



Published in final edited form as:

J Palliat Med. 2008 April ; 11(3): 444–450. doi:10.1089/jpm.2007.0120.

Ethical and Logistical Considerations of Multicenter Parental Bereavement Research

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Abstract

Background—Multicenter research has the potential to recruit participants with diverse racial, ethnic, and geographic backgrounds and is essential for understanding heterogeneity in bereavement. The National Institute of Child Health and Human Development Collaborative Pediatric Critical Care Research Network (CPCCRN) is a multicenter network charged with conducting research on the pathophysiology and management of critical illness in childhood. Among its research activities, the CPCCRN has undertaken research in parental bereavement because most childhood deaths in the United States occur in hospitals, primarily in critical care units.

Objective—The purpose of this paper is to discuss ethical and logistical issues found by the CPC-CRN to be problematic to multicenter research with bereaved parents and to explore research strategies that may be practicably implemented.

Results—Ethical and logistical challenges encountered by the CPCCRN included issues of privacy; confidentiality; voluntariness; minimizing risks; working with multiple institutional review boards; researcher qualifications, training and support; and methods of data collection. Strategies to address these challenges included local recruitment of participants; flexibility in consent methods across sites; participant options for methods of data collection; involvement of local bereavement support services; central training of researchers with systematic monitoring and opportunities for support; and use of a secure Web-based collaborative workspace.

Conclusions—Multicenter parental bereavement research has distinct ethical issues that must be addressed by the logistics of the research plan. Greater attention to the issues identified may facilitate research to reduce adverse mental and physical health outcomes in a diverse population of bereaved individuals.

INTRODUCTION

Although bereavement research has greatly expanded in recent years,¹ most original research reports focus on findings rather than methodological issues. Limitations in article length often preclude detailed explanations about the selection of research methods. Reviews have been published that discuss ethical and logistical issues in conducting research with the dying and bereaved²⁻⁸; however, most bereavement reviews focus on research participants who have lost adult family members and who were recruited from single sites. Methodological considerations specific to multicenter parental bereavement research have not been adequately explored. Multicenter research enhances recruitment of participants with diverse racial, ethnic and geographic backgrounds and is essential for gaining an understanding of heterogeneity in bereavement.

The National Institute of Child Health and Human Development Collaborative Pediatric Critical Care Research Network (CPCCRN) is charged with conducting multicenter research on the pathophysiology and management of critical illness in childhood.⁹ The CPCCRN has undertaken research in parental bereavement because most childhood deaths in the United States occur in hospitals, primarily in critical care units.^{10,11} The CPCCRN's experience conducting multicenter research with bereaved parents may be useful to others planning bereavement studies that use a multicenter approach. The purpose of this paper is to discuss ethical and logistical issues found by the CPCCRN to be problematic to multicenter research with bereaved parents and to explore research strategies that may be practicably implemented.

OVERVIEW OF CPCCRN BEREAVEMENT STUDIES

The long-term goal of the CPCCRN bereavement studies is to develop preventive interventions that can reduce adverse mental and physical health outcomes for parents whose child has died in the pediatric intensive care unit (PICU). The first CPCCRN bereavement study was a qualitative interview study to investigate parents' perspectives regarding the desirability, content and conditions of a physician-parent conference conducted after their child's death in the PICU.¹² Fifty-six parents participated in audio-recorded telephone interviews between 3 and 12 months after their child's death. Findings from this study suggested that parents do want to meet with the PICU physician in the months following their child's death in order to gain information and emotional support, and to provide feedback about their hospital experience.

The second CPCCRN bereavement study is a prospective survey to investigate the prevalence and risk factors for complicated grief in parents whose child has died in the PICU. This information will be used to plan future intervention trials that assess complicated grief as an outcome. Power analysis for the study indicated that 246 parents will need to participate; accrual in this 2-year study is proceeding according to the anticipated schedule. The survey consists of the Inventory of Complicated Grief,¹³ scales to assess proposed risk factors, and demographics. Surveys are distributed to parents by mail 6 months after their child's death and may be completed in writing or by telephone.

