

Neonatal research

## Participation in multiple neonatal research studies

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Doctors and members of ethics committees need guidance that is underpinned by sound evidence on parental attitudes to research

In recent years, the journal has carried several papers on parental consent (assent) for participation of their babies in clinical trials.<sup>1,2</sup> This is important because *Archives* is read by many of those who organise neonatal research projects. The approach to parents is often fraught with ethical dilemmas.

Clinicians and members of ethics committees alike need guidance that is underpinned by sound research evidence on parental attitudes and beliefs about participating in research, rather than well meant assumptions about how parents might feel. Readers of the *Journal of Medical Ethics* would find little of direct use when confronted by the clinical realities and research questions of neonatal care—although this journal once published a neonatal study on the variability of ethics committee views. Rather, it is to specialist or general clinical journals that clinicians look for good information in relation to parental views and perceptions, and for an evidence base on the process of consent.

Mostly, existing work has concentrated on consent for inclusion in single trials. Yet in many large tertiary centres, there is the likelihood that several studies are in progress simultaneously. Some may be local, but others may involve participation in large multicentre studies. Either way, it is likely that the experience of parents will be different if approached serially for a number of studies; and some ethics committees may take views on whether more than one approach is ethical. So it follows that we need good evidence in relation to parents participating in one or more trials.

The two papers on this topic that we carry this month<sup>3,4</sup> reinforce each other, and give us confidence that in general it will not be inappropriate to approach parents more than once in relation to clinical trials. The paper from Melbourne centred on a tertiary neonatal intensive care unit, and that from Philadelphia focused on neonates undergoing cardiac surgery. The first was dominated by babies at high risk because of prematurity, and was specifically concerned with the question of recruitment to multiple studies, whereas the second concerned larger babies at risk from major cardiac surgery, and, although primarily about parental attitudes in general, it involved parents whose babies could be recruited to a number of different studies.

What do we learn from these papers? As with research on consent for single studies, altruism was a strong driver, coupled with a general perception of the benefit of both research and participation in research; perhaps also there was consciousness that an environment in which research was undertaken was likely to be at the cutting edge of the specialty. A possible but tantalisingly elusive implication of the Philadelphia data is that rates of participation may have related to the nature of the study in question. This surely requires further investigation. Most importantly, engagement in more than one study did not emerge as a major problem. Many parents declined participation in some studies, although only 10% declined routinely, but that does not mean that they should not have been asked.

Indeed, given the flavour of the reasons for participation, would it be fair to deny parents the possibility of enrolling their baby in extra studies if their babies were eligible? And if parents decline participation in a study early in their baby's life, should we extrapolate that refusal to other studies at later times? Probably not—but here again, more research would be very useful.

Then there is what we don't learn. There is little research in general, and nothing in these studies, on the beliefs and attitudes of ethnic minorities, in either the United Kingdom or other countries into which there has been significant migration. What we cannot do is extrapolate from information obtained in western European or American culture to people of other cultures. This too would be fertile ground for future research.

We should never forget the fact that parents talk to each other, and many of us will have had the experience of parents approaching us about possible participation in a study even before we have raised the issue with them. The next challenge will be to ensure that the members of research ethics committees and review boards become aware of this information. But that's a separate problem.

*Arch Dis Child Fetal Neonatal Ed* 2005;90:F191.  
doi: 10.1136/adc.2004.067371

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Competing interests: none declared

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