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Parents' Views of Involvement in Concurrent Research with Their Neonates

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Abstract

It would be useful to researchers and bioethicists to know more about parents' decision processes and emotional state during the time they are deciding whether to enroll their infant in a clinical trial. The aim of this research study was to discover whether parents who had been previously asked to enroll their neonates in clinical trials would have found concurrent research about their decision-making overly burdensome. Twenty-seven parents of critically ill neonates who had been approached for their child's research participation in a clinical trial were asked what they believed about the potential burden or value of being interviewed during the time of research decision-making about their infant's participation. For this qualitative descriptive study, interviews were audio-recorded, transcribed, and analyzed using content analysis techniques. Participants considered concurrent research acceptable for them but potentially problematic for others. Theories of risk preferences and social comparison might explain these findings.

Keywords

decision-making; ethics; infant; high risk; research participation; risk; perception

Mothers and fathers are confronted with new sights, sounds, and persons when their infant is admitted to a neonatal intensive care unit (NICU). Within this overwhelming new environment, they must make important decisions about such things as their child's life support and participation in a clinical trial. Family-centered care in the neonatal intensive care unit encourages dialogues between parents and professionals and facilitates the involvement of parents in all aspects of the care of their critically ill children. The approach of protecting parents from knowledge that might distress them has changed to including parents in decision-making. This research asks: What do parents of critically ill neonates believe about the burden or value of being interviewed during the time of research decision-making for their children? Exploring decisions being made by parents about their infants' participation in research protocols while the parents are making those decisions will be referred to as *concurrent research* in this manuscript. Both to ensure apposite consent of parents who are asked to enroll their neonates in clinical trials and to support the decisions made by those parents, a better understanding of their process of research decision-making would be helpful. However, would interviewing parents at the time they are making decisions about their infants' research participation be too much to ask?

Treatment in neonatal intensive care units is increasingly driven by research protocols. Additionally, the clinicians are often the researchers, thus conflating their roles (Kraybill,

2004; Snowdon, Elbourne, & Garcia, 2004; Mason, 1997). Several researchers have investigated parental beliefs about research on neonates (Aylott, 2002; Burgess et al., 2003; Mason & Allmark, 2000; Singhal et al., 2002; Snowdon, Garcia, & Elbourne, 1997; Stenson, Becher, & McIntosh, 2004; Zupancic et al., 1997), and a few of these researchers noted that their studies of parents were conducted retrospectively because additional research involvement while their child was enrolled in a research protocol was assumed to be excessively onerous for parents (Aylott, 2002; Zupancic et al., 1997). However, even though retrospective designs can yield insights into parent views, it is important to gain an understanding of the perspectives of families during the actual experience, because parents' beliefs are inevitably affected by infant outcomes and the passage of time. Appreciation of the issues that influence parents' decisions and shape their evaluations of those decisions can assist healthcare providers in providing support to parents who are asked to enroll their neonates in clinical research.

Nevertheless, fear of excessively burdening families with research during a neonate's illness has prevented researchers from conducting interviews with parents about their experiences during the time when their child was in a research protocol. Cunningham and Hutchinson (1990) note that there is a particularly great potential for exploiting parents unfairly in neonatal research because prospective research participants are infants, and their primary natural protectors—the parents—are members of what ANA Guidelines (1985) refer to as a “captive ... population vulnerable to exploitation” ... Parents may ... be vulnerable both as potential research subjects and as decision makers for their children who are potential research subjects (p. 30).

Other researchers have identified NICU parents as potentially “vulnerable populations” (Aylott, 2002; Mason & Allmark, 2000; Zupancic et al., 1997).

To understand whether a prospective study of parents' experiences would have been too arduous, Aylott (2002) conducted interviews with eight parent dyads whose children were involved in research on extracorporeal membrane oxygenation (ECMO). Although parents viewed their research participation as therapeutic and said that it provided them with “a sense of purpose,” most believed that accounting for their experiences while their children were receiving ECMO would be a “more fraught and anxious activity than that experienced retrospectively” (Aylott, 2002, p. 168). Despite this, some parents in the study felt it would be valuable to researchers and potentially therapeutic for themselves to discuss their ongoing insights during their child's ECMO enrollment. Also, benefits of participation in qualitative interviews have been noted by numerous researchers, and identified by Hutchinson, Wilson, and Wilson (1994) in their study to include: catharsis, sense of purpose, empowerment, self-acknowledgment, self-awareness, healing, and providing a voice for the disenfranchised. Finally, recent research suggests that in other populations, talking about issues such as end-of-life and other sensitive topics may be beneficial for participants (Emanuel et al., 2004).

Ulrich and colleagues (2005) observe that minimal empirical data exist about what constitutes (and who decides) subject burden in clinical research. As healthcare providers learn more about the views of parents who are asked to enroll their neonates in clinical research, they might be able to better support their decision-making and their experiences. This study therefore examined the perceptions of parents of neonates who had been asked to enroll their children in clinical research to determine whether concurrent research with them and their neonate would have been too arduous. This article is part of a larger study of parents' views of research on neonates, which has been reported elsewhere (Ward, 2007; 2009). This descriptive study obtained in-depth interview data from parents who provided retrospective insights into their experiences as they were approached about enrolling their neonates into clinical trials of more than minimal risk. Their thoughts about concurrent

research were solicited toward the end of these interviews. Parent participants were basically asked, “Now that you have been through this interview, what would you have thought about being similarly interviewed at the same time you were making a decision about your child’s research enrollment?”

The value of concurrent research with parents deciding clinical trial enrollment for their children has been described in work in pediatric oncology trials. Specifically, Simon and colleagues (2006; 2004; 2003) have identified ways to improve the informed consent processes in these trials, and have reached their conclusions by observing these conferences and speaking with the parents making their decisions. I wanted to learn about the seeming disconnect between the claims of burden with concurrent research made by neonatal researchers and these apparently satisfactory parallel explorations with parents of oncology patients. Concurrent research with parents contemplating neonatal trial enrollment may reveal common misunderstandings or difficulties, and thus inform efforts to improve consent conferences. The aim of this research was to discover whether concurrent research with parents would have been overly burdensome for those who are experienced with being asked for their consent to neonatal research, and experienced with retrospective interviews about their decisions.

Study Design

This study was a retrospective examination of parents’ beliefs about the possibility of being interviewed during the time they were deciding about their infant’s clinical research participation. Using maximum variation sampling, a total of 27 parents of critically ill neonates discharged home from three different NICUs in the northeastern United States were interviewed for this qualitative descriptive study. Of these participants, five had refused their children’s enrollment in particular research studies and one mother withdrew one of her twins from a research protocol after the child had been enrolled and experienced initial steps of the protocol. This study’s participants were limited to those who had been asked to enroll their child in a moderate risk study as the researcher believed the concerns of these parents would be different from those asked to enroll their children in minimal risk studies. The moderate risk protocols the parents had considered for their children’s enrollment included surfactant and nitric oxide studies, and prenatal surgery protocols for congenital birth defects. Research posing greater than minimal risk, but with potential direct benefit to the participating child, may be approved only if the anticipated benefit justifies the risk to the subject, if the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that of alternative treatments, and with the permission of at least one parent (45CFR46.405).

Qualitative Description (QD) is a form of naturalistic inquiry that relies on straight description in an attempt to elucidate a particular phenomenon (Sandelowski, 2000). A QD approach was particularly appropriate for this study because the study purpose was learning the parents’ perspectives about research, and QD allowed presentation of their understandings in their own words. These parent-participants had been asked within the previous six months to enroll their infant in a moderate risk clinical trial. After the trial, the infant had been discharged home to the parent’s care.

