From Assessment to Authority: Designing Health Technology Assessment Systems That Shape Real Spending Decisions

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Contents

Executive Summary

Health systems in growing economies face a structural resource allocation problem: fiscal margins are narrow, opportunity costs are high, and misallocation directly displaces essential services. In these environments, prioritisation is not a normative ideal but a functional requirement for system performance.

Health technology assessment (HTA) provides a mechanism for systematic priority-setting. Its economic case is universal, but the rationale differs across contexts. High-income systems use HTA to manage complexity, rising expectations, and persistent fiscal pressure. Growing economies require systematic frameworks to support rapid benefit expansion, new technologies, and politically salient demands. Resource-constrained systems confront the starkest trade-offs, where adopting interventions above true opportunity-cost thresholds results in net health losses because gains from new technologies are offset by displaced services.

Despite this, a persistent paradox remains: the countries that would benefit most from HTA often have the least institutional capacity to implement it. Evidence from multiple regions shows that HTA activity, where present, is frequently technically competent but structurally marginal: assessments are produced, but decisions are made elsewhere, under different incentives, and without systematic reference to evidence.

This disconnect reflects a design problem, not an analytical one. HTA has often been built as a technical function rather than as a governance institution with authority over resource allocation, clear lines of accountability, and mechanisms that bind assessment to decisions. As a result, outputs are advisory, rarely determinative, and easily overridden without documentation or consequence.

This paper argues that effective HTA in growing economies requires two elements simultaneously:

- Economic sophistication in evaluating comparative value, opportunity costs, affordability, and uncertainty; and
- Governance architecture that embeds these functions within the institutions that control budgets, procurement, and benefit-package decisions.

Countries cannot wait for ideal institutions or perfect data before acting. A pragmatic approach is a dual-stream implementation model:

- Stream One: Use HTA methods immediately in live decisions — formulary updates, contract renewals, high-cost medicines, service redesign — to build capability, shape expectations, and deliver fiscal value now.
- Stream Two: Design institutional arrangements in parallel that give HTA a stable mandate, defined authority, transparent procedures, and mechanisms for reassessment and disinvestment.

These streams are complementary: analytical practice reveals which capabilities are necessary, while governance design converts analytical competence into sustained influence.
The paper proposes governance design based on established public-sector and corporate principles - clarity of purpose, defined decision rights, transparent criteria, documented rationale, and systematic portfolio review, rather than replication of legacy HTA models built for different innovation ecosystems and decision architectures.

This approach positions HTA not as a technical appendage but as a core element of fiscal governance, enabling sustainable access to innovation by directing resources toward high-value interventions and creating fiscal space through systematic reassessment of low-value technologies.

Success is therefore not measured by the existence of an HTA body, nor by the number of reports it produces, but by whether it shapes real spending decisions, supports adoption of high-value technologies, and ensures that scarce resources are allocated transparently, consistently, and in ways that improve population health.

Growing economies have an opportunity to design HTA systems suited to contemporary realities: systems that are pragmatic rather than idealised, embedded rather than peripheral, and oriented toward long-term institutional durability. Achieving this requires integration of economic analysis with governance design and the recognition that HTA is not merely a technical exercise, but a mechanism for system-level stewardship of public resources.

Introduction: The Priority-Setting Challenge

1.1 When Decisions Happen Without a Framework

Every health system makes coverage decisions: which medications to fund, which procedures to introduce, which programmes to expand, and which pressures to absorb by delaying or diluting services. Despite the importance of thorough decision-making, in many cases decisions are made without an explicit framework guiding how options are compared or how trade-offs are managed. They are driven by timing, visibility, political salience, or operational urgency rather than by consistent assessment of value.

Over the past two decades, many countries have sought to replace implicit decision-making with more systematic, evidence-informed approaches, yet progress is slow. The most recent WHO global survey (2020–21) found that although 53% of countries now report legislative requirements to consider health technology assessment results in coverage decisions, in reality only 39% have a dedicated HTA institution, and formal adoption often precedes effective implementation (Guzman et al., 2023). Reviews continue to find that even where priority-setting frameworks exist, they are frequently implemented episodically, lack meaningful stakeholder involvement, and are characterised by weak follow-through and evaluation (Seixas et al., 2021).

Without a systematic process, decision-makers rely on familiar heuristics, precedent, political pressure, or claims of clinical urgency (Angelis et al., 2017). The consequences are well-documented: inefficient spending, inequitable access, and recurrent fiscal stress. When choices are implicit, even substantial opportunity costs remain invisible.

