Reviewer’s report


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Reviewer: Lubna A Alansary

Reviewer’s report:

This is an interesting manuscript, which addresses an important aspect of clinical practice guidelines (CPGs) development and describes a hypothetical model to do so. I enjoyed reading it and I think it has many merits. There are many areas of concern that, I believe, should be addressed by the authors in more depth.

The introduction emphasizes on the importance of identifying and addressing disease-specific ethical issues (DSEIs) but gives no examples from the literature or experience of DSEIs in the introduction or in any part of the manuscript. Moreover, the introduction states that guideline development manuals from the WHO (2008), NICE (no date) and IOM have no clear instructions on how to address DSEIs. It does not verify the situation in other recent manuals such as NICE (2014), WHO (2010), the German Guideline development manual, SIGN 50, NHMRC, etc.

No formal question is posed but the objective is very clear and that is to propose a 6-step approach (EthicsGuide) to integrate DSEIs in CPGs in a transparent and systematic way.

The methods section is more of highlights on the factors that have helped in shaping this model but no rigorous methodology is provided. The authors have built this model based on previous work in the field of dementia (Ref# 6 and #16). This allowed for an earlier version to be pilot-tested which presumably lead to the final version described in this manuscript.

The first paragraph in the Results and Discussion Section is part of the Methods and should move up.

The proposed 6-step model is reasonably described but:
• I would expect, however, an introductory statement or an overview at the beginning of the results section.
• Step 1 and 2 are more or less the same with repetitions. So, I suggest joining them together.
• Step 2: The authors recommended involving trained ethicists. I believe that this recommendation is opinion-based and clear criteria should be given in order to make this step reproducible.
• Step 4: Not sure who will do it and can’t understand the leap from statements in
step 3 to verbalized recommendations in step 4. The advantages are described but the process and the practical steps of doing it are not!

- Steps 5 and 6 are sensible.

There is no formal discussion but the conclusions are sensible.

The title is attractive and covers what is written in an abstract form in the manuscript.

The abstract is informative of the 6 steps but it is interesting to find statements on the 2 core challenges of implementing an explicit method copied from the introduction of the manuscript and pasted in the results section of the abstract. Are they part of the background or conclusions? The conclusions part seems to be focused on ethicists and not guideline developers!

Generally speaking, the authors have provided the guidelines development teams (who are likely to be non-ethicists) with an attractive hypothetical model (EthicsGuide) that might be difficult to implement with no examples. It would be prudent and practical to use 2 different real life examples through the 6 steps. This will add more depth and help the reader to understand how to go about it.

The authors have made it very clear that this model will serve as basis for further discussion. Nevertheless, more depth is needed in putting forward for the non-ethicists involved in guideline development so that they can comfortably be on board in this discussion.

**Level of interest:** An article of importance in its field

**Quality of written English:** Needs some language corrections before being published

**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.