All names used in this manuscript are pseudonyms. The families that refused their child’s research participation (or withdrew their child) were no more likely than the other parents to find concurrent research objectionable.

After obtaining permission for study access from NICU attending physicians and obtaining institutional review board (IRB) approvals, parents were initially recruited through

brochures placed in parent waiting rooms and mailings to discharged NICU families. As the number of responses to the mass mailings was weighted so heavily toward those families not involved in research, and difficulties ensued with attempting access at one of the study sites, the researcher sought General Clinic Research Center (GCRC) approval to recruit through that site. The National Center for Research Resources at NIH funds a national network of GCRCs (now known as Clinical and Translational Research Units) that provides infrastructure and resources to support investigations funded by NIH. An application process was completed after contacting the GCRC program directors, approval was given, and targeted recruitment was enhanced. GCRC nurses and the coordinator of neonatal research at Hospital C were able to identify potential participants and provide the researcher with contact information, thus facilitating recruitment. The scattered nurses at Hospital B left project information sheets with all eligible families prior to their children's discharge. All parents who were informed of the study by these nurses consented to participate.

Parent-participants were purposively sampled for demographics and infant's research protocols for this study. Response rates to the participation requests varied from a 21% response rate from the targeted mailings to a 100% response rate from GCRC nurse-facilitated recruitment. The participants, twenty mothers and seven fathers, were well educated, with all having completed at least a high school education, and eleven completed graduate school. Participants were paid \$20.00 for their participation.

Interviews were audio-taped, transcribed, and compared with recordings for accuracy. Based on parent-participant preference, the majority of interviews took place over the telephone. Thoughtfulness of response and length of interview did not differ between those participants interviewed in person and those interviewed via telephone; each encounter lasted from between 65 and 105 minutes. Semi-structured interview guides were derived from the literature and from the context of individual parent experiences. Using conventional content analysis techniques, data analysis was ongoing throughout the study and used codes inductively derived from the data to form coding categories (Hsieh & Shannon, 2005). Examination of manifest data and detection of latent data facilitated development of categories and ensuing themes (Graneheim & Lundman, 2004).

Scientific adequacy for this study was addressed through efforts to achieve trustworthiness, including maintenance of audit trails, member checks with participants, peer debriefings, and expert consultations. Audit trails included contextual, methodological, and analytical documentation (Rodgers & Cowles, 1993) and were facilitated by the use of Atlas/ti (Scientific Software Development). The iterative nature of data collection and dynamic analysis led to ideas about concepts that were expanded upon, or occasionally discarded when they failed to be fully supported by the data.

Results

Chaos

The first theme to emerge from the analysis of the data was *chaos*. When parents interviewed for the study were asked their beliefs about the possibility of their participation in concurrent research while they were evaluating research enrollment for their neonates, almost all of the parents hesitated. Most commented on how confusing it was for them at the time surrounding their child's NICU admission.

Amy, a mother of prematurely born twins, commented that for most parents, "At that moment, they just can't even deal with anything." Although many of the parents interviewed had been introduced to NICU physicians and given cursory explanations about what to expect before the birth of their child, all of them reported not being "prepared" for their

child's arrival and admission to the NICU. When parents were asked how they might have reacted to requests for concurrent research, many indicated that this might have been seen as contributing to their feeling beleaguered. As Brian, father of a prematurely born child observed, "If it's during the midst of a lot of things going along with the baby, I think that's [concurrent research] the last thing parents are going to want to sign up for."

Information overload—Brian's comments resonate with the term "information overload," used by Thomas, the father of a prematurely born child, who remarked that participating in concurrent research would be difficult because he was already "trying to make too many decisions at once." This father, like other parents, noted that if too much is happening with the hospitalization and possible research enrollment of a critically ill child, then a parent will be unable to process relevant information and contribute to concurrent research. Tammy, mother of a daughter diagnosed prenatally with a birth defect, commented that during the time of making her decision about her daughter's research enrollment, she would not have wanted to talk: "I [wouldn't] want all that outside static in my brain ... right now I don't have all that chaos going on and it's a lot easier now."

