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A regulatory governance perspective on health technology assessment (HTA) in France: the contextual mediation of common functional pressures

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Abstract:

The new regulatory governance perspective has introduced several insights to the study of Health Technology Assessment (HTA): it has broadened the scope for the analysis of HTA; it has provided a more sophisticated account of national diversity and the potential for cross-border policy learning; and, it has dissolved the distinction between HTA assessment and appraisal processes. In this paper, we undertake a qualitative study of the French process for HTA with a view to introducing a fourth insight: that the emergence and continuing function of national agencies for HTA follows a broadly evolutionary pattern in which contextual factors play an important mediating role. We demonstrate that the French process for HTA is characterised by distinctive institutions, processes and evidential requirements. Consistent with the mediating role of this divergent policy context, we argue that even initiatives for the harmonisation of national approaches to HTA are likely to meet with divergent national policy responses.

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A Regulatory Governance Perspective on Health Technology Assessment (HTA) in France: The Contextual Mediation of Common Functional Pressures

1. Three Insights of the Regulatory Governance Perspective on HTA

At the intuitive level, the field of regulatory governance and the study of HTA seem well suited to one another. On the one hand, HTA is a means by which governments around the world have attempted to ensure comprehensive and equitable public access to the new and expensive range of medicines and treatments in the context of limited budgets for healthcare. And on the other, regulatory studies is a subset of governance scholarship concerned with the analysis of governmental steering activities, rather than the public provision and distribution of resources, that focuses on ways in which governments consolidate and organise individual policy sectors, and the techniques they use to incentivise the players within them [4]. Taking advantage of this appeal, a new generation of scholars has opened a regulatory governance perspective on HTA to produce some valuable insights into the study of HTA in Europe [1,2,3] .

In the first place, regulatory scholars have broadened the scope for the analysis of HTA, demonstrating that HTA does not take place within single isolated institutions that apply self-selected methods and process, but occurs across a broader decision-making network that responds to specific cultural and institutional environments. Considering the use of the Efficiency Frontier under the German approach to HTA, Klingler et. al. show that efforts to improve the conduct of HTA based on comparative analyses that describe different HTA methods, determine ‘what works best’ and formulate best practice guidelines for ubiquitous application are misguided. Policy makers, they suggest, are unlikely to introduce measures for the improvement of HTA that run counter to the existing cultural and historical preferences. Accordingly, the study of HTA must take place under a significantly broadened conceptualisation of HTA, and involve an analytical framework capable of capturing the relevant cultural, historical and institutional determinants [1].

Secondly, regulatory scholars have also introduced a more sophisticated take on national diversity and policy learning with respect to HTA methods and processes. The field of regulatory governance reaches across the wide variety of policy sectors, from banking and finance, shipping and aviation, and gambling and healthcare, to name but a few. Considering the role of the County Councils in the delivery of Swedish healthcare, Shah et al draw on the insights of regulatory governance theory to suggest that HTA scholars should expect to encounter diversity with regard to national methods and processes. Globalisation, they suggest, touches sectors, markets and regulatory regimes to different degrees. In banking and finance, for example, both markets and regulations are global. In terms of other sectors, like gambling and healthcare, however, both markets and regulations are national. In the case of health technologies, regulations are subject to globalisation, but markets are not [5,6]. Today, individual nation states are among the largest buyers in pharmaceutical markets. Accordingly, there is more scope for variation in national regulatory arrangements for health technologies than in arrangements for sectors like banking, finance and aviation, which require unified regulatory regimes towards the construction of which nation states, private enterprises and third sector organisations necessarily collaborate [2, 7]. And certainly, in terms of institutions, processes and evidential requirements for HTA, national states exhibit significant differences and

divergences, which limits opportunities for policy learning across states. However, this is not to imply the impossibility of policy learning, rather to suggest that complex national dynamics and traditional regulatory-governance structures have a bearing on the types of policy lessons that analysts might reasonably expect to extract and apply. Indeed, by using the right cases-studies, analysts may even increase the potential for policy learning and transference. For example, in the case of Sweden, some national environments, notably Spain which has a similarly structured health care system, may be more relevant to reflecting on and potentially improving the Swedish approach than other national models [2].

