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THE EVOLUTION OF PERFORMANCE MANAGEMENT SYSTEMS IN THE HEALTHCARE SECTOR: ADVANCING THE INTEGRATION WITH HEALTH TECHNOLOGY ASSESSMENT

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CHAPTER ONE

1. INTRODUCTION

One of the most important tools for raising organisational effectiveness, accountability, and service quality across a variety of global economic sectors is performance management. The design and development of performance management systems (PMS) have significant implications in the healthcare industry, and as a result, have a direct impact on people's survival and well-being. In the most general terms, performance management in the healthcare industry refers to the ongoing process of determining, assessing, and improving the efficacy and efficiency of medical personnel and services [1]. In terms of accountability, transparency, and cost-effectiveness in healthcare delivery, its development mirrors more general paradigm shifts in public administration, technology development, and societal expectations [1, 2].

According to Vainieri et al. (2019) [3], healthcare performance management systems have evolved over time from limited financial control mechanisms to multifaceted frameworks that incorporate clinical outcomes, patient safety, patient satisfaction, and process efficiency. The New Public Management (NPM) reforms of the 1980s and 1990s had a significant impact on early conceptualisations of performance management, which emphasised efficiency, financial restraint, and the integration of private-sector methods into the public sector [4]. In order to evaluate productivity and service quality under this paradigm, health institutions progressively embraced performance indicators, benchmarking instruments, and accountability frameworks. But as time went on, academics and professionals realised that, due to the intricate, patient-centred character of the healthcare industry, performance cannot be adequately assessed using cost and production measures alone [5].

Balanced scorecards, dashboards, key performance indicators (KPIs), and benchmarking systems are all part of modern healthcare performance management strategies that connect clinical performance to organisational strategy and patient outcomes [3]. These frameworks, which provide a comprehensive understanding of healthcare performance, aim to strike a balance between efficiency and quality, safety, and patient satisfaction. However, in spite of these developments, the healthcare industry still faces ongoing difficulties in providing and maintaining efficient PMSs, especially as health systems struggle with growing demands for evidence-based care, technological disruptions, and rising costs [6].

Over the past three decades, the body of research on performance management in the healthcare industry has expanded significantly, covering topics such as system integration, accountability, measurement, and quality improvement. Many groundbreaking publications [5, 2] built fundamental concepts and standards for organising performance frameworks in public health organisations and hospitals. Performance measurement, or the identification of indicators and the setting of standards for productivity and efficiency, was the main focus of early research. Despite being essential, this phase of research mainly ignored the institutional and behavioural aspects of performance management, such as how medical professionals evaluate, modify, and respond to performance data.

In the subsequent phase, researchers started looking into performance management as a process that integrates system feedback, employee motivation, and organisational goals [2, 7]. These studies emphasised the role that information systems, corporate culture, and leadership have in promoting successful performance improvement. However, as [3] contend, managers' and professionals' usage of performance measures inside organisational learning processes frequently determines how well they translate performance data into better outcomes.

In practical terms, the study addresses a critical demand among policymakers and healthcare management for proven strategies to improve performance systems that are contextually relevant, flexible, and sustainable. Because of rising expenses, medical errors, and inefficiencies, the healthcare industry is still closely watched in many nations [8]. Better policy design and institutional reforms can be influenced by an understanding of how performance management systems change over time and the factors that contribute to successful adaptation. Moreover, the COVID-19 pandemic underlined the significance of flexible, data-driven management systems capable of responding fast to crises while retaining quality and accountability [9].

1.1 Theoretical Background

The twin disciplines of Health Technology Assessment (HTA) and Performance Management Systems (PMS) have become central to the governance of contemporary health systems. While PMS supplies the managerial and administrative framework for goal-setting, performance monitoring, and accountability, HTA provides comprehensive, multidisciplinary evidence regarding the clinical, economic, ethical, and social effects of health technology [10-11]. Health Technology Assessment and performance Management have historically followed

different institutional and intellectual paths. Performance management developed from New Public Management reforms that prioritised transparency and quantifiable results, while HTA emerged as a science-policy interface for evidence synthesis and priority setting [12]. A significant theoretical and practical advancement that rethinks how technologies are evaluated, embraced, and tracked inside health systems is the combination of HTA and PMS [10, 13].

1.2 Conceptual Overview of Health Technology Assessment and Performance Management System

According to O'Rourke et al. 2020 [12], health technology assessment (HTA) is a multidisciplinary process that methodically assesses the characteristics, impacts, and effects of health technologies and interventions with the specific goal of guiding decision-making to support an equitable, effective, and high-quality health system. Pharmaceuticals, medical equipment, surgery, digital health apps, and organisational improvements are all included in the category of health technologies. To generate thorough assessments across clinical, economic, social, and ethical domains, HTA uses a range of techniques, including budget impact analysis, multicriteria decision analysis (MCDA), clinical evidence synthesis, economic evaluation (cost-effectiveness, cost-utility), and, increasingly, real-world evidence (RWE) evaluation [14, 15]. HTA has evolved from traditional market-entry evaluations (ex-ante) to lifetime approaches that combine post-market surveillance (ex-post) and early-stage assessments [16, 15]. As treatments spread into real-world settings and encounter diverse circumstances, this lifecycle concept specifically acknowledges the need for iterative evidence generation and continuous evaluation [17]. According to Drummond et al. 2022 [13], modern HTA therefore increasingly integrates with data gathering, outcome monitoring, and adaptive reimbursement systems.

According to Nicholls et al. 2000 [18], performance management in the healthcare industry refers to the formal procedures and processes for setting goals, creating performance indicators (KPIs), assessing outcomes, and implementing accountability and improvement. Performance Management Systems were developed as a result of reforms in public administration that aimed to introduce quantifiable results and managerial accountability into public services. Clinical audit cycles, hospital dashboards, contractual performance agreements, balanced scorecards, and health system performance assessment (HSPA) are some of the tools used in healthcare that are implemented at the system, institutional, and clinical levels [19]. One of PMS's main characteristics is its dependence on information infrastructures and indicator systems to make intricate organisational and clinical procedures visible and controllable [20]. As a result,

incentives and behaviours are shaped by the PMS design (metric selection, data governance, reporting cycles), which also affects the allocation of resources. The theoretical legitimacy of PMS is frequently associated with organisational learning and clinical governance, where performance data are used as inputs for ongoing quality improvement as well as for accountability [21].

HTA procedures have seen significant institutional consolidation and internationalisation during the last 20 years [22]. Cross-national cooperation and methodological harmonisation initiatives have aimed to lessen redundancy, encourage openness, and facilitate the joint use of evidence. International networks (INAHTA, EUnetHTA) and national HTA agencies have multiplied [23]. This trend is exemplified by the European Regulation (EU) 2021/2282, which formalises joint clinical assessments among Member States while retaining national considerations for economic, organisational, and ethical factors. This creates a multi-level governance architecture where national performance and adoption decisions are informed by EU-level HTA outputs [24].

HTA methodology has changed in tandem with institutional maturation. More specifically,

(a) Broader domains (social value, ethical, and environmental impacts) have been included.

(b) early-stage HTA has been prioritised to inform R&D and adoption decisions; and

(c) RWE and dynamic monitoring have been adopted to evaluate technologies after market entry [25, 26, 15].

The necessity for PMS links that capture performance, safety, and equality in operational contexts has also been reaffirmed by the emergence of digital health technologies and artificial intelligence (AI), which have brought attention to the shortcomings of purely static, clinical-trial-based assessments [27]. In order to guarantee continued value and safety in use, this trajectory places HTA as an ongoing governance mechanism rather than just a gatekeeper for market entry. It must be linked to performance data streams and organisational management procedures [28, 13].

Globally, HTA has expanded to include more aspects of healthcare performance and sustainability, moving beyond discrete clinical and economic evaluations. A significant turning point in this development is the European Union's Regulation (EU) 2021/2282 on HTA, which encourages the use of performance data to track post-adoption results and requires uniform approaches for evaluating clinical efficacy and safety across Member States [24]. By incorporating ongoing monitoring and iterative feedback as essential elements of technical governance, this legislation represents a paradigm change away from a static evaluation model and toward a dynamic, performance-informed HTA framework. These further emphasise this

shift by demonstrating how global networks like the European Network for Health Technology Assessment (EUnetHTA) and the International Network of Agencies for Health Technology Assessment (INAHTA) promote data sharing and methodological standardisation, allowing countries to move beyond compartmentalised evaluations [22, 28]. These advancements show an increasing understanding that HTA needs to be integrated with larger performance management infrastructures to support the accountability and learning cycles of contemporary health systems, rather than operating independently [13]. With this theoretical realignment, HTA is positioned as a strategic governance tool for managing healthcare innovation from a performance-oriented perspective, rather than just as a gatekeeper for technology adoption. It links HTA's evaluative rigour to PMS's outcome-oriented accountability since it aligns with the value-based healthcare paradigm, which places an emphasis on attaining optimal health outcomes per unit of expenditure used [29].

Measurement selection (which KPIs reflect priorities), data creation and governance (how reliable and timely the data are), and incentive/feedback mechanisms (how outcomes are acted upon) are the three analytical activities that shape performance management systems [19]. Theoretical perspectives emphasise that PMS are socio-technical systems, meaning that organisational behaviours (such as leadership and clinical engagement) and technical capabilities (including IT systems and analytics) determine their effectiveness [21]. Tensions are highlighted in current PMS discussions: the potential of metrics displacing unmeasured goals; the possibility of over-measurement resulting in gaming and administrative load; and concerns about contextual relevance, where generic indicators could not be in line with local priorities [20, 30]. In order to make PMS and HTA outputs compatible when both are centred around the same goals (quality, equity, and value), the literature advises that PMS design should be participative, context-sensitive, and anchored to meaningful outcomes. Furthermore, RWE and health system data infrastructures (electronic health records, registries) are increasingly included in performance management, allowing for the tracking of results after technology deployment. Accordingly, PMS is changing from static periodic reporting to learning systems that can provide the post-market evidence needed by HTA processes in almost real-time [31, 32].

1.3 Theoretical Convergence of Health Technology Assessment and Performance Management System

The integration of HTA and PMS can be conceptualised as a cyclical evidence-action-feedback loop. According to [10], HTA serves mainly as the input (generation of evidence) for decisions regarding technology adoption, coverage, and pricing, while PMS serves as the output (measurement of real-world performance) that either supports or contradicts those decisions and produces data for iterative reassessment. In addition to echoing cybernetic and systems thinking models, which depend on feedback for adaptive control, this cyclical relationship is situated within clinical governance and system learning theories [11].

Three theoretical linkages explain why integration yields value:

1. Feed-forward resource allocation and priority setting: PMS converts these into operational KPIs and monitoring plans that assess whether anticipated gains materialise, while HTA provides ex-ante projections (cost-effectiveness and budget impact) that guide budgeting and prioritisation [10].

2. Inputs for ex-post HTA: Performance management system produces real world evidence on clinical efficacy, safety, utilisation, and costs, which facilitate managed entry agreements, conditional reimbursement, or disinvestment in cases where performance falls short of expectations [15]. This feedback is used for adaptive governance.

3. Shared stakeholder legitimacy and accountability: By facilitating inclusive stakeholder interaction (clinicians, patients, and payers), the alignment of HTA criteria with PMS indicators enhances decision-making legitimacy and transparency [14].

Harmonised indicator sets, interoperable data architectures, and governance structures that safeguard data privacy while permitting evidence flows between managers and assessment bodies are frequently necessary to operationalise these links [32].

1.4 Case Study Insight: Malta as an Exemplar of HTA–PMS Integration

The centralised healthcare system in Malta offers a helpful empirical perspective for confirming theories. The Malta case study demonstrates an HSPA framework for system monitoring in addition to a structured HTA procedure connected to national formulary and procurement choices. However, there are still implementation gaps: the feedback loop is constrained by data fragmentation, inadequate local cost-effectiveness modelling, and partial integration between procurement and HTA units (Case study: Malta). From a theoretical standpoint, Malta illustrates both the possibilities and constraints of HTA–PMS integration:

In order to promote cyclical evidence flows, the Maltese experience highlights the necessity of capacity building, participatory KPI selection, and digital investments. It also illustrates how national capabilities to incorporate HTA outcomes into PMS-driven procurement and monitoring procedures must be reinforced by regulatory frameworks (such as the EU HTA Regulation) that can catalyse harmonisation [24]. The integration of HTA and PMS has several theoretical implications:

1. Redefining HTA as a Governance Tool: HTA should be conceptualised as a governance input integrated into ongoing performance cycles, rather than only as a static knowledge synthesis. This changes the goal of HTA from a one-time approval tool to a managed adoption and lifecycle stewardship tool [13].

2. PMS as Evidence Producer: Performance management systems serve as a crucial part of knowledge translation by evolving from passive reporting mechanisms into active evidence producers that inform policy and re-evaluation [11].

3. Systems-level thinking and adaptive governance are necessary for integration, which involves the interaction of multi-level loops at the clinical, organisational, national, and transnational levels. The focus shifts to adaptive governance theory, which emphasises resilience, iterative policy adjustment, and reflexivity [29].

4. Equity and Context Sensitivity: To avoid homogenised indicators concealing distributional consequences, HTA–PMS integration must maintain local contextual sensitivity and equity considerations. Broader value perspectives are ensured by integrating the social and environmental domains into HTA and PMS [26].

In conclusion, robust health systems will rely increasingly on integrated HTA–PMS architectures that align evidence, performance measurement, and governance. This will allow healthcare systems to monitor their real-world performance, adopt innovations responsibly, and modify policy actions to maintain value, safety, and equity.

1.5 Theoretical Framework and Analytical Orientation

Building on the preceding discussion, this study adopts an integrated theoretical framework that combines systems thinking, clinical governance, and organisational institutional theory to explain both the rationale for, and the observed limitations of, the integration between Health Technology Assessment (HTA) and Performance Management Systems (PMS). From a systems perspective, the relationship between HTA and PMS can be conceptualised as a dynamic and iterative feedback loop in which HTA generates ex-ante evidence on the clinical, economic, and social value of health technologies [16]. At the same time, PMS translates these expectations into operational indicators and continuously monitors real-world outcomes [11].

Ideally, this cyclical interaction enables adaptive governance, whereby performance data inform subsequent reassessments, thereby improving decision-making, resource allocation, and overall system performance [21]. However, while this model provides a strong normative justification for integration, empirical evidence suggests that such alignment is often partial and uneven. To account for this gap between theoretical potential and practical implementation, this study draws on organisational institutional theory, which shifts the analytical focus from purely technical efficiency to the role of legitimacy, norms, and structural constraints in shaping organisational behaviour [24].

Institutional theory provides a particularly useful lens for understanding why HTA-PMS integration has been slow despite its apparent logic. First, the concept of isomorphism suggests that healthcare organisations adopt HTA and PMS frameworks in response to coercive pressures (such as regulatory requirements, including European-level HTA regulation), normative pressures (arising from professional standards and epistemic communities), and mimetic pressures (through the imitation of perceived best practices across jurisdictions) [33]. While these forces promote the widespread diffusion of both HTA and PMS, they do not necessarily ensure their substantive integration. Instead, organisations may adopt these frameworks primarily to signal conformity and maintain legitimacy. This leads to the second key concept, legitimacy, whereby HTA and PMS function not only as technical tools but also as instruments for demonstrating accountability, transparency, and rational decision-making to external stakeholders. As a result, organisations may prioritise the formal adoption of these systems over their effective operational alignment. This dynamic is further explained by the concept of decoupling, which refers to the disconnection between formal structures and actual practices. In the context of HTA-PMS integration, decoupling manifests when HTA outputs do not meaningfully inform performance indicators or when real-world performance data are not systematically fed back into HTA processes, thereby weakening the intended evidence-performance-feedback cycle [34].

These institutional dynamics contribute to forms of organisational inertia that are evident in many healthcare systems, including the Malta case examined in this thesis. Path dependency, professional silos between HTA experts and performance managers, fragmented data infrastructures, and competing accountability demands all constrain the development of fully integrated systems. Consequently, HTA and PMS often coexist as parallel rather than interconnected mechanisms, limiting their combined impact on healthcare governance. Against this backdrop, this study advances a set of analytical expectations that guide the empirical investigation. First, it is expected that greater alignment between HTA outputs and PMS

indicators enhances organisational performance by ensuring that technology adoption is closely linked to measurable outcomes. Second, the presence of robust feedback loops, particularly through the use of real-world evidence, is expected to support adaptive governance and continuous improvement. Third, while institutional pressures are likely to drive the formal adoption of HTA and PMS, they may simultaneously contribute to superficial implementation, resulting in limited integration. Fourth, higher levels of decoupling between formal structures and actual practices are expected to reduce the effectiveness of decision-making processes [35]. Finally, the depth of HTA-PMS integration is anticipated to depend on organisational capacity, including data infrastructure, analytical capabilities, and stakeholder engagement mechanisms. Taken together, this theoretical framework provides a coherent lens through which the empirical chapters of this thesis are interpreted. It not only explains the functional complementarities between HTA and PMS but also illuminates the institutional constraints that shape their interaction in practice. By doing so, it enhances the analytical coherence of the study and positions the Malta case within broader debates on healthcare governance, organisational change, and evidence-based management.

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CHAPTER TWO

2. AIM AND STRUCTURE OF THE THESIS

The thesis aims to identify critical factors and strategic dimensions in the effective strategies for measuring the performance of healthcare organisations by conducting a multidisciplinary and comprehensive literature search. Specifically, this thesis aims to deepen the evolution of the performance management systems so as to understand how new technologies and existing practices combine to pursue sustainability, economic, social, and environmental healthcare organisations.

Research Objective 1: Health Technology Assessment and Performance Management: A Scoping Review on the Intersecting Realms. The study seeks to map existing literature to understand how HTA contributes to performance measurement and how performance management frameworks incorporate evidence generated through HTA. It also identifies the main performance dimensions addressed in HTA processes, examines the degree of integration between HTA and performance management across different settings, and highlights gaps in stakeholder involvement, real-world data use, and methodological alignment. Through this scoping review, the research provides a foundation for strengthening the coherence and synergy between HTA and performance management as complementary tools for health system governance.

Research Objective 2: The Evolution of Health Technology Assessment in a Global Context: A Content Analysis of National and International Guidelines. The study analyses how national and international HTA guidelines have evolved globally and aims to understand the methodological differences and commonalities that shape their application in healthcare decision-making. The study seeks to conduct a content analysis of ten HTA guidelines from various countries and international bodies, compare their structures, evaluation criteria, and evidence requirements, and identify emerging trends. Additionally, the study seeks to highlight global variations in economic evaluation methods, organisational considerations, and social dimensions, ultimately offering insights that support harmonisation and improved HTA practices worldwide. This information is useful to address multidimensional performance measurement by healthcare systems and organisations.

Research Objective 3: The Integration of Performance Management and Health Technology Assessment: A Case Study for Malta. The study examines how the health system of Malta integrates Health Technology Assessment into its broader performance management processes

and explores stakeholders' experiences with the implementation of these tools. The study examines the governance structures, regulatory mechanisms, and operational pathways that shape HTA in Malta. Furthermore, the study aims to understand stakeholder perspectives on the challenges and opportunities for deeper HTA–PM integration, offering practical recommendations for strengthening evidence-informed performance management in Malta and global contexts.

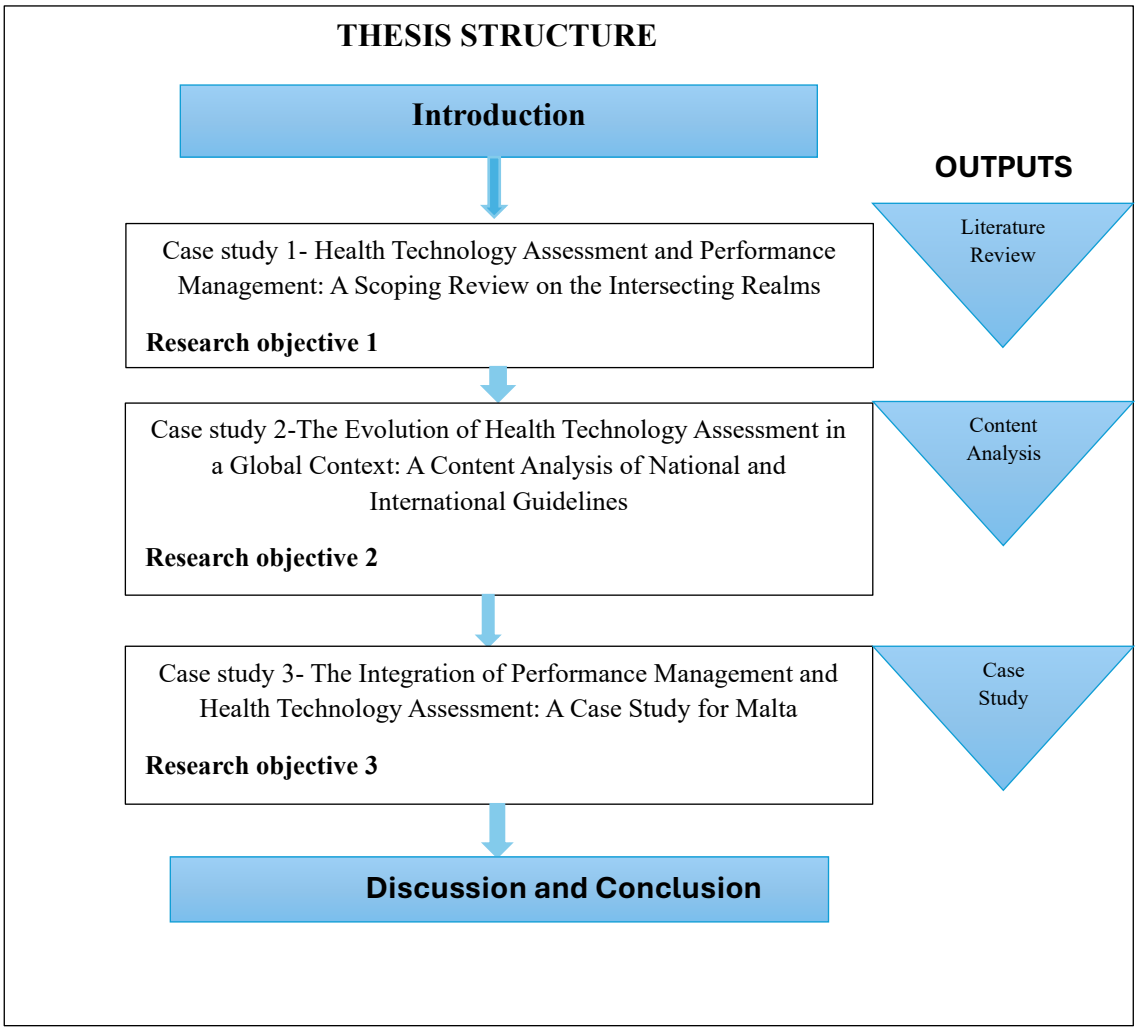
To strengthen the overall coherence of the thesis, this study is guided by a central overarching research question that integrates the three research objectives: *How and to what extent can the integration of Health Technology Assessment (HTA) and Performance Management Systems (PMS) enhance evidence-based decision-making and performance outcomes in healthcare systems, and what institutional factors shape this integration in practice?* This umbrella question provides a unifying analytical thread across the thesis, ensuring that the scoping review, guideline analysis, and case study are not treated as discrete inquiries but as interconnected stages of a cumulative research design. Specifically, the first objective (scoping review) maps the existing intellectual landscape and identifies conceptual and empirical gaps in the HTA-PMS nexus; the second objective (content analysis of guidelines) examines how these concepts are operationalised and institutionalised at the policy and regulatory level; and the third objective (Malta case study) empirically investigates how such integration unfolds in practice within a specific healthcare system, thereby allowing for theory refinement.

