International Journal of Technology Assessment in Health Care

www.cambridge.org/thc

What can early HTA bring to needs-based innovation?

Joan Fibla-Reixachs

Hospital Clinic de Barcelona, Barcelona, Catalonia, Spain

Dialogue

Cite this article: Fibla-Reixachs J (2025). What can early HTA bring to needs-based innovation?. *International Journal of Technology Assessment in Health Care*, **41**(1), e46, 1–2
https://doi.org/10.1017/S0266462325100299

Received: 26 April 2025
Revised: 26 April 2025
Accepted: 11 May 2025

Keywords:
Early HTA; Health innovation; Needs based innovation; Efficiency; Technology assessment; Value-based health care; Decision making

Corresponding author:
Joan Fibla-Reixachs;
Email: fibla@recerca.clinic.cat

Abstract

This commentary examines how early health technology assessment can mitigate risks during the development of innovative technologies.

The recently accepted paper by Grutters, J., Bouttell, J. et al. in the *International Journal of Technology Assessment in Health Care* offers a valuable contribution to the evolving field of early Health Technology Assessment (HTA). In this commentary, I will explore their definition of early HTA from the critical lens of a *needs-based* perspective, as I was invited to do so by the article's authors.

Developing an innovative health technology differs from product development in other sectors as it has additional complexity brought by the high number of stakeholders involved, specific regulations, and market-access conditions. Traditionally, innovations were driven by new research discoveries that could be applied to healthcare, the so-called *technology push*. Over time, this approach has shifted toward a *needs-based* perspective, influenced by the spread of *design thinking* across other sectors, changing the paradigm to a *technology pull*. This process has been adapted to the life sciences sector specificities by Yock et al. through *Biodesign* (1).

Setting the need to be solved as the starting point and engaging with all the stakeholders involved in the development process has several advantages to make the development process more efficient by selecting technologies that will bring the highest value to society, tailored to a specific purpose, and integrating all the requirements and perspectives at stake. Currently, developers can rely on several tools and guidelines, such as the Health Innovation Cycle framework, developed by the European Institute of Technology (EIT) Health and the Consortia for Improving Medicine with Innovation & Technology (CIMIT) (2) which integrates technological, clinical, regulatory, and market-business aspects of the process.

HTA methodology allows measuring the value of a technology by comprehensively evaluating its impact, leading to value-based decision-making. As the authors state, HTA is often used to inform decisions about adoption or reimbursement. A crucial aspect of the authors' definition, which denotes the main characteristic of early HTA as a specific application of HTA methodology, is that it is conducted to "*inform decisions about subsequent development, research and/or investment.*" This aligns well with the principles of needs-driven innovation because it informs the developer of healthcare systems' needs.

In a context where the number of innovations and the expenses of healthcare systems are increasing continuously, and notified bodies as well as HTA agencies are overwhelmed, many innovations struggle to access the system and fulfil their ultimate goal of delivering value to their end-users. At the market-access stage, the development of a technology has already required a high investment of time and resources (3), and the opportunity cost of delaying its market access or receiving a unfavourable assessment result is enormous. Early HTA has the potential to make this process much more efficient. It opens the possibility to estimate the value and costs that a given technology would bring to the system before incurring the higher costs of later development stages, guiding development towards improving its cost-effectiveness rate. Just as the shift toward *needs-based* innovation, the incorporation of a health economics perspective at early stages of development has the potential to drastically change the innovative landscape of health technology. Payers and decision-makers responsible for healthcare systems are concerned about how to match their needs with new technologies, as denoted by horizon scanning programs (4) and initiatives such as the Innovative Devices Access Pathway in the UK (5), or the Catalan Health System innovation Access Program in Spain (6). Early HTA contributes to this connection between health systems and innovators to ensure that new health technologies effectively address real-world needs at an accessible price.

Defining 'early HTA' is essential for setting the foundation of the discipline and incentivizing research within the field. Therefore, the high level of consensus regarding the author's work is a remarkable milestone. The next steps needed are the standardization of methods for

performing early HTA along the development cycle of a technology. In their work, the authors emphasize the confusion between early dialogue, early awareness or early scientific advice, and the timing of early HTA and provide some explanations regarding what early HTA can and cannot do. They also notice that its purpose is to guide innovators through the development process and identify the key parameters that will influence cost-effectiveness rather than providing an answer to the future adoption or reimbursement decision to be made, as it is well-known that HTA needs to be adapted to each context to ensure value (7), and early HTA will not be able to replace full HTA performed by HTA agencies. However, it is a great opportunity for the scientific community to align data generation along the developmental process with market-entry information requirements. Early HTA can simplify future adaptations recommended by HTA agencies in early scientific advice, reducing the risk of developers finding themselves in uncomfortable positions, such as lacking relevant data for assessment. Incurring the cost of developing additional studies to generate high-quality evidence to demonstrate the value of a technology has an impact on its final price, jeopardizing its cost-effectiveness ratio. Performing early HTA analysis also allows innovators to target cost-effectiveness thresholds to be reached and assess their probabilities of success by incorporating uncertainty. This is especially relevant for stakeholders incurring sunk research costs for whom risk assessment is crucial in making informed decisions.

Overall, the authors' work contributes to the field of early HTA, a field that generates a common ground for developers and evaluators in an exercise of transparency and trust. Although this commentary primarily analyses economic implications, early HTA also includes guidance in other domains, such as patients' and healthcare practitioners' perspectives, which are often the first to be interested in bringing innovations to market, as most technologies target their needs. Guiding innovation to be prepared for a full HTA streamlines the innovation process, leading to faster and cheaper available technologies. Ultimately, building a more efficient innovation ecosystem benefits society as a whole.

Disclaimer. The views expressed in the paper are those of the authors and not their employers.

Funding statement. This work was not supported by any funding.

Competing interests. The author declares no relevant financial or nonfinancial interests to disclose.

References

1. **Yock PG**, **Zenios S**, **Makower J**, et al. *Higher education from Cambridge University Press*. Cambridge: Cambridge University Press; 2015 [cited 2025 Mar 18]. Biodesign: The Process of Innovating Medical Technologies. Available from: https://www.cambridge.org/highereducation/books/biodesign/F71806C33C7BFA8C1B9A5660F68B2858.
2. **EIT Health** [Internet]. A Framework for Innovation in Healthcare. [cited 2025 Mar 19]. Available from: https://eithealth.eu/a-framework-for-innovation-in-healthcare/.
3. **Knowledge Portal** [Internet]. R&D costs. [cited 2025 Mar 19]. Available from: https://www.knowledgeportalia.org/costs-r-d.
4. **Vogler S**. "Ready for the future?" – Status of national and cross-country horizon scanning systems for medicines in European countries. *GMS Ger Med Sci*. 2022 Mar 31;**20**:Doc05.
5. **GOV.UK** [Internet]. The Innovative Devices Access Pathway (IDAP) - pilot phase. [cited 2025 Mar 19]. Available from: https://www.gov.uk/government/publications/the-innovative-devices-access-pathway-idap/the-innovative-devices-access-pathway-idap-pilot-phase.
6. **Learn about the Healthcare System Access Program (PASS)** [Internet]. [cited 2025 Mar 19]. Available from: https://www.biocat.cat/en/access-catalan-health-system.
7. **Nemzoff C**, **Ruiz F**, **Chalkidou K**, et al. Adaptive health technology assessment to facilitate priority setting in low- and middle-income countries. *BMJ Glob Health* [Internet]. 2021 Apr 26 [cited 2025 Mar 19];**6**(4). Available from: https://gh.bmj.com/content/6/4/e004549.