

Study Protocol: Project to Improve Communication About Serious Illness--Hospital Study (PICS-H)

- a. Project to Improve Communication about Serious Illness-Hospital study: Pragmatic Trial (Trial 1) (PICS-H) : NCT04281784
- b. **Project to Improve Communication about Serious Illness-Hospital study: Comparative Effectiveness Trial (Trial 2) (PICS-H) : NCT04283994**

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1) Brief Overview

For hospitalized patients with chronic illness, a key component of high-quality care includes goals-of-care discussions (GOCD) conducted early during a hospital stay to identify how patients' goals of care should inform current care plans. These goals-of-care discussions are associated with improved patient and family outcomes and reduced intensity of care at the end of life. Despite their importance, GOCD during a hospitalization often do not occur. The failure to conduct these conversations and to ensure that care received is aligned with patients' wishes for care is particularly a concern for older adults with chronic illness, and particularly those with Alzheimer's disease and related dementias (ADRD).

This study, funded by NIA, evaluates the Jumpstart intervention, the key to which is the "Jumpstart Guide." There are two versions of the Jumpstart Guide being tested, one that is "EHR-based, clinician-facing" and includes information identifying the dates of prior advance care planning documents (e.g., code status, healthcare directives, durable power of attorney for healthcare) and Physician Orders for Life Sustaining Treatments (POLST forms) in the electronic health record (EHR) to the clinician. It also includes "just-in-time" suggestions for having a GOCD. The other guide is "survey-based, bi-directional." It is survey-based because it provides goals of care information from patients' self-reported surveys (or proxy reports from family members if patients do not have decisional capacity) and is then shared with their clinicians. It is bi-directional because there is one version of the Jumpstart Guide that goes to the clinician and another version that goes to the patient or, if the patient doesn't have decisional capacity, a family member surrogate. These survey-based, bidirectional one-page Jumpstart Guides include patient-specific preferences with "just-in-time" tips to improve this communication, tailored either for clinicians or patients and family members. The clinicians' Jumpstart Guide also includes information identifying the dates of prior advance care planning documents.

The study comprises two linked, complementary randomized trials. Trial 1, a large pragmatic trial, compares usual care with the EHR-based clinician-facing Jumpstart for hospitalized older adults with serious illness (target n=2000; ADRD subset, target n=400). Trial 2, a comparative effectiveness trial, is a three-arm trial that compares the EHR-based clinician-facing Jumpstart, the survey-based bi-directional Jumpstart, and usual care (n=600). Subjects are enrolled from the UW Medicine hospitals (Harborview Medical Center, UW Medical Center - Montlake, UW Medical Center - Northwest). For Trial 1, eligible patients are ≥ 55 years, admitted for a minimum of 12 and a maximum of 96 hours prior to study enrollment to inpatient services, without a documented GOCD during admission, and meet criteria for serious illness; hospitalized patients >80 years are also eligible. For Trial 2, eligible patients meet the same criteria and, in addition, must be sufficiently fluent in English to complete questionnaires and not be under respiratory isolation precautions in order to allow in-person recruitment. If patients are eligible but do not have decisional capacity, a family member or friend involved with their care may participate as their surrogate; family members or friends include individuals who are legal guardians, durable power of attorney for healthcare, spouses, adult children, parents, siblings, domestic partners, other relatives, and friends. In addition, we will conduct qualitative interviews with key stakeholders including patients/families (n=60, subgroup of patients/families enrolled for Trial 2) and clinicians (n=50 across Trial 1 and Trial 2).

2) Specific Aims:

Specific Aim 1 (Trial 1): Evaluate the effectiveness of a novel intervention, the EHR-based clinician-facing Jumpstart, compared with usual care, for improving the quality of care; the primary outcome is EHR documentation of a goals-of-care discussion during the 30 days after randomization. Secondary outcomes focus on intensity of care: ICU admissions and readmissions, ICU and hospital free days, costs of care during the hospitalization, and 7- and 30-day hospital readmission.

Specific Aim 2 (Trial 2): Evaluate the effectiveness of the survey-based bi-directional Jumpstart compared to the EHR-based clinician-facing Jumpstart and usual care for improving quality of care; the primary outcome is EHR documentation of a goals-of-care discussion within 30 days after randomization. Secondary outcomes include intensity of care outcomes from Aim 1 and patient- and family-reported outcomes assessed by surveys at 3-5 days and 4-6 weeks after randomization, including occurrence and quality of goals-of-care discussions in the hospital, goal-concordant care, psychological symptoms, and quality of life.

Specific Aim 3 (Trials 1, 2): Conduct a mixed-methods evaluation of the implementation of both interventions, guided by the RE-AIM and CFIR frameworks for implementation science, incorporating quantitative evaluation of intervention reach and adoption, as well as qualitative analyses of interviews with participants, to explore barriers and facilitators to future implementation and dissemination.

3) Research Plan

a) Background and Significance

People near the end of life often receive care they would not choose.^{1,2} The National Academy of Medicine has documented these discrepancies in care and identified advance care planning and goals-of-care discussions as primary mechanisms for addressing them.¹ This type of communication is a focus for improvement for two key reasons: 1) when goals-of-care discussions occur, they are associated with improved quality of care and patient- and family-centered outcomes, including increased quality of life, reduced symptoms of psychological distress, and fewer intensive treatments at the end of life;³⁻⁶ and 2) clinicians frequently do not have goals-of-care discussions with their patients until very late in the illness.^{3,7-10}

