

**Halted Diffusion:
Epistemic Communities and the Non-Adoption
of Health Technology Assessment Agencies in
Central and Eastern Europe**

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Olga Löblová

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Abstract

International policy diffusion is often portrayed as a quasi-automatic process in which fashionable policy options spread from one country to another relatively unconstrained. This dissertation challenges this prevalent assumption and argues that variables mediating diffusion matter – not only as enablers of the process but also as potential hinderers. It studies the mediating role of domestic epistemic communities (groups of experts whose knowledge leads them to pursue a common policy goal) on the adoption of international policy trends. It finds that the central scope condition for the adoption of the communities’ preferred policies is decision-makers’ demand for their input. This is in contrast to existing scholarship, which assumes that decision-makers necessarily follow epistemic communities’ advice when facing complexity and uncertainty.

These findings result from a fresh look at the universe of cases of policy diffusion and epistemic communities’ influence that includes negative cases, often ignored in literature and policy debates, in addition to the well-analyzed positive ones. This dissertation studies the diffusion (and non-diffusion) of health technology assessment (HTA) agencies. HTA agencies are public bodies that evaluate available evidence on the medical, economic, ethical, legal, social and other aspects of health interventions – drugs, medical devices, diagnostic procedures, surgical interventions and the like. In a textbook case of policy diffusion, they have since the late 1980s spread from a handful of early adopters to most countries in Western Europe (leading to a “success bias” of the practitioner literature on HTA similar to the one prevalent in diffusion theory), but not to most Central and Eastern European countries.

The dissertation is composed of three independent papers which each examine the reasons for the halted diffusion of HTA agencies. Their findings are based on a set of 77 interviews with key health policy actors and document analysis. Paper I establishes a chronological taxonomy of HTA agencies

in the European Union. It finds structural variables unsatisfactory to explain the pattern of their diffusion, and proposes an alternative explanatory model focusing on the role of actors, more specifically domestic epistemic communities. Paper II tests this model empirically based on the Polish and Czech cases: Poland established an HTA agency in 2005, while the Czech Republic does not have one, despite a debate in 2011-2013. It finds a clear influence of the domestic epistemic community in both countries, which was, however, in the Czech Republic, moderated by a lack of policy-makers' demand for expert input. Paper III studies health policy actors' interests and policy positions regarding delegation of pricing and reimbursement competences to an HTA body in the Czech case, and confirms the key place of policy-makers' demand. It concludes that interests of actors (including the epistemic community of "aspiring agents") are close to irrelevant, as long as the principals do not perceive the need for expertise. Concluding remarks of the dissertation note the near non-existence of sound policy evaluation of HTA and suggest that policy-makers' willingness to listen to HTA epistemic communities may have more to do with their modernizing ambitions than with HTA's unclear achievements in improving the quality, equity or sustainability of health systems.

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To my mother.
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- Paper I: Löblová, Olga. 2015. “Three worlds of health technology assessment: explaining patterns of diffusion of HTA agencies in Europe.” Published in *Health Economics, Policy and Law* FirstView: 1–21.
- Paper II: Löblová, Olga. “When Epistemic Communities Fail: Exploring the Mechanism of Policy Influence”. *In revision*.
- Paper III: Löblová, Olga. “Who’s Afraid of Health Technology Assessment? Interests and policy positions for an HTA agency in the Czech Republic”. *Submitted*.
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List of abbreviations

EU	European Union
AAZ	<i>Agencija za kvalitetu i akreditaciju u zdravstvu i socijalnoj skrbi</i> , Agency for Quality and Accreditation in Health Care and Social Welfare (Croatia)
AHTAPol	<i>Agencja Oceny Technologii Medycznych i Taryfikacji</i> , Agency for Health Technology Assessment and Tariff System; also known as AOTM and AOTMiT (Poland)
AOTMiT	<i>Agencja Oceny Technologii Medycznych i Taryfikacji</i> , Agency for Health Technology Assessment and Tariff System; until 2015 known as AOTM, also known as AHTAPol (Poland)
AOTM	
CEE	Central and Eastern European
CMJ	<i>Centrum Monitorowania Jakości</i> , National Center for Quality Assessment in Health Care (CMJ)
CVZ	<i>College voor zorgverzekeringen</i> , Health Care Insurance Board (Netherlands)
DACEHTA	Danish Centre for Health Technology Assessment (Denmark)
EBM	evidence-based medicine
EUnetHTA	European network for Health Technology Assessment
FinOHTA	Finnish Office for Health Technology Assessment (Finland)
GDP	gross domestic product
GYEMSZI	<i>Gyógyszerészeti és Egészségügyi Minőség- és Szervezetfejlesztési Intézet</i> , National Institute for Quality and Organizational Development in Healthcare and Medicines (Hungary)
HAS	<i>Haute Autorité de Santé</i> , High Authority for Health (France)
HIQA	Health Information and Quality Authority (Ireland)
HTA	health technology assessment
ICER	incremental cost-effectiveness ratio
INAHTA	International Network of Agencies for Health Technology Assessment
IQWiG	<i>Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen</i> , Institute for Quality and Efficiency in Healthcare (Germany)
KCE	Belgian Health Care Knowledge Centre (Belgium)
LBI-HTA	Ludwig Boltzmann Institute for HTA (Austria)
LMICs	low- and middle-income countries
MD&D	medical devices and diagnostics
NFZ	National Health Fund (Poland)

NICE	National Institute for Health and Care Excellence (England & Wales)
OTA	Office of Technology Assessment
P&R	pricing and reimbursement
QUANGOs	quasi-autonomous non-governmental organizations
SBU	<i>Statens beredning för medicinsk och social utvärdering är en myndighet</i> , Council on Technology Assessment in Health Care (Sweden)
SMC	Scottish Medicines Consortium (Scotland)
SÚKL	<i>Státní úřad pro kontrolu léčiv</i> , State Institute for Drug Control (Czech Republic)
TLV	<i>Tandvårds- & läkemedelsförmånsverket</i> , Dental and Pharmaceutical Benefits Agency (Sweden)
VEC	<i>Veselības ekonomikas centrs</i> , Health Economics Centre (Latvia)
VZP	<i>Všeobecná zdravotní pojišťovna</i> , General Health Insurance Fund (Czech Republic)

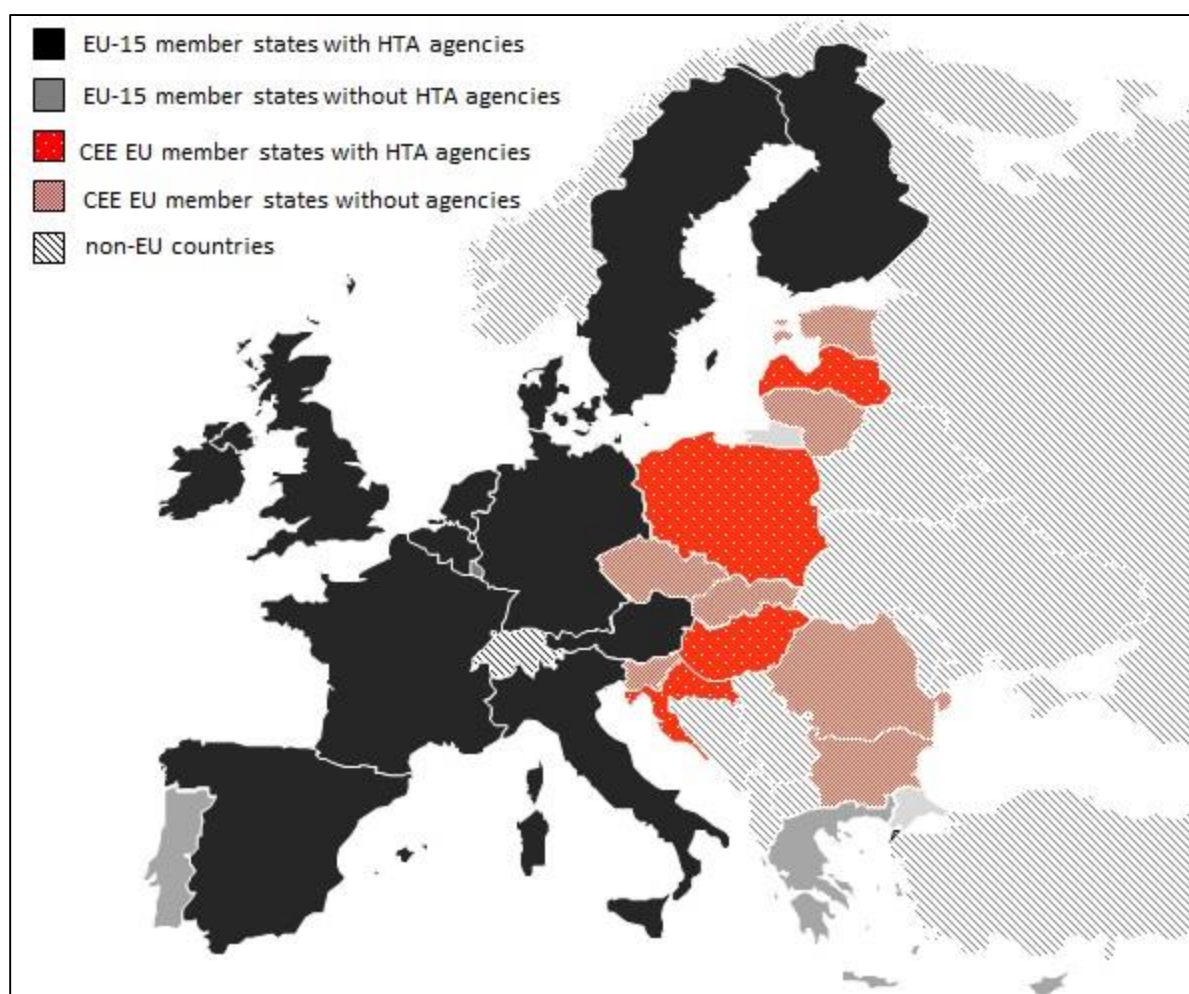
1. INTRODUCTION

Public health care is one of the pillars of the modern welfare state. In legal terms, the United Nations sees the entitlement to health care as a basic human right; in many European countries, the right to medical care is constitutionally guaranteed. In societal terms, modern medicine, access to health care and social policies have led to a dramatically increased life expectancy and quality of life over the past half a century (Bambra 2011; Deaton 2013). In economic terms, health care is responsible for the bulk of government spending in European Union (EU) countries, after pensions and social assistance (Eurostat 2015), and it constitutes about 9% of their gross domestic product, for which the largest payer is by far the state (European Commission & OECD 2014). Before the fall of Lehman Brothers, health expenditure grew faster than gross domestic product in most European countries (OECD 2015). Aging populations with increasing demands alongside the rising costs of new treatments and health care professionals' wages are the most often cited causes for this development (see Hartwig 2008), making it unlikely that health care will, in the near future, become a less costly enterprise. Given the limited resources available for health care, decisions must be made on how to allocate them without compromising on the advances in quality and availability of care achieved in the last century. This dissertation is about these decisions: specifically, who decides which treatments will be available to patients in EU countries and which will not.

In most of Western Europe, decisions on reimbursement from public funds are informed, or in some cases directly taken, by health technology assessment (HTA) agencies. HTA agencies are public bodies that evaluate available evidence on the medical, economic, ethical, legal, social and other aspects of health interventions – drugs, medical devices, diagnostic procedures, surgical interventions etc. In a textbook case of policy diffusion (Marsh & Sharman 2009; Benson & Jordan 2011; Shipan & Volden

2012), they have, since the late 1980s, spread from a handful of early adopters to most countries in Western Europe, with the goal of improving allocation of resources in health care by redirecting them from interventions whose effectiveness (and often cost-effectiveness) is not supported by scientific evidence (Sorenson et al. 2008). They differ in many respects, but share a belief in the superiority of evidence-based decisions, a goal of influencing policy, along with a commitment to the transparency of their methods, procedures and conclusions, the independence of their experts, and the inclusion of groups affected by their verdicts (see Drummond et al. 2008).

Figure 1:1. Map of HTA agencies in the European Union



Source: based on Table 3:1 in Paper I

In Central and Eastern European (CEE) countries, HTA agencies have been far less popular: only four of the eleven post-communist EU member states have so far established an HTA agency (see Figure 1 above). In these countries, decisions on pricing and reimbursement (P&R) of health interventions are usually taken at the ministry of health or within the public payer organization (typically the national health insurance fund). The extent to which they rely on scientific evidence is unclear, and the decision-making process in general lacks transparency (see Panteli et al. 2015, table S1). This is a concern to health economists and other proponents of HTA: the poorer the health system, the larger the opportunity costs of inefficiently allocated resources, making HTA even more desirable (Moran & Fidler 2010; Kaló et al. 2016). Why, then, do we see HTA agencies in some countries, mostly in Western Europe, but not in others? What has halted the diffusion of this popular policy trend?

The answer, as presented in the three papers making up this dissertation, based on an analysis of more than 70 interviews with health policy-makers and publicly available documents, lies in the efforts of domestic epistemic communities coupled with policy-makers' demand for their input. Epistemic communities are "network[s] of professionals with recognized expertise and competence in a particular domain and an authoritative claim to policy-relevant knowledge within that domain or issue-area", who pursue a common policy enterprise (in our case the establishment of HTA agencies) emerging from their shared set of normative and principled beliefs, shared causal beliefs and shared notions of what constitutes valid knowledge (Haas 1992, p.3). They do this by organizing dissemination activities to share information about their policy goal, actively framing the issue to which they link it, and by gaining access to policy-makers. They can become civil servants or advisors and consultants in the ministry of health, or get the "ear" of decision-makers informally, in order to convince them of the superiority of their proposed policy solution. All this activity, however, as this dissertation argues, is futile if policy-makers do not see the need for the advice of experts on the

matter. With issues like HTA, which are complex but not surrounded by uncertainty, this can happen if the problem the epistemic communities point out is more readily solved by alternative policy solutions. In other words, if it ain't broke, don't fix it – and if you can fix it with some duct tape, no need to call the mechanic.

That policies are not adopted if policy-makers do not see the need for them may sound like stating the obvious, yet neither the epistemic communities literature nor works on the diffusion of HTA pay due attention to the phenomenon. Much of the epistemic communities scholarship implicitly expects decision-makers to unquestioningly welcome and accept any advice coming from recognized experts (for a critique of this blindspot, see Dunlop 2009). This may well be true for previously unknown policy problems, such as environmental protection (Haas 1989), where significant uncertainty surrounds the nature of the issue itself, as well as the appropriate policy responses to it. But epistemic communities can be influential even in areas familiar to policy-makers, such as pension reform (Marier 2008) – or pricing and reimbursement of health care services. This suggests that the key condition for epistemic communities' influence is not uncertainty but the demand of those in power for their input: they actively seek or accept experts' solutions if they see the need for them. The reverse also applies: no amount of compelling scientific arguments will convince decision-makers to implement a policy if they fail to see the problem, or if the problem disappears with the proverbial duct tape application.

Similarly, acknowledging that alternative solutions play an important role is a challenge for the literature on the diffusion of HTA. Most of these works focus on low- and middle-income countries (Oortwijn et al. 2013; Lopert et al. 2013; Kaló et al. 2016; Sivalal 2009; Oortwijn et al. 2010), although some look at Western Europe (Ciani et al. 2012; Wild & Gibis 2003). More often than not, this literature operates with an implicit “laggard” hypothesis to explain the lack of HTA bodies in most low- and middle-income countries (LMICs): countries without HTA are “not *yet* part of the story”

(Banta & Jonsson 2009, p.1, emphasis added) but will inevitably institutionalize HTA if its proponents sufficiently engage in “promoting the understanding of the concept of HTA” (Oortwijn et al. 2010) and “training [...] government officials” (Danko 2014).¹ The epistemic communities literature provides theoretical backing to this practice-derived recipe for establishing an HTA agency based on intense advocacy with policy-makers – in LMICs and elsewhere. But just like the epistemic communities approach, the “laggard” writing on HTA focuses too much on the experts’ role, and consequently deprives decision-makers of agency. This dissertation aims to remind both literatures that policy-makers have their own concerns and priorities that sometimes do not overlap with experts’ policy preferences.

The remainder of this introduction first looks more closely at what health technology assessment and its institutional forms are. Next, it reviews potential explanations for why HTA agencies diffused to some EU countries but not to others, putting forward epistemic communities as the key mediating factor of the unhampered spread of the policy. It then explains the structure of the dissertation based on three individual papers, and finally elaborates on the contributions of the work to public policy literature and the practical policy debates on institutionalizing HTA.

1.1. Health technology assessment and its institutionalization

The object of study in this research project is relatively straightforward: the establishment, or non-establishment, of health technology assessment agencies. However, neither “health technology

¹ It is perhaps not surprising that the literature almost unanimously agrees on the inevitability of HTA as the best fix to problems of health care resource allocation: most authors writing on HTA from a public policy perspective belong to the international epistemic community of HTA experts. By definition, they believe in the appropriateness and superiority of their favored policy. Many of them are founding members of the field, and their writings tend to highlight the key role they played both as individuals and as members of international networks in institutionalizing HTA (Banta, Jonsson, et al. 2009; Banta & Jonsson 2009; Banta 2003; Battista & Hodge 2009; Jonsson 2002; Banta, Kristensen, et al. 2009). Others are involved in consulting activities on setting up HTA in LMICs (Lopert et al. 2013; Ecorys n.d.). The epistemic communities literature indicates their assessment may indeed be far from exaggerated.

assessment” nor “HTA agency” have immediately obvious delimitations grounded in theory or empirical observations. “HTA”, as commonly referred to in policy debates as well as in academic publications, has three different meanings: *HTA as a method*; *HTA as a policy*; and *HTA as organizations*. To illustrate the multifaceted nature of HTA, consider a question common in the milieu of P&R policy: “Does this country have HTA?” “Having HTA” in this context means primarily having a public body whose principal task is to provide formal and regular input, based on HTA methods, to P&R decision-makers. It could, however, also mean having input based on HTA guide decisions informally, or having an active community of researchers who use HTA methods. The three meanings have evolved together and are closely interlinked², which is why they warrant being briefly elaborated upon in the following paragraphs. Throughout the three papers, this dissertation focuses on the organizational and policy dimensions of HTA, paying less attention to the methodological details of HTA, but refers to all of its various meanings depending on the context.

The complexity of the three meanings of HTA is perhaps due to its origins at the intersection between science and policy, and its later development both within and outside of public structures. The beginnings of health technology assessment date to 1975, when the United States Senate Subcommittee on Health asked the Office of Technology Assessment (OTA, dismantled in 1995) to examine the potential benefits of evaluating medical technologies (Office of Technology Assessment 1976). OTA indeed found benefits in systematic evaluation, and later produced the first HTA reports. Other governmental and public bodies, notably the Swedish Council on Technology Assessment in Health Care (SBU), founded in 1987 and described usually as the first national-level HTA agency, also played an important role in stimulating the production of HTA reports based on policy demands (Banta, Kristensen, et al. 2009). The beginnings of HTA were therefore initiated by policy-makers who

² perhaps with an additional layer of HTA as an academic field of study

were actively searching for a way to inform decisions. In parallel, though, HTA reports were being developed in the pharmaceutical and medical devices and diagnostics industry as well as in academia (Banta & Jonsson 2009). Later, HTA first emerged in many countries (typically the “mainstreamers”, described in Paper I, who adopted HTA in the mid-2000s) without a similar pull from the government side, but rather through a push from HTA experts – academic researchers and consultants.

The interplay of method and policy is reflected in the commonly used definitions of HTA. The earliest comes from the United States Congress’ OTA that described HTA as “a comprehensive form of *policy research* that examines the short- and long-term social consequences (e.g. societal, economic, ethical, legal) of the application or use of technology” (Office of Technology Assessment 1976, p.45, emphasis added).³ The International Network of Agencies for Health Technology Assessment (INAHTA), uniting public bodies interested in HTA, defines HTA as

“the systematic *evaluation* of the properties and effects of a health technology, addressing the direct and intended effects of this technology, as well as its indirect and unintended consequences, and *aimed mainly at informing decision making* regarding health technologies” (INAHTA 2016, emphasis added).

In Europe today, the most commonly used definition is the one developed by EUnetHTA, a network of EU member states’ (and neighboring countries’) HTA bodies: HTA is

“a multidisciplinary *process* that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner [whose] aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value. *Despite its policy goals*, HTA must always be *firmly rooted in research and the scientific method*.” (EUnetHTA n.d., emphasis added).⁴

³ Health technology was understood here in all-encompassing terms to include all interventions used for prevention, diagnosis, treatment, support, and administration, including equipment and facilities but also knowledge and skills (Office of Technology Assessment 1976, p.4). All of the subsequent definitions here echo this understanding of HTA, as well as of what constitutes health technology.

⁴ The EUnetHTA definition is, for obvious reasons, routinely used by projects funded by the EU, both in academic publications and policy literature. However, it has also been employed by political science observers of EU involvement in HTA (see Böhm & Landwehr 2014).

In other words, HTA as a method and HTA as policy stand in symbiosis, whereby the method can sometimes exist without being directly used in policy, but is most often closely associated with it. As a method of inquiry, HTA can, in principle, be carried out by anyone with the right resources (academic centers, industry, for-profit consultancies etc.), for a number of purposes (e.g. to provide arguments for a medical device manufacturer to help a hospital decide whether to purchase an MRI scanner), but is mostly done by the government for its needs.

These definitions reveal a lack of consensus on *what* exactly HTA is: a “form of policy research” for OTA and a “process” for EUnetHTA, suggesting an understanding of HTA as a policy, and an “evaluation” for INAHTA, suggesting a method. To this we can add the various descriptions of HTA as a “field” (used interchangeably with “method” in e.g. Banta 2003; Goodman 2004) or a “discipline” (e.g. Sampietro-Colom 2012; EUnetHTA 2008, p.65), which point to the development of HTA within academic structures.⁵ These disagreements are, however, for the most part inconsequential to policy debates about HTA. Literature on HTA indirectly acknowledges that health technology assessment can mean different things in different contexts, and focuses instead on the broad points of consensus: its primary goal is to influence policy decisions, and its conclusions should be reached through a comprehensive, systematic inquiry. This is also very much the overarching stance of this dissertation.

The boundaries of HTA as a *method* are in themselves unclear. A number of methodological approaches co-exist, emphasizing various parameters and criteria: comparative effectiveness analysis, relative effectiveness analysis, cost-effectiveness analysis, cost-utility analysis, or health outcomes analysis would all generally be seen either as subparts of HTA or closely related to it, although some of these approaches emphasize economic consequences of an intervention, while others disregard economics altogether and focus on its added clinical benefit (see Messner & Mohr 2015; Luce et al.

⁵ Some academic journals also list “HTA” as a discipline on a par with political science or health economics (but also health services research).

2010). Within most of these approaches, more detailed debates can be found for instance on the appropriate levels of discounting of future costs or the inclusion of monetary costs and benefits for the entire society rather than for the payers (mandatory health insurance funds or national health service organizations) (Drummond et al. 2015; Jönsson 2009; van den Berg et al. 2004). Similarly, analysis of social or ethical aspects of health interventions is for some authors a key part of HTA, but often absent in practice (cf. Hofmann 2008). None of these approaches would be *a priori* excluded from being considered as HTA in academic or policy forums, leading to an understanding of HTA as an “umbrella term” (Eddy 2009, p.56). This is also the conceptualization of the methodological side of HTA used in the papers making up this dissertation: it is HTA if the authors call it HTA.

As a *policy*, HTA typically refers to the use of HTA methods for the purpose of informing decisions on pricing and reimbursement. Because of the broad delimitations of HTA as a method, HTA is here synonymous with the use of evidence for policy-making purposes – any evidence-based approach to P&R decisions is likely to be labeled as HTA. For instance, multi-criteria decision analysis, a similar method to HTA emphasizing the multitude of criteria as opposed to, for instance, only cost-effectiveness or only relative effectiveness, is sometimes viewed as separate from HTA, but is often portrayed as its subpart (see e.g. Tony et al. 2011; Devlin & Sussex 2011). This means that HTA does not have a directly competing policy option *per se*: the alternative to health technology assessment is *non-assessment* of health technologies.

In practice, this implies their inclusion in lists of reimbursed health interventions without due consideration of available evidence – the alternative to HTA, evidence-based policy-making, then becomes “evidence-blind” or “evidence-ignorant” policy-making, which is, for obvious reasons, hard to justify for policy-makers. An increased use of evidence has, for HTA, the overarching goal of improving “allocative efficiency”, which should theoretically in turn lead to the improved

sustainability, quality or equity of the health system. It is on these end-goals that other policies compete with HTA. Quality and equity concerns can be addressed with increased spending; decreased or controlled spending (“sustainability”), arguably the most urgent concern of European governments in the past decade, can be addressed by various cost-containment measures. International reference pricing or managed-entry agreements, for instance, would be popular health policy trends, diffusing with perhaps greater vigor than HTA. Neither of them, however, aim at changing the epistemic and normative foundations of how decisions on P&R are reached. The only acceptable alternative to HTA, then, is not adopting it, i.e. maintaining the status quo and engaging in similar parametric reforms of existing policies (the policy equivalent of duct tape). Status quo, in CEE countries at least, often means implicit rationing (see Ham & Coulter 2001), where interventions are either officially reimbursed, but in practice rationed at the bedside by health care providers, or are not added on reimbursement lists without explanation, making normative arguments for its sustaining difficult to find.

Considering HTA as *organizations* makes arguing against it even more difficult. Just as HTA both as a method and as a policy is associated with the trend of evidence-based policy-making (itself linked to the rise of evidence-based medicine, see Smith 2013), public bodies specializing in HTA have been linked to the popularity of the independent agencies and quasi-autonomous non-governmental organizations (QUANGOs), quasi-autonomous governmental organizations and non-departmental public bodies (Maggetti 2009; Pollitt et al. 2004; Christensen & Lægreid 2007; Gilardi 2008; Wettenhall 2005; for a direct application on P&R and HTA see Landwehr & Boehm 2011; Landwehr & Böhm 2014; Böhm et al. 2014). The *modus operandi* of these QUANGOs has followed the broader prominent policy fashions of transparency, inclusiveness and expert independence, associated with general trends of (good) governance (Rhodes 1996; Peters & Pierre 1998; Weiss 2000; Andrews 2010). All of these principles have been criticized regarding their effectiveness, both in health care and beyond (for instance, on transparency: Hood 2007; Etzioni 2010; O’Neill 2004; on evidence-based, rational-

comprehensive decision-making: Lindblom 1959). They represent nonetheless powerful forces in the policy-making of the past two decades, which have together created an ideal-typical model of an HTA body.

In practice, existing HTA bodies differ in many aspects, from the kind of competences and independence these institutions have, to the methods they use, the degree to which they make their proceedings transparent and inclusive of other parties such as patients or industry, or their human resources and their output (see Allen et al. 2013; Panteli et al. 2015). Some HTA bodies in Europe have formal regulatory power, with their decisions binding for payers (e.g. Sweden's TLV⁶); others have an advisory role (e.g. Austria's LBI-HTA). Most evaluate only medicines (with some evaluating only new applications for reimbursement and some reassessing older drugs, too) but some also, in accordance with the standard definitions of HTA, consider medical devices and diagnostics (MD&D) and health care services (e.g. the Polish AOTMiT). Some deal with all new applications for reimbursement, leading to hundreds of recommendations or decisions a year (NICE), while others focus on a handful of selected, typically high-cost, technologies (e.g. Belgium's KCE). Of these, some choose the topics of their assessment themselves while others are tasked by the ministry of health or payer organizations. Most HTA institutions are arm's length bodies with at least some degree of independence, but in some cases units within payers or the ministry of health use HTA for its decisions (e.g. Romania), while some EU countries have both (e.g. Ireland, Austria). Some are known for giving preference to economic criteria (NICE), while others put emphasis on clinical benefit (France's HAS). Some include major stakeholder groups such as patients, health professionals and the industry in their

⁶ For intelligibility purposes, the paragraphs in this section use abbreviations only, by which they are typically known in the P&R policy circles. TLV = Tandvårds- & läkemedelsförmånsverket, Dental and Pharmaceutical Benefits Agency; LBI-HTA = Ludwig Boltzmann Institute for HTA; AOTMiT = Agencja Oceny Technologii Medycznych i Taryfikacji, Agency for Health Technology Assessment and Tariff System; NICE = National Institute for Health and Care Excellence; KCE = Belgian Health Care Knowledge Centre; HAS = Haute Autorité de Santé, High Authority for Health; AAZ = Agencija za kvalitetu i akreditaciju u zdravstvu i socijalnoj skrbi, Agency for Quality and Accreditation in Health Care and Social Welfare

procedures (NICE), while others do not (AOTMiT). There is also variation in the degree of transparency of their procedures (Panteli et al. 2015). In short, none of the existing HTA institutions correspond perfectly to the ideal-type in all respects, but embracing some of the elements, to at least some extent, usually guarantees them acceptance of international associations of HTA bodies such as INAHTA or EUnetHTA.

