

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	What potential research participants want to know about research: a systematic review
AUTHORS	Helen Kirkby, Melanie Calvert, Heather Draper, Thomas Keeley and Sue Wilson

VERSION 1 - REVIEW

REVIEWER	Fiona Campbell Research Fellow University of Sheffield United Kingdom
REVIEW RETURNED	29/12/2011

THE STUDY	<p>There is an error in the flow diagram, the number of papers in the 'reasons for exclusion' only total 17.</p> <p>The question above regarding 'statistical methods' I have taken to include qualitative and systematic review methods. There is no description of attempts to assess the quality of the included studies. The method of 'basic thematic analysis' is insufficiently explained. The creation of themes based upon the categories recommended by NRES to be in a PIS does not suggest that the analysis allowed new themes to arise. It would have been preferable if comparison with NRES could have occurred after themes were created, and these should have been drawn directly from the primary data.</p>
GENERAL COMMENTS	<p>This is a well written paper and addresses an interesting and useful question. The review is limited to research seeking participants views of what information they want regarding the research they are agreeing to take part in. This is valuable but it is perhaps wrong to suggest that this work provides an 'evidence base' for designing information for research participants. In this context 'evidence' will be drawn from other sources such as from those with an expertise in ethics. Research participants will usually be novices as regards research methodology and in such situations, knowing what needs to be known can be difficult to define. This work is however a useful exploration of the existing literature and should inform further research and contributes to the discussion on how to manage information provision to those who might participate in research.</p>

REVIEWER	Dr Amanda Burls University of Oxford
REVIEW RETURNED	29/02/2012

THE STUDY	I think that most of the statistics are fine but rather than giving % agreement for inter-rater agreement the authors should have calculated Kappa. (A 10% sample would only be expected to identify
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	<p>one or two included papers so agreement due to chance will be expected to be very high.)</p> <p>-----</p> <p>There are some minor typos that will require correction on proof reading (e.g. PIS's instead of PISs)</p> <p>I have interpreted item 3 above as referring to the inclusion and exclusion criteria of studies.</p>
REPORTING & ETHICS	<p>Although the authors declare they have no non-financial conflicts of interest, some are co-authors of the Antoniou paper that is given a positive commentary in the discussion (Page 20 lines 28 to 26). While I don't think this needs to be removed, I wonder whether it would be helpful if the overlap in authorship should be made more explicit so that readers would be aware of this without having to cross-check. the authors in the reference?</p> <p>(I also have this conflict of interest)</p>
GENERAL COMMENTS	<p>I think this is an important but relatively neglected area (as demonstrated by the review itself). Therefore it is helpful that this review has been undertaken to highlight the lack of empirical evidence in this areas.</p> <p>The search was comprehensive, however, the non-specificity of the search terms make this search challenging and it is possible that relevant studies have been missed, it would have been interesting to know how many of the 14 included studies were found in the electronic searches or whether they came from the 37 studies identified by experts. This would have given an indication of how many studies may have been missed.</p> <p>The method of mapping the studies to the NRES themes was a useful methodology and enabled the production of some summary statistics. However, I was left wondering whether there might not have been more useful information that could have been extracted, especially of a qualitative nature. For example, the evidence supports the idea that different people have different information needsm was there anything in the differences between studies e.g. cancer versus other conditions, that may have been useful for hypothesis generating for future studies?</p>

VERSION 1 – AUTHOR RESPONSE

Reviewer #1 (Fiona Campbell)

1. There is an error in the flow diagram, the number of papers in the 'reasons for exclusion' only total 17.

We have amended the flow diagram.

2. The question above regarding 'statistical methods' I have taken to include qualitative and systematic review methods. There is no description of attempts to assess the quality of the included studies.

We did not conduct a formal quality assessment because the limited literature included in the review utilised a wide variety of methodologies and reported different types of results. Instead, a full critical appraisal of each paper was conducted and we have added a paragraph of information to describe this in the text (page 7) and a column has been added to table 1 that summarises the strengths and

limitations of each paper. The first paragraph of the discussion (page 20) also outlines a summary of the critical appraisal.

