Author's response to reviews

Title: Pay clinicians to join clinical trials? A review of guidelines and interview study of trialists

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Author's response to reviews: see over
We wish to thank the reviewer for her helpful comments and we have responded as follows:

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<td>1) Title - ‘survey of trialists’ I was expecting a questionnaire based study. Perhaps you may want to consider the term ‘qualitative / interview’ in their title?</td>
<td>We have changed the title.</td>
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<td>2) Background – A definition of ‘financial incentives’ would be helpful. I was unclear as to what these included.</td>
<td>Now included in background section.</td>
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<td>3) Methods More detail regarding methods used would be helpful in order for the work to be replicated. For example: a) List of the bibliographic databases, websites and UK agencies searched (with dates).</td>
<td>Text now added to the methods section and wording clarified. The bibliographic database search was carried out in parallel with a literature review of studies examining the effectiveness of incentives and we looked for guidelines during the inclusion/exclusion process of the effectiveness review. Therefore it was a very wide ranging search of multiple databases (not all of which have good coverage of guidelines) and we have not listed them in this paper but they are listed in the description of the effectiveness review published elsewhere. For completeness this search involved: Cochrane Library (Database of Systematic Reviews and Controlled Trials Register) Cochrane Library Issue 2, 2006 (06/2006) Medline (OVID) 1966 to 02/06/2006 Embase (OVID) 1980 to 02/06/2006 CinAHL 1982 to 02/06/2006 PsychINFO 1985 to 02/06/2006 Web of Science ISI SCI/SSCI 1981 to 2006 Web of Knowledge ISI Proceedings 1990 - 2006 Medline in process (OVID) June 2, 2006 Conference Papers Index 1982 to current Current controlled trialshttp://controlled-trials.com/ (02/06/2006) Clinical trials.gov HMIC Health Management Information Consortium June 2006 National Research Register Issue 2, 2006 (02/06/2006)</td>
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<td>c) 44 interviews were performed, however I make it 42 (38+4 (2/3 of inactive researchers identified through snowball sampling refused), please check.</td>
<td>We have clarified the wording here to avoid this confusion. 44 interviews were performed. The 6 inactive researchers represent 1/3 of those approached (i.e. 18 approached, 2/3 refused).</td>
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<td>d) Some text relating to interview schedule would be helpful. This would give the reader some appreciation of the questions asked and the topics covered.</td>
<td>Sentence now added to methods section summarising schedule content.</td>
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<td>e) Methods used to analyse qualitative data is required.</td>
<td>We apologies for this oversight. This has now been included.</td>
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<td>f) CH was responsible for analysing the data – who is CH (not listed as an author)?</td>
<td>We apologise for this typographical error which has now been corrected. This is CK, one of the authors.</td>
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| g) Sampling - on what basis were the pre-specified dimensions considered to be important, what is their possible influence? | Several tasks were undertaken to identify the scope of characteristics of health professionals to be included in the sample. Examination of clinical trials published in the *BMJ* and *The Lancet* between September 2004 and September 2005 confirmed that both primary and secondary care settings were important. Searches of the databases of ongoing and completed research trials in the National Research Register (NRR) and the Clinical Trials Register showed that PIs were principally clinicians, but a sizeable minority were other health professionals. Trial centres were spread throughout the UK, including major centres in London, Oxford and other large cities across England, Scotland and Wales. Trails covered the range of medical specialties. As a result of this scoping work, the sample aimed for maximum variation over these variables:  
- geographical location  
- primary and secondary settings  
- clinicians (GPs and hospital doctors) and nonclinicians  
- medical specialties  
- Plus active and inactive researchers  
We have not included the above in the text of the paper, but we hope this explanation satisfies the referee. |
5) Results:
   a) Would be helpful to know how many UK agencies were contacted. Are those agencies that responded a representative sample? (how many did not respond etc)

   While we understand the reviewer’s point, it is a difficult one to answer, as in our scoping review of guidelines we used several methods to identify guidelines, often more than one method for an agency. We searched Google, we looked through journal publications (identified in a related review), we used our own knowledge and our colleagues working for the NHS R&D programme, we examined the websites of key agencies, and we emailed agencies where we were unsure if we had the full information. It was not a questionnaire survey of a defined sample.

   b) Data only reported for those agencies that do not mention payment and the GMC. Is this because others did not respond? Or do you have more data to present?

