



Baystate  
Health



University of  
Massachusetts  
UMASS Medical School

# Challenges in Palliative Care Research: Navigating the Moral Terrain

**Peter A. DePergola II, Ph.D., M.T.S.**

Director of Clinical Ethics, Baystate Health

Assistant Professor of Medicine, UMMS – Baystate

Assistant Professor of Medical Humanities, Elms College

Research Scientist in Neuroethics, American Academy of Neurology

# Session Objectives

- Identify the relevant questions of moral analysis and moral reasoning in the context of palliative care research
- Articulate common myths and misconceptions about the ethical nature of palliative care research
- Determine an appropriate framework for analyzing ethics issues that arise in palliative care research

# Relevant Questions of Moral Analysis

- “What?” (Veracity)
- “Why?” and “How?” (Beneficence, Nonmaleficence)
- “Who?” (Dignity, Autonomy)
- “When?” and “Where?” (Justice, Privacy, Confidentiality)
- “What if...?” (Prudence)
- “What else?” (Fidelity, Courage)

# Relevant Questions of Moral Reasoning

- In light of the possible (medical) and permissible (legal), ethics asks: *What's prudent?*
- What form of treatment is *good* – for the patient, for the family, for the medical and legal systems, and for society?
- What are our personal and professional obligations to patients and families like this?
- How can we maximize the “good” (if at all) and minimize the “bad” in this scenario?

# Palliative Care Research Ethics: Common Myths and Misconceptions

- Participants in palliative care research are *more* vulnerable than other vulnerable populations and, as such, require additional protections
- Researchers must obtain informed consent from *both* participants *and* their families to avoid legal repercussions
- Balancing research and clinical roles is especially complex in the palliative care setting and, as such, is indicative of a moral obligation to avoid playing the ‘double-role’ of provider-researcher
- The risks and benefits of palliative care research are difficult to assess and, as such, should dissuade the research endeavor
- ❖ Recommended reading: D. J. Casarett and J. H. T. Karlawish, “Are Special Guidelines Needed for Palliative Care Research?” *Journal of Pain and Symptom Management* 20, no. 2 (August 2000): 130-39

# Conducting Palliative Care Research: A Practical Moral Framework

1. Define the research
  2. Maximize the benefits
  3. Minimize the risks
  4. Ensure decisional capacity
  5. Protect voluntariness
- ❖ Recommended reading: D. Casarett, “Ethical Considerations in End-of-Life Care and Research,” *Journal of Palliative Medicine* 8, no. 1 (2005): S-148-60.



# Conducting Palliative Care Research: Defining the Research, Part 1 (General)

- Support research that informs consensus regarding the role research and QI methods *should* play in defining and improving the standard of end-of-life care
- Encourage the use of QI methodologies in requests for applications for which they may be appropriate (e.g., overcoming barriers to symptom management)
- Encourage consensus regarding appropriate levels of review for minimal risk studies that use QI methods

# Conducting Palliative Care Research: Defining the Research, Part 2 (Value & Validity)

- Support research that informs consensus about standard measures of common constructs (e.g., pain, symptom burden, quality of life)
- Encourage and support studies that recruit from underrepresented populations (e.g., ethnic minorities, home hospice patients, nursing home residents)
- Encourage and support studies that are adequately powered to evaluate subgroup differences
- Support research that defines patient-centered endpoints, which reflect a patient's unique goals and preferences
- Support the evaluation of “research screening” techniques that identify patients and families who are interested in research participation

# Conducting Palliative Care Research: Maximizing the Benefits

- Encourage and support investigators' efforts to provide study results to research subjects and their healthcare providers
- Encourage and support investigators' efforts to make successful interventions available to subjects after a trial has ended
- Encourage study protocols that prescribe responses to patients who are identified as having uncontrolled symptoms

# Conducting Palliative Care Research: Minimizing the Risks

- Support research that better defines the risks and burdens that are important to patients and their families near the end of life
- Encourage and support investigators' efforts to minimize burdens through novel data collection techniques (e.g., automated telephone data collection)
- Support research to develop abbreviated forms of existing measurement instruments
- Encourage studies that provide all subjects with access to the standard of care

# Conducting Palliative Care Research: Ensuring Decisional Capacity

- Support research to define the prevalence of impaired decision-making capacity and to identify predictors of impaired capacity
- Support the development of guidelines that specify the need for assessments of capacity
- Encourage and support investigators to include informed consent safeguards in study protocols where appropriate (e.g., capacity assessments, dual consent)

# Conducting Palliative Care Research: Protecting Voluntariness

- Encourage studies at sites where all patients (both on and off protocol) will have access to high-quality palliative care
- Encourage investigators to develop effective mechanisms for subject withdrawal that ensure continuous access to care

# Additional Recommended Reading

- ❖ D. Casarett, A. Knebel, and K. Helmers, “Ethical Challenges in Palliative Care Research,” *Journal of Pain and Symptom Management* 25, no. 4 (April 2003): S3-5.
- ❖ A. M. Jubb, “Palliative Care Research: Trading Ethics for an Evidence Base,” *Journal of Medical Ethics* 28 (2002): 342-46.

# Open Floor: Questions and Comments



# Thank You

Thank you for your time and attention.

To continue this conversation, or to begin another one, please feel free to contact

Dr. DePergola via e-mail:

[Peter.DePergolaPhD@baystatehealth.org](mailto:Peter.DePergolaPhD@baystatehealth.org)