Patient-Centered Palliative Care Delivery for Adult Patients with Advanced Illnesses and Their Caregivers:

Workgroup Meeting Summary

Overview

On March 7, 2016, PCORI convened a multi-stakeholder workgroup to explore opportunities to fund comparative effectiveness research (CER) that would: 1) facilitate, over time, care planning that is consistent with the goals and preferences of patients and their caregivers; and 2) facilitate the delivery of coordinated palliative care that effectively implements those care plans. The population of interest was adult patients with advanced illnesses and their caregivers.

Workgroup members included patients; patient and caregiver advocates; clinicians; researchers; representatives of public and private payers, federal and private research funding organizations, clinical specialty societies, and industry; and researchers. The meeting was open to the public via webinar.

Before the meeting, PCORI staff conducted informational interviews with stakeholders to identify evidence gaps, areas of research where PCORI could have an impact, and potential CER questions. In addition, each participant was asked to identify up to three CER questions related to the delivery of palliative care for adult patients with advanced illnesses and their caregivers that warrant further research. A total of 112 questions were submitted. These questions were synthesized by PCORI staff and resulted in 31 distinct CER questions in two categories: communication, education, and decision making (n=14); and models of palliative care delivery (n=17). In the morning breakout session, participants prioritized research questions for PCORI to consider for a future funding announcement. In the afternoon breakout session, prioritized questions were further discussed and refined.

Related Information

- Workgroup: Prioritizing Comparative Effectiveness Research Questions for Patient-Centered Palliative Care Delivery for Adult Patients with Advanced Illnesses and Their Caregivers
- Patient-Centered Palliative Care Delivery for Adult Patients with Advanced Illnesses and Their Caregivers: Topic Brief
- Submitted Stakeholder Questions
- Synthesized CER Questions
- Archived Teleconference Audio Recordings

The Patient-Centered Outcomes Research Institute (PCORI) is an independent organization created to help people make informed healthcare decisions.

1828 L St., NW, Suite 900
Washington, DC 20036
Phone: (202) 827-7700
Fax: (202) 355-9558
Email: info@pcori.org
Follow us on Twitter: @PCORI

Introduction

As the US population ages, a greater proportion of individuals are likely to be diagnosed with advanced illnesses, resulting in tremendous burden associated with debilitating symptoms, compromised functioning, and reduced quality of life. In addition to patients themselves, family members also suffer profound physical and emotional consequences due to caregiver burden and associated decrements in their quality of life. The scope of the challenge associated with managing advanced and potentially life-limiting illnesses is only expected to increase: a growing proportion of the US population is aging and likely to have multiple complex, comorbid health conditions, and there is a projected shortage of clinicians to care for them. Palliative care is patient- and family-centered care that optimizes quality of life throughout the continuum of illness; it addresses physical, intellectual, emotional, social, and spiritual needs and facilitates patient autonomy, access to information, and options. Addressing the supportive care needs of individuals with advanced illnesses and their caregivers throughout the illness trajectory—from diagnosis to death—has been identified as a national priority.

Given the inherent patient-centeredness of palliative care—and the relative absence of CER from the evidence base related to advance care planning and models of palliative care delivery—PCORI has a unique role to play in funding patient-centered outcomes research that systematically evaluates the effectiveness of different approaches to delivering palliative care for adult patients with advanced illnesses and their caregivers. PCORI convened the Patient-Centered Palliative Care Delivery for Adult Patients with Advanced Illnesses and Their Caregivers Workgroup to identify questions that could eventually inform a targeted funding announcement in this area.

The workshop began with brief overview presentations by Dr. Neeraj Arora, Senior Program Officer from the Improving Healthcare Systems Program at PCORI, and Dr. Diane Meier, Director of the Center to Advance Palliative Care. Dr. Arora clarified that the population of interest was adults with advanced illnesses and their caregivers and that discussions throughout the workshop should consider the significance of palliative care in a variety of advanced illnesses and disease trajectories, and different healthcare delivery settings; it should not be limited only to the end-of-life phase of care. The workshop chair, Dr. Meier, welcomed participants, described the purpose of the workshop, and summarized the process that would be used for organizing the discussion over the course of the workshop. Dr. Meier emphasized the importance of conducting further research in palliative care and acknowledged the unique contributions PCORI could make to the field of palliative care research and practice.