To further clarify this intellectual progression, the structure of the thesis should be interpreted as a sequential and iterative process in which each study builds upon and informs the next. The scoping review provides the foundational theoretical and conceptual insights that inform the analytical dimensions explored in the guideline analysis, while the findings from the guideline analysis, in turn, shape the empirical focus and data interpretation in the case study. Ultimately, the case study feeds back into the broader theoretical discussion by validating, challenging, or refining the initial assumptions identified in the literature. This cumulative logic reinforces the thesis's contribution by linking theory development with empirical validation in a coherent manner.

From an epistemological standpoint, the thesis adopts a pragmatic and interpretivist orientation, recognising the complexity and context-dependence of healthcare governance systems. The pragmatic stance justifies the use of multiple qualitative methods: scoping review, content analysis, and case study as complementary approaches aimed at addressing different

dimensions of the research problem. At the same time, an interpretivist perspective underpins the analysis by acknowledging that organisational practices, policy frameworks, and stakeholder behaviours are socially constructed and influenced by institutional contexts. This epistemological positioning supports an in-depth exploration of how HTA and PMS are understood, implemented, and integrated across different levels of the healthcare system, rather than assuming a purely objective or universally applicable model of integration.

Finally, the relationship between the research objectives and the theoretical framework developed in Chapter 1 is explicitly articulated in this thesis. The scoping review (Objective 1) serves to identify and systematise the theoretical foundations of HTA-PMS integration, thereby informing the development of key analytical propositions. The content analysis of HTA guidelines (Objective 2) examines how these theoretical principles are translated into formal institutional frameworks, with particular attention to issues of standardisation, performance measurement, and evidence use. The case study of Malta (Objective 3) then provides an empirical setting to test and refine these propositions, especially in relation to institutional theory concepts such as isomorphism, legitimacy, and decoupling. In this way, each research objective contributes to a progressive refinement of the theoretical framework, ensuring strong alignment between theory, methodology, and empirical analysis throughout the thesis.


THESIS STRUCTURE
Introduction
OUTPUTS
Case study 1- Health Technology Assessment and Performance Management: A Scoping Review on the Intersecting Realms
Research objective 1
Literature Review
Case study 2-The Evolution of Health Technology Assessment in a Global Context: A Content Analysis of National and International Guidelines
Research objective 2
Content Analysis
Case study 3- The Integration of Performance Management and Health Technology Assessment: A Case Study for Malta
Research objective 3
Case Study
Discussion and Conclusion

CHAPTER THREE

Health Technology Assessment (HTA) And Performance Management (PM): A Scoping Review on the Intersecting Realms

Akinbobola, E. O., De Domenico, F., Manetti, S., & Noto, G. (2025). Health technology assessment (HTA) and performance management (PM): a scoping review on the intersecting realms. *BMC Health Services Research*, *25*, 917.

(Published)

ABSTRACT

Background

Both Health Technology Assessment (HTA) and Performance Management (PM) are clinical governance disciplines that aim to improve the quality, equity, and financial sustainability of health organisations and systems. Although HTA and PM share many features, to the authors' knowledge, few studies have investigated their interplay. This study attempts to fill this gap by analysing how the literature has explored and developed the integration between HTA and PM concepts and tools within the healthcare sector.

Methods

To address this gap, this study examines 33 papers selected through a scoping review that explores the intersection of HTA and PM within the healthcare sector. In particular, the paper adopted the preferred reporting items for systematic reviews and meta-analysis (PRISMA) methodology to select and analyse articles.

Results

The review highlights the dynamic convergence of HTA and PM, emphasising how combining these frameworks and functions can enhance decision-making in healthcare. This integration ensures that technologies are adopted on the basis of proven effectiveness in pursuing healthcare systems goals and that performance metrics align with evidence-based practices, leading to better resource allocation and improved patient outcomes. The literature review underscores the need for further research to understand the integration between HTA and PM and their combined impact on organisational performance, sustainability, and resilience in the healthcare sector.

Conclusion

This study contributes to the literature by providing a comprehensive overview of the current state of research on HTA and PM, offering insights for future studies, and practical recommendations for integrating these disciplines to improve healthcare management and policymaking.

Keywords Health technology assessment, Performance management, Scoping review, Evidence-based management, KPI

INTRODUCTION

The healthcare sector continually faces complex, "wicked" problems, necessitating the integration of advanced methodologies and research streams to ensure effective service delivery and timely assessment of healthcare innovations [1]. In the fast-paced landscape of healthcare innovation management, the demand for informed, evidence-based decision-making is essential to improve the efficiency and effectiveness of healthcare organisations and systems [2]. Within this context, adopting clinical governance frameworks is fundamental to implementing evidence-based practices in decision-making [3, 4]. Clinical governance encompasses a comprehensive set of leadership behaviours, policies, procedures, and mechanisms for monitoring and improving clinical outcomes [5, 6]. This structured framework is designed to promote accountability, increase care quality, and ensure high standards in healthcare delivery [7]. It includes various processes—such as risk management, clinical audits, and performance monitoring—focused on enhancing patient safety and clinical outcomes [5]. Central to clinical governance is the commitment to continuous improvement, encouraging healthcare professionals to assess their practices, identify areas for enhancement, and implement evidence-based practice (i.e. the systematic use of the best available evidence to improve decision making processes [8]). This framework fosters a culture of transparency and professional development, distributing responsibility among healthcare teams and aligning organizational structures with individual roles to improve the overall quality and safety of patient care [7, 9]. Clinical governance is often supported by two key healthcare management disciplines: Performance Management (PM) and Health Technology Assessment (HTA). These disciplines do not merely coexist within clinical governance; they actively reinforce its core objectives by addressing distinct yet interrelated aspects of healthcare improvement. In particular, PM is broadly defined as a set of tools, techniques, and activities aimed at guiding internal stakeholders to pursue organizational objectives by measuring, managing, and evaluating performance [10–13]. Introduced to the public sector in the 1990 s during the "New Public Management" (NPM) reform wave, PM aimed to introduce private sector efficiency and accountability standards into public organisations [14, 15]. The principles of NPM catalysed the corporatisation of public organisations, emphasising financial performance and productivity metrics that had been previously underexplored. The healthcare sector, particularly in countries with national health services such as the United Kingdom and Italy, was among the first to adopt these NPM principles [16]. Here, PM evolved from a management tool to a regulatory framework, requiring healthcare systems not only to demonstrate financial accountability but also to link financial planning directly to measurable healthcare outcomes.

Consequently, PM principles have become integral to public administration controls aimed at generating value in healthcare [16]. This shift paralleled the rise of clinical governance, which introduced a cultural transformation within healthcare, aligning with PM principles to encourage healthcare organisations to "continuously improve service quality and maintain high standards of care", fostering environments where clinical excellence thrives [17]. Evidence is foundational to PM, equipping decision-makers with key insights and metrics to assess and enhance organisational efficiency, productivity, and overall effectiveness [18]. By systematically collecting, analysing, and interpreting relevant data, organisations can establish key performance indicators (KPIs), track progress toward goals, and make informed decisions to optimise operational processes supporting clinical governance [19]. In this perspective, through the collection and framing of evidence, PM further supports clinical governance by enabling organisations to identify improvement areas, allocate resources more effectively, and align strategic objectives with tangible outcomes [16, 20, 21]. On the other hand, HTA "is a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making to promote an equitable, efficient, and high-quality health system" [22]. HTA, in fact, complements clinical governance by providing a multidisciplinary framework to evaluate the value of health technologies throughout their lifecycle [22]. Recent advancements in healthcare have led to marked improvements in patient care, operational efficiency, and organisational performance due to the rapid adoption of new technologies. However, the introduction of innovative healthcare solutions in advanced systems has also contributed to significant increases in healthcare costs and growing demand for services globally [23]. HTA plays a crucial role in informed decision-making and health policy formulation by providing comprehensive insights into the multidimensional impact of innovations—whether organisational, technological, or otherwise—throughout various stages of the technology lifecycle and levels of technological readiness [24–26]. In recent years, the application of HTA has garnered increasing attention, necessitating a more nuanced approach that accounts for the technological maturity and life cycle stage of the interventions being assessed [27]. Scholars and practitioners alike have recognised the significance of distinguishing between various 'species' or 'typologies' of HTA. This differentiation was articulated by the seminal work of Ijerman et al., which emphasised that the primary distinction lies in the purpose of the assessment [28, 29]. Early-stage HTA primarily aims to guide the development of innovations in their formative phases, encompassing activities from initial ideation and design to clinical validation studies. To achieve this, it employs tailored methodologies, including expert

elicitation, computational simulations, and bench studies. The other species of HTA, called mainstream or mature HTA, assesses the clinical and economic impact of technologies that have either entered the market or are in the process of securing market access, depending on country-specific regulatory frameworks. In some contexts, HTA is a prerequisite for market approval, while in others, it is conducted post-launch as part of reimbursement or adoption decisions. HTA assessments span a range of health technologies, including pharmaceuticals, vaccines, medical devices, surgical procedures, software, and healthcare systems [30]. This evaluative approach aids policymakers and healthcare decision-makers in making informed choices by weighing the benefits, limitations, and costs associated with the development, implementation, and use of each technology throughout its lifecycle [31]. Through PM and HTA, two key features of clinical governance are addressed: one that emphasises accountability and performance optimisation (PM) and another that fosters evidence-based evaluation and integration of innovations (HTA). With rapid advancements in areas such as precision medicine, gene therapy, and digital health solutions, the need for timely and comprehensive HTA assessments has intensified [32]. In many Countries, the first HTA practices and frameworks have focused on clinical effectiveness and economic efficiency when evaluating health innovations – even though most recent studies emphasize the need to account for other social variables (see for instance [33]). However, with the rise of new digital health technologies—such as digital therapeutics, platforms, and AI-driven innovations—HTA has broadened significantly due to their inner characteristics [34, 35]. For the successful integration of technological innovations within healthcare systems, assessing only their clinical and economic impacts is insufficient. This shift aims to provide a holistic understanding of the impacts of contemporary health innovations [35]. Over the past two decades, HTA has seen significant international growth, with countries collaborating to share data, methodologies, and best practices. Notable initiatives include the European Network for Health Technology Assessment (EUnetHTA) and the International Network of Agencies for Health Technology Assessment (INAHTA). Insights from these international partnerships are vital for shaping healthcare policies and regulations, providing essential information for payers and regulators to make informed decisions regarding the approval, coverage, and reimbursement of innovative technologies. The healthcare sector's dynamic nature, marked by constant technological evolution and shifting healthcare objectives, has led HTA into a transformative phase. This period of considerable evolution reflects the need for adaptable strategies to address the inherent complexities of modern healthcare. Following extensive discussions, the European Commission adopted a new regulatory framework for HTA, formalized in the European

Regulation for HTA (Regulation (EU) 2021/2282) [36] on December 15, 2021, which entered into force on January 11, 2022 with a concrete application only started on January 12, 2025. This new regulation is a foundational reference for our study, which explores the intersection between HTA and Performance Management (PM). Notably, the regulation emphasizes the importance of collaboration on the clinical domains with the aim to improve equity and access to beneficial technologies to all patients across the EU faster than before. By fostering a shared framework, it aims to streamline assessment processes, reduce duplication of effort, and accelerate the introduction of innovative treatments. Additionally, the regulation mandates that individual member states refrain from requesting duplicate evidence already assessed at the EU level, thereby promoting efficiency and reducing burdens on stakeholders, expanding HTA's traditional scope beyond purely economic assessments. This adaptation is critical for European nations, which must now integrate additional non-clinical factors related to PM within the HTA framework [37]. These developments underscore the interconnectedness of non-clinical evaluations, the broader HTA landscape, the common framework and the collaboration between countries reflecting a significant paradigm shift in HTA methodologies that allow countries not to require the same evidence.

Aim of the study

The principles of PM and HTA, as outlined above, enable healthcare systems and organizations to enhance performance, deliver quality and sustainable care, and prioritize patient-centred services, which are defined as services designed to be respectful of and responsive to the individual values, preferences, and needs of patients, ensuring that care decisions are guided by what matters most to them— as required by clinical governance standards [38]. These disciplines share foundational principles and can be integrated to improve the quality, timing, and effectiveness of healthcare decisions. By utilising evidence from HTA to inform management decisions, healthcare organisations ensure that technologies are adopted based on proven effectiveness. On the other hand, through performance monitoring, PM supports HTA activities by benchmarking the anticipated outcomes of innovations against organisational objectives, addressing questions such as: How does the adoption of this innovation impact organisational and patient outcomes? HTA provides evidence-based evaluations of health technologies, prioritising investments aligned with organisational objectives and cost-effectiveness [39]. While HTA assesses the effectiveness, costs, and broader impacts of health technologies, the resulting information becomes foundational for PM initiatives, enabling healthcare organizations to evaluate technology value, allocate resources efficiently, and

enhance patient outcomes. Integrating HTA data into PM frameworks thus supports evidence-based strategies, ensuring that resources are allocated appropriately, that technologies are adopted effectively, and that care delivery aligns with overarching performance objectives. Notably, the intersection of PM and HTA is particularly evident in budgeting processes, investment planning, and lifecycle management of technology, including obsolescence programming and control. Despite extensive studies on PM and HTA in the healthcare sector, few studies have focused on the integration between these two areas. Specifically, previous studies have not adequately explored the development of integrated frameworks to align performance management with health technology assessment, nor have they addressed how these systems could be effectively operationalised to support decision-making processes in healthcare organisations. Although both are widely applied, their intersecting significance has received limited exploration. Therefore, this research seeks to analyse the integration between PM and HTA. To that end, we conducted a scoping literature review to integrate and analyse findings from multiple studies. Specifically, our research aims to identify and contextualise trends in the contributions of HTA and PM practices within healthcare at the technology, organisation, and system levels. To achieve this purpose, the article is structured as follows: the next section describes the methodology used to conduct the scoping review; the third section presents and develops the results; the fourth section provides a discussion, including the development of a framework that integrates HTA and PM. Finally, the last section offers conclusions.

METHODOLOGY

A scoping review, also known as a "mapping review", was conducted to explore and understand the integration between the fields of HTA and PM. The primary aim of this review was to provide an overview of the available evidence, analyse the research methods employed by the authors, and assess the healthcare areas in which these methods were applied. A scoping review approach was chosen because it facilitates the synthesis of research findings, allowing for the development of recommendations for future studies. This method supports the systematic identification of both qualitative and quantitative evidence within the existing literature, enabling us to map and organise extracted material effectively, thus deepening our understanding of the findings in these fields [40]. To ensure transparency and thoroughness, the authors conducted scoping reviews and meta-analyses following the PRISMA (Preferred Reporting Items for Scoping Reviews and Meta-Analyses) Statement as a reporting standard [41, 42]. The article selection process involved multiple steps: (i) defining inclusion and

exclusion criteria; (ii) establishing a search strategy; (iii) identifying keywords based on the review's theoretical frameworks; (iv) assigning review tasks to each author; and (v) analysing the identified papers to make final inclusion or exclusion decisions.

Review protocol

Given the exploratory nature of this scoping review, we selected the Scopus database for our literature search, as it is the most comprehensive multidisciplinary database, encompassing a broad range of peer-reviewed literature across multiple fields and journals. Compared with PubMed and Web of Science, Scopus offers wider coverage and more robust citation analysis, as noted by Falagas and colleagues [43]. This choice allowed us access to an extensive and diverse pool of literature, ensuring that our performance analyses are thorough, informative, and insightful. In the initial phase, eligibility criteria were established based on English language, research type (both primary empirical studies and secondary reviews), and publication type (scientific articles, reviews and book chapters). No restrictions were applied regarding publication year, research area, or geographic scope, allowing for a comprehensive exploration of the relevant literature. Following this research, structured search query was developed to optimize the search related to these keywords: "health technology assessment" OR "hta" AND "performance manag*" OR "performance measur*" OR "performance indicator*" OR "kpi" OR "bsc" OR "Balanc* scorecard" OR budgeting OR "management control" without year limitations. This was our research query: TITLE-ABS-KEY ("health technology assessment" OR "hta" AND "performance manag*" OR "performance measur*" OR "performance indicator*" OR "kpi" OR "bsc" OR "Balanc* Scorecard" OR "budgeting" OR "management control") AND (LIMIT-TO (LANGUAGE, "English")). The search was performed in February 2024. Using the search keywords, the Scopus database provided 93 articles, as shown in Fig. 1, which synthesizes the article screening process based on the PRISMA protocol.

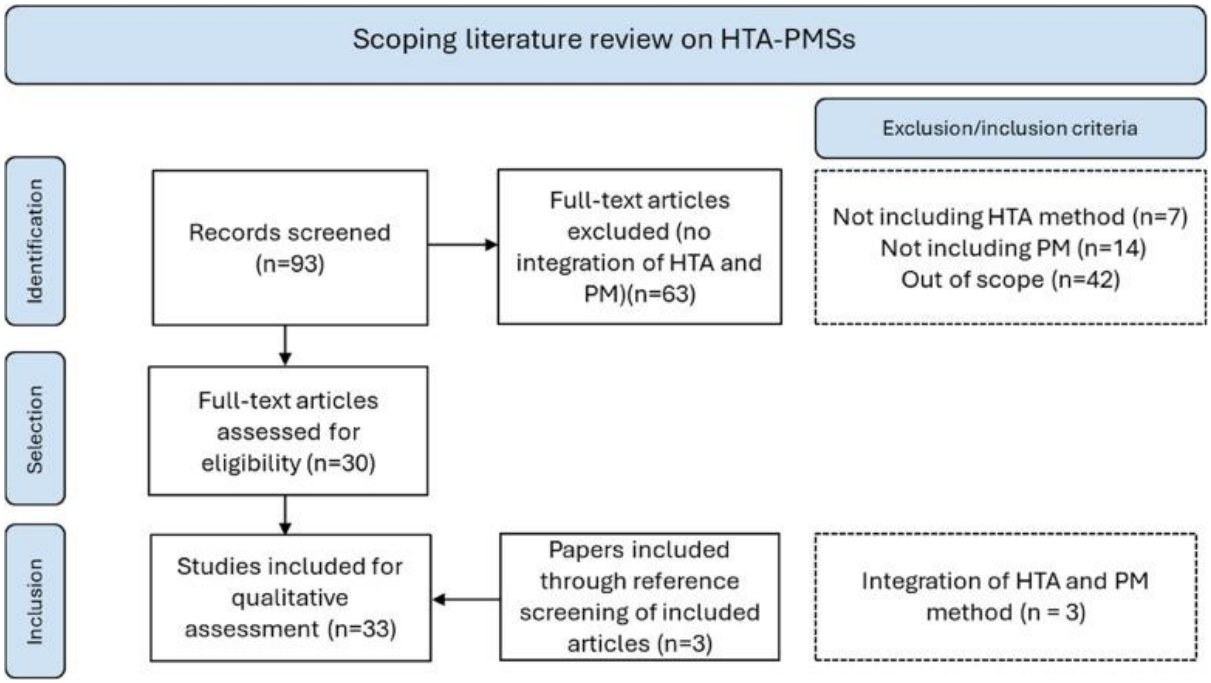


Figure 1: Article selection process - PRISMA flow diagram

Two members of the research team analysed the titles and abstracts of the results obtained to determine, based on the inclusion and exclusion criteria, whether to incorporate the article into the final sample. To ensure a rigorous selection of relevant studies, we included articles that explicitly addressed both PM and HTA within the healthcare sector, particularly those discussing their integration at the technology, organization, or system levels. Articles were excluded if they focused solely on either PM or HTA without exploring their integration, as well as those that were not peer-reviewed or written in languages other than English. When doubts arose about whether an article should be included, the whole research team discussed and built consensus on inclusion or exclusion. We carefully examined all the identified papers for eligibility, and after a thorough review, we selected the 30 articles that were most relevant to our scoping review. Upon the identification of the final sample of papers designated for analysis, the authors conducted an in-depth examination of the citations contained within each selected article. This hand-search methodology resulted in the identification and subsequent inclusion of three additional articles that were deemed pertinent to the research purpose. Upon finalizing the selection of the sample, a Data Extraction Form (DEF) was constructed in an Excel spreadsheet to facilitate systematic data collection. The variables delineated within the DEF for each included article encompassed the following dimensions: theoretical framework, research methodology, levels of analysis—specifically macro (system level), meso (hospital level), and micro (technology level)—as well as the critical link or nexus between HTA and

PM disciplines. These variables were determined according to a deductive-inductive approach. In particular, the authors followed a structured process consisting of different steps: (i) initially, two members of the research team identified the main emerging theoretical backgrounds, research methodology and levels of analysis explicitly mentioned within the abstract. Where such reference was not clearly present in the abstract, the analysis was extended to the content of the article, establishing it in an inductive way; (ii) subsequently, articles were categorised according to the variables by the four authors in groups of two, doubts that arose were clarified through two brainstorming sessions, facilitating the categorisation of contributions; (iii) lastly, a final brainstorming session was organised with all authors to review the 33 articles and check the consistency of the categorisation, ensuring that the assignment to clusters was appropriate and agreed upon. The DEF, along with the pertinent values for each variable, can be found in the Appendix for the included articles of this review.

