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A regulatory governance perspective on Health Technology Assessment (HTA) in Sweden

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Abstract:

Independent regulatory agencies (IRAs) for Health Technology Assessment (HTA) are a key means by which national governments have responded to the challenge of ensuring equitable public access to a new range of medicines and treatment options within the context of limited national budgets for healthcare. In this paper, we apply a regulatory governance frame to the study of the Swedish process for HTA. Based on qualitative interviews with key institutional stakeholders, we suggest that the major challenge for Swedish IRAs for HTA is successfully communicating nationally produced research outputs to the regional authorities responsible for the delivery of health services. We conclude that a regulatory governance approach to the analysis of national processes for HTA has the capacity to draw attention to a new range of challenges and issues which have direct relevance to improving the conduct of HTA within national regulatory spaces.

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1. Approaching Divergence and Hybridity in Methods and Processes for HTA

In Europe and around the world, policymakers have responded to common functional pressures of balancing limited health budgets against the requirement to ensure comprehensive and equitable public access to new medicines and health technologies by establishing independent regulatory agencies (IRA) for Health Technology Assessment (HTA)—such as the Haute Autorité de Santé (HAS) in France, the Dental and Pharmaceutical Benefits Agency (TLV) in Sweden and the National Institute for Health and Care Excellence (NICE) in England. These IRAs produce evaluations of new health technologies that integrate a range of economic, epidemiological and public health evidence for the purpose of supporting policies on reimbursement, pricing, and the use of technologies in clinical practice. In principle, these agencies provide more legitimate, transparent and accountable methods and processes through which governments can respond to pressures associated with delivering efficient and equitable public access to new health technologies. For the future, the role of IRAs for HTA within national policy making processes is likely to expand as a wider and more sophisticated array of treatment options becomes available to patients, thus placing additional demands on national health care budgets.

Despite their common remit, national IRAs for HTA exhibit diverse characteristics. Across the European Union (EU), for example, member states (MSs) have established a variety of dissimilar IRAs that utilize and apply a broad range of methods, processes and evidential requirements for evaluating the benefits and costs of health technologies. Typically, these divergences have prompted wider research initiatives and policy agendas for the harmonization of HTA methods and processes across the EU. Such agendas emphasize the benefits of adapting evaluations of individual technologies for cross border use, and developing systematic approaches for evaluating the efficacy of individual technologies [14, 15]. At the European level, the proliferation of national HTA agencies has produced interest in cooperation and the exchange of HTA knowledge for the purpose of reducing expenditure and the duplication of work programs [16, 17, 18]. At the industry level too, there is support from major pharmaceutical companies for a harmonization of HTA methods for the purpose of producing nationally transferable results [19, 20]. Policy analysts have also suggested the establishment of a European drug pricing and reimbursement agency similar to the European Medicines Agency (EMA) [21]. Further, they have also argued that comparative efficacy data should have a formal role in European drug approvals; and that European authorities should collaborate with national HTA agencies towards the better congruence of licensing and reimbursement requirements [22]. The European Parliament's directive on patient rights and cross-border health care also supported more formalized cooperation between national HTA agencies through the European Network for Health Technology Assessment (EUnetHTA) [23].

Recently, however, some scholars have taken a more nuanced position with regard to instances of divergence and difference, suggesting that the key challenge for the future study of HTA involves the construction of an analytical framework capable of identifying the institutional, domestic and other factors that shape national processes for HTA (Klingler et al 2013; Wright et al 2014). Taking a regulatory governance perspective, these scholars suggest that any reasonably sophisticated account of national approaches to HTA must recognize that globalization and the emergence of advanced industrial society involves the potential for widely varying processes, methods and evidential requirements. Globalization, they argue, touches policy sectors, markets, and regulatory regimes to different degrees and some sectors are more likely to exhibit hybridity and divergence at the national level than others [31, 32]. For example, in banking and finance, both markets and regulations are global. Alternatively, in other sectors like gambling and health care, both markets and regulations are national, meaning that national governments differ in terms of how much and what kinds of protections and services they offer. In the case of health technologies, however, regulations are subject to globalization, yet markets are not [33]. In other words, manufacturing practices for pharmaceuticals have been standardized to a very high degree, but individual nation states remain the monopolistic buyers in the largest markets, and so practices for HTA are mostly national [32]. Thus, in the health care sector, there is increased scope for policy mechanisms and innovations to become more political than technical, and more parochial than structural at the national level [34, 25]. Consequently, the fact that national processes for HTA exhibit significant divergences in terms of institutions, methods and evidential requirements should come as no surprise.

