Reviewer's report

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

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Reviewer: Stefanie Ettelt

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I have read this article with interest and think that it has potential to make a relevant contribution to this journal. I am always keen to read about the decision-making processes of the Federal Joint Committee and am sure that there is international interest in the German approach to health services coverage. However, I have three main criticisms: The current version of the article is both too detailed and too unclear to be accessible for an international audience. The article is also unclear about its aims and argument, and would benefit from refocussing and reorganisation. The use of language also requires attention (see terminology).

In its current form, the article presents much detail about the trajectory of health technology assessment in Germany, but it is not clear what the article contributes to the knowledge of readers outside the system which this journal aims to inform (especially in low and middle income countries). So the article should be clearer in answering the "so what?" question: Why do we need to know about these developments? What is interesting about them? Which larger body of research does this article contribute to? This would also help to set the paper apart from previous "histories" (e.g. Perleth et al. 2009) in addition to presenting an update on developments. The answer to these question will determine the aims and organisation of the paper, and this could lead to very different types of papers.

The article is currently framed as a contribution to debates about evidence based medicine and health technology assessment, but these fields have moved on considerably over the last decades and are now much more diversified. I recommend that the authors tease out what is special about the German 'case' of institutionalising HTA in decision-making on publicly funded health service coverage, focus on these aspects in detail (while discarding other debates) and frame the paper accordingly. I understand that the article is laid out as a history of developments and not as a piece of empirical research, but even as a history it remains vague and uninteresting especially as the actors who have shaped these developments (e.g. as legislators, as members of the self-governance system) are conspicuously absent. 'Politics' feature occasionally, but political arguments are often clouded by the use of language, which implies actors but never mentions them. If this is about legislative changes over time (rather than, say, methodological changes to HTA) the article needs to say so upfront and focus on changes to the legislative framework, the dynamics that have informed them and the implications for the GBA.
In several places, the article seems to measure the German approach on international EBM "best practice" (whatever this might mean). This should either be made more explicit, which than means that it has to be established first what "best practice" in this field looks like, or it may not be appropriate to make such normative statements. As it stands, other countries make a showing on the final page but the comparison does not inform the framing of the article.

I have a number of specific comments:

Background

The background should present a clearer aim of the article, which needs to reflect the aims and structure of the main text. An "outline" is too weak and "an outline of the current status and developments regarding" is not accurate (if anything it is the other way around). In other parts it is referred to as "review" (p3). However, I think it is essential that the "so what?" question is addressed - what is relevant to know about the German system for an international audience? As mentioned above, the paper could draw on a more specific literature focusing on the role of HTA in decisions on health service coverage in publicly funded health care systems and specific debates within this field. The broad focus on EBM feels inappropriate and outdated, unless it is used for something more specific such as comparing the German approach to EBM "standards" that have informed international best practice (not sure though whether there is necessarily consensus). This is likely to produce a less comfortable paper for authors who are associated with the GBA.

The discussion of medical devices and European activities would be interesting if it would resonate more strongly with the rest of the paper, but it only comes up towards the very end of the paper.

P2, lines 50-52: The second part of the sentence does not follow from the first.

Methods

The methods section is weak, which is probably owed to the fact that the article is written almost as a legal history. This section should provide more detail on how documents were obtained and how they were analysed. Policy documents etc. do not constitute "relevant literature" (see abstract). They are data sources. The problem with this history is that such "data" is very formalistic (for want of a better word), especially if these are official regulatory and legal documents, which allow little insight into the dynamics that have motivated the changes and developments that the article is interested in. This is a methodological problem of such analyses, hence the importance to use additional data sources (e.g. interviews).
Main body

The main body of the text presents the development of HTA informed decision-making in Germany. These sections would work better if more attention would be given to actors and to those aspects that are most relevant to an international audience (i.e. the "story" needs a clearer focus).

This problem affects both the aims/focus on the article and the style of writing. For example, a sentence like "The idea of technology assessment was initially discussed by the technology assessment office of the parliament."(p4) raises more questions than it answers: When was initially? What is the technology assessment office of the parliament? What do they have to do with HTA or health insurance coverage? If they were a key agenda setter, have they played any further role in the development of HTA in Germany?

In places, information needs to come earlier, e.g. p 5 "such as the predecessors of the G-BA" (who are they?) Followed by "In 2004, …, the former Federal Standing Committee … " in the next paragraph. OK - Are they the predecessors?

The GBA is referred to in different ways e.g. "the highest decision-making body of the joint self government of …" (p2) and "the supreme decision-making body" (p5) (I would avoid "supreme" in relation to public administration, which sounds like North Korea). If in doubt, use the wording that the organisation uses for itself.

I would separate health technology assessment and coverage decisions as two (related but) separate processes. "Benefits assessment" (p6) seems to conflate both. In my view, HTA is the EBM informed process, while decision making is as corporatist (and therefore political) as it always was give and take a few important changes such as changes to the voting rights, involvement of patient organisations etc. These processes need to be separated out.

P 6 It is a peculiarity of German policy-making that terms such as "methods" as health technologies are defined by the courts. This may require more background information.

"Wirtschaftlich" does not translate into "cost-effective". It is a legal term (perhaps expressing an ambition), not underpinned by any method of assessment (parliament has decided against cost effectiveness analysis as a method), except perhaps some cost impact analysis (although this pans out differently for pharmaceuticals).
"Principles of EBM" - what are they? (p7). If they are key to the argument they should be brought to the fore and discussed in the beginning. There is also mention of "the methods of EBM" (p12) - what are those?