RESULTS

The initial analysis conducted pertains to the temporal distribution of the acquired publications. An analysis of the temporal distribution of the examined sample, as depicted in Fig. 2, reveals a discernible growing trend. These preliminary findings suggest a continuing interest among the scientific community in this topic, particularly

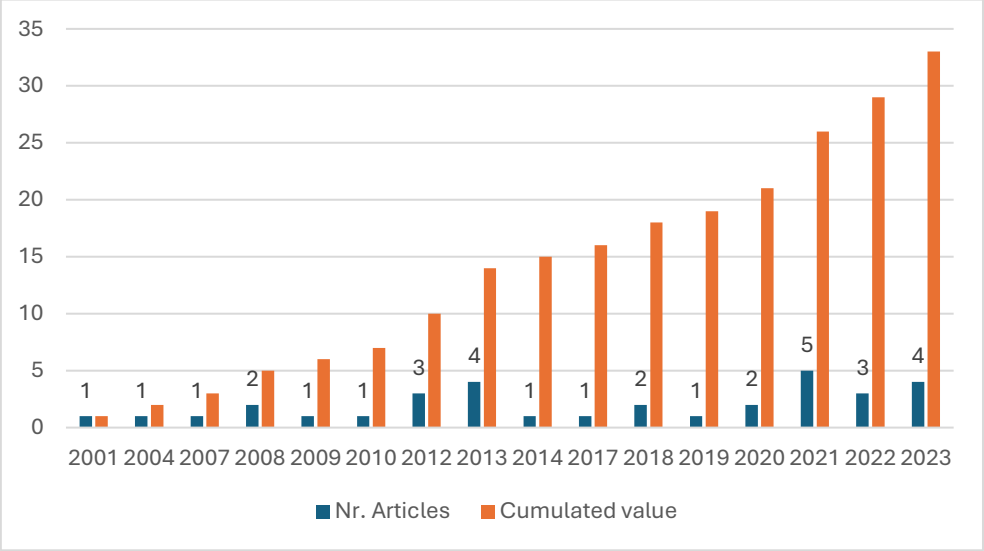


Figure 2: Temporal distribution of scientific products

from the year 2012 onwards. Notably, a period of stagnation was observed between 2014 and 2020; however, a resurgence of interest emerged from 2021 to the nowadays. This trend indicates a continuing interest in this thematic area, which is likely attracting an increasing number of researchers. Our investigation revealed that the earliest and most pertinent

publication considered during our PRISMA selection process dates back to 2001. Notably, the study by Herbert (2001), titled "Telehealth Success: Evaluation Framework Development" [44], serves as a foundational reference. Herbert established that HTA encompasses more than mere technological evaluation; it also integrates performance metrics, outcomes, and operational considerations. Although published in 2001, this study underscored the critical role of HTA in health system evaluations, which can significantly influence technology adoption decisions. It has been instrumental in advocating for a comprehensive perspective on the HTA discipline, positioning it as a methodological framework that incorporates various domains, including health economics—specifically, economic evaluations in healthcare, such as cost-effectiveness analysis, cost–benefit analysis, and cost-utility analysis. Furthermore, the article broadens the definition of technology to encompass the application of knowledge, incorporating both hard and soft technology dimensions [45]. The analysis of the publication year trend in our review emphasized that the research area of HTA-PM attracted great interest in 2021, when it peaked with five publications. It is equally evident that many (42%) of the articles selected in the study came in recent years (2020–2023) possibly related to the advent of the global pandemic that shook the entire global healthcare system, in which the adoption of technologies played a key role.

Table 1: Most important journals

Journal	**Number of articles published**
International Journal of Technology Assessment in Health Care	4
BMC Health Services Research	2
Health Policy	2
Sustainability (Switzerland)	2
Technology and Health Care	2
Value in Health	2
Other	19

Table 1 shows the scientific journals dealing with the subject. The journal that published the greatest number of articles (4 articles) in our review is the International Journal of Technology Assessment in Health Care, followed by BMC Health Service Research (2), Health Policy (2), Sustainability (2), Technology and Health Care (2), and Value in Health (2). The other 19 articles were published in 19 different journals. We also conducted a geographical analysis of the articles to determine the origins of the authors, thus defining their geographical area of provenance. This analysis is illustrated in Fig. 3. Notably, the data reveal a pronounced

concentration of research output, with Italy contributing 14 out of 33 articles, whereas Canada and the United States accounted for 6 and 3 publications, respectively. This distribution underscores the substantial variation in research interest across different nations.

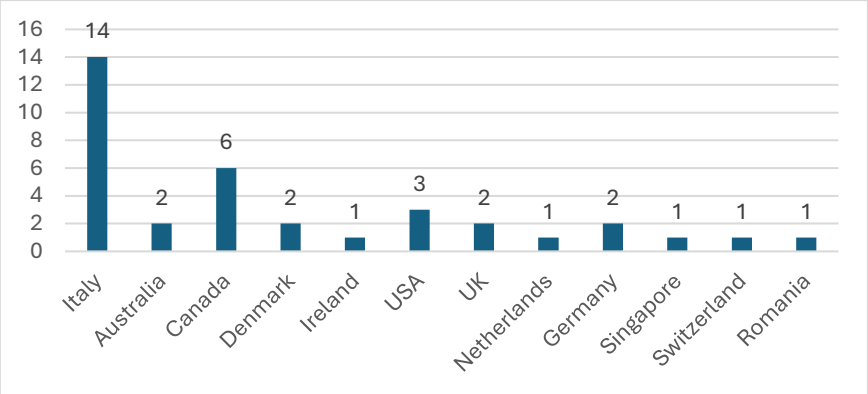


Figure 3: Geographical distribution of the reviewed articles

Theoretical perspectives

To enrich our review, we extended the analysis beyond the mere collection of empirical data to include an analysis of the theoretical perspectives expressed in the different articles. This approach allowed us to examine not only the results and conclusions reached by the authors but also the conceptual frameworks and theories that guided their investigations, providing a deeper understanding of the different perspectives and theoretical underpinnings that inform the academic and practical debate on HTA and PM in healthcare. As previously detailed in the Methodology section (review protocol), the authors identified eight theoretical backgrounds through a deductive-inductive approach, following a structured process to ensure consistency and agreement in article classification. Our analysis, illustrated in Fig. 4, identified eight distinct clusters: “value-based care”, “quality”, “human resources”, “hospital-based health technology assessment”, “digital technology”, “decision-making”, “collaborative governance” and “budgeting”. An analysis of the figure reveals that a significant number of the research articles included in the review are grounded in the theoretical framework of “budgeting”. This theoretical orientation has garnered significant attention from scholars since the emergence of heightened interest in HTA research and related investigations. Budgeting theoretical background (cluster 1) was adopted in eight studies. Budgeting is a tool of PM that allows decision-makers to understand the future effects of their choices. In this sense, budgeting represents a feed-forward tool that enhances the comprehension of how a specific technology or device may impact the different performance dimensions of a healthcare organisation/system. Three of these studies [46–48] focused on how to develop a budgeting

process at the hospital level. The remaining five studies were based on Program Budgeting and Marginal Analysis (PBMA), a technique used in resource allocation, particularly within the healthcare sector [49]. PBMA focuses on strategically allocating resources across various programs and activities in alignment with organisational priorities and objectives. This method employs a comprehensive framework to delineate different programs' costs and anticipated outcomes, promoting transparency and coherence with the organisation's goals. Additionally, PBMA facilitates the identification of optimal strategies for enhancing outcomes by evaluating the effects of incremental adjustments, thereby maximising the efficient utilisation of available resources [49]. These studies were conducted in Australia, Canada, and the USA [49–53]. Seven studies had theoretical foundations on "Decision-making" (cluster 2). This cluster includes articles aimed at discussing methodologies and techniques that can support decision-making during HTA processes. Three of the studies [54–56] give specific relevance to the development of a set of Key Performance Indicators (KPIs) to support decision-makers. The other four focus on combining multicriteria decision analysis (MCDA) and decision support systems (DSS) with HTA [57–60]. Overall, the authors based their theoretical framework on the belief that KPIs allow for an accurate and measurable evaluation of various aspects of the healthcare system and that these indicators may improve the quality of decision analytic models in HTA. The "Quality" theoretical background (cluster 3) was also appreciably used by some authors. This includes articles focusing on Donabedian's [61] framework [44, 62–64] and how to develop and use performance measures within the HTA process [44, 65, 66], such as the quality-adjusted life-years (QALYs) as an outcome for the economic evaluation of health interventions. The most cited article from this theoretical perspective is that of Garrido et al. [64], which discusses the development of HTA, emphasizing the information needs of all levels and areas of health policymaking through quality monitoring. Another relevant article in this category is the study by Carini et al. [62], which thrived to identify and classify the dimensions of hospital performance indicators to develop a common language and identify a shared evidence-based way to frame and address performance assessment.

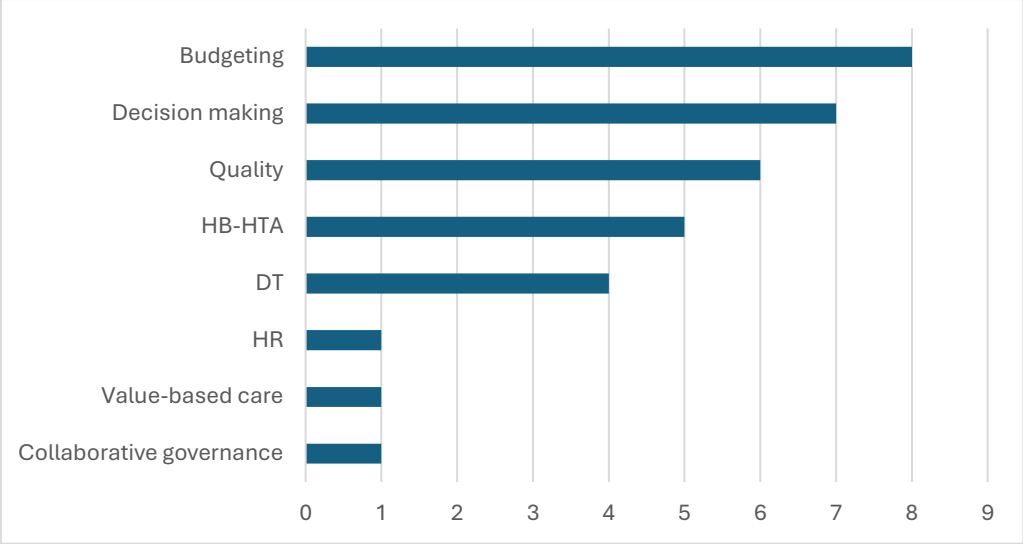


Figure 4: Theoretical background of scientific products

Another important theoretical model underscores the importance of "Hospital-based Health Technology Assessment" (HB-HTA) through five articles (cluster 4) [23, 58, 67–69]. HB-HTA involves the evaluation of health technologies within the hospital setting to facilitate informed decision-making regarding their adoption and utilisation. It is important to mention that also other articles that have been clustered in other background focuses on the HTA at the organisational level – e.g. Cionini et al. [50], Lettieri [47], Carini et al. [62]. Palozzi et al. [67] is the most cited article focusing on the integration of HB-HTA with specific attention to hospital-specific clinical, economic, organisational, and ethical considerations. The research emphasised the importance of tailored evaluations that account for the unique requirements and settings of individual facilities. The primary objective was to facilitate well-informed decision-making concerning health technologies, with the overarching goal of enhancing the effectiveness, quality, and sustainability of healthcare services. Additionally, Lafortune et al. [68] discussed the HB-HTA model as a decentralised approach aligned with clinical priorities and hospital management. This model advocates for comprehensive reviews that promote a participatory approach involving various stakeholders, such as patients, managers, and clinicians. Similar to the goal of Palozzi et al. [67], the focus on the selected referenced articles is to achieve a balance between innovation and resource allocation, optimising patient care, and organisational performance. Other emerging theoretical backgrounds that the literature reviewed in this study hinged on include the theory of Collaborative Governance [20], value-based care [70], Human Resource (HR) [71], and Digital Transformation [72–75].

Methodological perspectives

We finally examined the methodology adopted in the reviewed articles. The results show that many of the articles (17 articles) adopted the literature review approach in their studies. This means that many of the studies in the collection of reviews did a critical summary and evaluation of existing research literature on the topic of HTA or PM that was deemed relevant in understanding their touchpoints. They equally provided an overview of relevant studies, identified gaps in knowledge, and contributed to the theoretical framework of a research project that has been performed by some researchers. Most of the studies in the literature review address the development of performance measures to support HTA, e.g., Lafortune et al. [68], Carini et al. [62], Fasterholdt et al. [72], and Palozzi et al. [23, 67]. The wide use of this methodology can be explained by the novelty of the topic related to the integration between HTA and PM. Other methodologies that have gained the popularity of authors include statistical analysis and case study methodology, which were used in 7 reviewed publications and reported successful experience or evidence of HTA and PM integration, respectively. Statistical analyses have been applied to primary data collected [49, 69]. Seven case studies analysed HTA and PM at the hospital level [47, 48, 58, 69]. In addition to offering real-world applications, best practices, and lessons learned that can direct future implementations, the case studies in this analysis of the review also offer a comprehensive perspective on the influence of health technology on performance while accounting for a variety of contextual circumstances.

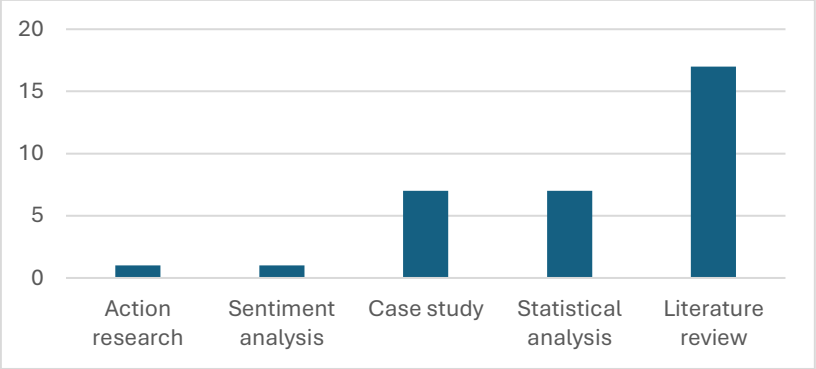


Figure 5: Methodology utilised in the publications reviewed

As shown in Fig. 5, action research and sentimental analysis were other approaches used in 1 reviewed publication. Action research is iterative and fosters interactively reflective practice among participants, which makes it a valuable tool for implementing technology in healthcare settings and measuring performance. Sentiment analysis, on the other hand, was used in one of

the reviewed publications to analyse and quantify opinions and attitudes expressed in text data, which complemented quantitative performance metrics and monitored sentiment trends.

DISCUSSION

The primary objective of this study is to thoroughly examine the literature that focuses on the intersection between HTA and PM. In this work, we explored and considered HTA within the broader healthcare system to understand the links between the multidisciplinary assessment of new technologies and performance management in the system. Given the increasing importance of HTA studies, as reflected in the studies by Hollingworth et al. [76], Uzochukwu et al. [77] and Joore et al. [78], we conducted a scoping literature review and analysis of the relevant literature published in peer-reviewed papers integrating HTA activities and PM activities. The scoping review approach offers the flexibility necessary for studying a multidisciplinary or cross-disciplinary field. Here, it was used to examine the intersection between HTA, PM, and clinical governance, thereby highlighting their combined impact on healthcare quality and innovation. This review thus may serve as a base for refining a theoretical framework aimed at healthcare improvement. In light of our scoping review, four issues emerged for scholarly discourse. First, our review reveals that the researchers have begun to explore the intersection of these two disciplines for over two decades, demonstrating interest in the scientific and academic world. However, only in recent works [20, 23, 67] have scholars focused on developing frameworks that integrate and intersect HTA and PM. Second, the identified outstanding and evidential potential of HTA and PM research shown through the publication domains in internationally renowned journals spanning diverse scopes (as shown in Table 1) is worthy of discussion. Overall, the most significant scientific disciplines that have devoted attention to the investigated topic are health policy, health service research and healthcare management. We believe that there is room to participate in this debate in accounting and general management journals, which currently devote significant attention to the topic of PM in healthcare but neglect the debate on HTA. Another interesting emerging result from our study is the widespread geographical locations of the study areas of the articles reviewed (as shown in Fig. 2). This implies that the subject or focus of the study has garnered global interest across countries over the years. However, our review revealed that most of the articles in our sample were produced in Italy, followed by Canada. The reason for this phenomenon may be attributed on the one hand to the reliance of their health systems on general taxation [79, 80]; on the other hand, to the institutionalization of PM practices in public service in countries such as Italy following the NPM reforms [14–16]. In addition, the constraints on their available

resources necessitate a rigorous ex-ante assessment of the financial implications and multidimensional health impacts expected with the adoption of new technologies. The representation of the Italian academic community highlights the active engagement and scholarly contributions of Italian researchers in the domains of HTA and PM within the healthcare sector. This could be facilitated by the specific Beveridge-type healthcare system (NHS) and the presence of specific mandatory laws and policies that impact both the introduction of performance management and HTA strategies, such as the National HTA Program for MDs (PNHTADM) [79–81]. In contrast, the comparatively lower output from other countries, including the United States, may imply a greater emphasis on these topics within government-funded health systems. Understanding these disparities could inform future strategies for collaboration and the allocation of resources to bolster international research initiatives. Finally, the descriptive analysis of the theoretical backgrounds and the methodologies utilised in the different studies reviewed was also identified and formed a significant pillar of our discussion. The four prominent theoretical frameworks upon which many of the articles were based were “Budgeting”, “Decision-making”, “Quality”, and “Hospital-Based HTA”. Overall, these insights highlight how HTA links well with budgeting activities to activate feed-forward mechanisms that explain ex-ante how the introduction of a new technology may impact healthcare organisation and system results. This supports priority setting and resource allocation processes by fostering decision-making at different governance levels [46, 49, 82]. In summary, the studies highlight the importance of a multidisciplinary approach in the budgetary process by involving healthcare practitioners, administrators, and policymakers in deliberations regarding budget priorities with the aim of optimising resource utilisation and enhancing patient outcomes. Decision-making in the HTA context needs to collect and process information related to different performance dimensions, including financial, effectiveness, and sustainability principles [58, 67]. The decision-making theoretical background holds the belief that HTA supports evidence-based decisions and policy-making that encourage the uptake of efficient and effective healthcare technologies [83], which ultimately helps the performance of healthcare systems. Moreover, combining HTA with PM is particularly relevant in organizational contexts such as hospitals. This may be explained by the fact that technology adoption and utilization are often decisions taken at the organizational unit level, and budgeting and other PM tools support investments and disinvestment decisions [48, 52]. Given that the HB-HTA is primarily done for individual hospitals, this review places a significant emphasis on this aspect. The integration of HB-HTA with PM is a strategic approach to enhancing hospital performance through evidence-based technology adoption and

rigorous performance monitoring, which ultimately results in improved patient outcomes and more efficient healthcare delivery. Hospital research institutes, teaching hospitals, large public hospitals, and private healthcare facilities are increasingly motivated to lead in technological innovation. This competitive landscape compels these institutions to adopt and deploy impactful and innovative technologies that optimize the health outcomes of patients and society both effectively and expeditiously. In this context, it becomes imperative for hospital organisations to be at the forefront of implementing mechanisms and strategies that integrate the iterative activities of HBHTA with PM activities. Such integration is required to facilitate comprehensive and strategic continuous monitoring of technological innovation, enabling a systematic comparison between ex-ante expectations and ex-post performance, while also addressing the growing demand for in-market surveillance. Especially, this approach is an opportunity for monitoring adverse effects associated with innovative medical devices and biomedical technologies in hospital organisations, an area that has traditionally been the domain of pharmaceuticals and medicinal products alone. Attempting to improve clinical governance and healthcare outcomes, three touch points have been identified on the basis of the scoping review results. The first touchpoint refers to the adoption and use of KPIs in HTA processes [54–56]. The integration and alignment of performance indicators and HTA criteria enable the effective coordination and targeting of healthcare organisations' efforts toward similar goals, such as improving healthcare outcomes and optimising the use of health technologies [20]. A second touchpoint refers to the need to track and organise the large volumes of data required for PM and HTA to ensure traceability, transparency, accuracy, reliability, and valuable insights [47]. While PM experts can consult the HTA to identify what data are suitable for assessing technologies, the tools developed to measure and manage healthcare performance with the data collected in the information systems may deliver useful performance related information to the HTA. Third, both HTA and PM are required to engage with stakeholders, both internally and externally, to understand and account for their interests and expectations. The involvement of various stakeholders (physicians, patients, and managers) ensures that their needs and concerns are considered in both performance results and technology assessments, improving the acceptance and effectiveness of implemented solutions [51, 62].