These dynamics are present in all systems, even though both the reasons for needing structured priority-setting and the fiscal impact of poor decision making differ. In lower-income regions, the consequences of implicit prioritisation are amplified by extreme resource constraints. Low-income countries spend an average of just USD 17 per capita on health, and low-middle income countries spend circa USD 47 per capita, both below the USD 60 minimum estimated for a basic package of essential services (World Bank, 2025). When fiscal space is this limited, misallocation directly displaces essential services and the need for explicit, quality decision making is even greater. However decisions in these settings are rarely grounded in systematic assessment and often lack transparency (Disease Control Priorities Network, 2017). In contrast, growing economies need systematic priority-setting to manage rapid expansion of benefits, new technologies and rising expectations. Further along the scale high-income systems face increasing demand, complex therapies and persistent fiscal pressure. Therefore regardless of the level of income of a country, the findings are the same: HTA should not be considered to be a tool reserved for well-resourced systems, but a governance mechanism that every health system needs, albeit for different reasons.

1.2 The Case for Systematic Priority-Setting

Systematic priority-setting is not about saying "no" to services. It is about systematically saying "yes" to the right things, interventions that deliver the greatest value for population health within available resources. Systematic priority-setting replaces ad hoc judgement with explicit criteria, structured use of evidence, and transparent reasoning about trade-offs. Defined criteria, such as cost-effectiveness, severity of disease, and financial risk protection, allow decision-makers to compare options consistently and to articulate why certain interventions are prioritised (Cromwell et al., 2015; Seixas et al., 2021). This framing matters in settings where budgets are tight, needs are high, and expectations are rising.

This is aligned with World Health Organisation (WHO) guidance on the inclusion of HTA in the context of universal health coverage (UHC). WHO has long emphasised that explicit choices must be made on the path to UHC and the design of a health benefit package requires identification of priority classes of services, defining the breadth, depth, and height of coverage, and revisiting these decisions as evidence, fiscal space, and health needs evolve (WHO, 2014). Without a systematic approach to determining what goes into the benefit package, UHC becomes a declarative commitment rather than an operational strategy.

1.3 Health Technology Assessment as Infrastructure

In many countries HTA remains narrowly applied, poorly connected to decisions, or limited to pharmaceuticals. Three principles should be considered when deciding on the set-up and infrastructure:

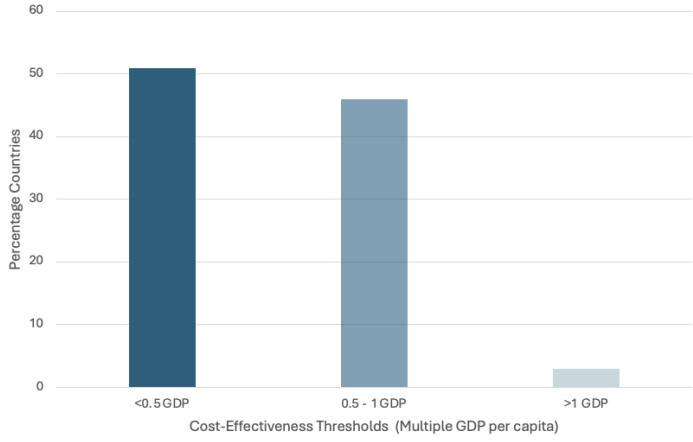
- **HTA should not be limited to pharmaceuticals and devices** and should be applicable across the entire health system, including diagnostics, procedures, programmes, delivery models and policies (WHO, 2021; Falkowski et al., 2023). If HTA is confined only to drug and device reimbursement, systems lose the opportunity to compare alternative service-delivery models, evaluate diagnostic and screening pathways, or assess the value of public health programmes. These uses are central to benefit-package design, where choices involve not only which medicines to fund but which services to include, at what level of coverage, and under which delivery arrangements.
- **HTA should encompass both adoption and disinvestment**. Many systems focus on evaluating new technologies; few have mechanisms to reassess or withdraw interventions that deliver limited value. Systematic disinvestment becomes essential when budgets are tight. Growing economies have the potential to lead where some high-income agencies have hesitated: by establishing explicit processes to evaluate whether long-funded interventions continue to represent good value (Falkowski et al., 2023). Reassessment also supports budget discipline and creates fiscal space for new priorities.

- **HTA functions as governance infrastructure.** Just as regulators oversee safety and quality, HTA provides the institutional process through which evidence is translated into decisions about what to fund, for whom, and under what conditions. Positioned at the intersection of health policy and public financial management, HTA clarifies how evidence informs coverage decisions, aligns choices with budgetary limits, and creates a documented rationale that can be scrutinised and revised.

1.4 Why the Economic Case Is Stronger in Growing Economies

The economic argument for HTA is often framed backwards. HTA is not a luxury for wealthy countries with fiscal space to optimize spending. It is most essential in resource-constrained settings where misallocation directly displaces essential services.