Participants were then organized by interest and expertise into two breakout groups across two topic areas: 1) communication, education, and decision making; and 2) models of palliative care delivery. At the end of the day, all participants reconvened to summarize and discuss the results of the breakout sessions and the prioritized CER questions.

Breakout Sessions

PCORI staff reviewed and synthesized the questions (n=112) submitted by workshop participants down to 31 distinct CER questions that represent a combination of: 1) the most complete CER questions submitted by stakeholders, 2) multiple questions submitted by stakeholders that addressed the same fundamental question and/or decisional dilemma, and 3) priority questions of interest that emerged from PCORI staff’s background work in this area. These 31 questions were divided in two categories: communication, education, and decision making (n=14); and models of palliative care delivery (n=17).

The two workshop breakout sessions were then devoted to these categories. Several subthemes were also identified to further categorize the questions received (Table 1). Dr. James Tulsky chaired the breakout session devoted to communication, education, and decision making, while Dr. Marian Grant chaired the breakout session for models of palliative care delivery.

Table 1. Stakeholder Submitted Questions (n=112) by Broad Topic Area and Subthemes

Models of Palliative Care Delivery		**Communication, Education, and Decision Making**	
Timing of palliative care delivery	**11**	Communication and shared decision making, to facilitate advance care planning	**24**
Organization/coordination of palliative care	**46**	Clinician, patient, and caregiver training, education, and support	**18**
Other	**1**	Other	**4**
Total	***58***	***Total***	***46***

**Table reflects questions received as of Friday morning, March 4, 2016.*

***PCORI staff also received questions (n=8) proposing comparative effectiveness of clinical treatment options (e.g., cognitive behavioral therapy, mindfulness, opioids, etc.) that were outside the scope of the workshop.*

In both of the breakout sessions, the morning was spent assessing the synthesized research questions according to three criteria: 1) the importance of the topic and patient-centered decisional dilemma, 2) the readiness for CER, and 3) the current evidence base. Discussion was intended to refine and narrow the list of questions in order to have a more targeted conversation in the afternoon session. Following a prioritization exercise, each breakout session discussed the prioritized research questions using the PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Settings) framework,[1] identifying target populations, potential interventions and comparators, and outcomes of interest; participants then revised and formulated potential CER questions that were aligned with PCORI's mission and that were most compelling in terms of their potential impact on practice. Participants also discussed potential challenges to conducting research on the proposed questions and how the challenges might be addressed.

Communication, Education, and Decision Making

Box A: Themes Discussed in Communication, Education, and Decision Making Breakout Group

1. Clinician training and education
2. Patient and caregiver support and education
3. Shared decision making
4. Approaches to advanced care planning
5. Facilitating family communication

The communication, education, and decision making group focused its conversation on 14 research questions that had been synthesized by PCORI staff based on the questions submitted by workshop participants. These 14 questions were further categorized into five themes to facilitate discussion (Box A). Discussion of each question focused on three criteria: 1) the importance of the topic and patient-centered decisional dilemma, 2) the readiness for CER, and 3) the current evidence base. Discussion was intended to refine and prioritize the list of questions in order to have a more targeted conversation in the afternoon session. Below is a summary of key points of discussion among the participants across each of the five themes.

Clinician Training and Education

- There are a number of clinician training programs/interventions that could be adapted to a broad range of illnesses and used in CER.
- Missing from these questions is the need to engage patients and families in order to give them information in a way that they understand, and to work with them to determine clinical and life goals.
- Focus should include educating clinicians on how to engage in the community and use community resources. Possibly expand questions into system support interventions.
- Focus should be on the *primary setting of care* (not primary care setting), as it has been understudied and important when discussing multi-morbidities.

