Published in final edited form as:

Contemp Clin Trials. 2020 November ; 98: 106163. doi:10.1016/j.cct.2020.106163.

Operationalizing needs-focused palliative care for older adults in intensive care units: design of and rationale for the PCplanner randomized clinical trial

Christopher E. Cox, MD MPH^{1,*}, Maren K. Olsen, PhD^{2,3}, David Casarett, MD⁴, Krista Haines, DO⁵, Mashael Al-Hegelan, MD¹, Raquel R. Bartz, MD⁶, Jason N. Katz, MD MHS⁷, Colleen Naglee, MD⁸, Deepshikha Ashana, MD MBA MS¹, Daniel Gilstrap, MD¹, Jessie Gu, MD¹, Alice Parish, MSPH², Allie Frear¹, Deepthi Krishnamaneni⁹, Andrew Corcoran¹⁰, Sharron L. Docherty, RN PhD¹¹

¹Department of Medicine, Division of Pulmonary & Critical Care Medicine and the Program to Support People and Enhance Recovery (ProSPER), Duke University, Durham, NC

²Department of Biostatistics and Bioinformatics, Duke University, Durham, NC

³Durham Center of Innovation to Accelerate Discovery and Practice Transformation, Durham Veterans Affairs Health Care System, Durham, NC

⁴Department of Medicine, Section of Palliative Care and Hospice Medicine, Duke University, Durham, NC

⁵Department of Surgery, Division of Trauma and Critical Care and Acute Care Surgery, Duke University, Durham, North Carolina

⁶Department of Anesthesia, Division of Critical Care Medicine, Duke University, Durham, NC

⁷Department of Medicine, Division of Cardiology, Duke University, Durham, NC

⁸Department of Anesthesia, Division of Neurology, Duke University, Durham, NC

*Corresponding author at: Christopher Cox / Duke University / Box 102043 / Durham, NC 27710, christopher.cox@duke.edu.

CRediT statement:

Conceptualization: CEC, SD, MKO, AC, DK, DC

Methodology: MKO, CEC, SD, AC, DK, AP

Formal analysis: MKO, AP

Data Curation: MKO, CEC, AC, DK

Investigation: CEC, MKO, AF, AC, DK, DC, KH, MA, RB, JK, DA, JG, CN

Writing - Original Draft: CEC, MKO, AF, AC, DK, KH, DA, SD, JG, DA, CN

Writing - Review & Editing: CEC, MKO, LP, AF, AC, DK, KH, SD, JS, DA, MA, JK, RB, DC, CN

Project administration: CEC, SD, AF, AC

Funding acquisition: CEC, SD

5 potential peer reviewers:

May Hua (Columbia University, New York, NY), mh2633@cumc.columbia.edu

Rebecca Aslakson (Stanford University, Palo Alto, CA), aslakson@stanford.edu

Richard Mularski (Kaiser Health, Portland, OR), Richard.A.Mularski@kpchr.org

Donald Sullivan (Oregon Health & Sciences University, Portland, OR), sullivan@ohsu.edu

Erin Kross (University of Washington), ekross@uw.edu

Competing interests statement

No author has conflicts of interest to report relevant to this manuscript.

Publisher's Disclaimer: This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

⁹Duke Health Technology Solutions, Duke University, Durham, NC

¹⁰Office of Academic Solutions and Information Systems, Duke University, Durham, NC

¹¹School of Nursing, Duke University, Durham, NC

Abstract

Introduction: The number of older adults who receive life support in an intensive care unit (ICU), now 2 million per year, is increasing while survival remains unchanged. Because the quality of ICU-based palliative care is highly variable, we developed a mobile app intervention that integrates into the electronic health records (EHR) system called PCplanner (Palliative Care planner) with the goal of improving collaborative primary and specialist palliative care delivery in ICU settings.

Objective: To describe the methods of a randomized clinical trial (RCT) being conducted to compare PCplanner vs. usual care.

Methods and analysis: The goal of this two-arm, parallel group mixed methods RCT is to determine the clinical impact of the PCplanner intervention on outcomes of interest to patients, family members, clinicians, and policymakers over a 3-month follow up period. The primary outcome is change in unmet palliative care needs measured by the NEST instrument between baseline and 1 week post-randomization. Secondary outcomes include goal concordance of care, patient-centeredness of care, and quality of communication at 1 week post-randomization; length of stay; as well as symptoms of depression, anxiety, and post-traumatic stress disorder at 3 months post-randomization. We will use general linear models for repeated measures to compare outcomes across the main effects and interactions of the factors. We hypothesize that compared to usual care, PCplanner will have a greater impact on the quality of ICU-based palliative care delivery across domains of core palliative care needs, psychological distress, patient-centeredness, and healthcare resource utilization.

Keywords

critical illness; intensive care units; palliative care; mobile app; electronic health record (EHR) systems; randomized clinical trial (RCT)

Introduction

Advances in intensive care unit (ICU) technologies increasingly preserve and extend lives. However, the experience of the 2 million older adults admitted to ICUs annually in the United States alone is more complex.[1]

In comparison to younger ICU patients, older adults have a higher incidence and longer use of life support, more prolonged hospitalizations, fewer discharges to home, and greater risks of death and readmission.[2–4] Patients often suffer from physical (pain, breathlessness) and psychological (delirium, anxiety, depression, post-traumatic stress disorder [PTSD]) symptoms both during and after ICU treatment that are often unrecognized.[5, 6] They may experience dehumanized deaths, often after multiple health care transitions in the last weeks of life, and frequently after receiving CPR or invasive life support.[7, 8] Family caregivers,

commonly acting as surrogate decision makers, often experience poor communication quality, unsupported decision making, and a lack of information about what to expect.[9–11] This uncertainty promotes psychological distress, as well as discordance between treatment preferences and the care provided—likely contributing to the escalating use of life support.[12]

Palliative care is particularly relevant to the older adult ICU population because it aims to improve quality of life and decrease suffering by addressing unmet physical, emotional, and existential needs. Although delivering high quality palliative care is often a struggle for health systems in general, it is particularly inconsistent and unreliable in the ICU settings.[13, 14] Furthermore, in contrast to the strong evidence that palliative care specialty care improves quality of life and symptoms in outpatient and hospital ward settings,[15] there is weak evidence for its impact in an ICU setting beyond length of stay and satisfaction.[16]

To address this problem and improve the delivery of ICU-based palliative care for older adults, we developed an intervention for patients, family members, and clinicians called PCplanner (Palliative Care planner). PCplanner is an innovative mobile app platform designed to help both primary (i.e., ICU teams) and specialist palliative care clinicians to deliver need-focused care. This intervention uses an innovative technological approach (1) to help clinicians identify older adults at high risk of having unmet palliative care needs by automating data capture directly from any health system's electronic health record (EHR); (2) to allow patients and families to self-report to clinicians their unmet needs across all eight domains of palliative care quality, and (3) to coordinate the delivery of need-targeted care in a stepwise manner by ICU teams, and the palliative care specialty team if needs remain high or increase over time. In a pilot trial including a historical palliative care control, PCplanner was feasibly delivered, rated as highly usable by participants, and improved unmet needs, family psychological distress, patient receipt of goal concordant care, patient-centeredness of care, and quality of communication.[17] While these data are promising, the intervention requires a rigorous evaluation. In this manuscript, we describe the design, methods, novel technological features that allow the mobile app to utilize data from any EHR regardless of vendor, and planned analyses for the randomized clinical trial (RCT) that will evaluate evidence of efficacy.

Materials and methods

Study objective

The overall objective of the PCplanner RCT is to compare the impact of the intervention with usual care on outcomes assessed over 3 months that are important to patients, family members, clinicians, and policymakers. The primary outcome is unmet palliative care needs measured 1 week post-randomization. This project aims to improve the delivery of collaborative palliative care and move beyond the limitations of current paradigms (Figure A.1.).

Study design

This is a prospective, two-arm, parallel group mixed methods RCT with 3-month follow up that includes ICU patients, family members, ICU clinicians, and palliative care clinicians.

