Palliative Care in the Outpatient Setting

A Comparative Effectiveness Report
Draft Report

February 9, 2016

Completed by:

Institute for Clinical and Economic Review

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DATE OF PUBLICATION: February 9, 2016

ICER would like to thank Rebecca Kirch, JD, Consultant to the Center to Advance Palliative Care for her peer review of the draft report.

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The New England Comparative Effectiveness Public Advisory Council (New England CEPAC) is an independent, regional body of practicing physicians, methodological experts, and leaders in patient advocacy and engagement that provides objective, independent guidance on the application of medical evidence to clinical practice and payer policy decisions across New England.

Council members are elected for three-year terms, and represent a diversity of expertise and perspective; they are purposely not selected for expertise in the clinical topic under discussion in order to maintain the objectivity of the Council and to ground the conversation in the interpretation of the published evidence rather than anecdotal experience or expert opinion. Acknowledging that any judgment of evidence is strengthened by real life clinical and patient perspectives, New England CEPAC recruits subject matter experts for each meeting who provide input to Council members before the meeting to help clarify New England CEPAC's understanding of the different interventions being analyzed in the evidence review. The same clinical experts serve as a resource to the Council during their public deliberation, and help form recommendations with New England CEPAC on ways the evidence can be applied to policy and practice.

Led by ICER, New England CEPAC is supported by a broad coalition of state Medicaid leaders, integrated provider groups, public and private payers and patient representatives. For more information on New England CEPAC, please visit cepac.icer-review.org.

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List of Abbreviations Used in this Report

ABMS	American Board of Medical Specialties
ACA	Affordable Care Act
ACGME	Accreditation Council for Graduate Medical Education
ACHPN	Advanced Certified Hospice and Palliative Nurse
ACHP-SW	The Advanced Certified Hospice and Palliative Social Worker
AIM	Advance Illness Management
APN	Advanced Practice Nurse
ATT	Average Treatment Effect on Treated Patients
CAPC	Center to Advance Palliative Care
CARES-MIS	Cancer Rehabilitation Evaluation System Medical Interaction Subscale
CCA	Commonwealth Care Alliance
CCCC	Coalition for Compassionate Care of California
CES-D	Center for Epidemiologic Studies Depression Scale
CG	Caregivers
CHF	Chronic Heart Failure
CHPN	Certified Hospice and Palliative Nurse
CHPPN	Certified Hospice and Palliative Pediatric Nurse
CHPVA	Certified Hospice and Palliative Care Administrator
CMS	Centers for Medicare and Medicaid Services
COPD	Chronic Obstructive Pulmonary Disease
CPLC	Certified Nurse in Perinatal Loss Care
DHMC	Dartmouth Hitchcock Medical
ED	Emergency Department
ESAS	Edmonton Symptom Assessment Scale
FACIT-Pal	Functional Assessment of Chronic Illness Therapy- Palliative Care
FACIT-Sp	Functional Assessment of Chronic Illness Therapy- Spiritual Well-Being
FACT-G	Functional Assessment of Cancer Therapy- General
FACT-L	Functional Assessment of Cancer Therapy- Lung
FAMCARE-p16	The Family Satisfaction with End-of-Life Care (16-item measure of patient satisfaction)
FFS	Fee For Service
GME	Graduate Medical Education
HADS-A	Hospital Anxiety and Depression Scale of anxiety
HADS-D	Hospital Anxiety and Depression Scale of depression
HCFA	US Health Care Financing Administration
HMP	Hospice and Palliative Medicine
HRQoL	Health-Related Quality of Life
HRSA	Health Resources and Services Administration
HRU	Health Care Resource Utilization
IAHPC	International Association for Hospice and Palliative Care
IPAL-OP	Improving Outpatient Palliative Care Project
LASA	Linear Analog Scales of Assessment
LCS	Lung Cancer Subscale
LOS	Length of Stay
NR	Not reported
NS	Not significant
MBCB	Montgomery- Borgatta CG Burden

MGH	Massachusetts General Hospital
mITT	modified Intent-To-Treat
MS	Multiple Sclerosis
MSW	Master of Social Work
NHPCO	National Hospice and Palliative Care Organization
NIH	National Institutes of Health
NSCLC	Non-Small Cell Lung Cancer
PCLC	Palliative Care Leadership Center
PC	Palliative care
PCP	Primary Care Physician
PHQ-9	Patient Health Questionnaire
POM	Profile of Mood States
PPCHETA	Palliative Care and Hospice Education and Training Act
PPS	Palliative Performance Scale
PROMIS	Patient Reported Outcomes Measurement Information System
PRISMA	Preferred Reporting Items for Systematic Reviews
QoL	Quality of Life
QUAL-E	Quality of Life at the End of Life
RCT	Randomized Control Trial
TOI	The Trial Outcome Index
USPSTF	U.S. Preventive Services Task Force

Executive Summary

Background

Palliative care is a management approach that provides symptom relief and comfort care to patients with serious or life-threatening illnesses, with the goal of improving quality of life (QoL) for both patients and their families.[1] Unlike hospice care, which is typically restricted to individuals with a prognosis of survival of six months or less, palliative care can begin at diagnosis and is often provided along with treatment aimed at prolonging life, such as chemotherapy or radiation for cancer.[2] One of the primary objectives of palliative care is to help patients prioritize their goals of care, and may include conversations around advance care planning (e.g., a "living will") depending the anticipated disease trajectory.[3]

Topic in Context

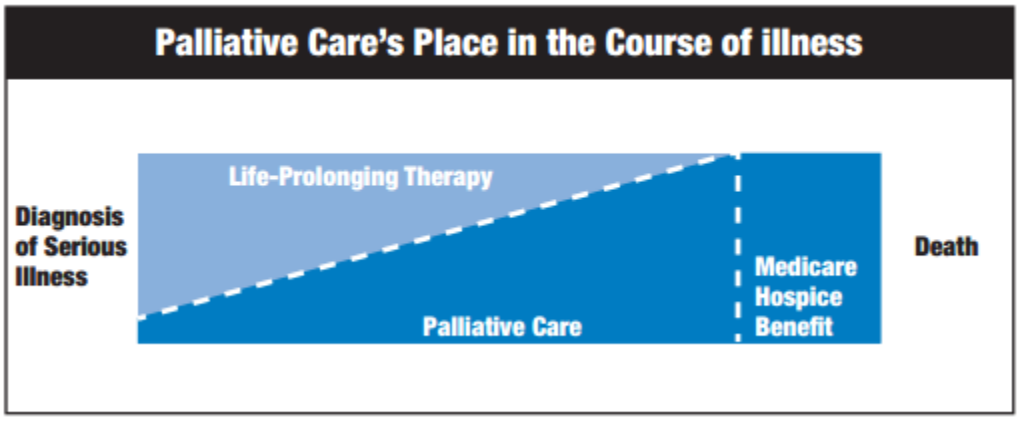
In summarizing the contextual considerations for outpatient palliative care, we seek to describe the following:

- The history and evolution of outpatient palliative care in the United States
- A description of settings in which outpatient palliative care is provided
- An overview of barriers and opportunities impacting the provision of palliative care as described by national and regional experts and the policy literature
- A snapshot of selected programs to shed light on existing approaches to outpatient palliative care

History

Palliative care in the United States grew largely out of the hospice movement. As life expectancy has increased and the number of individuals with chronic, advanced, or serious illness continues to rise, so increased the need for care that is targeted towards improving QoL through relief of pain, symptoms, and distress of serious illness. Palliative care was initially and continues to be offered predominately in the inpatient setting. However, due to the growing recognition of perceived barriers related to access, many feel that the next step in the evolution of palliative care is expansion of services into the outpatient setting. Individual health systems have begun to identify ways to expand access through programs focused on providing palliative services beyond the hospital setting to outpatient clinic, office, and home-based environment. This movement is intended to meet the needs of the growing number of patients that would benefit from palliative care services throughout the course of illness and care continuum.[4]

Figure ES1: Palliative Care in the Course of Illness



Graphic from the National Consensus Project for Quality Palliative Care

For the purpose of our evidence review, palliative care was defined by services that incorporate elements directed at both physical and psychosocial patient care, as both are considered essential and definitional components of palliative interventions.[5,6] Given the variability in health care systems and delivery worldwide, we have focused our evidence review on evidence from Canada and the US only.

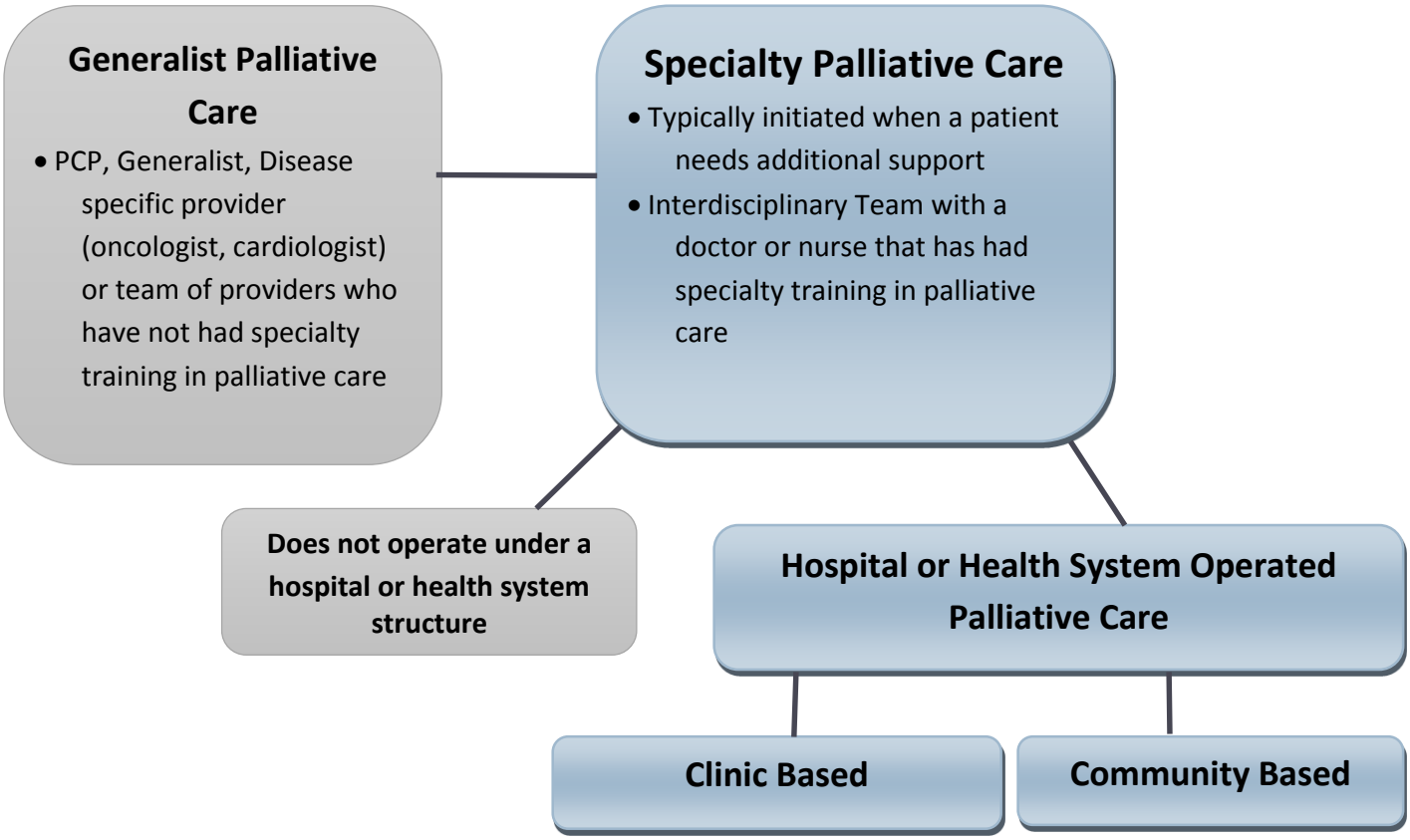
Settings of Care

Palliative care is growing in settings outside of the hospital. In the outpatient setting palliative care can follow a number of different models. Our report aims to describe common models and elements of outpatient care. Services are administered in a number of settings, including hospitals, outpatient clinics, skilled nursing facilities, or in the home.[4] Because of the growing demand for palliative care, primarily due to increasing numbers of patients living with chronic or serious illness, the field has evolved to include a number of approaches to maximize delivery of these services. While the structure of how these services are provided varies across population type and setting, two dominant models have emerged. These models are typically described as *generalist palliative care* and *specialty palliative care*.

Generalist Palliative Care is typically provided by professionals that have some clinical experience and basic training in palliative care concepts but whose primary specialty is not palliative care, including primary care physicians, generalists, oncologists, and other medical disciplines. These providers conduct needs assessments, educate patients about their disease, and provide basic symptom management and psychosocial support.[7]

Specialist Palliative Care involves hospice and palliative medicine (HPM) certified clinicians and advanced practice nurses with higher specialty education in palliative care. Specialist palliative care providers are those who have extensive training and experience in palliative care, and focus on those more complex aspects of disease management, including controlling refractory physical symptoms and worsening depression or anxiety, assisting with conflict resolution, and addressing issues of futility.[7]

Figure ES2: Specialty vs. Generalist Outpatient Palliative Care



Barriers and Opportunities

There are a number of barriers impeding the widespread use of outpatient palliative care. It is important to recognize that the landscape for palliative care is constantly evolving; therefore, our summary of barriers and opportunities should be viewed a "snapshot" of the status at the time of the report's publication. Through our evaluation we identified barriers that impact access to palliative care including:

- Workforce related barriers described as insufficient workforce capacity and a need for additional training and education opportunities for palliative care providers
- A lack of awareness of palliative care services among non-specialty providers
- Barriers specifically related to geography and socioeconomic status
- Limited knowledge about palliative care services among patients and families
- Limited availability of robust data on the impact of palliative care
- Scant funding opportunities for palliative care research
- Complex billing processes and inadequate reimbursement for palliative care services

We identified a number of opportunities that may contribute to the ongoing evolution of outpatient palliative care. In our overview we discuss opportunities related to:

- New payment methodology
- Use of electronic medical records to encourage care coordination
- Provider education
- Resources for existing providers and health systems
- Patient education
- Legislation aimed at eliminating barriers to providing palliative care

Existing Models for Outpatient Palliative Care

There are a number of ways in which palliative care programs function in the outpatient setting. Several existing programs provide exemplars and context for how palliative care is organized and coordinated through health systems. We found that most outpatient programs are operated by hospital systems. However, some models involve an integrated approach through an accountable care organization (ACO) framework. Several examples of programs available in New England are provided in the full report.

Comparative Clinical Effectiveness of Outpatient Palliative Care Programs

Our review of published evidence examines higher-quality comparative studies of palliative care interventions delivered outside the hospital. Interventions of interest were those implemented in outpatient or home-based settings that incorporate elements directed at both physical and psychosocial patient care, as both are considered essential and definitional components of palliative interventions.[5,6] We recognize that such studies vary substantially in terms of their entry criteria and description of the interventions. In order to inform our analysis of the comparative clinical effectiveness of outpatient palliative care, we defined several characteristics of the interventions as of *a priori* interest including:

- the **timing of the intervention** (whether it was specified as early [at or around time of diagnosis] or not);
- the **target population** of the intervention (patients with cancer only or patients with mixed diagnoses, given the concern that patients with diagnoses other than cancer receive palliative care substantially later in their disease trajectory than do patients with cancer, due to the lesser use of this intervention outside of oncology, as well as the waxing and waning of non-cancer diseases which results in a less predictable prognosis); and
- the **type of service** provided in the palliative care intervention (i.e., the level of training of care providers specialized [with input from a care provider described as having a palliative care specialty or certification] or generalist [with input from experienced care providers without reference to a specialty or certification]).

Our review focused on specific clinical benefits reported in terms of patient QoL, mood, symptom burden, patient satisfaction, health care resource utilization (HRU), psychosocial outcomes, caregiver impact, and survival, as an outcome that might indirectly result from other intervention outcomes.

Overall Evidence

The body of evidence derived from higher quality comparative studies of outpatient palliative care interventions in the US and Canada is somewhat constrained and variable with respect to intervention target and structure. We identified 13 good and fair quality studies describing a variety of outpatient palliative care interventions. As described in the methods, we recognized that such studies vary substantially in terms of interventions, and we defined several characteristics of the interventions as of *a priori* interest: intervention timing (early or not early); target population (cancer or mixed diagnoses); and type of service (specialty or generalist). Specialist-led interventions were described by 10 publications,[8-20] while generalist interventions were described

by three.[21-23] Four studies[8,9,19,20] evaluated outpatient palliative care's effect on patients with cancer; while nine studies[10,11,15-18,21-23] did so in populations of patients with mixed diagnoses. Five studies[8,9,19,20,22] evaluated the effect of interventions described as early, while eight studies[10,11,15-18,21,23] did so in populations of patients with mixed diagnoses.

Although we sought to identify any potential harms associated with palliative care, the studies included in our review did not report any adverse events connected with the interventions; therefore, our evaluation of net benefit is based solely on the noted benefits.

Overall, the evidence describing outpatient palliative care's benefit is strongest for resource utilization outcomes, with weaker evidence also suggesting a benefit on QoL, symptom burden, patient satisfaction, psychosocial, mood, and caregiver outcomes. These observations are consistent with the fact that outpatient palliative care programs are designed to increase patient social support, patient self-advocacy, and coordinated medical care; while not focused on improved survival as an indicator of effectiveness, the survival benefit may be mediated by the other more directly influenced outcomes of interest (e.g., mood, QoL).

Below, we present a summary evidence table capturing the strength of evidence around the relative effect of outpatient palliative care compared to usual care for several key outcomes of interest, with evidence around the more granular aspect of the intervention type (specialist vs. generalist).

Table ES1. Strength of Evidence

Outcome	Specialized care	Generalist care	Overall
QoL	6 studies	1 study	
Resource Use	8 studies	2 studies	
Survival	3 studies	1 study	
Symptom Burden	6 studies	1 study	
Patient Satisfaction	3 studies	1 study	
Psychosocial	1 study	2 studies	
Mood	4 studies	3 studies	
Caregiver outcomes	1 study	0 studies	

Moderate
Low
No evidence

The evidence base lacked detailed descriptions of the interventions, precluding analysis of the effect of specific elements previously identified by professional bodies as being essential to palliative care. In an effort to define potentially contrasting characteristics identified within the interventions included in our review, we noted that there were interventions which could be classified as specialist or generalist levels of palliative care, according to the definitions offered by Gomes et al.[6] Such specialist-led interventions reported a higher level of benefit on QoL than did the generalist studies; however, the findings are hampered the small number of studies and by the temporal bias given the specialty's introduction only in 2006.

Results for specific outcomes can be found in the sections that follow.

QoL

We identified three studies[8,19,20] of good quality and four studies[9,15,16,22] of fair quality that reported on patient QoL. The evidence base suggests that palliative care either improved patient QoL or had comparable improvements in QoL relative to usual care. Both study population (cancer versus mixed) and timing of palliative care may be drivers of the heterogeneous findings on QoL.

Mood Outcomes

We identified a total of seven studies evaluating mood outcomes–specifically, anxiety and depression, using a number of validated instruments: two good quality[8,19] and four fair quality[9,15,16,22] RCTs, as well as one fair quality cohort study.[21] Of these seven studies, four[8,15,19,22] found statistically-significant results in favor of the intervention, though not all studies evaluated both outcomes.

Both of the studies indicating relative benefit of the intervention on depression were conducted in cancer patients,[8,19] while neither of the studies with mixed populations favored the intervention.[15,21] For anxiety outcomes, similar proportions of studies in cancer and mixed populations showed positive effects.

Symptom Burden

The same seven RCTs reporting QoL outcomes also reported on symptom burden, and four of seven found no statistically significant differences in any symptoms between groups. Three studies showed reductions in some disease-specific symptoms (measured on the lung cancer subscale [LCS] of the FACT-L scale)[19] and physical symptoms (measured on the Linear Analog Scales of Assessment (LASA)-physical well-being scale[12,22] or the University of California, San Diego Shortness of Breath Questionnaire).[15] As with QoL, we found no clear evidence of heterogeneity associated with the study population or timing of care for symptom burden outcomes.

Patient Satisfaction

The available evidence suggests that palliative care improves patient satisfaction relative to usual care. One good quality prospective cohort study[11] and three RCTs, including one good quality[20] and two fair quality,[10,15] reported on patient satisfaction; three of these studies found higher satisfaction or a greater increase in satisfaction in the intervention group compared to controls. Another RCT in patients with mixed diagnoses found no difference in satisfaction between groups, likely due to small sample size.[15] We found no evidence of heterogeneity according to study population, intervention timing, or delivery of care by specialized or generalist teams.

Survival

Our review identified four good quality studies evaluating the hypothesis that outpatient palliative care may affect patient survival, of which three were RCTs, [8,10,19] and one a cohort study of patients with mixed diagnoses receiving generalist outpatient palliative care compared to a propensity score-matched cohort of patients receiving usual care.[23] The evidence base suggests that palliative care provided in the outpatient setting does not negatively affect patient survival,[8,10,23] and may in fact result in increased survival in populations with advanced cancer,[19] particularly when adjusting for potential confounders of the relationship between the intervention and survival (e.g. The Eastern Cooperative Oncology Group (ECOG) performance status score, or survival for less than one year).[8,19] Both target population (cancer) and timing of palliative care (early) may be drivers of the heterogeneous findings on survival; however, these factors are inextricably linked in the limited evidence base describing survival, with both studies in cancer patients also describing their interventions as early.[8,19]

Resource Utilization

Among the 10 studies reviewed with resource utilization data, there was a generally observed benefit of outpatient palliative care on overall resource utilization, measured variously as an increase in hospice utilization or death at home, or a decrease in utilization of acute care services.[8,10,11,14-18,21,23] Benefits were noted more predominantly among cohort studies than among RCTs, possibly a result of such data being more often collected in such study designs.[14-16] There was a suggestion of reduced acute care resource utilization among the four studies evaluating outpatient palliative care interventions both targeted to populations with mixed diagnoses and led by generalist palliative care providers.[10,11,15,18] Three studies evaluated the impact of outpatient palliative care on the location of death, and suggest that outpatient palliative care results in a larger proportion of patients dying at home, or a smaller proportion dying in the hospital.[10,14,18]

Psychosocial and Spiritual Outcomes

We identified three RCTs of fair quality evaluating psychosocial outcomes for patients, including spiritual well-being, advance care planning, and emotional and spiritual well-being, with

inconsistent findings.[15,16,22] One RCT showed a statistically significant improvement in spiritual well-being after a year of follow-up as measured on the Spiritual Well-Being Scale; however, between-group comparisons for consideration of durable power of attorney or plans for disposition of possessions after death were not significant.[15] Another study also reported statistically significant benefit for overall spiritual well-being on the FACIT tool in favor of the intervention after one month; however, this effect did not persist at weeks eight or 27.[22]

Caregiver Outcomes

We identified only one good quality secondary analysis[13] of an RCT[9] reporting on caregiver outcomes, including depression, QoL, and caregiver burden. This study found that caregivers of patients receiving early palliative care had greater reductions in depressive symptoms than those receiving usual care after three months of follow-up.

Summary and Comment

Despite the limitations of the published evidence derived from comparative studies, it is possible to use the ICER rating system to generate an estimate of the magnitude of the difference between outpatient palliative care and usual care. In summary, it is our judgement that there is moderate certainty that outpatient palliative care confers a comparable or better net health benefit relative to usual care. Additionally, given the lack of harms associated with such interventions, we have high certainty that the net health benefit is at least comparable. This yields an overall ICER Evidence Rating of C+: Comparable or Better for outpatient palliative care.

Components of Outpatient Palliative Care Programs Associated with Treatment Success

The comparative studies we reviewed did not provide evidence to distinguish successful and unsuccessful studies on the basis of many of the essential elements of palliative care described by professional organizations. However, we were able to identify several commonly described components of palliative care interventions in our evidence base, which we evaluated for their potential association with successful outcomes. Given that one of the primary goals of palliative care is to improve a patient's QoL,[24] we defined treatment success as a statistically significant effect on any QoL measure in favor of the palliative care intervention.

Of the seven studies we identified as evaluating QoL, four[8,19,20,22] were considered successful and three[9,15,16] were not. We found that three[8,19,20] of the four successful studies provided at least monthly in-person medical appointments with physicians or nurses present as part of the package of palliative services, while the studies not showing a QoL benefit followed up through telephone only. Other elements evaluated (multidisciplinary care team, specialist care, patient and family education, advance care planning) did not appear in substantially different proportions of successful and unsuccessful studies.

Comparative Value of Outpatient Palliative Care

We reviewed the published literature for analyses that have examined the economics of palliative care programs, including studies of the costs that are potentially offset through the use of such programs (e.g., reduced end-of-life medical costs). We also explored the potential health system budgetary impact of outpatient palliative care programs over a near-term time horizon, utilizing published information on program costs and cost offsets, as well as the potential population eligible for such services.

Our findings and analyses suggest that outpatient palliative care services appear to be cost-effective or even cost-saving for the health care system, by avoiding inpatient care and shifting care to home and outpatient settings. Expanding the use of these palliative care programs to larger proportions of eligible patients has the potential to substantially reduce the costs of health care for patients with advanced illness.

Costs and Cost-Effectiveness

Most recent studies that have compared direct health care costs for palliative care to usual care have found such programs to be cost-saving. Many of the costs of intensive inpatient admissions can be avoided, as more patients are able to be cared for at home or in an outpatient setting. A recent annual review by Hughes et al.[25] of the growth of palliative care (both inpatient and outpatient) in the United States reports that several studies of outpatient programs found cost savings through reduced hospital admission rates and movement of patients from high-cost settings such as hospitals to lower-cost settings such as home health care. In addition, three specific studies found lower costs (ranging from about $6,000 to $8,000 per patient) with outpatient palliative care compared to usual care in patients with mixed diagnoses (cancer and other serious illnesses). Importantly, however, these studies do not provide clear indication of the start-up and implementation costs of outpatient programs, so a full assessment of return on investment could not be performed.

Cost Burden and Unpaid Caregiving

While many economic analyses of palliative care take a payer or health system perspective, some find that at least some of the costs that outpatient and home-based palliative care averts by reducing hospitalizations and emergency department visits may actually be shifted to the home setting, where it is often provided by informal, unpaid caregivers. In some settings, it has been estimated that one-half to three-quarters of the costs of care in the last six to twelve months of life are attributable to family caregiving, suggesting a substantial economic burden on these individuals.

Potential Budget Impact Model

To inform possible cost savings at the health system level, we also estimated the potential budgetary impact of outpatient palliative care programs among candidate populations for such treatment in the U.S., based on estimates from the literature. We combined estimates of the mean cost per patient with estimates of the population potentially eligible for outpatient palliative care programs and different assumed levels of uptake of such programs.

We used the estimated savings per patient of $11,508 to estimate the total impact on the U.S. health care budget of implementing outpatient palliative care at different levels. Results suggest that, with immediate implementation for 10% of the eligible population, an estimated 78,665 individuals would receive palliative care each year. After one year of treatment, with net annual savings of $11,508 per patient, one-year budget impact is estimated to constitute savings of approximately $905.3 million. Over the entire five-year time horizon, we estimate that a cumulative total of 393,325 patients would be enrolled in palliative care, with a total potential savings of approximately $4.5 billion. Assuming that larger proportions of eligible patients could be enrolled in palliative care resulted in even greater savings. Alternatively, assuming that capacity to deliver palliative care has to be built up over time (i.e., 2% of eligible patients each year through year five) leads to fewer eligible patients being enrolled and results in fewer savings than with immediate implementation; our five-year savings estimate in this scenario is $2.7 billion. Full results at greater assumed uptake percentages (i.e., 25% and 50%) can be found in Table ES2 below as well as in the full report. If outpatient palliative care was targeted to only patients with cancer, 74% of these estimated savings would be realized.

