Author’s response to reviews

Title: Assessing value in health care: using an interpretive classification system to understand existing practices based on a systematic review

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Letter to the Editor

Dear Editor of BMC Health Services Research,

We appreciate the careful and insightful feedback on our paper entitled “Assessing value in health care: using an interpretive classification system to understand existing practices based on a systematic review”. Below this letter you will find our detailed responses to the reviewers’ comments. Our own sentences appear highlighted in yellow.

In addition, we also took into consideration your own comments and worked to improve the newer version. In this regard, there is one specific point we would like to bring up here. You stated that the English could be improved and that “some sentences sounded odd to my ears”. Do you have specific concerns about specific sentences you could point out to us? The first draft of this paper was written by BVS, which, although a non-native speaker, is an experienced writer in English. And the work was extensively revised and modified by senior researcher and English native speaker CM. So, it would be helpful if you could point out specific sentences that seem odd. We understand that the aesthetic appraisal of a text involves subjective elements and hardly achieves consensual judgements. Otherwise, in case the editor is minimally satisfied with the current quality of the English language employed in the paper, despite eventual discomfort with some phrasal constructions, the authors agree in putting it forward as it is.

In respect to abbreviation issues, ICER is indeed widely used both for “Incremental Cost-Effectiveness Ratio” and for “Institute for Clinical and Economic Review”. So, in order to bring consistency and avoid confusing the reader, we decided to employ the ICER abbreviation only for the institute and use the thorough word description for the CEA ratio, that is actually only once mentioned in the text.
Please notice that we introduced a substantial amount of contextual information for each framework in table 1, in response to reviewer 1’s comment on who use them and for which purpose.

We once more appreciate the constructive feedback and look forward to hearing from you soon.

Sincerely,

Brayan V. Seixas.

**Responses to Reviewer 1`s comments**

This is a very nice review of value frameworks. The authors seek to understand and categorize "value frameworks" based on a number of pre-specified criteria.

Overall, I would say that this is a useful review, but perhaps not as deep or insightful as one might like.

We really appreciate the respectful and insightful feedback. Each concern raised here was carefully addressed and our responses to them can be seen below.

1. the notion of value is problematic. Value is a term that comes from economics, but many of these frameworks are not primarily economic in nature. For each framework, would try to identify the specific construct that the framework is getting at....even when there are multiple criteria, developers are usually trying to get at something (best decision? efficiency? what)

We Thank you for this comment. In our view, this is an absolutely central topic and one that surprised us in the review. In fact, we are very critical of how the term ‘value’ has been used in a vague and reckless manner lately in the public health literature. We recognize the incoherent and theoretically weak use of language around this important concept, but we also made clear in our text that this is a systematic review that seeks to make sense of what is available in the literature. Our purpose is not to determine what is correct use or not of the term value. We incorporated in our analysis all empirical works that stated employing a value assessment framework. Personally that also caused some discomfort for us. However, our work was predominantly descriptive.

Historically, the concept of value emerges from neoclassical economics and keeps an intrinsic association with the idea of utility, which is usually expressed in price. Due to its inappropriate placement in the health care market, where often rationing has to replace the price mechanism due to its structural market failures, the notion of value has been gained other contours. Michael Porter has the most widely cited work in this realm, in which he defines value as “health outcomes achieved per dollar spent”. This one has been the most influential definition and places the concept value in a welfarist or extra-welfarist paradigm, where a maximand is sought. Yet,
this definition has also demonstrated to be inadequate in many contexts and other researchers have been trying to expand it. Recently, the ISPOR’s task force on value assessment published a paper in the journal “Value in Health” proposing a composite nature for value, including a lot of elements that have only barely mentioned in the literature. All that is said to demonstrate that the discussion of what value means would actually render itself another entire paper and it is not in the scope of our work.

Notice that in the objective of our work “we sought to comprehend the contexts in which these initiatives emerged and what definition of value underpinned it”. So, instead of having an a priori definition of value to be applied upon existing initiatives, we wanted to see which definitions of value were underpinning their empirical work. In this sense, our analytical work of this massive qualitative data had hues of grounded theory, letting the categories and idea that make sense of the data emerge from the actual data. In other words, using an a priori theoretical framework to analyzing the existing initiatives of value assessment would actually constitute a research endeavor substantially different from what we propose here.

2. Thus, many of these frameworks are in fact, "decision frameworks", rather than value frameworks, i would argue. If one takes a sufficiently expansive definition of value, this can of course cover a lot of territory. But I'd argue that this is potentially misleading because it causes us to adopt an economic lens with which to view the problem of how best to make a decision.

Thank you for the comment. This goes along the same lines of the previous reflection we provided. We agree with the reviewer that some frameworks found here are not adequately portrayed as “value framework”, for a lot of reasons (lack of a reasonable underpinning theoretical definition of value, constituting elements that make it closer to decision-making frameworks, lack of any explicit consideration of cost, etc.). However, our role in this systematic review was to shed light onto the frameworks of value assessment that have been published as such in the public health literature. All these works were published in reputable scientific journals as such, which means that part of the research community legitimated the use of the expression “value assessment frameworks” for the type of work they refer to. We did comment on the problem regarding a consistent use of the notion value in our Discussion Section.

