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The emerging social science literature on health technology assessment: a narrative review

Olga Löblová, PhD

ol264@cam.ac.uk

+44 (0) 1223334535

Department of Sociology, University of Cambridge, 16 Mill Lane, CB2 1 SB, Cambridge, United Kingdom

Trayan Trayanov

Department of Sociology, University of Cambridge, 16 Mill Lane, CB2 1 SB, Cambridge, United Kingdom

Marcell Csanádi

Doctoral School of Pharmacological and Pharmaceutical Sciences, University of Pécs, Hungary;

Syreon Research Institute, Budapest, Hungary

Piotr Ozierański, PhD

Department of Social and Policy Sciences, University of Bath, Bath, United Kingdom

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Precis: Social scientists contribute valuable critical perspectives to the study of health technology assessment but leave some important questions unanswered.

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Abstract

Objectives: To provide an overview of existing social scientific literature on health technology assessment (HTA), with a focus on sociology and political science and their subfields.

Methods: Narrative review of key pieces in English.

Results: Three broad themes recur in the emerging social scientific literature on HTA: the drivers of the establishment and concrete institutional designs of HTA bodies; the effects of institutionalized HTA on pricing and reimbursement systems and the broader society; and the social and political influences on HTA decisions.

Conclusions: Social scientists bring a focus on institutions and social actors involved in HTA, using primarily small-N research designs and qualitative methods. They provide valuable critical perspectives on HTA, at times challenging its otherwise unquestioned assumptions. However, they often leave aside questions important to the HTA practitioner community, including the role of culture and values. Closer collaboration could be beneficial to tackle new relevant questions pertaining to HTA.

1. Introduction

This themed section of *Value in Health* asks why the use of health technology assessment (HTA) in healthcare decision-making varies widely across countries. Specifically, the issue is interested in how this diversity may be shaped by culture, values and institutions. These are the core topics that social scientists have explored extensively in other areas of health policy, such as health care reform¹⁻⁵, rationing/priority-setting⁶⁻⁹, or pharmaceutical regulation¹⁰⁻¹⁴. Social science has so far paid less attention to HTA, a relatively new phenomenon: in 2003, a paper in *Social Science and Medicine* announced that “Despite its importance in governing the direction of innovation in health care delivery, there are hardly any empirical studies of HTA in practice”¹⁵. Since then, however, social

scientists have been increasingly attentive to HTA, and, as the present themed section demonstrates, the HTA community shows considerable interest in input from other disciplines.

We present a narrative review of the emerging empirical literature on HTA from several social scientific disciplines: sociology, political science, and their interdisciplinary subfields such as science and technology studies (STS), which is concerned chiefly with the social and political aspects of scientific practice and technology design and use, and political sociology / political economy, which focus on stakeholders' interests and strategies. The boundaries between these fields are permeable and, in the interest of interdisciplinarity, we avoid dwelling on them. Rather, we present a thematic narrative review of the common research questions, methods, and findings of social scientific scholarship on HTA. While we do not make any claims to exhaustiveness, this is, to the best of our knowledge, the first review of its kind.

After providing more details on our methods, we summarise the established policy analysis literature on HTA developed mostly by health economists and HTA practitioners. We then identify three broad themes recurrent in the emerging social scientific literature on HTA: the drivers of the establishment and concrete institutional designs of HTA bodies; the effects of institutionalized HTA on pricing and reimbursement (P&R) systems and the broader society; and the social and political influences on HTA decisions. We conclude with a brief discussion of social scientists' contributions to the study of HTA and suggest research avenues of interest to social science as well as HTA practitioners.

