

Policy diffusion and translation
The case of Evidence-Based Health Agencies in
Europe

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**Policy Transfer and Diffusion: Looking at Policy Features and the
Policy Process**

Introduction: from policy diffusion to the analysis of policy translation

Even if the concept of globalization raises a lot of questions (how can it be defined? what are its different dimensions? when did it start? etc.), it is obvious that the supra-national context of public policies has dramatically changed since the 1970's. In the field of policy studies, especially in political science, it has triggered two main research questions: the understanding of international policy diffusion processes and the convergence mechanisms related to globalization.

The first aim of this paper is to pinpoint how these questions are tackled by French policy studies discussing key concepts in the international literature: especially policy diffusion, policy transfer and policy convergence. The second aim is to put forward the analytical potential of the translation framework, which allows to grasp these different dimensions, by taking the case of the introduction and the development of evidence based-bureaucracies using quality evaluation and cost benefit analysis in western European healthcare systems.

Policy analysis itself has been introduced in France as the result of a double diffusion process: of policy sciences tools (especially the importation of predictive and budgeting tools) and of organisation's sociology by author's such as Jean-Claude Thoenig (1973), Michel Crozier, Erhard Friedberg (Crozier, Friedberg, 1977), and Jean-Gustave Padioleau (1980). It is only in the 1980's that it was developed in political science with more specific approaches leading to a dominant political sociology perspective in today's French policy studies (Halpern, Hassenteufel, Zittoun, 2017). Two main analytical specificities can be stressed. The first one is the importance given to the cognitive dimension of public policies, the core element of the "référentiel" model (Jobert, Muller, 1985, Surel 2000), which has been recently highlighted as the main component of a "French touch" in policy studies (Boussaguet and al., 2015). The second one is the sociological analysis of policy actors, a dimension developed as well by the sociology of organizations than by the sociology of fields with different methodological tools. Studies on policy brokers (Nay and Smith, 2003), policy elites (Genieys, Smyrl, 2008; Genieys and Hassenteufel, 2015), programmatic actors driving policy changes (Hassenteufel and al., 2010) or policy experts (Benamouzig, 2005) can be mentioned. These two perspectives, which can be combined (Genieys, Hassenteufel,

2012), are very useful to analyse policy diffusion contents, processes and effects. The two dominant concepts to analyse the globalization of policy orientations, concepts, arguments and tools, in international literature: policy diffusion and policy transfer, have been discussed by French scholars, especially in a historical perspective¹, who put forward two other notions: circulation and crossings.

Policy diffusion or circulation?

The policy diffusion literature is not directly related to the internationalization and/or transnationalization of public policy: its seminal work is Everett's Rogers book *The diffusion of innovations*, first published in 1962, studying the adoption of innovations. Later works, using the same notion to analyse public policies, are also focused on the mechanisms explaining policy diffusion at an international scale, especially cognitive mechanisms and incentives (constraints or competition) (Dobbin, Simmons, Garrett, 2007). One of the main limits pointed out by French scholars is its underlying linear vision of the diffusion process (often compared to a contagion process), without a sociological analysis of the actors involved (Dumoulin, Saurugger, 2010). It helps to understand why, in French policy studies the notion of "circulation" is more often used than the one of diffusion. Circulation implies a less linear and more complex process between different kind of institutions, actors and levels. Pierre-Yves Saunier (2008) has used the notion of "circulatory regimes" based on the high density of interactions between different actors involved in international or transnational circulation processes and stressing their institutionalization. Circulation also refers to the fact that the process can go back to its initiators (with feedback effects on them). Lastly, circulation also leads to the analysis of the role of a specific category of actors: those defined as "international brokers" (Dezalay, 2004) who hold positions at national and international levels and practice a "two-level game" in order to reinforce mutually both kind of positions. Hence, these key actors, who were for instance sociologically studied in the case of State reforms in Latin America (Dezalay, Garth, 2002), play a double role: an importer and an exporter role. These actors circulate between different institutions and

¹ The « socio-historical » perspective has become one of the most dynamic in French policy research (Payre, Pollet, 2013). It is focused on the historical construction of policy sectors based on institutions, actors and cognitive frameworks.

policy levels. Therefore the less linear and more actor-centred notion of circulation is also used as an alternative to “policy transfer”.

Policy transfer or crossroads?