Table ES2. Estimated Total Potential Five-Year Budget Impact (BI) of Outpatient Palliative Care: Immediate Implementation for Fractions of the Eligible U.S. Population (N=786,628)

	Immediate Implementation		Gradual Implementation	
Percent Enrolled	Cumulative Number Treated	Cumulative Total BI (billions)	Cumulative Number Treated	Cumulative Total BI (billions)
10%	393,325	-$4.53	235,995	-$2.72
25%	938,275	-$11.32	589,965	-$6.79
50%	1,966,575	-$22.63	1,179,945	-$13.58

Finally, we also estimated the budget impact of outpatient palliative care programs for a hypothetical health plan population of 1 million members. Enrolling as few as 10% of patients expected to die of cancer, CHF, and COPD in outpatient palliative care (n=248) would result in cost savings of approximately $2.8 million per year, or $0.24 per member per month. For benchmarking purposes, this is comparable to payments the state of Colorado makes to accountable care organizations for well-child visits.

Summary and Comment

Most studies that attempted to compare the cost to the health care system of providing outpatient or home-based palliative care to that of providing usual care found that such palliative care decreased overall costs, mainly through avoided hospitalizations and emergency department visits near the end of life. However, it was often unclear whether these evaluations incorporated the start-up costs of developing an outpatient palliative care program. While the literature seems to support cost savings associated with outpatient palliative care for the health care system, other studies have looked at the economic impacts of these programs from a societal perspective. These studies point out that, while outpatient and home-based palliative care may succeed in avoiding unnecessary or unwanted hospitalizations and emergency department visits, some of the care that would be provided in those settings is now shifted to the home, where it is often provided by informal, unpaid caregivers. We also used the health care costs for palliative care and usual care from an RCT conducted in 2002-2004 to estimate the impact on the U.S. health care budget of palliative care for the treatment of cancer, COPD, and CHF patients near the end of life. The potential money saved from the health care budget was substantial, and scaled up as more patients were assumed to enroll in palliative care. Even assuming a 2% uptake rate per year (i.e., 10% enrollment after five years) would result in estimated cumulative savings of about $2.7 billion after 5 years.

1. Background

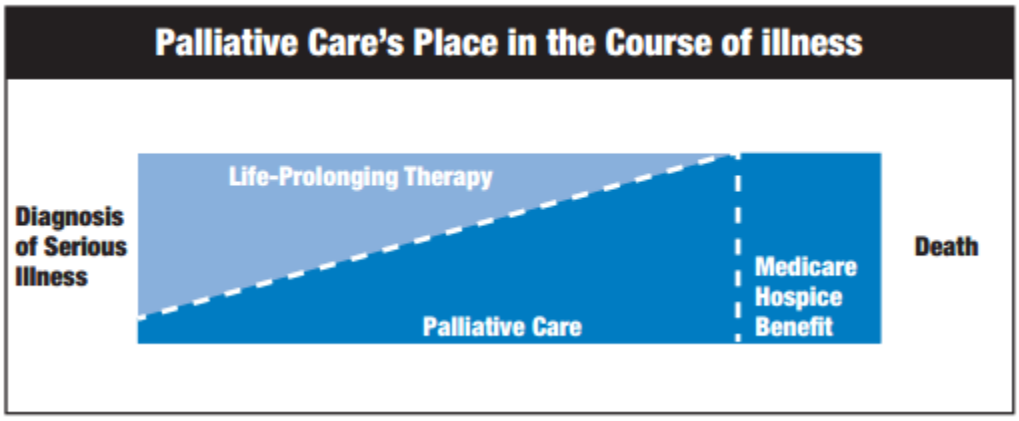
1.1 Introduction

The vast majority of health care in the United States is curative in nature; health care professionals are trained to execute scientifically-based practices that are primarily intended to diagnose, treat, and prevent disease and do not incorporate an equivalent focus on quality-of-life needs and values of patients and their loved ones. As the life expectancy and treatment objectives for patients with complex and chronic illnesses has evolved, clinicians are now faced with the challenge of meeting the entire breadth of patient and caregiver needs, of which curative or life prolonging therapies may only be a part of the solution.

Palliative care is specialized medical care that is focused on improving quality of life through relief of pain, symptoms, and distress of serious illness.[26] Palliative care is typically provided by an interdisciplinary team of doctors, nurses, and other specialists who lead a team or collaborate with a patient's long term care provider to administer an additional layer of support focused on improving quality of life for the patient and family.[27] Ideally, palliative care is initiated at diagnosis and is provided concomitantly with curative therapy.[2]

The National Consensus Project for Quality Palliative Care emphasizes that palliative care is best achieved through a coordinated partnership with the treating provider from diagnosis through end stages of illness, across the continuum of care, and in a variety of care settings and living situations. Figure 1, taken from Clinical Practice Guidelines for Quality Palliative Care,[1] outlines the progression of palliative care. Beginning at diagnosis, care focuses predominantly on curative treatments, with palliative care services provided as needed for such elements as pain and symptom management, or advanced care planning. As a serious illness progresses, more emphasis is placed on palliative services while the emphasis on curative care decreases, ultimately culminating in hospice care when curative therapies no longer serve to benefit the patient. Palliative care is intended to improve the quality of life (QoL) of patients with serious illness.[24]

Figure 1: Palliative Care in the Course of Illness



Graphic from the National Consensus Project for Quality Palliative Care

Additional definitions described by national and international palliative care organizations can be found in Appendix 2.

To date, palliative care has predominantly been offered to patients within the inpatient hospital setting due in part to the structures within the fee-for-service (FFS) delivery system. FFS is a payment system in which providers are paid for each individual service including office visits, test, and other procedures.[28] In the inpatient setting, palliative care has demonstrated success in improving patient satisfaction and QoL, among other factors.[29] Subject matter experts mentioned that hospitals were an early focus because they serve as a good entry point; at some point in every serious illness there is a likely to be a hospital admission, giving the palliative care team the opportunity to offer services.

A number of clinical trials have demonstrated that palliative care brings substantial benefits to patients and caregivers.[25] However, due to barriers surrounding access to care, the evolving needs of a growing patient population, and evidence supporting the use of palliative care outside of the hospital setting, many in the field suggest that hospital-based inpatient palliative care has reached a tipping point. As the aging and chronically or seriously ill population grows, palliative care will likely continue to evolve.[4] In response to the existing need and lack of access, many health systems are developing new programs to expand access to palliative care beyond the hospital setting to outpatient clinic, office, and home-based care. By providing palliative care in outpatient settings, services may be better suited to meet patient needs throughout the disease trajectory and continuum of care.[4]

If outpatient based palliative care is to become the next frontier in palliative medicine, decision makers will likely need to consider a number of barriers that impact the widespread use of palliative care in the outpatient settings. Barriers include a limited workforce, a lack of awareness or reluctance towards services among both patients and physicians, issues of access related to

geographic location or socioeconomic status, and other factors. For an in-depth description of barriers please see Section 2.3.

As stakeholders consider ways to expand access, they may benefit from a deeper understanding of the comparative clinical effectiveness and economic impact of outpatient palliative care services, and the elements related to successful outcomes. This report aims to evaluate the comparative effectiveness and value of palliative care services delivered outside the hospital, including outpatient or home-based settings. It is broadly divided into context-setting, evidence-based, and value assessment components.

1.2 Scope

Our review of the evidence examined studies of palliative care delivered outside the hospital, including outpatient clinic, office, or home-based settings. Palliative care was defined based on services that incorporate elements directed at both physical and psychosocial patient care, as both are considered essential and definitional components of palliative interventions.[5,6] We recognize that studies vary substantially in terms of their entry criteria and definitions of the interventions, and as such have attempted to identify the components of palliative care programs most closely associated with treatment success. Given the variability in health care systems and delivery worldwide, we have focused our review on evidence from Canada and the US.

Evidence on intervention effectiveness was limited to good- or fair-quality randomized clinical trials or comparative cohort studies, of any duration. For more information on methods used to ascertain study quality, please see Section 4.2.

The scope for this review is described below using the PICOTS (Population, Intervention, Comparators, Outcomes, Timing, and Settings) framework. The scope for this review is described below using the PICOTS (Population, Intervention, Comparators, Outcomes, Timing, and Settings) framework.

Population

The populations of interest include all adults (>17 years old) with serious or life-threatening illnesses, including but not limited to advanced cancer, chronic obstructive pulmonary disease (COPD), and congestive heart failure (CHF).

Interventions

Interventions of interest include those palliative care services provided either independently of, or in conjunction with, curative or life-prolonging treatment for serious and life-threatening illnesses. Studies which describe “hospice,” “end-of-life care,” “supportive care,” “comfort care,” or any such variation were considered alongside studies with interventions specifically described as “palliative.”

We include all studies regardless of their definition of the interventions. However, we have also attempted to identify components of care across studies, with the goal of identifying those that may influence the direction of effect. We also include studies describing "early" palliative care (as defined by initiation at or around the time of diagnosis) as compared to "late" interventions (e.g., initiated at or near the end of life) or no palliative services.

Comparators

Primary comparators of interest are current models of usual care, which may take multiple forms. This is alternatively referred to as either "usual" or "standard" care.

Outcomes

Outcomes of interest included the impact of palliative care on:

- Survival and mortality
- Health resource utilization, including location of death
- Symptom severity, including pain, breathlessness, fatigue, and nausea
- Patient, caregiver, and/or family psychological distress (e.g., stress, anxiety, depression)
- Ratings of patient, caregiver, family, and provider satisfaction
- Health-related QoL
- Economic outcomes, including program start-up costs, costs per patient, potential cost offsets, and measures of cost-effectiveness

The review includes evidence drawn from all measures of these outcomes as reported in the evidence base, but focuses on those that are drawn from validated instruments.

Timing

Evidence on palliative care provided outside the hospital or nursing care facility setting was gathered from the year 2000 to the present, reflecting the timeline and evolution of palliative care in these settings.

Evidence on intervention effectiveness was limited to higher quality randomized clinical trials or comparative cohort studies, of any duration.

Settings

While study participants could be identified in multiple settings, we focused on palliative care programs delivered outside the hospital, including outpatient or home-based settings. Included interventions were those in which services were clearly described as being for the most part offered in outpatient settings, and not in settings such as residential nursing or hospice facilities.[6]

In addition to conducting a review of available literature and analyzing the comparative value of palliative care, ICER staff conducted semi-structured interviews with national and regional experts in an effort to gain their perspectives on practice and delivery system innovations, barriers to change, and opportunities for improving palliative care in the outpatient setting. These key informants included experts from academic institutions, palliative care programs, hospitals, patient advocacy organizations, and health plans. A full methodology and list of organizations represented in interviews are available in Appendix 9. The report also provides an overview of legal, regulatory, and financial landscape factors related to palliative care in the United States.

The report attempts to answer some of the key issues confronting patients, provider organizations, payers, and other policymakers and includes the following:

1	An overview of the contextual factors impacting the delivery of palliative care services outside of the hospital, including a summary of clinical guidelines and payer reimbursement policies relevant to palliative care.
2	An evaluation of the evidence on the comparative clinical effectiveness of palliative care services delivered outside of the hospital relative to usual-care or alternative approaches.
3	An assessment of the costs, cost-effectiveness, and potential budget impact of delivering palliative care services outside of the hospital

2. The Topic in Context

Extending the duration of human life ranks as one of modern medicine's most significant achievements. In the US, average life expectancy has increased from approximately 71 years for persons born in 1970 to 79 years for those born in 2011,[30] which represents more than 25% of all gains in life expectancy since 1900. However, for many, living longer also means living with a chronic, advanced, or serious illness. Over 90 million Americans live with at least one chronic illness, and seven out of ten Americans die from chronic disease.[31] Within the Medicare population, nine of ten deaths are associated with at least one of nine chronic illnesses: CHF, chronic lung disease, cancer, coronary artery disease, renal failure, peripheral vascular disease, diabetes, chronic liver disease, and dementia. Evidence suggests that these patients often receive low-quality care as indicated by fragmentation and/or overuse of services, high frequency of medical errors, and poor quality of life.[29] As the population living with chronic, debilitating, and life-threatening illness continues to grow, the need for palliative care has become more acute.

2.1 History and Evolution of Palliative Care Services

In the United States, palliative care came to existence in part due to the hospice movement which began after Florence Wald, former Dean of Yale University's School of Nursing, established the Connecticut Hospice in 1974.[32] The formalization of hospice began when the US Health Care Financing Administration (HCFA) initiated the hospice demonstration program in 1979. A Medicare benefit for hospice was introduced by statute shortly thereafter in 1982.[32]

The Medicare hospice benefit is highly standardized by the Medicare Conditions of Participation and is accompanied by an important binding requirement: eligibility is based on a prognosis of living less than six months.[29] Patients must provide documentation from two physicians indicating a life expectancy of six months or less and agree to forgo insurance coverage for life-prolonging and curative treatments.[33]

The term palliative care originated in Montreal Canada when in 1974 Dr. Balfour Mount, a physician at McGill University, began using the term in an effort to engage patients and families experiencing chronic or life-limiting disease in holistic care practices without using the word hospice. Both hospice and palliative care services were aimed at addressing physical, psychological, social, or spiritual distress with the intent of improving quality of life for patients and families.

In the United States, palliative care differs from hospice in that services are accessible to patients without the restriction of a six-month life expectancy. Outside of the United States, this distinction is less prominent and palliative care and hospice are relatively synonymous terms.[29] Additional detail on the distinctions between palliative care and hospice is available in Appendix 1.

Modern palliative care took shape in the United States during the 1990s predominantly within academic medical centers in response to the recognition that patients with a variety of serious illnesses could benefit from the core components of hospice care, regardless of their life expectancy. Many cite the 1997 Institute of Medicine (IOM) report titled *Approaching Death: Improving Care at the End of Life* that shed light upon deficiencies in end-of-life care in the United States as having influenced this recognition.[34] More recently, palliative care has expanded beyond these settings due to a number of factors, including:[32]

- Monetary support from philanthropic foundations to improve care for the seriously ill including an effort on behalf of the Robert Wood Johnson Foundation and George Soros' Open Society Institute to fund efforts aimed at expanding the use of palliative care in mainstream medicine[34]
- An increase in the number of clinical demonstration projects, reviews, and randomized control trails documenting major inadequacies in care for the seriously ill and demonstrating the benefits of palliative medicine
- The 2002 establishment of a hospice and palliative care nursing certification by the American Board of Nursing Specialties
- The development and release of the 2004 Clinical Practice Guidelines for Quality Palliative Care which specifically expanded the focus of palliative medicine beyond care for those at the end of life
- The 2006 publication of a National Framework and Preferred Practices for Palliative and Hospice Care Quality by the National Quality Forum which established quality guidelines for standardized palliative care
- The 2006 recognition of the subspecialty of Hospice and Palliative Medicine by American Board of Medical Specialties (ABMS) and the Accreditation Council for Graduate Medical Education followed by first examination for the Hospice and Palliative Medicine (HPM) specialty in 2008
- The 2011 formation of the palliative care certification for hospital programs by the Joint Commission

The predominant model of palliative care in the U.S. is the hospital consultation model. This model typically involves a team of physicians, nurses, social workers, and other support staff who assist primary care providers and specialist in the hospital.[29] Palliative care is especially prevalent in the oncology setting. Almost all National Cancer Institute designated cancer centers have access to palliative care and 98% have a palliative care program, 59% of which have an outpatient palliative care clinic.[25] The widespread use of palliative care in oncology is likely due in part to the nature of the disease. The significant side effects of many treatments for cancer make it necessary to provide both curative care as well as palliative services such as pain and symptom management in tandem.

It should be recognized that even in settings and specialties where palliative care is accepted there remain challenges to access and appropriate use. There are a number of studies that describe limitations to access, even in oncology.[35] Some stakeholders interviewed noted that while palliative care services are prevalent in oncology settings, services or consults are often initiated late.

As noted, palliative care provides benefits to patients and caregivers[25] but numerous barriers to access exist. In order to extend the potential benefits of palliative care and address barriers to access, decision makers may turn to expanding palliative care services in the outpatient setting.

2.2 Settings and Elements of Palliative Care

During interviews, key informants emphasized that palliative care is growing in settings outside of the hospital. Stakeholders stressed that outpatient palliative care provides physicians with an opportunity to truly influence decision making about the patient's care and to prevent patients from needing to access the hospital in the first place.

Palliative care in the outpatient setting can follow a number of different models. Varying elements of care and specific settings make many palliative care programs distinct from one another, yet many share overlapping similarities. This section outlines common elements and models of outpatient care.

Program Structure

Palliative care programs aim to address physical and psychological symptoms, spiritual needs, treatment goals, and end-of-life preferences.[2] Palliative care can be provided concurrently with, or independently of, curative or life-prolonging care at any stage of a serious illness. These services are administered in a number of settings, including hospitals, outpatient clinics, skilled nursing facilities, or in the home.[4] Because of the growing demand for palliative care, primarily due to increase in the number of patients living with chronic and serious illness, the field has evolved to include a number of approaches to maximize delivery of these services. While the structure of how these services are provided varies across population type and setting, two dominant models have emerged and are described in detail below.

Generalist Palliative Care

Palliative care is often provided by professionals that have some clinical experience and basic training in palliative care concepts but whose primary specialty is not palliative care, including primary care physicians, generalists, oncologists, and other medical disciplines. These providers conduct needs assessments, educate patients about their disease, and provide basic symptom management and psychosocial support.[7]

Specialist Palliative Care

Specialists palliative care teams can be comprised of hospice and palliative medicine (HPM) certified clinicians and advanced practice nurses with higher specialty education in palliative care. Specialist palliative care providers are those who have extensive training and experience in palliative care, and focus on those more complex aspects of disease management, including controlling refractory

physical symptoms and worsening depression or anxiety, assisting with conflict resolution, and addressing issues of futility.[7]

HPM Certification

The HPM certification is a medical subspecialty that was approved by the American Board of Medical Specialties (ABMS) in 2006. The first HPM exam was administered in 2008, and from 2008 to 2012 there was a "grandfathering period," where those physicians with extensive experience in the field were able to achieve certification through direct pathway without having to complete a 12-month fellowship. Starting in 2012, any provider seeking an HPM subspecialty certification must complete a 12-month HPM fellowship through an accredited program. Once a fellowship has been completed the provider is able to take the certification exam.[36] There are fewer than 200 available fellowships per year.[29]

More information can be found at:
http://aahpm.org/hpm/number-certified

Nurse Certification

The National Board for Certification of Hospice Nurses was established in 1992 with the goal of initiating a certification process for hospice nurses and the first certification exam in 1994. Applicants must provide verification of licensure and meet specific program requirements which may include but specific work experience in a specialty which is often validated in the format of a test; a passing score would guarantee certification for period of 4 years. There are a number of available certifications through the National Board for Certification of Hospice and Palliative Nurses for various levels of hospice and palliative nursing care team, and administrators. Palliative care certifications offered for nurses include:

- Advanced Certified Hospice and Palliative Nurse (ACHPN)
- Certified Hospice and Palliative Nurse (CHPN)
- Certified Hospice and Palliative Pediatric Nurse (CHPPN)
- Certified Hospice and Palliative Care Administrator (CHPVA)
- Certified Nurse in Perinatal Loss Care (CPLC)

Additional information can be found at:
http://hpcc.advancingexpertcare.org/competence/certifications-offered/

The Advanced Certified Hospice and Palliative Social Worker (ACHP-SW)

The National Association of Social Workers Specialty Certification program began 2000 to address an increased need for specialization. The ACHP-SW was established 2008 in partnership with the National Hospice and Palliative Care Organization (NHPCO) for MSW level certification. This

certification is intended to improve specialized knowledge, skills, and abilities of professional social workers in hospice and palliative care settings.

Additional information can be found at:
http://www.socialworkers.org/credentials/credentials/achp.asp

Non-Certified Providers

While the HPM certification has created a pathway for professionals to become palliative care specialists, palliative care is often provided by professionals that do not have extensive training in palliative care. Many primary care physicians, generalists, community nurses, and others offer elements of primary palliative care to patients with any terminal or complex, serious illness with the intend of improving QoL. These providers conduct needs assessments, dispense information and advice, and when necessary often link patients to specialist teams for additional support.

Setting

Outpatient Setting

Through our conversations with stakeholders and review of the evidence we found that the specialty level outpatient palliative care programs are typically operated by hospital or health systems. There are a number of ways that specialty palliative care services can be delivered. Figure 2 provides an overview of specialty vs generalist outpatient palliative care. Following this figure, we have included a table using data from CAPC's Improving Outpatient Palliative Care Project (IPAL-OP) and our evidence review that contains information about different types of specialty-level outpatient palliative care programs.

Figure 2: Specialty vs. Generalist Outpatient Palliative Care

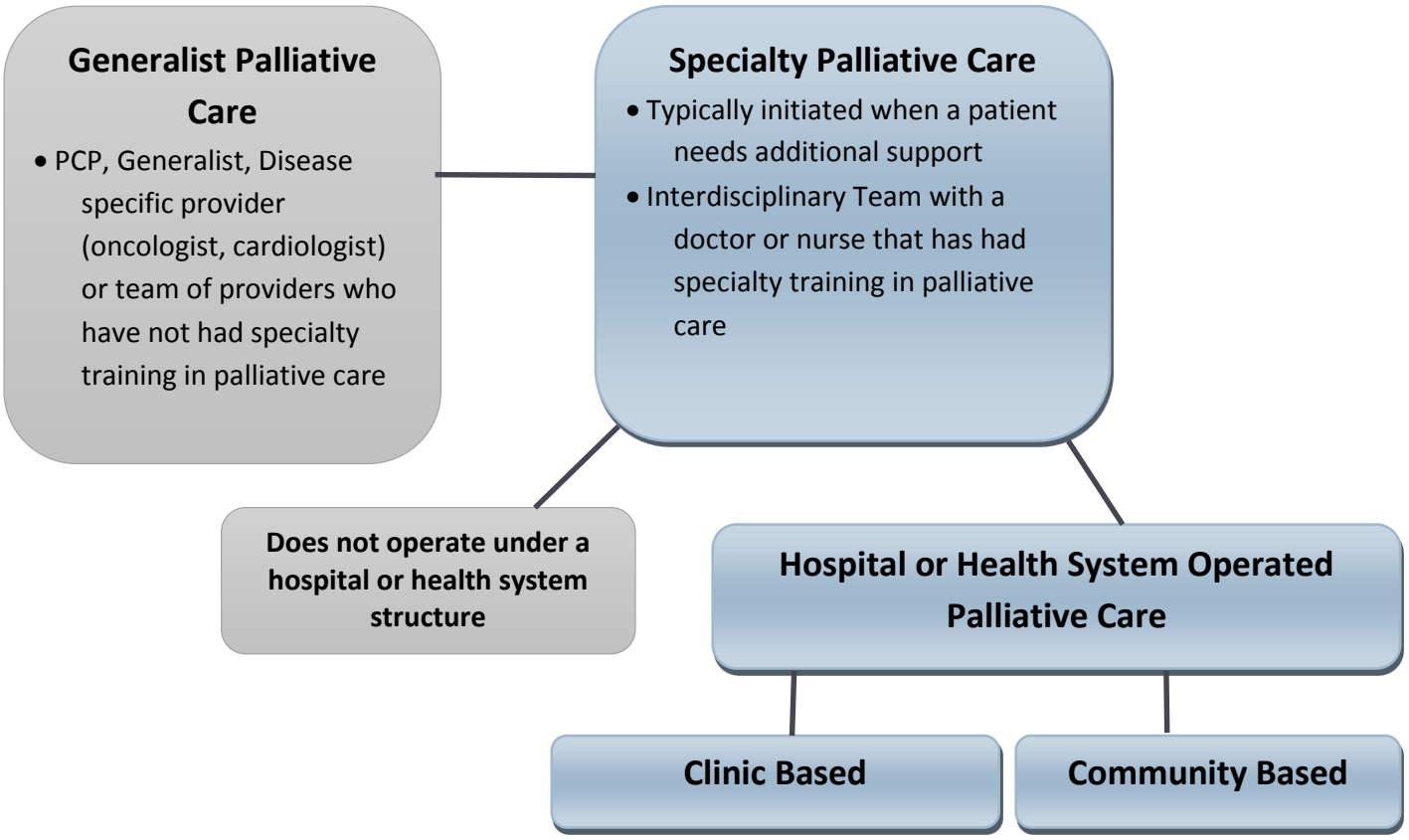


Table 1. Models of Outpatient Palliative Care[37]

Location	Description	Finance
Clinic Based Models		
Outpatient Stand-Alone Clinic	These are independently functioning, specialty clinics where patients receive palliative care services.	Palliative care clinic responsible for all costs.
Outpatient Co-Located Clinic	These clinics operate in a shared space with other medical services. Referrals to palliative care services may come from physicians within the clinic in other specialties, or from other practices entirely.	Costs may be shared between the palliative care clinic and the host clinic.
Outpatient Embedded	These services share similar characteristics with outpatient co-located clinics. Palliative care providers share space and work closely with other providers. There may be protocols defining how palliative care functions in tandem with other medical services.	The host clinic is typically responsible for all costs.
Community Based Models		
Home Visits	Palliative care consultants visit patients in their homes. This model is generally well-suited for patients who have complex needs that would require more time than is possible in an office setting, patients for whom travel to an office appointment would be difficult, or for practices with insufficient office space.	Billing can vary greatly depending on the services provided and the structure of the home care program.
Facility-Based Visits	Palliative care consultants visit patients in a residential care facility and provide palliative services to complement other medical services being administered by the facility's providers.	Consultants bill for consultation services.

Information adapted from https://central.capc.org/eco_download.php?id=1130

2.3 Barriers and Opportunities

There are a number of barriers impeding the widespread use of outpatient palliative care. This section provides an overview of the regulatory, financial, and administrative context affecting how palliative care is delivered in the United States. It is important to recognize that the landscape for palliative care is constantly evolving; therefore, this section should be considered a "snapshot" of the status at the time of the report's publication.

Barriers

Workforce: Capacity, Education, and Training

A primary barrier to the expansion of palliative care identified in our interviews with key stakeholders was a shortage of appropriately trained providers; the workforce capacity must increase in order to meet the needs of patients that may benefit from services.[2] As of 2014, the American Academy if Hospice and Palliative Medicine (AAHMP) reported that 7,000 physicians in the United States are HPM certified.[36] Data from a study examining 30-day readmissions among seriously ill older adults indicated the availability of only one HPM physician for every 20,000 older adults with life-limiting illness and one HPM physician for every 11,000 Medicare deaths.[25] There is an estimated shortfall of 6,000-18,000 palliative care physicians in the U.S., and an approximately equal deficit in the availability of advanced practice nurses.[38]

This shortage is exacerbated by the limited availability of specialty training opportunities for Masters-prepared nurses, as well as for physicians.[29] Key informants pointed to education and training requirements as a key barrier to expansion of palliative care programs. New physicians may be interested in pursuing such fellowships; however, these regulations may deter mid-career physicians from pursuing HPM certification, as they will likely be required to pause their career to complete fellowship training. The limited number of fellowship opportunities, paired with the lack of training exemption for physicians already working in the palliative care field, contribute to a shortage of HPM certified providers.

Awareness of Palliative Care Among Non-Specialist Providers

Key informants also identified attitudinal barriers or a general lack of awareness of palliative care among non-specialist providers. For many physicians, the perceived dichotomy between curative treatment and comfort care likely affects physician willingness or ability to refer patients to palliative care programs. Interviewees cited primary care practice as an example of this barrier. Many components of palliative care can be offered by a primary care physician, generalist, or disease specific-provider; however, many such providers either lack the training to discuss and provide palliative care services, or are not aware of services offered within their medical system to which they could refer patients. Additionally, some physicians may not recognize the distinction

between palliative care and hospice care, and may be reluctant to approach either due to the perception that beginning palliative care would interfere with the opportunity to offer the patient curative treatment. Stakeholders interviewed shared that a common misconception that creates a major barrier for consults is the perception that palliative care referral means that a patient or practitioner has as one stakeholder summarized "given up hope".

