International Journal of Technology Assessment in Health Care

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Assessment

Cite this article: Botwright S, Sittimart M, Chavarina KK, Merlin T, Suharlim C, Surgey G, Culyer AJ, Oortwijn W, Teerawattananon Y (2026). What makes health technology assessment guidelines effective in changing decision-making practice? A comparative analysis. *International Journal of Technology Assessment in Health Care*, **42**(1), e99, 1–11
https://doi.org/10.1017/S0266462326104218

Received: 24 March 2026 UTC
Revised: 31 July 2026 UTC
Accepted: 30 August 2026 UTC

Keywords:
health technology assessment; guidelines; decision-making practice; qualitative; comparative analysis

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What makes health technology assessment guidelines effective in changing decision-making practice? A comparative analysis

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Abstract

Objectives: Health Technology Assessment (HTA) agencies often lay out the methods and processes for recommendations through guidelines. However, evidence suggests that the presence of guidelines does not necessarily lead to more systematic, evidence-based decisions. This article explores the differentiating features of HTA guidelines that have successfully promoted change in decision-making practice.

Methods: We compared the development and impact of HTA guidelines over time in eight countries through a multi-case study design. Data from interviews and literature review were analyzed qualitatively by pattern matching.

Results: In settings without a guideline owner, guidelines were most successful if the development process targeted key stakeholders who are able to influence change in an open process of joint learning, and an agency with relevant expertise was assigned to oversee future guideline implementation and revisions. In settings with a clear guideline owner, guidelines were most successful if stakeholders continued to be engaged after guideline publication, to incorporate interim updates and when there was continuous learning between stakeholders and the HTA agency. Enforcing guideline compliance through laws was not found to be a predictor of guideline success nor was the level of HTA institutionalization in a country.

Conclusions: At any stage of HTA institutionalization, HTA guideline success depends on whether the development and revision process successfully builds shared understanding and trust among stakeholders. Ensuring HTA guideline impact requires an open and inclusive approach to stakeholder engagement during and after guideline development, as well as effective accountability mechanisms for guideline ownership.

Introduction

Formalizing how universal health coverage (UHC) priorities are set through written rules can enhance consistency and fairness of decisions and improve accountability in decision making and implementation (1–3). Health technology assessment (HTA) guidelines are written documents that set out one or more components of the methods, process, or broader governance for how decisions are made (4). HTA guidelines are often used as an indicator of progression toward institutionalized systematic, evidence-informed priority-setting (5–8) on the basis that they promote transparency (8–10) and create an enabling environment for the use of evidence in decision making (11–13).

Despite this, there is evidence that the presence of guidelines does not necessarily translate into a change in decision-making practices (14–16). HTA guidelines can overemphasize administrative procedures (17), be challenging to implement in fragmented decision-making systems (9), and/or focus on the technical aspects of evaluation without accounting for context-specific processes (18). A cross-country comparison of health priority-setting in Asia, for example, showed that the mere presence of guidelines did not predict systematic and evidence-based decision making (6).

Many studies have evaluated guideline quality or compliance (19–24). However, current research has not addressed the features that distinguish HTA guidelines that successfully change decision-making practice from those that do not. Identifying these features is important to ensure that HTA guidelines achieve their intended impact.

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To address this gap, we conducted a comparative multi-case study to identify the differentiating features of HTA guidelines that have successfully changed decision-making practice across diverse health systems in eight countries. The overarching goal was to understand how HTA guideline development teams can ensure that the guidelines contribute to more systematic, evidence-informed priority-setting.

Methods

Study design and sample selection

We adopted a qualitative comparative case study design to develop transferable findings while accounting for different country contexts over time (25). We included 24 publicly available guidelines from eight countries across different regions and income levels into the following three categories, based on their status in 2022, which was chosen as the year of data collection (see Supplementary Table S1):

(1) those that had completed at least one revision of their HTA guidelines (Brazil, Canada, Indonesia, and the Netherlands),
(2) those that had developed and implemented a single version of HTA guidelines (The Philippines and Tunisia), and
(3) those that went through the process of developing guidelines but for which a version of the HTA guidelines had not yet been officially launched (South Africa and Vietnam).

We used the term "HTA guidelines" to refer to laws, regulations, manuals, or operating procedures that define one or more elements of how evidence and decisions are (or should be) made. For each guideline, we classified the stage of HTA institutionalization in the country at the time of guideline development (Table 1), since in many settings HTA institutionalization has increased over time.

