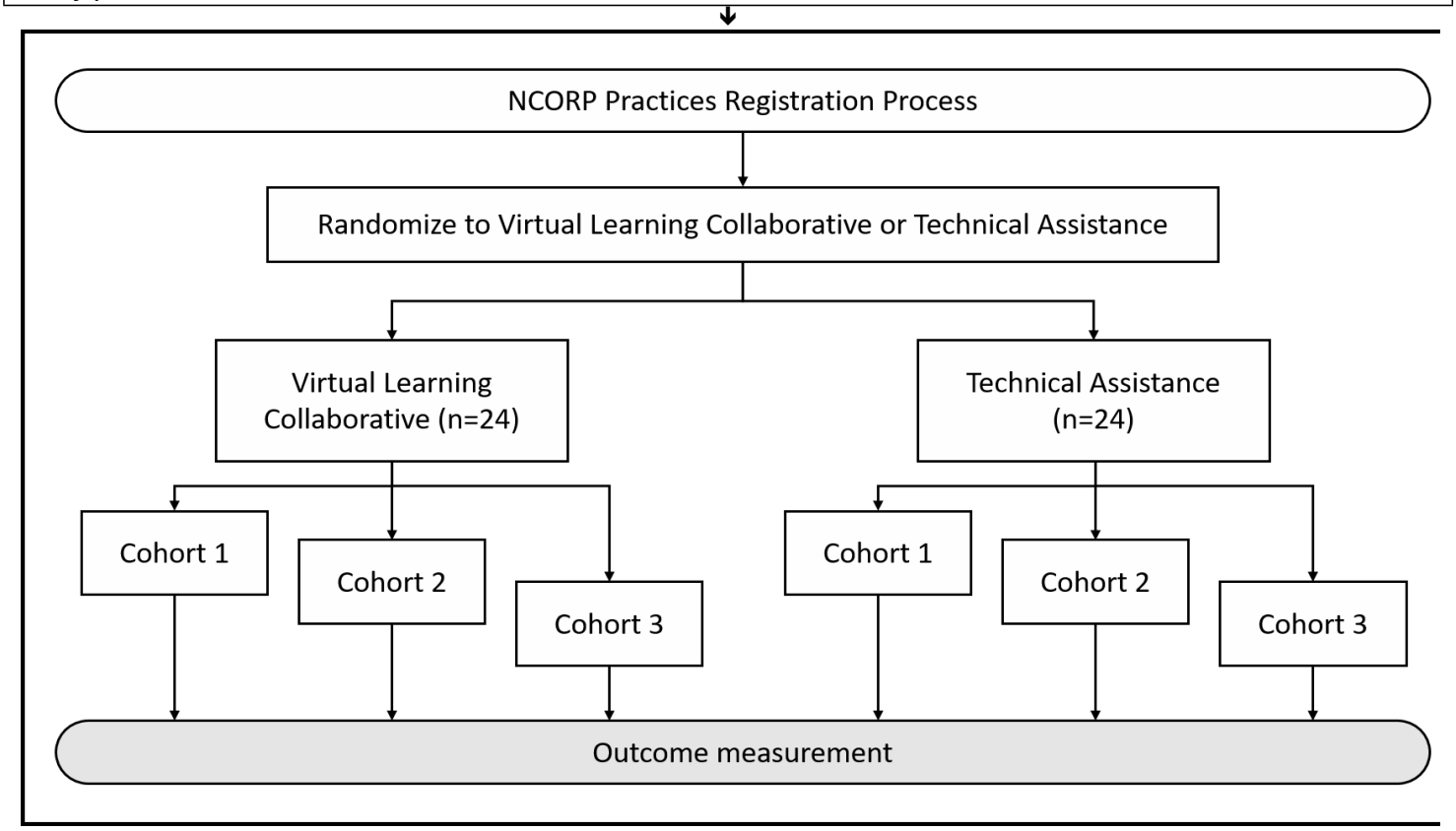
PRACTICE SCREENING / ELIGIBILITY/RANDOMIZATION

NCORP PRACTICE ELIGIBILITY CRITERIA: Presence of at least one staff member who meets criteria for participating as an ENABLE (***E***ducate, ***N***urture, ***A***dvise, ***B***efore ***L***ife ***E***nds) Nurse Coach, commitment of the ENABLE Nurse Coach(es), and capacity to implement ENABLE (see Section 4.1 for more details).
RANDOMIZATION: Cluster-randomized design in which 48 NCI Community Oncology Research Program (NCORP) practices are randomized to either Virtual Learning Collaborative or Technical Assistance. (Additional practices will be added if needed in Cohorts 2 and 3 if there are practices that drop out of the study.)