Parents noted that because so many concepts needed to be processed, they would not have had the energy required to participate in concurrent research. When parents' energies are devoted to understanding their child's illness in the foreign environment of an NICU, talking about their beliefs about research is more than they can handle. Amy remarked, "They're just so overwhelmed with all that's going on that they might not be able to give you the time." Brian and Steven, fathers of prematurely born children, observed that they would not participate in concurrent research if it meant taking time away from being with their children. Although both of these fathers noted that they were able to spend a good deal of time with their infants, they acknowledged that many other fathers had constraints that did not allow them to do so.

Emotional overload—In addition to information overload, the parents spoke of "emotional overload." David, father of a prematurely born child, remarked, "Would I want to go on an indepth interview during that period? No, I don't think so. I don't think I'd have the sanity or patience to do something like that." Barbara, mother of another child born prematurely, agreed, "I would be a lot less likely to participate because my focus would be on [my daughter]."

Vulnerability

A second theme that emerged from the analysis of the data was *vulnerability*. Parents recognized that they themselves could be made vulnerable by concurrent research. Although more than two-thirds of these parents thought they would have benefited from concurrent research (69%), such as the opportunity to discuss the potential study in depth with an interested observer with no vested interest in the research protocol, more than half thought that other parents would feel vulnerable. A few participants voiced concerns that parents might be so worried about their children that they would not be able to protect themselves from potential harms resulting from participation in concurrent interviews, such as increased distress and anxiety.

Parents spoke of their concerns about being susceptible to harm if they were to speak freely during their child's research enrollment. Some parents expressed concern, for example, about voicing potentially negative thoughts about the neonatal research if their children were still being cared for by researchers/clinicians. Indeed, this concern does merit further exploration as many researchers in the NICU are also the healthcare professionals involved in the care of the infants.

Two parents, Tina with a prematurely born child and Teresa with a child diagnosed prenatally with birth defects, noted their apprehension about an interview that was completed before results of the neonatal research were known. These parents worried that if they expressed satisfaction with their experiences and then something untoward happened with their children as a possible result of the research, other parents might be led inappropriately into research participation based on these parents' initial experiences. Tina remarked, "I would feel bad if ... they did it because they went by my opinion ... if it went bad a few weeks later ... then I would feel bad because this is one side that people won't get to hear about." This reflection was the primary reason that Tina gave for disagreeing with the idea of concurrent research. Teresa noted this as one reason for her disquiet about the concept of concurrent research, but ultimately noted that parents should be given the opportunity to participate and decide for themselves.

Unintentional Coercion—Another explanation given by the parents in this study for why they believed parents could be made vulnerable by being asked to participate in concurrent research during their children's research participation was fear of susceptibility to unintentional coercion. Sandra, the mother of prematurely born twins, declared that parents are "in a panic mode ... you would be willing to agree to just about anything." Her unease echoed other parents' concerns that requests for concurrent research with parents along with requests for participation of their infants in research might lead to confusion during a particularly unguarded time. Lisa and David, parents of prematurely born children, said they were consumed with fears for their children's survival. Their statements during concurrent research, they said, would have been "wary and emotional" as they waited to learn whether their children would come home.

Finally, two parents gave additional reasons for not wanting to participate in a study about their research beliefs while they were deciding on their child's research participation. Barbara, mother of a prematurely born daughter, "would not have wanted to analyze [her] own feelings at that moment," and Tina remarked that the potential pressure to participate would "make you make decisions that you might not make on a normal day." Both of these mothers thought that other parents would feel similarly and should not be asked to participate in concurrent research.

Control

Despite their concerns, the majority of parents (69%) who considered enrolling their children in clinical studies of greater than minimal risk said that they would have welcomed concurrent research because having control over the process would have provided benefit to them.