Data collection

We used two data sources: semi-structured interviews to understand stakeholder perceptions of guideline development and implementation, supplemented by published literature and policy documents to provide historical information with less recall bias or retrospective sense making (25). We sought diverse perspectives by interviewing different types of stakeholder and identifying literature written by different stakeholder groups, where possible (e.g., HTA agency, international researchers, local academia) (67). The search was conducted in 2022–2023 and included documents in any language. To ensure accurate data interpretation, bilingual researchers or interviewees reviewed findings for documents published in languages other than English.

We interviewed guideline developers (authors or focal points coordinating/overseeing the guideline development process) and guideline users (researchers and personnel overseeing the policy process). We identified interviewees through consultation with relevant networks (HTAsiaLink, ISPOR, and HTAi). We invited twenty-five potential interviewees, of which twenty agreed to participate in the study. Supplementary Table S2 shows the profile of interviewees.

Interviews were conducted between 01 December 2022 and 07 February 2023, using a semi-structured interview guide (Supplementary Information 1). Formal consent was collected in writing and verbally from all interviewees. Each interview was conducted online in English for approximately 60 min, via Zoom or in person, and recorded. Member checking was conducted, and repeated analysis was conducted in case of disagreement (Supplementary Table S4). Further details of the data collection process are provided in Supplementary Information 2.

Analysis

A research team (SB, MS, and KKC) applied content analysis and pattern matching to iteratively review the data to develop, test, and refine hypotheses, while an external advisory group (YT, AC, WO, TM, GS, and CS) periodically reviewed findings to assess whether emerging hypotheses were logical and were supported by the evidence, as well as to propose alternative hypotheses to investigate further.

We conducted two steps of analysis: (i) a within-country analysis to understand the process for developing and revising guidelines, the broader HTA context, and guideline impact and (ii) cross-country analysis to systematically compare similarities and differences in terms of how success of the guideline was defined and measured and factors influencing whether the guideline was successful according to these measures. Success was evaluated qualitatively according to the principles described in Table 2, through discussion and agreement across the research team. The resulting hypotheses were tested against three additional cases (Colombia, India, and New Zealand; 1–2 interviewees per country) to evaluate generalizability and whether theoretical data saturation had been reached. We shared findings (including success ratings) with interviewees to ensure validity of findings. In case of disagreement, the research team reviewed the data again and, if relevant, revised the analysis. Full details of the analysis are provided in Supplementary Information 2 and a list of changes following interviewee validation can be found in Supplementary Table S3.

Ethics

The study was approved by the Institute for the Development of Human Research Protection (COA No. IHRP2022115), Health Research System Institute (IHRP no. 106–2565). All data were managed in accordance with Thailand's Personal Data Protection Act B.E. 2562 (2019). All transcripts and audio files were de-identified and stored on HITAP secure servers for 5 years.

Results

Indicators to measure HTA guideline success

From our analysis, we defined and measured the success of guidelines by three components: (i) whether the stated objectives in the guidelines were achieved; (ii) the extent to which the guidelines advanced the institutionalization of systematic, evidence-informed decision making; and (iii) compliance with the guidelines (Supplementary Table S4). We evaluated each guideline according to these criteria (Supplementary Tables S5 and S6) to distil factors influencing guideline success.

Factors influencing HTA guidelines success

Factors influencing the success of HTA guidelines differed between two contexts: (i) guidelines developed by stakeholders with some level of constraint on their ability to influence decision making (e.g., institutions without a direct link to the decision-making process) and (ii) guidelines developed by an agency with a mandate to develop and implement guidelines. In the following sections, we discuss the success factors for each. Findings are summarized in Figure 1.

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Table 1. Classification of the stages of HTA institutionalization and guidelines included in the analysis