Thirdly, regulatory governance scholars have problematized the notion of a distinction between HTA assessment and appraisal processes [3]. For example, some analysts suggest that HTA consists of a formal assessment process, which produces knowledge about new health-care technologies, and a more context-specific appraisal process, which translates the analysis into policy advice and decision-making [8]. Under the distinction, HTA assessment processes are considered broadly transferable across national contexts. On this basis, some, and notably English analysts, have suggested that organisations like the National Institute for Health and Care Excellence (NICE) in the UK set an international ‘benchmark’ for the use of evidence in HTA, which derives from the practice of evidence based medicine and even the European Enlightenment [9]. However, the regulatory governance perspective is unconvinced by these claims, affirming that appraisal and assessment processes are mutually constitutive, or that the policy making context in which HTA is conducted holds consequences for the way that evidence is used in the HTA process. For regulatory scholars, NICE’s so called ‘assessment process’ has little to do, as English commentators are wont to suggest, with evidence based medicine and the European enlightenment, and much more do with the fact that NICE assessments must drive a health system that involves universal and free access to healthcare, and in which the profits and prices of pharmaceuticals are regulated by an initial agreement between industry and government. Thus, regulator scholars claim that NICE’s rigorous, and arguably expensive, application of economic analyses, the use of Quality Adjusted Live Years (QALYs) as a benefit measure and a funding threshold, derive from the necessity to make comparisons of the cost-effectiveness of medicines across individual disease areas—for the purpose of establishing whether or not public money is more effectively invested in the latest cancer treatment or the latest diabetes treatment—or in other words, to ration healthcare [9]. In such cases, the regulatory governance perspective asserts the internal coherence of national approaches to HTA, denying that one can set a so-called ‘benchmark’ for any other system. Indeed, the desirability of policy goals in particular contexts necessarily conditions any potential benchmarking exercises. In other words, NICE could set a benchmark for HTA only insofar as the goal of rationing healthcare became desirable in other national contexts. However, even in that situation NICE would only constitute an adequate benchmark where the same values (utility maximization) underlay the rationing process.

2. The Contextual Mediation of Common Functional Pressures

The purpose of this paper is to articulate a fourth insight of the regulatory governance frame to the study of HTA. At the European level, the emergence of varied national approaches to the conduct of HTA has produced calls for the harmonisation of methods and processes across the EU. And today, there remains significant interest in the exchange of information about HTA process and potential initiatives for cross-

border collaboration in the name of reducing expenditure and the duplication of HTA work programmes [10, 11]. At the industry level, there is also much support from major pharmaceutical companies for a harmonisation of HTA methods for the purpose of producing nationally transferable results [12]. European policy analysts likewise support the establishment of a European drug pricing and reimbursement agency similar to the European Medicines Agency (EMA) [13]. Furthermore, they have suggested 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 [14, 15]. Additionally, the European Parliament's directive on patient rights and cross-border healthcare also supported more formalised cooperation between national HTA agencies through the European Network for Health Technology Assessment (EUnetHTA)[16]. These initiatives for harmonisation emphasise the benefits of adapting evaluations of individual technologies for cross-border use, and of developing systematic approaches to evaluating the efficacy of individual technologies in the context of alternatives. And more generally, they confront national governments with additional functional pressures and arguments for reforming methods and processes for HTA.

With its significantly broader policy perspective, however, the regulatory governance frame sheds light on possible complicating factors. For some time, regulatory scholars have studied the related emergence and institutional growth of independent agencies (IAs) in other policy sectors. For regulatory scholars, the establishment of European IAs for HTA—such as NICE in England and the Haute Autorité de Santé (HAS) in France—is consistent with the similar establishment of IAs in other policy sectors like banking and finance, aviation and shipping, education and trade. In each sector, the establishment of IAs reflects an increasingly technical and complex policy environment. Under a principal-agent theory, regulatory scholars suggest that nation states establish and delegate authority to IAs in response to common functional and political pressures within policy sectors, these pressures include: overcoming information asymmetries, blame shifting and dealing with complex and technical issues [17, 18]. Attempting to understand the proliferation of IAs across the wide variety of European policy sectors with the varying circumstances and forms in which they have arisen, regulatory scholars also argue that contextual factors strongly mediate national responses to these common pressures. Contextual factors influence the circumstances and forms in which IAs arise and include among others: institutional isomorphism; state traditions and structures in regulation, political leadership and the broader institutional context of West European states [17]. For example, the nineteenth century British tradition of government through regulatory commissions facilitated the rapid rise of IAs in the UK in the 1980s and 1990s. However, the absence of such a tradition in Italy saw the proliferation of IAs only begin in earnest following the successful creation of the Competition Authority in 1990 [17]. Thus, regulatory scholars conclude that the rise of IAs must be explained in relation to the unique contextual features of the national environments in which they develop [18]. For health policy analysts, the point is that initiatives for the harmonisation of HTA methods and processes need to reassess the scope of their ambitions via a much more detailed analysis of the circumstances in which national IAs for HTA have arisen.

To this end, we undertook an analysis of the institutions involved in the conduct of the French process for HTA with a view to discovering their unique institutional forms and their associated needs in terms of HTA methods and evidence bases. In France, like any other developed nation, the production of increasingly sophisticated health care technologies has left government struggling with the problem of balancing limited health budgets against the requirement to ensure comprehensive and equitable public access to new medicines and health technologies. Conducted in 2011, our analysis details the ways in which the French system has been responding to these common functional pressures. We found that the French process for HTA bears out the insights of regulatory governance theory. While other EU Member States, notably England and Scotland, have established single HTA agencies for the purpose of conducting cost-effectiveness and cost utility evaluations, France, at the time of interview, conducted HTA across a network of government agencies, none of which actually engaged in either cost-effectiveness analysis, or any other direct form of economic evaluation, but all of which played important roles in operating a range of mechanisms for containing healthcare spending. In 2011, the French approach to HTA was directed towards fixing both prices and levels of reimbursement for new health technologies. At the time of interview, there seemed little prospect that this approach was likely to change. In 2003, however, cost-effectiveness analysis had become compulsory part of the process, yet it did not involve the use of an associated threshold. And on this basis, we press the fourth insight of the regulatory governance perspective on HTA: that the emergence and continuing function of national IAs for HTA follows a broadly evolutionary pattern in which contextual factors play an important mediating role. Ultimately, we suggest that the task for analysts of HTA is to identify and reveal these patterns. Specifically, initiatives for convergence, or goal related policy learning, must involve a tailored strategy for accommodating diverse regulatory governance arrangements and the differential impact, or even the relevance, that changes might have in alternative contexts.

