Patient-Centered Palliative Care Delivery for Adult Patients with Advanced Illnesses and Their Caregivers: Questions Submitted for Consideration by Workshop Participants

Prioritizing Comparative Effectiveness Research Questions: PCORI Stakeholder Workshops

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NOTE: This document includes questions submitted before 12 PM on Friday 3/4/16.

Submitted Questions on Communication, Education, and Decision Making:

- What scalable interventions (perhaps leveraging electronic health records) are most effective in improving the timeliness of goals-of-care conversations with seriously ill hospitalized patients as well as subsequent outcomes for patients and caregivers?
    - For this question, could append a secondary question: "How do the outcomes differ among patients with solid malignancies, hematologic malignancies, end-stage organ dysfunction (e.g., CHF, COPD, ESRD), or dementia?"

- Communication, shared decision making, and advance care planning among culturally diverse populations:
    - What is the comparative effectiveness of efficacious and widely used interventions designed to facilitate advance care planning conversations between culturally diverse patients, caregivers, clinicians, and healthcare agents on patient- and family-centered outcomes including understanding of prognosis, congruence between patient preferences and care choices made, healthcare utilization, production of advance directives, patient and caregiver activation, and decision satisfaction?

- What is the comparative effectiveness of models that include a standardized communication protocol (e.g. advance care planning documents, POLST) versus tailored patient/family education on improving patient and family outcomes?

- What is the comparative effectiveness of models that include a standardized clinician-directed education and training intervention designed to improve patient and family engagement in care planning on holistic care plans that address the four quality-of-life domains (physical, psychological, social, and spiritual well-being)?

- What is the comparative effectiveness of various advance care planning approaches in promoting culturally concordant communications, leading to better care outcomes and greater patient and caregiver satisfaction with those outcomes?
    - Rationale: We know that different cultures have different approaches to use of medications, use of end-of-life care, and may have culturally relevant use of other healing and palliative care processes. How do we ensure that the provisions of services are provided in culturally appropriate ways and ensure that patient and caregiver needs and desires are honored?

- Should hospice and palliative care services take a more outspoken position and express willingness to respond to requests for voluntary stopping eating and drinking (VSED), withdrawal of artificial fluids and hydration, and palliative sedation from patients (or their families) in the context of terminal illness? This question is prompted by the rareness and difficulty of finding hospitals and nursing homes willing to comply with such requests.

- How can physicians be more assertive in challenging the “do everything” default position and instead downplay aggressive treatment options and recommend palliative care when statistics suggest that these more aggressive treatments are likely to be ineffective or not especially helpful?

- What are the best ways to motivate seriously ill outpatients to prospectively document their desired approaches to care, and which of these most effectively promote patients’ satisfaction with their care plans, patients’ long-term outcomes, and caregivers’ bereavement outcomes?
    - For this question, could append a secondary question: “How do the outcomes differ among patients with solid malignancies, hematologic malignancies, end-stage organ dysfunction (e.g., CHF, COPD, ESRD), or dementia?”

- Two questions from what happened with my dad. I was power of attorney and primary caregiver. I have two older sisters. Situation was our dad had a stroke; prior to my dad’s stroke, he and I had very open communication including about his health. When he had the stroke, siblings basically threatened me and told me absolutely not to tell dad he had a stroke. Because oldest sister went to nurse and she was standing there one of the times nurses and I were talking (mind you, most of time, siblings were not around), nurses sided with older sister.

  No one was there when my dad and I struggled to communicate because he could no longer talk. Everything else was intact. So one, there need to be better ways to help family members communicate. In hindsight, once dad died and I didn’t have pressure from siblings, the inhumane thing was not letting dad know he had a stroke. Dad and I tried hard to communicate. After he died, I realized if anyone had suggested for us to have dad write, I think he couldn’t have. In hindsight, I think one of the things he tried to ask for was paper and pen. There was no paper and pen.

  It would have been good for hospital staff to better communicate with us, help problem-solve our communication, which was very good at first, and then it was a huge struggle. They also should have talked with me even without siblings, for I was the one there all the weeks before the stroke (my dad was in the hospital basically his last 11 months and mostly it was him and I. I was the only one with legal authority at the time, siblings came around here and there, and at times threw their weight of so-called power around).
  I know my family is not the only one with complex family dynamics. Communication with others, like now I am even thinking of my step-father too in 2008. My dad was 2003. There were communications in 1991 with my grandmother. My dad didn’t know that an IV was considered heroic measures and was shocked to find his mother’s IV gone. There is actually another whole story and communication problem with my grandmother. Right now, though, I need to go to a meeting.

  So I want to write a question about researching better ways to communicate with patients and primary caregivers. Then also how for staff, medical people to help patients and primary caregivers to communicate better together in cases of stroke and other conditions when the patient is unconscious and can't talk. Also, how to help patients and primary caregivers talk with other family members. I hope I am explaining this so you can understand.

- What is the impact of an intensive RN-residency program compared with staff training in palliative care on: 1) family/resident evaluation of care, 2) resident quality of life, and 3) burdensome transitions for persons receiving care in nursing homes?

- What is the comparative effectiveness of web- and video-based interventions versus enhanced clinical communication on advanced care planning in patients with advanced cancer?

- What is the comparative effectiveness of different formats of family meetings (face-to-face, technology-supported, synchronous, asynchronous, physician-led, non-physician-led) on goals of care and end-of-life wishes for adult patients with advanced malignancies who develop renal failure and are considering implementation of hemodialysis?

