

# Integration of a Palliative Care Intervention into Community Practice for Lung Cancer: A Study Protocol and Lessons Learned with Implementation

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## Abstract

**Background:** A notable gap in the evidence base for outpatient palliative care (PC) for cancer is that most trials were conducted in specialized oncology or academic centers with limited translation and further evaluation in “real-world” settings. Health systems are desperate for guidance regarding the most effective and sustainable PC service models.

**Objective:** Describe the study protocol to evaluate the dissemination of a previously tested nurse-led PC intervention (PCI) for patients with lung cancer and their family caregiver in community-based settings, lessons learned in adapting and implementing the PCI, and implications for future dissemination-translational efforts

**Design:** Two-group, prospective sequential, quasi-experimental design with Phase 1 (Usual care) followed by Phase 2 (Intervention) setting/subjects. Three Kaiser Permanente Southern California sites. Patients with stage 2–4 nonsmall cell lung cancer and their caregiver.

**Measurements:** Standard measures of quality of life (QOL; FACT-L, FACIT- SP12, City of Hope Family QOL), symptom burden, distress, and caregiver preparedness and perceived burden.

**Results:** Adaptations were made to the PCI (comprehensive patient/caregiver assessment, interdisciplinary care planning, and patient/caregiver education) to harmonize with existing workflows, minimize burden to patients, caregivers, and the PC team, and maximize chances of sustainability. Implementation facilitators include external competitive pressures, internal readiness, and adaptability of the PCI. Barriers include the changing lung cancer therapeutic landscape and perceived need for PC support by patients and providers, insufficient staffing, and people-dependent processes.

**Conclusions:** Efforts to disseminate and implement previously tested PC models into real-world community practices need to be more realistic and consider the local context.

**Keywords:** community practice; dissemination; implementation; lung cancer; palliative care

## Background

THE EVIDENCE BASE regarding the most effective approach and model for providing community-based palliative care (PC) for patients with advanced, serious illnesses continues to evolve. The most recent systematic review and meta-analysis of over 40 PC trials found that PC was generally associated with significant improvements in symp-

toms, quality of life (QOL), advance care planning, patient and caregiver satisfaction, and lower healthcare utilization without impact on survival.<sup>1</sup> While these findings are promising and contributed to American Society of Clinical Oncology’s (ASCO’s) recommendations for PC integration into standard oncology care,<sup>2</sup> a notable limitation is that much of the evidence base comes from specialized oncology or academic centers with limited translation and further evaluation

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in more “real-world” community-based settings. Health systems are desperate for guidance regarding the most effective, cost-effective, and sustainable PC service model that spans the care continuum.

For this study, we chose nonsmall cell lung cancer (NSCLC) as our target condition due to the high public health burden,<sup>3</sup> the striking early success of PC studies at specialized cancer centers demonstrating notable improvements in QOL and survival,<sup>4</sup> and our own experience with testing a nurse-led PC intervention (PCI) model for lung cancer at City of Hope.<sup>5</sup> Kaiser Permanente, being the largest integrated healthcare system with over 11 million members across the United States, was selected as the ideal, “real-world” test bed to extend this work, given its early leadership in the development, evaluation, and system-wide implementation of inpatient<sup>6</sup> and home-based PC services<sup>7,8</sup> since the mid 2000s. Specifically, in Kaiser Permanente Southern California (KPSC), where this study is being conducted, outpatient PC services had organically developed and were in operation for nearly 10 years at a few sites, and were only beginning to diffuse to the remaining sites in the past few years. Since adoption of PC services is subject to local control, budgets, and context across the 14 KPSC sites, this variability in implementation provides an opportunity for us to adapt and test the City of Hope PCI model at several KPSC sites that, if successful, would be disseminated to the remaining sites.

This article describes the study protocol and first phase to evaluate the dissemination of a previously tested nurse-led PCI for patients with NSCLC and their primary caregiver in a real-world community-based setting and the lessons learned in adapting and implementing the PCI. Implications for future dissemination-translational efforts, anchored within two common dissemination and implementation frameworks, are presented.

### Conceptual Framework

To advance the care of patients and caregivers facing lung cancer beyond highly specialized research settings, innovative practices such as the PCI must be disseminated and adapted to community-based care settings where the vast majority of patients are cared for and re-evaluated to determine if the effects are replicable. Our effort to adapt, refine, disseminate, and evaluate the PCI is guided by two models, RE-AIM<sup>9,10</sup> and the Consolidated Framework for Implementation Research (CFIR).<sup>11</sup> RE-AIM provides a broad perspective for program design and evaluation based on five rubrics: Reach, Effectiveness/Efficacy, Adoption, Implementation, and Maintenance. Since the study is still in progress, this article will only report on the Reach (the absolute number, proportion, and representativeness of individuals who are willing to participate in a given initiative) and Implementation (at the setting level, implementation refers to the intervention agents’ fidelity to various elements of an intervention’s protocol. This includes consistency of delivery as intended and the time and cost of the intervention) domains. While RE-AIM addresses implementation at a high level, CFIR which is derived from a number of theories about dissemination, innovation, organizational change, implementation, and knowledge translation, provides a more, in-depth comprehensive framework of the multilevel barriers and facilitators influencing implementation according to five domains (intervention characteristics,

outer setting, inner setting, characteristics of individuals, and process) and 39 constructs (Table 1).

