Parental Palliative Care Decision-Making: A Collaborative Approach to Protocol Development and IRB Approval

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PURPOSE

• To describe the development of a qualitative, research protocol with the aim of exploring parental complex healthcare decision-making.
• Strengthening of the protocol occurred following a collaborative, interprofessional process that emerged during IRB approval in a community healthcare system.

BACKGROUND & SIGNIFICANCE

• 23,910 infants are born yearly with life threatening/limiting conditions (LTC/LLC)4
• Medical care advances are increasing the life span of children with LTC/LLC1
• Complex healthcare decision-making puts parents at risk for stress such as decisional conflict, regret and complicated grief2
• These stressors are associated with detrimental health outcomes for parents2
• Pediatric palliative care teams may mitigate negative effects3
• Institute of Medicine (2003) highlights the importance of meeting spiritual, emotional, and physical needs of children with LLC/LTC and their families3
• There is a need for inductive research to examine decision-making and pediatric palliative care3

PROTOCOL DEVELOPMENT

• Develop clear view of research interest
• Make connections with community partner
• Meet with pediatric palliative care team building familiarity, support, and interest
• Choose method – Constructivist Grounded Theory
• Write protocol using theoretical language
• Submit protocol to university IRB
• Received IRB approval under expedited review

IRB PROCESS

• Following university IRB review, changes requested included:
  • Notification by participant to significant others, named as helpful during decision-making, that the researcher may contact them
  • Researcher will have permission of participant to name them when contacting significant others (7 weeks to approval)
• IRB Protocol submitted, under expedited review, to community partner IRB
• Expedited review not approved by community partner
• Invited and attended IRB meeting to discuss
  • Actively dying as a term
  • Script to use while recruiting parents
  • Procedure to follow if parents become distressed
  • Method and protocol terminology (theoretical sampling)
  • Concerns regarding confidentiality of significant others in decision-making
• Required IRB requested changes
  • Clarification of nurse recruiter/researcher roles in theoretical sampling and the term actively dying
  • Avoidance of approaching parents for recruitment during medically unstable event

CONCLUSION

• Research surrounding children raises concerns with IRB’s
• Strategies to strengthen IRB protocol include:
  • Detailed, clearly written protocols
  • Explicit processes to protect human subjects
  • When to approach families
  • Written consent to contact
  • Phone script
  • Plan for distressed parents
• Working with research partners can help researchers obtain greater breadth and quality of information while protecting human subjects

REFERENCES