Reviewer’s report

Title: Patient, caregiver, health professional and researcher views and experiences of participating in research at the end of life: a critical interpretive synthesis of the literature

Version: 1 Date: 2 November 2011

Reviewer: Janet R Hardy

Reviewer’s report:

1. This paper is generally well written and comprehensive although it could be a lot shorter and more concise. Figure 1 was not included in any of the documents I received

- Major Compulsory Revisions

1. There is no definition of what the authors would consider to be “end-of-life” research

2. Papers were excluded if they were “already included in previous reviews unless they were found to be relevant or added something new”. I am not sure on what grounds these papers were excluded. How could they not be relevant if they were included in other reviews of the same subject. What was the system used to decide whether they were relevant or not? There is no transparency in the selection process. Did this depend on the authors’ opinion only? There is obviously great potential for bias with this methodology even within a critical interpretive synthesis (CIS).

3. No attempt is made to grade the quality of any of the papers included. Although I appreciate that this is not part of a CIS some indication of sample size, and methodology at the very least would be informative

4. The nature of the evidence. This section is long and difficult to read. It would be better presented in a table.

5. Page 22 is confusing. Are the authors suggesting that rigorous and robust research is not possible in this patient group because of compromises that are demanded by ethics committees? Please clarify. Similarly, there is an assumption in this paper that ethics committees will put barriers in the way of EoL research whereas in our experience, many committees actively support research in this group of patients believing strongly that those receiving palliative care are entitled to have the opportunity to participate in research.

6. Page 24. It is not clear what “the issue of being used as a means to an end does not apply any longer…” actually means.

7. This paper suggests that research and care are diametrically opposed. This is
reflected in figure 2. We disagree with this assumption and suggest that patients on trial may actually receive better care than patients not on trial as a consequence of regular review, special attention, close assessment etc. Moreover, it has been shown that patients on trial “do better” than those not on trial. The development of the new model “research with care” does not seem consistent with the findings of the study ie that most patients have a positive experience from partaking in research within the current frameworks. The proposed model of research “embraced by care” assumes that care does not feature in current research models. Many researchers would object to this.

8. This paper repeatedly describes “end-of-life” patients as being vulnerable. This label is not recognised by regulatory authorities eg national human research ethics committees, nor by patients themselves. Good clinical practice (GCP) protects patients and ensures that the benefits of participating in research out ways the potential for harm. The Australian National Statement on Ethical Conduct in Human Research refers to vulnerability only with respect to patients with unrealistic expectations of benefit.

9. The concepts of altruism and gate-keeping are key to this literature but are not mentioned

10. What is meant by Direct, Hypothetical and Attitudes in table 1?

11. Figure 2. The statement that research” is (perceived as) cold” is not consistent with the findings of this or other reviews. Does it also suggest that patient’s rights are violated within current models?

12. Figure 3. What is meant by “intersubjective”. How is this model justified by the findings of this and other reviews.

Summary. This paper supports other reviews that have been done on this subject and concludes that ethical concerns regarding patient participation in EoL care research is unjustified. This conclusion does not support the need for a new research model as proposed by the authors.

**Level of interest:** An article whose findings are important to those with closely related research interests

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

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

'I declare that I have no competing interests'