The notion of “policy transfer” shares with the one of “policy diffusion” the idea, challenged by the notion of circulation, that there is a starting point of the process and an ending point, but it is less interested in the extension of the process, which is the key puzzle of the policy diffusion perspective, because it is focused on the use of elements taken from a public policy in a given political system in another political system (Dolowitz, Marsh, 2000). Like the policy diffusion literature, policy transfer literature also attaches a great importance to the different mechanisms (voluntary or imposed), sheds the light on the role of learning and “lesson drawing” (Rose, 1991) and emphasises the impact of competition in the context of globalisation. However it addresses more directly the issue of the content of the transfer, by differentiating the dimensions of a public policy (goals, knowledge, paradigm, norms, institutions, instruments...) and the issue of the impact of a policy transfer (Delpuech, 2008). Moreover the role of transfer entrepreneurs is more directly taken into account, especially international or transnational actors (Stone, 2004) who act as policy exporters. In the French literature one of the main critic of the policy transfer literature comes from the “crossed history” perspective (Werner, Zimmerman, 2003). It stresses the dynamics of the transfer process, especially the feedback effect of a transfer, transforming the exporting system by a process of mutual learning. Like the notion of circulation, the one of crossroads focuses on the interdependence between the systems that are analysed and their intertwined transformations.

The limits of policy convergence: the role of translation processes

If the notion of circulation is more dynamic than those of policy diffusion and policy transfer and helps to overcome the dichotomy between exportation and importation processes by the analysis of transnational policy brokers, it doesn't directly grasp the other key analytical issue related to globalization: the issue of policy convergence. The recent literature on policy convergence is, like the one on policy diffusion and transfer, focused on the identification of convergence mechanisms (Holzinger, Knill, 2005), which are close to diffusion or transfer mechanisms: imposition, competition, transnational communication,

harmonisation and independent problem solving. If these mechanisms explain rather well the convergence processes, they are less successful in explaining the limits of convergence. Authors like Levi-Faur and Jordana (2005), who have taken this issue into account, focus more on the contradictions of these processes using the notion of “convergent divergence” and on their unexpected effects (“policy irritants”). However they do not directly address the question of the explanation of the limits of convergence. The proposal we make here (based on previous reflections: Hassenteufel 2005, Hassenteufel and de Maillard 2013) is to use the concept of translation which is able to grasp together three different dimensions of public policies more analysed in the comparative policy literature (and less taken into account in policy diffusion and policy transfers studies which are rarely systematically comparative): the construction and formulation of policy problems sustaining policy proposals (discursive dimension), the interactions between different policy actors at different levels (actor’s dimension) and the institutional framework in which national public policies are embedded (institutional dimension). The notion of translation has been used in different ways, for different purposes, we try here to combine them in order to understand why and how international and/or transnational policy circulation does not necessarily lead to linear policy convergence, rather to a combination of convergence and divergence corresponding to a “divergent convergence process” (i.e. reduction of differences between public policies in different countries but in different ways and on different dimensions).

The first dimension is based on the reflections on translation in literature (Ricoeur, 2004), which can be summarized by the Italian phrase “traduttore, traditore” (translator, traitor). Translation cannot be something else than the transformation of the original text, it corresponds to a new creation necessarily different from the translated text, therefore a translation can be indefinitely started again (many translations of a same literary text exist). The meaning of the translation also differs from the original text because meanings and connotations are different from one language to another, all of them embedded in a different culture. Transposed to policy studies, translation corresponds to the process of reformulation of policy problems, orientations and proposals in a different language and context. Translation can be more or less complete and more or less far from the original formulation. It implies to analyse the policy discourses using international, transnational and/or foreign references and to focus on two main questions: how are these references

translated and how do they legitimate policy proposals? The discursive dimension of translation can be analysed in a pragmatic perspective which has been developed rather recently in the field of policy studies (Zittoun, 2014). This approach gives a great importance to the cognitive, discursive and analytical skill of the actors to define concepts and situation, to argue, to develop strategies, to discuss, to persuade and to convince, to build agreement and disagreement with other, to give meaning to their purpose, to adapt themselves to the different contexts, etc. It takes seriously into account the knowledge devices that actors mobilize as an essential but deforming filter to confront themselves to the reality. It is clearly inspired by the Weberian comprehensive and constructivist perspective which consider that behavior is linked to the subjective meaning actors give to it.

In that perspective policy discourses cannot be separated from the actors that shape and use argumentative strategies in order to legitimate and strengthen policy proposal by convincing other actors. The actor's dimension is centrally taken into account by the sociological approaches of "translation". The main contribution comes from the sociology of sciences, which makes a wide use of the notion of translation. Michel Callon (1986), analysing the knowledge transfer from one scientific world to another proposed an analytical translation framework, based on the distinction between four intertwined dimensions: the reformulation of a problem; the negotiation between the different actors involved in the process, the assignment of different roles to these actors and the mobilisation of actors that allows the achievement of the action. This conceptualization of the translation processes points out the role of actor's interactions, which is even more important in public policy fields than in scientific fields. The discursive activity of translation is also a political one, implying negotiations and conflicts between different policy actors with different kinds and amount of resources. On the one side negotiations in order to build a coalition supporting the policy statement proposals shaped and defended by the actors involved in the translation process and, on the other side, conflicts with policy actors defending alternative policy statement proposals or simply opposing policy changes in a veto-player logic. These interactions are political in the sense that they are related to the resources (positional, expertise, financial, relational, legitimacy, time...) of the different policy actors involved.