2. Comparative Policy Research and Regulatory Space

More to the point, these divergent perspectives on HTA also involve different analytical lenses. For example, policy initiatives and research agendas for the harmonization of HTA methods and process typically apply a comparative lens to the study of HTA. Broadly, comparative policy research involves the comparison and analysis of national health systems with a view to understanding why these behave in certain ways and what policy-makers can do to improve their performance [1]. Comparative research promises a detailed and policy relevant account of the restrictions and potentialities for the improvement of national health systems. The perspective highlights convergences and divergences across national contexts. On this basis, it makes prescriptive ‘best practice’ suggestions about how methods and process within national systems can be improved [2, 3]. Comparative approaches are interested in system configurations across national borders, and in identifying the factors and alternate constructions that produce comparable or dissimilar outcomes elsewhere [4, 5, 6]. In terms of HTA, some comparative studies offer statistical and largely descriptive reports that highlight data on a number of countries assumed to constitute a coherent class, analyzing the impact of HTA on policymaking across national contexts [7, 8, 9, 10]. Others offer collections of national case studies, describing institutions, roles and responsibilities. Some compare national studies emphasizing themes like competition and privatization. And others often take a specific medical theme as the focus of their analysis, such as oncology or diabetes [11, 12, 13].

In this way, comparative approaches also tend to focus on functional accounts of single national IRAs, like TLV, HAS or NICE, assuming that these are comparable organizations and the sole sources of power and legitimacy within the wider regulatory domain. Here, they often press distinctions between HTA as a process of providing new knowledge, or the structured assessment of a health-care technology; and HTA as an appraisal process that is more context specific, and which converts the analysis into policy advice [26]. Under the comparative lens, national IRAs for HTA sit at the interface of scientific knowledge and practical policy making. Accordingly, their 'scientific' assessment processes are considered broadly transferable across national contexts. And equally, some assessment methods are considered better than others. NICE, for example, is thought to set "the benchmark for the use of HTA placed at the centre of a transparent and consultative decision-making process" (Stevens and Longson 2013, p. 324; Stevens and Milne 2004). On this basis, the key aim of the comparative study is to place pressure on national HTA agencies to reform their assessment processes based on the better example of their peers [13]. In achieving this aim, comparative approaches tend to bracket, or to ignore altogether, issues of context, in favor of common policy lessons, core sets of structural, technical, and procedural requirements for the conduct of HTA that apply above and beyond the policy domain of individual states.

Alternatively, a regulatory governance perspective on the study of HTA takes a more holistic approach, sometimes styled a 'regulatory space' approach. Regulatory space is a holistic concept within the field of regulatory governance that frames steering and other regulatory activities within a spatially defined context (Hancher and Moran 1989). Under a regulatory space approach, the entire range of issues and processes to which any public decision within a specific sector is subjected defines the boundaries of the regulatory space [28, 36]. For example, in terms of HTA, a regulatory space approach considers the entire pathway from the regulatory approval of new health technologies to their use in clinical practice. Along the way, the approach analyses the wide variety of factors that intervene to influence the use and application of particular processes, assessment methodologies and evidence bases. Essentially, the regulatory space frame denies the construction of HTA as a twofold process of assessment and appraisal. Under the approach, institutional and cultural factors are essential to the reception and implementation of different methods and evidence bases across national policy contexts [13, 24, 25, 35]. Or, in other words, assessment and appraisal processes are mutually constitutive. As a result, the regulatory space frame is more comfortable with instances of difference and diversity. And by consequence, IRAs no longer sit at the interface of scientific knowledge and practical policy making. Equally, institutions like NICE no longer set the 'benchmark' for their peers. Under a regulatory space frame, an institution like NICE is better represented as making a scientifically rigorous, and arguably expensive, use of economic analyses for the purpose of driving a national health system characterized by universal and free access to health care, in which the profits and prices of pharmaceuticals are regulated by an initial agreement between industry and government (Wright et al 2014).

From this perspective, the point is that a wide variety of factors work against the possibilities for policy learning and transferability of methods and processes in any direct

and easy fashion. And by contrast, comparative approaches are often insensitive to the fact that national policy makers respond to multiple stimuli in establishing institutions and process for HTA, of which 'best practice' methods and optimum evidential requirements are but one element. Accordingly, the 'raw materials' of a regulatory space frame are much broader than those of the comparative perspective. For example, a regulatory space approach involves the analysis of policy networks for HTA, highlighting the multiplicity of institutions and actors who do, or have, the potential to participate in policy making [37]. Futhermore, the historical, political and cultural content of the national decision making environment, its relation to the use and mix of particular agencies and methods of operation, are also relevant to the approach (38, 24). Ultimately, regulatory scholars argue that the development of an analytical framework capable of identifying and critically analyzing these factors is a key challenge for future research given its potential to generate new range of policy relevant insights into HTA processes, how they work and how they can be improved.

