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Letters

Trial experience and problems of parental recollection of consent

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EDITOR—The Griffiths report refers to papers providing qualitative research evidence about informed consent in the neonatal extracorporeal membrane oxygenation trial.^{1–5} As authors (CS, DE, JG) and principal investigator (DF) of this trial, we focus on one aspect of the report.

The report states that several parents in North Staffordshire had a clear recollection of being asked to allow their children to have continuous negative extrathoracic pressure but no recollection of giving consent to randomisation in a research project (9.3.2). Our research with parents of surviving babies from trials of extracorporeal membrane oxygenation suggests that, in this trial at least, many complicated factors affected the consent process and subsequent recall and reactions.

We interviewed parents some time after their baby had been discharged. A small number had no recollection of randomisation. Others gave varied details about the trial and treatment allocation. The consent process could be difficult, and transmission and reception of important information could be blocked or distorted by several factors. Views and recall could, for instance, relate to treatment allocation. All parents described consenting to extracorporeal membrane oxygenation, but the trial's comparative nature was clear for more of the parents of babies allocated to conventional ventilation. If the comparison was unclear at consent, there was not necessarily a subsequent clarification if allocated to extracorporeal membrane oxygenation; some believed that they simply consented to and used a new treatment. When probed, however, these parents remembered the words randomisation and trial (with various understandings of the terms).

Later views of the trial could be similarly shaped by allocation and perceptions of its consequences. Extracorporeal membrane oxygenation was shown to be more effective than conventional ventilation, and it was viewed as a desirable treatment (new and life saving) that parents had wished to access. Continuous negative extrathoracic pressure is not viewed positively now, but as experimental and risky, and this may also have shaped reactions and later recall of traumatic events for parents in Staffordshire.

The research community is obliged to ensure trials are conducted in the best possible way. To guide practice, scientifically, ethically, and humanely, we need to know how they affect all involved. The research into extracorporeal membrane oxygenation has effected practical changes (including all treatments in trial titles to highlight comparisons), but more research is needed.

The Nuffield Foundation has funded research to examine views in several perinatal trials. It involves interviewing parents (including bereaved parents) and medical and nursing staff, and occasionally tape recording the consent process. Such research should lead to better informed practice, and address some of the uncertainties remaining following the Griffiths report.

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