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Evidence Based Bureaucracies and the transformation of health policies in Germany

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Evidence based bureaucracy and policy change in health care

Nearly all Western welfare states have been subjected to strengthened reform efforts since the end of the 1980th or, at the latest, since the beginning of the 1990th. The aim of most of those reforms was to stop the fast growth of health care costs. The limited effectiveness of traditional cost-containment policies and the trust crisis caused by contaminated blood conserves affecting all developed health systems brought the issues of cost effectiveness and quality assurance in healthcare on the political agendas. Policy-makers' major purposes in conjunction with the introduction of quality assurance and cost-effectiveness into healthcare sectors were the combatting of inefficiencies and wasting so as "blame avoidance" (Weaver 1986). The increasing importance of quality assurance and cost-effectiveness in health care was in nearly all Western health care systems accompanied by the introduction of new administrative organizations and institutions. They can be characterized as "evidence based bureaucracies" in order to insist on two main analytical traits: (1) the use of evidence is highly structured by standards and protocols, which gives them 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).

The main question raised in this paper is to analyze how far the introduction of these new administrative organizations and institutions has triggered policy change in the German health care sector. The German system is historically based on social insurance. The institutions of the collective self-government of service-providers and sickness funds have the authority to flesh out the details of a broad policy framework. The governance of the German health system also reflects German federalism. Nevertheless recent analysis (Gerlinger/Schmucker 2009, Hassenteufel, Klenk, 2013) have stressed two main structural evolutions: on the one side the marketization (based on competition between sickness funds, privatization of the hospital sector and managerialization of healthcare institutions), on the other a growing centralization with the strengthening of federal institutions steering at a distance (Kickert, 1995) this policy domain for the State.

The aim of the first part of the paper is to show the impact of the new institutions in charge of quality assurance and economic evaluation that have been called into being since the early 1990th on the governance of the German health system. In the second part, we give some insights of these evidence-based bureaucracies, focusing on the experts working for these institutions, their internal organization and the methods of instrument production (based on the examples of medical guidelines and quality indicators). The third part of the paper focuses on the role of these new administrative organizations in health policies. In our conclusion we tackle the issue of policy

convergence related to the diffusion of evidence based bureaucracies by giving some comparative insights with the English and French cases.

1. The introduction of evidence-based bureaucracies in the German health care sector

The first institutional changes were already introduced at the end of the 1980th or beginning of the 1990th. The most striking fact in Germany is that the federal government has not initiated the foundation of new institutions in the healthcare sector in the 1990th. The different partners of the collective self-government of service-providers and funding bodies, i.e. the traditional key actors of the German health insurance system, generated the new foundations for quality assurance.

The government of Christian Democrats and the Free Democratic Party had accentuated the responsibility of the medical profession on quality issues in healthcare in § 137 b of the fifth book of the code of social law and its justification under health minister Horst Seehofer (CSU) in the 1990's. In a first reaction to the growing political pressure to introduce quality assurance in healthcare, the regional associations of statutory health insurance physicians claimed some organizational preconditions as the creation of quality assessment offices and procedures (Kassenärztliche Bundesvereinigung 1999: 21).

Between 1995 and 2001, the corporatist partners of the collective self-government of the German healthcare sector set up several scientific institutes. In the following period, those institutes became the most important intellectual forums for the development of quality improvement instruments in healthcare (Weckert 2014: 98). They vary considerably in their structure and their juridical status.

The General Medical Council and the Federal Association of Statutory Health Insurance Physicians founded, in March 1995, under a common maintenance, the Central Point of the German Medical Profession for Quality Assurance in Medicine (ÄZQ). The ÄZQ started its operations in September of the same year (interview with a representative of the self-government of healthcare services; www.aezq.de/aezq/uber/aufgaben-und-ziele, 8/7/2011). The task of the ÄZQ consisted in the support of the General Medical Council and the Federal Association of Statutory Health Insurance Physicians in the field of quality assurance of healthcare. It provided for both institutions different modules for quality assurance instruments as medical guidelines, quality indicators or patient information sheets. It worked on the improvement of the methods of evidence-based medicine and it examined new issues of quality management and quality improvement in healthcare. Günter Ollenschläger has been working in the function of the director of the ÄZQ since 1995 (Weckert 2014: 99). The ÄZQ cooperates with German and foreign partners as the Alliance for Action Patient Security

(Aktionsbündnis Patientensicherheit), the Working-Group of Scientific Medical Societies (AWMF) or the James Lind Alliance (http://www.aezq.de/aezq/uber, 8/7/2011).