The purpose of this paper is to demonstrate the potential of this frame to deliver insights into national HTA systems: in this case, Sweden. We conducted a qualitative case study of key national agencies engaged in the Swedish process for HTA with a view to uncovering salient points at which HTA processes either work well, or require attention. Broadly, we found that the powers of the Swedish County Councils to levy taxes and finance the provision of healthcare at the regional level place limits the role of national HTA agencies in delivering cost effective health services. In Sweden, the major challenge for national HTA IRAs is much less about discovering 'best practice' methods and optimum evidential requirements, and much more about successfully communicating national findings and negotiating their uptake at the regions.[1]

3. The Swedish 'Regulatory Space' for HTA

Reflecting both the history and the organizational structure of Swedish government, the Swedish regulatory space for health technology assessment is highly decentralized. In Sweden, there are three levels of government: the national government, the county councils and the municipalities. Of these three levels, the county councils and the municipalities play the dominant roles in the provision of health care services. Under the Health and Medical Services Act of 1982, the county councils are responsible for providing services to persons living within their boundaries and also for promoting the health of all residents [40]. Critically, the councils have the power to levy income taxes on their residents and are not dependent on the national government for income. At the local level, the councils exist on a parallel basis with municipalities, which are responsible for the provision of public education, aged care and child care, infrastructure and utilities within their areas. Like the councils, the municipalities also hold the power to levy income taxes [40].

The significant responsibilities and powers of the municipalities and councils have important historical and cultural roots. Historically, the majority of the Swedish

[1] The first two sections of the paper appear similarly in other papers published by this research group [XXXXXX]. This is due to the fact that we have conducted this research together and have developed and applied the theoretical framework for analysis jointly.

population has resided in provincial areas, which are characterized by cultural, religious and legal differences. Within these areas, health care has been the historical concern of the functioning regional public authority. From about the seventeenth century, rural cities took responsibility for employing medical doctors within their communities. Established in 1862, the Swedish county councils adopted health care provision as one of their principal duties, and took responsibility for all aspects of health care [40]. Today, twenty-one county councils hold primary responsibility for planning, delivering and funding health care services within their areas, which many have further devolved to health care districts via the device of global budgets. Essentially, councils have consolidated their responsibilities for health care provision within larger health care regions in order to stem increased pressures for cost containment and to improve efficiency. Encompassing an average population base of about 1 million people, these health care regions have encouraged cooperation and joint learning between the councils [40] Although they operate independently, the regions often mimic each other's behavior, thus producing wider trends for Swedish health care reform. For example, recent structural reforms within the regions have concentrated on developing primary care and coordinated aged care [41].

At the national level, responsibility for health care is largely restricted to coordinating and supervising provision at the regional level. For example, the Ministry of Health and Social Affairs (MHSA) is responsible for ensuring that regional health care systems run efficiently, and that the councils live-up to their mandate of providing high quality public health care services [40]. The MHSA is also responsible for health care legislation, for social welfare services and for health insurance. It holds powers to legislate temporary ceilings on county council and local municipality tax rates. The MHSA also has authority to provide financial assistance for targeted treatments on issues of national public health concern [40].

Similarly, the National Board of Health and Welfare (NBHW) is a semi-independent public authority responsible for monitoring the activity of the county councils. The NBHW follows up the regions, evaluating the services they provide against the goals laid down by the Government, with the broader aim of ensuring equal standards of care across the regions. The NBHW is also the repository for official statistics on health and health care. It encompasses the Swedish Centre for Epidemiology (Epidemiologiskt Centrum), which reports on the distribution and development of health and diseases across the country [40]. The NBHW also produces recommendations and clinical guidelines for new and existing technologies and procedures [42, 43]

In terms of HTA process, however, there are four relevant agencies at the national level, these are: the Swedish Council on Technology Assessment in Health Care (SBU), The Dental and Pharmaceutical Benefits Agency (TLV), The National Board of Health and Welfare (NBHW), and the Medical Products Agency (MPA).

The MPA is responsible for evaluating the safety and efficacy of new pharmaceutical products and for granting permission for their production across the regions [44, 45]. A new product or a natural medicine can only be sold in Sweden following an MPA grant

of marketing authorization, which is valid across the country for five years upon renewal [41]. Upon approval, pharmaceuticals are made available through the National Corporation of Swedish Pharmacies (Apoteket AB), a national distribution system that operates both high street and in-hospital pharmacies to ensure a consistent drug supply at uniform prices throughout the regions. In 2004, there were about 880 pharmacies in the network, eighty of which were located in hospitals [40]. In 2009, however, the system of pharmacy ownership was re-regulated on the basis of choice and competition, and privately owned pharmacies and pharmacy chains were introduced into the state monopoly. Under the reform, almost 50% of the state owned pharmacies were privatized. Today, there are approximately 1200 pharmacies in Sweden, thirty percent of which are owned and operated by Apoteket AB [41].

