Reviewer's report

Title: Does Clinical Equipoise Apply to Cluster Randomized Trials?

Version: 1 Date: 25 January 2011

Reviewer: Peter J Allmark

Reviewer's report:

Major Compulsory Reviews
None

Minor essential revision
Typo
Page 4, Paragraph 1, Line 2: "address" - should be "addresses"

Discretionary revision
This paper is one of a series and as such the editor presumably needs to decide whether the whole package is satisfactory. This paper could function as a stand-alone, however. The key problem identified for CRTs is that the equipoise justification usually relies on a fiduciary relationship, whereas there is no such relationship between clinicians and populations. The solution draws on the notion of a trust relationship between the State and Research Subjects, something that has been explored before in a different context by one of the authors. The proposed solution is examined using an example. The authors have opened an online forum for discussion of the ideas in this paper and, presumably, the others in the series. I found the paper helpful, interesting and well argued.

Specific points

Page 4, Paragraph 2
The non-harm obligation is usually termed non-maleficence. Also, it's not really an obligation not to harm as much practice harms or risks harm (e.g. the pain following surgery). So health professionals need to seek a good balance of benefit over harm rather than no harm at all. I'm not sure much hangs on this point, however, and the authors may have chosen this wording intentionally.

Page 11. At the end of the section on clinical equipoise, perhaps it is worth alerting the reader to the fact that the usefulness of the concept is contested.

Page 14 - Solutions - I thought this section was helpful and well written.

Level of interest: An article of importance in its field

Quality of written English: Acceptable
**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