Geographic and Socioeconomic Access Disparity

In the outpatient setting, there are limited data related to access. However, data from CAPC indicates that regions that lack access to inpatient palliative care tend to:[39]

- have fewer hospitals that maintain nonprofit status, are academically-affiliated, and have formal teaching programs;
- be located in the southern U.S.; and
- have fewer faith-based health care organizations.

While less documented than other health disparities, there appear to be issues related to general access to symptom management and communication services among African Americans and Latinos as compared to white patients.[40] Factors impacting access specifically to palliative care are less well-understood, but some studies have identified contributors such as:

- gaps in palliative care knowledge among minority older adults;
- spiritual and religious beliefs that conflict with perceived palliative care practices;
- mistrust of the health care system due to past experience;[40] and
- cultural barriers including absence of minority staff, interpreters, and outreach/education to diverse communities.

Outpatient palliative care services may help to better serve patients in geographic regions with few nonprofit, academic, or faith based care organizations and could be tailored to appropriately serve populations that have experienced historical issues with access.

Patient and Family Knowledge of Palliative Care

Patients, families, and caregivers may not understand what palliative care entails and do not necessarily know at what point to request services. Palliative care is a relatively new concept to many patients and to some is still synonymous with end-of-life or hospice care. Nearly 90% of adults surveyed as part of a recent study reported either no knowledge or limited knowledge of palliative care. However, upon learning what palliative care entails, more than 90% of the respondents stated that they would want palliative care for themselves or their family member and that it should be universally available.[2] Key informants noted attitudinal barriers to patients and families discussing palliative care. Many connect the concept of palliative to the idea of hospice, and felt that using palliative care services meant that curative treatments were no longer of benefit.

As a result, patients may be uninterested in or reluctant to pursue palliative care, even if presented with the opportunity to receive it.

Availability of Data

While many specialty organizations advocate for the use of palliative care, the availability of data from high powered, well-designed RCTs is generally lacking.[25] Indeed our review of the published evidence derived from high quality comparative studies supports this observation that relevant comparative studies are lacking, with only 13 relevant studies identified.

Stakeholders referenced the need for data demonstrating that palliative care effectively improves patient experience, reduces resource utilization, and is not a high-risk investment. Our evidence review was able to highlight the relative impact of outpatient palliative care programs on particular outcomes of interest; however, we were not able to substantively identify particular components of such inherently multidisciplinary programs that may be able to best predict success. Such studies are difficult given the setting of so many interventions in closed health care systems with little heterogeneity in the patient populations and in the components of the offered interventions. Our finding that at least monthly in-person clinical interactions coincided with increased success on QoL measures suggests that additional studies might quantify this element of outpatient palliative care programs, and better characterize the relationship (see Section 4 for details).

Appendix 7 of this report describes comparative studies of outpatient palliative care currently ongoing in the US and Canada, some of which may provide information lacking in the current evidence base.

While many health systems have developed programs to address the needs of complex populations through pilot demonstrations, systems level interventions, and by designing reimbursement models intended to incentivize high value care, there exists a need for outcome data and cost effectiveness analyses.[41] A number of the stakeholders that we interviewed felt that some of the available data indicate that palliative care decreases health care costs. However, they stressed that health systems are looking for robust data demonstrating not only cost savings from outpatient palliative care but also increased patient satisfaction and improved patient-centric outcomes such as QoL. Stakeholders also highlighted a need for improved data surrounding symptom relief, specifically referencing the desire for explicit guidelines related to treating pain without opioids among those with serious illness.

Funding

While there has been an increase in the number of NIH funded investigations and grants in the past decade, only 1% of the current NIH budget is dedicated to palliative care. Institutional programs have been created in an effort to strengthen available evidence, but the field continues to require additional extramural funding.[25] Stakeholders noted that when starting a new palliative care

program, financial support on the local level, from hospitals or within provider organizations, and executive level buy-in was critical to success.

Billing for Services

Based on conversations with stakeholders and a review of available resources we found that billing for outpatient palliative care services covers a portion of direct staff costs but does not typically support all services provided. For example, a survey of 12 outpatient palliative care programs conducted by the Palliative Care Leadership Center (PCLC) Initiative of the Center to Advance Palliative Care found that billing supports 50% of outpatient palliative care services.

Reimbursement for services is impacted by a number of factors including:[42]

- Documentation and billing processes
- Palliative care team provider composition (impacts who can bill for direct costs)
- Contracts with payers and type of payer (Commercial or Medicare/Medicaid)
- Effort towards direct patient care vs. non billable efforts

One stakeholder shared an example of a facility that is able to bill for MD level palliative care services at a rate negotiated with the medical center. The stakeholder explained that this rate pays for junior faculty in clinic but the program is not reimbursement for social workers, chaplaincy, pharmacy; billing for nurse practitioners is possible, but the medical center keeps those revenues.

Many of the barriers listed in this section may be alleviated through increasing awareness of and access to palliative care services in the outpatient setting. We have identified a number of opportunities that may help to foster the continued development of outpatient palliative care programs, as listed in the sections that follow.

Opportunities

New Payment Methodology

Outpatient palliative care will likely advance in importance as the number of chronically ill individuals with significant symptoms continues to rise. These complex patients often lack predictable prognoses. For example, those with COPD and CHF are unlikely to forgo curative treatments (as is necessary to initiate hospice) but may experience benefit from symptom management techniques and comprehensive care services provided through palliative care programs.

Through stakeholder interviews and our review of the literature, we found that many consider integrated delivery systems operating under capitated or risk-bearing managed care payments to be best suited to execute outpatient palliative care programs. Kaiser Permanente and the Veterans Administration are examples of integrated systems that operate in multiple states and have initiated palliative care models designed to improve access to outpatient palliative care through care coordination efforts.[26] Integrated delivery systems are uniquely positioned to provide outpatient palliative care because of the established systems level structures that facilitate sharing of information, communication, and finances that allows for coordination of care across settings. The willingness and capacity of individual health systems to engage in care models and payment methodology outside of the fee-for-service realm will also have an impact on the continued expansion of outpatient palliative care. While the integrated delivery system has been identified by many as a promising avenue for palliative care, these systems are currently available to a minority of patients, and availability varies geographically. Access to palliative care could be further improved regardless of delivery system structure through policy initiatives that encourage the use of palliative care by providing additional reimbursement mechanisms for services.[26]

A recent example of a policy intended to change reimbursement mechanisms in order to support palliative care came from the Center for Medicare Services (CMS). In January 2016, CMS introduced the Medicare Care Choices Model, intended to allow Medicare patients to access palliative care services from specific hospice providers without giving up curative services. This program is intended to address barriers to access by extending home-based palliative care services to as many as 150,000 Medicare beneficiaries.[43] The model is also predicted to allow greater access to supportive care services provided by hospice; improve QoL and satisfaction for patient and families; and play a role in informing new payment systems for the Medicare and Medicaid programs. For a detailed list of programs in New England please see Appendix 3.

Use of Electronic Medical Records to Encourage Care Coordination

Several stakeholders mentioned that palliative care programs rely on significant systematic support structures. Experts emphasized the need for a mechanism to identify those who will benefit from

palliative care services in order to increase assess. One stakeholder noted that most of the predictors of risk are related to functional impairment. One way to address referral is through an EMR system-based check list similar to that used in hospitals for vital signs by nurses. A checklist may make it easier for physicians to identify patients that may benefit from palliative care. Suggested factors for screening include:

- Frailty
- Cognitive impairment
- Number of more chronic conditions
- Family caregiver burden
- Distress screening

Provider Education

Continued investment in palliative care medical education may help to address the existing shortage in the palliative care workforce. Stakeholders interviewed stated that medical schools and residency programs may want to consider expanding existing training options for palliative care. Currently program curricula provide training related core competencies of palliative care including communication, pain and symptom management, and psychosocial assessment, but many feel that there exists a need to expand the offerings.[2]

The clinical experts and stakeholders interviewed recommend a number of options to help build the existing workforce including:

- Distributing currently unused graduate medical education (GME) slots to Accreditation Council for Graduate Medical Education (ACGME) to accredited palliative medicine fellowship training programs in order to address the shortage of fellowship opportunities;[29]
- Providing Health Resources and Services Administration (HRSA) Title VII–supported career development awards (loan forgiveness programs) to incentivize medical and nursing faculty to enter the field; and[29]
- Offering educational loan forgiveness for physicians and advance-practice nurses.[29]

It may also be important to facilitate a conceptual understanding of palliative care among mid-career professionals who do not plan to specialize in HPM and who may not have received extensive training in palliative care techniques during medical school or residency programs.

Primary care and general practitioners often perform elements of palliative care as part of their practice but many lack formal training or capacity to address symptom management, spiritual needs, communication about care goals, and economic issues. Recently the Institute of Medicine (IOM) described a need for generalist level palliative care training designed to enhance communication skills among medical students and practicing clinicians in order to increase provider competency in identifying patient and family preferences and care goals.[44]

Additionally, it is recommended that more complex patients be referred by PCP's and other generalists to specialized palliative care teams. Providing continuing education training on elements of palliative care and encouraging referral to palliative care specialist teams when providers encounter complex patients may help address the perceived barriers.

A few of the stakeholders interviewed suggested that hospitals, nursing homes, and rehab facilities should conduct a palliative care needs screening for all patients upon admission for outpatients living with serious or complex illnesses. However, some noted that the processes for identification and referral have not been worked out on a wide scale.

Efforts could also focus on changing perceptions among providers that palliative care is appropriate only at the end of life. It may be necessary to emphasize that palliative care can be administered alongside curative treatment, is designed to ease symptoms and suffering throughout a serious illness, and should be considered early or at diagnosis. An emphasis on promoting and standardizing palliative care practices will only improve the existing landscape if the quality and quantity of the workforce is scaled up to meet the need.

Resources for Existing Providers and Health Systems

A number of agencies have developed materials intended to support practicing physicians and other providers, health systems, and communities expand and enrich the practice of palliative care.

- CAPC has developed tools and best practices for the inpatient setting and now are focusing on developing the same training support for palliative care outside the hospital called Improving Outpatient Palliative Care (CAPC IPAL-OP). This program is intended to serve as a central repository for learning how to start an outpatient palliative care program and in turn improve outpatient palliative care practices. Membership is required for full access to resources, tools and references from health care systems at the forefront of developing innovative outpatient palliative care services. More information can be found at CAPC's IPAL-OP homepage.
- The Coalition for Compassionate Care of California (CCCC) offers a number of resources for providers and families including monthly palliative care webinars, custom tools, presentations, studies, and fact sheets about palliative care. These resources are designed to provide support to organizations and communities in an effort to expand palliative care across the continuum of care. More information can be found on CCCC's palliative care site.
- The IOM produced a report titled Dying in America which includes recommendations regarding the need for increased palliative care communication training for all practitioners. IOM recognized VITALtalk as having a strong program for promoting basic palliative care communication skills to prepare providers for difficult conversations surrounding palliative care. VITALtalk communication skills building resources are available at http://vitaltalk.org/

Patient Education

Patients may benefit from conversations with providers or a public awareness campaign designed to inform individuals and families about palliative care options. Federal and private sector investment in a major social marketing campaign could help address this issue.[45]

Key informants and clinical experts noted that early engagement with patients is crucial. This may be easier with some patient populations than others. One participant noted that the success of palliative care in the field of oncology is partially due to the nature of the disease. When a patient is diagnosed with cancer, they know they are sick and are typically committed to a care plan. Patients with other chronic diseases such as diabetes and heart disease were characterized in discussion as potentially less engaged which can have a negative impact on the effectiveness of palliative care.

It is worth noting that until the workforce is adequate to address need, patient education may promote awareness but may not increase access.

Legislation Aimed at Improving the Palliative Care Landscape

Recently policy makers at the state and federal level have proposed strategy and legislation intended to address a number of barriers to widespread use of palliative care. Examples include but are not limited to:

- On the federal level, representatives recently introduced a bill on July 21, 2016 titled The Palliative Care and Hospice Education and Training Act (PCHETA/HR 3119) which is intended to strengthen support for palliative care. The bill calls for increased investment in health care workforce education efforts, additional backing for public awareness, and for assistance from the National Institutes of Health to expand the existing evidence base for improving QoL.[43] This is promising as many of the stakeholders interviewed highlighted the importance of continued support from government agencies in order to foster growth and development of new programs and research initiatives through grants and other funding mechanisms in order to create opportunities for future research.

- In Massachusetts, state level palliative care legislation was also recently enacted. Chapter 478 an Act to Improve Quality of Life by Expanding Access to Palliative Care authorized creation of a task force, chaired by Dr. Lachlan Forrow, to help advise the Commonwealth's strategic initiatives for improving palliative care access. More information can be found at: https://malegislature.gov/Laws/SessionLaws/Acts/2014/Chapter478

- In 2013 Rhode Island enacted House Bill 5204 An Act Relating to Health and Safety-State Palliative Care and Quality of Life Act intended to improve public awareness of and access to palliative care. The legislation calls for an Advisory Council led Palliative Care needs assessment in Rhode Island and the creation of a Palliative Care Consumer and Professional Information Education Program. The long range goal of this legislation include requiring Palliative Care Access in Rhode Island Health Facilities, the creation of a system for identifying those who could benefit from palliative care, and promoting awareness of and appropriate access to palliative care services for those with serious illness.[46] This legislation was cited by stakeholders interviewed as the first of its kind in the nation. More information can be found at: http://webserver.rilin.state.ri.us/BillText13/HouseText13/H5204aa.htm

- Additionally, a multi stakeholder collaborative spearheaded by the American Cancer Society and its advocacy affiliate, the American Cancer Society Cancer Action Network (ACS CAN) launched a palliative care campaign that includes efforts aimed at increasing research grant support, improving availability of information, promotion and support of outreach efforts, and implementing palliative care legislation. The overall emphasis of this campaign is to treat an individual beyond the disease; the initiative outlines three main objectives:[47]
    - Increase palliative care awareness, education, and research emphasis;
    - Boost workforce capacity, clinical communication skills, and palliative care training support; and
    - Pursue integration of palliative care services and quality standards in all care settings and associated payment reform promoting interdisciplinary care.

Summary

Throughout our interviews with stakeholders and review of the evolution of palliative care, there seemed to be an awareness that with continued investment in potential opportunities, including the expansion of palliative care in the outpatient setting, it may be possible to overcome the barriers identified and advance access to palliative care.

There are a number of institutions that have invested in palliative care. In the following section, we highlight existing approaches to palliative care in the outpatient setting.

2.4 Existing Approaches to Palliative Care Outside of the Hospital Setting

There are a number of ways in which palliative care programs function in the outpatient setting. The evidence review in Section 4 explores the comparative effectiveness of different models of outpatient palliative care and seeks to identify the key program components that correspond to improved patient outcomes. In this section we aim to describe several existing programs to provide context for how palliative care is organized and coordinated through health systems. Several programs provide examples and context for how palliative care is organized and coordinated through health systems. We found that most outpatient programs are operated by hospital systems. However, some models involve an integrated approach through an accountable care organization (ACO) framework. The following content comes from publically available websites, links to specific sites are included at the end of each description.

Hospital System Managed Models

The Palliative Care Program, Dartmouth Hitchcock

http://www.dartmouth-hitchcock.org/palliative_care/about_us.html

Dartmouth Hitchcock Medical Center (DHMC) offers both inpatient and outpatient palliative care services to patients in the hospital or being treated for serious illnesses in clinics. When needed, the staff works with hospice team in the patient's community to ensure an easy transition from the hospital to care at home or at an assisted living facility. The goal of the program is to improve quality of life for patients and families of patients with serious illness and complex needs.

- ***Staff:*** The Palliative Care Program involves care by a variety of providers. Physicians, nurse practitioners, and registered nurses manage the physical and emotional symptoms of serious illness. Social workers provide guidance and coordinate care, while other providers, including healing arts practitioners, spiritual care coordinators, and community volunteers provide additional supportive services.

- ***Outpatient specific services:*** DHMC runs an outpatient palliative care clinic where patients can receive evaluations and interim care through regular check-ups by the palliative care team. When possible, appointments are scheduled in coordination with other medical visits to avoid repeat trips to the medical center. Home health services are available in conjunction with the VNA and Hospice of Vermont and New Hampshire. DHMC has 24/7 on call service, family education services, and bereavement support.

Results from an RCT carried out in this setting are described later in this report, in in Section 4.[8]

Palliative Care Program, MGH

http://www.massgeneral.org/palliativecare/about/

Palliative care services at Massachusetts General Hospital (MGH) are offered to any patients diagnosed with a life-limiting or chronic conditions at various states of illness. Services focus on pain and symptom management, as well as on supporting patients and families in defining goals of care and related treatment choices. As much as possible, palliative services are coordinated with other specialists providing the patient's medical care. MGH offers inpatient care, outpatient clinic, home visits for nearby patients, and refers to hospice care when needed.

- ***Staff:*** MGH's palliative care division includes 16 physicians, eight nurse practitioners, fellows, clinical social workers, and a triage nurse.

- ***Outpatient Specific Services:*** Services provided in the outpatient setting typically focus on management of pain and symptoms, individual or family counseling, advance care planning, and arrangement of care through community resources.

Results from an RCT evaluating early outpatient palliative care to patients newly diagnosed with non-small cell lung cancer (NSCLC) in this setting are described in Section 4.[14,19]

Hoag Memorial Hospital Presbyterian CARES/Palliative Care Program, Tustin, CA

http://www.hoag.org/Specialties-Services/Other-Programs-Services/Palliative-Care/Services.aspx

The CARES team palliative care program at Hoag Memorial Hospital offers both inpatient and outpatient palliative care services to any patient with chronic and progressive illness, including cancer, advanced heart or lung disease, kidney or liver disease, and dementia.

- ***Staff:*** The CARES team includes a clinical nurse specialist, licensed clinical social worker, a palliative care certified physician, and a family medicine physician.
- ***Outpatient Specific Services:*** The CARES team outpatient services including complex pain and symptom management; outpatient clinic visits; supportive counseling; coordination of care with community resources; emotional and spiritual support; and advance care planning.

ACO Managed Models

Kaiser Permanente

http://www.growthhouse.org/palliative/

Kaiser Permanente is an integrated managed care consortium, based in Oakland, California. Kaiser Permanente offers palliative care services in several states, including California, Colorado, Georgia, and Hawaii. The information below is based on a publicly available toolkit outlining the Kaiser Permanente TriCentral Service Palliative Care Program (TCPC) in Downey, CA. TCPC offers both inpatient and outpatient services.

- ***Staff:*** TCPC uses a team-based approach. The team typically includes a physician, registered nurse skilled in management of pain and symptoms, and a social worker (licensed clinical social worker or Master's level social worker).[48] Additional providers may be added to the team based on each patient's unique needs. These may include home health aids, a chaplain, physical therapists, and other practitioners.

- ***Outpatient services:*** Under the outpatient palliative care program, patients are able to receive home visits by all members of their care team for medical services, psychosocial support, and education. Care management services are offered to make sure all of the patient's needs are met, and telephone support or after-hours visits are available 24/7 for added support when needed. Patients and families are encouraged to engage in advanced care planning discussions.

- ***Financing:*** The program receives fixed monthly reimbursements from Kaiser Permanente for each enrollee. This reimbursement is a capitated rate intended to cover all inpatient and outpatient services.[48]

Commonwealth Care Alliance (CCA)

http://www.commonwealthcarealliance.org/model-of-care

CCA is a Massachusetts-based non-profit, fully integrated, prepaid health care delivery system. CCA serves Medicare and dual eligible seniors through its Senior Care Options plan, and individuals with disabilities through its Disability Care Program. There are more than 5,500 members enrolled in CCA, the majority of whom are eligible for nursing-home placement. Stakeholders emphasized the complexity of the patient population; all patients have at least 2 chronic conditions.

- ***Staff:*** Several care delivery programs at CCA rely on a multi-disciplinary care teams managed by nurse practitioners (NP). In addition to the NP, the team includes social workers, behavioral health providers, community health workers, and other specialists.

- ***Outpatient Services:*** CCA runs a statewide program that provides care in the home and community settings utilizing a consultative model.[49] In this model, CCA initiates care with a formal palliative care consultation after which care is typically managed by a registered nurse, nurse practitioner, or physician assistant case managers.

- ***Financing:*** CCA has risk-adjusted capitated contracts with Massachusetts Medicaid and CMS.[50] It also has a contract with Neighborhood Health Plan to provide services through its Disability Care Program.

3. Summary of Coverage Policies

While many payers, both public and private, have coverage policies specific to hospice care, few offer publicly available policies specific to palliative care services offered in tandem with curative care. Medicare covers many services essential to provision of palliative care under parts A and B but does not have an explicit palliative care benefit. Similarly, New England state Medicaid programs do not have publicly available documentation outlining services covered as palliative care. Some private insurers offer programs that support the use of palliative care services.

Since payer policies are continually evolving and information is not always publicly available, this section is not intended to be a complete picture of private and public payer efforts related to palliative care.

While specific coverage policies vary by payer, the Center to Advance Palliative Care (CAPC) highlights a number of variables that affect the proportion of costs that are billable to an insurer. These variables include:

- The quality of the documentation provided by clinicians, and the quality of the billing process
- The mix of providers on the team
- Contracts with payers
- Amount of time the team spends on direct patient care as opposed to other activities that are related to patient care but may not be billable

CAPC offers tools and documents to assist palliative care teams in improving billing practices. Their resources fall into several key areas of consideration, including:

- Utilizing clinicians who are credentialed in HPM
- Strategies to increase consistency and efficiency of documentation
- Review of options for billing based on the complexity of services instead of billing for time
- Billing extended time codes
- Priorities for billing reports
- Using data to improve team performance

Medicare

A white paper authored by the Home Care and Hospice Financial Managers Association and the National Association for Home Care and Hospice summarizes Medicare billing rules for palliative care services. The white paper is available in full here, and is briefly summarized below.

Medicare does not have a designated palliative care benefit but covers many services related to palliative care under Parts A and B. Under Part A, many home health agencies that provide palliative care can bill for services such as nursing, social work, and spiritual care. Home health services are

covered under the Medicare Home Health Prospective Payment system. Certified Medicare Home Health Agencies may enter into contracts with hospice providers to purchase pain control services from the provider for patients who have been diagnosed with a terminal illness but have opted to continue curative treatments, making them ineligible for the Medicare hospice benefit.

Many services related to palliative care are also covered under Medicare Part B. Physicians use a Hospice palliative care code when billing for palliative care services. The code does not provide increased reimbursement rates, but does provide information for collection of data. Under part B, physicians, nurse practitioners, and licensed clinical social workers are able to bill for services. In many cases, the patient is responsible for a 20% coinsurance.

Medicaid

Of the six New England states, none offer publicly available coverage policies specific to palliative care. This does not mean that services related to the provision of palliative care are not covered, but they are not explicitly classified as palliative care services in any publicly available coverage policies.

Private Insurers

As with public payers, while many private insurers have coverage policies directly related to the provision of hospice benefits, few insurers have publicly available coverage policies specific to palliative care. Many services related to palliative care may be covered but are not explicitly identified as palliative care services. Some insurers also offer case management and chronic care programs that may share some overlap with palliative care services, but are not classified as such. Two examples of these programs are described briefly below:

Aetna Compassionate Care Program

https://www.aetna.com/individuals-families/member-rights-resources/compassionate-care-program/compassionate-care-description.html

The Aetna Compassionate Care Program offers supportive services for patients with a serious illness as well as for their family members. Nurse case managers skilled in discussing the physical, emotional, spiritual, and cultural needs of patients facing serious illness are available to speak to patients and families by phone. These case managers can help address issues with coverage, connect patients to appropriate resources, assist doctors and caregivers in managing pain or symptoms, aid in coordination among providers, and help with advance care planning.

Blue Cross Blue Shield of Massachusetts

Blue Cross Blue Shield of Massachusetts' Complete Care for Advanced Illness program was launched in January 2016 with the goal of improving quality of life for individuals with advanced illness. Under this program, BCBSMA will reimburse both medical providers as well as behavioral health providers for having conversations with patients about planning for advanced illness and end of life care. This program will also provide more education and training support to help patients, families, and clinicians manage a progressive illness. BCBSMA will also extend this program to help patients with advanced illness receive high-quality palliative care in their homes.

Read BCBSMA's recent press release on this program here.
https://www.bluecrossma.com/visitor/newsroom/press-releases/2015/2015-12-28.html

4. Comparative Clinical Effectiveness

4.1 Overview

Our review of published evidence examines higher-quality comparative studies of palliative care interventions delivered outside the hospital. Interventions of interest were those implemented in outpatient or home-based settings that incorporate elements directed at both physical and psychosocial patient care, as both are considered essential and definitional components of palliative interventions.[5,6] We recognize that such studies vary substantially in terms of their entry criteria and description of the interventions. In order to inform our analysis of the comparative clinical effectiveness of outpatient palliative care, we defined several characteristics of the interventions as of *a priori* interest:

- the **timing of the intervention** (whether it was specified as early [at or around time of diagnosis] or not);
- the **target population** of the intervention (patients with cancer only or patients with mixed diagnoses, given the concern that patients with diagnoses other than cancer receive palliative care substantially later in their disease trajectory than do patients with cancer, due to the lesser use of this intervention outside of oncology, as well as the waxing and waning of non-cancer diseases which results in a less predictable prognosis); and
- the **type of service** provided in the palliative care intervention (i.e., the level of training of care providers specialized [with input from a care provider described as having a palliative care specialty or certification] or generalist [without reference to a specialty or certification]).

A potential hurdle to drawing conclusions across studies is variability in the design of the outpatient palliative care interventions. As such, we investigated the potential contrast in outcomes between studies in which the intervention was described as being delivered by a care team incorporating individuals with higher specialist training or one made up of individuals with clinical experience in delivering palliative or end-of-life care and/or some level of in-service training, but not described as certified in palliative care medicine.[6]

We recognized that the evidence base might lack detailed descriptions of the interventions, including the type of training the palliative care providers received. Additionally, the HPM certification (as described in Section 2 on page X) was not available until 2008. Despite these limitations, we tried to determine if outcomes may have been influenced by the type of service (i.e., “specialist” vs. “generalist”) patients received in the palliative care intervention groups.

The comparator treatment of interest was usual care (also referred to variously in the literature as standard care), which was typically defined with very little detail beyond that it incorporated

standard access to clinical services provided at the study site. Our review focused on specific clinical benefits reported in terms of patient QoL, mood, symptom burden, patient satisfaction, health care resource utilization (HRU), psychosocial outcomes, caregiver impact, and survival, as an outcome that might indirectly result from other intervention outcomes.

4.2 Methods

Data Sources and Searches

Procedures for the systematic literature review assessing the evidence available for outpatient palliative care interventions followed established best methods used in systematic review research.[51] We conducted the review in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[52] Our search was conducted among MEDLINE-, CINAHL-, PsychInfo-, and Cochrane-indexed articles, and the timeframe for our search spanned the period from January 2000 through November 2015. We limited each search to studies of human subjects, and excluded articles indexed as guidelines, letters, editorials, narrative reviews, case reports, conference abstracts, or news items. To supplement the above searches and ensure optimal and complete literature retrieval, we performed a manual check of the references of recent relevant reviews and meta-analyses. Further details on the search strategy are available in Appendix 4. Our search was limited to studies conducted in U.S. and Canadian settings, we felt that differences in the use of palliative care and health-system interactions in other developed countries would limit generalizability to the U.S. system.

