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CURRENT OPINION

What is the Value of Developing an HTA Process?

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Abstract

Health technology assessment (HTA) processes are becoming increasingly established and embedded in healthcare decision making around the world. Yet, there is limited evidence on whether HTA processes at the system level offer value for money to those presiding over their creation, such as governments and ministries of health. That is, whether the value of improvements in the health system exceed the costs. To address this issue, we outline the approaches adopted in a sample of recent evaluations of HTA systems and propose a set of considerations for measuring and valuing HTA processes. The scale and remit of the process can help identify the relevant system-level impacts of HTA such as those on productive efficiency and population health, health equity, guiding innovation and care pathways, and broader impacts. We further describe the methodological challenges and potential approaches to evaluating HTA including the appropriateness of approaches. The considerations discussed can reveal the potential for ill-designed HTA processes to generate less social value than intended.

Key Points for Decision Makers

Recent studies have demonstrated a lack of consensus on how to establish the value for money of health technology assessment (HTA) processes.

The scale and remit of an HTA process can inform the range of outcomes that HTAs can impact such as improving efficiency and population health, improving equity, guiding innovation, guideline development and broader outcomes such as improving transparency.

Two important challenges that require resolution when evaluating HTA processes are establishing the counterfactual and valuing and aggregating the impact on social outcomes of interest.

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1 Introduction

Health technology assessment (HTA) processes are used in many countries to inform the supply of public healthcare [1]. They can be broad in remit but generally include a multidisciplinary approach using explicit methods to determine the value of health technologies (i.e. HTA) and inform decision making (i.e. HTA appraisal) [2]. As more countries establish and embed HTA processes in healthcare decision making, those presiding over their creation (i.e. governments and their ministries of health) should consider whether they offer value for money. That is, whether the HTA process leads to improvements in the health system, and whether the value of those improvements exceeds the costs.

The International Network of Agencies for Health Technology Assessment (INAHTA) surveyed 47 HTA agencies in 2020 [3] and reported a wide range of potential indicators of HTA agency impact. Only a third, however, employed any formal assessment of the impact of their process and none conducted a value-for-money assessment.

More broadly, there are few published economic evaluations of HTA processes, and those conducted have focused chiefly on the impact of healthcare interventions they have prioritised. Barlow et al. [4] simulate the value of basing healthcare funding decisions on a cost-effectiveness threshold compared to funding decisions without cost-effectiveness information based on ten positive funding examples from the National Institute for Health and Care Excellence (NICE) in England and Wales. Kingkaew et al.

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[5] adapt this approach to Thailand, using cost-effectiveness information from HTA reports produced between 2008 and 2020 and considering the cost of generating those reports. Barlow et al. and Kingkaew et al. both evaluate the net health and/or monetary benefit of an HTA process, which prioritised interventions based on using a cost-effectiveness threshold compared to either at random (Barlow et al.) or first-come-first served (Kingkaew et al.) funding decisions. In both cases the funding decision threshold is set to that applied by the relevant HTA body. Naci et al. [6] estimate the population health impact of new drugs approved by NICE between 2000 and 2020. They compare the health gain and costs of new treatments with standard of care and use the opportunity cost of additional funding based on the Department of Health and Social Care's measure of marginal productivity of National Health Service spending of £15,000 per quality-adjusted life-year (QALY), which is below the NICE decision threshold of £20,000–30,000 per QALY. Finally, Bahuguna et al. [7] examine the population benefits and costs of three selected interventions approved by Indian HTA and account for the cost of producing each HTA report. Benefits from the approved products are measured in QALYs, with one QALY valued at one gross domestic product per capita.

