Assessing the value of digital health tools: A comparison of methods used by the PHTI and NICE

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Introduction

In 2024, the Peterson Health Technology Institute (PHTI) began evaluating the clinical and economic value of digital health technologies (DHTs) in the US, publishing reports on the value of digital diabetes management tools and virtual musculoskeletal (MSK) solutions. This marked the first time that DHTs have been assessed through a centralised health technology assessment (HTA) process in the US. Since 2009, DHTs have been assessed in England through the National Institute for Health and Care Excellence (NICE) Medical Technologies Evaluation Programme (MTEP). Conducting a formal comparison of these two assessment programmes could uncover potential synergies and translatable insights applicable to both systems, which may be valuable for DHT manufacturers pursuing market access in the UK and US.

Objectives

This study aimed to compare the HTA methods used by NICE and PHTI for evaluating DHTs. It sought to:

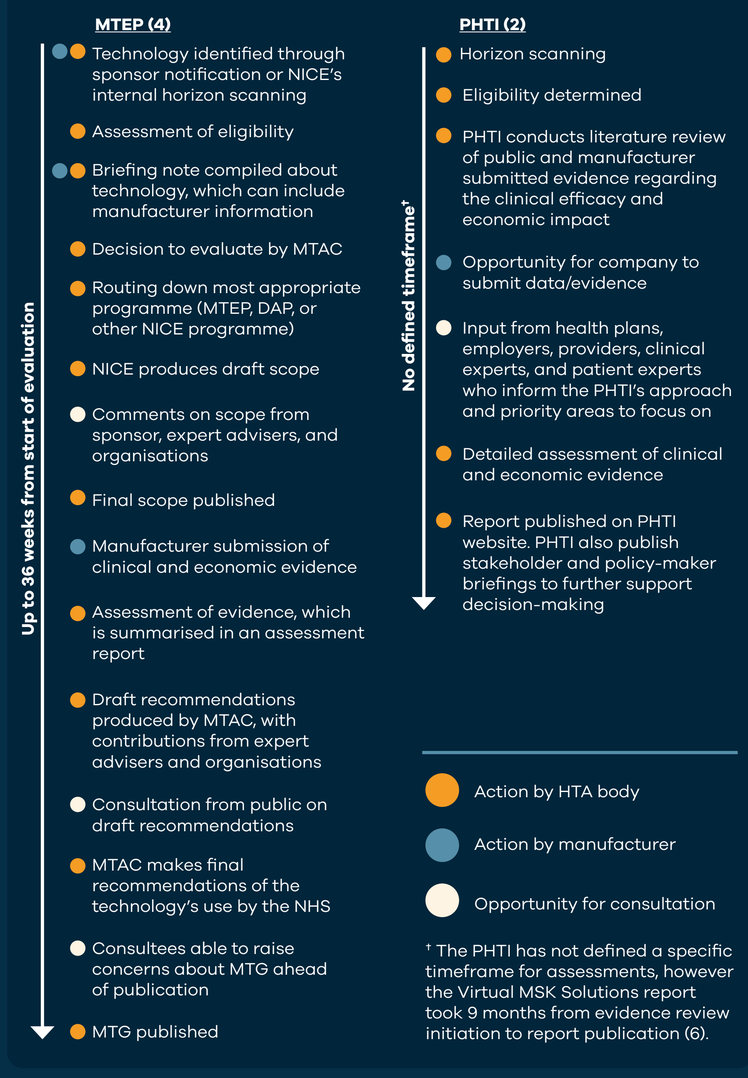
1. Describe the stages of each assessment process, from DHT identification to report publication and onward decision-making
2. Compare and contrast key aspects of the HTA methodology and approach
3. Understand the similarities of PHTI's process to established processes used by NICE, and how this may impact perception of the PHTI
4. Discuss the potential impact of the findings on DHT manufacturers in either country

Results

NICE and PHTI's assessments are rich sources of information tailored to the needs of the UK and US healthcare systems, respectively, and are designed to resonate with payers. Assessment reports are highly useful to all DHT manufacturers, as it enables them to understand the principles of how their evidence base will be perceived by HTA bodies, as well as how to communicate that their technology meets the needs of the healthcare system. Key similarities identified included horizon scanning to identify impactful technologies warranting assessment, evaluation of comparative clinical efficacy and economic impact, multiple opportunities for stakeholder and manufacturer engagement, and a shared goal to improve health outcomes and recommend cost-effective technologies (2-5).

Key areas of contrast were that MTEP promoted faster uptake of new medical technologies (including DHTs), whereas PHTI produced evidence-based reports to guide stakeholder decision-making; NICE relied on manufacturer-initiated submissions, whilst PHTI conducted its own analyses; NICE conducted cost-effectiveness and cost-consequence analyses, whereas PHTI assessed the budget impact of the technology and published threshold price ranges at which the DHT would produce cost savings compared with standard of care (Table 1). In addition, the scope of the MTEP also included medical devices (MDs), and the process of the MTEP contained more stages due to the various consultation phases (Figure 1) (2-5).