Study Selection

We screened the studies identified through our searches, first examining the titles and abstracts for clear exclusion criteria, and subsequently screening the full text of the remaining publications for both presence of inclusion criteria and absence of exclusion criteria. Trained investigators conducted screening according to defined inclusion and exclusion criteria, with any questions regarding their application being resolved in discussion with a second or third investigator. We did not exclude any study at abstract level screening due to insufficient information. For example, an abstract that did not describe reporting any outcome of interest was accepted for further review in full text if no exclusion criteria were present. We retrieved the citations that were accepted during abstract-level screening for full text appraisal. Two investigators reviewed full papers, and provided justification for exclusion of each excluded study. Inclusion and exclusion criteria are described below:

Inclusion Criteria:

- Any palliative care intervention outside hospital in outpatient, home or community setting, in conjunction with active treatment or not

- RCT or high quality observational studies (case-control or cohort studies)
- Adult population 18 years or older with serious or life-threatening illnesses
- Conducted in the US or Canada

Exclusion Criteria:

- Studies outside of the US or Canada
- Studies conducted in children or mixed population
- Studies conducted in a population residing in a hospital, nursing facility, or hospice.
- Evaluates a drug or procedure trial that is not part of a larger palliative care intervention
- Study design has no comparison group (usual care as control)
- Absence of at least one of the following outcomes of interest:
    - Survival or mortality, including location of death
    - Health resource utilization
    - Symptom severity, including pain, breathlessness, fatigue, and nausea
    - Patient, caregiver, and/or family psychological distress (e.g., stress, anxiety, depression)
    - Ratings of patient, caregiver, family, and provider satisfaction
    - Health-related QoL
    - Economic outcomes, including program start-up costs, costs per patient, potential cost offsets, and measures of cost-effectiveness

Data Abstraction and Quality Assessment

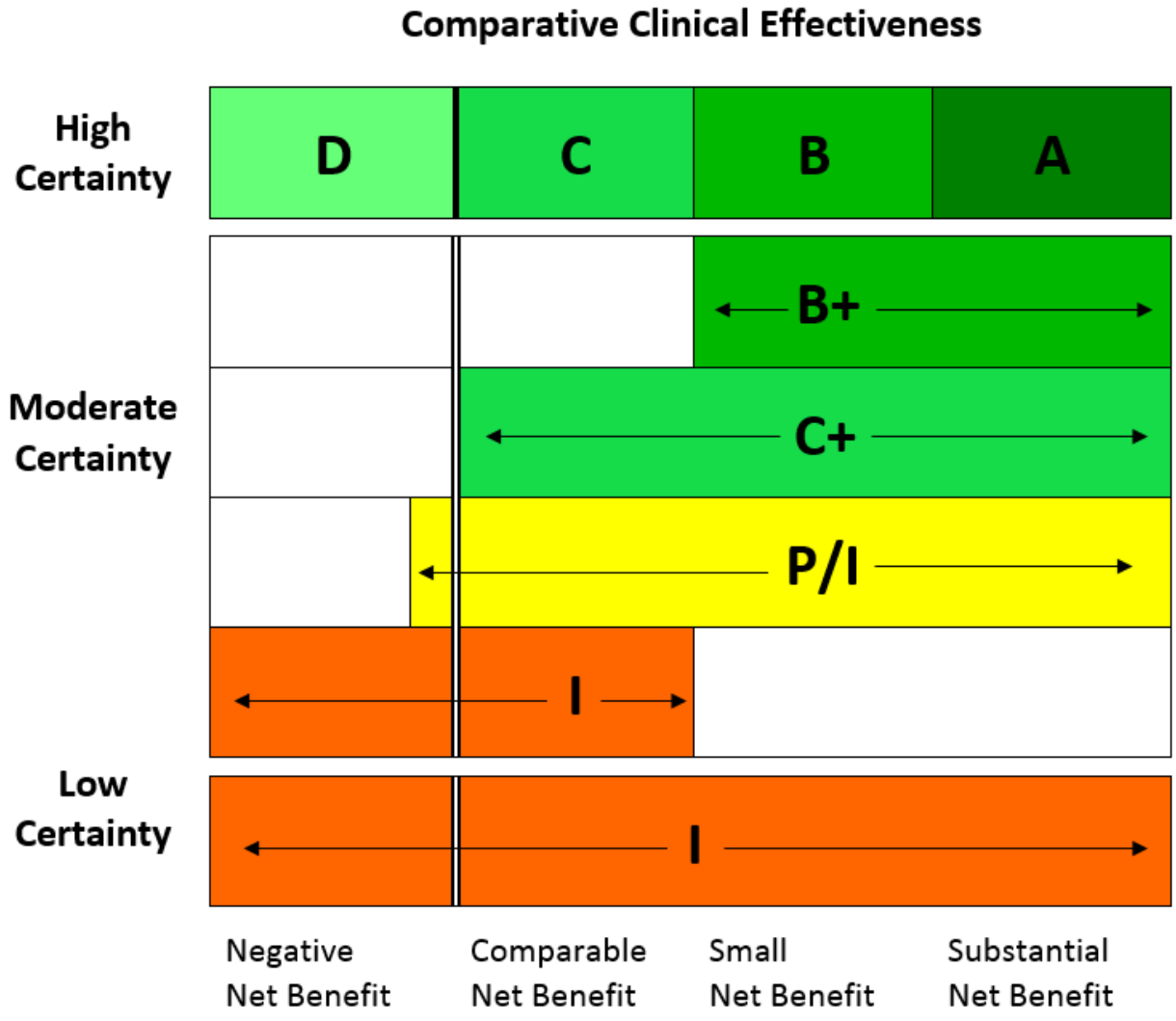
Summary tables capture evidence abstracted from the reviewed studies are available in Appendix 8. We abstracted outcome data for each treatment group, and criteria modified slightly from those published by the US Preventive Services Task Force (USPSTF) to assess the quality of RCTs and comparative cohort studies, using the categories "good," "fair," or "poor."[53] When randomized controlled trials used a modified intent-to-treat (mITT) analysis design in which the intervention group is defined those receiving a specified minimum amount of the intended intervention, we categorized those studies as of "fair" quality, rather than of "poor" quality on the basis of not utilizing a strict ITT analysis.

Assessment of Level of Certainty in Evidence (ICER EBM Matrix)

We used the ICER Evidence Rating Matrix (see Figure 3) to evaluate the evidence for a variety of outcomes. The evidence rating reflects a joint judgment of two critical components:

a) The **magnitude** of the difference between a therapeutic agent and its comparator in "net health benefit" – the balance between clinical benefits and risks and/or adverse effects AND
b) The level of **certainty** in the best point estimate of net health benefit.[54]

Figure 3. ICER Evidence Rating Matrix



A = "Superior" **-** High certainty of a substantial (moderate-large) net health benefit
B = "Incremental" **-** High certainty of a small net health benefit
C = "Comparable"- High certainty of a comparable net health benefit
D="Negative"- High certainty of an inferior net health benefit
B+="Incremental or Better" **–** Moderate certainty of a small net health benefit, with high certainty of at least incremental net health benefit
C+="Comparable or Better" **-** Moderate certainty of a comparable net health benefit, with high certainty of at least comparable net health benefit
P/I = "Promising but Inconclusive" - Moderate certainty of a small or substantial net health benefit, small (but nonzero) likelihood of a negative net health benefit
I = "Insufficient" **–** Either moderate certainty that the best point estimate of comparative net health benefit is comparable or inferior; or any situation in which the level of certainty in the evidence is low

4.3 Results

Study Selection and Patient Population

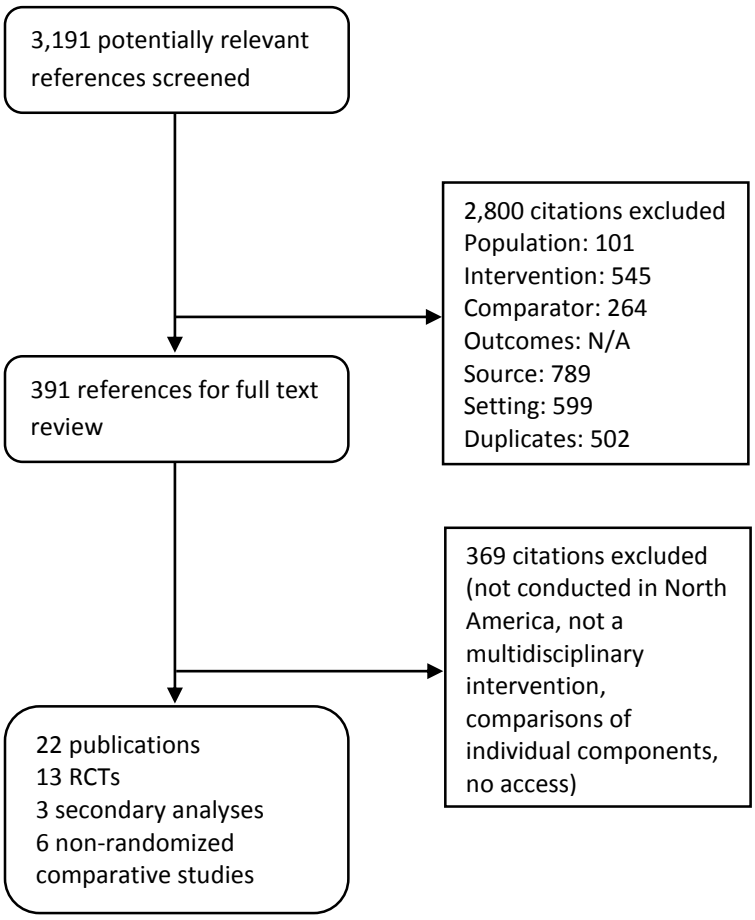
The literature search for comparative studies of outpatient palliative care identified 3,191 potentially relevant references (see Figure 4 on the following page), of which 16[8-23] publications (describing 13 studies) met our inclusion criteria and focus on good- or fair-quality evidence. An additional six publications describing six studies of poor quality were also identified, but are not described below.

We abstracted evidence from all studies included in this review; details around the populations, interventions, and outcomes are summarized in Appendix 8.

Assessment of Publication Bias

Scanning of the clinicaltrials.gov site to identify additional studies completed more than two years ago that would have met our inclusion criteria but have not been published revealed only one study that was completed in 2009 (NCT00648609). In this small comparative study (n=23), the investigators randomly assigned COPD patients 60 years or older to home-based self-management services provided by an interdisciplinary palliative care team or usual care. During the one-year follow-up period, health service utilization, symptom scores, and patient QoL were evaluated; no results were provided.

Figure 4. PRISMA Diagram



Overall Evidence Quality

As noted earlier, we used modified criteria from USPSTF to rate the quality of the comparative studies. Based on these criteria, we considered six studies (three RCTs and 3 cohort studies) to be of good quality, with study arms comparable at baseline, valid instruments to evaluate outcomes, and limited differential attrition occurring during the outcomes assessment.[8,11,18-20,23]

Also using these criteria, seven studies (5 RCTs and 2 cohort studies) were categorized as of fair quality,[9,10,15-17,21,22] most often on the basis of the use of a modified rather than full intent-to-treat analysis of randomized treatment arms. We also abstracted data from five studies deemed to be of poor quality[55-59] but do not describe them in detail in this review. We have included mention of these studies only when important for additional context around our findings. Studies were categorized as poor quality primarily because of substantial attrition without adjustment of data, or due to substantial and unaccounted for differences in the proportion of patients lost to follow-up in each treatment arm.

The overall dearth of RCTs and higher quality comparative studies in this area is perhaps unsurprising, as it is very difficult to implement a well-designed comparative study given ethical concerns and challenges with standardizing outpatient palliative care regimens across health care systems. Most studies described as fair compared patient groups with disparate demographic or clinical characteristics. Those described as poor did not present enough information to make this determination or did not sufficiently attempt to control for variables potentially confounding the relationship of the interventions to outcomes (in some cases reporting imbalances in factors such as disease mix or age of patients or home caregivers at baseline, and in some cases not reporting such baseline characteristics of comparison groups at all).

Interventions

Among the 13 studies identified were a variety of interventions. As described in the methods, we recognized that such studies vary substantially in terms of interventions, and we defined several characteristics of the interventions as of *a priori* interest: intervention timing (early or not early); target population (cancer or mixed diagnoses); and type of service (specialty or generalist).

Specialist-led interventions were described by 10 publications,[8-20] while generalist interventions were described by three. [21-23] Four studies[8,9,19,20] evaluated outpatient palliative care's effect on patients with cancer; while nine studies[10,11,15-18,21-23] did so in populations of patients with mixed diagnoses. Five studies[8,9,19,20,22] evaluated the effect of interventions described as early while eight studies[10,11,15-18,21,23] did so in populations of patients with mixed diagnoses.

Key Studies

Earlier sections of this report describe several model programs for delivery of outpatient palliative care. Below we describe several of the key studies arising out of those programs.

Bakitas 2009[8]

This RCT was performed at Dartmouth-Hitchcock Medical Center, whose palliative care services are described earlier in this report (Section 2.4, Existing Approaches to Palliative Care). This publication describes the implementation of the ENABLE II program, a specialized telehealth palliative care program designed to provide care to patients with advanced cancer living in rural areas; the outpatient palliative care intervention is based on a case management, educational approach, with four educational sessions conducted by an advanced practice nurse (APN) with specialty training in palliative care; patients also received at least monthly follow up by telephone until death or study end. This publication described results from an RCT designed to evaluate the effect of this intervention on QoL, symptoms, mood, and resource utilization. Investigators randomized 322 patients enrolled from 2003 to 2008 to either the intervention (n=161) or to usual care (n=161). As with many reports, usual care was not carefully defined; in this case, authors cite simply that patients in the control arm were allowed unrestricted use of all oncology and supportive services at

the study sites, the Norris Cotton Cancer Center/Dartmouth College and the Veterans Administration Medical Center, White River Junction, VT. Follow-up continued until death or study completion.

Temel 2010[19]

This RCT was performed at Massachusetts General Hospital, whose palliative care services are described earlier in this report (Section 2.4, Existing Approaches to Palliative Care); the RCT evaluates the impact of a specialized outpatient palliative care program on patients newly diagnosed with non-small-cell lung cancer (NSCLC). Patients randomly assigned to the intervention met with either a board-certified palliative care physician or APN within three weeks of enrollment. Meetings continued at least monthly thereafter until death, with additional visits scheduled at the discretion of the patient or provider. Investigators randomized 151 ambulatory patients with metastatic non-small-cell lung cancer (NSCLC) to the above-described intervention (n=77) or to routine oncologic care (n=71) within eight weeks of diagnosis; routine oncologic care was not further described. Outcomes evaluated included QoL (measured using the FACT-L) and mood (evaluated using the Hospital Anxiety and Depression Scale [HADS]) at 12 weeks, as well as end of life care as documented in electronic medical records.

Brumley, 2007[10]

This RCT was performed in the setting of the Kaiser Permanente home-based palliative care programs. In this RCT, investigators randomized homebound terminally ill patients to the palliative care program (n=145), or to usual care, for which no additional description was provided. (n=152). The specialized in-home palliative care plus usual care intervention was delivered to patients with mixed diagnoses by an interdisciplinary team of a palliative care physician who coordinated care from a variety of health care providers, including specialists and the patients' primary care physician; the focus was on comfort as well as patient QoL, through providing pain and symptom relief. The control arm received usual care, described only as "standard care to meet the needs of the patients following Medicare guidelines for home health care criteria". The population had primary diagnoses of cancer (47%), CHF (33%), and COPD (21%). The comparison groups were well-balanced at baseline, with the exception of measurement of patient satisfaction.

Rabow 2004[15]

This RCT evaluates the effect of providing an outpatient palliative care intervention based on a case management approach integrating care provided by family caregivers and primary physicians with specialist provided palliative and active care for patients with mixed diagnoses. The intervention aimed to improve advance care planning, reduce health care utilization, and support caregivers, through resources provided by a multidisciplinary team. In this publication, investigators evaluated the effect of this intervention on resource utilization and QoL; the authors randomized 90 patients with either cancer, advanced COPD or advanced CHF with a life expectancy between 1 to 5 years to either outpatient palliative care or usual care, for which no additional description was provided. The comparison groups were similar at baseline.

Seow 2014[18]

This comparative cohort study was carried out in Ontario, Canada, where several independently developed community-based, specialist palliative care teams operate; these teams serve patients with mixed diagnoses from different catchment areas, but have the same core team members and are within the same health financing system. In this study, 3,109 patients receiving specialist palliative care were matched by propensity score to 3,109 patients receiving usual care. The relative risk of a hospital or ED visit in the last two weeks of life for a patient receiving outpatient palliative care compared to usual care was 0.68 (95% CI 0.61-0.76), and that for an ED visit was 0.77 (95% CI 0.69-0.86). Fewer patients receiving outpatient palliative care died in the hospital (16.2%) compared to those receiving usual care (28.6%), yielding a relative risk of 0.46 (95% CI 0.40-0.52).

Strength of Evidence

In an effort to define potentially contrasting characteristics of the outpatient palliative care interventions described in the available literature, we noted that there were interventions which could be classified as "specialist" or "generalist" levels of palliative care. These were defined according to the education level and training of palliative care providers as described in a prior systematic review by the Cochrane Collaboration.[6]

Below we present a summary evidence table capturing the strength of evidence around the relative effect of outpatient palliative care compared to usual care for several key outcomes of interest, with evidence around the more granular aspect of the intervention type (specialist vs. generalist).

Table 2. Strength of Evidence

Outcome	Specialized care	Generalist care	Overall
QoL	6 studies	1 study	
Resource Use	8 studies	2 studies	
Survival	3 studies	1 study	
Symptom Burden	6 studies	1 study	
Patient Satisfaction	3 studies	1 study	
Psychosocial	1 study	2 studies	
Mood	4 studies	3 studies	
Caregiver outcomes	1 study	0 studies	

Moderate
Low
No evidence

Importantly, for no outcome did we determine that the strength of evidence was high. Moderate strength of evidence is suggested by a general trend toward statistically significant results among three or more studies, or consistent findings of benefit in two studies. Low strength of evidence is suggested by a mixed evidence base in which statistically significant benefit is observed only inconsistently, with no observed reduction in favorable outcomes related to the intervention, or if only one available study reports a statistically significant benefit. No evidence is suggested where there are either no studies evaluating the effect of a particular type of intervention on the outcome of interest, or where there is no evidence of statistically significant benefit.

While we found no strong evidence of specialist-led outpatient palliative care's benefit on any of the outcomes evaluated, we did find moderate evidence for such benefit on QoL, resource utilization, and patient satisfaction outcomes. Weaker evidence (low level) also suggests a benefit on symptom burden and mood. No evidence for benefit on psychosocial outcomes was noted in the one study of a specialist intervention evaluating this outcome, and no studies evaluated caregiver outcomes associated with a specialist palliative care intervention. Findings for those four studies evaluating generalist palliative care were mixed, likely due to the constrained evidence base.

Overall, the evidence describing outpatient palliative care's benefit is strongest for resource utilization outcomes, with weaker evidence also suggesting a benefit on QoL, symptom burden, patient satisfaction, psychosocial, mood, and caregiver outcomes. These observations are consistent with the fact that outpatient palliative care programs are designed to increase patient social support, patient self-advocacy, and coordinated medical care; while not focused on improved survival as an indicator of effectiveness, the survival benefit may be mediated by the other more directly influenced outcomes of interest (e.g., mood, QoL).

Results for specific outcomes can be found in the sections that follow.

QoL

We identified three studies[8,19,20] of good quality and four studies[9,15,16,22] of fair quality that reported on patient QoL. The evidence base suggests that palliative care either improved patient QoL or had comparable effects relative to usual care. Of note, no clinically important differences were identified for any of the QoL instruments used in the studies, nor were any responder analyses undertaken in the literature reviewed

Four[8,19,20,22] of the seven studies that evaluated palliative care interventions, all of which were conducted in cancer patients only, showed positive results for QoL outcomes. In the previously-described ENABLE II study, QoL on the FACIT-Pal instrument was statistically-significantly improved at 13 months of follow-up in the early palliative care (initiated within 8-12 weeks after diagnosis) group (mean difference, 4.6; p=0.02).[8] QoL was also improved in Temel's study of early palliative care (initiated within 8 weeks after diagnosis) as measured by the Functional Assessment of Cancer

Therapy- Lung (FACT-L) at 12 weeks (98.0 vs. 91.5 for usual care; p=0.03).[19] Zimmermann evaluated early initiation of a palliative care consultation and follow-up in an oncology clinic provided by a palliative care physician and nurse in 461 patients with an estimated survival of 6-24 months. At four months, the overall QoL measured by FACIT-Sp(a combination of FACT-General and Sp-12 spiritual well-being) had a greater increase in the intervention group vs. usual care(adjusted mean difference, 4.34; 95% CI, 0.70 to 7.98; p=0.02).[20] Finally, Rummans et al. evaluated the feasibility and effectiveness of a four-week, structured, multidisciplinary intervention with a physical therapy component targeted to maintain the overall QoL in 103 patients with advanced cancer undergoing radiation therapy.[22] At week four, the Spitzer QoL Uniscale in the intervention group increased by three points from baseline, compared to a nine-point decline in the control group (p=0.009); however, these differences did not persist at week eight or 27.

In contrast to the studies above, our review identified three studies[9,15,16] suggesting that outpatient palliative care's effects on QoL were comparable to usual-care approaches (i.e., both groups saw similar improvements in QoL); these comparable results may be explained by lower statistical power in these studies given small sample sizes (n<100 in 2 studies), shorter durations of follow-up (3 months in ENABLE III vs. 13 months in ENABLE II), or the use of an instrument that may not be generalizable to patients in patients with mixed diagnoses.

Target Population, Timing, and Type of Service

Both study population and timing of palliative care may be drivers of the heterogeneous findings on QoL. In general, the effect of palliative care on QoL was more often evaluated in cancer patients than other patient populations (5 cancer-only studies vs. 2 studies in mixed populations). Timing of care was directly addressed in one study[9] that compared early versus delayed palliative care, while three compared early palliative care to usual care and the other three did not specify the timing. It's difficult to separate the role of the temporal delivery of the intervention from the target of the intervention because all four early studies were conducted in cancer patients.

Early palliative care in cancer patients consistently yielded positive results compared to usual care. Specifically, palliative care for cancer patients yielded statistically significantly beneficial QoL effects (4 out of 5 studies), including all three studies that compared early interventions to usual care. However, early care showed no advantage over delayed care in cancer patients when compared directly in one RCT of early palliative care vs. a three-month delay in palliative care initiation, either before the delayed group started the intervention or during the one-year follow-up. The other two studies in mixed populations both reported non-significant results.

The evidence did not show any effect modification by type of service (i.e. specialized versus generalist); however, this observation is not conclusive due to the limited number of generalist care studies.

Mood Outcomes

We identified a total of seven studies evaluating mood outcomes, including anxiety and depression: two good quality[8,19] and four fair quality[9,15,16,22] RCTs, as well as one fair quality cohort study[21]. Of these seven studies, four[8,15,19,22] found statistically significant results in favor of the intervention, though not all studies evaluated both outcomes.

Only two[8,19] (33%) of the six studies evaluating depression showed statistically-significant improvements from palliative care interventions. Both Bakitas trials[8,9] evaluated depression on the CES-D measurement tool but only one[8] had a statistically significant finding in favor of the intervention based on a mixed model analyses for repeated measures (TE= -1.8, p=0.02). A longer duration of follow-up in the earlier study (12 months vs. 3 months in the 2015 study) may have influenced this outcome. However, in the Temel RCT,[19] statistically significant findings were in favor of an early palliative care intervention based on the proportion of patients with elevated depression scores on the HADS-D (16% vs. 38% for usual care, p=0.01) and with symptoms of major depression on the PHQ-9 (4% vs. 17% for usual care, p=0.04) after only three months of follow-up.

For studies evaluating anxiety, only two[15,22] (40%) out of five studies found statistically significant between-group differences for anxiety in favor of the intervention. The Rummans RCT[22] found a statistically-significant difference on the POMS tension/anxiety subscale after one month (p=0.042), but the authors did not report the mean scores associated with this outcome. Rabow et al.[15] reported that anxiety was reduced in the intervention group but increased for those receiving usual care between six and 12 months of follow-up in an analysis controlling for anxiety at baseline and adjusting for group X time interaction (-1.5 vs. +0.4 for control, p=0.05).

<u>Target Population, Timing, and Type of Service</u>

Both of the studies indicating relative benefit of the intervention on depression were conducted in cancer patients,[8,19] while neither of the studies with mixed populations favored the intervention.[15,21] For anxiety outcomes, similar proportions of studies in cancer and mixed populations showed positive effects.

Of the seven studies we identified for mood outcomes, three RCTs[8,9,19] evaluated early palliative care in cancer patients of which two[8,19] found significant differences in favor of an earlier intervention for depression. The 2015 Bakitas study noted that half of the delayed group received the intervention sooner than prescribed by the study protocol, which may have minimized differences between groups. The only RCT[19] to evaluate early palliative care's impact on anxiety did not find any statistically significant differences in favor of the intervention.

Of the six studies measuring changes in depression scores, three[8,9,19] were considered specialist palliative care. Interestingly, two[8,19] of these studies found significant differences in favor of the

intervention while none of those considered to be generalist care were positive. In contrast, of those studies measuring anxiety, both of the positive studies[15,22] had a generalist palliative care intervention.

Symptom Burden

Most available studies found that palliative care had no impact on overall symptom burden compared to usual care, but some studies found beneficial effects on certain disease-specific symptoms and physical symptoms in general. The commonly-reported symptoms included pain, fatigue, drowsiness, nausea, anxiety, depression, appetite, dyspnea, and sleep quality, as measured by composite scores or frequency and intensity of specific symptoms. The same seven RCTs reporting QoL outcomes also reported on symptom burden, and four of seven found no statistically significant differences in any symptoms between groups. Possible explanations for lack of benefit in these studies included some symptom scales were not validated in populations receiving home-based palliative care in one study;[16] a relatively low symptom severity in both groups at baseline in two studies;[8,20] and measurement insensitivity as patients approach death, which was mentioned in one study.[9]

The other three studies, one of good quality[19] and two of fair quality,[15,22] showed reductions in some disease-specific symptoms and physical symptoms. Rummans and Cheville described the results from the same RCT that evaluated an interdisciplinary palliative intervention featuring physical therapy in 90 cancer patients undergoing radiation therapy.[12,22] The investigators found that physical symptoms, as measured by Linear Analog Scales of Assessment (LASA)-physical well-being scale, were reduced in the intervention group while increased in the control group at week four (-10.0 vs. +0.4, p=0.022). However, additional subscales measuring the severity of frequency of pain, fatigue, activity, and symptom distress showed no differences. Also in cancer patients, Temel's RCT found that the intervention group scored better at 12 weeks on the lung cancer subscale (LCS) of the FACT-L scale (21.0 vs. 19.3 for usual care, p=0.04), which evaluates seven symptoms specific to lung cancer.[19] Finally, in patients with cancer, advanced COPD, or advanced CHF, Rabow et al. reported that palliative care reduced dyspnea, as measured by the University of California, San Diego Shortness of Breath Questionnaire.[15] After controlling for dyspnea at baseline, patients in the control group reported a significantly higher rate of dyspnea than the intervention group (OR=6.07, 95% CI, 1.04 to 35.56), as well as significantly higher degree of interference from dyspnea on daily activities (25.4 vs. 40.6 for controls, p=0.01) at 12 months.

<u>Target Population, Timing, and Type of Service</u>

As with QoL, we found no clear evidence of heterogeneity associated with the study population or timing of care for symptom burden outcomes. Results associated with symptom burden were similar in cancer-only studies and studies with mixed populations: two of five cancer-only studies and one of two studies with mixed populations reported positive effects. There also was no clear

pattern in terms of timing of care: two of three studies that did not specify timing reported positive effects while one of three studies that compared early palliative care to usual care in cancer patients showed a benefit. The one RCT comparing early versus delayed palliative care showed no statistically significant difference between groups.

In terms of type of service, both generalist interventions significantly improved symptoms compared to usual care, but only one of five specialist interventions had positive effects; this finding is not conclusive, however, due to the limited number of generalist care studies.

