

PEDIATRICS PERSPECTIVES

Honesty, Trust, and Respect During Consent Discussions in Neonatal Clinical Trials

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"Participating in the study provided an avenue for a premature baby like mine to receive an outstanding level of care and extra support from the research nurse that may not otherwise be available outside research. It was also fulfilling knowing that from this research may come the help that others with this same condition may need. It played a significant role in our education about improving and maintaining his health."

—Parents of a neonatal clinical trial participant

Participation in neonatal clinical trials is often viewed as risky, ethically challenging, burdensome for parents, and a favor that altruistic families are performing for future generations of babies.^{1,2} Views such as "valid consent in the antenatal/perinatal population is difficult, if not impossible, to obtain" are common.³ However, neonatal research need not be viewed through such a negative lens. Parents who have participated in clinical trials may view their research involvement very differently, as an exciting opportunity rather than a burden.⁴ Participation can have benefits for the newborn child and the family, even if the infant is not assigned by chance to a therapy that proves to be superior after completion of the trial.^{5,6}

Collectively, as a group of research nurses and clinical investigators, we have discussed research participation with >900 families. We have found that when done well, conversations about consent to research can empower and support families at a time of crisis and reassure them that health care professionals are committed to discovering the safest and most effective care for their baby. For such consent discussions to occur, 3 conditions must be met. First, all clinical and study staff must wholly believe in the importance and safety of the research. Second, the research team must cultivate open, trusting relationships with the families of potential research participants. Finally, the goal must be not a signature on the consent form, but parents who are able to make a well-informed decision that is right for their baby and their family.

"NEVER SEEK CONSENT FOR A STUDY YOU DON'T BELIEVE IN"

The literature rarely addresses the critical role of the study personnel in obtaining a valid consent. Study personnel assume direct responsibility for ensuring that the family carefully weighs the risks and benefits of study participation and understands how the research protocol will fit into the greater context of their baby's care. This task demands patience and diligence. In our view, it is best performed by health professionals with previous clinical experience (usually neonatal nurses, nurse practitioners, respiratory therapists, or neonatologists). Because newborns

whose research participation is sought are often immature or ill, study staff must be exquisitely sensitive to the current stress and vulnerability of the parents. It is imperative that the person who approaches the family for consent understands the scientific rationale for the research and firmly believes that the study question must be answered. Those seeking consent for a clinical research protocol must be convinced that the study is safe and that the results will improve medical care of infants in the future. If asked directly, the study staff must be able to honestly state that they would consider enrolling their own children in the clinical trial.

Having been briefed on all important aspects of the study protocols, the clinicians must also believe in the scientific importance of the studies in which their patients are enrolled. Ideally, the bedside nurse or another member of the clinical team joins the research staff and family during the consent conversation. This allows the clinical team to develop a deeper understanding of the research and of the family's questions and concerns. An initial joint meeting also reassures the family that the investigators and clinicians agree that participation in the proposed research would be meaningful and safe for their baby.

“EARN THE FAMILY’S TRUST AND KEEP IT”

The Belmont Report states that the “manner and context in which information is conveyed is as important as the information itself.”⁷ A kind and

ethical conversation begins with the acknowledgment that it is stressful and sometimes frightening to have a baby in the neonatal intensive care unit (NICU). The research staff should view themselves as intermediaries between parents and the NICU, rather than as a separate entity. In this role they can provide general medical updates and triage questions before broaching the subject of research. Parents cannot engage in a thoughtful conversation about research until they have understood what is happening with their baby and trust that the research team will always prioritize their child's best interest. Opening the discussion in this manner alleviates anxiety and helps the family and the research team establish a trusting relationship. The research team can then explain how current medical decisions are influenced by previous research and point out opportunities to refine existing therapies. In our experience, many parents are grateful that their infant has benefited from the altruism of families who have enrolled their children in past trials. Moreover, they value an honest discussion of the uncertainty surrounding many current clinical decisions and understand that this uncertainty may prompt new trials.

Consent is not a one-time event but an ongoing process. This process may include regular visits at the bedsides of all study participants by members of the research team to answer questions raised by the parents or the clinical team. The study team should supplement but never replace the efforts of the clinical team to keep the family

abreast of their child's clinical progress. The family's trust in both the researchers and the clinicians will grow when they see that both teams work together closely and collaboratively.

“REDEFINING SUCCESS”

When seeking consent, the neonatal research team must always respect the interests of the patient and family. We reject any notion that researchers should prioritize the science over the interests of study participants. Consent for research is valid only if the family understands the scientific importance of the study and the potential risks and benefits of participation. Families are sometimes hesitant to seek the information they need to make an informed decision. Patiently giving a family time to ask questions and permission to say “no” eliminates some stress. This allows them to process the information without feeling pressure to participate. Whether the family opts to participate or not, a consent conversation is successful if the research staff provides a family with extra support and ensures that the family understands all important aspects of the research.

In summary, good consent discussions in neonatal trials are characterized by honesty and transparency about the proposed research, development of a trusting relationship with the parents, and respect for their decision, whether or not they volunteer their baby for trial participation.

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