Study sites

This study is being conducted at three hospitals within the Duke University Health System: Duke Medical Center (Durham, NC), Duke Regional Community Hospital (Durham, NC), and Duke Raleigh Hospital (Raleigh, NC).

Participant eligibility

We aim to randomize 150 patient-family member dyads in this trial. We will aim to enroll a larger sample size if possible to enhance the cohort size remaining at the time of the 3-month follow up given the high mortality (30–50%) expected by 3 months among critically ill patients. Patients' ICU physicians and palliative care physicians will also be enrolled.

Eligibility criteria: The inclusion and exclusion criteria for all participant groups are shown in Table 1. In general, we are targeting older adult (≥ 65 years of age) ICU patients with clinical phenotypes that place them at high risk of having unmet palliative care needs. These phenotypes were derived from a mixed-methods study in which we explored attitudes and beliefs about ICU-based palliative care and the use of palliative care triggers among 303 ICU nurses and physicians.[18] While dyadic enrollment will occur, the patient is the key determinant of eligibility.

Duration of subject participation and RCT

Three months are required for the patient-family member dyad to complete the entire study from the time of randomization. We estimate that it will require 40–45 months to complete data collection (36 months for cumulative enrollment with 4–5 months to complete all long-term follow up; this time does not include start up) and 4–6 months to perform all final data analyses.

Retention plan

Participant retention may present unique challenges because of patients' underlying illnesses, the likelihood of patient death given their critical illness, and the stresses that family members experience. Our strategies for enhancing retention include: (1) stringent eligibility criteria designed to exclude those most likely to have atypical clinical courses, (2) preliminary formal usability testing of the intervention to improve user engagement, (3) use of a mobile app for all study data collection, (4) preparation of weekly reports using PCplanner mobile app analytics to identify participants who are not logging in to the app, (5) the low questionnaire burden (6) the use of reminder automated emails and/or texts to prompt survey completion, (7) participant compensation for their time.

Recruitment

Figure 1 demonstrates an overview of the study flow, which is also described below.

Step 1—PCplanner platform identification of potentially eligible patients: An algorithm guides the PCplanner app platform's automated daily screening of all hospitalized adult ICU patients in the Duke University Healthcare System. Briefly, the PCplanner mobile app platform communicates directly with the EHR's data layer every 24 hours by translating its e-trigger data elements (Table 2), mapped to Meaningful Use Common Data Set standards,[19] to an open-sourced application programming interface (API) that incorporates HL7 international health data standards (details shown in Appendix A and Figure A.2.).[20] Using this EHR-interoperable API, the PCplanner app platform identifies every ICU patient who meets the definition of at least one high risk phenotype.

Step 2—Study team curation of patient lists in ICU physician dashboard and physician approval: The PCplanner clinician dashboard will be populated with data derived from the EHR's data system layer via a unique EHR-interoperable API built by our team. At 7:00 AM each day, the list of patients who meet one of the 9 phenotype triggers will be automatically updated with new EHR-based data. Patients can be removed manually from the PCplanner clinician dashboard by the Study Manager if, on their daily early morning review of potentially eligible patients, they find that a patient meets an exclusion that can be ascertained through review of the EHR. Additionally, if an ICU clinician denies study staff approach of the patient/family member by recording such in the app dashboard, the patient will be removed from the dashboard and will also not appear again on a subsequent day (though this action will be recorded for tracking and reporting purposes). Because of daily data refreshing, patients will be removed automatically from the PCplanner clinician dashboard if they die, are discharged from the hospital, refuse to participate, or are randomized to control.

Step 3—Informed consent and randomization: After ICU team approval is recorded, PCplanner will send either an email or SMS text message (as preferred) to study staff members prompting them to approach the patient and family for informed consent. Staff will utilize a study 'infomercial' to quickly describe the trial to prospective participants (Appendix B video material). Randomization will be performed at the patient level by the app platform, stratifying participants by 3 binary factors including treating service (medical vs. surgical), baseline NEST score (<25 vs. ≥25), and palliative care phenotype (acute [mechanical ventilation, shock, acute neurological injury, cardiac arrest, multisystem organ failure] vs. chronic [dementia, admitted from facility, advanced cancer, declining health trajectory, poor functional status]). After a patient-family member dyad has been randomized to intervention, the PCplanner platform will generate a PHI-free secure text to both the dyad and the ICU attending.

Intervention

Background and rationale: By overcoming key care delivery process barriers, PCplanner is designed to help ICU and palliative care teams to proactively identify and address family caregivers' unmet palliative care needs.

PCplanner initial viewing by patients and family caregivers: After randomization to the PCplanner intervention group, family caregivers will view PCplanner's video, audio,

and text content on a tablet computer, also receiving login instructions for secure use on their own device as well as assistance in establishing a smartphone desktop icon link to PCplanner. They will complete baseline study surveys through the mobile app, including the NEST unmet palliative care needs instrument. This instrument acts as both the key data visualized during the study by intervention clinicians as well the primary trial outcome.

ICU clinician role and procedures: The first time a study ICU physician provides informed consent, study staff will review the study procedures and timeline; assist in establishing a smartphone, tablet, or desktop icon link to the PCplanner dashboard; and allow the clinician to complete a brief survey to assess their age, role, discipline, experience, and attitudes and beliefs about ICU-based palliative care derived from Wysham, et al.[18] Following this, ICU clinicians will use the mobile app in two ways. By following a link in an SMS text generated by the PCplanner platform, the clinician will login using a Duke University Shibolet procedure to see their patient panel's NEST values arranged by domain (Figure 2; palliative care clinicians see the same dashboard). Usual care control patients will not be visible in the PCplanner dashboard. ICU clinicians will discuss the areas of greatest need with patients and/or family caregivers within 72 hours during a semi-structured meeting as their schedule permits. ICU clinicians will also be encouraged to use the advice and tips contained within the clinician PCplanner interface to guide their discussion of relevant needs (Figure 2).

Need-prompted palliative care specialist consultation team procedures: A formal palliative care consultation will be conducted only for intervention-group patient-family caregiver dyads whose 4th day post-randomization NEST score is either very high (≥ 25) or has increased in comparison to the baseline NEST score. For each palliative care attending physician's first intervention patient, the CRC will briefly review the study procedures and timeline, provide them with a laminated card outlining the family meeting template, and assist in establishing a smartphone, tablet, or desktop icon link to PCplanner. Similar to the process for ICU clinician engagement, the PCplanner platform will send a PHI-free SMS text alert to the palliative care consult team pager stating that a new study family has been enrolled. The palliative care clinician can click a unique URL that will link them to the PCplanner clinician dashboard. The palliative care team, composed of a physician and at least one non-physician (e.g., nurse, social worker, chaplain) will then conduct an in-person family meeting with the patient, family caregiver, and ICU clinician on the same day if possible; up to 48 hours will be allowed accommodate weekends. The family meeting protocol is shown in Appendix C. Subsequent palliative care-led meetings will be scheduled as per the practice of the Duke palliative care service. Because each meeting will be documented in the EHR, staff will be able to abstract the completion of meetings, the content, and any impacts (e.g., change in goals of care).

Usual care condition

Control family caregivers will receive usual ICU care that does not include a protocolized palliative care consult. Data collection will be identical to the intervention group (email/text links with unique URLs integrated with the trial data system), though data reported by family members will not be visible in the PCplanner dashboard or otherwise available to

clinicians. Each usual care participant will be provided with telephone and email contacts for study staff to answer questions or address urgent distress. A palliative care specialist consult is allowed for any control patient or family caregiver if ICU clinicians believe it is needed. All such crossovers will be recorded (as will the total number of palliative care-family interactions).

Outcomes measures—Data will be collected at pre-randomization baseline (T1 Data Collection) as well as 4 days (T2 Data Collection), 8 days (T3 Data Collection), and 3 months (T4 Data Collection) post-randomization. Data to be collected are shown in Table 3. The timing of the PCplanner app’s messaging that prompts survey completion is shown in Figure A.3.