2. Methods

We reviewed key pieces on HTA from sociology, political science and their subfields. Inclusion criteria were: English language, mention of "health technology assessment" in the papers' title or abstract, and empirical content in the body of the paper. Given the difficulties of using conventional systematic review methods in social sciences, especially for multidisciplinary topics¹⁶⁻¹⁸, we employed a step-wise quadruple search strategy. The basis for our search was our pre-existing social scientific bibliography on HTA, which we had been developing independently since 2010 (e.g.¹⁹). We

then used reference snowballing techniques to identify additional literature, specifically reference checking and citation search in Google Scholar¹⁸. Next, we searched (in October 2018) Google Scholar for keywords associated with key topics emerging from our expanded bibliography (e.g. “HTA + uncertainty of evidence” or “HTA + public engagement”). Finally, we searched for these terms manually in selected top-ranking journals in health policy, sociology, political science and their subfields, namely *Sociology of Health and Illness*; *Social Science and Medicine*; *Social Studies of Science*; *Minerva*; *Health Economics, Policy, and Law*; *Health Policy*; and *Journal of Health Policy, Politics and Law*.

This resulted in a body of 41 references (see Appendix 1), from which we extracted central topics, research questions, methodologies and disciplines. Based on the central topics and research questions, we inductively identified a set of common broad themes covered by the papers and agreed on their relevance through discussion among authors. We paid special attention to dissenting opinions among our team which could help us identify dissent within the literature²⁰. We present the results in the form of a narrative review, which allows us to juxtapose “diverse forms of evidence” and literatures side by side²¹ – in this case, the established HTA literature, typically written by health economists and other HTA practitioners, and the emerging social scientific scholarship. For the purposes of this review, we set (health) economics apart from other social sciences, and we also leave aside the important contributions of normative political theory and philosophy, as well as of the humanities and the law.

3. Results

3.1. The established literature on HTA

Since the early years of HTA in the 1980s, much of HTA scholarship has been made up of publications on the methodologies for assessment of health technologies and of evaluations of individual technologies, useful to academics and decision-makers. Not far behind were conceptual essays on the nature of HTA, its relationships to evidence-based medicine, P&R processes, and biomedical research and innovation^{22–26}. HTA has also attracted the attention of philosophers and political and legal theorists^{27–30} and a number of publications documenting its history emerged (^{31–35}).

With one possible exception³⁶, a critical history of the rise of HTA as a discipline has yet to be written.

The vast majority of the social science literature is focused on studying HTA as national institutions and individual regulatory decisions – the policy analysis of HTA and P&R procedures, mostly written by health economists and other HTA practitioners. Health economists have an obvious disciplinary claim to HTA: they are the ones developing the necessary methodologies for quantifying and comparing value for money of health technologies. They also have a direct interest in understanding how their science is applied in practice – in appraisals and funding decisions. As a result, one of the three sections of the *International Journal of Technology Assessment in Health Care* has been since 2010 called “policies” (in addition to “methods” and “assessments”). Other journals, including *Value in Health*, have devoted special issues to overviews of HTA in selected countries³⁷. The aim of these policy analyses is primarily descriptive: to document and compare what methods are used in different jurisdictions and how they compare internationally (e.g.^{38–40}). In the rapidly evolving field of HTA, where policies change every couple of years, these records from individual countries provide valuable information. Insofar as HTA policy analysis has deeper analytical intentions, these are usually identifying various “barriers and opportunities” for the establishment, development, or increased use of HTA by decision-makers^{41–43} (with exceptions, e.g.⁴⁴). In these, political and societal factors are typically noted (often as “lack of political will” or “social acceptability” or “institutional capacity”) but rarely discussed in detail. Along with other themes, they are, however, central to the social science on HTA.

3.2. The emerging social science literature on HTA

The emerging social scientific literature on HTA can be divided according to its three most common research themes: the drivers of the establishment and design of HTA bodies; the effects of institutionalized HTA on P&R, medical practice, and the broader society; and the social and political influences on HTA decisions.