   Other agencies did not pass comment, we highlighted BMA, MRC and DH as we felt that it is significant that these key bodies do not mention individual payments. We have no more data to present.

   c) How many interviewees fell into the pre-specified sampling frame?

   The breakdown of the interviewees was as follows:
   
   Primary care clinicians 13
   Secondary care clinicians 14
   Other healthcare professionals 2
   Non-clinical researchers 9
   Non-research-active clinicians 6

   Total 44

   Text has been added to results section giving this breakdown.

   d) The third aim (financial incentives in relation to barriers and facilitators to healthcare professionals) no data (quotes) are presented regarding this aim. Nor are there any related to the pre-specified dimensions, especially regarding surgery etc

   Further quotes have been added throughout the results section to illustrate the qualitative analysis findings. Subheadings have also been added for clarity.

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4) Background:
   a) Not stated at outset why failing to meet recruitment targets is a problem. You may want to consider including some text relating to why it is so important for trials to meet their recruitment targets for example; underpowered trials are unable to detect important clinical differences / outcomes, trials not recruiting will take longer to complete therefore becoming more expensive to run and ultimately importance evidence may be delayed etc.

   Sentences added to background section.

   b) Reading the second aim “explore attitudes, beliefs and behaviour of healthcare professionals” I was surprised to read it was lead investigators (either clinicians or non-clinicians) that were interviewed. Would be helpful to clarify (in objectives) who were interviewed.

   We agree that this is misleading. We interviewed healthcare professionals who were also researchers involved in clinical trials. We have changed wording in objectives in background section for clarity.

5) Results:
   a) How many interviewees fell into the pre-specified sampling frame?

   See 5d) above.

   b) General comment – headings may help i.e. to meet objectives b and c.

   Subheadings added to results section to aid clarity.

   c) Consider including a table presenting characteristics of those interviewed (and perhaps comparing with those that declined to be interviewed)

   We do not think there is sufficient room in the paper to give tables of the characteristics of participants and non-participants. We have added some more detail to the text (results section) describing the participants’ characteristics.

   d) Last quote re probity test is difficult to follow – perhaps a larger proportion of the transcript needs to be presented.

   I think it is the grammar of the sentence (we have chosen to quote participants verbatim without correcting grammar). I have looked at the full transcript and to be honest I don’t think including a longer quote here would help matters.

   Instead I have deleted the repeated use of “you” as this was confusing, and I have added square bracketed text (the word “payments”) to clarify the wording.

   For completeness the full text of the quote (for the reviewer) is:

   "Yes, I think that you have to be careful about, I don’t have a problem with an incentive even a financial one, that you can use indirectly for professional related activities. I feel quite comfortable about that. I would have no
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<td>problem, I think the ultimate test I've always applied is “Are you, would you be comfortable discussing with a patient?” because if I’m doing [name of condition], it says what do we gain financially or why do you want to do it to gain financially, I feel quite comfortable saying “well, the reasons are as follows, these are the activities I support that we create, so I'd have a problem with it coming to me personally, I think that would put me into a rather difficult and unethical situation, but I think where the money is being used indirectly to support [other research activities] I have no problem with that. HD8”</td>
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<td>e) I would find it useful if the qualitative data were presented by identified themes.</td>
<td>This has now been done, with subheadings.</td>
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<td>f) Also if more quotes were presented, in order to provide examples of the data obtained. Presenting quotes relating to just positive and negative effects and probity test didn’t seem adequate. For example the affect on altruism, interviewees also suggested principles suggested (good study design, payments to organisations rather than individuals etc), I would have liked to see the qualitative data to support these themes.</td>
<td>We have presented more quotes as requested. We have moved the existing quotes from Box 1 and placed them in the text (of course they can be moved back to a box if the editor would prefer this).</td>
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