The AQUA-Institute[1] was another new foundation. It was also created in 1995 and superseded a cooperation of scientists and universities formed in 1993 under the name of "Task Force Quality in Ambulatory Care" (http://www.aqua-institut.de/de/ueber-aqua/wer-wir-sind/index.html, 8/7/2011). The AQUA-Institute works on projects as peer review for medical practitioners like quality circles, patient surveys, documentation and the evaluation of new models of healthcare.

As the ÄZQ, the AQUA-Institut cooperates with several partners like the university hospital of Heidelberg, the Centre for Quality of Care Research of the Radboud University Nijmegen Medical Centre and the Institute of General Medicine of the Johann Wolfgang Goethe University of Frankfurt (http://www.aqua-institut.de/de/ueber-aqua/partner/index.html, 8/7/2011).

However, the Federal Office Quality Assurance (BQS) – a new foundation under maintenance of different corporatist partners of the collective self-government became, in a first time, the central German institution for the production of quality indicators in healthcare. The institution emerged from a comparative project of surgery wards in Hamburg. In consequence of a first obligation to establish some measures for quality assurance fixed in the code of social law in 1989, the regional medical council, the regional hospital association and the sickness funds in Hamburg decided to draw on an already existing project and chose the project of the surgery wards for this purpose. With the creation of the Task Force External Quality Assurance QS Hamburg, the project made a first step to an institutionalization. That approach was copied by four other German states. The obligation for quality assurance and new payment models as per capita flat rates and extra-pays fixed in the code of social law since 1996 amplified the influence of the new institute. The quality comparisons were installed at the federal level and managed by the Service Point Quality Assurance (SQS). The SQS was replaced by the Federal Office Quality Assurance (BQS) in 2001. The administrative board of the latter has been placed under the oversight of the Federal Joint Committee as highest institution of the collective self-government in the German healthcare sector. With the creation of the BQS, the use of quality indicators became compulsory in all German states (interview with a representative of the BQS).

The aforementioned trend to create new institutions taking over governmental and administrative tasks in quality assurance continued in the 21st century and was extended to economic evaluation. In Germany, where the responsibility of doctors on quality issues had been

[1] AQUA-Institut for Applied Quality Promotion and Research in Healthcare

reinforced within the 1990th, 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 chances 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 as highest committee of the self-government in January 2004. The Federal Joint Committee 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 Federal Joint Committee 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, but it is no subordinate department (http://www.g-ba.de/downloads/17-98-2803/2010-01-01-Faltblatt-GBA.pdf, 01/07/2011). 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.

According to the Law for the Modernisation of the Statutory Sickness Funds (2003), the Federal Joint Committee created on behalf of the health ministry the Institute for Quality and Efficiency in Healthcare in 2004 (IQWiG) (http://www.gesundheitsinformationen.de/iqwig-ueber-uns.10.de.html, 13.06.2013). It has wide-ranging powers to evaluate the benefit and quality of

diagnosis and treatment methods. A strong focus was put on pharmaceuticals, one of the most important cost drivers in health care.

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). It started in 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 for 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 inked to the State, especially in charge of the assessment of pharmaceuticals, in the governmental law proposal formulated in June 2013. 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 embedded in the institutional world of self-administration, nevertheless more controlled by the Federal State as stressed above. The other important point is that neither the possibility to realize cost-benefit

evaluation of pharmaceuticals, nor the role of crafting of evidence-based guidelines aimed to guarantee quality, were given to the IQWIG.

The transmission of the compulsory extern quality assessment for hospitals from the BQS to the AQUA-Institute in 2009 was the next important institutional change in the German healthcare sector. This transmission arose from a decision of the Federal Joint Committee, intending that an independent institution should conduct the quality assessment of hospitals (interview with an employee of an institution for quality assessment in the German healthcare sector). For the governance of the German health system, this decision represented a novelty. The BQS was independent in its decisions but it was an institution under the maintenance of several corporatist partners of the collective self-government. The AQUA-Institute is a society of the private sector.