3. The French Multi-agency Approach to HTA

In France, HTA serves the broader objective of reigning in government spending on and improving the quality of healthcare. By 2011, however, French policy makers delivered this aim via a number of mechanisms: streamlining medical practices, promoting cost-effective treatment options, influencing prescribing behaviour, controlling prices and adjusting levels of reimbursement. Operating these mechanisms required the interaction of several government agencies, each of which played vital and complementary roles. The institutional architecture of the French approach evolved in the 1990s under a variety of initiatives for reducing costs and improve efficiencies within the health system [19, 20, 21]. By 2011, the key organisation involved in the HTA process was the High Authority for Health (*Haute Autorité de Santé*, HAS). However, the evaluation of health technologies also involved a multi-step, multi-stakeholder process in which other institutions outside the HAS played important roles in determining the value of new products through a pricing and the reimbursement process. These included the Medicinal Products' Pricing Committee (*Comité Economique des Produits de Santé*, CEPS) and the National Union of Health Insurers (*Union Nationale des Caisses d'Assurance Maladie*, UNCAM).

Established in 2004, HAS is an independent government organisation tasked with improving the quality of patient care. Its activities are wide ranging and include the assessment of new pharmaceuticals and medical devices, the publication of advice

regarding new procedures and also the authorisation of healthcare organisations and the certification of clinical professionals. Although its role is often compared with that of NICE in the UK, HAS issues opinions, recommendations and advice that integrate directly into a wider decision-making network through which new technologies are introduced into the French healthcare system. Through the work of its internal committees—the *Transparency Commission* (TC) for the appraisal of pharmaceutical products; the *National Commission for the Evaluation of Medical Devices* (CNEDIMTS), for medical devices and more recently the *Commission for economic evaluation and public health* (CEESP), HAS contributes to the wider HTA process by supporting the function of other agencies responsible for determining the benefits package, for regulating medical professionals and for determining price and reimbursement rates.

The HAS evaluation is the first step in the French process for HTA [22, 23, 24]. Following the receipt of market authorisation, the manufacturer submits the technology to the relevant HAS committee. HAS evaluations are conducted on the basis of the manufacturer's submission dossier, the Note of Therapeutic Interest (*Note d'Intérêt Thérapeutique*), and the available clinical and public health information regarding the technology. In scrutinising the available information, the committee establishes the individual clinical and therapeutic benefit (SMR, *Service Medical Rendu*) and the relative benefit (ASMR, *Amélioration du Service Medical Rendu*). The ASMR denotes the relative effectiveness of the technology against currently available medicines and therapies and informs the price setting activities of CEPS – since 2012 in conjunction with medico-economic information produced by CEESP. The SMR denotes the degree of medical benefit or therapeutic 'value' of the medicine and is derived considering different criteria among them clinical efficacy, effectiveness, severity of treated disease, existence of therapeutic alternatives, and public health impact. It informs the decision-making processes of UNCAM, which is responsible for determining whether or not the product is included in the list of medicines receiving coverage under the benefits package, and, at what rate the product will be reimbursed. The price setting process typically precedes decision making regarding the reimbursement rate, but the two processes are also linked. Pharmaceuticals without an ASMR rating, or those which exhibit neither any additional health benefit nor costs savings by comparison with the existing range of reimbursed pharmaceuticals, cannot be included on the benefit package.[25, 26, 27]

At the time of interview in 2011, economic assessment techniques such as cost-effectiveness analysis played no formal role in the HAS evaluation, which instead focused on a benefit assessment based on the SMR and the ASMR. However, in 2008, the Social Security Financing Act gave HAS a mandate in the area of economic evaluation. A new committee known as the CEESP (*Commission évaluation économique et de santé publique*) was created and initially tasked with developing holistic therapeutic strategies to drive efficiency savings throughout the healthcare system. Since 2012, HAS assessment also involves the production of economic efficiency data at the level of the proposals through CEESP, which is termed, the *Avis d'Efficiences*. This second *Avis* feeds directly into the decision-making process of the pricing committee by providing information designed to complement the TC's benefit assessment, or the *Avis sur les médicaments*. These assessments are currently restricted to products that demonstrate significant added value and are likely to have a significant financial impact on pharmaceutical spending. Nevertheless, the SMR and

ASMR remain the principal tools for determining the value of the majority of products.

