Reviewer's report

Title: Incomplete evidence: the inadequacy of databases in tracing published adverse drug reactions in clinical trials

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Reviewer: Dr Joseph Lau

Level of interest: A paper whose findings are important to those with closely related research interests

Advice on publication: Accept after revision, which I do not need to see

Major comments:

1. This is a basically sound paper with a simple focused question: "How well does the use of specific search strategies based on adverse effects textwords and indexing terms identify trials that report the rate of drug adverse effects" and the answer is "not well". The methodology is straightforward and appropriate. The finding will be useful to clinicians and researchers alike.

2. There are too many "biases" out there already, rather than inventing another one ("indexing bias") and it is not clear at all whether this is really a "bias" per se, I would suggest to simply refer to this problem as an reporting/indexing limitation or deficiency. This problem really is a combination of reporting problem by the author as well as indexing problem of the database. If the authors use adverse effects terms in the title or abstract or key words, these articles will no doubt be identified in the search strategies. The question here is whether the studies that did not use such terms in the title or abstracts have a higher rate of adverse effects than studies that used such terms openly. If there is a difference, then I would call it a bias, but you did not study this issue. This would be a future research topic. For the indexers at the database, I doubted that they deliberately used adverse effects indexing terms based on the rates of reporting of events so that their effects cannot be predicted (this is a limitation or deficiency, not bias).

3. Not analyzed in this study, but would not useful to know is whether there is any difference in the reporting or indexing of adverse effects terms between high and low citation impact journals.
Minor comments:

1. I would suggest making your recommendation (#2) stronger that journals should "require", not just "ask" authors to mention drug adverse effects in the abstract.

Competing interests:

None declared.