Thus the translation process is highly dependent from the power relationship between policy actors and their political strategies, as John L. Campbell (2004) stresses it. In his

institutional perspective, translation depends of four main factors: the institutional context, power struggles, leadership support and implementation capacities (p. 82). Policy actors are not only constrained by other actors but also by the existing institutions, inherited from past public policies, which determine the policy process, especially the implementation capacity. Therefore translation has to be analysed during the whole policy process: from problem construction to policy implementation.

In our case study we use an analytical translation framework combining these three dimensions:

- the discursive dimensions (analysis of the reformulation of policy problems, policy orientations, policy designs, policy tools coming from international institutions and /or other countries in order to make policy changes acceptable and legitimate at the national level);
- the actor's dimensions (analysis of the mobilization of actors for and against circulation and/or policy transfers and the power interactions between them);
- the institutional dimensions (analysis of the adaptation to the existing institutions and organizational capacities during the policy process).

Case study: from circulation of knowledge to the translation of health assessment agencies in Europe (United Kingdom, France, Germany)²

At first glance the case studied here fits quite well to the policy diffusion process framework. It is rooted in the worldwide spreading of a new method of clinical evaluation since the 1970's: evidence-based medicine (EBM). Its aim is to diffuse among clinical practitioners evaluation techniques of new therapies produced by the pharmaceutical industry. They are based on clinical randomised trials, defined as a "gold standard" by an American academic community (Timmermans, Berg, 2003) and diffused to a lot of other countries. Several

² The empirical elements mentioned here are taken from the EVALECO research project directed by Daniel Benamouzig (CSO-Sciences Po Paris) analyzing the introduction and development of quality and cost-effectiveness assessment in three different healthcare systems: France, Germany and the United Kingdom. The authors were part of the research team which also included Louise Hervier and Elina Weckert.

specialized journals and institutes using EBM have been created at the international level, the most famous one is the "Cochrane Collaboration" created in 1993: it has nowadays around 28 000 members in more than 100 countries. The transnational circulation of EBM methods among the medical community has triggered the development of a new policy tool: health technology assessment (HTA). Medicine is not the only discipline involved in the growth of HTA as a new expertise field: management and health economics also played an important role (Gorry, Montalban, Smith, 2011). The US Congress's Office of Technology Assessment played a pioneering role in the 1970's for the diffusion of HTA. The first international HTA conference was organised in Stockholm in 1979 and an International Society for Technology Assessment in Health Care (ISTAHC) was created in 1985, renamed HTA international in 2003. It has around 100 individual and organizational members from around 60 countries and an official journal (the International Journal of HTA in Health Care-IJTAHC). HTA agencies were created first in the US and Sweden, then in the early 1990's in other European countries (Cochrane Center in York in 1992, ANDEM in France). A formalized cooperation between national agencies began in 1993 through the founding of the International Association of Agencies for HTA.

NICE as an institutional model

A new step occurred in the late 1990's with the creation of the British National Institute of Clinical Excellence (NICE) in 1999. It was one of the first attempts to institutionalize to such an extent health economics in public decision-making, even if one would easily find precedents, both in the UK and in other developed countries. The abovementioned creation of the Office of Technology Assessment in the American Congress in 1976, or the subsequent experience of public choice based on cost-benefit analysis in the State of Oregon were early attempts to gather economic assessment and decision making (Bimber, 1996; Blumstein, 1997). One would also mention the previous PPBS experience developed in the United States in the mid sixties and several national similar experiences in other countries, like the RCB in France (Benamouzig, 2005).

The creation of NICE was not only specifically British. Built up to answer specific needs of the NHS in England and Wales, the agency represented also an innovation at the international level. From the beginning, it was a response to other international initiatives, in

Canada and Australia particularly (Smith and al 1994; Baladi and al. 1998). The NICE was an opportunity for the British community of health economists to export internationally the model of expertise, cost-benefit assessment based on the QALY (Quality Adjusted Life Years) indicator, they had conceived to solve domestic problems after the reform of the NHS in the early 1990's (Rovira, 1994; Freemantle and al. 1995). Above the systematic use of cost-benefit assessment, the NICE can be characterized as an "evidence based bureaucracy" in order to insist on two main analytical traits: (1) the use of evidence is highly structured by standards and protocols, which gives a bureaucratic flavor (Yesilkagit, 2004 ; Benamouzig, Besançon, 2005); (2) a high level of openness to non-state actors, like experts, citizens or interest groups, gives them meanwhile an inclusive and deliberative aspect (Moffit, 2010).

Therefore it was a powerful source of inspiration for similar new institutions across Western Europe, not least because of the creation of "NICE international" in order to diffuse the methods and practices of the new agency. In France, the creation of the *Haute Autorité de Santé* in 2004 was certainly, even if not always explicitly, an attempt to mimic the way health technology assessment had been implemented in the United Kingdom (Robelet, Minonzio, 2015). In Germany, the creation of the IQWiG the same year (2004) refers more directly to the NICE and was build up as an attempt to develop the use of health technology assessment in Germany.

We will focus here on two aspects of the NICE which were diffused: its centralized institutional model and the systematic use of cost-benefit assessment based on Bayesian statistical methods (Benoit, 2016, p. 228) so as the definition of cost-effectiveness ratio and thresholds. The NICE was conceived after the 1997 general elections as a Labour innovation, its central aim was to reduce health inequalities by providing national standards. The well-known aim of NICE was to end the so called "post-code lottery", i.e. the difference of odds of being cured properly according to geographic location, related to socially stratified positions. It can be analyzed as the result of the institutional convergence of two policy fields: the health services on the one side, and the management of medical research on the other (Benamouzig, 2015). This general process comes along with local dynamics of alignment, which characterize in parallel the practical organization of each field. The organization of both the health services and the medical research became more centralized in the 1990's. In 1999, the creation of NICE was not only the result of an original link

gathering the NHS with medical research: it was also the product of their respective centralization at national level. Economics played a crucial role in this context. In both fields a process of centralization and decision led to the creation of an agency that could both provide national guidelines on health technologies to medical decision makers and guarantee the impact of health economics in appraisals.

Hence, the creation of the agency was clearly an outcome of a national process of recentralization, after the decentralization managed by the conservatives (Hassenteufel and al., 2010). Explicitly mentioned in the designation of the agency, the national dimension refers in fact both to a national level of decision, based in London, and to a nationwide field of competence across the country. Such a national recentralization was however not only an output of the Labour centralist and egalitarian ideology, which was besides not so present in Tony Blair's government. It was also a demand of the pharmaceutical industry, which was directly interested in a national organization of clinical decision-making.

By using the translation framework we aim to give some evidence in order to understand two apparent paradoxes: the reference to the NICE was more direct and explicit in Germany than in France, but the French HAS is more centralized and powerful than the German IQWiG; the use of cost-benefit assessment was defined as a new duty for the IQWiG in Germany, not for the HAS, but it is nowadays used in France, not in Germany. We will stress here the three dimensions of the translation process in these two cases which are analyzed in a long term period (from the 1990's to nowadays), showing its partial character in Germany (the agency is embedded in the existing institutional framework and cost-effective assessment tools still play a marginal role) and its incremental character in France (progressive shaping of a State narrow agency and use of economic assessment).

A partial translation in Germany

In Germany, where the responsibility of doctors on quality issues had been reinforced within the 1990th (Weckert, 2014), the chosen pathway was rethought under the government of Social Democrats and Greens and the new health minister Ulla Schmidt (SPD). It initiated important institutional changes concerning the governance of the

healthcare sector at the beginning of the 2000's. The left-wing government, installed in 1998, strengthened the camp of the funding bodies in the institutions of the collective self-government. As in France and England before, the government of Social Democrats and Greens opted for the creation of national agencies as well as for the cooperation with private institutes and the development of public-private-partnerships. They were the consequence of governmental decisions having for purpose the reorganization of the collective self-government and the redistribution of powers between the corporatist partners. Therefore the creation of new federal institutions using evidence-based knowledge was part of a broader domestication process of the corporatist healthcare system (Gerlinger, 2010).

The restructuring of the collective self-government of the German healthcare sector was realized by the creation, from the merging of numerous national committees, of the Federal Joint Committee (*Gemeinsamer Bundes Ausschuss* - GBA) as highest committee of the self-government in January 2004. The GBA is made up of equal numbers of representatives of sickness funds, doctors and patients, plus three impartial members. The patients have no voting right (Gerlinger/Schmucker 2009: 9). The GBA issues directives defining the sickness benefits for the 70 Million patients in the statutory sickness funds. It is responsible for the implementation of the legislation concerning ambulatory care. Its authority has been expanded to all sectors of the statutory health insurance system and it acquired a multitude of new powers. It is put under the legal supervision of the health Ministry, nevertheless it is not a subordinate department. But it is forced to fulfill its responsibilities in a more restrictive frame of action set by the Federal Ministry of Health, which reduced its autonomy by professionalizing its members in another law adopted in 2007 (WSG). It also gave the Ministry, as the supervising authority, the right to request additional statements and information when scrutinizing directives (Gerlinger, Schmucker, 2009: 9-10). The creation of the Federal Joint Committee in 2004 and of a Federal Sickness Funds Organization - a new umbrella association for all sickness funds - in 2007 enables more control from the Health Ministry (Bandelow, 2009: 49). The creation of these new federal institutions led to a growing centralization of the regulation of the German health insurance system.