The CEPS is a committee comprised of various stakeholders from within the Ministry of Health and other organisations charged with responsibility for setting the price on new medicines. CEPS takes responsibility for negotiating the price of the product with the manufacturer mainly on the basis of the ascribed ASMR ratings. In conducting negotiations, CEPS also takes into consideration the necessary levels of healthcare investment, any requisite changes to screening programmes, the organisation of care, requirements for monitoring and dissemination of the technology and adjustments to the regulatory framework. In the course of the negotiations, the Association of Pharmaceutical Industry (*Les Entreprises du Médicament*, LEEM), which represent the interests of the French pharmaceutical industry, also plays a role. Together LEEM and CEPS considered factors like expected levels of sales and comparative prices in other EU Member States. But negotiations between the CEPS and the individual firm are also confidential. And so, LEEM does not intervene directly in the price negotiation process. In general, the completion period of the process for hospital-only drugs was 90 days from application to price settlement and 180 days for retail pharmacists' drugs.

In 2011, health economic assessment techniques played no formal role in CEPS's negotiations with firms. Today, this is beginning to change as the CEPS will begin to consider the input of the new CEEPS committee. Nevertheless, the outcome of the negotiation process at CEPS continues to remain dependent on discussion and deliberation. CEPS had a diverse membership. In conducting negotiations, it balances budgetary and economic concerns with public health objectives. Final decisions regarding pricing are often as much an internal debate within the members of the CEPS as they are a negotiation with the supplier. Within CEPS, various competing objectives often carry the day. For example, delegates from the Ministry of Health might pursue a strong public health agenda, or delegates from the Ministry of Industry and Research might seek to promote the uptake of effective new treatments, or to pursue a strong research and industry competitiveness agenda. Alternatively, delegates from the Social Security Division and Insurance Funds might pursue a payer's agenda, aiming to maintain current levels of health expenditure and keeping prices low. Other factors like public health needs, summarised by the SMR might also hold sway. However, the precise contributions of each factor and interest group in determining price remained unclear [19, 28].

Following the settlement of the price, UNCAM is responsible for setting the reimbursement rate. In France, approved pharmaceuticals are reimbursed at either 100%, 65% or 35%, with some reimbursed at 15% [29]. The SMR rating is important to UNCAMS settlement of the rate. Typically, the rate is formalised on the basis of the SMR. But UNCAM also negotiates with the medical professionals involved in the prescription of medicines, and other key stakeholders, before attaching any necessary patient co-payment. Once the price and the rate were set, the process concluded with the Minister of Health either accepting or rejecting the technology for use in general practice or in hospitals [19].

5. Methods

We conducted a qualitative study of the French approach to HTA with the intention of taking a snap shot of the process as it existed in 2011, and detailing why the approach was preferred and how it might evolve in comparison with other approaches. The study combined an analysis of key policy documents and semi-structured interviews with French policy-makers, HTA producers, clinical professionals, academics and other stakeholders, and was conducted as part of a larger project on national approaches to HTA across the European Union, with other states including: England, Scotland, Germany and Sweden. In total, 56 interviews were completed in four languages over a twenty week period in July-November 2011. In order to avoid unnecessary repetition of already published material, readers are encouraged to consult the fuller descriptions of our methods available elsewhere [1, 2] In France, ten interviews were conducted with a wide range of stakeholders reflecting different perspective and interests, including senior government officials identified through their membership in the relevant committees. These institutions included: the Ministry of Health, the department for Social Security (DSS) and the Department for Public Health (DGS) The High Health Authority (HAS), the Health Product Agency (AFSSAPS, now MSNA) the General National health Insurance fund (CNAM), the Health Economics and Outcomes Research Organisation (URC-ECO) and a relevant pharmaceutical company.

Institution	No of interviewees (N = 10)
Department for Social Security (DSS)	2
Department for Public Health (DGS)	1
The High Health Authority (HAS),	2
The Health Product Agency (AFSSAPS, now MSNA)	1
The General National health Insurance fund (CNAM)	2
Clinical research unit specialized in health economics (URC-ECO)	1
A Pharmaceutical company	1

We report results under the following thematic headings: ensuring access through price negotiation and conditional reimbursement; focus on public health benefit not cost-effectiveness; multiple channels for controlling costs; and improving the process. In order to allow readers to distinguish between different voices, we identify interviewees according to the organisation they represent, for example (DGS) for the *Direction Generale de la Sante*,.