P7 "Methods which are not necessary or ineffective" - this is legal text and should be treated as such. This is important given that what is seen as "not necessary" is often controversial.

"Eminence-based medicine" - this is a German in-joke that is not necessarily understood by an international audience (I have tried it and failed). The way it is presented seems to suggest that it is used in official parlance.

P9 I disagree that the processes before 1997 were "opaque" compared to today as this seems to imply that processes now are "transparent". This may be accurate with regard to the use of HTA as an assessment tool but it underplays the lack of transparency of the decision-making process between the corporatist actors who form the GBA.

P9 "Its work was being increasingly denounced as arbitrary and incoherent" requires a reference. By whom?

P11 "Innovations in health care find their way" - this is too unspecific and not well worded.

"This is justified by the (political) assumption that" - whose assumption specifically? How comes they have influence over the legislative framework? Why does this make the decision "justified"?

Table "Approach not existent" - not clear what this means.

P12 Some parts of this paragraph may work better in the past tense.

P13 "reflect the beginning of a shift towards improvement of evidence-based decision-making"/"apparent room for improvement" - this is a normative judgement that seems out of context (unless the paper is framed differently and the German approach is compared to a standard, but not sure this is the intention, it would make a much more critical paper).
"This can be explained by remaining inconsistencies between the two health care sectors in Germany" - Does it? Not sure the preceding paragraphs suggests that this is the reason. Are there alternative explanations?

"Health policy-making has partially responded" - Policy-making is not an actor, it therefore cannot respond.

"to the criticism" - whose criticism?

P 16 - This requirement can be understood as a reversal of the burden of proof." - If this is about comparing the German system, does this mean this is a retrograde step? How does this relate to notions of EBM (if at all)?

"market approval process" - probably better as "market authorisation", which is the official term used by EMA.

"Consequently, benefit is simply assumed" - by whom?

"these remaining deficiencies" - again, I would be careful with such normative claims. It also sounds as if there are only a few "deficiencies" remaining, but I am not sure this is consensus.

"A new statutory regulation" - is this different from law?

"interrelates" - not a good word in this context. Perhaps "amends"?

P17 "methods based on high risk MDs" - this is the first time that medical devices are mentioned in the empirical part of the paper. This seems very much as an add-on which is not what I expected given its prominence in the introduction.

"Coalition agreement"- this (I think) is the first time party politics is mentioned. If this is a relevant driver of developments, which I think it is given the importance of changes to the legislative framework to the work of the GBA, reference should be made to politics more consistently
Discussion

This discussion is not a discussion. It presents new information which it should not. It should relate back to the literature introduced earlier (i.e. international discussions on using HTA to inform health service coverage decisions in publicly funded health systems). It is striking that the discussion focuses on medical devices. Perhaps this should be a separate "results"/history chapter.?

P17 "increasing concerns" - by whom?

P18 "a fairly consistent development during the last 20 years" - Not sure I agree. There is certainly movement, but it does not always go in the same direction. It is telling that cost-effectiveness is absent in this paper. How about the argument of the "reverse burden of proof".

P19 "This is alarming, as patients might be exposed to a potentially harmful method" - True, but the discussion of potential harms needs to be introduced much earlier. It seems only an afterthought here, but as far as I am concerned harm avoidance is part of the entire rationale of EBM.

P20 "innovation-friendly principle of 'permission unless explicitly banned" - a politically driven euphemism? This argument should be much more critically made. This is the territory of political argument, not a matter of fact.

Here, examples of other countries are mentioned but only in a cursory fashion. It is important to bring out the international relevance of the German experience much more clearly.

"some even for longer time than in Germany" - the "even" is not appropriate for an international journal.

Not sure the differences between Germany and other countries is adequately captured. Does the "forth hurdle" not usually relate to cost-effectiveness analysis as a criterion for reimbursement decisions? If this is the difference (which I think it is) this has to be spelled out.

P20 "Considerable inconsistencies between in-and outpatient care settings" - this only warrants mentioning at the top of the conclusion if this is the main focus of the paper.
"learning system" - yes, but some lessons have not been learned or there was a political dynamic in place that did not allow for changes to be made. So this needs to be qualified.

Terminology

The terminology used also needs revisiting for a publication aimed at an international audience. It also should be more consistent. The German "Methoden" does not translate easily into English as "methods", which are typically used for research methods and the like. "Health services" or "health technologies" are more common terms. Some wording sounds a little too directly translated, e.g. "as a decisive basis" (p2) - "to inform decisions" would be better. "Direct corrective action" (p10) does not translate into meaningful English ("corrective" sounds like the penal system to me). Would "commissioning evaluation" or "health services research" be appropriate perhaps?

The word "ban reservation" is not a good translation of "Verbotsvorbehalt", which is probably better to be paraphrased. It is referred to as "prohibition right" (p 12) elsewhere, but this does not make it clearer. "Operator effects" (p3) needs an explanation. "Testing directive" is unclear.

Some wording is inappropriately normative (e.g. "a very useful concept and tool" (p2) - better "an established tool"). Some phrases that are common in German HTA parlance may need explanation (e.g. "patient-oriented decisions"). "Proprietary digital databases" needs an explanation, especially as they seem to comprise both organisational information management systems and profit oriented database outlets. "Controversial debate" (p3) is a tautology. "No proven evidence" is also a tautology (p18). "Evidence-based technology assessment" - is this different from "health technology assessment"?

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