3. The method of 'basic thematic analysis' is insufficiently explained. The creation of themes based upon the categories recommended by NRES to be in a PIS does not suggest that the analysis allowed new themes to arise. It would have been preferable if comparison with NRES could have occurred after themes were created, and these should have been drawn directly from the primary data.

A paragraph has been amended on page 9 that explains the basic thematic analysis used. The included studies based their questioning around current PIS guidance and, as such, results were summarised by these headings. An additional column was included in the data extraction sheet that allowed collection of any other results that did not fit into the NRES titles. This would have allowed new themes to arise from the data but nothing was collected in this column. We have noted this on page 8 and page 19.

4. This is a well written paper and addresses an interesting and useful question. The review is limited to research seeking participant's views of what information they want regarding the research they are agreeing to take part in. This is valuable but it is perhaps wrong to suggest that this work provides an 'evidence base' for designing information for research participants. In this context 'evidence' will be drawn from other sources such as from those with an expertise in ethics. Research participants will usually be novices as regards research methodology and in such situations, knowing what needs to be known can be difficult to define. This work is however a useful exploration of the existing literature and should inform further research and contributes to the discussion on how to manage information provision to those who might participate in research.

Thank you. Whilst we accept the reviewer's point that decisions about what to include in a participant information sheet may arise from many sources including expert opinion, we did not intend for the systematic review to be an exhaustive review of expert opinion in ethics literature. The aims of the review were to identify what current data there is to suggest what research participants themselves think they want to know about research before they agree to participate. The term 'evidence' as used in the paper refers to data and information available in the current literature. We believe that the authors and the reviewer may be taking the term 'evidence' to mean different things so we have edited 'evidence' to 'empirical evidence' to prevent confusion. We have also updated the conclusion to include using expert opinion in future participant information sheet design.

Reviewer #2 Dr Amanda Burls

1. I think that most of the statistics are fine but rather than giving % agreement for inter-rater agreement the authors should have calculated Kappa. (A 10% sample would only be expected to identify one or two included papers so agreement due to chance will be expected to be very high.) We have calculated the Kappa value (96.0%) and used it as the % agreement for inter-rater agreement on page 9.

2. There are some minor typos that will require correction on proof reading (e.g. PIS's instead of PISs)

The paper has been proof read by all authors and an independent party before resubmitting.

3. Although the authors declare they have no non-financial conflicts of interest, some are co-authors of the Antoniou paper that is given a positive commentary in the discussion (Page 20 lines 28 to 26). While I don't think this needs to be removed, I wonder whether it would be helpful if the overlap in authorship should be made more explicit so that readers would be aware of this without having to cross-check the authors in the reference? (I also have this conflict of interest)

We have made this conflict of interest clear in the competing interests section of the paper.

4. I think this is an important but relatively neglected area (as demonstrated by the review itself). Therefore it is helpful that this review has been undertaken to highlight the lack of empirical evidence in this areas.

Thank you.

5. The search was comprehensive, however, the non-specificity of the search terms make this search challenging and it is possible that relevant studies have been missed, it would have been interesting to know how many of the 14 included studies were found in the electronic searches or whether they came from the 37 studies identified by experts. This would have given an indication of how many studies may have been missed.

All included studies were identified by electronic databases; expert authors identified 37 unique references but 13 were duplicates from the electronic searches and 24 did not meet the inclusion criteria. We have included this information on page 9.

6. The method of mapping the studies to the NRES themes was a useful methodology and enabled the production of some summary statistics. However, I was left wondering whether there might not have been more useful information that could have been extracted, especially of a qualitative nature. For example, the evidence supports the idea that different people have different information needs was there anything in the differences between studies e.g. cancer versus other conditions that may have been useful for hypothesis generating for future studies?

We agree that it would have been useful to look at difference in informational requirements of sub groups of the population but the small numbers of studies identified and the limited data extracted from them meant that this was not feasible. We have, however, included this as a limitation to the review on page 21.