Reviewer's report

Title: Improved drug safety through intensive pharmacovigilance in hospitalized pediatric patients

Version: 0 Date: 04 Oct 2017

Reviewer: Nam Tran

Reviewer's report:

The paper titled: "Improved drug safety through intensive pharmacovigilance in hospitalized pediatric patients" addresses an important challenge in pediatrics. I have some comments/questions which I itemize below:

1. The methods section described statistical analyses to include mean, SD, as well as the use of the Chi-square test or Mann Whiny test. The latter is a non-parametric test. What is the justification for using the Mann-Whitney test. Was the data normal based an appropriate test for normality? Why was transformation of data not selected to enable using parametric statistics which may be more robust. The use of the Mann-Whitney test increases the chance for Type I error. Given the reasonably large sample size, parametric statistics may be adequate.

2. Expanding on the statistics above, if it is appropriate to use non-parametric statistics, it would be necessary to report the data as medians and interquartile range, rather than means and SDs. By assuming it is a non-parametric distribution, means no longer provide adequate estimation for central tendency.

3. The Chi-square test was used to look at ADRs. Were there situations where the Chi-square test assumptions were violated whereby it would have been more appropriate to use the Fisher's Exact test? This is possible since looking at the low incidence of some of the ADRs.

4. Selection bias should be addressed since the patients included in the study needed consent. Were there any ways to minimize the confounding effect of patients that could be consented vs. those that are not able to be consented. Its entirely possible that patients that did not have readily available family and/or capable of providing assent were at greater risk. So the study did not address this potential limitation.
Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

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.

I am able to assess the statistics

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

Acceptable

Declaration of competing interests
Please complete a declaration of competing interests, considering the following questions:

1. Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

2. Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

3. Do you hold or are you currently applying for any patents relating to the content of the manuscript?

4. Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript?

5. Do you have any other financial competing interests?

6. Do you have any non-financial competing interests in relation to this paper?
If you can answer no to all of the above, write 'I declare that I have no competing interests' below. If your reply is yes to any, please give details below.

I declare that I have no competing interests

I agree to the open peer review policy of the journal. I understand that my name will be included on my report to the authors and, if the manuscript is accepted for publication, my named report including any attachments I upload will be posted on the website along with the authors' responses. I agree for my report to be made available under an Open Access Creative Commons CC-BY license (http://creativecommons.org/licenses/by/4.0/). I understand that any comments which I do not wish to be included in my named report can be included as confidential comments to the editors, which will not be published.

I agree to the open peer review policy of the journal