### Study Aims

The prespecified aims of the Translation of a Lung Cancer Palliative Care Intervention (TLC-PCI) study are as follows:

- Adapt and implement the PCI that was previously tested at a specialized cancer center for dissemination to three community-based settings
- Determine the effects of the PCI on *patient* (symptom control, QOL, and distress) and *caregiver* (caregiver burden, caregiver distress, skills, preparation, and QOL) outcomes over three months compared to usual care.
- Determine the effects of the PCI on health care resource utilization (acute care use, chemotherapy in the last two weeks of life, hospice use, and use of other supportive services) compared to usual care.

### Methods

#### Study design

The design is a two-group, prospective sequential, quasi-experimental, tandem enrollment design, wherein the usual care group is accrued and followed during Phase 1 (Jan 2015–Mar 2016) and the intervention group is accrued and followed during Phase 2 (Jun 2016–Mar 2018) at three KPSC sites. Patients and caregivers accrued in Phase 1 continued to receive usual care and only participated in telephone surveys at baseline, one, and three months post-accrual. This was followed by a three-month interim phase in which data were analyzed and reviewed with each site to identify current gaps with PC support for patients and caregivers that were then incorporated in the adaptation and refinement of the PCI for Phase 2. The nurses identified a need for more training to address patients’ and caregivers’ spiritual concerns. A full-day training on the PCI was held with participation from nurses, physicians, and administrators from the three sites. Phase 2, which is focused on implementation of the PCI across the three sites is currently in progress, following the same measurement scheme, and will continue through mid-2018.

#### Sample

The sample includes English-speaking patients 18 years and older with a diagnosis of stage 2–4 NSCLC from three KPSC sites. Family caregivers who are 18 years or older and designated by the patient as a person closely involved in their care are eligible for the study. Based on power calculations, our target accruals are 170 patients and 156 caregivers.

#### Study procedures

To ensure the PCI has the greatest chance of being sustained, we worked with site PC department administrators to identify an existing PC registered nurse for training on the study protocol. The nurses are responsible for patient and caregiver recruitment, consent, and PCI implementation. The nurses’ time is covered by grant funding for “research” activities, for example, recruitment and participating in study meetings, and it is expected that implementation of the PCI is

TABLE 1. CONSOLIDATED FRAMEWORK FOR IMPLEMENTATION RESEARCH CONSTRUCTS RELATED TO TRANSLATION OF A LUNG CANCER PALLIATIVE CARE INTERVENTION IMPLEMENTATION

<i>Construct</i>	<i>Short description</i>	<i>TLC-PCI</i>
<b>I. Intervention characteristics</b>		
A Intervention source	Perception of key stakeholders about whether the intervention is externally or internally developed.	Externally developed at City of Hope (COH), but Kaiser Permanente stakeholders contributed to adapting to local context
B Evidence strength and quality	Stakeholders' perceptions of the quality and validity of evidence supporting the belief that the intervention will have desired outcomes.	Earlier evidence of PC on lung cancer was persuasive, but as evidence matures, impact on other outcomes important to health system, for example, utilization, is less clear
C Relative advantage	Stakeholders' perception of the advantage of implementing the intervention versus an alternative solution.	Other intensive physician led models are not financially feasible. Addition of structured education and skill training for patients and caregivers perceived as advantage
D Adaptability	The degree to which an intervention can be adapted, tailored, refined, or reinvented to meet local needs.	Interdisciplinary team care planning and education intervention highly adaptable to local needs; comprehensive QOL assessment not as flexible
E Trialability	The ability to test the intervention on a small scale in the organization and be able to reverse course (undo implementation) if warranted.	Slow ramp up to Phase II (intervention implementation) with close mentorship from senior COH nurse
F Complexity	Perceived difficulty of implementation, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy and number of steps required to implement.	PCI is aligned with current workflows and only expands scope of work to the extent that it imposes greater structure in the baseline QOL assessment, care plan, and patient/FCG education sessions
G Design quality and packaging	Perceived excellence in how the intervention is bundled, presented, and assembled.	Education handbooks are thought to be well packaged with comprehensive resources for patients and FCG
H Cost	Costs of the intervention and costs associated with implementing the intervention, including investment, supply, and opportunity costs.	Cost is mostly nurses' time with administering surveys, synthesizing into interdisciplinary plan, executing plan, and providing one-on-one patient/FCG education
<b>II. Outer context</b>		
A Patient needs and resources	The extent to which patient needs, as well as barriers and facilitators to meet those needs, are accurately known and prioritized by the organization.	We did not perform an internal needs assessment, but one could reasonably assume that KP patient/FCG needs for PC support are no different from published studies. Advances in lung CA therapeutics with improved survival and fewer side effects influence patients' and providers' perception regarding need for PC support
B Cosmopolitanism	The degree to which an organization is networked with other external organizations.	Collaboration with COH as a premier, specialty oncology referral center
C Peer pressure	Mimetic or competitive pressure to implement an intervention, typically because most or other key peer or competing organizations have already implemented or are in a bid for a competitive edge.	Many other health systems are developing their outpatient PC services. Desire for harmonization across sites to facilitate evaluation of effectiveness
D External policy and incentives	A broad construct that includes external strategies to spread interventions, including policy and regulations (governmental or other central entity), external mandates, recommendations and guidelines, pay-for-performance, collaboratives, and public or benchmark reporting.	National Consensus Project for Quality Palliative Care provides guidance on essential services reflecting quality of PC; ASCO guidelines for integration of PC in oncology care; KP is not participating in any PC collaboratives or registries for public reporting