A conceptual framework integrating health technology assessment and performance management

Based on the systematisation of this evidence, a process can be identified and outlined to enhance the integration of HTA evaluation methods with the continuous monitoring and improvement processes of PM. This integration and the consequent framework, although potentially applicable at the health system level, are relevant mostly at the hospital level, i.e., in the HB-HTA setting. It begins with thorough stakeholder involvement, forming multidisciplinary committees including clinicians, administrators, patients, and policymakers to comprehensively consider all performance dimensions. This collaborative approach enhances the legitimacy of the objectives and the relevance and applicability of both assessments and performance measurements. As the PM cycle identifies, through stakeholder engagement, the key objectives that should be addressed by the healthcare organization and hence, considered to be measured; HTA may provide information on how new technologies may contribute to achieve specific goals and how they may impact the overall organizational level – both ex-ante, through feedforward mechanisms such as budgeting (see cluster 1), and ex-post, through feedback coming from performance monitoring. A comprehensive framework may integrate performance metrics by utilising balanced scorecards and KPIs to actively monitor clinical outcomes, financial performance, patient satisfaction, operational efficiency, and the different pillars of sustainability (see cluster 2). It can facilitate informed decision-making by providing real-time, evidence-based guidance to healthcare providers through decision support systems and interactive dashboards (see cluster 2 and 3). Based on what is described above, a possible framework can be identified and outlined to enhance the integration of HTA evaluation methods with the continual monitoring and improvement processes of PM at the organisational level (Fig. 6). The conceptual framework was initially developed through insights garnered from the scoping review, accompanied by reflective discussions among the research team. Subsequently, it was further refined based on feedback obtained from scholars participating in internal seminars at the authors' universities, as well as during a scientific conference on health economics and management in 2023. In contemporary healthcare systems and organisations, the pursuit of defined objectives aimed at enhancing overall performance in alignment with established goals often is challenged by the necessity to integrate novel technologies. The foundational aspect of the conceptual framework presented in Fig. 6 underscores the multifaceted objectives – such as improvements in care quality, operational efficiency, patient satisfaction, cost reduction, and social and environmental sustainability –

that healthcare organisations or systems aspire to achieve. To realise these objectives and thus satisfy stakeholders' needs, the implementation of new technologies – including clinical innovations and sophisticated instruments – may serve as a catalyst for the organization, enabling the achievement of superior performance outcomes.

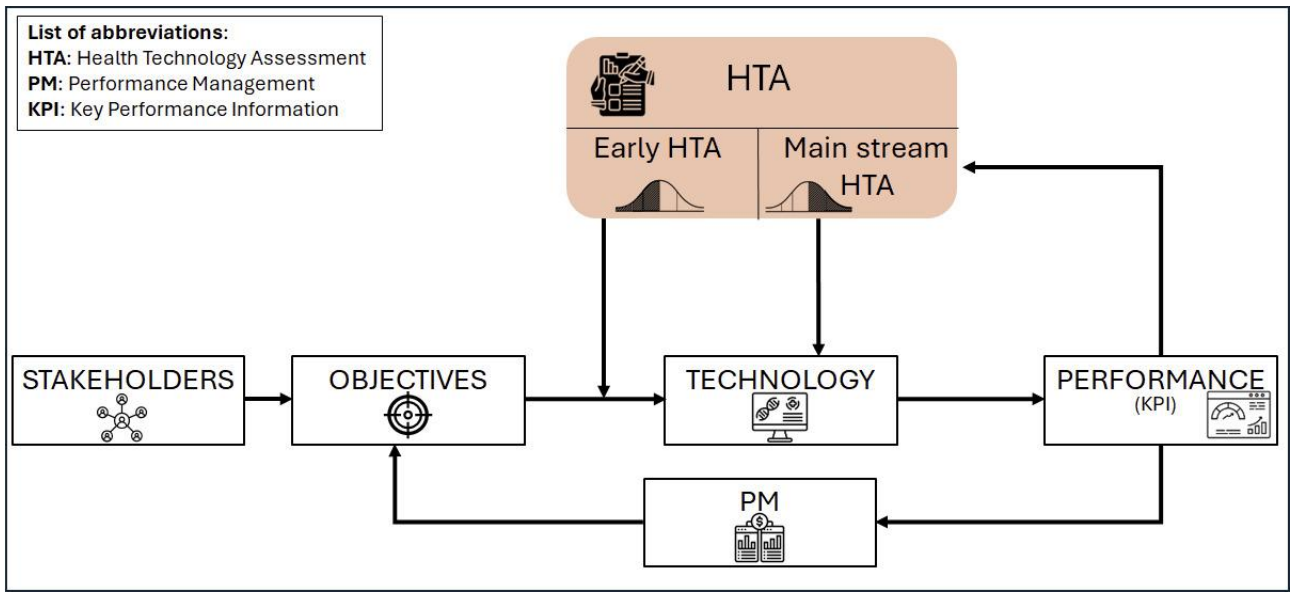


Figure 6: HTA and PM integration framework

Evaluating the appropriateness of these technologies is supported by the HTA process, which provides a comprehensive framework to systematically examine clinical, financial, economic, social, ethical, legal, and sustainability impacts. This dual approach fosters that the technology aligns with the objectives outlined in the PM cycle. The ex-ante assessment, conducted through HTA, involves budgeting and comparative analysis within established goals and projected performance metrics, ensuring that selected technologies have the potential to improve performance in alignment with these goals. Once the technology is integrated within the organization, KPIs serve as evaluative tools for an ex-post analysis to verify whether the technology has achieved the anticipated performance and met the objectives. Following the adoption of a technology, KPIs are used to continuously assess whether it enables the desired level of performance and supports achieving the planned objectives. This ongoing monitoring compares actual performance with initial objectives, thereby determining the effectiveness of the technology across multiple dimensions. The insights gained from this feedback loop inform strategy-makers in setting future objectives and enhance the HTA process by highlighting whether budgeting activities are conducted effectively or if additional factors need consideration. Such an iterative evaluation process can support ongoing performance monitoring against benchmarks, allowing a comprehensive assessment of the deployed

technology's multidimensional impact. A key aspect of our conceptual framework is the technology lifecycle (illustrated in Fig. 6 as early-stage and mainstream HTA), which reflects the maturity of the technology. Our framework acknowledges that the evidence supporting HTA assessments evolves alongside the technology, shaped by dynamic interactions between HTA and PM. As the technology matures and more multidisciplinary data become available, HTA assessments are increasingly grounded in real-world evidence. Consequently, feedback from PM informs HTA assessments as the technology reaches its mature stages of adoption and diffusion. In summary, integrating HTA with PM enables an understanding of whether performance aligns with organizational objectives and whether the new technology can support the achievement of these goals. By combining ex-ante assessment of technology's multidimensional impact prior to implementation with ex-post evaluations of performance post-implementation, we facilitate that technology introduction is both evidence-based and results-oriented, fostering improved performance and goal attainment. Our conceptual framework also emphasizes the role of real-world data collected during the post-launch phase, especially as technology matures within post-market surveillance of medical devices and advanced biomedical solutions. This focus on real-world data highlights the convergence of HTA and PM, presenting a valuable opportunity for effective implementation of new EU regulations—particularly in non-clinical evaluations. Future developments in our research aim to operationalize this conceptual framework into a practical tool for application at the hospital level. This tool, focusing on the predominant cluster identified in our scoping review— HB-HTA—intends to enhance the integration of HTA within PM activities, promoting transparency and effectiveness in healthcare technology management.

CONCLUSION

This study sought to examine the link between Health Technology Assessment (HTA) and Performance Measurement (PM). This was accomplished through a literature review of the 33 most relevant scientific publications selected via the PRISMA selection technique and the development of a conceptual framework that has been internally validated. In a nutshell, the integration between PM and HTA represents a dynamic and synergistic alliance essential for enhancing healthcare sustainability, quality, and value. By integrating HTA methodologies within robust PM frameworks, legislators and healthcare organizations can make evidence-based decisions that help to optimize resource allocation, improve clinical outcomes, and promote patient-centred care. This study's limitations primarily stem from the choice of a scoping review methodology, which introduces potential biases related to the research team's

judgments during data extraction, synthesis, and framework conceptualization. These biases may have influenced the development of the framework and its features. Additionally, the developed framework has only undergone internal validation, meaning that its practical utility and adaptability in real-world contexts remain untested. These limitations suggest that while the framework provides a foundation for integrating HTA processes with PM, its implementation may face challenges, such as contextual variations and differing governance structures. Future research could address these limitations by employing methods such as survey or Delphi panels to gather insights directly from healthcare organizations in various settings, potentially revealing context-specific practices and challenges. In addition, incorporating grey literature, such as national and hospital guidelines, could further enhance the framework's relevance and applicability. Moreover, validating the conceptual framework across various governance levels, including health systems and hospitals could strengthen its generalizability. Finaly, further studies might explore the integration between HTA and PM within real-world empirical cases, which could provide valuable insights into the practical challenges and opportunities of implementing integration strategies for PM and HTA, ensuring the framework is both robust and operationally feasible.

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CHAPTER FOUR

The Evolution of Health Technology Assessment in a Global Context: A Content Analysis of National and International Guidelines

Esther Oluwatosin Akinbobola, Guido Noto, & Patricia Vella Bonanno; The Evolution of Health Technology Assessment in a Global Context: A Content Analysis of National and International Guidelines. International Journal of Health Planning and Management

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ABSTRACT

Health Technology Assessment (HTA) guidelines are vital for evidence-based decision-making in healthcare. The field has evolved significantly due to technological advancements, changing healthcare goals, and a greater focus on transparency and stakeholder involvement. Initially centred around clinical efficacy and safety, HTA now includes economic evaluations and broader societal implications, such as ethical considerations and healthcare equity.

This study examines HTA guidelines from national and international contexts, using qualitative content analysis to assess how different approaches influence implementation and outcomes. A thorough search of public websites and databases was conducted to identify relevant guidelines, and these were analysed using a detailed coding framework.

The findings point to a shift towards more comprehensive and inclusive HTA frameworks that prioritise economic evaluation and stakeholder involvement. This evolution reflects a commitment to methodological rigour and responsiveness to healthcare challenges. Understanding the distinctions and similarities in national and international HTA guidelines is crucial for harmonising processes globally, while a consolidated general domains list was compiled.

Keywords: evolution, content analysis, guidelines, performance perspective, evaluation

INTRODUCTION

Health Technology Assessment (HTA) guidelines play a crucial role in the systematic evaluation of healthcare technologies. They are essential for making informed decisions regarding the adoption of new interventions, such as medical devices and pharmaceuticals,

ensuring that these choices are grounded in evidence, cost-effectiveness, and patient outcomes [1]. In healthcare systems that rely on public funding, HTA guidelines are vital for the effective allocation of limited resources, achieving a balance between clinical needs and financial sustainability [2] [3]. These guidelines promote transparency and utilize standardized criteria, which facilitate fairer and clearer evaluations for both providers and patients [4]. They also offer a structured framework for technology developers, encouraging innovations that clearly demonstrate benefits and adhere to specific evidence requirements. Moreover, HTA guidelines are instrumental in fostering the adoption of healthcare technologies that are effective, accessible, and sustainable [5]. The growth of technology has significantly impacted HTA methodologies by incorporating real-world evidence from sources such as electronic health records. This integration allows for a more comprehensive assessment of technologies within actual clinical environments[6].

The evolution of HTA documentation mirrors significant changes in healthcare priorities, regulatory requirements, and technological progress [1]. Upon its inception in the late 20th century, HTA predominantly concentrated on the clinical efficacy and safety of novel medical technology [7]. Initial HTA reports were predominantly technical documents, produced by a select group of experts, with minimal contributions from stakeholders, such as patients, healthcare professionals, and policymakers [8]. The approaches employed were inadequately standardized, frequently leading to discrepancies in quality and comprehensiveness among various countries and health systems. The principal objective was to educate decision-makers on the potential hazards and advantages of using new health technologies, with minimal focus on transparency or public involvement [1][3].

The complexity of healthcare systems and the rising costs of health technologies led to the adoption of more standardised methodologies in HTA guidelines to ensure consistent and reliable information [1]. Economic evaluations, such as cost-effectiveness and cost-utility analysis, became an integral part of HTA documentation by the 1990s, reflecting a growing awareness of the need to assess the clinical benefits of technologies and their financial implications for healthcare systems [9]. Methodological frameworks, including those proposed by organisations such as the National Institute for Health and Care Excellence (NICE) in the UK, have played a crucial role in guiding the systematic assessment of health technologies. This assessment utilises randomised controlled trials (RCTs) and meta-analyses to uphold rigorous evidence standards [10][11].

In the early 21st century, there were advancements in HTA documentation, with a focus on increased transparency and involvement of stakeholders [1]. HTA bodies began to include public consultations and stakeholder submissions in their assessments, recognizing the impact of healthcare decisions on various groups [8]. This period also involved formal input from different stakeholders, such as patient advocacy groups, healthcare providers, and industry representatives, leading to a more inclusive process [12]. Reports became more comprehensive in capturing how public and expert feedback were considered, resulting in greater transparency in decision-making processes.

In recent times, HTA reports have evolved to be more dynamic and are continuously updated to capture the swiftly changing evidence landscape, especially in fields such as digital health technologies and personalised medicine [13]. Overall, HTA guidelines have progressed from being expert-driven and relatively obscure reports to more structured, inclusive, and transparent processes that consider a broader array of evidence and viewpoints. HTA organizations are now developed not only to deliver thorough clinical and economic assessments but also to outline the ethical, social, and organisational ramifications of health technologies, showcasing a holistic approach to healthcare decision-making [4]. The European Commission presented its proposal for a Regulation on Health Technology Assessment on 31 January 2018. Adopted in December 2021, the Regulation, a key deliverable of the EU Pharmaceutical Strategy, entered into force in January 2022 and applied from 12 January 2025 (European Commission, 2021). This transformation embodies the growing complexity of HTA in a time characterised by patient-centered care, escalating healthcare expenses, and rapid innovation [4].

This study addresses the following objectives. Firstly, it seeks to trace the historical evolution of HTA frameworks, providing insight into how these frameworks have developed over time. Additionally, the analysis will delve into the structure and content of various HTA guidelines from around the globe, highlighting the differences and commonalities among them. Furthermore, it will explore the diverse methodologies employed in different countries, examining how these approaches shape their respective HTA processes and performance dimensions. Lastly, the analysis will investigate the various factors that contribute to the similarities and differences found in national and international HTA guidelines, shedding light on the complexities of health technology assessment in a global context.

METHODOLOGY

Study Design

This study employed a qualitative content analysis approach [14] to explore the evolution of health technology assessment (HTA) in a global context through the systematic examination of national and international HTA guidelines. The analysis focused on identifying trends, key components, and challenges associated with HTA implementation across different countries.

Data Collection

A comprehensive search was conducted to collect HTA guidelines from both national and international organisations. Guidelines were sourced from publicly available databases and organisational websites. Inclusion criteria were as follows: i) Published documents from recognised HTA agencies and organisations; ii) National guidelines representing diverse geographic regions and income levels, and international guidelines from global entities. The final dataset included 10 documents, comprising 8 national guidelines from various countries and 2 international guidelines (Table 1).

Data Analysis

A qualitative content analysis was conducted to examine the collected documents systematically using Atlast.ti software. Each document was assigned a descriptive title corresponding to its country of origin and categorised into national and international guidelines. The coding framework was developed through a deductive and inductive process, informed by the study objectives and the initial review of the documents. Initial codes included key themes, such as performance dimensions; clinical dimensions (clinical effectiveness, patient safety, patient satisfaction, health outcomes), economic dimensions (cost-effectiveness, budget impact, resource allocation, cost-benefit), organisational dimensions (staff satisfaction, organisational processes), and social dimensions (ethics and sustainability). Further coding categories included criteria for economic assessment (budget impact, quality of life, cost-effectiveness, cost-utility, cost-benefit, and cost of illness), methodologies for evidence synthesis (decision-analytical modelling, real-world data integration, and meta-analysis), and stakeholder engagement (organizational, clinician, and patient perspectives). A thematic analysis was performed to identify recurring themes and to examine variations between national and international guidelines. Patterns in applying and adapting HTA principles across

various contexts were examined through co-occurrence analysis and additional qualitative data visualisation techniques. All analysed documents were publicly available, negating the need for ethical approval.

RESULTS

The guidelines for this study are listed in Table 1

Country / Scope	Organisation Issuing the Guideline	Guideline Name	Year	Level	Key Description	Reference or Access Source
Australia	Pharmaceutical Benefits Advisory Committee (PBAC)	*Guidelines for Preparing Submissions to the Pharmaceutical Benefits Advisory Committee (Version 4.5)*	2015	National	Provides detailed requirements for clinical and economic evaluation of medicines seeking reimbursement under the Pharmaceutical Benefits Scheme.	pbac.pbs.gov.au
European Network (EU)	EUnetHTA (European Network for Health Technology Assessment)	*EUnetHTA HTA Core Model®*	2016	Regional or Network	A standardised framework for conducting and reporting HTA across EU member states, covering clinical, economic, organisational, and social dimensions.	eunethta.eu
Global/Framework	EVIDEM Collaboration	*Evidence and Value: Impact on Decision Making (EVIDEM)*	2017	International	A multi-criteria decision analysis (MCDA) framework integrating clinical, ethical, and economic dimensions for transparent healthcare decision-making	evidem.org
Canada	Canadian Agency for Drugs and Technologies in Health (CADTH)	*CADTH Methods and Guidelines for Health Technology Assessment*	2017	National	Provides methodological standards for HTA, including systematic review, clinical effectiveness, and cost-effectiveness evaluation.	cadth.ca
Indonesia	Indonesian Health Technology Assessment Committee (InaHTAC), Ministry of Health	*Guidelines for the Economic Evaluation of Health Technologies in Indonesia*	2017	National	Offers a structured approach to economic evaluation, including cost-utility and cost-effectiveness analyses, to support healthcare decision-making	htac.kemkes.go.id

Ireland	Health Information and Quality Authority (HIQA)	*Guidelines for the Economic Evaluation of Health Technologies in Ireland*	2020	National	Sets out principles and methods for conducting economic evaluations to inform healthcare funding and policy decisions in Ireland	hiqa.ie
United States (USA)	Institute for Clinical and Economic Review (ICER)	*A Guide to ICER's Methods for Health Technology Assessment*	2020	National	Describes ICER's approach to evaluating clinical effectiveness, cost-effectiveness, and value-based pricing for healthcare technologies	icer.org
South Africa	National Department of Health	*Health Technology Assessment Methods Guide (2022–2027)*	2022	National	Establishes a formal framework for HTA in South Africa, guiding evidence synthesis, evaluation methods, and decision-making processes	health.gov.za
United Kingdom	National Institute for Health and Care Excellence (NICE)	*NICE Health Technology Evaluations: The Manual*	2023	National	Comprehensive guidance on HTA methodologies used to appraise health technologies for use within the NHS	nice.org.uk
Saudi Arabia	Saudi Food and Drug Authority (SFDA)	*Health Technology Assessment Methods Guide*	2024	National	Provides HTA procedures and economic evaluation standards to support evidence-based decision-making in the Saudi healthcare system.	sfda.gov.sa

Figure 1 gives the timeline for the publication of the HTA guidelines in various countries and international frameworks. The years of publication span from 2015 to 2024, indicating a continuous global initiative to develop HTA methodologies through the years.

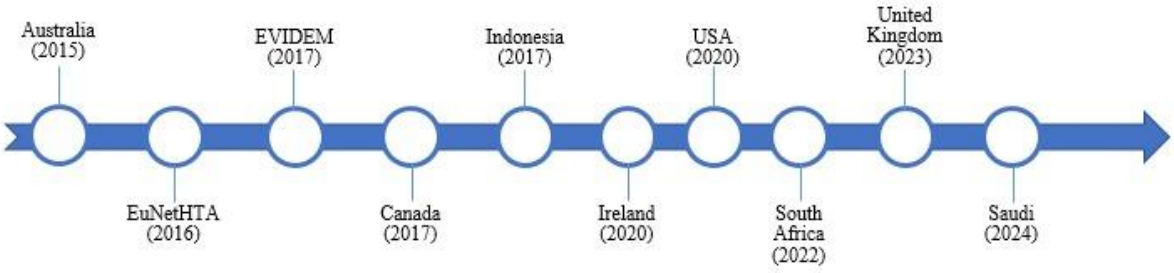

Figure 1: Timeline for the HTA guidelines

Performance Dimension Perspectives

The perspectives of performance dimension support the assessment of the value or effectiveness of HTA. These dimensions include clinical, economic, organisational, and social, which represent different perspectives through which performance is evaluated [15]. Each dimension highlights a distinct area of impact, allowing for a comprehensive understanding of how HTA performs across medical, financial, systemic, and societal factors. Comparative analyses of HTA recommendations across different nations and international organisations reveal significant disparities in the emphasis placed on various performance factors. Adopting the framework of Palozzi et al. [15] and frequency analysis of code occurrence of Performance Dimension illustrate that HTA guidelines in different countries approached the Clinical, Economic, Organisational, and Social Dimensions with varying degrees of focus (Table 2).

Table 2: Overview of guidelines by performance dimensions and key domains

Guideline	Clinical Dimension	Economic Dimension	Organisational Dimension	Social Dimension
Australia (PBAC)	★★Clinical effectiveness and patient safety	★★★Strong emphasis on cost-effectiveness, cost-utility, and budget impact	★★Moderate focus on implementation feasibility	★Limited ethical and societal inclusion
Canada (CADTH)	★★Comprehensive evidence-based clinical review	★★★Cost-effectiveness, cost-utility, and affordability	★★Integration into policy and system management	★★Consideration of equity and patient input

Indonesia (InaHTAC)	★★Clinical outcomes assessed via local data	★★★Major focus on budget impact and affordability	★Limited organisational focus	★Minimal attention to ethics and societal issues
Ireland (HIQA)	★★Clinical effectiveness and patient-reported outcomes	★★★Cost-effectiveness, cost-utility, and budget impact combined	★★Assessment of resource allocation processes	★★Growing focus on transparency and patient involvement
United Kingdom (NICE)	★★★Rigorous clinical appraisal and meta-analysis	★★★Cost-effectiveness, cost-utility, and quality of life	★★Organisational efficiency and service delivery	★★★Strong integration of patient, ethical, and equity aspects
United States (ICER)	★★Clinical evidence from published sources and experts	★★Moderate cost-effectiveness focus; emphasis on pricing	★Limited organisational coordination	★Minimal social and ethical integration
South Africa (NDoH)	★★Focus on population-level clinical impact	★★Budget impact and affordability central	★★Integration with national health system policy	★★Emerging inclusion of access and equity
Saudi Arabia (SFDA)	★★Baseline clinical efficacy and safety	★★Developing cost-analysis and budget focus	★Early-stage organisational integration	★Limited inclusion of ethics and patient roles
EuNetHTA	★★★High standardised clinical evidence and meta-analysis	★★★Balanced economic assessment (CEA, BIA)	★★★Cross-country coordination and process standardisation	★★★Ethical, patient, and sustainability components
EVIDEM	★★★Balanced clinical benefit evaluation	★★Integrated cost and utility analysis within MCDA	★★Organisational readiness considered	★★★Ethical, social, and sustainability emphasis

Key: ★★ = Moderate inclusion; ★★★ = Strong inclusion or major focus; ★ = Minimal or emerging inclusion

In the Australian PBAC guidelines, for instance, the Economic Dimension (ED) stands out as the primary area of concern, with nearly three-quarters of the emphasis score, indicating a robust prioritisation of cost-effectiveness analyses in healthcare decision-making. Organisational dimension and clinical dimension were secondary, and social dimensions were minimally addressed. This prioritisation reflects Australia's commitment to a pragmatic and budget-conscious healthcare system. Conversely, while maintaining strong economic scrutiny, it exhibited a more balanced approach, allocating roughly half of its evaluative criteria to cost-effectiveness, with the remainder distributed across clinical and organisational aspects. South Africa and the United Kingdom demonstrated comparable tendencies but incorporated somewhat greater attention to social and ethical considerations, constituting around one-fifth of their frameworks, indicating a growing awareness of societal equity and patient impact. In Saudi Arabia, all four dimensions were represented but at modest levels, suggesting a nascent

HTA system still developing its methodological structure. The United States, with its decentralised and market-oriented healthcare model, showed low overall emphasis across dimensions, though economic assessments remained slightly predominant.