PARTICIPANT SCREENING / ELIGIBILITY

Patients: English-speaking, age 18 or older, willing to complete palliative care assessment and ENABLE sessions, advanced cancer diagnosis within the last 90 days (defined as a newly diagnosed stage III/IV, recurrence, or progressive solid tumor cancer), expected survival of at least 6 months, access to a telephone that can receive phone calls, and able to provide informed consent.
Caregivers: Caregivers are identified as someone who is an unpaid relative or friend who knows the patient well and provides support to their cancer. Caregivers must be English-speaking, age 18 or older, willing to complete the ENABLE sessions, have access to a telephone that can receive phone calls, and able to provide informed consent.

PATIENT/CAREGIVER CONSENT, BASELINE DATA COLLECTION

SAMPLE SIZE: 720-1,296 patients will sign informed consent. Although not required, patients will be able to nominate one caregiver to participate.
PATIENT BASELINE DATA COLLECTED: Demographic information, cancer diagnosis, Palliative Care Assessment, functional assessment (FACIT-PAL), symptom severity (MDASI), global health (PROMIS Global Health), and mood (HADS), COVID Effects-Patient.
CAREGIVER BASELINE DATA COLLECTED: Demographic information, global health (PROMIS Global Health), mood (HADS), caregiver burden (Montgomery Borgotta Caregiving Burden Scale), positive aspects of caregiving (Positive Aspects of Caregiving Scale), and preparedness for caregiving (Caregiver Preparedness Scale), COVID Effects-Caregiver.

OUTCOMES ASSESSMENT

ENABLE PROGRAM UPTAKE: Proportion of enrolled patients at participating NCORP practices who *complete* the ENABLE program, defined as having a palliative care assessment and completing the 6 ENABLE sessions.

IMPLEMENTATION OUTCOMES: General Organizational Index, RE-AIM Self-Assessment Tool, Provider Perceptions of Early Palliative Care, fidelity to assigned implementation strategy measures.

PATIENT FOLLOW-UP DATA COLLECTED: Functional assessment (FACIT-PAL), symptom severity (MDASI), global health (PROMIS Global Health), and mood (HADS), COVID Effects-Patient.

CAREGIVER FOLLOW-UP DATA COLLECTED: Global health (PROMIS Global Health), mood (HADS), caregiver burden (Montgomery Borgotta Caregiving Burden Scale), positive aspects of caregiving (Positive Aspects of Caregiving Scale), and preparedness for caregiving (Caregiver Preparedness Scale), COVID Effects-Caregiver.

Design Overview. This cluster-randomized controlled trial uses a Hybrid Type III Implementation Design to compare implementation strategy effectiveness for the ENABLE (***E***ducate, ***N***urture, ***A***dvise, ***B***efore ***L***ife ***E***nds) early palliative care (EPC) program, while gathering additional information on the ENABLE clinical program and related outcomes.[1-3] In this study, using a 1:1 randomization scheme, 48 NCI Community Oncology Research Program (NCORP) practices will be randomized to either receive ENABLE training and a Virtual Learning Collaborative (**VLC**, *n* = 24 practices) or receive ENABLE training and Technical Assistance (**TA**, *n* = 24 practices). NCORP practices randomized to the VLC will participate in a 15-month VLC consisting of monthly group-based learning sessions, coaching, and applied quality improvement data collection, analysis and feedback opportunities. NCORP practices randomized to TA will receive 15 months of monthly practice-based consultation calls with an ENABLE/TA expert. For feasibility of carrying out tasks, there will be three cohorts of practices. For flexibility we will allow variation in cohort size. Practices will be randomized to study arm within each cohort.

Research Question. This study is designed to answer the question: "Is a VLC implementation strategy superior to a TA strategy with respect to implementation, service, and patient outcomes for implementing the evidence-based ENABLE EPC program in NCORP practices?" The primary (patient-level) implementation aim (Aim 1) is to evaluate ENABLE program uptake, measured as the proportion of patients at participating NCORP practices who *complete* the ENABLE program, defined as having a palliative care assessment and completing the ENABLE sessions. The secondary (practice-level) service aim (Aim 2) compares the effectiveness of the implementation strategy (VLC or TA) on overall ENABLE program implementation, as measured by the General Organizational Index (GOI). Exploratory aims assess the impacts on patient and caregiver outcomes and the relationship among ENABLE program uptake, overall ENABLE implementation, and patient-level outcomes.

