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PROTOCOL TITLE: Comparing primary care clinician-focused versus team-based implementation of advanced care planning: protocol for a cluster-randomized control trial

ABSTRACT

Background: Many people in the United States and Canada die after living with progressive, chronic conditions[1] and often after receiving care that is not always consistent with want they wanted. This study seeks to promote advance care planning in primary care (PC) so that patients with serious illnesses and limited life expectancies receive care concordant with their goals, values and preferences.

Methods/Design: We will conduct a multicenter cluster randomized trial comparing two models for implementing an evidence-based advance care planning program called the Serious Illness Care Program (SICP) in PC practices. The two models are 1) PC clinician-focused SICP and 2) team-based SICP. Units of randomization will be enrolled PC practices from across seven geographically diverse practice-based research networks (PBRNs) that are part of the Meta-network Learning And Research Center (Meta-LARC). Each participating PBRN will recruit practices to reach the goal of 160 eligible and enrolled patients who complete followup across all the participating practices for each PBRN. Practices must be willing and able to implement the SICP as randomized. The practices can vary in size, staffing configuration, ownership, and population served. The target population includes adults living in the community with serious illnesses or conditions who have a life expectancy of two years or less. The primary outcomes are goal concordant care and time at home. Multilevel modeling will be used to account for the hierarchical structure of the data. The study will obtain ethical approval from Institutional Review Boards (IRBs) in the United States and Research Ethics Boards (REBs) in Canada. The trial will comply with CONSORT guidelines adapted for reporting cluster randomized trials.

Discussion: The results of this study will fill a gap in the current evidence about how to facilitate effective implementation of advance care planning in primary care. The study will document the impact of different advance care planning models on patients and families or designated care partners as well as on primary care clinicians and staff.

Trial Registration: ClinicalTrials.gov ID: NCT03577002

Keywords (3-10): Advance care planning, Cluster randomized trial, Serious illness care, Primary care, Goal concordant care, shared decision making, interprofessional team-based care, US-Canadian comparative study

BACKGROUND

Today, many people in the United States and Canada die after living with progressive, chronic conditions[1] that are diagnosed months or years before death and that have known, probable trajectories. Three patterns are common: 1) steady and predictable decline (e.g., cancer); 2) unpredictable decline with repeating exacerbations (chronic illnesses); and 3) slow and prolonged decline with frailty.[2,3] Many patients with serious illnesses and their families value conversations that enable them to consider what is most important to them and share their preferences with their families, designated care partners, and health care providers.

Providing all possible treatments available to save or prolong life is often the default position in the current health care system; asking about and then honoring patient preferences is not yet the norm. Without crucial conversations exploring values and goals and aligning these with care plans, treatments can incrementally become more invasive and time-consuming as conditions progress and it can harm patients, worsen quality of life, and increase suffering.[4]

The mismatch between patient goals and health care is not inevitable; it is possible for health care to be a positive force even when life expectancy is limited. The development and implementation of hospice, palliative care, care management, and care navigator programs have demonstrated that the last years, months, and days of life can be meaningful, high quality, and more comfortable.[5-7] However, it is essential to have a process to identify what is most important to patients and families and to match treatments and services to patient-defined goals, values, and preferences.[8-11] This process is referred to as advance care planning (ACP). The Serious Illness Care Program (SICP) is an ACP program designed to target patients with a serious illness and a prognosis of two years or less.

When a patient's goals, concerns, and willingness to make tradeoffs are discussed and combined with an understanding of prognosis and options, plans to fulfill the patient's wishes can be made. These can align care with what patients and families want so that quality of life improves, patients and clinicians are more satisfied, death is more likely to occur at a patient-preferred location, and bereaved family members and care partners are less likely to experience regret or major depression.[9,12,13]. Yet, serious illness care conversations and ACP is not happening for most people.[14]

The proposed study aims to fill a critical gap in evidence about how best to implement ACP using SICP in primary care (PC). PC is an appropriate setting for many ACP conversations as PC clinicians are trusted by patients, understand the long-term trajectory of a patient's illness, and view guiding patients, families, and care partners through these conversations as important and within their scope of practice.[15] However, PC clinicians face burn-out from increasing demand for their services and growing requirements. In addition, PC clinicians may not have the time, self-efficacy, skills or confidence[16,17] to have serious illness conversations and help patients plan.[18] This gap between the desire and ability to reliably facilitate conversations and planning about serious illness care in primary care underpins the rationale for this study.