3.2.1. What explains variations in how HTA is institutionalized and practiced?

The first question social scientists ask takes the adoption of HTA as a dependent variable: why are HTA bodies established? Conventional wisdom from HTA policy analysis would presume that HTA spreads through the world and that, sooner or later, countries without HTA will all create HTA agencies as a necessary tool to organise an efficient distribution of limited healthcare resources (e.g. ⁴⁵⁻⁴⁷). However, some political scientists disagree with the presumption that HTA is inevitable. Functional pressures on healthcare can be very different across countries and therefore HTA may be promoted by local actors as a solution to very different problems^{48,49}. For example, in Poland HTA was presented as a way of complying with EU legislation on pharmaceuticals and defining the basic benefit package, while some in the Czech Republic saw HTA as a tool to control spending on medical devices and diagnostics⁵⁰.

Others agree with the basic premise that HTA diffuses because of a functional pressure on public finances but offer important nuance. For example, a series of studies on Sweden, France and Germany⁵¹⁻⁵³ claims that “the emergence and continuing function of national [independent agencies] for HTA follows a broadly evolutionary pattern” but that within this evolution, “contextual factors play an important mediating role”⁵³. What is mediated here are the concrete institutional, methodological and procedural aspects of HTA and its relationship to P&R in individual countries.

These differ starkly, as yet others have noted: no two HTA systems are the same and that none of the usual suspects (e.g. geography, GDP, timing of HTA institutionalization) explain this major institutional variation⁵⁴. But institutional context in individual countries may help us understand the bodies’ genesis and design. In France, for instance, the national regulatory context (pre-existing institutions with their own priorities and mandates) meant that the HTA body received a mandate which went well beyond cost-effectiveness analysis to pursue a range of mechanisms for containing healthcare spending⁵³. Similarly, the fragmented multi-level nature of Canadian healthcare has conditioned the extent and nature of intra-Canadian cooperation of HTA bodies⁵⁵. Further, conscious strategies of key actors may matter: functional pressures or historical administrative traditions of each

country may have less influence on what HTA bodies look like than high politics, such as the left-right divide⁵⁶. When given the chance, governments strategically shape the institutional design of HTA bodies according to their political preferences⁵⁷.

The use of specific methods for appraisal and assessment methods is also conditioned by their regulatory context. For instance, the use of the efficiency frontier in HTA in Germany (as opposed to cost-effectiveness threshold in the United Kingdom) is argued to be the result of different “regulatory spaces”, inhabited by a multiplicity of public, private and non-government actors, value judgements and cultural norms, and power dynamics: it is unacceptable in Germany to mention healthcare rationing or describe health gains in monetary terms⁵¹. In short, context matters for why HTA bodies emerge and what they do.

Finally, some of the empirical social science literature looks at why politicians and policy-makers would want HTA in the first place. There are other alternatives to implementing a national HTA agency in the P&R toolkit, especially if cost-containment is the goal⁴⁹. This could include reference pricing, reimbursement decision referencing (e.g.⁵⁸), managed-entry agreements, and delaying or preventing market entry to expensive or new therapies. Delegating authority to specialised HTA bodies, however, serves multiple purposes for politicians, including creating a pool of experts capable of resolving complex problems, but also gaining legitimation by adopting an “evidence-based policy” discourse, and avoiding blame in case of controversial decisions^{49,56,59}. Potentially, it also “*enhances* politicians’ capacities to institute their ideological preferences within a set of concrete rules and ‘expert’ decision making procedures”⁶⁰. Once established, arm’s-length HTA agencies are shown to have significant staying power in the face of efforts to re-politicize decision-making⁶⁰⁻⁶² though not full immunity from politics, especially if the political costs are too high or the political calculus itself changes exogenously^{60,63}.

3.2.2. What are the effects of institutionalized HTA on reimbursement decisions and beyond?

Another strand of empirical social science literature takes the existence and characteristics of HTA systems as an independent variable and asks what its consequences are for P&R and broader healthcare systems. The transparency and inclusiveness of the assessment and appraisal process are among the key aspects of HTA that are theorized to matter for outcomes. Within the established HTA literature, health economists have produced a growing body of quantitative analyses examining the link between HTA agencies and their often diverging P&R decisions^{64,65}. Differences in recommendations are thought to be due to an agency's approach to risk perception, the comparator choice used in clinical and cost-effectiveness studies⁶⁶, or the drug and disease characteristics⁶⁷. Although countries with similar institutional setup of HTA tend to reach somewhat similar P&R decisions, comparable procedural setups (namely, who assesses evidence and when) played an unclear role⁶⁸. "Process configuration", however, does not seem to have major effects on P&R outcomes – at least where evidence about a technology is strong; where evidence is uncertain, the inclusiveness of the HTA process (the number of stakeholders involved) increases the likelihood of a positive reimbursement decision⁶⁹.