ETHICAL AND LOGISTICAL ISSUES

Ethical issues in research must be addressed by the logistics of the research plan. Ethics and logistics are therefore highly interrelated. Not all ethical and logistical issues are discussed in this report, only those that were found by the CPCCRN to be problematic to multicenter parental bereavement research. These issues include privacy; confidentiality; voluntariness; minimizing risks; working with multiple Institutional Review Boards (IRBs); researcher qualifications, training and support; and methods of data collection.

Privacy

Privacy in research requires potential participants to have the right to control access to themselves and their information.^{6,14,15} Names and contact information are protected under the Health Insurance Portability and Accountability Act (HIPAA).¹⁶ Therefore, privacy issues may be perceived by IRBs as a barrier to recruitment. However, under the HIPAA Privacy Rule, covered entities (e.g., physicians) are allowed to use protected health information for purposes preparatory to research such as to aid in recruitment. All CPCCRN principal investigators are physicians practicing in the PICU at their local site. In compliance with HIPAA, CPCCRN investigators were able to access the medical records of children who died in their PICU for the purpose of requesting parents' participation in research.

To promote privacy, initial contact with the bereaved may be best accomplished by a written explanation of the research and invitation to participate.^{8,17,18} This method allows potential participants to consider the research before being approached directly by an investigator. In the CPCCRN bereavement studies, parents were initially contacted by mailed letter. For the qualitative study,¹² a letter informed parents that a research coordinator would telephone them within two weeks to request their participation in an interview. For the survey study, the letter was accompanied by survey booklets to be completed by the parents. The letter informed parents that if the booklets were not returned within 1 month, a research coordinator would telephone them to confirm that they had received the booklets and give them the option of completing the booklets by telephone. To respect parents' privacy, all mailings included a declination postcard or local telephone number to enable parents to refuse further contact by the investigators.

Confidentiality

In bereavement research, participants are often asked to share personal thoughts and feelings about a loved one's death. Respect for personal information requires that confidentiality be maintained.^{7,8,14} Confidentiality in research refers to agreements between participants and researchers about how identifiable data will be managed and to whom it will be disclosed.¹⁵ Special precautions are required to maintain confidentiality in multicenter research because data are usually transmitted to and stored at a Data Coordinating Center (DCC).

In the CPCCRN qualitative study, digitally recorded telephone interviews presented a challenge to confidentiality because voice is a biomarker that can potentially identify research participants. Confidentiality was maintained by secure transmission of voice recordings to the DCC via the Internet using a 128-bit encrypted Secure Sockets Layer connection. Recordings were stored in a secure Web-based collaborative workspace called *eRoom*TM. Once in *eRoom*TM, a recording could only be accessed by the researchers from the site where the interview was conducted, two investigators responsible for data monitoring and analysis, and administrative staff from the DCC responsible for maintaining the *eRoom*TM.

Researchers were prevented from listening to interviews conducted at sites other than their own. Such limited access to the recordings helped to protect participant confidentiality as well as that of the researchers and their institutions. For example, if a parent made negative comments during an interview about a specific health care provider, these comments would only become available to researchers at other sites after being transcribed in a deidentified form. Maintaining confidentiality of health care providers within the CPCCRN helped to increase the investigators' willingness to engage in exploratory bereavement research.

Voluntariness

The informed consent process requires disclosure of information to potential research participants, ascertainment that the information is understood and assurance of participants' voluntariness.¹⁹ In multicenter research, the method of obtaining and documenting consent may vary between sites because of local IRB requirements. For the CPCCRN bereavement studies, contact letters sent to parents contained the essential elements of informed consent.¹⁵ For the qualitative study, most sites were allowed by their IRB to obtain verbal consent by telephone and document consent by audio-recording. For the survey study, consent was implied by return of the completed survey in the mail, or obtained verbally from parents who completed the survey by telephone. Verbal consent was documented in the research record by the research coordinator administering the survey. However, one site's IRB required parents to sign and return a mailed consent document before being interviewed whereas another's required parents' signed consent before completing a survey. These requirements may reduce recruitment at these sites but are not prohibiting the sites' participation.