Catharsis—More than half of the parents stating they would have accepted research interviews spoke of the release that this type of interview would have provided them. Steven, father of a prematurely born child, noted that he would have viewed an interview as a way to "let out some steam." His wife, Shannon, concurred, noting that "anything like that would be good" because she did not believe "the mental aspect of the NICU" was appropriately handled. Other parents, including parents of premature infants and parents who had prenatal diagnoses of birth defects, remarked on the possible therapeutic aspects of an interview. Julie, mother of a prenatally diagnosed child, said that a research interview would not have served as therapy *per se*, but would nonetheless have been therapeutic for her. "It might have been helpful to have an interview ... as a catharsis ... and not that that's counseling ... but to me it's cathartic to talk about it." Cynthia, mother of a prematurely born infant, was not as clear in her distinction. "It would kind of be like therapy for me ... I

would be able to talk about my concerns, my worries, and any good things I felt about my son being in the research study.”

Action Facilitating Control—Parents often commented that any action they could have taken during their children’s hospitalization would have helped them gain control over an otherwise uncontrollable situation. Mothers and fathers in the study often spoke of their eagerness to “do something” while their child was hospitalized in critical condition. Many parents remarked on their heightened frustration resulting from inability to take action affecting the health of their child. This desire for action influenced some parents to enroll their children in clinical research (Ward, 2009). Many parents voiced the idea that active participation would benefit parents deciding about their children’s research enrollment. Shannon, mother of a prematurely born son, said, “People really feel so helpless and you feel like there’s no action steps that you can take ... if there’s some action that parents can take ... I think it would probably be beneficial.” Similarly, Brian said, “If someone came up and said, ‘we have this study’ ... I would jump at the chance of having some course of action that might have a positive effect.”

However, Lisa and Todd, two parents who did not enroll their children in clinical research of greater than minimal risk, and Sandra, who withdrew her child from a study, also remarked that participation in concurrent research would have benefited them by giving them an outlet or “something to do.” Lisa said, “I probably would have done it ‘cause to me I was very frustrated ‘cause I couldn’t do anything anyway.”

Receptivity to research in general did not determine which parents would consider enrolling in concurrent research. Parents who enrolled their children in clinical studies were no more likely than parents who declined their children’s enrollment or withdrew to say that concurrent research would have been useful to them.

Exploration—Many parents noted that participation in concurrent interviews would have enabled them to explore their reasons for neonatal research enrollment, and increased their understanding of their experiences. Steven and Brian, two fathers who enrolled their prematurely born children in clinical research, noted that interviews regarding their children’s involvement in research would have enabled them to “gather information.” Steven believed that if he had participated in this type of interview during his son’s research enrollment, he would have been “place[d] at a certain level of ease ... it would have been helpful to find a little more about what was going on.” Brian noted that concurrent interviews would have given him “a chance to distance [him]self from [the decision about his child’s research enrollment] and look at it from an analytical standpoint.” Brian stated on a number of occasions that he should not have let emotions about his daughter’s illness influence the decisions he made about her research enrollment, but his emotions did strongly influence his research decision. He felt that concurrent research interviews would have limited the influence of his emotions. Other parents noted that their interview with the author led them to consider concepts they had not previously considered. Julie remarked, “All these questions are getting me to think about it. And maybe it gets you to explore your own thought processes about the study.” No parents who acknowledged these thoughts expressed regret about their decisions about their child’s enrollment, but Amy observed, “It sometimes is helpful if you are a little bit in doubt about what you’re doing, maybe it’s helpful just to talk about it, to give it some thought.” Teresa concurred, saying, “Sometimes it helps to vocalize things that you’re thinking.”