Social scientists are similarly on the fence as to the impact of procedural aspects on P&R decisions. A large-N analysis of the impact of the design and procedures of HTA institutions (namely their transparency, inclusiveness to stakeholders, and consensus / majority voting) found only weak statistical evidence for any influence on reimbursement outcome⁷⁰. A qualitative Hungarian case study explains the limited influence of HTA on P&R outcomes by the lack of transparency of the HTA process, although other factors (including institutional design, human resources - "brain drain" to the private sector, and key actors' disinterest in reform) were also mentioned⁷¹. Recent work on the "practical" transparency of HTA bodies⁷¹⁻⁷³ may perhaps contribute to making transparency a better defined variable amenable to both qualitative and quantitative inquiry. As STS scholars emphasise, procedural choices and guidelines both reflect and result in privileging certain forms of rationality and

certain voices and perspectives over others, amplifying or creating new power disparities in the process⁷⁴.

Critical STS scholars see HTA as actively changing broader socio-political contexts. HTA, alongside other types of regulation, influences the very process of innovation, affecting the balance of social power by making new alliances possible, as well as by prioritizing or legitimizing particular actors and select forms of evidence and interest expression^{36,75}. Most importantly, HTA is both driven by and contributing to broader social tendencies, such as the shift toward the medicalization of society, the shift toward neoliberal governance and the consolidation of the regulatory state, and the “evolving modes” of scientific knowledge production, subsumed under labels such as regulatory science, trans-science, or post-normal science⁷⁵. We should note that health economists have recently also started to devise empirical strategies to study the broader effects of HTA beyond P&R⁷⁶.

Some HTA practitioners have proposed that HTA can complement and enhance evidence-based medicine (EBM) by giving doctors and patients information that goes beyond efficacy and effectiveness, concentrating on those outcomes that are most relevant and significant to the patient⁷⁷. HTA is intended to influence clinical practice (including prescription practice) through clinical guidelines, and patient behavior via publicly available appraisals. Empirical social scientists, and especially STS scholars, have, however, challenged whether access to the type of evidence ranked highly by HTA impacts clinical behavior in practice⁷⁸; whether EBM’s impact on clinical behavior is a positive development⁷⁹; and whether what HTA provides is commensurate with what patients seek^{74,80}.

3.2.3. How do the social and political contexts affect HTA decision-making?

A final, broad strand of the social science literature examines how HTA decisions are made in practice, within particular social and political contexts. Established HTA literature has been aware of the tension between HTA’s technocratic qualities and the political nature of rationing healthcare resources^{62,81} but often treats it as a “barrier to HTA adoption” by decision-makers that can be

overcome by improving HTA methods (e.g.⁸²). In contrast, the political science and sociology literature takes the politics of HTA as their main focus. It is particularly interested in “backstage decision-making”⁸³, which it most often investigates with the help of ethnographic methods such as semi-structured interviews, observation, and participation in HTA bodies’ meetings. It frequently focuses on “crucial case studies” of often controversial technologies^{84–86} or studies decision-making in individual HTA institutions^{72,87–89}. Two key subtopics emerge from this literature: the interests and behaviours of main “stakeholders” and the nature and role of what counts as “evidence” in HTA.

First, “stakeholder involvement” is an unquestionable normative principle of HTA⁹⁰, very much in line with the current paradigm of (good) governance⁹¹. In this context, stakeholders are quite often synonymous with patient advocacy organisations, and much of the HTA policy analysis literature seeks to assess (and possibly enhance) their involvement in HTA processes^{92–97}. STS scholars and sociologists ask very similar questions: they study the rationale and determinants of patient participation, its institutional frameworks, formal and informal modes of involvement, and the mechanisms for considering patient contributions^{98–100}.

