Reviewer's report

Title: Characteristics of Pediatric Adverse Drug Reaction Reports in the Japanese Adverse Drug Event Report Database

Version: 0 Date: 22 Jan 2020

Reviewer: Geneviève Durrieu

Reviewer's report:

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Please overwrite this text when adding your comments to the authors.

The aim of the study was « to characterize ADR reports from Japanese Adverse Drug Event Report (JADER) database in pediatric population».

Data on this topic were never published.

Comments:

- Abstract
  - Conclusion: text should be modified according to the comments contained in the conclusion of the manuscript

- Background
  - How did you evaluate the database's utility?

- Methods
  1. Some information on Japanese pharmacovigilance system and JADER would be useful. Who is allowed to extract data from JADER? Number of ADR reports from reporters other than companies are very low: how do you explain that? How a health professional or a patient can declare an ADR to public health authorities (such as a pharmacovigilance center)? Is ADR declaration mandatory for some health professionals? Are the ADR reports checked and analyzed before being registered in the PV database?
  2. Line 95: what does this sentence mean?
3. For ADR, why did you choose to present only PTs?
4. In the collected data, it was not listed "suspected drugs". Which drug classification is used for drugs? Only INN?
5. What about ADR seriousness? We read further that JADER only contains "serious ADR reports. This should be added here.
6. What is your definition of a serious ADR?
7. Same comment for age groups: explain that you are not able to use WHO age group classification
8. What about causality?

- Results
1. Percent of unknown age should be added in the text.
2. What are the characteristics of fatal ADR reports?: suspected drugs? ADR? Poisoning? Suicide?

- Discussion
1. A qualitative description of fatal ADR reports should be added.
2. Have you checked that oseltamivir and zanamivir did not influence on detecting other signals? Did you perform an analysis excluding these 2 drugs? Or did you compare data before 2010 and after 2010?

- Conclusion
  o This study described several weakness (age groups, duplicate…). The conclusion should include the areas that need to be improved in order to obtain reliable data.

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.

No

**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.

Not relevant to this manuscript

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

Acceptable

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