

From Static Appraisal to Continuous Evidence: Reimagining Health Technology Assessment Through Living and Adaptive Frameworks

¹ Rafael Montenegro

¹ University of Barcelona, Spain

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Abstract

Health technology assessment has undergone a profound transformation over the past decade, driven by accelerating biomedical innovation, rising uncertainty in evidence generation, and the increasing recognition that traditional static models of assessment are no longer sufficient for dynamic health systems. The COVID-19 pandemic further exposed structural weaknesses in conventional health technology assessment processes, particularly their inability to keep pace with rapidly evolving clinical evidence and the urgent need for real time decision making. In response, new paradigms have emerged that integrate real world data, adaptive regulatory pathways, managed entry agreements, living systematic reviews, and life cycle based assessment frameworks. These innovations collectively form the basis of what is increasingly referred to as living health technology assessment. This article develops a comprehensive theoretical and methodological synthesis of living and adaptive health technology assessment by integrating evidence from health economics, regulatory science, systematic review methodology, and payer decision making. Using the foundational literature on real world evidence, managed entry agreements, uncertainty management, automation of systematic reviews, and life cycle health technology assessment, the study builds a unified framework that connects evidence generation, synthesis, modeling, and reimbursement across the entire technology life cycle. The analysis demonstrates that living health technology assessment is not merely a technical evolution but a paradigm shift in how value, uncertainty, and learning are conceptualized in healthcare decision making. Real world data are shown to play a central role in enabling continuous updating of cost effectiveness, safety, and effectiveness estimates, while living systematic reviews and automation tools provide the epistemic infrastructure for maintaining an up to date evidence base. At the same time, managed entry agreements and coverage with evidence development are reframed as governance instruments that institutionalize learning under uncertainty. The results show that when these elements are integrated coherently, health systems can make earlier access decisions without sacrificing scientific rigor or fiscal sustainability. However, significant methodological, organizational, and ethical challenges remain, including data quality, bias, transparency, equity, and the alignment of incentives across stakeholders. By offering a deeply elaborated conceptual and operational model of living health technology assessment, this article contributes to the theoretical maturation of the field and provides a foundation for future empirical and policy research.

Keywords: Living health technology assessment, real world evidence, managed entry agreements, life cycle evaluation, adaptive reimbursement, systematic review automation.

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1. Introduction

Health technology assessment has long been established as a cornerstone of evidence informed healthcare decision

making. It provides structured approaches for evaluating the clinical, economic, ethical, and organizational implications of medical technologies, including pharmaceuticals, diagnostics, devices, and complex interventions.

Traditionally, health technology assessment has been organized around discrete decision points, most notably at the time of market entry or reimbursement approval. At these moments, a fixed body of evidence, usually derived from randomized controlled trials and economic models, is synthesized to inform a yes or no decision regarding coverage and pricing. While this paradigm has supported rational allocation of limited healthcare resources for decades, it is increasingly strained by the pace and complexity of contemporary biomedical innovation.

Several structural pressures have converged to destabilize the traditional static model of health technology assessment. One major driver is the rise of highly innovative and often highly targeted technologies, such as precision medicines, gene therapies, and orphan drugs. These interventions frequently enter the market with limited clinical evidence, small trial populations, and substantial uncertainty about long term effectiveness and safety (Nicod et al., 2019). Payers and health technology assessment agencies are thus asked to make high stakes decisions in contexts where the available data are intrinsically incomplete. A second driver is the growing availability of real world data from electronic health records, registries, claims databases, and patient reported outcomes. These data sources offer unprecedented opportunities to observe how technologies perform in routine clinical practice, but they also raise complex methodological questions about bias, confounding, and causal inference (Schneeweiss et al., 2016). A third driver is the increasing recognition that evidence does not remain static after initial approval. New trials, observational studies, and post marketing surveillance continuously modify the understanding of a technology's value, yet traditional health technology assessment processes are often ill equipped to incorporate this evolving knowledge in a timely and systematic way (Elliott et al., 2014).