Classification	Definition		Guidelines included in the analysis
Guidelines developed at a time when policies were not yet made through a systematic process	HTA is not recommended or required for national benefit package policy by formal mechanisms, such as law, government circular, or operating procedures for the policy body responsible for benefit package decisions.	(1) HTA guidelines were developed in the absence of an agency tasked with supporting the generation and use of evidence for benefit package decisions.	• 1991 Dunning Report on choices in health (the Netherlands) (26). • 2013 pharmacoeconomic guidelines (Indonesia) (27).
		(2) HTA guidelines were developed by an HTA agency without a formalized link to benefit package decisions.	• 2014–2018 (unreleased) HTA methods and process guidelines (Vietnam) (28;29).
		(3) The guidelines proposed significant changes to how HTA-informed benefit package decisions are made.	• 1994 pharmacoeconomics guidelines (Canada) (30). • 2022 Health Technology Assessment Methods Guide 2022–2027 (South Africa) (31).
Guidelines developed at a time when a systematic process for policymaking has been developed but is implemented on an ad hoc basis	There is inconsistent or limited use of HTA to inform benefit package policies, despite a formal mechanism to encourage the use of HTA for benefit package policy.	(4) There is a legal requirement for HTA to inform benefit package policy but limited conduct and use of HTA studies for policy.	• 2017 HTA guidelines (Indonesia) (32): use of HTA for benefit package decisions was mandated by the 2013 Presidential decree (6;33). • 2023 HTA guidelines (Indonesia) (34): use of HTA for benefit package decisions was mandated by the 2018 Presidential decree (35;36).
		(5) Government circulars and regulations have required the use of HTA for defined periods of time but there is no constant implementation of HTA.	• 2022 practical guide to health technology assessment in Vietnam (28;37;38).
		(6) Benefit package policy makers have formally endorsed principles for use of HTA in decision making but there is inconsistent implementation.	• 1997 guidelines for the economic evaluation of pharmaceuticals (Canada) (39): not all provinces had adopted economic evaluation for drug package policies (40).
		(7) The policy maker was in the process of formalizing the use of HTA in decision making at the time of HTA guideline development, but no formal mechanism was yet in place.	• 2009 National Policy on Health Technology Management (PNGTS) and accompanying 2009 methodological guidelines for HTA appraisals in Brazil (41–43). • 1999 pharmacoeconomic guidelines in the Netherlands (44–46). • 2021–2022 methodological guides for HTA (Tunisia) (47,48) (the public payer had endorsed the prior guidelines for dossier submission "Guide de soumission des données cliniques et générales en vue d'une évaluation *HTA*" and studies were being undertaken on behalf of the payer (49;50).
Guidelines developed at a time when a systematic process has been adopted as the basis for decision making	There is a high level of commitment to HTA among decision-makers, which has translated into the adoption of HTA (both formally and in practice) as a mechanism by which benefit package policies are informed.	(1) HTA guidelines developed following a legal requirement for benefit package decisions to be informed by HTA.	• 2020 Philippine HTA methods guide and HTA process guide, preceded by 2019 UHC Act (51–53). (Note: legal requirement for public health programs and benefit package decisions to be informed by HTA) • Law 12401/11 passed in Brazil in 2011 and subsequent HTA guidelines (43;54–56).
		(2) HTA guidelines developed by a body mandated to advise the government on benefit package decisions.	• 2006 revised guidelines for pharmaco-economic research and 2006 package management in practice guide (the Netherlands): developed following the 2006 Health Insurance Act, in which CVZ (now ZIN) assumed a legal responsibility to advise ministers on the benefit package (57–59).

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Table 1. (*Continued*)

Classification	Definition		Guidelines included in the analysis
			• 2003 procedures for the Common Drug Review and 2006 guidelines for the economic evaluation of health technologies (Canada): developed following an inter-governmental agreement in 2003, which required all new drugs to be assessed at the federal level through the Common Drug Review (CDR) process before provincial decisions (60–62).
Guidelines developed in settings with a long history of implementing a systematic process for decision making	HTA has consistently informed benefit package policy for more than 10 years.	N/A	• 2017 economic evaluation guidelines in Canada (4th edition) (63). • 2020 procedures for CADTH reimbursement in Canada (64). • 2016 and 2024 revisions of the health economic evaluation guidelines in the Netherlands (65;66).

Table 2. Criteria to measure the success of the included guidelines. Full definitions of success are provided in Supplementary Table S4 and supporting evidence to measure the success of each guideline is provided in Supplementary Table S5

Indicator of success	Rating principles
Objectives	If the objectives in the guidelines were met, they were scored as moderate. If the objectives were exceeded, the guidelines were rated up, and if the objectives were not met, the guidelines were rated down.
Institutionalization	For moderately successful guidelines, there was evidence that the principles of HTA and the guidelines were adopted in decision making within around 5 years. Guidelines were rated down if either decision making did not become more systematic or there is evidence to suggest that the guidelines did not play a big role in systematizing decision making. Guidelines were rated up if there was evidence that guideline development influenced systematic decision making in more than one decision-making process and/or garnered the support across a wide range of stakeholders.
Compliance	Guidelines that were mostly followed in the target policy pathway were rated as moderate, those with evidence of broader implementation in other policy processes and/or higher adherence were rated up, and those with limited implementation and/or lower adherence were rated down.
Overall success	All three success factors were taken into account, with more weight given to higher quality evidence (e.g., evidence with consistency across multiple evidence sources and/or indicators, an appropriate timeframe for data collection, direct applicability to the guidelines).

