

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Core requirements for successful data linkage – an example of a triangulation method
AUTHORS	Hopf, Yvonne; Francis, Jill; Helms, Peter; Haughney, John; Bond, Christine

VERSION 1 - REVIEW

REVIEWER	Chutwichai Tovikkai Siriraj Hospital, Mahidol University Bangkok, THAILAND
REVIEW RETURNED	02-Apr-2016

GENERAL COMMENTS	<p>Comments to the authors: Hopf et al. present a study on the views of healthcare professionals on the data linkage for paediatric pharmacovigilance. This is of interest and timely as routine data and data linkage have recently been promising resource for research purposes. The authors reviewed their four recent studies using different tools on this topic, and combined them using a triangulation process. However, there are a few concerns regarding the results and presentations of the study as described below.</p> <ol style="list-style-type: none">1. Most of the results were dedicated to previously published studies. The novel results of this study (triangulation process and the process in building the conceptual model for the system implementation) should be explained in more details.2. The results did not clarify how the findings categorised into requirement groups (practical/technical, mandatory, essential, preferable). This was partially described in the discussion section (page 12-13), but explicit criteria explained in the results section will help readers to understand the process.3. In Table 2, it was noted that bold font indicates agreement across three or more arms. However, there were several rows painted in bold even they were agreement only in two arms.
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REVIEWER	Fraknk Sullivan University of Toronto Canada
	I may have been one of the interviewees and I have worked with 2 of the authors(Bond and Haughney) on projects
REVIEW RETURNED	22-Apr-2016

GENERAL COMMENTS	This is an adequately rigorous study of an important area with significant ammounts of related work but little published in the specific area of children.
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REVIEWER	Dr Laetitia Hattingh Curtin University, Australia
REVIEW RETURNED	16-Jul-2016

GENERAL COMMENTS	<p>Thank you for the opportunity to review this paper that reports on the triangulation of results from various studies. I found the paper to be of a high quality and my comments are minor with the aim to further improve the paper.</p> <p>Abstract: Methods: Why are the interviews not included? Results: Please include the number of participant from the various studies. Even though the various studies have been published and are cited in the article, the triangulation described in this paper justifies inclusion of the numbers in the abstract. Background and significance: Line 14: The summary of Product Characteristics is terminology that is specific to Scotland and other countries use different terminology. For example, this is referred to as Product Information in Australia. I recommend you explain this to the reader. Lines 27, 29, etc: There are various instances in the paper where abbreviations are used without it being written out first time: UK, FDA, US, GP, IT Line 31: add how many papers were included in the review Objective: Line 10: Add 'to' therefore 'The aim of this study was to explore' Change HCPS to HCPs Methods and materials: Please add more details of how the focus group and Delphi participants were selected. The authors mention that for the Delphi they all had an interest in paediatric medicine but it will be useful to indicate whether they were form primary care or hospital settings. P6 lines 39-40: The sentence starting 'First, a matrix' does not make sense. Add 'those' therefore '... against those as represented'? Results: Line 17: Add when (year) the literature review was conducted P 8 line 18: Same comment: when was the Delphi study conducted? P8 line 48: add % to be consistent with other sentences. Discussion: page 10 lines 46, 48: provide full details of legislation therefore include the date of the Act Under requirements for data linkage, it will be useful to indicate who will be the users of the system. Will it be pharmacists and doctors working primary and secondary facilities. What about nurses and other health professionals. This will be useful in providing context to the system and highlight significance. Limitation: Some of the studies took place some time ago: interviews and focus groups in 2010 and the paper does not mention when the Delphi study took place. This needs to be added to the limitations as some of the opinions from the stakeholders and HCPs could have changed over time.</p>
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VERSION 1 – AUTHOR RESPONSE

Comments made by Reviewer 1:

- (1) Most of the results were dedicated to previously published studies. The novel results of this study (triangulation process and the process in building the conceptual model for the system

implementation) should be explained in more details.

Thank you for your suggestion. We have added a paragraph in the results section and a further paragraph in the discussion section.

(2) The results did not clarify how the findings categorised into requirement groups (practical/technical, mandatory, essential, preferable). This was partially described in the discussion section (page 12-13), but explicit criteria explained in the results section will help readers to understand the process.

Again, a very helpful suggestion. We have added a paragraph detailing the explicit criteria in the results section.

(3) In Table 2, it was noted that bold font indicates agreement across three or more arms. However, there were several rows painted in bold even they were agreement only in two arms.

