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Developing a health technology assessment framework for digital health technologies in Singapore

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Introduction

Digital health technologies (DHTs) are increasingly relevant in the global and local clinical practice to meet the growing demand for healthcare innovations. However, their rapid iteration, frequent lack of high-quality evidence, and additional technical domains such as cybersecurity, good data practice and user acceptability, pose challenges to conventional health technology assessment (HTA) frameworks.

The Agency of Care Effectiveness (ACE) is developing a DHT-specific HTA framework, which intends to be pragmatic but sufficiently robust to inform government funding decisions on DHT. It may also serve as a reference for public healthcare institutions and industry on the evidence standards for DHT from the HTA perspective.

Methods

The HTA framework for DHT was developed through a multi-pronged approach as shown in **Figure 1**. The key overseas DHT evaluation frameworks referenced are (i) the National Institute for Health and Care Excellence (NICE)'s Evidences Standards Framework for DHT (2022) and (ii) the Institute for Clinical and Economic Review-Peterson Health Technology Institute (ICER-PHTI) Assessment Framework for DHT (2023).

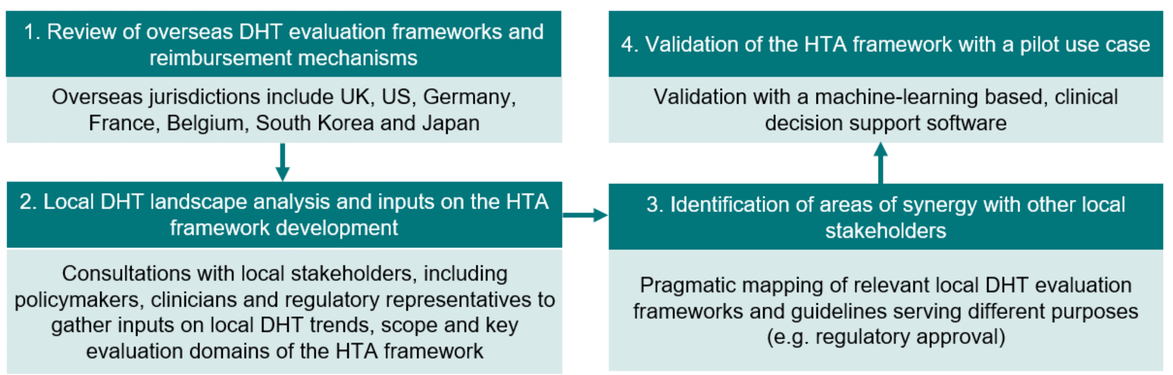

Figure 1. Overview of key steps in developing ACE's DHT HTA framework.

Results

DHTs can be classified into eight groups according to their primary health purpose in the order of increasing clinical risk to an individual (**Figure 2**).

The scope of the draft framework includes DHTs meeting all the criteria below:

- Registered with the Health Sciences Authority (HSA), primarily software as a medical device;
- Associated with higher clinical risks (Groups 4 to 8 DHTs in **Figure 2**);
- Patient-focused; and
- High cost per patient and/or high budget impact.

DHT grouping	Group 1	Group 2	Group 3	Group 4	Group 5	Group 6	Group 7	Group 8
Type of DHTs by health purpose	Whole-of-system level for health administration	General health and well-being	General population-based screening	Clinical data tracking (primarily consumer-facing)	Predictive or prognostic tool	Clinical monitoring (primarily healthcare professional-facing)	Diagnosis	Therapeutics
Description	Non-health system software, health system operational software, health system clinic software	Wearable personal fitness trackers, mobile apps purchased by consumers	Artificial intelligence for image reading for breast or lung cancer screening	DHTs that support patient self-management	DHTs that are used to estimate the future health trajectory of a person	DHTs that are used to measure progression or recurrence of disease	DHTs that are used to confirm, characterize, or measure the features of a specific health condition	DHTs that are intended to directly improve health outcomes

Increasing clinical risk to an individual

Figure 2. DHT classification by primary health purpose.

Table 1. Clinical evidence standards based on DHT classification.