(continued)

TABLE 1. (CONTINUED)

<i>Construct</i>	<i>Short description</i>	<i>TLC-PCI</i>
III. Inner context		
A Structural characteristics	The social architecture, age, maturity, and size of an organization.	PC service is still relatively young at two of the three sites. Stability of the administrative leaders and their broad responsibilities for multiple departments also present challenges re: commitment to implementation of new practices
B Networks and communications	The nature and quality of webs of social networks and the nature and quality of formal and informal communications within an organization.	PC lead physician and administrative peer groups meet on quarterly basis, but front-line nurses do not yet have regular peer group meeting Connectedness, bonding, and “teamness” appear strong at two of three sites
C Culture	Norms, values, and basic assumptions of a given organization.	Note: similar to “Climate” below, but is generally stable, socially constructed, and subconscious
D Implementation climate	The absorptive capacity for change, shared receptivity of involved individuals to an intervention, and the extent to which use of that intervention will be rewarded, supported, and expected within their organization.	Nurses are appreciative of the patient and FCG teaching resources and external facilitation by COH specialist nurse, although they are uncertain whether the time required for one-on-one patient/FCG education will be scalable
1 Tension for change	The degree to which stakeholders perceive the current situation as intolerable or needing change.	PC consultation and care are already provided by team under the current resource constraints; local teams do not necessarily perceive current situation as intolerable since they feel the services they provide are meeting the core patient needs. However, they recognize the large gap in supporting FCG
2 Compatibility	The degree of tangible fit between meaning and values attached to the intervention by involved individuals, how those align with individuals’ own norms, values, and perceived risks and needs, and how the intervention fits with existing workflows and systems.	PCI is partly aligned with current workflows and while the comprehensive QOL assessment of patients and FCG highlights unmet needs that team would not have been attuned to, survey assessment may need to be condensed for sustainability
3 Relative priority	Individuals’ shared perception of the importance of the implementation within the organization.	PC team members recognize that the organization prioritizes PC expansion; oncology colleagues also point out the limited investments in oncology care management structures to promote primary PC
4 Organizational incentives and rewards	Extrinsic incentives such as goal-sharing awards, performance reviews, promotions, and raises in salary, and less tangible incentives such as increased stature or respect.	Recognition that site is participating in a research study and that they are pioneers in integrating PC in community practice
5 Goals and feedback	The degree to which goals are clearly communicated, acted upon, and fed back to staff, and alignment of that feedback with goals.	Monthly newsletters updating teams on accrual and enrollment
6 Learning Climate	A climate in which: (a) leaders express their own fallibility and need for team members’ assistance and input; (b) team members feel that they are essential, valued, and knowledgeable partners in the change process; (c) individuals feel psychologically safe to try new methods; and (d) there is sufficient time and space for reflective thinking and evaluation.	Nurses feel empowered to provide feedback regarding what is working well and what is not with all aspects of the study, including recruitment activities to intervention implementation *Unable to fully assess all dimensions

(continued)

TABLE 1. (CONTINUED)

