

Peer Review Report

Review Report on Domains and methods of medical device technology evaluation: a systematic review

Systematic Review, Public Health Rev

Reviewer: Reviewer 2

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EVALUATION

Q 1 Please summarize the main theme of the review.

Dimensions, attributes and methods of medical device technology evaluation from the perspective of incorporating technology into healthcare systems

Q 2 Please highlight the limitations and strengths.

The systematic review methodology and evaluation of the quality of the studies is sound. The interpretation of the findings from the selected studies and how they relate to the stated aims of the review are not presented in an understandable and convincing manner.

Q 3 Please provide your detailed review report to the authors, structured in major and minor comments.

Review

The authors have done a good job of collecting an important body of literature that clearly relates to the aims of their study. They have the start of a useful and comprehensive analysis of current knowledge on the topic, but the paper needs major revision in order to both better present their findings and, mostly, select and interpret the information collected in the studies and how it relates to the aims of the study.

Methods -

The section is generally very thorough and clear regarding how the literature search was conducted according to sound methodological guidelines. However, there are some major problems in how the information was extracted and categorized from the selected studies.

The authors mention how they assessed each type of study, e.g., AMSTAR 2 for systematic reviews, SANRA for narrative reviews, JBI Text and Opinion tool for descriptive review articles. But how they determined the type of study is not clear and a spot check of some of the references did not reveal that the authors themselves categorized their studies as one type or another, except in the case of systematic reviews (Table 2). Perhaps a table with all the types of studies, with a brief definition/description for each, could be added to the supplemental materials, along with the references/sources of the definitions and key components or differences between each.

But the main problems to be addressed refer to the categorization of the information extracted from the studies ultimately chosen for this review and the interpretation of what they mean. The authors list the inclusion criteria and exclusion criteria in Table 1. Regarding inclusion criteria, the authors state: "Full studies conducted between 2017 and October 14, 2022, with a focus on capturing recent HTA processes, practices, and methods within the broad dimension of DM." What do you mean by "within the broad dimension of DM"? Again, DM as an abbreviation is not defined (see Other issues below), but even if I substitute "medical device" for DM, I do not understand what you mean. In fact, what is missing from this section is a clear description of what the authors used to define attributes and dimensions in their classification system, since these are the main findings of the paper. How did the authors come up with the list of attributes and dimensions? What research underlies their selection? This is not defined clearly and understandably enough in the paper (referring specifically to lines 204 to 213 on page 7). It is here that some literature on HTA is needed and clarifications and explanations provided. For instance, are the dimensions the same as commonly used "domains" in HTA, as they are described in, e.g., the EUneHTA Core Model, or in definitions and resources

provided on the INAHTA website, or even in the papers chosen for this review. This would strengthen considerably the results and discussions on what the findings of this review mean and how they address the aims of the paper and contribute to the literature. The authors should define clearly what they mean by attributes, dimensions and how they relate to domains in HTA.

Results

Please check and correct a few terms in Table 3. For example, the Dimension column choices do not always have the correct term, e.g., "Clinic" should be "Clinical". I recommend you cite and refer to the EUnetHTA Core Model or similar for the descriptions of the domains. Also, rechecking the Methods section, the authors could improve on the column headings. For instance, Attributes refers to MD attributes in the methods section, but at some point in the table, attributes seems to refer more to study attributes. Dimension, meanwhile, is listed as HTA Dimension in the Methods, and the distinction between the two seems to become blurred. Perhaps attributes is not the best word, either. Checking a thesaurus for similar terms might serve to better define or widen the concept behind that first column in Table 3. I recommend doing the same for Dimension or Domain. Under attributes, I believe Security should be Safety. Under Dimension, Clinic should be Clinical, and so on. Some terms in Table 4 are still in Portuguese (Clinica). Economical is both an attribute and a dimension. Please check.

The paragraphs at the top of page 11 (lines 261–273) are rather confused. How is MD (not DM) performance monitoring and incremental innovation an economic dimension? In any case, I could not come up with a clear list of 8 dimensions from Table 3.

Table 4 is not understandable. Also, the methods don't appear to line up with the dimensions, making it hard to see which method/type of analysis refers to which domain – probably the rows are centered and spacing of the columns is not ideal. Aside from this, the stated aim of the paper was to "to characterize the dimensions, attributes and identify innovative methods for HTA studies with a focus on incorporating MD into healthcare systems" but the methods mentioned don't appear related to this goal. Please think again of how Table 4 relates to this goal and not a list of methods in the papers for certain dimensions. It is confusing for the reader.

Discussion

Please start the discussion section with a short reiteration of what the paper sought to do, then go on to discuss how well you met these goals and how to interpret your results. That is, the discussion should show how you met your goals, what your findings mean, where your research fits in with previous research (especially what makes it a contribution to the literature), what research/studies support or contradict what you found, limitations, future research areas, conclusions.

At present, the Discussion section just appears to refer to some of the Dimensions and general difficulties in conducting HTA on MDs (versus medicines), plus a few recommendations put forth by various authors or associations (e.g., IDEAL Collaboration, EUnetHTA). Later in the section, there is some effort to tie the group of studies selected to the Brazilian context, but not in any organized fashion. This section needs to be revised according to a clear organizational structure with the goal of discussing the findings from this article and how they relate to the aim (introduction) and research question (mentioned in the Methods section).

Other issues, mostly related to language

There are some grammatical errors, which would be easily solved with a spell check.

Abbreviations change throughout the process and need to be checked. For instance, the abbreviation MD for Medical Devices becomes DM (which presumably stands for Dispositivos Mediciniais in Portuguese) in the Methods and Discussion sections. MS is an unreferenced abbreviation that appears in the introductory section, which I presume stands for the Ministry of Health (previously abbreviated as MoH). Please check all of these and standardize throughout. What is an ATS (line 209, p. 7)?

PLEASE COMMENT

Q 4 Is the title appropriate, concise, attractive?

It sparks interest but has a grammatical error (take out "the" before medical device technology evaluation).

Q 5 Are the keywords appropriate?

They are ok, but the words related to equipment and supplies are not really related to the article itself. Others that are more related to the review could be substituted.

Q 6 Is the English language of sufficient quality?

There are some problems that I have mentioned in the review. In the discussion section, the terminology, though grammatically correct, is not always understandable. Perhaps in trying to summarize some of the findings, they have paraphrased parts of the papers and left out some information. The discussion section needs major revision before this article can be published.

Q 7 Is the quality of the figures and tables satisfactory?

No.

Q 8 Does the reference list cover the relevant literature adequately and in an unbiased manner?

Yes. I think this is an important part of the contribution of this paper. They need to better present what they found in this list of articles and what it means, but the papers and the means of selecting them is methodologically sound and seems quite thorough.

Q 9 Does this manuscript refer only to published data? (unpublished data is not allowed for Reviews)

Yes.

Q 10 Does the manuscript cover the issue in an objective and analytical manner

Yes.

Q 11 Was a review on the issue published in the past 12 months?

No answer given.

Q 12 Does the review have international or global implications?

Yes.

QUALITY ASSESSMENT

Q 13 Quality of generalization and summary	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q 14 Significance to the field	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q 15 Interest to a general audience	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q 16 Quality of the writing	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

REVISION LEVEL

Q 17 Please take a decision based on your comments:

Major revisions.