- What are the most effective decision-making and communications model(s) for patient-centered care related to discontinuing medications? How can we select the most effective model(s) for patient-centered shared decision making on discontinuing medications based on the patient and family's culture, ethnicity, or religion?
    - <u>People</u>: Adults with life-limiting illnesses (+social/cultural diversity)
    - <u>Option</u>: Communications models for shared decision making
    - <u>Outcome</u>: Impact on meeting patient/family goals of care

- Is there a difference in the care between what people wrote in an advance directive and the care they ultimately received?
    a. <u>People</u>: People who have died
    b. <u>Options</u>: Difference in care that was outlined in an advance directive and care that was received
    c. <u>Outcomes</u>: To find out if advance directives are an effective way to communicate end-of-life wishes

- Is it more effective to include the patient and their family caregiver as consistent members of the care team for care planning and decision making compared to only occasionally including the caregiver in dialogue as is the usual care model in most progressive illness situations?

- Does supportive care (education, peer dialogue) offered to patient and caregiver dyads encourage adoption of suggested tools and support more effectively than separate support group functions for patient or caregiver?

- As America continues to be a melting pot of cultures and ethnicities, what method of social marketing (i.e., Internet, television, billboards, etc.) could be most effective in reaching older adults regarding advanced illnesses among Native American, Asian, Hispanic, and other growing sectors of the population?

- How would patients with protracted chronic pain (<10 years) and their caregivers define their condition as "advanced disease" or as "typical" chronic pain as healthcare providers understand it to be? A difference in definitions could help explain the patient/caregiver attitudes about opioid use at all or overuse.

- What is the best way to communicate palliative care decisions for patients with conditions that severely limit their participation, and that are most likely to ensure input from patients and respect for the patient's decision as opposed to that of surrogate decision makers?

- How can different kinds of assistive technology support caregivers in their role with patients with conditions that severely limit their participation?

- Clinician communication training:
    - What is the comparative effectiveness of palliative care training inventions for nephrologists on improving communication with patients, patient understanding of treatment options, and patient satisfaction with care?

- Models of delivery:
    - What is the comparative effectiveness of traditional advance care planning outcomes such as goals of care discussion in advance directives/POA in advanced illness vs. implementation of the POLST paradigm on presence of needed documentation at point of care at necessary time, congruence of preferences stated and system response in the face of change in condition, healthcare utilization, and patient/family satisfaction?

- Regarding the need recognized by NINR for greater partnerships with patients and families, with scientists allowing the community to define priorities and the effectiveness of interventions limited to completion of ACP documents versus communication interventions.

  Promising but limited findings regarding the effectiveness of research in the areas of Affective Forecasting, Prospect Theory, Response Shift, and Transformative Learning in their application to end-of-life decision making and advance care planning have resulted from studies in recent years. Could methodological studies comparing these approaches—especially for community-dwelling persons living with life-limiting illness, progressive disease, and age-related frailty (outside the acute care and long-term care institutional setting)—prove beneficial for understanding the changes that take place over time for that population? Relative measures of independence, quality of life, and functional status that seek to incorporate these more social ("non-clinical" physiologically related) methods could prove invaluable in addressing the NINR priorities and may actually relieve the need for and expected benefit of RCTs.

  (I apologize that the above question does not fit the suggested format for comparative effectiveness, but the total absence of any reference to these types of research methods in the Topic Brief caught me a little by surprise.) I would be happy to refine the question if we learn through the workshop that these types of methods are considered by PCORI to be potentially beneficial and effective ways to gather patient and family perspectives.

Target Populations: Class IV heart patients as a category of patient (beyond cancer).
Outcomes research in the area of heart disease.

- Linking advance care planning to care plan in systems of care that are designed to honor those values, when possible
    - The 2014 IOM report recommended a life cycle approach to advance care planning. For example, for a healthy 22-year-old, the focus may be on naming a proxy decision maker and ascertaining preferences that are unique to that person. Contrast this with a person with multimorbidity with progressive serious illnesses that are impacting the patient's quality of life; the focus for the majority of persons in advance care planning, as well as current shared decision making, should be on working with the patient to formulate clear preferences for care now and in the future. In this latter case, linking the goals of advance care planning to the actionable care plan is key to honoring and achieving the patient's goals of care.[1] As will be explained below, this linking of the results of ACP to EMR care plan will only be successful in conjunction with organizational structure elements (e.g., sufficient staff to make visits in times of crisis) and government/insurer regulations and payment incentives that align with those goals.
    - ***What is the comparative effectiveness of a decision support system that links specific preferences to an EMR care plan in a healthcare system with the right structure, regulations, and financial incentives that ensure that healthcare providers anticipate and formulate actionable care plans to ensure patients' goals are achieved?***
    - We need to create reproducible, multifaceted interventions informed by key organizational structures, government, or insurer policies including reimbursement, and regulations that facilitate key processes of care that must be changed to achieve the objective of honoring a patient's values and goals.
    - Too often, we focus on advance care planning as a decision aid with the assumption that the use of such an aid will impact a very complex process. It is incorrect to assume that merely increasing access to hospice services would impact the overall quality of end-of-life care from a population perspective without addressing the financial incentives under fee-for-service Medicare that result in late hospice referral. It is important to understand the key steps as well as the right organizational structure and government/insurer payment policies and regulations that are needed to ensure advance care planning will honor a patient's preferences.

- Severe Acute Brain Injury
    - Severe acute brain injury (SABI) kills 12 million people annually and is the leading cause of disability worldwide. This group of diseases includes vascular, traumatic, and hypoxic-ischemic injury, each of which has a high mortality and can leave survivors in a state some consider worse than death. The clinical and financial impacts of SABI make this disease a significant public health concern. In 2010, the estimated economic cost of stroke and traumatic brain injury together was over $130 billion including direct and indirect costs. The prevalence and costs of both diseases are expected to increase substantially over the next decades.
    - A key challenge in SABI is long-term prognostication with various concerns about existing prognostic models as well as physicians' ability to predict future function, let alone quality of life.