We have amended the font types in Table 2.

Comments made by Reviewer 2:

Thank you very much for your kind comment. No changes or further explanations were requested.

Comments made by Reviewer 3:

Thank you very much for your detailed and constructive comments.

Methods:

(1) Why are the interviews not included?

Thank you for highlighting this omission to us. We have added the interview study to the methods paragraph of the abstract.

Results:

(2) Please include the number of participant from the various studies. Even though the various studies have been published and are cited in the article, the triangulation described in this paper justifies inclusion of the numbers in the abstract.

The number of participants for each single study has been included in the results section of the abstract.

Background and significance:

(3) Line 14: The summary of Product Characteristics is terminology that is specific to Scotland and other countries use different terminology. For example, this is referred to as Product Information in Australia. I recommend you explain this to the reader.

We have added a short insert after mentioning the Summary of Product Characteristics, referring to it as the legally binding product information in the UK for medication.

(4) Lines 27, 29, etc: There are various instances in the paper where abbreviations are used without it being written out first time: UK, FDA, US, GP, IT

We have written out the mentioned abbreviations.

(5) Line 31: add how many papers were included in the review

A total of 18 papers was included in the review. We have added this information to the abstract.

Objective:

(6) Line 10: Add 'to' therefore 'The aim of this study was to explore'

Added.

(7) Change HCPS to HCPs.

Done.

Methods and materials:

(8) Please add more details of how the focus group and Delphi participants were selected. The authors mention that for the Delphi they all had an interest in paediatric medicine but it will be useful to indicate whether they were from primary care or hospital settings.

The selection of participants for the focus group and the Delphi survey was very complex and is described in detail in the referenced papers. From a qualitative research viewpoint the term “stratified purposive sampling” in combination with the information of the different locations and job descriptions should be sufficient. We have however added information that participants were indeed sampled from primary and secondary care as well as information to the paediatric experience.

For the Delphi survey examples for sampling frames are listed for a selection of professions included. The full list is accessible in the Delphi paper referenced.

(9) P6 lines 39-40: The sentence starting ‘First, a matrix’ does not make sense. Add ‘those’ therefore ‘... against those as represented’?

We have amended the sentence as suggested. Thanks.

Results:

(10) Line 17: Add when (year) the literature review was conducted

The literature review was conducted 2011, the year was added to the results section.

(11) P 8 line 18: Same comment: when was the Delphi study conducted?

The Delphi study was conducted from August 2011 to February 2012. The dates have been added to the results section.

(12) P8 line 48: add % to be consistent with other sentences.

Thanks for pointing this out. We have added the %.

Discussion:

(13) page 10 lines 46, 48: provide full details of legislation therefore include the date of the Act Both Acts were passed in 1998, we have added the years to the text.

(14) Under requirements for data linkage, it will be useful to indicate who will be the users of the system. Will it be pharmacists and doctors working primary and secondary facilities. What about nurses and other health professionals. This will be useful in providing context to the system and highlight significance.

We hoped to be able to create a national resource that would allow monitoring for long term outcomes of exposure to medicines during critical phases of growth and development. Adverse reactions to medicines could be identified by stop dates, reduction of initial doses or switches of medication.

Access to the data was supposed to be shaped by the results of this study. It is not supposed to be a databank where a HCP, for example a GP could look up a specific patient. It would be more along the line of known epidemiological datasets where researchers can apply for data for a specific question.

Access would only be allowed after review of the application by an internal ethics committee. We added a paragraph to the end of the background section in order to inform the reader.

Limitation:

(15) Some of the studies took place some time ago: interviews and focus groups in 2010 and the paper does not mention when the Delphi study took place. This needs to be added to the limitations as some of the opinions from the stakeholders and HCPs could have changed over time.

We have added a paragraph discussing this to the strengths and limitations section of the discussion.

VERSION 2 – REVIEW

REVIEWER	Chutwichai Tovikkai Faculty of Medicine Siriraj Hospital, Mahidol University Thailand
REVIEW RETURNED	11-Sep-2016

GENERAL COMMENTS	After the revision, the manuscript has improved and is much better in term of its contents and clarity.
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REVIEWER	Dr Laetitia Hattingh Curtin University, Australia
REVIEW RETURNED	11-Sep-2016

GENERAL COMMENTS	I have reviewed the updated paper and I am satisfied that the authors had addressed my previous comments.
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