Reviewer's report

Title: Clinical coding of paediatric adverse drug reactions: a retrospective review of patient records

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Reviewer: Corinne Hohl

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This is an important and very timely study, as researchers and clinicians struggle with attempts to define improved methods to collect reliable ADE and ADR data for research and surveillance purposes. While the gold standard for establishing the ADR diagnosis in the primary study was far from perfect (e.g., limited medication history taking), the authors did a good job of establishing the sensitivity of the ICD-10 code set that they used.

Major Compulsory Revisions:

1. The case-finding method for this study is prospective, based on the quoted primary study. However throughout the manuscript I was confused as to whether it was prospective or established via “audit” (usually retrospective) or review of electronic records (usually retrospective. Please clarify throughout.

2. More detail is required to assess how complete the code set was for ADRs. If your code set was very restrictive, you may have found low sensitivity as a result. Please report the number of codes or code categories you used, and provide access to the code set. This limitation should be discussed in the Discussion section.

Minor Revisions:

3. Abstract, line 14: Data…are (not “is”).

4. Methods: Lines 46-51: I am confused as to the design of the primary study based on this paragraph. The use of the word “prospective” and “audit” is confusing. This needs clarification.

5. Methods: Lines 64-72: Did you account for variation in the certainty of the medication-related cause in the code set you used? There are many ICD-10 codes that refer to syndromes that may be medication-related without referring specifically to the agent (e.g., agranulocytosis). Without making the code set you used available, and providing more details it is difficult for the reader to determine whether you found low sensitivity because the code set was too restrictive, or because ADRs were not coded as ADRs. The following references below may be useful in this regard.1-3

5. Results: Line 77. I would refrain from the use of the word “correctly”. The ADRs may have been accurately coded with regard to the syndromes or diagnoses that they caused, but external cause codes were omitted. These
cases were simply "not coded as ADRs".

6. Discussion: Line 113-119. This is an interesting finding and worth highlighting. Another thought is that in oncology there is generally better documentation of ADRs within clinical records, leading coders (if they are not physicians) to code ADRs more precisely. Please discuss who codes within your institution. Also, it is known that pharmacists identify a greater proportion of ADRs than physicians. Were oncology patients more likely to see pharmacists in the primary study?

7. Discussion: The following points should be touched upon:
   a. A mention of the restrictiveness of your code set should be provided. In comparison to other studies how many codes did you search with?
   b. Please provide a brief discussion of the limitation of the gold standard determination in the primary study (e.g., lack of pharmacist use, lack of taking medication histories in all pts, etc.) This is important, because if you did not identify all ADR cases in your primary study, your estimate of sensitivity may be falsely high.

8. For reference number 3 the journal is incorrect.

References:

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare that I have no competing interests