  - There are two critical time periods for treatment decisions after SABI: 1) the decision during the initial hospitalization to use tracheostomy and/or PEG feeding tube and 2) decisions at a later time regarding benefits and burdens of continuing life-sustaining treatment once a clearer prognosis emerges.
  - Work is needed in the areas of communication and prognostication during both time periods to help all stakeholders arrive at the most patient-centered treatment decisions and eventually outcomes.
  - ***What is the comparative effectiveness of new prognostic models, decision aids, and longitudinal models of care that help persons with SABI and their families make patient-centered treatment decisions during two critical time periods?***

- If care and treatment were focused on the most important health problems or health goals as expressed by adult patients with advanced illness, and if progress toward those goals was measured across primary and specialty care, would the patient achieve better health outcomes and greater satisfaction? Would the provider have more satisfaction? Would the caregiver have lower stress (caregiver strain index)? What, if any, measurement barriers would need to be addressed?

- What is the comparative effectiveness of using caregiver interventions designed to improve/ maintain the safety and quality of patient care on caregiver preparedness? (Patient outcomes: symptom management, mental and physical health, healthcare utilization, and caregiver satisfaction.)

- Among [various] patients with advanced non-cancer illness* receiving palliative care, are implicit provider measures (e.g., judgement of prognosis) compared with explicit measures (e.g., specific disease criteria, risk assessment) of risk associated with better patient- and family-centered decision making and outcomes?
  - *For example, dementia, heart failure, COPD defined by condition-specific or general and mixed (e.g., multiple admission) populations

- Does a workshop in communication and advance care planning for neurologists and neurology advanced practice providers durably improve rates of completion of advance directives for patients with neurodegenerative illnesses compared to current standards of education or provision of written materials?

- Communication: What is the impact on patients and caregivers of training practicing clinicians to communicate effectively regarding goals of therapy and the transition to palliative care?

- What are the comparative risks and benefits for older adults receiving palliative care (measured in terms of patient-centered outcomes such as those listed above as well as surrogate outcomes, including: surrogate satisfaction with care, surrogate decisional conflict, and surrogate psychological distress) of palliative care consultations received either (a) as a function of preferences articulated in an advance directive or (b) as a default “usual practice”?

- For persons living with serious and progressive disabilities associated with aging (frailty and advanced organ system illnesses), does comprehensive care planning, with the plan available in all settings over time, improve patient/caregiver outcomes and experience, compared with the fragmentary, hit-or-miss, and short-term planning that is not generally transferred across settings and is commonplace now?

- For persons living with serious and progressive disabilities associated with aging (frailty and advanced organ system illnesses), does it improve patient/caregiver outcomes and experience to provide real-time information from very large database(s) about the outcomes (survival, disability course, satisfaction, costs) for persons with similar situations in the recent past, sorted by major decisions as to treatment and setting?

- How can the primary care setting be optimized to assist in goal-directed decision making for older adults with multimorbidities?
    - Provider education vs.
    - Provider education + decision support tools incorporated into the EMR

- What is the experience of delivering advance care planning/decision-making interventions across the following populations of patients and families: those with patients with cognitive impairments; ethnic/diverse populations? In our work with a very diverse family caregiver community in the San Francisco Bay Area, we've found that there is no single strategy suitable for all subgroups. So our question centers on **the comparative effectiveness of advance planning interventions across the variables of cognitive impairment and diverse cultural groups.**

- Understanding that a family caregiver that is taking care of a relative with advanced illness typically has more demands on his/her time and is handling more complex care in the home—including an increase in medical tasks—our next issue concerns how technologies might be utilized in the process. So the question might be: ***What is the comparative effectiveness of multi-component advance care planning interventions, including decision aids that utilize technology, on increasing competence and capacity for caregivers of individuals with cognitive impairment to make advance care decisions?***
    - Finally, in reviewing and analyzing "evidence-based practices" in caregiver interventions, we have noted a lack of data on the time burden on patients and families to participate. Understanding that cost-effectiveness is not a part of this discussion, it has been our observation that moving interventions into practice that have a significant time burden are more difficult and usually reach a lower than expected number of individuals because the burden is too great for either the clinician/provider or for patients and families to participate. No question here, just an observation.

- To determine patient preferences and responses to a different form and order of standard versus personalized information provided regarding late-stage disease. Patients may be more receptive to information if they can be oriented to general concepts of uncertainty, mortality salience, and possible choices before learning specific information about their own situation.
    - <u>Population:</u> Patients with advanced disease with anticipated survival rate modeled to be less than x % for whom discussion is planned regarding prognosis and goals of care.
    - <u>Intervention:</u>

Randomized to

1) Usual personal verbal approach to discussion
2) Discussion preceded by standard information presented impersonally (video or written?) that is clearly <u>not</u> patient-specific, which addresses:
    a) The uncertainty about survival for any patient even toward end of disease
    b) The ways in which death can occur
    c) Options of therapies to choose or decline
    d) Examples of families having to make difficult decisions for patient
    e) (Could include the CPR video from Volandes?)

- <u>Outcomes at time of intervention and after one week, two months:</u>
    - Patient and caregiver:
        - Estimation of life expectancy
        - Sense of understanding information
        - Patient's self-described level of comfort making decisions about therapies in future
        - Patient's documents completed

- In response to your query regarding palliative care priorities for adult patients with advanced illnesses and their caregivers, we posed the following question to UsAgainstAlzheimer's 5,000-member Facebook Alzheimer's Caregiver Community:
  "What is the biggest problem you are facing (or faced) while a loved one receives palliative care? (This is care focused on quality of life and symptom management.) This could be any aspect—for example, dealing with health professionals or home vs. nursing care."

