PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Decision aids for randomised controlled trials: a qualitative exploration of stakeholders' views.
AUTHORS	Gillies, Katie; Skea, Zoe; Campbell, Marion

VERSION 1 - REVIEW

REVIEWER	Fiona Wood Cardiff University, UK
REVIEW RETURNED	18-Jun-2014

GENERAL COMMENTS	This is an interesting study which examines various stakeholders' views about DA rather than PILs to help assist the process of informed consent for the recruitment of patients to trials. It is generally well written and clear. I do have a few concerns which I hope the authors will be able to address fairly easily. 1. There should be some mention that the study received ethical approval. It may have been enough for the study to be given institutional ethical review, although patient participants are also recruited. I'm sure this did happen, but it needs to be reported. Also missing are considerations of informed consent discussions/documents for this study. 2. The authors should make it clear how many letters of invitations were sent for each of the categories. For example were all UK Clinical Research Collaboration Trial Managers on listserv sent an invitation. I would then also expect to see some reference to response rates for each of these groups. 3. Abstract. In the section on 'design' I would put a full stop after 'interviews'. Delete 'that included' and new sentence on 'Participants....' 4. Abstract. I think there should be some reference to the concerns / cautious views expressed by some respondents. The results in the abstract suggest that all respondents were totally supportive of DAs. 5. Some of the results are perhaps too specific to the specific decision aids that the participants saw rather than views about DA for consent in general. In particular I am thinking about the reference to the comments about sentences which are over-emotive. If the authors wish to include these views then they should pick up on it again in the discussion and say how it might effect DA in general. 6. In the discussion I would have liked to have seen some discussion about the types of trials that the authors think the DA would be better than the more traditional PILs. Would this be for all trials or perhaps the more high risk trials or drug trials, or for certain patient groups? This is important particularly in relation to the comments made by some participants about the DA over-

	complicating issues for some patients. 7. The authors make reference to other studies which have discussed patients' views of DA (ref 13 and 14) which 'show promise'. But I would have liked a bit more detail on what these papers concluded. Also I would have liked to have seen in the discussion some reflection on how the author's studies complements or contradicts these earlier findings.

REVIEWER	Anne Townsend University of British Columbia Canada
REVIEW RETURNED	23-Jun-2014

GENERAL COMMENTS	10. The paper is very clearly written, but the findings/results are not clear to me in terms of the thematic analysis described. Are the headings, themes that emerged from the data, or are they describing/illustrating what participants responded to in the interview questions, so rather than themes, are they organised around questions asked? If they are themes, which emerged and which were a priori? It would help to identify how all stakeholders discussed each 'theme' or if some were only discussed by some of the stakeholders. Also when stating 'the majority...' - were there differences between stakeholders which are important? Could you be more explicit about similarities and differences between stakeholders e.g patients and other groups where there was disagreement or agreement. How closely did the group align/disagree? Between and within groups? It would help to identify themes in the description of the analysis section and attach an interview schedule for transparency. 12. The findings may not apply to those beyond this group, not only in other countries. The sample is very small. Although the authors quote Guest et al (ref22) Why only 4 patients? Could you describe in more detail the justification for this? Because the participants are heterogeneous group of 5 I think the numbers are very low for each stakeholder. Ref 22 notes 12 if the group is homogeneous was ideal. Given this is the reference you use could you justify such low numbers? Thank-you for inviting me to review this paper which I enjoyed. Very easy to read. Good topic, interesting mix of stakeholders. Analysis and presentation of findings looks thin as it stands. Page 5 Line 28 "Whilst trial participants perspectives are important..." I fully agree that it is importnat to gain the perceptions of PI's, ethics board members and triallers and all concerned views and support, but still think that the decision aids are to be used by trial participants ad understood by them, so I think their perspective is key rather than important. Page 7 line 19: Did all other stakeholder participants select face-to-face interviews? Where were the interviews held? Lines 55-56 - "prompted further analytic consideration" was this

