Author's response to reviews

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

Authors:

Gillian H Vernon (g.vernon@liverpool.ac.uk)
Zarko Alfirevic (zarko@liverpool.ac.uk)
Andrew D Weeks (aweeks@liverpool.ac.uk)

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Response to reviewers

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In response to the concern raised that the authors of the above paper are commending their own practices, I would argue on behalf of my colleagues that this is not the case, we simply wish to present the issues we have come across and our approaches to them, for discussion.

The notion of ‘gatekeeper’ and others presented in the paper have been developed in collaboration with the London Multi-centre Research & Ethics Committee (MREC) and consumers; they are not paternalistic if this is what women want.

Regarding the concern that the paper lacks specialist ethical or social input, and is written from the perspective of clinicians only, the solutions presented here have been developed by a consent group (details are given in the acknowledgements) not by the authors themselves (also I myself am not a clinician). Of the seven individuals involved in devising the potential solutions presented, only two are clinicians.

We believe the publication of the paper is timely. We feel it is important to encourage the discussion of these issues given the wide range of MREC and trial protocols in this area of research. We wish to present the novel features in our protocol for consideration by other researchers, and to highlight the importance of finding solutions in collaboration with other researchers and experts in the field, for current ethical dilemmas in the area of intrapartum research.

A wide array of literature on the recruitment of pregnant women to research has been considered during preparation for this paper, specifically the recruitment of women during the intrapartum period. Literature reviewed has come from both literature searching and from recommendations from a number of individuals of different specialities within the area.
Revisions

In response to the reviewers’ comments on the above titled paper, the following revisions have been made.

In the discussion of the paper by Jackson and colleagues, we have highlighted the fact that the authors discuss information needs concerning treatment not research, distinguishing between the two.

We have included a study by Kenyon & Dixon-Woods to introduce discussion around the issues of presenting information to try and optimise understanding by trial participants, and the evaluation of that understanding.

When discussing the use of websites as a means of disseminating trial information, we have discussed the limitations of this approach.

We have clarified in the introduction that guidelines are not unavailable, but that they are not ‘readily’ available. The little guidance that is available, as discussed in the introduction, is then discussed briefly in the discussion section.

We have re-addressed some of the language used to give a more balanced view of the ethical issues discussed. It was never the intention to present ethical issues as obstacles to trial recruitment and nothing more. We have also emphasised that consent procedures are in place for a good reason, i.e. to safeguard the wellbeing of trial participants. However, we have maintained that guidance to addressing ethical procedures are needed to help those recruiting women into intrapartum trials according to good ethical principles.

We have re-addressed the statement in our conclusions that women value the opportunity to take part in research, emphasising that although this is often the case, it is not always so, and that the decision making process is very complex depending upon the woman’s circumstances and own personal beliefs.

We have altered the language throughout, avoiding the term guidelines when referring to our practices. We have also softened the tone of the discussion, to avoid being perceived as ‘ranting’ about the bureaucracy of the ethics approval process, and hope it now reads as
simply presenting some of the concerns presented in the literature by the research community.

I hope you find the above responses and revisions appropriate,

Regards,

Gillian Vernon