

Adam Rapoport MD, FRCPC, MHSc

Associate Staff, Division of Paediatric Medicine, Hospital for Sick Children

Pediatric Palliative Care Consultant, Max and Beatrice Wolfe Children's Centre, Temmy Latner Centre for Palliative Care, Mount Sinai Hospital

Introduction

Pediatric palliative care (PPC) research – ranging from observational to interventional study designs involving children with life-threatening conditions, their parents, or their siblings – is greatly hindered by ethical concerns. Yet, evidence suggests that these concerns may be inflated or unsubstantiated. With appropriate (but not prohibitive) safeguards in place, PPC research can be conducted ethically, promoting evidence-based improvement in the care provided to these children and their families.

“The families who participated in our [study] unanimously expressed gratitude for the opportunity to “tell their stories” and to provide input into a future palliative care program...The enthusiastic gratitude expressed by families may indicate that there is an unmet need for opportunities to discuss such tragic events as the death of a child.”

-Researcher-³

“It leaves a good feeling to know that I might help others in the same situation by sharing my experiences through the research.”

-Bereaved Father-⁴

“It was positive and challenging in a way to look at and talk about my situation together with a person from outside.”

-Bereaved Mother-⁴

Concerns Regarding the Balance of Risks & Potential Benefits

All studies involving human subjects must obtain ethical endorsement from a Research Ethics Board (REB). Approval is based primarily on the balance of potential harms and benefits to participants.

No benefit can come to participants in PPC research

- Interventional trials must exhibit clinical equipoise – a state of genuine uncertainty regarding the relative merits of the intervention under investigation. Provided equipoise is established, the notion that PPC research subjects will always be exposed to risks greater than potential benefits is unsubstantiated.
- In fact, there is evidence that both dying children^{1,2} and their families³⁻⁷ can directly benefit from participating in PPC research
- Significant indirect benefit may also arise from engaging in the altruistic act of PPC research^{7,8}
 - Participating in research that will help others facing similar threats in the future offers dying children a chance to leave a legacy behind

The psychological and emotional risk of participating in PPC research is too great

- It is important to note that participation in PPC research can be emotionally challenging and simultaneously worthwhile and beneficial⁷
- Researchers should anticipate that some participants will find discussions about dying and grieving difficult
 - Participants of PPC research should have access to trained psychologists or counsellors

Potential recruits of PPC research are “vulnerable”; REBs have a duty to protect them from undue harm

- There is evidence that REBs may be overly protective when reviewing research on end-of-life issues^{7,9,10}
 - “[I am concerned about] intruding at a particularly sensitive moment...it is a very stressful and traumatic time”
 - “Here is a very vulnerable population that might be asked to take a particularly high level of load for very little outcome for them[selves]”
- These concerns, though legitimate, apply to all vulnerable populations (psychiatric patients, the severely disabled, etc.), not just PPC research participants
- Care for vulnerable groups can only be improved by confronting these concerns directly, not by avoiding research with these populations altogether

Concerns Regarding Informed Consent & Autonomy

Informed consent for research requires complete details of the study to be shared. The decision to participate must be autonomous; no undue influence should be exerted and no conflict of interest should exist.

Children who lack the capacity to consent are unable to participate in PPC research

- When children are unable to appreciate the information required to give consent, parents can make decisions on their behalf
- Adequately informed parents may consent for their child to participate in research, even when the child may not directly benefit from the experience¹¹
- A child's assent, or agreement, should be sought whenever feasible
 - Participation in research is always optional; to enrol a dying child in a study when he or she has refused would be immoral¹²

Honest and clear language required for consent is too blunt; there is too much focus on “death” and “dying”

- Complete details about the purpose and goals of a study may be shared using non-threatening, sensitive language¹³
 - Rather than “children dying of cancer”, a consent form could refer to participants as “children with difficult-to-treat cancer”¹⁴
- Once consent is obtained, sensitive language may be maintained throughout the study to facilitate discussion without openly examining a child's terminal state
- The need to be sensitive must never compromise honesty and full disclosure

Fear of abandonment will place pressure on desperate families to unwillingly participate in PPC research

- Although a legitimate concern, this applies no more to PPC research subjects than it does to other vulnerable populations
- Human subjects must always give voluntary consent; there must be no undue influence on the decision to participate
 - The researcher must emphasize that refusal to participate will have no consequences on the quality of care
 - Participants must appreciate that they can drop out of the study at any time without fear of repercussion
- Available evidence suggests that families are just as comfortable declining to participate in PPC research as they are other areas of pediatric research¹⁵

“If I can help someone else, that's wonderful, I think.”

-14-year-old girl with a brain tumor-⁸

Conclusions

PPC poses a unique challenge to research ethics because the principal subjects represent an amalgamation of two vulnerable groups – children and persons dying. Yet, many of the ethical concerns about PPC research are unsubstantiated while others may be addressed through thoughtful study design. REBs must avoid the impulse to prohibit research due to concerns of emotional harm; subjects are capable of weighing the risks and benefits of participation themselves. Voluntary informed consent for PPC research may be obtained using sensitive language without compromising the need to share complete study details.

References

1. Breen M. *Paediatr Nurs*. 2006;18(4):38-40.
2. Hays RM, Valentine J, et al. *J Palliat Med*. 2006;9(3):716-728.
3. Contro N, Larson J, et al. *Arch Pediatr Adolesc Med*. 2002;156(1):14-19.
4. Dyregrov K. *Soc Sci Med*. 2004;58(2):391-400.
5. Mongeau S, Champagne M, et al. *J Palliat Care*. 2007;23(1):5-13.
6. Seemark DA, Gilbert J, et al. *Palliat Med*. 2000;14(1):55-56.
7. Hynson JL, Aroni R, et al. *Palliat Med*. 2006;20(8):805-811.
8. Hinds PS, Drew D, et al. *J Clin Oncol*. 2005;23(36):9146-9154.
9. Fine PG. *J Pain Symptom Manage*. 2003;25(4):S53-62.
10. Stevens T, Wilde D, Paz S, et al. *Palliat Med*. 2003;17(6):482-490.
11. Kodish E. *J Pediatr*. 2003;142(2):89-90.
12. Levetown M, American Academy of Pediatrics Committee on Bioethics. *Pediatrics*. 2008;121(5):e1441-1460.
13. Casarett DJ, Knebel A, et al. *J Pain Symptom Manage*. 2003;25(4):S3-5.
14. Tomlinson D, Capra M, et al. *Eur J Oncol Nurs*. 2006;10(3):198-206.

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