

**Expanding Access to Home-Based Palliative Care
Through Primary Care Medical Groups
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Study Protocol

- **Summary**

Patients with serious illness arising from cancer, heart failure (HF), and chronic obstructive pulmonary disease (COPD) often receive poor quality of care, resulting in unmitigated pain and related symptoms, unmet psychosocial needs, and significant caregiver burden. Palliative care—a patient-centered approach that provides pain and symptom management and psychosocial and spiritual support—has strong evidence for improved outcomes for seriously ill patients. Although similar to hospice care in its focus on comfort measures, palliative care differs from hospice in that it may be offered early in the course of an illness and in conjunction with other therapies intended to prolong life. Most palliative care programs are hospital based; few offer care at home, where patients spend most of their time and require the most support.

This study compares outcomes from two groups: patients who receive enhanced usual care (EUC), with usual care enhanced by provider training in palliative care, and patients who receive home-based palliative (HBPC) care provided by a primary care team. About 1,155 seriously ill patients with cancer, HF, or COPD (and 884 of their caregivers) will be randomly assigned to either group. The HBPC model will be integrated into primary care clinics. HBPC team members—a physician, nurse, social worker, and chaplain—will provide pain and symptom management, psychosocial and spiritual support, disease management education, and other services in response to patient and caregiver needs. Services are delivered at the patient's home. The model also features a 24/7 call center.

- **Objectives:**

1. **Primary objective:** To test the comparative effectiveness of an evidence-based model of HBPC integrated within Medicare Advantage and ACO-participating primary care clinics and enhanced usual care (EUC) on patient and caregiver outcomes.

2. **Secondary objectives:**

Evaluate the effectiveness of HPBC compared to EUC in patient subgroups defined by: (1) medical condition (cancer, CHF, COPD), (2) age, (3) race (white/nonwhite).

Determine the ability to engage primary care physicians in primary palliative care training and practice.

- **Subjects:** Seriously ill patients (and their caregivers) who receive primary care from regional Accountable Care Organizations (ACOs) in California. Specifically:

Patient Inclusion Criteria:

1. Age 18 or older
2. Diagnosis of heart failure (HF), COPD or advanced cancer
3. ≥ 2 hospitalizations or ED visits in the past year
4. Palliative Performance Scale: <fully able on both Ambulation and Self-Care
5. English- or Spanish-speaking

Patient Exclusion Criteria:

1. Receiving hospice care
2. End stage renal disease
3. Lives in a nursing or assisted living facility or a group home

Caregiver Inclusion Criteria:

1. English- or Spanish-speaking
2. Age 18 or older
3. Able to provide informed consent

Caregiver Exclusion Criteria:

1. Professional paid caregiver

- **Sample size:** 1155 participants (approx. 577 per treatment arm); 884 caregivers
- **Interventions:** Patients will be randomized in a 1:1 allocation ratio to HBPC or EUC. Randomization will be stratified on ACO; randomization will be further blocked within ACO strata.
 1. **Home-based Palliative Care (HBPC):** The HBPC model will consist of home visits by a trained, interdisciplinary primary palliative care team comprising a physician, nurse, social worker, and chaplain. This core team will provide pain and symptom management, psychosocial support, ACP, disease management education, spiritual counseling, grief counseling, and other services in response to patient and caregiver needs. Following the patient's initial assessment, the frequency of subsequent home visits will be based on the patient's and caregiver's needs and preferences. *At a minimum*, a core team member will visit the patient at home once per week.
 2. **Enhanced Usual Care (EUC):** We will enhance the usual primary care services provided by each participating medical group with training in palliative care to all PCPs at the regional ACOs. The training program will align with CAPC's recommended curriculum for enhancing the palliative care skills of frontline clinicians and address core elements of palliative care.
 3. All patients (HBPC and EUC) enrolled in the study may continue to seek and receive curative and usual care in addition to palliative care

- **Follow-up:** Trial recruitment is planned for 2.5 years. Each patient and caregiver will be followed with outcome assessments at baseline, 1 month, and 2 months. Caregivers will receive an additional assessment 2 months following a patient death.
- **Primary patient outcomes:**
 1. Patient-reported symptoms (measured by Condensed Memorial Symptom Assessment Scale [CMSAS])
 2. Depression (measured by Hospital Anxiety and Depression Scale [HADS] and the PHQ-9)
 3. Anxiety (measured by Hospital Anxiety and Depression Scale [HADS])
- **Secondary patient outcomes:**
 1. Hope (measured by the Herth Hope Index)
 2. Patient-physician communication (measured by Consultation Care Measure)
 3. Survival time
 4. Number of emergency department (ED) visits, number of hospitalizations, length of hospital stay
- **Secondary caregiver outcomes:**
 1. Caregiver burden (Zarit Burden Scale)
 2. Experience of death (measured by Family Assessment of Treatment at the End of Life)
 3. Depression and anxiety (HADS)
 4. Quality of Life (Promis)