  Caregiver respondents highlighted the following questions and priorities:
    - ***What is the best method of delivering high-quality communications, outreach, and education to family caregivers?***
        - Respondents emphasize that effective, high-quality outreach, communication and education for caregivers, as well as patients, is critical "caregiver care," especially for inexperienced and overwhelmed family caregivers. This will positively impact caregiver wellbeing and patient care.
        - As one Alzheimer's caregiver notes, "When my mom was receiving palliative care I feel like it was more for me really than her. As a child caring for a parent I feel like a fish out of water, and mind you I try to educate myself and be very aware of this disease as it progresses. So, having said that, I can't imagine what people who aren't educated feel like. I originally requested palliative services as my mom was progressing and I was feeling insecure in what I would do if something were to happen. Here is the bottom line. I, as most caregivers, have not walked this path before. I have no idea what to expect except for what I read in a book or look up online. I know what will happen to my mom as she progresses, but it isn't real life; it is black and white. I need color."
    - ***Does use of behavior tracking logs by Alzheimer's caregivers lead to improved quality of care?***

        - Behavior tracking logs were cited as a useful tool to help caregivers cope with the challenge of figuring out why a family member with Alzheimer's is behaving in a challenging manner, and prepare for the behaviors, and not just react or become frustrated.
        - One respondent notes, "I see my [family member] revert back to childhood. And there are always reasons for behaviors she expresses. For example, crying at a certain time of the day because that's when she might have [been] waiting for a child to get off the bus and can't find them. Or maybe she is just hungry and needs a snack. The biggest challenge is figuring out why they have these behaviors."

- Communication and decision making:
    - What is the comparative effectiveness of customized information (e.g., clinician, navigator, health coach) vs. standardized information (decision aid) about major medical decisions on both patient outcomes (decision quality, satisfaction) and clinician/system outcomes (time, feasibility within the clinical setting, resources required)?

- Communication and decision making:
    - What is the comparative effectiveness of a communication strategy focused only on cognitive information versus a communication strategy focused on both emotional and cognitive communication on major medical decisions (advance care planning, major surgical intervention, etc.)?

- Within the natural course of Parkinson's disease (PD), when is the optimal time to discuss palliative care options and advance directives with patients and caregivers, and how is this education best delivered?
    - People: Patients with mild, moderate, and advanced Parkinson's disease and their primary caregivers
    - Options:
        - A. Sharing information about palliative care when Parkinson's disease is mild vs. moderate vs. advanced.
        - B. Providing patients and caregivers with detailed printed educational resources on palliative care without discussion vs. providing printed educational resources on palliative care plus discussion by a qualified professional.

	Printed Materials Only			Discussion-based Education		
	Mild	Moderate	Advanced	Mild	Moderate	Advanced
Group 1	✓					
Group 2		✓				
Group 3			✓			
Group 4				✓		
Group 5					✓	
Group 6						✓

  - Longitudinal Outcomes:
    - A. For PD patients: PDQ-39 questionnaire, Katz ADL scale, # of referrals to palliative care, # of advance directives (including DNR) completed
    - B. For caregivers: Quality of life/satisfaction surveys (working group to develop)
    - C. Group comparisons: # of referrals to palliative care and # of advance directives (including DNR) completed

- Patients with end-stage heart failure followed in the hospice setting often struggle with when to deactivate an implanted defibrillator (AICD). Often these patients report that the defibrillator has never fired. Patients often understand that the defibrillator will not prevent their heart failure death and that it may fire repeatedly at the time of death in a very disturbing way for families as well as the patient. Is there any data available to help guide the discussion as to when to deactivate the defibrillator? Would establishment of a set point on the trajectory of the illness be helpful to be able to say, "This is when the AICD should be deactivated"? Do cardiologists have this discussion with their patients when they implant the device?

- The American Heart Association/College of Cardiologists (AHA/ACC) guidelines for management of Stage D/ NYHA Class IV heart failure have included palliative care and end-of-life discussions, addressing advance directives as part of the responsibility for care of the patient since 2007. However, cardiologists still seldom address prognosis with their end-stage cardiac patients and often fail to recognize the approach of the final year of life for these patients. Are there any educational initiatives that could be implemented to help cardiologists in this regard? How might we help cardiologists to have discussions with patients about prognosis, end points of aggressive care, and the trajectory of the patient's illness much earlier in the course of the illness? Is payment for these discussions sufficiently incentivizing?

- The large hospice in which I work has provided palliative chemotherapy and palliative radiation to patients for many years using grant money and donor dollars. We have learned that management of these patients requires a special skill set, and we have developed unique protocols to assure that they are safe and comfortable given the vast diversity of side effects possible with chemotherapies and the significant danger of neutropenic sepsis. In new models of palliative care in which supportive care is given concurrently with aggressive care, such as the Medicare Care Choices Model, hospices that have never managed patients on chemotherapy may suddenly be doing so. Is this something that we need to be concerned about? Is special training in place to help hospices assume responsibility for patients with much more complex needs, chemotherapy as well as other therapies, than they have cared for in the past?

Submitted Questions on Models of Palliative Care Delivery

- Should specialized outpatient palliative care programs be instituted to care for patients who choose not to undergo treatments such as dialysis or other arduous therapies for illnesses such as cardiomyopathy or end-stage COPD, and how would such programs be organized?

- What distribution of activities among a fixed supply of palliative care specialists (e.g., inpatient consultation, inpatient office hours, outpatient clinic) maximizes the overall effectiveness of their work for all patients who could potentially benefit from their services?
    - For this question, could append a secondary question: "How do the outcomes differ among patients with solid malignancies, hematologic malignancies, end-stage organ dysfunction (e.g., CHF, COPD, ESRD), or dementia?"

- <u>Timing of palliative care delivery:</u>
    - What is the comparative effectiveness of models involving palliative care specialists early in the disease course versus at key points based on changes in symptom burden on improving patient functioning and quality of life, reducing caregiving burden, and avoiding hospital and emergency department visits?

- What is the comparative effectiveness of models including person-centered measures of family caregiver outcomes and caregiver care planning on improved patient care?

- What are the comparative benefits and risks of nurse-delivered models of palliative care for cancer patients and their families?