Despite the narrow focus on health impacts of funding recommendations, there is divergence in the methods and scope of the evaluations. For example, the primary results produced by Naci et al. and Bahuguna et al. do not allow for the uptake of the interventions being considered by the HTA agency in the absence of an HTA process (i.e. without an HTA process, these interventions would not be used). Only Bahuguna et al. and Kingkaew et al. include costs beyond the intervention costs such as the costs of conducting HTA research and the fixed costs of HTA infrastructure. The studies by Naci et al. and Kingkaew et al. take a comprehensive approach and evaluate all relevant health technologies whereas Bahuguna et al. and Barlow et al. base their results on a subsample of conducted evaluations.

The literature includes frameworks for measuring HTA impact [8, 9] with a notable example from Millar et al. [8], which provides mechanisms and questions to consider when evaluating the performance of HTA agencies. This serves as a useful resource to help map out the objectives of having an HTA agency. Yet recent evaluations in the literature [4–7] indicate a lack of consensus on how to determine the value for money of HTA processes, thus providing the motivation for this paper. We aim to propose a set of considerations for measuring and valuing the impacts of an HTA process. We start by describing impacts of HTA processes that determine their value. We highlight the importance of considering what the alternatives are to a system-level HTA to help define the counterfactual. We discuss how to value different benefits and how to identify potential data sources. We outline policy implications and further considerations.

2 The Impact of System-Level HTA

The scale and remit of an HTA process can vary, including the types of interventions or areas covered by the health system and the degree of coverage within those areas. For example, some processes focus on pharmaceuticals whereas others encompass medical technologies, such as diagnostics, and public health policies. Some evaluate all coverage decisions within an area, whereas others take a selective approach. For existing HTA processes, this remit can help to inform the boundaries and scope of the evaluation of the value of an HTA process. Careful consideration must also be given to the opportunity costs, which may fall outside of this area if the expansion of public funds to pay for HTA is at the expense of funding elsewhere in the healthcare system, or more broadly.

The decision on what to include in an evaluation of HTA should reflect the government's policy objectives for the health sector and the intended achievements from the introduction of HTA processes. Within HTA decision making, there is considerable variation regarding what defines societal value [10], meaning there will be variation in the value of HTA as a whole. We outline the range of social outcomes that HTA processes may potentially impact and therefore are important to consider in determining their value.

2.1 Productive Efficiency and Population Health

The health sector comprises the set of resources that are used to deliver services to improve population health. Health technology assessment processes can be seen as a tool for deciding how to use a given set of these resources. The HTA process generates information and offers guidance to inform decisions to determine the allocation of resources, limiting spending on some aspects of healthcare and increasing it on others. This mechanism could be effective at increasing population health if the information accounts for the additional health benefits of a decision less the health that could have been generated elsewhere through alternative use of the health resources (i.e. the net health effect). Alternatively, if the information provided does not highlight net health effects, the impact of the HTA process on population health may be uncertain. The realised population health benefits (or harms) also require that the HTA appraisal and implementation should reflect the information generated in the HTA.

Health technology assessment processes are associated with a policy goal of using scarce resources more efficiently

to deliver high-quality health systems. This could be viewed as a social objective to maximise the productivity of public funds across sectors. The mechanism by which HTA processes may achieve this could be by generating information that increases the likelihood of avoiding inefficient spending within the health sector [11, 12]. Care can also be driven to where it is most clinically effective and cost effective through the reimbursement or listing on a national insurance scheme, thus improving population health benefits.

Influencing through pricing and funding negotiation for interventions is a mechanism by which HTA processes can alter the costs to the health system and potentially correct for market failures. For example, the joint procurement of new technologies through an HTA agency can increase the negotiation power through access to a larger pooled market [13].

A centralised HTA process may also reduce the time taken by multiple duplicate assessments and decisions across lower levels (e.g. local decision makers or clinicians) versus a centralised HTA process, resulting in better, quicker decisions and less resources wasted on duplicate assessments. An example is the joint clinical assessment of health technologies at the European Union level [14].