The creation of the Institute for Quality and Efficiency in Healthcare (IQWiG), included in the Law for the Modernisation of the Statutory Sickness Funds (2003), is part of this process. It has wide-ranging powers to evaluate the benefit and quality of diagnosis and treatment methods. It is defined as an independent expert body working in relation with the Federal Joint Committee. A strong focus was put on pharmaceuticals, one of the most important cost drivers in health care and since the late 1980's a core dimension of health-insurance costs-containment policies in Germany.

The creation of this institute, institutionally corresponding to the agency model (a public institution based on expertise and with some degree of autonomy from the State), can be related to two main factors. The first one is the intertwined diffusion of Evidence Based Medicine (EBM) and Health Technology Assessment (HTA) in Germany (Perleth, Gibis, Göhlen, 2009) corresponding to an international circulation process. It started at the end of the 1980's in the academic sphere and was in the mid-1990's sustained by the Health Ministry who financed a first feasibility study on the assessment of medical treatment and technologies (Blitzer, Busse, Dörnig et al., 1998). It triggered the definition of a "German HTA project" which was progressively implemented. In the 1997 law (2 GKV-NOG) the competency to evaluate medical treatments and technologies was given to the joint federal commission for health insurance (a corporatist institution composed of representatives of sickness funds boards and medical unions). The 2000 law (RG-2000) created the German institute for medical information and documentation (DIMDI), financed by the State and including a new German Agency for HTA (DHATA). The main aim given to these institutions was to give advices on health policy decisions based on EBM and HTA.

The second explanatory factor was the public debate on the efficiency of the German health care system after the publication of the WHO report in 2000 ranking different health systems. The relatively bad performance of Germany (ranked 25st for its global results) gave rise to a public debate and to an interest for the English system, especially the NICE which was praised by the WHO and the European Commission (Bußman, 2012: 24, 18). The debate was also fostered by the 2001 report of the expert commission on health insisting on the quality and efficiency flaws of the German system. This helps to explain that in 2002 a report from the Frederich Ebert Stiftung, written by experts close to the SPD, proposed the creation of an institute based on the model of the

NICE. This proposal was included in the SPD electoral manifesto for the 2002 elections (Weckert, 2014 : 110-111). Therefore it was not a surprise to find the creation a new institute linked to the State, especially in charge of the assessment of pharmaceuticals, in the governmental law proposal formulated in June 2003. But, it was strongly opposed by Doctor's associations and the pharmaceutical industry, sustained by the Christian-Democratic party defending the "self-administration" of the health insurance system against the strengthening of the Health Ministry (Bußman, 2012: 25).

These oppositions explain that the IQWiG's was finally put under the supervision of the Federal Joint Committee which decides (so as the Federal Health Ministry) what diagnosis and treatment it is allowed to assess (Gerlinger/Schmucker 2009: 10). The new institute was thereby embedded in the institutional world of self-administration, more controlled by the Federal State as stressed above. The other important point is that neither the possibility to realize cost-benefit assessment of pharmaceuticals, nor the role of crafting evidence-based guidelines aimed to guarantee quality, were given to the IQWiG, contrary to the initial plans of the policy reformers (among them professor Karl Lauterbach, close adviser of the Health Minister Ulla Schmidt and one of the main promoter of HTA in Germany) facing the opposition of doctor's an the pharmaceutical industry sustained by the right-wing opposition (which had the majority in the *Bundesrat*, the second Chamber, at that time).

Physician's, a very strong organized interest group in Germany (Hassenteufel, 1996), are a main actor to take into account in order to understand the translation process. The majority of the German experts involved into the development of quality indicators in the different kind of new administrative organizations come from the medical profession (Kuhlman, 2007). Most of them have also studied public health. Usually they were not practising any longer or they had never practised as doctors. They rather dedicated their career to research and worked for research institutions or for the self-government of service-providers. This dominance of medical experts using evidence-based methods has led to the importation of mainly medical quality indicators. At the beginning of the 1990's, the first scientific papers about new instruments of quality assurance in healthcare so as quality indicators EBM and HTA, had principally been translations referring to the international literature – especially from Anglo-Saxon countries or from the OECD. This led to a policy

transfer of knowledge and policy programs into the German health system. The international discussion and especially the development in the Anglo-Saxon countries were a major factor for the development of quality indicators in the German health system. The most influential authors of the German scientific debate on healthcare indicators (Schrappe, Simoes, Mayer, Boukamp and Schmahl, Groene) based their observations on the principal elements of the definition of the Joint Commission on Accreditation of Health Care Organizations (JCAHO).