It also guarantees them a consideration in this dissertation. To reflect the diversity of possible institutional models and the many meanings of HTA, this introduction as well as the concluding remarks refer to HTA “bodies” and “institutions”. In the first paper, however, HTA institutions are defined more narrowly as HTA “agencies” that “provide expertise in order to advise decision-makers or make decisions themselves on reimbursement matters, and are public bodies with some degree of independence”, following Pollitt and colleagues’ (2004) broad working definition of agencies and QUANGOs. Such a reduction in complexity is necessary for the purposes of observing the diffusion of a policy trend across a medium number of cases, although this operationalization leads to an emphasis on the independence from government of the HTA bodies, perhaps to the detriment of other dimensions. For instance, Croatia’s AAZ was considered as an HTA agency because of its relative arm’s length distance from the ministry of health, despite the fact that in terms of human resources, number of HTA reports produced and influence on P&R decisions, it would be comparable with HTA units of the ministry of health and payer in Lithuania, which would not be considered HTA agencies (see Wild et al. 2015; Huic 2014). The independence dimension nevertheless testifies to policy-makers’ commitment to the ideal-typical HTA body – an independent institution is likely to be more transparent and more inclusive than a ministerial unit or a committee.

The label “HTA agency” is maintained in the second paper, following the ideal-type model. Avoiding detailed discussions of the nature of HTA and formulating the dependent variable as the establishment

of an agency is necessary for political science readers. As the aim of the paper is theoretical improvement of the mechanism of epistemic communities' influence on policy-making, HTA could in principle be any policy proven to diffuse in some contexts but not in others. Whether HTA uses cost-effectiveness or relative-effectiveness analysis is mostly irrelevant for the paper.

This strict operationalization of HTA as an ideal-typical agency is relaxed in the third paper and replaced with an understanding of HTA as both the organizations and the policy of incorporating their input into decisions. Together, these are understood as "HTA institutionalization", in line with the interpretation of some HTA literature on the one hand (Moharra et al. 2009; Henshall et al. 2002; Gibis et al. 2001), and the new institutionalist understanding of institutions as sets of rules and practices on the other hand (March & Olsen 1996; March & Olsen 1998; Hall & Taylor 1996). In a single case study, it is possible to observe how the various possible ways of institutionalizing HTA, overtly proposed by policy-makers or anticipated by health policy actors, impact upon the formation of policy positions in favor or against HTA in general. It also shows how intertwined the three facets of HTA are, and how their demarcation, although sometimes useful for analytical purposes, can be illusory: uncertainty about the institutional design of the organizations sometimes triggers resistance to its policy foundations, and expectations about methodology affect preferences for the institutional design.

1.2. Why do countries institutionalize HTA?

This dissertation argues that the intriguing distribution of institutionalized HTA in Europe is the result of a process of international policy diffusion, mediated by intervening factors in the adopting countries. The alternative explanation to policy diffusion would be that HTA bodies are the result of

independent problem solving on the part of individual governments. However, that decision-makers across Europe (and around the world) arrive on their own to a policy as complex as HTA, with its sophisticated methods, vocabulary and objectives, as well as similar institutional features, is highly unlikely. To some extent, this could in theory be plausible for the original innovators (the “forerunners” in Paper I). However, the conscious and coordinated efforts of the founders of the field, as described in a number of memoir papers (Banta 2003; Banta & Jonsson 2009; Banta, Kristensen, et al. 2009; Jonsson 2002; Battista & Hodge 2009), contradict this null hypothesis – the ideas of HTA spread to the forerunners’ governments through international and national communities of its proponents, informed by its applications in the very early adopting countries. Arriving independently to the same solution without any international inspiration is even less likely for the later adopters. Policy diffusion, or in other words the influence of one country’s policy choices over others’, is therefore the starting point of our analysis.

Policy diffusion is a popular concept in political science, with nearly a thousand scholarly articles published on the topic in the past 50 years (Shipan & Volden 2012). The term routinely subsumes a number of closely related labels, such as policy transfer, learning, lesson-drawing, policy convergence, institutional mimicry or institutional isomorphism (see Graham et al. 2013). Although these concepts are sometimes distinct (cf. Marsh & Sharman 2009), they are united by their central assumption that decision-makers’ policy choices are often not independent, but influenced by the previous choices of other decision-makers (Simmons et al. 2006; Gilardi 2015; Graham et al. 2013). A vast literature has demonstrated that policy choices make their way across cities, states, countries or regions; for later students of diffusion, the question then became *how*, focusing on mechanisms through which diffusion works, rather than *whether* they spread (Heinze 2011; Shipan & Volden 2008; Meseguer & Gilardi 2009; Howlett & Rayner 2008). This has recently been challenged by a call for a renewed look at the universe of cases diffusion scholars typically study. Without disputing the overwhelming body of evidence that

policies diffuse, Karch and colleagues (2016) point out the biased case selection in most of the literature and note that policies sometimes diffuse, but sometimes they do not – as in the case of HTA in Central and Eastern Europe.

Reasons for this may lie in the characteristics of the policies that diffuse, or of the polities that decide on adopting them. The former explanation, suggested recently (Makse & Volden 2011) and relatively unexplored so far (see Petridou 2014), supposes that some policies, i.e. complex ones or those that are difficult to try, are less likely to diffuse than others. However, there is little reason to expect that HTA would fall into this category: its spread to the mainstreamers demonstrates its potential for diffusion, suggesting that the differential variable is to be found rather within the latter category: the adopting polity. This is why this dissertation does not study in detail the attributes of HTA as a policy, but focuses instead on the factors mediating diffusion in countries considering its adoption.

The policy diffusion literature recognizes a number of these mediating variables. These are typically of a structural nature, perhaps owing to the quantitative dominance in the diffusion literature. They include path dependency and institutional and structural impediments (i.e. important veto players), both of which are more or less similar across the post-communist countries of Central and Eastern Europe; ideological compatibility between transferring countries (e.g. governments of the same political color); and resource limitations of the receiving country (Benson & Jordan 2011). Most of these, especially resource limitations, are taken over by the health policy literature, including works on the diffusion of HTA, and adapted to the health sector, such as the degree of centralization of health system governance (i.e. the amount of veto players) and the type of health system financing (Bismarck vs. Beveridge) (Bravo Vergel et al. 2005). A twist on the ideological compatibility variable specific to the diffusion of HTA agencies, would be the attitude of individual countries to establishing QUANGOs and agencies in general. Finally, international organizations (or other significant

countries) can influence policy diffusion (Meseguer 2004; Meseguer 2005; Weyland 2005; Marsh & Sharman 2009). These mediating factors are elaborated upon in more detail and juxtaposed with empirical findings from 28 EU member states in Paper I, which finds that none of them explain the patterns of diffusion of HTA agencies in Europe in a satisfactory manner.

This dissertation therefore proposes to look beyond the medium-to-large N perspective conducive to pointing out structural factors, and to explore in detail the role of actors. In diffusion studies, this means examining the roles of policy entrepreneurs and experts, elected officials, political parties, bureaucrats, or pressure groups (Dolowitz & Marsh 1996; Rose 1993). Interest group politics are perhaps the most ready explanation, as they are likely to be highly influential in low-salience policy areas such as HTA (Lohmann 2003; Culpepper 2010). Some of the “laggard” HTA literature also points to the vested interests of powerful actors as one of the reasons for the non-existence of HTA in many countries (Kaló et al. 2016). Literature on HTA provides relatively little information on the interests and preferences of key actors regarding HTA and its institutionalization; a quick overview is given by way of Banta’s use of interest groups’ priorities to explain diverging institutional designs of HTA organizations and policies in Europe:

“Probably a considerable part of the differences in HTA by country has depended on the interests of particular societal groups:

- 1) Policy-makers: Broad concerns, but tending toward the value for money perspective.
- 2) Insurers: Over-riding concern for expenditures and their control.
- 3) Clinical physicians: Mostly interested in quality, little attention to expenditures or other public policy issues.
- 4) Epidemiologists and other researchers: Interest in the poor state of research and how to improve it, including attention to systematic reviews and dissemination of information.
- 5) Industry: Over-riding concern for profits, however, competition forces increasing attention to efficacy and cost-effectiveness.
- 6) The general public: Access to personal care of acceptable quality” (Banta 2003, p.129).

Banta’s theorization is useful despite its brevity. It has the merit of advancing falsifiable hypotheses about actors’ interests, which can serve to inform, or complement, expectations derived from

literatures on authority delegation (Moe 1990; Bendor et al. 2001; Gilardi 2008; Sweet & Thatcher 2002; Thatcher 2002) and regulation (Posner 1974; Stigler 1971). Combining these literatures is done in Paper III. The result is a simple qualitative political economy model of actors' interests and policy positions on institutionalizing HTA, amenable to empirical testing. Studying it with the help of the Czech case suggests that interest group resistance is not necessarily the key mediating factor in the diffusion of HTA, owing to the extremely low salience of the topic for most actors. By extension, the same holds for other common groups of actors identified by the policy diffusion literature, including political parties and politicians (but see King 2005 on how increased salience brings electoral politics back into the picture).

There is one group of actors, though, for whom HTA is of high priority: the epistemic community. In Banta's overview, this is the fourth group: "epidemiologists and other researchers", who have a strong interest in improving knowledge. This corresponds remarkably closely to Peter Haas' (1992) concept of epistemic communities – groups of experts with a common policy goal derived from their shared knowledge. Epistemic communities can be understood as policy entrepreneurs driving policy change, especially at the international level (cf. Zito 2001; also Haas 1992; Adler & Haas 1992; Galbreath & Mcevoy 2012). This dissertation argues that they are the crucial mediators of policy diffusion – not only at the international level, but also domestically. They influence domestic politics by disseminating their views and perspectives, gaining access to decision-makers (most often ministry of health) and convincing them of the superiority of their policy proposition. How they do this is explored in detail in Paper II, which also insists that there is a condition to the success of their enterprise: policy-makers must perceive the need for the epistemic communities' input. Without it, epistemic communities' efforts in dissemination, getting the attention of decision-makers and putting forward persuasive arguments, are futile.

Of course, demand can be stimulated by the epistemic communities themselves. This dissertation argues, in Paper III, that in addition to the purely scientific and evidence-oriented motivations authors like Banta as well as the epistemic communities literature assign to them, members of the group are perhaps also moved by self-interest. Because of their specialized expertise, they can expect to gain material and reputation benefits from any new institutions created by their favored policy solutions. For this reason they should be seen, in the numerous policy areas amenable to authority delegation to expert bodies, as “aspiring agents” with an extra stake in seeing their favored policy option adopted.

1.3. Structure of the dissertation

Following this introduction a *methodological chapter* elaborates on the selection of cases for this dissertation, data and sources, methods and researcher positionality. The substantive part of this dissertation is made up of three independent papers, each of which address, from a different angle, the overarching research question: why have some EU countries not established HTA bodies? Together, Papers II and III provide empirical support to the explanatory model for HTA-agencification as a result of the activities of domestic epistemic communities, suggested in Paper I.

Paper I elaborates in more detail on the uneven distribution of HTA bodies in Europe, describing how the policy trend of setting up HTA agencies has diffused in Europe, forming the “three worlds of HTA” in the 28 EU countries: the *forerunners*, who set up HTA bodies in the 1990s, the *mainstreamers*, following in the mid-2000s, and the *non-adopters* – countries which have not set up HTA institutions. It goes on to examine a number of structural variables that political science and health policy literature would expect to mitigate the smooth diffusion of the trend. All of them leave the position of numerous countries within their respective “world of HTA” unanswered, which is why the paper proposes an

alternative explanatory model focusing on the role of actors, more specifically domestic epistemic communities, in the diffusion of HTA agencies.

Paper II tests this model empirically. It goes part by part through the mechanism of influence of epistemic communities on policy-makers in a mainstreamer country (Poland) and in a non-adopter (Czech Republic), and compares how the respective domestic epistemic communities influenced – or did not influence – policy-makers to establish a specialized HTA institution. In Poland, the mechanism went smoothly and reached its endpoint – the adoption of an HTA agency – as expected by the epistemic communities theory. The Czech Republic, surprisingly, followed an almost identical process: here, too, an epistemic community came together around the policy goal of HTA, started promoting its policy objective, gained access to decision-makers and convinced them of the desirability of HTA. In fact, the Czech HTA community managed to convince three successive ministers of health of the advantages of HTA. In contrast to Poland, however, the problem to which the Czech epistemic community linked HTA (uncontrolled medical devices and diagnostics spending) was more straightforwardly addressed by an alternative policy. This points to the crucial role of decision-makers' demand for expert input – if there is no need for the advice of HTA experts, then institutionalized HTA is unlikely to see the light of day.

Paper III echoes this conclusion from the perspective of authority delegation dilemmas. It takes up a matter often neglected by the epistemic communities literature: interests. Although it is acknowledged that epistemic communities do not operate in a vacuum, unopposed by any other actors (Sebenius 1992; Dunlop 2000; Zito 2001), relatively little is known about how they position themselves with regards to other actors of the health policy subsystem, and how they compete with them to convince decision-makers of the superiority of their ideas. The paper uses the recent Czech debate on HTA to examine the preferences of key health policy actors. It does so by studying the creation of HTA bodies

as a case of authority delegation, rather than a generic, replaceable example of a policy diffusing across polities. From a delegation perspective, decision-makers' demand for expertise is, again, the central scope condition for principals to create an agent to take over some of their competences. If they do not see the need – because they can perform the tasks themselves without delegation, or perhaps delegate to a different agent with lesser discretion – they have no motivation to create new agents. The Czech case suggests that interests of other actors are close to irrelevant (be they in favor of delegation, as with the epistemic community of “aspiring agents”, or against it, as with the MD&D industry), as long as the principals do not perceive the need for expertise.

The final article takes the form of an opinion piece to venture into the normative realm and serves as *concluding remarks* to this dissertation. Continuing the discussion in Paper III, it criticizes the prevalent tendency in HTA policy practice to overestimate the benefits of the policy, noting the near non-existence of serious policy evaluation of HTA, and puts forward a hypothesis that policy-makers' hesitation to introduce HTA into pricing and reimbursement decision-making may well be because due to its ability to solve their most urgent problems not having so far been demonstrated. It suggests, in line with Paper II, that their willingness to listen to HTA epistemic communities may have more to do with their modernizing ambitions than with HTA's track record in improving the quality, equity or sustainability of health systems.

Work on this dissertation has led to three additional co-authored papers related to matters of HTA and pricing and reimbursement in Europe. They address questions of HTA in Central and Eastern Europe (Gulácsi et al. 2014), pricing and reimbursement decision-making in CEE (Rotar et al. n.d.), and HTA at the EU level (Greer & Löblová 2017). These papers are not submitted as part of this dissertation but their findings complement the points made by this dissertation.

Gulácsi et al. (2014) give an overview of HTA in CEE countries, including its institutionalization, the scope of its analysis, criteria for analysis, its outputs and human capacities. This adds nuance to the claim made by Papers I and III that there are blank spots on the map of European HTA. Gulácsi et al. show that these spots are rather in varying shades of grey, but support the overall claim of this dissertation that, while knowledge about HTA bodies has indeed diffused to most countries without HTA them, actually adopting the policy is a different matter entirely.

Rotar et al. (n.d.) take a deeper look at one of the policy alternatives to HTA mentioned in Paper III of this dissertation as preferred by some key health policy actors: managed-entry agreements (“risk-sharing agreements” in the words of the interviewee in Paper III). The paper provides context to the diffusion of HTA bodies as opposed to other policies tackling pricing and reimbursement – it shows that managed-entry agreements have been adopted by CEE countries much faster than the comparatively older policy of HTA. This suggests that there are no inherent structural obstacles to quickly adopting international policy trends in CEE countries as such – for instance, a lack of the administrative culture necessary to absorb policy innovations in pricing and reimbursement – and emphasizes the relevance of asking why HTA followed a different pattern.

Greer & Löblová (2017) look at the institutionalization of HTA at the EU level, describing the keen interest the European Commission had in HTA and the activities with which it supported the development of European and national networks of HTA experts. This on the one hand moderates the conclusion in Paper I about the limited impact of the EU on national-level HTA institutionalization – clearly EU influence was not negligible, at least in some countries. On the other hand, it confirms the lack of coercion on the part of the European Union: the EU did not actively try to force – or even to incentivize in a significant manner – member states without HTA bodies to establish them.

The three co-authored papers are available to the readers of this dissertation upon request.

1.4. Contribution to policy debates and scholarship

The three papers in this dissertation draw on different scholarly traditions and target different readerships: political scientists and HTA specialists working on European health policy in Paper I, public policy scholars and political scientists in Paper II, and interdisciplinary health policy practitioners as well as academics in Paper III, as well as in the concluding remarks. For these reasons they offer different contributions to scholarship and policy practice, summarized individually in each piece.⁷ However, they also aim at advancing practical and scholarly debates when read together.

Regarding the policy discussions on institutionalizing HTA in countries without dedicated HTA bodies, the papers in this dissertation start by debunking a common misperception a reader of the HTA policy literature might easily have: that HTA has been adopted nearly everywhere across Europe – innumerable papers on HTA start by asserting the importance of the topic by listing the many countries that have institutionalized HTA, leaving aside those that have not (e.g. Drummond et al. 2008). While focusing on cases of adoption makes sense for describing and analyzing developments in HTA, which is admittedly the aim of most practitioner HTA literature, it creates a distorted picture of the universe of cases. This is most crudely reflected in the discourse within countries that do not have HTA agencies: a well-circulated, widely accepted, map of HTA in Europe by a Czech HTA proponent suggested that all European countries, except for the Czech Republic, had HTA institutions (Doležal 2013, p.8). Both policy-makers in countries without HTA institutions and the international HTA community pushing for their favored policy solution then risk adopting the “laggard”

⁷ It is also for these reasons that the general presentation, including the referencing style, differ between the three papers and the concluding remarks. While this may be unusual, it makes it immediately visually clear for the reader that the papers are indeed targeting different audiences.

hypothesis, which decrees that all countries will inevitably establish HTA agencies in the near future – it is just a matter of time.

The laggard assumption is far from insignificant; on the contrary, it costs money. The European Union, as well as the World Health Organization, the International Monetary Fund and high-profile consultancies such as NICE International, all indiscriminately recommend and promote introducing HTA in P&R decision-making in low- and middle-income countries. These recommendations sometimes come with direct financial conditionality, as in the case of World Bank loans. Sometimes they are accompanied by unconditional, but earmarked, financial or technical assistance, as with the EU pre- and post-accession technical assistance funds in Croatia or Poland. In countries receiving the advice, as well as in those disseminating it, governance resources are invested based on the reluctance to question the theoretical argument that having an HTA agency is undoubtedly an important asset for all health systems, particularly those of poorer countries. This may well be true – but it is an empirical question, and one that deserves to be raised. By focusing on the critics of HTA in countries that did not follow the trend, this dissertation brings attention to the unclear ratio of costs and benefits of institutionalized HTA for policy-makers.

As concerns contribution to academic knowledge, the starting point for all three papers is identical: a fresh look at the universe of cases which includes a serious consideration of negative outcomes. This leads to a renewed set of questions for the study of policy diffusion as well as the epistemic communities scholarship and the delegation literature. The vast body of works on policy diffusion (and related concepts such as policy transfer, learning or convergence) has produced extensive knowledge, both theoretical and empirical, on how and why policies diffuse, but has for the most part ignored the obvious fact that many policies do not diffuse at all or not everywhere and not with the same speed (Graham et al. 2013; Karch et al. 2016). By ignoring an entire universe of negative cases,

the policy diffusion scholarship, similarly to the HTA laggard literature, overestimates the importance of diffusion (Karch et al. 2016) and too often tacitly assumes that whoever wants to adopt a policy tried abroad can do so, and focuses rather on why and how this process works than on whether it works (see Benson & Jordan, 2011; Marsh & Sharman, 2009). This dissertation challenges this prevalent assumption and argues that variables mediating diffusion matter – not only as enablers of the process but also as potential hinderers. It explicitly tests a number of factors possibly mediating the diffusion of a particular policy, from broad structural variables such as a country's gross domestic product to issue area specific ones such as its health system financing. Comparing both negative and positive cases of diffusion with potentially common mediating variables contributes to the correction of the pro-innovation bias and the overestimation of findings about its mechanisms and processes, which the literature exhibits in its current state (Karch et al. 2016).

The benefits of studying negatives cases are perhaps most apparent in this dissertation when applied to the epistemic communities literature, whose “success bias” is even more evident than in the case of the diffusion scholarship. Following the concept's launch in the *International Organization* special issue (Haas 1992; Adler & Haas 1992), most of its applications focused on single case studies where the influence of epistemic communities on policy-making was substantial and unquestionable (Cross 2012; Dunlop 2009). This can be explained by the concept's initial focus on explaining cases of policy convergence and cooperation at the international level, which were a puzzle to prevailing international relations theories at the time of Haas' seminal work. If the concept is to be applied more broadly as a framework for explaining policy change, it needs to explain an absence of change, as well as successful change. By unlocking a universe of cases at the domestic level where comparison is more straightforward than at the international scene, this dissertation demonstrates that the weakness of the epistemic communities approach in explaining cases of non-adoption of the communities' preferred policies can be attributed to the literature's underdeveloped understanding of the causal mechanism

and the scope conditions necessary for its smooth functioning. It makes the mechanism explicit, and empirically tests it on a positive and a negative case – which leads to a double theoretical refinement of the epistemic communities approach. First, this dissertation insists on the integral role of access to decision-makers: access is an inseparable part of the causal mechanism, rather than an optional one, circumventable by providing learning opportunities to decision-makers as suggested by Haas (1992, p.4). Second, it argues for a reconceptualization of the key scope conditions for epistemic communities' influence: demand of decision-makers for expert input is found to be the crucial scope condition, rather than uncertainty and complexity as put forward by the original definition of the approach (Adler & Haas 1992). This is an important amendment to the approach with potentially far-reaching consequences for the study of epistemic communities and policy change, as it implies (supported by the empirical evidence of the Polish HTA case) that epistemic communities can be influential not only in highly uncertain issue areas, but also in relatively certain ones, where policy-makers are playing on their home turf. It also implies that without policy-makers perceiving the need to consult experts, the well-executed efforts of the epistemic communities might not result in their favored policies being adopted.

The analysis of a nearly successful but ultimately negative case of epistemic communities influence also informs literature on authority delegation. This dissertation links the epistemic communities literature and scholarship on delegation and independent agencies. The public policy delegation literature has been quite explicit about which factors lead principals (politicians, policy-makers) to delegate authority to, for instance, independent central banks or telecom regulators: complexity of the issue, blame-avoidance strategies, credible commitments or protection from reversals (Hood 2007; Gilardi 2008; Bendor et al. 2001; Moe 1990). Being lobbied by a group of the policy subsystem is not a traditionally recognized reason for setting up new agencies. On the other hand, the epistemic communities literature has long ascribed the role of carriers of international policy ideas to the

communities (Haas 1992; King 2005; Galbreath & Mcevoy 2012). By conceptualizing epistemic communities as “aspiring agents” in policies linked to the creation of a new body, this dissertation offers a conceptual bridge between the two literatures. For the delegation literature, it presents an additional reason for principals’ willingness to delegate authority – sometimes, groups or individuals who would like to become employed by the future agency, or play an otherwise important role in the new, agencified environment, can simply manage to convince them of the need for delegation. For the epistemic communities literature, conceptualizing epistemic communities as aspiring agents puts the question of interest of the community members in a new light. Although Haas’ original manifesto approach did not unequivocally exclude material or other non-epistemic interests of the community members, it also did not clearly consider what stakes a new policy regime presents for them. Where the policy lends itself to a new regulatory body, aspirations to play important roles in the future agency may add interests into the epistemic communities equation.

Finally, this dissertation connects, in Papers II and III, the epistemic communities literature with interest group scholarship. It is unfortunately impossible for this dissertation to analyze how epistemic communities interact with other actors if faced with opposition. Given the early stages of the policy process, the interests and preferences of other actors involved in the policy debates were either not well-defined or not strongly polarized. That the one notable exception was the epistemic community presents a “straw-in-the-wind” evidence (Mahoney 2012; Collier 2011) that the epistemic communities literature is right to assume that epistemic communities are the only groups pushing for their cause, with little resistance from other actors. On complex or uncertain issues, the dyad of epistemic communities and decision-makers may well be the most, and perhaps the only, relevant relationship among actors.⁸ This dissertation adds to the body of the epistemic communities literature by taking

⁸ Admittedly, an intellectually more exciting enterprise would be to infirm this assumption. This could have happened, for instance, if the Czech epistemic community had persevered in their efforts even after the ministerial changes in 2013 and

interests into account. It suggests, however, that there does not have to be any sophisticated backroom lobbying against the epistemic community's preferred policy – it is enough if the actors in favor of it are weak in order for diffusion to halt. Whether this suggestion can be confirmed by further empirical findings is, just as with the other conclusions of this dissertation, a task for future research.

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2. MATERIALS AND METHODS

This research consists of qualitative case studies, ranging from a medium N comparison in Paper I to a single case study in Paper III. It follows the positivist tradition of public policy scholarship. Findings in the three papers making up this dissertation are based mainly on a set of 77 interviews with key health policy actors in Poland, Czech Republic and at the European Union level, and document analysis. The following subsections provide more detail on case selection and research design, data and materials, and methods, as well as a reflective note on the researcher's engagement with the field.

2.1. Case selection and research design

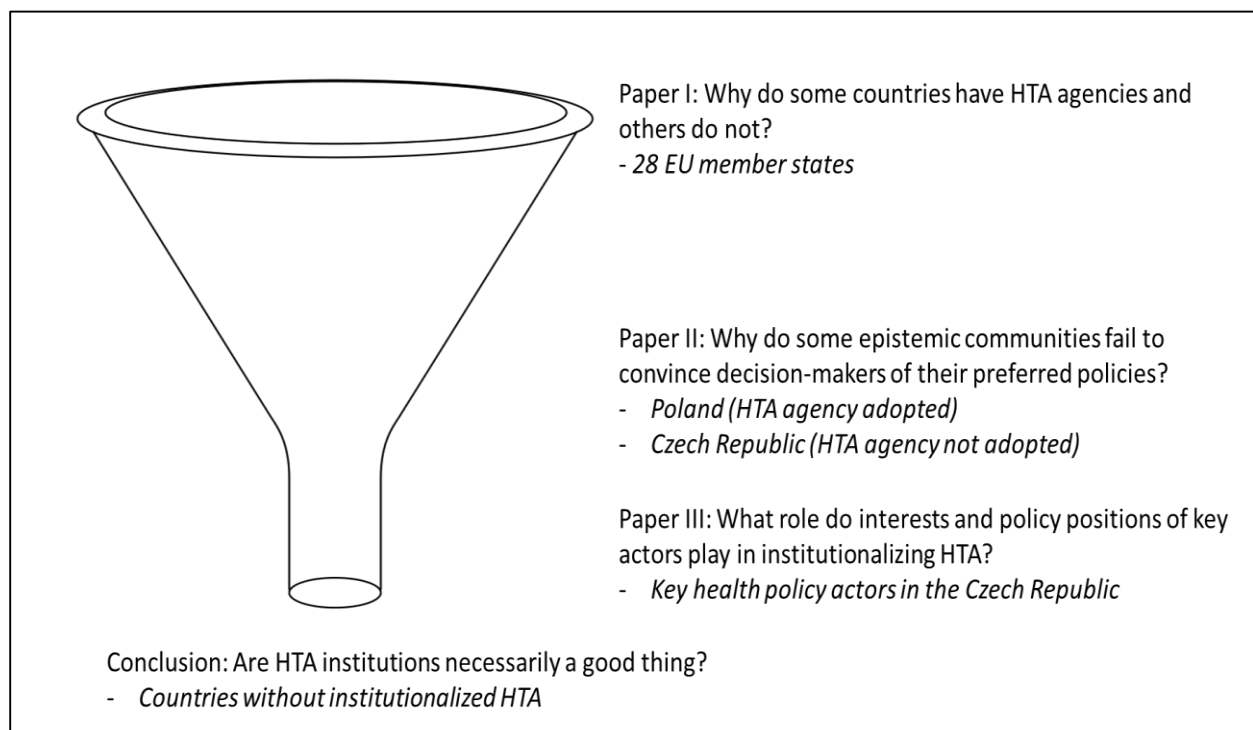
The three papers making up this dissertation each use different samples of cases, following a “funnel” structure (see Figure 2:1 below): from all 28 current EU member states, through a two country comparison, to a single country case study. This allows us to first note the larger patterns of diffusion of HTA bodies before investigating small-N studies in greater detail.

The aim of Paper I is to describe the universe of cases of HTA institutionalization and to analyze the temporal patterns of its diffusion. The European Union offers a ready delimitation for our sample for two reasons. First, most HTA agencies are located in Europe – 30 of the 54 members of the current International Network of Agencies for Health Technology Assessment (INAHTA) are European (INAHTA 2016)⁹. Globally, interesting cases of diffusion would include well-known examples of HTA bodies in countries with universal health systems such as Australia and Canada (which would both fall into the category of forerunners) as well as for instance Korea or Brazil (which would be

⁹ Note that INAHTA members include a variety of public bodies, for instance ministries of health or quality institutes, which would not be considered as specialized HTA bodies in this dissertation. The numbers are nevertheless illustrative of the worldwide distribution of interest in HTA, and its institutionalization.

closer to the mainstreamers) but cases of non-diffusion would be too numerous and heterogeneous to encompass. The number of non-adopters within the EU, in contrast, is limited, and many of these countries share similar important structural characteristics due to their post-communist heritage. Second, given the interest of the EU in HTA, looking exclusively at its member states makes for a more homogeneous sample to observe EU influence. This comes at a price – Norway, for instance, an influential forerunner, Switzerland, a mainstreamer of sorts, or Serbia, a non-adopter with noticeable epistemic community activity are left out of the analysis¹⁰. Nevertheless, the impact of the EU can be expected to affect member states and European Economic Area countries or candidate countries differently, leading to their exclusion from the analysis.

Figure 2:1. Case selection funnel



Source: author.

¹⁰ Croatia was added to the analysis when it became an EU member in July 2013.