The empirical STS literature echoes the HTA analysts’ concerns that patient involvement is, in one way or another, limited. In meetings of the English National Institute for Health and Care Excellence (NICE), patient voices have been found to have a “symbolic and representative” function, “relegated to the periphery of participation”¹⁰⁰, reflecting skewed power dynamics between experts and patients⁹⁸. An Australian study found that these power differentials lead patients to strategically align with industry to amplify their views during the HTA process¹⁰¹. Quite often, these social scientists would agree with HTA practitioners’ premise that more stakeholder (patient) engagement is necessary and desirable, although they place a much greater emphasis on informal practices in addition to formal rules of participation.

A more critical take on stakeholder involvement, rooted in political sociology / political economy, examines the roles of other actors than patients, including members of appraisal committees, clinical experts, policymakers and bureaucrats^{71,72,102,103}. Just like work by established HTA analysts⁸⁷ and

scholars of pharmaceutical regulation¹⁰, this literature examines the way various actors attempt to “game the system” by biasing or capturing HTA regulators. For instance, several studies of lobbying methods deployed by drug manufacturers in Poland to secure favourable HTA outcomes document a mixture of universal lobbying strategies, such as endorsements by clinical experts, coupled with context-dependent approaches, such as informal clique influence^{102,103}. But manufacturers are not the only stakeholders with vested interests in HTA. There are also HTA consultancies assisting the industry in developing evidence submissions, who may be interested primarily in creating business for themselves, rather than creating or reforming HTA systems^{71,102}, and the “epistemic community” of HTA experts, who have potential material or reputational gains from creating and maintaining HTA institutions^{36,50}. In addition, politicians and bureaucrats have a strong stake in limiting impact on public budgets. This may result in additional pressure on HTA bodies to avoid, delay or impose restrictions on positive reimbursement decisions; this influence can be formal⁸⁶ or informal⁷¹.

Second, an alternative way of considering HTA practice as part of a socio-political context is to shift focus from actors to evidence. Close to the STS take on patient involvement, this scholarship asks about the forms of expertise and evidence privileged by HTA processes, how they interact and why some of them seem to be more influential than others^{84,98,100}. A key conclusion reached by this literature points to the limitations on objectivity and rationality in HTA decision-making^{9,88}. The question of what counts as evidence is non-trivial – HTA privileges “hard”, quantitative evidence conveyed by experts in economics and medicine^{36,74}, while lived experience of practitioners and patients is seen as less important^{100,101,104,105}. Rationality is further limited by an issue well-known to health economists and other HTA analysts: the uncertainty of evidence. Moving beyond the statistical understanding of uncertainty⁸⁴, qualitative studies of HTA decision-making see uncertainty as being present within the “epistemology, procedures, interpersonal relations, and technicality” of HTA⁸⁸, which result in a decision-making process that is subtly biased. Crucially, the HTA process is characterized by a “negotiation with the use of pragmatic methods to navigate through complexity and layers of uncertainty”⁸⁸. With high uncertainty, the scope for rational-comprehensive decision-making becomes limited, and is supplemented by decision-making based on other criteria, for instance trust in

other stakeholders¹⁰⁶. With their focus on formal and informal practices, social scientists thus show how far removed concrete processes may be from HTA's basic promise of purely rational "evidence-based" policy.

