Reviewer's report

Title: Drug-related admissions and hospital-acquired adverse drug events in Germany: a longitudinal analysis from 2003 to 2007 of ICD-10-coded routine data

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Reviewer: Zachary Marcum

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Major Compulsory Revision:
Unfortunately, the main concern of potential misclassification of ADEs remains. While the reliability of the ADE data may be sufficient, it remains unclear how one can establish validity of these data. The authors state in the cover letter: “…studies in Germany analyzed the reliability of the German data in terms of inter-rater reliability as well as the validity in terms of congruence with the patient file or the patient. The studies do not necessarily present a high PPV. However, the studies show, that a moderate PPV allows the use of routine date from German hospitals in order to estimate prevalence and incidence rates in large cohorts.” This reviewer attempted to read the referenced articles provided by the authors in their cover letter, but the majority of them are in German. However, one question is, “How does your study differ from those German studies which have already shown that these data to be reliable and valid?” This would be important information for the background and for justifying the rationale for the current study (i.e., identifying the gap in the literature).

Also, the authors state the following in the background section of the manuscript: “…routinely collected reimbursement data have only rarely been evaluated for their suitability in pharmacovigilance and, especially, in the assessment of the ADEs of in- and out patients. Nonetheless, as the results of those few studies were in part encouraging, we decided to analyze the suitability of such databases in Germany. In a recent report focusing on data from 2006, we showed that routinely collected hospital reimbursement data can be used to identify the frequency and type of ADE.” It becomes confusing to the reader whether the authors are referring to Germany-specific background information or information from other countries. Overall, it is not clear how what prior work has been done in Germany to suggest that ICD-10 codes are valid measures to identify ADEs.

Minor Essential Revisions:
Tables: In response to the statement about a lack of medication information presented in the manuscript, the authors state that “little information about medication is provided by ICD-10.” However, the authors were able to report on the most commonly associated drugs with admissions in a previous publication using ICD-10 data. (Stausberg, 2010) Please clarify.
Level of interest: An article of limited interest

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.