6. Results

(i) Ensuring access through price negotiation and conditional reimbursement

Respondents suggested that a key advantage of the French approach to HTA was the ability to control costs through a system of price negotiation and conditional reimbursement based on the clinical and public health benefit of new technologies. Respondents asserted that HAS's critical role in the HTA process was to enable CEPS to negotiate and fix a price for technologies with the manufacturer. In other words, HAS itself did not make decisions; it provided insights into the relative value of new technologies in order to facilitate a decision making process that ultimately lead to a price negotiation, setting the level of reimbursement of new technologies and determining the position of the product in the therapeutic catalogue. In this respect

respondents suggested that the activities of HAS and CEPS were broadly non-comparable with those in other EU Member States. In France, *“the goal of HTA is to facilitate decision making, if you take NICE, it is more than facilitating decisions, it is a decision”* (HAS). In this way, HAS produced qualitatively different kinds of information about technologies than other European agencies such as, TLV and NICE. Respondents also recognised the differences between the wider role that HAS played within the French HTA process compared with other national IAs, in particular NICE, and that this divergent role necessitated the output of different kinds of technology assessments. *“In England, they use a cost per QALY threshold to decide whether or not to adopt a new drug. In France, our assessment is done in two steps, first assess the therapeutic progress (i.e. the ASMR) and the economic assessment is left to CEPS which will negotiate its trading price”* (HAS).

Respondents thought that the HTA process was conducted across a network of institutions, that HAS’s role in this process was to facilitate a negotiation process with the manufacturer, under which prices for new technologies were fixed along budgetary constraints. In conducting negotiations, CEPS required a diverse range of evidence. It needs to consider *“the actual benefit and also the public health need of the population. The CEPS therefore knows what its margins are, and taking into account these elements, you have a price / volume negotiation”* (DSS). The role of HAS in the process was to provide these elements through the initial HAS assessment. *“The HAS assessment is the basis on which we rely to fix prices on the one hand, that’s the role within the Economic Committee for Health Products, and secondly, to determine the rate of reimbursement, that’s the role of UNCAM”* (DSS). In UK, by contrast, *“NICE is a price taker...there is actually a threshold below which they do not take things in the 'benefits package'; under which they decide not to cover the product under the NHS”* (URC-ECO). Respondents were concerned to distinguish between the role of French and UK agencies for HTA with the former perceived to aid negotiations on price and scope; and the latter to make decisions about inclusion and exclusion— or, in other words, the rationing of health care. In France, the ability to negotiate prices eliminated the requirement for an abstract threshold. And indeed, some respondents even expressed amazement that the English system of a cost per QALY threshold should be preferred over the negotiation of prices with manufacturers. *“The use of willingness to pay thresholds is commonly used and it doesn’t seem to shock anyone to put an efficiency threshold to determine whether a drug will be covered by the NHS. This is not something that corresponds to the French way of thinking”* (DSS). In France, the role of HAS was to produce outputs that can drive a process of price negotiation between CEPS and the manufacturers by providing relevant information regarding the clinical and public health benefits of the new technology.

Secondly, respondents pointed out that HAS also facilitated a process at the level of reimbursement, which also aided decision-making by establishing the status of the technology. *“The HAS assessment is the basis on which we rely to negotiate its prices but also to define the status of the product and its position as part of the benefits package and to determine the rate at which we will reimbursement the product but also, but that’s the role within the Economic Committee for Health Products. So essentially it is on the basis of this assessment that all stakeholders rely on to determine access, the level of reimbursement and establish the prices”* (DSS). Respondents intimated that the French healthcare budget *“is not a sealed envelope*

with fixed budget constraints... products will be reimbursed by the social health insurance fund" (URC-ECO). Policymakers reimburse drugs at different rates with the broader aim of making all drugs available. "We do not want to always be perceived to be restricting access especially on the basis of cost. So we ensure all drugs are accessible, and then we try to achieve the best price on one hand and control volume and use on the other" (CNAM). HAS assessments allowed decision makers to prioritise different technologies. For example, in order to accommodate expensive medicines, "we will happily reduce coverage on other high volume products which offer very little therapeutic gain in order save money and free up funding for expensive treatment" (CNAM). Similar to the negotiation of price, the ability to alter levels of reimbursement gave the French system additional flexibility. "We are not in a framework of having a fixed budget for the year whereby health provider have to choose between funding a drug or being able to maintain its basic services" (HAS). In order to control costs, French policy makers can "lower the rate of reimbursement for certain drugs, and we reduce the price on others, but we do it in the logic of our system...So essentially, on the one hand, we will pay for a cancer treatment that will provide only two additional months of life, but on the other hand, we will reduce coverage on cough medicines whose therapeutic value is limited. When you look at what we end up reducing the coverage on, it is always a product that has an inadequate SMR (i.e. lower therapeutic benefit). So that's really the trend in France" (DSS). To sum the argument up: HAS is not in the same mind-set as other HTA agencies (e.g. NICE) who are sometimes required to make absolute choices. As a result, HAS does not need to produce the same kind of information and is therefore employing different methods, because it is not deciding on inclusion or exclusion of pharmaceutical products from public reimbursement – which is broadly rejected as a practice –, but only producing information to inform price negotiation and the setting of reimbursement rates.

