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Health Technology Assessment in the Era of Digital and Evidence Adaptive Health Systems A Theoretical and Empirical Reexamination of Methodology Context and Decision Making

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Abstract

Health Technology Assessment has emerged over the last three decades as one of the most influential and contested instruments in health system governance. Originally designed to support rational decision making regarding the adoption and diffusion of medical technologies, Health Technology Assessment now operates in a radically transformed environment characterized by digital health systems, real world evidence, living clinical guidelines, and increasingly complex regulatory landscapes. This article develops a comprehensive and theoretically grounded analysis of Health Technology Assessment as both a methodological framework and a political and institutional practice. Drawing strictly on the foundational and contemporary references provided, the paper examines how Health Technology Assessment has evolved from a primarily evidence synthesis enterprise into a dynamic governance tool embedded within health system structures, regulatory agencies, hospitals, and international networks.

The analysis begins by revisiting the conceptual foundations of Health Technology Assessment as articulated by the World Health Organization, European institutions, and academic scholars. These definitions reveal an inherent tension between methodological rigor and contextual relevance, a tension that has been identified as one of the defining challenges of modern Health Technology Assessment. This tension is explored in depth through the lens of policy theory, organizational behavior, and knowledge translation. The article then situates Health Technology Assessment within the broader digital transformation of health systems, focusing on electronic health records, regional eHealth infrastructures, and the emergence of real world data as a key input for evidence generation.

Building on this conceptual groundwork, the article advances a detailed methodological discussion of how Health Technology Assessment can integrate traditional clinical evidence, economic evaluation, and ethical analysis with newer forms of evidence such as real world data and living guideline processes. The implications of these methodological shifts for decision making, innovation, and equity are critically examined. Particular attention is paid to the role of European collaboration frameworks, especially the EUnetHTA Core Model, and to the ways in which regulatory agencies increasingly rely on real world evidence to complement randomized controlled trials.

The results section synthesizes insights from the literature to demonstrate how Health Technology Assessment is now functioning as a hybrid system that links evidence production, policy deliberation, and clinical practice. The discussion section explores the limitations and risks of this transformation, including challenges related to data quality, institutional capacity, and the potential politicization of evidence. The article concludes by arguing that the future of Health Technology Assessment depends on its ability to remain methodologically robust while becoming more adaptive, transparent, and embedded within digital health ecosystems. In doing so, Health Technology Assessment can continue to fulfill its core mission of informing decision makers and promoting the efficient and equitable use of health technologies.

Keywords: Health technology assessment, digital health, real world evidence, eHealth systems, health policy, living guidelines.

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1. Introduction

Health Technology Assessment, often abbreviated as HTA, occupies a central position in contemporary health policy, yet its meaning, scope, and practical role are frequently misunderstood or oversimplified. At its core, HTA is concerned with the systematic evaluation of health technologies in order to inform decisions about their use, reimbursement, and integration into health systems. The World Health Organization defines health technology broadly as the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures, and systems developed to solve health problems and improve quality of life (World Health Organization, 2019a). Health Technology Assessment, in turn, is defined as a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its life cycle, with the purpose of informing decision making in order to promote equitable, efficient, and high quality health systems (World Health Organization, 2019b).

These definitions immediately signal that HTA is not merely a technical exercise. It is a form of organized inquiry that sits at the intersection of science, policy, and clinical practice. Panteli and Busse have famously described HTA as being caught in a fundamental dilemma, namely the need to reconcile strong, standardized methodology with the inherently context dependent nature of health systems and policy environments (Panteli and Busse, 2019). This dilemma, which they metaphorically describe as squaring the circle, reflects the reality that evidence is always produced in specific settings, using particular populations, technologies, and institutional arrangements, while decisions must be made in diverse national and local contexts with different values, budgets, and priorities.

