HTA37

Digital Health Value Assessment Frameworks: An International Landscape

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Objective

To analyze the Institute for Clinical and Economic Review-Peterson Health Technology Institute (ICER-PHTI) framework, published in September 2023, alongside other national value assessment frameworks to define the landscape for national digital health technology value assessment frameworks.

Background

- An increasing number of healthcare payer systems are now reimbursing digital health technologies (DHTs).[1] However, the nature of these technologies, including the difficulty in running robust randomized controlled trials (RCTs), necessitates tailored value assessment frameworks (VAFs) to ensure appropriate evaluation.[2] These challenges in evidence generation are not addressed by traditional health technology assessments (HTAs), and so there is a lack of appropriate guidance for the evaluation of DHTs.[1–4] Recently, the Institute for Clinical and Economic Review (ICER) and the Peterson Health Technology Institute (PHTI) published a novel DHT framework to support rigorous evaluation in the USA.[5]

Methods

- Targeted searches were conducted in November 2023 to identify relevant frameworks specifically tailored to support the value-based evaluation of DHTs. VAFs of all countries were eligible. Only frameworks for which the guidance was publicly available were included. Based on the content of the identified frameworks, an extraction grid was created that covered seven domains and 31 subdomains (**Table 1**). Data from each VAF were extracted from all domains by a single reviewer, and reviewed by a second. If any uncertainties remained, these were resolved by a third reviewer.

Results

- A total of seven VAFs from the USA (ICER-PHTI),[5] Germany (DiGa),[6] France (PECAN),[7] the UK (NICE DHT ESF and DTAC),[8,9] Finland (FINCCHTA Digi-HTA)[10] and Australia (mHealth Assessment Framework)[11] were analyzed (**Table 1**). All included a requirement for DHTs to adhere to data privacy laws and for submission of safety and clinical efficacy evidence. However, evidence requirements, including the need for an RCT, varied; Germany and UK VAFs were also the only to specifically reference acceptance of real-world evidence. The USA VAF detailed budget impact model (BIM) requirements, whilst the UK VAF noted both BIM and cost-effectiveness modeling requirements; all other VAFs did not include health-economic modeling requirements. Consideration of health inequalities, environmental sustainability, and DHT usability were also inconsistent across countries.

Conclusion

- Information on data security, clinical efficacy, and safety are universally required by national VAFs. The US (ICER-PHTI) VAF covers a broad range of domains, including BIM requirements, suggesting a robust framework.
- Only the UK considers more domains by employing two complimentary frameworks to support DHT evaluation (ESF and DTAC).
- Differences between national VAFs may introduce country-specific complexities for DHT adoption, which could be mitigated by manufacturers developing evidence to meet the most robust VAFs.

TABLE 1

Domains and sub-domains assessed in seven national digital health technology value assessment frameworks

Domain	DiGa	FINCCHTA Digi-HTA	ICER-PHTI	mHealth Assessment	NICE DHT ESF + DTAC	PECAN
	Number of sub-domains assessed per framework					
Role in care ♦ Purpose of DHT ♦ Target population ♦ Description of landscape ♦ Reliability and usability of health information ♦ Credibility among HCPs ♦ Other	3/6	3/6	3/6	4/6	6/6	3/6
Privacy and data security ♦ User control over PHI ♦ Compliance with laws and regulations ♦ Risk management and data security	3/3	2/3	2/3	3/3	3/3	2/3
Technology assessment ♦ Design ♦ Update to Technical Performance ♦ Real-world deployment ♦ Environmental considerations ♦ Protection for vulnerable groups ♦ Communication with users ♦ Dataset and/or algorithm requirements ♦ Other	4/8	5/8	0/8	4/8	8/8	4/8
Developer assessment	0/1	0/1	1/1	0/1	0/1	0/1
Clinical impact ♦ Description of evidence required ♦ User experience/usability ♦ Safety ♦ Effectiveness ♦ Safety and effectiveness per evidence tier ♦ Health equity ♦ Professional oversight ♦ RWE ♦ Impact measures ♦ Other	6/10	4/10	6/10	4/10	10/10	5/10
Economic impact ♦ Description of evidence required ♦ Budget impact ♦ Cost-effectiveness ♦ Other	0/4	1/4	3/4	0/4	3/4	1/4
Final analysis or recommendation	0/1	1/1	1/1	1/1	0/1	1/1

Abbreviations: BIM: Budget Impact Model; CE: Conformité Européenne; DHT: Digital Health Technology; DiGa: Digitale Gesundheitsanwendungen; DTAC: Digital Technology Assessment Criteria; ESF: Evidence Standards Framework; FINCCHTA: Finnish Coordinating Center for Health Technology Assessment; HCP: healthcare professional; HTA: health technology assessment; ICER: Institute for Clinical and Economic Review; PECAN: Prise en Charge Anticipée Numérique; PHI: personal health information; RCT: randomized controlled trial; RWE: real-world evidence; UKCA: United Kingdom conformity assessed.

Points of interest

Role in care
- VAFs from the UK, Finland and Australia required HCP involvement in the design of the application, to ensure usability and credibility.

Privacy and data security
- All VAFs required compliance with (inter)national laws and regulations such as CE/UKCA marking or privacy acts. Consistency between VAFs in the privacy and data security domain indicated the importance of this area.

Technology assessment
- The only VAFs to consider environmental sustainability were the UK VAFs.

Clinical impact
- VAFs from the USA and UK specifically considered aspects of health inequalities, including the need to consider equity within the design of DHTs.
- Despite growing interest in the use of RWE to support evidence generation activities, only the UK and Germany VAFs mentioned the acceptability of RWE. Whilst RWE may be considered within other frameworks, this appears to be a striking omission given the evidence generation challenges for DHTs.
- The USA VAF specifically called out the requirement for RCTs for some DHTs, depending on their category.
- Whilst the UK VAFs noted a preference for RCT evidence where appropriate, high quality real-world study designs were also acceptable.
- The Germany VAF noted minimum evidence requirements of a retrospective comparative study, although higher evidence levels were welcomed.

Economic impact
- Only the USA and UK VAFs required economic evaluations. A number of other countries will have pricing negotiations, but there is no methodology to determine economic value in these instances.
- The USA VAF only focused on budget impact, whilst the UK VAF considered both budget impact and cost-effectiveness.

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Acknowledgements: The authors thank Melanie Howes, Costello Medical, for graphic design assistance.

Presented at ISPOR International 2024 | Atlanta, GA, US | 5–8 May