Established in 2002, the Pharmaceutical Benefits Board (LFN) is the national government agency responsible for determining whether individual technologies should receive a subsidy. The establishment of the LFN responded to financial pressures associated with rapidly increasing costs for pharmaceutical technologies. The LFN reflected the need to ensure value for money, the need for rational and cost-effective public use of medicines and the requirement for the equitable availability of new technologies across the regions [40]. In 2008, the LFN gained additional responsibilities for determining dental benefits. Subsequently, the agency became known as the Dental and Pharmaceutical Benefits Agency (TLV). Today, the TLV is a national government IRA tasked with determining whether or not a medicine or product should be included in the pharmaceutical benefits scheme, and at what price. To these ends, it produces clinical and cost effectiveness data based on the analysis of reimbursement applications presented by the product manufacturers [46, 47]. Since 2002, the TLV has also maintained the list for the National Drug Benefit Scheme, which it continues to review and revise [48].

Consistent with its role of coordinating prices and access across the regions, the TLV uses a value-based pricing model of assessment, under which the price of a drug reflects its value to patients, rather than its production costs or costs in other countries. The TLV expresses the cost–effectiveness of pharmaceutical technologies in terms of costs per quality-adjusted life-years, or QALY [41]. Critically, the TLV has no role in establishing guidelines for the use of new technologies. Its sole remit is to make reimbursement and pricing decisions within 120 days of the receipt of the manufacturer's submission [49, 50]. These decisions apply across the regions. And today, the TLV is also responsible for monitoring the pharmacy market with regard to the implementation of decisions [41].

The Swedish Council on Health Technology Assessment (SBU) evaluates ethical and social consequences of medical technologies alongside considerations of clinical and cost-effectiveness. SBU assessments involve multidisciplinary teams of 10-15 national and international experts [44, 8, 51, 52]. However, the SBU has no regulatory function. SBU synthesizes research findings, providing focus on the clinical aspects of new technologies and also their ethical, economic and social implications [51]. Essentially, the SBU publishes procedures for the use of new technologies including diagnosis, treatment and management of conditions [41]. Usually, it completes appraisals within two to three years [49]. In 1996, however, the SBU developed the SBU-Alert program

for the purpose of delivering more rapid and policy relevant assessments of medical innovations within six to twelve months [49].

However, given the authority of the councils over budgets and its own lack of a regulatory function, a key issue for the SBU is the extent to which its activities actually succeed in influencing practices and policy at the regions [53, 54, 55]. Having the power to raise taxes independently of the central government, the country councils enjoy significant levels of autonomy regarding the uptake and use of medical technology [44]. And to some extent, they replicate the functions of agencies like the SBU at the regional level. Today, the councils are establishing 'mini-HTA-organizations' within their governance structures for the purpose of evaluating health technologies. These organizations include: the HTA-centrum in Region Västra Götaland (RVG), 'Metodrådet' in Stockholm county council, and Centre for Assessment of Medical Technology in Örebro county council. The methods by which each of these bodies conduct HTA varies. For example, HTA-centrum conducts the assessment on the basis of literature reviews, evaluating clinical effectiveness only [56], whereas the 'Metodrådet' utilises cost-effectiveness data [57]. In addition, county councils also have formulary committees (läkemedelskommitté) that make recommendations concerning the use of pharmaceuticals. And by law, every county council is required to have at least one formulary committee (Medical Products Committees Act 1996) [41].

4. Methods

This study was conducted as part of a larger project on national regulatory spaces for HTA across the European Union, with other participants including: England, Scotland, Germany and France, much of which we have already published elsewhere [XX, XX]. In total, 56 interviews were completed in four languages over a twelve week period in July-November 2011. In Sweden, 12 individuals within key agencies involved in the process from regulatory approval to use in clinical practice were interviewed, and carefully selected to represent the Swedish government at both the national and regional level. These agencies included: the Ministry of Enterprise (MoE), the TLV, the SBU, the SBU-Alert programme, the NBHW, the IHE, the NCSP, the SDA, HTA-centrum and the Region Västra Götaland (see Table 1). A semi-structured interview pro-forma was developed, questions were asked under three themes: functional pressures associated with the conduct of HTA; the response of the institution to those pressures; the response of outside institutions to pressures. Questions under each theme varied according to the role and position of individual with organization, and also to reflect issues relevant to the individual organization. Interviews were carried out by the first author and recorded and transcribed in Swedish and Norwegian. No translator was needed. The first author translated key statements into English to make them available to other non-Swedish speaking members of the research team. In order to avoid unnecessary repetition of already published material, readers are encouraged to consult the fuller descriptions of our methods available elsewhere [XX, XX]