Whether the bereaved should be considered vulnerable in research and in need of enhanced protection has been debated.^{2,3,6-8} Vulnerability in research is a condition in which individuals have difficulty providing voluntary informed consent due to limitations in decision-making capacity or situational factors, or in which they are at high risk of exploitation.¹⁵ The bereaved may be vulnerable because of the emotional pain associated with loss and the sensitive nature of the data to be collected. In the CPCCRN bereavement studies, attempts were made to personalize the research and reassure parents of the investigators' credibility. Although personalizing the research may comfort parents, caution must be taken not to compromise parents' understanding of the research aims or exert undue influence on their decision to participate.^{7,17} For example, to personalize the research, all contact letters and telephone calls originated from the local site rather than the DCC. Letters were printed on hospital letterhead, addressed by hand and signed by both the site investigator and research coordinator. The investigator's title identified him or her as a critical care physician. Surveys were accompanied by return envelopes addressed to the local site. Hand-written thank you cards were sent to participants. This personalized approach may have led some parents to the misconception that the aim of the research was to provide direct feedback to the staff at the local site. When parents expressed this misconception, research coordinators reiterated the multicenter nature of the research and the aim of summarizing research findings to yield new knowledge rather than to provide specific feedback to individuals.

Issues affecting voluntariness that may arise when participants have prior relationships with the recruiting institution include the possibility that they may find it difficult to refuse, or fear that refusing may jeopardize their ability to receive future care.⁷ These problems are potentially avoided by careful explanation of the voluntary nature of research and by explicitly defining criteria for "passive refusals" in the research protocol. For the CPCCRN bereavement studies, participant response was defined as passive refusal if the parent agreed to be interviewed or surveyed by telephone but failed to keep the appointment, or agreed to complete surveys and return them by mail but never did so.

Minimizing risks

Research has shown that the bereaved can participate safely in research and that many find the process helpful.^{20,21} Participation in research may provide bereaved persons with the opportunity to tell their story to an empathic listener interested in the details of their experience, a situation that may not happen often in every-day life.^{6,18,20,22} Emanuel et al.²⁰ reported that 73% of bereaved caregivers found participation in an interview about their

loved one's death to cause little to no distress and that 41% found the interview helpful. In the CPCCRN bereavement studies, parents were not specifically asked about their reaction to research participation.

Although some bereaved parents may be willing to participate in research, the CPCCRN was careful to minimize potential risks.²³ All contact letters included information about bereavement support services offered by the local site that were available regardless of research participation. At the end of each telephone contact, parents were reminded of these bereavement support services. IRBs at some sites required an emergency plan in case a parent seemed severely distressed or suicidal. These plans included calling a designated psychologist familiar with the study who would be available to the parent, or community emergency services. To date, in none of the CPCCRN's interactions with bereaved parents have these emergency contacts been needed.

Working with multiple IRBs

A growing body of literature addresses the variability of IRB judgments across sites participating in multicenter studies.^{24–26} This variability poses a challenge to collaborative research because the validity of research findings often depends on the consistent application of methods across sites. For the CPCCRN bereavement studies, several local IRB concerns had to be resolved or incorporated into the research.

One site's IRB initially disallowed the research coordinator from contacting bereaved parents by telephone to complete mailed surveys. The investigator responded to these concerns by providing the IRB with references to studies that safely completed telephone surveys with bereaved parents.^{27,28} The investigator also provided documentation that low socioeconomic status and illiteracy are related to pediatric mortality,^{11,29–32} potentially compromising the ability of some bereaved parents to complete a written survey. Ultimately, the IRB approved telephone contact after reviewing the information and rationale.

Several sites' IRBs required the title of the research protocol to be included on contact letters and consent forms. Therefore, investigators had to consider how a proposed title might affect participants.^{3,5} For example, the CPCCRN survey study was originally titled "Prevalence and Risk Factors for Complicated Grief in Bereaved Parents." This title might cause parents to fear a psychiatric diagnosis even though the study intends to investigate the range of responses to a questionnaire that has not yet been validated in a parent population. The title of the survey study was changed to "PICU Bereavement Study" and included on all study documents.