The value of advance care planning discussions with healthy individuals is a topic of debate; however improving goals-of-care discussions for those with serious illness facing difficult treatment decisions is widely agreed upon as an urgent need that can improve patient outcomes.¹¹⁻¹⁶ There is an emerging consensus on this important distinction between advance care planning (ACP) for healthy individuals and goals-of-care discussions for those with chronic life-limiting illness and on the critical importance of timely goals-of-care discussions.^{11,17,18} Furthermore, even if advance care planning does occur in the outpatient setting, effective goals-of-care discussions (a component of advance care planning for more proximal decision-making) are still needed for hospitalized patients whose prior preferences may have changed or may not have been specific to the current circumstances.¹⁹⁻²¹ In short, for hospitalized patients with chronic illness, a key component of high-quality care includes goals-of-care discussions conducted early during a hospital stay that build on prior advance care planning and identify how patients' goals inform current care.^{8,11,22} These early hospital discussions are supported by the National Quality Forum.²³ Despite their key importance to a large number of patients, early hospital goals-of-care discussions often do not occur.^{8,24} A recent research agenda for serious illness communication, supported by the National Institute on Aging and published in *JAMA Internal Medicine*, highlights the importance of promoting high-quality goals-of-care discussions, as well as the potential opportunity to use the EHR to both identify those patients who would benefit from goals-of-care discussions and to guide clinicians in high-quality discussions.²⁵ We propose two complementary trials to examine the effectiveness of such interventions, and we use an innovative hybrid effectiveness-implementation approach that evaluates the interventions and their implementation.²⁶

b) Innovation

Use of the EHR to identify seriously ill, hospitalized patients without a goals-of-care discussion: Recent research agendas highlight the lack of research utilizing the EHR to implement interventions that improve serious illness communication.^{25,27} We will use a validated EHR-based quality metrics program to identify hospitalized patients aged 55 years and older with chronic serious illness who do not have EHR documentation of a goals-

of-care discussion. We have developed an innovative natural language processing/machine learning (NLP/ML) protocol to identify inpatient and outpatient documentation of goals-of-care discussions in any type of EHR note, including admission notes, progress notes, and discharge summaries. In this way, we not only target a population likely to benefit from the intervention but also do so with methods that are generalizable and scalable.²⁸

Examine the comparative effectiveness of an EHR-based clinician-facing Jumpstart, a survey-based bi-directional Jumpstart and usual care in an innovative study design: The intervention is based on our recently completed trial in the outpatient setting of the survey-based bi-directional intervention (Jumpstart), which is an individualized communication-priming intervention, targeting both patients and clinicians and providing each with information obtained from patient surveys in order to guide a goals-of-care discussion.²⁹ This intervention is innovative because it is one of the few that involves clinicians as well as patients and family members (bi-directional). However, a question raised by reviewers of our prior trial² was whether the individualized survey-based component was necessary, especially given the resources needed to implement it. Therefore, we have developed this innovative study design that combines a large pragmatic trial of an EHR-based clinician-facing Jumpstart compared to usual care (Trial 1, using a waiver of informed consent to facilitate enrollment and the pragmatic approach) and a smaller comparative effectiveness trial of three arms: an EHR-based clinician-facing Jumpstart, a survey-based bi-directional Jumpstart, and usual care (Trial 2). In contrast to Trial 1, this comparative effectiveness trial includes individual patient or surrogate consent for participation as well as completion of surveys to generate Jumpstart Guides.

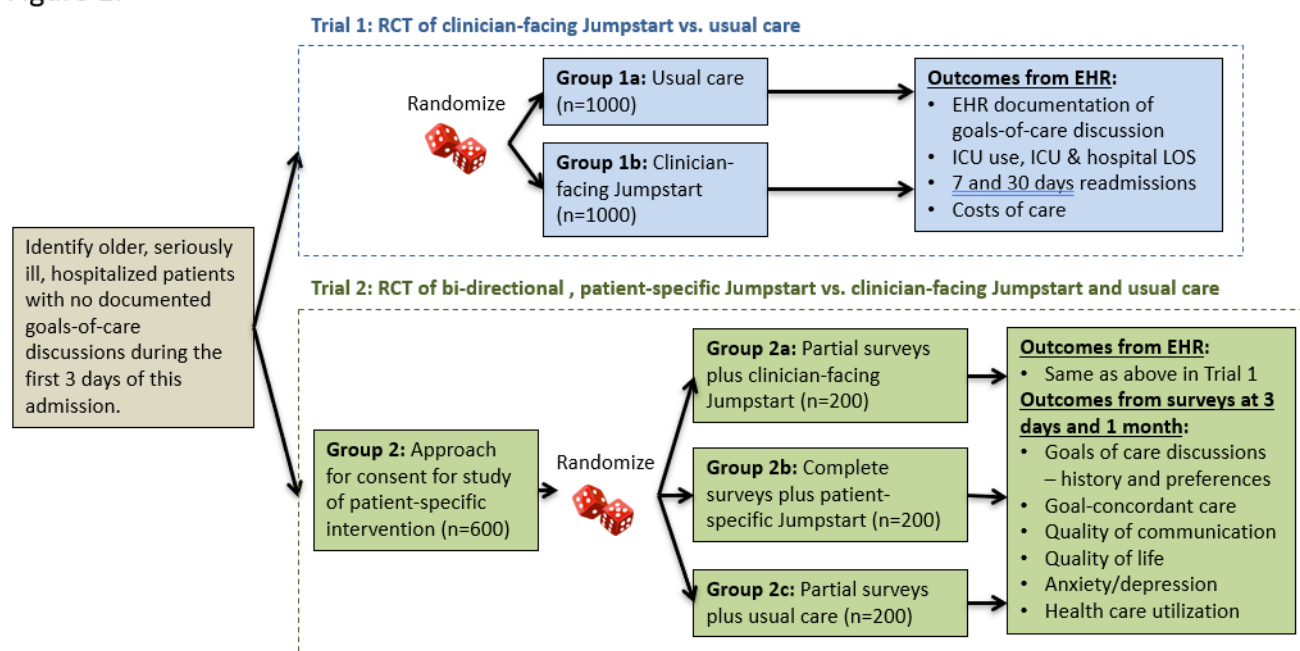
Develop an innovative effectiveness-implementation approach that advances implementation and dissemination: Few evidence-based communication interventions are widely adopted. Barriers to implementation include factors at the level of individual patients, clinicians, operating clinical units, and healthcare systems.^{30,31} The RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) framework systematically addresses these factors and, in turn, translates interventions like Jumpstart into the “real world”.³²⁻³⁵ Similarly, the Consolidated Framework for Implementation Research (CFIR) offers another framework that examines implementation of evidence-based interventions, including domains representing intervention characteristics, outer setting, inner setting, characteristics of individuals and process.³⁶ This study will include a novel hybrid effectiveness-implementation approach that can accelerate implementation and dissemination of the interventions after the study by allowing us to evaluate—during the study—strategies and outcomes that will facilitate uptake of the interventions in the future.^{26,36-39} This innovative design offers the opportunity to advance implementation science in palliative care and increases the utility of this study.