Opportunity cost determines whether an intervention improves overall health: resources used for one technology cannot be used elsewhere. The widely cited 1–3× GDP rule lacks empirical basis (Ochalek et al., 2018) and much empirical research has shown that to address opportunity costs, cost-effectiveness thresholds are below 0.5× GDP per capita in 51% of countries and below 1× GDP per capita in 97% of countries (Pichon-Riviere et al., 2023). This potential misjudgement of thresholds carries real consequences. Adopting interventions above the true opportunity-cost threshold reduces overall health, because the gains from the new intervention are offset by losses from displaced services (Ochalek et al., 2018). In growing economies, the margin for error is small, making systematic evaluation essential.



However a significant structural challenge is that the countries that would benefit most from systematic priority-setting often have the least institutional capacity to establish it (Babigumira et al., 2016). A landscape assessment across 19 low- and middle-income countries found no dedicated independent HTA bodies, and only informal HTA-like activities in eight (Babigumira et al., 2016). This capacity gap intensifies the need for pragmatic implementation approaches that build capability while delivering immediate decision value.

Why Technically Competent HTA Often Fails to Influence Decisions

HTA's impact depends not on technical quality alone, but also on whether its outputs connect to actual resource allocation decisions. Although established HTA units often produce methodologically sound assessments, these may be ignored, overridden, or implemented inconsistently, a pattern known as assessment-decision disconnect. This pattern of technically competent HTA with weak policy influence reflects structural problems.

2.1 The Assessment-decision disconnect

The assessment-decision disconnect appears when HTA sits outside the governance architecture that controls budgets and authorises spending, for example advisory HTA reports for high-cost technologies which ultimately have no formal link to benefit-package decisions, (Fasseeh et al., 2020), outputs developed through stakeholder consultation which have no clarity on how they integrate into the national pharmaceutical list or procurement decisions (Erku et al., 2025), and reports which policymakers may struggle to interpret or apply (Behzadifar et al., 2025).

Decentralised systems introduce additional forms of disconnect. In these cases authority tends to be retained by autonomous communities, with the result that regions may conduct their own assessments or diverge from national guidance (Pinilla-Dominguez & Pinilla-Dominguez, 2023) (Tarricone et al., 2021). However the issue is often not decentralisation itself but the absence of mechanisms - shared procurement, financial incentives, or explicit adoption protocols, that translate central HTA outputs into regional decisions.

Coordination failures compound these problems. Even in single payer systems, HTA bodies and financing authorities may operate with different evidence standards, timelines, and decision criteria (Jaksa et al., 2025). Misalignment also occurs between national HTA decisions and hospital level contracting (Pereira et al., 2021). When procurement, pricing, and coverage decisions sit in different institutions with weak coordination mechanisms, then recommendations become just one input among many rather than a structured basis for decision-making.

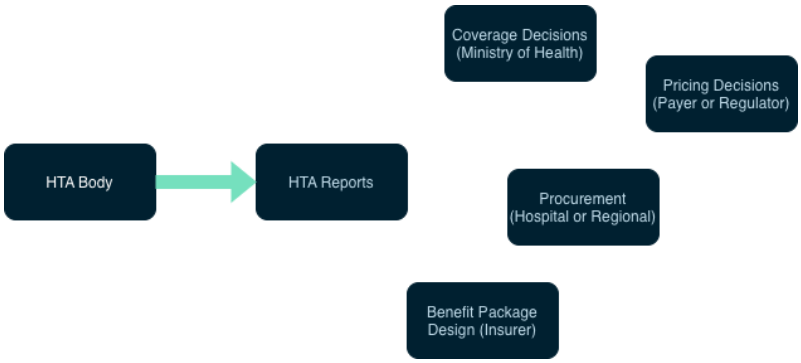
2.2 Stakeholder dynamics

Political and stakeholder dynamics further shape HTA influence. Recent decisions in the UK to raise NICE's cost-effectiveness threshold reflect not only methodological considerations but also trade and industrial policy pressures, as external negotiating priorities have been shown to influence technical threshold positions (Ruiz & Briggs, 2025; Blake Morgan, 2025). Systematic concentration of patient organisation funding has been found in areas aligned with life science commercial interests, underscoring potential areas of confusion in conflict-of-interest policies (Gentilini & Parvanova, 2023). There is also a lack of clarity about stakeholder engagement, as

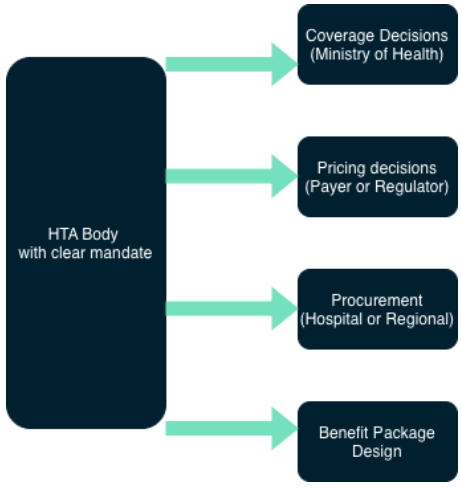
multi-stakeholder surveys of European processes reveal gaps between participation and perceived impact: patient groups, clinicians, and payers consistently rated their own influence lower than external observers did (Van Haesendonck et al., 2023).

