Reviewer’s report

Title: Psychometric properties of the Confidence and Trust in Delivery Questionnaire (CTDQ): A pilot study

Version: 3 Date: 17 June 2012

Reviewer: Heather Rowe

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Advice from the ethical committee of the German Society for Nursing Science is referred to. Notwithstanding any opinion of an in-country committee, however, the international standards for publication of ethically compliant research are spelt out in the COPE (Committee on Publication Ethics) GUIDELINES ON GOOD PUBLICATION PRACTICE, 1999 (http://publicationethics.org/static/1999/1999pdf13.pdf).

Two articles in these guidelines are relevant to this paper:

Article (2) Research protocols should seek to answer specific questions, rather than just collect data.

The authors of the manuscript under review have elected not to address this problem and do not provide a good justification for the study. They describe four other questionnaires for use during pregnancy that investigate women’s expectations about the forthcoming birth and that tap related psychological constructs to those in the CTDQ piloted in the study. Of particular is relevance to the CTDQ is “the Childbirth Self-Efficacy Inventory (CBSEI) [9] introduced by Lowe in 1993 (that) focuses on self-efficacy and coping expectancies”. The authors state that “we wanted to develop a short but reliable instrument that focuses more on the fundamental aspects of confidence and trust as meaningful dimensions and sources of support”. However, questions remain about why these “fundamental aspects” are “meaningful dimensions and sources of support”. No empirical or theoretical justification for the importance of these related constructs is provided and the psychological constructs themselves not elaborated. Nor do the authors make any argument about how a new questionnaire would inform clinical care, what a high or low score might mean in clinical practice or how the results of the study would add to existing knowledge.

In response to reviewers’ comments, the authors argue that this kind of information is not relevant to the manuscript because the investigators were only interested in the psychometric properties of the CTDQ. However, at least brief reference to this should be made in the introduction to any paper reporting on the questionnaire, whether or not a detailed justification has been made in a previous publication (which it appears not to have been in this case).

Therefore no clear case has been made that the study was not “just to collect data” (COPE, 1999) and the study fails this test of ethical research.

The second problem is spelt out in Article 7 of the COPE Guidelines.
Article (7) Formal and documented ethical approval from an appropriately constituted research ethics committee is required for all studies involving people, medical records, and anonymised human tissues.

It is well understood that inter-country differences in requirements for ethical approval for human research mean that this Article of the COPE statement is implemented in practice with some flexibility. For example, some resource-constrained countries do not have institutional ethics review boards. It is common practice under these circumstances for journal editors to require that authors identify the ethical principles that apply in their study and clearly describe how the research protocol has addressed each principle. This enables important research that has been conducted in the absence of institutional ethical review to be published. The authors of this manuscript have not done this and there are some ethically problematic features of the research protocol.

First, the principle of voluntary participation: The authors state that recruitment of participants was carried out by midwives in antenatal clinics. Using clinicians to recruit participants to a study creates a dependant relationship between a recruiter and a potential participant. These relationships are usually not permitted in ethically compliant research because they compromise the capacity of an individual to make a voluntary decision (not) to participate in the research. The research protocol fails this test of ethical compliance - avoidance of dependent or unequal relationships.

The second problem related to Article 7 is the use of anonymous questionnaires. Women who are pregnant were asked sensitive, personal information relating to their hopes, fears and expectations for the birth of their baby. Contemplating the impending birth is anxiety-provoking for many women and therefore the questionnaire had the potential to arouse psychological distress. Anonymity in this circumstance means that women who become distressed or scored high or low (both scores likely to be indicative of distress) could not be identified and offered individual assistance. The research protocol therefore fails this test of ethically compliant research – protecting participants from potential harm.

Level of interest: An article of limited interest

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

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests: I declare that I have no competing interests