Objectives

Our objective is to determine if it is more effective to focus SICP implementation on a model where a single PC clinician is responsible for the conversation and planning, given the nature of the patient-clinician relationship, or use a team-based model, given the time and resource constraint on clinicians. Our aims are to:

1. Assess the comparative effectiveness in primary care of team-based SICP vs. primary care clinician-focused SICP on concordance of care with patient goals and

time spent at home (primary outcomes) and secondary outcomes (e.g., anxiety, depression, quality of life).
2. Explore contextual factors influencing the implementation of the two different models of SICP and how these vary across the primary care practices, with a focus on the comparison of practices in the US and Canada and on practice-level characteristics (e.g., size, rural/urban, affiliation with an integrated health system, prior ACP activities, PCP staff disciplines and training)

METHODS

Trial design

We will conduct a cluster-randomized controlled trial (cRCT) with two active intervention arms in a 1:1 ratio. This trial is designed to evaluate the comparative effectiveness of two models of Serious Illness Care Program (SICP), one focused on primary care clinicians; the other focused on teams; this design requires the clustering to be at the practice level. Participating PC practices will be recruited from seven geographically distinct practice-based research networks (PBRNs) in the U.S. and Canada. The practices within each PBRN will be randomly assigned to implement either a primary care clinician-focused model or a team-based model. A cRCT is proposed because the two models cannot be implemented simultaneously in the same practice. SICP requires changes in workflow and the daily operations of the participating PC practices that impact the entire practice. Also, the training for the clinician-focused and team-based models differ and it would be difficult to isolate the effect of training on specific clinicians or patients in a clinic.

The models will be implemented at the cluster level, but the primary outcomes will be measured at the individual patient level and compared across the two models, with appropriate adjustment in the analyses. Secondary outcomes include clinician-level and practice-level variables as well as patient-level variables. The study is designed to determine if the team-model performs better than the clinician-focused model, as the clinician-focused model is the current standard of care.

Ethics Approval and Trial Registration

Institutional Review Board Approval (IRB) will obtained for the U.S. practices from a central IRB with all participating practices IRB's ceding reliance to the central IRB. Research Ethics Board Approval will be obtained in Quebec) and Ontario. The trial will be registered in ClinicalTrials.gov.

Setting and Target Population

Primary care practices will be recruited by seven primary care PBRNs that provide care to approximately three million patients in five U.S. states (OR, WI, CO, IA, NC) and two Canadian provinces (QB, ON) from practices that are members of these networks. The PBRNs all have experience in recruiting practices for participation in research and supporting patient identification and enrollment. The target population is adults living in the community with serious illnesses or conditions who have a life expectancy two years or less and are patients of a participating primary care practice.

Inclusion/Exclusion Criteria for primary care practices and patients

To be eligible for inclusion the primary care practices must have sufficient numbers of patients likely to meet eligibility criteria to justify the training and workflow changes, be willing and able to be randomized to either ACP model, and must not currently be engaged in a

standardized ACP program. Specifically, the practices must have clinicians or teams participate in training, identify appropriate patients for ACP, document and follow-up on ACP conversations, assist with the recruitment of patients, family members, and care partners into the study, allow observations and staff interviews, and assist with data collection. Practices will be compensated for data collection activities that fall outside of normal care delivery.

Patients must be adults (over 18 years of age), community dwelling (i.e., not residents of nursing homes), and have a serious illnesses or conditions that are likely to limit their life expectancy to less than 2 years as defined by using either an algorithm or clinical intuition or both. Inclusion is not limited to patients with any specific condition. Patients could have diagnoses of heart failure, chronic obstructive pulmonary disease, cancer, debilitating stroke, multiple diagnoses, or any other life-limiting condition such as frailty. Models based on comorbidity and utilization as well as clinical intuition (e.g. asking if clinician would be surprised if the patient died in the next year) for patient identification will be developed as part of the study. The exact identification mechanisms will be customized for each participating practice based on its resources (e.g. if an EHR is used and which one) and workflows.

Patients may **not** already be enrolled in hospice or currently in an ICU or hospital with no expectation of discharge. Patients who have advance directive documents (e.g., a do not resuscitate order [DNR] or Physicians orders for life sustaining care [POLST]) will not be excluded as these documents do not mean that discussions and planning are finished or static given that options and values may change over time. Family members and care partners will be recruited from those named by patients when the patients are asked if there is a person who is most involved in their health care.