The unit of analysis in Paper I (as well as Paper II) are countries. Subnational HTA agencies, common in decentralized health systems such as Spain, Italy or the United Kingdom, are not analyzed as distinct observations. This is because the independent variable in this dissertation is *international* policy diffusion, rather than cross-regional policy diffusion. Applying the domestic epistemic communities' model to study why only some regions in Italy have set up their own HTA bodies (in addition to a national-level HTA agency) could be an interesting test to the external validity of this dissertation's conclusions, but is beyond its primary focus.

Paper II focuses on Poland and the Czech Republic in order to compare a case of adoption of an HTA agency with a case of non-adoption. Based on the taxonomy elaborated in Paper I, this amounts to comparing a mainstreamer to a non-adopter (the forerunners being the originators of the HTA agency model, not part of its international diffusion), preferably from among CEE countries. Focusing exclusively on post-communist EU countries has the advantage of keeping many potentially interfering structural variables constant. Poland's AOTM is the most prominent HTA body in CEE, similar in many aspects to the ideal-type of an HTA agency diffused among the mainstreamers: it has today a large staff of about 60 employees as well as a significant output (870 decisions as of 2014), its recommendations are mandatorily taken into account in pricing and reimbursement decision-making, and it operates with greater transparency than typical in the region (Gulácsi et al. 2014).¹¹ Among the non-adopters, the Czech Republic presents a suitable comparison because of its similarity on a number of structural factors: historical legacies of the Semashko health systems, levels of economic development, a strong role of the ministry of health in health policy-making and the potential influence

¹¹ These characteristics are not necessarily key for the research question of Paper II or this dissertation, which both focus on the moment of adoption of the policy rather than its output, outcome or further evolution. In principle, even the short-lived Latvian VEC, the Croatian AAZ or the Hungarian GYEMSZI would have made acceptable candidates to study the decision to establish an HTA body but each come with potential confounding factors: VEC was dismantled mere two years into its existence; in Croatia the impact of the EU could be expected to exhibit different patterns than in countries of the 2004 and 2007 enlargements; and in Hungary the rather secretive *modus operandi* of GYEMSZI can be expected to make research difficult.

of international factors. At the same time, a domestic epistemic HTA community was present in the Czech Republic, making it unlikely that researching the role of the epistemic communities would prove irrelevant. The Czech Republic therefore presents a puzzle to the “laggard” hypothesis on HTA in LMICs, which rarely considers that policy-makers might discuss HTA and reject its institutionalization, while Poland is an example of a “good pupil”.

The two countries also serve as appropriate cases for theoretical improvements to the epistemic communities approach – which is the main aim of Paper II. Here, Poland is a typical case, similar to other cases usually studied by the epistemic communities scholarship. Because the causal mechanism through which epistemic communities are expected to influence decision-making has not been tested in depth in the literature, it is useful to study a typical case to confirm the validity of the mechanism succinctly suggested by early theorizations. The Czech Republic, on the other hand, serves as a deviant case where the outcome has not materialized despite the cause (diffusion of knowledge about HTA) and epistemic communities’ activities being present. Such research designs are conducive to searching for omitted scope or causal conditions influencing the mechanism (Beach n.d.) – which is what Paper II does in its final substantive section.

Finally, Paper III looks at the interests and policy positions of key health policy actors on institutionalizing HTA, in order to test interest group influence as an alternative hypothesis to epistemic communities’ impact on policy-makers, and explore the interaction of epistemic communities with other actors. The Czech Republic is an appropriate case because the debate on HTA has taken place very recently – in fact, the policy was continuously evolving during the data collection phase for this research. This made for relatively high quality data on actors’ attitudes to HTA and their reactions to various institutionalization proposals: the policy debate took place in the Internet age and therefore a number, if limited, of conference presentations, proceedings and opinion

posts are publicly available. In addition, interviewees were generally interested in discussing the topic in depth and eager to elaborate on their positions and their rapports with other health policy actors.

A comparison with a country with institutionalized HTA would of course be beneficial to further any claims of causation – unfortunately, there is a shortage of countries that set up HTA bodies in recent years in Europe and in older cases of HTA institutionalization obtaining good data is unlikely. The case of Polish AOTM illustrates this point: although the same questions on actors’ attitudes to HTA were asked to (nearly) all Polish interviewees, the data was not sufficient for further analysis. If, in the future, a new HTA agency is created in Europe, a comparison with the Czech case would be beneficial. Overall, however, the Czech case is worth exploring and presents at least a partial answer to the main research question of this dissertation: why some countries have *not* institutionalized HTA bodies.

2.2. Data and sources

Most of this dissertation’s empirical observations are based on data from a set of in-depth, semi-structured expert (and/or elite) interviews (see Littig 2009; Dexter 2006). 66 key HTA and health policy actors in Poland (32 interviewees) and in the Czech Republic (34 interviewees) were interviewed. In addition, 11 interviews were carried out with EU-level actors – although these interviews focused primarily on a related research project focusing on integration of HTA at the EU level (Greer & Löblová 2017), they included questions relevant to the Polish and Czech case studies, and provided useful background knowledge.

All interviewees were promised anonymity, and are therefore presented in this dissertation by anonymized numbers or broad affiliation categories. This includes interviewees who agreed to present their remarks on the record: because the policy communities in the two countries, as well as at the EU

level, are small, their statements also needed to be anonymized in order to protect the identities of interviewees who requested anonymity. Promising anonymity was crucial for obtaining high-quality data – few interviewees volunteered to waive anonymity. Similarly, while only a handful of interviewees refused for the interview to be recorded, some took the advantage of my offer to interrupt or stop the recording any time, and spoke more freely with the tape-recorder off. A full list of interviewees is available to the members of the Doctoral Committee (Annex I).

Potential interviewees were selected based on their appearance in publicly available documents (e.g. conference or meeting reports, company websites, press coverage etc.) and their institutional affiliations, as well as through snowball sampling based on referral from previous interviewees. The resulting purposive sample (Tansey 2007) aimed at including all categories of main health policy actors in Poland and the Czech Republic (see table 2:1 below): ministry of health, health care payers, pricing and reimbursement and HTA consultancies, academia, pharmaceutical and medical devices industry, specialized health care press, physicians' professional societies and patient organizations. At the EU level, the sample was similar, with a focus on EU institutions and member state permanent representations. Non-responses and refusals were distributed evenly across categories in the Czech Republic and at the EU level. In Poland, gaining access to current staff of the National Health Fund (NFZ) and to clinicians proved problematic – the former presumably because of institutional policies on talking to researchers, the latter probably due to language barriers¹².

¹² In Poland interview requests were sent out in English and most interviews took place in English; three interviews started in English but continued in Polish. Interviews with Czech actors were conducted in Czech. EU-level interviews were all conducted in English.

Table 2:1. Number of interviewees by affiliation

<i>Interviewee category (most relevant affiliation)*</i>	Number of interviewees CZ (number of repeated interviews)	Number of interviewees PL (number of repeated interviews)	Number of interviewees EUR (number of repeated interviews)
<i>Ministry of Health</i>	7 (2)	4	--
<i>Payers</i>	2 (1)	1	0
<i>Pharmaceutical industry</i>	2	3	1
<i>Medical devices and diagnostics industry</i>	2 (1)	1	0
<i>Státní úřad pro kontrolu léčiv (pharmaceutical PČR regulator CZ)</i>	2 (1)	--	--
<i>Agencji Oceny Technologii Medycznych (HTA agency PL)</i>	--	5	--
<i>HTA/ pharmacoeconomics consultancies</i>	6 (1)	5 (1)	0
<i>Academia</i>	2 (1)	6	1
<i>Clinicians</i>	4	2	0
<i>Health journalists</i>	2	1	0
<i>Lawyers</i>	2	3	0
<i>Patients organizations</i>	3	2	2
<i>European Union institutions (Commission, Parliament)</i>	--	--	4
<i>EU Member State Permanent Representation</i>	--	--	1
<i>EU Member State and other HTA agency</i>	--	--	2
Total	34	32	11

* Given the multiple affiliations of most interviewees over time (see Ozieranski et al. 2012b), it is impossible to provide specific numbers of interviewees per organization, especially in Poland (e.g. many interviewees listed above as “academics” also have consulting businesses, while some listed as “consultants” also worked at some point at the ministry of health or the payer).

Interviews were conducted between May 2013 and November 2015 in Prague, Brno, Warsaw and Cracow (and in Brussels, Rotterdam, Bad Hofgastein and Paris for EU-level interviewees). The vast majority of interviews were conducted in person; only 6 interviews in Poland and the Czech Republic took place over the telephone. A typical interview lasted around one hour and took place in the interviewee's office or a café. Interviewees were asked broad open-ended questions about the history of HTA in their country as well as detailed questions on specific events and processes. The interview guide was adapted to each interviewee and evolved throughout the data collection phase as some themes became more or less relevant. There were three standardized questions at the end of each interview (see Annex II). In general, the interviews tended toward the unstructured end of the semi-structured interview continuum, which encouraged most interviewees to elaborate their points in greater depth than a structured question-answer format.

In Poland and at the EU level, all interviewees were interviewed once (with one exception where multiple short interviews were carried out due to scheduling issues); in the Czech Republic, seven interviewees were interviewed twice and two were interviewed three or more times. This was due to two factors: the evolving nature of Czech HTA policy and the lack of other sources than interview data. The fall of Minister Heger's government came in June 2013, shortly after the first round of Czech interviews. In order to establish what was happening with the policy proposal, additional interviews needed to be carried out once the caretaker minister was replaced with a popularly elected one. Given that the policy process was interrupted in the formulation phase, few publicly available primary and secondary sources exist. Extensive interviewing, beyond saturation (Guest et al. 2006), was therefore a strategy to enable triangulation of evidence in the absence of other data sources (Davies 2001).

This is in contrast to Poland, where institutionalization of HTA has been documented by academic literature on the one hand (Ozieranski et al. 2012b; Ozieranski et al. 2012a), and by its main

protagonists on the other hand (Lipska n.d.; Nizankowski & Wilk 2009; Gulácsi et al. 2012). It should also be noted that because the period of interest to this research in Poland dates back about a decade, recall bias and perhaps “rewriting history” (Lilleker 2003) were features of a number of Polish interviews. The creation of AOTM was a closed chapter for most actors – those who wished to reflect on it had done so in memoirs. Other issues related to HTA or the agency have since become more important than the circumstances of its establishment in the early noughties, and dissecting its foundation was of less interest to them than the uncertain fate of HTA in the Czech Republic to their Czech counterparts. The quality of the data was nevertheless still sufficient to trace the process of institutionalization of HTA in Poland with reasonable confidence.

Finally, publicly available documents such as legal drafts, conference proceedings and PowerPoint presentations, official websites and press releases serve as primary sources to complement interview data and allow for triangulation for Papers II and III. Similar documents, together with secondary sources, namely academic and policy literature, form the main basis for empirical observations in Paper I.

2.3. Methods and data analysis

The three papers making up this dissertation all follow qualitative research traditions in positivist public policy (and political science more generally). Basic qualitative content analysis (Schreier 2014) was used to analyze interview data. Interviews were first coded based on concepts derived from the research questions and the relevant theoretical frameworks (epistemic communities for Paper II, delegation literature and HTA-specific publications for Paper III). Second cycle coding (Miles et al. 2014, chap.4) supplemented the coding frame with codes inductively derived from the interview

dataset. For instance, although in the first cycle all mentions of “agency”, “independence”, “scope” or “willingness-to-pay thresholds” were coded as “institutional setup”, it later became clear that the latter two themes would be more appropriately analyzed under the code “HTA methodology”. Data was coded partly with the help of NVivo 10, partly manually. Given the relatively straightforward nature of the research questions and the aims of the projects (to reconstruct a policy process in Paper II; to establish interests and policy preferences of key actors in Paper III), the subsequent analysis was done without further use of data analysis software.

Paper II uses a “light” variant of theory-testing process-tracing of a causal mechanism (Beach & Pedersen 2013). Because of space limitations and the style of the target journal, Paper II, as presented in this dissertation, does not go through all the motions maximalist process-tracers hope for. It does not define observable manifestations *ex ante*, or specifies whether a given piece of evidence passes through “smoking gun”, “straw in the wind” or other empirical tests (Collier 2011; Mahoney 2012). They are, however, mentioned in Annex III.

2.4. Reflections on interacting with interviewees and potential conflicts of interest

It is somewhat unusual for a positivist PhD project to include a reflective note on the position of the researcher in her field. Most research based on elite and expert interviews implicitly assume a more or less straightforward relationship between the researcher and the interviewee, where “rapport” is constructed by the researcher with the sole purpose of gaining quality data from the interviewee (see for instance Leech 2002; Lilleker 2003). In the case of elite interviews, this is less naïve than it may

seem: most of my interviews with ex-ministers or high-level bureaucrats followed this pattern. In some cases, however, my positionality in the field deserves a brief explanation.

Deviations from the ideal-typical researcher-interviewee interaction were sometimes due to my work as a consultant for the pharmaceutical industry. In 2011/2012, on leave from my PhD studies, I worked as an intern in an EU affairs department of a multinational pharmaceutical company and as a junior consultant in a consultancy representing mainly pharmaceutical clients. After my return to being a full-time PhD student, I continued working as a health care consultant on a freelance basis, taking on occasional projects either directly for pharmaceutical companies or patient associations, or via the consultancy which had previously been my employer.

This has had several advantages for my research. One is the help in identifying interviewees and facilitated access to some of them, both within the industry and elsewhere, which my work colleagues provided. In addition, I had a preexisting working relationship with two Brussels-based interviewees myself. Another is the deeper understanding I have been able to gain of the priorities of the pharmaceutical and MD&D industry when it comes to pricing and reimbursement of their products – I was able to observe firsthand, in conference rooms and on conference calls, how global positions on HTA are developed and what the main concerns of the industry are. While I have not used these insights directly in my dissertation, they have provided me with important contextual knowledge, notably about the views of the industry's public policy (or regulatory) departments on policy-makers' concerns and their internal tensions between the overarching objective of financial profit and a wish to operate in robust, sustainable, predictable health systems.

The reverse side of understanding industry perspectives is of course, as with any participatory research, the potential bias this might have had on my analysis. It cannot be excluded that I am unconsciously more sympathetic to the industry's claims than a researcher without pharmaceutical consulting

background. My research topic in its details of pricing and reimbursement policy-making in Poland and the Czech Republic, however, is relatively distant to my experience with EU and global level pharmaceutical industry. This hopefully limits the extent to which my interpretation of the data (and possibly also its generation during interviews) may be influenced by my work experience.

Surprisingly, my past industry experience and my part-time consulting activities did not seem to create better rapport with most industry and consulting interviewees. Most of them, just like interviewees of other affiliations, treated me as a young researcher or a student, and seemed at ease in a traditional interview situation. On several occasions, I was promised employment opportunities, “once you finish your studies”, both in Poland and in the Czech Republic. There was one notable exception to this general trend: after we had ended the interview, one Polish interviewee asked me to collaborate with his company as a freelance consultant. I put the company in touch with my colleagues. Later, the same company turned to me with several other collaboration proposals, one of which I took up after careful consideration. The offer came more than eighteen months after the interview, when both my fieldwork and analysis stage related to the interviewee had been closed.

In a similar vein, one Czech interviewee asked me to join the editorial board of a new local journal at the intersection of academia and policy, *Economics in Health Care*¹³. He explained his interest in my participation by my focus on health policy and my affiliation with an international university, necessary for the journal’s domestic and international recognition. I accepted the offer but have not actively participated in the journal’s activities so far.

This engagement with the field is to a large extent a consequence of the disciplinary positioning of my doctoral project in public policy. Similar to, for instance, labor market scholars who consult

¹³ First issue available at: <http://czechhta.cz/wp-content/uploads/2016/03/EZ-casopis-obsah-vol.-12015-no.-1.pdf>

governments on migration reforms, my comings and goings between academia and practice have provided me with insights into both worlds. On the minus side, I have spent hours reflecting on potential conflicts of interests and I can no longer tick the “no competing interests” box in journal submission forms. On the plus side, working on a topic both as a researcher and a consultant for hire has created clear synergies. The knowledge and skills gained during my PhD studies have served me well in my consulting assignments. *Vice versa*, working for those who are among the quickest to react to recent or impending policy changes – business practitioners – has allowed me to stay in touch with developments in the policy world. Without the year I spent in Brussels immersed in day-to-day interest representation, I would have probably stayed with topics more comfortable to a political scientist, instead of venturing into the highly technical issue of health technology assessment. Later, it was often in discussions with industry clients I saw the relevance of bringing more political science into health policy, especially when the detailed analyses of sophisticated health economic parameters invariably ended on the topic of institutions and the ultimate black box leading to them: politics.

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3. PAPER I: THREE WORLDS OF HEALTH TECHNOLOGY ASSESSMENT: EXPLAINING PATTERNS OF DIFFUSION OF HTA AGENCIES IN EUROPE¹⁴

Abstract: In the past two decades, setting up independent health technology assessment (HTA) agencies has become a popular tool to inform reimbursement decision-making in health care, spreading from Northern European countries across Western Europe but much less so to post-communist countries. Structural political science explanations leave gaps in clarifying this diffusion pattern. This paper proposes a theoretical model focusing on the influence of domestic epistemic communities mitigating policy diffusion. Based on a review of HTA institutions in the EU, it proposes a chronological taxonomy of HTA agencies in Europe (the forerunners, the mainstreamers and the non-adopters) and asks why there is such an important East-West divide. The paper discusses theoretical explanations from different literatures, finding unsatisfactory many traditional political science answers such as the degree of centralization of a country's health system, its financial organization (Bismarckian or Beveridgian), the attitude towards independent regulatory bodies in general, the influence of international actors, or lack of resources. Finally, it suggests cases for empirical testing of the domestic epistemic communities model.

Keywords: health policy; health technology assessment; policy diffusion; domestic epistemic communities

3.1. *Introduction: HTA agencies in Europe today*

Health technology assessment (HTA), a multidisciplinary evaluation of “value for money” of health care treatments, should by all accounts be an irresistible tool for politicians and policy-makers. After all, it helps solve one of the biggest challenges in health policy: how to decide on allocation of scarce resources in health care, and potentially even how to control health care spending without compromising too much on quality. HTA has many of the important attributes of fashionable policy ideas of the past two decades: it is evidence-based, relies on experts associated with independent regulatory agencies or other quasi autonomous non-governmental organizations, and one of its

¹⁴ Published in *Health Economics, Policy and Law* FirstView: 1–21. This version reflects an online corrigendum correcting “author references” in production.

mantras is quest for transparency. On top of this HTA gained non negligible interest at the European and international level, culminating with the establishment of EUnetHTA (Böhm & Landwehr 2014; Greer & Löblová 2017), a network of HTA bodies, in 2006. All this should lead us to expect HTA bodies appearing in all countries of the European Union (EU).

However, as this paper will show, in reality the former Iron Curtain division is still visible in the world of health care reimbursement decisions. Western Europe organized expert input into formal HTA agencies in two waves in the 1990s and mid-2000s, while most Eastern European countries did not follow this trend. This is somewhat of a surprising finding, given that other policy trends in health care (for instance international reference pricing, see Espin et al. 2011) have spread East of Berlin just as massively as in the West.

How can we explain these patterns of diffusion of HTA agencies in Europe? Traditional structural explanations used by policy diffusion literature (Benson & Jordan 2011; Dolowitz & Marsh 1996; Rose 1993) leave several important questions unanswered: if, for instance, Bismarckian systems block HTA, how come we have HTA agencies in Germany or Austria? The solution to fill in the gaps left by structural accounts of diffusion lies in focusing on the role of actors who are in a position to act to enable or block adoption of policy ideas coming from abroad in their countries. In the case of a highly technical policy idea with *a priori* low political salience such as HTA, these actors can be conceptualized as domestic epistemic communities – assemblies of experts united in their professional perspectives and policy goals. In order to go beyond a simple correlation of presence/absence of such communities, this paper argues for a more mechanism-centered approach to the concept and proposes a theoretical model of how domestic epistemic communities influence, step by step, the diffusion process.

The aim of this text is twofold: first, to empirically verify the inadequacy of structural explanations of diffusion of HTA agencies and second, to put forward an alternative mechanism for further empirical testing. To do this, the paper explores, after reflecting on matters of definitions, the patterns of distribution of HTA agencies in Europe by putting forward a chronological taxonomy of HTA agencies in the EU and describing the three worlds of HTA agencies – the frontrunners, the mainstreamers and the non-adopters. Next it presents traditional structural explanations to the observed pattern and shows their insufficiencies. The final section proposes a theoretical model to explain the patterns by focusing on how epistemic communities (Haas 1992; Adler & Haas 1992) at the domestic level mediate diffusion of policy ideas such as HTA agencification. The conclusion points to the importance of empirically studying the spread of HTA agencies.

The paper is part of larger research on HTA agencies in Central and Eastern Europe (CEE) from a public policy perspective (of the positivist persuasion). It is based on desk-research and analysis of publicly available documents.

3.2. HTA agencies: a popular policy trend

Health technology assessment can be described as multidisciplinary analysis of costs and benefits of health care treatments focusing on its therapeutic, economic, ethical, social and other aspects (for a more thorough discussion see Garrido et al. 2008, pp.31–49). HTA, as a relatively new field of applied analysis, has fluid boundaries. Definitions of what kind of analysis constitutes HTA differ in practice; textbooks and introductory publications typically make reference to broad delimitations by international associations of HTA bodies, such as the one above (Goodman 2004). There is no definitive consensus on what elements an HTA evaluation needs to include and which concrete

methodology it should use. For instance, while many HTA scholars and practitioners would agree that economic evaluation is an integral part of any health technology assessment (Sorenson et al. 2008, p.5), some bodies largely accepted as doing HTA (for instance France's HAS) do not employ traditional health economics. Other agencies (most famously UK's NICE) rely mainly on health economics and cost-effectiveness analyses, with limited importance accorded to other factors (ethical, organizational etc.). Some bodies use methods close to HTA but steer clear of the term – for instance the Czech SÚKL which has long avoided any mention of HTA, using instead “pharmacoeconomics” or “cost-effectiveness analysis” (see Státní úřad pro kontrolu léčiv 2013). In short, HTA is to some extent a self-assigned label. For the purposes of this analysis, bodies not using this label are not considered HTA agencies.

The diffusion of HTA as a field has been linked to the establishment of independent regulatory agencies or other quasi autonomous non-governmental organizations (QUANGOs) – owing perhaps partly to the legacy of the US Office of Technology Assessment and partly to the more general governance trend of agencification (Elston 2014; Pollitt et al. 2004; Pollitt et al. 2001). These agencies today differ in many dimensions, most notably (in addition to how they understand and use HTA) on their regulatory power and independence, which has led to complex typologies of HTA bodies (Allen et al. 2013). Some HTA bodies have an advisory role only (Germany's IQWiG or Croatia's AAZ), with a varying impact on final reimbursement decisions; others make decisions themselves (NICE or the Swedish TLV). Some are independent, in as far as a QUANGO can be (Belgian KCE); others have a close link to reimbursement decision-makers (Hungary's GYEMSZI). Some are standalone; others are separate departments within independent bodies with a broader remit, typically institutes for quality (Ireland's HIQA). In yet other cases, HTA units have been created directly within payer organizations or ministries of health (Romania, Lithuania). They also differ on how many, if any, HTA

reports the agency produces itself and how many it commissions or assesses from academia and technology manufacturers. This article is less concerned with the output or impact of HTA bodies than with how and why they are, or are not, adopted across Europe.

What these organizations have in common is the broad ideal-typical agency model: they provide expertise in order to advise decision-makers or make decisions themselves on reimbursement matters, and are public bodies with some degree of independence (see Pollitt et al. 2004). HTA as a form of expert input for reimbursement decision-making can be in principle performed by anyone: universities, for-profit firms or in-house units within ministries of health or payer organizations. However, these alternative models have not been as popular and are hardly to be seen as a competing trend of HTA-agencification. For this reason they are excluded from analysis in this text.

In addition, perhaps due to a tradition of thinking about accountability in health care rationing (Daniels & Sabin 1998) in combination with general trends in regulatory governance (Bertelli 2008; Jordana & Levi-Faur 2004), the agency model for HTA is strongly associated with principles of transparency and inclusiveness. HTA itself is presented as a way of increasing transparency by means of making the decision process evidence-based and therefore explicit, predictable and replicable (see Garrido et al. 2008); most agencies have made their criteria and analytical guidelines public (although with a varying degree of detail). Systematically including “stakeholders”, including notably patient organizations but also manufacturers, is also a prominent feature of the ideal-type of an HTA agency, as advocated for instance by NICE (Drummond & Sorenson 2009), although – again – who sits at the table varies in practice. These principles, together with the idea of an independent expert body that has “HTA” as its main mandate, form the broad policy fashion of an HTA agency. The question then is: why has this policy trend diffused from its originators to some European Union countries, for the most part in Western Europe, but not to others?

3.3. Three worlds of European HTA agencies

When we look at the history of HTA agencies in Europe, we can easily distinguish a temporal pattern in their establishment (see table 3:1). Three groups of countries, or worlds of HTA agencies, emerge. They can be called the “forerunners” (countries which shaped the concept and created their HTA agencies in the 1990s or before), the “mainstreamers” (countries which set up HTA agencies in the mid-2000s) and the “non-adopters” (countries which postpone or oppose creating an HTA agency). Their characteristics are briefly discussed below.¹⁵

Table 3:1. Chronological taxonomy of HTA agencies in Europe

Forerunners	Mainstreamers	Non-adopters
Sweden (SBU, 1987)	Belgium (KCE, 2004)	Bulgaria
Finland (FinOHTA, 1995)	Croatia (AAZ, 2009)	Cyprus
Denmark (DACEHTA, 1997)	France (HAS, 2004)	Czech Republic
United Kingdom (NICE, 1999, SMC, 2002)	Germany (IQWiG, 2004)	Estonia
Spain	Hungary (GYEMSZI, 2004)	Greece
(COHTA - Catalonia, 1991)	Poland (AHTAPol, 2005)	Lithuania
Osteba – Basque, 1992	Austria (LBI, 2006)	Luxembourg*
AETS – central, 1993)	Netherlands (CVZ, 2006)*	Malta
AETSA – Andalusia, 1996)	Ireland (HIQA, 2007)	Portugal
	Italy (AGENAS 2006)	Romania
	Latvia (VEC, 2009-11)*	Slovakia
		Slovenia

Legend: * outlier, specific case – see description below for short discussion

Former communist countries in bold

Source: own compilation

¹⁵ Although this division is taxonomical, based on a chronological sequence of establishment of HTA agencies, rather than typological, based on substantive characteristics or consequences of individual agencies, it can be expected that countries within each of the three worlds of HTA agencies share important points together. This is, however, a separate topic for related research.

3.3.1. The forerunners

The first HTA agencies were established in the UK (NICE, 1999), Sweden (SBU, 1987), Denmark (1997, DACEHTA), and Finland (FinOHTA, 1995). In addition, the Netherlands were very active in developing HTA as an academic discipline and a policy-making tool and repeatedly discussed throughout the 1980s and early 1990s creating a national HTA agency. However, no such body was created until 2006 (see Banta & Oortwijn 2009). Taken in a global context, other countries active in HTA and establishing HTA bodies during the 1980s and 1990s include Norway, Australia, Canada and of course the United States, whose Office for Technology Assessment is usually described as the *Ur*-HTA agency (Banta & Jonsson 2009). Lastly, Spain has had a relatively long history of HTA at the regional level (Sampietro-Colom et al. 2009), although competences of the national body responsible for HTA are *de facto* very limited to this day and Spain is naming the creation of a central HTA agency as one of its top priorities for health policy (Cappellaro et al. 2009).¹⁶

These countries were the ones to lay the groundwork and experiment with different powers and designs of HTA agencies. The competences, jurisdictions and often also names of these agencies evolved throughout the years: for example, the Swedish SBU no longer exists as it was replaced and merged with other institutions. Similarly, there have been developments in Denmark and in Finland in the level of centralization and sharing of institutional responsibilities of HTA functions among different institutions.

¹⁶ This development, reflecting the balance of power between the regions and the center in Spain, would tend to suggest the attractiveness of the (national) HTA agency for the central government. In addition, even though Spain as a forerunner would be outside the scope of our explanatory model (the research question here being “why has the model of HTA agencies *diffused* differently across EU countries?” rather than for what reasons were HTA agencies established in the first place), it might be interesting to look into the role of epistemic communities in the original creation of the individual Spanish regional agencies.

3.3.2. The mainstreamers

The next big wave of HTA agencies' proliferation began in the mid-2000s as the idea of an institution of public interest charged with health technology assessment as a tool to aid coverage decision-making made its way to mainstream health policy in Europe. Seven EU member states set up national HTA bodies in this period: Belgium (KCE, 2004), France (HAS, 2004), Germany (IQWiG, 2004), Hungary (GYEMSZI, 2004), Poland (AHTAPol, 2005), Austria (LBI, 2006) and Ireland (HIQA, 2007), and with some delay Croatia, whose Quality and Accreditation Agency (AAZ) created an HTA department in 2009. A specific case is Latvia, which had an organizationally separate body for HTA (Health Economics Centre, VEC) from 2009 to 2011. In 2011, VEC was merged with a payment organization as a consequence of massive cuts in public administration provoked by the economic crisis (see also Nacionālais veselības dienests 2012; Mladovsky et al. 2012). In addition, CVZ was created in the Netherlands in 2006 as somewhat of an outlier case for a country so active in HTA practice, yet doting itself of an HTA body relatively late. In Italy (and Spain) HTA was recognized politically at a national level in 2006 by national health plans, with ministries of health taking on supporting roles to develop and coordinate HTA at regional level. In the UK, Scotland established an HTA agency in 2002 (SMC).