Patient Satisfaction

The available evidence consistently suggests that palliative care improves patient satisfaction relative to usual care. One good quality prospective cohort study[11] and three RCTs, including one good quality[20] and two fair quality,[10,15] reported on patient satisfaction; three of these studies found higher satisfaction or a greater increase in satisfaction in the intervention group compared to controls. Another RCT in patients with mixed diagnoses found no difference in satisfaction between groups, likely due to small sample size.[15]

In a two-year study, Brumley et al. prospectively compared 161 patients enrolled in a home-based palliative program for end-of-life care and 139 receiving usual care, with a life expectancy of less than one year.[11] Patient satisfaction was measured by the Reid-Gundlach Satisfaction with Services instrument. At 60 days, the satisfaction score of the intervention group was statistically significantly higher than baseline (t=-2.75, p=0.01) while the control group had no change (t=-0.5, p=0.6); statistical differences between groups were not evaluated, however. In a more recent RCT by the same authors, Brumley et al. evaluated the same intervention in 298 terminally ill patients using the Reid-Gundlach Satisfaction with Services instrument.[10] In this study, the authors defined the rate of satisfaction as the proportion of patients reporting being "very satisfied" (score of 37 or above), and found similar rates of satisfaction at baseline and increased rates in the intervention group at 30 days (OR=3.37 vs. controls; 95% CI, 1.42 to 8.10; p=0.006) and 90 days (OR=3.37 vs. controls; 95% CI, 0.65 to 4.96, p=0.03). Another study reported that patients receiving early palliative care had significantly greater satisfaction at four months as measured on the FAMCARE-P16 (+3.7 vs. -2.4 for control, p<0.0001); sensitivity analyses also revealed similar results.[20]

<u>Target Population, Timing, and Type of Service</u>

We found no evidence of heterogeneity according to study population, intervention timing, or delivery of care by specialized or generalist teams.

Survival

Our review identified four good quality studies evaluating the hypothesis that outpatient palliative care may affect patient survival, of which three were RCTs [8,10,19], and one a cohort study of patients with mixed diagnoses receiving generalist outpatient palliative care compared to a propensity score-matched cohort of patients receiving usual care.[23] The evidence base suggests that palliative care provided in the outpatient setting does not negatively affect patient survival,[8,10,23] and may in fact result in increased survival in populations with advanced cancer,[19] particularly when adjusting for potential confounders of the relationship between the intervention and survival (e.g. The Eastern Cooperative Oncology Group (ECOG) performance status score, or survival for less than one year).[8,19] The finding that early outpatient palliative care plus usual oncological care compared to usual oncological care alone conferred a significant survival advantage among patients with NSCLC was also noted in a study carried out in a population with mixed cancers which compared an early intervention to palliative care delayed by three months after diagnosis.[9,19]

Temel et al.[19] reported that median survival was significantly improved in the early outpatient palliative group compared to the usual care group (11.6 vs. 8.9 months, p=0.02). In an adjusted regression analysis, the investigators estimated the hazard ratio for death in the usual care group to be 1.70 (95% CI 1.14-2.54, p=0.01).[19] Another RCT, conducted by Bakitas et al., also reported a longer overall median survival in the intervention group but these results were not statistically significant.[8] As in the Temel paper, the authors present a Cox regression model adjusting for chemotherapy and site of care, which found a significantly reduced risk of death in the intervention group during the first year of follow-up during the first year of follow-up (HR=0.67; 95% CI, 0.50 to 0.91; p=0.009).[8] In another RCT conducted by the same investigators, in which outcomes among advanced cancer patients randomized to early outpatient palliative care were compared to those among such patients receiving the same intervention with a 3 month delay, there was a significant improvement in one-year survival rates in the early group compared to the delayed group (63% vs. 48%, respectively, p=0.04).[9] Two other studies identified in our review reported no association between outpatient palliative care and survival of patients with mixed diagnoses, one a retrospective comparative cohort study[23] examining survival at 30 days, and another an RCT incorporating Kaplan-Meier survival analysis.[10]

Target Population, Timing, and Type of Service

Both target population (cancer) and timing of palliative care (early) may be drivers of the heterogeneous findings on survival; however, these factors are inextricably linked in the limited evidence base describing survival, with both studies in cancer patients also describing their interventions as early.[8,19] Three of the four studies evaluating survival as an outcome of palliative care described specialist-led interventions, rendering it difficult to contrast the findings relative to this category.[8,10,19]

Resource Utilization

Among the 10 studies reviewed with resource utilization data, there was a generally observed benefit of outpatient palliative care on overall resource utilization, measured variously as an increase in hospice utilization or death at home, or a decrease in utilization of acute care services.[8,10,11,14-18,21,23] Benefits were noted more predominantly among cohort studies than among RCTs, possibly a result of such data being more often collected in such study designs.[14-16]

We analyzed the effect of outpatient palliative care on specific health resource utilization outcomes as outlined below: death at home/outside the hospital (evaluated as one category of outcome), emergency department (ED) visits, hospital visits, and hospice utilization. Among the nine studies providing appropriately powered results, seven reported a significant association of outpatient palliative care with at least one of these outcomes.[10,11,14,16-18,21,23] Two of these studies reported no such associations with either hospital or ED visits.[8,15]

Death at Home/Outside the Hospital

The available studies suggest that outpatient palliative care results in a larger proportion of patients dying at home, or a smaller proportion dying in the hospital. Three studies (two fair quality RCTs, one good quality cohort study) evaluated the impact of outpatient palliative care on the location of death.[10,14,18] While presented here as a resource utilization outcome, the concept of death at home is highly nuanced and incorporates elements of patient desire and satisfaction.

Brumley et al. reported the results of an RCT estimating that the proportion of patients who died at home over the period of follow-up was statistically-significantly greater in the outpatient palliative care group than in the control group after adjusting for age, survival time, and medical conditions (69% vs. 50%; OR, 2.20; 95% CI, 1.3 to 3.7; $p<0.001$).[10] An alternative to the analysis of death at home as an outcome was evaluated in a propensity-matched cohort study which found that fewer patients receiving outpatient palliative care died in the hospital compared to those receiving usual care (16.2% vs. 28.6%; RR 0.46; 95% CI, 0.40 to 0.52).[18] In contrast to these findings, a secondary analysis of data derived from another RCT[19] yielded no significant difference in the proportion of patients dying at home between the group receiving outpatient palliative care or usual care.[14]

The findings are similar across interventions with different characteristics. We found no evidence of heterogeneity according to study population, intervention timing, or delivery of care by specialized or generalist teams.

ED Visits

Mixed results were noted regarding associations of outpatient palliative care with a reduction in ED visits. Our review identified five good and fair quality studies evaluating the effect of outpatient palliative care on emergency department (ED) visits, of which three were RCTs.[8,10,11,15,18] Three of

these studies report significant associations of outpatient palliative care with a reduction in ED visits,[10,11,18] while two reported no significant effect.[8,15]

In three publications, outpatient palliative care was associated with fewer ED visits.[10,11,18] A cohort study conducting multivariate analyses (MANCOVA) controlling for differences in severity of illness at baseline revealed that patients receiving outpatient palliative care had significantly fewer ED visits (0.93 vs. 2.3 visits; p<0.001).[11] In a later RCT by the same author, investigators randomized patients to a palliative care program delivered by an interdisciplinary team (n=145), or to usual care (n=152), and regression analysis controlling for survival time indicated that the intervention reduced emergency department (ED) visits by 0.35 (r^2=0.04, p=0.02) compared to the usual care group.[10] Similarly, Seow et al. incorporated propensity score matching into a cohort study and estimated the relative risk of an ED visit in the last 2 weeks of life among the intervention group compared to the control to be 0.77 (95% CI, 0.69 to 0.86).[18]

Hospital Admissions

Our review identified six publications describing the effect of outpatient palliative care on the frequency of hospital admissions.[8,10,11,15,18,23] Of the six studies, three RCTs reported no effect of outpatient palliative care on measures of hospital utilization[8,10,15], while three cohort studies reported a significant reduction in such measures[11,18,23].

In a previously described cohort study, Brumley et al. evaluated 300 patients with life-threatening disease and reported that patients treated with specialized outpatient palliative care had significantly fewer hospital visits than did those treated with usual care (2.36 vs. 9.35, p<0.001).[11] Another previously described cohort study compared outcomes between propensity score-matched cohorts of seriously ill patients receiving outpatient palliative care provided and usual care.[23] Patients receiving home palliative care (n=392) were matched with patients receiving usual home care (n=890), and while 30-day mortality rates were similar in the two groups, the outpatient palliative care group had a reduced rate of 30-day hospital readmission compared to usual care yielding an average treatment effect on treated patients (ATT, a measure of the impact of palliative care on re-admission in the palliative care group) significantly greater than 0: 8.3% (95% CI, 8.0 to 8.6). A third cohort study also reported a reduction in hospital visits in the last 2 weeks of life in patients with mixed diagnoses receiving specialized outpatient palliative care (RR 0.68[95% CI 0.61-0.76]).[18]

Hospice Utilization

Our review identified four studies evaluating the effect of outpatient palliative care on hospice utilization.[10,14,17,21] Three of these, one RCT[14] and 2 cohort studies,[17,21] reported a significant association of outpatient palliative care on some element of hospice utilization. In contrast, one RCT reported no such association.[10]

In a secondary analysis of data derived from an RCT[19], Greer et al. evaluated the effect of early outpatient palliative care on hospice care and found that while there was no significant difference in the rates of referral to hospice, patients receiving outpatient palliative care were more likely to enroll in Similar findings were observed in Scheffey et al., who compared prior outpatient palliative care reported in a cohort of hospice patients diagnosed with mixed terminal illnesses with that reported by a matched group without such prior care.[17] This study found that the outpatient palliative care group (n=342) had a significantly longer length of stay in hospice than did the usual care group (n=1368) (median LOS 24 vs. 15 days, p<0.001). Another retrospective cohort study conducted in 435 patients with mixed indications and a life expectancy of less than six months evaluated 140 patients receiving outpatient palliative care and two different groups of patients receiving usual care (n=68 and n=227 respectively).[21] In this study, Ciemins et al. report that a higher proportion of patients receiving outpatient palliative care received hospice referrals (47%) compared to those receiving usual care(33%) (p=0.003); this finding was particularly pronounced among African American patients, of whom 47% receiving outpatient palliative care were referred to hospice compared to 18.8% receiving usual care (p=0.008).

In contrast to the findings of the above three publications, one study in our review did not report a significant effect of outpatient palliative care on hospice utilization.[10] Brumley et al. randomized homebound terminally ill patients to a palliative care program delivered by an interdisciplinary team (n=145), or to usual care (n=152); regression analysis controlling for survival time revealed no significant association between the comparison groups with respect to enrollment in hospice or days in hospice before death.

Target Population, Timing, and Type of Service

There was a suggestion of reduced acute care resource utilization among the four studies evaluating outpatient palliative care interventions both targeted to populations with mixed diagnoses and led by generalist palliative care providers. [10,11,15,18]. This was in contrast to a report that outpatient palliative care delivered in a specialist-led intervention to a population of patients with newly diagnosed NSCLC, in which no such significant association was noted. [14]

Psychosocial and Spiritual Outcomes

We identified three RCTs of fair quality evaluating psychosocial outcomes for patients, including spiritual well-being, advance care planning, and emotional and spiritual well-being.[15,16,22] Radwany et al. was a small pilot study not powered to detect differences in these primary outcomes, so those results are not described in further detail.[16]

The Rabow RCT showed a statistically significant improvement in spiritual well-being after a year of follow-up as measured on the Spiritual Well-Being Scale for both the mean effect over time (f=8.21, p=0.007) and group-by-time (f=4.24, p=0.05) interaction analyses in favor of the palliative care

intervention.[15] Advance care planning was also measured based on a pre-tested questionnaire which asked if patients had completed or considered a durable power of attorney, funeral plans, and plans for disposition of possessions after death.[15] Of the patients who had not completed funeral arrangements at baseline, 35% of intervention patients and 5% of control patient had done so by the end of the study (p=0.03), but between-group comparisons for consideration of durable power of attorney or plans for disposition of possessions after death were not significant.

Although Rummans et al. also reported statistically significant effects for overall spiritual well-being on the FACIT tool in favor of the intervention after one month (92.9 vs. 83.9 for control; p=0.003), this effect did not persist at weeks eight or 27.[22] This study also evaluated emotional and social well-being, which were measured as distinct items on the LASA measurement tool. Scores for social well-being were considered in terms of financial issues (7.0 vs. -3.6 for control, p=0.025) and legal concerns (6.7 vs. -4.7, p=0.048), both of which were statistically significant in favor of palliative care for trends in assessment scores. For the same analysis, emotional well-being significantly improved as well (2.8 vs. -5.4, p=0.046).

Target Population, Timing, and Type of Service

Due to the limited number of studies evaluating psychosocial outcomes, it is unclear whether the patient population in these studies (those with caner vs. mixed indications) or timing (early vs. late) had any effect on these outcomes. Interestingly, the only study[16] with a palliative care specialist was the only one that did not find statistically significant outcomes in favor of the intervention for spiritual well-being. As previously mentioned, however, this study was not powered to detect between-group differences.

Caregiver Outcomes

We identified only one good quality secondary analysis[13] of an RCT[9] reporting on caregiver outcomes, including depression, QoL, and caregiver burden. While this study did not find any differences between groups for QoL or caregiver burden, caregivers of patients receiving early palliative care had greater reductions in depressive symptoms than those receiving usual care based on the CES-D after three months of follow-up (mean difference, -3.4; SE, 1.5; p=0.02).

We identified three additional RCTs[56-58] in which the intervention specifically targeted caregiver outcomes and appeared to favor the palliative care intervention with regards to lessening strain/burden, reducing stress, and improving QOL. However, these studies received a poor quality rating and were excluded from our narrative analysis; details of these studies can be found in the data abstraction tables (Appendix 8).

Target Population, Timing, and Type of Service

Given that only one higher quality study reported on caregiver outcomes, no comparisons of intervention characteristics across studies for the intervention target or service type can be made. However, one study[13] evaluated for caregivers receiving palliative care early compared to a group receiving the intervention three months later and found that caregiver depression (CES-D; mean difference, -3.8; SE, 1.5; p=0.02) and stress burden (MBCB; mean difference, 1.1; SE, 0.4; p=0.01) were statistically better in the early intervention; however, the findings were not significant for caregiver QOL, objective burden, or demand burden at 36 weeks of follow-up.

Overall Summary: Net benefit and level of certainty for all comparisons

The body of evidence derived from higher quality comparative studies of outpatient palliative care interventions in the US and Canada is somewhat constrained and variable with respect to intervention target and structure. Some studies reported on interventions specifying early enrollment of patients into a palliative care program, while others made no such distinction; some studies evaluated interventions in patients with cancer, while others were implemented in patient populations with a variety of serious illnesses; some studies describe interventions in which at least one member of the core care team has a specialty in palliative care, while others describe interventions implemented by care teams with experience but no specialty or certification.

It is also challenging to pool information across comparative studies because these studies examined distinct patient populations with different disease entities and variable severities of illness; it is for this reason that we investigated the potential contrast in outcomes between studies carried out in cancer patients versus those carried out in populations of patients with mixed diagnoses, given evidence of different entry points into palliative care relative to temporal disease trajectories between patients with cancer compared to those with other diagnoses.

Despite the limitations of the published evidence derived from comparative studies, it is possible to use the ICER rating system to generate an estimate of the magnitude of the difference between outpatient palliative care and usual care, the “net health benefit” describing the balance between clinical benefits and risks and/or adverse effects.

Although we sought to identify any potential harms associated with palliative care, the studies included in our review did not report any adverse events connected with the interventions; therefore, our evaluation of net benefit is based solely on the noted benefits.

It is our judgement that there is moderate certainty that outpatient palliative care confers a comparable or better net health benefit relative to usual care. Additionally, given the lack of harms associated with such interventions, we have high certainty that the net health benefit is at least comparable. This yields an overall ICER Evidence Rating of C+: Comparable or Better for outpatient palliative care.

4.4 Elements for Successful Palliative Care Programs

In the sections that follow we describe essential components of palliative care as defined by professional organizations as well as quality reporting standards promulgated by federal legislation. We then undertake our own analysis of the elements of outpatient palliative care programs described in our evidence review that appear to be correlated with successful treatment outcomes.

Essential Elements of Palliative Care as Described by Professional Bodies

The International Association for Hospice and Palliative Care lists the following essential practices in palliative care:

Figure 5. IAHPC List of Essential Practices in Palliative Care.[5]

Identify, evaluate, diagnose, treat and apply treatment and solution measures for:
Physical care needs:
Pain (all types)
Respiratory problems (dyspnea, cough)
Gastro intestinal problems (constipation, nausea, vomiting, dry mouth, mucositis, diarrhoea)
Delirium
Wounds, ulcers, skin rash and skin lesions
Insomnia
Psychological / Emotional / Spiritual care needs:
Psychological distress
Suffering of the relative and/or caregiver
Anxiety
Identify and evaluate - provide support and when possible, refer for diagnosis, treatment and solution measures for:
Physical care needs:
Fatigue
Anorexia
Anaemia
Drowsiness or sedation
Sweating
Psychological / Emotional / Spiritual care needs:
Spiritual needs and existential distress
Depression
Family / caregivers grief and bereavement issues
Other:
Care Planning and Coordination issues:
Identify the resources and support available and develop and implement a plan of care based on the patient's needs.
Provide care in the last days/weeks of life
Identify, evaluate and implement solutions to facilitate the availability and access to medications (with emphasis on opioids)
Identify the psychosocial / spiritual needs of self and other professionals involved in the care
Communication issues:
Communicate with patient, family and caregivers about diagnosis, prognosis*, condition, treatment, symptoms and their management, and last days/weeks care issues.
Identify and set priorities with patient and caregivers.
Provide information and guidance to patients and caregivers according to available resources. Sensitize other health care professionals and workers about palliative care.

***Note**: The determination of prognosis and safe delivery of this information requires appropriate training and knowledge.

Measurement

The Patient Protection and Affordable Care Act (ACA) mandated a quality reporting program for hospice programs; CMS is tasked with setting the exact quality measures that hospices must utilize. Unlike hospice, there are currently no external quality-reporting requirements for palliative care programs, which means that the data measuring quality of palliative care is limited.[29] There are efforts under way to increase measurement of outcomes for quality improvement and public reporting of palliative care programs.[29] The Center to Advance Palliative Care (CAPC) launched a voluntary program registry in 2009 for voluntary reporting on palliative care structure and process measures derived from the National Quality Forum Framework and Preferred Practices. Outcomes are available in various formats and can be found at https://registry.capc.org/cms/

The Joint Commission's Advanced Certification Program for Palliative Care, was launched in 2011 under the ACA to create a mechanism to recognize hospital inpatient programs that demonstrate exceptional patient and family-centered care and optimize the QoL for adult and pediatric patients with serious illness. The incentives associated with this program are believed to have created a demand for the expansion of palliative care services in new care settings.[2]

While essential elements of palliative care have been outlined by various entities, the evidence linking specific practices to outcome measures is less clear. This may be in part due to the regulatory requirements related to collecting data on palliative care outcomes. Efforts to evaluate such linkages will further our understanding of how the essential elements of palliative care contribute to success or positive outcomes.

Elements of Outpatient Palliative Care Aligned with Treatment Success

Subsequent to our description of the comparative effectiveness of outpatient palliative care, we attempted to identify specific elements of a palliative care program that may be aligned with treatment success. Given that one of the primary goals of palliative care is to improve a patient's QoL,[24] we defined treatment success as a statistically significant effect on any QoL measure in favor of the palliative care intervention, and evaluated those higher-quality original studies included in our sample that quantitatively assessed such outcomes regardless of the measurement tool used. We then compared the frequencies of various specific components of the interventions described in "successful" studies relative to those described in the "unsuccessful" studies (those in which the outcome was measured, but not found to be significantly impacted by the intervention). The comparative studies we reviewed did not provide evidence to distinguish successful and unsuccessful studies on the basis of many of the essential elements of palliative care described above. However, we were able to identify several commonly described components of palliative care interventions described in our evidence base; the table below lists the components of palliative care we evaluated for their potential association with successful outcomes. Notably, all

studies identified in our review that measured QoL as a primary or secondary outcome had detailed descriptions of the intervention, including the frequency and duration of contact with patients.

Table 3. Components of Palliative Care Across Studies Evaluating QoL

Author, Year	Bakitas, 2015[9]	Rabow, 2004[15]	Radwany, 2014[16]	Bakitas, 2009[8]	Rummans, 2006[22]	Temel, 2010[19]	Zimmermann, 2014[20]
Program Components	***Unsuccessful Studies***			***Successful Studies***			
Multidisciplinary Care Team	N	Y	Y	N	Y	N	N
Palliative Care Specialist	Y	N	Y	Y	N	Y	Y
Patient & Family Education	Y	Y	Y	Y	Y	N	Y
Advance Care Planning	Y	Y	Y	Y	N	Y	Y
Monthly In-person Office Visit	N	N	N	Y	N	Y	Y

Of the seven studies we identified as evaluating QoL, four[8,19,20,22] were considered successful and three[9,15,16] were not. We found that three[8,19,20] of the four successful studies provided at least monthly in-person medical appointments with physicians or nurses present as part of the package of palliative services, while the studies not showing a QoL benefit followed up through telephone only. These in-person appointments gave patients and caregivers an opportunity to have in-depth discussion about issues related to their disease and treatment, including symptom management, insurance, and social services. These successful studies also described an "early" palliative care intervention for advanced cancer patients. The Rummans RCT,[22] which included patients with cancer who were diagnosed in the last 12 months, was considered successful but did not specify monthly medical appointments as part of the palliative care intervention. Notably, patient QoL showed improvement at week four, but not at week eight and week 27. Thus, the timing of a palliative care intervention (i.e., at or around the time of diagnosis) and the length of follow-up may also be correlated with successful outcomes.

In addition to the structural components of palliative care, we also considered other characteristics of the interventions as potentially influencing success. For those palliative care interventions that were considered successful, the data are most robust for those studies evaluating early palliative care for oncology patients. Importantly, one of the reasons why the most recent study[9] assessing early palliative care did not show a benefit despite being conducted in the same setting as an earlier successful study[8] may have been a shorter duration of follow-up for the QoL outcome (3 months vs. 13 months, respectively).

5. Comparative Value

5.1 Overview

We reviewed the published literature for analyses that have examined the economics of palliative care programs. This included studies of the costs that are potentially offset through the use of such programs (e.g., reduced end-of-life medical costs). Below we summarize recent literature about the economic impact of palliative care programs and components, the strength and validity of that evidence, and where gaps in knowledge still exist. Unfortunately, data on costs for these programs was not generally reported in a way that would allow us to highlight those programs or program components that best correlated with cost-offsets or favorable cost-effectiveness. There was also a dearth of studies on the cost to initiate and operate outpatient palliative care programs or specific components of such programs.

We also explore the potential health system budgetary impact of outpatient palliative care programs over a near-term time horizon, utilizing published information on program costs and cost offsets, as well as the potential population eligible for such services.

5.2 Prior Published Evidence on Costs and Cost-Effectiveness of Outpatient Palliative Care Programs

Comparisons of Palliative Care to Usual Care

Most recent studies that have compared direct health care costs for palliative care to usual care have found such programs to be cost-saving. Many of the costs of intensive inpatient admissions can be avoided, as more patients are able to be cared for at home or in an outpatient setting. A recent annual review by Hughes et al.[25] of the growth of palliative care (both inpatient and outpatient) in the United States reports that several studies of outpatient programs found cost savings through reduced hospital admission rates and movement of patients from high-cost settings such as hospitals to lower- cost settings such as home health care.

The three studies reviewed below found lower costs with outpatient palliative care compared to usual care in patients with mixed diagnoses (cancer and other serious illnesses); one specifically examined a palliative care program that included specialist ("board certified") staff. However, while these studies compared ongoing costs of care, there is lack of evidence on the development and implementation costs of establishing outpatient palliative care programs. In addition, a limitation of many of these studies is that they are conducted on one particular type of program in one type of setting, limiting their generalizability.

Brumley et al.[10] evaluated costs in the Kaiser Permanente RCT that compared generalist in-home palliative care plus usual care to usual care alone in terminally ill patients with COPD, CHF, or cancer. In regression analyses controlling for days on service, age, severity of illness, and primary disease, patients receiving palliative care had significantly lower health care costs than did the patients receiving usual care (p=0.03), with adjusted mean cost of $12,670 for the palliative care group and $20,222 for usual care. This difference in costs was largely due to fewer ED visits (20% vs. 33% with ED visits, respectively; p=0.01) and hospitalizations (36% vs. 59%, respectively; p<0.001). Strengths of this study included its design as an RCT, and the relatively large sample for this type of study; limitations include being conducted only in one integrated health system and the use of proxy costs, which may limit generalizability to other settings.

Prior to the 2007 study, a "comparison group study" in 1999-2000 by Brumley et al.[11] compared end-of-life palliative care intervention to usual care, enrolling 558 patients with various life-threatening diseases (mainly cancer, COPD or CHF). Of the 300 patients who died during the study, 161 received the palliative care intervention and 139 usual care. The intervention was a generalist, home-based multidisciplinary approach to managing end-of-life care, including pain and symptom relief, patient education, and emotional and spiritual support. Brumley et al. found that the palliative care patients had 45% lower average costs than the usual care patients ($7,990 vs. $14,570, p<0.001), with fewer physician visits, ED visits, and days in hospital or skilled nursing facility.

A more recent analysis by Lukas et al.[60] examined hospital outcomes for a specialist, home-based (non-hospice) palliative medicine consulting service in 369 patients with "advanced complex illness" (life-limiting diagnosis with need for frequent or intense medical care, including cancer, chronic illness/end-stage organ failure, and frailty/dementia) in the mid-Atlantic region of the U.S. Retrospective chart reviews were used to compare hospital and emergency department utilization and costs for the 18 months prior to and after palliative care enrollment. In mixed models analyses of covariance with repeated measures on time (pre- versus post-palliative care enrollment), mean total costs for all hospitalizations decreased from $23,386 pre-enrollment to $16,467 per patient post-enrollment (p<0.001). Limitations of this study include that it is a pre–post design with no control group, and that hospitalization data was only available from one health care network, which may limit the generalizability of these results.

Cost Burden and Unpaid Caregiving

While many economic analyses of palliative care take a payer or health system perspective, some have examined home-based palliative and end-of-life care from a societal perspective, with an emphasis on assessing unpaid care. In general, these studies find that at least some of the costs that outpatient and home-based palliative care averts by reducing hospitalizations and emergency department visits may be shifted to the home setting, where it is often provided by informal, unpaid caregivers.

In the U.S., Rhee et al.[61] attempted to estimate the quantity and economic value of informal family caregiving for community-dwelling older persons in the last year of life, using data from the Health and Retirement Study (a biennial, nationally representative, longitudinal survey) for respondents who died between 2000 and 2002 (n=990). Total average hours of informal caregiving were estimated using ordinary least squares regression, and valued using the 2002 national average home aide wage ($9.16 per hour). Community-dwelling older persons received an adjusted average of 65.8 hours of informal caregiving per week. The annual replacement cost of informal care averaged $31,342, based on the average home aide wage. Replacing the informal care provided in the U.S. in the last year of life with home health aides was estimated to require approximately $1.4 billion in funds. Limitations of this study include the use of survey data, which may underestimate caregiving time, and the assumption that home health aide time can be substituted 1:1 for informal caregiving time. Finally, lost productivity and other burdens on caregivers were not included in these cost estimates.