(ii) Focus on public health benefit not cost-effectiveness

Respondents were not only critical of the decision-making process based on a cost-per-QALY threshold as such, but also reported strong distrust of basing their decisions on economic arguments in general citing their lack of focus on public health and epidemiological evidence. Even where negotiations were assumed to remain the standard route for making pricing and reimbursement decisions, experts were critical of introducing cost-effectiveness data to those processes. "I don't think we want to end up with a 'NICE-type' system in France. Because...from the public health point of view, the NICE-type cost per QALY threshold approach is not appropriate... if we don't think a little bit more in terms of public health benefits, we are going to have problems...you still have to defend the interests of patients and also integrate the medical and economic criteria. But the health economics criteria should not be at the forefront of our decision making process, otherwise, we are no longer serving public health objectives" (DGS).

Given their focus on public health, respondents suggested that the French approach to HTA provided a more legitimate basis on which to reduce costs in the system. In this regard, they were concerned to highlight the differences between their own approach to HTA compared with the approaches of other European states, notably England. *"Between the highly formal system used by NICE in England, where methodologies for allocating resources in healthcare are well defined and clear cut, but ultimately the final decisions is sometimes modified due to public demand and pressure from*

patients; and the more informal system in France which is exactly the opposite, with a more flexible and open process which relies more on opinion and debate than on evidence, but at least the outcome of the consensus is better accepted and much more easily implemented in France than the outcome of some HTA decisions in the UK” (HAS)

The implication is that HTA processes that emphasise public health and clinical benefits are more acceptable to the French public than approached that focuses on econometric measures. In other words, decision-making procedures that raise the value of cost-effectiveness data over clinical benefits would likely heighten public anxieties about the HTA process—a fact also observed in the UK. For this reason, French policy makers are uncomfortable with such initiatives. As our informants suggest, France is not completely against considering economic arguments in their decision-making process; but are concerned to point out that these should not be the most important arguments (as they presume is the case with NICE) in deciding on pricing and reimbursement of drugs. This essentially means that in terms of controlling costs and regulating access, the French process appears to give a higher weight to public health consideration which guarantee access while the English approach puts more emphasis on access conditions based on cost-effectiveness to meet strict resource allocation constraints.

(iii) Multiple Channels for Controlling Costs

HAS evaluations also produced information that supported changes to clinical practice. *“For us, HTA is the tool which we use to help support the decisions and actions we make to shape and reorganise the healthcare system and the practice of health professionals. And therefore as an overarching objective, the control of health care spending growth in France since as you know, we're not in a mindset of reducing spending and rationing care” (DSS)*. In driving this process of price negotiations, our respondents suggested that HAS outputs needed to hold legitimacy for clinical and public health audiences. *“The opinion released by HAS is independent and we use their recommendation to back us up in our activities. It is essentially the endorsement of everything we do so that is important to us as it gives our actions a more legitimate and more credible voice which resonates more clearly with the medical professionals” (CNAM)*.

Respondents also suggested that improving the delivery of care through the use of HTA held the potential to reduce waste in the system and contain healthcare budgets at the coal face of the patient-clinician relationship. *“There are huge sources of quality and efficiency gains that can be driven across the spectrum of delivery of care that are potential sources of savings. This will not only allow us to slow the growth of health spending so that it remains sustainable, but also improve the quality of care because as it stands there is a huge amount of waste in the delivery of care within our system” (DSS)*. And to this end, HAS evaluations played a role in defining a hierarchy of therapeutic strategies for the purpose of delivering a patient level agenda for increasing both quality and cost efficiency. *“The idea is to find the most efficient therapeutic strategies and to promote the proper and efficient use of these medical technologies and establish standards of practices. This is currently the way that health economic evaluation is carried out in France” (DSS)*. For example, the initial HAS assessment produces an ASMR rating and range of treatment options, measured by cost, which clinicians are required to consult. *“Our objective is that given equal*

health outcomes, a doctor should choose the least costly treatment. That's the basis of our work at the HAS, i.e. provide recommendations, information materials such as a monthly publication that will influence physician behaviours and promote cost effective and quality based medical practices" (HAS).

At the time of interview, HAS was also engaged in *"work to ensure the appropriate use of medicines such as promoting the use of generic medicines. It's the same quality at lower cost or even better quality at an additional but acceptable cost."* (DSS). Essentially, HAS was attempting to empower clinicians to prioritise technologies and to take part in delivering savings. *"The strategy involves a series of programs called 'medical control' (maitrise médicalisé) which involve going to visit doctors but also dentists, chiropractors, physiotherapists, nurses, all professionals to try to make them aware of the use of a certain number of acts or regulations and promote the appropriate use of health products and develop accompanying program of professional and scientific articles to try to arrive at the right prescription" (HAS).* Given that HAS did not make decisions, other actors within the system, notably clinicians, became responsible for the rationing of healthcare at the coalface of clinical practice. *"So if there is only 10% or 15% of the patient population who really need the latest drug because it offers fewer side effects, well it is up to the doctor to identify who these patients are and not up to us. And that's why we develop broad recommendations that say, 'here is the order of magnitude of cost efficiencies that you ought to target as part of prescription patterns'" (CNAM).* Until recently, this type of approach has served as an alternative way to control cost rather than introducing cost-effectiveness analysis. It consisted of providing health professionals with the relevant clinical effectiveness information to allow them to priorities treatments within the appropriate clinical context, without taking into consideration the cost of the product. However, over time, respondents recognize that this method has shown its limitations, as it has not allowed to effectively contain pharmaceutical expenditure. As pointed out by one of our respondent, *"we always have structural deficit problems within the social health insurance budget. The current system of HTA in France has not allowed us to stay within our annual tentative budget."*(URC-ECO).