4. Discussion & Conclusions

This paper summarised the growing empirical social science literature on HTA from political science, sociology and adjacent (sub)disciplines of STS, political sociology and political economy in a narrative review organised around the key themes of the literature. We are conscious of five potential biases of this paper. First, we focused on (sub)disciplines with which we are most familiar. Second, we considered empirical papers only. Third, we included works that identify health technology assessment as their key topic. As a result of these biases, we may have omitted work from other empirical disciplines, and we have ignored works from political and social theory and humanities or law altogether. We have also excluded closely related social scientific scholarship on priority-setting, rationing, reimbursement decisions, or value, which often addresses similar questions to the study of HTA. Fourth, we reviewed exclusively works in English, possibly introducing a NICE-bias. While this may well be a faithful reflection of the literature¹⁰⁷, we may be perpetuating an Anglo-centric perspective on the study of HTA to the detriment of alternative views. Fifth, by juxtaposing the social scientific literature to the more established HTA policy analysis, we may have inadvertently oversimplified existing health economic scholarship.

We argue that social scientists peer into the black box of "political will", "barriers and opportunities", "societal values", or "institutional capacity" that are usually referred to in passing by most of the established literature on HTA. Ontologically, the universe social scientists seek to understand comprises two sets of entities: institutions/processes (e.g. HTA bodies and approaches) and actors/stakeholders (e.g. patient organisations, bureaucrats, manufacturers), which are used interchangeably as dependent and independent variables against each other. These two foci are near-exhaustive, with most topics falling into one of the two categories. For instance, common interests of

HTA policy analysis such as transparency or methodology of HTA, are often conceived as institutional traits, while topics such as uncertainty of evidence are conceptualised as resulting from social construction or negotiation by individual actors.

This ontological orientation reflects broader trends in sociology and political science since the 1980s, namely the ascendance of new institutionalism, emphasising the role of institutions, defined broadly as organizations, norms and practices, in decision-making^{108,109}, and the rise of actor-network theory, interested in social mechanisms involved in the operation of networks formed by “human” and “non-human” actors, such as technologies¹¹⁰. Similarly, the more critical approaches to HTA in our review, mainly from political economy and STS, are consistent with major critiques of the capitalist state¹¹¹⁻¹¹³, viewing organisations as sites of strategic struggle for resources and control between competing social forces. That said, notable from our review is the limited interest of social scientists of HTA in the analytical category of culture, including values (with exceptions⁵¹). This contrasts, in particular, with some areas of medical sociology, in which culture plays a prominent role in explaining how organisations deliver patient care¹¹⁴.

Methodologically, social science studies of HTA tend to emphasise the “depth” of explanation over its “breadth”. They tend to study “crucial” single cases or adopt a small-N design based on a limited number of key similarities or differences between the studied HTA systems (with exceptions⁷⁰). These studies tend to provide qualitative “thick description”¹¹⁵ of two-way relationships between HTA and its social context. While these small-N studies may, in aggregate, help identify broad patterns, their ability to provide generalizable answers remains limited by the idiosyncratic and ever-evolving nature of national HTA systems.

What insights, then, can social science offer to HTA practitioners? It is certainly too early to expect, as this themed section suggests, an integrated account of the relative role of “culture, institutions and values” in many dimensions of HTA. Questions of interest for social scientists as “outsiders” or “strangers”¹¹⁶ may also be uncomfortable for those “on the inside”, especially when these questions problematize or even challenge some of the key principles of HTA as a science and practice (e.g.:

“Can evidence-based, rational decisions be reached under high uncertainty?”, “Is stakeholder involvement universally beneficial?”). Compounding the potential frustrations may be fundamental differences in disciplinary training between social scientists and HTA practitioners. Here, this division could perhaps be overcome via closer collaboration and shared disciplinary understanding (which this themed section fosters), similarly to the initially strained but today well-established relationship between medicine and medical sociology¹¹⁷. One possible step towards greater collaboration would be to incorporate social scientific questions more closely into future HTA research projects. Another would be to emphasize social science in HTA curricula.

A more integrated collaboration could also help address the big question so far neglected by both social science and most HTA policy analysis¹¹⁸⁻¹²⁰: what is HTA actually good for? Assessing the real-world monetary, health and broader societal effects of HTA as currently implemented in countries around the world will require the expertise of not only traditional HTA practitioners, but also the unique perspectives of social science (as well as the humanities, law and other disciplines).

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Appendix 1: List of empirical social science publications on health technology assessment

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