Existing HTA methodology for Digital Health Technologies (DHTs): A review of the literature, HTA Frameworks for DHTs and HTA Reports

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Research motivation

The European Digital Health Technology Assessment (EDiHTA) consortium aims to develop the first flexible, inclusive, validated and ready-for-use European HTA framework for different digital health technologies (DHTs). The design and innovative features of EDiHTA are detailed in Figure 1.

However, before a framework can be developed. It is important to understand what is currently being done. The aim of this review was to identify, analyse and summarise existing methodological approaches, guidelines, and best practice for the assessment of DHTs.

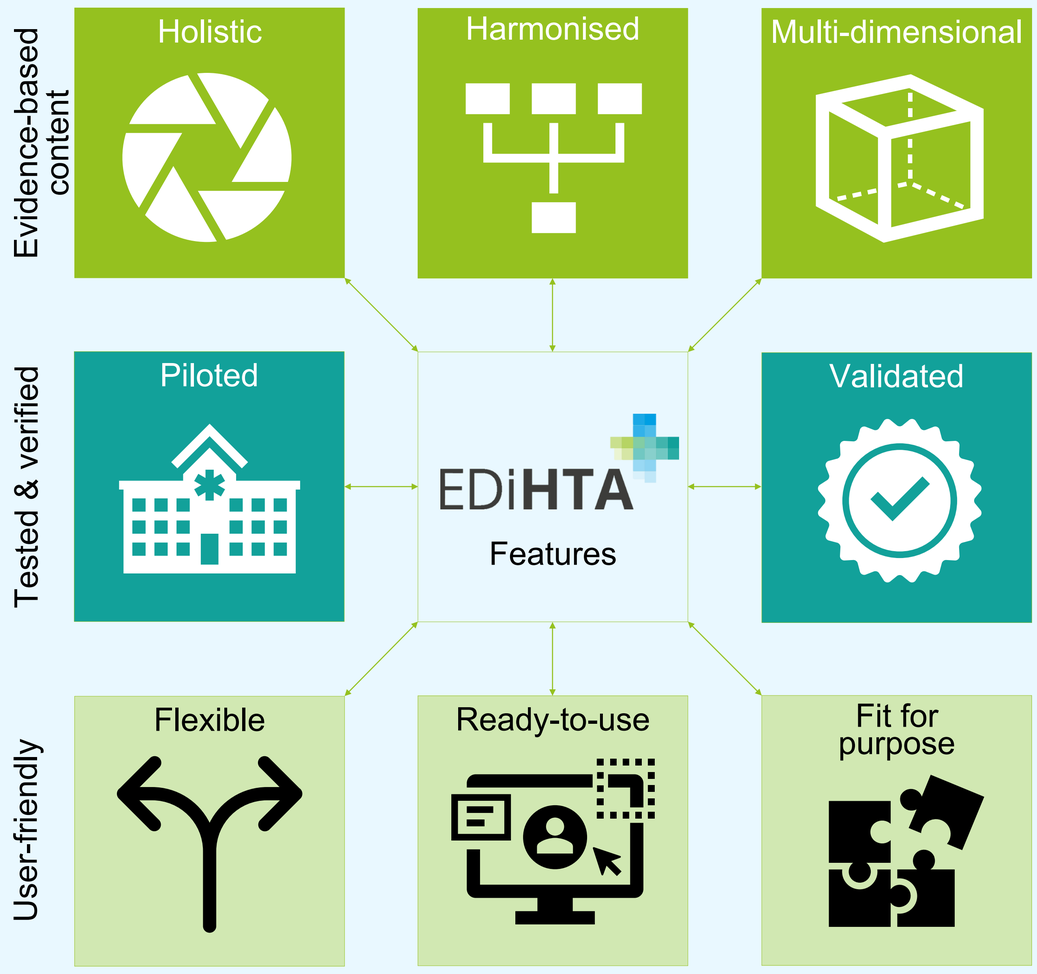
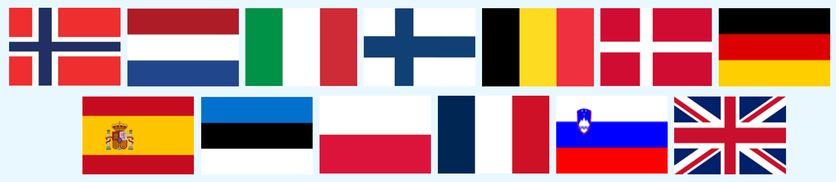


Figure 1 (above). Innovative features of EDiHTA. EDiHTA is a 4-year Horizon Europe Research and Innovation Action. The project is ongoing, it began January 2024 and will conclude December 2027.
Figure 2 (below). The 13 European countries selected for the review of DHT assessment frameworks from HTA agencies.