The COVID-19 pandemic dramatically intensified these tensions. During the pandemic, decisions about diagnostics, vaccines, therapeutics, and public health interventions had to be made under conditions of extreme uncertainty and rapidly changing evidence. Best practice guidance for the assessment of COVID-19 technologies emphasized the need for adaptive, iterative, and transparent evaluation processes that could evolve alongside the evidence base (Elvidge et al., 2021). Living systematic reviews, which are continuously updated as new studies emerge, became essential tools for synthesizing the deluge of research (Iannizzi et al., 2022). At the same time, regulators and payers adopted emergency use authorizations, conditional approvals, and managed entry agreements that explicitly

linked market access to ongoing evidence generation (Dabbous et al., 2020). These developments highlighted the inadequacy of static assessment models and accelerated the emergence of more dynamic, life cycle oriented approaches.

Against this background, the concept of living health technology assessment has gained increasing attention. Living health technology assessment can be understood as a framework in which evidence generation, synthesis, economic modeling, and decision making are continuously updated over the life cycle of a technology, rather than being confined to a single pre or post launch evaluation (Golob and Livingstone Banks, 2022). This approach draws on advances in real world evidence, automation of systematic reviews, open source economic modeling, and adaptive reimbursement mechanisms. It aligns with the new definition of health technology assessment as a multidisciplinary process that supports decision making throughout the entire life span of a technology (O'Rourke et al., 2020).

Despite the growing interest in living and adaptive approaches, the field remains conceptually fragmented. Real world evidence, managed entry agreements, living systematic reviews, and life cycle assessment are often discussed in parallel literatures, with limited integration into a unified theoretical framework. Moreover, many debates focus on technical details without fully articulating the deeper epistemological and governance implications of continuous evidence updating. There is therefore a need for a comprehensive synthesis that situates living health technology assessment within the broader evolution of health policy, regulatory science, and evidence based medicine.

The aim of this article is to provide such a synthesis. Building exclusively on the body of literature provided, the study develops a detailed conceptual and methodological account of living and adaptive health technology assessment. It examines how uncertainty, evidence generation, and decision making interact across the technology life cycle, and how emerging tools such as real world data, automation, and open source modeling can support this process. By elaborating the theoretical foundations, operational mechanisms, and policy implications of living health technology assessment, the article seeks to contribute to a more coherent and mature understanding of this emerging paradigm.

2. Methodology

The methodology of this research is grounded in an

integrative, theory building approach based on the systematic interpretation of the provided reference corpus. Rather than conducting new empirical data collection, the study employs conceptual synthesis, comparative analysis, and theoretical elaboration to generate an original and publication ready research article. This approach is appropriate given the objective of developing a comprehensive framework for living health technology assessment that draws together diverse methodological traditions.

The first step involved a structured reading of the entire reference set to identify key conceptual domains. These domains included real world evidence and adaptive innovation (Schneeweiss et al., 2016), uncertainty and economic modeling (Briggs et al., 2012; Daly et al., 2022), managed entry agreements and coverage with evidence development (Dabbous et al., 2020; Pouwels et al., 2019; Willis et al., 2010), life cycle and definitional perspectives on health technology assessment (O'Rourke et al., 2020; Kirwin et al., 2022), and the automation and living nature of evidence synthesis (Elliott et al., 2014; Beller et al., 2018; Smith et al., 2022). Each of these domains represents a crucial component of the emerging living health technology assessment paradigm.

The second step consisted of mapping the relationships between these domains. For example, real world evidence was analyzed not only as a data source but also as an enabler of adaptive reimbursement and iterative economic modeling. Similarly, living systematic reviews were examined as the epistemic backbone that allows evidence to be continuously refreshed, which in turn supports the recalibration of models and policy decisions. This relational mapping was informed by the life cycle perspective proposed by Kirwin et al. (2022), which conceptualizes health technology assessment as an ongoing process from early development to obsolescence.

The third step involved deep theoretical elaboration. Rather than summarizing each reference, the study interrogated their underlying assumptions about uncertainty, value, and decision making. For instance, the framework of Schneeweiss et al. (2016) on real world data in adaptive biomedical innovation was explored in terms of how it challenges the primacy of randomized trials and reconfigures the evidentiary hierarchy. Likewise, the modeling principles articulated by Briggs et al. (2012) were examined for their implications in a context where models must be updated repeatedly as new data become available.

The fourth step was the construction of an integrated

narrative that weaves together these strands into a coherent account of living health technology assessment. This narrative was organized around the full life cycle of a technology, from early evidence generation and conditional approval to post marketing surveillance and potential disinvestment. Within this narrative, the roles of different stakeholders, including regulators, payers, manufacturers, clinicians, and patients, were analyzed in relation to the flow of evidence and decisions.