2.3 Capacity Constraints

Challenges also exist in terms of capacity constraints, leading to mismatches between what bodies can realistically produce on the one hand, and what decision-makers need on the other. For example, in countries with limited data infrastructure, reports are likely to be based on international evidence and expert judgement, yet financing authorities may find this approach difficult to defend politically or indeed difficult to use in price negotiations. Similarly, growing economies with complex portfolios of gene therapies, immunotherapies, and digital health investments, will require technical skills which allow for modelling of uncertainties, as well as skills in the negotiation of managed-entry agreements. Methodological capability must match pipelines and fiscal pressures in order for HTA reports to remain relevant. This issue has been found in several cases where reports focussed narrowly on cost-effectiveness modelling, despite ministries needing rapid budget-impact assessments, service reconfiguration analyses, or disinvestment frameworks (Erku et al., 2025; Behzadifar et al., 2025; Mundy & Maddern, 2023).



Disconnected System



Aligned System

2.4 Procedural legitimacy gaps

Procedural legitimacy gaps also undermine influence. When processes appear opaque, criteria are inconsistent, or reasoning is undocumented, stakeholders will, understandably, question decisions (Jaksa et al,. 2025). The HTAi/ISPOR Special Task Force on guideline development emphasises that transparency, clearly defined criteria, and strong leadership are essential for accountability (Botwright et al., 2025).

Design Choices: Building HTA for the System You Have

HTA systems across Europe were designed in the 1990s and early 2000s for a specific type of pharmaceutical innovation. They require sequential assessment, complete evidence packages, and cost-effectiveness evaluation before reimbursement. They were built for daily medications with mature clinical data, not for transformative therapies delivered once with evolving evidence.

Financing arrangements are more heterogeneous, procurement is increasingly consolidated or donor-fragmented, treatments reach the market with unprecedented speed, and governance responsibilities are often distributed across multiple agencies. Rather than replicating the processes of established HTA bodies, countries strengthening their systems in 2025 face different design constraints from those that shaped HTA development in the 1990s, and should design within the current landscape.

Sustainable systems emerge when technical functions, governance arrangements, and decision pathways are aligned. Thailand's 15-year trajectory shows how semi-autonomous technical capacity becomes influential when embedded within established benefit-package processes (Teerawattananon et al., 2023; Tantivess et al., 2017). Brazil's legal framework illustrates how clarity about mandate and procedure creates predictable implementation (Wang et al., 2020). Conversely, countries with fragmented authority or unclear institutional linkages demonstrate how HTA can remain technically competent yet weakly connected to actual decisions (Tarricone et al., 2021) (Pinilla-Domínguez, 2023) (Erku et al., 2025) (Fasseeh et al., 2020).

3.1 Starting Point: Understanding System Architecture and Decision Pathways

Realistic HTA design begins with clear assessment of the system in which it will operate.

Financing architecture
How a system is financed determines who makes allocation decisions and how HTA evidence is used.

- Tax-funded, single-payer systems can often enable direct integration of HTA into benefit-package decisions and national procurement. Semi-autonomous agencies can allow for technical integrity while also remaining linked to ministries or health services for decision-making (Teerawattananon et al., 2023). In this case political visibility of decisions is high, meaning that transparent processes matter as much as methodological rigour.

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- Social health insurance systems with multiple funds, whether statutory insurers or mixed public-private arrangements, require coordination to avoid divergent implementation. Without coordination mechanisms, assessments may be adopted by some payers and ignored by others (Kim et al., 2021).
- Decentralised or regionalised systems where regional authorities control budgets may re-evaluate national guidance. These systems can introduce HTA nationally, but implementation requires explicit adoption pathways, incentives, or shared procurement arrangements. Without such mechanisms, HTA becomes a reference point rather than a binding input to decisions.

Decision authority mapping

Countries often underestimate how many institutions influence resource allocation. Both formal and informal mapping of decision-making authority is foundational to success. This includes:

- Who approves additions to benefit packages or essential lists?
- Who controls procurement budgets (central, regional, hospital-level)?
- Who sets pricing?
- Who authorises reassessment or disinvestment?
- Which decisions are politically sensitive versus technocratic?