Practice Participation

Primary care clinicians, other clinicians, and staff at the participating practices will also be included as research participants. All clinicians and staff participating in training will be asked to evaluate the training, selected staff and clinicians will be interviewed during quarterly practice site visits, and all personnel involved in SICP implementation will be asked to complete a web survey twice during the study (one and two years after training is complete). Staff completion of surveys or interviews will be voluntary.

Patients and Family Participation

Patients engaged in SICP at the participating practices will be recruited and enrolled in the study. Clinicians or other practice staff will briefly explain the study and ask patients to sign a waiver opt-in form, enabling the research team to contact them. Secure methods to send patient contact information to the study team will be determined by each PBRN and practice in order to accommodate their current recording system and comply with local IRB/REB determinations. Patient information will only be shared if the patient/family provides written approval. Research coordinators (from the local PBRN) will contact patient and family members to describe the research study and procedures, obtain informed consent, and collect initial information.

Interventions: Two ACP Models

The Serious Illness Care Program (SICP) is a program of Ariadne Labs (www.ariadnelabs.org) and was developed based on extensive evidence on best practices in advance care planning, palliative care and patient-clinician communication,[19-23] and data on the needs of patients, families, and clinicians.[15,24,25] SICP is designed to help clinicians initiate serious illness care conversations at the right time and in the right way so that patients and families can make better informed choices and plans that align with their values with the goal of

assuring well-being and quality of life in the context of serious illnesses and limited life span. The underlying idea of the program is that a complicated, difficult task can be facilitated and encouraged by providing a structured approach to serious illness care conversations, even when the content needs to be individualized to meet specific patient and family needs. SICP includes the Serious Illness Conversation Guide, which defines the subtopics common across these conversations and provides patient-tested language for initial and follow-up conversations as well as guides for clinicians and patients in multiple languages, training materials including didactic materials and case studies for structured role playing; and implementation guidance including recommended approaches to identifying appropriate patients and templates for documentation of conversations.