Context 1: Guideline developers had limited ability to influence decision making

One of the main barriers to guideline success in our analysis, especially in settings without systematic decision making, was the limited ability of the guideline developers to influence change. In certain cases, this was because guidelines were initiated by stakeholders that did not have a mandate to oversee and set standards for decision making, but it was also due to unclear or overlapping mandates, such as lack of clarity between the benefit package committee and the national formulary, or federal standard-setting with autonomy of provincial-level processes (Supplementary Table S7).

In these settings, successful guidelines strategically engaged stakeholders who could facilitate or block guideline implementation and engaged in an open dialogue to come to a shared understanding, through a series of consultations throughout guideline development. Importantly, these consultations did not impose how the HTA system should work, but instead actively shaped guideline content with stakeholder input. We refer to this as "joint learning." Secondly, guideline developers ensured that, at the end of the guideline development process, key decision makers appointed an agency with the relevant expertise, capacity, and independence from the decision maker to oversee guideline implementation and future revisions (Table 3).

These features are illustrated by the 1994 pharmacoeconomics guidelines in Canada. Although the Pharmaceutical Manufacturers Association of Canada (PMAC) did not have the authority to impose use of HTA guidelines, they established government ownership by convening a workshop to identify consensus areas and co-leading guideline development with the recently established Canadian Coordinating Office for HTA (CCOHTA, later to become CADTH then CDA) (69). As a result of this collaborative process, the federal and provincial ministries of health endorsed the guidelines within a year and officially requested CCOHTA to lead implementation and revisions of the guidelines (70–80). Assigning CCOHTA as the guideline owner meant that CCOHTA could work with researchers to improve compliance (70) and ensured that the guidelines were updated with experience to better meet user needs (71;81). This process arguably strengthened CCOHTA's position as a normative body, enabling the establishment of the Canadian Drug Review process and pan-Canadian HTA strategy in 2003 (82).

By contrast, the unreleased HTA methods and process guides developed from 2014 to 2018 in Vietnam did not show features of local leadership and open collaboration. Throughout guideline development, stakeholder consultation meetings were held, but these focused on guideline content as opposed to two-way dialogue to come to a shared understanding and were supported by international partners who had proposed cuts to the benefit package and, therefore, were unpopular with influential stakeholders (28;29;77;83).

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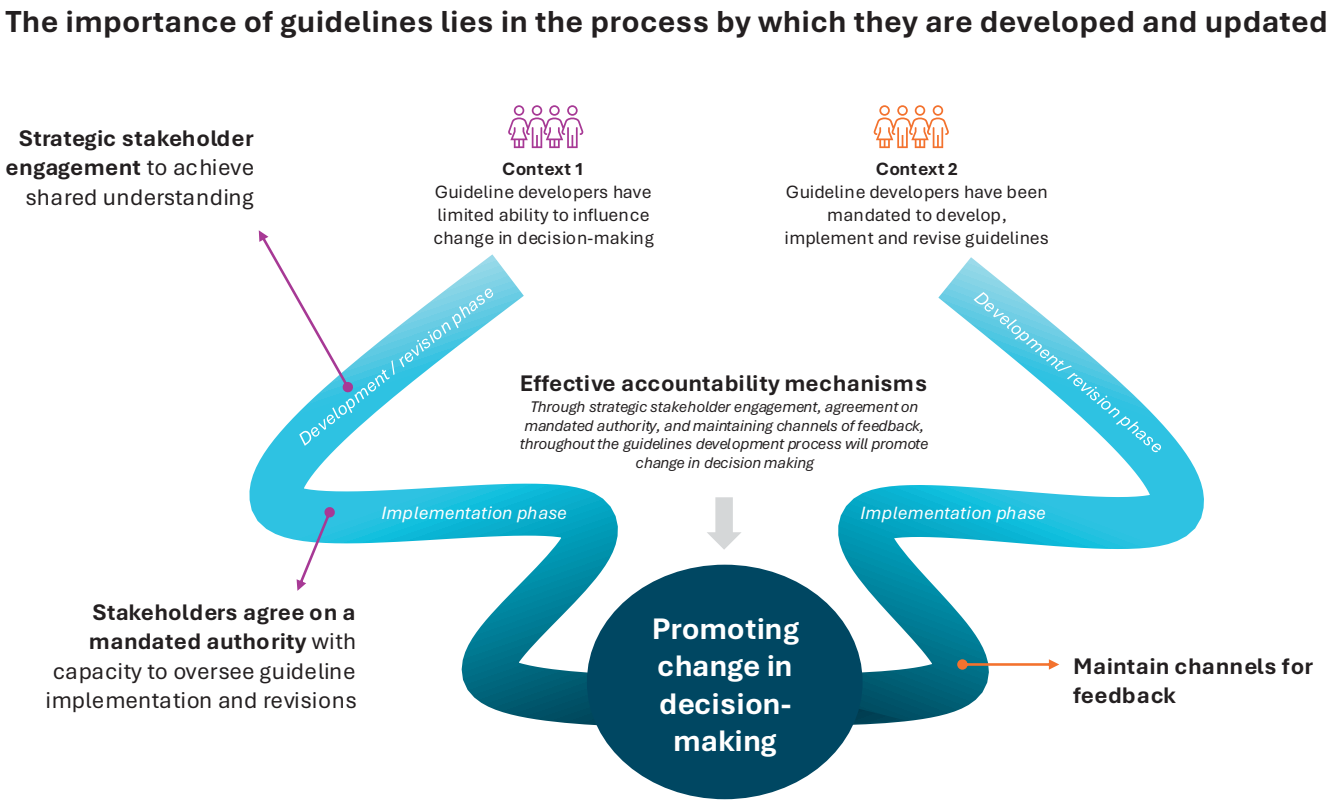


