

**Title:**

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

**Elizabeth A. Olafson, MSN, MEd, BSN**

*Christine E. Lynn College of Nursing, Florida Atlantic University, Boca Raton, FL, USA*

---

**Session Title:**

Rising Stars of Research and Scholarship Invited Student Posters

---

**Keywords:**

Collaborative IRB approval, Parental healthcare decision-making and Pediatric palliative care

**References:**

Bakitas, M., Kryworuchko, J., Matlock, D. D., & Volandes, A. E. (2011). Palliative medicine and decision science: The critical need for a shared agenda to foster informed patient choice in serious illness. *Journal of Palliative Medicine*, 14(10), 1109-1116. doi:10.1089/jpm.2011.0032

Burns, K. H., Casey, P.H., Lyle, R. E., Bird, T. M., Fussell, J.J., & Robbins, J. M. (2010). Increasing prevalence of medically complex children in US hospitals. *Pediatrics*, 126(4), 638-646. doi:10.1542/peds.2009-1658

Caeymaex, L., Joussemme, C., Vasilescu, C., Danan, C., Falissard, B., Bourrat, M., Garel, M., & Speranza, M. (2013). Perceived role in end-of-life decision making in the NICU affects long-term parental grief response. *Archives of Disease in Childhood: Fetal & Neonatal*, 98(1), F26-F31. doi: 10.1136/archdischild-2011-301548

Charmaz, K. (2014). *Constructing Grounded Theory* (2nd ed.). London, England: Sage Publications.

Feudtner, C., Womer, J., Augustin, R., Remke, S., Wolfe, J., Friebert, S., & Weissman, D. (2013). Pediatric palliative care programs in children's hospitals: A cross sectional national survey, *Pediatrics*, 132(6), 1063-1070. doi:10.1542/peds.2013-1286

Field, M. J., & Behrman, R. E. (2003). *Institute of Medicine Committee on Palliative and End-of-Life care for Children and their Families. When children die: Improving palliative care for children and families.* Washington, D.C.: National Academy Press.

Hamilton, B. E., Hoyert, D. L., Martin, J. A., Strobino, D. M., & Guyer, B. (2013). Annual summary of vital statistics: 2010-2011. *Pediatrics*, 131(3), 548-558. doi: 10.1542/peds.2012-3769

Jones, B. L., Gilmer, M., Parker-Raley, J., Dokken, D. C., Freyer, D. R., Sydnor-Greenberg, N. (2011). Parent and sibling relationships and the family experience. In J. Wolfe, P. S. Hinds, & B. M. Sourkes (Eds), *Textbook of Interdisciplinary Pediatric Palliative Care* (pp. 30-40). Philadelphia, PA: Elsevier Saunders.

Youngblut, J. M., Brooten, D., Cantwell, G. P., del Moral, T., & Totapally, B. (2013). Parent health and functioning 13 months after infant or child NICU/PICU death. *Pediatrics*, 132(5), e1295-e1301. doi: 10.1542/peds.2013-1194

**Abstract Summary:**

Medical advances result in children living with conditions requiring parental complex healthcare decision-making. Pediatric palliative care team support may decrease negative consequences. A grounded theory study was developed and strengthened during a community healthcare partner's IRB process to explore the process of decision-making for parents who consult with palliative care.

**Learning Activity:**

LEARNING OBJECTIVES	EXPANDED CONTENT OUTLINE
The learner will be able to describe the significance and development of a research protocol during the poster presentation.	I. Incidence of pediatric complex conditions a. Life limiting, life threatening, and complex chronic conditions II. State of the science a. Complex healthcare decision-making b. Pediatric palliative care c. Gap in literature III. Protocol development a. Engaging a community partner b. Constructivist grounded theory
The learner will be able to decipher obstacles and improvements to a protocol through a community partner healthcare system's IRB process during the poster presentation.	I. IRB process a. University IRB process and approval b. Community partner healthcare system IRB process and approval i. Sampling ii. Term clarification iii. Timeline II. Collaborative result

**Abstract Text:**

**Background and Significance**

Every year in the United States, 23,910 infants are born with life threatening conditions (LTC) or life limiting conditions (LLC) (Hamilton, Hoyert, Martin, Strobino, & Guyer, 2013). Advances in medical care have resulted in an increased incidence of children living with complex chronic conditions (CCC) (Burns et al., 2010). When infants and children are affected by LTC, LLC, or CCC parents are faced with many complex healthcare decisions. Complex healthcare decision-making puts parents at risk for decisional conflict and regret or unresolved grief which has been associated with detrimental effects on physical and psychological health (Caeymaex et al., 2013; Youngblut, Brooten, Cantwell, del Moral, & Totapally, 2013). Pediatric palliative care teams that provide decision-making support to families have been increasing at healthcare facilities over the past decade (Feudtner et al., 2013) and could be an answer. However, there is little evidence to support the effectiveness of the support efforts.

**Purpose of this Poster Presentation**

The purpose of this poster presentation is to describe the development of a qualitative, research protocol to explore parental complex healthcare decision-making and the strengthening of the protocol through a collaborative, inter-professional process that emerged during IRB approval in a community healthcare system.