The idea of a systematic review like the one conducted here is to provide a snapshot of the existing practices in this realm. That does not mean that a critical reasoning is not welcome and, above all, necessary. Actually, as health economists, the findings of this systematic review revealed to us that there is a lot of space for a serious and committed theoretical discussion on “value”, which has been used in a vague and, sometimes, irresponsible way. We are very interested in developing another piece in which we discuss these findings from an extensive theoretical perspective and encourage others to do.

3. I'd indicate the theoretical foundation, if any, used by each framework. In some cases (CEA) is will usually be obvious. In other cases, not really so easy to identify. Absence of a theoretical foundation is important, and should be reported.
Thanks for the very pertinent comment. Indeed, our extraction tool (appendix 2) had a question about the definition of value contended in each paper and its theoretical foundation. We could have this information available. There are two problems in reporting it though. First, its appraisal is not exactly objective. We asked different authors to do the information extraction of the same papers and the findings are not consensual in this specific point. Just as you said that in your view some frameworks are actually “decision-making frameworks” while the authors of those papers call it “value assessment frameworks”, we also found that categorizing the theoretical foundation of each framework is extremely problematic. There is no consensual analytic framework for analyzing these initiatives and doing that implies necessarily taking a stance. That would go beyond the scope of a systematic review that seeks to reveal for the research community a snapshot of what has been called “value assessment frameworks”. In fact, we see an additional value in keeping the work like that because it reveals the extent and nature of the problem regarding the epistemological view on value and its practical implications.

Second, our narrative synthesis already describes in the text the papers that explicitly state an underpinning definition value and its theoretical foundation. In our view, that stance is in accordance to the purpose and scope of the work here presented.

4. It seems that the authors conflate types of frameworks (e.g. CEA, MCDA) with specific instantiations thereof. I would argue that the ICER framework, for example, is an MCDA framework without weights. A better approach I would have thought would have been to come up with a typology of frameworks, then list specific examples of those types.

Thanks for this comment as well. We understand the discomfort, and we share part of this feeling. In analyzing the existing practices of value assessment as defined by their authors, we saw a lot of similarity between some practices that have been defined as something separate. A similar reasoning could be applied to CEA, comparative effectiveness research and HTA, for example. There is no consensually established way to define such broad typology. The boundaries are blurry and deserve a collaborative work of clarification and epistemological definitions by the health economics, health policy and health services research community. As discussed previously, it was not the purpose of the work to employ an a priori analytical framework onto the papers found in the literature search. That would involve a lot of arbitrary decisions by ourselves and would create a very “biased” snapshot of the existing practices. The ICER framework, for example, is not defined by their authors as a MCDA tool. Defining it as a MCDA without weights would require some sort of theoretical elaboration around the literature on operations research that defines very specific processes classified as MCDA, not just any group of people making decisions together.

5. Process and context are key components of frameworks.

WHO uses the framework, and for what purpose....important

Thank you for this comment! We recognize that this was an important flaw of our first version and we introduced substantial changes in table 1 to include these types of information. Please see the two entire new columns highlighted in yellow that respond to your comment.
HOW is the framework implemented...e.g. who generates, who reviews, and who presents the evidence. How are decisions achieved...is there a consensus process, voting etc.

We actively sought to collect this information. However, that generated a very inconsistent dataset. While some papers provide some level of information in this regard, others provide no information at all on how decisions are ultimately achieved. Who are responsible for the decision, existence of appeals mechanisms, etc, nothing has been systematically reported and we stated that in our paper. For example, as we say in the result section “explicit process evaluation took place in about one third of the 38 papers”. Because of that, including inconsistent information in the final narrative synthesis could create more harm than gain. The ultimate objective of the review was to generate a snapshot of the existing practices, making use of analytical tools as minimal as possible just in order to make sense of the massive amount of qualitative data. In analogous terms of the language employed in qualitative research, we would say that this work is a fundamentally descriptive qualitative work (as described by Sandelowski) with hues of grounded theory. So, going that far in the analysis and presenting inconsistent information would involve an excessive participation of the review authors in speaking for the authors/doers/describers of the value assessment frameworks.