Primary outcome: The Needs; Existential concerns; Symptoms; and Therapeutic interaction (NEST) scale, which assesses palliative care needs among both critically ill older adult patients and their family caregivers (and is completed by family caregivers), is the primary trial outcome and T3 is the primary timing of its measurement.[21] The NEST’s 13 items (score range 0–130) sample each of the National Consensus Project’s eight domains of palliative care quality.[22] We have piloted the NEST among 32 ICU family caregivers, finding a mean total score of 33 (range 3–89).[17] Domain scores correlated with depression symptoms ($r=0.76$), anxiety symptoms ($r=0.85$), and satisfaction ($r=0.55$). The NEST was responsive to change over 1 week (median 9 units, range 1–19) without ceiling or floor effects (range 3–89, skewness 0.6). Additionally, using data derived from 207 participants in an ongoing ICU-based clinical trial ([NCT03506438](#)), the mean baseline NEST score was 26.4 (SD 21.1), the range was 0 to 103, and correlation between time points was 0.64. This mean baseline NEST score data directly informed our definition of the ‘high needs’ stratification variable. The minimal clinically important difference (MCID), the smallest change in survey score associated with a clinically relevant change, is unclear for the NEST. However, it seems likely that this study will have adequate power to detect at least what is likely to be the MCID (and possibly even smaller) for three reasons. First, an 8.8-unit NEST difference is small overall for a scale scored from 0 – 130, speaking to the analytical power our sample size will provide. Second, an 8.8-unit change represents a marked change in score for approximately one NEST item, providing assurance that we are likely to detect the smallest clinically important change. Third, a NEST change of this magnitude was associated with a measurable change in the PHQ-9 and GAD-7 in our pilot work.[17]

While the NEST will be administered over three time points (T1, T2, and T3), the timing used as the primary study outcome will be T3. The rationale is that this timing will include the full intervention (i.e., ICU team plus palliative care team) in all cases in which it used. Using T2 as the primary outcome timing would not include this potential palliative care team effect.

Secondary outcomes: The Patient Health Questionnaire 9-item scale will be used, as in the pilot study, to assess depression symptoms. The PHQ-9 has excellent psychodynamic properties including reliability, test-retest stability, accuracy, responsiveness, and validity as supported by confirmatory factor analysis.[23] PHQ-9 scores range from 0 (no distress) to 27 (high distress). Symptom severity is interpreted as mild (scores of 5–9), moderate (scores

of 10–14), moderately severe (scores of 15–19), and severe (scores of 20–27), while the minimal clinically important difference is 5 units.

The Generalized Anxiety Disorder 7-item scale (GAD-7), a measure of anxiety symptoms, has excellent psychodynamic properties including reliability, test-retest stability, accuracy, responsiveness, and validity as supported by confirmatory factor analysis.[24] GAD-7 scores can range from 0 (no distress) to 21 (high distress). Symptom severity is interpreted as mild (scores of 5–9), moderate (scores of 10–14), and severe (scores of 15–21), while the minimal clinically important difference is 5 units.

The Post-Traumatic Stress Syndrome inventory (PTSS) rates 10 post-traumatic stress symptoms (range 10 [no symptoms] to 70 [high burden of symptoms]). A score >20 represents clinically important PTSD symptoms, while a score ≥34 suggests a likely clinical diagnosis of PTSD with 98% specificity and 77% sensitivity in comparison to DSM-IV criteria.[25]. Although formal psychometric testing has not clearly defined the PTSS's minimal clinically important difference, a 5-unit change represents a significant change in score in a single PTSS item and will therefore be used as a benchmark for the proposed project.

Receipt of goal concordant care is a dichotomous outcome that is assessed by comparing 2 items tested in the SUPPORT study assessing the family caregiver's perception of the patient's treatment goal preferences and the actual care being provided to them.[26] Although many patients want both, this forced choice helps to identify patients' top priority as perceived in this case by their family caregiver.

The Patient-centeredness of Care Scale (PCCS) is a 12-item (score range 0–36) instrument that measures to what extent the patient's treatment is aligned with their values, a key goal of the intervention.[27, 28] The PCCS will also potentially provide nuance to other study findings as well as help to explain findings that are unexpected or require interpretations within a certain context. For example, although past end of life interventions have not increased mortality, it is possible that by better focusing decision makers' attention on patients' values, higher mortality could be observed in the intervention group by identifying patients for whom prolonged life support would be a state worse than death. Yet if PCplanner—a non-directive intervention—led to more decisions to forego life support, this would be ethically permissible if the treatments received reflected patient-centered care as assessed by the PCCS.

Other variables will include patient and family caregiver age, gender, race, ethnicity, employment status, insurance status, and marital status; a single item assessing financial distress we used in a past trial;[29] a summary item from the Quality of Communication instrument;[30] patients' medical comorbidities using the Charlson-Deyo Index;[31] and physical function.[32, 33]

Clinical measures: We will record ICU admission and discharge diagnoses; illness severity (APACHE II); ICU service (medical vs. surgical); duration of ventilation; duration of vasopressor use; surgeries; length of stay; post-randomization hospital length of stay (LOS);

use, timing, and duration of aggressive medical care (e.g., mechanical ventilation, cardiopulmonary resuscitation, acute dialysis, tracheotomy, surgical feeding tube placement, advanced directive change, and code status), and discharge disposition. Using EHR abstraction, we will record all inpatient and outpatient patient/family member interactions (formal family meeting, informal ‘check-ins’) with palliative care providers as well as ICU teams for both treatment groups from the time of randomization throughout the 3-month follow up period.

Analytics: We will employ analytics to assess numerous PCplanner mobile app use characteristics for clinicians and family caregivers alike including: total uses, time window of use, uses per day, average time per session, number of pages visited, average time per page, clicks per session, clicks per page, pages visited most (and least), use of weblinks, access of specific elements (e.g., audio, video), and others. These analytics will also permit exploration of dose and effect as well as the impact of individual clinicians’ app behaviors on outcomes.

Data collection and management—Most data entry will be self-completed by participants online that they will access via timed, automated protected health information-free links sent via text from the mobile app platform. Study staff will complete electronic case report forms securely integrated within the data system. Using tested password-based customization strategies, the data system will allow only the Study Manager to view patient-level data such as treatment group assignment; all others will be blinded both to treatment group and to other sites’ participants. We will use a parallel study operations workflow tracking application to manage participants’ contact history log, survey schedule, and recorded adverse events.

Human subjects and regulatory oversight—Our study will include standards such as strict investigator oversight, safety monitoring by an independent data safety monitoring board, and approval by the Duke University institutional review board (protocol number 00101745), and redundant technological and human processes designed to protect the safety of participants embedded within the app platform. More specifically, the trial includes the PHQ-9 survey and its single item addressing suicidality, to which we will add branching logic about intent and plan for clarity. By virtue of the app platform’s integration with the study data system, real-time alerts will be sent to the study team to notify them of the presence of active suicidality among any intervention or control participant. Participants endorsing this item will also be shown a list of phone numbers to distress hotlines and local resources for distress assistance available 24 hours a day. Those endorsing active suicidality will be contacted immediately by a study investigator who will follow the trial’s distress management protocol. The trial is registered at [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT04414787) (NCT04414787).

Statistical analysis

Quantitative analyses: We will test the primary study hypothesis that the NEST score is lower (i.e., fewer unmet needs) for intervention family caregivers compared to usual care at T3 (~1 week post-randomization). All participants will be analyzed as part of the group they were assigned, regardless of adherence or crossover status (i.e., intention to treat). We will

use a general linear model to estimate mean NEST changes and corresponding confidence intervals over time using SAS PROC MIXED (SAS Institute, Cary NC). Different correlation structures will be examined (e.g., unstructured, autoregressive) and model fit indices will be used to guide the choice of the final model's structure.