<i>Construct</i>		<i>Short description</i>	<i>TLC-PCI</i>
E	Readiness for implementation	Tangible and immediate indicators of organizational commitment to its decision to implement an intervention.	Joint oncology and palliative chiefs' goal for referral of stage 3–4 lung CA at the point of diagnosis to PC
1	Leadership engagement	Commitment, involvement, and accountability of leaders and managers with the implementation.	Variable commitment across sites and by oncology champions as study unfolds over past two years Active involvement of department administrators (DAs) in problem solving and sense of accountability is critical
2	Available resources	The level of resources dedicated for implementation and on-going operations, including money, training, education, physical space, and time.	Limited grant funding for full-time equivalent support to RN (10%) and MD (5%) for "research"-related activities beyond usual PC services
3	Access to knowledge and information	Ease of access to digestible information and knowledge about the intervention, and how to incorporate it into work tasks.	Availability of protocols, documentation and project management assistance, and external content expert
IV. Characteristics of individuals			
A	Knowledge and beliefs about the intervention	Individuals' attitudes toward and value placed on the intervention as well as familiarity with facts, truths, and principles related to the intervention.	Nurses received group and one-on-one training and thus have the how-to knowledge and underlying principles to implement the PCI. Positive feedback from patients/FCG re: value of PC support reinforces positive affective response by nurses
B	Self-efficacy	Individual belief in their own capabilities to execute courses of action to achieve implementation goals.	Nurses have high efficacy for implementing PCI, but feel they have limited to no control over patient referrals to PC
C	Individual stage of change	Characterization of the phase an individual is in, as he or she progresses toward skilled, enthusiastic, and sustained use of the intervention.	All nurses are in the action stage of change since they were designated and trained to implement the PCI
D	Individual identification with organization	A broad construct related to how individuals perceive the organization, and their relationship and degree of commitment with that organization.	Mix of nurses with very long tenure in organization (2) and those who recently joined (4), thus commitment to organization is variable; PC services are traditionally associated with high emotional exhaustion
E	Other personal attributes	A broad construct to include other personal traits such as tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity, and learning style.	Unable to assess
V. Process			
A	Planning	The degree to which a scheme or method of behavior and tasks for implementing an intervention are developed in advance, and the quality of those schemes or methods.	Implementation of the PCI is localized with the PC team with the RN being primarily responsible for most of the activities; thus there was no formal implementation plan. However, key to implementing the PCI is the ongoing need for systematic referral of all patients newly diagnosed with stage 2–4 lung cancer to PC.
B	Engaging	Attracting and involving appropriate individuals in the implementation and use of the intervention through a combined strategy of social marketing, education, role modeling, training, and other similar activities.	See below for the different types of implementation leaders
1	Opinion leaders	Individuals in an organization who have formal or informal influence on the attitudes and beliefs of their colleagues with respect to implementing the intervention.	Limited internal expert or peer opinion leaders since PC is a fairly new and young specialty.

(continued)

TABLE 1. (CONTINUED)

<i>Construct</i>	<i>Short description</i>	<i>TLC-PCI</i>
2 Formally appointed internal implementation leaders	Individuals from within the organization who have been formally appointed with responsibility for implementing an intervention as coordinator, project manager, team leader, or another similar role.	Implementation coordinated by research staff, not on the ground project managers supported by the departments; PC DAs partially fulfill the role of a “formally” appointed internal implementation leader, but two of the three DAs were not involved in developing the grant proposal and thus may perceive limited “ownership.”
3 Champions	“Individuals who dedicate themselves to supporting, marketing, and ‘driving through’ an implementation, overcoming indifference or resistance that the intervention may provoke in an organization.”	Oncology chiefs who are fully onboard and encourage routine referrals from other oncologists in their department
4 External change agents	Individuals who are affiliated with an outside entity who formally influence or facilitate intervention decisions in a desirable direction.	COH investigator and expert resource RN serve as effective external facilitators due to their strong reputation as leaders in the field
C Executing	Carrying out or accomplishing the implementation according to plan.	Fidelity and timeliness of assessments, IDT care planning, and education sessions are acceptable once patients enroll in intervention Engagement of on-the-ground implementation leaders requires regular reminders
D Reflecting and evaluating	Quantitative and qualitative feedback about the progress and quality of implementation accompanied with regular personal and team debriefing about progress and experience.	Group reflection and team debriefing are driven by external research team versus the local implementation team, and has been driven by patient accrual needs.

PC, palliative care; PCI, palliative care intervention; TLC-PCI, translation of a lung cancer palliative care intervention.

subsumed under their existing responsibilities. Nurses participate in weekly telephone meetings during Phase 2 to debrief regarding ongoing challenges and share implementation best practices. Nurses also have access to an expert master’s prepared PC nurse from City of Hope for one-on-one training and mentorship with any aspect of the PCI.

