Reviewer’s report

Title: Research involving adults lacking capacity to consent: a content analysis of participant information sheets for consultees and legal representatives in England and Wales

Version: 0 Date: 14 Aug 2018

Reviewer: Mark Jayes

Reviewer's report:

Dear Authors,

Thank you for submitting this interesting paper for review. You describe the investigation of an important and rarely examined aspect of clinical research practice.

Generally, your paper is well written. However, there are sections that require revision to make them more concise and to make your intended meaning clearer. The discussion in particular requires significant revision to make it clear to the reader why your findings are important and relevant. There appear to be some errors in terms of your presentation of numerical data. I also have concerns about your study classification system.

Please see my detailed comments below:

Abstract: Results section final line: "a small number inaccurately interpreted the law" - it is not very clear to what you are referring; do you mean a small number of studies? It may also be helpful to actually specify the number of studies rather than write "a small number".

P1 Line 13: "they" - please revise to make it clear to whom you are referring.

P1 Line 24: "a professional to act as a nominated consultee" - I am not aware that the MCA has this provision. Could you please provide a reference to the appropriate section of the MCA?

P2 Line 37: "never had decision-making capacity" - I would reconsider this phrase. It suggests that mental capacity is global or generic rather than time and decision-specific, as stated by the MCA. How could we ever know if someone "never had decision-making capacity"?

P2 line 48: Ref 17 - I think a page ref would help here.

P3 line 52: "examining the content empirically" - I am not sure what you mean here; please consider revising this phrase to make it clearer.

P3 line 58: I would consider changing "has" to "had".
P3 line 61: "frame of reference" - please explain what you mean by this phrase; consider revising it to make your meaning clearer.

P3 line 61: "legislation" - please remind the reader what the legislation is and provide a reference.

P3 line 67: Please change "National Institute of Health Research" to "National Institute for Health Research"

P4 lines 77-79: I think these categories are problematic. How was this classification system created? I am concerned that it is reductive and actually discriminatory to assign labels relating to mental capacity status to diagnostic categories. It certainly is not within the spirit of the MCA. Also, your use of terms such as "progressive loss", "sudden loss" and "no prior capacity" suggests that mental capacity is global or generic rather than time and decision-specific (see my earlier comments). Furthermore how does your system apply to people with multiple diagnoses? Please consider reformulating / relabeling this classification system.

P7 Table 1: "Care home(s)" - in relation to the comments above, many different types of people live in a care home and they are likely to differ in terms of their ability to make informed decisions. Please consider revising this.

P7 Table 1: I think the total no of CTIMPs included should be 6 not 9

P8 lines 151-154: please revise this long sentence to make it easier to read.

P8 line 157: "7-67%" - it is not clear to me from Table 2 how these percentages were derived.

P9 line 163: "nominated consultee or professional legal representative" - it may be helpful to the reader to explain who these people might be.

P9 line 167: "12 documents (29%)" - it says 13 docs and 31% in Table 2.

P11 line 202: "A number of the study documents" - please specify which ones.

P11 line 209: "when decisions are made" - I think it would be helpful to clarify that here you are talking about decisions about research participation for people who lack capacity to decide for themselves.

P11-12 lines 214-223: these two sentences are very long and quite difficult to read; please break them up into a number of smaller sentences.

P12 lines 231-236: again, please break up this very long sentence to make the content easier to read.

P12 lines 236-238: this sentence does not make sense to me; please revise it.
Inaccurate use of terminology - I think it would be helpful in this section to inform the reader what the correct terms should be.

I agree that the term "assent" is not used in the MCA; however it is used by research professionals in relation to adults who cannot provide informed consent. It might be helpful to acknowledge this.

"The MCA clearly states...." - please reformulate this sentence, as it does not make sense as it is.

I think this section needs to explain more explicitly why the results you have obtained are important - what are the potential risks to participants and proxies and to research integrity if researchers don't get this right? It might be helpful to pick up some of the themes you alluded to in the introduction.

"nomenclature and terminology" - do you need both words?

"This risk of clarity.....who lack capacity" - it is not clear to me how the lack of clarity reinforces confusion and leads to exclusions - please make the links more explicit.

these two paragraphs feel more like summaries of previously reported results or even new results, rather than a discussion of your findings - please revise.

care home residents... - I think this sentence appears to suggest that care home residents are likely to have dementia. This may not be the case. I think it would be helpful to provide some data to back up this proposed association between living in a care home and having a dementia diagnosis.

discussion is very long and difficult to follow; please revise it.

"if that had not been met" - I am not sure what you mean by this; please revise this phrase.

"if the person had never had decision-making capacity" - please see my earlier comments about this problematic contention.

"intractable questions under the requirements of the current legislation" - I am not sure the questions are intractable "under" the requirements; do you mean they are intractable due to the nature of the legal requirements?

these sentences are difficult to read; please revise them to make their content clearer.

"Strengths and limitations" - I think this section could be edited to make it more concise.
P18 line 378: "primary strength" - why is this a strength?

P18 lines 387-391: this is a very long sentence which is difficult to read; please revise it.

P18 line 393: "stratification of samples by the three groups of conditions" - please revise this phrase to make the meaning clearer. What are the samples?

P19 line 396: "a small sample...were reviewed" - please change to "was reviewed".

P19 line 403: "never had capacity" - please see my earlier concerns about this categorisation descriptor.

P19 line 418: "will add to the context of proxy decision-making" - could you be more specific? What exactly do you mean here?

P20 lines 424-426: does this sentence describe a research or practice recommendation?

P20: lines 438-445: what are these recommendations based on? Legal requirements? Or your opinion? Please explain where they come from.

P21 line 449: "consultees" - please see my earlier comment; I am not sure whether professionals can be consultees.

P21 line 459: "the clinical and representation roles were conflated" - I don't think you've stated this observation previously. I would expect to see this first in the main body of the discussion.

P21 line 460: "adequate information" - how would you define "adequate"? By which / whose standards? Please consider revising this.

P22 line 468/14: "UK Clinical Trial Gateway" should be "UK Clinical Trials Gateway".

P22 line 481: "National Institute of Health Research" should be "National Institute for Health Research".

P30 Additional file 1: Please explain all acronyms, e.g., ITU, CNS.

P31 Additional file 1: "massive haemorrhage" - is this the exact phrase used in the study? It seems a little strange!

P32 Additional file 1: "National Institute of Health Research" should be "National Institute for Health Research".
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Please indicate how interesting you found the manuscript:

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Is it essential that this manuscript is seen by an expert statistician? If so, please give your reasons in your report.

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No