In contrast to the national frameworks, the European network for Health Technology Assessment (EuNetHTA) adopts a more balanced perspective, significantly distributing its focus almost equally among clinical, organisational, and social dimensions, each accounting for approximately one-quarter to one-third of total emphasis. Similarly, the Evidence- Based Decision Making (EVIDEM) framework fosters a balanced assessment through its modest yet structured approach. These findings underscore the varied HTA methodologies employed globally, shaped by distinct governmental structures, healthcare objectives, and available financial resources. A prominent focus on cost-effectiveness emerges as a key determinant of HTA decision-making across the majority of nations. Countries such as Australia, Ireland, and the UK exemplify well-established HTA frameworks characterised by systematic economic analyses that prioritise budget impact considerations.

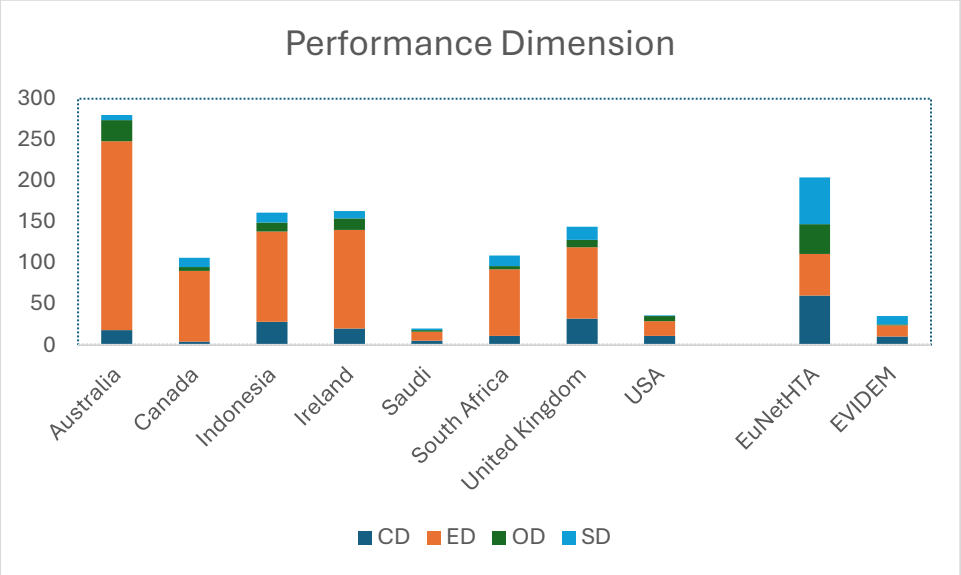

Figure 2: Frequency analysis of code occurrence of Performance Dimension

Source: Authors' own work

CD- Clinical Dimension; **ED**- Economic Dimension; **OD**-Organisational Dimension; **SD**-Social Dimension

Analysis of Assessment Criteria for HTA Guidelines

The data highlight different approaches for economic assessment: Budget Impact Analysis (BIA), Quality of Life (QOL), Cost-Effectiveness Analysis (CEA), Cost-Utility Analysis (CUA), Cost-Benefit Analysis (CBA), and Cost of Illness (COI). Figure 3 presents the frequency of the key economic assessment criteria in the HTA guidelines which were evaluated. Quality of Life (QOL) (85%) and Budget Impact Analysis (BIA) (78%) emerged as the most prevalent economic evaluation criteria, together representing more than half of all coded references. Their prominence reflects the growing alignment between HTA and patient-centred, as well as financially sustainable care paradigms.

Quality of life measures were particularly prominent in Australia, the United Kingdom, and Indonesia, where they are integrated into HTA processes through patient-reported outcomes and quality-adjusted life years (QALYs). This indicates a widespread recognition of patient well-being as a primary indicator of technological value. Similarly, the prominence of BIA, most visible in South Africa, the United States, and EuNetHTA, illustrates the increasing importance of assessing financial feasibility and short-term affordability. Approximately one-quarter of the economic assessments incorporated BIA, signalling its significance in policy formulation under budget constraints.

Cost-Effectiveness Analysis (CEA) and Cost-Utility Analysis (CUA) were also consistently employed, accounting for about one-third of economic assessments, particularly in countries with mature HTA infrastructures such as the UK, Canada, and Australia. These methods enable standardised cross-intervention comparisons and provide a rational basis for resource prioritization. By contrast, Cost-Benefit Analysis (CBA) and Cost of Illness (COI) appeared infrequently, collectively representing less than 10% of coded references, which may be due to methodological difficulties in monetizing health outcomes and obtaining accurate cost-of-disease data. Overall, these findings confirm that while traditional economic tools such as CEA and CUA remain foundational, the increasing incorporation of QOL and BIA signals a shift toward holistic, value-based assessment that balances efficiency, equity, and patient experience.

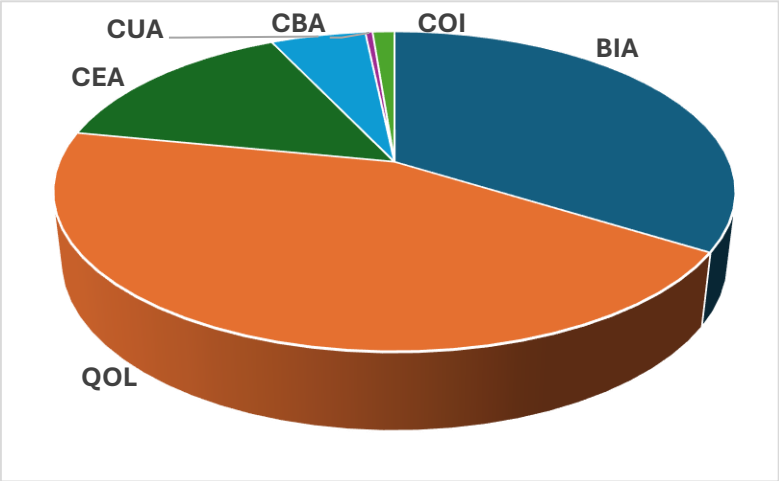

Figure 3: Frequency analysis of code occurrence of HTA evaluation criteria of guidelines
Source: Authors' own work
BIA-Budget Impact Analysis; **QOL**- Quality of Life; **CEA**-Cost-Effectiveness Analysis; **CUA**-Cost-Utility Analysis; **CBA** Cost-Benefit Analysis; **COI**-Cost of Illness

Evidence synthesis of HTA guidelines

The main methods for evidence synthesis in the guidelines were decision analytical modelling, meta-analysis (MTA), and real-world data (RWD). As shown in Figure 4, the predominant evidence synthesis strategy across most guidelines is the predominant evidence synthesis strategy across most guidelines, accounting for approximately two-thirds of coded references. MTA is essential for assessing clinical and financial results and is required by National HTA agencies such as the National Institute for Health and Care Excellence (NICE) UK, Canadian Agency for Drugs and Technologies in Health (CADTH) Canada, and Pharmaceutical Benefits Advisory (PBAC) Australia, which consistently require meta-analyses to substantiate evaluations, ensuring methodological rigour and reproducibility. The use of real-world data (RWD) represented about one-fifth of the overall emphasis and is gaining traction, particularly in the UK, Canada, and Indonesia. Its integration reflects a shift toward contextualising evidence beyond controlled trials, especially in rare diseases, digital health, and personalised medicine. Real-world data enhances the relevance of HTA findings by providing data on how interventions perform in everyday clinical practice.

Decision Analytical Modelling (DAM) accounted for about 13% of coded references, with notable use in South Africa, Canada, and EuNetHTA. Decision Analytical Modelling enables

long-term projections and scenario testing, helping to evaluate cost-effectiveness under varying conditions. Emerging patterns indicate growing efforts to combine MTA, RWD, and DAM to generate more dynamic, adaptable, and context-sensitive evaluations. This integrative trend aligns with recent global calls for comprehensive and forward-looking HTA methodologies capable of responding to rapid technological advances [16].

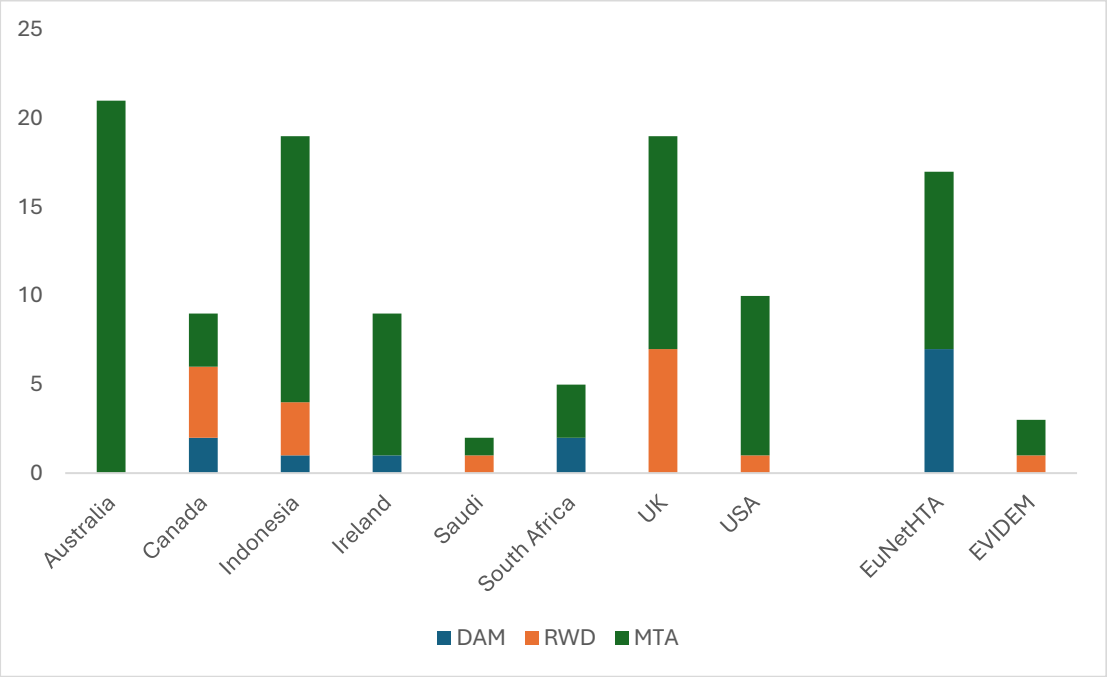

Figure 4: Visualization for the frequency analysis of Evidence syntheses of HTA guidelines
Source: Authors' own work
DAM- Decision Analytical Modelling; **RWD**- Real World Data Integration; **MTA-** Meta Analysis

Stakeholder involvement

The frequency analysis in Figure 5 highlights stakeholder involvement in HTA economic evaluation guidelines. Patients were the most frequently referenced stakeholders, being represented in approximately half of all engagement activities. Organisational stakeholders, including policymakers and health administrators, constituted around one-quarter of engagement activities, often providing oversight and ensuring policy coherence. Clinicians accounted for approximately one-fifth of participatory instances, primarily contributing technical expertise and ensuring clinical feasibility of recommendations. These results underscore a paradigm shift from expert-driven to participatory assessment processes, where

patient perspectives inform research priorities, value judgments, and the interpretation of health outcomes.

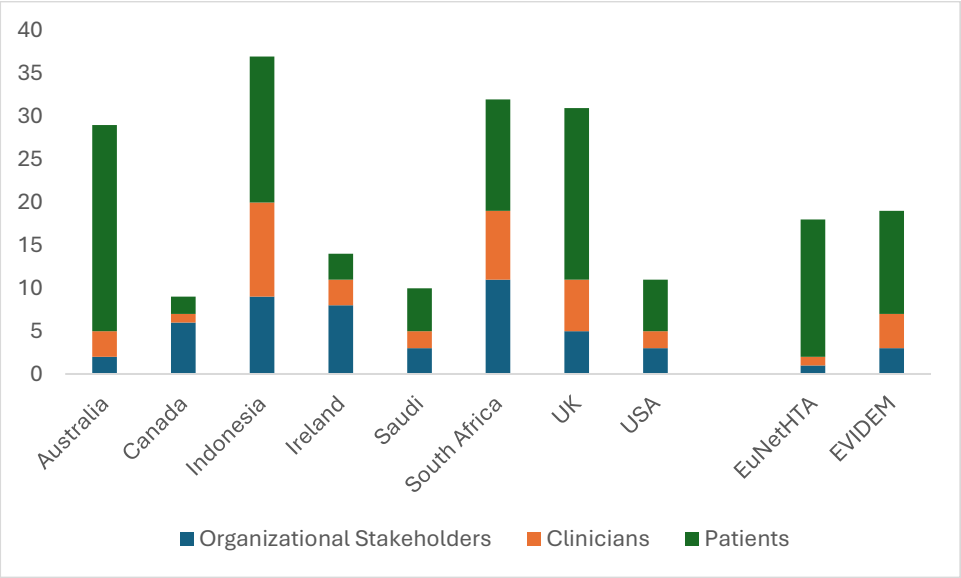

Figure 5: Frequency distribution of stakeholders' involvement

Source: Authors' own work

Countries such as Australia, Ireland, and the United Kingdom have institutionalized formal patient involvement mechanisms, integrating consultation and feedback processes into HTA decision-making. Internationally, EuNetHTA exemplifies best practice in cross-border collaboration by embedding patient and public consultation within its transparency framework. This inclusive approach enhances legitimacy, accountability, and policy relevance. The strong emphasis on patient engagement and multi-stakeholder involvement signifies a decisive evolution toward democratic and transparent HTA governance, echoing broader movements in global health policy that prioritise equity, participation, and social accountability.

DISCUSSION

The findings from this study underscore the diversity in HTA guidelines, revealing distinct priorities across different evaluation approaches. The countries selected showcase a varied global viewpoint on the adoption of HTA guidelines. Countries with high income, including Australia, Canada, and the UK, possess developed guidelines for HTA that prioritise both economic and clinical evaluations, showcasing well-organised healthcare policies. Countries such as Indonesia[17], Saudi Arabia [18], and South Africa [19], which are process of developing their HTA strategies, are beginning to integrate these frameworks into their

healthcare decision-making processes. The United States serves as a notable instance, as its market-driven healthcare system has influenced its HTA methodologies by emphasising economic efficiency, innovation, and competition in the marketplace rather than centralised public oversight. In contrast to numerous countries where HTA is managed by the government to guide national coverage choices, assessments in the United States are frequently carried out by private or independent entities (such as the Institute for Clinical and Economic Review, ICER) and insurance companies to shape pricing, reimbursement, and coverage policies [20]. Consequently, HTA in the United States tends to concentrate more on cost-effectiveness, budget implications, and value-based pricing instead of broader social or ethical considerations. Moreover, due to the competitive nature of healthcare providers and payers, HTA findings in the United States are commonly utilised to facilitate negotiations and substantiate decisions regarding market access instead of establishing uniform national standards. EuNetHTA and EVIDEM provide a global viewpoint on the standardisation of health technology assessment. EuNetHTA represents a European initiative aimed at enhancing the efficiency of HTA practices among member states, promoting collaboration and uniformity in healthcare evaluations. This is essential for minimising redundancy in HTA assessments and enhancing decision-making efficiency throughout Europe. EVIDEM functions as a comprehensive framework for multi-criteria decision analysis (MCDA) in the healthcare sector, providing a systematic method for evaluating health interventions across different countries. It has been applied in various contexts, including Italy (Lombardy) for regional funding decisions [21], South Africa in private health plan evaluations [22], China for hospital drug procurement and orphan drug assessment [23], and across several European countries, such as Spain, the Netherlands, and Poland, to support decision-making for complex healthcare interventions [24].

Notably, Australia and EuNetHTA exhibit the most comprehensive frameworks, addressing a wide spectrum of performance dimensions, including clinical effectiveness, safety, economic viability, patient-reported outcomes, ethics, and sustainability. This aligns with previous research highlighting the structured and multidimensional nature of HTA frameworks in high-income countries, which often incorporate broader evaluation criteria to ensure a balanced assessment of health technologies [25]. In contrast, HTA guidelines in Saudi Arabia and EVIDEM demonstrate a comparatively narrower scope, with a predominant focus on economic considerations. While economic evaluation, particularly “cost-effectiveness analysis and budget impact assessment,” remains a cornerstone of HTA worldwide [26] the emphasis on financial metrics in these guidelines suggests a constrained perspective that may overlook

crucial social, ethical, and organisational factors. This economic-centric approach, though essential for resource allocation in healthcare systems with limited budgets, raises concerns about the adequacy of such evaluations in capturing the full spectrum of healthcare needs and societal values [27].

Furthermore, the results reveal a relative underrepresentation of social and organisational dimensions in most HTA guidelines. This finding resonates with existing literature emphasising the need for more integrative HTA methodologies that go beyond cost-effectiveness and clinical efficacy[28]. Ethical considerations, sustainability, and organisational efficiency are increasingly recognised as essential components of decision-making in healthcare policy, yet they remain inconsistently integrated into existing HTA models. A broader, more inclusive approach to HTA could facilitate more equitable and context-sensitive healthcare decisions, ensuring that health technologies contribute positively not only to clinical and economic outcomes but also to broader societal well-being.

The results in Figure 2 reveal that QOL and BIA are dominant, which is consistent with worldwide trends that emphasise fiscal responsibility and cost-effectiveness [29]. The QOL is distinctly regarded and utilised in developed countries like Australia, Indonesia, and the United Kingdom [30], as reflected in the cross-national analysis shown (Figure 2). This could be because this economic evaluation criterion focuses on well-being and patient satisfaction, which is the core of the health care system in many of these countries. The wide spectrum of applicability is also a pointer to the high frequency of its annotation in the content analysis. This criterion emphasizes and guarantees effectiveness, particularly in resource-constrained situations.

Similarly, the dominance of BIA predicts the acceptance of this criterion, as opined by van de Wetering et al. (2023) [31]since it offers a financial feasibility perspective based on the existing budget [32] and because of its affordability in comparison with other cost and effectiveness (utility-focused) criteria. The popularity of BIA across the nations' guidelines and its uniqueness in the EuNetHTA international guideline could be a result of the opportunity it gives for scenario testing and its most influential role in making adoption decisions for stakeholders[33] [34]. However, the poor usage of COI signals a wasted opportunity to assess the whole economic burden of diseases, which could provide a more thorough justification for intervention efforts.

Furthermore, it was observed during the analysis that there is a growing trend demanding the incorporation and integration of two or more of these criteria in evaluating the economic aspect of HTA in many countries, demonstrating a trend toward value-based healthcare. This strategy aligns economic evaluations with patient-centered treatment, which is becoming more important in modern healthcare systems in European countries [35] and similarly in Ireland with the updated Ireland's Health Information and Quality Authority (HIQA) guideline. This guideline recommends incorporating QOL measures and conducting BIA alongside traditional economic evaluations, such as CEA and CUA, to promote a holistic approach to HTA. This observation aligns with the findings of Farah et al. 2024 [31] and Zemplényi et al. 2023 [32], which investigated the integration of evaluation criteria and comprehensive usage in low- and middle-income countries (LMICs) and India, respectively.

Meta-analysis emerged as the most used technique. This dominance demonstrates the widespread reliance on meta-analysis as a reliable tool for synthesizing evidence from several studies, resulting in comprehensive and statistically sound findings. Recent literature emphasizes the importance of meta-analysis in HTA, particularly in data aggregation to support policy decisions [36]. This means that the dominance could be due to a wide range of evidence from various sources of information and data that are pooled together to arrive at the stakeholders' rational decision-making.

Furthermore, the highlight of real-world data integration as the second most popular technique reflects a growing emphasis on basing economic evaluations in concrete, real-world circumstances. This could be because integration of real-world data improves HTA by giving information about the performance of interventions outside of controlled experimental conditions, making findings more relevant to decision-makers. Real-world data integration facilitates faster and more efficient trials and real-world causal analysis [37]. This finding supports the opinion of Makady et al. (2018) [38], Kjellberg et al. (2022) [39], ISPOR (2024) [26] that real-world data is now having an expanded importance, as regulatory and HTA authorities have issued more frameworks and standards for using real-world evidence in healthcare decision-making.