Our recruitment approach is similar across both study phases. Patients who are referred to PC by their oncologists or other specialists are approached by the nurse in person during their initial PC consult or by telephone about the study. Patients are then asked if they have a caregiver who would also like to participate. Nearly two-thirds of our accruals from Phase I was based on referrals to the PC clinic. Since referrals are provider dependent, we also proactively identify patients recently diagnosed with lung cancer through regular queries of the electronic medical records. The nurse performs a second level of chart review to determine patients’ appropriateness for the study before a letter and brochure are sent through postal mail and subsequently followed up through telephone 7–10 days after the mailing, to assess patients’ interest in the study.

During Phase 1, patients and caregivers had limited interactions with the nurses other than to complete the consent forms. All telephone assessments at baseline, one, and three months were conducted by the research staff. For Phase 2, nurses recruit and consent patients and caregivers, complete the baseline assessments, develop the interdisciplinary care plans, and provide the teaching sessions and telephone follow-ups. We aimed to mini-

mize burden on the nurses with intervention fidelity monitoring by asking them to only document on completion of the PCI components. Research staff not involved with the PCI complete the one- and three-month assessments to minimize bias.

#### **TLC-PC intervention**

The TLC-PCI was adapted from extensive completed work as part of a National Cancer Institute (NCI) Program Project grant at City of Hope.<sup>5,12</sup> The PCI consists of three key components: comprehensive patient/caregiver assessment, interdisciplinary care planning, and patient/caregiver education, which are implemented over a one- to two-month period. A comparison of usual PC at KPSC and the PCI is summarized in Table 2. The first component involves a comprehensive baseline assessment of the patient’s and caregiver’s QOL (physical, psychological, social, and spiritual) using the measures described below. This is followed by the development of an individualized interdisciplinary care plan. The care plan identifies domains where patients indicate moderate or greater concern. Caregiver issues captured from the assessment are also noted in the care plan. This care plan is then discussed by the interdisciplinary PC team and members make recommendations for any additional supportive services with follow-up by the nurses to ensure appropriate referrals are generated. Sites have latitude on how the interdisciplinary discussion is structured.

The third component includes tailored educational sessions for patients and caregivers based on needs identified in the care plan or other interests expressed to the nurses. Caregivers are encouraged to join the two patient focused sessions. The session content is organized around the QOL model specific to concerns for NSCLC. The first covers physical and psychological issues and the second, social and spiritual; nurses can combine both sessions depending on patients' preferences and needs. A third teaching session is held with the caregiver alone without the patient to give the caregiver an opportunity to discuss their perspectives and focus on their needs. Patients and caregivers also receive 1–2 semistructured follow-up calls where the nurse reinforces content from the teaching sessions and reviews any outstanding concerns.

**Outcome measures**

The outcome measures were selected based on their importance to patients and caregivers and include assessments with minimal participant burden, and are most likely to be used in routine clinical practice, to the extent that core instruments had to be preserved from an earlier study for cross-study comparisons. For patient-centered outcomes, the following instruments were used: QOL is measured with the Functional Assessment of Cancer Therapy-Lung (FACT-L).<sup>13</sup> Spiritual well-being is measured with the Functional Assessment of Chronic Illness Therapy-Spirituality Subscale (FACIT-Sp-12).<sup>14</sup> The distress thermometer provides an overall assessment of distress.<sup>15</sup> Although not presented in this article, we are also collecting healthcare utilization measures from KPSC's comprehensive electronic records, including acute care encounters (hospitalizations, observational stays, emergency department visits, and urgent care) and use of supportive services. Quality of end-of-life care measures includes documentation of advance care planning and a proxy decision maker, chemotherapy in the last two weeks of life, use of home-based PC, hospice referral, enrollment, and length of stay, and place of death.

Family caregiver outcomes were measured with the Caregiver Burden Scale,<sup>16</sup> Preparedness Scale,<sup>17,18</sup> and City of Hope-QOL-Family instrument.<sup>19,20</sup>

**Data analysis**

For the main study, the primary intent-to-treat analyses of patient and caregiver reported outcomes will utilize a repeated-measures mixed model with linear contrasts of the between phase differences in the estimated change from baseline to one and three months. Relevant covariates will be included in the models and standard approaches for handling missing data will be used as needed.

For this article, an ethnographic approach was taken to document lessons learned with implementation through meeting minutes, field and site visit notes, journal notes, and on-going e-mail and telephone communications. Detailed notes were taken of all virtual and in-person meetings, including weekly to bi-weekly meetings with the nurses and research team, full-day in-person trainings for all team members, including physicians and administrators, and semiannual site visits. A doctoral student supported through an NINR Minority grant supplement conducted focus groups and one-on-one interviews with 19 clinicians from PC, oncology, and thoracic surgery in preparation for Phase 2 to elicit perceived facilitators and barriers to PCI implementation. We identified themes and subthemes and used components of the CFIR model to group facilitators and barriers by factors related to the external context, internal context, and intervention attributes.