The mainstreamers set up their HTA bodies following a relatively similar model, sometimes explicitly acknowledging their source of inspiration, for instance NICE which serves as a model to the Polish AHTAPol and the Scottish SMC (Kolasa & Wasiak 2012). As a result, most of these HTA bodies have the formal status of independent institutes financed from public sources, with advisory roles only. Of course, the HTA landscape is more varied than a single national autonomous HTA agency (or regional ones in some decentralized health systems): in Ireland, for example, a university institute (National Centre for Pharmacoeconomics) acquired advisory functions to the ministry of health

regarding HTA in 2006, one year before HIQA was established. Similarly, in Finland, the Centre for Pharmacotherapy Development ROHTO as a unit within the health ministry, albeit with some autonomy, was created in 2003 in addition to earlier HTA bodies. Nevertheless, HTA agencies created in the 2000s look surprisingly alike in their institutional setup.

3.3.3. The non-adopters

The rest of EU member states belong to the last category, non-adopters, who have so far not followed the trend of HTA-agencification. Bulgaria, Cyprus, Czech Republic, Estonia, Greece, Latvia, Lithuania, Luxembourg, Malta, Portugal, Romania, Slovakia and Slovenia have not yet set up HTA agencies, although the topic has been on the agenda in many of these countries. Slovenia in particular has been discussing the creation of HTA bodies since the mid-2000s (Tit 2010; Turk & Tit 2008). Romania has postponed creating an HTA body until 2012, when it introduced HTA into its pricing and reimbursement decision-making under pressure from the International Monetary Fund and the World Bank (Gulácsi et al. 2014). The body in question is a unit within the ministry of health rather than a full-blown agency. A similar development followed in Lithuania, where HTA as a scientific discipline has had a relatively long tradition (Danguole 2009). The country recently established an HTA unit within the ministry of health (Wild et al. 2015). In line with our reasoning that the agency model itself is significant, a recent report describes this unit as underwhelming (Wild et al. 2015).

This is not to say that some aspects of HTA as a method are not used in these countries. Health economics and selected elements of health technology assessment have been reported in use by academics as well as some decision-makers (reimbursement committees of ministries of health or payers) (Sorenson et al. 2009; Gulácsi et al. 2012). In other words, there is probably no country in the

EU today without any notion of HTA, but the decisive step of creating an institution whose main responsibility would be to perform HTA analyses has not been taken in the non-adopting countries.

It is not surprising that the forerunners correspond to the group of European countries which traditionally set trends in health policy (and which lead developments beyond the health sector more generally, in public policy, administration and management).¹⁷ However, the distribution of countries between mainstreamers and non-adopters is puzzling as it to a large extent mirrors the Iron Curtain: most of the mainstreamers are from Western Europe, while CEE countries have been significantly more hesitant and form the majority of the non-adopters. Given that other trends in health care policy have spread to Central and Eastern Europe just as across the old EU-15, the question therefore is why Western European countries adopted HTA agencies *en masse* in the mid-2000s but most CEE countries resisted their creation or postponed it – and why there are exceptions to this rule such as Hungary or Poland.

3.4. From diffusion theory to intervening factors: how structural theories do not explain the three worlds of HTA agencies

What are the factors that interfere with the diffusion of a policy model or idea and, in our case, “make or break” an HTA agency? Diffusion scholars identify different structural and actor-based

¹⁷ Spain is somewhat of a surprise among the frontrunners as it is usually not the country at the forefront of worldwide governance trends – this could, again, indicate a strong role of epistemic communities or other experts in health policy in particular.

explanations. The former include the following intervening variables: path dependency, institutional and structural impediments, ideological compatibility between transferring countries, resource limitations of the receiving country (Benson & Jordan 2011), while the latter discuss the role of policy entrepreneurs and experts, elected officials, political parties, bureaucrats, pressure groups and supranational institutions (Dolowitz & Marsh 1996; Rose 1993). In the case of HTA in Europe, some of these intervening variables prove insufficient already at this stage: path dependency and structural impediments (such as in Immergut's (1992) veto-ridden political systems preventing health care reform) are roughly similar among CEE countries; similarly, ideology does not seem to play a role as governments of different ideological leanings introduced HTA agencies across the EU. This leaves us, on the structural side, with resource limitations, which are also often cited as a constraint to development of HTA by practice-oriented policy literature. To this we should add two potential mediating factors often picked up by health policy literature: the degree of centralization of health system governance and the Bismarck vs. Beveridge cleavage. Likewise, drawing on literature on agencies as a form of governance, the attitude of individual countries to agencification in general should be considered. Finally, another factor influencing diffusion (known typically as "coercion", see Meseguer 2004; Meseguer 2005; Weyland 2005; Marsh & Sharman 2009) can be international organizations. This section briefly reviews all of these possible intermediate variables and confronts them with the distribution of European countries within each of the three worlds of HTA, and concludes that their explanatory power is unsatisfactory.

3.4.1. Resource limitations

Lack of resources, financial or human, is often put forward by practitioner-oriented capacity-building literature (cf. Moharra et al. 2009). It is reasonable to assume that *financial resources* are needed to set up

a new agency. A new public agency whose mission is to advise decision-makers needs qualified experts who need to be remunerated and new staff needs to be trained. Countries where a new HTA agency would require a significant additional investment that they cannot afford are less likely to establish one – or are more likely to lag in diffusion in comparison to other countries because the high costs of policy adoption make waiting for more evidence about the policy more attractive (see Brooks 2007). At first sight this seems rather plausible when we look at HTA agencies in Europe but financial resources might have difficulties explaining why Portugal does not have an HTA agency and Poland does (the GDP per capita of Portugal has been about twice – or, further back in time, more – than that of Poland), or why Hungary has one and the Czech Republic does not (at roughly similar levels of economic development). Certainly, money is a condition for establishing new agencies but definitely not a sufficient one and maybe even not even a necessary one.

Human resources could provide another explanation. If a country has to train 15 to 50 health economists and other experts (for the size of a Western European HTA agency, see table 5.1 in Garrido et al. 2008, p.90) *ex nihilo*, it is probably not going to establish an agency for them. There is evidence, however, that countries without trained health economists first set up HTA agencies and then sought to fill in the lack of human resources: Poland set up a twinning program with French experts to train more specialists for its new HTA agency (Nizankowski & Wilk 2009), Croatia used pre-accession EU funds for similar goals (Mittermayer et al. 2014). In Romania, HTA has been in the making – even before the International Monetary Fund’s and World Bank’s intervention – with the help of NICE International, as well as other HTA bodies from Western Europe supported by a World Bank project (Swiss Tropical and Public Health Institute 2013). Lithuania benefitted from knowledge transfer from Swedish experts and has trained a number of health economists since the early 1990s (Danguole 2009), and similarly, Slovenia is a leader of a EUnetHTA work package, which shows commitment to HTA

as a field in the country, yet neither of the countries established a formal HTA agency to date. Lack of human resources, therefore, does not look like it has major explanatory power regarding HTA establishment (although financial and human resources may become hurdles when it comes to implementation of a diffused idea).

3.4.2. Centralized vs. decentralized health system governance

There is recognition within studies on health technology assessment that the degree of centralization of a country's health care system influences the practicalities of HTA (Drummond & Sorenson 2009; Ciani et al. 2012; Cappellaro et al. 2009), although how centralization promotes or impedes the initial introduction of HTA is “open to debate” (Sivalal 2009, p.286). Neumann (2009, p.S45) suggests that “the idea of establishing public HTA organizations has been a more natural fit with the more centralized, government-funded, and administered health-care systems of Europe” as opposed to the decentralized and more privately funded system in the United States. This is far from a naïve assumption, given that health care reform in general is thought to be more likely to succeed in countries where the authority of the central government is strong compared to other actors in the sector (Freeman 2000; Immergut 1992). It also goes in line with Wild and Gibis' (2003, p.188) argument that corporatist health care governance, notably the larger professional autonomy of physicians that accompanies it, “can be seen as an obstacle in the diffusion of HTA”.

A quick look at the distribution of EU countries between the mainstreamers and non-adopters suggests, however, that this hypothesis is not likely to be confirmed. Of course, operationalizing what constitutes “strong central decision-making” is a tricky exercise in any given country; comparing power of institutions across all the 22 mainstreamers and non-adopters is even more problematic.

There is, however, one critical case whose positioning on the strong-weak decision-making continuum raises little doubt: Germany. With its corporatist decision-making in the health sector, which typically involves the government on a par with health insurance funds and health professionals, Germany is a country where few would doubt the relatively weak role of the central decision-making power (in this case, the Federal Ministry of Health). By this logic, Germany should refuse to set up an independent HTA agency. In spite of this, IQWiG was established in 2004. When we look at other countries in the mainstreamers' category, we can reasonably suppose that Germany is not an outlier: at the very least Austria and Belgium could be characterized as countries with weak central institutions, especially in comparison with some of the non-adopters. The fact that Germany created an active HTA agency suggests that a high degree of centralization of health policy decision-making is neither a sufficient, nor in fact a necessary condition to establishment of HTA agencies.

3.4.3. Bismarck vs. Beveridge

The Bismarck vs. Beveridge division constitutes another plausible theoretical explanation for the distribution of countries between the mainstreamers and non-adopters. Although it has been forcefully argued that the Bismarck and Beveridge distinction has been increasingly blurred to the point of becoming irrelevant (see for instance Kutzin et al. 2010; Schmid et al. 2010), it is still worth investigating whether the organization of a health system's financing influences the establishment or not of an agency whose primary objective is to advise what to finance. However, despite the fact that the Bismarck vs. Beveridge divide is widely used as a major criterion for case selection in health policy studies, literature exploring its relationship to HTA seems limited. Although Cavazza and Jommi (2012) look at how a country's health care system (in addition to broader governance traditions) affects the concrete work practices of its HTA agencies, only Wild and Gibis (2003) draw a clear link between

a country's health care financing model and its willingness to engage in HTA activities and establish formal HTA institutions. According to them, Beveridge systems (in which care is financed by the state through taxation) are more likely to establish HTA agencies, whereas Bismarckian systems (where care is financed by third-party payers, typically insurance funds, based on employers' and employees' mandatory contributions) are likely to resist. This is because of four main reasons: the “unduly strong” (p. 189) role of physicians in Bismarckian corporatist decision-making, their resistance to “evidence-based medicine”, limited opportunities for funding of public health research such as HTA, and the lack of interest of the government in health policy tools, including HTA.

This hypothesis is to some extent confirmed by the empirical division between the forerunners and the mainstreamers, which was the only significant one when Wild and Gibis wrote their article (see table 3:2). Sweden, Finland, Denmark, United Kingdom and Spain all had tax-based Beveridge health systems, whereas Bismarckian systems lagged behind with regard to establishing HTA agencies when the forerunners did. To explain further development, however, especially the division between mainstreamers and non-adopters, this hypothesis seems to be of little help. Positioning a country on one extreme of the Bismarck vs. Beveridge divide is, once again, not so simple: Hungary, for instance, has a system based on work-related social contributions but with a single national insurance fund. Similar mixed elements of the two ideal-types can be found in most countries, especially in the post-Semashko post-communist ones. In fact, only Latvia would qualify as following a Beveridge model among post-communist countries. This means that once the forerunners established HTA agencies, there were relatively few Beveridge-type countries left in Europe to show a clear trend: Ireland, Italy and Latvia followed in the 2000s, whereas Portugal, Greece and Malta have not to this date. More importantly, this division based on the type of health care financing does not explain why some of the Bismarckian countries established HTA agencies and some did not.

Table 3:2. Bismarck vs. Beveridge explanations for diffusion of HTA agencies in Europe

Forerunners	Mainstreamers	Non-adopters
Sweden (SBU, 1987)	Belgium (KCE, 2004)	Bulgaria
Finland (FinOHTA, 1995)	Croatia (AAZ, 2009)	Cyprus
Denmark (DACEHTA, 1997)	France (HAS, 2004)	Czech Republic
United Kingdom (NICE, 1999, SMC, 2002)	Germany (IQWiG, 2004)	Estonia
Spain	Hungary (GYEMSZI, 2004)	Greece
(COHTA - Catalonia, 1991)	Poland (AHTAPol, 2005)	Lithuania
Osteba – Basque, 1992	Austria (LBI, 2006)	Luxembourg*
AETS – central, 1993)	Netherlands (CVZ, 2006)*	Malta
AETSA – Andalusia, 1996)	Ireland (HIQA, 2007)	Portugal
	Italy (AGENAS 2006)	Romania
	Latvia (VEC, 2009-11)*	Slovakia
		Slovenia

Legend: * outlier, specific case – see description above for short discussion

Beveridge health systems in bold italics

Source: own compilation

3.4.4. General trends in agencification

Leaving aside explanations specific to the health sector, it is also possible that the non-adopters have so far not established HTA agencies because they are reluctant to create independent agencies and other forms of QUANGOs in general. Surprisingly little is known about the patterns of agencification in Central and Eastern Europe in particular – most studies focus on the Western World (particularly EU-15 plus Australia and New Zealand: see for instance Verhoest et al., 2010; Gilardi 2008; Pollitt & Bouckaert 2004; Christensen & Lægreid 2007). Van Thiel (2011) concludes from an expert survey in Western European countries and Hungary, Estonia, Lithuania and Romania that CEE countries (with the exception of Hungary) have delegated more tasks to agencies than their Western European counterparts and created more agencies, although typically without legal independence. According to her conclusions, most agencies in these countries are semi-autonomous, directly depending on the ministry for budget, personnel etc., but these patterns are in a way similar to the patterns of independence of agencies in some Western European countries. Studies of independent agencies in

individual sectors, such as for instance anti-corruption or gender equality agencies (Batory 2012) suggest that some autonomous (or semi-autonomous) bodies exist in almost all CEE countries. Randma-Liiv et al. (2011) underline that although agencies as such existed during the communist regimes as well, there has been an increase in their numbers in some CEE countries after 1990, followed by a decrease in the mid-2000s, owing perhaps to global de-agencification tendencies (see Elston 2014).

In short, empirical accounts of agencification in Central and Eastern Europe from political science scholarship, where most of the HTA non-adopters come from, do not point to any general unwillingness to create semi-autonomous public bodies. If we accept Randma-Liiv and colleagues' arguments (based on a limited number of countries) about increasing de-agencification in the region as true, it might mean there the trend toward setting up new QUANGOs indeed passed or peaked around 2005 and countries which have not set up HTA agencies by that time will remain unlikely to establish them at all. Ireland and Latvia are here the two notable exceptions; the Romanian and Lithuanian case of creating a unit within the executive might be an illustration of a move away from agencies to a different set-up, but the hypothesis of refusal to create HTA agencies as a consequence of resistance to agencification in general does not seem plausible.

3.4.5. Influence of international actors

In Europe of mid-2000s onward, the European Union is clearly the most important international actor with the possibility to influence adoption of new policy trends, both for CEE and old EU member states. Until recently, the EU had very limited leverage to promote establishment of HTA agencies in countries that did not have them – despite its longstanding interest in HTA, more ambitious EU-level

collaborations started at about roughly the same time that the mainstreamers were founding their institutions, with the EUnetHTA project launched in 2006. In October 2013, with the entry in force of the EU Cross-Border Healthcare Directive (Directive 2011/24/EU), a “voluntary network connecting national authorities or bodies responsible for health technology assessment” was created, to which all EU member states, even those without HTA agencies, nominated representatives. These representatives were, however, often from ministries of health rather than HTA institutions (DG SANCO 2014) – the Directive did not give the EU a mandate to require countries to establish HTA bodies if they did not have one. In other words, the influence of the EU was, before the Directive, limited to encouraging capacity building through socialization within EUnetHTA and occasional provision of funding (such as the Polish Twinning project) – and not so greatly enhanced after the Directive. Although a lack of means of coercion *per se* has not necessarily limited the EU’s influence in many policy areas, it can also be said that, despite its interest, HTA has not been high enough on the priority list for the European Commission (Greer & Löblová 2017) – certainly not enough to warrant the EU promoting a particular organizational model.

Similar conclusions can be drawn for the World Health Organization (WHO), which also focused on awareness raising, socialization and capacity building (World Health Organization 2014; Garrido et al. 2008). In contrast, the International Monetary Fund and the World Bank have had at their disposal hard conditionality linked to financial incentives such as international loans. The Romanian case mentioned above suggests that this coercive power might indeed lead to establishment of HTA institutions (although not necessarily an agency in the forerunners’ or mainstreamers’ sense) – but it is also exceptional, depending on the macro-economic and political context of a country with deep economic problems, giving the international actors extraordinary leverage.

These circumstances were not present for most other countries (or if they were, such as in Latvia, they did not necessarily lead to a strengthening of HTA, much less so in an agency form). At the time when the mainstreamers founded their HTA agencies, international actors were only starting to consolidate their interest in the field – in this sense, the forerunners can be conceptualized as uploaders of their policy innovation to the international level. However, the interplay between the international and national levels becomes more complex past the mid-2000s, with no clear top-down influence of the EU or WHO over either the mainstreamers or the non-adopters. In any case, although international actors are likely to be influential in promoting awareness of and capacity in HTA as a field, they do not push for an agency model that we observe across the mainstreamers but not the non-adopters.

To sum up, none of the macro explanations taken from the “usual suspects” in the health sector or policy sciences explains sufficiently why concrete countries did not set up their HTA agencies and why most of those countries are in Eastern Europe. A brief reflection of their potential conjunctural causation is not more promising. Given the unclear role of international actors and the general attitude to agencification, an obvious combination of variables to explore further would be resources coupled with the centralization of health care system or the Bismarck/Beveridge divide, or both. A cursory consideration of these combinations, however, still leaves many cases unexplained (for instance, a rich, Bismarckian Germany with its weak central decision-maker contrasted with a not-so-rich, Bismarckian Hungary with a strong center, etc.).

Attention should therefore be given to actor-centered explanations as suggested by policy diffusion scholars: interest group politics or the variety of public policy meso-theories such as policy communities, iron triangles, policy networks, advocacy coalitions and the like, should be better equipped to explain the distribution of HTA agencies in Europe. The remainder of this text develops

a theoretical model around domestic epistemic communities – a group of actors particularly relevant for the diffusion of HTA.

3.5. A new model for empirical testing: domestic epistemic communities as crucial mediators of policy diffusion

Ultimately, policies are not disseminated mechanically because of GDP per capita or a certain type of health care system, but because of human activity. This is why a detailed model of actor-centered mediation to diffusion is necessary. The activity of domestic actors can explain variation in policy diffusion, including lack of diffusion (Dolowitz & Marsh 1996; Rose 1993). Interest group explanations are often named by students and practitioners of health priority-setting (of which HTA is a subset) as the limits of priority-setting policies (Robinson 1999; Neumann 2009; implicitly also Wild & Gibis 2003; Goddard et al. 2006). Banta (2003, p.129) provides a basic overview of possible positions on HTA of the traditionally most important actors in health care (health care professionals, payers, the pharmaceutical and medical device industry, patients, the general public), although at a closer look their preferences and interests are anything but straightforward.

In contrast, there is one group, apart from the traditional actors in health care, whose preferences when it comes to HTA are clear. Banta (2003) calls them “epidemiologists and other researchers”, who have an interest in promoting and disseminating methods and findings of evidence-based medicine. This description echoes Haas’ concept of *epistemic community*, a “network of professionals with recognized expertise and competence in a particular domain and an authoritative claim to policy-relevant knowledge within that domain or issue-area”, emerging around a shared set of normative and principled beliefs, shared causal beliefs, shared notions of validity of knowledge and a common policy

enterprise (Haas 1992, p.3). Despite its origins in the international relations literature to explain policy coordination at supranational level, the concept is adaptable to domestic politics (Thomas 1997; see Salvador & Ramió 2011; as well as the plethora of similar public policy meso-concepts), with the simple difference that a *domestic epistemic community's* primary goal is to shape domestic, rather than international, policy. One of the crucial beliefs of an HTA epistemic community would be that health care technologies that offer an unfavorable cost-benefit ratio should not be reimbursed (unless there are overriding concerns), and that this ratio should be established by a thorough scientific multidisciplinary analysis.

Simple presence/absence of a domestic epistemic community around HTA does not explain the establishment, or lack thereof, of HTA agencies in Europe – the Slovenian and Lithuanian cases mentioned above, despite having a noticeable HTA community, did not lead to a formal HTA agency, although Poland seems to have established an agency following advocacy of an active HTA community (see Nizankowski & Wilk 2009). To shed light on the pattern we need to conceptualize *how* exactly a domestic epistemic community influences policy. The epistemic community conceptual manifesto already contains a relatively explicit suggestion of a simple causal mechanism:

As demands [for information in a context of uncertainty] arise, networks or communities of specialists capable of producing and providing the information emerge and proliferate. The members of a prevailing community become strong actors at the national and transnational level as decision makers solicit their information and delegate responsibility to them. [...] To the extent to which an epistemic community consolidates bureaucratic power within national administrations and international secretariats, it stands to institutionalize its influence and insinuate its views into broader international politics. Members of transnational epistemic communities can influence state interests either by directly identifying them for decision makers or by illuminating the salient dimensions of an issue from which the decision makers may then deduce their interests (Haas 1992, p.4).

In other words, epistemic communities are expected to operate according to a parsimonious causal mechanism in four parts (to use Beach and Pedersen's (2013) process-tracing terminology) with a “pitchforked”, two-way possibility in the penultimate step. Applied to the diffusion of HTA agencies

in Europe, it would start from individuals from different countries learning about the existence of the policy idea at an international level (academic or policy conferences, professional exchanges etc.). In the second phase, we expect these individuals interested in HTA to form a community at the domestic level on the basis of the four definitional attributes put forward by Haas (1992). Such community spreads its stances by sharing information and actively framing the issue in question: organizing conferences, meetings, presentations, workshops and the like, which include policy-makers and other actors close to decision-makers, typically high-ranking civil servants at the ministry of health or in other health care institutions. Thirdly, members of the epistemic community acquire access to policy-makers by becoming civil servants or advisors and consultants in the ministry of health, or potentially by getting the “ear” of decision-makers otherwise, through informal processes – and/or by systematically drawing attention to those aspects of the issue that imply the superiority of their preferred policy. Finally, decision-makers are persuaded of the superiority and appropriateness of having an HTA agency and establish one.

Although empirically investigating this model is beyond the aims of this paper, there is no shortage of cases to test the model on: among the 10 mainstreamers and 12 non-adopters, few countries would disqualify as outliers (Luxembourg, Cyprus etc.). To keep contextual variables such as historical legacy or political culture as similar as possible while allowing for a juxtaposition of complete diffusion with non-diffusion, a comparison of post-communist countries, from the mainstreamers’ category and from among the non-adopters is in order. Here, Hungary and Poland are two obvious candidates for the mainstreamers, while the Czech Republic or Slovakia could be their equivalents from the non-adopting countries. Poland in particular is interesting because of the relatively strong role of AHTAPol (Ozieranski et al. 2012); the Czech Republic is a case (similar perhaps to some of the Baltic states) of an active HTA community with little success in institutionalization (Gulácsi et al. 2014) – which would make a detailed study of each step of the causal mechanism all the more interesting.

Findings from a qualitative process-tracing comparison of HTA agencies' fate in Poland and the Czech Republic (Löblová n/a) suggest that epistemic communities indeed play a major role in the diffusion of HTA agencies. In Poland, the path towards AHTAPol developed almost entirely as theorized by Haas. First, a community of HTA enthusiasts emerged in the early 2000s around clinicians and civil servants interested in quality assurance and evidence-based medicine. The community then engaged in autodidactic substantive learning from the international HTA community and, in parallel, reached out to decision-makers. When its key members acquired top bureaucratic positions, they managed to rally decision-makers behind the idea of establishing an HTA agency, and AHTAPol was created in 2005 – with human (as well as financial) resources gradually increased after the agency's foundation through internal and EU capacity-building projects. In the Czech Republic, the first three parts unfolded in an almost identical manner, although nearly a decade later. In fact, the Czech HTA community even managed to convince decision-makers of the desirability of their policy – but a government fall in 2013 prevented a smooth passage. The new administration was favorable to the general principles of HTA but the original HTA community did not maintain access to key decision-makers. With the new ministry's demand for expert input refocused on solving an ever more salient problem (unregulated medical devices and diagnostics' costs) as fast as possible, an alternative arrangement to an HTA agency (or even a division of one of the existing institutes subject to ministry of health) was chosen in 2014 instead: a ministerial committee engaging in "HTA-like" evaluations, whose decisions are binding for payers on a voluntary basis.

These micro-level findings confirm the crucial role of epistemic communities in the diffusion of policy innovations, and at the same time refine Haas' causal mechanism of their influence by underlining that having access to decision-makers is not optional, as is paying attention to their changing demand for input (rather than conceptualizing them as uninformed in a state of uncertainty). They also suggest none of the competing explanations played a decisive role – for instance, a lack of experts and money

to train them did not stop the Poles from creating what is today one of the bigger HTA agencies in Europe, nor did it stop the Czechs from seriously considering doing the same. The role of doctors in the two countries' Bismarckian systems, as well as the strength of their ministries of health do not explain the diverging outcomes; the popularity of QUANGOs and the influence of international actors have of course evolved over the past decade but do not seem to play a central role in deciding whether to found an HTA agency or not. To answer this question, studying the interaction of an epistemic community with decision-makers, including how well the policy fits their needs, is a more promising avenue.

3.6. Conclusion

The peculiar distribution of health technology assessment agencies in EU countries today, with most countries of Central and Eastern Europe not having an HTA agency, cannot be explained by structural interfering factors such as resource limitations or centralization of the health system. Instead, if we want to explain why HTA agencies became a popular way of informing rationing decisions in Europe but not in others, we need to turn to actor-based explanations. Among the number of important actors in health care, domestic epistemic communities of scientists and experts are uniquely positioned to aim at influencing policy in new, highly technical, low salience sectors such as HTA. This article proposes a theoretical model of domestic epistemic communities influencing international policy diffusion by engaging in active promotion of their policy goal, gaining access to bureaucracy and providing learning opportunities to decision-makers.

Beyond scholarly contributions to the discipline of public policy, an empirical test of the model using the case of HTA agencies in Europe should also be informative for students of health policy. Health

technology assessment, as a tool to inform, guide or constrain coverage decision-making, has potentially far-reaching consequences affecting all patients and tax-payers in the European context. Likewise, the independent agency model associated with it in many EU countries can affect governance culture in health policy-making. Uncovering how international ideas about priority-setting trickle down – or not – to individual countries and how actors at the domestic level promote them – or not – seems therefore a worthwhile enterprise.

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4. PAPER II: WHEN EPISTEMIC COMMUNITIES FAIL: EXPLORING THE MECHANISM OF POLICY INFLUENCE¹⁸

Abstract: Epistemic communities are an established concept in the study of international relations but can also explain policy change at the domestic level. This paper asks why some epistemic communities manage to convince decision-makers of their preferred policies while others do not. It suggests that the reason lies in the causal mechanism of epistemic communities' influence on decision-makers, mediated by decision-makers' demand for expert input. To counter the customary overestimation of the groups' influence, this paper compares a successful case of epistemic community influence (health technology assessment in Poland) with an unsuccessful example of the same policy (in the Czech Republic). The juxtaposition allows for unpacking of the necessary parts of the causal mechanism (emergence of an epistemic community, its activity, access to decision-makers and successful suasion) and separating them from the crucial scope condition. Decision-makers' uncertainty about the policy issue at hand has traditionally been the key scope condition for epistemic communities but the successful Polish case demonstrates that epistemic communities can be influential even in highly certain areas of routine policy-making, leading to a reconceptualization of uncertainty as policy-makers' demand for expert input.

Keywords: epistemic communities, causal mechanism, policy non-adoption, health technology assessment, Poland, Czech Republic

4.1. Introduction

Twenty years after Peter Haas and Emmanuel Adler (1992) formulated the research agenda for their new concept of epistemic communities, we still know relatively little about why some epistemic communities are more successful than others in persuading decision-makers of their policy preferences. Two decades into the concept's life, Mai'a Davis Cross (2012) notes that most of the empirical works that followed Haas' and Adler's kick-off focus almost exclusively on single case studies where these "networks of professionals with [...] an authoritative claim to policy-relevant knowledge" (Haas 1992, 3) played a very clear role in shaping policy. As a result, the literature on

¹⁸ This paper was submitted to a journal focused on theories of public policy.

epistemic communities tends to overestimate the communities' influence (see critique in Dunlop 2009). It does not explain well why, sometimes, epistemic communities fail to push their favored solution through, and what happens with members of the group after they have reached their goal – or failed to do so (King 2005 would be one exception). In this respect, the epistemic communities approach is similar to other meso-level frameworks of policy sciences, be they policy communities (Richardson and Jordan 1979), policy networks (Marsh and Rhodes 1992), issue networks (Heclo 1978) or advocacy coalitions (Jenkins-Smith and Sabatier 1994; Sabatier 1988; Weible, Sabatier, and McQueen 2009), most of which have been criticized as overly descriptive and lacking meaningful explanatory power (Carlsson 2000; Dowding 1995, 2001). Addressing the causality gap for epistemic communities might by extension shed light on similar problems of its related public policy concepts.