Broadly, we found that interactions between Swedish national agencies for HTA were characterized by strong doubts about the ability of national government agencies to secure uptake of research outputs at the regional level. Embedded within a decentralized

governance context, Swedish IRAs for HTA are fundamentally different to organizations like NICE in the UK. Accordingly, meaningful opportunities for convergence, transference and policy learning, in any direct and uncomplicated way, may well be limited between these two players. The major challenge with which Swedish HTA agencies are confronted is successfully communicating nationally produced research outputs to the regional authorities responsible for the delivery of health care services. We detail our findings under three themes: (i) national and regional sources for HTA; (ii) producing coordinated research messages; (iii) the absence of formal regulatory powers.

5. Results

(i) National and Regional Sources of HTA Research

In Sweden, regional institutions often produce HTA data over and above the data produced by national organizations. For example, the TLV is responsible for assessing the cost and clinical effectiveness of pharmaceutical products. Sources at the regions duly reported that "it was more or less decided that we should not evaluate drugs" to the extent that regional organizations like HTA-centrum focused on the assessment of non-pharmaceutical technologies (HTA-centrum). At the time of interview, however, this demarcation regarding pharmaceutical and non-pharmaceutical products was becoming blurred. HTA Centrum and local agencies within the county councils were commonly performing appraisals of pharmaceuticals. In particular, informants at HTA-centrum reported that they "had done quite a lot of drugs" because the other organizations within the county council "wanted [their] help" (HTA-centrum) in establishing the cost-effectiveness of technologies.

Sources at the SBU also remarked on the increasing number of organizations currently engaged in the production of information on new pharmaceutical technologies at the regions. For example, the SBU is responsible for the conduct of systematic reviews on new technologies. However, these reviews were also being conducted by the IHE, IHA, HTA-centrum, Metodrådet and other local HTA-agencies. Sources at the SBU questioned the sophistication of these reviews. "They all have started doing assessments nowadays…but… I would say that the SBU is the only one doing HTA in a proper way" (SBU-A).

With the dramatic increase in the numbers of agencies actually conducting HTA research, The National Corporation of Swedish Pharmacies (Apoteket AB) cited the difficulties of extracting a distinct lesson: "there are so many actors… the risk is that these views…may contradict each other if one doesn't cooperate" (Apoteket AB). The existing system "is overly complicated…it is good if one coordinates even better the different initiatives" (Apoteket AB). In order to extract clear messages from the wide variety of agencies engaged in the HTA process, Apoteket AB had "set up a separate group" within their organizational structure "to draw conclusions from studies…follow the literature and the development, looking at the SBU-reports, go through the recommendations of the NBHW, the MPA's recommendations …and put it all together" (Apoteket AB).

SBU informants saw a role for the central government in resolving differences between organizations national and local organizations through a clearer specification of institutional responsibilities. "We want the government to give very clear tasks to the different agencies" (SBU). They suggested that the national government had a role in ensuring that "duplicate work is not done" (SBU-A). Government needed to "centralize this work to one agency", and thereby "increase the quality [of assessments], because then it would be done in the same way" (SBU). Despite these admonitions, however, we also found that the structure of Swedish government, and the considerable authority of the county councils over the provision of health care, actually limited the capacity of the national government to centralize the work being conducted at the regions in one national agency.

(ii) Producing Coordinated Messages

For example, the multiple sources at which HTA information was being produced had prompted some national agencies to engage with each other towards the production of coordinated research messages. At the time of interview, the SBU was in regular communication with all national agencies, the TLV, NBHW and the MPA, in order "to prevent us from giving different messages" (SBU). Likewise, the NBHW also coordinated the release of its reports with the SBU with the aim of ensuring better uptake of the guidelines at the regions. As one informant reported, "we try…to have a good timing with SBU Alert reports and our own production so that we take advantage of the basis [of the SBU's report]" (NBHW). The NBHW recognized the importance of communication and co-ordination when conducting appraisals in similar areas to other organizations. In these cases, informants identified a requirement to co-ordinate both the timing and substance with other agencies. For its part, the SBU also made significant efforts to communicate findings "both nationally and regionally" (SBU-A). Specifically, the SBU engaged in outreach exercises, employing external experts to take research messages to the regions. Informants suggested that experts needed to act as ambassadors for SBU research. They are "the quality leaders within the area…. when they go back to the health care after finishing their report, they are one of the best ambassadors of the report" (SBU-A). The TLV was also engaged in communication exercise with the regions. The councils were a particular focus for the TLV, "we always work together with them in our decision-making" (TLV) Further, the TLV also communicated results to stakeholder-organizations at the regional level: "We send our agenda memorandum to all the organizations; patient organizations, county councils, different…organizations that are affected by or could be affected by our decisions. And so, I do believe there is a fair chance for everybody to get informed" (TLV).

