Reviewer’s report

Title: Compliance of Clinical Trial Registers with the World Health Organization Minimum Data Set: A Survey

Version: 2 Date: 16 January 2009

Reviewer: Ludovic Reveiz

Reviewer’s report:

This is a very interesting and relevant study that Compliance of Clinical Trial Registers with the World Health Organization Minimum Data Set.

Major Compulsory Revisions

Methods
1. The definition of a trial register should be in accordance with the definition of WHO.
2. The registries chosen were widely know by whom? Is there any literature to support this?
3. How was calculated the sample of ten of 184 entities? Why not 20?
4. “For each register in our sample, we abstracted whether key protocol items were present”. Was this done by only one reviewer?
5. How were disagreement solved between both evaluators that “continued to monitor trial registers’ websites”.
6. How was calculated the sample of “From each of the 21 selected registers we randomly sampled a preset number of trial records, to reach a planned total of 600 records (final sample of 610 single trial records).” It is well known that some registries have a very large number of records while others only registered few trials. Was this stratified in any way? What was the total number of records of the 21 registries?
7. Some registries include observational studies. Do they included them in their sample?
8. Did the author used a predefined tested format for assessing each record? It would be interesting if they provide the format in a link for other researchers. In addition, authors should detail the way key methodological data fields were assessed. Did they used a specific tool to evaluate this (i.e : Consort)? For example some RCT may have reported the total sample size while other may have reported each arm number of participants. Where both considered adequately reported?

Minor Essential Revisions

Introduction
1. “In the interim, hundreds of trials registers have emerged, for many different purposes, including recruiting patients to trials.[3]” This reference do not provide a list registries to support that hundred of registers have emerged.

2. Which terms should authors used: registries or registers; registry or register? The World Health Organization used the term “registries” to define the entity that houses the clinical trial register. WHO glossary [http://www.who.int/ictrp/glossary/en/index.html]:

   Clinical Trial Register
   The formal record of an internationally agreed minimum amount of information about a clinical trial (trial registration data set). This record is usually stored in and managed using a database.

   Clinical Trial Registry
   The entity that houses the clinical trial register. It is responsible for ensuring the completeness and accuracy of the information the register contains, and that the registered information is used to inform health care decision making.

3. The introduction should mention efforts of the WHO International Clinical Trials Registry Platform to promote and ensure global trial registration.

4. There are a number of reason’s that have been mentioned to justify trial registration. Authors only mentioned that in is useful for those performing systematic reviews. Is there evidence that trial registers are useful for systematic reviewers?

5. Authors may wish to mention other initiatives such as the Ottawa group, Spirit and Proctor.

Results & Discussion
- Authors says that “Our findings revealed that registers often do not contain meaningful information on many key methodological”. However they did not evaluate or report key methodological aspect that may introduce bias and are crucial for systematic reviewers (namely sequence generation, allocation concealment, blinding, selective outcome reporting, disease and outcome report and definition among others). It was not clear if they used an structured instrument to evaluate such domains.
- The spirit and proctor initiatives could be mentioned in the discussion
- Authors should mention if the study has external validity, taking into account that it was not clear how the sample was chosen and how many records were evaluated

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.
Declaration of competing interests:

'I declare that I have no competing interests'