Several economic analyses from Canada examine home-based palliative care from a societal perspective. For example, Yu et al.[62] compared the societal costs of home and hospital end-of-life care for a propensity score-stratified cohort of 186 palliative care cancer patients in Ontario, Canada. This hospital-based palliative care program provided "community and team-based multidisciplinary palliative care to patients at home," with hospital care available when needed. Societal costs included health system costs, as well as patient out-of-pocket and informal caregiving costs. Mean total societal costs for end-of-life care for all patients was $34,198 (2012 Canadian dollars). Approximately 13% of this was for hospitalization, 33% for outpatient/home care, and 46% for unpaid caregiver time. Mean costs for the six months prior to death were not significantly different between home death and hospital death patients ($31,911 and $29,117, respectively). While hospitalization costs were lower for home death patients, outpatient and unpaid caregiving costs were higher, leading to small differences in overall costs.

In another Canadian study, Chai et al.[63] examined home-based palliative care in Toronto, including estimates for unpaid care. Caregivers of patients with malignant neoplasm (n=169) were interviewed at time of referral to palliative care and periodically thereafter until the patient's death. Data were collected on palliative care resource use and costs, as well as unpaid caregiving time. Average monthly palliative care costs were $14,924 (2011 Canadian $) in the last year of life, 77% of which was unpaid caregiving costs, 21% public costs, and 2% out-of-pocket costs. The authors suggest that the burden of this unpaid cost to patients' families could threaten the sustainability of home-base palliative care.

Finally, Dumont et al.[64] conducted a prospective cohort analysis of 248 Canadian palliative care patients and their caregivers. Data on health care resource utilization and payments were collected via biweekly interviews for up to 6 months or until the patient's death. Their analysis found that the largest component of health care costs was for inpatient care, followed by home care and informal caregiving time. They estimated that the mean total cost per patient ($18,446, in 2005/2006

Canadian dollars) was comprised of 71% public payments, 27% family payments and 2% non-profit organization costs.

5.3 Potential Budget Impact of Outpatient Palliative Care Programs

We have also provided an estimate of the potential budgetary impact of outpatient palliative care programs among candidate populations for such treatment in the US. Our estimates are based on those found in the literature. We combined estimates of the mean cost per patient with estimates of the population potentially eligible for outpatient palliative care programs and different assumed levels of uptake of such programs.

Potential Budget Impact Model: Methods

Potential budgetary impact was defined as the total incremental cost of outpatient palliative care for the treated population, calculated as the incremental health care costs of palliative care treatment minus health care costs that would be incurred without palliative care (i.e., usual care). All costs were undiscounted and estimated over one- and five-year time horizons.

The potential budget impact analysis included the entire candidate population for palliative care programs in the U.S., which was considered be comprised of those with cancer, COPD, or CHF with an expected life expectancy of less than 12 months.

To estimate the size of the potential candidate population for palliative care, we used tabulations from the National Center for Health Statistics of the number of deaths by cause for 2013. We summed the total numbers of deaths (across all ages) for cancer (identified as "malignant neoplasms", ICD-10 codes C00-C97), COPD (identified as "other chronic lower respiratory diseases", ICD-10 codes J44 and J47) and CHF (identified as "heart failure", ICD-10 code I50). This resulted in a candidate population size of approximately 787,000 individuals in the US, of which approximately 585,000 (74%) were cancer decedents.

In estimating potential budget impact, we recognized that not all patients nearing the end of life will have access to outpatient palliative care. Therefore, our calculations assume that the utilization of such programs reaches only some fraction of eligible patients. To estimate the population size that would use outpatient palliative care, we assumed that some percentage of the eligible population would enter palliative care in each year and that this percentage would stay constant over time (years one through five). Our assumed percentages were 10%, 25% and 50% of eligible patients.

In another scenario, we assumed that utilization of outpatient palliative care programs may increase over time, with accompanying increases in the percent of candidate patients being treated over the five-year time horizon of our analysis. In this scenario, uptake was assumed to occur in equal proportions across the five-year timeframe, with costs adjusted to account for the different

number of patients treated with palliative care each year. For example, if 10% of patients were assumed to be enrolled at the end of five years, 2% of eligible patients were assumed to initiate therapy in the first year, 4% in the second, 6% in the third, and 8% in the fourth year, before finally growing to 10% in the final, fifth year. Note that patients only incur costs (or savings) in the year in which they enroll in palliative care, as we assume that all patients have less than 12-month life expectancy at time of enrollment.

To estimate the cost per patient of outpatient palliative care compared to usual care, we used the results from the U.S.-based RCT reported by Brumley et al.[10], with adjusted mean costs of $12,670 per palliative care patient and $20,222 per usual care patient, using 2002 costs. We updated these costs to 2014 dollars, using the medical care component of the Consumer Price Index, to obtain mean costs of $19,308 for palliative care and $30,816 for usual care. This indicates a cost savings of $11,508 per patient enrolled in palliative care rather than receiving usual care. Because the published cost estimates used for this analysis indicated that outpatient palliative care is cost-saving compared to usual care, there was no need to compare our estimates to a budget impact threshold.

Potential Budget Impact Model: Results

We used the estimated savings per patient of $11,508 to estimate the total impact on the U.S. health care budget of implementing outpatient palliative care at different levels. Table 4 presents the potential budgetary impact of one year and five years of palliative care in the candidate population, assuming immediate implementation of outpatient palliative care programs for different fractions of the population. Results are presented for both one-year and five-year time horizons.

Results from the potential budget impact model showed that, with immediate implementation for 10% of the eligible population, an estimated 78,665 individuals would receive palliative care each year. After one year of treatment, with net annual savings of $11,508 per patient, one-year budget impact is estimated to be savings of approximately $905.3 million. Over the entire five-year time horizon, we estimate that a cumulative total of 393,325 patients would be enrolled in palliative care. Across the full five-year time horizon, the total potential savings are approximately $4.5 billion.

Assuming that larger proportions of eligible patients could be enrolled in palliative care resulted in even greater savings. At 25% of eligible patients treated in years one through five, approximately $2.3 billion are estimated to be saved per year, summing to $11.3 billion over five years. At 50% enrollment, estimated savings increase to $4.5 billion in year 1 and $22.6 billion over five years.

We also estimated the potential savings from implementing palliative care in only the eligible patients with cancer (74% of the total eligible population). Annual budget impact ranged from saving approximately $673 million per year at 10% enrollment, to approximately $1.68 billion at

25% and $3.37 billion at 50% enrollment of cancer patients. Cumulative savings over 5 years would range from approximately $3.4 billion at 10% enrollment to approximately $16.8 billion at 50% enrollment.

Table 4. Estimated Total Potential Budget Impact (BI) of Outpatient Palliative Care: Immediate Implementation for Fractions of the Eligible U.S. Population (N=786,628)

	Analytic Horizon = 1 Year		Analytic Horizon = 5 Years	
Percent Enrolled	Number Treated	Total BI (billions)	Cumulative Number Treated	Cumulative Total BI (billions)
10%	78,665	-$0.91	393,325	-$4.53
25%	196,655	-$2.26	938,275	-$11.32
50%	393,315	-$4.53	1,966,575	-$22.63

The above scenario assumes that there would be full capacity to absorb 10% to 50% of eligible patients into palliative care programs beginning in year one. However, it may take some time to ramp up the implementation of outpatient palliative care programs. In separate analyses, we estimated the budget impact of such a ramp up in implementation, assuming a 20% increase in capacity per year. For example, 10% enrollment at 5 years would imply 2% enrollment in year one, 4% in year two, etc.

Assuming that as capacity is ramped up, there will be fewer eligible patients to enrolled in palliative care which will result in fewer savings than with immediate implementation, this is displayed in Table 5. With a linear increase to 10% of the eligible population enrolled in year five, an estimated 15,733 individuals would receive palliative care in year one, increasing to 78,665 patients enrolled in year five. After one year of treatment, budget impact is estimated to be a saving of approximately $181 million. Over the entire five-year time horizon, we estimate a cumulative total cost saved of approximately $2.7 billion. Assuming linear increases to reach 25% of eligible patients by year five, approximately $453 million are estimated to be saved per year and $6.8 billion over five years. Ramping up to 50% enrollment by year five would imply an estimated savings of $905 million in year 1 and $13.6 billion over five years.

Table 5. Estimated Total Potential Budget Impact (BI) of Outpatient Palliative Care: Gradual Implementation for Fractions of the Eligible U.S. Population (N=786,628)

	Analytic Horizon = 1 Year		Analytic Horizon = 5 Years	
Percent Enrolled	Number Treated	Total BI (billions)	Cumulative Number Treated	Cumulative Total BI (billions)
10%	15,733	-$0.181	235,995	-$2.72
25%	39,331	-$0.453	589,965	-$6.79
50%	78,663	-$0.905	1,179,945	-$13.58

Finally, we also estimated the budget impact of outpatient palliative care programs for a hypothetical commercial health plan population of one million members. We applied the proportion of the 2013 U.S. population with deaths from cancer, COPD and CHF (0.002475) to estimate the number of patients eligible for palliative care (2,475). Enrolling 10% of these patients in outpatient palliative care would result in an estimated savings of approximately $2.8 million per year, or approximately $0.24 on a per-member-per-month basis. For benchmarking purposes, this is comparable to payments the state of Colorado makes to accountable care organizations for well-child visits.[65]

5.4 Summary and Comment

We found several studies that attempted to compare the cost to the health care system of providing outpatient or home-based palliative care to that of providing usual care. Most of these studies found that such palliative care decreased overall costs, mainly through avoided hospitalizations and emergency department visits near the end of life. However, it was often unclear whether these evaluations incorporated the start-up costs of developing an outpatient palliative care program. We were unable to identify any publications that clearly delineated the costs of implementation vs. ongoing costs of such programs. In addition, there was little detailed information on the costs of specific components of palliative care programs in the U.S., which makes comparisons of different programs difficult, given that programs often vary in the specific palliative services provided.

While the literature seems to support cost savings associated with outpatient palliative care for the health care system, other studies have looked at the economic impacts of these programs from a societal perspective. These studies point out that, while outpatient and home-based palliative care may succeed in avoiding unnecessary or unwanted hospitalizations and emergency department visits, some of the care that would be provided in those settings is now shifted to the home, where it is often provided by informal, unpaid caregivers.

The economic value of that unpaid caregiving time (valued at prevailing wages for paid home aides) may replace much (if not all) of the cost saving from reduced inpatient care. For example, Yu et al.[62] concluded that: "Higher hospitalization costs for hospital death patients were replaced by higher unpaid caregiver time and outpatient service costs for home death patients. Thus, from a societal cost perspective, alternative sites of death, while not associated with a significant change in total societal cost of end-of-life care, resulted in changes in the distribution of costs borne by different stakeholders."

There is a need for studies that compare the economic outcomes of different types of outpatient palliative care programs in similar settings to each other and to usual care. Especially helpful would be studies that are designed to evaluate the effects of individual components of such programs, so that services can be tailored to provide palliative care in the most cost-effective manner. To estimate the up-front investment required, studies of the cost to initiate and operate palliative care programs or specific components of such programs would also be useful. Finally, formal cost-effectiveness analyses of outpatient palliative care programs are needed to allow comparisons of the quality-adjusted life-years gained by such programs compared to usual care.

We used the health care costs for palliative care and usual care from an RCT conducted in the U.S. in 2002-2004[10] to estimate the impact on the U.S. health care budget of palliative care for the treatment of cancer, COPD, and CHF patients near the end of life. The potential money saved from the health care budget was substantial, and scaled up as more patients were assumed to enroll in palliative care. Even assuming a 2% uptake rate per year (i.e., 10% enrollment after five years) would result in estimated cumulative savings of about $2.7 billion after 5 years.

Our estimates of levels of outpatient palliative care uptake in the health care system by five years were based on arbitrary assumptions, so actual uptake may not reach these levels this quickly. In addition, the costs used in our analysis came from only one study, and so may not be representative of the costs for such programs in other setting in the U.S. Finally, our budget impact analysis did not include the costs of setting up and implementing new palliative care programs, or the economic value of unpaid caregiving time.

In summary, outpatient palliative care services appear to be cost-effective or even cost-saving for the health care system, by avoiding inpatient care and shifting care to home and outpatient settings. Expanding the use of these palliative care programs to larger proportions of eligible patients has the potential to substantially reduce the costs of health care for patients with advanced illness. It should be kept in mind, however, that some portion of these services may be shifted to unpaid caregiving rather than being avoided altogether.

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APPENDICES

A1. Palliative Care as Compared to Hospice

Palliative Care as Compared to Hospice (NEJM 2015)

Palliative Care as Compared with Hospice		
Characteristic	**Palliative Care**	**Hospice**
Model	Team of interdisciplinary providers that may include nurses, social workers, chaplains, and other support staff. Primary goal is to improve outcomes related to QoL	Team of interdisciplinary providers including physicians, social workers, chaplains, and volunteers as directed by statute; primary goal of care are improved QoL and relief of physical, emotional and spiritual suffering
Eligibility	Patients of any age, diagnosis, or state of illness. Patients may continue life prolonging or disease directed therapy	Patients of all ages who have a prognosis of 6 months or less if the disease follows the usual course. Patients must forgo Medicare coverage for curative or disease directed treatments related to the terminal diagnosis
Location	Most common in hospital setting. Also available in hospital clinics, group practices, home care programs, and nursing homes	Most common in the home based setting. Also available in assisted living facilities, nursing homes, residential hospice facilities, inpatient hospice units, or hospice-contracted inpatient beds
Payment	Physician and nurse practitioner fees are covered by Medicare part B for inpatient or outpatient care; hospital teams are included within Medicare Part A or commercial insurance payments to hospitals for care episodes; flexible bundled payments under Medicare Advantage, Managed Medicaid, ACOs, and other commercial payers	Medicare hospice benefit; standard hospice benefit from commercial payers is usually modeled after Medicare; Medicaid, although coverage varies by state; medication costs are included for illnesses related to terminal illness

Source: http://www.nejm.org/doi/full/10.1056/NEJMra1404684

A2. Definitions of Palliative Care

The following definitions reflect the modern concept of palliative care:

WHO Definition of Palliative Care[4]

An approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual.

The Centers for Medicare and Medicaid Services (CMS) Definition of Palliative Care[4]

Patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and facilitating patient autonomy, access to information, and choice.

The Center to Advance Palliative Care Definition of Palliative Care[4]

Specialized medical care for people with serious illnesses…focused on providing patients with relief from the symptoms, pain and stress of a serious illness — whatever the diagnosis. The goal is to improve quality of life for both the patient and the family. Palliative care is provided by a team of doctors, nurses and other specialists who work together with a patient's other doctors to provide an extra layer of support. It is appropriate at any age and at any stage in a serious illness and can be provided along with curative treatment.

National Hospice and Palliative Care Organization uses the National Consensus Project's definition of Palliative care

Palliative care is patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy, access to information and choice.

The following features characterize palliative care philosophy and delivery:

- Care is provided and services are coordinated by an interdisciplinary team;

- Patients, families, palliative and non-palliative health care providers collaborate and communicate about care needs;
- Services are available concurrently with or independent of curative or life-prolonging care;
- Patient and family hopes for peace and dignity are supported throughout the course of illness, during the dying process, and after death

A3. Medicare Care Choices Model

The Centers for Medicare and Medicaid describes the Medicare Care Choices Model as follows:

> Through the Medicare Care Choices Model, the Centers for Medicare & Medicaid Services (CMS) will provide a new option for Medicare beneficiaries to receive palliative care services from certain hospice providers while concurrently receiving services provided by their curative care providers. CMS will evaluate whether providing hospice services can improve the quality of life and care received by Medicare beneficiaries, increase patient satisfaction, and reduce Medicare expenditures. Under current payment rules, Medicare and dually eligible beneficiaries are required to forgo curative care in order to receive services under the Medicare or Medicaid Hospice Benefit. Fewer than half of eligible Medicare beneficiaries use hospice care and most only for a short period of time.
>
> The model is designed to:
>
> - Increase access to supportive care services provided by hospice;
> - Improve quality of life and patient/family satisfaction;
>
> **Model Summary**
>
> **Stage:** *Announced*
> **Number of Participants:** *141*
> **Category:** *Initiatives to Accelerate the Development and Testing of New Payment and Service Delivery Models*
> **Authority:** *Section 3021 of the Affordable Care Act*

Participating Organizations:

Vermont					
Model Name	Organization Name	Address	City	State	Notes
Medicare Care Choices Model	Addison County Home Health & Hospice Inc New Haven, VT	254 Ethan Allen Hwy	New Haven	VT	Not Applicable
Medicare Care Choices Model	Bayada Home Health Care, Inc. dba Bayada Hospice Norwich, VT	316 Main St., P.O. Box 1590	Norwich	VT	Not Applicable
Medicare Care Choices Model	Caledonia Home Health Care Saint Johnsbury, VT	161 Sherman Dr	Saint Johnsbury	VT	Not Applicable
Medicare Care Choices Model	Central Vermont Home Health and Hospice Barre, VT	600 Granger Rd	Barre	VT	Not Applicable

Medicare Care Choices Model	Franklin County Home Health & Hospice Saint Albans, VT	3 Home Health Circle, Suite 1	Saint Albans	VT	Not Applicable
Medicare Care Choices Model	Lamoille Home Health Agency Inc dba Lamoille Home Health & Hospice Morrisville, VT	54 Farr Ave	Morrisville	VT	Not Applicable
Medicare Care Choices Model	Orleans/Essex VNA & Hospice Inc. Newport, VT	46 Lakemont Rd	Newport	VT	Not Applicable
Medicare Care Choices Model	Southwestern Vermont Hospice Network dba Rutland Area Visiting Nurse Association and Hospice Rutland, VT	7 Albert Cree Dr	Rutland	VT	Not Applicable
Medicare Care Choices Model	Visiting Nurse Association & Hospice of Vermont and New Hampshire White River Junction, VT	205 Billings Farm Rd Bldg 5	White River Junction	VT	Not Applicable
Medicare Care Choices Model	VNA of Chittenden & Grand Isle Counties Colchester, VT	1110 Prim Rd.	Colchester	VT	Not Applicable
Maine					
Medicare Care Choices Model	Community Health and Counseling Services Bangor, ME	42 Cedar St	Bangor	ME	Not Applicable
Massachusetts					
Medicare Care Choices Model	Care Dimensions, Inc. Danvers, MA	75 Sylvan St., Suite B-102	Danvers	MA	Not Applicable
Medicare Care Choices Model	HopeHealth, Inc. Hyannis, MA	765 Attucks Lane	Hyannis	MA	Not Applicable
Medicare Care Choices Model	Notre Dame Health Care, Inc dba Notre Dame Hospice Worcester, MA	555 Plantation Ave	Worcester	MA	Not Applicable

A4. Search Strategies

Ovid – Medline 1996 to Present with Daily Update and Cochrane Central Register of Controlled Trials

#1	Palliative Care/ or Terminal Care/ or Terminally Ill/ or Palliative Medicine/
#2	((palliat* adj25 care) or (supportive care or comfort care) or (terminal* and (care or caring or ill*)) or ((advanced or end stage or terminal*) adj4 (disease* or illness* or cancer* or malignan*)) or (last year of life or LYOL or life* end or end of life)).ti,ab.
#3	1 or 2
#4	Home Care Services/ or Mobile Health Units/ or Community Health Nursing/ or Outpatients/ or Ambulatory Care/
#5	((home adj4 palliat*) or ((home* or in-home or domicile or outreach or residential or housing or posthospital or post-hospital or communit* or mobile or ambulatory or outpatient or door to door) adj25 (team* or center* or centre* or clinic treat* or care or interven* or therap* or management or model* or program* or service* or base* or nurs*))).ti,ab.
#6	4 or 5
#7	(((comprehensive* or integrative or systematic*) adj3 (bibliographic* or review* or literature)) or (meta-analy* or metaanaly* or "research synthesis" or ((information or data) adj3 synthesis) or (data adj2 extract*))).ti,ab. or (cinahl or (cochrane adj3 trial*) or embase or medline or psyclit or (psycinfo not "psycinfo database") or pubmed or scopus or "sociological abstracts" or "web of science").ab. or ("cochrane database of systematic reviews" or evidence report technology assessment or evidence report technology assessment summary).jn. or Evidence Report: Technology Assessment*.jn. or ((review adj5 (rationale or evidence)).ti,ab. and review.pt.) or meta-analysis as topic/ or Meta-Analysis.pt.
#8	randomized controlled trial.pt. or controlled clinical trial.pt. or randomized.ab. or placebo.ab. or Clinical Trials as Topic/ or randomly.ab. or trial.ti.
#9	exp Animals/
#10	Humans/
#11	9 not 10
#12	8 not 11
#13	(Costs.mp. and "Cost Analysis"/) or Models, Economic/ or cost-effectiveness.mp. or Cost-Benefit Analysis/ or cost utility.mp. or Quality of Life/ or qol.mp. or quality adjusted life year.mp. or Quality-Adjusted Life Years/ or qaly.mp. or Cost of Illness/ or burden of disease.mp. or caregiver burden.mp. or Health Expenditures/ or Health Care Costs/ or Cost Control/ or Direct Service Costs/ or Cost Sharing/ or cost analysis.mp.

#14	Cohort studies/ or Longitudinal studies/ or Follow-up studies/ or Prospective studies/ or Retrospective studies/ or cohort.ti,ab. or longitudinal.ti,ab. or prospective.ti,ab. or retrospective.ti,ab.
#15	Control Groups/ or (control* adj2 (clinical or group* or trial* or study or studies or design* or method*)).ti,ab.
#16	Controlled before-after studies/ or (before adj4 after).ti,ab.
#17	(quasi-experiment* or quasiexperiment* or quasi random* or quasirandom* or quasi control* or quasicontrol* or ((quasi* or experimental) adj3 (method* or study or studies or trial or design*))).ti,ab,hw.
#18	Pilot projects/ or pilot.ti. or (pilot* adj3 (program* or project? or study or studies)).ab.
#19	Comparative study.pt. or (comparative and (study or studies)).ti.
#20	Intervention studies/ or intervention.hw. or (intervention? or multiintervention? or multi-intervention? or postintervention? or post-intervention? or preintervention? or pre-intervention?).ti,ab.
#21	Evaluation studies.pt. or (evaluation and (study or studies)).ti.
#22	or/15-21
#23	14 and 22
#24	Case-Control Studies/ or Control Groups/ or Matched-Pair Analysis/ or ((case* adj5 control*) or (case adj3 comparison*) or control group*).ti,ab.
#25	7 or 12 or 13 or 23 or 24
#26	Pediatrics/ or Adolescents/ or Child/ or Infant/ or Infant, newborn/
#27	(child* or adolescent* or infant* or baby or babies or neonat* or juvenil* or pediatric* or paediatric* or young person* or young people or youth* or young adult* or matern*).ti.
#28	26 or 27
#29	25 not 28
#30	29 not (guideline or practice guideline or letter or editorial or news or case reports or clinical conference or congresses).pt.
#31	limit 30 to (english language and humans and yr="2000 -Current")
#32	3 and 6 and 31
#33	nursing home.mp.
#34	32 not 33

Ovid – PsycINFO

#1	exp palliative care/ or exp terminal care/ or terminally ill patients/
#2	palliat*.mp.
#3	(terminal* and (care or caring or ill*)).mp.
#4	((advanced or end stage or terminal*) adj4 (disease* or illness* or cancer* or malignan*)).mp.
#5	(last year of life or LYOL or end of life).mp
#6	or/1-5
#7	exp home care/ or exp home visiting programs/ or community services/ or outpatients/ or ambulatory care/
#8	(home adj4 (hospital or palliat*)).mp.
#9	(homecare or home-care or homebased or home-based).mp.
#10	((home or in-home or domicile or outreach or residential or housing or posthospital or post-hospital or communit* or mobile or ambulatory or door to door) adj2 (team* or center* or centre* or treat* or care or interven* or therap* or management or model* or program* or service* or base* or nurs*)).ti,ab.
#11	(outpatient* or ambulatory).ti,ab.
#12	or/7-11
#13	((case* adj5 control*) or (case adj3 comparison*) or case-comparison or control group*).ti,ab.
#14	((cohort or longitudinal or prospective or retrospective).ti,ab,id. or longitudinal study.md. or prospective study.md. or retrospective study.md.)
#15	(((comprehensive* or integrative or systematic*) adj3 (bibliographic* or review* or literature)) or (meta-analy* or metaanaly* or "research synthesis" or ((information or data) adj3 synthesis) or (data adj2 extract*))).ti,ab,id. or ((review adj5 (rational or evidence)).ti,ab,id. and "Literature Review".md.) or (cinahl or (cochrane adj3 trial*) or embase or medline or psyclit or pubmed or scopus or "sociological abstracts" or "web of science").ab. or ("systematic review" or "meta analysis").md.
#16	exp clinical trials/ or cross-over studies/ or random allocation/ or double-blind method/ or single-blind method/
#17	exp clinical trials/ or crossover design/ or random assignment/
#18	exp clinical trials/ or double blind method/ or random allocation/
#19	random$.mp.

#20	(cross-over or cross? over or (clinical adj2 trial$) or single-blind$ or single? blind$ or double-blind or double? blind$ or triple-blind or triple? blind).tw.
#21	random sampling/
#22	or/13-21
#23	6 and 12 and 22
#24	(child* or adolescent* or infant* or baby or babies or neonat* or juvenil* or pediatric* or paediatric* or young person* or young people or youth* or young adult* or matern*).ti.
#25	23 not 24
#26	limit 25 to (human and english language and yr="2000 -Current")

EBSCO – CINAHL

#1	MH palliative care OR MH Terminal Care OR MH Terminally Ill Patients
#2	((palliat* n25 care) or (supportive care or comfort care) or (terminal* and (care or caring or ill*))
#3	TI advanced or end stage or terminal*) and (disease* or illness* or cancer* or malignan*)) or (last year of life or LYOL or life* end or end of life)
#4	AB advanced or end stage or terminal*) and (disease* or illness* or cancer* or malignan*)) or (last year of life or LYOL or life* end or end of life).
#5	or/1-4
#6	MH Home Health Aide Services or MH Mobile Health Units or MH Community Health Nursing or MH Outpatients or MH Ambulatory Care
#7	TI ((home and palliat*) or ((home* or in-home or domicile or outreach or residential or housing or posthospital or post-hospital or communit* or mobile or ambulatory or outpatient or door to door) and (team* or center* or centre* or clinic treat* or care or interven* or therap* or management or model* or program* or service* or base* or nurs*)))
#8	AB ((home and palliat*) or ((home* or in-home or domicile or outreach or residential or housing or posthospital or post-hospital or communit* or mobile or ambulatory or outpatient or door to door) and (team* or center* or centre* or clinic treat* or care or interven* or therap* or management or model* or program* or service* or base* or nurs*)))
#9	or/6-8
#10	(TI (systematic* n3 review*)) or (AB (systematic* n3 review*)) or (TI (systematic* n3 bibliographic*)) or (AB (systematic* n3 bibliographic*)) or (TI (systematic* n3 literature))

	or (AB (systematic* n3 literature)) or (TI (comprehensive* n3 literature)) or (AB (comprehensive* n3 literature)) or (TI (comprehensive* n3 bibliographic*)) or (AB (comprehensive* n3 bibliographic*)) or (TI (integrative n3 review)) or (AB (integrative n3 review)) or (JN “Cochrane Database of Systematic Reviews”) or (TI (information n2 synthesis)) or (TI (data n2 synthesis)) or (AB (information n2 synthesis)) or (AB (data n2 synthesis)) or (TI (data n2 extract*)) or (AB (data n2 extract*)) or (TI (medline or pubmed or psyclit or cinahl or (psycinfo not “psycinfo database”) or “web of science” or scopus or embase)) or (AB (medline or pubmed or psyclit or cinahl or (psycinfo not “psycinfo database”) or “web of science” or scopus or embase)) or (MH “Systematic Review”) or (MH “Meta Analysis”) or (TI (meta-analy* or metaanaly*)) or (AB (meta-analy* or metaanaly*))
#11	(MH "Case Control Studies+") or (MH "Control Group") or (MH "Matched-Pair Analysis") or (TI (case or cases) n5 TI (control or controls)) OR (AB (case or cases) n5 AB (control or controls)) OR (TI (case or cases) n3 TI (matched)) OR (AB (case or cases) n3 AB (matched)) OR TI (control group*)
#12	MH Prospective studies OR MH case control studies OR MH Correlational studies OR MH Nonconcurrent prospective studies OR MH Cross sectional studies OR ((cohort and (study or studies)) OR ((observational and (study or studies)))
#13	MH Clinical Trials OR PT Clinical trial OR TX clinic* n1 trial OR (TX ((singl* n1 blind*) or (singl* n1 mask*)) or TX ((doubl* n1 blind*) or (doubl* n1 mask*)) or TX ((tripl* n1 blind*) or (tripl* n1 mask*)) or TX ((trebl* n1 blind*) or (trebl* n1 mask*))) OR TX randomi* control* trial* OR MH Random Assignment OR TX random* allocat* OR TX placebo* OR MH Placebos OR MH Quantitative Studies OR TX allocat* random*
#14	or/10-13
#15	5 and 9 and 14 (Limiters - Published Date: 20000101-20151130; Exclude MEDLINE records; Human; Age Groups: All Adult; Language: English)

A5. Clinical Guidelines

While we did not identify any clinical guidelines specific to outpatient palliative care, a number of professional societies provide guidelines on palliative care generally (in all settings). Guidelines outlined below were identified through a web search as well as through conversations with key informants. Disease specific guidelines related to provision of palliative were also identified and are listed at the end of this section. Please note, this list is not intended to be exhaustive.