4) Research Design and Methods

a) Overview

We will conduct two linked, complementary randomized trials of an EHR-based clinician-facing or a survey-based bi-directional intervention to promote and guide goals-of-care discussions for older, seriously ill, hospitalized patients using an innovative method for identifying eligible participants through the EHR. Trial 1 assesses the effectiveness of the EHR-based clinician-facing Jumpstart compared with usual care in a large pragmatic trial not requiring patient or family consent (Aim 1, Trial 1). Trial 2 examines the efficacy of the survey-based, bi-directional Jumpstart as compared with the EHR-based, clinician-facing Jumpstart and usual care (Aim 2, Trial 2). In addition, we will examine the implementation of the interventions using the RE-AIM and CFIR frameworks³²⁻³⁶ (Aim 3). Figure 1 provides an overview of the design.

Figure 1:



b) Setting

We will conduct this study with a diverse population drawn from 3 hospitals at UW Medicine, including a university hospital (UW Medical Center - Montlake), a county, safety-net hospital (Harborview Medical Center, HMC), and a community hospital (UW Medical Center - Northwest). UWMC - Montlake provides specialist care for the Pacific Northwest region and has 529 acute care beds and 75 ICU beds. HMC is operated by the University of Washington and has 413 acute care beds and 94 ICU beds. HMC is the only Level 1 Trauma Center serving five states, and its mission population includes inner city poor, recent immigrants, and persons with HIV/AIDS. UWMC - Northwest is a community hospital with 218 acute care beds and 15 ICU beds, serving north Seattle with a large geriatric and nursing home resident population. Our prior studies have included each of these sites.⁴⁰⁻⁴² These 3 sites offer the advantage of caring for diverse patients while also using a unified EHR incorporating Epic systems into a platform we have been able to access and use.⁴³⁻⁴⁸

c) Patient population

Trials 1 and 2: Eligible patients aged 55 years and over will be identified by ICD-10 codes for one or more of the nine chronic conditions used by the Dartmouth Atlas⁴⁹: dementia, malignant cancer/leukemia, chronic pulmonary disease, coronary artery disease, heart failure, chronic liver disease, chronic renal disease, diabetes with end-organ damage, and peripheral vascular disease. These nine conditions account for 90% of deaths among Medicare beneficiaries in the US.^{50,51} To increase inclusivity of important and under-studied populations, we will also include all hospitalized patients over age 80. Among patients meeting these criteria, we will include only those with no identified documentation of goals-of-care discussions during the current hospitalization and prior to enrollment.

Trial 2: Eligible patients or their surrogates will have sufficient English language proficiency to complete surveys. Additionally, patient's providers will be alerted via SecureChat in Epic that study staff are planning to recruit the patient or their family member and given the opportunity to notify study staff if they believe the patient or patient's family should not be approached for any reason.

d) Description of participants

We will collect the following information about study participants.

Patients: For Trials 1 and 2, using the EHR, we will identify the following demographics: age, race, ethnicity, sex, marital status, comorbidities, limited spoken English proficiency, and acute severity of illness including the Deyo-Charlson comorbidity index. For Trial 2, using survey-reported data, we will report education, health status (SF-1), and income.

Families: For Trial 2, using survey-reported data, we will report the following demographics for participating family members/surrogates: age, race, ethnicity, sex, education, marital status, health status (SF-1), relationship to patient, and living situation related to patient.

Clinicians: For Trials 1 and 2, using information collected during the interview, we will report the following demographics for clinicians participating in qualitative interviews: age, race, ethnicity, sex, clinical specialty.

e) Sampling patients with ADRD

Given the dramatically increasing prevalence of ADRD in the US and the rising intensity of care among these patients,^{52,53} it is particularly important that we understand the effect of interventions to improve quality of palliative care in this group. We designed both trials to be powered to examine heterogeneity of treatment effects (HTE) in this important group. For Trial 1, we plan to continue recruitment as needed to meet our sample requirements for this subgroup. For Trial 2, we will prioritize recruitment of patients with ADRD to maximize this subgroup sample size. We hypothesize that the interventions will be equally effective in this population, but that the proportion of patients with decisional capacity will be lower (enrolling more family members in Trial 2). However, we believe it is important to explicitly examine this hypothesis given the unique features of intensity of care at the end of life for this important and increasing population.

f) Randomization

Patients are randomized in a 1:1 ratio in Trial 1 and 1:1:1 ratio in Trial 2 using variable size blocks and stratified for hospital and ADRD vs. no ADRD. Participating family members or legal surrogate decision makers are assigned to the same arm as the corresponding patient.

g) Intervention

EHR-based clinician-facing Jumpstart (Trials 1 and 2): First, we use automated methods to examine inpatient and outpatient EHR notes prior to the current admission, identifying current code status as well as all prior POLST forms and advance directives; this information is included on Jumpstart Guides to inform discussions. Second, we deliver the Jumpstart Guide to the primary hospital team (all attending and resident physicians and advanced practice providers) via secure email and either a page alerting the providers to the presence of the Jumpstart Guide in their email (Trial 1) or via in-person delivery (Trial 2). See Appendices 1 and 2 for Trial 1 EHR-based clinician-facing Jumpstart Guides (PDF and HTML formats), and Appendix 3 for Trial 2 EHR-based clinician-facing Jumpstart Guide.