Analyses similar to those conducted for the NEST (primary outcome analyses) above will be performed for the secondary family caregiver hypotheses involving PHQ-9, GAD-7, and PTSS scores at T3 and T4. While family caregivers will be interviewed at T4 regardless of patient survival, patient death could complicate the analyses in two key ways: (1) Presence of missing data due to family loss to follow up (i.e., non-random missing data) and (2) differences in family caregiver distress by patient survival status (i.e., heterogeneous effect). [34] To address the impact of patient death on outcomes, after first exploring reasons for and predictors of dropout, we will conduct a 2-step supplemental analysis. In Step 1, missing T4 data due to loss to follow up among family caregivers of survivors will be multiply imputed via SAS PROC MI. In Step 2, we will account for T4 outcomes that are missing due to death via composite endpoint and principal stratification methods to estimate the causal effects of the intervention in the presence of these unidentified outcomes and complicated missing data patterns.[35, 36] For the key patient outcome, receipt of goal concordant care, we will use logistic regression models adjusting for the stratification variables, to examine if rates at T3 differ by treatment group. The key healthcare systems outcome, post-randomization hospital length of stay (LOS), provides a unique challenge due to the high expected mortality rate (40–50%). In addition to descriptive analyses, steps to examine treatment group LOS differences will include: (1) a proportional hazards model with death treated as a censoring event; (2) a chi-square test of mortality rate differences; and (3) a Brunner-Manzel rank test for the composite death-LOS outcome. This last step implements a recently developed methodology of a composite outcome that incorporates a numerical value for death (i.e., coded as the worst possible outcome or the longest possible stay) in the observed LOS distribution.[37, 38]

Qualitative analyses: We will also explore family caregiver and clinician experiences with the PCplanner intervention using a mixed-methods approach to characterize how intervention components may have impacted cases (patient, family caregiver, clinician) across a variety of implementation contexts. Each month we will purposefully sample 1–2 patient cases (patient, family caregiver, 1 ICU physician, and 1 palliative care team member) from the intervention group until we reach a total that will be sufficient to reach informational saturation (~ 30 cases). We will stratify sampling to ensure variability in factors that may influence experiences. We will combine data from the analysis of semi-structured interviews with family caregivers and clinicians, with quantitative outcomes.[39, 40] Findings will provide insight into mechanisms of action, and highlight methods for future intervention optimization through enhanced personalization, replicability, and scalability.

Sample size and power considerations.—Calculations were conducted via the mixed models with the differences in slopes option in PASS 2020 (Kayesville, UT). With a total of 130 participants at T3 (n=65 per treatment arm), we will have 80% power to detect a

differential NEST improvement between treatment groups at T3 of 8.80 units (SD=21.1, $p=0.64$ between T1-T3 based on pilot data and an additional ongoing trial [NCT03506438]). To account for 10% dropout by T3, we plan to consent and randomize 150 participants ($n=75$ per treatment arm). This sample size will also provide a power of 80% (type-I error of 5%, dropout rates as noted above) to detect a 2.33-unit PHQ-9 change (SD=5.3, $p=0.6$) at T3—far smaller even than its 5.0-unit MCID. These estimates are based on our pilot work as well as an ongoing RCT (NCT03506438) we are conducting that uses the NEST.

Results

The trial will begin screening and enrollment on November 1, 2020.

Discussion

The clinical gap that exists with palliative care delivery

At a time when the utilization of ICU care is growing among older adults who consistently experience worse outcomes compared to younger patients, the delivery of high quality palliative care remains suboptimal. Palliative care has improved quality of life and symptoms in outpatient and hospital ward settings.[41] Yet there is weak evidence for its impact in an ICU setting. Aslakson's systematic review of 30 ICU-based palliative care interventions found that none focused on older adults; none used patient-centered primary outcomes; few involved structured collaboration between ICU and palliative care clinicians; few were adequately powered; and most linked eligibility to a disease.[42] More recently, a supportive information program with palliative care-led family meetings did not reduce LOS or family distress compared to control.[43] Palliative care rounding advisors reduced LOS, but not family caregiver distress in a before/after study.[44] Finally, compared to control, a communication facilitator reduced 6-month (but not 3-month) depression symptoms among caregivers of patients with >30% risk of death.[45]

PCplanner addresses key process and structural care delivery barriers

Currently the quality of ICU-based palliative care is limited by three key process barriers, technical and interpersonal factors that limit the consistent delivery of the right care, to the right person, at the right time.[46]

1. Identifying patients with unmet palliative care needs is currently inefficient, inaccurate, and unstandardized because no ICUs to our knowledge routinely perform formal palliative care needs assessments. In the consultative model that dominates current care, intensivists order specialist palliative care infrequently, variably, and often so late that patients' accumulated life support adjuncts preclude hospice transfer.[43] In the trigger model, specialist care is activated by the presence of proxies for need associated with death or LOS. Interest is high in using 'e-triggers' for EHR screening to avoid manual chart searches or case-finding discussions with busy clinicians. However, sophisticated e-triggers that are highly specific for need (e.g., presence of conflict) are difficult to extract from EHRs, even with advanced analytics due to clinicians' imperfect cut/paste documentation. And simpler e-triggers (e.g., cancer, LOS) are disease-centered,

often poorly accepted by clinicians because they lack clinical context,[18, 47] and can result in rates as high as 50% for false positives (i.e., trigger positive, need negative) due to their low specificity for actual need.[48]

2. Engaging family caregivers, though rarely an intervention focus,[49] must be improved to address their high informational needs as surrogate decision makers, [50] and to overcome common misunderstandings about palliative care (e.g., ‘giving up’).
3. Coordination of care between ICU and palliative care teams remains unstandardized despite calls to improve it from funding agencies:[51] professional groups:[52] and experts in palliative care, critical care, and geriatrics.[53–55]

PCplanner (Palliative Care planner) is a mobile app platform that helps clinicians to address the self-reported needs of older adults in ICUs that was developed to address palliative care delivery barriers. It addresses the three key process barriers by:

1. Identifying ‘true positives,’ defined as those with unmet needs, as the intervention target. It uses an innovative technological approach to identify older adults at high risk of having unmet palliative care needs by automating the capture of data directly from any health system’s EHR to construct ‘high risk’ phenotypes that are clinician-accepted, clinically intuitive yet difficult to recognize consistently (e.g., declining health status), and able to be uniformly applied very early in the ICU stay (48 hours). Such timing is important because proactive palliative care expedites decision making, reduces length of stay and resource use, and increases hospice use:[4, 44, 56] effects observed in our successful pilot.[17] PCplanner also enables clinicians to quickly visualize the type and severity of actual patient and family needs from family caregiver self-report (Figure 2). Such knowledge of needs can lead to more family meetings, social work attention, and spiritual care, all factors that improve communication quality.[48]
2. Engaging older family caregivers with family-facing app content targeting common information gaps including: a self-produced video on the purpose of palliative care, a question coach feature (e.g., how to convey patient values), links to web resources that address common ICU conditions, and a self-reported need survey. This successfully piloted content is designed to increase acceptance, activation, medical comprehension, and confidence—factors that impact satisfaction and incident distress, yet are often lacking from family-ICU team interactions.[49, 50]
3. Coordinating care by acting as infrastructure for a replicable ICU team and palliative care team care delivery model. The clinician-facing app allows one-click approval for patient/family study involvement, automatically messages teams when needs data are available, and uses clinician-accepted gentle ‘nudges’—elements designed to influence behavior predictably without restricting choice

—to reinforce consistent use.[57] The app emphasizes a common language of need understood by all, rather than insular ICU or palliative care terminologies.

Structural barriers to palliative care delivery also exist, difficult-to-change care setting factors that limit the consistency and scalability of care delivery. The palliative care workforce is too small to address the demand of the >1 million older ICU patients who meet triggers,[14, 53] while many ICU clinicians lack the skills or confidence to elicit and address many needs themselves.[58] Because the number of ICU beds is still rising, scalable clinician supports like PCplanner that can identify the ‘true positives’ who have high levels of unmet needs (i.e., high NEST scores) as a clinical focus for palliative care providers are needed to anchor a durable collaborative model to overcome these barriers.