	undertaken by more than one person? Did more or higher level themes emerge? Could you identify some here? Page 9 line 19 'respondents' could you use participants for consistency? Page 10 line 40 - in this section of results/findings "Provision of information about positive and negative features of taking part in the trial" No patient extract. This is one example of not all stakeholders included in all themes/headings - so can you clarify whether these are themes across stakeholders? Or (as queried above) is this section organized around themes or the structure on the interview guide? Overall very few patient quotes across the sections. Conclusion and discussion - can you identify differences between stakeholders, in particular the patient views, as patients are giving their perceptions of using decision aids and informed consent, while other stakeholders are commenting on/making assumptions about how patients may perceive the decision aids. Page 21 lines 19-24 Reflecting your cooments about 'how participants see taking part for them as individuals' see ref for patient perspectives on research participation (including trials) Townsend A, Cox SM. Volunteering for research: Accessing health services through the back door? Highly Accessed. BMC Medical Ethics November 2013,14:40. doi:10.1186/1472-6939-14-40.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1 – Fiona Wood

1. There should be some mention that the study received ethical approval. It may have been enough for the study to be given institutional ethical review, although patient participants are also recruited. I'm sure this did happen, but it needs to be reported. Also missing are considerations of informed consent discussions/documents for this study.

The following text was included in the original manuscript, see page 28.
'Ethical approval: The study was approved by the North of Scotland Research Ethics Committee 1 (REC Reference Number 09/S0802/105) and NHS Grampian Research and Development department (Reference Number 2009HS002). All interview participants provided their signed consent, which included consent for anonymised quotes from their interviews to be published.'
To ensure that this is more accessible we have now moved this into the body of the manuscript. Within the 'Sampling and recruitment' section of the Methods on page 8, further information has been included to be more explicit about the consent process for participation in the interview study reported in the manuscript, See page 8 paragraph 2.

2. The authors should make it clear how many letters of invitations were sent for each of the categories. For example were all UK Clinical Research Collaboration Trial Managers on listserv sent an invitation. I would then also expect to see some reference to response rates for each of these groups.

Details of the number of invitation letters, or members on the list serv, are now included in the 'Sampling and recruitment' section on page 8, paragraph 2. In addition, response rates for each of the groups have been included within the 'Sample characteristics' section on page 10.

3. Abstract. In the section on 'design' I would put a full stop after 'interviews'. Delete 'that included' and new sentence on 'Participants....'

This has now been amended in the abstract as requested.

4. Abstract. I think there should be some reference to the concerns / cautious views expressed by some respondents. The results in the abstract suggest that all respondents were totally supportive of DAs.

This has now been amended in the abstract as requested.

5. Some of the results are perhaps too specific to the specific decision aids that the participants saw rather than views about DA for consent in general. In particular I am thinking about the reference to the comments about sentences which are over-emotive. If the authors wish to include these views then they should pick up on it again in the discussion and say how it might effect DA in general.

Whilst the information contained within the decision aids could have been considered with regard to the specific trials, we believe it is more likely it was considered generally. This is for two main reasons. Firstly, the section on advantages and disadvantages were written as generic sections within the decision aids and were not specific for the individual trial context. For example:

ARE THERE POSSIBLE BENEFITS OF TAKING PART IN THE TRIAL?
You will receive proper health care by your consultant whether you choose to participate in the study or not. There is no guarantee that either type of surgery will be better for you than the other. You will receive extra personalised care and attention from research nurses by taking part in the trial. You may receive a treatment which you would not have access to should you not participate.

And the converse:

ARE THERE POSSIBLE BENEFITS OF NOT TAKING PART IN THE TRIAL?
By not taking part in the trial you, and your doctor, will be able to choose which treatment you receive. Also, you will not be required to complete any of the questionnaires associated with the trial and will only get additional care for your haemorrhoids if there is a clinical requirement to do so.

Secondly, as none of the Trial Managers, Research Nurses, or Ethics Committee Chairs were involved directly in the trials in which the decision aids were set, we believe it may be appropriate to consider that these statements were made about the general information and certainly much of the data, on this section and others, supports this to be the case.