Although informants cited the willingness of organizations to communicate with each other; they also doubted the effectiveness of their communication strategies. For their part, SBU informants reported that the impact of HTA research messages at the regional level was often closely associated with the remit of the agency performing the analysis, "different people, different groups and agencies, might come back with quite different evaluation of the evidence" (SBU). In addition, the various forms of technical language associated with the conduct of HTA also complicated the reception of reports at the regional level. Often enough, the sheer size of SBU reports functioned as a barrier.

Currently, the length of the SBU' reports tends to be "500 pages typewritten, which is not very useful" (SBU). Agencies needed to "improve on the way we present the data to make it more palatable for the health care professionals" (SBU). They should use "language which could be understood" (SBU-A), avoid jargon and "very technical" reports (SBU-A). Sources within the Ministry of Enterprise (MoE) believed that "agencies [should] present the material so that, even if you're not an expert, you should understand the reports" (MoE). Researchers and regional policy-makers "spoke different languages sometimes" (MoE), which restricted policy-makers' abilities to access specific research messages.

In general, levels of communication reflected both the quantity of agencies engaged in the production of HTA research and doubts about the effectiveness of communication reflected the different remits of these agencies. Consequently, agencies often talked past each other. Informants reported that well-conducted collaboration strengthened messages emerging from agencies, but did not guarantee that messages, however strong, actually influenced HTA agencies and policy-makers at the regions. At the time of interview, some agencies were making internal changes to their methods of assessment with a view to enabling the transmission of more user friendly research outputs. For example, the NBHW is currently exploring new means for increasing communication with regional policy-makers and stakeholders that are more relevant to the use of HTA assessments at the regions by establishing reference groups that involve patient organizations. "We arrange conferences all across the country where we open up…for discussions around the guidelines" (NBHW). Like the NBHW, the SBU is also interested in the influence patients groups have on decision-making: "They are quite powerful these days. The politicians are listening to them…they're gaining more and more influence" (SBU). In addition, the SBU was also focusing on professional organizations, which have a significant influence on research uptake "…that's why we try to uses the professional organizations…as…external expert in our reports" (SBU). By including professionals in the conduct of HTA "we know that whatever we say is based on…the group of professionals which are going to use the knowledge or use the product" (SBU).

(iii) The Absence of formal Regulatory Powers

Given the significant responsibilities of the country councils over the provision of health care, national agencies also lacked necessary regulatory powers and organizational resources to ensure the uptake of HTA research at the regions. For example, national and regional bodies worked to different time frames. At the regional level, the councils were critical of the SBU's lengthy work schedules: "one can criticize SBU for these very long processes, three years and so on, that's much too long" (HTA-centrum). And even informants within the SBU suggested that the organization needed "to find a way to produce the reports faster than we do today" (SBU-A). Informants reported that the SBU Alert reports, which were purposefully introduced to provide information more quickly, "take one year to write, which is way too slow" (SBU).

At the national level, agencies criticized the capacities of regional organizations to conduct HTA. For example, sources within the IHE suggested that the councils lacked the necessary competence to access the HTA-reports from the TLV. They should "adopt

some health economists" (IHE) for the purpose of strengthening both their interest in, and their ability to understand, TLV reports. Equally, however, human resource capacitates were also a key issue at some of the national agencies. At the SBU, external experts were largely responsible for the conduct of all assessments. But the use of external assessors also complicated the SBU's work schedule. Informants at the regions remarked that: "there are people from the whole country who shall travel and who shall decide about dates when they can meet" (HTA-centrum). For its part, the SBU acknowledged that human resources and resource use were areas in which it "could really improve…by letting the employers at the SBU do more of the work and put less on the external expert" (SBU). External experts often "have so much other obligations to attend that they cannot work focused on this report" (SBU). Moreover, the additional use of more external experts in the quality assurance process following the completion of the report further delayed the output of research messages "we have too many external people in the quality assurance process, and I'm not sure that they add so much more quality to it, but it takes a long time" (SBU).

