Author's response to reviews

Title: Identifying complications of interventional procedures from UK routine healthcare databases: a literature review of methods using clinical codes

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Author's response to reviews: see over
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Dear Ms Mangiameli,

Thank you for reviewing our submitted manuscript “Identifying complications of interventional procedures from national routine healthcare databases: a review of methods “, Keltie, Cole, Arber, Patrick, Powell, Campbell, & Sims.

Please note the following changes (highlighted in red font) made to our manuscript in order to address the comments from the following two reviewers:
Reviewer 1 (R1): Hude Quan

R1.0: This is a very interesting topic and authors have done tremendous work to summarize literature on the important topic.
- No changes made to the manuscript

R1.1: My major concerns: this literature review is focusing on UK data alone. This restricts international application. There are huge amount of literature in other countries. Thus I highly recommend authors to rethink: enlarge the literature search scope to all countries.
- Administrative databases are well established in the UK and have been studied extensively. The primary focus of this literature review was to summarise techniques applied to UK data. The title of the manuscript has been altered to clarify this. However all methods of identifying complication found in the literature review are generalizable internationally, as indicated by the second reviewer (see comment R2.0). We have further emphasised the international applicability of all reviewed methods in the discussion section of our revised manuscripts.

R1.2: I am also aware that the large amount of literature on this topic will give hard time to summarize the literature. Thus authors may think restrict their topic to Complications defined using ICD-10/9 codes alone. Thus they will have manageable number of papers for the review. In addition, administrative data have been widely used for evaluating system performance.
- To limit the scope, we have split the original manuscript into two separate papers: a review of all methods using clinical codes (paper 1); a review of all methods using non-codified data (paper 2). This approach has enabled us to discuss the advantages of international coding systems (such as the International Classification of Diseases, ICD) in more detail.

R1.3: The complications should be well defined in this paper. Current paper included various types of complications reported in the literature. To narrow the scope, authors may focus on in-hospital complications alone coded in ICD (such as AHRQ PSIs), excluding mortality, LOS, and readmission. The systematic review on ICD-10/11 codes will be helpful for readers to apply these codes in their data and also inform readers the variation in ICD definitions and compatibilities across studies.
- See response to comment R1.2.

R1.4: ICD focused systematic review will be very helpful for ICD revision for ICD-11 for application of coded data to quality and safety assessment. The following paper will inform how ICD-11 is to be linked with safety.

- The above suggested paper was cited as a reference in our original manuscript. An additional reference was also included in the original manuscript (originally reference 131) from the same World Health Organisation (WHO) topic group.
- The scope of this study was to review all methods using routine data to identify complications of interventional procedures and medical devices, to highlight the different ways in which routine data can be interrogated. A much more focused systematic review of methods using only ICD would require a separate literature search, and was not the purpose of our original study. However, separation of the manuscript has allowed us to discuss ICD more extensively.

R1.5: I highly recommend authors to reconsider the scope (focusing on ICD coded data and also clinical complications -- means medical condition) and topics of the systematic review.
- See response to comments R1.2 & R1.4.
Reviewer 2 (R2): Pentti Nieminen

R2.0: This is an interesting study looking at literature on the complications from devices or procedures. Although the study reflects the use of UK healthcare databases, I feel that many of the points raised are applicable to other settings in many countries. I have some observations that should receive the attention of the authors.

- No changes made to the manuscript

R2.1: Minor essential revisions - this is a localized study. For publication in an international journal, it would help if the authors include a short review to literature that referred to non-UK databases.

- Our literature search was specifically designed to include only UK routine databases (we have changed the title of our manuscript to clarify this). However all of the identified methods are generalizable to other healthcare settings internationally. This is also highlighted by the reviewer in comment R2.0.
- The original manuscript has been separated into two (please see response to comment R1.2). In both cases we have emphasised the international applicability of all methods of identifying complications from routine data

R2.2: Page 5, rows 4-11: Consider performing an agreement analysis between reviewers.

- Following abstract and full paper review of eligibility by two reviewers, arbitration by a third was required for 43 papers (1.2%). This has been added to the Results section of the manuscript.

R2.3: Results and discussion section: This section includes more than 10 pages. For a reader, it is hard to read. Consider narrowing the scope of your paper.

- In order to narrow the scope, our original manuscript has been separated two complementary, but independent manuscript (see response to comment R1.2).

R2.4: Page 17, row 11: Help your reader and clarify “the practical difficulties associated with free-text analysis”.

- This statement has been clarified in the discussion section of the appropriate manuscript (i.e. paper 2).

We thank you for your initial comments and look forward to receiving your comments following the peer-review process.

Yours sincerely,

Dr Andrew Sims