Procedures. The study is a hybrid type III superiority cluster RCT, with patients clustered within each of 48 practices (n=24 practices per group), and a recruitment goal of approximately 15-27 patients per practice cluster (n=720-1,296 patients total; 360-648 patients per strategy). Practices in the University of Rochester Cancer Center (URCC) NCORP Research Base network will be eligible to participate in the study. Practices determined to have capacity and support for the project (e.g., ENABLE Nurse Coach) will be randomly assigned to one of the two study arms (Virtual Learning Collaborative, VLC or Technical Assistance, TA); randomization will be stratified by rural/urban location of the practices. For feasibility of carrying out the key tasks and intervention arms, there will be three cohorts of approximately 8-20 practices (each cohort will have approximately 4-10 practices receiving VLC and approximately 4-10 practices receiving TA). The variation in cohort size will permit flexibility for practice cluster recruitment. We will keep eligible and interested practices on a list in case there is drop-out of original practices. To account for practice clusters that may be unable to recruit 15 patients, we will include an option to recruit additional practices (up to 20% of 48) in Cohorts 2 and 3 (see section 11.2.1). Additionally, if necessary we will recruit additional cohorts. Overall, we aim to recruit so that 20% of practices are Rural Urban Commuting Area (RUCA) defined as rural, consistent with national statistics.[4,5]

Oncologists will be enrolled from practices participating in the study. Eligible patients from those oncologists will be recruited to participate. Eligible patients are English-speaking, age 18 or older, willing to complete the

palliative care assessment and ENABLE sessions, have an advanced cancer diagnosis (metastatic stage III/IV solid tumor cancers), and have access to a telephone that can receive phone calls. Eligible patients will undergo the informed consent process; those patients who agree to participate in this study will participate in the ENABLE program that consists of a nurse-led clinical palliative care assessment and 6 semi-structured ENABLE telehealth 20-45 minute sessions using the Charting Your Course guide, and monthly follow-up calls. Patients will also complete assessments of mood and quality of life at baseline (within 14 days of study enrollment), 12 weeks (±2 weeks) and 24 weeks (±2 weeks). Patients will be invited to, but not required, to identify someone (the caregiver) who is an unpaid relative or friend who knows the patient well and who provides support to their cancer that can participate in the study. Caregivers who participate must be English-speaking, age 18 or older, willing to complete the ENABLE sessions, selected by the patient when asked if there is an "unpaid relative or friend who knows them well and who provides regular support to their cancer", have access to a telephone that can receive phone calls, and able to provide informed consent. Caregivers will complete 3 ENABLE sessions, monthly follow-up calls, and assessments of mood and quality of life at baseline (within 14 days of study enrollment), 12 weeks (±2 weeks), and 24 weeks (±2 weeks). Caregivers will also receive a bereavement call if the patient dies while in the study.

Participating NCORP practices with sufficient nurse staffing will be required to have two ENABLE Nurse Coaches. For those practices (e.g., small or rural) with only one available nurse, we will allow for one ENABLE Nurse Coach. The ENABLE Nurse Coach can be either a registered nurse or advanced practice provider with 2 or more years of oncology or palliative care experience. ENABLE Nurse Coaches will be trained to implement the ENABLE program, including how to conduct a palliative care assessment and deliver the ENABLE sessions to patients and caregivers. ENABLE Nurse Coaches will also participate in the assigned implementation strategy activities.

Assessments. Guided by Proctor's Outcomes for Implementation Research Framework[6], our primary outcome will be ENABLE program uptake. This measure will be defined as the proportion of patients at NCORP practices that *complete* the ENABLE program (i.e., palliative care assessment and 6 ENABLE sessions); it will be assessed via practice-based ENABLE Nurse Coach contact logs that document patient program completion. The secondary (practice-level) outcome will assess overall ENABLE program implementation via semi-structured phone interviews using the General Organizational Index (GOI) instrument with NCORP practice staff (e.g., the ENABLE Nurse Coach) at baseline, month 6 (±8 weeks), and 1 year (±8 weeks). We will also assess implementation progress via responses to the RE-AIM (Reach, Efficacy, Adoption, Implementation, Maintenance) survey, and measure participation in and fidelity to the assigned implementation strategy. Exploratory aims will explore patient and caregiver quality of life (QOL) and mood outcomes. Patient and caregiver measures of quality of life and mood will be collected at baseline (within 14 days of study enrollment), 12 weeks (±2 weeks), and 24 weeks (±2 weeks).