**Results**

**Sample characteristics of phase I patients and caregivers**

The sociodemographics and clinical characteristics of NSCLC patients (*n* = 118) and caregivers (*n* = 62) are similar to previous studies (Table 3) as are the baseline levels of

TABLE 2. USUAL CARE VERSUS PALLIATIVE CARE INTERVENTION IMPLEMENTATION

	<i>Usual PC</i>	<i>PCI</i>
Patient assessment	Unstructured; ESAS and PPS used at one site	QOL: physical, psychological, social, and spiritual; distress
Family caregiver assessment	None	QOL: physical, psychological, social, and spiritual; distress, burden, and preparedness
Interdisciplinary care plan	Unstructured	Standardized based on needs identified from assessment
Patient education	Unstructured as needed	Individually tailored (two sessions) addressing QOL domains
Caregiver education	Unstructured as needed	Individually tailored (one session) addressing QOL domains
Care coordination/management	As needed	As needed
Phone follow-up	As needed	Patients (two calls); FCG (one call)
Duration	Until transition to home-based PC or hospice	Three months
Palliative care team structure		
Site 1	Physician, Nurse, Social Worker, Chaplain	
Site 2	Physician, Nurse, Social Worker, Chaplain	
Site 3	Physician, Nurse, Social Worker	

ESAS, Edmonton symptom assessment scale; PPS, palliative performance scale.

TABLE 3. PHASE I SOCIODEMOGRAPHIC CHARACTERISTICS OF PATIENTS AND FAMILY CAREGIVERS

	Patients (n = 118)	Caregivers (n = 62)
Age	67.5 ± 10.3	63.8 ± 11.5
Gender, n (%)		
Female	71 (60.2)	38 (61.3)
Male	47 (39.8)	24 (38.7)
Education, n (%)		
High School	45 (38.1)	20 (32.3)
College	73 (61.9)	42 (67.7)
Marital status, n (%)		
Married or partnered	80 (67.8)	54 (87.1)
Widowed	19 (16.1)	4 (6.5)
Divorced	10 (8.5)	3 (4.8)
Single	9 (7.6)	1 (1.6)
Living with..., n (%)		
Spouse and children/other	76 (64.4)	—
Alone	18 (15.2)	—
Children	10 (8.5)	—
Parents	3 (2.5)	—
Other	11 (9.3)	—
Employment status, n (%)		
Self-employed	3 (2.5)	—
Employed <32 hours/week	3 (2.5)	—
Employed ≥ 32 hours/week	15 (12.7)	—
Homemaker	1 (0.8)	—
On medical leave/disabled	16 (13.5)	—
Unemployed	4 (3.4)	—
Retired	76 (64.4)	—
Race, n (%)		
Caucasian	102 (86.4)	53 (85.5)
Asian	9 (7.6)	3 (4.8)
African American	6 (5.1)	5 (8.1)
Other	1 (0.8)	1 (1.6)
Hispanic or Latino	15 (12.7)	5 (8.1)
Religion, n (%)		
Protestant	44 (37.3)	22 (35.5)
Catholic	43 (36.4)	18 (29.0)
Jewish	3 (2.5)	2 (3.2)
Mormon	2 (1.7)	1 (1.6)
Buddhist	1 (0.8)	2 (3.2)
Other	9 (7.6)	6 (10)
None	16 (13.6)	11 (17.7)
Household income, n (%)		
\$10,000 or less	2 (1.7)	1 (1.6)
\$10,001 to \$20,000	10 (8.5)	5 (8.1)
\$20,001 to \$30,000	16 (13.6)	4 (6.5)
\$30,001 to \$40,000	11 (9.3)	4 (6.5)
\$40,001 to \$50,000	15 (12.7)	13 (21.0)
Greater than \$50,000	61 (51.7)	32 (51.6)
Prefer not to answer	3 (2.5)	3 (4.8)
Year of lung dx, n (%)		
≤2013	14 (11.9)	—
2014	26 (22.0)	—
2015	66 (55.9)	—
2016	12 (10.2)	—
Lung cancer stage, n (%)		
II	10 (8.5)	—
III	32 (27.1)	—
IV	76 (64.4)	—

(continued)

TABLE 3. (CONTINUED)

	Patients (n = 118)	Caregivers (n = 62)
Relationship of caregiver to patient, n (%)		
Spouse/partner	—	42 (67.7)
Daughter	—	9 (14.5)
Son	—	2 (3.2)
Other	—	9 (14.5)

Data are presented as mean ± standard deviation (SD) or n (%).

symptom burden, QOL, distress, and caregiving preparedness and burden (Tables 4 and 5). A majority of caregiver participants (85%) were also Kaiser Permanente members.

