Trillium Health Partners
Better Together

Engaging in the Review of "End of Life" Research –

Quandaries, Quagmires, and Questions

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Who am I?

- Background
  - Nurse (hematology & cardiology)
  - Researcher (focus on older adults & end of life)
- Current Roles (Trillium Health Partners)
  - Healthcare Ethicist
  - Co-Vice Chair, Research Ethics Board
  - Co-Chair, Assistance in Dying Oversight Committee

Outline

- To provide an overview of the current literature related to “end of life” research and research ethics
- To discuss three case scenarios involving end of life research
- To identify factors that REB’s and REB members should consider when reviewing end of life research submissions and strategies for conducting a thorough and fair review of end of life research

Why is end of life research important?

- To improve care of dying persons (e.g., symptom management, compassion fatigue of healthcare providers, new treatments)
- To identify strategies to support formal and informal caregivers of dying persons
- To provide justification (evidence-based) for investment of financial and other resources to support patients and families at end of life

Why is exclusion from research of persons who are dying problematic?

- Violates principle of justice – Dying persons may want an opportunity to participate in advancing knowledge and "future" dying persons may benefit from research
- Could be construed as a form of discrimination
- Treatment based on anecdote, not evidence

Challenges/Concerns in Conducting End of Life Research: Stakeholder Perspectives

Societal/Health Care/Family

- Ambivalent attitudes toward death (death denying society)
- Research activity perceived as intrusive/burdensome at a sacrosanct time
- Healthcare provider reluctance to support patient participation (paternalism)
- Family acting as gatekeeper to patient
- Lack of standardized definitions for commonly used terms (e.g., terminal illness, palliative care)

Societal/Health Care/Family (cont.)

- Challenges in prognostication
- Cultural differences in conception of causes of illness and a "good death"
- Cultural differences in truth-telling and disclosure of diagnosis/prognosis
- Patients at end of life perceived as universally vulnerable

Research Ethics Board

- Absence of end of life expertise on REB's
- Worries about participant vulnerability and susceptibility to therapeutic misconception – REB acting as gatekeeper
- Anxieties related to participant's impaired functional status and fatigue and ability to complete tasks
- Concerns about capacity to consent (and provide ongoing consent as their status may deteriorate)
- Ensuring equipoise amongst study arms
- Challenges in identifying a proxy to consent for incapable patients

Researcher/Research Methods

- Limited time frame, logistical challenges
- May need to modify usual research methods (e.g., participant may not be able to review and verify transcripts)
- Emotional impact of conducting end of life research on researchers
- Safety issues when conducting research in a participant's home
- Boundary blurring (researcher/heathcare provider; researcher/participant; researcher/self)

Researcher/Research Methods (cont.)

- Actual/potential fiduciary relationship between researcher/participant
- Limited funding for end of life research

Participant

- Rapidly changing/unpredictable health status
- Participant fatigue/burden
- Patients who are unable to consent – prior wishes related to participation in research
- Desire to leave a legacy (potential for coercion) – e.g., participants may want to use their real names rather than pseudonyms
- Differing individual views of a “good death”
- False expectations about benefit (therapeutic misconception)

Participant (cont.)

- Heterogeneity of patient groups (acute/chronic/terminal; trauma/disease/disability; home/hospital/hospice)

Overarching Themes

- Vulnerability
- Capacity
- Diversity
- Nature of Researcher/Participant Relationship

Case #1: Unmet Care Needs of a Dying Patient

Case #1: Unmet Needs

- A study is underway that is examining the role of mindfulness meditation in symptom management and quality of life in persons with end-stage lung cancer (control group receiving usual care).
- Midway through the 6 week study, a participant in the intervention group discloses to the nurse-researcher that she wants to pursue an assisted death and is seeking her help.
- The nurse-researcher through her research is aware that the participant is struggling with pain and fears about death.
- The participant does not want to speak to her doctor or her family about this request.

Small Group Discussion

- What ethical concerns does this situation raise?
- What should the researcher do?
- What strategies can be put in place to avoid/manage similar situations in the future?

Should the nurse-researcher continue further research visits with this participant?

Considerations…

- Avoiding therapeutic misconception in intervention studies at the end-of-life
- Addressing issues of vulnerability
- Setting appropriate boundaries in researcher/participant relationship at outset
- Ensuring equipoise between study arms

Strategies…

- Consent Process – written and verbal reminders about therapeutic misconception
- Anticipate Requests – develop referral process in advance
- Avoid Conflation of Researcher-Participant versus Healthcare Provider-Patient Roles – explicit references in consent form about role of researcher (as contrasted with role of healthcare providers) and how any health issues/concerns that arise will be addressed
- Self-Reflection – journaling throughout study

Case #2: Conducting Research with Children/Adolescents with Terminal Illnesses in ICU

Case #2: Dying in the ICU

- A study has been submitted to the REB for review which involves the direct participation of children and adolescents who are dying in the ICU.
- The researchers would like to measure several variables (i.e., pain, fear, quality of life) and evaluate the effectiveness of an arts-based intervention in reducing those symptoms.
- The researchers propose seeking permission from the parents of the child/adolescents before approaching them to see if they would like to participate.
- Child/adolescent participants will be given an iPad for their participation (donated by Apple).