Innovative features

PCplanner provides a need-targeted collaborative care delivery model that currently does not exist. By combining high risk phenotype e-triggers and needs, PCplanner is the first ICU-based intervention to feasibly match specialist palliative care to ‘true positives’ with quantified unmet needs, thereby improving efficiency, enhancing patient-centeredness, reducing the ‘healthy person’ dilution effect on outcomes, and addressing structural barriers by minimizing ‘false positives.’ Its e-trigger phenotypes advance the science with simple profiles of health trajectories distilled from complex arrays of universal standards-based Meaningful Use Common Data Set EHR elements. They also serve to increase the accuracy and efficiency of palliative care by forming a manageable pool of patients and their families at high risk for unmet needs within which actual unmet needs can be feasibly measured.

PCplanner’s technological innovations enhance scalability. Interoperability—functionality across multiple platforms—powerfully enhances replicability and scalability. Although interoperability is the primary current healthcare information technology focus of the Office of the National Coordinator,[59] few examples of EHR-interoperable applications exist. PCplanner has the ability to capture many data directly from any EHR by translating its e-trigger data elements to an open-sourced API. This means that PCplanner could be adapted to work with any EHR regardless of its vendor with minimal effort.

There have been numerous negative palliative care-themed trials conducted in ICU settings, most of which have included primary outcomes such as length of stay or symptoms of psychological distress weeks to months after discharge. The PCplanner trial proposes a relatively novel primary outcome, the NEST, to better capture the proximal impact of an intervention that aims to help ICU teams and palliative care more effectively address unmet needs. The multi-domain NEST may be better able than single domain instruments to more holistically measure the global impact of the complex, multi-faceted, and relatively unstructured palliative care ‘medicine in the syringe’ that the clinicians provide.

PCplanner was developed so that it could be used in clinical settings with different capacities and resources. Hospitals with EHRs but limited staffing can use PCplanner to ‘right size’ the number of ‘true positives’ by reducing the number of activated phenotypes, increasing the need score cutoff for specialist care, prioritizing care by total need scores, or defining specific need categories for care from non-physician providers. For hospitals without EHRs

or specialists, PCplanner can give information to families and measure the presence, type, and severity of unmet needs—without requiring additional staff.

Last, PCplanner can serve as a foundation for future innovations. Without requiring changes to its core architecture, PCplanner can be adapted to refine case-finding (e.g., machine learning, artificial intelligence [A.I.]), for use in clinic or ward settings, to include new content (e.g., decision aids), or to anchor a community-based model in which candidates are identified in the EHR and managed within a population cohort via the app. A logical extension of the model is further specification of roles (e.g., specialists vs. primary providers, physicians vs. non-physicians) based on the type and severity of need present.

Potential limitations and plans for addressing them in this clinical trial

Although this is a clinical trial conducted among three hospitals within a single health care system, we believe that its results will be broadly generalizable. The setting includes academic and community hospitals with both open and closed ICUs with practices that mirror US norms (e.g., lack of detailed protocols for palliative care activation, communication, decision making). The proposed participants have common diagnoses and, based on our past trials, are expected to be diverse in geography (1,000 mi² 3-state urban/rural catchment area), race (>35% minorities), and gender (>50% female).

Given the use of technology, consideration of PCplanner's replicability is important. PCplanner use in the future at other sites is ensured by its ability to capture data directly from any EHR; its automated screening, messaging, and data collection; and its accessibility on any device with a cellular or internet connection because of its web app (vs. native app) build.[17] For clinical operation, it requires only one person to review a patient list, hand a tablet to a family member, and activate available services if needs warrant.

Last, patient-level randomization could cause treatment diffusion from intervention-sensitized ICU clinicians to control families. However, the likelihood of significant diffusion, problematic only in the case of a negative trial, is low. Randomizing by physician could increase contamination because their short on-service periods (e.g., 3–7 days as per the predominant US ICU staffing model) would frequently lead to overlap of intervention and control physicians managing a single patient/family caregiver. Recordings of control group physician-family interactions in recent ICU-based communication and decision making RCTs with patient-level randomization showed no intervention content diffusion. [60] A stepped-wedge design may be subject to bias from evolving clinical changes (e.g., impact of COVID) evolving during a long enrollment phase, while the resources required for the additional sites needed for ICU-level clustering likely exceed the study budget and timeline. Also, the discontinuity of ICU staffing itself serves as the greatest protection against passive uptake of complex communication skills or consistent recall of the NEST's 13 items.[61, 62] During the course of the RCT, we expect the 8 study ICUs will be staffed by a total of >750 different nurses (each working 3-shift blocks, 4 times per month), and >100 physicians (each of whom work ~8–10 total weeks per year in 3–7-day blocks, each typically separated by a 3-week period). Also, there is evidence of equipoise regarding the benefits of protocolized palliative care consultation based on our epidemiological study of

ICU clinician attitudes [18] and the relatively low number of ICU-initiated palliative care consults nationally.

Conclusion

In conclusion, PCplanner is a highly novel intervention designed to act as digital infrastructure for the reliable, scalable delivery of palliative care to older adults by both primary and specialist palliative care practitioners. The current RCT aims to establish its efficacy in reducing unmet palliative care needs, reducing psychological distress and improving patient centeredness of care, and reducing inpatient resources utilization.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgements:

Matt Gauger, Ariana Stokes, and Nickie Bruckner (One Cow Standing, Durham, NC); Derek Jones, MDiv; Wen Reagan, PhD; and the reviewers for their important suggestions.

Funding: This work was supported by the National Institutes of Health (award R01 AG058915)

Role of the funding source

This project was funded by National Institute on Aging (NIA) award R01AG058915. The funder had no involvement in study design; in the collection, analysis and interpretation of data; in the writing of the report; and in the decision to submit the article for publication.

Abbreviations:

ICU	intensive care unit
EHR	electronic health record system
RCT	randomized clinical trial

References

- [1]. S.o.C.C. Medicine, Critical care statistics in the United States, 2017.
- [2]. Wunsch H, Guerra C, Barnato AE, Angus DC, Li G, Linde-Zwirble WT, Three-year outcomes for Medicare beneficiaries who survive intensive care, JAMA 303 (2010) 849–56. [PubMed: 20197531]
- [3]. Guidet B, Leblanc G, Simon T, Woimant M, Quenot JP, Ganansia O, Maignan M, Yordanov Y, Delorme S, Doumenc B, Fartoukh M, Charestan P, Trognon P, Galichon B, Javaud N, Patzak A, Garrouste-Orgeas M, Thomas C, Azerad S, Pateron D, Boumendil A, Network I-CS, Effect of Systematic Intensive Care Unit Triage on Long-term Mortality Among Critically Ill Elderly Patients in France: A Randomized Clinical Trial, JAMA 318 (2017) 1450–1459. [PubMed: 28973065]
- [4]. Teno JM, Gozalo PL, Bynum JP, Leland NE, Miller SC, Morden NE, Scupp T, Goodman DC, Mor V, Change in end-of-life care for Medicare beneficiaries: site of death, place of care, and health care transitions in 2000, 2005, and 2009, JAMA 309 (2013) 470–7. [PubMed: 23385273]
- [5]. Baldwin MR, Wunsch H, Reyfman PA, Narain WR, Blinderman CD, Schluger NW, Reid MC, Maurer MS, Goldstein N, Lederer DJ, Bach P, High burden of palliative needs among older