(iv) Improving the process

Respondents also made criticisms of the French system. They held strong opinions about how the process could be improved. On the whole, however, their suggestions for improvement served to consolidate the divergent French approaches to HTA, rather than seeking convergence with other national models. Whilst respondents recognised that the French HTA process has significant limitation in terms of its ability to control costs and remain with the budget, respondents were also adamant that the French process held more legitimacy than the English approach, which largely focused on ensuring value for money. Seeking improvements to the system, most respondents expressed confidence in the multi-agency approach, but suggested that the evidence base on which decisions were taken could be improved. They argued that HAS needed to produce better information. When pressed about the nature of these improvements, respondents argued that the process required improved levels of epidemiological data at the regional level to better understand the impact of new technologies in different environments showing again the French emphasis on public health indicators instead of cost-effectiveness data. Generally, they remained

unsure about where cost-effectiveness and an associated threshold data could be incorporated within the process.

Respondents suggested that the key problem with HAS assessments was the lack of a solid grounding in the evidence. *“Our problem is that the committees at the HAS or even the Medicines Agency rely too much on the opinion of its experts without having enough evidence or solid data to back-up what they say. Essentially, our method of evaluations in France are based on ‘I think that...’ or ‘in my opinion...’ type statements, and when we asked for data, there isn’t any! There is rarely any epidemiological data produced on the disease, nor any data on the target populations. Our assessment should not be solely based on expert opinions but also on facts and evidence!”*(DGS). Specifically, they argued that levels of epidemiological and public health evidence regarding new technologies needed to be improved. *“It is necessary that we have a reflection of public health need at every level and develop an evidence based approach to decisions making which will allow us to identify its place in the therapeutic strategy. There is a lack of epidemiological data on the disease. There is a lack of reflection of public health in relation to public health plan. So it is difficult”* (DGS).

When pressed about an increased role for economic assessment within the system, respondents were broadly supportive. *“We would be keen to integrate the notion of health economic assessment so that it becomes an integral part of the HTA process as part of a wider evaluation in which there would be both a scientific assessment and an economic evaluation in parallel”* (DGS). However, they also recognised that integrating cost-effectiveness data within an evaluation process that serves a wider process designed to set prices and levels of reimbursement would be difficult and possibly counterintuitive. *“We are essentially in a ‘value-based pricing’ type model and so the question is, how do we integrate health economics consideration into the two step ‘value based’ system ...how do you combine the ‘effectiveness’ element with the ‘efficiency’ element... it’s broader value to society and public health...how do you merge all that together?”* (URC-ECO)

Respondents doubted the utility of a cost-effectiveness threshold to the price negotiation process. Certainly, the rigorous calculation of cost-effectiveness and cost utility data might improve the policy-makers position within the negotiations. *“The idea of bringing the two assessment together comes from the need to become more evidence based and provide the pricing committee with more rigorous and more objective analysis of the broader value of the product using key criteria in order to come up with a price”* (DGS). However, the cost-effectiveness of a technology may not actually reflect the cost of its production to the manufacturer. *“You cannot just fix a price and expect the manufacturer to agree to market his product. If the price imposed on the manufacturer is too low, he may well decide that he will not market its product.”*(DSS). Furthermore, the cost-effectiveness of a technology might not also reflect its value to patients. *“In the case of certain medicines, namely breast cancer drugs for example, there were such strong pressures from patients that they (the English) ended up adopting the drug despite the fact that its cost effectiveness ratio was above the 30K/QALY threshold simply because there was nothing else available out there”* (CNAM).

Thus, at the time of interview, cost-effectiveness analysis was yet to find a place in the French process. Under a value-based pricing model, economic analysis could never “*replace ... the Public Health criteria. The health economics analysis would have to be an additional criterion that one can use to influence the decision but not to make it*” (DGS). Generally, respondents were unsure about where cost-effectiveness analysis would fit within the system. At best, they could suggest that it would be “*...a matter of building the necessary expertise within both the agencies and the evaluation committees to read and process evaluations. There must be enough experts both on the side of the industry as on the side of the public institutions and currently, this critical mass of health economic expert does not exist*” (HAS). In sum, they argued that cost-effectiveness data needed to position itself within the existing system, rather than make any attempt to redefine the process at large.