Over the last two decades, this tension has been intensified by several major transformations in health care. One of the most significant has been the digitalization of health systems. Electronic health records, regional eHealth infrastructures, telemedicine platforms, and integrated information systems have fundamentally altered how data are generated, stored, and used (Reponen et al., 2004; Harno and Ruotsalainen, 2006; European Commission, 2012; World Health Organization, 2019c). These digital systems have created unprecedented opportunities for the generation of real world evidence, which refers to data collected outside the controlled environment of randomized clinical trials, often as part of routine clinical care (Bakker et al., 2023). At the same time, the rise of living systematic reviews and living clinical guidelines has introduced a new temporal dimension into evidence based decision making, emphasizing continuous updating and rapid incorporation of new findings (Akl et al., 2017; Cheyne et al., 2023a).

These developments raise profound questions for HTA. If evidence is no longer static but continuously evolving, how should assessment processes be designed? If data come increasingly from heterogeneous real world sources rather than from standardized trials, how should quality, bias, and uncertainty be handled? And if health technologies themselves are becoming more complex, often combining digital platforms, algorithms, and service delivery models, how can HTA maintain its traditional focus on safety, effectiveness, and cost effectiveness while also addressing broader social and ethical implications?

The existing literature provides important but fragmented answers to these questions. The European Network for Health Technology Assessment, known as EUnetHTA, has developed a Core Model intended to standardize and harmonize HTA processes across countries, yet industry evaluations suggest that this model may not fully accommodate the diversity of real world contexts and innovation pathways (EUnetHTA, 2018; Gyldmark et al., 2018). Meanwhile, scholars of HTA have emphasized the importance of value based decision making and the need to balance innovation with affordability and equity (Henshall and Schuller, 2013). Hospital level tools such as Mini HTA have been developed to support local decisions, illustrating the multi level nature of HTA practice (Danish National Board of Health, 2005).

Despite these contributions, there remains a significant gap in the literature. What is missing is a comprehensive theoretical and methodological synthesis that connects traditional HTA principles with the realities of digital health systems, real world evidence, and living guideline processes. Many studies address one or another of these elements, but few attempt to integrate them into a coherent framework. This article seeks to fill that gap by providing an in depth, theoretically informed analysis of HTA as it is being reshaped by digitalization and evidence adaptation.

The central research problem addressed in this article can therefore be stated as follows. How can Health Technology Assessment maintain methodological rigor and decision relevance in an environment characterized by digital health infrastructures, real world evidence, and continuously evolving clinical knowledge? To address this problem, the article draws exclusively on the provided references, using them to construct a detailed and nuanced account of the evolution, current state, and future challenges of HTA.

The significance of this inquiry extends beyond academic debate. HTA influences which technologies patients can access, how resources are allocated, and how innovation is rewarded or constrained. As health systems face growing pressures from aging populations, rising costs, and rapid technological change, the stakes of HTA have never been higher. Understanding how HTA can adapt without losing its core principles is therefore essential for policy makers, clinicians, industry actors, and patients alike.

2. Methodology

The methodological approach adopted in this article is a structured theoretical and interpretive synthesis of the provided literature. Rather than conducting a new empirical study, the research employs a form of integrative review and conceptual analysis that is appropriate for examining complex policy and methodological questions. This approach is grounded in the recognition that Health Technology Assessment is not a single technique but a constellation of practices, institutions, and epistemological commitments that must be understood in relation to one another.

The first step in the methodology involved a close reading and thematic coding of all the provided references. These references include conceptual and policy oriented documents from the World Health Organization and the European Commission, methodological and evaluative studies from the HTA literature, and research on digital health systems, real world evidence, and living guidelines. Each text was analyzed to identify its core arguments, assumptions, and implications for HTA.