- intensive care unit survivors transferred to post-acute care facilities. a single-center study, *Annals of the American Thoracic Society* 10 (2013) 458–65. [PubMed: 23987743]
- [6]. Nelson JE, Meier DE, Litke A, Natale DA, Siegel RE, Morrison RS, The symptom burden of chronic critical illness, *Crit Care Med* 32 (2004) 1527–34. [PubMed: 15241097]
- [7]. Cook D, Swinton M, Toledo F, Clarke F, Rose T, Hand-Breckenridge T, Boyle A, Woods A, Zytaruk N, Heels-Ansdell D, Sheppard R, Personalizing Death in the Intensive Care Unit: The 3 Wishes Project A Mixed-Methods Study The 3 Wishes Project, *Annals of Internal Medicine* 163 (2015) 271–279. [PubMed: 26167721]
- [8]. Hart JL, Harhay MO, Gabler NB, Ratcliffe SJ, Quill CM, Halpern SD, Variability among us intensive care units in managing the care of patients admitted with preexisting limits on life-sustaining therapies, *JAMA Internal Medicine* 175 (2015) 1019–1026. [PubMed: 25822402]
- [9]. Cox CE, Martinu T, Sathy SJ, Clay AS, Chia J, Gray AL, Olsen MK, Govert JA, Carson SS, Tulskey JA, Expectations and outcomes of prolonged mechanical ventilation, *Crit Care Med* 37 (2009) 2888–94; quiz 2904. [PubMed: 19770733]
- [10]. Cameron JI, Chu LM, Matte A, Tomlinson G, Chan L, Thomas C, Friedrich JO, Mehta S, Lamontagne F, Levasseur M, Ferguson ND, Adhikari NK, Rudkowski JC, Meggison H, Skrobik Y, Flannery J, Bayley M, Batt J, dos Santos C, Abbey SE, Tan A, Lo V, Mathur S, Parotto M, Morris D, Flockhart L, Fan E, Lee CM, Wilcox ME, Ayas N, Choong K, Fowler R, Scales DC, Sinuff T, Cuthbertson BH, Rose L, Robles P, Burns S, Cypel M, Singer L, Chaparro C, Chow CW, Keshavjee S, Brochard L, Hebert P, Slutsky AS, Marshall JC, Cook D, Herridge MS, Investigators RP, Canadian G. Critical Care Trials, One-Year Outcomes in Caregivers of Critically Ill Patients, *N Engl J Med* 374 (2016) 1831–41. [PubMed: 27168433]
- [11]. Sudore RL, Fried TR, Redefining the “planning” in advance care planning: preparing for end-of-life decision making, *Ann Intern Med* 153 (2010) 256–61. [PubMed: 20713793]
- [12]. You JJ, Dodek P, Lamontagne F, Downar J, Sinuff T, Jiang X, Day AG, Heyland DK, Team AS, the N. Canadian Researchers at the End of Life, What really matters in end-of-life discussions? Perspectives of patients in hospital with serious illness and their families, *CMAJ* 186 (2014) E679–87. [PubMed: 25367427]
- [13]. Wachterman MW, Pilver C, Smith D, Ersek M, Lipsitz SR, Keating NL, Quality of End-of-Life Care Provided to Patients With Different Serious Illnesses, *JAMA Intern Med* 176 (2016) 1095–102. [PubMed: 27367547]
- [14]. Hua MS, Li G, Blinderman CD, Wunsch H, Estimates of the need for palliative care consultation across united states intensive care units using a trigger-based model, *Am J Respir Crit Care Med* 189 (2014) 428–36. [PubMed: 24261961]
- [15]. Temel JS, Greer JA, Muzikansky A, Gallagher ER, Admane S, Jackson VA, Dahlin CM, Blinderman CD, Jacobsen J, Pirl WF, Billings JA, Lynch TJ, Early palliative care for patients with metastatic non-small-cell lung cancer, *N Engl J Med* 363 (2010) 733–42. [PubMed: 20818875]
- [16]. Halpern SD, Toward Evidence-Based End-of-Life Care, *N Engl J Med* 373 (2015) 2001–3. [PubMed: 26465826]
- [17]. Cox CE, Jones DM, Reagan W, Key MD, Chow V, McFarlin J, Casarett D, Creutzfeldt CJ, Docherty SL, Palliative Care Planner: A Pilot Study to Evaluate Acceptability and Usability of an Electronic Health Records System-integrated, Needs-targeted App Platform, *Annals of the American Thoracic Society* 15 (2018) 59–68. [PubMed: 29121480]
- [18]. Wysham NG, Hua M, Hough CL, Gundel S, Docherty SL, Jones DM, Reagan O, Goucher H, McFarlin J, Cox CE, Improving ICU-Based Palliative Care Delivery: A Multicenter, Multidisciplinary Survey of Critical Care Clinician Attitudes and Beliefs, *Crit Care Med* 45 (2017) e372–e378. [PubMed: 27618270]
- [19]. Meaningful Clinical Use Common Data Set elements, 2016.
- [20]. H.L.S. International, About HL7, 2018.
- [21]. Scandrett KG, Reitschuler-Cross EB, Nelson L, Sanger JA, Feigon M, Boyd E, Chang CH, Paice JA, Hauser JM, Chamkin A, Balfour P, Stolbunov A, Bennett CL, Emanuel LL, Feasibility and effectiveness of the NEST13+ as a screening tool for advanced illness care needs, *Journal of palliative medicine* 13 (2010) 161–9. [PubMed: 19821699]

- [22]. N.C.P.f.Q.P. Care, Clinical practice guidelines for quality palliative care, 2018.
- [23]. Kroenke K, Spitzer RL, Williams JB, The PHQ-9: validity of a brief depression severity measure, *J Gen Intern Med* 16 (2001) 606–13. [PubMed: 11556941]
- [24]. Spitzer RL, Kroenke K, Williams JB, Lowe B, A brief measure for assessing generalized anxiety disorder: the GAD-7, *Arch Intern Med* 166 (2006) 1092–7. [PubMed: 16717171]
- [25]. Stoll C, Kapfhammer HP, Rothenhausler HB, Haller M, Briegel J, Schmidt M, Krauseneck T, Durst K, Schelling G, Sensitivity and specificity of a screening test to document traumatic experiences and to diagnose post-traumatic stress disorder in ARDS patients after intensive care treatment, *Intensive Care Med* 25 (1999) 697–704. [PubMed: 10470573]
- [26]. Teno JM, Fisher ES, Hamel MB, Coppola K, Dawson NV, Medical care inconsistent with patients' treatment goals: association with 1-year Medicare resource use and survival, *J Am Geriatr Soc* 50 (2002) 496–500. [PubMed: 11943046]
- [27]. Johnson SK, Bautista CA, Hong SY, Weissfeld L, White DB, An empirical study of surrogates' preferred level of control over value-laden life support decisions in intensive care units, *Am J Respir Crit Care Med* 183 (2011) 915–21. [PubMed: 21037019]
- [28]. Stewart M, Brown JB, Donner A, McWhinney IR, Oates J, Weston WW, Jordan J, The impact of patient-centered care on outcomes, *J Fam Pract* 49 (2000) 796–804. [PubMed: 11032203]
- [29]. Cox CE, Hough CL, Carson SS, White DB, Kahn JM, Olsen MK, Jones DM, Somers TJ, Kelleher SA, Porter LS, Effects of a Telephone- and Web-based Coping Skills Training Program Compared with an Education Program for Survivors of Critical Illness and Their Family Members. A Randomized Clinical Trial, *Am J Respir Crit Care Med* 197 (2018) 66–78. [PubMed: 28872898]
- [30]. Engelberg R, Downey L, Curtis JR, Psychometric characteristics of a quality of communication questionnaire assessing communication about end-of-life care, *Journal of palliative medicine* 9 (2006) 1086–98. [PubMed: 17040146]
- [31]. Deyo RA, Cherkin DC, Ciol MA, Adapting a clinical comorbidity index for use with ICD-9-CM administrative databases, *J Clin Epidemiol* 45 (1992) 613–9. [PubMed: 1607900]
- [32]. Katz S, Ford AB, Moskowitz RW, Jackson BA, Jaffe MW, Studies of illness in the aged. The index of ADL: a standardized measure of biological and physiological function., *JAMA* 185 (1963) 914–919. [PubMed: 14044222]
- [33]. Lawton MP, Brody EM, Assessment of older people: self-maintaining and instrumental activities of daily living, *Gerontologist* 9 (1969) 179–86. [PubMed: 5349366]
- [34]. Kurland BF, Johnson LL, Eggleston BL, Diehr PH, Longitudinal Data with Follow-up Truncated by Death: Match the Analysis Method to Research Aims, *Stat Sci* 24 (2009) 211. [PubMed: 20119502]
- [35]. Chiba Y, VanderWeele TJ, A simple method for principal strata effects when the outcome has been truncated due to death, *Am J Epidemiol* 173 (2011) 745–51. [PubMed: 21354986]
- [36]. Colantuoni E, Scharfstein DO, Wang C, Hashem MD, Leroux A, Needham DM, Girard TD, Statistical methods to compare functional outcomes in randomized controlled trials with high mortality, *BMJ* 360 (2018) j5748. [PubMed: 29298779]
- [37]. Courtright KR, Madden V, Gabler NB, Cooney E, Small DS, Troxel A, Casarett D, Ersek M, Cassel JB, Nicholas LH, Escobar G, Hill SH, O'Brien D, Vogel M, Halpern SD, Rationale and Design of the Randomized Evaluation of Default Access to Palliative Services (REDAPS) Trial, *Annals of the American Thoracic Society* 13 (2016) 1629–39. [PubMed: 27348271]
- [38]. Lin W, Halpern SD, Prasad Kerlin M, Small DS, A “placement of death” approach for studies of treatment effects on ICU length of stay, *Stat Methods Med Res* 26 (2017) 292–311. [PubMed: 25085115]
- [39]. Bonell C, Fletcher A, Morton M, Lorenc T, Moore L, Realist randomised controlled trials: a new approach to evaluating complex public health interventions, *Soc Sci Med* 75 (2012) 2299–306. [PubMed: 22989491]
- [40]. O'Cathain A, Thomas KJ, Drabble SJ, Rudolph A, Hewison J, What can qualitative research do for randomised controlled trials? A systematic mapping review, *BMJ open* 3 (2013).
- [41]. Kelley AS, Morrison RS, Palliative Care for the Seriously Ill, *New England Journal of Medicine* 373 (2015) 747–755. [PubMed: 26287850]

