Obtaining consent for neonatal research

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Obtaining consent for neonatal research

Informed consent is given when a competent person who has received and understood sufficient information voluntarily decides whether or not to receive treatment or take part in research. It is widely seen as an essential component of most medical research. In the case of neonates, parents must make the decision. However, there are a number of reasons to think that such consent is not likely to meet the criteria for being genuine informed consent.

1. Neonatal research often takes place in fraught circumstances. Parents may be suffering the emotional shock of unexpectedly having given birth to a seriously ill baby.
2. The need for consent may be urgent; in other words, there may only be a few hours in which the parents are able to decide (as in birth asphyxia trials).
3. The trial may be an "emergency trial" (1). These trials combine an urgent need for consent with the fact that the research is into interventions that are aimed at dealing with a life threatening condition (e.g. ECMO [2]).
4. The trial may involve a number of complexities. These may be difficult for lay-people to understand, particularly when under stress.

In other words, the anguished parent of a severely ill baby has to process very complex information and make a decision on behalf of that child in a short period of time. It is hardly surprising that clinicians have long doubted that such decisions constitute informed consent. These doubts seem to be confirmed by recent research (3,4).

One of these research projects, the Euricon trial (4), involved neonatologists, ethicists sociologists and legal experts from 11 European countries. Their discussions of possible improvements to the informed consent process form the basis of this editorial.

Not all neonatal trials are "fraught". There are, for example, feeding trials, where there is plenty of time to obtain consent, and where the background condition of the neonate may not be worrying. One of the surprises of the Euricon research was that the standard of consent often seemed poor even in these types of projects. This suggests that those obtaining consent could do better. Researchers often seemed unaware of legal or Research Ethics Committee (REC) guidelines governing the process in their geographical area. This situation seems likely to improve as medical students are increasingly expected to address such issues in their training (5). However, formal training should be available to those who do not.

A second area for improvement relates to the information sheet. Many parents do not read this sheet or fail to do so prior to consent (1). Thus, one way to improve the use of information sheets is to draw them up with a trial specific checklist of points of information that the researcher can then go through with parents prior to their consent decision.

These sorts of measures may improve the general quality of parental consent. However, this leaves the problem of the apparent impossibility of achieving a reasonable standard of informed consent in situations of urgency and emergency. How can we tackle this problem? There are a number of possibilities.

1. Two alternative consent procedures

We should accept that there is likely to be a significant reduction in the quality of parental consent in the "fraught" trials. Clinicians may give all the relevant information, but the parents may not have the capacity to understand and process that information in the time available. There are two possible alternative consent procedures here.

The first is a step-like process of consent. This involves giving parents a bare minimum of information (that which is most important for parents to understand) prior to enrolling the infant in a trial; then giving more information and repeating the request for consent as time goes on. Information sheets should be adjusted accordingly. Parents would receive a preliminary information sheet with a short series of points for the clinician to go through with them.

It might be argued that once parents have committed themselves on the basis of limited information they will find it hard to withdraw when they gain fuller information. This would raise concerns about the voluntariness of parents' decisions to remain in a trial following their original consent.

However, these concerns arise equally with a standard consent procedure; for whilst parents may have received all the relevant information, they may not have understood and processed it. They are likely to do this only later (when the research is under way). The virtue of the step-like approach is that it enables the researcher to focus parents' attention on a bare minimum of crucial information, and to emphasise

voluntariness then and later. The "bare minimum" would include that: the treatment is being given as part of a trial; their child may be receiving experimental or unproven treatment; they are free to say "no" and opt for the standard treatment; this is preliminary information and that more information is available if they wish to see it now (and will be given to them anyway, at a future point).

However, a further concern with the step-like approach is that parents may find that they receive information later in the research process that would have caused them to refuse consent had they received it earlier. This leads us to the second alternative consent procedure; the continuous consent approach. This involves giving parents all information at the outset (and asking for their consent) and then repeating this at later stages in the research. This avoids the problems of step-like consent whilst sharing the virtue of recognising that parents may not truly have understood first time round. However, it lacks the virtue of enabling the researcher to focus on a core of essential information. Neither of these approaches has been formally assessed.

2. Recognising the limited role of parental consent

If the role of parental informed consent were to protect the neonatal research subject, then our acceptance that the consent process is sometimes less than ideal would seem to imply that research subjects have reduced protection in such cases. This would not be acceptable. Hence, parental informed consent should not be seen as being the sole or main safeguard of the neonate's welfare in research. Researchers drawing up proposals, grant-giving and professional bodies, senior staff within the hospital structure undertaking a scientific review process and RECs considering the proposals have independent responsibility for the welfare of the child and to ensure that parents

are not asked to consent to bad research (6). The role of parental consent should be to do with respecting parents as decision makers for their children. Protecting neonates' welfare should be the concern of all involved.

3. Informing parents about RECs

If we accept this last point, then parents are unnecessarily burdened if they feel that their consent decision is of great import to their child's welfare. This could be eased. The Euricon study found that parents were usually unaware of the fact that the proposed research had been scrutinised by an REC. Some said it would have helped them if they had known this. As such, information sheets should include the fact an independent committee (an REC) has approved the research (7). Parents should be aware that such approval is consistent with its being both reasonable to give or to withhold their consent. Such a statement would need careful wording to prevent its coercing or cajoling parents to enter children into trials. The following is a proposed formulation.

"You have been asked to consider whether or not you wish to enter your baby into the x trial. An independent research ethics committee (REC) has looked at the overall likely health risks and benefits of the trial and have given it their approval. You are still entirely free to decide whether or not you want to enter your child into this research. Whatever you decide, your child will receive the best possible care."

4. Doing without informed consent?

There may be situations in which even step-like consent fails. For example, the time available in which to obtain consent may be so short that it is not possible for most

parents to digest even the basic minimum of information. At this point, the key decision must be whether or not to do the research. Euricon partners were divided on this: some felt strongly that neonatal research without parental consent should never occur, others that *in extremis* it should.

The Helsinki declaration does allow for research to take place, "*on individuals from whom it is not possible to obtain consent, including proxy or advance consent … [but] only if the physical/mental condition that prevents obtaining informed consent is a necessary characteristic of the research population*" (8 [at B26]).

Arguably, neonates with parents in the extreme situations hypothesized would meet this criterion. As such, perhaps there will be rare occasions on which neonatal research ought to be allowed at least to begin without parental consent. If so there would have to be further safeguards. One would be especially careful review by the relevant RECs; another that parents are informed on admission to hospital that research occurs in the hospital, and allowed to put in place a blanket refusal on all research.

Finally, the measures discussed in this paper might be described as "supply side"; implemented by clinicians on behalf of parents. Organisations such as Consumers for Ethics in Research (CERES) (9) and the Cochrane Collaboration Consumer Network (10) show that we should not neglect "demand side" measures. Thus, for example, any proposal for non-consensual research might first be put out to community consultation (an American model implemented following a Food and Drug Administration amendment to consent regulations [11]). Similarly, such consultation

could occur if the “step-like” consent model, outlined above, were proposed. However, the benefits of such consultation need to be set against concerns such as delaying the research and the difficulty of finding citizens genuinely representative of research participants.

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