Author’s response to reviews

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

Authors:

Britta Olberg (britta.olberg@googlemail.com)
Sabine Fuchs (sabine.fuchs@tu-berlin.de)
Katja Matthias (katja.matthias@g-ba.de)
Alexandra Nolting (alexandra.nolting@g-ba.de)
Matthias Perleth (matthias.perleth@g-ba.de)
Reinhard Busse (rbusse@tu-berlin.de)

Version: 3 Date: 18 Sep 2017

Author’s response to reviews:

Reviewer #1

Comment #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.

Answer to comment #1: Suggestion applied

Comment #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.

Answer to comment #2: We thank the reviewer for this remark. We modified the sentence and do not use the term ‘generalizability’ anymore.

Comment #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).

Answer to comment #3: We thank the reviewer for this feedback. However, we do think that the lack of additional interviews can be seen as a general limitation. Therefore, we decided to keep this limitation in the section, but modified (softened the wording) the content.

Comment #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?

Answer to comment #4: We thank the reviewer for this comment and added more information.

Comment #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.

Answer to comment #5: We thank the reviewer for this comment and added more information regarding the strengths of the GBA (Germany) to underpin our assumption/speculation.