The Challenges Medical Device Technologies Pose to Health Technology Assessment Methods and Implications for the Evaluation of Future Digital Devices

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OBJECTIVES: Health technology assessment (HTA) is an established process for aiding reimbursement decisions for pharmaceutical agents and is increasingly used for medical device technologies (MDT). MDTs utilizing digital and artificial intelligence (AI) technologies are more complex than standard MDTs and may present further challenges in assessments. Our aim was to review challenges identified in the current methods for HTA for MDTs compared to pharmaceutical agents and to determine their relevance to digital/AI MDTs.

METHODS: PubMed and grey literature were searched in December 2021 to identify reports published in the previous 5 years evaluating methods for the HTA of 1) biomedical devices and medical technologies, and 2) digital/AI MDTs. Search terms included medical technologies, medical device, artificial intelligence, health technology assessment, methods, economics, and cost-benefit analysis.

RESULTS: Our searches identified 90 articles for MDTs and 183 for digital/AI MDTs, of which 14 and 6, respectively, were relevant for full text review. Most of the study designs were HTA-specific targeted literature reviews (TLRs) (7) and systematic literature reviews (SLRs) (6). The remaining surveys consisted of expert opinion, case studies, and a structured review.

In recent years, unique challenges that MDTs have posed to HTA methods traditionally used for pharmaceutical agents have included: MDT intrinsic properties, incremental innovations, lower quality/non-RCT/observational clinical evidence base, existence of a learning curve, dynamic pricing, and organizational impact (**Table 1**).

New challenges identified in the literature for digital/AI MDTs, which build upon those recognized for MDTs, include (**Table 2**):

- Increased speed of development and incremental innovations, more complex clinical pathways, and multiple indications per device, which augment the complexity of economic evaluations
- Increased difficulty in the determination of associated utility and costs
- The potential for greater variation in the real-world use of digital/AI MDTs from clinical trial populations/settings, necessitating further reliance on RWE data from real-world cohorts
- New ethical and legal implications

CONCLUSION: New digital/AI devices are associated with unique additional challenges for HTA methods compared to those already recognized for MDTs. As the technology and supporting evidence increase in complexity, subsequent economic evaluations will need to adapt. Moreover, the faster pace of incremental innovations will challenge the pace of change in HTA methods. There is a need for specific tools for critical evaluation of MDT-specific evidence and greater formal methodologic guidance for the appraisal of MDTs by HTAs.

Table 1. Challenges posed to HTA methods by MDTs

MDT challenges	Description of challenges
Intrinsic properties of MDT	• Each MDT has unique intrinsic properties; challenges posed to HTA differ across types/categories of MDT (Basu, 2019) • Inadequate consideration of intrinsic properties in HTA can result in inaccurate estimates of cost-effectiveness of the device (Polisena, 2018)
Incremental innovations	• Constant improvement in MDTs are associated with numerous variables (shorter lifecycle, potential increase in maintenance or update frequency, and potential dependency on the industry's use of other MDTs) (Polisena, 2018) • It is difficult to establish when incrementally improved MDTs require reassessments and to what degree the reassessment should be completed (Bluher, 2019) • Due to incremental innovations, MDT version(s) being evaluated may differ in countries considered early adopters vs late adopters (Daubner-Bendes, 2020)
Evidence base	• Compared to drugs, regulatory approval of MDTs relies on a lower quality evidence base (non-randomized controlled trials [RCT], real-world evidence [RWE], smaller patient numbers) (Ciani, 2017; Campbell, 2018; Borsci, 2018) • Low-quality evidence generated for MDTs and lack of long-term data impact the HTA process from scoping to evidence development for reimbursement (Campbell, 2018; Federici, 2021; Crispi 2019; Schnell-Inderst, 2018) • RWE may not be transferable across jurisdictions due to patient heterogeneity, local factors, and differences in healthcare systems (Daubner-Bendes, 2020) • Evidence synthesis for economic evaluation is challenging, particularly to support appraisals across multiple indications (Borsci, 2018; Schnell-Inderst, 2018) • The utilization of early dialogues with HTA agencies is not common for MDT, missing an opportunity to improve the evidence base (Blankart, 2021)
Learning curve	• Safety and effectiveness of MDTs depend on a practitioner's ability, previous training, and health systems' acceptance of MDT (Daubner-Bendes, 2020) • User learning curve is a key criterion that should be included in economic models of MDTs (Bluher, 2019), along with the extended learning curve associated with ability to properly use MDTs (Polisena, 2018) • Evaluations should consider the level of risk involved with the potential improper use of MDTs, which have a high learning curve (Basu, 2019)
Pricing	• MDT pricing is more dynamic than drugs, as incremental innovations and new/updated MDTs impact the price of current MDTs (Tarricone, 2017b; Daubner-Bendes, 2020) • The initial investment that accompanies MDTs may outweigh clinical benefits that are generally seen over the long-term (Bluher, 2019)
Organizational impact	• Compared to drugs, MDTs require a heightened level of training, which involves an increased investment in an organization's resources (Polisena, 2018) • The ability to use an MDT and associated costs may vary across departments, specialties, and practitioners, thus potentially affecting patient outcomes (Borsci, 2018; Daubner-Bendes, 2020) • HTA reports often highlight issues associated with MDTs that arise within an organization, but do not evaluate their clinical and economic impact (Bluher, 2019; Borsci, 2018; Tarricone, 2017b; Ciani, 2017)

Abbreviations: AI, artificial intelligence; HTA, health technology assessment; MDT, medical device technologies; RCT randomized controlled trial; RWE, real-world evidence; SLR, systematic literature review; TLR, targeted literature review

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Table 2. Further challenges posed to HTA methods by digital/AI MDTs

Digital/AI MDT challenges	Description of challenges
Rapid development of new digital/AI MDTs or incremental innovations	• Healthcare systems may not have the ability to implement digital/AI MDTs due to lacking data and technology capabilities (Alami, 2020) • It may be difficult to define appropriate comparators for economic analyses of new digital/AI MDTs (Wolff, 2020) • Adoption of regulations will need to match the pace of development of digital/AI MDTs (Belisle-Pipon, 2021; Love-Koh, 2018)
Increased complexity of economic evaluations	• As the complexity of the technology and clinical pathways increases, economic model structures/techniques will need to be developed that can adequately model different types of digital/AI MDTs (Jiang, 2019; Love-Koh, 2018) • Estimating the economic impact of a digital/AI MDT may prove to be difficult, as they may provide a wide range of results that correspond to numerous clinical pathways or indications (Phillips, 2017)
Measuring utility of digital/AI MDTs	• Difficulties associated with measuring the value of other types of utilities associated with digital/AI MDTs (e.g., personal utility) (Phillips, 2017) • New health-related quality of life (HRQoL) instruments may be required to measure the "value of knowing" to incorporate into HTA (Love-Koh, 2018)
Greater reliance on RWE	• Due to differences in data quality and variations in healthcare organizations, outcomes achieved in clinical trials for digital/AI MDT are not always reproduced in real-world use, which can increase the level uncertainty surrounding cost-effectiveness estimates (Alami, 2020; Belisle-Pipon, 2021) • A greater reliance on RWE is anticipated and associated issues such as controlling for risk of selection bias and confounding need to be considered (Love-Koh, 2018)
Ethical & legal implications	• The management of large volumes of sensitive data used by digital/AI MDT has ethical and legal implications that need to be considered in HTA (Alami, 2020; Belisle-Pipon, 2021)

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