However, to clarify this point to the reader we have included text to reflect these points. See page 25, paragraph 1.

6. In the discussion I would have liked to have seen some discussion about the types of trials that the authors think the DA would be better than the more traditional PILs. Would this be for all trials or perhaps the more high risk trials or drug trials, or for certain patient groups? This is important particularly in relation to the comments made by some participants about the DA over-complicating issues for some patients.

We thank the reviewer for highlighting this important point. It is of course naïve to imagine that a

decision aid, in the form developed for pilot in this study, would be required for all clinical trials. It may be that decision aids could be more effective for some decisions rather than others e.g. where interventions being trialled are very different (like medical management vs. surgery), or for specific contexts or patients. It may also be that the decision aid could be broken up into component parts and used as appropriate in different contexts to facilitate and support the informed decision making process. However, this would all require further evaluation before recommendations could be made. Text to reflect these points text has included in the discussion section on page 25, paragraph 1 and page 26, paragraph 1.

7. The authors make reference to other studies which have discussed patients' views of DA (ref 13 and 14) which 'show promise'. But I would have liked a bit more detail on what these papers concluded. Also I would have liked to have seen in the discussion some reflection on how the author's studies complements or contradicts these earlier findings.

More detail on the findings of some of the preliminary trial decision aid studies has been included in the introduction on page 6, paragraph 2.

Likewise, we have now included a section within the Discussion to reflect how our findings complement the existing evidence but also contribute additional insights through the involvement of a wide range of stakeholders. See page 23, paragraph 3.

Reviewer 2 – Anne Townsend
1. The paper is very clearly written, but the findings/results are not clear to me in terms of the thematic analysis described. Are the headings, themes that emerged from the data, or are they describing/illustrating what participants responded to in the interview questions, so rather than themes, are they organised around questions asked?
If they are themes, which emerged and which were a priori?

The reviewer raises an important point for clarification. The data is reported with regard to themes defined a priori, which were those that the interview questions were structured around. As such the reported findings illustrate the ‘themes’ participants responded to in the interviews. Text to make this clear has now been incorporated into the Methods section on page 9, paragraph 2.

2. It would help to identify how all stakeholders discussed each 'theme' or if some were only discussed by some of the stakeholders. Also when stating 'the majority...' - were there differences between stakeholders which are important?

Further explanation regarding the design of the topic guide has been included on page 7, paragraph 3. This section now also explains that due to the pre-defined areas of importance for investigation informing the topic guide, all themes were discussed by all stakeholder groups but the extent to which their opinions converged differed between groups and across themes.

Within the findings where we have stated ‘the majority’ we have now included detail to be more specific about which groups this related to and likewise, where there was disagreement, the specific stakeholder groups are now mentioned. Other sections of the text have been amended to be more explicit about which groups we are referring to when reporting findings. See tracked changes.

3. Could you be more explicit about similarities and differences between stakeholders e.g patients and other groups where there was disagreement or agreement. How closely did the group align/disagree? Between and within groups?

This question has been largely addressed by point 2 above. In addition, we have included text to illustrate how closely groups converged or diverged at both intra- and interdependent levels. See changes tracked throughout.

4. It would help to identify themes in the description of the analysis section and attach an interview schedule for transparency.

A copy of the interview schedule has now been included as Additional file 1 and is referred to in the Methods section on page 7, paragraph 3.

5. The findings may not apply to those beyond this group, not only in other countries. The sample is very small. Although the authors quote Guest et al (ref22) Why only 4 patients? Could you describe in more detail the justification for this? Because the participants are heterogeneous group of 5 I think the numbers are very low for each stakeholder. Ref 22 notes 12 if the group is homogeneous was ideal. Given this is the reference you use could you justify such low numbers?

We acknowledge in the Discussion section that the findings may be limited to our sample. However, our findings do complement the existing studies that have explored patients' perceptions which gives some indication of their transferability to other contexts.