2.2 Health Equity

Health equity is an important social objective that underpins universal health coverage at national and local levels [15]. It is increasingly considered in HTA guidelines albeit the concept is broad and defined in numerous ways [16]. Health technology assessment processes can enhance equity by generating information on disparities in access to and use of health services, on heterogeneity in the effects of interventions and the consequent health outcomes, and prioritising groups during resource allocation. Health technology assessment processes, such as those embodied by NICE, can also be accompanied by legal mandates that seek to enhance equal rights to healthcare. However, it may be possible that HTA processes can adversely affect equity. For example, failure to reflect the opportunity costs in decisions so 'other' patients incur a bigger health decrement than those getting the new health technology or if HTA processes encourage undue focus on the aspects of healthcare more amenable to HTA, such as pharmaceuticals, which favour the less deprived. The magnitude of such inequity may be insignificant compared to the counterfactual of having no HTA process, but empirical evidence would be required to assess the direction and magnitude.

2.3 Guiding Innovation and Care Pathways

The production of explicit clinical and economic evaluation guidelines that provide clear criteria for technology evaluation and funding may have potential to guide manufacturer research and development decisions. This may link to other policy objectives if the guidelines increase investment in producing products that meet these criteria, thereby aligning industry output with health policy. It may depend on the size of the market such as the disproportionate power of the US market [17]. Guideline development may also improve healthcare quality through influencing pathways of care and homogenising care supply [18].

2.4 Broader Impacts

Beyond impacts on health outcomes, social value may be generated through other positive experiences of the health sector, for example by increasing trust and transparency between citizens and healthcare providers. It can help remove asymmetries of information, which is good for pricing of technologies but potentially also care quality and consumer belief in the healthcare system. The implementation of an HTA agency can also offer institutional strength such as protection against legal challenges.

The health sector often comprises a large portion of an economy, and one social objective may be to improve economic welfare by creating employment and fostering economic growth. The mechanisms by which HTA processes influence these outcomes may be contained within the institute itself in the form of job creation. We reflect the described impacts in Fig. 1. It depicts the reach of HTA agencies across health and other sectors and informs how any resulting supply can inform aspects of value.

3 Methodological Challenges and Potential Approaches to Evaluating an HTA

3.1 Counterfactual

A key challenge in evaluating the introduction of an HTA process is estimating the counterfactual, i.e. what would happen in the absence of an HTA process. A number of approaches have been adopted in the literature [4–7]. All of these studies have retrospectively appraised HTA processes after its implementation (known as 'ex post' evaluations), meaning assumptions are made about what would have happened in the absence of HTA. Prospective ('ex ante') evaluations could also be conducted but similar consideration would need to be given to what happens if an HTA process is or is not introduced. We take the general perspective of ex post evaluations as these reflect

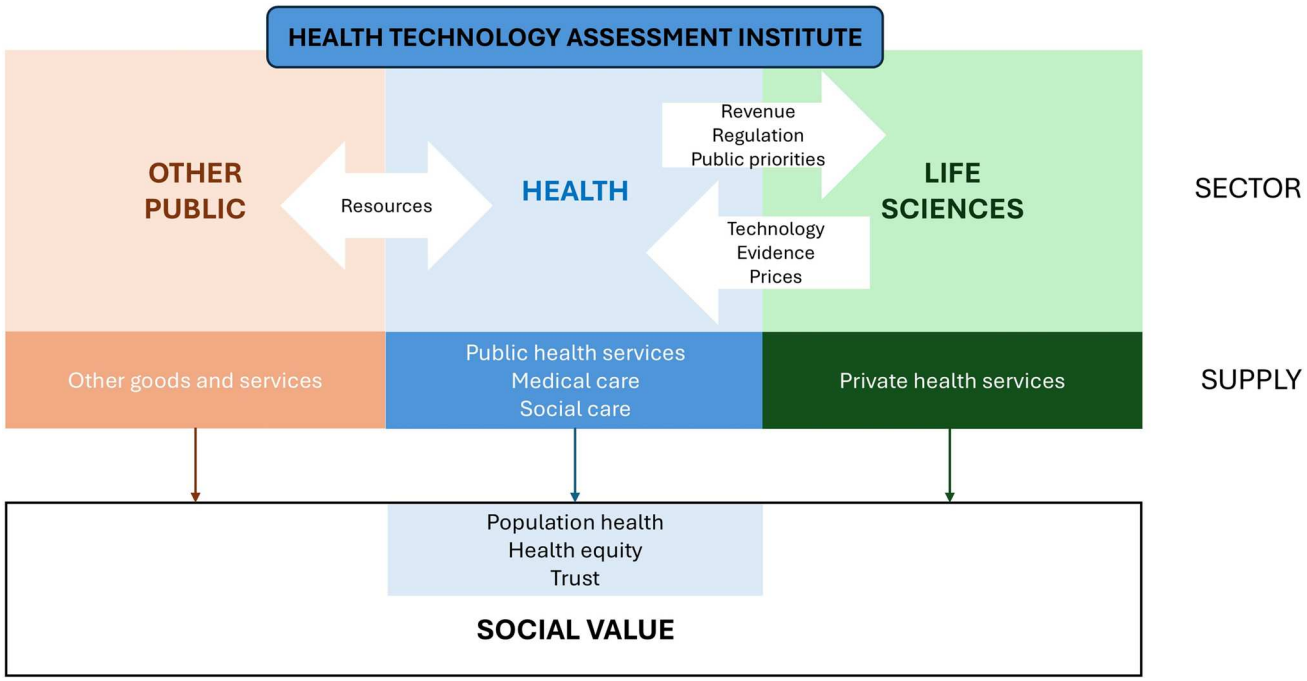

Fig. 1 Broader influence of health technology assessment processes to inform assessments of value

the evaluations in the literature, but the considerations apply to both. Indeed, ex ante evaluations are potentially more important as they inform the decisions of whether to implement a HTA process (or whether to continue one).

It is important to consider the range of alternative HTA processes that could be implemented to achieve a given set of policy objectives. A first step may be to define the relevant mechanisms for decision making that existed before the introduction of an extant HTA process, or that represent current practice within a jurisdiction that is yet to introduce an HTA process. The utilisation of theory-of-change approaches as part of the systematic evaluation of public health processes could benefit ex post evaluations [19, 20].

Evaluations may take a historical lens by looking at the uptake of new technologies and the distribution of uptake across different types of technology in society before an HTA process was introduced and then comparing it with what happened after. That said, caution would need to be applied as to whether a change in uptake or distribution is something that led to the initiation of an HTA process. It may be the case that technologies delivered in the health sector are skewed towards expensive technologies on the basis of a business case being proposed for their use or advocacy from industry, clinicians or consumers, and ideally HTA processes should counter this and shift the distribution towards only socially valuable innovation. Related, it may be pertinent to consider whether HTA processes alter the distribution of technologies, and if so how? Many HTA processes focus on areas where there is a strong vested interest (e.g. pharmaceuticals), and so to value it should counter this. Health technology assessment processes that focuses on areas without a vested interest may also add value as without a public assessment there may be less information on these options.

Alternatively, an ecological lens may be adopted by comparing to a relevant international comparison. This may involve comparing to countries with different HTA processes but similar health systems. Comparison could be made to countries with varying degrees of HTA maturity and selection could be based on gross domestic product health spend and the life expectancy of the population for each of these systems. In practice, the factors that vary across countries would likely make it difficult to isolate the value of an HTA in this manner.

Statistical methods such as synthetic controls [21] may also allow inter-country comparisons to estimate the counterfactual of no HTA process. However, the heterogeneity in different countries' health systems will pose challenges, some that may be more amenable to observation such as healthcare structure, finance and funding, and those that are less easy to measure such as contextual factors like the needs of the healthcare system [22]. There is a growing literature on the methods for impact evaluation that should be considered alongside other modelling approaches [23].