3.2 Scope: Deciding What HTA Will Assess First

Scope decisions shape early workload, credibility, and political exposure and successful systems sequence scope deliberately.

- Most countries begin HTA with high-cost medicines because decisions are unavoidable and evidence is relatively organised (Teerawattananon et al., 2023; Wang et al., 2020).
- Evidence for devices, diagnostics, and procedures is more heterogeneous, requiring methodological flexibility and often stronger coordination between assessment bodies and implementing authorities (Tarricone et al., 2021).
- As benefit packages evolve and analytical capacity strengthens, HTA can extend to service configuration, preventive interventions, and population-level programmes. WHO guidance emphasises that this broader scope requires strong deliberative processes to incorporate social values, feasibility, and equity considerations (WHO, 2023).

3.3 Methodological Approach: Designing HTA Methods That Are Fit for Purpose

Traditional HTA processes - data-intensive, sequential, requiring complete information before decisions, are not designed for therapies launching with high initial uncertainty but transformative potential. These decisions require structured approaches to uncertainty, scenario modelling, affordability assessment, and, where relevant, capacity to support managed-entry agreements.

Similarly, regions with significant fiscal pressures do not require extensive modelling for novel treatments. The task is to select methods that are proportionate to the country's policy questions, fiscal pressures, and anticipated pipeline of technologies. Methodological choices should be shaped by what the system needs to decide, not by legacy expectations about what HTA "ought" to look like.

3.4 Evidence Standards and Data Infrastructure: Designing Evidence Pathways That Match System Needs

HTA systems do not begin with ideal data. They begin with the data a country already generates, the data it can realistically access from other regions, and the data that matter for the decisions it must make. The task is not to replicate the evidence environment of long-established HTA bodies, but to design an evidence architecture that is coherent, transparent, and feasible, and that can expand over time without compromising the credibility of early decisions.

Lack of data in resource poor regions is often cited as a fundamental obstacle which prevents the development of national HTA bodies. However enablers do exist and recent work on health systems strengthening in LMICs has shown that even modest investments in digital registries, electronic medical records, and surveillance systems can produce substantial gains in data completeness and quality, (Frost et al., 2021). These developments result in more robust HTA inputs over time, with the potential that establishing HTA evidence requirements can itself drive improvements in health information systems, provided that expectations are realistic and sequenced.

Implementation Framework: Developing HTA Culture and Institutions in Parallel

Countries do not have the luxury of sequencing HTA reform neatly. High-cost technologies continue to enter the market, budgets tighten, and benefit-package decisions cannot be paused while institutional arrangements are built. A pragmatic approach is to commence two streams of work simultaneously. One focuses on using HTA approaches in current decisions to establish culture, expectations and practical insight. The other focuses on designing institutional arrangements that give HTA a formal mandate, clear governance, and durability. These streams reinforce one another: analytical work reveals what institutions must deliver, while emerging governance structures stabilise and scale the use of evidence.

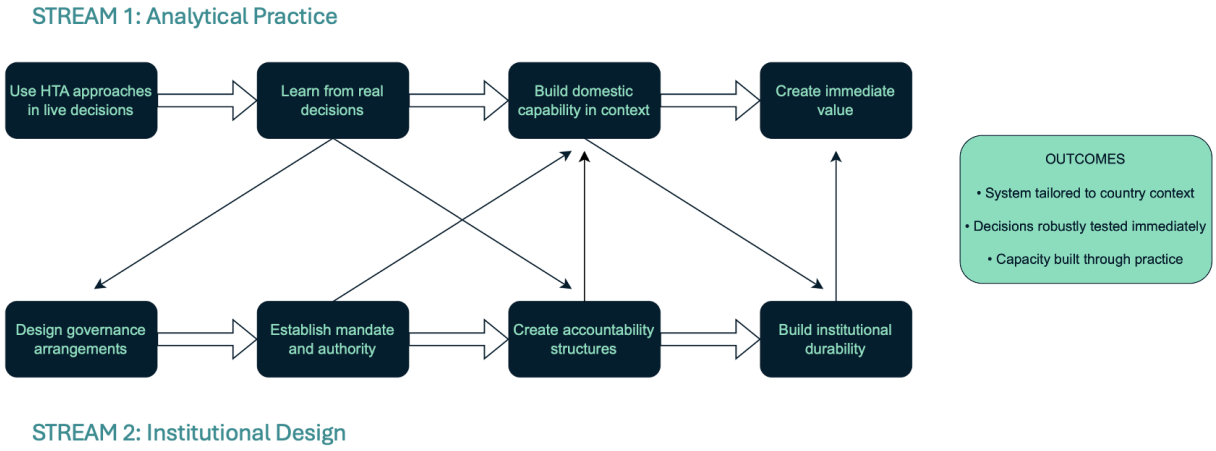
4.1 Stream One: Developing HTA Culture and Analytical Practice

This stream strengthens decision quality immediately, without waiting for formal legislation or agency creation. It uses HTA approaches pragmatically inside existing processes - formulary decisions, donor-funded programme reviews, high-cost procurement, insurance reimbursement, and creates the analytical backbone that eventual institutions will rely on.