Value for Researchers—A concept that many parents introduced when questioned about the idea of concurrent research was its potential value for researchers. A few parents thought that concurrent research would be helpful for researchers in their attempts to understand

parents' beliefs about clinical research with their children. Julie observed, "It's a lot fresher in your mind as you're going through it" and Teresa agreed: "A parent in the NICU who's in the middle of a study is maybe going to give you answers that are pertinent to what parents are gonna go through." Two other parents thought differently about the value of concurrent research to researchers. Maria said, "You will get more honest answers in retrospect because you have time to think about those things, and especially once you're out of the NICU, life is completely different." Barbara concurred: "I think there's more benefit gained from the perspective that I've gained over the past few months."

Some parents stated concerns about the usefulness of the data that might be obtained from parents who are in a highly emotional state. "The information you receive might be more emotional than fact," advised Julie. Steven agreed: "I think you might have to filter through a lot of the emotions that they're feeling." These same parents, however, also said that they personally would have benefited from concurrent research. They believed that since "experiences change over time," their thoughts gathered concurrently with their children's research would have been useful for the researcher.

Discussion

More than half of the parents interviewed for this study believed that research with parents done while they were making decisions about their children's research participation would be positive both for themselves and for the research enterprise. However, half of the parents also said that although this research would have been beneficial for them, it would be detrimental for other parents. Thus, the conundrum: Why would participants express, on the one hand, the desirability for concurrent research, and on the other, state that this type of research might be unacceptable for others? Research done on risk preferences and social comparison might help to explain that apparent discrepancy.

Risk Preferences

Hsee and Weber (1997) used hypothetical financial scenarios in three studies to investigate subjects' predictions about others' risk preferences. These researchers concluded that people made predictions of another person's risk preference based on their own feelings or on risk neutrality (reflecting their lack of specific feelings). People base their predictions on their own feelings, the researchers concluded, when they lack a vivid perception of the other person. Hsee and Weber (1997) thought that if the referent were more abstract, empathizing would prove problematic, and subjects would choose risk neutrality for making predictions.

This literature on risk preferences might explain why many of the parents in this study were reluctant to advocate concurrent research for other parents. None of the parents talked about parent support groups or other formal mechanisms for sharing stories and information, hence they probably had limited understanding of the feelings of other parents. Only one parent, Tina, remarked that she had sought interactions with another family. The interaction occurred when Tina realized that a baby new to the NICU had been admitted in an isolette next to her daughter, and this "new baby" had been born at the same gestational age as her own daughter. Tina noted that she often provided counsel to the inexperienced mother in the NICU. Consistent with the conclusions of Hsee and Weber (1997), Tina was able to empathize with another NICU parent, and because Tina was opposed to concurrent research, she thought that another mother would be also. None of the other parents remarked on a similar connection with another parent. Thus, it is not surprising that these parents gravitated toward "risk neutrality" and cautioned against concurrent research with other families.

Social Comparison

Social comparison theories assume that individuals evaluate themselves based on comparisons with other people. If an individual can compare his or her situation to that of another person in a presumably worse situation, thus engaging in downward social comparison, the individual might experience increased self-assurance because his or her own situation no longer appears as bleak. Downward social comparison is a defense mechanism that might be used by parents to create social distance between their own situations and the presumed vulnerability and chaos that surrounds others, and thus moderate feelings about their own vulnerability.

Many of the parents in this study compared themselves favorably to others, suggesting that other parents (often perceived as having less significant resources and in a situation worse than their own) would not be able to manage the situation of their critically ill child and concurrent research as well as these parents potentially could. The parents in this study were not comparing themselves to hypothetical others in a mean-spirited fashion, rather, they expressed concern for other parents faced with difficult decisions during a time of crisis, and might have used mechanisms of downward social comparison to reduce their own feelings of vulnerability.

Although this study concerned parental beliefs about neonatal research, many of its implications are applicable to parents of critically ill children who may never be approached for clinical research. Most of the parents in this study did not make distinctions between treatment and research protocols, but spoke about their “desperate situations.” Further, many parents’ recollections of their experiences in the NICU remained vivid and disturbing, including some parents’ expressions of feelings of “paranoia” during their children’s hospitalization and research participation. These recollections confirm the work of other researchers who have investigated incidence of, and prevention strategies for, post-traumatic stress syndrome in mothers of children in the NICU (Holditch-Davis et al., 2003; Melnyk et al., 2004).

