Reviewer’s report


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Reviewer: Jako J Burgers

Reviewer’s report:

This is an interesting paper addressing a relevant and original issue for guideline developers and implementers. It describes the development and outline of a guide how to address ethical issues in guidelines. Although the guide seems to be helpful and useful, I have major concerns about the reporting of the methods for the following reasons:

1) The authors define standards for inclusion of ethical recommendations in guidelines in addition to four principles of bioethics, which are based on bioethics research. The standards are presented in the Introduction, but the evidence for these standards is, however, not clear.

2) Two pilot tests were performed with the guide, but limited information is provided about the design of these test. The Methods only includes a phrase that ‘pilot-testing concerning two ethical issues in dementia care’ and that ‘the test informed a revision addressing issues of validity and consistency’. No information is provided about the context of the guideline development, the country and healthcare system, the guideline working group(s) involved, the number of group members, how the issues were discussed, how consensus was defined and achieved. Therefore, the reliability and validity of the pilot tests cannot be assessed.

3) Beyond the lack of information, a second, shorter pilot test concerning ethical issues in chronic kidney disease in the Results is described, which is inconsistent with the information in the Methods. As the paper primarily focuses on physical restraints in patients with dementia, the description of the results of the pilot tests is unbalanced.

The authors could address these concerns by providing more information about the development of the standards (e.g. who were involved in drafting the standards and how these were validated) and about the design of the pilot tests. The Results section should not only described the guide but also the findings from the pilot tests as announced in the Abstract. If the authors would follow the outline of the Methods in the abstract, the paper could be improved.

A few minor comments are:

- In general, the authors often use ‘must’ whereas ‘should’ would be more appropriate. As long as the guide is not validated internationally, the recommendations should be less directive.
- P. 3: ‘being aware of ethically sensitive situations may lead to ethically problematic behaviour’. I am not sure about ‘aware’. I think that it should be ‘unaware’.

- P. 4: ‘[...] objective inclusion [...]’. How would you define ‘objective’? I think ‘intersubjective’ might be more appropriate.

- P. 4: the standards include criteria such as ‘pragmatic’, ‘reductive’ and ‘simplistic’. In addition, the ethical recommendation should not be ‘useless’ and ‘unjustified’. I would reformulate these positively (‘useful’ and ‘justified’), so that you could come up with five criteria (three about the development, and two about the recommendations).

- The Conclusions section is more Discussion. To raise the interest of the international audience of the paper, a reflection of similarities and differences of ethical concerns between countries could be useful.

- Table 1 includes an example without justification. I would add an example with justification to clarify what kind of justification is acceptable.

- Table 2 is not a table but a box. It is difficult to read and might be removed or considered as an additional file.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests.