
VIII Annual Symposium on Biomedicine, Ethics and Society: "Rethinking Informed Consent: The limits of autonomy"

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The decision to decline to participate in a clinical trial: the need for informed refusal

Much empirical effort has been directed towards understanding decisions that people make about participation in clinical trials. Whilst research describing attitudes and experiences of those accepting participation has grown in its range of focus and methodological sophistication, refusal is far less frequently considered empirically. We know little about how individuals who decline participation interpret clinical trials, how they view their actions, or whether their decisions shape their subsequent experiences in any way. Research which addresses the choice to decline participation is largely embedded into, and therefore shaped by, the need to improve trial recruitment rates, with refusal commonly described as a "challenge", "obstacle" or "barrier" to be overcome.

This paper considers three parental accounts of declining to participate in a UK neonatal trial, taken from a large qualitative study involving parents and clinicians. The trial in question involved two clinically effective forms of surfactant which were compared to consider differential cost implications of their use at delivery of babies born under 30 weeks of pregnancy. The accounts show major gaps in parental knowledge; none was aware of what the trial interventions involved but all perceived them as new and unnecessary. All felt that doctors had been prepared to place their premature newborn at risk and saw their refusal to participate as crucial to their baby's survival.

This research highlights long- and short-term sequelae for these parents, including unease, mistrust and anger. It suggests particular ways in which those declining trial participation can be left with inadequate and distorted information, and that in such situations informed refusal is not achieved.