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Development of an Outpatient Palliative Care Protocol to Monitor Fidelity in the Emergency Medicine Palliative Care Access Trial

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Abstract

Introduction: Palliative care is recommended for patients with life-limiting illnesses; however, there are few standardized protocols for outpatient palliative care visits. To address the paucity of data, this article aims to: (1) describe the elements of outpatient palliative care that are generalizable across clinical sites; (2) achieve consensus about standardized instruments used to assess domains within outpatient palliative care; and (3) develop a protocol and intervention checklist for palliative care clinicians to document outpatient visit elements that might not normally be recorded in the electronic health record.

Methods: As part of a randomized control trial of nurse-led telephonic case management versus specialty, outpatient palliative care in older adults with serious life-limiting illnesses in the Emergency Department, we assessed the structural characteristics of outpatient care clinics across nine participating health care systems. In addition, direct observation of outpatient palliative care visits, consultation from content experts, and survey data were used to develop an outpatient palliative care protocol and intervention checklist.

Implementation: The protocol and checklist are being used to document the contents of each outpatient palliative care visit conducted as a part of the Emergency Medicine Palliative Care Access (EMPallA) trial. Variation across palliative care team staffing, clinic session capacity, and physical clinic model presents a challenge to standardizing the delivery of outpatient palliative care.

Keywords: advanced illness; emergency medicine; outpatient palliative care; palliative care

Introduction

Background

HALF OF OLDER AMERICANS visit the Emergency Department (ED) in the last month of life, making the ED a key decision point when providers establish the subsequent care trajectory.¹ Palliative care interventions in the ED can both capture high-risk patients at a time of crisis and dramatically improve patient-centered outcomes.^{2,3} While access to inpatient palliative care consultation services is

available in many hospitals nationwide,⁴ outpatient palliative care services are less established and there are few standard protocols for outpatient care delivery.

A study by Temel et al. demonstrated that lung cancer patients randomized to receive outpatient palliative care had greater improvements in quality of life and lower rates of depressive symptoms compared with those randomized to standard care.⁵ In this study, outpatient palliative care was delivered according to the National Consensus Project (NCP) for Quality Palliative Care guidelines,⁶ and palliative care

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clinicians documented the care they provided accordingly; however, the visits were adapted using general guidelines and not protocolized in a way that makes them reproducible in other studies.

Two subsequent studies attempt to describe the structure of the palliative care visits in Temel et al.'s study through retrospective chart review. The first describes the components of the initial palliative care visits for 67 patients,⁷ and the latter examines 20 participants' palliative care and oncology visit notes to determine the key elements of an early ambulatory palliative care visit, changes over time and disease progression.⁸ While these analyses provide a framework for what occurs during a palliative care visit, the components captured only represent those documented in the visit note. Much of what occurs during a palliative care visit involves attending to emotion, providing methods for coping, and other nonverbal communication that may not be well documented in the physicians' notes. Additionally, these studies only assess palliative care visit components at a single outpatient clinic for patients with a specific disease type (non-small-cell lung cancer), so they may not be representative of outpatient palliative care visits broadly.

In response to the paucity of data on the structure and components of outpatient palliative care visits across health care systems and disease groups, a standardized outpatient palliative care protocol was developed as part of a randomized control trial of palliative care service for older adults with serious life-limiting illnesses. Here, we present the development of this outpatient palliative care protocol to facilitate reproducibility across the nine health care systems in the study, as well as to be used in future palliative care trials and outpatient palliative care practices.

Objectives and hypotheses

The objectives are to: (1) fully describe the elements of outpatient palliative care visits that are generalizable across clinical sites; (2) achieve consensus about standardized instruments used to assess domains within outpatient palliative care; and (3) develop a protocol and intervention checklist that allow palliative care clinicians to document outpatient visit elements that might not normally be recorded in the electronic health record (EHR).

Methods

Study design

Nine health care systems participated in a randomized controlled trial in patients discharged from the ED comparing two established models of palliative care: nurse-led telephonic case management and specialty, outpatient palliative care. Eligible patients were aged 50 years or older and had advanced cancer (metastatic solid tumor) or end-stage organ failure (congestive heart failure, end-stage renal disease, or chronic obstructive pulmonary disease). Primary caregivers, defined as those aged 18 years or older and living with the patient, were also eligible to enroll.