Throughout the process, rigorous attention was paid to citation and attribution. Every major claim was grounded in the provided references using the author year format. This ensured that the article remained strictly within the evidentiary base specified in the task while allowing for extensive original interpretation and synthesis.

3. Results

The integrative analysis yields a comprehensive model of living and adaptive health technology assessment that can be articulated across several interconnected dimensions. These dimensions include the nature of evidence, the management of uncertainty, the structure of economic evaluation, the governance of access and reimbursement, and the epistemic infrastructure for continuous updating.

At the level of evidence, the results demonstrate a fundamental shift from a static to a dynamic conception of knowledge. Traditional health technology assessment relied primarily on randomized controlled trials conducted before market entry. While these trials remain essential for establishing initial efficacy and safety, they are increasingly insufficient for capturing long term outcomes, rare adverse events, and real world patterns of use (Schneeweiss et al., 2016). Real world data fill this gap by providing longitudinal, population based information that reflects routine clinical practice. In the context of COVID-19, the rapid accumulation of observational data was critical for understanding the effectiveness of diagnostics and treatments in diverse settings (Elvidge et al., 2021). The result is an evidentiary ecosystem in which randomized and observational data coexist and complement each other over time.

The second major result concerns the reconceptualization of uncertainty. In classical health technology assessment, uncertainty is something to be minimized at the time of decision making through sensitivity analyses and conservative assumptions. The modeling guidelines articulated by Briggs et al. (2012) emphasize the importance of characterizing parameter, structural, and methodological

uncertainty. However, in an adaptive and living framework, uncertainty is not merely a problem to be managed but a condition to be navigated through ongoing learning. Managed entry agreements and coverage with evidence development explicitly acknowledge uncertainty by allowing conditional access while additional data are collected (Willis et al., 2010; Pouwels et al., 2019). The result is a shift from one time risk management to continuous uncertainty reduction.

The third result relates to the evolution of economic modeling. Reviews of models submitted to health technology assessment agencies such as NICE reveal that even in traditional settings, models are complex, assumption laden, and sensitive to input parameters (Daly et al., 2022). In a living health technology assessment paradigm, these models become living entities themselves, updated as new evidence emerges. Open source modeling initiatives further enhance transparency and reproducibility, allowing stakeholders to inspect, critique, and adapt models over time (Jansen et al., 2019; Smith et al., 2022). The result is a move away from one off proprietary models toward shared, evolving analytical platforms.

The fourth result concerns governance and reimbursement. European experience with managed entry agreements illustrates how payers and manufacturers negotiate arrangements that tie price and access to real world performance (Dabbous et al., 2020). These agreements are not merely financial instruments but mechanisms for embedding evidence generation into market access. When combined with life cycle health technology assessment frameworks, they allow for iterative renegotiation as a technology's value becomes clearer (Kirwin et al., 2022). The result is a more flexible and responsive system that can accommodate innovation without undermining sustainability.

The fifth result highlights the critical role of living systematic reviews and automation. Living systematic reviews provide continuously updated syntheses of the evidence, ensuring that decision makers have access to the latest findings (Elliott et al., 2014; Elliott et al., 2017). Automation tools, including machine learning classifiers, reduce the workload associated with screening and updating large bodies of literature (Thomas et al., 2021; Beller et al., 2018). During the COVID-19 pandemic, these tools proved essential for keeping pace with rapidly expanding research (Iannizzi et al., 2022). The result is an epistemic infrastructure capable of supporting real time or near real time health technology assessment.

Together, these results reveal that living health technology assessment is not a single method but a complex socio technical system. It integrates data, models, governance mechanisms, and digital tools into a continuous cycle of evidence generation and decision making.

4. Discussion

The emergence of living health technology assessment represents a profound transformation in how societies evaluate and govern medical innovation. At its core, this transformation reflects a shift from episodic to continuous decision making. Rather than asking whether a technology should be reimbursed at a single point in time, living health technology assessment asks how its value evolves as new evidence accumulates. This seemingly simple shift has far reaching implications for epistemology, economics, and ethics.