National Consensus Project (2013)

http://www.nationalconsensusproject.org/Guidelines_Download2.aspx

Guidelines written by the National Consensus Project for Quality Palliative Care include the consensus views of key professional organizations including:

- American Academy of Hospice and Palliative Medicine
- Center to Advance Palliative Care
- Hospice and Palliative Nurses Association
- National Hospice and Palliative Care Organization
- National Association of Social Workers
- National Palliative Care Research Center

The guidelines separate recommendations into eight domains, each addressing a distinct aspect of palliative care. The eight domains include:

- **Domain 1:** Structure and Process of Care
- **Domain 2:** Physical Aspects of Care
- **Domain 3:** Psychological and Psychiatric Aspects of Care
- **Domain 4:** Social Aspects of Care
- **Domain 5:** Spiritual, Religious, and Existential Aspects of Care
- **Domain 6:** Cultural Aspects of Care
- **Domain 7:** Care of the Patient at the End of Life
- **Domain 8:** Ethical and Legal Aspects of Care

After reviewing the features of each domain, we have combined domains that share similar recommended considerations related to aspects of care. The combined domains include Psychological, Social, Spiritual, Legal, Ethical, and Cultural Aspects of Care to summarize characteristics.

Structure and Process of Care: This domain makes recommendations related to care teams, care plans, and quality assessment. According to the guidelines, an interdisciplinary team should assess each patient and develop a care plan based on the patient and family's specific goals and values. The plan should evolve as patient needs or goals change. The physical environment of care should meet the preferences and needs of the patient and family as much as possible. Quality improvement should involve a documented, data-driven process focused on making care safer,

ensuring that each person and family is engaged in care, promoting coordination, ensuring use of the most effective treatment practices, and increasing affordability.

Physical Aspects of Care: Guidelines in this domain recommend that management of pain and other symptoms be based on the best available evidence and that assessment and management be delivered in accordance with the status of the disease. Treatment for physical symptoms should be based on the disease, prognosis, and patient's functional limitations.

Psychological, Social, Spiritual, Legal, Ethical, and Cultural Aspects of Care: Guidelines within these domains recommend that these factors are considered in developing and executing a care plan.

End of Life: This domain related specifically to care at the end of life.

Institute for Clinical Systems Improvement (2013)

https://www.icsi.org/_asset/k056ab/PalliativeCare.pdf

ICSI recommends that palliative care discussions begin soon after a patient's diagnosis with a serious illness, especially in cases where there are complex needs. Primary care clinicians should have palliative care conversations with patients to encourage early planning. Providers should complete a systematic assessment of patients' palliative care needs and document goals and advance directives. The assessment should consider physical as well as cultural, psychological, social, spiritual, financial, ethical, and legal factors, and palliative care should seek to manage all of these areas when possible. Patients and families should be engaged in decisions about care, including setting of realistic goals. Palliative care should be compatible with any other medical treatments being administered.

American Academy of Family Physicians (2006)

http://www.aafp.org/afp/2006/0315/p1104.html

AAFP guidelines address recommendations for the care team as well as for the care plan. Care teams should be skilled in communication to establish the goals of the patient and family and should collaborate with professionals across all health care systems to ensure coordination. The team should include individuals with specialist-level skill in physical, social, psychological, spiritual, and legal aspects of medical care. Support and education should be available for the team, as well as the patient and family. Community-based health resources should be incorporated when appropriate to aid in continuity of care. A patient's care plan should be based on assessment of the goals of the patient and family and should be regularly reviewed and adapted to changing needs and preferences. All treatment decisions should be made in line with the goals of the care plan, with a focus on management of pain and other symptoms, and should incorporate pharmacologic

treatments as well as nonpharmacological and complementary therapies. When possible, the setting of care should be based on the preferences of the patient and family.

The option of hospice referral should be introduced as the patient's health declines, and end-of-life concerns, hopes, fears, and expectations should be discussed openly. Following death, bereavement support should be offered to the family for at least 12 months.

Other Organizations

A number of other organizations have developed guidelines for palliative care relevant to specific disease areas. These guidelines include (but are not limited to):

- Joint Guidance by the American Society of Clinical Oncology and the American Academy of Hospice and Palliative Medicine
- The National Comprehensive Cancer Network
- The American Thoracic Society
- The American College of Chest Physicians
- The American Society for Radiation Oncology

A6. Previous Systematic Reviews

We identified nine systematic reviews which examined the effectiveness of outpatient or home-based palliative or end-of-life care on various patient and caregiver outcomes and utilization indicators. These reviews are summarized by population type in the sections below. We also looked for reviews conducted by other national and international HTA organizations, but did not find any that specifically evaluated palliative care in outpatient or home-based settings.

Life-limiting and Advanced Illnesses

Luckett 2013

Luckett et al. is a systematic review and meta-analysis comparing community specialist palliative care services (SPCSs) offering home nursing to no SPCSs in patients with life-limiting illnesses. Meta-analysis of all nine studies indicated a significantly higher rate of home death for SPCSs with home nursing (odds ratio 4.45, 95% CI 3.24-6.11; p<0.001); two high-quality RCTs found no effect, however. Among the two studies measuring symptom/QoL and five studies measuring cost, one study reported a significant effect on symptom control in favor of SPCSs and three studies reported significantly lower cost in SPCSs, while the others found no effect.

Gomes 2013

A Cochrane systematic review of 23 studies (16 RCTs), including 37,561 participants and 4,042 family caregivers, examined the clinical effectiveness and cost-effectiveness of home palliative care services for adults with advanced illness and their caregivers. Meta-analysis showed a higher rate of dying at home in patients receiving home palliative care compared to usual care (OR 2.21, 95% CI 1.31 to 3.71; p=0.003 [7 trials; n=1222]). There was a small but statistically significant beneficial effect of home palliative care on reducing symptom burden. Evidence was conflicting on patients' experience of pain, breathlessness and sleep disturbance, caregiver burden, and patient and caregiver satisfaction. Moderate evidence showed no statistically significant effect on nausea/vomiting, constipation, diarrhea, fatigue and appetite loss. Evidence on cost-effectiveness was inconclusive.

Thomas 2006

Thomas and colleagues evaluated 23 RCTs about care at the end of life, one of the themes being the effect of providing palliative care through dedicated community teams on quality of life, management of symptoms, satisfaction of care, duration of palliation period, and place of death. A high risk of bias was detected in most of the included RCTs, and conflicting results were found for all outcomes of interest. Six studies found some improvement in ratings of quality of life and perceived management of symptoms, while three RCTs found no improvement in symptoms. In terms of

satisfaction, one study reported higher patient satisfaction in the intervention patients than the controls, one found equal increases in both groups and two found no significant increase in the intervention group over time. Three studies found increased satisfaction of caregivers in the intervention group over time. In addition, one study found hospital-at-home (24-hour home care from nurses for final 2 weeks) did not increase the likelihood of home death and another study found survival time in the palliative care group was shorter but the difference was non-significant, but there was a significantly higher rate of home death ($p=0.02$) and lower rate of dying in nursing homes ($p<0.01$).

Shepperd 2011

A systematic review included four RCTs about end-of life care at home evaluating death at home, functional status, psychological well-being or cognitive status, admission to hospital, and patient satisfaction. The authors found patients receiving home-based end of life care were statistically significantly more likely to die at home (RR 1.33, 95% CI 1.14 to 1.55, $p=0.0002$ [3 trials; n=652]) than those receiving usual care. But there was no statistically significant difference for any other outcome of interest.

HIV/AIDS

Harding 2005

Harding and colleagues identified 17 studies evaluating 22 programs of home and inpatient palliative care on patient outcomes in patients with HIV/AIDS; the results were synthesized by evidence grade (grade 1-4: strong, fairly strong, weaker, and weak, and qualitative). Only those results for outcomes associated with home palliative care are summarized here. An RCT (n=57) provided strong evidence (grade 1) that integrated multi-professional case managed home care showed a possible advantage in quality of wellbeing and survival over usual home care, but this difference did not reach statistical significance. A small observational study (n=42) provided fairly strong evidence (grade 2) that patients accessing home palliative care in addition to hospital care were not statistically different in Quality of Wellbeing Scale but had lower hospital admissions and reduced length of hospital stays compared to patients attending hospital care only. They found mixed results from five studies providing weaker evidence (grade 3) in terms of symptom and pain control. Additionally, a cross-sectional study provided weak evidence that patients (n=52) accessing HIV home care reported higher satisfaction, more control over care and communication, and more frequent contact with staff while perceived health status remained unchanged. Qualitative data from interviews with patients receiving home care reported less disturbance of daily routine, fewer hospital visits, higher satisfaction, and better quality of care, but some reported anxiety and fear induced by home care and poor communication.) of cancer patients using home-based palliative care services

Caregivers

Harding 2003

The authors reviewed interventions for carers, including family members. They identified 22 relevant studies that included/targeted carers, of which six interventions were included for evaluation, including home care, respite care provision, social networks and activities, and individual- and group-based sessions. Rigorous evaluation of interventions was rare, with only two (quasi-) experimental evaluations identified in this review. An RCT found that one-to-one intervention had no impact on emotional, social or physical function, while another RCT evaluating the effect of a stress and activity management group found that attendees improved knowledge scores, achieved activity goals, coped better with medical situation, and were more satisfied with care. The authors called for development and evaluation of targeted interventions for palliative care carers.

Candy 2011

A Cochrane systematic review evaluated the effect of supportive interventions to improve the psychological and physical health of informal caregivers of patients with terminal illnesses. The 11 RCTs included in this review involved 1,836 caregivers. There was low quality evidence that interventions directly supporting caregivers significantly reduced psychological distress in short term (SMD -0.15, 95% CI -0.28 to -0.02), but effects on coping skills and quality of life were not statistically significant. Evidence was less clear on the indirect interventions: two trials found that interventions that provided support to the patient reduced caregiver psychological distress but none of the assessments were statistically significant. Another trial found no difference between trial arms in the proportion of caregivers reporting good physical health.

Not Specified

Finlay 2002

In a systematic review of palliative care in the hospital, hospice, and at home, the authors identified 22 studies examining home care services, most of which were classified as grade III evidence indicating poor quality. In general, the outcomes were in favor of home care services, showing improved satisfaction and pain symptom control in home care services compared with conventional care. All studies that considered costs suggest lower cost for the home care group. Taken together, the authors suggested that home care is cost-effective.

Davis 2015

A systematic review of outpatient and home palliative care for patients with serious illnesses including 15 RCTs of outpatient palliative care and 13 RCTs of palliative home care. While some trials demonstrated advantages of palliative care over usual care, including improved depressive symptoms and patient quality of life; reduced aggressive care at the end of life; increased advanced directives; reduced hospital length of stay and hospitalization; improved caregiver burden and quality of life; reduced medical cost; and patient and family satisfaction. Thus, the authors concluded that evidence on the benefits of palliative care was mixed due to methodological issues and suggested that better designed and executed studies be conducted.

A7. Ongoing Studies

Title/ Trial Sponsor	Study Design	Comparators	Patient Population	Primary Outcomes	Estimated Completion Date
Does Outpatient Palliative Care Improve Patient-centered Outcomes in Parkinson's Disease? NCT02533921	RCT	Standard of care Interdisciplinary outpatient palliative care	N=300 Age 40 years and older Inclusion Criteria: • Fluent in English • UK Brain Bank criteria for diagnosis of probable PD • At high risk for poor outcomes as identified by the Palliative Care Needs Assessment Tool (PC-NAT) Exclusion Criteria: • Immediate and urgent palliative care needs • Unable or unwilling to commit to study procedures including; a. randomization, b. study visits or c. the addition of a neurologist to their care team • Presence of additional chronic medical illnesses which may require palliative services • Already receiving palliative care and/or hospice services.	Changes in the Subjects Quality of Life (QOL) at 6 months Changes in caregiver distress at 6 months	September 2018
Randomized Study of Early Palliative Care Integrated With Standard Oncology Care Versus Standard Oncology Care Alone in Patients With Incurable Lung or Non-Colorectal	RCT	Early palliative care and standard oncology care Standard oncology care	N=700 Age 18 years and older Study Patient Participant Eligibility Requirements: • Documentation of Disease: Confirmed advanced lung cancer (NSCLC, small cell lung cancer, or mesothelioma) or non-colorectal GI cancer (esophageal, gastric, hepatic, biliary, or pancreatic) not being treated with curative intent.	Change in FACT-G scores from baseline to 12 weeks	November 2016

Title/ Trial Sponsor	Study Design	Comparators	Patient Population	Primary Outcomes	Estimated Completion Date
Gastrointestinal Malignancies NCT02349412			• Diagnosed with incurable disease within the previous 8 weeks. • Age ≥ 18 years • ECOG Performance Status 0-2 • Ability to read and respond to questions in English or able to complete questions with minimal assistance required from an interpreter or family member. • Planning to receive all medical care for cancer at the enrolling institution. • Participants must be under the care of an oncologist, but their current plan may or may not include chemotherapy or other forms of tumor-directed therapies. Study Family Caregiver Participant Eligibility Requirements: • Relative or friend who is identified by the patient participant who plans to regularly accompany the patient to the majority of their clinic visits. • Family caregiver must live with the patient or have in-person contact with him or her at least twice per week. • Ability to read and respond to questions in English or able to complete questions with minimal assistance required from an interpreter or family member. • Age ≥ 18 years Note: An eligible patient may participate in this trial without an eligible family caregiver being registered.		
Clustered, Randomized, Controlled Trial of the Home Care Nurse Carer Support Needs Assessment Practice Tool With Family Caregivers	RCT	Active Comparator: Existing Home Care Nursing Practice	N=476 Age 18 years and older Inclusion Criteria: For home care nurse participants: • registered or licensed home care nurse at one of the following Vancouver Island Health Authority Home and Community Care	Trajectory of change in family caregiver quality of life while caring for a palliative patient at home, as measured by the Quality of Life in Life Threatening Illness - Family carer version	March 2017

Title/ Trial Sponsor	Study Design	Comparators	Patient Population	Primary Outcomes	Estimated Completion Date
of Palliative Patients at Home NCT02261935		Experimental: Practice Support Tool Intervention	offices: Victoria, Esquimalt/Westshore, Peninsula, Royal Oak, Duncan/Ladysmith, Oceanside, Comox Valley, Campbell River • practiced in home care for > 6 months • work a minimum of 10 shifts per month • communicate well in English For family caregiver participants: • currently a family caregiver of palliative patient at home • patient and family caregiver must be 18 years of age or older • must communicate well in English Exclusion Criteria: For family caregiver participants • diagnosed cognitive impairment • identified safety risks in the home care environment	(QOLLTI-F) total score at 8 to 96 weeks Family caregiver grief symptoms after patient death, as measured by the Texas Revised Inventory of Grief (TRIG) subscale scores 12 weeks after patient death	
Collaborative Care to Alleviate Symptoms and Adjust to Illness in Chronic Heart Failure (CASA) Trial NCT01739686	RCT	Collaborative Care to Alleviate Symptoms and Adjust to Illness (CASA) Usual care	N=312 Age 18 years and older Inclusion Criteria: • Age 18 years of age or older • Able to read and understand English • Consistent access to a telephone • Patients have a primary care or other provider who is willing to facilitate intervention medical recommendations • A diagnosis of heart failure with at least one of the following: [hospitalization primarily for heart failure in the year prior (including current); taking at least 20 mg oral furosemide (or equivalent) daily in a single or divided dose; Brain natriuretic peptide(BNP) ≥ 100 or N-	Difference in Kansas City Cardiomyopathy Questionnaire (KCCQ) overall score at 6 months	December 2016

Title/ Trial Sponsor	Study Design	Comparators	Patient Population	Primary Outcomes	Estimated Completion Date
			terminal prohormone of brain natriuretic peptide(NT-proBNP) ≥ 500; EF≤40%] • Report a low health status (KCCQ-SF≤70) • Bothered by at least one target symptom: [Pain; Depression; Fatigue; Breathlessness] Exclusion Criteria: • Previous diagnosis of dementia • Active substance abuse or dependence, defined by either a diagnosis of abuse or dependence or an AUDIT-C ≥ 8, or self-reported substance abuse in the past 3 months • Comorbid metastatic cancer • Nursing home resident • Heart Transplant recipient • LVAD recipient		
Randomized Study of Early Palliative Care Integrated With Standard Oncology Care Versus Standard Oncology Care Alone in Patients With Advanced Lung and Non-colorectal Gastrointestinal Malignancies	RCT	Early palliative care Standard of care	N=350 Age 18 years and older Inclusion Criteria: • Confirmed metastatic lung cancer (NSCLC, small cell lung cancer, and mesothelioma)or non-colorectal GI cancer (esophageal, gastric and hepatobiliary) not being treated with curative intent • Informed of metastatic disease within the previous 8 weeks • No prior therapy for metastatic disease • Able to read questions in English or willing to complete questionnaires with the assistance of an interpreter • Relative or friend of patient who will likely accompany the patient to clinic visits	Change in Functional Assessment of Cancer Therapy (Quality of life measure) at 12 weeks	April 2018

Title/ Trial Sponsor	Study Design	Comparators	Patient Population	Primary Outcomes	Estimated Completion Date
NCT01401907			Exclusion Criteria: • Significant psychiatric or other co-morbid disease		
SmartCare: Innovations in Caregiving Interventions NCT02058745	RCT	CAU+(Enhanced Care as Usual) CAU+ and SmartCare (online symptom management intervention for caregivers) Enhanced Care as Usual and SmartCare and Beating Blue (online therapy for depressive symptom)	N=420 Age 21 years and older Inclusion Criteria: Care recipient: • Over 21 years of age. • Newly (within 1 month) diagnosed with a PMBT (tumor verified via pathology report to be a glioblastoma multiforme, anaplastic astrocytoma, anaplastic oligodendroglioma, anaplastic oligoastrocytoma, medulloblastoma, or anaplastic ependymoma). Caregiver: • Primary nonprofessional, non-paid caregiver, as identified by the care recipient. • Over 21 years of age with telephone access. • Reads-speaks English • Obtains a score of >6 on the shortened CES-D. • Caregivers may or may not be receiving pharmacotherapy for depressive symptoms Exclusion Criteria: Caregiver: • Currently considers self to be a primary caregiver for anyone else other than children • Currently receiving any type of formal counselling for depressive symptoms	Change in depression from baseline at 4 months on the shortened CES-D	June 2017

A8. Evidence Tables

Author & Year	Study Quality	Study Design	Interventions (sample size)	Mean/Median Duration of Follow-up	Inclusion and Exclusion Criteria	Patient Characteristics	Outcomes
Aiken 2006	Poor	RCT	PC group (100) -MCO medical treatment for disease plus PC including: -Symptom self-management and education -Advance care planning -Interdisciplinary care coordination and management -Assessment of psychological, spiritual, and emotional needs of the patient and family Control group (90) -MCO medical treatment for disease -Occasional home visits provided by some MCOs -Individual case management to some patients *PhoenixCare Demo*	NR Outcomes presented every 12 weeks up to 36 weeks	Patients ≥18 years with COPD or CHF (class 3b or 4) with an estimated 2-year life expectancy and marked limitation of physical functioning and recent (<3 months) exacerbation of symptoms	Age: 68.5 % female: 64% Indications: COPD, CHF	**PC group, *Patient*** *QoL:* SF36, physical function (based on 100pt scale)-Slope over 9 months CHF: 0.18 COPD: 1.00 SF36, general health (based on 100pt scale)- Slope over 9 months CHF: 0.16 COPD: 0.54 ***Control group, Patient*** *QoL:* SF36, physical function (based on 100pt scale)- Slope over 9 months CHF: -1.39 COPD: -0.95 SF36, general health (based on 100pt scale)- Slope over 9 months CHF: -0.17 COPD: -1.67 Overall control slope is declining while overall PhoenixCare slope is rising (for physical function, p <0.05) or remains stable (for general health, p<0.05)

							There were no statistically significant between-group differences in symptom severity at 6 months or health resource utilization (ED visits) Patients with COPD showed stronger responsiveness to the intervention.
Bakitas 2009	Good	RCT	PC group (161) -Case management -Patient education - Symptom self-management and education -Advance care management -Phone-based format in rural populations -Problem-solving -Monthly medical appointments with caregivers -PC-certified nurse practitioner Control group (161) -All oncology and supportive services without restrictions -Referral to the institutions' interdisciplinary palliative care service *Project ENABLE*	58.4 weeks Monthly follow-up until death or study completion	Newly diagnosed (8-12 weeks) patients with advanced gastrointestinal, lung, genitourinary, or breast cancer Patients with impaired cognition, a psychiatric disorder, or active substance use were excluded	Age: 65.0 % female: 42.0 Indications: Advanced cancer	*QoL:* FACIT-Pal 184pt Scale difference in change scores 4.6, p=0.02(higher QoL in the intervention group) *Psycholgical distress/depression:* *CES-D 60pt Scale difference in change scores* -1.8, p=0.02 (lower depression mood in the intervention group) PC better than control *1-year Survival* HR=0.67 (95% CI, 0.50-0.91, p=0.009) There were no statistically significant between-group differences in health resource utilization, symptom severity, or survival rate (post-hoc*)*
Bakitas 2015	Fair	RCT	PC group (104) -In-person PC consultation	NR	Adults (≥18 years) with advanced-stage solid tumor or	Age: 64.3 % female: 52.7	**PC group, *Patient*** *Survial rate:* 63%

			-Structured PC telehealth nurse coaching sessions - Problem solving -Symptom management -Symptom management -Self-care -Advance care planning Control group (103) -Symptom control treatments -Consultation with oncology and supportive care specialists, including a clinical PC team (provided when requested) Early vs. delayed (3 months) palliative oncology care	Follow-up every 6 weeks until 24 weeks then every 12 weeks until death	Hematologic malignancy, oncologist-determined prognosis of 6 to 24 months Exclusions included impaired cognition, psychiatric or substance use disorder, uncorrectable hearing disorder, or unreliable telephone service.	Indications: Advanced cancer	**Control group, *Patient*** *Survial rate:* 48% PC > control *Survial rate:* p=0.038 at 1 year There were no statistically significant between-group differences in s*ymptom severity, QOL, psychological distress, resource utilization (ICU days, hospital days, ED visits), overall median survival, or location of death (home)*
Brumley 2003	Good	prospective comparative cohort Matched groups? ☐ Deceased subgroup was selected in order to attempt to control for baseline differences	PC group (161) -Interdisciplinary team-based approach, including the patient and family members plus a physician, nurse, and social worker with expertise in symptom management and biopsychosocial intervention	NR 60-day follow-up interval	PC group- Kaiser Permanente members presenting with a life-threatening disease (primarily COPD, CHF, or cancer) and a prognosis of approximately 1 year or less to live	Age: 60.0 % female: 53.0 Indications: CHF 27.4% COPD 18.3% Cancer 50.8% Palliative care group members were more likely to be married,	**PC group, *Patient*** *Health resource utilization:* Physician visits: 5.3 Hospital visits: 2.4 ED visits: 0.9 Skilled nursing care visits: 0.9 Total home health visits: 35.0 *Location of Death:* % died at home: nearly 90% **Control group, *Patient*** *Health resource utilization:*

			-Patient and family education medication use, and self-management -24-hour telephone support Control group (139) -Various amounts and levels of home health services, acute care services, primary care services and hospice care		Control group-Kaiser Permanente members presenting with a life-threatening disease (primarily COPD, CHF, or cancer) and a prognosis of approximately 24 months or less to live	not have CHF, have fewer days on service, and to be sicker as determined by a lower score on the PPS (0-death, 100-normal)	Physician visits: 11.1 Hospital visits: 9.4 ED visits: 2.3 Skilled nursing care visits: 4.6 Total home health visits: 13.2 *Location of Death:* % died at home: 57% PC better than control (based on reduced resource utilization) Physician visits: p=0.001 Hospital visits: p<0.001 ED visits: p<0.001 Skilled nursing care visits: p=0.005 Resource utilization analysis included physician, hospital, ED, and skilled nursing visits controlled for days on service, CHF diagnosis, and severity of illness as covariates using MANCOVA Patient satisfaction improved significantly in the PC group and stayed the same in the control group based on the Reid-Gundlach Satisfaction with Services instrument but these differences were not compared statistically
Brumley 2007	Fair	RCT	PC group (145) -Pain control and other symptom management	PC group: 196 days Control group: 242 days	Patients with a primary diagnosis of CHF, COPD, or cancer and a life	Age: 73.8 % female: 73.2 Indications: Cancer 46.6%	**PC group, *Patient Satisfaction:*** 93.4% at 90 days *Health resource utilization:* ED visits: 20%