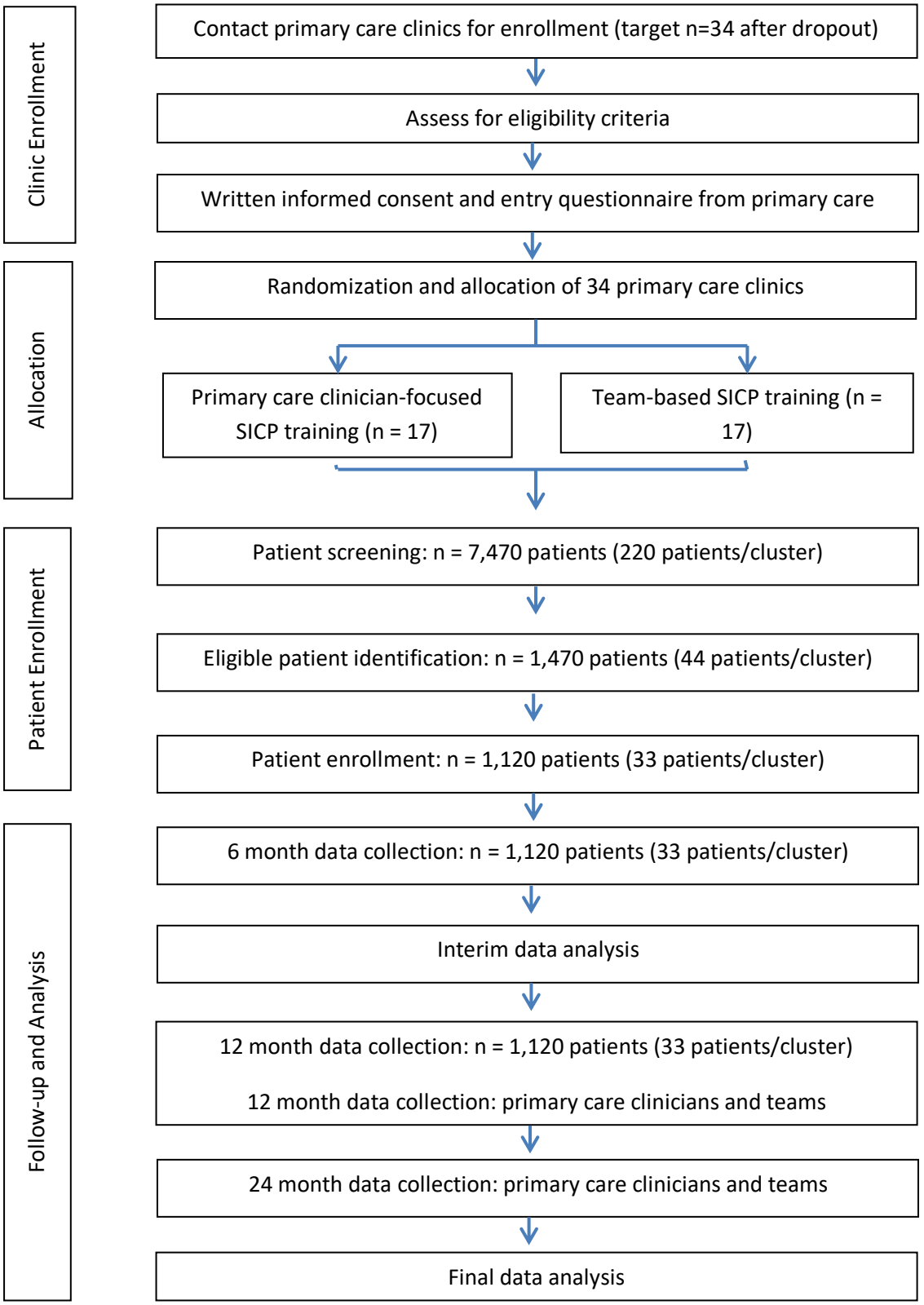
Arm 1: Clinician-focused ACP model

The **clinician-focused model** will center serious illness care planning on the conversations between a single primary care clinician (physicians, NPs, PAs) and the patient and family. In this model, the primary care clinician who is knowledgeable about the patient provides individualized assessment and care. The clinician will receive SICP training and utilize SICP tools to have serious illness care conversations and help them plan. Training will include how to identify appropriate patients, skills for initial and follow-up serious illness conversations, and how to document the conversation and planning in the medical record. Serious illness care planning benefits from individualized assessment and care from a clinician who knows the patient and has medical expertise; this is emphasized in the clinician-focused model.

Arm 2: Team-based ACP model

The **team-based model** will also draw on the medical expertise of the clinician; however, the team identified by the practice will receive training and use SICP tools. Team members will share care planning tasks appropriate to their scope of practice and coordinate communication and follow-up across the team consisting of the primary care clinician and at least one other person from a different profession or practice role (e.g., nurses, care managers, social workers, medical assistants, chaplains, peer counselors, community health workers etc.). Training will include how to divide the tasks and work together as a team in addition to the SICP-specific training provided in the clinician-focused arm. In this model, non-primary care clinician team members become involved in conversations with the patient, family, and care partners. The team-based approach focuses on the importance of having time and ability to address the holistic range of patient and family concerns in serious illness care planning.

Flow Chart (NOTE: NUMBERS ARE ESTIMATES BASED ON PRELIMINARY ESTIMATES OF DROP OUT AND LOSS TO FOLLOW UP)



Randomization, Allocation Concealment, and Minimizing Bias

The unit of randomization will be the PC practices stratified by PBRN and practice size. Once PBRNs have recruited practices, each practice will be assigned an identification number and will complete a short practice survey. The practice survey will include demographic information about the practice related to rurality, size of practice, ownership and the estimated number of patients the practice plans to recruit for the study. A biostatistician will use this information to design and execute stratified randomization to balance these factors across the two study arms. Practice size is an acceptable proxy for characteristics of the practices that we would like to have distributed across the arms such as such as the number and types of clinicians, the roles of people who could be part of the team model, and having an EHR and other information systems such as registries.

In order to assure allocation concealment, involvement in randomization will be limited to statisticians not involved in other aspects of the project. Staff at the participating PBRNs, practices, and the Coordinating Center will not be involved in the randomization. The participating practices and PBRNs will be assigned identification numbers and the statistician will receive these numbers along with the information needed for stratification.

Statisticians completing the analysis will be different from those who executed the randomization and they will be blinded to allocation, using study IDs for practices rather than names and using codes for arm assignment. These IDs and codes will be known only to the co-PIs. Investigators, PBRN leadership, participating practices, and research staff (who monitor practices and enroll patients) will not be blinded to assignment; they will know which practices are in which arm. Practices cannot be blinded to which model of SICP they are assigned as they need to actively implement the team or clinician model.

