Reviewer's report

Title: Clustering in surgical trials - database of intra-cluster correlations

Version: 1 Date: 4 October 2011

Reviewer: John Martin Bland

Reviewer's report:

Major Compulsory Revisions

1. Something which is not clear in the methods is how treatment has been allowed for. Do these any of the ICCs include treatment differences in the between surgeon components? This would be possible in an expertise based design, where different surgeons perform different treatments. On the other hand, in a stratified design, where each surgeon performs both treatments, does the treatment effect influence the variation within surgeons? I think that this needs some comment.

2. On Page 5, the design effect is defined as 1+(average cluster size−1)*#. I think that a better estimate for clusters of size mi replaces the average by

\[ \frac{m_i^2}{m_i} \]

This is always greater than the average if the cluster sizes vary. Intuitively, we would expect equal cluster sizes to be the most efficient design for a fixed sample size, which would not be the case with the approximation given.

Minor Essential Revisions

I have a few minor typographical comments:

3. Page 4, line 1: “an number” should be “a number”.
4. Page 4, line 3 of Methods: “Trials recruited” should be “Trials were recruited”.
5. Page 7, paragraph 2, line 9: “outcome” should be “outcomes”.

Discretionary Revisions

6. I think that it would be useful in the Background to say something about the stage in the trial at which measurements are made, there are no baseline measurements in this paper, reasonable enough as surgeon should not influence these at all. Centre might, but this is not the focus of the paper. What might we anticipate the effect might be on things measured at different times and why? Would we expect the ICC to decline over time, for example?

Level of interest: An article of importance in its field

Quality of written English: Acceptable
**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I have no competing interests,