However, the cooperation with the AQUA-Institute should be of limited duration. The institute had the commission for the external quality assessment of health facilities for five years. In 2014, the Law of Further Development of the Financial Structure and Quality in the Statutory Sickness Fund stipulated the foundation of the Institute for Quality Assurance and Transparency in Healthcare (IQTiG) mirroring the institutional structure of the IQWIG. The focus of the new institute shall be the overall quality assurance covering different sectors of the health system and the improvement of transparency.

The new foundation arose from the conviction that the transfer of the external quality assessment of hospitals from the BQS to the AQUA-Institute had led to a loss of expertise. The lengthy procedures to place orders or to change them requiring always a decision of the Federal Joint Committee were another problem. This kind of procedure gave also the possibility to the corporatist partners of the collective serf-government to influence decisions corresponding to their own interests (Paquet 2014: 61 f).

The new institute shall take over the former tasks of the BQS and the AQUA-Institute. Like the IQWiG, the IQTiG is conceived as a foundation of private law in order to assure its independence. It has been officially created in January 2015 by the Federal Joint Committee and is still under construction. The institute shall start its work from January 2016 onwards (http://www.iqtig.org/index, 04/06/2015).

2. German health evidence-based bureaucracies from inside

The characterization of the institutions (BQS, AQUA, IQWIG, IQTiG) as evidence-based bureaucracies is clearly more related to the first dimension (the core role of evidence-based expertise) than to the second (openness to non-state actors). This is particularly obvious when looking at the internal structure of the IQWIG and the IQTiG.

The governing structure of the IQWIG is the Foundation for Quality and Efficiency in Health Care, composed of two bodies: the Foundation Council and the Board of Directors. The twelve members of the Foundation Council are divided equally between representatives of the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) and the service providers, represented by the Federal Association for Statutory Health Insurance Physicians (KBV), the German Federal Association of Sick Fund Dentists (KZBV) and the German Hospital Federation (DKG). It is the same formation as the GBA's council. The Foundation council's responsibilities include approving the Institute's budget and appointing four out of the five the Board of directors, the fifth member is appointed by the Federal Ministry of Health.

The two advisory boards of the IQWIG are the Board of Trustees and the Scientific Advisory Board. The Board of Trustees, who may submit comments on the scientific recommendations of IQWiG, consists of 30 members, including five representatives of patients' organizations and one patient representative commissioned by the Federal government. The remaining members represent leading organizations of service providers, social partners, as well as the self-administration bodies of the Federal Joint Committee. The Scientific Advisory Board is appointed by the Board of Directors and consists of national and international researchers who advise the Institute Management on fundamental issues (https://www.iqwig.de/en/about-us/institute-structure/bodies-and-committees.2957.html, 10/06/2015).

The IQTiG is under maintenance of a foundation of the same name. The board of trustees assembles two representatives of the German Hospital Association, two representatives of the Federal Association of Statutory Health Insurance Physicians, one representative of the Federal Association of Statutory Health Insurance Dentists as well as five representatives of the National Association of Statutory Health Insurance Funds. The executive committee is composed of three representatives of the service-providers, three representatives of the health insurance funds, a representative of the health ministry and the head of the Federal Joint Committee (http://www.iqtig.org/index, 07/06/2015).

The openness of these public agencies is limited: the non-state actors who sit in the governing structures of the two institutes are the highly institutionalized corporatist actors traditionally managing the German health insurance system. Patient's representatives have only marginal positions in advisory bodies.

An other characteristic of these new institutions is the role of medical experts using evidence-based methods. 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. 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. In addition to this strictly medical knowledge, some representatives of other disciplines as human biology, epidemiology, mathematics or medical sociology participated to the development of healthcare indicators. At the level of the Federal Joint Committee, there are also some economists and some experts of public administration but they have not been directly involved in the development of quality indicators (interview with a representative of the Federal Joint Committee, Manual Qualitätsindikatoren 2009).

