Reviewer's report

Title: Surgical trials and trial registers: A cross-sectional study of randomized controlled trials published in journals requiring trial registration in their author instructions

Version: 1 Date: 19 August 2013

Reviewer: Andrew Prayle

Reviewer's report:

I like this manuscript. Trial registration is a major advance in clinical research, and it's important to look at compliance with trial registration and reporting in specific domains, such as surgical management. I am not aware of any other studies which specifically addressed surgical trials, so this is an important analysis to publish. The clarity of the search strategy and analysis is appreciated.

- Major Compulsory Revisions

> The author must respond to these before a decision on publication can be reached. For example, additional necessary experiments or controls, statistical mistakes, errors in interpretation.

1. Regarding the Results section, "Reporting results" subsection. The authors report that a large number of trials were "clearly" required to report results. However, I think they may have misinterpreted the FDAAA. My understanding of this legislation is that it applies to only a specific subset of all clinical trials, termed "applicable clinical trials" (ACTs) in the literature surrounding this area of the FDAAA. The authors give the correct definition of an ACT in the introduction. However, in the methods and results they do not assess whether any of the trials are ACTs.

The authors haven't given us the data to look at, which makes it difficult for the reviews to make an assessment as to whether these trials were in fact ACTs.

Our group's experience of categorising trials into ACTs or otherwise is that this area is very difficult, but it turns out that most trials within the ClinicalTrials.gov database are not in fact ACTs. Therefore I suspect that most of the trials were not ACTs and are not required to publish summary data on ClinicalTrials.gov.

An assessment of whether or not the trials were ACTs is required before using such strong language in the results. If this analysis is kept in the manuscript, a discussion of the limitations of trying to determine if a trial is and ACT or otherwise with only the ClinicalTrials.gov record is required. This area requires careful analysis and very clear writing up, as if you state that a trial is not in compliance with the relevant legislation, your are implying that a responsible party is breaking the law.
2. I think that the raw data should be deposited in a repository. This would allow us and others from being able to review the data.

3. When comparing registered versus unregistered trials the authors state in the final paragraph of the results "Trial Registration" section that sample sizes were smaller. Were any statistical tests to confirm this carried out?

4. I think from several sections of the methods that 2 authors independently did the data collection and then compared the study records, and then resolved differences with a third arbitrator. But it's possible that they shared the workload of data collection from the way it is written. Please could this be clarified.

- Minor Essential Revisions

1. Table 3. In country of origin is "Korea" actually "South Korea" or "North Korea".

2. Table 3. The study sample size ranges are very wide. Having a measure of location (e.g. median) may be helpful in interpreting them. See also the Major revision 3 above.

   The author can be trusted to make these. For example, missing labels on figures, the wrong use of a term, spelling mistakes.

- Discretionary Revisions

1. Table 4 is difficult to interpret at first glance. A legend or re-design may be helpful.

**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.