Methods

This review had 3 parts. Data was extracted across all 3 parts into a template based on the domains, dimensions, and subdimensions in the AQuAS DHT framework.[1]

A review of the literature
- Updating of a review by AQuAS published in 2022
- Search run in MEDLINE ALL and Embase

A review of DHT assessment frameworks from HTA agencies
- Documents needed to be specific to DHTs
- A sample of 13 European countries

A review of DHT HTA reports
- Reports from HTA agencies that are assessing DHTs
- Purposeful selection from agencies across Europe

Results

- Literature review: 8,171 unique studies were identified in the search, and a further 3 were identified via citation searching. Ultimately, 11 studies met eligibility and were included.
- HTA frameworks: Of the 13 European countries the consortium selected, a total of 11 HTA documents from 7 countries (UK - England, UK - Scotland, Spain, Finland, Germany, France, Belgium) were identified.
- DHT HTA Reports: A total of 20 reports were reviewed across 5 broad categories: 1) population health 2) DHTs used by patients for treatment 3) DHTs used for monitoring a condition 4) DHTs that include AI 5) DHTs used by healthcare professionals to manage workload or services.

Key findings

No additional domains beyond the 13 of the AQuAS framework (1 – Health problem; 2 – Technology; 3 – Content; 4 – Safety; 5 – Clinical efficacy and effectiveness; 6 – Economic; 7 – Human and sociocultural; 8 – Ethical; 9 – Legal and regulatory; 10 – Organisational; 11 – Technical; 12 – Environmental; 13 – Post-deployment monitoring) were identified in the literature, HTA frameworks, or HTA reports. However, the extent to which the 13 AQuAS domains were used varied, with some areas more frequently used and other areas used less. The domains of the AQuAS framework that are also part of the EUnetHTA core model[2] were used more frequently than domains in the AQuAS framework that were not part of the EUnetHTA core model[2] (content, technical aspects environmental and post-deployment monitoring).

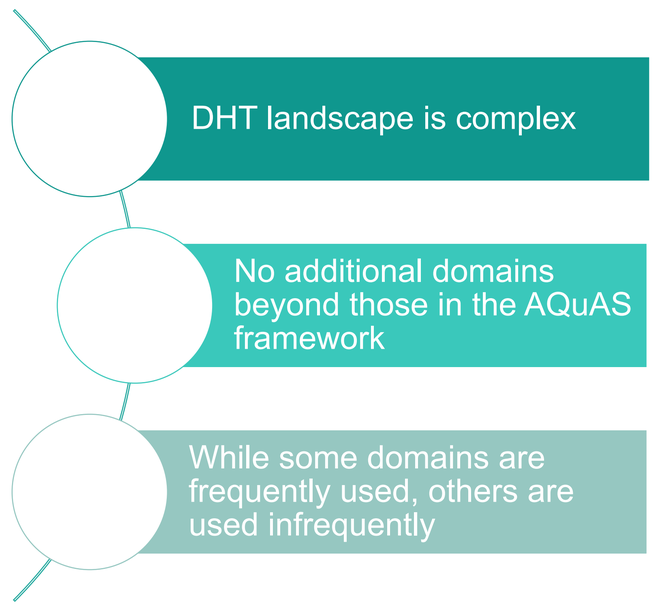


Figure 3. Main findings

Conclusion and outlook

This is the first review to look at the literature, HTA frameworks and HTA reports simultaneously. The review reinforces the fact that the DHT landscape is complex. Based on this analysis, we have identified that the EUnetHTA Core model with the added elements of the AQuAS framework represent an appropriate starting point for considering the domains, dimensions and subdimensions for HTA of DHTs.

The next step in the project will be to determine which domains, dimensions and subdimensions should ultimately be included in the EDiHTA framework. After this, the framework will be piloted. These pilots will provide evidence of the usability of the framework, ensuring that the framework is not just well designed, but that it is useful and usable and can be implemented by all relevant stakeholder groups.

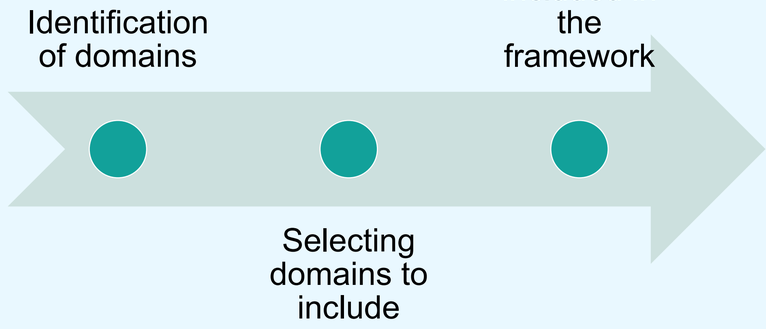


Figure 4. Next steps

References
1. Segur-Ferrer J, Moltó-Puigmartí C, Pastells-Peiró R, Vivanco-Hidalgo RM. Health Technology Assessment Framework: Adaptation for Digital Health Technology Assessment.; 2023. Available from https://aquas.gencat.cat/web/.content/minisite/aquas/publicacions/2023/framework-adaptation-digital-hta-redets-aquas2023.pdf
2. EUnetHTA Joint Action 2, Work Package 8. HTA Core Model ® version 3.0 (Pdf); 2016. Available from www.htacoremodel.info/BrowseModel.aspx.

EDiHTA consortium

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