Figure 1. Summary of factors influencing the success of guidelines from the analysis.

Despite support from the Vice Health Minister (29), support for HTA among policy makers remained low. As a result, the lead guideline developer in Vietnam could not justify dedicating staff time and resources for guideline completion.

> **VN001:** Human resources were primarily prioritized for other missions, rather than [guidelines] … if there's a strong demand from the government, the official requirement from the MOH or from policymakers, it's going to be strong motivation to push this work [to] move forward better.

Context 2: Guideline developers have a mandate to develop and implement guidelines

If the guideline developer had a mandate to develop and implement guidelines, continued stakeholder dialogue and revisions after publication were important for advancing HTA institutionalization (Table 4). Contrary to the targeted approach to stakeholder engagement in context 1, opportunity for dialogue and input across all stakeholder groups (including professional societies, patient groups, local government, and the public) was important in context 2. This finding was consistent across process and methods guidelines, as well as across mandatory and recommendatory guidelines. Conversely, adherence to methods guidelines in research studies was most closely related to the levels of HTA institutionalization and maturity of HTA research networks at the time of guideline development, not to the level of stakeholder engagement (Supplementary Table S10).

In Brazil, using HTA methods guideline development as a platform for ongoing dialogue with stakeholders has successfully supported progressive HTA institutionalization. DGITS, a department within the Ministry of Health (MOH) plays a central coordinating role between the benefit package advisory body (CONITEC), the decision maker for incorporation of technologies (MOH), and the network of HTA researchers and practitioners (REBRATS) (84;54). This coordination role has allowed DGITS to successfully cultivate a system for HTA in the country, coordinating across policy makers, HTA producers at national, state, municipal, and hospital levels, and HTA researchers conducting studies and advancing HTA methods.

> **BZ001:** We are very close to the HTA network, and we are the executive secretariat and responsible ones for the methodological guideline, so it makes things way easier. You know the fact that we hold events, we hire for the HTA network, we hire the courses for educating them on the most recent methods, and etc. So, we have an agenda power on this, and it's easier to disseminate this knowledge and to guarantee that the guidelines are being used. We are so directly connected to them, so fostering the HTA network of experts closely is very helpful.

The Brazilian methods guides have been successful not only in increasing the number and quality of HTA studies in the country but also in improving the quality of evidence used for policy making.