Patient and Caregiver Support and Education

- There is a need for an interdisciplinary team that examines the patient and caregiver both as a dyad and as individuals.
- It is useful to discuss outcomes of interest (downstream vs. upstream), scalability of interventions, and what the patient's goals are.
    - Acknowledge that patients' understanding of independence and goals change over the course of their illness—this requires constant communication with the provider.
- Culture can influence palliative care:
    - The culture of family could influence decisions—these conversations should begin early in the disease progression.
    - Patients need interventions that use different models of care delivery tailored to cultural backgrounds.

Shared Decision Making

- Advocate for using a broad definition of shared decision making.
- Needs to include patients with diminished capacity:
    - Shared decision making models should include training of physicians to elicit communication from patients with advanced illness, including nonverbal patients.
    - Needs to include people with cognitive impairment. There is a need to distinguish between those who no longer have the capacity to communicate and those who just need more help communicating (i.e., it is important to separate out disability from cognitive impairment).
- For consideration of the discontinuation of medications:
    - There is limited evidence to support the discontinuation of medications; there is a need for studies to be able to show it is safe and that it will reduce the burden of care, especially at certain stages in a disease.
    - We need to know the endpoints to measure if we're going to examine the discontinuation intervention.

Approaches to Advance Care Planning

- Consider using comprehensive care planning rather than advance care planning.

- Usual care is so heterogeneous and ill-defined.
    - How do we design studies to provide the type of evidence we want without an adequate comparator?
    - Context matters—it is unlikely to have a generalizable result when this matters. Communication very much depends on context.
- Changing circumstances are a big factor and can be mediated by beginning interventions earlier to allow time to plan and review.

Facilitating Family Communication

- This concept can be folded into previous questions while noting family dynamics and cultural differences.
- The population may not be right, but the construct of family-oriented communication offers interesting opportunities.
    - Works in terms of scalability and ease of access, and is very related to context.

At the end of the morning breakout session, attendees were asked to individually prioritize the five questions they felt were most worthy of further discussion in the afternoon. Each stakeholder was given five votes. The five questions that received the most cumulative votes were discussed in the afternoon session; the other nine were dropped from the conversation. In the afternoon, the five prioritized questions were reviewed using the PICOTS model in order to add specificity to the discussion and further refine relevant CER questions. Note that as the five questions were discussed, modifications and refinements were made to the prioritized questions in order to reflect areas of group consensus. The questions in Box B reflect the five prioritized CER questions that were refined and modified based on the group's discussion.

During the afternoon session, the group discussed the PICOTS for questions 1, 2, 3, and 5. The group had

Box B: Prioritized CER Questions in the Communication, Education, and Decision Making Breakout Group

Prioritized Question 1:

What is the comparative effectiveness of (different clinician- or non-clinician-led) interventions designed to facilitate advance care planning between culturally diverse patients living with serious life-threatening chronic/advanced illness, caregivers (formal and informal) and family members, clinicians, and healthcare agents on patient and family-centered outcomes?

Prioritized Question 2:

What is the comparative effectiveness of different provider/clinician training and education and multi-component interventions (and combinations of the two) to facilitate person-centered goal-directed decision making among adults with multi-morbidities in the primary setting of care?

Prioritized Question 3:

What is the comparative effectiveness of different approaches for facilitating patient and/or caregiver preparedness and self-care ability across the trajectory of advanced illnesses on patient and caregiver functioning and quality of life, and how does it differ across patient and caregiver subgroups?

Prioritized Question 4:

What is the comparative effectiveness of different approaches to shared decision making aimed at facilitating conversations around discontinuation of low-value treatment for patients with advanced illnesses? Can it be done in a way that is consistent with patient and family goals of care?

Prioritized Question 5:

What is the comparative effectiveness of comprehensive care planning approaches that make the care plan available in all settings over time versus short-term nontransferrable planning across diverse settings?

differing thoughts about how question 4 should be modified and refined; given time constraints, no consensus was reached regarding the relevant PICOTS for this question. The discussed PICOTS for the remaining four questions are summarized below.

