Reviewer's report

Title: Issues of informed consent for intrapartum trials: A proposed consent pathway from the experience of the RELEASE trial (ISRCTN13204258)

Version: 1 Date: 17 December 2005

Reviewer: Mary Dixon-Woods

Reviewer's report:

General
1. Does it address an important or timely issue?

This paper addresses the important and interesting ethical issues that arise when recruiting women to intrapartum care.

2. Is it well reasoned?

The authors argue that there has been little specific attention to the ethical issues that arise in conducting research with labouring women. This is not strictly true; there is a relevant literature in the area, particularly from North America. In the US, federal regulation and NIH policy require that women, including women of childbearing potential, be included in NIH research unless there is a compelling rationale that inclusion would harm the subjects or the purpose of the research. A body of research and ethical debate has grown up around the specific issues of pregnant women and of emergency situations. I would suggest that the authors have a look at Mastroianni AC, Faden R, Federman D (eds) Women and health research. Institute of Medicine, 1994.

The discussion of the problems of providing information ante-natally is interesting and well-balanced.

The authors claim in the first para of the conclusions that “Current guidelines developed by professionals in conjunction with individual consumers display a lack of understanding of what consumers want, and struggle to strike a balance between providing adequate information without causing information overload and unnecessary anxiety”. It is unclear what guidelines they are referring to, since they claimed in the introduction that there was no guidance in this area.

3. Is it relatively balanced, or does it make plain where the author's opinions might not represent the field as a whole?

The paper appears to have been written by three clinicians who are involved in running trials in intrapartum care, and lacks specialist ethical or social science input. This is reflected in the tendency to construct the ethical issues as a problem to be overcome to avoid compromising trial recruitment, rather perhaps than constructing ethical issues as something to be addressed in order to safeguard the interests of participants. For example I find the argument on the last para of p3 that consent “barriers” could halt clinical research rather unbalanced.

The claim that women value the opportunity to take part in research is a contested one, but the authors present it here has an assertion of fact, particularly in their conclusions. They should consider evidence that does not support this view; for example: Baker L, Lavender T, Tincello D. Factors that influence women's decisions about whether to participate in research: an exploratory study. Birth. 2005 Mar;32(1):60-6.
Overall my concern with this paper is that it does not report an evaluation of practices in the RELEASE trial; it reports a description of a set of procedures with some supporting literature, but nonetheless ends up commending its own practices. I would be very wary of some of the recommendations – particularly the notion that the attending midwife or doctor should act as the “gatekeeper” to the research. This seems prone to paternalism and to introduce the possibility of biases in recruitment.

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

The author must respond to these before a decision on publication can be reached.

1. My major problem with the paper is that it presents itself as offering guidance on how to approach these issues, when in fact all it is really doing is describing the procedures adopted in one particular study (RELEASE) and offering a brief literature review in support of the approach taken in that trial. Given that an evaluation of the processes used in the RELEASE trial is underway, this paper seems premature to me. I would like the authors to provide a full justification for why this paper should be published now.
2. The authors need to demonstrate that they are aware of and have considered a wider literature on the recruitment of pregnant women to research.
3. The authors should be more cautious in their claim that women value the opportunity to take part in research.
4. The authors should offer some reflections on how their professional status and interests have led them to construct the issues in this area and the proposed solutions.
5. As this paper does not report an evaluation, it must avoid recommending the practices of the trial reported here as an example of good practice. In particular they must avoid calling them guidelines, especially as the authors indicate in their final para that there is in fact an evaluation under way.
6. The conclusions section seems unfocused and rather polemical. It needs to be made more coherent, to avoid bringing in issues that have not previously been discussed (such as developing countries) and to avoid “ranting” about the bureaucracy of the ethics approval process.

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

Please could the authors number the pages in the manuscript.

The quality of academic prose in this paper is sub-optimal, and the writing comes across as quite naïve at times. Some deft editing would improve it a lot.

Discretionary Revisions (which the author can choose to ignore)

Although it is not essential for the publication of the paper to include an ethicist as an author, this is something the authors may wish to consider.

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article of limited interest

Quality of written English: Needs some language corrections before being published
Declaration of competing interests:

I declare that I have no competing interests.