Participants for each stakeholder group were selected based on their involvement and experience in clinical trials. Whilst the original proposed sample in our study was guided by methodological criteria (of 6-8 [Guest et al]), the final sample was largely pragmatic due to the number of participants who responded to invitation letters within the time period for the project. A further justification of the relatively small numbers relates to the overall purpose of this study, which was not to provide definitive findings or evaluation of these interventions, but more to establish whether decision aids have potential (and what that might be) over existing methods used in informed consent discussions for clinical trials. We have now included text in the strengths and weaknesses section of the Discussion to highlight the potential limitations of the small sample. See page 25, paragraph 1.

6. Page 5 Line 28 "Whilst trial participants perspectives are important..." I fully agree that it is important to gain the perceptions of PI's, ethics board members and triallers and all concerned views and support, but still think that the decision aids are to be used by trial participants ad understood by them, so I think their perspective is key rather than important.

The reviewer raises an important point that requires clarification in the manuscript. As the decision aids are designed to support potential trial participants and, as such, the main (potential) beneficiaries of such interventions are potential trial participants, it is important to identify their perspectives as key rather than important. The text in the manuscript has now been amended to reflect this. See page 6 paragraph 2.

7. Page 7 line 19: Did all other stakeholder participants select face-to-face interviews? Where were the interviews held?

All participants were offered the option of either a face-to-face or telephone interview. All but one patient participant requested telephone interviews. The face-to-face interview was conducted at the University of Aberdeen as agreed by the participant and the researcher. Text to reflect this has now been included on page 8 paragraph 3.

8 Lines 55-56 - "prompted further analytic consideration" was this undertaken by more than one person? Did more or higher level themes emerge? Could you identify some here?

The further analysis was conducted by two authors (KG and ZS). Specifically this process, identified key differences between the groups and identified consensus on the importance of the potential of decision aids across all groups. Text to reflect this has now been included on page 9, paragraph 2.

9 Page 9 line 19 'respondents' could you use participants for consistency?

This discrepancy has been addressed throughout, ensuring there is clarity between interview participants and (potential) trial participants. See tracked changes.

10 Page 10 line 40 - in this section of results/findings "Provision of information about positive and negative features of taking part in the trial" No patient extract. This is one example of not all stakeholders included in all themes/headings - so can you clarify whether these are themes across stakeholders? Or (as queried above) is this section organized around themes or the structure on the interview guide? Overall very few patient quotes across the sections.

We felt it was important to give a balanced view of all stakeholders. However, where appropriate we have supplemented themes with additional patient quotes. Where possible, we have provided both positive and negative perceptions when reported. All themes were identified across stakeholder groups. If deemed necessary we could provide a table of additional stakeholder quotes as an Additional File.

As clarified above, the findings are organised around the structure of the interview guide, which was designed on themes informed by existing literature and previous work by our group.

11 Conclusion and discussion - can you identify differences between stakeholders, in particular the patient views, as patients are giving their perceptions of using decision aids and informed consent, while other stakeholders are commenting on/making assumptions about how patients may perceive the decision aids.

Yes. The main themes in which patients views differed to the majority of other stakeholders groups were provision of information about positive and negative features of taking part in a trial (and the exacting information contained within that section) in that patients felt it to be balanced but others reported worries about coercive language. In addition, many of the stakeholders felt that the decision aids were too long, but none of the patients reported this with all of them saying that all of the information was important.

Text to reflect this is now included in the discussion on page 21, paragraph 1.

12 Page 21 lines 19-24 Reflecting your cooments about 'how participants see taking part for them as individuals' see ref for patient perspectives on research participation (including trials) Townsend A, Cox SM. Volunteering for research: Accessing health services through the back door? Highly Accessed. BMC Medical Ethics November 2013,14:40. doi:10.1186/1472-6939-14-40.

Thank you for highlighting this interesting study. We have now referenced it in the discussion to highlight how our study also contributes to the wider literature on sense-making with regard to research participation . See page 24, paragraph 1.

VERSION 2 – REVIEW

REVIEWER	Anne Townsend University of British Columbia Canada
REVIEW RETURNED	28-Jul-2014

- The reviewer completed the checklist but made no further comments.