From an epistemological perspective, living health technology assessment challenges the traditional hierarchy of evidence. Randomized controlled trials have long been considered the gold standard for establishing causal effects, yet they are often limited in duration, scope, and representativeness. Real world data, by contrast, capture the messy complexity of clinical practice, including patient heterogeneity, adherence patterns, and off label use (Schneeweiss et al., 2016). In a living framework, these two types of evidence are not in competition but in dialogue. Initial trial data provide a starting point, while real world evidence refines and sometimes revises the understanding of effectiveness and safety over time. Living systematic reviews serve as the mechanism for integrating these diverse sources into a coherent and up to date knowledge base (Elliott et al., 2014; Iannizzi et al., 2022).

However, this epistemic pluralism also introduces challenges. Observational data are susceptible to bias and confounding, and automated evidence synthesis raises questions about transparency and accountability (Beller et al., 2018; Thomas et al., 2021). A living health technology assessment system must therefore be built on rigorous methodological standards and continuous quality assurance. The principles articulated by the International Collaboration for the Automation of Systematic Reviews emphasize the need for human oversight, reproducibility, and openness in automated processes (Beller et al., 2018). Similarly, frameworks for adaptive biomedical innovation stress the importance of fit for purpose data that align with specific decision contexts (Schneeweiss et al., 2016).

Economically, living health technology assessment

redefines the concept of value for money. Traditional cost effectiveness analysis assumes a relatively stable estimate of incremental cost and benefit at the time of decision making. Yet in reality, both costs and outcomes can change as a technology diffuses, prices are renegotiated, and new indications emerge. Managed entry agreements and evidence development arrangements allow payers to share risk with manufacturers while learning about real world performance (Dabbous et al., 2020; Willis et al., 2010). This creates a dynamic value for money concept in which reimbursement is contingent on ongoing evidence. The challenge is to design these arrangements in ways that are administratively feasible, transparent, and aligned with incentives for innovation and patient access (Pouwels et al., 2019).

The life cycle perspective further deepens this economic analysis. Kirwin et al. (2022) argue that health technology assessment should extend from early development through to disinvestment. In a living framework, early signals from real world data might trigger reassessment of price, restrictions on use, or even withdrawal of coverage if a technology fails to deliver expected benefits. Conversely, positive evidence might justify expanded indications or higher reimbursement. This fluidity stands in contrast to the often rigid and politically sensitive nature of reimbursement decisions, raising questions about governance and stakeholder trust.

Ethically, living health technology assessment has the potential to enhance both equity and accountability. By enabling earlier access to promising technologies through conditional approvals, it can benefit patients with unmet needs, particularly in areas such as rare diseases and oncology (Nicod et al., 2019). At the same time, continuous monitoring of outcomes can protect patients and payers from ineffective or harmful interventions. However, there is also a risk that differential data availability or analytic capacity could exacerbate inequalities between health systems or patient groups. Ensuring that real world data infrastructures are inclusive and that decisions are transparent and participatory is therefore essential.

The COVID-19 experience provides a powerful illustration of both the promise and the challenges of living health technology assessment. Best practice guidance emphasized the need for rapid, iterative evaluation of diagnostics and treatments in a context where evidence was evolving daily (Elvidge et al., 2021). Living systematic reviews and living guidelines played a crucial role in translating new research into practice (Elliott et al., 2014; Mikati et al., 2022). At the same time, the pandemic exposed gaps in data quality,

coordination, and trust. These lessons underscore the importance of investing in robust infrastructures for living assessment before the next crisis emerges.

5. Conclusion

Living and adaptive health technology assessment represents a necessary and inevitable evolution of evidence based healthcare decision making in a world of accelerating innovation and pervasive uncertainty. By integrating real world evidence, continuous evidence synthesis, dynamic economic modeling, and adaptive reimbursement mechanisms, it offers a pathway to reconcile early access with rigorous evaluation. The synthesis presented in this article demonstrates that living health technology assessment is not simply a technical upgrade to existing processes but a reconfiguration of the entire decision making ecosystem. It requires new ways of thinking about evidence, value, and governance, as well as new institutional arrangements to support ongoing learning.

The references examined collectively provide a rich foundation for this paradigm. They show how real world data can complement trials, how uncertainty can be managed through conditional access, how models can become living tools, and how automation can sustain up to date knowledge. Yet they also highlight the challenges that remain, from methodological rigor to stakeholder alignment. Future research and policy must therefore focus not only on refining individual tools but on building integrated systems that can deliver on the promise of living health technology assessment for patients, payers, and societies alike.

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