Early analytical work should be anchored in real decisions already underway: additions to formularies, contract renewals, high-cost medicines approaching tender, or diagnostic technologies competing for provider budgets. Budget-impact analyses, structured comparisons of alternatives, and adaptation of international evidence are feasible even where routine data are limited. Engaging with real decisions, even in analytically constrained environments, rapidly clarifies what information is actually needed and which gaps matter most for decision quality (Erku et al., 2025; Behzadifar et al., 2025). Rather than relying purely on classroom-based training, domestic analysts gain capability by conducting real assessments - targeted economic evaluations, synthesis of comparative evidence, and structured expert elicitation (Tantivess et al., 2017).

These early assessments create immediate value for finance ministries, payers and procurement units. They also set expectations: decisions can be grounded in evidence, timelines can be predictable, and transparency is possible even before institutionalisation.

Furthermore this approach clarifies which outputs influence decisions, whether via short briefing notes for procurement officials, multi-year budget projections for finance ministries, or discussions around therapeutic uncertainty for reimbursement committees. This should become the evidence base for later guidance, by assessing what level of sophistication is useful, how to communicate uncertainty, and what decision formats are workable.



4.2 Stream Two: Institutionalisation and Governance Design (Running in Parallel)

In parallel with this early analytical work, countries must also design governance arrangements that give HTA a stable mandate, organisational home, and transparent procedures. The purpose is not to replicate established models from other countries but to embed the HTA function where it can most directly influence decisions and to protect it from the political cycles, stakeholder pressures, and fragmentation that otherwise erode its impact.

This requires addressing six governance fundamentals:

- defining vision and institutional boundaries;
- mapping stakeholder relationships;
- establishing lines of authority and accountability;
- building analytical capability matched to mandate;
- creating transparent decision processes;
- establishing mechanisms for reassessment and disinvestment.

Section 5 examines each of these governance requirements in detail, drawing on principles from public and corporate governance rather than HTA-specific templates.

4.3 How the Two Streams Reinforce Each Other

Running the analytical and institutional streams together avoids two common pitfalls: institutions that do not reflect real decision needs, and analytical work that has no authority to shape implementation.

- Analytical practice informs institutional design. Real assessments reveal where HTA must be located, what evidence standards are feasible, what timelines are workable, and what governance safeguards are essential.

- Emerging institutions stabilise analytical practice. Once mandates, procedures and reporting lines are established, the culture of using evidence becomes durable rather than dependent on individual champions.
- Parallel development builds credibility early. Decision-makers see practical value immediately, while the institutional framework is built with clarity about what works.

The outcome is an HTA system that should be both institutionally robust and tailored to the country's actual decision architecture and technology profile rather than copied from other jurisdictions.

Governance as the Basis for Sustainable Resource Allocation

Health Technology Assessment is routinely defined as a technical process that produces evidence for policymakers. In practice, it also performs a governance function: it structures how public resources are allocated, which claims are funded, and how discretionary spending is constrained. These are organisational and fiscal decisions, not merely analytical ones, and they require authority, accountability and predictable rules.

The common failure is to build HTA as an analytical unit without embedding it in the governance architecture that controls budgets and authorises spending. When this occurs, HTA produces technically competent outputs but has limited influence because decisions are taken elsewhere or under different incentives.

If we understand this as a governance mechanism as well as an analytical, technical service, then development should draw from best practice in public and state governance, as well as from the templates and practices of existing HTA agencies. This means designing mandate, authority, accountability, reporting, risk management and performance oversight in the same way that any institution with consequential spending powers would be designed.

This means applying established governance principles, clarity of purpose, alignment of decision rights, transparency, documented rationale, and procedural accountability, to the structure of assessing health resources.

5.1 Vision, Mission and Institutional Boundaries

Organizations with ambiguous mandates cannot be held accountable. Research on public sector organizations demonstrates that how managers define organizational purpose has measurable effects on performance (Weiss & Piderit, 1999). This means vision, mission, and values are not symbolic statements but governance foundations that determine how the organization functions and what it can be evaluated against.

Vision articulates what the health system should achieve: sustainable coverage of innovations, fiscally disciplined resource allocation, equitable access, or transparent decision-making that commands public trust. Mission defines the HTA body's specific contribution: which decisions it will inform (coverage, pricing, procurement), what evidence it will produce, and where its authority ends. Values establish operational principles - independence, transparency, timeliness, scientific rigour, that guide how trade-offs are resolved.