Simplifying assumptions may help inform the upper or lower bounds for potential impacts. For example, it could be assumed that without an HTA process the

same total pharmaceutical budget would be spent, but with a different mix of pharmaceutical activity. Health technology assessment processes are often regarded as distinct from the process of setting the health sector budget. That is, they determine how the budget is spent, but they do not determine the size of the budget. In this case, it could be assumed that without the HTA the same pharmaceutical budget would be spent, but on a different mix of pharmaceutical activity. However, if the HTA process does in any way impact on the volume of spending or on prices, then this assumption may be considered unreasonable. For example, if countries with formal HTA processes observe an increase or decrease in the budget assigned to the activities covered by the process over time.

Another approach may be to estimate the potential gain or loss compared to a counterfactual of 0% uptake for a positive decision (alternatively for a negative decision, 100% uptake). It is important to note that this provides at best a necessary condition for value for money but not a sufficient condition. That is, we can say whether an HTA has been poor value if it costs more than the maximum potential gain, but we cannot say whether it is beneficial or not.

It may be difficult to isolate the impact of an HTA process from other institutional mechanisms. For example, in England and Wales, NICE may influence pharmaceutical spending, but so do other various agreements between government and the industry such as the Voluntary Scheme for Branded Medicines Pricing, Access and Growth [24].

The ability to estimate the impact of an HTA process will also depend on data availability, which may be limited in some settings including those with less digital record keeping or in the presence of confidential pricing agreements. Data on administrative processes and timelines for funding decisions may be available only in more regulated sections of the health system, for example, licensed pharmaceuticals, and less so in areas such as the delivery of public health interventions. Data on clinical practice patterns, guideline adherence and variations in care provision may be obtainable from an audit, but outcomes such as trust between citizens and providers may require primary data collection.

3.2 Valuing Benefits

An overall assessment of the value of an HTA process requires the consideration and aggregation of the various social outcomes of interest (e.g. Fig. 1). Literature exists on valuing health and equity within the context of an HTA decision on a particular treatment [25, 26] but these approaches have not been widely applied to evaluating system-level HTA processes.

Naci et al. [6] used a government measure based on available evidence of marginal productivity of changes in National Health Service expenditure to value health benefits at £15,000 per QALY and reflect the opportunity cost of additional funding. This represents the health that could be gained elsewhere in the health system and is considered a 'supply-side' value, meaning health is valued relative to the health forgone. In Bahuguna et al. [7], health benefits were valued at 1 × gross domestic product per capita. This values health according to income and is derived from the money individuals are willing to pay for an improvement in health. It more commonly represents a 'demand-side' value of health focusing on preferences. Demand-side values may be considered most relevant when the objective is to reflect societal preferences about how much should be spent on health. By contrast, supply-side estimates aim to capture the health opportunity costs of the displaced existing activities of additional spending within the healthcare system. Barlow et al. [4] and Kingkaew et al. [5] used the HTA institution thresholds to value health, i.e. the threshold at which cost effectiveness is judged. The threshold values nominally represent the amount an HTA agency is willing to pay for health improvements but may not be based on the population's preferences for spending on health improvements. The interpretation of using an institution threshold if it does not represent foregone health (in the case of supply-side) or individual preferences for foregone consumption (in the case of demand-side) is unclear and its use as a decision rule has been compared to alternative decision rules in simulation studies [27].

Not all countries with HTA processes have an explicit threshold [28]. The lack of an explicit threshold may be by design if it is believed that industry would price to the threshold. Where there is no formal threshold, the prices submitted for new technologies could be lower [29].

Where an HTA agency adopts a narrow perspective because it is assumed that its decisions about which individual technologies to implement impact only on the health sector, then it may still be appropriate to evaluate the system-level impact with a broader perspective as the system level may be more likely to impact on outcomes outside the health sector. For HTA agencies without a formal threshold, the added value of individual decisions may be harder to determine depending on how individual appraisals are reported. Indeed, the degree of information reported from the individual assessments undertaken within an HTA process is crucial data to enable a system-level evaluation.