The themes that emerged from this analysis can be grouped into five broad domains. The first domain concerns the conceptual foundations of HTA, including definitions of health technology and the stated purposes of HTA as a decision support tool (World Health Organization, 2019a; World Health Organization, 2019b; EUnetHTA, 2018). The second domain relates to methodological frameworks and tools, such as the EUnetHTA Core Model and Mini HTA, which operationalize HTA in different contexts (Gyldmark et al., 2018; Danish National Board of Health, 2005). The third domain focuses on the relationship between HTA, innovation, and value based decision making (Henshall and Schuller, 2013). The fourth domain addresses digital health infrastructures, including electronic health records and regional eHealth systems (Reponen et al., 2004; Harno and Ruotsalainen, 2006; European Commission, 2012; World Health Organization, 2019c). The fifth domain involves new forms of evidence generation and synthesis, particularly real world evidence and living guidelines (Akl et al., 2017; Bakker et al., 2023; Cheyne et al., 2023a).

Once these domains were identified, the next step was to analyze the relationships between them. This involved asking how digital health systems influence the availability and nature of evidence, how real world evidence and living guidelines challenge traditional HTA methods, and how institutional frameworks such as EUnetHTA mediate these changes. The analysis was informed by the insights of Panteli and Busse, who emphasize the need to reconcile strong methodology with contextual dependency (Panteli and Busse, 2019).

The synthesis process was iterative and reflexive. Concepts and arguments from one domain were continuously compared and contrasted with those from others in order to identify convergences, tensions, and gaps. For example, the promise of real world evidence for more timely and relevant decision making was weighed against concerns about data quality and bias, as discussed in the regulatory context by Bakker and colleagues (Bakker et al., 2023). Similarly, the flexibility and responsiveness of living guidelines were considered in relation to the need for stable and transparent decision criteria in HTA (Akl et al., 2017; Cheyne et al., 2023a).

Throughout this process, particular care was taken to avoid introducing external assumptions or data not supported by the provided references. All claims and interpretations are grounded in the cited literature, and every major analytical step is linked back to specific sources. This ensures that the resulting article is not only theoretically rich but also faithful to the empirical and conceptual foundations established by the existing research.

The final stage of the methodology involved organizing the synthesized insights into a coherent narrative structure that moves from conceptual foundations to methodological implications and policy relevance. This structure reflects the belief that HTA must be understood as an evolving system of knowledge and governance rather than as a static set of

techniques.

3. Results

The integrative analysis of the provided literature yields several interrelated findings that together illuminate the current and emerging nature of Health Technology Assessment. These findings are not empirical results in the traditional statistical sense but rather analytically derived insights that emerge from the systematic comparison and interpretation of the sources.

One of the most important findings concerns the expanding scope of what counts as a health technology and, by extension, what HTA must assess. The World Health Organization explicitly defines health technology in very broad terms, encompassing not only physical devices and pharmaceuticals but also procedures, systems, and organizational arrangements (World Health Organization, 2019a). This definition implies that HTA cannot be confined to evaluating discrete products. Instead, it must also address complex interventions that involve multiple components, such as digital platforms integrated into care pathways or regional eHealth infrastructures.

This expansion of scope is vividly illustrated by the literature on electronic health records and regional eHealth systems. Reponen and colleagues describe the extension of a multimedia medical record into a regional service that supports electronic referrals and discharge letters, demonstrating how digital systems become embedded in clinical workflows and interorganizational communication (Reponen et al., 2004). Harno and Ruotsalainen similarly emphasize the importance of sharable electronic health record systems in Finland as a foundation for integrated care (Harno and Ruotsalainen, 2006). These examples show that health technologies increasingly operate at the level of systems rather than individual tools, which complicates traditional HTA approaches that were designed for drugs or devices.

A second major finding relates to the growing importance of real world evidence in regulatory and decision making processes. Bakker and colleagues provide detailed evidence that real world data are now routinely used by the European Medicines Agency to support regulatory decisions, complementing and sometimes extending the findings of clinical trials (Bakker et al., 2023). This shift reflects the recognition that randomized controlled trials, while methodologically rigorous, often fail to capture how technologies perform in routine practice across diverse populations.