Figure 1: A comparison of the assessment process used by NICE and PHTI (2-4)



† The PHTI has not defined a specific timeframe for assessments, however the Virtual MSK Solutions report took 9 months from evidence review initiation to report publication (6).

The MTEP process has proven to enhance access to innovative DHTs in the UK. Therefore, similarities between the PHTI's approach and NICE's well-established MTEP process can enhance credibility of the PHTI's approach as a new HTA body.

Table 1: A comparison of key HTA domains used by NICE and PHTI for assessing DHTs

	NICE	PHTI
Aim	MTEP promoted faster uptake of new medical technologies (including DHTs) in the NHS; fostered collaborative research between industry and the NHS to generate clinical utility and/or healthcare system benefits	Set evidence standards to support manufacturers in generating robust evidence for DHTs through the development and publication of evidence-based reports; supported decision-makers and payers in adopting DHTs with improved outcomes and cost savings
Topic selection	Identified by NICE via horizon scanning or manufacturer notification	Identified via horizon scanning and Purchaser Advisory Council (including health plans, employers, and providers). Other factors influencing selection included market relevance, disease burden, level of spend and claimed savings, and evidence quality and availability
Types of technology assessed	UKCA marked or equivalent innovative MDs or diagnostic technologies, including those with digital components	Technologies compliant with the FDA's DHT definition, including software as an MD and AI technologies
Clinical evidence assessment	Demonstrated measurable benefits to patients and the NHS compared with comparators in clinical efficacy, effectiveness, user experience, and safety	Demonstrated that DHT is favourable compared with comparators in safety and efficacy, user experience, and health equity considerations. PHTI computed overall evidence rating based on the level of certainty in the evidence, the comparative clinical effectiveness, and comparative net health benefit
Economic evidence assessment	Cost-effectiveness and cost-consequence analyses showing NHS cost savings or a reduction in healthcare utilisation	Budget impact analysis showed that the DHT is favourable compared with comparators; identified a threshold price at which the DHT would produce cost savings over standard of care
Evidence submission and manufacturer engagement	Manufacturers submit evidence, draft recommendation is public for comment before final MTG publication	PHTI conduct an independent review of publicly available published research and information submitted by manufacturers, however it is not a requirement for manufacturers to engage with the PHTI or submit evidence. During the assessment process, PHTI partners with clinical advisers, experts in HTA, and health economists to evaluate the evidence
Outcome/ recommendations	Published in the MTG on the NICE website. Final recommendations include: • Technology recommended for use • Use with conditional circumstances • Use within research • Not recommended The MTG recommend whether the technology should be reimbursed in the NHS but this is not legally binding	Published as an HTA report on the PHTI website. Final recommendations include: • Evidence inadequate to support field testing • Evidence adequate to support field testing in broader populations • Evidence adequate to support wide adoption Final recommendation is non-binding but can be used by payers to inform DHT purchasing decisions
Decision criteria	Benefit to patients and NHS over current technologies; demonstration of cost effectiveness and improved health outcomes	Considered the market relevance, disease burden, claimed savings, and evidence quality and availability

Methodology

Adapting the framework for evaluating and comparing HTA processes from Drummond et al (2008) (1), a targeted literature review of public documents was conducted on core HTA dimensions used by NICE and PHTI, including the following:

- The structure of HTA programmes, including the aims and scope of the assessment
- Methods, including clinical evidence and economic evidence assessment approaches
- Processes, including stakeholder engagement and implementation of findings
- Use in decision-making, including the communication of results, and link between results and decision-making processes

Conclusion

Robust methods for assessing the value of DHTs can support efforts to manage healthcare expenditure and ensure value for money, yet manufacturers face challenges in establishing a robust evidence base to support adoption of their technology (7). Manufacturers may find NICE and PHTI's assessments useful for navigating evidence generation, and ensuring that the evidence collected will be accepted by HTA bodies and payers. Companies can leverage their assessment outcome to refine their evidence strategy and communicate any positive recommendations from PHTI to payers.

The outputs from the PHTI assessment could also inform the manufacturer's approach to assessment via MTEP. Manufacturers who have progressed through the MTEP pathway will be in an optimal position to engage with the PHTI if their technology is selected for assessment, with the benefit of having already assimilated their evidence base. As the PHTI increases its prominence and influence, understanding the similarities and differences of its approach compared with well-established processes used by NICE may enable technology developers to apply translatable insights from both assessment processes to enhance their evidence generation and market access strategies.

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Scan to see video walkthrough and references

Abbreviations

AI, artificial intelligence
DAP, Diagnostics Assessment Programme
DHT, digital health technology
FDA, Food and Drug Administration
HTA, health technology assessment
MD, medical device
MSK, musculoskeletal
MTAC, Medical Technologies Advisory Committee
MTEP, Medical Technologies Evaluation Programme
MTG, Medical Technologies Guidance
NHS, National Health Service
NICE, National Institute for Health and Care Excellence
PHTI, Peterson Health Technology Institute
UKCA, United Kingdom Conformity Assessment