### Reach to patients and caregivers

In estimating our “reach” (RE-AIM) for Phase I, we relied on our cancer registry tabulation of newly diagnosed stage 2–4 NSCLC patients from 2015 across the three sites to estimate the study’s reach, which ranged from 19% to 31%. Since we did not restrict the study to newly diagnosed patients, Figure 1 illustrates the overall reach or uptake by all eligible patients who were approached about the study (consented and completed baseline assessments, n = 118 out of 251, 47%). Finally, the reach of our usual care, outpatient PC services for the 118 patients from the point of diagnosis through three months after study enrollment, was 69%. Only 52% of caregivers agreed to participate.

A summary of the CFIR implementation (RE-AIM) constructs, definitions, and our assessment of their relevance to the ongoing study are detailed in Table 1. We highlight below key considerations related to implementation facilitators and barriers under the three most influential CFIR domains of the outer and inner contexts and intervention characteristics.

### Implementation facilitators

**Outer context.** The landmark findings by Temel et al.<sup>4</sup> and the subsequent ASCO provisional statement<sup>21</sup> regarding

TABLE 4. PHASE I BASELINE PATIENT QUALITY OF LIFE, SPIRITUAL WELL-BEING, AND DISTRESS (N = 118)

	Mean	SD
Overall FACT-L Index (0–144↑)	97.6	20.0
Physical	19.4	5.8
Social	20.9	5.6
Emotional	18.3	4.8
Functional	16.3	6.1
Additional concerns subscale	22.7	5.2
FACIT-SP12 Overall Index (0–48↑)	36.3	9.1
Peace	12.8	2.8
Meaning	12.1	3.4
Faith	11.3	4.4
Distress level (↓0–10)	4.5	2.9
Instrumental activities of daily living (0–14↑)	8.1	1.9

Arrows indicate direction of better scores.

FACT-L, functional assessment of cancer therapy-lung; FACIT-Sp-12, functional assessment of chronic illness therapy-spirituality subscale.

TABLE 5. PHASE I BASELINE FAMILY CAREGIVER QUALITY OF LIFE, PREPAREDNESS, AND BURDEN (N=62)

	Mean	SD
Quality of life family scale total (0–370↑)	232.6	50.0
Physical	36.4	7.7
Psychological	90.5	26.0
Social	59.7	15.0
Spiritual	46.0	13.0
Caregiving preparedness (0–32↑)	23.0	5.1
Caregiver burden total (↓0–70)	45.2	5.2
Objective	20.0	4.1
Subjective demand	11.9	1.0
Subjective stress	13.3	2.0
Distress level (↓0–10)	5.2	2.6

Arrows indicate direction of better scores.

integration of PC in standard oncology care as a strategy to achieve the triple aim were critical external forces that helped catalyze attention from key decision makers within our health system to promote the expansion of outpatient PC services. Securing external funding that supports the adaptation and evaluation of a potentially affordable and spreadable, structured PC model in collaboration with highly respected PC experts from City of Hope greatly facilitated implementation.

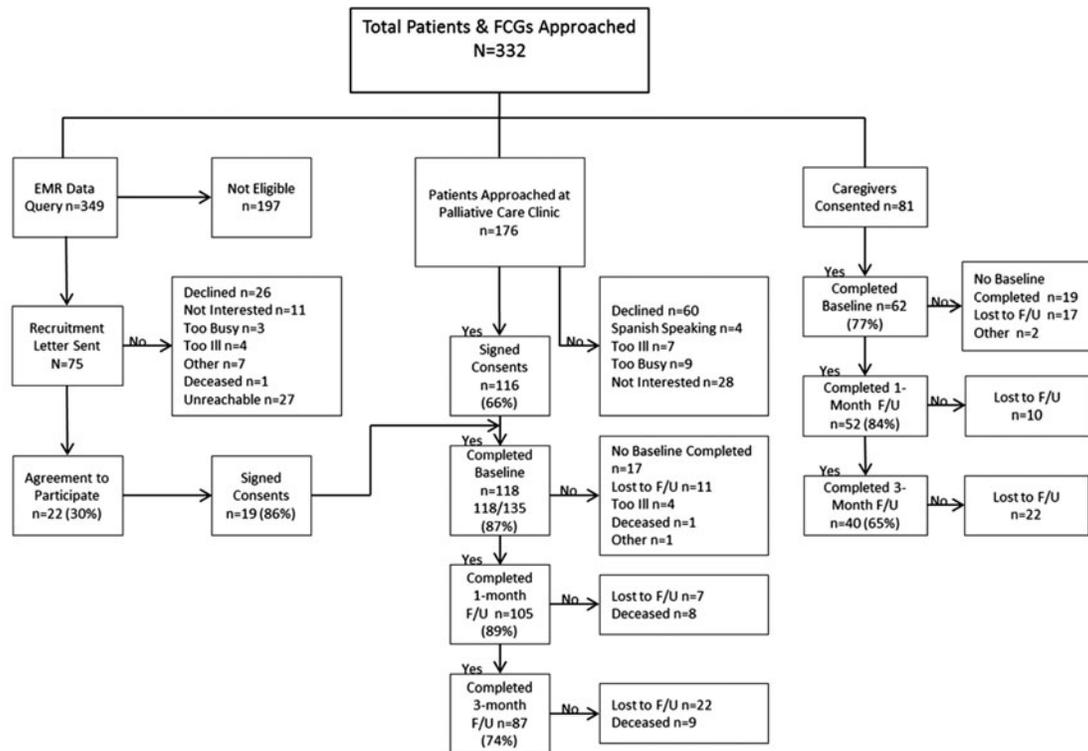
**Inner context.** The prioritization of specialty PC services for newly diagnosed stage 3–4 NSCLC in the form of a clinical strategic goal for the oncology and PC departments that started in