For HTA, the rise of real world evidence has profound implications. On the one hand, it offers the potential for more contextually relevant and timely assessments, which directly addresses the concern raised by Panteli and Busse about the gap between standardized methodology and local realities (Panteli and Busse, 2019). On the other hand, it introduces new challenges related to data quality, comparability, and bias. Real world data are generated through clinical information systems, billing records, and other administrative processes that were not designed primarily for research, raising questions about their suitability for HTA.

A third finding concerns the temporal dynamics of evidence and decision making. The literature on living systematic reviews and living guidelines highlights a shift away from static evidence syntheses toward continuously updated knowledge products (Akl et al., 2017; Cheyne et al., 2023a). Living guidelines are designed to incorporate new evidence as it becomes available, thereby ensuring that recommendations remain current and relevant. This approach is particularly valuable in rapidly evolving fields where new technologies and treatments are constantly emerging.

When viewed through the lens of HTA, living guidelines suggest a move toward more adaptive and iterative assessment processes. Traditional HTA often involves lengthy review cycles that can lag behind technological change. The living guideline model, by contrast, implies that assessments and recommendations should be revisited and revised on an ongoing basis. This raises important questions about how HTA agencies can manage continuous evidence updates while maintaining transparency, accountability, and methodological rigor.

A fourth finding relates to the institutionalization and standardization of HTA through frameworks such as the EUnetHTA Core Model. The Core Model is intended to provide a common structure for HTA reports across Europe, facilitating collaboration and reducing duplication of effort (EUnetHTA, 2018). From an industry perspective, however, Gyldmark and colleagues argue that the model may not be fully fit for purpose, particularly in terms of accommodating the diversity of technologies and national decision contexts (Gyldmark et al., 2018). This critique underscores the ongoing tension between harmonization and contextualization in HTA.

Finally, the analysis highlights the role of HTA as a mediator between innovation and value based decision making. Henshall and Schuller argue that HTA plays a crucial role in

aligning innovation with societal values by providing evidence on the clinical and economic impacts of new technologies (Henshall and Schuller, 2013). This mediating function becomes even more important in a digital and data rich environment, where the pace of innovation can outstrip the capacity of health systems to evaluate and absorb new technologies.

Taken together, these findings suggest that HTA is undergoing a fundamental transformation. It is no longer merely a gatekeeping mechanism for new drugs and devices but a dynamic system that must integrate diverse forms of evidence, operate across multiple institutional levels, and adapt to the continuous evolution of health technologies.

4. Discussion

The results of this integrative analysis invite a deeper theoretical and practical reflection on the future of Health Technology Assessment. At the heart of this reflection lies the enduring tension identified by Panteli and Busse between methodological rigor and contextual dependency (Panteli and Busse, 2019). This tension is not a problem to be solved once and for all but a structural feature of HTA that must be continuously managed.

Methodological rigor in HTA has traditionally been associated with the use of standardized evidence hierarchies, systematic reviews, and economic evaluations. These tools are designed to minimize bias and maximize comparability, thereby supporting fair and transparent decision making. However, as health technologies become more complex and more deeply embedded in local systems, the relevance of evidence generated in controlled settings may diminish. Real world evidence offers a way to bridge this gap by capturing how technologies actually perform in practice, but it also challenges traditional notions of evidence quality (Bakker et al., 2023).

From a theoretical perspective, this shift can be understood as a move from a positivist to a more pragmatic epistemology. In a positivist framework, the goal is to identify universal truths through controlled experimentation. In a pragmatic framework, the emphasis is on what works in specific contexts. HTA increasingly operates in this pragmatic mode, seeking to inform decisions that are inherently local and value laden. This does not mean abandoning rigor, but it does require redefining what rigor means in a world of heterogeneous data sources and rapidly changing technologies.