Populations: Across the four questions, the breakout group identified several relevant patient populations, including any patients with serious illnesses, those with anticipated mortality within one or two years, individuals with multiple morbidities with different trajectories of decline, persons living with serious and progressive disabilities, and people with social and medical needs. For the clinician-training question (Question 2), the group encouraged focusing on a variety of clinicians and not only physicians. For the question on patient and caregiver preparedness and self-care ability (Question 3), the group recommended focusing on illnesses where good self-care can make a difference on important patient outcomes, including chronic illnesses where patients are receiving disease-modifying clinical interventions.

Interventions: For Question 1 on advanced care planning, the group encouraged including telehealth and e-interventions; culturally congruent interventions; and billable interventions (e.g., POLST, Respecting Choices, 5 Wishes). To improve clinician training (Question 2), the group endorsed multi-component interventions that go beyond clinician education alone and also include systems-level interventions that may facilitate care planning and decision making. To facilitate patient and caregiver preparedness and self-efficacy (Question 3), the group acknowledged that there were several efficacious interventions on self-care, patient activation, and care transitions that could be evaluated within the context of CER on the delivery of palliative care. For Question 5, the group emphasized that comprehensive care planning interventions should facilitate revisions to the plan over time based on changes in the patient's situation, goals, and preferences. In general, a recommendation was to leverage billable interventions.

Comparators: Many participants were of the opinion that the comparators should be active interventions instead of usual care alone and that a thoughtful defense of the comparators should be presented.

Outcomes: Across the four questions, the group identified a range of relevant outcomes that should be evaluated, including patient and caregiver understanding of prognosis, patient and caregiver empowerment and confidence/self-efficacy, patient engagement in care, congruence between patient value preferences and choices made, culturally appropriate care planning, production of advance directives, patient enrollment in palliative care programs, goal-concordant care, patient and family satisfaction and care experiences, reduced anxiety and distress, and reduced healthcare utilization. The group recommended additional exploration of the right combination of process- and patient-centered outcomes to be studied.

Timing: In general, the group encouraged longitudinal studies with multiple points of assessment.

Settings: In terms of settings of care, the group recommended studies be encouraged to include multiple care settings and emphasized a focus on community-based outpatient, ambulatory care.

Models of Palliative Care Delivery

The models of palliative care delivery group focused its conversation on 17 research questions that had been synthesized by PCORI staff; these questions were based on the questions submitted by workshop participants. These 17 questions were further categorized into seven themes to facilitate discussion (Box C). Discussion of each question focused on three criteria: 1) the importance of the topic and patient-centered decisional dilemma, 2) the readiness for CER, and 3) the current evidence base. Discussion was intended to refine and prioritize the list of questions in order to have a more targeted conversation in the afternoon session. Below is a summary of key points of discussion among the participants across each of the seven themes.

Box C: Themes Discussed in Models of Palliative Care Breakout Group

1. Timing of palliative care delivery
2. Integrated versus consultative approaches
3. Nurse-led models of palliative care
4. Settings of palliative care delivery
5. Integration of different professionals in the palliative care team
6. Models of care focused on caregivers
7. Leveraging technology to deliver palliative care

The 17 questions were introduced one at a time, and a robust discussion followed. Below is a summary of the key discussion points across the seven themes.

Timing of Palliative Care Delivery

- The question of timing of palliative care should apply to neurodegenerative diseases as well. Applications should be solicited on a broad range of illnesses.
- Availability of workforce is a key issue facing the palliative care community, so it’s really time to look at alternative models of palliative care delivery.
- The fundamental issue behind the timing of palliative care is how to identify when patients need palliative care. For a CER question, this may be reworded as: What is the impact of implicit versus explicit modes of patient identification (e.g., clinicians’ subjective perception of whether the patient is going to die in a certain number of months vs. functional or quality-of-life measures used by investigators)?
- We need to look at models that could address multiple diseases.

- Models need to account for the developmental trajectory of different advanced illnesses over time.
- Timing is a little too narrow; we should think about access to palliative care services, which is broader than timing; focus on racial minorities and rural populations.