At the national level, limited understanding of pressures on local budgets also restricted the uptake of HTA research outputs at the regions. Specifically, national failures to consider these pressures resulted in the production of HTA research that had little relevance to the county councils in terms of both their interest and understanding of key problems. In some cases, local policy-makers simply ignored national outputs. The fact that "the budgets for the county councils are separate from the national budget" (MoE) often meant that the financial priorities may differ at the regions: "they have regional targets and local targets that can be opposite from the national targets. That can be frustrating" (MoE). At the TLV, the sense of frustration was palpable. Informants reported that the county councils managed a local budget, and that their focus was on the budget, and "money…rather than cost-effectiveness" (TLV). While the TLV produced research outputs based on cost-effectiveness per QALY, these outputs lacked relevance to regional budgetary considerations. "On the national level, TLV understand value per QALY, but don't understand budget…on the county councils' level…they only understand what…budget is. They have no understanding of what value is" (IHE). The lack of understanding of budgetary limitations at the regional level produced friction between the TLV and the Councils: it "is a very specific conflict…in the Swedish health care system" (IHE). As a consequence, county councils may, due to "pure budget circumstances…take decisions that are not in line with what we say or what Socialstyrelsen or the NBHW, recommends as the guidelines" (SBU).

Perhaps most significantly, the absence of formal regulatory powers acted against the impact of national agencies across the regions. Having control of both regional health care budgets and health care priorities, the county councils enjoy a high degree of autonomy. As a result, the TLV, the NBHW and the SBU can only recommend policies. For example, where the TLV recommends that "these drugs…are accepted by us and should be subsidized, it might later get to the county council level…and then they say no" (SDA). Further, informants at the IHE reported that "guidelines issued by the NBHW is…not at all powerful…because it's more recommendations" (IHE). There is no obligation for regional policy-makers to enforce them. The NBHW reiterated the point:

"we cannot decide. We can only recommend what should be done" (NBHW). Similarly, the SBU also highlighted their advisory rather than regulatory role, "we don't have any means to force our reports into the health-care, none whatsoever" (SBU-A).

Without means to enforce their recommendations, several agencies were engaged in conducting assessments of whether or not their research outputs had actually been implemented. For example, the SBU follows-up the transmission of research outputs with implementation evaluations, which they currently conduct "by enquiries" (SBU-A). For the future, informants reported that these exercises needed to become more rigorous. SBU should conduct formal evaluations regarding the uptake of outputs that ascertain "where we do succeed and where we don't succeed" (SBU-A). The NBHW also follows up the transmission of research outputs with implementation evaluations: "after we have published a guideline… we do a follow-up across the country…and see how the recommendation are being followed" (NBHW). Although none of these procedures were formalized, they indicate the broader uncertainty across the regulatory space regarding the uptake of HTA research outputs. In general, there was widespread consensus that current levels uptake of HTA-research needed to be lifted: "I think implementation of the result is one thing that we need to…improve…it's not enough that we do very good reports if nobody uses them in the way they're intended to be used" (SBU-1).

6. Discussion

Potentially, comparative research can involve assumptions that improving methods and processes for HTA is a straightforward task of surveying national approaches to HTA, discovering commonalities and deducing best practice mechanisms and processes for universal application. In this way, comparative research has a tendency to bracket contextual concerns via an assumption that HTA is a two-fold process of assessment and appraisal, in which IRAs sit at the interface of scientific knowledge and practical policy making. Our research, by contrast, suggests that context in which IRAs for HTA are embedded influences both their interactions with other agencies and the methods through which they generate research outputs.

In Sweden, for example, the powers of the county councils to levy taxes and finance the provision of health care at the regional level limits the role of national HTA agencies in the delivery of cost-effective health services. Certainly, national HTA agencies produce relevant information on the use of new pharmaceuticals, but the influence of this information on regional health systems is uncertain. This potential for differences to emerge between regional and national priorities serves to differentiate the conduct of HTA in Sweden from its conduct in other European states. In Sweden, the national government is unable to operationalize multiple mechanisms for pursuing cost efficiencies within the system in an effective way, and must rely largely on the production and uptake of cost effectiveness data. As we have argued elsewhere, in France, by contrast, rigorous economic modeling techniques play little authoritative role in the current framework for HTA (XX). And indeed, French policy makers harbor strong doubts about the legitimacy and practicality of setting budget constraints on financing health care service. The French approach to HTA is a consequence of the open

nature of the French national health care budget, the structure of its financing mechanisms, and strong cultural values associated with ensuring unrestricted access to care (XX). As a result, French IRAs for HTA pursue cost-effectiveness gains in the system via that mechanisms rely on expert opinion rather than rigorous calculations of cost per QALY currently operated by organizations like the TLV. In Sweden, however, national agencies are unable to bring expert opinion to bear on the delivery of health services in a coordinated way because they lack authority to decide regional health care priorities. In order to have any influence over regional priorities, Swedish national agencies have little choice but to rely on economic modeling and the production cost effectiveness data, involving the use of QALYs, to maintain their relevance in the regions.