The third edition of the Canadian guidelines for the economic evaluation of health technologies, however, was drafted exclusively by Canadian health economists, with external peer review. The revision was undertaken after CCOHTA obtained a substantial increase in funding and support, and therefore expanded the guidelines to non-drug technologies. Although the updated guidelines were associated with an increase in published economic evaluations of vaccines between 2010 and 2015, there is limited

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Table 3. Level of joint learning and profile of the body mandated to oversee guideline implementation, in settings where the guideline developer had a significant constraint on their ability to influence change (further details in Supplementary Tables S7 and S8)

HTA guideline	Overall success	Joint learning	Guideline owner with mandate and capacity to fulfill role	Brief narrative: institutional arrangements before and after guideline development
Canada: Procedures for the Common Drug Review (2003)	Very high	High	Yes	At the time of guideline development, an inter-agency agreement had defined the role of the Canadian Coordinating Office for Health Technology Assessment (CCOHTA) relative to federal- and provincial-level decision-making bodies, but tension remained between provincial autonomy and national standardization (60). CCOHTA invited members of provincial drug plan committees to design the Common Drug Review procedures, based on existing provincial processes (60). Although the Common Drug Review remained non-binding, the Common Drug Review has been very successful and principles for decision making set out in the procedures have been adopted into provincial processes (60;68).
Canada: 1st edition pharmacoeconomic guidelines (1994)	High	High	Yes (assigned during process)	Guideline development was initiated by the Pharmaceutical Association of Canada (PMAC), which had limited ability to influence drug listing processes (30). PMAC led an extensive stakeholder consultation process that focused on common areas of understanding and agreement (69). As part of this process, PMAC co-opted the federal HTA agency (CCOHTA) onto the guideline Steering Committee (69), as an independent agency that had the competence to oversee the quality of commissioned studies (70). The process was not only successful in achieving endorsement by provincial and federal Ministries of Health (69) but also resulted in federal and provincial governments assigning CCOHTA responsibility for implementing and updating the guidelines (70;71).
Brazil: Law N° 12.401 (2011)	Moderate	Medium	Yes, but may be perceived conflict of interest in accountability mechanisms	The draft bill for Law 12.401 was based on principles that had been agreed through wide stakeholder consultation and endorsed across all levels of the health system (41;56), but separate processes were being led by the Supreme Federal Court and National Council of Justice (72). There was limited engagement between the two processes, resulting in contradictory rulings and continued high litigation against the Ministry of Health for patient access to pharmaceuticals, which Law 12.401 had sought to reduce (72,73). The law designated authority for implementation to a department under the Ministry of Health (DGITS) and CONITEC as the advisory committee for health technology inclusion under the national health system (SUS) (56). However, over 50% of CONITEC members were Ministry of Health representatives (74), which appears to have led to poorer adherence to mandatory criteria and public consultations for Ministry of Health-nominated topics (75,76). For instance, a study of CONITEC recommendations made between 2012 and 2018 found that all recommendations made without mandatory public consultation were nominated by the public sector, with 66/70 topics nominated by the Ministry of Health (75).
Vietnam: HTA methods guide and HTA process guide (2014–2018, not published)	Very low	Low	No	Guideline development was initiated by international development partners in collaboration with the Health Strategy and Policy Institute (HSPI) (29), who had limited ability to change the benefit package policy process (28). Although stakeholder consultations were held throughout guideline development, they focused to a large extent on capacity building and feedback on guideline content, as opposed to coming to a shared vision and understanding across stakeholders (29;77). At the time, HSPI had limited capacity to dedicate to guideline development and limited authority to influence the decision-making process (28). As a result, guideline development stopped when international support was withdrawn (28).
Indonesia: Pharmacoeconomic guidelines (2013)	Very low	Low	No	Guideline development was led by the pharmaceutical directorate of the Ministry of Health, in parallel to the development of the decree on benefit package policy (27,78). Subject matter experts were involved on the committee for guideline development, but there was limited stakeholder engagement, and no authority was mandated to oversee guideline development and

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Table 3. (*Continued*)

HTA guideline	Overall success	Joint learning	Guideline owner with mandate and capacity to fulfill role	Brief narrative: institutional arrangements before and after guideline development
				implementation (27). Although guidelines may have influenced national formulary decisions, there is little evidence of guideline compliance (21).
Indonesia: 1st edition HTA guidelines (2017)	Very low	Very low	Partial (mandated owner, may have limited capacity for oversight)	The guideline owner (InaHTAC) had been mandated to make benefit package recommendations (79). However, the National Formulary still had a separate process for decision making that was not aligned with InaHTAC (78). Aside from peer review by international experts close to the time of guideline release, no stakeholder engagement is mentioned in the guidelines (32). Lack of clarity around the role of the National Formulary and InaHTAC remained and the guidelines have seen limited uptake and adherence (21), potentially due to the limited capacity of InaHTAC to oversee their implementation.

