Author’s response to reviews

Title: A Systematic Review of the Implementation and Impact of Asthma Protocols

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Author’s response to reviews: see over
The authors would like to thank the editor and the reviewers for taking the time and effort to provide us with reviews and suggestions for the manuscript. We feel the comments and suggestions have helped improve the manuscript. We have addressed the comments below and made track changes edits to the manuscript.

Editorial comments

In accordance with BioMed Central editorial policies (http://www.biomedcentral.com/about/editorialpolicies#StandardsofReporting), could you please ensure your manuscript reporting adheres to PRISMA guidelines (http://www.prisma-statement.org/) for reporting systematic reviews. This is so your methodology can be fully evaluated and utilised. Can you please include a completed PRISMA checklist as an additional file when submitting your revised manuscript.

Figure 1 has been replaced with the PRISMA flow diagram.

PROSPERO Registration: Please see attached rejection email from Prospero due to the review being completed.

Reviewer 1: Knut Magne Augestad

1. I miss a reference to The PRISMA statements for comprehensive reviews and whether or not the authors have followed these guidelines when performing the review.

   The reviewer makes an excellent point and we have attached the PRIMSA outline to review comments.

   Page 8, paragraph 1: We added a reference to the PRISMA guidelines and a description of that we followed guidelines with the exception of performing a meta-analysis.

   We did not create a central review protocol and followed PRISMA guidelines except for meta-analyses [17].

2. The use of the data from the Kawamoto et al BMJ 2005 review may be misleading. That study and others like it (e.g., the Garg et al jama one and more recent BMJ 2013 one from same group) looked at the odds of a “positive result” as a dichotomous outcome. The actual effect sizes of implementing guidelines/decision support may be very small. Another approach to reviewing this literature (Effect of point-of-care computer reminders on physician
behaviour: a systematic review. CMAJ. 2010) the median effect from CDS was 4, meaning that whatever behaviour was being targeted, the absolute improvement in the % of patients who received the targeted process of care was only 4%. Only a minority of study reported larger effects (18% or higher). At least this should be discussed as a limitation in the paper.

Thank you. This is a very valuable point and the references have been added to the manuscript with a brief description in the discussion section to update the success of clinical decision support.

Page 24, paragraph 2:

Automatically prompting providers increases adherence to recommendations [133], however in a newer systematic review, effective decision support is still provided to both the patients and physicians and is lower for electronic systems [134]. The benefits of decision support still remain small [135]. Table 1 is over flooded with information, and does not provide a summary of the identified trials. The trials is simply listed in alphabetical order, and no summary whatsoever is provided. The table needs to be rewritten, and data merged to provide meaningful information for the reader.

We agree that table 1 is very large. However, we have used a similar table presentation in the past and feel that it provides a large amount of data about the included studies individually for when readers are interested. (Judith W Dexheimer, Thomas R Talbot, David L Sanders, et al. J Am Med Inform Assoc 2008 15: 311-320 doi: 10.1197/jamia.M2555)

The summary of the articles is found in the text of the results section. We feel that to include a summary table would be to replicate this information. However, we are willing to do so if the editorial staff deems it is necessary.

3. Similarly for table 2 and 3: only absolute numbers are provided and it is difficult for the reader to make any conclusions. Some percentages must be provided and the authors must discuss whether some stats are needed.

We feel this is a valuable point. The table data are discussed in the manuscript (pages 18, 20), we have added percentages to help clarify what proportion of studies examined each of the “important” success factors. The text and tables were rearranged to correct a labeling mistake and help to clarify the results.

Page 22, paragraph 1: We have added some information into the discussion about the data analysis and data presentation.

Due to the disparate nature of the results across manuscripts, we did not perform a meta-analysis but presented the descriptive data in aggregate form.
4. I miss a more detailed discussion about the obstacles of performing this type of research. Research on clinical decision support (CDS) tools has rapidly evolved in the last decade. CDS provides clinicians with patient specific assessment or guidelines to aid clinical decision making and improve quality of care and patient outcome. CDS has been shown to improve prescribing practices, reduce serious medication errors, enhance delivery of preventive care services, and improve guidelines adherence, and likely results in lasting improvements in clinical practice. However, clinical research on CDS tools faces various methodological problems and is challenging to implement in the field of health informatics.

We added an additional paragraph to the discussion to address these issues.

Page 22, paragraph 2:

Clinical decision support research is difficult to perform. Alerting methodologies and their effectiveness have been studied in the literature but are frequently limited in scope in terms of time and conditions [126-129]. The results suggest that reminder systems are effective at changing behavior and improving care, and they are more successful when designed for a specific environment [127]. This individualized design and the necessary study design demands, help to make clinical decision support more difficult to evaluate homogenously.

