Reviewer’s report

Title: Strategies for obtaining unpublished drug trial data: A qualitative interview study

Version: 1 Date: 1 March 2013

Reviewer: Sanket Dhruva

Reviewer’s report:

Professors Wolfe, Gotzsche, and Bero perform an important and impressive qualitative study with a good response rate on strategies for obtaining unaccessed pharmaceutical data by using open-ended interviews with authors of systematic reviews of pharmaceutical data. Their project is well-encapsulated in their manuscript, which is overall well-written. The abstract summarizes the study well and the introduction provides a good background. The results are detailed - as necessary for such a paper - and the discussion makes important suggestions on a move forward.

Major Compulsory Revisions: none

Minor Essential Revisions:
- there are several situations where 2 words are one and should be separated by a space (likely just a formatting issue)
  1. Introduction, first paragraph: "legal settlements" should most likely be changed to "legal action," given that some information is obtained in the discovery process as well.
  2. Introduction, second paragraph: should add "In an effort to provide a more thorough picture" before the 3rd sentence starting "The Cochrane Collaboration is a major producer..."
  3. Methods: the authors state that 200 Cochrane authors agreed to be interviewed. How many were asked?
  4. Methods: the authors write "the investigators for this project identified authors of published systematic reviews." Can they detail the process of identifying such authors? Particularly the non-Cochrane authors? This would help us understand the background of their source of data
  5. Results: Was it 11 geographical regions or 11 countries?
  6. Results, under section "Pharmaceutical companies." First paragraph, about 2/3 through, would change the word "excuses" to something less pejorative.
  7. Results, under section "Regulatory agencies" Would be helpful to have a discussion of thoughts on EMA here, as it is currently all focused on the FDA and then the EMA pops up in the discussion (and rightfully so), but is not discussed in the results.
Discretionary Revisions:

1. Introduction: can the authors provide an example of a case where our perception of a drug was changed by unpublished data? Perhaps one sentence to give an example (e.g. gabapentin as they have cited)

2. Results: it would be helpful if the authors explained how many systematic reviews were conducted by the 32 respondents, and the mean or median and range. This would give the reader a sense of the respondents' experience.

3. Results, under section "Unresponsiveness or refusal to share data". In stating "the third reason was that authors wanted to maintain control..." There should be a statement stating that respondents believed this (since there is no evidence that an author told this to a respondent)

**Level of interest:** An article of outstanding merit and interest 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