- What are the comparative benefits of palliative care models that offer professional social work services to every patient and family, versus models that use professional social workers on an "as-needed" basis, on improving patient functioning and quality of life, reducing caregiver burden, facilitating advance care planning, and decreasing hospital and emergency department visits?
    - <u>Rationale</u>: Some palliative care programs rely on disciplines other than social work, such as nursing, to screen for psychosocial needs. Thus, although the National Consensus Project's Clinical Practice Guidelines for Quality Palliative Care specify that every palliative care patient and family should have access to professional social workers, in practice, another discipline sometimes (or frequently) determines if individuals and families need social work intervention. Limited resources are often cited as the rationale for this practice, although such limitations probably don't extend to nursing. This practice can deprive patients and families of the full psychosocial benefits associated with palliative care, and can cause only requesting social work intervention when psychosocial needs become more severe and more difficult to deal with.

- What are the comparative benefits of different nursing home palliative care models (including hospice) on improving patient functioning and quality of life, reducing caregiver burden, and decreasing hospital and emergency department visits?
    - <u>Rationale</u>: External palliative care teams, including hospice teams, need to work collaboratively with the facility's interdisciplinary team—although we know that, in practice, there can be

conflicts and miscommunications, impacting plans of care, quality of care, quality of life, and resident outcomes.

- What is the comparative effectiveness of models involving palliative care specialists early in the disease course versus at key points based on changes in symptom burden on improving patient functioning and quality of life, reducing caregiving burden, and avoiding hospital and emergency department visits?
  - Rationale: In theory, anyone with a serious illness can benefit from palliative care from the time of diagnosis; in practice, even well-staffed programs can't respond to the needs of every patient. What is the best system for determining referrals, and how should different diseases and diagnoses—for example, advanced cancer or Alzheimer's—be prioritized differentially for palliative care interventions?

- What is the impact of traditional hospice services compared with palliative care case management on: 1) family assessment of EOL care and 2) patient pain and symptoms for older adults receiving care in nursing facilities under the Medicare SNF benefit?

- What is the impact of a family-care team partnered care planning innovation compared with palliative care consultation on: 1) family/staff evaluation of resident quality of life and 2) rate of burdensome transitions and treatments for nursing home residents with advanced dementia?

- What is the comparative effectiveness of a primary palliative care intervention delivered by oncologists versus specialty palliative care in patients with advanced cancer?

- What is the comparative effectiveness of an early specialty palliative care model versus palliative care triggered by clinical turning points in patients with advanced cancer?

- There are exclusion criteria that help determine suitability for home peritoneal or kidney transplantation. When should advanced age, cognitive impairments, active substance abuse, or even the absence of a family member or supportive friend appropriately call for palliative rather than alternative medical surgical treatments (e.g., withholding dialysis or ventilators)? In other words, should exclusionary variables play a major role in the consideration of aggressive and/or expensive care?

- Caregiver burden:
  - What is the comparative effectiveness of different approaches for facilitating patient and 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 in multicultural communities?

- What is the comparative effectiveness of nurse-led (APRN) outpatient palliative care programs for home-based patients with advanced heart or lung failure (includes: CHF, COPD, ILD, lung cancer resulting in symptoms of chest pain or dyspnea requiring advanced medical interventions such as: VADs, continuous parenteral infusion therapy, or BiPAP?)

- What is the comparative effectiveness of a psychoeducational caregiver support group facilitated by a palliative care clinician in reducing stress and improving a sense of wellbeing in the patient caregiver?

- What is the comparative effectiveness of introducing concepts of palliative care to nursing home residents prior to diagnosis of an advanced illness?

- What is the comparative effectiveness of palliative care models that integrate a pharmacist into the interdisciplinary patient care team versus models without a pharmacist on improved healthcare utilization and patient safety for patients with life-limiting illness?
  - Can integration of a pharmacist into the interdisciplinary team improve patient safety pertaining to the medication use process as assessed by the five components of drug regimen review identified in the Medicare Hospice Benefit [CoP 42 CFR 418.54(c)(6) Drug profile; Interpretive Guidelines L-tag: L530]?
  - Can integration of a pharmacist into the interdisciplinary team improve outcomes pertaining to optimal medication use and optimal use of healthcare resources in patients with life-limiting illness?
    - <u>People</u>: Adults with life-limiting illnesses (+pharmacist-provided drug profile review, i.e., pharmacist becomes a core service provider in the hospice IDT)
    - <u>Option</u>: Integration of pharmacists into hospice and palliative care multidisciplinary and interdisciplinary patient care teams
    - <u>Outcome</u>: Impact on patient safety, quality of life, and optimizing healthcare resources.
      - 1. Effectiveness of drug therapy
      - 2. Drug therapy currently associated with lab monitoring
      - 3. Drug side effects
      - 4. Actual or potential drug interactions
      - 5. Duplicate drug therapy

- When terminally ill adults have a consultation with a palliative care specialist versus no consultation, do they opt for a less aggressive treatment or do they continue to ask for the most aggressive treatments?
  a. <u>People</u>: Terminally ill adults
  b. <u>Options</u>: Palliative care consultations versus non-palliative consultations
  c. <u>Outcomes</u>: Frequency rate of less aggressive treatments

- Are people who receive advanced illness care that is part of a comprehensive wraparound system, such as Sutter Care at Home, more likely to have their end-of-life wishes honored than those who do not?
  a. People with advanced illnesses enrolled in comprehensive wraparound systems
  b. <u>Options</u>: Difference between having end-of-life wishes honored with wraparound care versus standard care
  c. <u>Outcomes</u>: To determine if wraparound care is more effective at honoring a person's wishes at the end of life.

- Do caregivers of persons with dementia participate in advance planning within a palliative care treatment model more often than caregivers of dementia patients who are not being treated in a palliative care model?

- What is the impact of palliative care on the quality of life for a person with dementia?

- What is the impact of palliative care on the burden and stress of the caregiver for a person with dementia?