Responses to Reviewer 2`s comments

The authors state that the purpose of their manuscript was to "understand which approaches to value assessment have been used in developed countries.", In addition, the authors "sought to comprehend the contexts in which these initiatives emerged and what definition of value underpinned it". To achieve this objective the authors used performed a rapid literature review and a gray literature search focusing on existing value assessment frameworks of health care technologies within the context of developed countries. The results found by the authors showed: "1176 references were identified and 38 papers were selected for full-review. Among these 38 articles, 22 distinct approaches to assess value of health care interventions were identified and classified according to four points. The authors conclude that "the contextual nature of value assessment in health care becomes evident with the diversity of existing approaches. Despite the predominance of cases relying on the Incremental cost-effectiveness ratio as the measure of value, this approach has not been sufficient to meet the needs of decision-makers. The use of multiple criteria has become more and more important, as well as the consideration of patient-reported measures. Considerations of costs are not always explicit and consistent. The article is well written, interesting and brings contributions to the literature in the area. However, the authors should invest more effort in the development of work to make the article publishable, essentially for the following reasons:

1. The authors are already beginning their speech addressing a specific market: developed countries, without arguing the reasons why they chose this market. Is not this research question critical to underdeveloped countries? Why study developed countries and not any other market? What is the reason for studying this particular period? And not another period (2007-2017)? Justify the choice of Ovid MEDLINE base.

Thank you for the comment! Your questions are very important and were object of careful consideration by the authors.
We determined to focus on developed countries for two reasons. First, although the topic is also very important for low- and middle-income countries (LMICs), the structural variability of their health care systems and the degree of scarcity of these settings make them substantially different in terms of the incentives and barriers of decision-making practices regarding priority setting and resource allocation. While high-income countries have had to deal with growing expenditures, often times over-utilization of health care technologies and use of low-value interventions in usually well-structured health care organizations, LMICs display a wide variety of scenarios, from extremely unstructured health care efforts (like some Sub-Saharan African countries) to very well-coordinated and particular system designs (such as Brazil). Thus, in order to make sure that the set of practices found in this review belong to roughly the same semantic and operational environment, the focus on one specific social universe is quite reasonable. Second, non-systematic literature searches carried by us, not presented here, show an almost complete absence of published works on “value assessment” in LMICs.

In regard to the period of study, that is an arbitrary number but that has a reasonable logic. We wanted to see what are the existing practices in the field recently. Looking back 10 years seems a reasonable choice given our fast has been the technological advancement process in the health care system. We wanted to capture a reasonable period of efforts of value assessment that are relevant for decision-makers today. Looking much further back would possibly return strategies that are not necessarily relevant for the today’s audience. Our review did not intend to provide a historical overview of this topic, but rather to provide a somewhat comprehensive snapshot of the current existing practices. In addition, systematic reviews almost always are made upon choices that are ultimately arbitrary, like the settings chosen, the period of time, the search terms, etc. The most important thing is here is not necessarily why we made these choices, but how reasonable and relevant these choices are. And, in general, review authors do not provide an extensive explanation of the whys in systematic reviews, focusing more on the narrative that demonstrates their importance and which knowledge gap it addresses.

In respect to Ovid MEDLINE, we included a sentence in the text to make explicit the relevance of this database in the field of health economics and health policy: “an extensive database of public health journals with a powerful platform for building searching strategies” (Methods, p. 4, line 21).

2 - Figure 1 is cited but does not appear in the text or in the annexes.

➔ Thanks for noticing that. There must have occurred some problem with the upload processes. We made sure of the inclusion of figure 1 in the newer version. Please let us know if any formatting issue prevents you from seeing this figure.

3- Table 1 is cited but does not appear in the annexes. I believe that Figure 2 that is presented in the appendix be Figure 1. I suggest a review in detail for the Figures, Tables, and Appendices.

➔ Thank you for pointing out these inconsistencies. In fact, there was likely a problem in the process of generating the PDF submission that changed the automatic numbering of figures and tables.
4 - I suggest the inclusion of abstract graph and also a Diagram summarizing the methodology of the systematic review.

→ Sure, thank you! Figure 1 presents that information.

5 - Include in the conclusions the suggestions for future research.

→ We included an additional paragraph in the conclusion suggesting future research:

“Furthermore, our work reveals several important pathways of future research. First, the inconsistency found in the use of the notion of “value” shows the importance of a careful and robust epistemological reflection about this concept and its practical implications. Originally born within the realm of neoclassical economics with an intrinsic association with the notion of utility and its manifestation in price, value has gained other contours in the health economics literature. The widely cited work(1) by Michael Porter defines value as “health outcomes achieved per dollar spent”, which seems to place value as a maximand that fits well in a welfarist or extra-welfarist paradigm. More recently, the ISPOR’s task force(51) on value assessment presented a complex composite nature of value, although according to them only a few elements have been consistently addressed in the literature. Thus, not only a further reflection on the notion of value must be pursued by the health economics community, but also explicit statements about the underpinning theoretical notions of value should be encouraged by those who delve into empirical initiatives in this realm. Second, as many of the self-described value assessment frameworks did not present any explicit consideration of cost, it would be very important to understand how we can develop more appropriate tools that take into account the costs of health care interventions within each framework. That is related to the fact that the traditional cost-effectiveness approach does not seem to be currently fulfilling the needs of decision-makers and new manners to adequately consider cost may be also necessary. Lastly, just as our interpretive classification scheme, novel approaches to guide decision-makers and managers on how to choose and/or develop adequate practices to assess value of health care technologies need to be further investigated.” (Conclusion section, page 15, line 15).