Table 4. Mechanisms for ongoing stakeholder dialogue following guideline publication in settings with a mandated authority to oversee guideline implementation (further details in Supplementary Table S9)

HTA guideline	Level of HTA at the time of guideline development (see Table 1)	Success in supporting HTA institutionalization	Ongoing dialogue after guideline release	Mandatory/ recommendatory
Canada: Procedures for the Common Drug Review (2003)	High	Very high	Yes (formal channels)	Mandatory
Brazil: National Policy on Health Technology Management (PNGTS) (2010)	Medium	High	Yes (piloting)	Mandatory
Canada: Guidelines for the economic evaluation of health technologies, 4th edition (2017)	Advanced	High	Yes (formal channels)	Recommendatory
Canada: Procedures for CADTH Reimbursement Reviews (2020)	Advanced	High	Yes (formal channels)	Mandatory
The Netherlands: Guidelines for health economic evaluations, 3rd version (2016)	Advanced	High	Partial (help desk for questions)	Mandatory
Netherlands: Report of the Commission Choices in Health Care (1991)	Low	Moderate	Yes (informal channels)	Not implemented
Brazil: Methodological guidelines available on the CONITEC website published from 2011 to 2021	High	Moderate	Yes (informal channels)	Mandatory
The Philippines: Philippine HTA process guide (2020)	High	Moderate	Yes (formal channels)	Mandatory
Brazil: Law N° 12.401 (2011)	High	Moderate	Partial (from 2019 to 2021)	Mandatory
Canada: Guidelines for the economic evaluation of health technologies (3rd edition) (2006)	High	Low	No	Recommendatory
Canada: 2nd edition guidelines for economic evaluation of pharmaceuticals (1997)	Medium	Low	No	Recommendatory
Netherlands: Revised guidelines for pharmacoeconomic research (2006)	High	Very low	No	Mandatory
Indonesia: 1st edition HTA guidelines (2017)	Medium	Very low	No	Mandatory

evidence that these evaluations were incorporated into decision-making processes (Supplementary Table S6).

Across contexts, guidelines were most influential when they were treated as living instruments embedded in formal institutional systems rather than static technical documents. Sustained stakeholder dialogue, transparent revision processes, and responsiveness to feedback helped build legitimacy and, therefore, influence change in decision making.

Discussion

Our findings suggest that successful HTA guidelines were developed by those who were open to engaging with stakeholders holding very different perspectives and willing to adapt their views through such engagement. Where developers faced constraints in implementing change, open stakeholder engagement was most important *during* guideline development to align across key

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stakeholders with the power to influence change. Where developers were responsible for guideline development and implementation, maintaining channels for engagement across a broad range of stakeholders was most important *after* publication for continued updates and minor revisions.

Open dialogue with stakeholders may help maintain credibility with professional associations and researchers by keeping abreast of new methods and thinking, while also allowing for incremental change to processes as other stakeholders engage, learn, and change their views on how decisions should be made. Our findings are consistent with institutional theories that written rules and guidelines only influence behavior if they align with how stakeholders believe decisions should be made (15), and that iterative discussion can gradually align stakeholders (16;85).

It is often recommended to use legal frameworks to promote adherence to HTA processes (86–89). However, we found no evidence that presence of laws or regulations improved HTA guideline success. In certain cases, rules and regulations may even constrain the ability to make continued updates to guidelines with stakeholder inputs. Aligned with international guidelines, our findings suggest that countries looking to institutionalize HTA would benefit from understanding the legal environment in which HTA will be implemented in their setting, in order to identify and make necessary legal amendments to uphold the values and principles necessary for effective HTA (90). For example, without effective accountability mechanisms, a legal mandate may not translate into changed decision-making practice. Our findings highlight that it is the design and content of legal frameworks that are important, not merely putting laws in place.

A final implication concerns methods used to evaluate guideline success. Current research typically assesses methodological adherence in published studies; however, our analysis found that such adherence reflects the maturity of the HTA ecosystem in a setting, rather than the impact of guidelines on changing decision-making practice. Guideline compliance could also be measured by reviewing evidence presented during the decision-making process and assessing adherence to defined procedures.

A strength of our research is that we considered different types of guidelines developed over time and across countries with different geographies, healthcare financing and governance mechanisms, and norms for decision making (16). Nonetheless, alternative explanations for variations in success observed between guidelines may not have been fully captured. Data constraints limited our ability to assess the relative success and contextual factors of each guideline. For historical data, we were often unable to triangulate data sources; for more recent guidelines, we had access to rich interview data, but often insufficient time to properly assess the level of success. Our analysis could not fully address sociocultural norms and attitudes toward the use of evidence for priority-setting, perceptions around what constitutes good practice (91), or institutional culture that shapes the use of evidence in priority-setting (15).