Survey-based bi-directional Jumpstart (Trial 2 only): First, information about the patient is abstracted from the EHR in the same way as for the EHR-based clinician-facing Jumpstart. Second, patients or their family member/surrogate complete baseline survey items assessing three domains: a) preferences for discussions about goals of care; b) barriers and facilitators for having such discussions; and c) current goals of care. Third, using the EHR and baseline survey, we use the automated algorithm from our prior trial²⁹ adapted to the

hospital setting using human-centered design methods⁵⁴ to create a survey-based Jumpstart Guide to prompt and guide goals-of-care discussions between the patient and hospital team or, if the patient isn't able, the family member and the hospital team. Finally, in the fourth step, we deliver the Jumpstart Guides to the primary team via secure email as well as in-person delivery to members of the team. We also provide a survey-based Jumpstart Guide to the patient or family, adapted with phrasing and terminology specifically for the patient and family. All Jumpstart Guides are delivered on the day of randomization with the goal of prompting a goals-of-care discussion early during hospitalization, as supported by the National Quality Forum.²³ The clinicians' survey-based bi-directional Jumpstart includes both EHR-data and patient-tailored suggestions for conducting goals-of-care discussions based on survey responses. The patients' survey-based bidirectional Jumpstart includes patient-tailored suggestions for starting a conversation with their doctor. The suggestions are guided by the educational experience of VitalTalk, a nationally acclaimed program for teaching serious illness communication, and adapted to the inpatient setting.^{55,56} See Appendix 4 for clinicians' survey-based bi-directional Jumpstart Guide, and Appendix 5 for patients' survey-based bi-directional Jumpstart Guide.

5) Outcomes

a) Outcomes from the EHR and Death Certificates (Trials 1 and 2):

The primary outcome for both trials is EHR documentation of goals-of-care discussions within 30 days after randomization. Our rationale for this as the primary outcome is that this is the primary target for all interventions and important to diverse stakeholders including patients and their families.^{11,43,57-59} We will use NLP/ML methods to identify goals-of-care discussions.⁶⁰ We will manually review the EHR for goals-of-care discussions using our standard EHR abstraction methods⁴⁰⁻⁴² for a randomly selected subset of patients in each trial to evaluate potential misclassification with NLP/ML methods.

Secondary outcomes for both trials, obtained from the EHR, include utilization metrics associated with intensity of care (e.g., any ICU admissions, hospital readmissions, and ICU- and hospital-free days). ICU admissions will be assessed 30- and 90-days post-randomization, as well as 7- and 30-days post-discharge. Hospital readmissions will be assessed for 7- and 30-days post-discharge. ICU- and hospital-free days are defined as the number of days alive and outside of the ICU (or hospital) within the specified time period after randomization (i.e., 30- or 90-days).^{61,62} We will also examine the following outcomes: 1) emergency department visits within 30- and 90-days post-randomization (Trial 1 only); 2) palliative care consults completed in the 30- and 90-days post-randomization; 3) costs of care during hospital admission and within 30- and 90-days following randomization (obtained from institutional billing systems); 4) all-cause mortality at 30-days (both Trials) and 120-days (Trial 2 only) post-randomization (using EHR and Washington State death certificate data); 5) time to first goals-of-care discussions during the 30-days post-randomization (Trial 2 only); and 5) days spent in the hospital post-randomization during the index hospitalization (Trial 1 only). See Table 1 for a summary of study outcomes.

b) Outcomes derived from patient- and family-reports (Trial 2 only):

Additional outcomes for Trial 2 will be obtained from patient-reported or family-reported surveys (Table 1). Depending on the research question, surveys will be completed during at least one of the following time points: 1) baseline; 2) 3-5 days after randomization; and 3) 4-6 weeks after randomization. Surveys may be completed in person, online, by mail, or by phone, based on respondents' preferences.

Occurrence and quality of discussions: We use previously validated items to assess the occurrence and quality of goals-of-care communication during the hospitalization after randomization.^{5,29,63-68} Communication occurrence is assessed with a single item.^{29,64} Quality of goals-of-care communication is assessed with the end-

of-life communication subscale (QOC_eol) of the Quality of Communication (QOC) survey, developed from qualitative interviews and focus groups with a diverse group of patients, families, and clinicians.^{63,65,67}

Goal-concordant care: Concordance between the care patients want and the care they are receiving will be measured with two questions from SUPPORT.⁶⁹ The first question defines patients' priorities for extending life or ensuring comfort. The second question assesses patients' perceptions of their current treatment using the same two options.⁶⁹ Concordance is defined as a match between preference for care and the type of care currently received, as reported by patients or families. Although most patients want both quality and life-extending care, requiring respondents to pick one is a useful way to identify patients' top priority.⁷⁰⁻⁷² If patients are unable to respond, goals of care are elicited from family as they would be in clinical practice.⁷³ Additionally, goal-concordant care will be assessed with an investigator developed question, "Is your care (or your family member's care) in line with your (their) goals?". Data from this question complements the SUPPORT items but also addresses some of the shortcomings that have been associated with responses to SUPPORT.

