Reviewer’s report

Title: Oral prednisolone for acute otitis media in children: a pilot, pragmatic, randomised, open-label, controlled study (OPAL study)

Version: 1 Date: 28 Apr 2020

Reviewer: Nyasha Mafirakureva

Reviewer's report:

General comment

This is a well written manuscripts on ADRs in Zimbabwe. It presents potentially important work on post marketing surveillance for drugs in the context of LMIC. The authors may wish to consider the following few comments.

Abstract
I think this statement needs rephrasing since there is probably no link with the previous statement. "Therefore, there is need to strengthen the pharmacovigilance system…". Are the authors making this conclusion based on the finding in the previous statement? I do not see how this is derived from the study findings. This conclusion in a bit different from the one presented in the main text.

Materials and Methods
'The timeliness of reporting was calculated by subtracting the date of onset of ADR from the date of VigiBaseTM entry'. I am just wondering if this is the standard approach for this calculation? What if there are delays in data entry into the VigiBaseTM database? Are there any corrections for these?

Results
'...4071 ICSRs met the inclusion criteria'. What was the inclusion/exclusion criteria? May be this needs to be explicitly stated upfront.

'The median age was 34.00 years (IQR: 14.00; 43.00)'. Need for consistency with the significant figures.

'No reports were captured into VigiFlow® in the calendar years 1994, 1997 and 2002'. I am just wondering if there is any explanation to this?

Figure 1 uses abbreviations and it's not easy to figure out what they mean. The author should make all figures self-explanatory by including a complete figure legend.

I think Figure 3 is wrongly labelled on the x-axis. And maybe consider using conventional age ranges e.g 5-19years.
Discussion
'...the male to female ratio was higher in children under 5 years of age and even higher in infants as expected from previous studies'. I think the authors should provide a short explanation for this explanation particularly in the Zimbabwean context.

'The overall predominance of female ICSRs could be due to underlying physiological differences,...'. I think some further explanation is required here - the authors need to describe what they mean by this.

'The ATC code had an influence on the number of reported 291 ADRs....'. Not too sure if influence is the right word to use here. Perhaps 'associated'? Also in subsequent sentences. I also think this association needs to be discussed in a sentence or two.

Level of interest
Please indicate how interesting you found the manuscript:

An article whose findings are important to those with closely related research interests

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

Were you mentored through this peer review?

No