Another limitation relates to potential selection and respondent bias. Our sample was purposively drawn from countries with documented HTA guidelines, potentially over-representing systems with a narrative of progress. Within these countries, interviewees were predominantly guideline developers, agency staff, and affiliated experts who have perspectives on understanding design intentions and institutional history but may only reflect "official narratives." Some observations, particularly those concerning the relative importance of legal framework, governance arrangement, and institutional design, might place greater emphasis on factors perceived as important by system architects than on factors relevant to patient groups, industry, and the public. To alleviate this potential bias, we triangulated interviews with a critical review of published literature (including academic critiques and implementation evaluations) and policy documents and actively sought disconfirming evidence, examining cases of failure with the same rigor as successes. Nonetheless, the views of frontline decision makers, patient groups, or industry stakeholders are less represented and could provide an alternative lens on the factors influencing practice change.

We recommend further research on techniques for successful cross-stakeholder learning in HTA. Most literature on health priority-setting addresses evidence synthesis and capacity to manage the decision-making process, rather than establishing the decision-making architecture itself (87). Although a recent good practice report provides a checklist for deliberation in both the design of and within the decision-making processes (92), there remains limited research on how stakeholder deliberation may be conducted effectively and efficiently given a specific context and set of goals. The role that technology may play in sustaining stakeholder engagement also needs exploration. Further research could identify features of successful approaches to guideline implementation used across different settings. This study also highlighted the importance of effective accountability mechanisms while remaining open to learning and change, particularly in settings where healthcare priority-setting may mature faster than higher-level institutions and governance mechanisms. Finally, this study measured success of guidelines in changing decision-making practice, but it did not consider the link between better decision making and improved quality and accessibility of health services at the population level, which is another area for future research.

Conclusion

The promotion of systematic, evidence-informed decisions in health is often encouraged by establishing formal rules for decision making through laws, codes of practice, or operational guidelines. Our study suggests that HTA guidelines influence change not merely by their existence, but through a process of open stakeholder dialogue that underpins their development and revision.

Supplementary material. The supplementary material for this article can be found at http://doi.org/10.1017/S0266462326104218.

Acknowledgments. The authors thank all study participants for their time and insights. We acknowledge the contributions of Kanchanok Sirisorn, Diana Beatriz Bayani, and Angela Kairu to this work. We also thank Oresta Piniazhko (HTA Department, State Expert Centre of MOH, Ukraine), Manuel A. Espinoza (Pontificia Universidad Católica de Chile, Chile), Gihan Hamdy El-Sisi (HTA office and Faculty of Pharmacy, Future University, Arab Academy for Science and Technology and Cairo University, Egypt), Jasmine Pwu (Fu Jen Catholic University and Taipei Medical University, Taiwan), Ying-Li Chen (Centre for Drug Evaluation, Taiwan), Izzuna Mudla Bt Mohamed Ghazali (the Malaysian Health Technology Assessment Section, Malaysia), Somsak Chunharas (National Health Foundation (NHF), Thailand), Hugo Turner (Imperial College London, UK), and Anna Vassall (London School of Hygiene and Tropical Medicine (LSHTM), UK) for their guidance and continued collaboration throughout the work. We are sincerely grateful to the project collaborators who provided coordination and contributed to this work. These include Antonio Migliore (HTAi), Kelly Lenahan (ISPOR), Robert Selby (ISPOR), Wanrudee Isaranuwatchai (HTAsiaLink), and the HTAsiaLink Secretariat team. Grammarly 1.175.0.0, WebUI 2.16.22 was used to check grammatical errors and harmonize spelling upon revision of this manuscript.

Funding statement. This research has received funding support from the National Science, Research and Innovation Fund (NSRF) via the Research and

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Innovation Acceleration Agency for Competitiveness and Area Development (RCAD) Program Management Unit for Frontier Brainpower and Future Industries) (grant number: B41G670025). HITAP staff in this work is supported by the Thailand Science Research and Innovation (TSRI) Fundamental Fund. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Competing interests. All authors declare no conflicts of interest related to the content of this article. C.S. declared no conflict of interest at the time the study was conducted, analyzed, and the manuscript was written. Before manuscript submission, there was a subsequent change in affiliation to Thermo Fisher Scientific.

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