- [42]. Aslakson R, Cheng J, Vollenweider D, Galusca D, Smith TJ, Pronovost PJ, Evidence-based palliative care in the intensive care unit: a systematic review of interventions, *Journal of palliative medicine* 17 (2014) 219–35. [PubMed: 24517300]
- [43]. Carson SS, Cox CE, Wallenstein S, Hanson LC, Danis M, Tulskey JA, Chai E, Nelson JE, Effect of Palliative Care-Led Meetings for Families of Patients With Chronic Critical Illness: A Randomized Clinical Trial, *JAMA* 316 (2016) 51–62. [PubMed: 27380343]
- [44]. Braus N, Campbell TC, Kwekkeboom KL, Ferguson S, Harvey C, Krupp AE, Lohmeier T, Repplinger MD, Westergaard RP, Jacobs EA, Roberts KF, Ehlenbach WJ, Prospective study of a proactive palliative care rounding intervention in a medical ICU, *Intensive Care Med* 42 (2016) 54–62. [PubMed: 26556622]
- [45]. Curtis JR, Downey L, Back AL, Nielsen EL, Paul S, Lahdya AZ, Treece PD, Armstrong P, Peck R, Engelberg RA, Effect of a Patient and Clinician Communication-Priming Intervention on Patient-Reported Goals-of-Care Discussions Between Patients With Serious Illness and Clinicians: A Randomized Clinical Trial, *JAMA Intern Med* (2018).
- [46]. Donabedian A, Evaluating the quality of medical care, *Milbank Mem Fund Q* 44 (1966) Suppl:166206.
- [47]. Cox CE, Curtis JR, Using Technology to Create a More Humanistic Approach to Integrating Palliative Care into the Intensive Care Unit, *Am J Respir Crit Care Med* 193 (2016) 242–50. [PubMed: 26599829]
- [48]. Creutzfeldt CJ, Engelberg RA, Healey L, Cheever CS, Becker KJ, Holloway RG, Curtis JR, Palliative care needs in the neuro-ICU, *Crit Care Med* 43 (2015) 1677–84. [PubMed: 25867905]
- [49]. Haines KJ, Kelly P, Fitzgerald P, Skinner EH, Iwashyna TJ, The Untapped Potential of Patient and Family Engagement in the Organization of Critical Care, *Crit Care Med* 45 (2017) 899–906. [PubMed: 28234753]
- [50]. Heyland DK, Dodek P, Mehta S, Cook D, Garland A, Stelfox HT, Bagshaw SM, Kutsogiannis DJ, Burns K, Muscedere J, Turgeon AF, Fowler R, Jiang X, Day AG, C.C.C.T. Group, C.R.a.E.o.L. Network, Admission of the very elderly to the intensive care unit: family members' perspectives on clinical decision-making from a multicenter cohort study, *Palliat Med* 29 (2015) 324–35. [PubMed: 25645668]
- [51]. N.I.o.N. Research, Innovative Questions in End-of-Life and Palliative Care, 2015 <http://www.ninr.nih.gov/newsandinformation/iq/eolpc-workshop#.VV4wLWBB18x>. (Accessed May 21 2015).
- [52]. Aslakson RA, Reinke LF, Cox CE, Kross EK, Benzo RP, Curtis JR, Developing a Research Agenda for Integrating Palliative Care into Critical Care and Pulmonary Practice To Improve Patient and Family Outcomes, *Journal of palliative medicine* 20 (2017) 329–343. [PubMed: 28379812]
- [53]. Kamal AH, Maguire JM, Meier DE, Evolving the Palliative Care Workforce to Provide Responsive, Serious Illness Care, *Ann Intern Med* 163 (2015) 637–8. [PubMed: 26258800]
- [54]. Horton JR, Morrison RS, Capezuti E, Hill J, Lee EJ, Kelley AS, Impact of Inpatient Palliative Care on Treatment Intensity for Patients with Serious Illness, *Journal of palliative medicine* 19 (2016) 936–42. [PubMed: 27248056]
- [55]. Angus DC, Truog RD, Toward better ICU use at the end of life, *JAMA* 315 (2016) 255–256. [PubMed: 26784767]
- [56]. Norton SA, Hogan LA, Holloway RG, Temkin-Greener H, Buckley MJ, Quill TE, Proactive palliative care in the medical intensive care unit: effects on length of stay for selected high-risk patients, *Crit Care Med* 35 (2007) 1530–5. [PubMed: 17452930]
- [57]. Patel MS, Volpp KG, Asch DA, Nudge Units to Improve the Delivery of Health Care, *N Engl J Med* 378 (2018) 214–216. [PubMed: 29342387]
- [58]. Curtis JR, Back AL, Ford DW, Downey L, Shannon SE, Doorenbos AZ, Kross EK, Reinke LF, Feemster LC, Edlund B, Arnold RW, O'Connor K, Engelberg RA, Effect of communication skills training for residents and nurse practitioners on quality of communication with patients with serious illness: a randomized trial, *JAMA* 310 (2013) 2271–81. [PubMed: 24302090]
- [59]. O.o.t.N.C.f.H.I. Technology, Connecting health and care for the nation: a shared nationwide interoperability roadmap, 2016.

- [60]. Nelson JE, Hanson LC, Keller KL, Carson SS, Cox CE, Tulskey JA, White DB, Chai EJ, Weiss SP, Danis M, The Voice of Surrogate Decision-Makers. Family Responses to Prognostic Information in Chronic Critical Illness, *Am J Respir Crit Care Med* 196 (2017) 864–872. [PubMed: 28387538]
- [61]. Tulskey JA, Interventions to enhance communication among patients, providers, and families, *Journal of palliative medicine* 8 Suppl 1 (2005) S95–102. [PubMed: 16499474]
- [62]. Curtis JR, Treece PD, Nielsen EL, Downey L, Shannon SE, Braungardt T, Owens D, Steinberg KP, Engelberg RA, Integrating palliative and critical care: evaluation of a quality-improvement intervention, *Am J Respir Crit Care Med* 178 (2008) 269–75. [PubMed: 18480429]

Author Manuscript

Author Manuscript

Author Manuscript

Author Manuscript

HIGHLIGHTS

- The quality of intensive care unit (ICU)-based palliative care is highly variable across clinicians and hospitals. This represents a missed opportunity to improve care delivery.
- PCplanner is a mobile app intervention designed to improve care delivery by directly capturing electronic health record (EHR) data to automate the identification of high risk older adults, facilitating self-report of actual unmet palliative care needs by patients and families; and coordinating collaborative needs-targeted care from ICU teams and palliative care specialists.
- This randomized clinical trial (RCT) tests the impact of PCplanner vs. usual care on unmet needs, psychological distress symptoms, and clinical outcomes.