For epistemic communities, this shortcoming might be explained by the concept's historical and disciplinary origins – in international relations of the early 1990s, lack of international coordination, rather than its existence, was the perceived norm that authors dealing with epistemic communities initially sought to explain as a challenge to prevailing theoretical perspectives at the time. Policy change, rather than its opposite – inertia, was the analytical endpoint of Haas' and Adler's contemporaries. Over the past two decades, however, our world has become one where expert input is the norm (despite the potential turn away from scientific advice, see Weingart 1999). Today, international experts not only set standards but also routinely impose their preferred policies on individual countries (for instance the International Monetary Fund in Latin America in the 1980s and Eastern Europe in the 1990s). Policy-making is increasingly claiming to be “evidence-based” (Davies 2012; in practice see e.g. Wilsdon 2014), with regulatory impact assessments of new policies now mandatory in many jurisdictions around the world. In short, we tend to suppose all, or at least most, policy decisions follow the science, or at least have taken it into account. But sometimes this is not the case. The concept of epistemic communities holds the promise of shedding light on how science,

knowledge and evidence make its way into policy, and by extension, when they are more likely to influence the final decision. As such, the concept is worth applying beyond its native international relations to domestic decision-making, as suggested already by Adler (1992) and later confirmed by Thomas (1997), King (2005) and others (Meijerink 2005; Salvador and Ramió 2011), to present an analytical alternative to traditional nation-state bound conceptualizations of expertise and policy, in line with the blurring line of nation-state and supranational public policy (Stone 2008). If it is to be truly useful, though, it needs to move beyond initial empirical confirmations and answer questions any other framework of explaining policy change would.

This includes explaining cases of low or no influence, which is what this paper intends to do, in line with Cross' (2012) call for a renewal in the epistemic communities research program by inclusion of comparative studies that take into account also negative cases (see also Beach n.d.; Capoccia and Kelemen 2007; Mahoney and Goertz 2004). This text compares a case of successful diffusion of a popular international trend in health policy – the establishment of a health technology assessment (HTA) agency – in Poland, as a result of efforts of the Polish HTA epistemic community, with a negative case in the Czech Republic, where despite similar activities of a comparable HTA epistemic community no agency was established. It proposes to tease out some of the reasons for possible success or failure of epistemic communities' influence. This is made possible by refocusing the attention of the epistemic communities approach on the domestic level, and thus unlocking an additional universe of cases beyond single instances of international cooperation, and adding a comparative element to the study of epistemic communities.

To do so, rather than to look for ever more conditions for success of epistemic communities, this paper proposes to follow the causal mechanism of their influence. Despite the mechanistic turn in social science (Beach and Pedersen 2013; Brady and Collier 2010; Falleti and Lynch 2009; George and

Bennett 2005; Gerring 2008; Mayntz 2004; Rohlfing 2012) and the, by now, established consensus that a plausible causal mechanism should be part of any theory or framework, few studies of epistemic communities (with the notable exception of Dunlop 2009) have examined the way the community strives to achieve its ends. The abundance of explicit and implicit conditions and variables of epistemic communities' influence might indicate we lack an understanding of their causal mechanism, understood as a system of logically interlinked parts that are all expected to be present in order for the outcome to happen (Beach and Pedersen 2013, 29–40). Concretely, the dozen or so conditions identified by empirical and theoretical pieces on epistemic communities which try to specify when the groups are likely to be persuasive (Cross 2012; Zito 2001) mix scope conditions (*when* epistemic communities influence decision-making; e.g. in the agenda-setting phase of the policy process, if there is uncertainty surrounding the issue) with parts of the causal mechanism (*how* they do it; e.g. they use respected data to convince decision-makers, they become a cohesive, professional group, they anticipate actors' preferences and behavior) and observations about the nature of the groups (*what* they are; e.g. their cohesiveness or professionalism). By subjecting the mechanism proposed in Haas' and Adler's original formulation of the concept to a comparative empirical test, we can separate scope conditions and details about their nature from integral parts of the mechanism of influence.

The findings of this paper are based on document analysis and semi-structured in-depth expert interviews with 66 main HTA and health policy actors in Poland and in the Czech Republic¹⁹. All interviews here are presented anonymously in order to protect the identities of those interviewees who requested anonymity.

¹⁹ These include individuals affiliated with: the ministry of health, health care payers, pricing and reimbursement and HTA consultancies, academia, pharmaceutical and medical devices industry, specialized health care press, physicians' professional societies and patient organizations (given the multiple affiliations of most interviewees over time - see Ozieranski, McKee, and King 2012 - it is impossible to provide specific numbers of interviewees per organization).

The remainder of this paper first explores the causal mechanism of epistemic communities' influence on policy-makers as formulated in Haas' and Adler's original research program. It then follows individual parts of the mechanism in the case studies of health technology agencies in Poland and the Czech Republic, exploring whether the epistemic community's failure to push through their policy alternative was due to a breakdown in the mechanism or changing scope conditions. The article then discusses uncertainty – the key scope condition in Haas' formulation – and proposes its more general reconceptualization as decision-makers' demand for expert input, which can be triggered by other factors than uncertainty and complexity, but which regardless of its source affects epistemic communities' behavior and nature, both during their quest to convince policy-makers of their preferred solution and after. The conclusion briefly stresses the importance of studying negative cases.

4.2. The mechanism of epistemic communities' influence

The key to uncovering the ways in which epistemic communities influence policy-making should lie in the factors that bind the community together. Haas' original definition of epistemic communities has remained relevant over time (Cross 2012, 2015; Dunlop 2000, 2009; Zito 2001): epistemic communities are “networks[s] of professionals with recognized expertise and competence in a particular domain and an authoritative claim to policy-relevant knowledge within that domain or issue-area”, emerging around (1) a shared set of normative and principled beliefs, (2) shared causal beliefs, (3) shared notions of validity of knowledge and (4) a common policy enterprise (Haas 1992, 3). This definition provides the basic point of departure for what epistemic communities are and how they relate to other conceptualizations of semi-formal groups looking to shape policy. What sets epistemic communities apart is their reliance on their shared set of normative and principled beliefs, shared causal beliefs, shared notions of validity of knowledge, often in practice meaning science (or some

other acknowledged discipline able to give the group a claim to authoritative knowledge - see Cross 2012). This is opposed to interest groups or policy communities, where (material) interests play a more prominent role – in fact, Haas only talks about epistemic communities’ interests where the common policy goal is concerned. In other words, epistemic communities are held together by their scientifically grounded beliefs and little else.

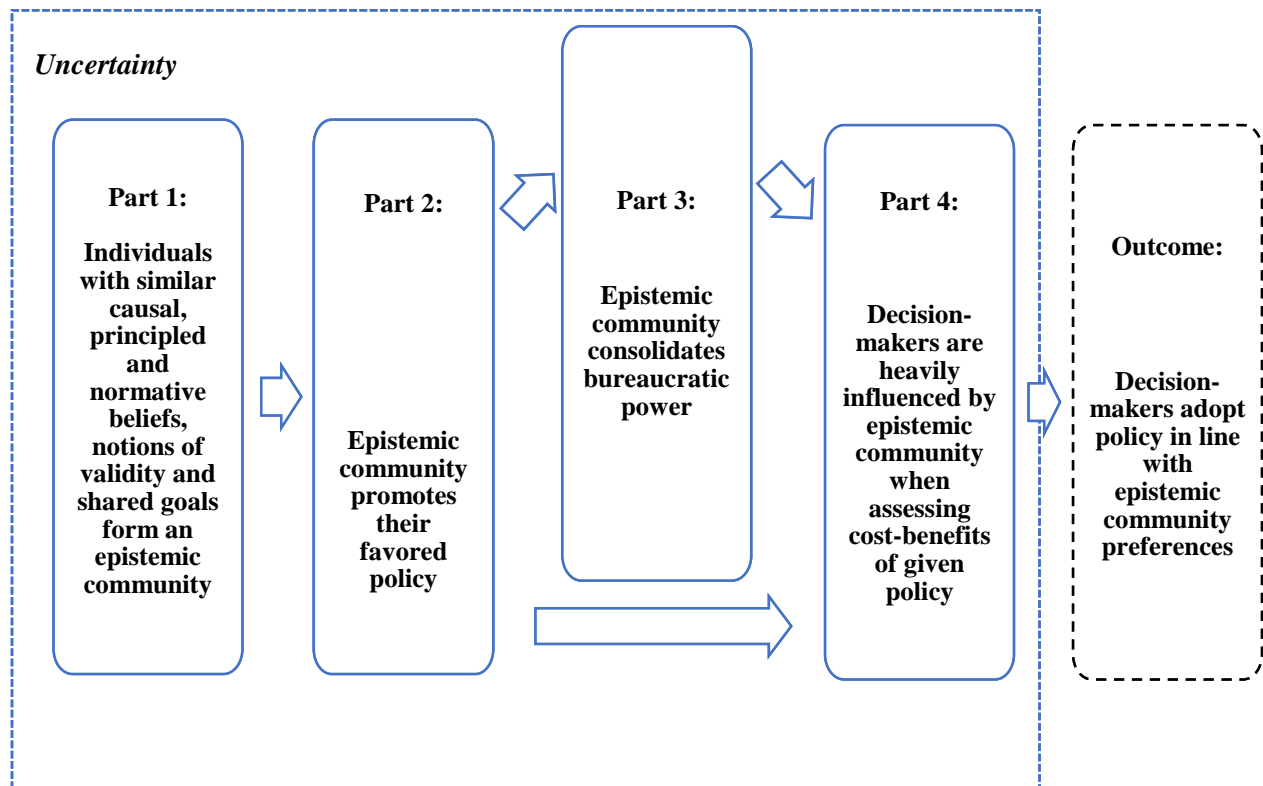
It is this focus on science that determines the nature of the community’s interactions with decision-makers. Epistemic communities try to influence policy by providing expertise and arguments, as opposed to other strategies such as lobbying – although some authors (Dunlop 2000; Sebenius 1992) suggest that epistemic communities in the end have to engage in bargaining or coalition building just like any other actors in the policy process. Haas provides quite an explicit suggestion of a parsimonious causal mechanism in the concept’s manifesto:

“As demands for such information arise, networks or communities of specialists capable of producing and providing the information emerge and proliferate. The members of a prevailing community become strong actors at the national and transnational level as decision makers solicit their information and delegate responsibility to them. [...] To the extent to which an epistemic community consolidates bureaucratic power within national administrations and international secretariats, it stands to institutionalize its influence and insinuate its views into broader international politics. Members of transnational epistemic communities can influence state interests either by directly identifying them for decision makers or by illuminating the salient dimensions of an issue from which the decision makers may then deduce their interests” (Haas 1992, 4).

In other words, epistemic communities are expected to operate according to a simple causal mechanism in four “parts” (Beach and Pedersen 2013) with a “pitchforked”, two-way possibility in the penultimate step: first, a group corresponding to the definition of an epistemic community must emerge, unless it predates the issue in question. Second, the community must actively pursue their policy goal by disseminating their views. Third, members of the community either penetrate decision-making structures and shape their preferences from within, or continue providing learning opportunities in line with their views to those in power (or both). Finally, decision-makers adapt their

preferences to those of the epistemic community, and act accordingly – there is little space for dissent (for instance in terms of party politics cleavages) if the epistemic community manages to establish its views as dominant.

Figure 4:1. Causal mechanism for domestic epistemic communities' influence on policy



Source: author, based on Haas (1992, 4).

This mechanism, summarized in Figure 4:1, is parsimonious yet detailed enough to be subject to empirical testing and thereby refining the theoretical approach. Surprisingly, few authors set out to verify or challenge this basic operating assumption of the epistemic community concept. The notable exceptions focus on possibly the weakest point in Haas' framework: part 4 in the causal mechanism, which amounts to one of political science's biggest specters – *suasion*. Haas in fact implicitly equates policy adoption with good arguments of the epistemic community: parallel to direct identification of interests or issue framing described in the excerpt above, he also suggests that whether an epistemic community's ideas are adopted or not is “a function of whether the causal beliefs of epistemic communities demonstrate the need for it” (1992, 30). All of these potential causal pathways attribute agency in the policy process entirely to the epistemic community. Dunlop (2009), however, points out that decision-makers enjoy more control over the knowledge transfer process between themselves and epistemic communities than suggested by the original case studies that shaped the concept, because not all decisions are made in a state of complete uncertainty and bounded rationality about highly complex issues. In other words, to what extent the epistemic community is able to convince decision-makers of its arguments depends also on how much decision-makers need its information. Ultimately, epistemic communities are not the only players in town (Peterson 1992) and they have to resort to traditional exercises in interest representation such as bargaining and alliance-building (Dunlop 2000; Sebenius 1992; Zito 2001). This suggests, unsurprisingly, that other factors in addition to the supply of policy solutions by the epistemic community may influence the outcome – and also modifies the implicit assumption of the epistemic communities approach that any ideas can be uploaded to ignorant government by knowledgeable experts, questioned by other students of science-policy relationships (Halfman 2005; Hoppe 2005).

The preceding parts of the causal mechanism are seldom challenged by the epistemic community literature but this does not mean they should not be subject to empirical testing. The nature of causal mechanisms means that the individual parts of the process are more than just interfering variables jointly increasing or diminishing the probabilities of success; they are “cogs and wheels”, and when one of them breaks down, the entire mechanism can be expected to stop working. By verifying the mechanism with the help of a case of an epistemic community’s success we can see if all the individual parts Haas proposes are necessary to how an epistemic community influences policy. Correspondingly, by inspecting a case of limited influence we should see where the spokes in epistemic communities’ wheels are. This is what the next section of this paper does, inspecting the example of health technology assessment agencies in Poland and the Czech Republic.

4.3. Health Technology Assessment agencies: comparing the Polish and Czech cases

Health technology assessment (HTA) is a multidisciplinary analysis evaluating the medical, economic, ethical, legal, social and other aspects of health care treatments (drugs, medical devices, surgical interventions etc.). In contemporary Europe it is one of the most popular tools to inform decisions on reimbursement of health interventions (and by consequence, allocation of resources in health care) based on evidence. In the past two decades, specialized HTA agencies have proliferated throughout Europe and around the world, making their establishment a fashionable, but not universal, policy trend. Specifically, by the mid-2000s, most countries of Western Europe had set up HTA agencies; in Central and Eastern Europe only a few countries followed suit (Löblová 2015). One of them, Poland, set up a national HTA agency AOTM (Agency for Health Technology Assessment; *Agencja Oceny Technologii Medycznych*) by a ministerial decree in 2005. Its legal situation was further confirmed in 2009

when the agency became by law an independent legal entity under the supervision of the ministry of health with its own budget, and the agency's role in Polish health care decision-making is today well established. For the purposes of this analysis, the main focus is on the years that preceded AOTM's creation in 2005.

Most other Central and Eastern European countries have not taken up the HTA agency model. In the Czech Republic, HTA was a largely non-existent topic in policy-making circles until about 2012 when the minister of health announced an intention to create a national HTA body. Works on the content and form of an establishing legal act for the new body came to a halt in June 2013 with the fall of the government and the law-making vacuum of the successive immediately outgoing caretaker government. Plans for an HTA institution on the part of the following minister of health have been halted since. The Czech story is comparable with other countries in Central and Eastern Europe: HTA is not a completely unknown matter – there are individuals and groups aware of the idea, which sometimes even makes it on decision-makers' agenda – but its institutionalization, unlike in Western Europe, does not happen.

HTA in Poland and the Czech Republic are typical cases where we could expect epistemic communities to play a decisive role in impeding or enabling the diffusion of an attractive policy option. Structural explanations are not helpful as both countries share important structural characteristics, notably the legacy of the Semashko health system and post-1989 Bismarckian reforms, a strong role of the ministry of health, as well as a similar general cultural, political and economic background, and relations to important supranational actors, particularly the European Union (see Löblová 2015). Among actor-based approaches, interest group explanations are problematic because HTA is a policy option with no immediately clear-cut material stakes for most actors (see below). The advocacy coalition framework, as well as the policy communities/networks and other policy sciences

approaches, are in principle just as suited to studying our cases (see Meijerink 2005) but compared to the epistemic communities' concept they lack the strong focus on science, knowledge and evidence as the main drivers of policy change. HTA is a highly technical policy field of relatively low salience even within the health policy sector (as compared to, for instance, the level of overall health care spending, physicians' salaries or closing down of hospitals in rural areas). The policy in itself is of interest above all to international and national networks of HTA professionals convinced that a multidisciplinary evidence-based assessment is the right way to decide on allocation of resources in health care. Given its low salience, just as for interests, there are no obvious competing epistemic communities who would favor other policy solutions (e.g. "evidence-blind decision-making") based on different knowledge. It is, then, epistemic communities that we can expect to affect the diffusion of HTA in Central and Eastern Europe – the question is *how* exactly they work and, if their nature and efforts are comparable, what made the Polish community successful while the Czech one failed. To do that, the remainder of this section follows the four parts of Haas' causal mechanism.

4.3.1. HTA epistemic communities in Poland and the Czech Republic: members united by shared beliefs

Domestic epistemic communities that pushed for HTA agencies to be established emerged both in Poland and in the Czech Republic, with remarkable similarities despite a difference in timing. About ten names were consistently mentioned by nearly all interviewees in each country as people crucial for HTA. In Poland, these individuals were mainly civil servants and academics with medical science education, formed from around 2002 on, that is roughly three years before the foundation of AOTM. In the Czech Republic a group with similar composition came to life around 2011.

What unites members of the community in both Poland and the Czech Republic are, in accordance with Haas' theory, their shared normative and principled beliefs (e.g. that only treatments that are effective, and perhaps cost-effective, should be reimbursed), causal beliefs (that evidence-based decisions lead to a superior distribution of resources in health care), notions of validity of knowledge (that it is possible to assess the value of treatments), and the conviction that HTA is an answer to problems of resource allocation in health care. This is best seen when members of the community explain why other actors do not belong to their group. In both Poland and the Czech Republic, insiders of the HTA community tend to have a common explanation for the exclusion of other groups: outsiders either do not care or do not have the capacity to understand the complexity of HTA and evidence-based medicine (EBM) in general (Interview 161 2013; Interview 94 2013; Interview 96 2013). HTA communities in both countries see themselves as assembled around a central principle which they share: the usefulness of EBM and evidence-based decision-making in general, with related principles of modernization (as opposed to the previous system of allocating health care resources) and, especially in the Czech case, transparency.

Concretely, there are three notable groups of actors who should be interested in HTA but who are almost completely absent from the picture: physicians, patients and payers. In both Poland and the Czech Republic, patient organizations are dismissed by insiders of the HTA communities as lacking capacity or manpower to grasp the complexities of HTA and uninterested (Interview 10 2013; Interview 104 2013; Interview 40 2013; Interview 96 2013). Indeed, by ignoring HTA as a topic, patient organizations implicitly question or dismiss the validity of knowledge as used in HTA (e.g. measures of disease burden or quality of life etc.), as well as its importance (i.e. the causal belief that HTA can improve health care). Sometimes they are also described as mere proxies of pharmaceutical companies and in consequence as lacking legitimacy (Interview 126 2013; Interview 137 2013; Interview 58 2013; Interview 71 2013; Interview 86 2014; Interview 96 2013). Patients' perceived main

objective of is to get funding for their particular disease, which is in contrast with the HTA community's goal of promoting evidence-based decision-making across disease areas. Although by this logic patients should oppose the policy, the low profile of HTA means they ignore it instead of actively fighting it.

Disinterest in HTA is again the main reason for excluding payers in both countries. In the Czech case, members of the HTA community agree that representatives of the payers, especially the largest and most influential state-owned health insurance fund, General Health Insurance Fund (*Všeobecná zdravotní pojišťovna*, VZP), do not care about HTA. According to members of the HTA communities, payers are only interested in savings, and HTA as a tool does not offer sufficient savings opportunities, if any (Interview 37 2013; Interview 63 2013). Another oft-repeated theme is the omnipresent corruption and clientelism in Czech health care system: an official HTA process would most likely mean added transparency of resource allocation by the payers (notably VZP) which is not in the interest of the institution, nor the local and national politicians linked to it (Interview 105 2013; Interview 37 2013; Interview 94 2013). In Poland, although individual members of the community were sometimes linked to the national health insurance fund (*Narodowy Fundusz Zdrowia*, NFZ), it is also agreed that the Fund itself was uninterested in HTA (Interview 106 2013; Interview 185 2013). HTA activities of the members of the community who worked as civil servants for the Fund are described mainly as their personal initiative which did not have major importance for the functioning of the NFZ (Interview 110 2013; Interview 119 2013; Interview 166 2014; Interview 27 2013). As in the Czech Republic, the NFZ had different priorities and decision-making criteria than HTA. Although payers are typically interested in matters of allocation of resources (which is after all their *raison d'être*), both VZP and NFZ tended to be more preoccupied with managing total expenses rather than improving procedures to decide on individual interventions. They do not question the foundations of HTA but rather its relevance for their concerns. One Czech payer representative

articulated his disinterest in HTA by questioning the essential beliefs of the epistemic community: “I don’t believe in ICERs (incremental cost-effectiveness ratios, author’s note), numbers, models. I’ve seen how you can play around with those [to get the results you want]” (Interview 65 2014) but this is a rare instance of challenging a fashionable governance paradigm.

Finally, although many, if not most, members of the HTA communities have their first degree in clinical medicine, organized groups of clinicians in both countries, such as medical chambers or unions, are by and large uninterested (and perhaps also ignorant) about the existence and implications of health technology assessment (Interview 119 2013; Interview 159 2015; Interview 177 2013; Interview 56 2013). The same is true for specialized clinical societies (e.g. cardiologists, oncologists) that tend to focus more on the quality and availability of care for their particular disease area than broader issues of reimbursement decisions (Interview 117 2015; Interview 40 2013; Interview 93 2015). Even if clinical societies know about the broad characteristics of HTA, the issue is one of general consensus but low priority, with no immediately foreseeable negative consequences, and policy efforts are instead invested in other areas (Interview 117 2015; Interview 93 2015). Sometimes they are described by insiders of the HTA communities as hostile to HTA because it takes away part of their capacity to lobby for their preferred interventions (Interview 161 2013; Interview 36 2013; Interview 40 2013), although at other times they are portrayed as in favor of HTA because of its roots in evidence-based medicine (which in turn is linked to quality assurance) (Interview 177 2013). This is interesting especially in light of the existing literature on the politics of HTA which implies, based on mainly Western European experience, that doctors are against HTA, especially centrally organized, as it represents a major constraint to their professional autonomy (Wild and Gibis 2003). It would seem that Banta’s (2003) intuition, though argued cursorily, about clinicians having little interest in HTA because their major interest lies in issues of quality of care rather than in expenditure and public policy, is confirmed in the Polish and Czech cases.

For insiders of the HTA community, actors who focus on other aspects, including notably traditional lobbying of clinical societies and patient organizations or the pork-and-barrel politics of the VZP in the Czech Republic, are a target of disapproval. This does not mean members of the epistemic communities and other actors in the policy subsystem have no interests to fight for, as the epistemic communities literature sometimes assumes (Cross 2012). In our two cases, some – if not most – members of the HTA communities had direct (financial and/or reputational) interests in institutionalizing HTA in their country. The Polish pharmaceutical and medical devices industry, for instance, saw in health technology assessment reports an opportunity to gain “stronger arguments for reimbursement of pharmaceuticals” (Interview 185 2013; also Interview 64 2013; Interview 73 2013; Nizankowski and Wilk 2009, 158). Similarly, several senior civil servants, key members of their respective HTA communities, had hopes of becoming directors of the future HTA bodies – such information regularly comes up in interviews both in Poland and in the Czech Republic, including sometimes the hopeful bureaucrats themselves (Interview 161 2013; Interview 27 2013; Interview 36 2013; Interview 96 2013). This would suggest that while the group is certainly to some extent bound together by knowledge-focused criteria, interest cannot be completely excluded. It is, however, through fundamental arguments about knowledge, evidence and policy-making (and evidence-based policy as well as medicine in particular) which are never questioned that the group defines itself – those who disagree with them, such as the payer representative mentioned above, are not considered part of the community.

In short, the first part of the causal mechanism is in the Czech and Polish cases confirmed. The idea of HTA diffused to Poland in the early 2000s and to the Czech Republic almost a decade later, and domestic epistemic communities coalesced around it. This is a necessary first part of the mechanism of influence - in fact, the late appearance of HTA on the policy agenda in the Czech Republic can be

explained by the non-existence of a domestic HTA epistemic community that would invest its time and resources into promoting the idea.

4.3.2. Activity of the Czech and Polish HTA communities: first building capacity, then disseminating

Once assembled, HTA communities in Poland and the Czech Republic initiated educational activities disseminating knowledge about HTA through conferences, workshops, talks or publications. These activities were aimed at an audience of the health policy community, notably academics, ministry of health officials but also payers and industry.

The first step, though, was capacity building in the topic. Neither Poland nor the Czech Republic had any experience with HTA and had only limited expertise in pharmacoeconomics in general. Evidence-based medicine was also a relatively new concept in both countries in the early 2000s. In fact, HTA activities in Poland and in the Czech Republic both evolved from an interest in quality issues in health care, and related notions of evidence-based medicine and clinical guidelines, introduced to the domestic environment by prominent clinicians. Nowhere is this logical link more visible than in Poland, where first HTA reports were produced by a department of a newly established National Center for Quality Assessment in Health Care (*Centrum Monitorowania Jakości*, CMJ) (Interview 110 2013; Interview 185 2013; Interview 27 2013; Interview 73 2013; Nizankowski and Wilk 2009). In the absence of formal university programs or trainings on HTA or health economics, HTA enthusiasts in both countries learned from textbooks and international conferences (Interview 10 2013; Interview 110 2013; Interview 169 2014; Interview 185 2013; Interview 27 2013; Interview 4 2013; Interview 94 2013). CMJ employees in Poland received trainings in the early 2000s from international HTA

academics (Nizankowski and Wilk 2009). No international trainings comparable in scale took place in the Czech Republic.

At the same time, individual academics or university departments started to develop research interests in HTA and pharmacoeconomics. In both countries, the trend is strongly associated with individual academics, typically medical doctors or pharmacologists associated with medical faculties, and often linked to health care management courses and MBA degrees. In both countries we can follow a growing interest and expertise in pharmacoeconomics, with the Polish Society for Pharmacoeconomics founded in 2000 and the Czech one in 2005, rapidly producing first notable research outputs (guidelines for pharmacoeconomic analysis in local languages). The two professional societies also organized a number of meetings, working groups and conferences. All of these efforts testify to a bottom-up capacity-building: we observe in both countries the emergence of a new field, driven by individuals with an interest in the topic. In Poland, this process took place at a time where HTA was still a relatively fresh discipline - with major international HTA organizations founded in the 1990s and interest from the European Union (EU) intensifying only in the early 2000s (Böhm and Landwehr 2014; Greer & Löblová 2017). In the Czech Republic this happened ten years later at a time of comparatively intense EU focus on HTA, massive online open courses and high-speed internet access. Yet in spite of these differences the process seems remarkably similar in both countries and echoes the epistemic community concept in that detailed shared expert knowledge is key for uniting the epistemic community.

Parallel to this internal learning process dissemination efforts targeted at health practitioners (mainly hospital managers) and policy-makers, including ministry of health and payers' staff, took place in both countries. In Poland, CMJ organized week-long trainings on quality management and evidence-based medicine, related to HTA, as a conscious educational enterprise (Interview 110 2013; Interview

27 2013; Nizankowski and Wilk 2009). The educational outreach of CMJ employees, during their stay at the institute and after, was substantial (Interview 110 2013; Interview 151 2014; Interview 27 2013). In addition, a Cracow-based HTA consultancy founded a nonprofit arm in order to organize meeting of an international HTA association in Poland in 2004 (Nizankowski and Wilk 2009) and organized numerous trainings in evidence-based medicine (HTA Consulting 2004). Its audience included ministry of health as well as NFZ staff (Interview 185 2013; Interview 73 2013). In the Czech Republic, a number of policy-maker oriented conferences and talks were often set up around 2011-2013 as the topic started to emerge on the ministerial agenda. Association Citizen (*Sdružení Občan*), a nonprofit organizing monthly debates on various health care topics, has hosted approximately one HTA-related discussion a year since 2009 (Sdružení Občan 2009, 2011, 2012, 2013). Academic institutes ran conferences including ministry of health participation (Ministerstvo zdravotnictví ČR and Fakulta biomedicínského inženýrství ČVUT 2010; Pharamaround.cz 2013a, 2013b). A non-profit branch of a pharmacoeconomic consultancy (iHETA) gave a number of presentations on HTA and pharmacoeconomics and, similar to CEESTAHC activities in Poland, has offered health economics trainings since 2011, and ran a “capacity-building” project co-financed by Swiss development funds (see iHETA 2013). These activities, although hardly coordinated according to some grand plan, were in both countries targeted at policy-makers in order to familiarize them with HTA and promote its basic ideas and assumptions; interviewees repeatedly emphasize “educational efforts” toward ministry of health and payer staff. This would suggest that the respective domestic epistemic communities were indeed actively promoting their shared policy enterprise.

In sum, the epistemic communities in Poland and the Czech Republic both engaged in activities aimed at promoting their preferred policy among decision-makers, by enhancing their own expertise on the topic (and thus their authoritative claim to knowledge) and by presenting their beliefs, findings and

interpretations in all the usual forums. So far, then, the cogs and wheels of our causal mechanism seem well oiled.

4.3.3. Consolidation of bureaucratic power

In the ideal-typical part 3 of our causal mechanism the sequence of events is simple: members of an HTA community, with a common policy goal, take on employment (or advisory posts) within bureaucratic structures that decide on their policy of interest, and influence the preferences of these structures (in Haas' international context, states; in our case the ministries of health) in favor of their preferred course of action. This is exactly what happened in Poland as well as in the Czech Republic with HTA.