- Certified Peer Specialists have seen a huge uptick in their profession, enough to get the President to order 800 to be hired by the VA in 2015. What impact did the Peer Specialist's inclusion in the care team have on outcomes of patients with advanced illness and their caregivers compared to those care teams/patients without a Peer Specialist?

- For patients with Parkinson's disease (PD) or dementia, are patient outcomes and symptom management improved by having a dedicated care coordinator to liaise between palliative care specialists and the primary neurological specialist (who makes initial referral to palliative care)?
    - <u>People</u>: Patients with advanced Parkinson's disease (marked by motor complications, debilitating motor symptoms, psychosis, and/or dementia), patients with neurodegenerative dementia, and their primary caregivers
    - <u>Options</u>: Providing palliative care to patients with or without a dedicated palliative care case manager who coordinates care and communication between palliative care and neurology clinics. Roles and responsibilities of the case manager would include triaging calls to direct to either neurology or palliative care, ensuring one physician (either neurologist or palliative care specialist) took the lead on all medication management, caregiver's needs were being met, etc.
    - <u>Longitudinal Outcomes</u>:
        - A. For PD or dementia patients: Validated scales for motor symptoms, medication complications, psychosis, quality of life, and impairment of activities of daily living (e.g., Parts I, II, and IV of the MDS-UPDRS)
        - B. For caregivers: Quality of life surveys (working group to develop) investigating sleep and mood disturbances (measured by treatment required), financial burden, and social and occupational strain related to caregiving

- What is the best way to communicate pain management needs of patients with severe pain that may result from neurological conditions and that address the needs of the patient?

- <u>Models of Care Delivery:</u>
    - What is the comparative effectiveness of models involving social workers to facilitate palliative care discussions with patients who are approaching end-stage renal failure (CKD stages 3-4)? What is the impact on patient functioning, quality of life, reducing avoidable hospital and emergency department visits, and reducing caregiver's burden?

- <u>Models of Care Delivery:</u>
    - What is the comparative effectiveness of coordinated patient-centered palliative care delivery models (i.e., dialysis centers, home-based programs, hospice, and hospital inpatient consultations) for patients on dialysis with multiple comorbidities such as uncontrolled diabetes and congestive heart failure?

- First, a general question: One of the physicians I work with asked me to define “fully integrated palliative care services.” She explained that a variety of models are used in her academic medical setting—specifically identifying consultative as a distinct model from fully integrated (e.g., comprehensive cancer treatment). Is there any appetite to be more descriptive of the different models?

- What are the comparative benefits and risks of allowing concurrent care in oncology patients compared to patients who must choose either standard oncology care or palliative care?
    - Population: Advanced cancer patients electing palliative care
    - Rx Options: Concurrent standard oncology therapy (chemotherapy) and simultaneous palliative care services or the choice between either standard oncology therapy or palliative care services.
    - Outcomes: Patient and family satisfaction with option of concurrent care, quality of life between the two groups, and length of continuing standard oncology therapy compared to patients who were not offered concurrent palliative care services.
    - This question would likely relate to both decision making as well as models of care delivery

- Multimorbidity and Hospice
    - A concern with the Medicare Hospice Benefit is that it is based on a cancer dying trajectory of the 1980s. The expansion of the benefit to non-cancer diagnosis and persons with multi-morbidity raises the concern that payment incentives are not aligned with patient needs.
    - ***What is the comparative effectiveness of a newly developed model of care and payment that would involve co-management with time-limited escalation of involvement of the interdisciplinary team based on the needs of the patient and family?***
    - From the onset, any new proposed reform that involves payment needs to be created in light of the concerns about fraudulent activities that have occurred with the Medicare Hospice Benefit.

- For adult patients with advanced illnesses, does access to community-based palliative care versus usual care (hospital-based palliative care only or no palliative care) improve health outcomes, identification of patient priorities/goals, attainment of patient priorities/goals (examples: maintain independence, maintain or improve function, reduce pain and symptoms, maximize length of life), and completion of an advance directive.

- Are adult patients with advanced illnesses more likely to “get the care they want and avoid the care they don’t want” when they receive palliative care? Additionally, are adult patients with advanced illness more likely to “get the care they want and avoid the care they don’t want” for a longer duration when they have access to community-based palliative care (versus hospital or no palliative care)?

- Palliative care delivery:
    - What is the comparative effectiveness of integrated palliative care models (including training of existing providers, improved multidisciplinary 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 minimizing patient and family burden?

- Caregiver burden:
    - What is the comparative effectiveness of different palliative care delivery models (physician consult-based, nurse education, or social work supportive services) for reducing caregiver burden and distress in the outpatient setting?

- Symptom assessment and monitoring:
    - What is the comparative effectiveness of palliative care approaches that emphasize non-pharmacologic symptom management (e.g., nurse and social worker education, support, and follow-up) versus traditional specialty physician-based palliative care consultation models?

- Using RCTs, what is the comparative effectiveness of (fully integrated) models of palliative care initiated early in the course of advancing disease (cancer) versus when disease is progressing or at the point when treatment has failed, on the quality of patient lives at the end of life, including reducing symptom burden, improving mental health, preserving physical function and healthcare use as well as reduction in caregiver burden? (Select cancers with rapid decline such as pancreas or lung)
    - How does this CE differ if using a fully integrative US consultative model of delivery?
    - Does the introduction of E-technology together with palliative care produce a comparative advantage over palliative care alone in reducing symptoms and maintaining mental and functional health? And do these advantages differ depending upon whether they are introduced early in treatment, at time of disease progression, or at the point of treatment failure?
    - Does supportive symptom management for the patient and family caregiver produce a comparative advantage in patient outcomes?

- What is the comparative effectiveness of using a fully integrated model of palliative care if introduced early versus late in the course of advancing disease (cancer) on the family caregiver outcomes? (Quality of life, physical and mental health, caregiver burden, hours of care, satisfaction of care, and quality of care provided to the patient? And use of healthcare services (hospital, ER, urgent care, hospice).