This study illuminated the feelings of powerlessness parents felt not only about their children’s potential research participation, but also about their children’s hospitalizations. Many of the parents were keenly aware of the power differentials existing between themselves and their children’s healthcare providers, (who were in most cases, the neonatal researchers). Some parents expressed fears about provoking anger in their children’s healthcare providers and others voiced anxiety associated with potential researcher loyalty to the research instead of to their children’s welfare.

Best Practices

The primary practice implication of this study is to support parents’ attempts to make sense of their critically ill child’s research participation. The parents in this study who disclosed their attempts at feigning understanding, especially early in their children’s hospitalization, bid healthcare professionals to consistently reinforce information with frequent discussions. That parents primarily relied on what they were told rather than what was written in consent forms speaks to the need for open communication with families, and a consent process to ensure that parents understand the research in which they have enrolled their children.

Parents gained perceived control over their children’s hospitalizations and research enrollment by intensively gathering information from their children’s healthcare providers and outside resources including the Internet (see, for example, Schaffer et al., 2009). Work by Penticuff and Arheart (2005) demonstrates that specific interventions such as “infant progress charts” maintained by parents, and care-planning meetings with parents and

healthcare professionals may improve NICU parents' understandings of their children's clinical progress. These types of interventions may be similarly used to aid parents' understanding of neonatal research. Concurrent research with parents may facilitate this understanding.

Research Agenda

Themes related to parents' sense of *chaos*, *vulnerability*, and *control* identified in this study merit further investigation. The value of concurrent research with parents considering their neonate's research enrollment may support improved consent conferences and is deemed acceptable by parents experienced with the concept. Appropriate formats for this type of research may include interviews, observation, and/or recording. Future descriptive research should consider longitudinal design. For this study, parents were interviewed within four to six weeks after their child's discharge home and within six months after their decision about neonatal research. The determination about time intervals was made specifically to ensure that parents' impressions would still be fresh and would not be altered substantially by the child's arrival home. All the parents in this study expressed their satisfaction with the decisions they had made. It would be enlightening to speak with parents at different time intervals, (e.g., one month, six months, one year, and two years after decision), to evaluate their continued levels of satisfaction with their decisions. Once the effects of prematurity on the children involved are better known, for instance, would parents be as likely to declare their decisions were informed and correct? On the other hand, if the parents viewed research participation as part and parcel of the whole NICU experience (as did the parents of prematurely born children in this study), perhaps it would be more likely that they would consider any difficulties experienced by the child to be related to the child's initial diagnosis and not the research trial. Schwartz (2004) cautions, however,

Bad results make people equally unhappy whether or not they are responsible for them. But bad results make people regretful only if they bear responsibility ... the more that our experiences result from our own choices, the more regret we will feel if things don't turn out as we had hoped (p. 151).

Perhaps the vulnerability to regret experienced by some parents who enroll their critically ill children in research may be attenuated by more intensive counseling during the time of decision-making. Alternatively it may help to provide parents with recordings of their informed consent conference to aid their recollection of the details they discussed and the information that was conveyed to them. Koh et al. (2007) found that mothers of NICU babies who were given recordings of their conversations with a neonatologist improved their information recall of specific events in the NICU and their psychological well-being. More generally, it has been found that providing patients with recordings of their consultations improves information recall, and has a positive effect on adult patients' satisfaction with the care they received (Ong et al., 2000; Tattersall & Butow, 2002).

The parents interviewed for this study believed that they had played active roles in ensuring their children's health by giving their children the opportunity to participate in clinical research or by protecting them from possible research harms. Future research is warranted to answer questions about whether and how the psychological health of the family is impacted by parents' choices about their children's research participation.

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Biography

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