Symptoms of anxiety and depression: Patient and family symptoms of anxiety and depression are assessed with the Hospital Anxiety and Depression Scale (HADS).^{74,75} Patients and families will complete these surveys for themselves only; we do not ask for surrogate report of patients' psychological symptoms. The goal is not to diagnose the clinical syndromes of anxiety or depression, but rather to identify the burden of symptoms.

Health related quality of life: The EQ-5D-5L is a 5-item questionnaire derived from the widely-used and well-validated EQ-5D. In this revision, questions similarly represent 5 dimensions of health-related quality of life: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. In contrast to the EQ-5D, each dimension has 5 levels rather than 3, ranging from no problems (1) to severe problems (5). Its psychometric properties including responsiveness have been supported across a broad range of populations, conditions and settings⁷⁶, including dementia⁷⁷ and for proxy use⁷⁸, making it particularly appropriate for the current study.

Shared decision-making: The CollaborATE instrument is a 4-item survey that assesses patients' perception of shared decision making—that is, feeling and reporting being informed and involved in decision-making steps as part of their interactions with their physician.⁷⁹ It has been shown to demonstrate intra-rater validity, discriminative and concurrent validity, as well as sensitivity to change.⁸⁰ In this study, we will be able to evaluate it both as an outcome and as a mediator, exploring whether the Jumpstart interventions alter patients' and surrogates' perceptions of shared decision-making or whether it mediates the occurrence of the primary outcome (EHR documentation of goals of care).

c) Implementation outcomes (Trials 1 and 2)

Assessment of the implementation of the interventions in Aim 3 is guided by the RE-AIM Framework for implementation research³²⁻³⁵ and the Consolidated Framework for Implementation Research (CFIR).³⁶ RE-AIM is a multidimensional framework for evaluating the public health impact of efforts to translate research into practice.³³ The five dimensions of RE-AIM are reach of the intervention within the target population, effectiveness of the intervention, adoption by target staff members or settings, implementation consistency and quality, and maintenance of intervention delivery and effects.³²⁻³⁵ CFIR is a pragmatic meta-theoretical framework that synthesizes constructs related to implementation of evidence-based interventions. The five overarching domains are intervention characteristics, outer setting, inner setting, characteristics of individuals, and process, and include a total of 37 constructs that can be used to understand what works, and why, in a certain setting.³⁶ We collect quantitative and qualitative data on reach, effectiveness, adoption, implementation, and maintenance (RE-AIM) of the intervention. Quantitative data are collected as routine tracking as part of the implementation of both trials, with data on participation, intervention use, fidelity to the intervention, and changes over time. Qualitative data are collected through short, semi-structured

interviews guided by the CFIR domains. The interviews are conducted in-person or by phone with patients and family members from Trial 2, and clinicians from either Trial 1 or 2 after study involvement. Participants are selected using purposive sampling to provide diverse perspectives; we will consider level of participation in the study, race, ethnicity, age, gender, and, for clinicians, specialty. A trained qualitative interviewer will interview participants using an interview guide, and interviews will be audio-recorded and transcribed.^{58,81-97.}

Table 1: Outcome measures and data collection

OUTCOME MEASURES	CONCEPT	TIME FRAME
Outcomes derived from the EHR		
Primary Outcome		
EHR documentation of goals-of-care discussion	Goals-of-care discussion	30-days post-randomization
Secondary Outcomes		
ICU admissions (post-randomization)	Intensity of care	30- and 90-days post-randomization
ICU admissions (post-discharge)	Intensity of care	7- and 30-days post-discharge
Hospital readmissions (post-discharge)	Intensity of care	7- and 30-days post-discharge
ICU- and hospital-free days	Intensity of care	30- and 90-days post-randomization
Other pre-specified/exploratory outcomes		
Emergency department visits (Trial 1 only)	Intensity of care	30- and 90-days post-randomization
Palliative care consults completed	Intensity of care	30- and 90-days post-randomization
Costs of care	Intensity of care	During hospital stay, 30- and 90-days post-randomization
All-cause mortality	All-cause mortality	From EHR and death certificates: Trial 1: 30-days post-randomization Trial 2: 30- and 120-days post-randomization
Time to first goals of care discussion (Trial 2 only)	Goals-of care discussions	30-days post-randomization
Days spent in hospital (index hospitalization) (Trial 1 only)	Intensity of care	Length of index hospital stay post-randomization
Outcomes derived from survey data		
Secondary Outcomes		
Patient/family reported discussion of goals ^{29,64}	Goals-of-care discussion occurrence	3-5 days and 4-6 weeks post-randomization
Quality of Communication (QOC) ^{63,65,67}	Quality of communication	3-5 days post-randomization
SUPPORT question ⁶⁹	Goal-concordant care	3-5 days and 4-6 weeks post-randomization
Other pre-specified/exploratory outcomes		
HADS – anxiety and depression ^{74,75}	Symptoms of anxiety and depression	4-6 weeks post-randomization
EQ-5D-5L ⁷⁶⁻⁷⁸	Health-related QOL	4-6 weeks post-randomization
CollaborATE ^{79,80}	Shared decision-making	3-5 days post-randomization

Goal Concordance	Goal-concordant care	3-5 days and 4-6 weeks post-randomization
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6) Analyses

We will follow the intention-to-treat principle for all analyses.

a) Primary Outcome (presence of goals of care discussion within 30 days after randomization)

