Reviewer’s report

**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

**Version:** 1 **Date:** 8 May 2013

**Reviewer:** David Riley

**Reviewer’s report:**

1. The question posed by the authors of “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” appears to be new and clearly defined.

2. And I believe that their conclusions about the uneven reporting of data from case reports is consistent with published reports in other medical specialties.

3. I was surprised that there was no references to the work of Jeffrey Aronson who has written extensively on this topic: “The tenets of evidence-based medicine include a hierarchy of evidence with systematic reviews of randomized clinical trials at the top and anecdotes near the bottom. Our observations show that anecdotes can, under the right circumstances, be of high quality and can serve as powerful evidence.” Or Diaz and Neuhauser (Qual Saf Health Care 2005;14:140-3). Have the authors considered Aronson’s extensive work in this area? Particularly in the area of causality assessment. (This point should be addressed in a minor revision by the authors.)

4. The method of data extraction and analysis appear to be sufficient and their attention to identify duplicate publications in the FDA AER and the published medical literature.

5. This article is an important contribution to the need for reporting guidelines for case reports so that systematically reported data (e.g. Meaningful Use 2 in the United States) become routinely collected and is available for analysis.

6. I do not have extensive experience using the causality assessment tools they described. I have delved into causality in the area of case reports. (This reference may prove useful to the authors as a background article rather than a specific tool.)

7. I believe that information from the point of care and published case reports will become increasingly use to assess adverse events and this article points out the importance of a checklist for case reports. Case report guidelines will be presented at the Peer Review and Biomedical Publication Congress this fall sponsored by JAMA and the BMJ.
8. The writing of this article was clear, understandable and balanced.

**Declaration of competing interests:**

I have no competing interests.