We will take the following measures to attempt to minimize bias: Patients will know they are in a study of ACP but they will not be explicitly told that the purpose of the study is to compare two models. The packaging and materials used for data collection will be identical. Study interviewers and data abstracters will be based at the PBRNs and Coordinating Centers and provided only as much information as is needed to contact participants or obtain data. Nevertheless, it is unlikely that complete blinding of interviewers and data collection will be possible as responses to questions or the nature of the data obtained may reveal the site or the model being implemented.

Training and ACP Materials

Existing SICP materials and trainings will be assessed and adapted for each of the two ACP models. The training and materials will focus on both necessary skills and practice fidelity to the assigned model. We will compile sample workflows for adaptation by both the clinician and team arms, with specification of roles and responsibilities. These workflows will help the practices randomized to the team model identify their team members, delineate tasks, and create the processes that facilitate planning and implementation of the team model of SICP. For the clinician arm, we will facilitate clinician training in communication about serious illness care and implement workflows to support these conversations and documentation.

We will pilot the SICP materials in English, Spanish, and French. Training and materials for both models will be tested at one U.S. and one Canadian pilot practice each. After piloting and revising the training and materials, the training will be scheduled for each practice according to the randomization. Practices will receive ongoing support including at least quarterly in-person visits from a PBRN practice facilitator to structure and adapt workflows and with open phone

coaching/ technical support calls (separate for each model to avoid contamination) hosted by the Investigators.

Data Collection

Data will be collected from patients, family members, care partners, family members of deceased patients, primary care clinicians and teams, and the primary care practices. Patients, family members, or care partners will be interviewed at enrollment and again six months and one year later. Family members and care partners of patients who die during the study will be interviewed 6 to 12 weeks after the patient's death. Clinicians and team members will be surveyed after training and 1 and 2 years later. Data about the primary care practices (e.g., size, ownership, HER, clinic care team composition, patient demographics) will be collected at recruitment and updated during quarterly visits for the 2 years of the active intervention. Data collection activities will continue for 18 months after the last patient is enrolled to allow for data collection from patient records and surveys of the primary care staff.

Table: Data Collection

Data Collection Timing	**Patient and Family**	**Family (Patient Deceased)**	**Clinicians and Primary Care Teams**	**Primary Care Practices**
	Enrollment	Contact 2-3 weeks post death. Interview when available 2-12 weeks post death	Post training	Recruitment
	+ 6 months		+ 1 year	+quarterly visits for 2 years
	+12 months		+2 years	+interviews 1st and 4th quarter

Outcomes

The primary outcomes are a) goal concordant care, that is whether care received corresponds to patient goals, a patient reported outcomes measure and (b) time spent at home Both will be measured at six-months as well 1-year after enrollment. These will be measured at the patient level and compared across the two models, but can also be compared at the cluster level. Several secondary outcomes will be included as well. Common measures are being coordinated across the ACP and community palliative care projects funded by PCORI in order to allow comparisons across projects as appropriate.

As there is currently no validated measure for goal concordant care, we will develop measures for this project based on the experience of other studies of SICP as well as general approaches to patient-reported outcomes. Early studies of SICP have use Life Priorities Questions and a single item rating of the extent to which the care patients received matched their preferences and advanced their goals. The Life Priorities Questions are based on research on what people have identified as important when faced with a serious or life-limiting illness. Respondents are first asked to rate the importance of a short list of priorities (e.g., live as long as possible, be at home, not be in pain, be at peace etc.). Second respondents are asked to rank their top five goals. Lastly, they are asked to report to what extent their care in the last two months supported their efforts to achieve their top five goals. The single item asks respondents

to rate whether healthcare in the last two months corresponded to their goals and preferences on a scale of 0 to 10 (0 = care did not match goals and preferences at all and 10 = care exactly matches goals).

Days spent at home will be calculated by subtracting the number of days in hospitals or nursing homes or with ED visits from the number of days in the reporting period. The number of days in hospitals, nursing homes or ED visits will be collected through electronic health record query combined with chart abstraction and patient self-report. Days spent at home is a more patient-centered measure of utilization than number of hospital admissions.[26]

Secondary patient outcomes will also be collected at the 6-month and 1-year interviews. These will include measures of anxiety, depression, quality of life, self-reported health and symptoms (PROMIS-10 and ESAS), engagement (e.g., CollaboRATE scale), quality of communication and ACP experience and acceptability and decisional regret, all measured at the patient level. For patients who die during the study period, outcomes will also include hospice use, location of death, and correspondence of location of death to patient preference and family bereavement. All identified family and care partners will be asked about caregiver burden (Zarit scale) as well as ACP experience.