These choices have structural consequences. A mission focused on fiscal sustainability requires budget-impact modelling and opportunity-cost analysis. A vision emphasizing rapid access to innovation demands methods designed for speed. Values prioritizing equity require distributional analysis and subgroup modelling. Without explicit direction, staff resolve these tensions inconsistently, stakeholders develop conflicting expectations, and no party can assess whether the organisation is performing its intended role.

Explicit purpose also creates boundaries. An HTA body cannot simultaneously assess all technologies, develop clinical guidelines, regulate safety, and design provider payment systems. Clarity about remit prevents workload expansion without corresponding resources or authority. It also establishes accountability: an HTA body created to support benefit-package decisions can be evaluated on whether it produces timely, methodologically sound assessments that inform those decisions. Without explicit purpose, performance cannot be measured.

5.2 Stakeholder Mapping and Decision Authority

Stakeholders with legitimate interests in the work of these bodies will ultimately determine whether or not recommendations translate into practice. This will occur regardless of institutional placement of the agency, whether embedded in ministries, semi-autonomous, or formally independent. An important governance task is mapping these relationships explicitly so that accountability, decision authority, and the HTA body's role are clearly understood.

This mapping exercise is a senior leadership responsibility. It requires identifying who the HTA body is accountable to, which decisions it informs versus participates in directly, and what different stakeholders legitimately need from the organization. This clarity shapes reporting lines, determines required outputs, and defines how the HTA body engages with ministries, payers, procurement authorities, clinical committees, and other actors in the decision architecture.

- Decision owners hold formal authority over coverage, pricing, or procurement. Clarity about who they are determines where HTA outputs must flow and in what format.
- Decision shapers influence allocation without final authority (clinical advisory committees, finance ministries, insurance actuaries, regulatory bodies). Understanding their role clarifies where the HTA body must engage early and what evidence they require.
- Decision implementers operationalize coverage or procurement decisions: hospital networks, regional authorities, procurement units. Mapping these actors reveals whether HTA recommendations can be acted upon or whether implementation barriers exist that HTA design must address.
- Legitimacy stakeholders shape decisions' acceptability without controlling them directly: courts, patient organizations, professional associations, external donors. Understanding their influence clarifies where transparency, documentation, and stakeholder consultation become governance requirements rather than optional practices.

Explicit stakeholder mapping means that concerns regarding institutional placement can be minimised. Whether an HTA body sits inside a ministry or functions as an independent agency matters less than whether it has clearly defined interfaces with decision owners, transparent accountability mechanisms, and structured engagement with actors whose participation determines whether recommendations are implemented.

5.3 Authority and Accountability in Decision-Making

HTA recommendations carry different levels of authority depending on governance arrangements. Recommendations may be binding, advisory, or operate under presumption of adoption unless formally overridden. The choice reflects both constitutional and administrative priorities. Institutional arrangements must specify decision rights, override procedures, and documentation requirements.

Overrides are not governance failures. They are often legitimate when considerations outside HTA's technical remit, such as equity, political feasibility, and implementation capacity, warrant deviation. What matters is not that these occur, but that overrides are documented and justified.

Accountability requires defined reporting lines. Even when HTA bodies are positioned as independent, they remain accountable to some authority: a governing board, a ministry, a statutory oversight body. Independence does not mean absence of accountability; it means protection from inappropriate influence while maintaining responsibility for performance. Governance arrangements must specify to whom the HTA body reports, through what mechanisms (annual reporting, performance review, budget scrutiny), and for what deliverables (assessments completed, timeliness, quality standards, adoption rates).

Effective governance also requires protecting institutions from short-term political and fiscal volatility. Countries establish legally independent regulators and statutory mandates specifically to signal commitment to long-term goals beyond political cycles (OECD, 2021). For HTA bodies, this means stable funding that is not project-dependent, legal or statutory mandates that survive changes in government, and workforce structures that retain analytical capacity. Systems that have lost momentum when pilot funding ended, or political champions departed, demonstrate that authority without institutional durability produces episodic rather than sustained influence (Kim et al., 2021; Mundy & Maddern, 2023).

5.4 Analytical Capability Matched to Mandate

HTA depends on technical capacity including evidence synthesis and economic evaluation. Analytical capability must match the decisions the organization exists to inform. Countries with a need for gene therapies and advanced oncology must have the skillset to assess complex medications with high degrees of uncertainty, as well as capabilities to support managed-entry agreements. Countries and health systems addressing diagnostics, chronic disease, or service delivery need rapid comparative assessment and budget-impact analysis.