The regionalization of health care funding is perhaps the most serious barrier to the influence of national HTA agencies [49, 52]. In Sweden, the regions often work to different perspectives, time frames and processes. For example, national HTA-organizations like the TLV evaluate the effectiveness of innovations from a societal perspective based on cost per QALY [40;46, 48]. But the county councils are concerned with maintaining their local budgets and are often less concerned with whole-society notions of cost-effectiveness. Lacking powers to set regional priorities and to alter regional budgetary contexts, national agencies must focus on producing cost-effectiveness data, which, at best, might serve to guide the decisions of regional policy makers. And in such a case, it is perhaps even unreasonable to expect that Swedish national agencies should play an authoritative role in deciding regional priorities given their lack of responsibility for the delivery of health care services.

The point is that the responsibilities of the county councils for strategizing and financing the delivery of regional health services raises serious intra- and extra-organizational barriers at the national level, which limit the capacity of national IRAs to exercise influence. Certainly, Sweden has solid levels of expertise for the conduct of HTA at the national level. But, under the decentralized governance structure, the capacity of national government agencies to deliver expert advice across the wider regulatory space is debatable. The emergence and multiplicity of HTA IRAs at the national level, each with different roles and remits, has no doubt exacerbated this issue. Today, national agencies produce a wide and, as informants suggest, sometimes confusing array of research outputs, which the county councils often elect to ignore. While national agencies are busily engaged in communication exercises to harmonize and amplify the strength of their research messages in the regions, doubts regarding the effectiveness of these strategies remain. And while the fragmented national institutional environment might benefit from government initiatives aimed at improving the coordination of national roles and outputs—for example, policy-makers might consider centralizing the conduct of systematic reviews in one national body by consolidating the TLV, the NBHW and the SBU in a single government agency—there is no guarantee that the even consolidation of these bodies would increase the appeal of national research outputs at the regional level given the lack of national authority in the regions.

Such a finding sits well with other analysts who have suggested that bridging the gap between HTA research and policy making is the most significant challenge facing Swedish HTA organizations in contributing to higher quality health care [44, 52]. For several decades, Sweden has been at the forefront of achievements for the development of well-established national, regional and academic organizations for the conduct of HTA. At all levels, Swedish policy-makers, clinical professionals and health-care workers are largely supportive of HTA [44]. But, under the decentralized structure of governance, national research outputs do not speak for themselves and must rely on the regions for uptake. In meeting this challenge, Swedish policy makers might do well to look to the similarly decentralized example of the Spanish healthcare system in which the regional *Comunidades Autonomas* have their own HTA agencies, while a national agency is called upon to implement national programmes and provide partial funding for regional HTA projects. Certainly, the Spanish regulatory space involves very different administrative and cultural traditions, which we lack the space to consider here; but the mutual problems of managing resources and sharing authority within a decentralized governance context maybe sufficiently similar to admit some meaningful policy learning and transference between the two MSs. At the very least, Swedish policy makers might gain some inroads towards a regulatory solution that could reasonably expected to work in a Swedish context.

7. Conclusion

While the key utility of a regulatory governance perspective on HTA is its capacity to draw attention to a greater range of challenges and issues with direct relevance to improving the conduct of HTA within national regulatory spaces; it achieves this end by discarding many of the key assumptions the comparative approach. Essentially, a regulatory governance frame takes a very subtle position with respect to instances of diversity and difference. In the first place, it expects to find them; and in the second place, it also hopes to build better methods and processes for HTA on the basis of this expectation. The problem with the distinction between HTA as an assessment process involving the structured analysis of a health-care technology, which is transferable across state boundaries, and an appraisal process, in which the analysis is converted into policy advice, is the implicit assumption that methods and processes are not connected, or in other words, that HTA takes places within isolated and largely scientific institutions that apply self-selected methods. On the contrary, our analysis suggests that the process through which research outputs are converted into policy advice affects the process through which these outputs are generated in the first place. Put another way, national contexts often complicate the uptake of HTA methods and process. The point is that policy makers need to develop regulatory solutions specifically tailored for national circumstances. In Sweden, for example, policy makers might need to consider the prospect of semi-autonomous regional HTA organizations operating with some element of supervision from a methodologically rigorous national organization.

TABLES

Table 1. Characteristics of interviewees.	
Characteristics	No of interviewees (*N* = 12) (%)
National HTA-agencies	
The MoE	1 (8.3)
The TLV	1 (8.3)
The NBHW	3 (25.0)
SBU	1 (8.3)
SBU-Alert	1 (8.3)
Regional HTA-agencies	
HTA-centrum	1 (8.3)
Academic HTA-agencies	1 (8.3)
IHE	
HTA-stakeholders	1 (8.3)
NCSP	1 (8.3)
SDA	
Policy-makers	1 (8.3)
RVG	

Table 2. Themes.
• Multiple HTA-production and overlapping tasks • Communication and collaboration attempting to unify messages • Influence of HTA on policy-making

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