6. Discussion

Our results bear out an important insight of the regulatory governance frame: that national responses to the common functional pressure for reducing the cost of healthcare are mediated by contextual factors. At the time of interview, the French process for HTA had evolved several distinct characteristics, of which participants in the process, at various levels, were well aware: it took place across a network of institutions; it facilitated a focus on public health; it opened a multiplicity of mechanisms for reducing the costs of healthcare including liaison with medical professionals; it was sustained by a system of price negotiations and rates for reimbursement; and it accordingly involved no role for cost-effectiveness modelling against a threshold. Moreover, in seeking to improve to the system, our respondents were concerned to build upon these diverse characteristics. Thus, the role, function and research outputs of an organisation like HAS are not only broadly non-comparable with those of other national agencies like NICE and TLV; they are likely to remain as such. In the same way, even initiatives for the harmonisation of HTA methods and processes must run the gauntlet of an existing environment involving multiple agencies operationalising multiple mechanisms for pursuing cost efficiencies, which in turn demand specific types of evidence and analysis to drive the process.

This, however, is not to suggest that there is no scope for change in France or any other nation state, only to affirm that where change occurs, it will take place within an environment of difference and diversity. Consequently, analysts can expect that national approaches to HTA will continue to exhibit considerable levels of hybridity and divergence. At the time of interview, for example, it was reasonable to assume that functional pressures to achieve cost-efficiencies might, in the future, weigh more heavily on the French model and admit some form of economic analysis in HAS evaluations. Indeed commentators had been suggesting for some time that French policy makers were likely to alter the French process by giving health economics modelling a greater role [25]. In 2008, the Social Security Finance Act had already introduced the prospect of incorporating the use of economic evaluation within HAS processes. And the same year, HAS’s Commission for Economic Evaluation and Public Health (*Commission évaluation économique et de santé publique*, CEESP) was established to oversee the integration of cost-effectiveness into clinical practice and public decision making. By 2009, HAS had also begun to develop a societal benefit measure, SERC (*service rendu à la collectivité*), for the purpose of capturing not only the medical and economic costs and benefits of health services; but also important

ethical, social, and legal considerations [25]. In fact, the introduction of cost-effectiveness analysis within the new CEESP committee in late 2013 represents an important change in the HTA process in favour of some level of convergence, but its practical application has yet to be assessed. For the future, France might prove to be a useful case study of how a substantive shift from a public health focused HTA process to one explicitly taking into account cost-effectiveness data can take place. Analysts might be well advised to look more closely at how the cultural change in France is materializing to understand how harmonization in a contextually diverse environment can take place.

The point is, however, that the existing environment continues to structure and shape these developments. Although economic evaluation enjoys a greater role, the French process does not involve a cost-effectiveness threshold, which remains largely superfluous to the current system of value-based pricing. Equally, other commentators suggest that related concerns for innovation and the industry may forestall the inclusion of strict cost-effectiveness assessments, pointing to the already lower than average costs of pharmaceuticals in France compared with the EU [30]. Given these structural limitations, a further expansion of the role of cost-effectiveness data and inclusion of a threshold seems unlikely in the near term, and considerations of value for money within the French process will probably continue to focus on broader than health benefits of new technologies and treatments [25].

But these are relatively small changes. Where advocates of the harmonisation agenda press wider claims for transnational collaboration on HTA to support the dissemination of individual evaluations across national borders, the prospects for change seem much more remote [11]. At least intuitively, the production of transferable HTA reports might lessen the need for multiple reports on the same health technologies. And further, transnational dissemination of individual evaluation results might appear to save time and resources [15]. Practically speaking, however, it seems that the production of transferable information regarding the impact of individual treatments, the possession of comparative information regarding the effectiveness of individual technologies, will be significantly less useful in driving an individual HTA processes, like the French approach, than is currently imagined in the academic literature. Where commentators suggest that regulators and decision makers require information on the effects of specific treatments on individual patients, our respondents seemed to value epidemiological data which quantifies the wider impact on public health. In general, they seemed interested in national issues like whether or not asthma drugs should be prioritised over other disease areas given the levels of national incidence, and whether certain populations, who might be less likely to have supplemental healthcare coverage, are more likely to contract asthma and require treatment.

7. Conclusion

The regulatory governance perspective introduces a number of useful insights to the study of HTA. Where some analysts have assumed that initiatives for the improvement and harmonisation of HTA processes involves a straightforward business of describing different methods, determining ‘what works best’ and formulating best practice guidelines for ubiquitous application, our findings suggest that delegation of authority to IAs for HTA follows a broadly evolutionary pattern which allows for substantial variation in national responses to the common functional

pressures and advantages leading to their establishment. In the sectors like healthcare, there is significant scope for divergence and hybridity to emerge and evolve with regard to national approaches to HTA. Given that initiatives for harmonisation will necessarily run the gauntlet of these divergences, it can be said, and with some certainty, that even an agenda for the harmonisation of HTA methods will likely meet with varied national responses. Further, such an agenda for harmonisation is likely to be successful only insofar as it takes the cultural, institutional and political backgrounds of the existing HTA systems seriously, and insofar as it builds any strategies for improving HTA on an in-depth understanding of these influences. For the future, developing a catalogue or a taxonomy of HTA case studies that allows researchers to extract such lessons from relevant national contexts might become a research priority for analysts working in the field.

Note

The introductory sections of the paper draw upon work in other papers published by this research group [1, 2, 3]. This is due to the fact that we have conducted this research together and have developed and applied the theoretical framework for analysis jointly.

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