2014 illustrate a “climate” primed and ready for implementation of the PCI. Site performance with PC referrals is tracked annually and is coupled with financial incentives. Structurally, physical colocation of PC within oncology at one site facilitated integration of PC into routine oncology care. Provision of outpatient PC was seen as a bridging support for patients who do not yet qualify for home-based PC services or hospice. Finally, the external facilitation by PC experts from City of Hope is another notable enabler.

**Intervention characteristics.** The ability to adapt the PCI components to the existing workflows and staffing structure to minimize burden to patients, caregivers, and the PC team, while retaining the core intervention elements, was perceived as a notable implementation facilitator. Specifically, the paper-based care plan was streamlined and modified to include only the most salient elements for discussion during the existing interdisciplinary team “huddles.” The education sessions are individually tailored to patients’ and caregivers’ specific needs and preferences and are provided in person or through telephone.

**Implementation barriers**

**Outer context.** Rapid advances in therapies for NSCLC<sup>22</sup> over the past two years during our transition from Phase 1–2 as well as the changing patient demographics<sup>23</sup> with more non-smokers, women and younger individuals, have affected patients’ and providers’ perceptions regarding the added value of early specialty PC supportive services.



Note: Lower participation by caregivers was mostly due to patients’ reluctance to impose additional burden on their loved ones

FIG. 1. Phase I sample flow. Note: Lower participation by caregivers was mostly due to patients’ reluctance to impose additional burden on their loved ones.

**Inner context.** Despite executive-level support for outpatient PC service expansion, funding is highly dependent on local budgets and thus remains inconsistent across sites to adequately meet competing demands. Another notable barrier is the absence of reliable, hard-wired processes to ensure referral to PC services. Moreover, buy-in from oncology providers regarding the added value of specialty PC also remains variable. Finally, increased investments in specialty PC services without concurrently buttressing oncology's ability to provide primary PC support may create friction across teams.

**Intervention characteristics.** While the PC team sees value with the structured, one-on-one education sessions, the nurses expressed early concerns regarding their ability to meet this level of service expectations for all PC patients. With the exception of one site that uses a short symptom survey, sites had limited knowledge, experience, or appetite for using a battery of structured patient-reported outcome measures (PROM). Nevertheless, sites had not fully appreciated the benefits of PROM to proactively identify needs and track patients' and caregivers' progress. However, this is balanced with concerns regarding their ability to adequately address all issues uncovered with the comprehensive assessments.

## Discussion

We recognize the main threat to internal validity for this study is the historical trends owing to the sequential, non-randomized design. It was not practical to randomize at either the participant or site level due to potential cross-contamination across PC team members and study costs associated with a large number of sites, respectively. Moreover, many of the sites under consideration were starting to implement an outpatient PC program and would not be agreeable to postponing their program roll-out, even if a stepped-wedge design was used. Nonetheless, an ancillary study is planned to compare EMR-based outcomes between participants at the three study sites with patients from the other 11 nonparticipating sites.

We identified a number of early key lessons learned with regard to facilitators and barriers that we believe would be informative to other ongoing or planned dissemination efforts. Implementation facilitators include external pressures, internal readiness, and adaptability of the PCI to local contexts. Barriers include the rapidly changing lung cancer therapeutic landscape and perceived need for PC support by patients and providers,<sup>24</sup> insufficient staffing to meet existing demands for PC services by patients with malignant and nonmalignant disease, and acceptability of efforts to hard-wire PC integration given existing constraints. In conclusion, efforts to broadly disseminate and implement any new practice derived from the "ideal" research settings to the "real world" need to give serious consideration to the local structures, processes, and context, as well as the shifting and evolving evidence base for the practice.

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## Author Disclosure Statement

No competing financial interests exist.

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