Clinicians and primary care practice teams' outcomes will include intention to engage patients in ACP, measures of communication and collaboration, and burnout (single item burn out for Primary Care). Measures of implementation will include formal and informal documentation of ACP conversations (e.g., (1) completion of a formal document; (2) discussion with clinician documented in chart; (3) verification that patient informally (written or verbal) designated someone to make decisions for him/her) and indicators of incorporation of ACP in workflows (e.g., routine patient identification, billing for ACP as appropriate).

Process Measures and Fidelity Assessment

In addition to outcomes, we will compare process measures related to the implementation of each ACP model. These include measures of 1) training (e.g., number trained, percent of target staff trained; trainee evaluations), 2) patient screening and identification (e.g., number of practices completing screening, patients identified as appropriate/high risk), 3) Serious Illness Care Conversations (e.g., numbers of scheduled appointments, completed conversations), and 4) documentation of discussion of goals (e.g., use of templates, number of records with documentation). We will conduct observations and structured interviews with staff to obtain qualitative data about barriers to and facilitators of implementation of both models that will be combined with the quantitative information.

We will use these observations and interviews to track fidelity to the program and adherence to the model assigned. Semi structured interviews and observation check lists will be used to record specific markers of fidelity as well as characteristics of implementation and execution.

Sample Size and Recruitment Targets

Power calculations and sample size estimates on were based on differences in the primary outcome measures, patient reports of goal concordant care and days at home. To adjust for clusters, we used intracluster correlation estimates to generate sample size and recruitment targets. These ranged from .01 for days at home based on Medicare Claims data from the Transforming Outcomes for Patients through Medical Home Evaluation and reDesign (TOPMED) trial[27] to .025-.05 from estimates of Patient-Centered Medical Homes (ref AHRQ).[28]

For goal concordant care, we decided that an approximately 15-percentage point difference for an expected difference between two advance care planning interventions would be reasonable, achievable, and clinically relevant. We assumed conservative (near the mid point; we expect the rates may be lower) estimates of 50% and 65% for the two arms. We calculated that we would need 34 clusters (17 per arm) and 23 patients per cluster (782 total) to detect the 15-percentage point difference with 90% power and a 5% significance level. We calculated that if the ICC is .05 the power would still be acceptable at 80% given the same sample size.

For days at home, Groff, Colla, and Lee found rates for the last six months of life ranging from 118.8 to 145.9 in the US.[26] For this second primary outcome, days at home, we set proportion of days at home in the control group at 80%, and computed the power for a number of clusters between 17 and 20 at various detectable effect sizes. With overall sample size of 782 (34 practices*23 patients) we have >90% power to detect at 10 percentage point difference, and 8.8 percentage point difference with >80% power. If we increase the number of clusters slightly to 20, as well as the number of patients per cluster to 30, we can achieve >90% power to detect an 8.8 percentage point difference

We plan to recruit up to 49 practices and randomize at least 42 practices (allowing for dropout after recruitment and randomization) equally to each arm and recruit and consent at least 160 patients from each of the 7 PBRNs (N=1,120). Allowing for attrition of clinics and up to ~20% of patients, we will be powered at ≥90% with a final minimum sample size of 782 (34 practices*23 patients) to detect the specified difference using a two-sided test. Because we have two primary outcomes, we specify $\alpha=0.025$ for each.

Analysis Plan

We will perform a descriptive analysis of practice, clinician, and patient characteristics to assure comparability of the two study arms and we will include potentially confounding variables, including those identified as important by stakeholders through our engagement process, as covariates in analyses. Multilevel modeling will be used to account for the hierarchical structure of the data. We will specify random effects at the practice (cluster) level and, when comparing baseline to follow-up, at the respondent level. For each outcome, we will assess goodness of fit and model assumptions. For binary outcomes, we will use either the mean proportions from logistic regression or risk-difference regression to estimate the difference between arms. For days at home, we will evaluate Poisson or negative binomial models for fit and include days observed as an offset, or rate denominator.