In Poland, the line between the epistemic community and bureaucratic structures is blurry to the point of being nonexistent. The HTA community itself was born within a state institution: CMJ was a semi-autonomous department of the ministry of health. In what was possible perhaps only in the transition years, CMJ employees for several years created HTA reports commissioned by the industry and paid for through a private foundation linked to CMJ (Interview 110 2013; Interview 185 2013; Interview 27 2013; Interview 73 2013; Nizankowski and Wilk 2009). In this sense the nascent HTA community had access to decision-makers from the very start; the decision to leave the government institution would not make sense for an epistemic community in Haas' sense. In fact, leaving CMJ can probably best be explained by the macro political context of changing governments and ministers of health, which had repercussions on the personnel of CMJ (Interview 110 2013; Interview 73 2013), as well as the problematic nature of the financial arrangement where pharmaceutical companies were de facto hiring civil servants (Interview 27 2013). Following the dismissal in 2001 of the CMJ head, Rafal

Nizankowski, one of the main HTA proponents in Poland, and the departure of key CMJ staff to form private consultancies, there was a brief period during which no core members of the Polish HTA community had positions inside relevant bureaucratic structures, but in general either the ministry of health or the NFZ almost continuously included at least one key member of the HTA epistemic community. The key moment for the establishment of an HTA agency was, however, the nomination of Nizankowski as deputy minister of health in 2004 as a result of his previous professional collaboration with the minister (Interview 110 2013; Interview 151 2014; Interview 27 2013). Nizankowski pushed for the creation of an agency and HTA was recognized by the minister as one of the top legislative priorities. He was also the chairman of the expert working group preparing the legislative basis for an HTA agency, to which he appointed several other key members of the HTA community, and continued, with a pause, to actively participate in the working group despite his dismissal in December 2004. During this time another key member of the HTA community, Nizankowski's former employee at CMJ, was uninterruptedly employed at the ministry of health and served as a vice-chairman of the group.

In the Czech Republic, a similar breakthrough came in 2011 when a longtime advocate of health care reform, Pavel Vepřek, became advisor to the minister of health. Vepřek suggested HTA to the minister as a mid-term priority and put together an informal working group which was to prepare a first draft for an HTA institution. The group included several key HTA and evidence-based medicine community members and its work resulted in a ministerial order in February 2012, which created an “HTA council”. The HTA council was a formalized working group at the ministry tasked with developing a legislative draft and coordinating a public tender for the development of methodological guidelines for the future HTA body, as well as a “Committee for health technologies”, which included other stakeholders, notably payers, professional societies and “the public” (Interview 40 2013; Vepřek 2012a; Vrabel 2012). Before Vepřek's arrival at the ministry, no important members of the HTA

community were directly integrated in bureaucratic structures, although there were individual supporters of ideas behind HTA and evidence-based medicine among mid-level staff of the ministry and in the drug agency SÚKL. With Vepřek at the ministry, the Czech HTA community enjoyed broad access to decision-makers, similar in nature, scope and duration to the Polish one during Nizankowski's time.

In both countries, then, members of the HTA epistemic communities took up positions within bureaucratic structures with privileged access to decision-makers. This allowed them to promote their policy goals on the agenda and push forward with their legislative formulation. This means that as far as the communities in the two countries could actively work on their influence on decision-makers, they did so. The final part of our causal mechanism takes the matter out of the epistemic communities' hands: convincing those in power of their ideas and taking up influential positions in government was enough to lead to an HTA agency in Poland but not in the Czech Republic.

4.3.4. Convincing decision-makers – or not?

In the final part of our causal mechanism, Haas suggests that decision-makers are convinced by the epistemic community's arguments about the superiority of their preferred policy and adapt their preferences accordingly. The policy is then adopted because transnational epistemic communities convinced also all other players in the international system – in a domestic application, the sum of relevant decision-makers. Given that so far the Czech HTA community followed the way for influence Haas sketched out almost exactly like the Poles but we still observe diverging outcomes in the two countries, this should be where the Czech influence mechanism broke down. In fact, this is not the case. The difference has more to do with a change of scope conditions, as described in the next section;

but as far as Haas' causal mechanism is concerned, the Czechs managed to persuade decision-makers just as effectively as the Poles.

In Poland, the working group's efforts resulted in a draft ministerial ordinance establishing AOTM as an advisory body to the minister of health, signed by minister Marek Balicki in September 2005. Most interviewees agree that the reason for the minister's positive decision was that he was convinced of the benefits of the policy while not seeing any disadvantages (Interview 110 2013; Interview 27 2013; Interview 36 2013) – one interviewee recalls that Balicki was convinced “naturally” (Interview 151 2014). A key member of the HTA community imputes Balicki's reasons in almost Haas' terms:

“[It] doesn't matter what party is in power, there is a need. And if you create that need and understanding on every side and you promote the idea, then [it] doesn't matter what party is in power, they will change the system towards [your policy]” (Interview 27 2013).

In other words, the policy was perceived by the decision-makers as appropriate and desirable, and the epistemic community itself sees (in retrospect) its role as one of active framing, teaching and advocacy. The policy's passage in Poland was unproblematic because of the absence of veto points for the chosen legal act (ministerial ordinance). Importantly, the Polish epistemic community continued to exert influence beyond the adoption point, well into the implementation stage: with a change of government in October 2005, it might have been expected that the new minister of health, Zbigniew Religa, under a different color of government, would easily annul the ordinance or halt any implementation steps to make the new body operational. Here, again, interviewees cite three main reasons, copying our causal mechanism, as to why the opposite happened and AOTM started work: general persuasiveness of HTA proponents' arguments, good access of key members of the community to the new minister and the presence of mid-level staff in favor of HTA in the ministry of health (Interview 110 2013; Interview 151 2014; Interview 73 2013). In short, we observe an almost ideal-typical confirmation of the causal mechanism in Poland.

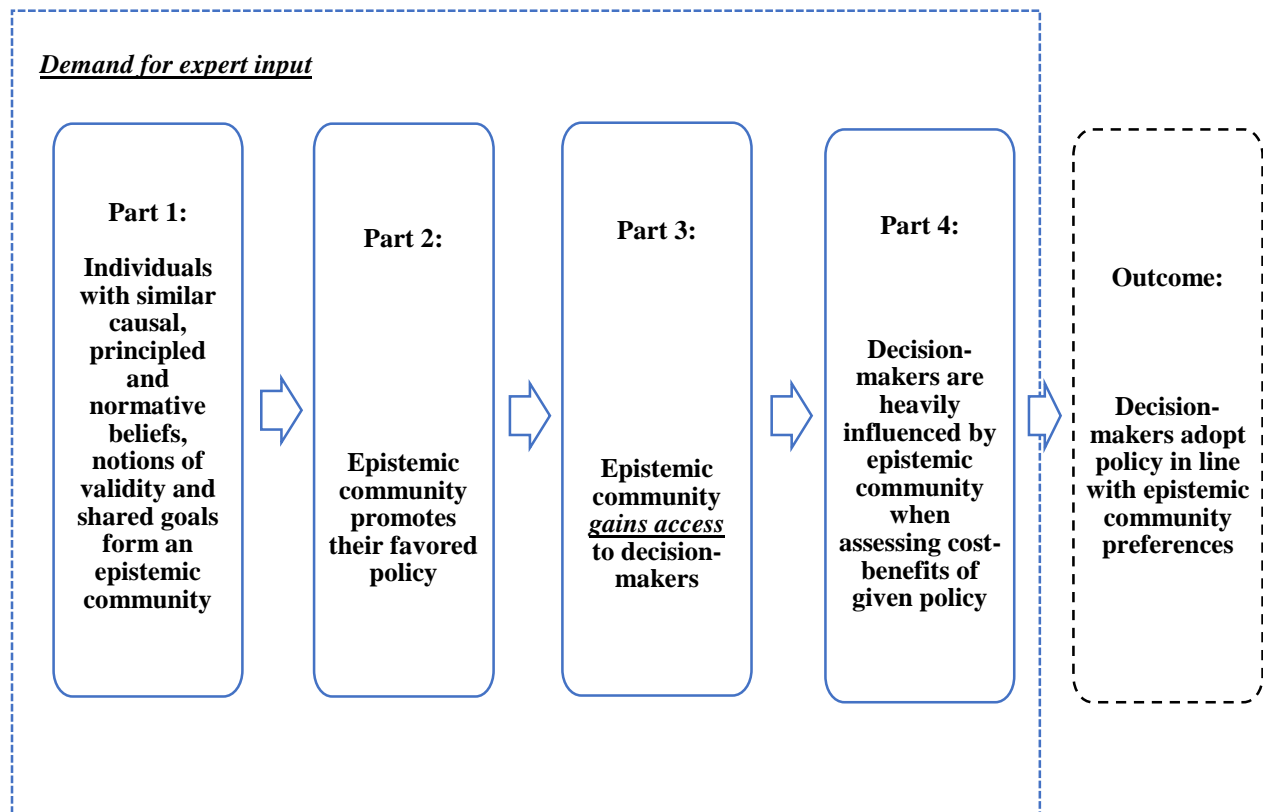
In the Czech Republic, on the other hand, the mechanism was interrupted by what is, for a policy subsystem, *force majeure*. Minister Heger was clearly convinced by the community of the desirability of HTA to the point of moving into the policy formulation phase, but in June 2013, in the midst of debates on the design, responsibilities and guidelines of the future HTA body, the Czech government fell. A caretaker government was never given the Parliament's confidence, and as a result, very little major legislative work was done for 6 months. The caretaker minister, Martin Holcát, was aware of HTA and discussed the topic repeatedly with some members of the community out of personal interest (Interview 16 2015; Interview 161 2013). At the ministry, though, in the interregnum of the government *démisionnaire en affaires courantes*, the previous government's efforts were put on ice. HTA was of low priority to the caretaker minister, whose mandate was limited both by time and by democratic legitimacy, despite his favorable attitude to the policy in general (Interview 16 2015; Interview 161 2013; Interview 68 2015). The following minister, Svatopluk Němeček, who took office in January 2014, and his staff were also not hostile to HTA in principle. Although concrete plans for HTA were absent from any initial policy documents such as the government's manifesto, introducing HTA as a tool of evidence-based decision-making reappeared after a couple of months as a long-term ambition in the context of medical devices and diagnostics (MD&D) regulation (Čabanová 2014; Interview 161 2013; Interview 68 2015; Vymazal 2015). By this time, though, several key members of the Czech HTA community effectively lost access to the new administration, either because they had been fired or sidelined from their bureaucratic positions or because they perceived a lack of interest on the part of minister Němeček (Interview 161 2013; Interview 177 2013; Interview 68 2015; Interview 94 2013). Others, but excluding many original key members, were included in the ministry's new initiatives around MD&D.

In other words, the causal mechanism broke down. With a change of decision-makers, the epistemic community lost access to those with the power to adopt their policy. New decision-makers in the

Czech Republic may have well been on board with the general ideas of the epistemic community, but the concrete steps towards implementation were lost. The fact that new decision-makers agreed on the desirability of their policy is, in itself, not enough for the community to continue exerting sufficient influence to see the policy through. This is in line with the role of any causal mechanism: its interrelated parts are more than a sum of interfering variables, and need to act in a specific sequence (Beach and Pedersen 2013, 31). Having a sympathetic decision-maker and a community with a track record of policy activity is not sufficient if access is lost.

So far, Haas' initial causal mechanism is empirically validated – all parts are necessary, in their logical order, with one minor adjustment: on the basis of the Czech case, it would seem that the pitchforked third part (either continuing providing learning opportunities or consolidating bureaucratic power, or both) should be considered more broadly as “epistemic community gains access to decision-makers” (see Figure 4:2 below), as suggested already by Drake and Nicolaïdis (1992). Access should be understood as a continuous notion which can include both formal and informal dimensions – the Czech case shows that even high levels of formal access (e.g. members of the epistemic community within top bureaucratic structures) do not necessarily imply effective access, in the sense of having the ear of decision-makers. Access should not be seen as an optional part in a pitchforked causal path, but as integral to the mechanism – our negative case suggests that learning and framing opportunities without good access to decision-makers are not sufficient to lead to persuasion. This is, despite Haas' original formulation, consistent with the internal logic of the mechanism – without access to decision-makers, epistemic communities can provide learning opportunities and frame issues *ad libitum*, but their ideas will not make it to those with the mandate to decide on them.

Figure 4:2. Revised causal mechanism for epistemic communities' influence



Note: The central scope condition is reconceptualized as demand rather than uncertainty. Access becomes an integral part of the causal mechanism, rather than one of the options for influence.
Source: author.

This is somewhat surprising. After all, one of the central premises of the epistemic communities approach is that decision-makers implement the community's policy if they are convinced of their desirability as a result of the community identifying interests or framing the issue. A change coming from politics, above the policy subsystem, should therefore only matter if new decision-makers have not (yet) been convinced by the epistemic community. If they have, the epistemic community provides, similarly to policy communities (Marsh and Rhodes 1992; Wilkinson, Lowe, and Donaldson 2010), continuity to the policy process to shield it from political disruptions. The Polish HTA agency, with minister Religa actively implementing the policy of his predecessor despite his nomination for a

different government, confirms this logic. On the other hand, an instance where new decision-makers are also convinced that the policy is a good idea and yet do not adopt it, as in the Czech Republic, presents a puzzle.²⁰

In Haas' and Adler's original formulation, such a situation should not happen because the high uncertainty they face does not leave decision-makers other options than to follow, to a greater or lesser extent, the solutions set forth by the epistemic community. But if epistemic communities can be influential even in routine policy-making, as evidenced by the Polish HTA case, then a reformulation of uncertainty as a more general concept is in order. By using a broader concept – namely decision-makers' demand for epistemic communities' input – we can shed light on how this revised scope condition influences the causal mechanism. This is what the final substantive section does.

4.4. Beyond uncertainty: demand as the key scope condition for epistemic communities' influence

Together with complexity, uncertainty is the key scope condition of the epistemic communities' concept and has remained so until recently. Cross (2012, 153) calls for a “broader interpretation” of uncertainty, which would include also some certain issues; Dunlop (2009, 290) points out that decision-makers are often not behind an “all encompassing veil of ignorance” but solicit instead information from epistemic communities with varying degrees of control over what they want to find out and how they do it. Both of these critiques suggest that the role of uncertainty in the original

²⁰ It also refutes an important alternative explanation for non-adoption of HTA in the Czech Republic, namely policy learning. Decision-makers refusing to implement a policy despite its international fashion could be seen as an instance of learning during the policy transfer process (Dunlop 2009; Stone 2012) – with those in power coming to the conclusion that the policy is not worthy of adoption. Despite the ample evidence from other countries' experience with HTA bodies available to Czech policy-makers in 2013, there is no evidence that their decision not to create an HTA body would be the result of such a process.

approach is overstated, and that there may be other reasons why decision-makers become influenced by epistemic communities. All these reasons have, however, one outcome: the demand of those in power to hear from well-informed experts. Without demand, the mechanism of influence of epistemic communities is disrupted – in fact, this is a likely scenario because the causes of policy-makers’ demand can cease to exist for many reasons outside the power of the epistemic community. Using the Polish and Czech HTA examples, the following subsections first explore the many sources of demand and how it can be satisfied by alternative policy options, before briefly examining how the change in demand affects epistemic communities, not only before a decision on their policy is made but also after.

4.4.1. Demand for expert input and its many sources

The general trigger for the influence of an epistemic community can be imputed from Haas’ formulation cited above: “As *demands* for such information arise” (Haas 1992, 4 emphasis added). Demand for epistemic communities’ input – a general willingness to listen – is then the key scope condition for their influence, rather than uncertainty. Sources of demand for expertise are multiple. Uncertainty and complexity, as identified by Adler and Haas (1992, 373) and the knowledge utilization literature (see Radaelli 1995), in an echo of Weberian rational-comprehensive understanding of policy-making, would be one group of reasons. Legitimation and the use of expertise to substantiate decision-makers’ preferred positions (Boswell 2009) would be another. All of them presuppose the existence of a problem in need of tackling. Problems can be to a large extent (co-)created by experts themselves, as remarked both by science and technology studies (Hoppe 2005; Jasanoff 1994) and mainstream positivist public policy scholars (Kingdon 1984). Kingdon’s theory of agenda-setting in particular emphasizes that, in policy-making, contrary to the rationalist view, problems often emerge to fit

solutions, and not the other way around. Social and natural world phenomena need to be first *constructed* as problems in order to be recognized as such, by new framings of existing phenomena due to – among others – “focusing events” (shocks within or external to the subsystem) or new evidence (Kingdon 1984; see also Oxley, Vedlitz, and Wood 2014). In Kingdon’s view, experts (and epistemic communities) are well-placed to affect policy-makers’ perception of problem pressure by virtue of their authoritative knowledge of the issue area. They are not agency-less until called upon by policy-makers in need of an appropriate response to a “real-world” problem; on the contrary, they have the power to actively create demand by framing events as problematic.

This is what happened with HTA agencies both in Poland and in the Czech Republic. In Poland, there were two principal problems in the area of health care reimbursement in the early 2000s. One was the lack of additions of new drugs and medical devices on the list of reimbursed interventions – for several years no new innovative medicines were approved for reimbursement in Poland. This set off pressure from innovative pharmaceutical companies and, following Poland’s accession to the EU in 2004, led to the European Commission considering an infringement procedure for non compliance with the EU Transparency Directive (89/105/EEC), which sets binding timelines for approval of pricing and reimbursement of new medicines. The procedure was eventually officially launched in December 2005, a few months after the ministerial ordinance setting up AOTM but before the agency started its work – but there had been arguments coming from the HTA community earlier that an HTA agency might be positively perceived by the Commission and mitigate EU pressure (Interview 119 2013; Interview 166 2014; Interview 22 2013; Interview 48 2013; Interview 58 2013; Interview 73 2013). Parallel to this, there was the debate on the scope of entitlements and rights to care as part of the mandatory health insurance intensified by a 2004 ruling of the Polish Constitutional Court, which made the need to clarify the basic benefit package an urgent legislative matter for the ministry of health. Again, advocates of an HTA agency could present it as a solution to determining the extent of

benefits – a new agency would in the future be in charge of determining to which interventions Polish patients are entitled, based on an authoritative, scientific method (Interview 151 2014; Interview 73 2013). In other words, decision-makers in Poland faced two problems to which establishing an HTA agency was presented by the epistemic community as a solution. A demand for policy alternatives to address these problems was clearly present in Poland in the mid-2000s – and the Polish HTA epistemic community provided such a solution.

In the Czech Republic, the field of health policy also offered problems that HTA could be construed as an answer to. European Union pressure was one of them: Article 15 of the EU Cross-Border Healthcare Directive (2011/24/EU) set up a network of national HTA bodies, which meant the Czech Republic needed to decide on an institution to represent it in the new network – a lack of a dedicated HTA body made this decision more difficult. European cooperation was therefore cited by the epistemic community as a reason to set up an HTA agency (Vepřek 2011). Another problem was curbing the expenses for high-cost medical devices and diagnostics which had benefitted from unregulated market entry since 2007, when the Czech Constitutional Court struck down a ministerial expert MD&D committee for lack of transparency and accountability in its procedures.²¹ As a result, hospitals throughout the Czech Republic (often owned by regional governments and linked to political parties) were free to purchase expensive diagnostics (e.g. magnetic resonance imaging scanners) for whose use they later sought reimbursement from payers, above all VZP (also linked to political parties – see Johnstone 2014). This was minister Heger's problem a year into his mandate. While the need for action was not immediately urgent, it was well-established over the three years of unregulated diagnostics purchasing, and Heger looked for a way of reinstalling the MD&D committee. He sought

²¹ While the competence for regulation of pricing and reimbursement of pharmaceuticals was promptly given to the State Institute for Drug Control, no regulator was found for medical devices – there seems to be a consensus among interviewees that rather than active lobbying of MD&D industry the omission was a genuine mistake by the ministry of health (Interview 105 2013; Interview 149 2013; Interview 9 2014; Interview 94 2013).

advice from Pavel Vepřek, his advisor and deputy minister, who suggested the creation of an HTA body instead (Interview 40 2013; Interview 94 2013; Interview 96 2013). The Czech HTA community did not construct the problem of MD&D purchasing and the resulting demand for expert advice on the part of minister Heger, but it actively seized it and coupled it with their policy alternative. The demand for its input continued well into the policy formulation stage where members of the community fed into pre-legislative proposals of the policy. Following the government fall, the demand all but disappeared during the short term of minister Holcát. His caretaker administration only dealt with pressing matters, and long-term spending on diagnostics was not of them (Interview 16 2015; Interview 68 2015). With demand gone, so was the epistemic community's access to decision-makers.

The problem itself was inherited by minister Němeček who, like his predecessor Heger, wanted to reinstate a variant of the old MD&D committee. His demand for input of the epistemic community was, however, short-lived. It was almost instantly satisfied by his senior advisors, who found a quick way of establishing, within three months, a new committee on expensive MD&D as an advisory body to the minister whose decisions are binding for health care payers on a voluntary basis (Ministerstvo zdravotnictví ČR 2014). Němeček's advisors had a relatively clear idea of the crucial goals of the committee (which include, in the long run, elements of HTA as a basis for decision-making) and of the fastest way to achieve them under time pressure – a committee had to be up and running as soon as possible, and methodological details were to be sorted out on the fly (Čabanová 2014; Interview 183 2014; Interview 60 2015; Interview 68 2015). Demand for input from the existing HTA epistemic community, which had previously discussed various agency-like institutional arrangements for HTA with strong methodology in contrast to an advisory committee, was minimal. A competing policy alternative was more compelling to minister Němeček's administration, and reduced the immediate need to turn to an established epistemic community – or to any other policy actors outside the bureaucracy: the institutional setup of the MD&D committee hints at a go-to solution of the

administration influenced by path-dependency rather than outside advice (Interview 68 2015). Parallel to this process, it turned out that the problem of having an HTA body for the purposes of the EU cross-border health care directive was not too urgent: decision-makers, as well as members of the HTA community, were aware that (unlike in the case of the Polish infringement procedure) there would be no sanction from the EU for not having an HTA body (Interview 40 2013; Interview 72 2013; Interview 96 2013). In addition, an easy, fast solution was at hand: the Czech Republic could simply nominate a representative of the ministry of health or of the State Institute for Drug Control, as had been the case for previous EU projects on HTA (Interview 96 2013).²² Again, alternative solutions were manifestly easier to implement and had lesser costs, and were in the end selected by decision-makers. The problems with which HTA as a solution was originally coupled were addressed by other means, thus satisfying the original demand, and the road to influence of the community was closed.

In the Czech Republic, an additional source of policy-makers' demand for advice was a need for legitimization, varying in time. Heger's administration engaged in a larger modernizing effort of health care reform (Government of the Czech Republic 2010) and involving internal and external experts to determine how to best achieve individual modernizing goals was a way of increasing legitimacy of the ministry's effort. In line with these goals, HTA was presented by the epistemic community as "the way forward", inevitable progress towards an ideal of better governance and a general overhaul of Czech health care governance (Vepřek 2012b). A similar overarching modernization agenda was not present for Němeček's mandate, which defined its priorities more in terms of consolidation of finance

²² The institute in particular had some expertise in HTA because it had been out carrying pharmaco-economic and budget impact assessments (which are a major, but not the only, part of any HTA evaluation) for all medicines applying for pricing and reimbursement decisions since 2008, but its tasks had not been described as "HTA", either by the institute itself or by other Czech health policy actors before the height of the HTA debate around 2012-13, and even then only carefully: the Institute mentions "HTA" only once in its cost-effectiveness guidelines, and other actors speak of "*de facto* HTA" (Interview 183 2014; Interview 94 2013).

management and cost containment (Government of the Czech Republic 2014; Interview 177 2013; also Interview 183 2014), likely making the ministry more susceptible to accepting path-dependent, low-cost solutions. Although key decision-makers from the new administration were convinced that HTA as such was a good idea, without motivation to listen to experts (problem, legitimization or using experts as ammunition – which is an unlikely source of demand in a low political salience area such as reimbursement decision-making processes – or other potential reasons), the community's influence disappeared.

In short, just as demand can be stimulated by many factors, including epistemic communities themselves, it can be satisfied by many policy options, including those coming from other sources than the epistemic community. This is similar to Drake and Nicolaïdis' (1992, 41) claim that “direct epistemic community influence often declines once ideas and interests have been clarified” – as soon as policy-makers' demand for expert input is satisfied, the experts' influence diminishes, and other considerations, such as competing ideas, material interests, electoral gains (King 2005) and the like, enter the equation, making the epistemic community just one factor of influence among many. A source for policy-makers' demand can disappear (e.g. need for information can be satisfied, a problem might be addressed by alternative policies, legitimization through expert collaboration might not be of interest to new decision-makers), weakening demand and thereby closing the way through which epistemic communities affect policy-making.

4.4.2. Demand influencing the nature of the community after the decision

Regardless of its sources, the existence or non-existence (and anything in between) of decision-makers' demand for expert input affects the causal mechanism of epistemic communities' influence every step

of the way. Without demand, access to decision-makers is null. Without seeing a chance to sell their ideas to those in power, members of the epistemic community stop undertaking policy-oriented activities. Without activity, the community falls apart. In this way, demand as the crucial scope condition goes as far as to affect the nature of the community itself – strong or weak, large or small, existent or non-existent etc.

The Czech case illustrates this process: once the minister's demand for policy alternatives to tackle MD&D diffusion was satisfied by a path-dependent solution, access of the HTA epistemic community disappeared. HTA proponents stopped promoting the policy, citing a general skepticism as to the chances of success of their enterprise (Interview 161 2013; Interview 94 2013). Although some prominent members of the 2011-2013 HTA community were included in the new MD&D committee, others remained cautious or dismissive about the willingness of the new administration to take the principles and consequences of HTA seriously and, to paraphrase, “do things properly” (also Čabanová 2014; Interview 161 2013; Interview 177 2013; Interview 94 2013). Lacking a plausible chance of achieving its policy goal, members of the Czech epistemic community stopped organizing events on HTA for a policy audience and focused instead on other topics in health policy (Interview 161 2013; Interview 177 2013). The community essentially disintegrated – or has become dormant. Demand, in other words, influences one of the key elements holding epistemic communities together: shared policy enterprise. This common goal is after all what makes epistemic communities assemble in the first place and makes them into players within the arena of policy, rather than academic disciplines, communities of practice or professions. If attainment of the goal becomes unlikely, disintegration may follow.

Conversely, continuous demand beyond policy adoption may, as Cross (2012) expects, reinforce the epistemic community. This is what happened in Poland where the HTA community has consolidated

its influence and grown since its establishment of AOTM, owing partly to the growth of the agency itself and partly to a boom in associated consulting business. The community's policy enterprise, naturally, changes if their original goal is achieved – in Poland, it shifted from the adoption of the policy (establishment of an HTA agency) to details on its implementation, such as expert contributions to AOTM's methodological guidelines (Agencja Oceny Technologii Medycznych 2007, 2009 - note also the increased number of task force members in the document's preface), or evaluation and reform, such as new responsibilities of AOTM under the 2011 Reimbursement Act (Stefańczyk 2011). The policy goal of the community evolves alongside the development of the policy itself but also in line with the group's normative and principled beliefs and notions of validity of knowledge – something that moderates the findings of some epistemic communities research, which contends that their influence is far greater in the agenda-setting stage than later (see Raustiala 1997).

On the basis of the Polish and Czech cases we can hypothesize that an epistemic community should, if anything, become stronger after a successful passage of its policy because demand for its input continues (and maybe even increases, with policy implementation typically requiring in depth expertise). In contrast, failed passage can lead to a weakening or disintegration of the community, as lacking demand impedes its access to decision-makers and its willingness to meet and engage in promotional activities. This is not necessarily an automatic development – a possible caveat could be that the disintegration of an epistemic community might have more to do with the nature of the group itself rather than external conditions such as whether they are in good graces with policy-makers. Cross' (2012, 149–151) point on epistemic communities' internal cohesion would be a possible way to explore this assumption. In her view, it is the group's professionalism²³ that increases its chances

²³ Operationalized as: competitive selection and demanding training, frequent interaction including informal meetings, shared professional norms crucial for resolutions of disagreements, and common culture that includes identity and symbolic elements (Cross 2012, 149–151).

of successful influence. If an epistemic community is cohesive (or professional) enough, it might survive the withdrawal of demand, and continue its activities while perhaps lying in waiting. That is entirely plausible, although it is questionable in how far such a group, without a common policy goal, remains an epistemic community rather than becoming a subgroup of a profession, an issue network etc.

Another exception to the disintegration rule could be if demand persists from other decision-makers such as opposition (shadow cabinets) or alternative decision-making bodies (regulatory agencies, international organizations) for highly polarizing issues, if the epistemic community perceives a potential re-opening of the window of opportunity. But even in this case, demand is key for maintenance of the common policy enterprise. In other words, demand becomes the way through which decision-makers exert influence on epistemic communities, reversing the traditional research question of the epistemic communities literature in an example of an interlinked relationship between experts and governments described by neighboring scholarship (Halffman and Hoppe 2002; Hoppe 2005; Jasanoff 1994).

