Author's response to reviews

Title: Use of Case Reports and the Adverse Events Reporting System in Systematic Reviews: Overcoming Barriers to Assess the Link between Crohn's Disease Medications and Hepatosplenic T-Cell Lymphoma

Authors:

Saranya A Selvaraj (sselvar1@jhmi.edu)
Elizabeth Chairez (elizabeth_chairez@valleymed.org)
Lisa M Wilson (lisawilson@jhmi.edu)
Mark Lazarev (mlazare@jhmi.edu)
Eric B Bass (ebass@jhmi.edu)
Susan Hutfless (shuffle1@jhmi.edu)

Version: 3 Date: 22 June 2013

Author's response to reviews: see over
Author Response to Comments

Manuscript Title: Use of Case Reports and the Adverse Events Reporting System in Systematic Reviews: Assessing the link between Crohn’s Disease Medications and Hepatosplenic T-Cell Lymphoma

We thank the editors for their previous thoughtful comments that led to the acceptance of our revised manuscript. We are happy to correct the minor typo and have resubmitted the manuscript with the correction.

Additionally, we made two other minor revisions to the manuscript in Figure 1 and in Table 2 to improve consistency and clarity. Please find the details listed below.

Sincerely,
Saranya Selvaraj, on behalf of the authors

EDITOR’S COMMENTS:

There is a minor typo towards the end of the conclusions section where the authors state "Peer Review and Biomedical Publication Congress". This should be deleted and replaced with "International Congress on Peer Review and Biomedical Publication."

We have corrected this typo.

MINOR CORRECTIONS MADE BY AUTHORS:

Figure 1: The two boxes listing the number of cases identified from FDA AERS and the published literature prior to matching the cases from both sources now includes both the number of cases eventually classified as “unique” as well as those classified as “possible.”

<table>
<thead>
<tr>
<th>Original version:</th>
<th>Revised</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reported at least 1 case of Crohn’s disease-related HSTCL 19 articles 6 abstracts (28 unique cases)</td>
<td>Reported at least 1 case of Crohn’s disease-related HSTCL 19 articles 6 abstracts (28 unique cases) (6 possible cases)</td>
</tr>
<tr>
<td>Original</td>
<td>Revised</td>
</tr>
</tbody>
</table>
Table 2: In the rows describing the number of patients reporting survival, the percentages in the original manuscript were calculated using the total number of cases as the denominator (denominator = 37) rather than using the number of cases reporting survival or death as the denominator (denominator = 26 and denominator = 4 for unique and cases with insufficient information, respectively). We have recalculated the percentages in those rows changing the denominator to reflect the number of cases reporting that statistic to make sure that these percentages are consistent with how the other percentages in the table were calculated (using the number of cases reporting the information as the denominator, rather than the total number of cases as the denominator). These changes are visible in the main manuscript using the track changes feature.