The effect of intervention on the primary outcome will be quantified by the difference in proportions and evaluated with a linear regression model with robust standard errors. The predictor of interest is randomization arm (EHR-based clinician-facing Jumpstart or usual care for Trial 1; or EHR-based clinician-facing Jumpstart, survey-based bi-directional Jumpstart, or usual care for Trial 2). The model will adjust for hospital site and ADRD status, since randomization is stratified on these factors. This model assumes the effect of intervention is the same for patients with and without ADRD. We will also include an interaction between randomization arm and ADRD, which allows the effect of intervention to vary by ADRD status and allows evaluation of the effect among those with and without ADRD. We will evaluate the timing of goals-of-care discussions with a Cox proportional hazards model.

b) Additional Outcomes

For the analysis of the other outcomes, we will use a strategy similar to that for the primary outcome. For continuous outcomes (e.g., ICU-free days, HADS score), the effect of intervention will be quantified by a difference in means. For survey outcomes which are collected at more than one time point after randomization, we will use a mixed model to account for the correlation between repeated measures. Our initial model will allow the average response to be different at each time point, but assume the intervention has the same effect at each time. We will also allow the effect of intervention to be different across time by including an interaction between time and intervention. The advantage of using the data at the multiple time points and a mixed model approach is that we can gain precision; it also allows for missing responses, assuming responses are missing at random. Missing data are more of an issue for the survey outcomes than the primary outcome; we will quantify the amount and type of missing data, evaluate associations of missingness with participant characteristics, and apply appropriate methods to account for missing data.⁹⁸

c) Evaluate implementation and identify barriers and facilitators to future implementation.

We will perform thematic content analysis of transcribed interviews to explore feedback on the intervention, ways to improve intervention implementation, and aspects of care not adequately addressed by the intervention.⁹⁹⁻¹⁰¹ Interview guides and analyses will be guided by the RE-AIM and CFIR frameworks as described above.³²⁻³⁶ Qualitative data will be imported to analytic software (Dedoose), where investigators will perform the following analytic steps using an iterative approach to thematic analysis¹⁰²: 1) initially code material, devising a coding framework and using that framework to reduce the text into smaller segments; 2) identify themes from the coded text; 3) construct thematic networks that include basic themes, organizing themes and global themes; 4) describe and summarize thematic networks; and 5) interpret patterns that have emerged in and across thematic networks.

7) Sample size

a) Sample size considerations for the primary outcome

The focus for sample size considerations is the primary outcome: proportion of patients with documented goals-of-care discussions within 30 days after randomization.

Trial 1: With a total sample size of 2000 (1000 per group), two-sided significance level (α) of 0.05, and a variance estimate based on the proportion in the control group only, we have 80% power to detect a difference in proportions between those randomized to the EHR-based clinician-facing Jumpstart and usual care of at least 0.06. We assumed a proportion in the control group of 0.54 based on preliminary data. If the total number of patients with ADRD in Trial 1 is 400 (200 per group), we would have 80% power with $\alpha=0.05$ to detect a difference in proportions of 0.14 among those with ADRD.

Trial 2: With a total sample size of 600 (200 per the EHR-based clinician-facing Jumpstart, 200 per survey-based bi-directional Jumpstart, and 200 per usual care), we have 80% power to detect a difference in proportions of 16% for each of the 3 pairwise comparisons assuming an overall $\alpha=0.05$ and a Bonferroni adjustment for the 3 comparisons ($\alpha=0.017$ for each comparison) and variance based on a proportion of 0.54.

b) Sample size for qualitative analyses

For Aim 3 qualitative analyses, it is important to achieve theoretical saturation (no new themes emerging).^{101,103} Based on our prior studies, we anticipate achieving saturation by 80 interviews for understanding patients/families and clinician perspectives.^{58,84,92-97} We will monitor for saturation and will recruit additional participants if needed.

8) Data management and quality control to achieve scientific rigor

This project requires the creation, maintenance, and analysis of a database that includes a variety of measures from multiple sources. This study, like all studies, depends on the quality of the data and therefore systematic data collection, quality control, and data-management procedures will be implemented: 1) protocols for data collection; 2) rigorous training, certification, and periodic re-training of study staff, with ongoing monitoring of adherence to protocols; 3) regular review of questionnaire response rates, respondent burden,¹⁰⁴ and missing items to identify and correct problems; 4) verification of all data through custom-designed data entry systems; and 5) weekly team meetings to provide feedback to study staff to ensure problems are resolved quickly. To ensure reliability and validity of data, we will use our current methods for training and quality control.¹⁰⁵⁻¹⁰⁹ Staff conducting EHR review will undergo the following training: instruction on the protocol, guided practice abstraction, and independent abstraction with reconciliation by a trainer.

9) Protocol modifications

1. Changes to inclusion/exclusion criteria for Trials 1 and 2 (except where noted)
 - a. Lowering the inclusion criteria age from ≥ 65 to ≥ 55 years
 - b. Removing “English speaking” as an inclusion criterion (Trial 1 only)
 - c. Adding hospital admission for a minimum of 12 hours as an inclusion criterion
 - d. Removing markers of frailty as an eligibility criterion
 - e. Adding pregnancy, suicide attempt, and same-day discharge as exclusion criteria
 - f. Adding COVID-19 as a specific inclusion diagnosis (Trial 1 only)
2. Study design
 - a. For Trial 2, in addition to comparing the survey-based bi-directional Jumpstart to the EHR-based clinician-facing Jumpstart, we will also include a third arm in which patients receive usual care.