Small Group Discussion

- What ethical concerns does this study raise?
- As currently described, if you were an REB member would you approve this study?
- What strategies might you put in place to mitigate any potential harm?

Should parents be asked to consent for their child/adolescent to be approached about the study?

Considerations…

- Obtaining consent in an emotionally-charged, critical care situation
- Minimizing the impact of the research on care provider/patient/family relationships
- Protecting from undue influence

Strategies…

- Consent Process – use patient advisors to ensure readability and comprehension of consent form; promote agency of participant – if child/adolescent is capable, consent should be sought from them and they can direct whether they want parents to be engaged in process as well
- High-touch Engagement of Staff – help them understand the "why" of the study, opportunity to ask questions and have concerns alleviated
- Proportionate Compensation for Participation – perhaps iPad could be provided for duration of hospital stay

Case #3: Controversial Topic

Case #3: Controversial Topic

- A local researcher who is also a provider of assistance in dying has submitted a proposal to conduct a qualitative study of the experience of family members who were present at the time of the patient's assisted death (including his own patients).
- The researcher will require a list of all patients who are scheduled to receive assistance in dying.
- The researcher wishes to seek consent from patients to speak with their family members prior to the patient receiving assistance in dying and seek the family member's consent to be contacted for participation in the study 1 to 2 weeks after the patient's death.

Small Group Discussion

- What ethical concerns does this study raise?
- What strategies might you put in place to mitigate any potential harm?
- How should an REB member respond if they are morally opposed to assistance in dying?

Should the REB approve this study?

Considerations…

- Managing conscientious objection from REB members or the organization
- Protecting participants, researchers, and even REB members from stigmatization because of their involvement in the review or conduct of studies where the focus is on assisted death
- Ensuring that participation in the research does not influence a patient's decision about assisted death (in either direction)
- Safeguarding patient confidentiality

Strategies…

- REB members with an explicit bias that would unduly influence their decision should recuse themselves from review of the particular study
- Reiterate respectful workplace policies; safety plans for researchers (e.g., location of research)
- Review recruitment process and study procedures to ensure a neutral stance (neither encouraging or discouraging patient with respect to their decision)

Submission and Review of REB Applications for End of Life Research

Factors to Consider (Methods)

- Have the researchers demonstrated (provided evidence of):
  - their expertise in conducting end of life research
  - how their research methods are flexible and responsive to potentially volatile situation of participants
  - the use of clearly defined terms to avoid confusion (e.g., terminally ill, serious illness, palliative care)
  - how patients/families/communities have been involved in the development of the research question and protocol (and if not, why not)
  - how they will account for potential drop-outs

Factors to Consider (Consent)

- Have the researchers demonstrated (provided evidence of):
  - how they tailored consent forms to minimize burden without compromising integrity of the consent process
  - that consent will be obtained by someone other than the patient's primary healthcare provider
  - an emphasis on voluntariness in consent process and the opportunity to withdraw at any time
  - a plan to assess capacity in an on-going manner (and how loss of participant capacity and ability to provide ongoing consent will be managed)

Factors to Consider (Participants)

- Have the researchers demonstrated (provided evidence of):
  - that they have taken into consideration cultural context of participants
  - how they will incorporate language employed by participant and follow their lead on what terms are acceptable
  - how they will address possible effects of study participation on the participant's well-being and clinical care
  - how they will respond if a patient's clinical condition deteriorates during researcher/participant interaction
  - a plan for managing distress and symptoms
  - when and how information will be shared between researcher and healthcare providers

Factors to Consider (Researchers)

- Have the researchers demonstrated (provided evidence of):
  - compassion by showing a heightened sensitivity to needs of the population
  - strategies in place to support their own safety and well-being (e.g., debriefing opportunities, reflective diary, check-in before/after home visits)

Strategies for REBs

- Ensure adequate training for REB members around end of life research (e.g., case study review).
- Include ad hoc reviewers with necessary expertise as needed.
- Support ongoing opportunities for enhanced communication between researchers and REB members – face to face discussions are generally more effective at resolving areas of misunderstanding or disagreement.
- Be open to flexible and responsive research methods.

Strategies for REB Members

- Determine vulnerability on a case-by-case basis; vulnerability in and of itself does not equate to involuntariness; vulnerability should be considered in the context of the clinical situation and type of research.
- Be aware of and set aside one's own biases related to end of life.

Closing Thoughts…

- There is limited evidence to suggest that end of life patients are too vulnerable or unwilling to take part in research. Blanket exclusion would be unjust.
- High consent rates in studies and descriptions of patient experiences (empowering, satisfying) suggest conducting end of life studies is feasible.
- Long-standing principles in research ethics –autonomy, beneficence/non-maleficence and justice are important in end of life research – end of life research should be held to the same standards as other clinical research.

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Questions/Comments