Primary analyses will be conducted under an intention to treat assumption, and thus missing data will be multiple imputed using baseline measurements and standard tools. Multiple imputation[29,30] procedures generate multiple datasets with predictions for missing values, then combine estimates from standard analyses across those datasets such that they reflect the uncertainty in the missing values. Because missingness may be informative in this study, we also plan to evaluate potential bias with (1) a worst-case sensitivity analysis, in which the 'worst' outcome is substituted for missing outcomes, and (2) a Heckman selection model,[31] in which we will model the probability of having non-missing outcome data using available information, then test the correlation between the residuals of that model and the residuals in our main outcome model. A non-zero correlation indicates the presence of bias. This approach will also allow us to compare bias-corrected with uncorrected estimates of treatment effects.

We will test for significant heterogeneity of effects in subgroups defined by practice and patient characteristics, including location in the U.S. vs. Canada or in urban vs. rural

environments, number of clinic providers/FTE, and clinical or diagnostic subgroups (e.g., cancer, advanced chronic conditions, frailty/advanced age, and dementia). We will include interaction terms for these groups (*model * characteristic*) in our models; rejection of the null hypothesis that the interaction is equal to zero or a large estimated effect will be considered evidence of subgroup difference.

After we have collected six-month outcomes on 408 participants (12 per cluster), we will conduct an interim analysis to determine whether to stop. Specifically, we will perform a one-sided test at $\alpha=0.05$ against a null hypothesis that the proportion of patients *in both arms combined* reporting goal-concordant care is 0.15. Because we will not be comparing the two approaches, we not need to un-blind the statisticians or adjust significance levels of primary analyses for multiple comparisons. Our effective sample size at this point will be 408/DE = 263, where $DE = 1 + (m-1)\rho = 1 + (12-1)(0.05)$, and to reject the null with 90% power, our observed proportion will need to be 0.22 or higher. We choose these cutoff proportions because failure to reject the null would mean that (a) neither arm is performing meaningful ACP, or (b) one arm is outperforming the other dramatically, e.g. 0.10 in one arm and 0.34 in the other, which average to 0.22. While not expected, either of these cases provides justification for stopping.

Trial Steering Committee and Stakeholder Engagement

A trial steering committee, known as the research practice partnership (RPP), was established when funding was awarded. The RPP includes all the Investigators, including a co-Investigator from each PBRN, as well as nine Patient/Family Advisors(PFA) (one from each PBRN and one "at-large" from the U.S. and Canada). The RPP will meet quarterly throughout the trial and review and approve procedures, analyses, and reports. Each PBRN will establish an operations group to oversee recruitment and trial activities within their network. This group will include the PBRN co-investigator, PBRN coordinator, PBRN PFA, as well as clinicians, staff and patients and family advisory councils members (PFACs) from the participating practices. These groups will meet quarterly, oversee implementation in their participating practices, and report on process to the RPP. The project will also engage with national patient and family organizations in both the U.S. and Canada as well as individual subject matter experts, policy makers, and professional organizations to obtain their input both on trial conduct and dissemination potential.

Reporting results

Results will be summarized and first presented to the RPP and then made available for review and comment to all participating practices and stakeholders, including PFAs. The report will also undergo a peer-review process organized by the funder (PCORI). Comments, requests for clarification, or further analysis will be incorporated into the final report. This final report will be publically available. We also make all data and analysis files available in accordance the funder's open access policy in effect at the time the study is completed.

The final report will be structured to facilitate the dissemination and implementation potential and to allow potential users to assess the study's internal and external validity. Specifically, the final report and any publications will adhere to the CONSORT extension for reporting cluster randomized trials. The report will specify how the tools and materials can be used by others and will provide an implementation toolkit to facilitate replication and spread.

Discussion

While there is a need for ACP expansion, it is unclear how to best promote rapid, effective implementation and overcome communication challenges and systems barriers to ACP in primary care.[32] This study will help address this gap in evidence by comparing a primary care

clinician-focused model and a team-based model of an ACP program, the Serious Illness Care Program (SICP) developed by Ariadne Labs.[33]

Our objective is to integrate ACP in primary care so that ultimately health care is more concordant with patients' goals and values and increases their time at home. The advantage of our approach and the use of PBRNs is that the study results will be relevant to primary care practices in the U.S. and Canada. PBRNs were created to generate and share knowledge across practices[34,35] and this trial will continue to promote collaborations across practices and countries designed to improve health care and benefit seriously ill patients and their families. The results of this trial will provide information on implementation options and expected outcomes that will help practices outside the participating practices plan their own implementation more quickly and provide benchmarks for improvement.

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