Medical expertise is therefore strong in the IQWiG. In 2015 it had 5 scientific departments producing reports. They primarily handle the commissions that IQWiG receives from the GBA or the Ministry (BMG). The main department is the Drug assessment department, assessing the benefits and harms of drugs approved in Germany. Headed by a doctor in medicine (Thomas Kaiser, the co-founder of the German Institute for Evidence-based Medicine –DieM- in Cologne) and a biologist (Beate Wieseler), it has 45 co-workers (10 doctors). Then the Non-drug interventions department mainly assesses medical interventions that are not solely dependent on the use of drugs. It is headed by a physician (Prof. Stephan Sauerland) and a sociologist with a main focus on evidence-based medicine (Fulöp Scheibler) and has 21 co-workers (10 doctors). Third, the Quality of health care department has the task to produce clinical practice guidelines. It is also headed by a physician (Alric Rütger, former head of the German Agency for Health Technology Assessment –DAHTA- at the German Institute for Medical Documentation and Information - DIMDI-) and a sociologist (Ulrich Siering) and has 10 co-workers. The Medical Biometry Department, responsible for the biometric evaluation of studies, is headed by two statisticians and has 10 co-workers. Last, the Health Economics Department works on economic research questions concerning the German health care system. Headed by Andreas Gerber (paediatrician, and health economist) It has only 10 co-workers. The most important fact to stress is that the cost-benefit assessment of drugs and medical interventions which was discussed in 2003 and finally introduced in the 2007 law was not implemented because of strong oppositions and debates on the methods used. The Health Economics Department of the IQWiG, which was created after the passing of the 2007 law, promoted the Efficiency Frontier method, refusing the British QUALY approach (for mainly ethical reasons). This reformulation of cost-effectiveness assessment in a “German way” was highly contested by academic health economics (Caro and al., 2010). The compulsory

character of cost-benefit assessment was withdrawn in the 2010 law on the Reform of the Market for Medical Products (AMNOG) under a right-wing government (coalition between Christian-Democrats and Liberals). However this law introduced the early assessment of new drugs, based on the dossiers submitted by the drug manufacturer to the G-BA. These benefit assessments, which are only based on EBM methods not on cost-benefit assessment, are submitted to the GBA who decides either to put it into in an existing therapeutic class (if the medical benefit is low) or that the federal sickness funds association has to negotiate the level the reimbursement with the producer (if the medical benefit is established). The emphasis put on drug assessment in the IQWiG's activity is part of a long-term regulation of the reimbursed drug expenses which started already in the 1988 healthcare reform (GRG). It created the therapeutic classes for drugs and the principle of the reimbursement at the level of the least expensive drug of the class.

In Germany a less powerful evidence-based bureaucracy than its British counterpart (Chalkidou and al., 2009) was created without systematically using economic knowledge, despite strong international references in the public and experts debates (Zentner, Busse, 2004). On the contrary, in France, where NICE was not directly mentioned as a model, a centralized evidence-based bureaucracy using the same cost-benefit assessment tools as the NICE (QUALYS) was incrementally institutionalized in the long term (from the 1990's up to today).

The incremental translation process in France

In France like in other European countries, the need to keep healthcare expenditure under control has been present since the end of the seventies. However, the use of economic knowledge in decision-making in health care has known a renewal for only a decade in France. One reason for this late introduction of economic evaluation in decision processes can be found in the institutional roots of the French healthcare system. In such a Bismarckian welfare State, health expenditure are considered as the due returns to the social contributions paid by employees. In this context, any attempt to reduce the costs could be viewed as a restriction to access to medical care, an attack against social rights (Palier & Hassenteufel, 2007). Another reason relates to the way the academic community of health

economics develops in France, almost autonomously apart from health administration (Benamouzig, 2005).

After its methods have been credibly established, Health economy progressively gained political legitimacy by offering new tools dedicated to control Health expenditures, whereas a large consensus emerged about the need for a Health Insurance reform. Economists were thus enrolled in two new institutions: the National Agency for Medical Evaluation development (*Agence nationale pour le développement de l'évaluation médicale* (ANDEM) and the Transparency Commission (« *Commission de la transparence* » CT), created in 1992, which gave recommendations about Drugs reimbursement prices to Health Insurance institutions. However Economic assessment was strictly subordinated in ANDEM and dominated by physicians, who, like in Germany, were afraid of a dummy or blind use of economy to cut Health budget (Robelet, 1999). ANDEM creation must be however replaced in a wider context of two convergent dynamics: the development in France of evidence-based medicine, promoted by a few isolated physicians and the development of policy evaluation in French administration, which was more largely promoted by the French government since the early 1990s.