The decision analytical modelling (DAM) was the least frequently employed technique, maybe because of the complexity of use. However, despite its lower frequency, the combination of DAM with RWD integration or meta-analysis reflects a shift toward more dynamic and adaptable techniques in HTA. This integrated approach allows for robust scenario testing and the prediction of outcomes under various assumptions, thereby addressing uncertainties inherent in healthcare decision-making. Recent studies advocate for applying DAM in

economic evaluations of integrated care interventions, emphasising its relevance in contemporary HTA practices [40]. Such combinations provide a richer, more nuanced understanding of health technologies and their impact, aligning with global trends toward comprehensive, multi-method evaluations [41] [42]. The dynamic differences, variation and scope of content in the technique of HTA used by various countries, organisations, and continents around the globe should encourage a global trend towards the standardisation and integration of comprehensive clinical evaluation criteria, especially in the new Regulation for HTA in Europe.

The findings show that patients are the focus and drivers among the stakeholder involvement in HTA economic evaluation standards (Figure 4). All the stakeholders have their various perspectives, roles, and participation in the HTA process evaluation. The patients could be the most involved stakeholders because of the peculiarity of the prominent criteria utilised by the countries. Therefore, the patients will be key stakeholders in the development and evaluation process, as they will help in advocating for outcomes and decisions that improve quality of life and accessibility of the same. The patients will be at the forefront of ensuring that the stakeholders and guideline developers prioritise important health outcomes and encourage transparency. With these, the guidelines become more robust, actionable, and representative of the complexities of healthcare decision-making.

The organization's stakeholders also have an important role, such as resource allocation and policy implementation, which is the decision-making aspect itself. On the other hand, the clinicians are the least highlighted stakeholder in the HTA evaluation process, although they have a close count with the organizations' stakeholders. This could be because they are more focused on the clinical relevance and feasibility of the application of any decisions that were made. Succinctly, this implies that all the stakeholders are important to the HTA guidelines' economic evaluation, despite the varying degrees of their involvement.

CONCLUSION

This study provides a comprehensive qualitative content analysis of HTA guidelines across different national and international contexts, revealing significant variations in performance dimension evaluation criteria and other methodological approaches. The findings highlight the dominance of economic assessment, such as cost-effectiveness and budget impact analysis, particularly in resource-limited settings, while more comprehensive frameworks in high-income countries integrate broader social, ethical, and patient-centred considerations.

Additionally, the increasing trend toward integrating multiple evaluation criteria reflects a shift towards more holistic, value-based healthcare assessments.

This study has limitations. The selection of documents was subject to accessibility constraints, which may have led to the exclusion of relevant guidelines. Additionally, the qualitative nature of content analysis introduces a degree of subjectivity, despite efforts to ensure rigor through an iterative coding framework. Future research should consider incorporating stakeholder interviews and expanding the dataset to enhance the depth and applicability of the findings. A more integrative approach, combining qualitative and quantitative methodologies, could further enrich the understanding of global HTA practices.

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CHAPTER FIVE

The Integration of Performance Management and Health Technology Assessment: A Case Study for Malta

Esther Oluwatosin Akinbobola, Guido Noto, Patricia Vella Bonanno, Sandra C Buttigieg, Gianpaolo Tomaselli; The Integration of Performance Management and Health Technology Assessment: A Case Study for Malta**.**

(**Ready for Submission**)

ABSTRACT

The integration of Performance Management (PM) and Health Technology Assessment (HTA) is increasingly recognised as a critical mechanism for strengthening evidence-informed governance in contemporary health systems. A centralised healthcare system, such as Malta's, offers unique insights into how these functions can be aligned within centralised institutional structures. This study examines the interaction between HTA and PM in Malta, identifying the institutional, procedural, and system-level factors that shape their convergence.

An exploratory qualitative case study approach was adopted. Data were gathered through three focus group discussions with 23 participants from policy, health technology assessment and public procurement, as well as one key informant interview. Inductive thematic analysis was conducted following Braun and Clarke's methodological framework.

Findings yielded important thematic domains capturing the operational and strategic dimensions of PM-HTA integration in Malta. The findings demonstrate that integrating PM and HTA is a complex process that builds on some key pillars. In the case of Malta, results show that there is an evolving alignment between HTA outputs and performance management practices for different activities, including procurement and clinical practice. Concurrently, EU-level harmonisation and national capacity-building initiatives are reinforcing institutional preparedness for deeper integration of performance management and HTA across the EU.

Malta's experience illustrates that health systems can progressively build linkages between HTA and PM to support value-based governance. The study proposes a multilevel integration framework relevant for healthcare systems seeking to enhance accountability, optimise resource allocation, and strengthen evidence-informed policy.

INTRODUCTION

At its core, performance management in healthcare involves setting clear objectives for both professionals and organisations [1]. This encompasses the continuous monitoring of clinical and operational performance, providing feedback and support for improvement, and ensuring that individual and team efforts align with the broader goals of the health system [2]. As healthcare systems around the world face rising costs, growing patient expectations, and rapid advancements in medical technology, the need for evidence-based decision-making is more crucial than ever [3]. In this context, performance management acts as a strategic tool that aligns organisational goals with measurable results, promoting a culture of continuous improvement within healthcare institutions [4, 5].

A key aspect of effective performance management involves evaluating not only the monitoring of the delivery of healthcare services but also the value and impact created through the use of health technologies in those services. This necessitates the increasing incorporation of health technology assessment (HTA), which serves as an essential mechanism for guiding resource allocation, clinical guidelines, and policy decisions [3]. HTA employs a multidisciplinary approach to assess the medical, social, economic, and ethical dimensions of health interventions, thus facilitating informed choices that enhance both system efficiency and the quality of patient care [6]. The relationship between performance management and HTA is increasingly acknowledged as vital for the sustainable transformation of healthcare systems [7]. Integrating performance management into HTA frameworks enables healthcare providers and policymakers to evaluate the real-world effectiveness and cost-effectiveness of technologies more effectively [8]. This ensures that innovations contribute significantly to health outcomes while maintaining system sustainability [1].

Performance Assessment and Health Technology Assessment in Healthcare Systems

Performance assessment in healthcare systems represents a cornerstone of effective health sector governance, as it enables policymakers and managers to make sense of the intrinsic complexity that characterises modern health systems [9-10]. Health systems are composed of multiple actors, governance levels, and service delivery arrangements, and performance assessment provides a structured approach to capturing this complexity through the systematic measurement, monitoring, and evaluation of how services, organisations, and the system as a whole achieve their intended health objectives. In line with World Health Organisation–inspired Health System Performance Assessment (HSPA) frameworks, performance

assessment is conceived as a country-owned and participatory process, closely linked to strategic priorities and policy objectives rather than a purely technical exercise [11].

This process is inherently multidimensional, encompassing a broad range of performance dimensions such as quality of care, efficiency in resource use, accessibility of services, equity in health outcomes, safety, and responsiveness to patients' needs and experiences. The literature emphasises that focusing on a single dimension, such as financial performance or service volumes, is insufficient and may even generate dysfunctional behaviours. Instead, multidimensional performance frameworks allow decision-makers to capture trade-offs and synergies across objectives, supporting a more balanced and value-oriented understanding of system performance [12].

Beyond measurement, performance assessment plays a crucial role in guiding decision-making, strengthening accountability, and fostering a culture of continuous improvement. Through systematic benchmarking across organisations, geographical areas, or even countries, performance information enables the identification of unwarranted variations and good practices, thereby supporting learning and evidence-informed policy interventions. Transparent disclosure and timely availability of performance data further enhance the legitimacy and use of performance information, reinforcing trust among stakeholders and aligning managerial and clinical behaviours with broader health system goals [3, 13]. In this sense, performance assessment functions not only as an evaluative tool but also as a governance mechanism that connects measurement, learning, and strategic action within healthcare systems.

HTA is a clinical governance tool aimed at improving the results obtained by the adoption of health technologies and controlling the related expenses. The European Union's new Health Technology Assessment (HTA) framework, established by Regulation (EU) 2021/2282, became effective in January [14]. It aims to harmonise clinical assessments across Member States through joint evaluations, consultations, and horizon scanning of emerging technologies [15]. While economic, ethical, and social aspects remain national responsibilities, the Regulation promotes transparency and stakeholder involvement. It also emphasises performance management, using real-world data to assess health technology outcomes, safety, and efficiency after adoption. This approach enables feedback between assessments and monitoring, facilitating conditional reimbursement and informed policy adjustments [15].

The model for health technology assessment in the EU developed by Bonanno and Flores [16] provides an early and influential framework for understanding how health systems can

integrate regulatory, policy, and assessment functions to support coherent decision-making across the medicines lifecycle. This model emphasises the need for joined-up processes linking marketing authorisation, pricing, reimbursement, formulary inclusion, and post-market oversight. Figure 1 adapts and extends the model by Bonanno and Flores to reflect an evolving HTA–PM interface within the healthcare systems, illustrating how health technology assessment (HTA) supports value-based and evidence-informed decision-making across five core domains: marketing authorisation, reimbursement, pricing and procurement, and clinical use.

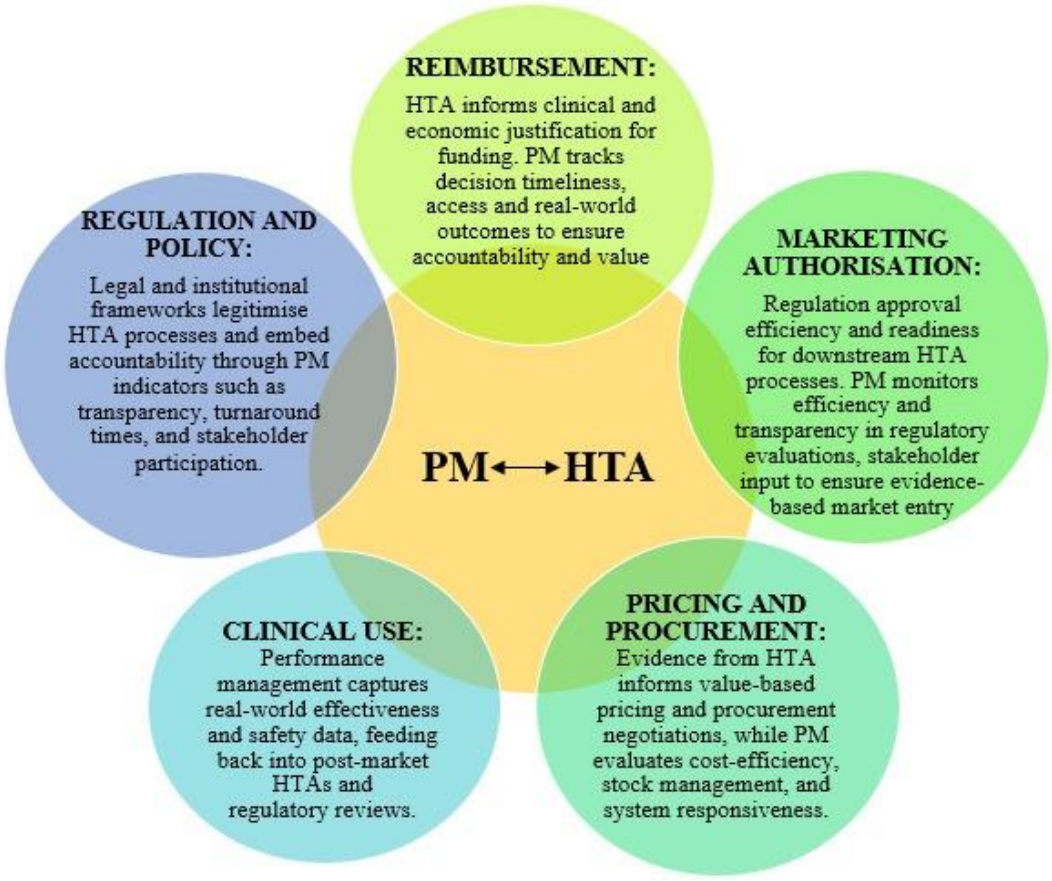

Figure 1: PM-HTA Integration

Source: Adapted from Bonanno and Flores (2011)

As depicted in the framework presented in Figure 2, modern health policy discussions highlight the importance of integrating Health Technology Assessment and Performance Management as complementary components within performance assessment frameworks [17]. The authors focused on the critical importance of merging Health Technology Assessment HTA with

Performance Management as mutually reinforcing components within comprehensive performance assessment frameworks. This framework suggests that following the adoption of a technology, key performance indicators (KPIs) are used to continually assess whether it provides the expected level of performance and supports the achievement of the desired objectives. This continual monitoring compares actual performance to initial objectives, establishing the technology's effectiveness across multiple dimensions. The insights gained through this feedback loop assist strategy-makers in setting future objectives and improving the HTA process by emphasising whether budgeting activities are carried out properly or whether additional factors should be considered.

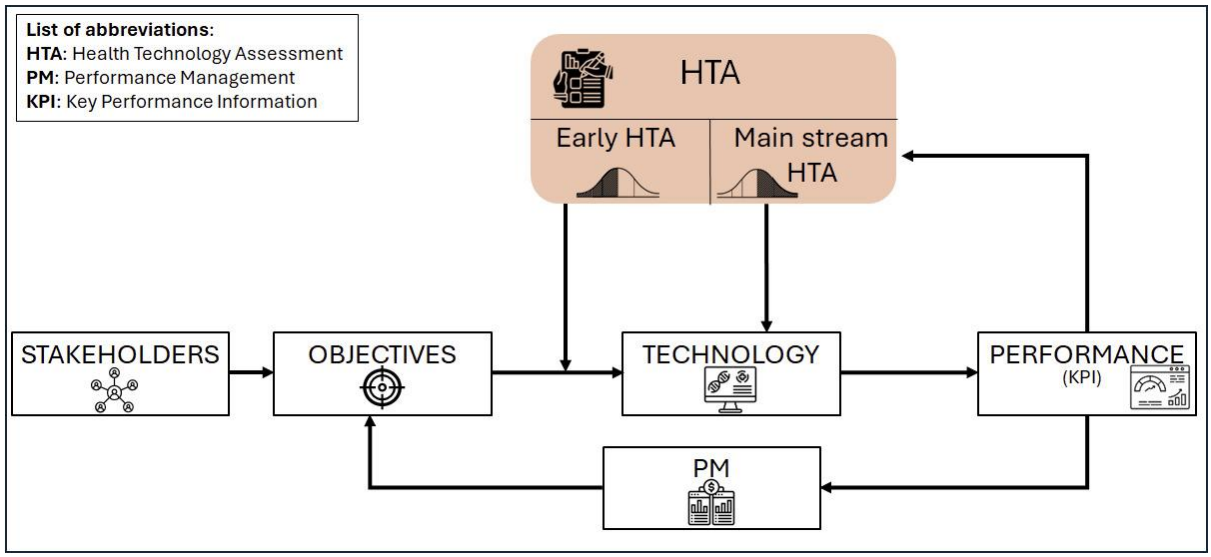

Figure 2: HTA and PM integration framework

Source: Adopted from Akinbobola et al. (2025)

HTA provides structured, evidence-based evaluations of medical technologies, interventions, and innovations by assessing their clinical effectiveness, safety, cost-effectiveness, and organisational impact [18], while PM functions as a cyclical process. Performance assessment within healthcare systems stands as a cornerstone of effective health sector governance. This intricate process entails the systematic measurement, monitoring, and evaluation of the efficacy with which services, institutions, and overarching systems achieve their desired health objectives [19]. It encompasses a multitude of dimensions, including quality, efficiency, accessibility, equity, and patient responsiveness. Each of these elements plays a pivotal role in guiding decision-making, enhancing accountability, and fostering a culture of continuous improvement [20].

Thus, as explained in the framework Figure 2, performance management and HTA are increasingly recognised as key mechanisms for meeting these challenges: performance management offering systematic monitoring and feedback to drive organisational improvement, while HTA supports evidence-based decisions on the adoption and diffusion of new technologies and interventions.

Research explicitly linking PM and HTA in a unified analytical framework remains scarce. Most existing studies focus on isolated reforms, specific disease programmes, or EU-wide benchmarking [21, 22], leaving limited insight into how these tools intersect to shape strategic decision-making. This study addresses this gap by presenting a case study of Malta, analysing the convergence of performance management and HTA as complementary instruments of health system governance. Malta, a small island in the Mediterranean Sea, is an EU Member State with a small size and population, a unique national governance structure, a centralised healthcare system and full adoption of EU legislation of Malta makes this Member State an ideal case study to describe performance management and health technology assessment and the interaction between them. Examining how PM and HTA operate in tandem within the Maltese context can therefore provide valuable lessons not only for domestic policy but also for other small or resource-constrained health systems seeking to balance innovation, efficiency, and sustainability.

This article delves into the synergies between performance management and HTA, using a case study for Malta to explore how their interaction can bolster Malta's health system responsiveness, accountability, and value-based care. This case study within a centralised healthcare system was used to draw up a generalisable Performance Management and Health Technology Assessment Integration Framework.

METHODOLOGY

Empirical setting: the context of Malta

Nestled in the heart of the central Mediterranean, Malta is an island nation characterised by its rich history and vibrant culture, with a population of just over half a million residents [21] (Figure 3).

Figure 3: A Map showing the location of Malta

The country operates a publicly funded healthcare system that guarantees universal coverage to all its inhabitants [23]. Despite its relatively small size, Malta's health sector faces challenges similar to those encountered by larger nations, soaring healthcare costs, an aging population, and the growing prevalence of chronic diseases [24]. These pressures have amplified the urgency for systematic and strategic approaches to allocate resources efficiently, uphold the quality of care, and ensure the financial sustainability of the health system [25]. Public hospitals and primary care services primarily benefit from funding through general taxation, reflecting a strong commitment to collective health and well-being.

Malta became an EU Member State in 2004. Malta has embarked on a transformative journey through a series of health reforms aimed at modernising its healthcare infrastructure and fortifying governance. At the helm of this initiative is the Ministry for Health and Active Ageing, which is responsible for policy formulation, strategic planning, and regulatory oversight [23]. In pursuit of alignment with European Union (EU) obligations and the adoption of best practices, Malta has increasingly adopted performance monitoring frameworks to benchmark its health services against those of its EU counterparts [26]. Key initiatives in this

endeavour include the meticulous use of health indicators, comprehensive hospital performance audits, and the formulation of national strategies focused on continuous quality improvement [19].

Health Technology Assessment has emerged as a crucial element of Malta's healthcare strategy, as the country endeavours to optimise its decision-making processes regarding the adoption of new medicines, medical devices, and innovative interventions. As an active member of the EU, Malta benefits from cross-border collaborations and participates in HTA networks, which provide access to a wealth of shared methodologies and robust evidence. Given the constraints of local resources for comprehensive, large-scale HTA, Malta often adapts assessments from other jurisdictions, tailoring them to fit its specific population size, healthcare service capacity, and fiscal considerations [27].

Despite Malta's progress in strengthening its health system, evidence from the 2015 Health System Performance Assessment (HSPA) underscores persistent challenges in efficiency, resource allocation, and population health determinants [28]. These findings raise fundamental questions about how a small-state health system can maintain universal coverage, sustain financial viability, and adopt innovation without compromising equity or quality.

Philosophical approach

This study employed an exploratory qualitative case study to investigate the processes and perceptions surrounding the adoption of performance management and HTA in Malta. This approach was chosen because it allows for an in-depth exploration of participants' lived experiences, beliefs, and attitudes regarding decision-making processes.

Study Design and Data Collection

Data collection took place between March and May 2025 using two qualitative inquiry methods: focus group discussions and a key informant interview. A total of three focus group discussions were conducted with three stakeholder groups, and one key informant interview was conducted with a senior official to capture individual-level perspectives that may not have been fully expressed in group discussions. Focus group discussions facilitated the exploration of group dynamics and shared experiences, while the key informant interview allowed for a deeper understanding of individual perceptions.

Sampling Strategy

Participants were purposively selected to ensure that key stakeholders directly involved in health policy, pharmaceutical management, and procurement decision-making were represented. The final sample consisted of 23 participants [P1 to P23] drawn from policy, health technology assessment and public procurement. The focus group discussions were primarily aimed at generating an understanding of the decision-making processes related to performance management and HTA adoption in Malta. In contrast, the key informant interview sought to elicit deeper insights into individual perceptions, beliefs, and attitudes regarding the identification, prioritisation, adoption, and implementation of these tools within the national health system of Malta.

The qualitative data were analysed using thematic analysis. The responses from the focus group discussions were transcribed using a digital transcription application. Following transcription, an inductive codebook was used to guide the setting of the themes, consistent with qualitative data analysis approaches as described by Cresswell and Poth [29]. The unit of analysis included single words, sentences, or groups of sentences, from which meanings and interpretations were derived. Data were analysed inductively in accordance with Braun and Clarke's [30] thematic content analysis. In-vivo quotes are used in the results explicitly and with a clearer interpretation, progressing from open codes to axial codes to selective codes, ensuring that themes remained grounded in participants' experiences.

RESULTS

Theme 1: Policy, Strategy, and Governance

The legal basis for HTA in Malta is provided by regulatory tools, mainly legislation and policies. Parts of the process have been standardised through the progressive implementation of legislation and structured guidance. Applications for new medicines are prepared and submitted by companies, clinicians, and market authorisation holders to be considered for HTA.

> *"…. We do receive requests from the marketing authorisation holders from companies, be it from abroad or also local companies, who could also submit in Malta. There is also another option that we have, a separate template, a separate application for clinicians who can also submit if they consider that some medicines are missing and there is a gap of some sort in the formulary..."* (P3)

Stakeholders that were in the focus group discussions stressed continued participation in the formulation of policies, with legal tools acting as guarantees of accountability and openness.

> *"But requests for information or action can only originate from marketing authorisation holders or companies in line with procedures explicitly identified in local legal notices. This ensures that communications regarding these matters are properly directed and recognised within the legal framework."* (P4)

The structured nature of HTA in the system in Malta was further reinforced. The assessments are presented at a legally constituted committee that includes technical, financial expertise. Provisions for appeals are in place where transparency is built into the process, allowing applicants to challenge decisions.

> *"...then the report is discussed with the assessor who has taken the time to draw up the report and work on a particular application. We'll take it up first at the discussion by the GFLAC Committee [Government Formula List Advisory Committee]. This is mainly a technical committee which basically sees to the technical aspects of the HTA of the product."* (P5)

The participants considered that the implementation of regulations across the EU is still different and that national sovereignty in setting prices may make it more difficult to harmonise processes across the EU. Opportunities for collaborative assessments and access to best practices have been made possible by membership such as EU coordination groups; yet participants pointed out conflicts between EU-driven frameworks and national interests. This dichotomy demonstrates the enabling and restricting functions of policy frameworks: they provide structure and legitimacy, but they may also lead to bureaucratic hold-ups and issues with sovereignty.