Integrated versus Consultative models

- There is a need to include behavioral health/psychosocial care as part of the palliative care team.
- How can telemedicine be leveraged to improve access to palliative care services for rural patients?
- Given the limited workforce of palliative care specialists, there is a need to evaluate the impact of training front-line clinicians (e.g., primary care providers, specialists) in basic palliative care skills.
- Access issues for remote patients, not just rural patients, need to be studied.
- The question on integration of palliative care specialists into primary care settings should be expanded to primary and specialty care settings in a way that is aligned with the patient's goals of treatment.
- The question on integrating palliative care specialists into primary care is well worded, is very patient-centered, and would cut across diseases and care models; it is a good example of an important CER question.
- Studies of alternative models of care delivery would benefit from having multiple sites.
- Integrating palliative care specialists upfront with primary and specialty care physicians is likely to overcome the resistance physicians have to refer patients to palliative care and the resistance of patients to receive it.
- Studies must clearly define who qualifies as a palliative care specialist.

Nurse-led Models of Palliative Care

- There are lots of nurse-led programs, but there have not been studies of effectiveness or quality of those care models.
- The focus of the question should be expanded to neurodegenerative diseases, because often patients don't make it in for appointments and often fall off neurologists' radar.
- Nurse-led models are one form of integrated care models, and this question can be considered as one of the interventions under the theme of integrated versus consultative models.

Settings of Palliative Care Delivery

- The group had questions about the readiness of the nursing home setting; there are almost no data on efficacy of palliative care models in that setting.
- For studies of models of home-/community-based palliative care, access to no palliative care/usual care should not be a comparator.
- There is really good evidence for different community-based models, and there is a huge need to meet needs of patients who are home-based and in care transitions over time.
- The question on community-based palliative care has the opportunity to move palliative care upstream.
- For all models that may be tested, we have to test them in systems where incentives are aligned to facilitate their implementation.
- Traditional hospice models don't fit people with dementia or cancer.

- Don’t limit to a single setting of care; focus on longitudinal support to patients across settings.

Integration of Different Professionals in the Palliative Care Team

- These questions about testing the relative impact of a single clinical specialty—such as social work, nursing, pharmacy—on the delivery of palliative care were deemed to be not as important as the previous questions that focused on different approaches to delivering interdisciplinary palliative care.
- Every patient should get a comprehensive assessment of his or her palliative care needs and those needs should then be linked to the appropriate intervention and provider; the idea of testing one element at a time is not in the spirit of palliative care.

Models of Care Focused on Caregivers

- Focus on caregivers is important; studies should focus on the patient and caregiver dyad as the unit of intervention.
- This theme can be folded into the theme of integrated versus consultative models of care, and studies should be encouraged to include a caregiver component.

Leveraging Technology to Deliver Palliative Care

- There is an evidence base of telehealth applications in palliative care. Telehealth approaches should be folded into the theme of integrated versus consultative models as a potential intervention.
- Telehealth applications can improve access to palliative care services for patients who have mobility issues or who live in rural settings.

Through this discussion, the workgroup narrowed down the original list of 17 to seven questions, and modifications were suggested for some of them. The seven questions were posted throughout the room, and stakeholders individually voted for their top three choice(s) from this list, yielding four priority questions (Box D).

Box D: Prioritized CER Questions in in Models of Palliative Care Breakout Group*

Prioritized Question 1:

What is the comparative effectiveness of different models of palliative care (fully integrated vs. consultative approaches) when initiated early in the course of advanced cancers, such as lung and pancreatic cancers, versus when disease is progressing rapidly versus when all medical treatments have failed to control the disease on patients' symptom burden, physical and mental functioning, healthcare utilization, and caregiver outcomes, including burden, quality of life, hours of care, and satisfaction?

Prioritized Question 2:

What is the comparative effectiveness of integrated palliative care models (including training of existing providers, improved multi-disciplinary support for palliative care interventions, and quality measurement), compared to specialty palliative care consultation models, for improving patient- and family-centered outcomes for patients with advanced illness and for minimizing patient and family burden?

Prioritized Question 3:

What is the comparative effectiveness of different approaches to integrating palliative care specialists into the primary care setting (integrated care vs. co-location vs. offsite consultation) for patients with advanced illnesses on patient-centered and caregiver outcomes?

