care*** is to improve the person's comfort level and quality of life. Note on hospice: To receive hospice care under the Medicare benefit, a patient must meet certain criteria including less than 6 months life expectancy.
Link goals and treatment preferences (CPR) **{SKIP IF PATIENT IS DNR}**	Now we are going to talk about specific treatments and how they fit with your goals of care. {describe CPR using key points} *If patient goal is prolonging life:* If your main goal is to **prolong life**, CPR can be attempted if your heart and breathing stops. Breathing machines may be used to increase the chance of restarting the heart and lungs. *If patient goal is maintaining function or comfort care:* If your	If the patient's goal of care is clear, suggest what makes sense for the patient. Share CPR outcomes - less than 3 out of 100 residents will survive CPR. Describe side effects in survivors including brain damage, broken ribs, or organ damage. If applicable in the specific assisted living center, educate surrogate that CPR may not be started in many assisted living centers until the EMTs arrive. It is extremely unlikely the resident will be able to return to his/her current quality of life.

	main goal is to **improve comfort or maintain function**, CPR should not be attempted. Do you have any more questions about CPR? If you heart and breathing stops, would you want CPR?	Document CPR preference.
Link goals and treatment preferences (HOSPITALIZATION) {**SKIP IF PATIENT IS DNH**}	Next, we'll talk about going to the hospital *If patient goal is prolonging life:* If your goal is to **prolong life**, the hospital may be the right place to get treatments that are only offered in that setting. These include treatments that can only be given in an intensive care unit like mechanical ventilators or a breathing machine *If patient goal is maintaining function:* If your goal is to **maintain function**, hospitalization may be appropriate for selective treatments, usually does not include care in the intensive care unit or breathing machines. *If patient goal is comfort care:* If your goal is **comfort care**, hospitalization should be avoided unless treatments needed to make you comfortable are not available outside the hospital.	If the patient's goal of care is clear, suggest what makes sense for the patient. Explain that hospitalization involves evaluation, stabilization of medical conditions, or treatment intended to prolong life. Describe ICU care using lay language including breathing tubes (Intubation) and breathing machines (ventilation). Comfort-focused can usually be provided in the AL facility through hospice or palliative care services. Ask if they want to know more about hospice or palliative care. Document decisions appropriately. If patient wants to go to the hospital, explore further if that includes use of a breathing machine or not.

	Do you have any more questions about hospital care? What are your thoughts about whether you would want to go to the hospital if you get sick?	
Link goals and treatment preferences **(ANTIBIOTICS)**	Now we will talk about infection management and antibiotics. Antibiotics help treat several different infections caused by bacteria, such as urinary tract infections and pneumonia. Antibiotics do not treat colds or the flu, which are caused by viruses. *If the patient goal is prolonging life or maintaining function*: If your goal is to **prolong life or maintain function,** antibiotics are usually used for all infections (if medically indicated). *If the patient goal is comfort care*: If your goal is **comfort care,** antibiotics are usually not provided unless needed to enhance comfort.	If the patient's goal of care is clear, suggest what makes sense for the patient. Describe antibiotics using lay language. Explain that sometimes even the right antibiotic will not work if an infection is overwhelming. A patient who is very frail or has multiple medical problems may not be able to fight off the infection even with antibiotics. If a patient's overall care goal is focused on **comfort care**, consider whether the antibiotic will make them more comfortable or if there are other ways to keep him or her comfortable. Document antibiotic use preferences appropriately.
Link goals and treatment preferences **(TUBE FEEDING)** **{SKIP IF PATIENT IS NO ARTIFICIAL FEEDING OR DOES NOT HAVE DEMENTIA}**	Now we are going to talk about eating problems. {Describe artificial feeding using key points} Eating problems are very, very common in late stage dementia, and often indicate the end-of-	**Feeding tube discussion is only appropriate for patients with dementia.** If the patient's goal of care is clear, suggest what makes sense for the patient. This discussion should mainly focus on eating problems in **late-stage dementia**. Feeding

	life may be near. The choice at this point is to eat and drink to extent it is still enjoyable and comfortable for you, and not worry too much about how much food you get. The other option is to have a feeding tube. These tubes go through the skin and into your stomach and liquid food is given through the tube. This procedure must be done at a hospital. *If patient goal is prolonging life:* If your goal is to **prolong life**, it is important to know that there is no evidence feeding tubes help residents with advanced dementia live longer. *If patient goal is maintaining function or comfort care:* If your goal is to **maintain function** or **comfort care**, then continuing to eat and drink by mouth, sometimes with the help of another person, makes sense. Do you have any more questions about feeding problems? If you had feeding problems in late-stage dementia, what would you want?	problems for other specific conditions, like Parkinson's or stroke, are very different. Educate that for patients with dementia, 15 years of research have shown that feeding tubes do not prolong life, prevent aspiration or improve pressure ulcers. Educate that many assisted living communities do not support tube feeding. The patient may need to move to a different facility to receive tube feeding. Describe complications associated with tube-feeding in dementia, like diarrhea, risk of pulling out tube and needing restraints, need to go to hospital for blockages or dislodgement. Document tube feeding decision.
Explain next steps	Let me share the next steps with you.	Summarize your understanding of patient's wishes.

	Based on our discussion, I'm first going to summary my understanding of your wishes (*summarize here)*… Did I get this right? Now we will write down your wishes in your medical chart / fill out a POLST form / complete HCP / relevant state-specific forms.	Describe process for getting medical orders signed. Describe process for formalizing health care proxy if relevant. Reassure them that preferences will be reviewed periodically and can be revisited anytime.
Address any questions	Do you have any other questions?	Provide additional information or record questions for the Physician/Advanced Practice Provider as appropriate.