> *"Member States can't ask at the national level what's [information] already been asked at the European level."* (P11)

Theme 2: Health Technology Assessment and Market Access

The focus group discussions showed that Malta has developed a relatively structured HTA process, with designated officers overseeing dossier submissions initiated by companies, clinicians, or any form of problem-induced requests. The structure exists to ensure that every dossier or request submitted by the companies or hospitals undergoes validation, and assignment for either a brief review or a comprehensive assessment from the designated staff. This formal structure was evident from the focus group discussions.

> *"There is this regulation that is putting the HTA in a spotlight situation at the EU level, which will obviously impact the various EU Member States. And so, Malta, like all the other Member States, should improve access to medicines and harmonise aspects of the HTA."* (P13)

Challenges that emerged from the discussion included gaps in data, fragmented information systems, and undermining the synthesis of evidence required for HTAs. These gaps often require assessors to scan data from international practices and to synthesise external information for HTA.

> *"We are familiar with certain aspects, but very often data is lacking."* (P 4)

> *"…Our population is small, so in reality our data will still be small, and I think one of the ways we could go is to see also data from views of registers in the other countries, probably in terms of effectiveness to get to the level of effectiveness of treatment."* (P6)

The participants noted that cost-effectiveness is not a mandatory requirement, meaning that assessments often emphasise clinical effectiveness and budget impact over broader value considerations. Customisation of models to Malta's small-state context was seen as both necessary and challenging.

> *"And in the evidence, there is uncertainty, especially in the longer term. To have a model [for the use of the new medicines] that is specific to Malta is very difficult."* (P10)

Participants highlighted adaptive efforts and expressed optimism that integration with EU-level processes could enhance institutional capacity and sustainability of the HTA in Malta.

> *"Obviously, HTA at an EU level is happening. So, we are living that as well. And there are certain aspects of the EU HTA where we are cooperating with the other Member States at the moment…"* (P6)

Theme 3: Stakeholder Engagement

A robust and successful framework for HTA hinges on more than just technical rigour; rather, it depends on the critical pillars of stakeholder engagement and capacity building. During the discussion, it was evident that departments are clearly aware of the different stakeholders related to the HTA process. During the focus group discussions with the different groups, participants highlighted the central role of stakeholders in the success of PM-HTA integration, and mentioned different types and classifications of stakeholders, ranging from the individual stakeholders (clinicians, patients, carers), institutional stakeholders (companies, assessors), and organisational stakeholders (the procurement agency and the committee making the reimbursement decision) with their roles, expectations, and boundaries clearly defined.

Participants emphasised differences in considerations of HTA across stakeholder groups; each stakeholder group approached HTA and performance management with varying priorities, concerns, and perspectives. While companies often submitted dossiers with a lot of technical detail, submissions originating from clinicians were more specific in clarifying the needs of patients for the product within the reimbursement list.

> *"We're aware that companies usually have teams dedicated to preparing these submissions, so their dossiers are more polished. For us, it's more about sharing our experience and patient outcomes"* (P21)

The inclusion of diverse stakeholders, patients, clinicians, industry, and regulators in both national and EU processes was identified as a strength. In centralised health systems such as Malta's, where professional, institutional, and social networks are closely interlinked, the potential for overlapping roles and interests is inherently higher. Without well-defined and consistently applied conflict-of-interest policies, stakeholder participation, though valuable for

its inclusivity, can inadvertently create perceptions of biased influence. Clear criteria for the management of conflicts of interest between stakeholders were considered essential. Establishing explicit procedures for conflict-of-interest declaration, documentation, and mitigation ensures that all participants, whether from clinical, academic, regulatory, or industry backgrounds, operate under a shared understanding of accountability and ethical conduct.

> *"Having clinicians, patients, and industry involved is crucial, but it only works with clear rules on conflicts of interest so that everyone feels confident and the process is fair and transparent."* (P6)

Overall, stakeholder engagement was seen as a dynamic and iterative process, with optimism that continued training, collaboration, and inclusive consultation would strengthen the legitimacy and effectiveness of HTA in Malta.

Theme 4: Training and Capacity building

Capacity building initiatives, including technical support projects and EU-level collaborations, were identified as crucial. These mechanisms strengthen institutional resilience, enhance procedural quality, and empower national teams to implement more robust and consistent HTA processes.

The focus group emphasised that capacity building is essential, and people must be empowered by the system. Projects support the funding of training and ongoing professional development. Teams can manage cooperative projects, successfully use new technologies, and negotiate intricate HTA procedures through the capacity-building investment. The creation of a dynamic system with iterative learning procedures is the ultimate objective. Continual training can help the health system transition from static, disjointed solutions to a framework that is responsive and flexible.

Theme 5: Procurement, Pricing, and the Medical Supply Chain

Insights from the focus group discussions showed that performance management-HTA integration is both a challenge and an opportunity in procurement procedures.

One major challenge involves the transparency of prices. Prior transparency efforts and World Trade Organisation-affiliated projects on an international level were recognised, but national-level sensitivities and cost variances have hindered the adoption of centralised price databases.

> *"...for pricing and transparency ……: we have been trying to lead, also with the World Trade Organisation, since 2016, and we were also educated on procurement processes."* (P14)

> *"...management agreements and certain negotiations, help to get the best prices. Because it is confidential and not transparent."* (P14)

Performance management is integrated in procurement processes, despite a lack of key performance indicators (KPIs), with mention of procedures for blacklisting, whitelisting, and penalties. There are still problems with transparency, especially when it comes to price negotiations and confidentiality claims.

Respondents from the procurement department stressed the importance of linking between HTA and procurement.

> *"The fact that currently things [HTA and procurement] are being done separately does not help, even though we're trying our best to meet up and discuss failures and successes. But from what I see from meetings, it is like we are used to doing this, so no one will eventually integrate other procedures unless it is something done in a certain direction."* (P21)

An effective, integrated technological framework is critical for upholding the highest standards of patient care, operational effectiveness, and procurement efficiency. Strong forecasting and IT-enabled stock management are two advantages of Malta's unified procurement system that contribute to waste reduction and improved accountability. Challenges faced during procurement-HTA integration included the lack of complete information about HTA recommendations or quality specifications. There was lack of agreement on whether procurement and HTA should be completely merged or just better aligned through institutionalised partnership is still up for dispute. Some stakeholders believed that independent but coordinated processes (collaboration) were more practical, while others advocated for more integration.

> *"We're still not there. So we need something coming up, like something comprehensive, because I believe that we need to work more in collaboration on it to get the benefits of the HTA and procurement… since we are two different departments, it's quite hard to*

integrate…what maybe could be done is to get the formalised mechanism. which will basically help for accountability…" (P20)

Theme 6: Integration of performance management and HTA

Although the discussion with various stakeholders reflects that performance management (PM) is acknowledged as a vital instrument in Malta's healthcare system, its integration with HTA is still in its infancy. Despite the existence of hospital, national, and EU Performance Management frameworks, participants characterised implementation as erratic and disjointed. Although procedures for monitoring, longitudinal evaluation, and performance management are prevalent in some departments, the influence of HTA results on decision-making is limited since they are only partially used in performance management processes.

> *"For performance management and HTA… for certain pharmaceuticals, there is uncertainty with performance management and effectiveness, and especially if they [the medicines] are high-cost. There is a system which is, at the moment, a bit limited."* (P15)

The participants viewed the performance management organisation of the health system in Malta from a system level, which is managed through the Health System Performance (HSPA) framework that is regularly reviewed [31]. The participants tried to approach performance management through a domain approach by referring to performance management at various levels or domains, such as system level, hospital level, national level, and European Union level management domains.

> *"Well, if you want to look at it at the system level, we have our Health System Performance Assessment Framework, which was developed. For the first time in 2015, and then we had the second iteration in 2018. This is a tool that is used by many countries to assess the performance of the health system."* (P2)

> *"So, both at the hospital level, but also at the country level. At the hospital level, obviously, there will be various cases, especially after the hospital has a clinical performance."* (P3)

Several challenges were attributed to the lack of substantial integration of HTAs for performance management. They include data fragmentation, a lack of communication infrastructure, and a lack of human resources, which are obstacles to integration. Crucially,

HTA evidence is not always employed to improve patient care outcomes, even while performance management data is utilised for financing and service allocation. This points to a discrepancy in the use of HTA assessments for decisions on whether to include a drug on the formulary. The potential to support more comprehensive performance management and system-level efficiency is still underutilised.

Theme 7: Emerging Challenges and Future Directions

Significant obstacles to the integration of performance management and HTA still exist despite institutional advancements. Stakeholders pointed to ongoing data fragmentation, a lack of a comprehensive national framework for cost-effectiveness, and human resource scarcity. Initiatives for integration are made more difficult by industry opposition to centralisation and long-term doubts about the financial viability of HTA-informed decisions. At the EU level, there are still conflicts between national sovereignty and collective approaches in pricing, even if harmonisation presents chances to enhance access to medications and lessen duplication. These developments present Malta with both opportunities and risks: small states run the danger of losing their ability to respond locally while also potentially benefiting from collective procurement leverage. Participants of the focus groups pushed for strong, performance management-HTA frameworks that change over time and incorporate procurement and performance management factors. Therefore, the future of performance management-HTA integration in Malta depends on ensuring that evidence is translated into policies that maximise resource allocation and enhance patient outcomes, developing capacity, and striking a balance between EU-driven harmonisation and national context.

> *"We cannot really measure the HTA up to this level, but what we do is we collect this data qualitatively and do, for example, case summaries to try and share them with our colleagues…"* (P7)

> *"…when we are a bit more up and running… we will also move on to looking into the other evaluation and HTA aspect".* (P8)

DISCUSSION

The case study for Malta highlights how a small, centralised health system navigates the intersection of Performance Management (PM) and Health Technology Assessment (HTA). Operating under a unified governance model and with Malta's HTA functions at the macro level, the case study for Malta serves as an evidence-based input mechanism guiding reimbursement, procurement, and policy decisions. The findings indicate that the legal and

procedural frameworks for HTA are well established, but the feedback loop into PM is still evolving. Stakeholder perspectives reveal fragmented data systems, limited capacity for cost-effectiveness evaluation, and partial integration of HTA outputs into performance indicators. Malta's participation in EU-wide HTA collaborations (e.g., joint evaluation at the EU level in line with Regulation (EU) 2021/2282) enhances capacity and provides a foundation for alignment with broader European performance management standards. The generalisability of the case study for Malta will also be considered.

Regulation and Policy

In Malta, the frameworks that govern Health Technology Assessment (HTA) play a crucial role in ensuring regulatory legitimacy and policy accountability. In EU Member States, the national frameworks adhere to European Union (EU) directives regarding the regulation of medicinal products and health technology governance, embedding HTA processes within existing legal mandates [32]. Performance Management indicators are essential for ensuring accountability throughout all phases of the HTA process. Engaging transparency and inclusion would foster stakeholder trust and bolster the legitimacy of policy outcomes. Altogether, these governance tools elevate HTA from merely a technical appraisal instrument to a regulatory function that adheres to the principles of fairness, efficiency, and evidence-based policymaking [8].

The focus on legislation and structured regulatory guidance highlights the essential role of legal frameworks in legitimising HTA processes. Regulatory tools such as legal notices, policy directives, and institutional guidelines serve as means of ensuring accountability and transparency, aligning with principles noted in the literature [33-34]. The case study for Malta reflects a reality applicable to all EU Member States where efforts for policy harmonisation need to balance national sovereignty with supranational coordination [35]. The ongoing phased implementation of the EU HTA Regulation 2021/2282, which includes joint clinical assessments, illustrates both an opportunity for shared learning and a challenge in maintaining national flexibility regarding pricing and reimbursement.

Marketing Authorisation

In Malta, the marketing authorisation process primarily follows the guidelines set by the European Medicines Agency (EMA) and mutual recognition agreements within the EU [36]. However, within Malta's resource-constrained regulatory environment, the integration of performance management principles has become essential to maintaining efficiency, consistency, and transparency. Performance management mechanisms track key operational

indicators such as the duration of assessment procedures, the timeliness of dossier review, and the publication of decision rationales, which together enhance both the predictability and accountability of authorisation processes. These measures ensure that decision-making remains evidence-driven while respecting the constraints of limited human and technical resources. Importantly, by embedding performance practices within HTA-aligned regulatory operations, Malta promotes a culture of continuous process improvement. The centralised system for the regulation of medicinal products in Europe helps to achieve standardisation across the EU.

HTA process

Malta's organised HTA process, which incorporates contributions from companies, clinicians, and problem-driven submissions, demonstrates an evolving institutional framework. Nonetheless, ongoing issues with data fragmentation and a lack of local evidence hinder the thoroughness of assessments. As was pointed out, the small population size limits the generation of statistically robust real-world data, necessitating dependence on international sources. This dilemma is typical for small or resource-constrained states [37], where adaptation instead of direct replication of global models becomes crucial. This challenge may also be significant in joint assessment because it will be difficult to perform an assessment in line with a model which consolidates the different requirements and practices of all the Member States.

The case study of Malta also highlights how capacity-building initiatives and regional cooperation with EU agencies have strengthened the technical capabilities for HTA. Participation in joint assessments, training programmes, and information-sharing platforms under the European HTA and regulatory networks is essential and of great benefit to the Member States, especially the smaller ones, which may have more restricted resources and expertise. Joint assessment across Member States is already being applied for regulatory evaluation, and there are lessons to be learnt from this.

Stakeholder engagement

The findings indicate that engagement of various stakeholders, including clinicians, patients, industry representatives, and policymakers, is not just a formality but vital for the legitimacy and sustainability of PM-HTA integration. The varying expectations and technical abilities among stakeholder groups stress the need for capacity-building initiatives, echoing calls in the literature for more inclusive, transparent, and iterative assessment processes [38]. The focus groups from Malta revealed an understanding of these dynamics and acknowledged that meaningful engagement can help balance conflicting interests and enhance the social

acceptability of HTA decisions. There was agreement that implementing this collaboration is challenging.

Reimbursement

Health technology assessments provide the clinical and economic justification for inclusion of drugs in the national formulary, ensuring that limited public resources are directed toward interventions with proven value for money [36]. These assessments draw upon clinical evidence, cost-effectiveness analyses, and budget impact models to inform reimbursement recommendations. Performance Management complements this process by providing measurable indicators to monitor how effectively and equitably reimbursement decisions are implemented. Key performance management metrics include the time from submission to decision, speed of patient access post-reimbursement, and evaluation of real-world health outcomes once technologies are in use [39]. Such data enable policymakers to assess not only the efficiency of reimbursement decision-making but also its downstream impact on access and population health.

In Malta's case, where system capacity and market size can delay technology uptake, performance management plays a critical corrective function. Identifying delays or bottlenecks in the reimbursement pathway, performance management metrics help to streamline workflows and inform policy adjustments. The merging of HTA evidence with PM metrics would provide a more transparent and outcome-focused reimbursement landscape, aligning policy goals with benefits for patients and the health system. The integration of performance management into reimbursement governance facilitates value-based decision-making. For example, post-reimbursement monitoring enables reassessment of technologies based on real-world effectiveness and cost-efficiency, feeding back into iterative HTA reviews [40]. This cyclical process ensures that reimbursement remains a dynamic policy tool rather than a one-time administrative action. As a result, this approach aligns with European trends toward adaptive reimbursement and managed entry agreements, which link funding to measurable performance and outcomes.

Pricing and Procurement

Malta does not have a system for the setting of prices of medicines on a national level. Within Malta's publicly funded healthcare system, pricing and procurement decisions are guided by evidence from HTA regarding therapeutic and economic value. This evidence-driven approach supports value-based pricing strategies, ensuring that spending corresponds with anticipated

clinical benefits and financial sustainability. Performance management extends this governance by monitoring efficiency metrics such as contract turnaround times, reliability of supply, and cost-efficiency ratios to assess whether procurement practices are achieving their intended results. In Malta, the integration of HTA with PM would bring transparency in procurement, reduce supply and shortages risks, and improve accountability in managing expenditures. This synergy exemplifies how evidence-informed procurement can implement regulatory goals related to value, equity, and efficiency within small-state health systems. As Malta has a centralised public procurement for both the hospital as well as the primary care systems, the impact of HTA and performance management in the procurement process will be at the national level. In contrast, some countries have a decentralised system of procurement, with procurement being done at a regional, trust or even hospital level. In such decentralised models, the integration of HTA and PM may be more fragmented, but it is even more important to ensure equity in the allocation of resources.

Clinical Use

The domain of clinical use represents the point at which policy decisions informed by HTA translate into real-world healthcare practice. It is here that the effectiveness, efficiency, and sustainability of HTA-driven decisions are ultimately tested. Merging performance management mechanisms into clinical practice ensures that technologies adopted through evidence-based assessment deliver measurable improvements in patient outcomes, quality of care, and system performance.

In the case study of Malta, HTA recommendations guide the selection, funding, and deployment of medicines and medical technologies within the national health service. However, once these technologies enter clinical settings, their use must be continuously monitored to ensure adherence to clinical guidelines, equitable access, and appropriate utilisation. Performance management thus plays a critical role by tracking key indicators such as prescribing patterns, treatment adherence, patient outcomes, and resource utilisation. These data provide feedback to policymakers and HTA bodies, allowing for the refinement of clinical protocols and formulary listings based on real-world performance.

A major strength in Malta's approach lies in the growing emphasis on interdisciplinary collaboration between clinicians, HTA assessors, and policymakers. Clinicians should increasingly engage not only as end-users of HTA recommendations but as active contributors to the evidence feedback loop. This collaboration ensures that HTA outputs are relevant to

everyday clinical realities and that implementation challenges such as workflow integration, patient communication, and resource allocation are promptly identified and addressed.

Ultimately, the integration of PM within the clinical use domain enables iterative learning and continuous improvement across the healthcare system. By closing the feedback loop between clinical practice and policy, Malta is moving toward a more dynamic and responsive model of health governance, one that ensures HTA does not end at reimbursement, but extends into ongoing evaluation of value in real-world settings. The next step would be to also increasingly involve structured feedback from patients and direct users of the technologies.

Integration of Performance Management and Health Technology Assessment across the multi-level structure of the healthcare system

The framework developed by [17] that combines Health Technology Assessment (HTA) and Performance Management (PM) (Figure 1), combined with the model for health systems of Europe (Figure 2), consolidated through the case study for Malta, show that health technology assessment and performance management operate across three interconnected levels: macro, meso, and micro. Building on this theoretical basis, Malta's approach exemplifies the co-evolution of evidence-based technology assessment and performance monitoring within a compact and centralised healthcare system.

The multi-level structure, which illustrates the links between legislation, regulation, health systems, and clinical accessibility, is described in Figure 4.

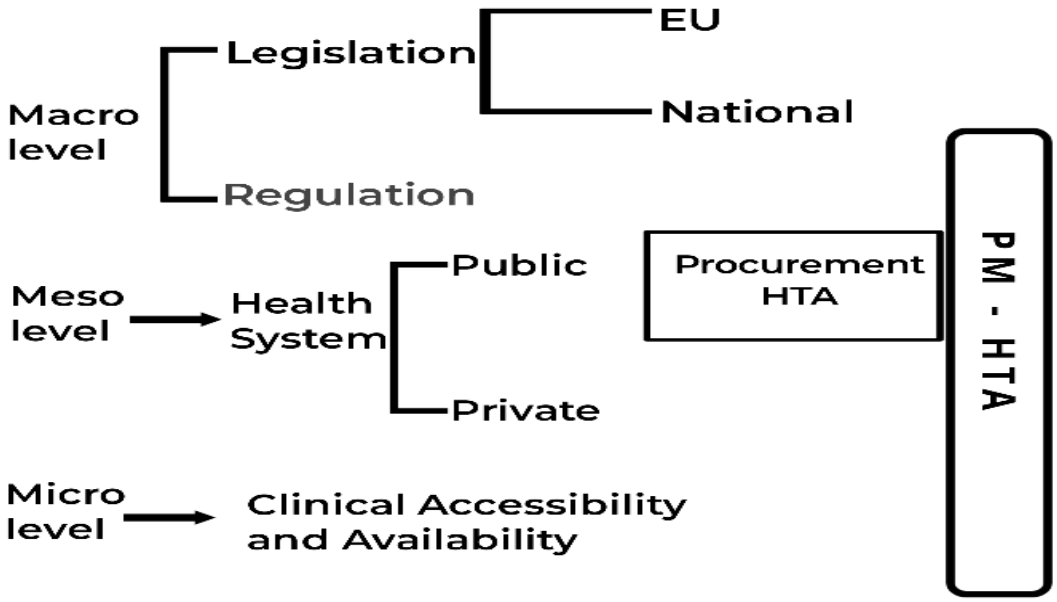

Figure 4: Health Technology Assessment – Performance Management (HTA-PM) Structure

Source: Authors' own work

At the national (macro) level, the EU establishes governance, transparency, and uniform methodologies to standardise evaluations of clinical effectiveness and safety, while permitting economic and organisational assessments to be handled by national authorities [41]. At the organisational (meso) level, HTA entities, payers, and healthcare organisations use these evaluations, give evidence for reimbursement decisions, and enhance capabilities for generating and monitoring real-world evidence from the use of the technologies [42]. At the clinical (micro) level, clinicians and patients participate directly through stakeholder engagement and data gathering, ensuring that technologies function as anticipated in practice and that patient outcomes and safety are prioritised in performance management. This multilevel strategy promotes accountability and feedback mechanisms between prior assessments and subsequent monitoring, allowing for conditional reimbursement and flexible policies [43].

The framework presented in Figure 4 illustrates an integrated, multilevel framework in which Health Technology Assessment and performance management operate as mutually reinforcing functions across macro, meso, and micro levels of the health system. This framework aligns closely with the direction established by the European Union's new HTA Regulation (EU

2021/2282) [14], which emphasises coordination, transparency, and evidence standardisation across Member States. The EU framework supports a shift toward more structured, interconnected HTA processes, while maintaining national autonomy in appraisal, pricing, and reimbursement.