Primary health purpose	Evidence standards
DHTs for therapeutic purposes *(Group 8 DHTs)*	• High-quality RCTs (preferred) or comparative real-world studies to demonstrate impact of the DHT on: o Patient or clinically relevant outcomes o Health system outcomes • The intervention should be compared to the comparator that is most likely to be replaced in the local clinical practice and is typically the current standard of care for the health condition being reviewed.
DHTs for diagnostic purposes *(Group 7 DHTs)*	• Observational studies to demonstrate: o Diagnostic-related outcomes (e.g. test accuracy against a valid reference standard, or concordance with standard practice) o Impact of the DHT (e.g. time to diagnosis, resource utilisation) • Linked evidence preferred, demonstrating the linkage between test accuracy and subsequent patient or clinically relevant outcomes
DHTs for predictive or prognostic purposes *(Group 5 DHTs)*	• Prospective observational (preferred) or retrospective follow-up studies to demonstrate the ability of the DHT to provide predictive or prognostic information over time
DHTs for clinical data tracking or clinical monitoring *(Groups 4 or 6 DHTs)*	• Observational or real-world evidence to demonstrate the impact of the DHT on: o Change in behavioural or relevant clinical or system outcomes • For DHTs which may directly impact therapeutic or diagnostic decisions, the respective evidence standards highlighted above may apply

The draft framework comprises six key evaluation domains (**Figure 3**).

- Technology design assesses whether the DHT meets technical standards for safety and reliability in the local context.
- Clinical evidence standards are commensurate with the DHT's primary health purpose and clinical risk (**Table 1**). Adherence to these standards is especially important for DHTs targeting serious or critical conditions, where inaccurate information or ineffective use can lead to significant harm.
- Budget impact analysis (BIA) is the primary method for assessing the value of DHTs, as many DHTs are perceived to improve care at lower costs compared to existing alternatives.
- Economic evaluation may supplement BIA when the DHT offers superior health outcomes at a higher cost, considering factors such as scale of use and implementation costs.
- Performance monitoring allows the measurement of the DHT's performance post implementation, particularly important for DHT with adaptive algorithm that is expected to change over time.
- Organisational feasibility assesses contextual barriers and enablers for DHT deployment and uptake.

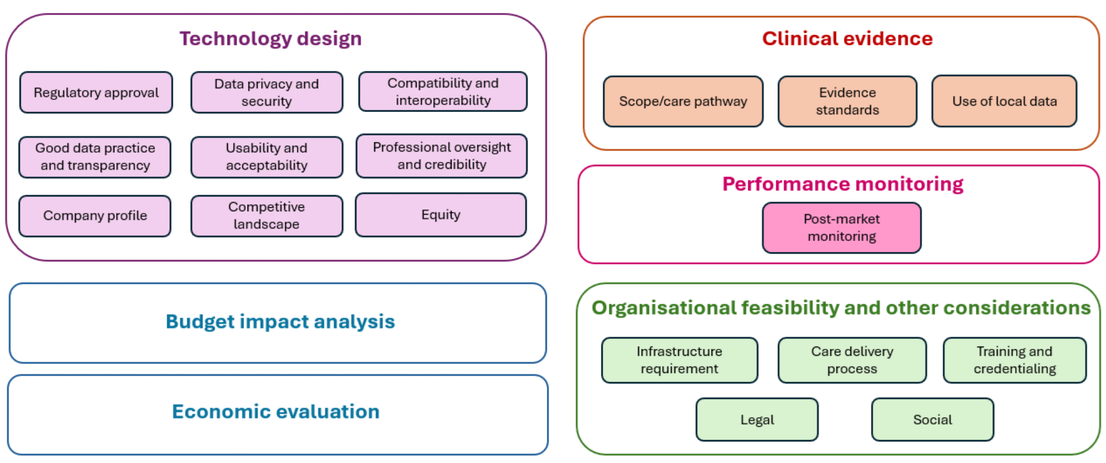

Figure 3. Overview of the HTA domains for DHT.

Discussion

- The HTA framework for DHT will be reviewed periodically to ensure its continued relevance based on insights from future DHT evaluations, the evolving DHT landscape, stakeholder feedback, and emerging international DHT evaluation practices.

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