Reviewer’s report

Title: Evidence-based decision-making for diagnostic and therapeutic methods: the changing landscape of assessment approaches in Germany

Version: 2 Date: 07 Sep 2017

Reviewer: Stefanie Ettelt

Reviewer's report:

This is a much improved and much more readable and coherent paper. Congratulations.

I am happy to recommend the paper for publication in this journal and only have few minor comments and suggestions for improvement.

1. I suggest not to call the paper a case study as this raises the question as to what it is a 'case study of' (Ragin). It obviously is a case study of HTA development, but for a case study as a study design I would expect a more pertinent claim to generalisation. I do not mind that there is not much to generalise, but I would not call it a case study. In my view, "analysis" would to the job.

2. I would also remove the point on generalisation from the limitations, unless a stronger claim is made as to what to generalise. In my opinion, there are two themes that could be candidates: 1. German HTA as an example of the difficulty of developing a coverage decision-making mechanism through legislation, which exposes it to political party bargaining (much easier to be coherent via Government decree, but this is not how the German political system works). 2. That having separate regulatory approaches for inpatient and outpatient services is not a good idea, as they tend to undermine each other (similar to the boundary problem of GKV and PKV actually). The paper makes all these points but does not claim to draw 'lessons' from them. I agree with this approach but then the question remains whether there is anything that can be generalised.

3. The write-up of the methods is much improved. Given that the analysis is now more coherent I wonder whether it needs the limitation section. Clearly, interviews could add to a more complete picture, but I think for this type of analysis a documentary analysis will suffice (I would advise interviews though if the paper were to be more strongly focused on the politics of law making or of GBA decision making).
4. I am intrigued by the observation of a shift in discourse from 'benefits' to 'potential' of inpatient methods. Would it be possible to add some information about the scientific implications of assessing 'potential'? How does it differ from assessing benefit?

5. On the GBA's role in a future Europe, I am afraid to note that this sounds rather hopeful. However, the hope seems to rest on a potential gap left by Brexit (a job opening so to speak) rather than the strength of the GBA. It would be great if the authors could add a strength to underpin their ambition.

**Level of interest**
Please indicate how interesting you found the manuscript:

An article of importance in its field

**Quality of written English**
Please indicate the quality of language in the manuscript:

Acceptable

**Declaration of competing interests**
Please complete a declaration of competing interests, considering the following questions:

1. Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

2. Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

3. Do you hold or are you currently applying for any patents relating to the content of the manuscript?

4. Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript?

5. Do you have any other financial competing interests?

6. Do you have any non-financial competing interests in relation to this paper?
If you can answer no to all of the above, write 'I declare that I have no competing interests' below. If your reply is yes to any, please give details below.

I declare that I have no competing interests.

I agree to the open peer review policy of the journal. I understand that my name will be included on my report to the authors and, if the manuscript is accepted for publication, my named report including any attachments I upload will be posted on the website along with the authors' responses. I agree for my report to be made available under an Open Access Creative Commons CC-BY license (http://creativecommons.org/licenses/by/4.0/). I understand that any comments which I do not wish to be included in my named report can be included as confidential comments to the editors, which will not be published.

I agree to the open peer review policy of the journal.