- Among [various] patients with advanced cancer and non-cancer illness*, how do single provider (nurse, social worker) models compare to team-based (physician, nurse, and social worker) models for specialty palliative care provision regarding patient- and family-centered decision making and outcomes?
    - * For example, dementia, heart failure, COPD defined by condition-specific or general and mixed (e.g., multiple admission) populations, and metastatic cancer

- Among [various] patients with advanced cancer and non-cancer illness*, how do non-specific (e.g., case management) outpatient and inpatient models of palliative care compare regarding patient- and family-centered decision making and outcomes?
    - A. How do embedded or primary care models compare with specialty-based referral models?
    - *the same as above

- Does telemedicine for patients with neurodegenerative illnesses with mobility or transportation issues improve quality of life compared to outpatient care?

- Palliative care delivery: What is the real-world effectiveness of an electronic Clinician Reporting System on patient and caregiver quality of life (papers attached of research population)?

- What palliative/supportive care interventions are most effective in improving patient health outcomes, caregiver well-being, and optimizing healthcare utilization?

- What models of care are most effective at delivering palliative/supportive care to patients and caregivers? Can interventions be scaled to be delivered remotely while preserving fidelity and dosage? Given provocative findings in oncology by Temel and others on increases in patient survival, patient- and family-centered outcomes for early versus late initiation of palliative care, at what point in the care continuum are palliative/care interventions most beneficial?

- Legislation was passed by 20 states under the AARP-sponsored C.A.R.E. (Caregiver Advise Record Enable) Act, which deems that hospitals should (1) record the name/contact info of the primary caregiver for a newly hospitalized patient, (2) advise the caregiver prior to the patient's discharge, and (3) prepare/educate the caregiver in the context of discharge planning. How should researchers be incorporating these changes into study designs for palliative care, and how should assessments related to this act be designed and evaluated?

- What are the comparative benefits of incorporating patient-reported outcome measures such as the Palliative Care Outcomes Scale (POS)[1] and the McGill Quality of Life Questionnaire (MWOL)[2] feedback in home-based and office care versus hospital care?
  - References:
    - 1) Antunes B, Harding R, Higginson IJ. Implementing patient-reported outcome measures in palliative care clinical practice: A systematic review of facilitators and barriers. Palliat Med. 2014;28(2):158-75.
    - 2) Cohen SR, Mount BM, Strobel MG, Bui F. The McGill Quality of Life Questionnaire: a measure of quality of life appropriate for people with advanced disease. A preliminary study of validity and acceptability. Palliat Med. 1995 Jul;9(3):207-19.

- What are the comparative patient-centered outcomes for palliative care delivered by palliative care specialists versus primary care clinicians who are not palliative care specialists but who have received training in basic palliative care competencies?

- What are the comparative risks and benefits of closed healthcare systems versus open healthcare systems when looking at information sharing for people with dementia and their families?

- For persons living with serious and progressive disabilities associated with aging (frailty and advanced organ system illnesses), is it better for the experience of the affected persons and their families for their community to have integrated management of medical services and long-term services and supports or to continue to have no management and integration?

- How do we best identify patients in need of palliative care interventions in the primary care setting?
  - Ad hoc, through PCP referral or "surprise question" panel reviews vs.

    - EMR screening for disease-specific criteria and utilization patterns vs.
    - Additional waiting room-based screening through needs assessments

- How do we best integrate palliative specialists into the primary care setting?
    - Coordinate care: off-site consultant vs.
    - Co-located care: on-site co-location vs.
    - Integrated care: shared evaluations and treatment plans

- This will test the level of interest and satisfaction in a program of enhanced access to care that offers broad enhanced contact with a health team for advanced chronic illness (like HF) but limits use of “do everything” diagnoses and therapies (in general, does not use intensive care units), but provides more active intervention than hospice.
    - Patient population: Target patients with a chronic illness with which survival models predict < 50% one-year survival (e.g., heart failure).
    - Intervention: **ACE=** “Appropriate Care Enhancement”
    - One randomization and then patient choice results in four arms:
        - Randomization to
            - A) Usual care, with option to switch to ACE after six months
            - B) **Option** to join ACE, leading to one of the following:
                - B1) Patients who choose to accept ACE initially
                - B2) Patients who decline ACE then enroll later (minimum period one month)
                - B3) Patients who decline ACE and do not choose it later.
    - **Access intervention**: Patient has access 10/7 to face-to-face contact with a member of dedicated health care team (RN/PA-NP/MD), all of whom they have met previously, and 24/7 access by phone to RN with patients’ health information at hand. They do not need to go to the emergency department (are discouraged from this) to be seen. They will be admitted if necessary, but not admitted or transferred to an intensive care unit. There will be an understanding with the patient, but not strictly enforced, that they will not have high-intensity diagnostic tests (such as MRI) or surgical intervention for life-threatening problems (such an intracranial hemorrhage or acute abdomen). (Patients may or may not be required to be DNR/DNI—different possible designs of study and use of ICU post-resuscitation).
    - **Outcomes:**
        - Patient and family satisfaction with quality of care
        - Patient quality of life since randomization
        - Patient levels of concern regarding “being taken care of”
        - Severity and hierarchy of concerns from patient and caregiver

- In response to your query regarding palliative care priorities for adult patients with advanced illnesses and their caregivers, we posed the following question to UsAgainstAlzheimer’s 5,000-member Facebook Alzheimer’s Caregiver Community:
  “What is the biggest problem you are facing (or faced) while a loved one receives palliative care? (This is care focused on quality of life and symptom management.) This could be any aspect—for example, dealing with health professionals or home vs. nursing care.”

Caregiver respondents highlighted the following question and priorities:

- ***How can healthcare professionals help caregivers coordinate delivery of care?***
    - Respondents emphasize that support for coordinating care is critical, especially for overwhelmed family caregivers who are often tasked with this responsibility.
    - As one Alzheimer's caregiver notes, "Coordinating care is huge. I do this on my own private basis (three private caregivers rotating), and really it is like a full-time job in order for me to retain my sanity and continue to be a mom and wife too."

- What is the comparative effectiveness of specialized hospital palliative care teams on outcomes (symptoms, clinical outcomes, utilization) across populations defined by primary diagnosis, functional impairment, cognitive impairment, symptom burden, and comorbidity?

- What is the comparative of effectiveness of community-based models of palliative care (co-management, care management models, concurrent hospice) on patient and family outcomes (symptoms, treatment decisions, utilization, caregiver burden, PTSD, anxiety, or prolonged grief disorder, and family out-of-pocket spending) for different patient populations as defined by primary diagnosis, functional impairment, cognitive impairment, symptom burden, and comorbidity?

- What is the comparative effectiveness of external palliative care consultation versus systematic training in palliative care knowledge and skills for regular care staff on patient outcomes (symptoms, burdensome transitions, feeding tube placement, development of resistant organisms, family satisfaction) in nursing homes?

- <u>Models of care delivery:</u>
    - What is the comparative effectiveness of pre-palliative care/primary palliative care (provided by lay persons, navigators, peer support, nursing, primary care physician) versus tertiary palliative care (board-certified, specialty-trained, multidisciplinary teams) on patient outcomes (symptom control, QOL, value-treatment concordance) and system outcomes (access, feasibility, acceptability, etc.)?

- What is the comparative effectiveness of models of palliative care in the emergency department on salient patient and caregiver outcomes (e.g., symptom management, QOL, satisfaction) as well as referral to specialty palliative care and/or hospice, for patients with a diagnosis of advanced cancer?

- For patients with advanced cancer, what is the comparative effectiveness of models of palliative care that distinguish between primary palliative care delivered by the oncology treatment team versus specialty palliative care on patient and caregiver outcomes?

- What is the comparative effectiveness for patients and caregivers who receive palliative referral through case management models to facilitate oncology care?

Submitted Questions on Treatment Options

- What is the comparative effectiveness of clinician-directed cognitive behavioral therapy (CBT) in assisting the patient to recognize how the impact of prior life trauma and experience plays a role in their ability to develop effective coping mechanisms to deal with the emotional and psychological impact of an advanced illness diagnosis?

- What is the comparative effectiveness of discontinuing medications for select chronic, comorbid conditions for adults with limited life expectancy (prognosis less than two years) versus usual care on patient safety and quality of life? What is the impact on patient safety (risk of hyper/hypoglycemia) and quality of life when discontinuing medications for type 2 diabetes management in patients with limited life expectancy who are experiencing unwanted effects?
  - People: Adults with life-limiting illness (+DM2)
  - Option: Deprescribing and discontinuing medications for chronic comorbid conditions
  - Outcome: Impact on patient safety and quality of life

- What are the comparative risks and benefits of de-escalating drug therapy related to other comorbid conditions that are unrelated to symptom management in patients with a life-limiting illness choosing to receive palliative care? Examples might include antihypertensives, oral diabetic agents in selected patients, cholesterol management agents, glaucoma management therapies, and other classes of therapies aimed at long-term maintenance of comorbid conditions.
  - Population: All patients electing palliative care
  - Rx Options: Continue maintenance therapies for comorbid conditions or discontinue maintenance therapies for comorbid conditions
  - Outcomes: Impact on overall quality of life and symptom management, possible ease of caregiver burden when coordinating the delivery, and administration of medication
  - I would see this question as having overlap with both decision-making interventions and models of palliative care delivery

- What is the impact on symptom management and quality of life for minimizing broad spectrum antibiotic usage in patients with COPD who are receiving palliative care services?
  - Population: All COPD patients electing palliative care
  - Rx Options: Use of broad spectrum antibiotics to treat COPD exacerbations compared to non-antibiotic symptom management of COPD exacerbations
  - Outcomes: Impact on overall quality of life and symptom management, any changes in expected disease trajectory or overall survival, impact to society of reduced antibiotic exposure to avoid resistance development
  - This question would likely relate to decision-making interventions

- I also want to note that the reason why palliative care interventions are generally not effective for outcomes such as symptom management and quality of life is, in part, a reflection of the lack of evidence for how to manage symptoms well in these populations. I recognize that this is not a focus of this topic brief, but this is a huge area for much-needed future research. When faced with a patient with pain, when are opioids the best option? When faced with a patient with pain and sleep disturbance (an extremely common combination), what is the best approach? Address pain first or sleep? There is so little comparative effectiveness research in any of these areas.

- Does mindfulness-based stress reduction training for caregivers of patients with neurodegenerative illnesses improve caregiver distress compared to cognitive behavioral therapy or access to a social worker?

- What are the comparative risks and benefits (measured in terms of patient-reported pain, fatigue, functional abilities, subjective well-being) of various non-pharmacological interventions in outpatient and long-term care facilities (e.g., Mindfulness Based Stress Reduction, Tai Chi, arts-based therapies) for chronic pain in older adults with advanced illness?

- Do patients with a limited life-expectancy disease who are not enrolled in hospice derive benefit—either in symptom relief or in the sense of recourse for comfort—from receiving a Relief Package of a small number of narcotic and anxiolytic doses at the time of discharge from hospital?
    - Population: Patients for whom hospice therapy would be appropriate but is declined.
    - Intervention:
      Randomized Intervention to A or B:
        A. Narcotics and anxiolytics (10 doses each) with suggested instructions for use, education of patient and family. After patient uses five doses, will contact care team for further prescription.
        B. Some over-the-counter medication for use as needed (e.g., stool softeners and extra-strength acetaminophen)
    - Outcomes:
        - Patient report of severity and frequency of symptoms
        - Patient and family sense of concern/relief at having such medication available
        - Family sense of comfort, worry regarding anticipation of future events
        - Subsequent enrollment in hospice