**Literature**

In 2003, The Institute of Medicine called for a change in care for children and their families facing LTC and LLC to minimize suffering and meet their spiritual, emotional, and physical needs (Field & Behrman). Bakitas, Kryworuchko, Matlock, and Volandes (2011) wrote that “palliative care clinicians and scientists have just begun to establish an evidence base for best practice in assisting patients and families in complex decision making” (p. 1109). There is a need for inductive research data gathered on pediatric

palliative care and the decision-making process as decisions made by parents are often later doubted and compounded by feelings of guilt or failure (Field & Behrman, 2003; Jones, et al., 2011).

## **Protocol Development**

Engaging a community partner healthcare system and successfully navigating the IRB process begins long before the protocol is written. Once the researcher had a clear view of her research interest, the research partnership began by making connections with the community hospital partners. The researcher met with the pediatric palliative care team several times to build familiarity, support, and interest in the study.

Constructivist grounded theory (Charmaz, 2014) was selected to provide structure and flexibility to support the exploration of meaning, perception, and feelings regarding involvement and consequences of decision-making for parents of children consulting with palliative care. This theoretical perspective supports the study of situations through the view of those experiencing it and is based in pragmatism.

Palliative care and IRB members were queried and communicated support for the proposed research. The protocol was written using theoretical language and submitted to the university IRB. An expedited review was granted.

## **IRB Process**

Following university IRB review, one recommended change to the protocol was identified; If parents indicate the importance of a significant other person in the decision-making process, the parent participant will notify the significant other person that they have been named and may be contacted by the researcher and the researcher will ask for permission to use the parent's name when contacting the significant other person. This change was made and the protocol was resubmitted. The total time for approval from the university IRB was 7 weeks.

The protocol was then submitted to the community partner healthcare system's IRB with a letter of support from the pediatric palliative care physician. After several phone calls with IRB lead members in an attempt to clarify initial questions, an expedited review was not approved. The researchers were invited to an IRB meeting to discuss the study and offer clarifications including: a definition for the term actively dying, a script to use when recruiting parents for the study, and a procedure in the event a parent becomes distressed during an interview. Verbal clarification regarding the method and protocol terminology including theoretical sampling was given. Dialogue regarding consent to contact theoretically significant others identified by the researcher followed. Committee members verbalized concerns with the researcher contacting persons identified as helpful during decision-making and protecting confidentiality.

A letter was received from the IRB committee outlining required changes to the protocol which included clarification of theoretical sampling and concerns about approaching parents during a medically unstable event. In addition, actively dying as an exclusion criteria continued to cause confusion requiring additional explanation.

An updated protocol was written with a thorough explanation of theoretical sampling including information of how representational sampling could produce conceptually inadequate data (Charmaz, 2014). The protocol clearly defined the palliative care nurse's role to approach parents from various units meeting inclusion criteria to determine interest in the study and the researcher's role in theoretical sampling. Lay language was used to enhance understanding for a broad audience. A written consent to contact and a phone script were also added. Potential participants personally known and identified by parents as helpful in the decision-making process were removed from the study to avoid parental burden.

The updated protocol was resubmitted and scheduled for review at the following month's IRB committee meeting. Minor wording edits for the protocol were discussed at the meeting. In addition, the need to

clearly add to communications that the researcher is not a member of the palliative care team and participating in the study would not affect the family's relation with the palliative care team was deemed necessary. Pregnant participants were added to the protocol as not excluded and not a focus of the study. Lastly, the term actively dying was removed and replaced with medically unstable to better parallel the terminology used at the partner healthcare system.

The protocol was edited as requested and resubmitted. The new version of the protocol was approved and stamped by the community partner healthcare system's IRB. The new protocol was then resubmitted to the university IRB with the new adult consent, consent to contact, and phone script for approval. The new protocol and additional items were approved within two weeks. The IRB process from initial submission to the university IRB to final approval took 28 weeks.

### **Collaborative Result**

Inclusion criteria were described as: English speaking parents, who have made a healthcare decision after pediatric palliative care referral for a child under the age of 18 who is an inpatient preparing for discharge or discharged. Other significant persons such as members of the palliative care team may also be included. Exclusion criteria included the family of a child who is known to be in a medically unstable condition and parents who are minors. Pregnant mothers are not excluded but are not the focus of the study. The participant recruitment plan included: the palliative care nurse will screen parents, from a variety of pediatric units for participation in the study who meet the inclusion criteria and who do not have a child who is known to be medically unstable. In addition, the researcher may identify other theoretically significant persons at the healthcare facility through purposeful theoretical sampling, such as members of the palliative care team. Following screening and identification, the palliative care nurse will make initial contact, to determine interest in participating in the study and obtain written permission for the researcher to contact. If there is interest and written permission to contact, the researcher will make contact by phone to review the study, arrange an initial interview in a setting convenient to the participant, and answer any initial questions pertaining to the study. A signed informed consent will be obtained from each participant by the investigator before demographic data collection and interviewing begins. If participants experience anxiety or discomfort the researcher will give the participant time to express their feelings and ask the participant if they would like to continue the interview, reschedule the interview, stop the interview, or withdraw from the study.

### **Conclusion**

Research surrounding children as a vulnerable population raises concerns with IRB committees requiring detailed, clearly written protocols and processes to protect human subjects. Working with a community healthcare system strengthened this proposal in multiple ways. Clarifying the roles of the researcher and pediatric palliative care nurse improved the quality and credibility of the study by ensuring that participant sampling will follow a standardized plan. In addition, human protections were strengthened by adding a detailed description of when families could be approached, written consent to contact, phone script, and plan for distressed parents. Working with our community partners can not only assist researchers obtain a greater breadth of information but also improve the quality of research ensuring protection of human subjects.