Recruitment Issues with Pediatric Populations in Palliative Care Research

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Introduction

Within the group of children commonly referred to as *Children with Special Health Care Needs (CSHCN)* exists a smaller group of children known as *Children with Complex Medical Conditions (CCMC)*, which includes those children with intense medical needs that result from congenital, multisystem, or life-limiting disease states, technology dependence, or complex medication regimens.

CCMC are one of the smallest, yet fastest growing, populations of children, and they have an enormous impact on the healthcare system.
Over 53,000 infant and child deaths occur annually in the US  
(Heron, 2011)

48% of these deaths occur in hospitals and 86% of those in neonatal (NICU) or pediatric (PICU) intensive care units  
(Ramnarayan, Craig, Petros, & Pierce, 2007)

While some pediatric deaths are attributable to trauma, acute illness or other events, many of the children who die each year can be described as children with complex medical conditions.
With advancements in medical and surgical pediatric care, many CCMC survive birth, infancy and are living longer and, as a result, require **integrative approaches to care**, which can be met through the provision of **pediatric palliative care**, and when appropriate, **pediatric hospice care**.
Timely and appropriate pediatric palliative/hospice care can prevent or relieve the physical and emotional distress produced by a complex medical condition or its treatment, help patients with such conditions and their families live as normally as possible, and provide them with accurate information and support in decision making, particularly regarding end-of-life care.
American Academy of Pediatrics, 2013, p. 968:

“Pediatric Palliative Care-Pediatric Hospice Care should vigorously promote and pursue rigorous research and quality improvement projects in all aspects of interdisciplinary care, including evaluation of specific pharmacologic and nonpharmacologic interventions to alleviate symptoms; medical and psychosocial interventions to improve quality of decision-making and quality of life for patients and family members; various modes of education and training to improve clinicians’ knowledge, attitudes, skills, and behaviors; and different program or service delivery models to improve access, outcomes, and cost-effectiveness.”
At the 2011, *NINR Summit on Compassionate Care*, experts called for additional research on Perinatal and Pediatric Issues in Palliative and End-of-Life Care, with an emphasis on:

- Families
- Clinical management of palliative and end-of-life care
- Communication
- Health care delivery system
- Transdisciplinarity

(Youngblut & Brooten, 2012)

And of course, NINR’s Strategic Plan (September, 2016) includes “end-of-life and palliative care,” as one of the four areas of scientific focus for the Institute.
Pediatric Recruitment Challenges...  
A Brief Review of the Literature...


**Method:**

- Search terms: palliative care, research, pediatrics, parents, end-of-life, ethics and challenges
- Database: PUBMED™, from 1966—2006

**Results:**

- 127 citations, 28 relevant, 16 original research
- Two themes:
  - Ethical concerns in palliative care or hospice research
  - Logistical issues with accessing parents and children receiving palliative or end-of-life care

**Method:**

- Search terms: LLC/LTI recruitment; Terms relating to palliative care, death, bereavement and recruitment practices were also included.
- Databases: MEDLINE, PsycINFO, Web of Science, Sciences Citation Index and SCOPUS, from 2009 and 2014

**Results:**

- 215 studies – 152 qualitative, 54 quantitative and 9 mixed methods
- **All stages of recruitment were under reported**
- Clinician judgment, perception of potential burdens

International Delegates (*n* = 76) surveyed at the 7th Paediatric Palliative Care Conference in Cardiff, UK:

Four themes:

- Time and other resources
- Clinician’s attitudes towards research
- Clinician’s perceptions of patients and their families
- Ethical approval process
Clinicians make many assumptions about families/situation that interfere with referral to research:

- That families are “unaware” of the progressive nature of the disease
- That families should not be “burdened” (burden is poorly defined)
- That families will not want to participate
- That the study will not “benefit” family (benefit is poorly defined)
Examining the Role of Clinicians: "Gate Keepers"

Additional factors influencing "gate keeping" actions:

- **Relationship with family**
  - Can increase paternalistic or protective feelings toward patient/family

- **Communication Practices / Ability**
  - May be impacted by language and sociocultural barriers
  - May be based upon clinician’s comfort/discomfort with discussions regarding palliative and/or end-of-life care

- **Clinician bias based on numerous other factors**
  - Past history with research
  - Type/purpose of research
The Consequences of “Gate Keeping”

For research:
- Results in selection bias, which compromises external validity
- Reduces sample size
- Increases time required for recruitment
- Limits evidence/knowledge obtained from study

For parents/patients:
- Interferes with decision-making
- Excludes families who may want to participate
- Prevents families from experiencing “benefits” associated with participation
Examining the Ethics...
Ethical Principles

Medical Ethics

- Autonomy
- Beneficence
- Non-maleficence
- Justice

Dignity
Honesty
Examining the Ethics...

Ethical concerns include:

- The potential **vulnerability** of the research participants, which includes a potential risk of coercion from the research study team
- The **burden** of participation on the participant
- The potential that the **child is unaware** of the severity of the disease or that they are dying
- The possibility that the **parents have not yet come to terms** with the severity of the child’s disease or the inevitability of the child’s death
Conflicts

- Tendency toward overly paternalistic protection
- The view that participation in research is an undue burden
- The concern that a potential for harm will outweigh any burden

Consequences

- Risks intruding upon the rights of a potential participant to make decisions; can be considered discriminatory and unjust
- May deny participants a potential benefit; also an issue of justice

Method:
- Search terms: Parent/family; Terms relating to palliative care, attitudes, death, bereavement and grief were also included.
- Databases: MEDLINE, CINAHL, PsycINFO, from 1988 to 2008

Results:
- Increase in research on parental perspectives in pediatric palliative care from 2005-2010,
- “Parental” = “Maternal”
- Mothers constituted 75% of the total sample of parents across studies.

Gender shapes experiences of both parenthood and grief
Balanced gender sampling is essential for research on “parental perspectives”
Psychometric Evaluation of the Palliative Care Parental Self-Efficacy Measure

- **Purpose**: to assess acceptability of a new tool, the Palliative Care Parental Self-Efficacy Measure (PCPEM) for use with English- and Spanish-speaking parents of children with complex medical conditions; and to conduct preliminary psychometric analysis

- **Sample**: English and Spanish-speaking parents of children, aged 0-21 years receiving care receiving care for cancer or cancer related condition at a regional children’s hospital cancer institute

- **Method**: Survey
  - Demographic questionnaire (30 questions)
  - PCPEM (43 questions, 5 domains)
Conducting Palliative Care Research in Pediatric Populations...

Recruiting across Pediatric Cancer Institute

Target: \( n = 100 \) parents
\( n = 50 \) English-speaking; \( n = 50 \) Spanish-speaking

Current total:
English-speaking = 47
1 father
Spanish-speaking = 14
2 fathers
<table>
<thead>
<tr>
<th>Challenges</th>
<th>Response / Lessons Learned</th>
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<tbody>
<tr>
<td>Clinician Gate-Keeping</td>
<td>Education, education, education!</td>
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<tr>
<td></td>
<td>Organizational culture, resources</td>
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<tr>
<td>Gender Imbalance</td>
<td>Physician champion</td>
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<tr>
<td>Recruitment of Spanish</td>
<td>Flexibility; Appointments in &quot;off hours&quot;</td>
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<tr>
<td>speaking parents</td>
<td>Referral from bilingual, <em>bicultural</em> RN, SW</td>
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<tr>
<td>Language (&quot;palliative&quot;)</td>
<td>Education</td>
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Conclusion

Despite calls for increased research into pediatric palliative care and pediatric hospice care, barriers at institutional and clinician levels persist.

Careful study design with attention to participant burden and specific effort in obtaining a representative sample, in combination with extensive education of clinicians and institutional review boards can facilitate data collection and make much needed contributions to the body of evidence for pediatric palliative


Thank you...