- b. We have increased the target sample size from n=400 to n=600 to accommodate the addition of a third “usual care” arm to the study.
 - c. We have modified the questionnaires that patients receive at baseline such that only patients in the survey-based bi-directional Jumpstart arm are presented with items that are used to create the bi-directional, survey-based Jumpstart. These items are an integral part of the survey-based bi-directional intervention and therefore not appropriate for the other arms to complete.
- 3. Procedures
 - a. Removing data collection for acute severity of illness (e.g., SOFA score) for Trial 2 and replacing with a Deyo-Charlson comorbidity index
 - b. Revisions to instruments included in surveys for Trial 2
 - c. Increasing subject numbers for clinician interviews from 20 to 50 across both trials
 - d. Addition of demographic items (required by study sponsor, NIH) to the clinician interview
- 4. Materials
 - a. Updated instructional video for clinicians in Trial 1
 - b. Revision of the Jumpstart Guide into an HTML format as a delivery option. This version includes optional feedback buttons at the bottom (options: will definitely use; will use if time allows; maybe, will consider; not appropriate; will not see this patient; already done; opt out; other/free text)
 - c. Updated language and formatting for all versions of the Jumpstart Guide (patient survey-based bidirectional, clinician survey-based bidirectional, EHR-based clinician facing) using a human-centered design approach⁵⁴

10) Potential limitations and alternative approaches

a) Including ADRD and other diseases in same study

Patients with ADRD receive different intensity of care at the end of life compared to other chronic diseases,^{52,110} and there may be differences in the effectiveness of the interventions. Our hypothesis is that these interventions will work for all diseases, but because of the unique issues of increasing ICU use among those with ADRD,^{52,110} we will target adequate sample size for patients with ADRD to be able to test this hypothesis for the primary outcome of each trial. We could have proposed separate trials for ADRD and other illnesses, but this would decrease the generalizability of the interventions.

b) Generalizability

This study occurs in a single healthcare system but includes three diverse hospitals thus enhancing generalizability.

c) Misclassification of goals-of-care discussions

Goals-of-care discussions may be misclassified for two reasons: 1) the sensitivity and specificity of the NLP/ML algorithm is not perfect; and 2) documentation of goals-of-care discussions in the EHR will never perfectly reflect actual discussions. This misclassification could affect outcome assessment and patient identification. For outcome assessment, we will assess the accuracy of the NLP/ML algorithm against manual EHR review in a randomly selected sample of patients to evaluate the extent of misclassification. For our final algorithm, we will use human abstractors to verify the first documentation of a goals-of-care discussion for each patient to maximize positive predictive value and specificity, as has been done by others.^{111,112} However, since our goal is to prompt and guide more discussions than would happen without the interventions, the limitations of the

NLP/ML algorithm for patient identification do not invalidate the randomized trials. We could have included all hospitalized patients regardless of prior documentation, but we believe that untargeted prompts might limit the impact of the intervention. In addition, we will use the interviews in Aim 3 to understand clinicians' perspectives on the effect of misclassification.

d) Contamination

It is possible that this intervention might change behavior for clinicians caring for patients randomized to the comparator arms. Our prior studies suggest that most clinicians require a patient-specific prompt to have timely goals-of-care discussions, which may mitigate this concern.^{29,64} However, we will assess for an increase in goals-of-care discussions in the comparator groups over time, which might signify contamination or temporal trends, but could be used to assess the potential degree of contamination if present. This issue would bias the results toward the null hypothesis and only be a major issue for a negative study.

e) Scalability of surveys in Trial 2

Study staff will distribute surveys, which is challenging for implementation in clinical practice. Aim 3 will provide insights into how best to address scalability for implementation.

f) Objective assessments of the quality of goals of care discussions

Our NLP/ML approach identifies goals-of-care discussions without assessing their quality. Since our prior trials demonstrated increased patient-assessed quality with the Jumpstart intervention, this is less of a concern.^{29,64} Future NLP/ML advances may permit quality assessments. Trial 2 assesses quality of communication from patient and family perspectives.

g) Costs assessments focus on UW Medicine

Cost assessments for Aim 1 are limited to costs available in the UW Medicine EHR, and we will not be able to assess costs from other healthcare systems after hospital discharge. Most of the benefits we anticipate for this intervention will occur during the hospitalization, although there may be ongoing reductions in costs after hospitalization related to changes in the goals of care as a result of the intervention. We will evaluate for such effects in Trial 2, and the limitation of not having access to these costs from outside UW Medicine in Trial 1 is diminished somewhat because this is a randomized trial.

11) Anticipated findings

These interventions use the EHR to identify patients who should have documentation of a goals-of-care discussion but do not, and then prompt and guide such discussions with either: a) an EHR-based clinician-facing prompt and guide for clinicians only, along with information about prior advance care planning completed prior to the hospitalization; or b) a survey based bi-directional intervention that provides patient-specific support to clinicians, patients and family members. We anticipate that both interventions will be effective compared to the usual care arm, and that this study will provide important options for healthcare systems. Economic analyses will allow us to evaluate the effect on costs of care and may enhance the intervention's dissemination. If either or both of these interventions are not effective, the results and the interviews in Aim 3 will provide important information to shape, direct and deliver future interventions.

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APPENDIX 1: Trial 1 EHR-based clinician-facing Jumpstart Guide (PDF format)

UW Medicine

Date Created: 2/28/20

Jumpstart Guide**Your patient may benefit from a goals of care talk.**

We have chosen your patient based on a diagnosis of one or more chronic illnesses.

Please treat this guide as CONFIDENTIAL.

Your patient: John Doe, MRN: H1234567

Code Status	Full code	10/15/2019
Advance directive	YES	12/15/2018
DPOA health care	NO	
POLST	NO	

1. Give yourself 5-10 minutes. The conversation does not have to be long.

2. Introduce the talk as a routine part of care. Some patients are reluctant— don't start with death or CPR.

"I want to know what's important to you so that we provide the best care to fit your goals. Is that okay?"

3. Pick the best topics for your patient. You don't have to do them all.

Topics**Words to try**

Understanding

"What have other doctors told you about how serious your illness is and what to expect?"

Acceptable states

"What abilities are so important to you that you can't imagine living without them?"

Values

"If you were to get sicker, what would be most important to you?"