Prioritized Question 4:

What is the comparative effectiveness of patient access to community-based palliative care versus usual care (hospital-based palliative care only or no palliative care) on improvement in health outcomes of adult patients with advanced illnesses; identification of patient priorities/goals; attainment of patient priorities/goals (e.g., maintain independence, maintain or improve function, reduce pain and symptoms, maximize length of life); and completion of an advance directive?

** The wording of the questions is what was originally submitted to PCORI. During the meeting, participants suggested potential modifications to the language for consideration.*

During the workshop's afternoon session, results from the morning prioritization session were shared. The group discussed opportunities to further combine and improve those questions. A general discussion on potential PICOTS was initiated, followed by an individual exercise proposed by the breakout group chair. For this exercise, the chair posed a theoretical opportunity to the group:

> *There is an opportunity to fund a five-year, $10 million palliative care study in one of the following potential patient populations: elderly, frail, multi-morbidity; Alzheimer's or dementia; organ failure; or cancer. Before awarding the $10 million, we want to know the PICOTS, specifically: what is the patient population, what is the intervention and what are you comparing it to, what are the outcomes, what is the timeframe, and what is the setting? The $10 million can be split up in multiple studies, but you need to be very specific.*

Participants were given 10 minutes to craft a question using the PICOTS framework. Several participants shared their PICOTS, and the group used this opportunity to find common elements or qualities that would be critical in a research project on this topic. The summarized PICOTS and comments from the discussion are below.

- **Populations**: The patient/caregiver dyad should be the primary focus. Ensure involvement of diverse populations and a range of illnesses such as neurodegenerative diseases—advanced dementia, class 3 or 4 heart failure, advanced cancer, advanced chronic kidney disease, and patients with multi-comorbidity and high symptom burden.
- **Interventions**: Several proposed interventions focused on comparing different approaches to delivering community-based palliative care—nurse-led models versus interdisciplinary palliative care team; consultative versus telehealth versus integrated models; home-based palliative care delivery versus hospital-based consultative model; and community models that are based on different levels of integration of palliative care specialists (e.g., community health worker, social worker/nurse, nurse practitioner, palliative care physician), depending on patient need versus standard care provided by home health agency.
- **Comparators**: Head-to-head comparisons of active interventions were proposed.
- **Outcomes**: A range of patient- and caregiver-centered as well as system-level outcomes were proposed, including shared decision making, delivery of goal concordant care, impact on patient and caregiver health-related quality of life, improved functioning and symptom management, caregiver self-efficacy, caregiver burden/coping skills, patient and caregiver distress, patients' care experiences, healthcare utilization, out-of-pocket costs for family, use of advanced directives, nursing home placement, and referral to hospice.
- **Timing**: Palliative care should be delivered earlier and throughout the progression of illness and not limited to end of life alone.
- **Settings**: Follow patients across multiple settings of care, such as home/community dwelling patients, telehealth, and outpatient primary and specialty care.

Discussion comments included the following:

- Models should leverage innovative technologies to improve access.
- Models need to work in a capitated system, accountable care organization, or Medicare/Medicaid.
- Patient and caregiver satisfaction surveys should be included.
- Consider the role of nurses, behavioral specialists, psychiatrists, and other members of the care team when developing the approach.

Report Back Session

At the end of the day, workshop participants from both breakout sessions came back together for a brief presentation and discussion. Dr. James Tulsky and Dr. Marian Grant separately presented the resulting prioritized CER questions from their respective groups and provided context related to the discussion that occurred for each prioritized question.

Next Steps

To conclude the day, Dr. Chris Gayer, Program Officer of the Communication and Dissemination Research Program at PCORI, thanked participants for their input and noted that PCORI intends to continue to conduct further analyses and refinement of the questions put forth by the workgroup. Chris thanked the attendees on behalf of PCORI and described PCORI's intent to take priorities and concerns raised by attendees into account when considering future opportunities. Moving forward, prioritized questions and deliberations from the workshop will be shared with PCORI leadership, and PCORI governance will determine the next steps.