At the macro level, the framework situates regulation, policy, and strategic HTA oversight, reflecting the dual influence of EU legislation and national governance. This level aligns with the EU HTA Regulation, which requires Member States to integrate EU Joint Clinical Assessments, horizon scanning outputs, and joint scientific consultations into their domestic systems. In the context of Malta, the macro level determines the level of adoption of EU methodologies and standards; alignment of national HTA processes with EU timelines; strategic oversight to ensure HTA–PM coherence; legally mandated transparency and stakeholder inclusion. Thus, the macro tier reflects the regulatory backbone that enables Malta to interface effectively with the EU HTA system.

The meso level corresponds to health system operations, particularly pricing, procurement, and organisational performance tracking. This mirrors how the EU framework expects Member States to use EU-wide clinical evidence outputs while retaining independence in economic evaluation, pricing negotiations, formulary decisions, and managed entry agreements. The meso level shows how HTA outputs feed into procurement strategies and organisational performance management, ensuring value-based resource allocation. This reflects the EU's intention to strengthen national capacity for evidence-informed purchasing. The micro level is central to both adaptive reimbursement models and post-market monitoring. This corresponds to the EU framework's emphasis on: collecting real-world effectiveness data, feeding real-world evidence back into HTA reassessments, and monitoring equity and access across Member States. Stakeholders sit at the side of the framework because, as under the EU HTA Regulation, they operate at all levels: macro (policy input), meso (implementation feedback), and micro (patient experience, clinical adoption). The model reflects this by showing stakeholders feeding directly into HTA, regulatory processes, and performance monitoring.

Integration of Performance Management and Health Technology Assessment across the critical domains

The case study of Malta provided a structured understanding of how performance-driven mechanisms can embed accountability, efficiency, and value-based principles into the health system's decision-making processes. It showed that aligning performance management with

HTA across the key domains could help institutionalise value-based pricing, a fundamental aspect of modern healthcare governance. Figure 5 illustrates the interdependence between Performance Management (PM) and Health Technology Assessment (HTA) across five critical domains: Regulation and Policy, Marketing Authorisation, Reimbursement, Pricing and Procurement, and Clinical Use adapted from [16].

At the macro level, national authorities oversee strategic direction, ensuring regulatory consistency, resource prioritisation, and the design of national performance indicators. This aligns with the feedforward stage of the conceptual framework, where ex-ante HTA directs budget allocation, technology adoption, and overarching system objectives, such as quality, efficiency, and sustainability. The meso level, which includes the Health Technology Assessment Unit and hospital management structures, puts national policies into practice through procurement, reimbursement, and performance evaluation. This reflects the translation phase of the framework, where HTA outputs are integrated into PM systems using Key Performance Indicators (KPIs), balanced scorecards, and interactive dashboards that assess implementation and organisational outcomes. At the micro level, healthcare providers, clinicians, and patients produce real-world data on clinical results, safety, and patient satisfaction, serving as feedback for both PM and HTA cycles. This corresponds with the ex-post phase of the framework, where performance monitoring confirms whether technologies meet their intended objectives and guides iterative updates to HTA assessments and strategic goals.

A consolidated Performance Management and Health Technology Assessment Integration Framework

Figure 5 represents a consolidated Performance Management and Health Technology Assessment Integration Framework. This multi-level integration promotes a learning healthcare system where the generation of evidence, policy development, and performance evaluation are continuous and mutually beneficial. Although stakeholder objectives differ, ranging from policy stability at the macro level to operational efficiency and clinical quality at the micro level, the shared data infrastructure facilitates the alignment of national objectives with performance-based accountability. Malta's centralised governance structure enhances this integration by allowing for swift policy implementation and consistency among institutions. In contrast, decentralised systems like those in Spain or Italy often encounter regional discrepancies in HTA adoption, data reporting, and performance monitoring. Thus, Malta

serves as a model for how smaller health systems can utilise structural unity to achieve dynamic integration of PM and HTA, alongside evidence-driven governance.

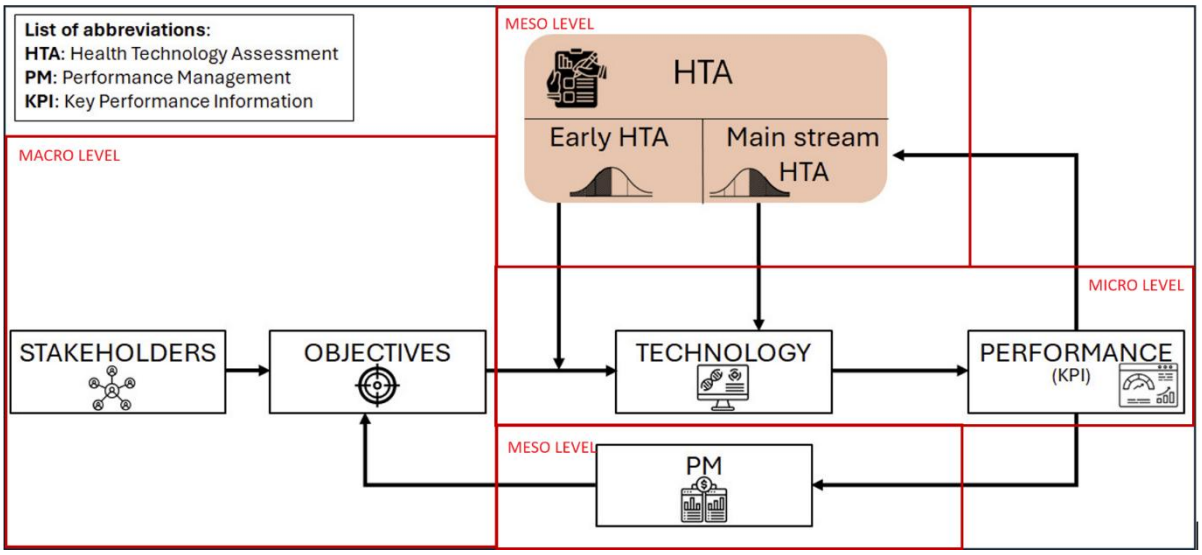

Figure 5: PM and HTA integration framework (compiled by the authors)

A significant insight drawn from this study is that continuous monitoring of HTA in conjunction with PM converts real-world data into usable intelligence. Incorporating feedback loops within the performance management cycle facilitates ongoing collection of data on safety, cost, and effectiveness, directly influencing adaptive policy and procurement choices. With interoperable data systems and real-time dashboards, performance indicators can consistently update HTA evaluations, ensuring that technologies continue to generate value throughout their lifespan. This operationalises the concept of dynamic evidence flow from the framework, where ex-ante HTA is progressively enhanced by ex-post-performance data. This strategy aligns with EU priorities related to real-world evidence-informed HTA and adaptive reimbursement [44]. For Malta, sustaining this integrated cycle necessitates enhancing analytic capabilities, standardising data sharing, and fostering cross-sector collaboration among public health authorities, hospitals, and academic institutions.

The integration of HTA and PM goes beyond mere procedural coordination; it represents an innovative strategic governance approach within all health systems. In Malta, HTA serves as the input mechanism, generating structured evidence regarding technology value and suitability, while PM acts as the output mechanism, translating strategic decisions into measurable results. Establishing this cyclical process across the macro, meso, and micro levels

guarantees coherence, accountability, and value-driven healthcare delivery. Therefore, Malta's model reinforces the theoretical assertion made by [17] that systematic integration of HTA and PM transforms health systems into adaptive and learning-focused environments. Malta's experience provides a replicable model for balancing innovation, efficiency, and sustainability through integrated governance in small or resource-limited countries.

CONCLUSION

This study provides an integrated understanding of how Health Technology Assessment and Performance Management intersect within a small-state health system. In Malta, HTA functions as the critical input mechanism providing evidence on effectiveness, safety, and value, while PM serves as the output mechanism, translating decisions into measurable performance outcomes. The proposed framework captures this cyclical relationship, where assessment informs action, and performance data feeds back into policy refinement. For Malta, the practical implications are clear: strengthening institutional capacity, data infrastructure, and cross-departmental collaboration are prerequisites for achieving full integration. Beyond Malta, this framework offers a transferable model for health systems seeking to balance innovation, efficiency, and accountability in healthcare governance. While this framework may be more decentralised in larger health care systems, the fundamental concept still applies. Digitalisation may help to standardise and consolidate the elements of the framework, particularly in larger and more disjointed systems.

In conclusion, integrating HTA and PM is not merely a procedural alignment but a strategic shift toward value-based, evidence-driven health system management. By embedding HTA evidence throughout the medicines lifecycle and linking it to performance outcomes, all countries can enhance transparency, optimise resource use, and ultimately improve population health outcomes.

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CHAPTER SIX

DISCUSSION AND CONCLUSIONS

Chapter 3 offers a scoping review that explores the theoretical, methodological, and operational connections between HTA and performance management across different health systems. The paper assesses the relevant academic and policy literature to determine how HTA processes incorporate performance indicators and how performance management frameworks utilise evidence sourced from HTA. It emphasises four primary performance dimensions: clinical, economic, organisational, and social, which are essential perspectives through which health systems measure the efficacy and value of health technologies. The review notes considerable variation among countries, highlighting that some systems integrate HTA within broader performance management frameworks, while others primarily use it as a tool for economic appraisal. Crucially, the paper discovers that stakeholder engagement, real-world data use, and multi-criteria assessment are underutilised in most regions, despite their importance in strengthening decision-making processes. The study charts and consolidates existing knowledge on the interaction between HTA and performance management, while also identifying shortcomings in the current frameworks that aim to merge both processes. Its main aim is to clarify how and where HTA contributes to system performance and to identify areas with either weak or emerging integration. By doing so, the paper establishes a conceptual basis for enhancing the alignment between technology evaluation and overall performance assessment within health systems.

The study has a conceptual and strategic significance as it illustrates that HTA and performance management are fundamentally interconnected, even though they are frequently treated as separate entities. Its findings highlight to researchers and policymakers that incorporating performance management aspects into HTA can improve the relevance of evaluations and that integrating HTA results into performance management processes enhances accountability and alignment with health system objectives. The review also contributes to global conversations on value-based healthcare, equity, and transparency, offering evidence for policymakers to rationalise reforms in the governance of evaluation systems. It also makes a notable contribution to clarifying how healthcare performance can be improved by incorporating HTA into performance management frameworks. Its identification of performance domains assists health systems in understanding how HTA affects clinical outcomes, resource distribution,

organisational efficiency, and social equity. Addressing gaps like inconsistent stakeholder involvement or limited use of real-world data, it provides guidance for improvement strategies aimed at ensuring that technologies provide not only economic value but also tangible enhancements in health system performance. Thus, Study 1 serves as a foundational element in the development of more responsive, evidence-based, and accountable health systems.

Chapter 4 embarks on an intricate qualitative content analysis of ten diverse national and international Health Technology Assessment guidelines, meticulously comparing various aspects such as their structural organisation, criteria for assessment, evidence requirements, performance dimensions, and methodological approaches utilised across the globe. This comprehensive examination includes guidelines from prestigious organisations including the National Institute for Health and Care Excellence (NICE) in the UK, the Canadian Agency for Drugs and Technologies in Health (CADTH), the Pharmaceutical Benefits Advisory Committee (PBAC) in Australia, and the Institute for Clinical and Economic Review (ICER) in the USA, along with influential international frameworks like EUnetHTA and EVIDEM. The analysis reveals striking discrepancies in emphasis and focus among different countries. The overarching objective of this study is to systematically compare, categorise, and glean insights into the evolution of HTA guidelines across diverse contexts, thereby pinpointing significant trends, areas of convergence, and noteworthy discrepancies. The study aspires to deliver a clearer understanding of how these methodologies have adapted in response to technological advancements, constraints on resources, and the unique priorities of health systems. Furthermore, it seeks to propose a consolidated framework of domains and criteria that could facilitate the future harmonisation of HTA processes worldwide.

This research holds considerable methodological and policy implications, providing one of the rare comparative analyses that intricately maps the content of HTA guidelines across varying regions. Its recognition of pivotal trends such as the increasing significance of patient-centred evidence, the burgeoning use of real-world data, and the transition toward broader, multidimensional evaluations offers critical insights for national agencies that are either revising or establishing their HTA systems. Moreover, the study plays a vital role in the ongoing global discourse about the necessity of harmonisation and collaboration across countries. In essence, this study contributes profoundly to the performance efficiency of healthcare systems by elucidating how HTA guidelines influence the quality of decision-making, transparency, and operational efficiency. By meticulously analysing the performance dimensions integrated into each guideline, the paper illustrates how various countries navigate the balance between

clinical outcomes, financial sustainability, organisational preparedness, and societal values. This analysis empowers policymakers to identify best practices and address methodological shortcomings. Ultimately, the findings advocate for the adoption of more inclusive, evidence-driven, and patient-oriented HTA procedures, thereby enhancing health system performance by fostering the application of robust, standardised, and comparable methodologies that support improved resource allocation, better health outcomes, and more equitable access to effective technologies.

Chapter 5 presents a qualitative case study of Malta, exploring how a small, centralised health system integrates or attempts to integrate HTA into its performance management framework. Through focus group discussions and a key informant interview with government stakeholders, the study describes Malta's HTA processes, governance structures, procurement practices, stakeholder involvement, and challenges. The study highlights issues such as fragmented data, limited local real-world evidence, capacity gaps, and the need for clearer alignment between HTA outputs and performance indicators. It also underscores Malta's reliance on international collaboration, especially EU mechanisms, due to its small population and resource constraints. This study investigates the actual operational convergence between HTA and performance management within an applied national context, focusing on the lived experiences, perceptions, and practices of Maltese health system actors. The study seeks to understand how HTA contributes to strategic decision-making, how performance management frameworks shape adoption and diffusion of technologies, and what barriers hinder full integration.

The impact of Chapter 5 lies in its practical and contextual contribution. Unlike the previous chapters, which take theoretical and comparative approaches, this case study offers ground-level evidence of how HTA and performance management operate in real life within a small-state health system. It gives voice to policymakers, clinicians, and procurement officials, offering nuanced insights into the operational realities of implementing HTA. This evidence is invaluable globally, providing a replicable model for adapting HTA and performance management frameworks.

This research provides critical insights into how HTA can support performance improvement in areas such as procurement efficiency, formulary management, governance transparency, and clinical adoption of technologies. Emphasising the need for better data infrastructure, capacity building, stakeholder engagement, and policy harmonisation, the study contributes to shaping

a more coherent and responsive performance management system. This integration is essential for sustaining universal coverage, efficiency, and equitable access.

The objective of the thesis, “The Evolution of Performance Management in the Healthcare Sector,” offers an in-depth examination of three papers, analysing their content, goals, influence, and contributions to healthcare performance. The collective findings highlight a compelling argument for merging Health Technology Assessment with Performance Management to establish health systems that are evidence-based, accountable, efficient, and responsive to population needs. These studies collectively create a unified body of work that enhances scholarly understanding and provides actionable recommendations for health policy and governance at both national and global scales.

The three studies collectively deliver a thorough and interconnected perspective on how Health Technology Assessment and performance management enhance the effectiveness and accountability of health systems. Chapter 3 lays the groundwork conceptually, illustrating the interconnection between Health Technology Assessment and performance management. Chapter 4 adds a global, methodological viewpoint, showcasing how guidelines put HTA into practice and influence performance metrics, while Chapter 5 presents a practical case study that uncovers how integration occurs in an actual health system while identifying challenges and opportunities. A key theme arises in all three papers: Health Technology Assessment and performance management are complementary mechanisms that, when combined, bolster the efficacy of healthcare systems by enhancing evidence-based decision-making, resource distribution, care quality, accountability, and patient outcomes.

However, this chapter provides an integrative discussion of the findings presented across the three empirical components of this thesis and articulates their collective theoretical, methodological, and practical contributions. Moving beyond a sequential summary of individual studies, the chapter synthesises cross-cutting insights to advance a coherent understanding of how Health Technology Assessment (HTA) and Performance Management Systems (PMS) interact as complementary governance mechanisms within healthcare systems. It also presents a consolidated framework emerging from the thesis, discusses overarching limitations, outlines a future research agenda, and reflects on the implications for policy and practice.

While Chapters 3, 4, and 5 each contribute distinct perspectives, conceptual, institutional, and empirical, their combined analysis reveals a set of cross-cutting patterns and tensions that are not fully visible within any single study.

First, a consistent finding across all three studies is the structural complementarity between HTA and PMS. Chapter 3 demonstrates, through the scoping review, that both domains share common objectives related to improving quality, efficiency, and accountability, yet they have historically evolved along separate trajectories. Chapter 4 further shows that global HTA guidelines increasingly incorporate performance-related dimensions, such as outcome monitoring and real-world evidence, suggesting an implicit recognition of this complementarity at the policy level. Chapter 5, however, reveals that in practice, particularly in the Malta case, this integration remains partial and fragmented, highlighting a persistent gap between conceptual alignment and operational implementation.

Second, the thesis identifies a fundamental tension between standardisation and contextual adaptation. The content analysis of international guidelines (Chapter 4) points to a growing trend towards methodological harmonisation, particularly within European regulatory frameworks. However, the case study (Chapter 5) illustrates that local institutional contexts, resource constraints, and organisational capacities significantly shape how these frameworks are interpreted and applied. This suggests that while standardisation enhances comparability and efficiency, it may also limit flexibility and responsiveness to local needs.

Third, the findings highlight the critical role of data infrastructures and feedback mechanisms as enablers of integration. Across the three studies, the ability to generate, share, and utilise real-world performance data emerges as a key determinant of whether HTA and PMS can function as a coherent system. However, empirical evidence points to persistent challenges, including data fragmentation, limited interoperability, and weak feedback loops, which constrain the development of adaptive governance models.

Finally, drawing on the theoretical framework introduced in Chapter 1, the thesis identifies institutional dynamics, particularly isomorphism, legitimacy, and decoupling, as central explanatory mechanisms. While healthcare organisations adopt HTA and PMS frameworks in response to regulatory and normative pressures, their integration is often symbolic rather than substantive. This results in decoupling, where formal structures exist without being fully embedded in decision-making processes. The Malta case illustrates this phenomenon, showing how institutional inertia can limit the realisation of theoretically sound governance models.

Building on the cumulative findings of the thesis, this study proposes a consolidated HTA–PMS Integration Framework as its central theoretical contribution. The framework conceptualises integration as a multi-level, cyclical, and institutionally embedded process comprising three interconnected components: Evidence Generation (HTA Domain), which involves the systematic evaluation of health technologies across clinical, economic, social, and organisational dimensions. It provides ex-ante and lifecycle evidence to inform decision-making. Also, Performance Operationalisation (PMS Domain), where HTA outputs are translated into measurable indicators, key performance metrics, and monitoring systems that guide organisational behaviour and resource allocation. Lastly, Feedback and Adaptive Governance (Integration Domain), of which real-world performance data generated through PMS is fed back into HTA processes, enabling iterative reassessment, policy adjustment, and continuous learning. These components operate across three levels of analysis, including: macro, the system level (policy frameworks and regulatory structures); meso, the organisational level (hospitals and healthcare institutions) and micro, the technology level (specific interventions and innovations).

Importantly, the framework is mediated by institutional factors, including regulatory pressures, professional norms, organisational capacity, and data infrastructures. These factors can either facilitate integration (through alignment and coordination) or hinder it (through fragmentation and decoupling). This consolidated model integrates and enhances the frameworks developed in Chapters 3 and 5, offering a unified representation of the HTA-PMS relationship and addressing the need for a definitive theoretical output.

Theoretical Contributions

This thesis makes several contributions to the literature on healthcare management and policy. First, it advances the conceptualisation of HTA and PMS as interdependent components of a unified governance system, rather than as separate analytical domains. Second, it introduces an institutional perspective into the study of HTA-PMS integration, providing a novel explanation for the persistent gap between theory and practice. Third, it develops a multi-level and dynamic framework that captures the complexity of healthcare systems and highlights the importance of feedback loops and adaptive governance.

Limitations of the Thesis

Despite its contributions, this thesis has several limitations that should be acknowledged. The research design primarily uses a qualitative approach, incorporating a scoping review, content

analysis, and a single case study. While this method allows for an in-depth exploration of the subject, it also limits the generalizability of the findings. Additionally, the empirical analysis focuses exclusively on a single-country case, Malta. Although this case is theoretically relevant, it may not fully represent the diversity of healthcare systems worldwide. Furthermore, the proposed framework has not been externally validated through quantitative testing or applied in multiple contexts. Lastly, data limitations, particularly regarding real-world performance measurement, may have restricted the analysis of integration mechanisms.

Future Research Directions

This thesis highlights several limitations and identifies potential avenues for future research. First, upcoming studies could use quantitative and mixed-method approaches to test the relationships outlined in this thesis and validate the proposed framework. Second, conducting comparative analyses across different countries would shed light on how various institutional contexts affect the integration of Health Technology Assessment (HTA) and Performance Management Systems (PMS). Third, further research is needed to explore the role of digital health infrastructures and data systems in facilitating real-time feedback loops. Fourth, it would be beneficial to study the perspectives of stakeholders, particularly clinicians and patients, to gain a deeper understanding of the behavioural aspects of integration. Finally, future work could investigate the impact of HTA-PMS integration on health outcomes and system performance, providing empirical evidence of its value.

Practical and Policy Implications

The findings of this thesis have significant implications for policymakers, healthcare managers, and health technology assessment (HTA) agencies. For policymakers, it is essential to move beyond merely adopting HTA and performance management system (PMS) frameworks towards their active integration, which should be supported by regulatory incentives and clear governance structures. Healthcare organisations must invest in data infrastructure, interoperability, and analytical capabilities to enable effective performance monitoring and feedback. HTA agencies should collaborate closely with performance management units to ensure that evaluations are linked to real-world outcomes and organisational objectives. Ultimately, the unique contribution of this thesis lies in its ability to bridge theory and practice. It offers a novel, institutionally informed perspective on the integration of HTA and PMS, thereby advancing the discourse on how healthcare systems can better align evidence, performance, and policy to achieve sustainable, high-quality care.