In the ANDEM a department dedicated to economic evaluation was created, it was then integrated to the Certification and Evaluation National Agency (*Agence nationale d'accréditation et d'évaluation* - ANAES) the successor of the ANDEM in 1997. Both in ANDEM and ANAES, economic assessment (translated into "*médico-économie*" by the main stakeholders to stress the combination of medical and economic dimensions³) was dominated by a medical approach. It appeared quite impossible to find the compatibility between economic assessment and the professional rhetoric of Physicians, who also denied to the ANAES its ability to recommend best practices and defended strongly their clinical autonomy. Economic evaluation came at this time secondly after clinical evaluation and was restricted in the area of public Health, which was very limited at beginning of ANAES. It had a bad reputation for Physicians and was related to a specific policy tool: the "opposable medical references" (RMO) negotiated between the ministry of Health and a minority physicians union in 1993 in order to "medicalize" cost-containment. It consisted in a list of

³ In Germany only the purely economic expression of „cost benefit“ („*Kosten-Nutzen*“) was used to promote economic evaluation.

"negative" medical guidelines, associated with inefficiency. Physicians with bad practices were supposed to be sanctioned, which has given rise to protests from the vast majority of physicians. This measure was considered as a strict rationing tool and has discredited for a long time any economic evaluation project among clinicians.

The next institutional step was the creation of the "*Haute Autorité de Santé*" (HAS) in 2004 by the health insurance reform law (LAM). That is very significant for its purpose in order to contribute to Health Insurance regulation. This reform aimed at creating an institution, which should be legitimate enough for the physicians while introducing new kinds of expertise, far from the clinician culture of the previous agencies. The HAS is an autonomous scientific body dedicated to the assessment of health products. It delivers to Health Insurance institutions expert advices which are supposed to help fixing the reimbursement rates for drugs, medical practices or devices. In the very few years before the HAS foundation, the Health Department established lists of drugs that were appraised as inefficient. These lists did not conduct to deregistration from the reimbursement list. Physicians strongly criticized this evaluation as partial and underlined the conflict of interests in which the Health Department took part insofar as it drove also the negotiation with the pharmaceutical industry about pricing in the Economic Comity of Health products (CEPS, created in 1993). The independent status of the HAS responds to these critics. But neither the Health ministry, the Social Security Direction nor the sickness funds succeeded in their attempt to introduce economic assessment in the new agency's tasks because of the opposition of physicians and of the CEPS directed by senior civil servants (Benoit, 2016, p. 242-252).

The HAS is run by an executive body, "*le Collège*", a small body of eight persons which collegially managed this institution and jointly assumed the formulated recommendations. In 2006, a health economic academic, Lise Rochaix, was appointed as a HAS College member. She was the only woman and the only non-physician member of the *Collège*, most of them being professors of medicine. Just after her nomination she launched a working group called "*Serc*", for "*Service rendu à la collectivité*" ("Community helpfulness") that aimed at harmonising reflexions driven in the different HAS commissions in order to take into account collective and societal dimensions in the evaluation process. The working group also aims at enlarging "Public Health Interest" to take into account non-medical dimensions, as a part of a global Health technology assessment strategy (Robelet, Minonzio, 2015). Therefore it

played an important role in the reformulation of the introduction of non-medical dimensions in health technology assessment (especially pharmaceuticals), less focused on cost-benefit than in the UK and in Germany.

Whereas government expectations towards cost-benefit assessment became more pressing, this working group appeared as an inadequate institutional response. In order to strengthen the HAS function in "medico-economic" evaluation, the budgetary Law of Social Security for 2008 established a new commission inside HAS, the *Economic Evaluation and Health Policy Commission (CEESP)*, chaired by Lise Rochaix. The creation of this dedicated commission results from a joint lobbying action driven by economists and the Social Security Direction of the Health and Social Affairs Department who wanted to create a "French NICE" (Benoit, 2016, p.442-445).

At the very beginning of the CEESP, some influential physicians, members of the college or members of the diverse departments of the HAS, attempted to restrict its competence area to Health policy. Despite this internal opposition, CEESP became a key actor for Health technologies and drugs assessment. External actors like the Transparency Commission and the Health Products Economic Comity (CEPS) progressively begun to take into account its expert advice in their own decision-making. The cost benefit evaluation praised by the CEESP includes the consideration of price, which constitutes a major step forward for "medico-economic evaluation". Until then, current institutions like the Transparency Commission tended to use medical data to assess the effectiveness of drugs, without weighting it with their cost. From then on, a specific department inside the HAS was dedicated to provide new kind of information, dealing with the costs of the drugs and their and benefits for the whole population.

The development of economic evaluation guidelines and practices progressively altered the HAS internal equilibrium between the CEESP and the Transparency Commission, both involved in the drug evaluation process. At the same time, two major French institutional bodies in charge of Health policy, the Accountability Court⁴ (Cour des Comptes) and the General Inspection of Social Affairs⁵ (Inspection générale des affaires sociales – Igas),

⁴. Cour des comptes (Paris). *Rapport sur la Sécurité sociale*. Paris : Cour des comptes. sept. 2011.