One site's IRB required the hospital risk management team to play a gate-keeping role with regard to the investigator's access to bereaved parents. The investigator was required to present a list of deceased children to the risk management team. The team was empowered to exclude eligible parents based on the perceived risk to the institution. Gate-keeping by a risk management team can be detrimental to the validity of research findings because bereaved parents who are especially angry or dissatisfied may be systematically eliminated from the research. Although CPCCRN investigators were strongly opposed to the IRB's ruling, the investigators were forced to either comply or forfeit data collection at that site. We chose to include the site and to evaluate "research site" as a potential confounding variable in the analysis. To date, the risk management team has prevented contact with only 2 of 32 eligible families. Other researchers have voiced their opposition to gate-keeping mandates in the absence of formal studies showing benefit to research designs that employ such prior approvals.^{3,5,17,18}

Qualifications and training of researchers

The background, training, and resources that best qualify individuals for conducting bereavement research are unknown.^{14,33} Of utmost importance, these individuals must be equipped to maximize participant safety, data quality and consistency of methods across sites. The IRB at each site viewed the principal investigators' clinical and research backgrounds as sufficient to conduct bereavement research. However, at each site, research coordinators rather than principal investigators were assigned the tasks of recruitment, data collection and follow-up. Research coordinators had backgrounds in nursing or respiratory therapy; all had experience working in intensive care settings.

Research coordinators underwent extensive interview training including didactics, modeling, role-playing, and verification of skills. A behavioral scientist with expertise in health communication provided a lecture and readings on interview techniques and conducted audio recorded pilot interviews with bereaved parents for research coordinators to review and discuss. Research coordinators practiced their interview skills by role-playing various case scenarios. Coordinators were required to demonstrate their skills by interviewing the behavioral scientist playing the role of a parent over the telephone. Feedback was provided to each coordinator and practice interviews were repeated until satisfactory skills were demonstrated. During the study, one of two investigators reviewed each recorded parental interview and provided feedback to the interviewer within 24 hours of the interview's completion. Ongoing monitoring served to maintain coordinators' skills and ensure quality across sites.

Researcher support

After all qualitative interviews were complete, research coordinators participated in a focus group to provide feedback about their training and experience interviewing bereaved parents. Research coordinators reported feeling that they were well trained but still experienced some anxiety conducting interviews. Coordinators' anxiety was often related to the uncertainty of how parents might respond to the recruitment telephone call and the need to adopt a research rather than a therapeutic role. Support should be provided to researchers who have direct interactions with bereaved participants. The interview monitoring process allowed supportive relationships to develop between the two investigators providing feedback and the research coordinators. The two investigators acknowledged difficult interviews and provided praise for coordinators' performances. Research coordinators also attended quarterly CPCCRN meetings during which they had scheduled time to share problems encountered in the research.

Data collection

A variety of data collection methods have been used in bereavement research.^{4,34} The CPCCRN chose telephone interviews and mailed surveys because these methods tend to be less disruptive to parents and more amenable to multicenter research. Telephone interviews and mailed surveys can be completed from home at parents' convenience. This may help parents who have other young children to care for, who lack transportation, or who prefer not to return to the hospital where their child died. Also, these methods are relatively inexpensive and do not require that the physical appearance of the researcher or research location be standardized across sites. Disadvantages to collecting data via telephone and mail include inaccurate contact information in medical records, frequent changes in and lack of a central directory for cell phone numbers, and family relocations after a child's death. These challenges need to be considered when estimating the available sample size.

Providing parents with flexibility for data collection may enhance participation. First, research coordinators were flexible in scheduling interviews and surveys with parents who

preferred to participate during evenings or weekends. Second, either or both parents of a child were invited to contribute data. If both parents participated, they were interviewed or surveyed independent of each other. Third, parents were given the option of completing interviews and surveys in English or Spanish. This required translation of all research documents and training of Spanish speaking interviewers at each site. Fourth, for the survey study, parents were given the option of completing the survey in writing or by telephone. A disadvantage of allowing options for data collection is that parent preference may influence the data that he or she provides; these preferences become additional confounding variables that need to be considered in the analysis.

CONCLUSION

The CPCCRN bereavement studies illustrate challenges to multicenter parental bereavement research and provide reasonable strategies to address ethical and logistical concerns. Multicenter research networks must work collaboratively with local IRBs to address participant privacy, confidentiality, voluntariness, risks, and data collection methods. Researcher training, monitoring and support may enhance data quality and consistency of methods across sites. A limitation of this paper is that the efficacy of these strategies has not been empirically tested. However, attention to these issues has the potential to facilitate research to reduce adverse mental and physical health outcomes in a diverse population of bereaved individuals.

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