			-Pain control and other symptom management -Palliative care physician who coordinates care from a variety of health care providers -Educations focus on identifying goals of care and the expected course of the disease Control group (152) -Various amounts and levels of home health services, acute care services, primary care services, and hospice care	Outcomes measured every 30 days up to 90 days (outcomes at 120 days were excluded due to sample attrition)	expectancy of 12 months or less, have visited the emergency department or hospital at least once within the previous year; and scored 70% or less on the PPS (0-death, 100-normal)	CHF 32.5% COPD 30.8% Only those analyzed, not ITT	Hospitalizations: 36% *Location of Death:* Home death: 71% **Control group, *Patient*** *Satisfaction:* 33% at 90 days *Health resource utilization:* ED visits: 33% at 90 days Hospitalizations: 59% *Location of Death:* Home death: 51% PC better than control *Satisfaction:* OR=3.37 (95% CI: 0.65-4.96, p=0.003) *Health resource utilization:* ED visits- p=0.01; Cramer's V=0.15 Hospitalizations- p<0.001; Cramer's V =0.23 (no significant changes in services use after adjusting for survival, age, and severity of illness) *Location of Death:*home death (after controlling for age, survival time, and medical conditions): OR=2.20, (95% CI: 1.3–3.7, p<0.001)
Cheville 2010	Fair	RCT Secondary Analysis of Rummans 2006	PC group (49) - Physical therapy with educational components -A psychiatrist or psychologist with co-facilitation provided	NR Outcomes assessed at week 4, 8, and 27	Adult patients undergoing radiation therapy for advanced cancer with prognoses ≥6 months and 5-year survival estimates ≤50% and no evidence of	Age: 59.5 % female: 35.9 Indications: (tumor type) GI 37.9% Head and neck 17.5% Lung 14.6%	**PC group, *Patient*** *QoL:* LASA physical well-being change score at week 4: +0.4 **Control group, *Patient*** *QoL:*

			by an advanced practice nurse, licensed social worker, or certified hospital chaplain -Goal settings and coping strategies Control group (54) -Regular assessments for treatment toxicities and weight loss by an advanced practice nurse or radiation oncologist		alcohol or nontobacco substance dependence Patients with recurrent disease following a 6-month disease-free interval were excluded	Brain 11.6% Other 18.4%	LASA physical well-being change score at week 4: -10.0 PC better than control at week 4, p=0.02 Fatigue and vigor (on POM) were not significantly different between the groups and all intergroup differences were no longer significant at 8 and 27 weeks
Ciemins 2006	Fair	retrospective comparative cohort Matched groups? ☒ Patients in the Usual Care cohorts were matched to the AIM cohort on selected symptoms and prognosis	PC group (140) -Patients and families not ready for hospice but eligible for home care -Disease process education, symptom management, goal clarification, advance care planning and contingency planning -Pain and symptom management Control group 1 (68) - Standard home health services, without the programmatic focus on palliative care Control group 2 (227) - Same as Control 1	NR	Adult patients with life expectancy of 6 months or less and two of the following: 1) Diagnosis of advanced cancer, advanced CHF, end-stage pulmonary disease, end-stage hepatic disease, end-stage neurologic disease, other end-stage medical diagnosis, or advanced debility and decline 2) Failing or reduced effectiveness of non-palliative treatment of primary disease process 3) Decline in functional status and/or nutritional status in past 30 days.	Age: (based on groups) <65, 16.6% 65-75, 17.5% 76-86, 32.5% >85, 33.5% % female: 62.6 Significant differences for some characteristics, e.g., life expectancy of 6 months, gender, race, primary caregiver *No differences between groups at baseline for pain, breathlessness, depression or anxiety*	**PC group, *Patient*** *Health resource utilization:* Discharge to hospice: 47% **Control group, *Patient*** *Health resource utilization:* Discharge to hospice: Control group 1: 33% Control group 2: 16% PC better than control group 1: p=0.003 group 2: p<0.0001 AIM was particularly effective in African Americans for referral to hospice

			PC group vs. Control 1: patients from the same home health site Control 2 patients were drawn from another site (demographic-ally similar but without an AIM program)				
Dionne-Odom 2015	Good	RCT Secondary Analysis of Bakitas 2015	PC group (61) -See Bakitas 2015 -Patients and CGs each were assigned a different nurse coach Control group (61) -Same as PC group but received the intervention 3 months later Early vs. delayed (3 months) palliative oncology care	NR Minimum follow-up time was 24 weeks or until patient death if it occurred during that period. Not all caregivers were followed beyond the initial 24-week period.	Patients >18 years; new diagnosis, recurrence, or progression of an advanced-stage cancer within approximately 30 to 60 days of the date the patient was informed of the diagnosis by his or her oncology clinician and oncologist-determined prognosis of 6 to 24 months Exclusions included impaired cognition, psychiatric or substance use disorder, uncorrectable hearing disorder, or unreliable telephone service.	Age: 60 % female: 78.7 Indications: Advanced cancer The early group had a higher proportion employed, fewer retired, and fewer unemployed (p=0.05).	**PC group, *Caregiver*** *Psycholgical distress/depression:* Change in CESD Score for depression from enrollment to 3 months: -3.2 **Control group, *Caregiver*** *Psycholgical distress/depression:* Change in CESD Score for depression from enrollment to 3 months: -1.8 PC better than control mean between group difference in change from baseline (change represents average follow-up minus baseline), -3.4; SE, 1.5; d=-0.32; p=0.02 *There were no statistically significant differences in QOL or burden subscale*

Greer 2012	Fair	RCT Secondary Analysis of Temel 2010	PC group (n=77) -At least monthly consults with a PC team member implementing National Consensus Project for Quality Palliative Care guidelines -Routine oncology care Control group (n=74) -Routine oncology care -Palliative care upon request	18 months	Patients receiving treatment at MGH for metastatic NSCLC diagnosed in previous 8 weeks, ECOG PS 0-2	Age: 64.9 % female: 52 % Caucasian: 97 % Hispanic: 1.3 % Married: 62 Indications: Non-small cell lung cancer	**PC group, *Patient*** *Chemotherapy* *Within 60 days of death*: PC: 52.5% *Days between last IV chemo and death*: PC: median 64, mean 100.6, SD 89.6 *Hospice received >7 days before death*: PC: 60% **Control group, *Patient*** *Chemotherapy* *Within 60 days of death*: Control: 70.1% *Days between last IV chemo and death*: Control: median 40.5, mean 75.5, SD 42.6 *Hospice received >7 days before death*: 33.3% PC better than control (based on reduced resource utilization) *Chemotherapy* *Within 60 days of death*: p=0.05 *Days between last IV chemo and death*: p=0.02 *Hospice received >7 days before death*: p=0.004

							There was no statistically significant between-group difference in death at home
Keefe 2005	Poor	RCT Matched groups? ☐	PC group (41) - Three pain management training sessions with patient and partner at home - Patient and partner education about cancer pain and its management - Patient and partner education about a variety of pain coping strategies - Partner education about how to help the patient acquire and maintain coping skills Control group (37) - usual care through their medical outpatient or hospice program	1 week Mean 7.56 days, range 0 to 31 days	Inclusion criteria: Advanced cancer diagnosis (i.e., metastatic or disseminated disease) with disease-related pain, a worst pain rating>3 on the Brief Pain Inventory, a life expectancy of less than six months, no change in disease treatment planned, and over 18 years of age. All patients met the Medicare hospice benefit definition for hospice eligibility, i.e., a prognosis of six months or less.	Patient Age: 60.5 % female: 44 % white: 78 Partner Age: 58.5 % female: 62 % white: 79 Indications: advanced cancer	**PC group** **Caregiver** Other: a caregiver version of the Chronic Pain Self-Efficacy Scale, mean: pain: baseline: 53.2 post-tx: 62.6 Other symptoms (Self-Efficacy for Other Symptoms Scales): baseline: 63.4 post-tx: 68.8 **Control group** **Caregiver** Other: a caregiver version of the Chronic Pain Self-Efficacy Scale, mean: pain: baseline: 44.1 post-tx: 39.6 other symptoms: baseline: 61.0 post-tx: 52.5 PC better than control Other: a caregiver version of the Chronic Pain Self-Efficacy Scale, mean: pain: p=0.006 other symptoms: p=0.012 *There were no statistically significant between-group differences in patient QOL or*

							pain or caregiver strain or caregiver mood
Lindell 2010	Poor	RCT Matched groups? ☐	PC group (10) -Group sessions discussing cognitive behavior techniques -Care planning -Symptom management Control group (11) -Usual care: seen by clinical team of nurse specialist and physicians -Psychological counseling if indicated *counted as patient/care giver dyads	6 weeks	Patients were required 1) to be aged more than 21 years; 2) to be able to read and understand English; 3) to be diagnosed with IPF; and 4) to have an FVC reflecting moderate (FVC 55%-70% predicted) or severe (FVC < 55% predicted) disease. Care partners were required 1) to be aged more than 21 years; 2) to be able to read and understand English; and 3) to live with or care for the patient with IPF.	Patient Age: 66 %Female: 34 % Caucasian: 95 Caregiver Age: 65 %Female: 76 % Caucasian: 95 Indications: Idiopathic pulmonary fibrosis ANCOVA used to control for significant differences at baseline	**PC group** ***Patient*** QoL: Health-related quality of life (HRQoL) measured by SF-36 v2-physical: 31.06 ***Caregiver*** Psycholgical distress/depression: Stress measured by Perceived Stress Scale: 17.61 **PC group** ***Patient*** QoL: Health-related quality of life (HRQoL) measured by SF-36 v2-physical: 36.04 ***Caregiver*** Psycholgical distress/depression: Stress measured by Perceived Stress Scale: 20.99 PC worse than control Patient QoL: p=0.038 Caregiver stress: p=0.018 *There were no statistically significant between-group differences in patient symptom severity or patient anxiety or patient depression*

							or caregiver QoL or caregiver anxiety or caregiver depression
McMillan 2006	Poor	RCT Matched groups? ☐	PC group (111) Caregiver training on -Creativity: to view problems from different perspectives and develop strategies to solve problems -Optimism: to have a positive but realistic attitude -Planning: to set reasonable caregiving goals and steps to reach goals -Expert information: knowledge about the nature of problems and symptom assessment -Standard hospice care Control group I(109) -Standard hospice care Control group II (109) -Standard hospice care - three supportive visits providing individual support to caregivers, discussing feelings, fear and relationship	4 weeks 30 days follow-up	Inclusion Criteria: caregivers had to be providing care for adult patients with cancer, and both had to consent to participate, have at least a sixth grade education, be able to read and understand English, and achieve a minimum score of seven on the Short Portable Mental Status Questionnaire. Exclusion criteria: caregivers were in active treatment for cancer themselves. Primary caregivers were identified by the hospice, and dyads were excluded if it was unclear who the primary caregiver would be or if patient performance status suggested that patients would not survive more than a few days.	Caregiver Age: 61.5 %Female: 85.5 Patient Age: 70.7 %Female: 40.0 Indications: Advanced cancer	***Caregiver*** QoL: Caregiver Quality of Life Index-Cancer (CQOL-C) 0.096, p=0.042 Psycholgical distress/depression: Burden of cancer symptoms measured by Memorial Symptom Assessment Scale (MSAS): -0.14, p<0.001 Other: Caregiver Demands Scale (CDS): 0.01, p=0.033 *Only comparison between intervention and standard care control were presented. Statistics are Estimate of Group*Time Interaction and p-values from Random effects model *There was no statistically significant between-group difference in* general caregiver mastery

Meyers 2004	Poor	prospective comparative cohort Matched groups? ☐	PC group (44) -Nurse focused on chemo toxicity and symptom management and care coordination -Social worker focused on emotional support, family and interpersonal issues and end of life planning -Services provided in patients' homes -Investigational therapy trials Control group (20) -Standard supportive care -Investigational therapy trials UC-Davis Cancer Center	NR Patients were traced until death	All patients entered onto a University of California Davis Phase I or Phase II cancer investigational therapy protocol were considered eligible for Simultaneous Care protocol entry. Randomized Phase III studies were allowed if they compared different chemotherapy regimens for advanced disease.	Age: median 62 in PC, 57 in usual %Female: 45 Indications: Advanced cancer	**PC group** ***Patient*** Health resource utilization: % entering hospice in those who died: 92 **Control group** ***Patient*** Health resource utilization: % entering hospice in those who died: 53 *PC > control* Health resource utilization: p=0.034 *There were no statistically significant between-group differences in* patient QoL or cycles of chemo or days in hospice
Rabow 2004	Fair	RCT Cluster RCT Matched groups? ☐	PC group (50) -Consultation with PCPs based on assessments conducted by social works -Symptom management -Case management -Family caregiver training and support -Chart review of medication	52 weeks Questionnaires at enrollment, 6 months and 12 months, patients who completed all three were analyzed	Inclusion criteria: Physicians in both practice modules were invited to refer adult patients with diagnoses of cancer, advanced COPD, or advanced CHF, whom they believed had a life expectancy of 1 to 5 years and who were not yet ready for	Age: 68.6 %Female: 64 % White: 53 % live alone: 43 Indications: Cancer, advanced COPD, advanced CHF	**PC group** ***Patient*** Psycholgical distress/depression: Anxiety (Profile of Mood States) At 6 months: 6.8 At 12 months: 5.3 Symptom severity: Dyspnea (UCSD Shortness of Breath Q-degree dyspnea interferes): At 6 months: 32.6 At 12 months: 32.6

			-Spiritual and psychological support -Support groups discussion symptom management and care planning -Telephone support and advocacy Control group (40) -Usual primary care		hospice care. Exclusion criteria: Patients with non-melanoma skin cancers, dementia, or psychosis; those enrolled in hospice care; and those unable to complete a written survey in English or Spanish.		Other: Sleep quality (6 items from Medical Outcomes Study): At 6 months: 11.9 At 12 months: 12.5 Spiritual well-being Scale (overall): At 6 months: 98.0 At 12 months: 105.5 Health resource utilization: Primary care visits: 7.5 Urgent care visits: 0.3 **Control group** ***Patient*** Psycholgical distress/depression: Anxiety (Profile of Mood States) At 6 months: 5.5 At 12 months: 5.9 Symptom severity: Dyspnea (UCSD Shortness of Breath Q-degree dyspnea interferes): At 6 months: 40.3 At 12 months: 40.6 Other: Sleep quality (6 items from Medical Outcomes Study): At 6 months: 10.0 At 12 months: 11.0 Spiritual well-being Scale (overall): At 6 months: 91.2 At 12 months: 92.4 Health resource utilization: Primary care visits: 10.6

							Urgent care visits: 0.6 *means were adjusted for baseline, ANOVA F and p value for Between Groups were presented as following: PC better than control Psycholgical distress/depression: Anxiety (Profile of Mood States) 4.09, p=0.05 Symptom severity: Dyspnea (UCSD Shortness of Breath Q-degree dyspnea interferes): 7.06, p=0.01 Health resource utilization: Primary care visits: p=0.03 Urgent care visits: p=0.04 Other: Sleep quality (6 items from Medical Outcomes Study): 4.05, p=0.05 Spiritual well-being Scale (overall): 8.21, p=0.007 *There were no statistically significant between-group differences in patient depression or patient pain or patient satisfaction or patient QoL or patient survival*
Radwany 2014	Fair	RCT Matched groups? ☐	PC group (40) -Home visit by interdisciplinary team	1 year	Inclusion criteria: All new PASSPORT enrollees > 60 years old who passed a mental	Age: 69.2 %Female: 75 % White: 85	***Patient*** Other: Palliative Care Outcome Scale:

			for assessment and care planning -Symptom management -Psychological support and spiritual need communication and legal support Control group (40) -Usual PASSPORT care Ohio's PASSPORT program (community-based long term care Medicaid waiver program)		status screening and had one of the following: congestive heart failure and being actively treated); chronic obstructive pulmonary disease and on home oxygen; diabetes with renal disease, neuropathy, visual problems, or coronary artery disease; end-stage liver disease or cirrhosis; cancer (active, not history of) except skin cancer; renal disease and actively receiving dialysis; amyotrophic lateral sclerosis with history of aspiration; Parkinson's disease stages 3 and 4; or pulmonary hypertension. Exclusion criteria: Active alcoholics (i.e., those who drink > 2 drinks per day on average) and illegal substance users; clients who have schizophrenia or are psychotic; consumers who could not pass the Mental Status		Mean difference between groups at 12 month: -4.546 (95% CI, -7.853 to -1.238) *There were no statistically significant between-group differences in patient symptom severity or patient anxiety or patient depression or patient QoL or patient survival or health care utilization*

					Questionnaire; consumers who were already enrolled in hospice		
Ranganathan 2013	Good	retrospective comparative cohort Matched groups? ☒ propensity score and the Mahalanobis matching procedure	PC group (392) -Palliative home care staffed by hospice nurses - Biweekly discussion in interdisciplinary team meetings that include the patient's nurse as well as a physician, chaplain, and social worker -Access to a telephone triage line that provides 24-hour access to a hospice nurse Control group (890) -Home care program staffed by home care nurses Penn Homecare and Hospice Services	4 weeks Follow up for 30-day readmission	Inclusion criteria: Patients discharged from one of the three health system hospitals and were admitted to either a home care program or a palliative home care program.	Age: 67 % Female: 51.4 *demographics in PC group, controls were matched Indications: 67.3% cancer diagnosis	**PC group** ***Patient*** Health resource utilization: 30-day readmission (%): 9.1 **Control group** ***Patient*** Health resource utilization: 30-day readmission, n (%): 17.2 PC better than control Mean ATT (the average treatment effect on treated patients) 8.3% (95% CI, 8.0-8.6) *There was no statistically significant between-group difference in mortality*
Rummans 2006	Fair	RCT Matched groups? ☐	PC group (49) -Cognitive intervention -Emotional intervention -Physical intervention -Social intervention -Spiritual intervention	NR Primary outcomes measured at 4 weeks	Inclusion criteria: A diagnosis within the last 12 months, an expected survival time of at least 6 months, a 5-year survival probability of no more than	Age: 59.5 % Female: 36 Indications: Advanced cancer	**PC group** ***Patient*** QoL: Change in Linear Analog Scale of Assessment (LASA) at 4 weeks: 3 Symptom severity:

			Control group (54) -Standard medical care as recommended by their radiation oncologist. -Interactions with their oncologist -Referrals to specialists when indicated -Opportunities for receiving support through a range of outside agencies Mayo Clinic Rochester		50% (as routinely determined by the primary radiation oncologist), and a Treatment recommendation of radiation therapy of at least 2 weeks. Exclusion criteria: Previous radiation therapy, recurrent disease after a disease-free period of greater than 6 months, and a previous cancer diagnosis within 5 years; a Mini Mental Status Examination score of less than 20,an Eastern Cooperative Oncology Group performance score of 3 or more, active alcohol or substance dependence (except nicotine), active thought disorder, or suicidal plans or were participating in another psychosocial research trial; receiving psychotropic medications or counseling		Change in LASA-physical symptom subconstruct at 4 weeks: 0.4 Other: Change in LASA-emotional wellbeing subconstruct at 4 weeks: 2.8 Change in LASA-social wellbeing subconstruct at 4 weeks: 7.0 Change in LASA-legal concerns subconstruct, at 4 weeks: 6.7 **Control group** ***Patient*** QoL: Change in Linear Analog Scale of Assessment (LASA) at 4 weeks: -9 Symptom severity: Change in LASA-physical symptom subconstruct at 4 weeks: -10.0 Change in LASA-emotional wellbeing subconstruct at 4 weeks: -5.4 Change in LASA-social well-being subconstruct at 4 weeks: -5.4 Change in LASA-legal concerns subconstruct, at 4 weeks: -4.7 All scores on 0-100 scale **PC>control**

							QoL: Change in Linear Analog Scale of Assessment (LASA) at 4 weeks: p=0.009 Symptom severity: Change in LASA-physical symptom subconstruct at 4 weeks: p=0.022 Other: Change in LASA-emotional wellbeing subconstruct at 4 weeks: p=0.046 Change in LASA-social well-being subconstruct at 4 weeks: p=0.025 Change in LASA-legal concerns subconstruct, at 4 weeks: p=0.048
Scheffey 2014	Fair	retrospective comparative cohort Matched groups? ☒ matched by age, gender, median income of their zip code, and diagnostic group	PC group (342) -Symptom assessment using a new Edmonton Symptom Assessment System tool -Advance care planning -Discussion about goals of care Control group (1368) - no PC prior to hospice	NR	Inclusion criteria: All patients who died under CC hospice services during the five-year period 2008 to 2012. Exclusion criteria: Patients with a hospice diagnosis of HIV or who were younger than 18 years	Age: 40-54, 17% 55-64, 21% 65-74, 24% 75 and older, 38% % Caucasian not Hispanic: 62 *numbers from PC group, controls were matched Indications: 17% nonmalignant conditions	**PC group** ***Patient*** Health resource utilization: Hospice length of stay (LOS), median (day): 24 **Control group** ***Patient*** Health resource utilization: Hospice length of stay (LOS), median (day): 15 PC>control Difference between group medians: 6 (95% CI, 5-13, p<0.001)

			Capital Caring (CC), a large nonprofit hospice and palliative care organization in the Washington, District of Columbia, area.				
Seow 2014	Good	retrospective comparative cohort Matched groups? ☒ Propensity score based on age at death, sex, comorbidity, cancer dx, hospital/ED use before intervention, then matched by propensity score, region and time, homecare service type and time in homecare	PC group (3109) -Palliative care team to manage symptoms -Provision of education and care -Coordination of services Control group (3109) - no specialist palliative care team available	0.33 years The study duration is 4 months	Exposed Inclusion criteria: Formal palliative care specialist teams that (*a*) provided interdisciplinary, home based, palliative care; (*b*) were the only such team in their respective region; (*c*) had little or no change in staffing between 2009 until 2012; (*d*) had broad admission criteria not limited to one disease (such as cancer); (*e*) admitted more than 50 patients a year; (*f*) were available to patients 24/7; and (*g*) had the same core members of their team as the past randomized trials. Exclusion criteria: Patients who were alive after fiscal year 2011, were <18	Age: median 74 in PC, 75 in control % female: 51.7 Indications: about 80% had cancer and 78% received end of life homecare services (after matching)	**PC group** ***Patient*** Health resource utilization: Being in hospital in the last 2 weeks of life, n (%): 970 (31.2), p<0.001 RR=0.68 (95% CI, 0.61-0.76) Having an emergency department visit in the last 2 weeks of life, n (%): 896 (28.9), p<0.001 RR 0.77 (95% CI, 0.69-0.86) Location of Death: Dying in hospital, n (%): 503 (16.2), p<0.01 RR=0.46 (95% CI, 0.40-0.52) **Control group** ***Patient*** Health resource utilization: Being in hospital in the last 2 weeks of life, n (%): 1219 (39.3) Having an emergency department visit in the last 2 weeks of life, n (%): 1070 (34.5) Location of Death: Dying in hospital, n (%): 887 (28.6) PC better than control Health resource utilization:

					years old, or had an invalid or missing provincial health insurance number. Unexposed were sampled using historical and geographical methods.		Being in hospital in the last 2 weeks of life: RR 0.68 (95% CI, 0.61-0.76) Having an emergency department visit in the last 2 weeks of life: RR 0.77 (95% CI, 0.69-0.86) Location of Death: Dying in hospital: RR 0.46 (95% CI, 0.40-0.52)
Strasser 2014	Poor	retrospective comparative cohort Matched groups? ☐	PC group (80) - Assessment by an interdisciplinary team -On-site counseling, specific patient and family education, and simple interventions -Appropriate follow-up that is tailored to the needs of the patients and their caregivers Control group (32) -The PSM clinic team (physician and nurse) can request an assessment by any of the members of the MD clinic team -No handwritten or audiotaped recommendations are routinely given to patients The MD clinic at The University of Texas M. D. Anderson Cancer Center	NR In the MD clinic, follow-up data obtained a median of nine days (mean 26; range 3–63) In the PSM clinic 32 (42%) patients were seen for follow-up within a median of 28 days after the initial visit (mean 26; range 3–56).	The MD clinic at The University of Texas M. D. Anderson Cancer Center was established five years after the pain and symptom management (PSM) clinic. The investigators identified the first 138 consecutive patients seen at the MD clinic and selected a consecutive sample of 77 patients seen at the PSM clinic during the same time period	Age: 54 % female: 54.7 Indications: Advanced cancer	**PC group** ***Patient*** Survial rate: Median: 10 weeks **Control group** ***Patient*** Survial rate: Median: 51 weeks PC<control p<0.0001

Temel 2010	Good	RCT Matched groups? ☐	PC group (77) -Meeting with a member of the palliative care team within 3 weeks after enrollment and at least monthly thereafter in the outpatient setting until death -Assessing physical and psychosocial symptoms -Establishing goals of care -Assisting with decision making regarding treatment Coordinating care on the basis of the individual needs of the patient Control group (74) -Not scheduled to meet with the palliative care service unless a meeting was requested by the patient -Continuation of routine oncologic care throughout the study period *MGH*	9.8 months Median survival 9.8 months in the entire sample	Eligible patients were enrolled within 8 weeks after diagnosis and were randomly assigned to one of the two groups in a 1:1 ratio without stratification.	Age: 64.9 % female: 52.1 Indications: non–small-cell lung cancer	**PC group** ***Patient*** Psycholgical distress/depression: % patient with mood symptoms @ 12 weeks HADS-D: 16 PHQ-9: 4 Survial rate: Median survival, month: 11.6 (95% CI, 6.4-16.9) **Control group** ***Patient*** Psycholgical distress/depression: % patient with mood symptoms @ 12 weeks HADS-D:38 PHQ-9: 17 Survial rate: Median Survival, month: 8.9 (95% CI, 6.3-11.4) PC better than control HADS-D: p=0.01 PHQ-9:p=0.04 FACT-L scale difference between intervention and control at 12 weeks 6.5 (95% CI, 0.5-12.4, p=0.03) Symptom severity: the lung cancer subscale (LCS) of the FACT-L scale

							difference between intervention and control at 12 weeks 1.7 (95% CI, 0.1-3.2, p=0.04) Survival rate: p=0.02 Adjusted HR for death in controls: 1.70 (95% CI, 1.14-2.54, p=0.01) *There was no statistically significant between-group difference in anxiety*
Zimmerman 2014	Good	RCT Cluster Matched groups? ☐	PC group (228) -Assessment of symptoms, psychological distress, social support, and home services -Routine telephone contact from a palliative care nurse -Outpatient palliative care follow-up -A 24-h on-call service for telephone management of urgent issues Control group (233) -No formal intervention -Palliative care if requested Princess Margaret Cancer Centre (Toronto, ON, Canada)	16 weeks The study duration is 4 months	Inclusion criteria: Ambulatory patients with newly diagnosed metastatic non–small-cell lung cancer; aged 18 years or older, had stage IV cancer (for breast or prostate cancer, refractory to hormonal therapy was an additional criterion; patients with stage III cancer and poor clinical prognosis was included at the discretion of the oncologist); an estimated survival of 6–24 months (assessed by their main oncologist); and Eastern Cooperative Oncology Group	Age: 60.7 % female: 56.6 Indications: advanced cancer, European Cooperative Oncology Group performance status of 0–2, and a clinical prognosis of 6–24 months	QoL: FACIT-Sp adjusted difference between change scores at 4 months 6.44 (95% CI, 2.13-10.76, p=0.006; d= 0.44, ICC=0.024) QUAL-E scale adjusted difference between change scores at 4 months 3.51 (95% CI, 1.33-5.68, p=0.003;d=0.45, ICC=0.015) Symptom severity: ESAS 4 month -4.41 (95% CI, -8.76 to -0.06, p=0.05; d=-0.31, ICC=0.034) Satisfaction: FAMCARE-P16 4 month 6.00 (95% CI, 3.94-8.05, p<0.0001;d=0.73, ICC=-0.018)

					(ECOG) performance status of 0, 1, or 2 (assessed by their main oncologist). Exclusion criteria: Insufficient English literacy to complete questionnaires and inability to pass the cognitive screening test (Short Orientation-Memory-Concentration Test score <20 or >10 errors).		**Sensitivity analysis** - Last value forward Adjusted difference between change scores FACIT-Sp 4 months 4.34 (95% CI, 0.70-7.89, p=0.02) QUAL-E at 4 months 2.75 (95% CI, 0.56-4.95, p=0.02) FAMCARE-P16 at 4 mo 5.59 (95% CI, 3.65-7.52, p<0.0001) *There was no statistically significant between-group difference in ESAS at 4 months* Sensitivity analysis using complete cases and multiple imputation were not presented here

A9. Key Informant Interviews

	Affiliation
Research	University of Alabama
	Center to Advance Palliative Care
	Harvard Pilgrim Health Care Institute
	University Health Network
	Mt. Sinai Hospital
	University of California San Francisco
Palliative Care Programs	Commonwealth Care Alliance
	Beth Israel Deaconess Medical Center
	Coalition for Compassionate Care of California
	Massachusetts General Hospital
	The Conversation Project
Payers	Blue Cross Blue Shield of Massachusetts
	Aetna
Professional Societies	Hospice and Palliative Nurses Association
Other	MedEthics Consulting

To develop a list of potential interviewees, we reviewed the policy literature and identified the key groups of stakeholders relevant to palliative care. Within each group, we relied on input from the New England CEPAC Advisory Board to identify key individuals and organizations to interview as part of our research process. When conducting interviews with initial contacts, we sought recommendations for additional regional and national experts to include as part of our assessment. We conducted 30 minute telephone interviews with 17 individuals using a semi-structured guide. We attempted contact with a range of stakeholders within each New England state, though due to time limitations and scheduling challenges, were unable to interview all relevant stakeholders. To help ensure that key barriers and solutions were not left out of our assessment, we performed a scan of the existing policy literature.