Author's response to reviews

**Title:** Reporting of complex interventions in clinical trials: development of a taxonomy to classify and describe fall-prevention interventions.

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**Version:** 2  **Date:** 13 April 2011

**Author's response to reviews:** see over
Dear Editor

RE: Manuscript for Submission to Trials titled ‘Reporting of complex interventions in clinical trials: Development of a taxonomy to classify and describe fall prevention interventions.’

Please find enclosed our revised manuscript with all the changes made using ‘tracked changes’. Below we provide a point-by-point response written in italics underneath the concerns raised by the reviewers. We have collated the reviewer’s comments as some points overlap but all individual points are addressed with reviewer 2’s comments dealt with first.

1. The consensus panel included 33 representatives but only 30 are named.  
   We have amended this.

2. There are typographical errors in the first two points of table 1  
   ▪ Question 1: Did you mean “i.e. is the taxonomy complete” rather than “completeness”. – Have changed to complete.
   ▪ Question 2: I don’t understand the second question – Slightly re-worded question as it contained a typographical error.
   ▪ Question 8: I believe this question is important for interpreting the outcome of the taxonomy, but not for the development of the taxonomy. – We have deleted the question.

3. In the last paragraph, first sentence of the discussion the 2009 Cochrane review should be cited, not the 2003 review. – We have added the 2009 Cochrane reference.

4. Interventions in the paper are always described as complex and certainly not all are. The taxonomy should be of value in all fall prevention interventions. In the paper either "complex" should be omitted or interventions described as "some of which are complex".

   We have changed the first line of the abstract, and removed the term complex from several parts of the text (now marked in revised paper). We believe that the great majority of interventions delivered for falls prevention fit the MRC definition of complex
interventions. We have inserted the definition of complex interventions according the MRC to reduce confusion in the meaning of the term, and hope that the changes provide a more balanced account.

5. Discussion/Table 2: domains of the taxonomy – Please discuss the importance of the distinction of the four domains. What is the added value of each of the domains (e.g. selection criteria and recruitment may be overlapping)? Why does the taxonomy not include questions about the effectiveness of the intervention?

The domains provide a framework for the taxonomy, and help to divide it into distinctive areas.

In response to this question we have
1. Expanded the text to describe that the domains are designed to provide a framework to the taxonomy and added a link to Table 2 in the methods section (we realised that this was missing).
2. We have clarified the definition of Approach provided in Table 2 to show that it is the theoretical approach as opposed to general approach.
3. We have clarified this in the taxonomy by using the heading recruitment site as opposed to recruitment.
4. We accept that the sub-domains may or may not be mutually exclusive, but this varies by study or situation and hence is not something that can easily accommodated. We have added a comment to this end into the discussion (page 10, paragraph 2).

Why does the taxonomy not include data extraction for these studies

The answer to the second half of this question is that the tool is designed to report and categorise the type of intervention. It is not designed as a tool to extract data on the effectiveness of the intervention (this would be better accomplished through materials already developed alongside the Cochrane review, and through the Cochrane collaboration). We never suggested this was the intention of the taxonomy.

We have inserted text to clarify this issue (page 10, paragraph 2 “The taxonomy is intended for a number of purposes, including to assist with data extraction alongside meta-analysis of research data, reporting of interventions tested in research studies, and in the process of development of interventions. The list is purposefully not exhaustive.

6. The paper doesn’t discuss the manual. How was the manual developed? Were raters asked for feedback regarding the manual (clarity, ease of use, completeness)?

We have inserted manual into the second paragraph under the heading Stage 2: Refining and agreeing the final version of the taxonomy “and manual” – first line of paragraph “The taxonomy “and manual” was then tested using the remaining 27 articles retained after our search of trials published in the Cochrane review [9].

Page 8 paragraph 1 already includes a statement that the raters were asked to indicate areas of the taxonomy and manual that required clarification. We have added text so that it is easier to see that this meant clarity, ease of completion, and completeness as
follows: “We also worked with individual raters to determine areas of the manual and taxonomy that lacked clarity, were difficult to complete, or were incomplete.”