4.5. Conclusion

The main aim of this article was to shed light on why some epistemic communities manage to convince decision-makers of their preferred policies while others do not. It concluded that epistemic communities fail to affect policies when the mechanism of their influence is interrupted. A major reason for an interrupted mechanism of influence is a change in scope conditions, which this paper argues should be conceptualized as policy-makers' demand for epistemic communities' input, rather than more narrowly uncertainty or complexity as suggested by Adler and Haas (1992). Demand may

stem from many different sources – the need for advice because of complex or uncertain “real-world” problems, a will to use experts to legitimize decision-makers’ roles or a motivation to support their already formed positions with expert arguments. Although these sources can be created or stimulated among other by the epistemic communities themselves, they may intensify or weaken for reasons beyond their power, thus changing the way their activities affect decision-makers.

To show this, the paper hypothesized that the differences do not lie in one of the many “conditions for success” identified by the epistemic communities scholarship, but rather in a causal mechanism, little explored by the literature so far. In order to prevent overestimation of the influence of epistemic communities as done by a majority of epistemic communities scholarship, it engaged in a comparative study of a positive case of successful influence (Poland) and a negative one where a comparable community failed to push through the same policy (establishment of an HTA agency) in a neighboring country (Czech Republic). The juxtaposition demonstrated that the simple causal mechanism put forward by the original epistemic communities’ manifesto (Haas 1992) can be empirically verified. All parts of Haas’ mechanism are necessary and not redundant. On the basis of our negative case this paper proposes an adjustment to the original mechanism: bureaucratic capture, which Haas conceptualized as optional to a continuous provision of framing and learning opportunities, is demonstrated to be an integral part for the “cogs and wheels” of the mechanism to function. To encompass the informal framing and teaching opportunities of the original formulation, this paper proposes to rephrase bureaucratic capture as a broader category of “access to decision-makers”, in line with some of the existing scholarship (Drake and Nicolaïdis 1992). Focusing on the mechanism of influence rather than on the nature of the community or the policy changes the thinking about epistemic communities: the move is from a probabilistic view based on conditions for success (“the better their access to decision-makers, the higher the chance of their success”) to one where scope conditions and parts of the causal mechanism are clearly separated and their interaction with each

other and with overarching scope conditions is specified. A similar in-depth testing of related public policy approaches from the community/network family would be beneficial in order to move beyond the “metaphor” problem (Dowding 1995). It can, however, be expected that demand will be the key scope condition to many of these, with individual parts of the causal mechanism changing shape depending on the nature of the concept (e.g. interests for policy communities or iron triangles).

The successful case of HTA institutionalization in Poland is in itself interesting because the issue in question is a highly technical one of low political salience, as are the issues existing epistemic communities scholarship typically considers, but of high certainty, and thus presents an additional example that epistemic communities can be influential even in routine policy-making at the domestic level, rather than only in times of international crises (see also King 2005; Marier 2008; Salvador and Ramió 2011; Thomas 1997). The negative case explores where and why the mechanism of their influence can be interrupted, and whether these interruptions necessarily mean a loss of influence. While a single study of a negative case is far from providing a definitive answer to why epistemic communities succeed or fail – there may be many pathways to failure and many moments in which the causal mechanism may break down, in particular the final suasion part – it presents a contribution to the study of epistemic communities in that it offers to correct the customary overly confident view of epistemic communities’ role in policy-making. In-depth process-tracing is well placed to deal with the problems of equifinality; further study of unsuccessful cases should be able to uncover additional scope conditions or perhaps new causal chains which would, alongside the findings of this paper, contribute to our understanding of why, sometimes, ideas put forward by experts with authoritative knowledge in their domain do not make it into policy.

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5. PAPER III: WHO'S AFRAID OF HEALTH TECHNOLOGY ASSESSMENT? INTERESTS AND POLICY POSITIONS FOR AN HTA AGENCY IN THE CZECH REPUBLIC²⁴

Abstract:

Objectives: To identify the interests and policy positions of key health policy stakeholders regarding the creation of an HTA agency in the Czech Republic, and what considerations influenced them.

Background: Vested interests have been suggested as a factor mitigating the diffusion of health technology assessment (HTA) bodies internationally. The Czech Republic recently considered and discarded establishing an HTA agency, making it a good case for studying actors' policy positions throughout the policy debates.

Methods: Findings are based on in-depth, semi-structured expert and elite interviews with 34 key Czech health policy actors, supported by document analysis and extensive triangulation.

Results: The HTA epistemic community of "aspiring agents" was the only actor strongly in favor of an HTA body. Payers and the medical device and diagnostics industry were against; patients and clinicians had no clear preferences. Original decision-makers were in favor but a new minister of health opted for a policy alternative to solve his need for expertise.

Conclusions: Existing institutions, policy alternatives and the institutional design of a future HTA body influence domestic actors' preferences for or against an HTA agency. Domestic and international proponents of HTA should give serious thought to their concerns when advocating for HTA bodies.

Keywords: health technology assessment; policy diffusion; interests; policy positions; stakeholders; delegation

Highlights:

- Diffusion of health technology assessment bodies is not inevitable but is mitigated by domestic politics
- Actors' positions are influenced by existing institutions, policy alternatives and proposed institutional design for HTA
- Decision-makers (principals) must see the need for delegation to an HTA body as superior to policy alternatives
- Domestic and international proponents of HTA should consider alternatives and existing structures

²⁴ This paper was submitted to a health policy journal targeting a mixed academic and practitioner audience.

5.1. Introduction

Health technology assessment (HTA), a multidisciplinary evaluation of health, economic, social and other aspects of health interventions [1,2], seems firmly established in Europe today [3]. There are compelling arguments for using HTA as an evidence-based analytical tool for informing decision-making on health interventions' pricing and reimbursement [4–7]. As a result, many countries founded dedicated HTA institutions. Although they differ greatly in their institutional setup, competences and role in decision-making systems [8,9], they share a general commitment to informing decisions based on a rigorous, transparent and independent evaluation of evidence [10]. The European Union (EU), with the HTA Network founded by Article 15 of Directive 2011/24/EU, supposes that all EU member states have “HTA bodies” [11,12]. It would therefore seem that deciding whether to establish an HTA institution is a no-brainer, especially given that fashionable policies and institutions, as having an HTA body undoubtedly is [13], tend to diffuse internationally [14–16].

A closer look, however, reveals that not all EU countries have specialized HTA bodies [10]. Some use HTA as an analytical tool to inform decision-making without dedicated institutions (e.g. Lithuania [17]), but most countries without specialized bodies have a limited use for HTA in decision-making, predominantly in Central and Eastern but also in Southern Europe [8,10,18]. In short, there are blank spots on the map of European HTA.

Why is this? The implicit assumption of much of the practitioner as well as scholarly literature is that HTA analyses, usually performed by specialized HTA bodies, are an evolutionary necessity. By this logic, HTA will inevitably diffuse everywhere and laggards will eventually catch up with the good pupils [19–23]. However, new HTA institutions have been rare in recent years: since 2007, only three EU countries established an HTA body [10]. This suggests their unfettered diffusion has encountered mediating factors [24]. These include resistance from key domestic actors [25], which can be expected

to be particularly influential in a low-salience policy area such as HTA [26,27]. In fact, vested interests of powerful actors have been pointed to as one of the reasons for the non-existence of HTA in many countries [18].

This paper therefore examines actors' stances as mediators of the diffusion of HTA bodies. It asks what the interests and policy positions of key health policy actors are regarding the establishment of new HTA bodies, and how these positions are formed.

To answer these questions, this paper analyzes the case of HTA in the Czech Republic. As of 2016, the country does not have a dedicated HTA body and is unlikely to establish one in the near future. However, HTA is a known term in the Czech Republic and the option of creating an HTA agency to inform pricing and reimbursement decisions was actively debated in 2011-2013. The project came to a halt in June 2013 following the government's fall. This makes the Czech Republic a "near miss" as opposed to an irrelevant case [28], as it excludes the possibility that the policy idea has simply not reached the country. Because a debate took place, we can expect interests and positions to have been formed and formulated. The Czech case then helps uncover the patterns of interests and positions around HTA and its institutionalization in countries with no, or limited, HTA, and determine if interests can impede or encourage the diffusion of HTA institutions. Its findings can inform discussions on HTA institutionalization in similar cases, most directly in Central and Eastern European countries without HTA bodies.

The main argument of this paper is that important domestic actors are well aware of arguments for establishing HTA institutions, but perceive the policy as ill-adapted to their needs. Domestic and international efforts to institutionalize HTA, especially in low and middle income countries, should take these needs into consideration.

5.2. Background and theoretical expectations

Establishing HTA bodies, even when inspired by a process of international policy diffusion, is an instance of authority delegation [13,29]. Domestic policy-makers face a double dilemma: first, do they want to establish a specialized body using HTA? Second, if yes, how much discretion should they give it? The answers depend on their motivations. Scholarly literature on delegation puts forward that policy-makers (principals) have an interest in creating specialized institutions (agents) in order to solve an information asymmetry problem and make use of the agents' specialized knowledge in a highly complex policy area [30–32]. They award the agent more discretion (formal independence and decision-making powers [33,34]) when they are looking to: a) resolve problems of commitment credibility, b) shield their policies from future reversals, or c) avoid blame for unpopular decisions [31,32,34,35]. Specialized independent HTA bodies with a say in pricing and reimbursement (P&R) decisions can therefore be a means for policy-makers of ensuring consistent, evidence-based P&R, while deflecting blame for rationing care – a theme well-known in health policy [36,37], as well as in HTA [38].

The delegation literature is generally not explicit on the interests and positions of actors other than the principals in this initial dilemma. But there are other actors than just policy-makers and (would-be) agents in the delegation relationship, most importantly those who the new institution intends to regulate (e.g. industry), but also others [39]. Banta's 2003 review provides the clearest, if brief, reflection on interests and goals (though not concrete positions) of the most important actors ("stakeholders") regarding HTA (p. 129) [40]. His notes allow us to formulate the following theory-informed expectations about actors' interests and policy positions on HTA institutions, summarized below in table 5:1. They are further informed by literature tackling interests in priority-setting and evidence-based medicine [41–43], as well as by status quo *ex ante* in Czech pricing and reimbursement.

Table 5:1. Theoretical expectations about interests and policy positions on introduction of HTA

<i>Actor</i>	Policy position on HTA	Interests	Literature
<i>Policy-makers</i>	In favor	Need for expertise: HTA provides expertise in advising on spending allocation	Banta [40]; Sweet & Thatcher [30], Bendor et al. [31], Moe [32]
	In favor	Blame avoidance: HTA process/body takes off blame for unpopular decisions	Hood [35], Gilardi [34]
	Against	Distrust in complex methodology of HTA	Dankó [44]
<i>Payers</i>	In favor	Budget control: payers are concerned with budget impact only, not cost-effectiveness and other considerations – if HTA delivers budget control, in favor, and <i>vice versa</i>	Banta
	Against	Bureau maximization: payers are reluctant to let go off P&R competences, and prefer to keep HTA in-house	Niskanen [45], Downs [46], Dunleavy [47]
<i>Clinical physicians</i>	Against	Loss of professional autonomy	Saarni [43]
	No preference	Quality concerns only: clinicians do not have spending or public policy concerns as priorities	Banta
<i>Industry</i>	Against	No regulation preference: new regulation is a barrier to profit	Banta, Stigler [48], Posner [49]
	In favor	Predictability & transparency: HTA makes for a more predictable business model	Banta, Stigler
<i>Patients (general public)</i>	Against	Access & quality concerns: HTA limits availability of interventions	Banta, Saarni
	No preference	Complexity and low salience of the issue	Lohmann [26]
<i>Epistemic community</i>	In favor	Epistemic belief in evidence-based policy-making	Banta, Battista & Hodge [50]; Haas [51], Löblövá [52]

Policy-makers are attracted to the “value for money” promise of HTA [40]: a specialized body that would solve a functional need for expertise – much in line with the central delegation premise. In the post-communist Czech Republic, this need for expertise had been satisfied by advisory expert committees on drugs, medical devices and diagnostics (MD&D) and health care services, convened by the minister of health. In 2007, a Constitutional Court ruling effectively dismantled the drug and MD&D committees on the grounds of lack of transparency and accountability (lack of appeal) of their procedures. Subsequently, P&R competence for pharmaceuticals was given to the State Institute for Drug Control (*Státní úřad pro kontrolu léčiv – SÚKL*), illustrating a need for expertise (in pharmacology at least) in addition to the need for a clearer legal procedure triggered by the Constitutional Court ruling. The MD&D committee was not replaced, suggesting a puzzle for the delegation theory as well as Banta’s hypothesis – by this logic, Czech decision-makers can be expected to feel pressure for an HTA body to fill the void. They might, however, prefer less complex alternatives as they do not trust the complex statistical models of HTA outputs [44].

Insurers (payers) are interested in budget containment [40] – and would therefore be in favor of HTA to the extent that a new HTA body would help them with this goal. As any bureaucracy, payers should be interested in bureau or budget maximization [45–47], and should therefore prefer in-house HTA to an external (independent) agency. The Czech Republic has a multiple-payer social health insurance system, with limited competition between insurance funds, characterized by a dominance of the largest, publicly owned insurance fund (*Všeobecná zdravotní pojišťovna – VZP*). VZP plays a key role in P&R setting for all health care interventions; smaller insurers, grouped in an association representing them in P&R procedures and broader policy questions, typically follow its lead. Together they have an unusually strong position in the country’s P&R governance: they essentially determine the acceptability of the P&R levels for medicines in SÚKL’s procedure, and unilaterally set reimbursement levels for both out-patient and in-patient MD&Ds based on their internal calculations (as part of,

respectively, direct reimbursement or pseudo diagnosis-related group payment schemes). They are also represented on the ministerial expert committee for health care services (along with representatives of the ministry, clinicians and – at times – patients), and can negotiate different levels of reimbursement for services. Czech payers can therefore be expected to be reluctant to let go of their power, unless HTA helps them control budgets better than the status quo – concrete policy proposals, rather than a general commitment to the policy idea, are likely to shape the payers' positions.

Clinical physicians have little interest in issues other than quality of care [40], which HTA promises to improve overall through improved allocation of resources but at the expense of selected individual treatments, making for an unclear position. Others have pointed out that clinicians are interested in maintaining broad professional autonomy which is threatened by a regulatory body [43]. They should therefore be against HTA in general. There is no reason to expect Czech clinicians to have different priorities.

The *pharmaceutical and medical device industry* has an overriding interest in financial profit, which new regulation threatens; on the other hand, Banta suggests it is also increasingly aware of cost-effectiveness constraints through ever fiercer market competition for reimbursement [40]. Their preference for or against an HTA body depends on the extent predictability of reimbursement decisions introduced by new HTA regulation offsets costs of expanded regulation, in line with the capture theory of regulation [48,49]. Policy preferences therefore depend on individual firms' market position. The dividing lines in the Czech Republic can be expected between those parts of the industry that anticipate an HTA body to become a hurdle to market entry on top of existing regulation [53] (e.g. the pharmaceutical industry and the wholly unregulated expensive MD&Ds purchased by providers), and those who stand to benefit from increased predictability (e.g. producers of MD&Ds

regulated single-handedly by payers). Like payers', the industry's position can therefore be heavily contingent on the concrete policy proposals regarding the amount of discretion of the new HTA body.

The *general public* has a predominant interest in maintaining (or gaining) access to care of acceptable quality [40]. Traditional political economy approaches would argue that the general public has no preference on such highly technical issues [26]. However, it is represented in health policy-making by *patient organizations* [54], who should, following Banta's logic, be against HTA if they expect it to lead to benefit exclusion, and in favor if they see HTA as an opportunity to add more care to the reimbursement list. Czech patient organizations, as well as the broad public, are unlikely to be exceptional in this respect.

Banta also mentions "epidemiologists and other researchers" who have an interest in "in the poor state of research and how to improve it" (p. 129) [40]. This category is sometimes also described as "Champions" of HTA [50]. Because of its knowledge-centered motivation, this group can be reconceptualized as an *HTA epistemic community*: a group whose members recruit from across other stakeholder affiliations but are held together by a shared set of normative and principled beliefs, causal beliefs and notions of validity of knowledge, which motivate a strong preference for HTA [51]. The epistemic community is a different kind of actor than traditionally considered by the special interests scholarship, but its aim to influence policy is clear and its need to co-exist, bargain and build alliances with other actors is well-established [55,56]. As such they should not be left out of our analysis. The Czech HTA epistemic community was indeed influential in putting HTA on the agenda around 2011 and can be expected to pursue its preference for HTA with vigor [52].

5.3. Materials and methods

The findings in this paper are based on a set of in-depth, semi-structured expert and elite interviews [57,58] with 34 actors knowledgeable about Czech HTA and reimbursement decision-making. All interviewees were promised anonymity and are identified here by randomly assigned interview numbers (e.g. “I-20”) and broad categories (see table 5:2). Taking into account the sensitive nature of ongoing policy-making, this was a necessary tradeoff between transparency of the data and its quality (availability, trust and openness of interviewees).

All interviews were carried out in person in Prague and Brno in three main rounds of fieldwork between May 2013 and December 2015; two were conducted over the phone. Three interviewees were interviewed twice; two were interviewed three or more times. The typical duration of an interview was one hour.

Table 5:2. Interviewee affiliations

<i>Interviewee category (most relevant</i>	<i>Number of</i>	<i>Number of</i>
<i>Ministry of Health</i>	7	2
<i>Payers</i>	2	1
<i>Pharmaceutical industry</i>	2	
<i>Medical devices and diagnostics industry</i>	2	1
<i>State Institute for Drug Control</i>	2	1
<i>HTA/ pharmacoeconomics consultancies</i>	6	1
<i>Academia</i>	2	1
<i>Clinicians</i>	4	
<i>Health journalists</i>	2	
<i>Lawyers</i>	2	
<i>Patients organizations</i>	3	
<i>Total</i>	34	7

Interviewees were identified using purposive sampling [59] in order to cover main actors involved in Czech HTA. Publicly available documents (conference reports, specialized press articles) were used to identify interviewees in the first round; snowball sampling [59] was used later to identify additional important actors and to reach non-responsive interviewees. In total 72 potential interviewees were identified between 2013 and 2015; 58 were prioritized and contacted; 10 (17%) refused (5 of whom suggested alternative interlocutors) and 8 (13%) did not respond despite repeated contact attempts (refusals and non-responses were spread evenly across interviewees' institutional affiliations); 2 interviewees could not be located and 2 interviews were cancelled due to scheduling issues.

Semi-structured interviews are the most appropriate way of obtaining data for the object of our study, that is, a policy in the making, halted in the early days of the pre-legislative phase of the policy cycle. Few written traces exist and even fewer are publicly available. By definition, interviews with those in the know are in such cases, barring participation or observation [60], the only way of gathering information for a researcher. To counter most potential risks of omission, misrepresentation or deception by the interviewees, information was systematically triangulated with data from other interviews and, where available, written documents [61]. For this reason, interviews were continued even beyond saturation (the point where additional interviews produce little new information or relevant themes [62]) in an effort to reach as many relevant actors as possible. Data was analyzed by qualitative content analysis using NVivo 10 software, based on deductive (theory-driven) and inductive (data-driven) codes [63]. The findings presented below are those where a reasonable level of confidence in their validity could be established through direct or indirect corroboration [64].

5.4. Results

Czech policy-makers were divided on institutionalizing HTA, with one minister of health pro-HTA and another favoring an alternative policy option. Payers and the MD&D industry were against an HTA body, while patients, clinicians, pharmaceutical industry had no clear preferences. Only one group of actors was strongly in favor of institutionalizing HTA in the Czech Republic: the epistemic community of “aspiring agents”.

5.4.1. Policy-makers

Czech ministers of health were split on HTA: Leoš Heger (July 2010-June 2013) initiated work on institutionalizing HTA midway through his mandate, whereas Svatopluk Němeček (January 2014 onward, following six months of caretaker government) promptly implemented an alternative to HTA.

Heger’s administration was favorable to HTA. The minister was originally unfamiliar with HTA but wished to solve a growing problem in his sector: unregulated entry of expensive diagnostics and devices on the market, later seeking reimbursement from public health insurance. He looked for ways to reinstall the old MD&D Committee which had, until the Constitutional Court’s 2007 ruling, authorized their purchasing by providers. His advisors, members of the epistemic community, convinced him HTA would be an appropriate solution to the issue (I-40, I-96, I-37), overcoming the initial distrust expected by Dankó[44]:

“The Minister wanted [his advisor] to reintroduce the old MD&D Committee. So [his advisor] explained to him the ministry no longer has the competence to centrally decide who can buy what. [...] The minister complained that it’s too complicated [...] but somehow he was eventually convinced [of the necessity of HTA], so he learned about it” (senior civil servant).

The central problem-pressure assumption of the delegation literature is here confirmed: the principal needs to create a new body to introduce regulation, and needs experts with specialized knowledge to determine the body's output. Beyond this *prima facie* legitimizing function of experts, however, we find little trace of blame-avoidance motivation in interviews with policy-makers. Instead, the ministry aimed at starting public debate about the price of life and limits of health care free at the point of use, in order to manage public expectations [65] – quite the opposite of blame-avoidance strategies of not attracting attention to potential rationing controversies.

As the principal, Heger's ministry had a key say in formulating the details of the policy, which influenced the stances of other actors. The ministry had initially hoped for an independent agency but a new independent institution was deemed too expensive to get the approval of the ministry of finance (I-40, I-96): "It's not so easy to create an independent public organization. [...] No-one can afford another NICE [UK's National Institute for Health and Care Excellence] here" (civil servant). The subsequent option included hosting an administrative bureau and an appraisal committee, composed of the ministry of health, two payer representatives, clinicians and the ombudsman (representing patients), within an upcoming "Health Insurance Bureau" (eventually never created). Assessment of manufacturers' HTA dossiers was to be outsourced to external experts (academia and consultancies), and decisions would be taken by the relevant decision-maker depending on the technology (SÚKL for drugs, ministry of health for services etc.) [66]. Later formulations again mentioned a separate "Czech HTA Agency" [67], followed eventually by an idea to add an HTA department to SÚKL [68], as SÚKL had the organizational and financial capacity to absorb new functions [69] (p.3) (I-40).

This evolution seems to be motivated by emerging budgetary and practical constraints rather than a fundamental change in thinking. Some elements were constant, however: firstly, a strict separation between assessment and appraisal. Second, a focus on transparency: in all options detailed

methodological guidelines as well as appraisal recommendations and reasonings were to be public. Third, the body was to have formal independence (even when joined up with SÚKL, itself an independent regulatory agency) but limited regulatory powers: its function was to be advisory. Finally, Heger's administration was relatively agnostic as to the methodological details of HTA but had a clear position on the scope of its competences: all possible health technologies were to be mandatorily covered, not only pharmaceuticals but also MD&Ds and health care services [66].

This changed with Němeček's administration, and the debate around creating a specialized HTA body disappeared from the agenda. Problem-pressure persisted: Němeček still needed to control high-cost MD&D spending. Instead of establishing an HTA institution, the new administration tackled the issue by creating a new advisory committee within the ministry which evaluates requests from individual providers (typically hospitals) for purchasing and geographical distribution of MD&Ds over 5,000,000 CZK ($\approx 185,000$ EUR). Payers committed to following the committee's decisions through a voluntary memorandum of understanding – a very different kind of discretion than Heger's HTA agency. The topic of HTA was to a certain degree absorbed by this policy solution: Němeček declared that “analyses based on HTA methodology should be one of the inputs for the committee's decisions” [70]. Several members of the committee describe the committee as an effort to “strive to introduce HTA”, speaking of “HTA-light-light” (I-68, I-161). Others, however, doubt the committee's methodological soundness [71], given that individual reasonings and detailed methodology are confidential [72]. This is also a departure from the ideal-typical HTA agency as advocated by Heger. In any case, a dedicated HTA institution was off the table.

The new MD&D committee is composed, among others, of representatives of clinical societies and some HTA experts [73]. This suggests that Němeček perceived the need for expertise, and therefore delegation – but was able to satisfy it with less discretion, which in practical terms implied less time-

consuming legislative, and budgetary, effort to set up a new institution. As one member of the new committee put it, “the [minister’s] assignment was to restore the [old] MD&D committee *fast*. [The team] had 2 weeks, maybe 2 months” (I-68, senior civil servant). This demonstrates how important the problem-pressure element in delegation dilemmas is: new principals may be convinced of the problem but choose a different solution than preferred by their predecessors, diminishing or dissipating the need for delegation or significant discretion.

5.4.2. Payers

Czech payers for the most part dismissed HTA and its various institutionalizations. On the one hand payers agreed on the usefulness of HTA as a tool to provide information whether a certain technology is worth funding, and agreed that the Czech health care system needed a similar decision-making tool (p. 17-18) [69] (I-105, I-65). They wanted a “basic consideration, with clear criteria” of costs and benefits, defined broadly, of new health technologies (I-65, payer). To a certain extent they had been already performing this function in-house to inform internal decision-making for selected interventions (I-105, I-65, I-183). Their need for expertise was therefore low. The value added of an external HTA body for the payers would be a societal and political consensus on willingness-to-pay thresholds beyond which payers would be justified in refusing reimbursement:

“Let us take a technology which fails to convince us or other stakeholders that it is better for the patient, more efficient for the system and less costly for the insurer. [Having an HTA body] would [...] make it easier for us to face the [public] pressure to fund it” (I-105, payer).

On the other hand, the promise of blame-avoidance did not offset the payers’ ambition to keep control of reimbursement decision-making. They were apprehensive of a third-party regulator imposing reimbursement decisions (or even non-binding recommendations) which would be beyond their

budgetary possibilities. As a result, they would face blame either from the patients and general public, if they denied funding, or from politicians if they exceeded their budgets (I-65). All plausible institutional arrangements for HTA involved too much discretion for the payers to accept, as none would give a prominent enough role to budgetary concerns (I-65, I-105).

Banta's hypothesis about budget impact being the primary interest of payers (rather than cost-effectiveness or patient quality of life etc.) is in the Czech case confirmed. Policy solutions that do not address this concern directly are not attractive to Czech payers, including HTA:

"I don't believe in ICERs [incremental cost-effectiveness ratios], numbers, models. I've seen how you can play around with those [to get the results you want]. [...] The Hungarian way – risk-sharing – is the solution" (I-65, payer).

In contrast to alternative options, such as managed entry agreements [74,75], HTA was identified by the payers as a policy that could, unless extremely sensitive to budget impact considerations, increase rather than maintain or reduce health care spending, and as such undesirable.

The payers' reluctance to see a new body decide (or advise) on P&R would be readily explained by public choice theorists as a bureaucracy's tendency to maximize its size, budget or competences [45–47]. Payers would be seen as incumbent agents defending themselves against bureaucratic competition. However, Czech payers should be, in matters of pricing and reimbursement, considered as near *co-principals* together with the ministry of health rather than agents. They have a *de facto* veto power in the drugs P&R procedure at SÚKL, a decision-making authority on MD&Ds and a seat at the table for health care services but are not subject, on P&R, to any extensive controlling mechanisms, usual in delegation arrangements, by the ministry. In addition, VZP has on many issues power almost equal to the ministry of health, stemming from its links to high politics: members of its board are nominated proportionately by parliamentary parties, leading to notorious clientelistic nexuses [76–80].

Reconceptualizing Czech payers as co-principals explains their concerns for blame-avoidance, not predicted by Banta or public choice bureaucratic theories. As principals, not only policy-makers, but also the payers needed to be convinced of the need for delegation in the first place. Solving a problem without delegation (such as in-house P&R decision-making) or with minimal discretion (such as signing a memorandum of understanding within a committee), may be more attractive.

5.4.3. Clinical physicians

Clinical physicians had no clear position on HTA and its institutionalization. The president of the umbrella association of Czech clinical societies summarized its members' views in 2013: "Almost all representatives of clinical societies feel that HTA is something that does not, and will not, concern them" (p. 19) [69]. In accordance with Banta's hypothesis, clinicians' priorities revolve around the quality and availability of care, including standard-setting and guideline writing, with a strict focus on their particular disease area (I-93, I-117, I-161). They are interested in those matters of pricing and reimbursement of health technologies that are of direct relevance to them, but their efforts are targeted at obtaining favorable reimbursement within the existing rules by finding alternative, often informal procedures, rather than investing time and resources into convincing policy-makers to change the rules of the game for all reimbursement decisions.

There is little direct opposition to HTA on the part of clinical physicians. If they have concerns, these are mostly about issues of transparency and inclusiveness of the future institution [69]:

"It would be good if some institution like NICE existed but not if it meant doing things the Czech way, all corrupt. It should be a transparent tool" (I-159, senior clinician).

Saarni's hypothesis about clinicians' resistance to HTA is refuted – lack of HTA under the status quo does not equal a lack of regulation of physicians' freedom by other means. In public-payer universal health systems, clinicians are already restricted in their autonomy by extant rules and regulations. As assumed by the special interest literature [26], concrete characteristics of new institutions are therefore of more concern but anticipating consequences on matters of principle (“for or against HTA?”) is complex and costly, and therefore avoided.

5.4.4. Industry

Industry is in the Czech case divided into the pharmaceutical industry, and the medical devices and diagnostics industry, a large minority of which is united within the association CzechMed (most manufacturers of expensive devices and diagnostics are not members).

The pharmaceutical industry's position on HTA was an uncomplicated endorsement in line with the general European response. Pharmaceuticals had been undergoing a relatively sophisticated P&R procedure within SÚKL since 2008, which has sometimes been described as “*de facto* HTA” (p. 18) [69], even though SÚKL itself has been cautious of using the label and prefers to call its analysis pharmacoeconomics instead [52]. The pharmaceutical industry therefore expected little tangible change to their business processes as a result of an HTA process or a new institution; at best, it would create a more level playing field where other interventions would be subject to similarly rigorous assessment as drugs (I-171, I-69).