6. The authors state that "The double-blinded randomized controlled trial is considered the gold-standard for study design but it is difficult to implement any kind of reminder system that could be effectively blinded and randomized". This statement needs to be clarified and further debated. In a recent paper (Augestad et al Standards for reporting randomized controlled trials in medical informatics: a systematic review of CONSORT adherence in RCTs on clinical decision support, JAMIA 2011) these challenges are addressed. What is the best research method to assess a successful guideline implementation? Although not the main task of the review, these obstacles should be addressed.

This is an excellent point and we have added a brief discussion and citation to the discussion section to begin to address this issue.

Page 23, paragraph 2:

Randomized controlled trials are not well-presented in the informatics literature [130], and many potential issues exist in implementation research including issues such as randomization (e.g. by patient, physician, day, clinic) and outcome measures (e.g. informatics-centric or patient outcomes centric). 7. Important references to systematic reviews of clinical decision support are missing. These reviews must be discussed and differences from your own conclusions identified.
Thank you for this point. We have added additional information to the discussion section (page 24).

8. In conclusion, the tables need to be improved to provide some meaningful information for the reader. In addition, there exist central reviews of clinical decision support systems that are not cited nor discussed.

We have rearranged text and tried to increase the clarity of the tables and added the additional references to the discussion.

Reviewer 2 Tim Holt

This paper gives a very broad review of literature concerning the impact of asthma guidelines in clinical practice. The capture is so inclusive and the studies identified of such variable quality that it is difficult to know whether any firm conclusions can be drawn, particularly as there is likely to be significant publication bias in favour of beneficial results (as the authors acknowledge). Nevertheless the review itself has been conducted rigorously and reported clearly (apart from the issues below).

Thank you, we appreciate this comment.

Major Compulsory Revisions

1. The Characteristics of clinical guidelines subsection in the Background (paper-based, computer-generated, computerized) is important but is written in the past tense and so sounds like Results. I think it should simply be rephrased as 'We defined reminders as follows:' or 'Reminders are defined as follows:'

   Page 6, paragraph 2: We updated the manuscript to reflect this change.

   Reminder methods are defined as follows:

2. The authors refer to ‘15 non-blinded’ trials but as they state later, it isn’t clear how such a trial could be blinded - this needs clarifying.

   Page 23, paragraph 1: We updated the manuscript to help explain some examples of blinding that are feasible in clinical decision support research.

   While blinding is frequently difficult, decision support implementations can be blinded if the interventions occur at different locations or for different providers.

3. There is also a statement that ’48 studies were educational interventions’ but educational interventions are named as an exclusion criterion - this should be clarified.
Page 17, paragraph 2: We updated the manuscript to clarify that the educational component was part of the intervention (but we excluded studies where they were only the educational component).

...included an educational component (48 studies).

4. As a reviewer from the UK, where health record systems (certainly in primary care) are now usually paperless or paper-light, I think it would be useful to give an indication of which country (or region) the studies were based in. This could be added either as a new paragraph in Results or as a small Table.

Studies were performed in the United States (48 studies), the United Kingdom (10 studies), Canada (9 studies), Australia (8 studies), the Netherlands (6 studies), Singapore (5 studies), New Zealand (2 studies), Brazil (2 studies), Saudi Arabia (2 studies), Germany (2 studies), and 1 study each in France, Oman, Switzerland, Italy, Iran, Japan, Taiwan, Korea, Thailand, and the United Arab Emirates.

Discretionary Revisions

5. Given concerns mentioned above over the tendency to emphasise favourable outcomes I think it would be useful to comment on the reporting of actual risks to safety, as this is a currently topical issue with an interesting paper published last year in this same journal (Carling et al. Risks to patient safety associated with implementation of electronic applications for medication management in ambulatory care - a systematic review. BMC Medical Informatics and Decision Making 2013, 13:133.). It might be acknowledged that such systems have the potential for adverse outcomes eg detriment to processes of care, workflow and/or decision making but these are rarely reported. I expect the literature identified here will corroborate this finding.

We feel this is an excellent point and have amended the discussion section to address this point.

Page 25, paragraph 2:

Because we only included published manuscripts, a publication bias may exist where studies with positive results are more likely to be published. Given the tendency to publish and emphasize favorable outcomes, decision support systems have the potential to increase adverse outcomes however, these are rarely reported [136].