7. Please discuss in the paper how this taxonomy should be used: does it replace the CONSORT guidelines or should it be used in addition to this (or other) guidelines?

  We have inserted a new sentence on page 11 saying that the guidance is complementary to but does not replace the CONSORT guidance.

In the manual

In response to the comments regarding the manual and taxonomy it is very important that you are aware that it is very difficult for us to make substantive changes to the manual or taxonomy because it would invalidate the research methods used – because they would not have been through the consensus agreement process. We have made changes where these are minor and do not substantially affect the content of the taxonomy or manual, and have noted more substantial suggestions in the text of the paper.

8. Introduction (page 2) – Tips on using the taxonomy: Please add here how the taxonomy should be used in regards to other guidelines such as the CONSORT guidelines.

  At bottom of introduction we have inserted sentence “The taxonomy is complementary to but does not replace the Consort Guidance on the reporting of complex interventions.”

9. Table 1 (page 3) – Domain 2 – Primary site of delivery: “the site at which the <the>> majority of the intervention is delivered or targeted” – the second “the” has been deleted.

10. Approach (page 7) – primary selection criteria – Screening tool: Many tools are available, did you deliberately decide not to specify this? What are the implications if selection criteria based on tools with different aims (e.g. single fall risk, multiple fall risk, fracture risk) are categorized as one group?

  There are many screening tools/algorithms available for falls screening, many of which have unproven validity and reliability. If we made an exhaustive list then the taxonomy would be huge, and from the point of view of meta-analyses and data pooling, categorising data by the screening tools used is not a likely source of enquiry. The point about whether the screening tool identified people at single fall risk, multiple fall risk or fracture risk is a good one (although there are few tools that have robustly proven themselves capable of doing this in independent cohorts), and is something that should be considered for future versions of the taxonomy. We have inserted a sentence into the text of the discussion, along these lines. Page 10 Paragraph 1 as follows “For example, further refinement of the selection criteria section might include refinement of the data captured on screening tools used, for example whether the tool intends to capture single or repeat fallers, or aims to identify osteoporotic fracture risk.”

11. Base (page 8) – The manual uses the heading “Case Identification/Primary Site of Delivery”, whereas the taxonomy uses the heading “Recruitment Site/Main site(s) of delivery”. To avoid confusion, I think it is better to use the same terminology in the headings in the manual and taxonomy.
Replaced heading in Manual with recruitment/Main site(s) of delivery also replaced “case identifications” in text of manual with “recruitment.”

In the Taxonomy

1. Approach – primary selection criteria – Age group: only a lower limit for age range is asked, but some studies do have an upper limit. Would it be relevant to add?

   *We agree but will hold this over for the next version of the taxonomy.*

2. Approach – primary selection criteria – Selected ethnic group: what if no specific selection criteria regarding ethnicity were used, but because of the setting/country, all participants are from one specific ethnical group?

   *Amended the manual to state that if the inclusion and exclusion criteria for a study or programme did not state a specific ethnic group, but all members of the sample are from one ethnic group, then this box should not be ticked.*

3. Descriptors – Control group – medication – The control group could be given other drugs (according to existing protocol/usual care) or lower/different doses. Maybe add a free text option here for further specifications?

   *If the control group are given existing protocol/usual care drugs this comes under routine care. If different or lower doses are given than usual care, then this would constitute an active intervention, and the taxonomy would be completed in full for this. No changes made to the manual.*

Other changes

We have also noted some changes that were required.

1. In the Manual under Introduction [2] there is a typographical error “away” which has been replaced with “a way”.

2. Also we have inadvertently provided a copy of the taxonomy which is explicitly designed for data extraction alongside meta-analysis. The front sheet is designed to capture information on the study being included in meta-analysis. As this is not a generic component of the taxonomy, ie it is purpose specific we have removed this front sheet to avoid confusion.

Thanks to the reviewers for their comments we hope that we have adequately addressed them.
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If there are any queries, please do not hesitate to get in touch.
Kind Regards

Yours Faithfully

S.Lamb (On behalf of all the authors of the manuscript)