4. Document a short note. A brief summary and a quote (a few of the patient's words) are enough. Your colleagues will appreciate it.

APPENDIX 2: Trial 1 EHR-based clinician-facing Jumpstart Guide (HTML format)**Jumpstart Guide: A UW Medicine Program****Your patient may benefit from a goals of care talk.**

We have chosen your patient based on a diagnosis of one or more chronic illnesses.
Please treat the PHI on this guide as CONFIDENTIAL - okay to share with team.

Your patient: John Doe, MRN: H1234567

Code Status	Full code	10/15/2019
Advance directive	YES	12/15/2018
DPOA health care	NO	
POLST	NO	

1. Give yourself 5-10 minutes. The conversation does not have to be long.

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Topics**Words to try**

Understanding

"What have other doctors told you about how serious your illness is and what to expect?"

Acceptable states

"What abilities are so important to you that you can't imagine living without them?"

Values

"If you were to get sicker, what would be most important to you?"

4. Document a short note. A brief summary and a quote (a few of the patient's words) are enough. Your colleagues will appreciate it.

Optional Feedback

Select an option below to send us feedback on this message.

Will Definitely Do

Will Do If Time Allows

Maybe, Will Consider

Not Appropriate

Already Done

Other

APPENDIX 3: Trial 2 EHR-based clinician-facing Jumpstart Guide

Jumpstart Guide: A UW Medicine Program

Your patient has a chronic illness and may benefit from a goals of care conversation.

The PHI below is CONFIDENTIAL. Consider speaking with the patient's family if the patient is unable. It is OK to share this guide with other clinicians.

Your patient: John Doe, MRN: H1234567

Code Status	Full code	10/15/2019
Advance directive	YES	12/15/2018
DPOA health care	YES	10/20/2018
POLST	NO	

- 1. Give yourself 5-10 minutes.** The conversation does not have to be long.
- 2. Introduce the talk as a routine part of care.** Some patients are reluctant—don't start with death or CPR.

"I want to know what's important to you so that we provide the best care to fit your goals. Is that OK?"

- 3. Pick the best topics for your patient.** You don't have to do them all.

Topics

Words to try

Understanding

"What have other doctors told you about how serious your illness is and what to expect?"

Acceptable states

"What abilities are so important to you that you can't imagine living without them?"

Values

"If you were to get sicker, what would be most important to you?"

- 4. Document a short note** A brief summary and a quote (a few of the patient's or their family member's words) are enough. Your colleagues will appreciate it.

APPENDIX 4: Trial 2 Clinicians' survey-based bi-directional Jumpstart Guide

Jumpstart Guide: A UW Medicine Program

Your patient has a chronic illness and may benefit from a goals of care conversation.

The PHI below is CONFIDENTIAL. Consider speaking with the patient's family if the patient is unable. It is OK to share this guide with other clinicians.

Your patient: John Doe, MRN: H1234567

Code Status	Full code	10/15/2019
Advance directive	YES	12/15/2018
DPOA health care	YES	10/20/2018
POLST	NO	

- 1. Give yourself 5-10 minutes.** The conversation does not have to be long.
- 2. Your patient completed a survey about their goals and preferences.** Pick the best topics for your patient based on their responses. You don't have to do them all.
- 3. Document a short note.** A brief summary and a quote (a few of the patient's words) are enough. Your colleagues will appreciate it.

From your patient's survey:

Words to try:

- They are unsure if they want to talk about goals of care.
- Your patient reported a barrier to talking about their goals: they would rather concentrate on staying alive than talk about death.
- They perceive the current focus of care as extending life but PREFER quality of life.
- They *probably* want CPR in current health and *definitely do NOT* want CPR if in a state of dependence for ADLs.

"It is helpful for me if I make sure I understand your thoughts about the care you would want if you were too sick to speak for yourself."

"Some people find it hard to talk about what they would want in the future if they got sicker. Would you consider giving it a try for a few minutes? At any time, you can just say, 'Ok, that's enough for today.'"

"Some people prefer care focused on extending life as much as possible; other people prefer care focused on quality of life and comfort. Would it be helpful for me to clarify how I see the focus of your care?"

"You indicated you would want to receive CPR if your heart were to stop beating in your current health, but NOT if you were to get much sicker and be dependent on others. Is that correct?"

APPENDIX 5: Trial 2 Patients' survey-based bi-directional Jumpstart Guide

Jumpstart Guide: A UW Medicine Program

Your doctor is interested in hearing your thoughts about your medical care and what is important to you. You can show this guide to your doctor to help start a conversation.

We encourage you to bring up two important topics:

1. The care you would want if something more serious were to happen *now*.
2. The care you would want if something more serious were to happen *in the future*.

Here is information from your survey. **PATIENT NAME**, you said:

- You were not sure if you prefer medical care focused on living as long as possible or being as comfortable as possible.
- You did not provide a response regarding what you perceive is the current focus of the medical care you're receiving.
- You did not provide a response about whether, in your current health state, you would want CPR if your heart were to stop beating and you were to die.
- You did not provide a response about whether, if you were to be permanently confined to bed and dependent on others, you would want CPR if your heart were to stop beating and you were to die.

Here's language you can use to start a conversation with your doctor:

- "Can we talk about medical care focused on being as comfortable as possible compared to medical care focused on living as long as possible? I'm not sure which focus I prefer."
- "Is my current medical care more focused on living as long as possible or being as comfortable as possible? Can we talk about whether that is the right focus for me?"
- "I don't think I would want CPR. Can we talk about that? Should I complete a POLST form or advance directive?"
- "I don't think I would want CPR in the future if I were dependent on others for the rest of my life. Can we talk about that?"

Thank you for using the Jumpstart Guide. We hope this information is helpful.