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Medical Devices Evaluation: Aqualitative Investigation from the Validate Viewpoint

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Abstracts

Goals : Our aim was to investigate the procedures and techniques employed by health technology assessment (HTA) agencies in evaluating medical devices, as well as the perspectives of HTA professionals regarding suitable methodologies to pinpoint obstacles in the implementation of new assessment methods for devices. We concentrated on the significance of normative commitments among HTA practitioners in embracing new methods.

Methods: Members of the International Network of Agencies for Health Technology Assessment received an online survey that included questions about processes, scopes, and medical device assessments. Interviews were conducted with survey respondents and HTA practitioners involved in transcatheter aortic valve implantation assessments to acquire a thorough grasp of their decision-making and perspectives on medical device evaluation. Survey and interview questions were influenced by the "values in doing assessments of health technologies" approach to HTA, which asserts that HTA deals with value-laden questions and data.

Conclusions: There is widespread understanding that medical device assessments may require revisions to HTA methodology. To do this, the HTA community may need to engage in a discussion about the function, responsibilities, and aims of HTA, as well as make changes in institutional environment to adopt new approaches.

1. Introduction

Health technology assessment (HTA) seeks to assist decision-makers by evaluating the potential value of health technologies.As a result, HTA practitioners (those in charge of conducting assessments, including scoping, collecting, synthesizing, and interpreting available evidence) must identify evidence that can answer policy-relevant questions about the potential value of health technology, which necessitates making decisions about which information is reliable and relevant. Current talks about proper HTA technique for assessing (high-risk) medical devices indicate that this is a difficult undertaking (O'Rourke B, 2020).

Despite these demands to analyze medical devices differently, recent research has revealed that HTA authorities utilize comparable techniques when evaluating medicines and medical devices. Although practical factors like as capacity constraints and current regulatory frameworks contribute to this consistency, we contend that normative commitments of HTA bodies and practitioners also play a role. Inspired by the "values in doing assessments of health technologies" (VALIDATE) approach, which emphasizes that the relevance and meaning of evidence considered in HTA are determined by underlying values, we reasoned that both stakeholders' and HTA practitioners' value perspectives are useful in conducting assessments. This suggests that the operations of HTA agencies and practitioners are affected not only by established HTA principles, but also by practitioners' perspectives on how HTA might improve health technology results for society (Enzing, 2021;Torbica,2022).

To investigate the significance of these pledges, in addition to practical constraints, in the adoption of novel technique (e.g., real-world data, stakeholder involvement) for (high-risk) medical device assessments, we performed a survey and interview study with relevant HTA organizations. Our goal was to identify the present procedures and methodology employed by various HTA agencies, as well as to get feedback from HTA practitioners on the function of HTA, stakeholder involvement, and relevant evidence in HTA.

HTA methodology for medical devices:

Despite the acknowledged need for modifications in HTA approach for medical devices, HTA agencies continue to use methods created for medication evaluation and focus on analyzing clinical features (safety, effectiveness) and cost-effectiveness using quantitative data (Fuchs , 2017).

Current practice at HTA agencies does not fully reflect the expansion of who is involved (stakeholder involvement), what is assessed (which aspects of health technology), and which information is taken into consideration (e.g., real-world evidence, qualitative research), as suggested by VALIDATE and other groups of HTA experts.This gap is consistent with earlier findings from surveys and guidelines reviews. A recent analysis of entire HTA reports on TAVI for patients with low surgical risk, including the ones mentioned in this article, revealed a strong reliance on standard RCT data and clinical outcome metrics (Enzing , 2021; Ciani, 2015).

As previously noted in a study on real-world data policies for HTA of drugs, our findings contribute to these studies by highlighting the fact that, despite acknowledging the importance of other forms of evidence and methodologies, HTA practitioners adhere to established

epistemological principles (e.g., evidence hierarchy, risk of bias) that automatically devalue non-RCT data, thereby preventing it from influencing recommendations. The quality of real-world evidence utilized in HTAs of high-risk medical devices has also been criticized by HTA experts (Ming , 2022; Bluher , 2019).

The resistance to implementing new techniques for evaluating medical equipment may also be explained by some pragmatic considerations. It became evident from survey responses and interviewees that HTA practitioners are subject to time constraints, have to consider decision-makers' requests, and must follow current legal frameworks and HTA guidelines, which restricts their ability to try out novel approaches. As a result, HTA professionals require an institutional setting that is encouraging and acknowledges the significance of evolving medical device assessment methodology.

impact of changes in HTA methodology on decision- making:

The HTA community must have a conversation about the objectives, roles, and responsibilities of HTA as well as how to achieve them in order for HTA agencies to embrace a new approach for evaluating medical devices. Recognizing the implicit normative foundations of HTA procedures and techniques is part of this. For instance, we concur with interviewees that HTA's job is to teach the public about the usefulness of health technology, which calls for knowledge, procedures, and techniques that guarantee the data gathered is impartial (Torbica , 2022).

This does not, however, mean that HTA professionals must abstain from value judgments. HTA organizations and academics are realizing more and more that performing assessments necessitates making value judgments. Every assessment necessitates making value-laden decisions about what are appropriate methods and outcome measures to consider when evaluating a health technology, though this may vary to some extent depending on the HTA practitioner's mandate (e.g., working within a decision-making body or at an academic institute) (Pomey , 2020).

It is possible to consider whether current epistemic norms, such as rigorous adherence to a hierarchy of evidence, are still useful in carrying out the role of HTA in decision-making in light of this acknowledgment of the normativity of HTA. As methods advance, new avenues for acquiring trustworthy data on the impact of health technology become available, and HTA guidelines currently allow for some consideration of a variety of outcome measures. Together with the larger HTA community (those who use or are affected by HTA outcomes), HTA practitioners can investigate how this new methodology could aid in the evaluation of medical devices and increase the applicability of HTA (Tarricone , 2017).

2. Recommendations:

Although we were able to collect survey results and conduct interviews with HTA practitioners from seventeen different agencies, we cannot guarantee that we captured all of the variability in methodology and practitioner perspectives. Future research could strive to include more agencies from other locations and interview many practitioners at each agency. However, we are confident in the validity of our findings because they are consistent with the findings of prior studies on

HTA practice for medical devices and interviews with HTA practitioners regarding their perspectives on suitable methodology. By integrating surveys and interviews, we have gained a thorough understanding of why different approaches are employed.

Although we attempted to validate findings by exploring websites, published rules, and HTA reports of participating agencies, we were occasionally unable to access or comprehend material that was not (publicly) available.

3. Conclusion:

In Conclusion, Despite acknowledging the need for improvements in HTA technique for medical devices, HTA authorities continue to apply methodologies created for medication evaluation. Adoption of a new approach is hampered by practical issues (available capacity, current legislative frameworks, and HTA guidelines) as well as HTA practitioners' devotion to evidence-based medical principles. As a result, the adoption of new approaches at HTA agencies may necessitate a conversation within the HTA community about the duties, responsibilities, and goals of HTA, and how these might be accomplished through changes in methodology and institutional environment.

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