⁵ Inspection générale des affaires sociales (Paris). "Recommandations n°6". *Rapport l'expertise sanitaire*. Paris : Inspection générale des affaires sociales. avril 2011.

claimed for a strengthening of economic evaluation in decision-making. They also claimed for the strengthening of the regulatory status of the CEESP, which was endorsed by the Social Security Law for 2012. The CEESP became a regulatory entity like the Transparency Commission. The recommendations of each of both commissions have now the same enforceable value. This law also introduced a systematic economic evaluation for new drugs that are registered for the first time on the Health Insurance reimbursement list (like in Germany). For this and until now, Drug industry must transmit to the HAS not only a medical effectiveness evaluation but also an economic evaluation (a main difference with Germany). The CEESP has 90 days to evaluate these data. The efficiency will be renewed after five years in order to assess drug medical efficiency in "real life".

Economic evaluation methods and practices have been introduced by a small group of entrepreneurial experts (Robelet, Minonzio, 2015). They benefited from several favourable organisational conditions and used organisational rules in order to create a quite autonomous jurisdiction inside the HAS. The first favourable condition is linked to the context under which the HAS has been created. As abovementioned the creation of the HAS is part of the 2004 health insurance reform. This independent agency was therefore supposed to participate to the control of health expenditure by expert advice submitted to decision makers. It raised the question of how healthcare costs should be taken into account in these expert advices. A need for economic expertise arose for the HAS, whose cultural background was quite exclusively medical. Secondly, the HAS's governance is conducive to organisational redesigning. Its governance consists in an executive body (*Collège*) and in different commissions specialized in one specific field of expertise, the president of each commission being a member of the *Collège*. These include a commission dedicated to fields not yet developed in the HAS like the conditions of guidelines implementation in the daily medical practices or health technology assessment. The jurisdiction of the commission was not clearly delineated and a group of entrepreneurial experts was able to take advantage of this fuzzy organisational framework.

Even if the economists seemed to have obtained "their" commission in 2008, they advanced under cover inside the HAS, anticipating the oppositions to the introduction of economic evaluation, coming particularly from physicians by the promotion of a "societal" dimension in health technology assessment. The hallmark of their action was to answer to

the imperative of the evaluation of “collective outcomes” of healthcare (public health strategies as well as individual medical practices), which are not taken into account through the classical methods of medical evaluation. The members of the commission organized conferences and roundtables to raise awareness of actors inside and outside the HAS about what should be an extension of the missions of the HAS on economic assessment. The concept of “collective outcome” was vague enough to not frighten the clinicians but specific enough to justify the development of first a dedicated working group and further a dedicated department, specific methods and practices. By doing so, they progressively constructed a niche of expertise inside the HAS on the non-medical dimensions of the evaluation, including social, ethical and political dimensions. The definition of such a jurisdiction requires the expertise of other social sciences like sociology, philosophy, political science or geography, which were progressively introduced in the CEESP. They gained autonomy inside the HAS, especially from the other commissions (run by clinicians) and from the departments dealing with the production of medical guidelines. The CEESP also launched a coalition with some members of the College (first of all with the President of the HAS), reassured that the economic evaluation will not lead to barriers in access to care. The college was very keen to preserve the reputation of the HAS to protect the population from bad medical practices or products and from health inequalities.

These experts build a discursive coalition with actors and institutions outside the agency (health economic academics, representatives of the ministry of Health and of the national health insurance organization), launching exchanges of resources with them. They gained their support by involving them in the debates on the definition of the content of non-medical dimensions of evaluation. These actors were also invited to attend the meetings of the commission. These exchanges were also means to obtain information on the strategies and resources of these actors in the decision process. This objective alliance helps to encode in the law the concepts and practices of economic evaluation defined by this group of entrepreneurial experts, who was more successful than his German counterparts facing a stronger coalition of opponents at different levels: at the political level (opposition between political parties), at the policy level (opposition of the medical profession) and at the expertise level (opposition of academic health economists).

Conclusion

Even in such a highly internationalized policy field as healthcare, the circulation of knowledge (EBM), policy tools (HTA) and institutional models (evidence based bureaucracies) has not led to a linear policy convergence, rather to a “divergent convergence” based on a three-dimensional translation processes: discursive (problem formulation), actors (power relations and interactions between them) and institutional (national paths and context). As our case study shows these processes need to be analysed over long time periods in order to grasp all these dimensions. Like in the UK, EBM knowledge has spread in the healthcare systems, HTA tools and methods were introduced and new agencies were created. All these evidence-based bureaucracies share common traits, roles and methods but also important differences have been put forward: in their institutional definition, in their organization, in their functioning and in their use by different policy actors. Even more, they are part of national reform trajectories (they were created and developed in relation to broader healthcare reforms) and of different national health policy fields (they interact with different institutions in each country). Taking into account divergences in convergence processes and the translation activity of policy actors is therefore a way to bypass some common shortcomings of the policy diffusion literature, more focused on the comparison of mechanisms than on the comparison of national cases, and of the policy convergence literature which aims more to explain convergence than its limits.

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