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: 28 Nov 2019

Reviewer: Lise Aagaard

Reviewer's report:

Thank you for the opportunity to review this manuscript. The studied topic is very interesting, and it has been very time consuming for the authors to get access to, extract and analyse the data.

The manuscript is well-written, but the presentation of the results could be done differently, so that it was possible to get a quicker overview of these.

I suggest that you merge the figures and tables including data from the supplementary files into two-three large tables. One large table presenting the data with respect to annual number of reports, distribution of reports on age, sex, seriousness, ATC codes, System Organ classes, DDDs etc. could be made. Additionally one to two tables where the comparisons between the two age groups are presented including statistics.

For the background section I suggest that you include this article, as it will be useful for discussion of your results: Aagaard et al. Global patterns of adverse drug reactions over a decade: analyses of spontaneous reports to VigiBase™. Drug Saf. 2012 Dec 1;35(12):1171-82. doi: 10.2165/11631940-000000000-0000

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.

Unable to assess

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:

Acceptable

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