Reviewer’s report

Title: Adverse drug reactions in older adults: a retrospective comparative analysis of spontaneous reports to the German Federal Institute for Drugs and Medical Devices

Version: 0 Date: 11 Dec 2019

Reviewer: Mahmathi Karuppannan

Reviewer's report:

1. The English should be proofread. Example: Abstract. Line 45, page 4, should read "For some drug substances which were reported the most (e.g. rivaroxaban), the ADRs reported most frequently differed...". Kindly check the whole document.

2. Page 9, Line 123. Author mentioned about a definition of an ADR revised in 2012 but did not quote the reference.

3. Page 10, Line 149. Author did not mention how 250 reports were randomly selected and how this number was decided.

4. Page 11, Line 179. The sentence is not clear. What does "higher-level overview" mean?

5. The author seems to be using many codes/list/criteria to classify drug, drug classes, outcomes, PIMs and etc. Suggest to put these in a table to make the purpose of each list/code clearer.


7. Page 20, Line 328. Rofecoxib was withdrawn in 2004. It is surprising that the reports on the drug were still received in 2007. Any comments on this?

8. Page 34, Line 532. ASS. When an abbreviation appears for the first time in the text, spell it out in full term.
Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I am able to assess the statistics

Quality of written English
Please indicate the quality of language in the manuscript:

Needs some language corrections before being published

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