The rise of living guidelines further reinforces this pragmatic orientation. By continuously updating recommendations, living guidelines acknowledge that knowledge is provisional and that decisions must be revisited as new evidence emerges (Akl et al., 2017; Cheyne et al., 2023a). For HTA agencies, this implies a shift from one time assessments to ongoing processes of monitoring and reassessment. Such a shift has significant organizational implications, requiring new workflows, information systems, and stakeholder engagement strategies.

Digital health infrastructures play a crucial enabling role in this transformation. Electronic health records and regional eHealth systems generate the data that underpin real world evidence and support continuous learning (Reponen et al., 2004; Harno and Ruotsalainen, 2006). The European Commission and the World Health Organization have both emphasized the strategic importance of eHealth for modernizing health systems and improving the quality and efficiency of care (European Commission, 2012; World Health Organization, 2019c). For HTA, these infrastructures offer the possibility of integrating evidence generation and decision making more closely than ever before.

However, these opportunities are accompanied by significant risks and limitations. Data from routine clinical systems may be incomplete, inconsistent, or biased, reflecting variations in coding practices, patient populations, and care pathways. Without careful methodological safeguards, the use of such data in HTA could undermine rather than enhance the quality of decisions. Moreover, the increasing reliance on digital systems raises ethical and governance issues related to data privacy, ownership, and access.

Institutional frameworks such as EUnetHTA represent attempts to manage these complexities through standardization and collaboration. By providing a common structure for HTA reports, the Core Model aims to facilitate the sharing of evidence and reduce duplication of effort (EUnetHTA, 2018). Yet, as Gyldmark and colleagues point out, standardization can also create rigidity and may not adequately reflect the needs of different stakeholders or the characteristics of specific technologies (Gyldmark et al., 2018). This suggests that institutional design is as important as methodological innovation in shaping the future of HTA.

The mediating role of HTA between innovation and value based decision making is another critical dimension of the discussion. Health technologies are not neutral tools; they embody particular assumptions about disease, care, and the distribution of resources. HTA provides a forum in which these assumptions can be examined and debated, drawing on evidence to inform value judgments (Henshall and

Schuller, 2013). In a digital era, where technologies can rapidly reshape care pathways and patient experiences, this deliberative function becomes even more important.

Looking to the future, several implications emerge from this analysis. First, HTA agencies will need to invest in methodological development to make better use of real world evidence while maintaining standards of transparency and reproducibility. Second, closer integration between HTA, regulatory processes, and clinical guideline development will be necessary to avoid fragmentation and duplication. The experiences of regulatory agencies in using real world evidence, as documented by Bakker and colleagues, provide valuable lessons in this regard (Bakker et al., 2023). Third, digital health infrastructures should be designed with HTA and evidence generation in mind, ensuring that data are collected in ways that support robust analysis and ethical governance.

5. Conclusion

Health Technology Assessment stands at a critical juncture in its evolution. Born as a tool for rationalizing the adoption of medical technologies, it now operates within a complex ecosystem of digital health systems, real world data, and continuously evolving clinical knowledge. The analysis presented in this article demonstrates that HTA is no longer a static or purely technical exercise but a dynamic process of knowledge production and policy mediation.

Drawing on the provided literature, the article has shown that the fundamental challenge of HTA lies in balancing methodological rigor with contextual relevance. Digital health infrastructures and real world evidence offer powerful new resources for achieving this balance, but they also introduce new methodological and ethical challenges. Living guidelines exemplify a shift toward more adaptive and responsive forms of evidence based decision making, suggesting a future in which HTA is an ongoing rather than episodic activity.

Ultimately, the future of HTA will depend on its ability to integrate these developments into a coherent and transparent framework that serves the needs of patients, clinicians, and policy makers alike. By embracing methodological innovation while remaining grounded in its core principles of evidence based and value oriented decision making, HTA can continue to play a central role in shaping equitable and sustainable health systems.

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