Governance failure occurs when existing staff skills, rather than health system needs, influence methodological approaches. The result is likely to be technically competent analyses that do not address decision-makers' questions. Senior leadership must define analytical functions based on what the HTA body exists to inform, then build capability through targeted recruitment, skills development, or external partnerships.

5.5 Transparent Processes and Explicit Criteria

Best practice in public sector decision-making requires that decisions be made on an objective, impartial and consistent basis, supported by clear procedures that promote transparency and accountability (OECD, 2012; OECD, 2021). When decision criteria are implicit or reasoning is undocumented, recommendations appear arbitrary regardless of technical quality. This undermines confidence and makes it difficult to assess whether an agency is functioning consistently with its mandate.

Agencies should establish explicit criteria that guide deliberation - clinical benefit, cost-effectiveness, equity, budget impact, feasibility, social value, and structured processes that make clear how these criteria are weighed when they conflict.

Furthermore, documentation of processes must be prioritised, as recording of assumptions and uncertainties underlying recommendations enables internal quality control, supports reassessment when new evidence emerges, and provides defensible rationale when decisions are contested.

Even in cases where stakeholders disagree with recommendations, they are more likely to accept them when the process is transparent, criteria are explicit, and reasoning is traceable. Without this, HTA bodies function as technical advisors whose influence depends on persuasion rather than as governance institutions whose authority rests on procedural legitimacy.

5.6 Reassessment and Disinvestment as Routine Stewardship

Failure to revisit legacy medicines and technologies will result in the accumulation of spending on interventions that no longer represent value. Routine portfolio review is standard practice in corporate governance and should be mirrored in public sector governance. Successful companies systematically assess whether business units continue to fit strategy and contribute to shareholder value, divesting those that do not, and, similarly, public sector governance operates on parallel principles: investments should be grounded in value for money, and continued expenditure requires demonstration that value persists (OECD, 2012).

From a governance perspective, reassessment for potential renegotiation or divestment creates organisational discipline and demonstrates stewardship of public resources rather than passive acceptance of spending patterns. It reinforces credibility with finance authorities and payers by signalling responsiveness to fiscal constraints and willingness to identify low-value expenditure.Furthermore it provides transparency that protects allocation decisions from legal or political challenge, as demonstrated in systems where documented reassessment processes have strengthened judicial defensibility (Wang et al., 2020).

Reassessment also signals that HTA exists to optimise resource use, not to block access to innovation. Systems that reallocate spending from low-value legacy technologies create fiscal space for high-cost innovations without budget expansion, positioning HTA as an enabler of access to new therapies rather than an obstacle to adoption.

Conclusion

Health technology assessment in growing economies is not merely a technical challenge, nor an institutional puzzle solved by copying established models. It is fundamentally an economic and governance challenge: how to allocate scarce resources systematically when opportunity costs are high, fiscal margins are narrow, and the consequences of misallocation directly displace essential services.
The economic case for HTA is strongest precisely where institutional capacity is weakest. Countries spending between USD $17 - $47 per capita on health cannot afford the luxury of implicit priority-setting. Empirical evidence shows that cost-effectiveness thresholds consistent with actual opportunity costs fall well below conventional benchmarks in most countries, meaning that technical competence in economic evaluation is not optional, it determines whether resource allocation improves or worsens overall population health.

Yet technical competence alone does not translate into influence. HTA fails when it sits outside the governance architecture controlling budgets and procurement, producing methodologically sound assessments that are then ignored or overridden. This disconnect persists not because of analytical failures, but because HTA bodies are designed as technical units rather than as governance institutions with authority, accountability, and procedural legitimacy.

The solution requires simultaneous work on two fronts. The first stream - 'analytical practice in live decisions', builds capability in context, clarifies what decision-makers actually need, and creates immediate value without waiting for formal infrastructure. The second stream - 'institutional design', applies governance principles from corporate and public sector practice to create mandate clarity, stakeholder accountability, transparent processes, and protection from political volatility. These streams reinforce one another: analytical work reveals what institutions must deliver, while governance structures make evidence use durable rather than champion-dependent.
This approach demands expertise that spans health economics, public policy, and institutional governance. It requires understanding both opportunity-cost principles and the political economy of resource allocation, how to structure managed-entry agreements for gene therapies and how to design disinvestment processes that withstand judicial review, as well as recognising that vision statements, stakeholder mapping, and deliberative architecture are not administrative formalities but governance foundations that determine whether HTA influences actual spending decisions.

Growing economies have the opportunity to establish HTA systems designed for 2025 realities rather than 1990s templates, systems tailored to their decision architecture, matched to their technology pipelines, and built on governance principles that create institutional durability. Success is measured not by whether an HTA body exists, but by whether it enables access to high-value innovations, creates fiscal space through systematic reassessment, and provides transparent rationale for allocation decisions that command confidence from finance ministries, payers, and the public.

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