Contemp Clin Trials. Author manuscript; available in PMC 2021 November 01.

Fig. 2.
Screenshots from the PCplanner mobile app.

Table 1:

Inclusion and exclusion criteria

Inclusion criterion	Definition
<i>Patients</i>	
Older adult	Age ≥ 65 years
High risk of unmet needs phenotype	<p>Meets ≥ 1 of 9 high risk phenotypes</p> <p>a. Dementia (e.g., Alzheimer's, multi-infarct, other dementia etiology)</p> <p>b. Declining health status defined by EITHER:</p> <p>i. ≥ 2 hospital admissions in 3 months preceding current admission</p> <p>OR</p> <p>ii. ≥ 1 ICU admission in 3 months preceding current admission</p> <p>c. Poor functional status defined by EITHER:</p> <p>i. admit from Skilled Nursing Facility (SNF) or Long-Term Acute Care (LTAC) facility</p> <p>OR</p> <p>ii. ≥ 3 activities of daily living (ADL) limitations at admission</p> <p>d. Severe acute illness defined by EITHER:</p> <p>i. cardiac arrest</p> <p>OR</p> <p>ii. multisystem organ failure (≥ 3 of: lung, kidney, hematological, brain, cardiac, liver) that has worsened over 48 hours (i.e., Sequential Organ Failure Assessment [SOFA] score increase)</p> <p>e. Severe acute stroke (e.g., acute intracranial hemorrhage, ischemic stroke, or traumatic brain injury)</p> <p>f. Acute respiratory failure (ventilation for ≥ 24 hours)</p> <p>g. Acute renal failure (new hemodialysis or continuous venovenous hemodiafiltration for ≥ 1 hour)</p> <p>h. Advanced cancer (Advanced / metastatic cancer diagnosis)</p> <p>i. Shock (use of vasopressor or inotrope for ≥ 4 hours)</p>
ICU setting	Managed in an adult medical, cardiac, trauma, surgical, or neurological ICU for ≥ 24 hours
<i>Family members</i>	
Adult	≥ 18 years of age
Family member	Self-described as the individual (related or unrelated) who provides the most support and with whom the patient has a significant relationship (per definition of 'family' described in the Society of Critical Care Medicine 2016 Guidelines for Family-Centered Care in the Neonatal, Pediatric, and Adult ICU)
<i>ICU physician</i>	
ICU physician	≥ 18 years of age
Type	Attending or fellow physician in a study ICU
Exclusion criteria	Description
<i>Patients</i>	
	<ul style="list-style-type: none"> - Palliative care consultation performed during the hospitalization before eligibility determination - Current admission to ICU at the index hospital ≥ 8 days - Imprisoned - No known family or surrogate decision maker - Death expected within 24 hours - Patient dies before T2
<i>Family members</i>	
	<ul style="list-style-type: none"> - Lack a knowledge of English such that the potential participant and/or study team is not confident that they could complete study tasks (app viewing, surveys) - Imprisoned - Unable to complete surveys for any reason - Low need burden (NEST score <10) at baseline
<i>ICU physicians</i>	
	None

Table 2:

High risk palliative care phenotypes

Phenotypes	Narrative description of 'positive' trigger	Time period relevant for screening by PCplanner	Data source in EHR
<i>Acute phenotypes</i>			
Mechanical ventilation	Mechanical ventilation delivered via either an endotracheal tube or tracheotomy for 24 hours	At any point during the first 48 hours of the current ICU admission	Respiratory care provider flowsheet
Shock	Defined as ANY use of ANY continuous intravenous vasopressor medication for 4 hours	At any point during the first 48 hours of the current ICU admission	<ul style="list-style-type: none"> • Medication list • Nursing flowsheet • Vital signs flowsheet
Severe acute neurological injury	<ul style="list-style-type: none"> • Acute intracranial hemorrhage • Ischemic stroke • Traumatic brain injury 	At any point in current hospitalization until time of screening (i.e., 48 hours after ICU admission)	<ul style="list-style-type: none"> • Physician billing • Problem list
Cardiac arrest	Has cardiac arrest managed in ED or during hospitalization	At any point in current hospitalization (or preceding ED visit for out-of-hospital cardiac arrests)	Physician Billing
Multisystem organ failure that is worsening	Present if Sequential Organ Failure Assessment [SOFA] score on ICU day 2 (i.e., hours 25–48 after ICU admission) is greater than SOFA score on ICU day 1 (i.e., hours 0–24 after ICU admission)	ICU days 1 and 2 (i.e., comparing first 24 hours of ICU admission to second 24 hours of ICU admission)	<ul style="list-style-type: none"> • Lab • Medications • Respiratory care provider flowsheet
Acute renal failure	Use of continuous venovenous hemodiafiltration (CVVHD) for 1 hour during screening period	on <u>EITHER</u> ICU day 1 (i.e., within 24 hours of ICU admission) <u>OR</u> ICU day 2 (within 48 hours of ICU admission)*	<ul style="list-style-type: none"> • Medication list from nursing flowsheet • Dialysis flowsheet • Laboratory test
<i>Chronic phenotypes</i>			
Dementia	<ul style="list-style-type: none"> • Alzheimer's • Multi-infarct • Other dementia 	<ul style="list-style-type: none"> • Present before hospitalization (i.e., Problem List) • Present at any point in current hospitalization until time of screening (i.e., 48 hours after ICU admission) 	<ul style="list-style-type: none"> • Physician billing • Problem list
Admitted from facility	Admitted from Skilled Nursing Facility (SNF) or Long-Term Acute Care (LTAC) facility	At any point in current hospitalization up until time of screening (i.e., 48 hours after ICU admission)	Intake flowsheet
Declining health trajectory	<ul style="list-style-type: none"> • 2 hospital admissions (includes Emergency Department visits)* • 1 ICU admission 	Within the 3 months that preceded the date of the current hospital admission	Admission records
Declining functional status	2 activities of daily living (ADL) limitations	At any point in current hospitalization	Nursing intake flowsheet
Advanced cancer	Cancer and/or metastatic cancer diagnosis	At any point in current hospitalization	<ul style="list-style-type: none"> • Physician billing • Problem list

Table 3:

Data collection and timing

A. Clinical / patient information	T1 Baseline	T2 4 days post- randomization	T3 8 days post- randomization	T4 3 months post- randomization
<i>Baseline</i> General information Comorbidities Diagnoses APACHE II illness severity CPR information / baseline ICU type & admission source	x	-	-	-
<i>Across entire hospitalization</i> CPR information / changes Palliative care consults Procedures and therapies Dates (mechanical ventilation, hospital, ICU)	(x)	-	-	-
<i>3 months</i> 3 month status	-	-	-	(x)
Patient & family member information				
Contact info Gender DOB, race / ethnicity, gender, marital status, children Employment Relation to patient Social support Financial distress	x	-	-	-
NEST	x	x	x	-
Goal concordant care	x	x	x	-
Quality of communication	x	x	x	-
Patient-Perceived Patient-Centeredness (PPPC) scale	-	-	x	-
PHQ-9	x	-	x	x
GAD-7	x	-	x	x
PTSS	x	-	x	x
Relationship with physician	x	x	x	-
Physician discussed needs	x	x	x	-
Readmitted?	-	-	-	X
Clinician information				
Gender Age Race / ethnicity Rank Service	Study initiation	-	-	-
Physician responses				
I did family meeting	-	X	X	-

CPR: cardiopulmonary resuscitation; GAD-7: generalized anxiety disorder 7-item instrument; ICU: intensive care unit; NEST: Needs; Existential concerns; Symptoms; and Therapeutic interaction scale; PHQ-9: patient health questionnaire 9-item depression instrument; PTSS: post-traumatic stress scale