For the valuation of a broad range of social outcomes, the opportunity cost across public expenditure and not merely across the health system may be required. This allows the valuation of health expenditure relative to different public budgets (e.g. education, environment). A framework by Longo et al. [30] has been developed to consider valuation in public expenditure. A simplification may be to value net health benefits using a policy threshold

(i.e. a derived supply-side or demand-side estimate) as in Naci et al. [6] or Bahuguna et al. [7]. The distribution of net health across the population can be equally weighted across individuals, groups or geographic regions, or it can be weighted according to equity-relevant concerns valuing some health gains in the population relative to others. A framework has been proposed to consider evaluations that fall across multiple sectors [31]. To allow aggregation, the broader aspects of value will need to be in units that can be combined with the valuation of health and health equity benefits. For simplicity, this may be achieved through using a common numeraire such as monetary valuation, but this poses challenges [32]. The use of monetary valuations may raise the prospect of industry pricing to threshold, which can erode the social value gained from health technologies. For some outcomes, a consumption value might be available, for example from market prices or estimated via a contingent valuation. However, some non-health outcomes may be considered unmonetisable, for example impacts on trust in institutions. These would necessarily fall outside any quantitative assessment of value.

4 Further Considerations

We outline considerations for policymakers in terms of the breadth of HTA process impacts and potential challenges. Millar et al. [8] lay out an impact pathway and suggest the route forward to an impact evaluation. We have expanded this to consider how you might measure and value impacts across the pathway laid out by Millar et al. There are several additional considerations that warrant attention. The first is that the quality of an HTA process is built on the quality of the evaluations. All HTA evaluations are inherently subject to some evidential uncertainty; however, ideally, there should be consistency in processes to ensure that evaluations are as comparable as possible. This would include standard methodologies and reporting of results.

A common framework for evaluations of system-wide HTA processes could enhance comparability and ensure that uncertainty in the outputs of an HTA is reflected in system-level estimates of value. To truly inform governments and finance ministries, the results of the evaluation should be presented in the same decision-making metrics as other policy evaluations within the jurisdiction. For example, return on investment or calculating the internal rate of return. Within the UK for example, this would be in the form of a cost-benefit analysis or a cost-effectiveness analysis as outlined in *The Green Book* [33]. As noted previously, this would exclude non-monetisable impacts.

A final consideration is that an HTA process might not emerge from a legislative design framework but organically from bottom-up followed by formal recognition of its value. It may emerge from one part of the health system and as a result is not integrated throughout the health system or legally mandated. We distinguish a formal HTA process from ad hoc processes or the informal use of an HTA by parts of the health system. The latter form part of the counterfactual or relevant comparators to a formal HTA institution. That is, in the absence of an HTA institution, this does not mean that evidence on value for money is not used to inform decision making. Thus, the key challenge is in establishing whether a formal process (consistent, applied across all decisions, transparent) offers sufficient value to justify any additional cost over other means of making decisions. Indeed, avoiding multiple actors independently assessing value for money within the health system may be one way in which a formal body could in fact generate some cost savings.

5 Conclusions

We have offered thoughts on how a government or ministry of health may wish to measure and value an HTA. The considerations discussed herein are by no means exhaustive, but they hopefully reveal the potential for ill-designed HTA processes to generate less social value than intended.

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Declarations

Conflict of interest Simon Walker and Mark Sculpher are editorial board members of *PharmacoEconomics*. They were not involved in the selection of peer reviewers for the manuscript nor any of the subsequent editorial decisions. Peter Murphy, Septiara Putri, and Susan Griffin have no conflicts of interest that are directly relevant to the content of this article.

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Consent to participate Not applicable.

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