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Three worlds of health technology assessment: explaining patterns of diffusion of HTA agencies in Europe

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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 toward 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.

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Introduction: health technology assessment (HTA) agencies in Europe today

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

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with independent regulatory agencies or other quasi-autonomous non-governmental organizations (QUANGOs), and one of its 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 and Landwehr, 2014, Author reference 1), 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 (Rose, 1993; Dolowitz and Marsh, 1996; Benson and Jordan, 2011) 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 (Adler and Haas, 1992; Haas, 1992). 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 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.

HTA agencies: a popular policy trend

HTA 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: 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 HTA (Sorenson *et al*., 2008: 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 QUANGOs – owing perhaps partly to the legacy of the US Office of Technology Assessment and partly to the more general governance trend of agencification (Pollitt *et al*., 2001, 2004; Elston, 2014). 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 and Sabin, 1998) in combination with general trends in regulatory governance (Jordana and Levi-Faur, 2004; Bertelli, 2008), 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 and 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 EU countries, for the most part in Western Europe, but not to others?

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 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.[1]

1.1. The forerunners

The first HTA agencies were established in the United Kingdom (NICE, 1999), Sweden (SBU, 1987), Denmark (DACEHTA, 1997) and Finland (FinOHTA, 1995). In addition, the Netherlands were very active in developing HTA as an

1 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.

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Table 1. Chronological taxonomy of health technology assessment 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**
	Hungary (GYEMSZI, 2004)	Greece
Spain (COHTA – Catalonia, 1991, Osteba – Basque, 1992, AETS – central, 1993, AETSA – Andalusia, 1996)	**Poland (AHTAPol, 2005)**	**Lithuania**
	Austria (LBI, 2006)	Luxembourg[a]
	The Netherlands (CVZ, 2006)[a]	Malta
	Ireland (HIQA, 2007)	Portugal
	Italy (AGENAS, 2006)	**Romania**
	Latvia (VEC, 2009–2011)[a]	**Slovakia**
		Slovenia

Source: own compilation.
Former communist countries in bold.
[a]Outlier, specific case – see description below for short discussion.

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 and 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 and 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).[2]

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.

2 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.

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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 HTA 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 Mladovsky *et al*., 2012; Nacionālais veselības dienests, 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 United Kingdom, 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 that serves as a model to the Polish AHTAPol and the Scottish SMC (Kolasa and 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 set up.

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 (Turk and Tit, 2008; Tit, 2010). 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 HTA 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 that traditionally set trends in health policy (and which lead developments beyond the health sector more generally, in public policy, administration and management).[3] 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 CEE 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.

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 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 and Jordan, 2011), while the latter discuss the role of policy entrepreneurs and experts, elected officials, political parties, bureaucrats, pressure groups and supranational institutions (Rose, 1993; Dolowitz and Marsh, 1996). In the case of HTA in Europe, some of these intervening variables prove

3 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.

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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, 2005; Weyland, 2005; Marsh and 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.

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 with 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 gross domestic product (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 15–50 health economists and other experts (for the size of a Western European HTA agency, see table 5.1 in Garrido *et al*., 2008: 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 and 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).

Centralized vs decentralized health system governance

There is recognition within studies on HTA that the degree of centralization of a country's health care system influences the practicalities of HTA (Cappellaro *et al*., 2009; Drummond and Sorenson, 2009; Ciani *et al*., 2012), although how centralization promotes or impedes the initial introduction of HTA is 'open to debate' (Sivalal, 2009: 286). Neumann (2009: 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 with other actors in the sector (Immergut, 1992; Freeman, 2000). It also goes in line with Wild and Gibis's (2003: 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.

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' (Wild and Gibis, 2003: 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 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

Table 2. Bismarck vs Beveridge explanations for diffusion of health technology assessment 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
	Hungary (GYEMSZI, 2004)	***Greece***
Spain (COHTA – Catalonia, 1991, Osteba – Basque, 1992, AETS – central, 1993, AETSA – Andalusia, 1996)	Poland (AHTAPol, 2005)	Lithuania
	Austria (LBI, 2006)	***Luxembourg***[a]
	Netherlands (CVZ, 2006)[a]	***Malta***
	Ireland (HIQA, 2007)	***Portugal***
	Italy (AGENAS, 2006)	Romania
	Latvia (VEC, 2009–11)[a]	Slovakia
		Slovenia

Source: own compilation.
Beveridge health systems in bold italics.
[a]Outlier, specific case – see description above for short discussion.

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.

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 CEE in particular – most studies focus on the Western World (particularly EU-15 plus Australia and New Zealand: see for instance Pollitt *et al*., 2004; Christensen and Lægreid, 2007; Gilardi, 2008; Bouckaert *et al*., 2009; Verhoest *et al*., 2010). 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 CEE 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 *et al.*'s 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.

Influence of international actors

In Europe of mid-2000s onward, the EU 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 (Author reference 1) – 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 (Garrido *et al*., 2008; World Health Organization, 2014). 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.

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 (Rose, 1993; Dolowitz and Marsh, 1996). 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 and Gibis, 2003; Goddard *et al*., 2006). Banta (2003: 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: 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 and 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 and 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.

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> 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 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. Third, 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 (Author reference 2) 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.

Conclusion

The peculiar distribution of HTA agencies in EU countries today, with most countries of CEE 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. HTA, 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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