The MD&D industry, on the other hand, had a more nuanced stance. Some companies were frustrated with the status quo where P&R of some MD&Ds were determined by a largely arbitrary power of VZP administration with little transparency (I-60), and would have welcomed the transparency and

business environment predictability HTA promised. However, in general the industry feared any additional regulation as a hurdle to market access, especially if it would be as demanding as the drugs' SÚKL procedure (p. 20) [69], (I-37, I-60):

“Our experience is that every change eventually means more work, delay etc., than benefits” (I-37, MD&D industry).

This is reflected in public comments of CzechMed's president who had been an early proponent of HTA [81] but later insisted on its limitations and pitfalls [82]. These included reservations about the scope and methodology of HTA analyses, which the MD&D industry deemed ill-adapted to their products (p. 20) [69]. In consequence CzechMed later called for a “common sense” evaluation instead of sophisticated health economic models (p. 31) [82]. Discretion of the new body mattered; the main concerns of the MD&D industry were that HTA would target exclusively MD&Ds (as opposed to all health technologies), and that among MD&Ds, even low-cost devices would have to go through a cumbersome evaluation procedure. This threat was the clearest with a hosting option at SÚKL where organizational culture could be expected to replicate the pharmaceuticals' procedure without many adjustments (I-60, I-37) but other policy formulation alternatives were also criticized [82].

In contrast to expectations of the economic theory of regulation [48], no part of the MD&D industry used HTA as an opportunity to improve or protect its market position. New regulation could have brought business predictability but compliance costs were deemed disproportionate, and less regulated status quo was preferred. Regardless of dividing lines, the Czech MD&D industry could easily voice its opposition to HTA as a whole.

5.4.5. Patients

Patient organizations did not see HTA as an issue high enough on the policy agenda and consequently worthy of their attention (I-35, I-17, I-81) [69]. Some even dismissed it as a policy whim that is unlikely to be implemented, and estimating its impact on patients' lives as premature [69] (p. 17). Patient organizations explain this disinterest by their limited human resources:

“Finding information and data [including about ongoing policy projects] is investigative work even for [full time health policy professionals] that takes up most of their work hours. So you can imagine how difficult it is to access information for a patient organization that has 3-4 people who are doing all this as a hobby, after their day jobs” (I-81, patient representative).

As a result, they need to prioritize their lobbying efforts and HTA was not sufficiently advanced in the policy process to deserve detailed attention.

One exception were rare disease patient groups, who clearly formulated their concern about HTA. They feared that any new HTA body would impose a uniform, rigid willingness-to-pay threshold using cost-effectiveness as the main criterion for reimbursement recommendations and disregard benefits of therapies outside of the health care system and require amounts and kinds of evidence unachievable for their disease areas [69] (p.17) (I-81). These methodological concerns were more important than uncertain questions of institutional design. In line with the general interest group assumption that actors will not engage in lobbying if the costs of acquiring information on complex issues and acting on it are higher than potential benefits, even if the policy has direct consequences for them [26], rare disease organizations, just as their non-rare counterparts, preferred to engage in monitoring of the policy development without action.

5.4.6. Epistemic community – “aspiring agents”

The epistemic community’s clear position in favor of HTA is in the Czech case confirmed: they were a group with a strong preference for an HTA institution. The delegation literature does not deal with positions and interests of future agents – the agent has no say in its own creation. The Czech case, however, implies that there are individuals who can reasonably expect to be later employed by, or otherwise involved with, the new body, and by virtue of their knowledge of the topic, members of the epistemic community are the most likely candidates. As such, they are “aspiring agents”, and have a clear interest in shaping the future institution to their liking.

Unlike interest groups, epistemic communities are not united by concurrent direct material (or other) interests but by their shared epistemic beliefs. Their members recruit from various institutions and organizations, and the Czech HTA epistemic community counted individuals whose primary work affiliations were as diverse as the ministry of health, SÚKL, MD&D industry, health care consultancies and academia. Each of them could, however, aspire to obtaining a high-level post in the future HTA institution – something regularly brought up by interviewees as a motivation for other members’ efforts:

“He was working on the concept for an HTA agency because he’d like the Czech Republic to have such an institution and he’d like to turn his [organization] into this agency” (I-161);

“He wanted the legislative draft to be good because his ambition was to continue working in the [future] HTA agency” (I-96).

Similarly, the community’s members often preferred such an institutional design that would prioritize (if not directly benefit) their original organization. In a classical example of “where you sit is where you stand”, members of the epistemic community who worked for consultancies and academia advocated for a “decentralized” outsourcing system with a network of (public or private) suppliers of

HTA analyses and a coordination role of a central agency [69] (p.16) (I-161). Unlike the payers or the industry, their preference for an HTA body in general was not conditional on the kind of discretion it was to get. They were the one actor in Czech health policy who was in favor of HTA nearly irrespective of its details. The community, however, rapidly disintegrated following the unanticipated end of Heger's mandate, which halted its access to decision-makers. They did not sustain their lobbying efforts during the caretaker minister's term, and perceived advocating with minister Němeček as pointless (I-94, I-161, I-177).

As a result, the composition of actors and their positions altered with a change of decision-makers: all actors who could potentially lobby decision-makers were either against an HTA body (payers, MD&D industry) or did not find the issue important (patients, clinicians, pharmaceutical industry). With the disappearance of the epistemic community as aspiring agents, there were no actors who would advocate in favor of institutionalizing HTA and push for it as a solution to minister Němeček's MD&D problem. These results are summarized in table 5:3.

Table 5:3. Findings: observed interests and policy positions of Czech health policy actors on HTA

<i>Actor</i>	Policy position on HTA	Interests	Relevance for literature
<i>Policy-makers (principals)</i>	In favor (Heger)	Need for expertise	<ul style="list-style-type: none"> - Confirms: Banta [40]; delegation literature (Sweet & Thatcher [30], Bendor et al. [31], Moe [32]) - Does not confirm: blame-avoidance (Hood, [35] Gilardi [34]); distrust [44]
	Against (Němeček)	Need for expertise solved by alternative means	<ul style="list-style-type: none"> - Confirms: delegation literature

<i>Payers (co-principals)</i>	Against	Blame exposure	- Contradicts: blame-avoidance
		No need for expertise (not appropriate for budget control)	- Confirms: delegation literature - Contradicts: Banta
		Bureau maximization – loss of control over P&R process	- Confirms: Niskanen [45], Downs [46], Dunleavy [47]
<i>Clinical physicians</i>	No preference	Quality concerns only	- Confirms: Banta - Contradicts: Saarni [43]
<i>Pharmaceutical industry</i>	In favor / No preference	Predictability & transparency	- Confirms: Banta, Stigler [48]
<i>MD&D industry</i>	Against	Preference for no regulation (i.e. for status quo)	- Confirms: Stigler, Posner [49]
<i>Patients</i>	Unclear preferences	Lack of information	- Confirms: Lohmann [26] - Contradicts: Banta, Saarni
<i>Epistemic community (aspiring agents)</i>	In favor (under Heger)	Epistemic belief in evidence-based policy-making	- Confirms: Banta, Haas [51], Löblová [52]
		Employment or other gains from the new HTA body	- Confirms: Löblová
	Non-existent (under Němeček)	n/app	- Confirms: Löblová

5.5. Discussion and conclusions

This paper sheds light on an understudied question of health policy: the dynamics of policy position formation and interests linked to emerging HTA policies. By focusing on what domestic actors think about institutionalizing HTA as a matter of authority delegation, we can observe how their interests and positions mediate the international diffusion of HTA institutions.

The present study is not without limitations. Studying actors' positions is a delicate enterprise, which exacerbates pitfalls common to most qualitative political science research: reliability of the data is problematic, among others because of recall bias of interviewees and doubts about their trustworthiness. Its interpretation and presentation are not separable; moreover, there is a risk of presenting complex positions as caricatures. Finally, generalizability of findings from a single case

study is *a priori* limited, even more so in cases of non-events, such as here the non-adoption of HTA agencies. The government fall is one obvious idiosyncrasy of the Czech case; the strong role of the Czech VZP and other payers is another. Nevertheless, external shocks leading to a reorganization of the *rapport de forces* among key actors happen in most countries, and the presence of actors whose influence approaches the principals' power could be a more universal pattern.

Findings from the Czech case notably challenge four implicit assumptions that underpin conventional discourse about countries without institutionalized HTA (typically low and middle income countries – LMICs). First, the diffusion of HTA agencies is not inevitable; it is mediated by domestic politics. The domestic context has been underlined to explain the varying institutional characteristics of HTA agencies worldwide [40,83]. Our findings suggest it also plays a role in the logically preceding question: does a country wish to establish an HTA agency in the first place? Too often, the answer tacitly follows the “laggard” hypothesis: some countries have not “yet” (p.76) [21] established HTA bodies because they have a low awareness of the topic, or a limited administrative, human resources, financial or other capacity. The near-institutionalization of HTA in the Czech Republic demonstrates that, in some cases, awareness about HTA diffuses, and countries sometimes even take active steps towards creating HTA bodies. There are, however, a number of actors involved in the making of a new institution, all of whom have a stake in the outcome of the policy process: not only decision-makers, but also interest groups, existing bureaucracy and “aspiring agents” – individuals or communities who expect to play key roles in the future institution. Important actors carefully evaluate HTA against the domestic context and their own interests and priorities, as they would do with any other policy, and aim at influencing decision-makers' preferences. Sometimes, they have serious arguments against creating HTA bodies: HTA does not respond to their most urgent problems, which are either satisfactorily tackled by existing institutions and regulations, or by other policy alternatives. If they display distrust

and criticism to the method, such as some Czech payers and the MD&D industry, it is informed, rather than intuitive as suggested by Dankó [44].

Second, countries without HTA institutions are not *tabulae rasae*. They have existing procedures and practices that regulate the entry of new interventions in the health system, even if these are not evidence-based, methodologically rigorous or particularly transparent (especially in democratic transition countries such as Central and Eastern Europe). For some actors, such as Czech patients and clinicians, little change can be expected from an HTA body as opposed to the status quo: it matters little if availability of treatments is determined by an HTA agency, or a ministerial committee or insurance fund bureaucrats. For others, however, such as the Czech MD&D industry or rare disease patients, the status quo can be more beneficial and HTA presents potential threats. The interests of actors as determined by the domestic context need to be taken into account, including their potential resistance [18] but also support or neutrality – it can be reasonably expected that, in other countries without HTA, clinicians and patients will not actively oppose the institutionalization of HTA unless they perceive it as a significant burden, in contrast to Banta's and Saarni's arguments [40,43].

Third, alternatives to HTA are crucial for understanding why some actors do not choose HTA as their preferred policy. For delegation to an HTA body to happen, principals must perceive the need for the agent's input [30–32]. This need may well be constructed or fostered by other actors – as when the Czech HTA epistemic community of aspiring agents persuaded minister Heger of the desirability of institutionalized HTA – but it may also be easily satisfied by other policy solutions, as when minister Němeček chose an advisory committee on costly MD&Ds over an HTA agency. If HTA does not respond to the principals' most urgent problem, they are likely to choose a different option. Czech payers' dismissal of HTA is illustrative of these dynamics: their most salient problem is not allocative inefficiency (which the laggard hypothesis presumes as a functional pressure common to most health

systems), but budget containment. An HTA body would, according to their assessment, not provide as ready a solution to this problem as payer-controlled managed-entry agreements or *ad hoc* reimbursement; at worst, it could lead to an increase in expenditure if the HTA institution privileged other criteria than budget impact. It may be easier for policy-makers in countries without HTA institutions to opt for parametric adjustments of existing policies, than to invest resources into building a new institution.

Finally, institutional arrangements of HTA matter. While warning against a simplistic emulation of the English NICE [19] is certainly reasonable advice, the opposing temptation is to avoid recommending any institutional setup altogether (p.50) [17,84]. HTA as a method of analysis becomes decoupled from its institutionalization, suggesting it is unimportant whether evidence is evaluated by an independent agency, a unit at the ministry of health or an academic institute – as long as it respects general international HTA standards. Literature on HTA in Western Europe recognizes, however, that institutional details have far-reaching influence, from determining how HTA conclusions feed into decision-making and what kind of advice is produced [13] to what kind of technologies are funded [85]. There is no reason to expect institutions to be neutral in LMICs, but the plethora of possible institutional models makes anticipating their consequences difficult. Because of the uncertainty about institutional setups, some Czech actors focused more on the methodological details of HTA: rare disease patients, for instance, were more preoccupied with a potential binding cost-effectiveness threshold (as seen in Poland or Slovakia) than with institutions. However, for other actors (payers, MD&D industry) institutional details were crucial, and influenced heavily their stance on HTA. Although some institutional features were uncontroversial (notably transparency of the future body), others (such as the scope of its competences or its organizational structure) were the reason for opposition. This shows that, at the domestic level, the devil lies within the statutes of any HTA body

– not only in the parameters of its economic models, but also in its institutional design, in LMICs just as in Western countries.

These assumptions influence policy activities in many countries. The European Commission, for instance, recommends the use of HTA [86]. The World Bank actively funds projects introducing HTA in individual countries (e.g. in Romania [22,87]). The most common argument of the “laggard” literature is that HTA is even more important in lower income countries, as they have less resources to waste by allocative inefficiencies stemming from evidence-ignorant decisions [23,44]. This is a theoretically sound claim. Nevertheless, the findings show that allocative inefficiency is, in some resource-tight contexts, not the main problem of policy-makers or other key actors; and if it is, other policy alternatives may be more attractive to them.

Naturally, “more attractive” does not necessarily mean “right”, and resistance to change should not be taken as an excuse for avoiding reform. Still, HTA advocates, both international and domestic, should consider domestic actors’ concerns. They should give serious thought to the possibility that, in some cases, adapting existing institutions and procedures, could present significant benefits (e.g. faster and cheaper implementation) for low and middle income countries, rather than creating new HTA bodies.

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6. CONCLUDING REMARKS: WHAT HAS HEALTH TECHNOLOGY ASSESSMENT EVER DONE FOR US?²⁵

This research project started with a simple observation: most countries in Western Europe have health technology assessment agencies but many Central and Eastern European countries do not. This is surprising given that other health policy innovations have often diffused east of the Elbe just as in the West. The three papers of this dissertation examined, and discarded, a number of structural explanations for this halted diffusion, including the traditional go-to answer of any analysis: money, both in the sense of national wealth and when understood as the motivation of special interest groups. Instead, it proposed an alternative account to explain this puzzling pattern of diffusion of HTA bodies in Europe: the activity of domestic epistemic communities, moderated by the willingness of policy-makers to listen. The fact that policy-makers sometimes prefer alternative solutions to HTA hints that the problem might not lie with the actors, but with the policy itself. This concluding section therefore looks, in a provocative manner, at the costs and benefits of the trend of establishing HTA agencies – and how they compare to other fashions in pricing and reimbursement.

Abstract: Health technology assessment (HTA) has been a fashionable trend in health policy in developed countries over the past thirty years. Despite this, very little is known about HTA's impact on health systems. This lack of manifest benefits may explain why many countries, primarily low and middle income ones, have been reluctant to institutionalize HTA, although by conventional logic they need HTA even more urgently than their rich counterparts. It may be premature, though, to dismiss the policy altogether: its less tangible modernizing goals may well be enough to convince some policy-makers.

²⁵ The main body of the following text (including the abstract) was commissioned as a “Perspective” piece by *Journal of Health Services Research & Policy* with the aim stimulating a discussion on the desirability of HTA agencies. Given that it builds on the research for this dissertation, it serves as its concluding remarks.

6.1. Introduction

Health technology assessment (HTA) has been one of the most popular trends in health care reimbursement, pricing and purchasing of the past three decades. With the aim of informing coverage decisions by means of multidisciplinary evaluation of evidence, HTA has the backing of a large epistemic community. Public and private consultancies spread the message of HTA around the world (1,2), as do international actors such as the World Health Organization (3), the World Bank (4) and the European Union (5).

Indeed, many governments have been seduced by HTA's promise: to improve allocation of resources in health care. Since the late 1980s, most of Western Europe as well as Australia, New Zealand, Canada and several US payer organizations have established dedicated HTA agencies. HTA has also been a hot topic in low and middle income countries (LMICs). Hungary, for instance, set up an HTA agency in 2004 and Poland founded an HTA agency in 2005 that has grown from an initial handful of employees to a staff of more than sixty (6). Brazil, Mexico or Taiwan also have dedicated HTA bodies (7). Yet most LMICs do not have specialized HTA institutions.

This is something to be changed for HTA proponents because, according to the conventional narrative, HTA is especially important in resource-tight contexts because opportunity costs of misdirected resources are higher, in relative terms, than in rich economies (8,9). This discrepancy between the ideal state of affairs and reality is typically explained by an implicit “laggard” hypothesis: it is only a matter of time until LMICs catch up with the good pupils and institutionalize HTA – as soon as they overcome the “barriers” to the adoption of HTA: low awareness of the topic, limited human resources, inadequate financial or administrative capacities (2,7,10).

There is, however, an alternative explanation: policy-makers today hesitate to establish HTA institutions because decades of international experience have not convinced them it is a good idea. This piece explores what HTA has to offer to countries without institutionalized HTA, especially LMICs.

6.2. Clear costs, vague benefits

Setting up an HTA body comes with relatively clear upfront costs, but vague benefits. An HTA agency is not cheap: the German IQWiG has an annual budget of approximately EUR 13 million (USD 14.8 million); the Polish AOTMiT EUR 3.5 million; the Belgian KCE EUR 10 million (11). To compare: KCE's budget represents about 30% of the annual budget of a large university hospital in the Czech Republic (12). It is also not easy to implement: creating new public bodies and adjusting pricing and reimbursement processes requires more than a couple of days' worth of legislative effort in democratic countries. In Lithuania, for instance, HTA has been debated since the early 1990s (13) but has so far not been institutionalized.

The benefits, on the other hand, are unclear. Policy evaluation of HTA is practically non-existent (14,15). A 2008 review found that only four published studies assessed the impact of HTA on either health outcomes or spending, the self-proclaimed goals of HTA (16). Most studies focus on *outputs* of HTA agencies (e.g. number of HTA reports produced) and the extent to which conclusions of HTA reports are followed by decision-makers (e.g. 14) – leading an observer to conclude that “the available knowledge to assess the effectiveness of HTA is just a bunch of ‘case series’ and ‘case reports’, with little external validity and usually surrogate outcomes” (17). Indeed, we know next to nothing about HTA's impact on health outcomes: an Austrian study, probably the most comprehensive evaluation

to date, excludes health outcomes “due to methodological limitations” (18), and earlier reports are both scarce and vague (16). Improved access to care as a result of institutionalized HTA is not mentioned in any reviews (although see 19). Evaluations of economic impact are mixed. An early Canadian study found projected annual savings between \$16 and \$27 million (20, also 21); the Austrian analysis concludes that HTA recommendations had led to a “significant” reduction in expenditure, but deems precise monetary quantification impossible (18,22). Another review, however, notes that while HTA’s effects on spending are unclear, the guidance of the United Kingdom’s NICE has led to an increase in spending, rather than decrease (14).

A concern that HTA might increase expenditure is not unfounded. An independent HTA agency may prioritize evidence of cost-effectiveness or relative effectiveness over budget impact (more than the ministry of health or payers), leading to coverage of technologies that would have otherwise been denied reimbursement. Even a purely advisory body may make implicit rationing difficult for decision-makers, and bring unwanted attention to the lack of funds or inefficiencies in the health system. Likewise, introducing a new institution may destabilize the practice of delaying reimbursement decisions, common to some LMICs. In short, the immediate and medium-term budgetary consequences of establishing an HTA body, especially in low-resource contexts, are far from clear – and uninvestigated.

6.3. Modernizing mission

A more alluring promise of HTA may well lie not in its uncertain direct effects on health systems but in its consequences for the decision-making styles and cultures. Some evaluations indeed suggest, in line with Weiss’ “Enlightenment” conceptualization (23) of the knowledge-policy relationship, that

HTA acts by changing mindsets rather than immediately determining actions (16,18). Institutionalized HTA marks a departure from the opaque and arbitrary pricing and reimbursement practices customary in many LMICs. It is a departure underpinned by normative and epistemic beliefs in the superiority of evidence-based decisions, independence of expert input, transparency and inclusiveness of social actors (“stakeholder dialogue”) (24). These are linked to the rise of evidence-based medicine (25), procedural justice in rationing (26) and perhaps more generally “good governance” and the trend of independent agencies (27). None of these principles guarantee improving the quality, equity or sustainability of health systems. Whether rational-comprehensive policy-making leads to better outcomes than “muddling through” incremental adjustments, has been a debate for decades (28). Good governance probably attracts more critics than advocates (29). However, for some decision-makers, a focus on evidence, transparency and inclusiveness may represent values in themselves – worth the budget of a provincial hospital.

These same values make it difficult for skeptical policy-makers to reject HTA altogether. Other policies, from international reference pricing to risk-sharing agreements (not to mention implicit rationing), may be easier to implement and fare better at containing costs, but lack a larger modernizing vision. It was this vision, advocated by the international and domestic epistemic communities (4,30), that likely convinced most high-income and some low and middle-income countries to embed HTA in their coverage decision-making in the first place and made HTA into a policy without direct alternatives. Until viable alternatives appear, or until HTA demonstrates results in its main objectives, the modernizing mission is all it can offer to potential reformers.

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ANNEX I. LIST OF INTERVIEWEES (CONFIDENTIAL)

(For Dissertation Committee members only)

ANNEX II. SAMPLE INTERVIEW GUIDE (POLAND)

Introduction: *I focus on the circumstances of introducing HTA and HTA agencies in the Czech Republic and Poland. I have prepared a few questions, but please tell me anything you deem important. I study public policy – I am not an economist or a medical student, and do not focus on the health economic technicalities of HTA, but rather on how HTA became institutionalized in Poland in 2005-6.*

May I record this interview for my own purposes only?

The interview is anonymous and the data are anonymized.

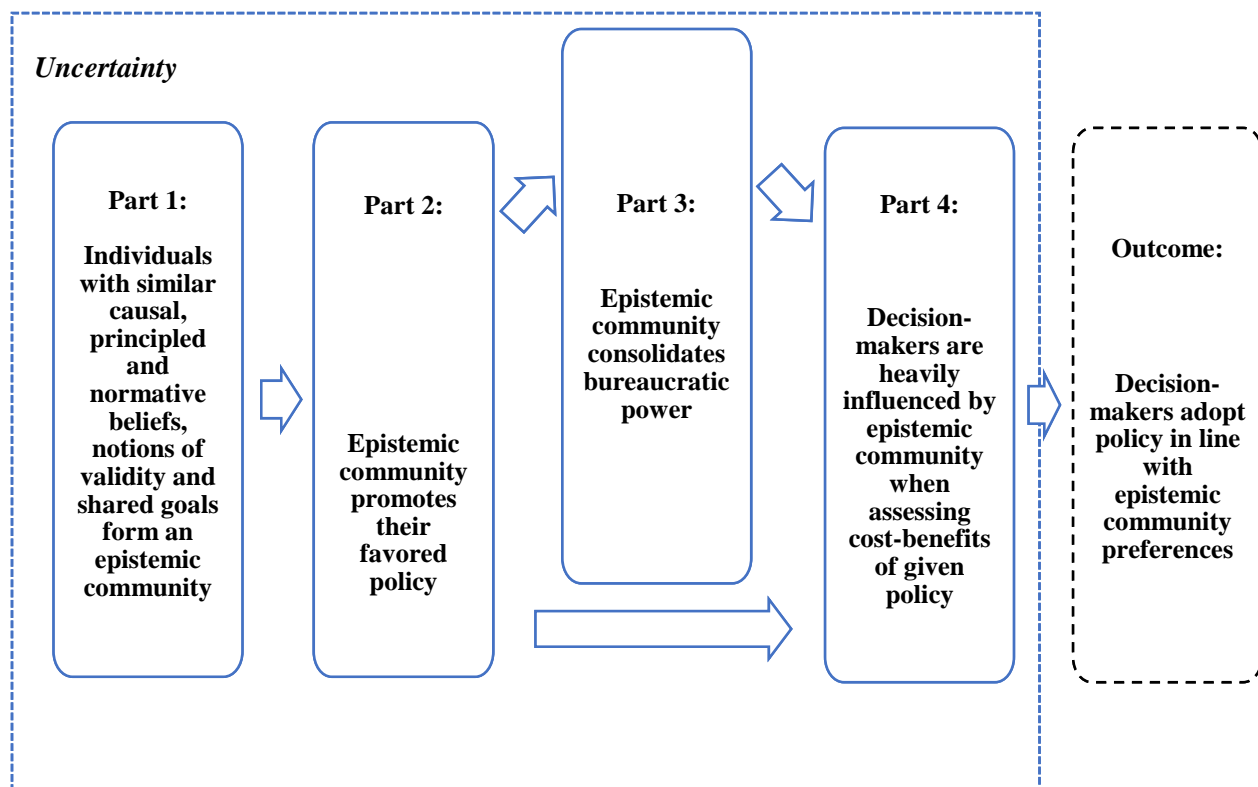
- What has been the history of HTA as a discipline in Poland since the 1990s?
- How did HTA become a topic for the Ministry of Health?
- What is the story of pharmacoeconomic societies and other academics? What were their links to the MoH and NFZ and other decision-makers?
- How was AOTM established? Was the Constitutional Court's verdict regarding the transparency of the previous procedure the only impetus?
- Who were the key originators of the idea of AOTM? Why?
- [STANDARD QUESTION] What were the main sources of inspiration for HTA from abroad in the early days/ now?
- [STANDARD QUESTION] Who are (historically and currently) the most important proponents and opponents of HTA?
- [STANDARD QUESTION] Who are the key players in HTA? Who should I talk to?

If I find out later there are more things I need to ask you, can I call you?

ANNEX III. OBSERVABLES FOR PAPER II

In line with calls of the process-tracing method for a more rigorous approach to evidence (Collier 2011; Beach & Pedersen 2013), it is appropriate to specify what kind of evidence we expect to find for each part of the causal mechanism at work. The causal mechanism from Paper I follows below as a reminder in Figure 0:1. Because the aim of the exercise is to announce expected observable manifestations *ex ante*, the mechanism below is as derived from Haas (1992), as opposed to its revised version.

Figure 0:1. Causal mechanism for domestic epistemic communities' influence on policy



Source: author, based on Haas (1992, 4).

The diffusion of the idea of HTA agencies as a desirable policy option for health care priority-setting at the international level is our starting point. For Part 1 we expect to find individuals interested in HTA forming a community at the domestic level on the basis of the four definitional attributes put forward by Haas (1992). Interview data and academic and specialized expert activities such as academic publishing or conferences should be enough to confirm or disconfirm the presence of a domestic epistemic community in a given country.

For Part 2 we can expect to find the traditional means through which an epistemic community aims at spreading its stances through sharing information and actively framing the issue in question: organizing conferences, meetings, presentations, workshops and the like, which include policy-makers

and other actors close to decision-makers, typically high-ranking civil servants at the ministry of health or in other health care institutions.

Part 3a requires evidence of members of the epistemic community acquiring access to policy-makers by becoming part of the government decision-making structures as civil servants or by securing places as advisors and consultants in the ministry of health, or potentially by getting the “ear” of decision-makers otherwise, through informal processes (in which case evidence will be hard to find). For part 3b we need to look for similar evidence as in part 2: epistemic communities within and without government systematically drawing attention to those aspects of the issue that imply the superiority of their preferred policy.

Part 4 requires traces of argumentation in policy-papers, bills, regulatory impact assessments and the like, as well as in interview data that repeat or closely follow the arguments put forward by the HTA epistemic community.

These observables are summarized in Table 0:1 below, along with their status post-analysis. Concrete existing observables (e.g. specific conference reports or websites) are not identified here but are cited in the main text of Paper II. Table 0:1 also suggests which empirical tests of uniqueness and certainty in its predictions (Van Evera 1997; Beach & Pedersen 2013; Collier 2011) each observable evidence passes to update the confidence in our hypothesis. Hoops and smoking gun tests are among the stronger in the arsenal of process-tracing in social science, giving us relative confidence in our findings. However, they do not definitively eliminate rival hypotheses – hence the need for Paper III to look into interest-group influence, the usual suspect among actor-based explanations of policy change.

Table 0:1. Observable manifestations of causal mechanism parts

Part of the causal mechanism	Expected observables	Observed in PL	Observed in CZ	Passes which empirical test
Part 1	Interview data; academic and specialized expert activities such as academic publishing or conferences on HTA	Yes; Yes	Yes; Yes	Hoop
Part 2	Mentions of conferences, meetings, presentations, workshops etc., including policy-makers and other actors close to decision-makers, typically high-ranking civil servants at the ministry of health or in other health care institutions	Yes	Yes	Hoop

Part 3a	HTA community members become civil servants or by securing places as advisors and consultants (documents, LinkedIn pages, conference biographies etc.); informal access to ministers mentioned in interviews	Yes; Informal access not found in documents but mentioned in interviews	Yes; Informal access not mentioned in interviews as a noteworthy theme	Hoop
Part 3b	(same as Part 2)	(same as Part 2 – plus found as necessary)	(same as Part 2 – plus found as necessary)	n/app
Part 4	Argumentation in policy-papers, bills, regulatory impact assessments and the like; interview data	No; The convincing nature of the epistemic community's arguments mentioned in interviews	Yes (newspaper articles, the existence of ministerial decree 2012/6 for Heger; mention of HTA by Němeček during inauguration of new MD&D committee on camera); The convincing nature of the epistemic community's arguments mentioned in interviews	Smoking gun

Source: author