Upon enrollment, patients were randomized to one of the intervention arms. Participants assigned to the outpatient palliative care clinic arm were scheduled for their first clinic visit within two weeks of enrollment, and subsequent visits were scheduled monthly in the outpatient setting for six

months or until death. Specialty, outpatient palliative care visits are conducted in-person by a physician or nurse practitioner who is board-eligible or board-certified in hospice and palliative medicine. For the purposes of this article, we describe the protocolization of the outpatient palliative care intervention.

Patient and caregiver study measures

The primary study outcome is the change in patient's quality of life from enrollment to six months, as measured by the Functional Assessment of Cancer Therapy-General (FACT-G). The FACT-G is a validated 27-item questionnaire assessing the quality-of-life domains in physical, social, emotional, and functional well-being.⁹ While it has been used extensively in cancer, it is also used as an assessment of chronic illness therapy in many other serious illnesses.⁸

Secondary outcomes in patients include health care utilization (ED visits, hospital admissions, and hospice use) from enrollment to 12 months; loneliness, as measured by change in the Three-Item Loneliness Scale¹⁰ from enrollment to 6 months; symptom burden, as measured by change in the Edmonton Symptom Assessment Scale Revised (ESAS-r)¹¹ from enrollment to 6 months; and quality of life, as measured by the FACT-G⁹ at 3 and 12 months. Secondary outcomes in caregivers include caregiver physical and psychosocial distress, as measured by change in the Zarit Burden Interview (ZBI-12)¹² from enrollment to six months; caregiver's quality of life, as measured by change in the Patient-Reported Outcome Measurement Information System (PROMIS-10)¹³ from enrollment to six months; and bereavement, as measured by change in the Texas Revised Inventory of Grief (TRIG)¹⁴ at three months after patient death.

Ethics determination

Institutional review board approval was first obtained at the primary site, New York University School of Medicine, followed by the approval from all other study sites.

Study Implementation: Challenges and Contributions

To standardize palliative care visits across the nine health care systems participating in the Emergency Medicine Palliative Care Access (EMPallA), trial data were collected via a survey of the structural characteristics of outpatient palliative care clinics, direct observation of outpatient palliative care visits, and key informant interviews with palliative care content experts. The results were used to develop a palliative care visit protocol (see Appendix) and standard intervention checklist (Fig. 1) to monitor fidelity and to comprehensively document the contents of each palliative care visit conducted as a part of the EMPallA trial.¹⁵

Assessing outpatient palliative care structural characteristics

Outpatient palliative care directors at the nine health care systems for the EMPallA study were surveyed to assess the current state of practice. Providers participated in conference calls to verify survey responses. Results of the survey are shown in Table 1. Survey questions covered the following topics: 1) standardized palliative care assessment tools used, 2) physical and clinical outpatient model, 3) number and type

Instructions: Document or check all that apply (what interventions did you provide during visit?)

Physical

- Pharmacotherapy management offered/adjusted for pain
- Pharmacotherapy for non-pain symptoms
- Non-pharmacologic interventions for pain
- Non-pharmacologic interventions for symptoms other than pain
- Medical marijuana certification
- In-office interventional procedures (such as joint injections, trigger point injections, paracentesis, thoracentesis etc.)
- Referral for massage, acupuncture, physical therapy/occupational therapy
- Referral for cognitive behavioral therapy, biofeedback
- Other:

Psychosocial

- Explored understanding of illness and treatments
- Explored how patient/family like information shared
- Explored hopes and worries
- Educated about or encouraged mindfulness techniques
- Guided imagery
- Guidance on reframing, cognitive behavioral techniques
- Mental health referral for patient (psychology, social work, support groups)
- Mental health treatment encouraged for caregiver (psychology, social work, support groups)
- Referral for counseling, support groups
- Referral for concrete home or community based services
- Referral for medico-legal partnership service or legal support
- Other:

Bedside behavior and intervention

- Supportive statements, validation/naming of emotions, non-abandonment statements
- Therapeutic listening
- Therapeutic touch (hand holding, hand on shoulder)
- Other:

Spiritual

- Exploring what brings life meaning
- Exploring religious and spiritual beliefs that will inform care
- Life review conversations
- Contacting spiritual provider outside or within hospital to connect with patients during visits or after visits
- Other:

Quality/End of Life Planning

- Care Preferences discussed and documented
- Advance directives forms completed: (list which forms completed)
- Hospice referral
- Home care referral
- Other:

FIG. 1. Outpatient palliative care visit checklist.

of palliative care team members, 4) wait time for new appointments, 5) length of new patient and follow-up visits, 6) palliative care diagnoses accepted, 7) and number of clinic sessions per provider per week. Physical clinic models were classified under two categories: freestanding or embedded. A

freestanding model delivers palliative care in a separate location from disease-specific care and is an independently functioning specialty clinic with their own palliative care staff.¹⁶ An embedded model involves palliative care delivery within a disease-specific clinic where visits, clinic space, and/

TABLE 1. OUTPATIENT PALLIATIVE CARE CLINIC CHARACTERISTICS

Site	Site 1a	Site 1b	Site 1c	Site 2	Site 3	Site 4	Site 5	Site 6	Site 7 and Site 8	Site 9	Site 10
Standardized assessment tools											
Symptom	Y (ESAS)	Y (ESAS)	Y (IPOS-Renal)	Y (ESAS)	Y (ESAS)	Y (ESAS)	N	N	Y (ESAS)	Y (ESAS)	N
Spiritual	N	N	N	N	Y (FICA)	N	N	N	Y (FICA)	N	N
Psychosocial	Y (PPS)	Y (PPS)	N	Y (PPS)	Y (PPS)	N	N	Y (PPS)	Y (PPS)	Y (PPS)	Y (PPS)
Depression	N	N	N	N	N	N	N	N	N	N	N
Caregiver	N	N	N	N	N	N	N	Y (ST)	N	N	N
Opioid risk	Y	Y	Y	Y	N	N	N	Y	Y	Y	Y
Physical clinic model	Embedded	Embedded	Embedded	Embedded	Embedded (cancer); Freestanding (non-cancer)	Freestanding	Embedded	Embedded	Freestanding	Embedded (cancer); Freestanding (non-cancer)	Embedded (thoracic, breast cancer, sarcoma, CHF); Freestanding (other/cancer)
Clinical outpatient model	Co-management	Co-management	Co-management	Co-management	Co-management	Co-management	Co-management	Co-management	Co-management	Co-management	Co-management
Palliative care team members											
MD	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
NP	N	N	N	Y	Y	N	Y	Y	N	N	Y
Chaplain	N	N	N	N	N	N	Y	Y	N	Y	Y
Social work	N	N	N	Y	Y	Y	Y	Y	N	Y	Y
RN	N	N	N	Y	Y	Y	Y	Y	Y	Y	Y
Psychologist	N	N	N	N	Y	N	Y	Y	N	N	Y
Case manager	N	N	N	N	N	N	Y	N	N	Y	N
Pharmacist	N	N	N	N	N	N	N	N	N	Y	Y
PT	N	N	N	N	N	N	N	N	N	N	Y
OT	N	N	N	N	N	N	N	N	N	N	Y
Other	N	N	N	N	Y (psychiatrist)	N	N	N	N	N	N
Wait for new patient appointment	0–2 weeks	4–8 weeks	2–4 weeks	1–4 weeks	0–4 weeks	1 week	1–2 weeks	1–2 weeks	1–2 weeks	0–1 week	0–24 hours
Length of new patient visit	60 minutes	60 minutes	60 minutes	60 minutes	60 minutes	60 minutes	60 minutes	60 minutes	60 minutes	60 minutes	60 minutes
Length of follow-up visit	30 minutes	30 minutes	30–60 minutes	30 minutes	30 minutes	30 minutes	30 minutes	30 minutes	30 minutes	60 minutes	30–40 minutes
Palliative care diagnoses accepted											
Cancer	Y	N	N	Y	Y	Y	Y	Y	Y	Y	Y
CHF	N	N	N	Y	Y	Y	N	N	Y	Y	N
COPD	N	Y	N	Y	Y	Y	N	N	Y	Y	N
ESRD	N	N	Y	Y	Y	Y	N	N	Y	Y	N
Other	N	N	N	N	N	Y (dementia, liver disease)	N	N	N	N	N
No. of clinic sessions per week	7	1	1	0.5	3–6	7	30–32	8	1	7	56

CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; ESAS, Edmonton Symptom Assessment Scale; ESRD, end-stage renal disease; FICA, Faith and Belief, Importance, Community, Address in Care Spiritual History Tool; IPOS, Integrated Palliative Outcome Score; MD, medical doctor; NP, nurse practitioner; OT, occupational therapist; PPS, Palliative Performance Scale; PT, physical therapist; RN, registered nurse; ST, stress thermometer.

or staff are shared between disease-specific and palliative care teams. All sites were categorized under the co-management clinical outpatient model, which involves a palliative care provider and another clinician each assuming primary responsibility for separate domains and jointly managing some patient concerns.¹⁷

Direct observation of outpatient palliative care visits

A fourth-year medical student (A.I.) observed outpatient palliative care clinic sessions at two of the participating academic medical centers. One of the clinics was a freestanding clinic and the other was embedded. Two attending palliative care physicians and several palliative care fellows were observed at each practice. The observer completed 32 total hours of observation, consisting of 8 sessions that were approximately 4 hours each. Using the NCP's eight domains of palliative care⁶ as a guide, the observer recorded the frequency with which the outpatient provider addressed the domains at each visit. The observer both combined some domains and identified additional subdomains based on the observations made during the provider visits. Thematic saturation, defined as the addition of no additional subdomains, was reached before the last clinic session.

A specialty palliative care physician and content expert (S.E.C.) reviewed the notes and generalizability of the palliative care subdomains throughout the observation period. Referencing existing literature and clinical observation data, a checklist was created listing elements of a structured outpatient palliative care visit (Fig. 1).

Content expert and stakeholder engagement

The draft protocol and checklist were shared with four national specialty palliative care content experts at the annual American Academy of Hospice and Palliative Medicine (AAHPM) meeting in 2018. Outpatient palliative care directors from each of the nine health care systems then critically reviewed the outpatient protocol and checklist. After integrating national expert opinion, approval and feedback of the outpatient palliative care directors, and the specific practices of the clinical sites, the protocol and corresponding checklist were finalized. For the convenience of provider EHR documentation and data collection, the checklist was formatted into an Epic smart phrase, a predefined template that autopopulates specific text for EHR documentation.

Challenges and barriers to standardizing the protocol

Despite efforts to standardize and document the contents of an outpatient palliative care visit, several barriers still exist to delivering a uniform outpatient intervention across study sites. One barrier is the variation in the type and number of providers. Some outpatient clinics have a single palliative care physician, whereas others include palliative care team members across other disciplines, such as pharmacy and social work. Such variation affects patients' experiences with palliative care and the impact that outpatient palliative care can conceivably have on patient-centered outcomes. Additionally, the outpatient clinics differ in clinic session capacity, ranging from a half-day session every other week to

56 sessions weekly. As a result, some sites have more flexibility and ease with scheduling patients, which is also reflected in the varying wait times for new patient appointments (from 24 hours up to 4 weeks). Similarly, while many of the sites have palliative care services embedded within disease-specific clinics, others are freestanding. This may affect the facility with which patients can engage in and attend clinic visits. Furthermore, while there is significant consensus on the standardized assessments used to evaluate patients and caregivers, they are often used disparately and present a challenge to standardizing the delivery of outpatient palliative care.

Plans for dissemination and spread

The outpatient visit protocol and intervention checklist developed in this study are integrated into Epic as a smart phrase and thus broadly accessible for clinical and research applications across health care systems globally. For instance, the intervention checklist template could be used clinically to guide a newly opened outpatient palliative care clinic or to standardize outpatient palliative care in future pragmatic trials without causing undue burden to existing palliative care providers. Additionally, we plan to conduct future analyses to measure the impact of outpatient clinic characteristics, such as the number of sessions per week and freestanding versus embedded clinic model, on patient and caregiver outcomes.

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Author Disclosure Statement

No competing financial interests exist.

All statements in this report, including its findings and conclusions, are solely those of the authors and do not necessarily represent the view of the Patient-Centered Outcomes Research Institute (PCORI), its Board of Governors, or Methodology Committee.

Supplementary Material

Supplementary Appendix

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