The head of the BQS, Christof Veit, was a doctor and belonged to the surgeons who created, at the end of the 1980th, the comparative project of surgical wards in Hamburg. The BQS assembled always three parts of expert panels working together on the development of quality indicators. Doctors and nurses worked on their content. External experts from the current discipline, such as cardiologists for quality indicators in the field of cardiology and gynaecologists in the field of gynaecology, supported them. Disposing the methodical knowledge, the staff of the BQS chaired the conferences of the expert panels. Those panels worked together with statisticians and experts in biometry. The members of both groups had some additional expertise in quality management and quality assurance acquired in an extra training according to the curriculum of the General Medical Council. The third group assembled IT specialists programming the software necessary for the elicitation and analysis of data. In addition to the three expert panels, a supporting team answered for example questions at the telephone. Until the transfer of the compulsory external quality assessment of hospitals to the AQUA-Institute in 2009, the BQS had 58 employees. Economists and according to that economic aspects have wilfully not been integrated into the development of quality indicators. The experts of the BQS wanted to develop quality indicators describing an ideal definition of medical quality without economic pressures or other kinds of constraints not always considered as compatible with the professional ethics of doctors (interview with a representative of the BQS). The

structure of the BQS and the regional points of quality assurance (LQS) reflected the big autonomy that the medical profession traditionally had in the German health system (Kuhlmann, 2007).

The AQUA-Institute to whom the Federal Common Committee gave the commission for the external quality assessment of hospitals in 2009, had been founded by the physician and sociologist Joachim Szecsenyi. The expert panel of the AQUA-Institute is multi-disciplinary and assembles social scientist, doctors, nurses, experts in public health and jurists. As the BQS, the choice of the disciplines for the compulsory external quality assessment depended on the decisions of the Federal Joint Committee (interview with an employee of the AQUA-Institute).

The new Institute of Quality and Transparency in Health is still under construction. The former director of the BQS, Chritof Veit, has been chosen as head of the new institute. Actually, the expert panels are composed. The institute is looking for doctors, statisticians and experts in biometry, medical documentarists, computer specialists, software developers and IT specialists.

Even if the strived expert panels are very similar to those of the BQS and there are still no economists, the German health ministry has more influence on the work of the new institute. In order to drive the goal of "pay for performance" forward, as announced in the coalition agreement of Christian Democrats and Social Democrats, economic aspects might soon become more important.

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 (Russeil 2010, Dolowitz/March 2000) 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 first scientific papers (Schrappe, Groene) treated the question of quality assessment in healthcare in a very theoretical way. Quality indicators in healthcare were discussed in a broad sense of the word taking into consideration different definitions used at the international level as well as different categories of quality indicators and the principal methods and problems of their development. The most influent 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) describing health care indicators in the following way:

"An indicator is a quantitative measure that can be used to monitor and evaluate the quality of important governance, management, clinical und support functions that affect patient outcomes. An indicator is not a direct measure of quality. Rather, it is a tool that can be used to assess performance that can direct attention to potential performance issues that may require more intense review within an organisation." (JCAHO 1990 in Schrappe 2001).

The authors presented specific indicators describing purely medical factors in conjunction with a medical discipline or an indication and they presented also more global indicators that were related to administrative or economic factors. In spite of the broad discussion in the early period of the quality assessment in healthcare, the BQS chose purely medical quality indicators for the compulsory external quality assessment of hospitals. Economic or administrative quality indicators as they are used for example in France had no importance in the compulsory external quality assessment in Germany.

In 2003, the BQS documented 18 types of medical interventions distributed to six medical disciplines in its quality reports. In the following years, more disciplines and types of medical interventions have been added to the compulsory external quality assessment and there are also indicators for a volunteer quality assessment. In 2008, there were 206 quality indicators for 26 types of medical interventions in seven disciplines. The BQS published 107 of the 206 quality indicators in its quality report of 2008. For developing the quality indicators, the BQS used a method based on the method of the Joint Commission on Accreditation of Health Care Organizations (JCAHO 1990) and the method of the RAND Corporation adapted to the needs of the German health system. This method met all the requirements formulated the WHO (2003) and the OECD (2006) and it follows the recommendations of the General Medical Council, the Federal Association of Statutory Health Insurance Physicians and the Working-Group of the Scientific Medical Societies concerning the evaluation and the improvement of healthcare (ÄZQ 2001). The AQUA-Institute kept the quality indicators of the BQS without major changes.

Medical expertise is also strong in the IQWIG. It has 5 scientific departments producing reports. They primarily handle the commissions that IQWiG receives from the G-BA or the 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 Rüther, 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 and finally withdrawn in the 2010 law on the Reform of the Market for Medicinal Products (AMNOG).

Despite these dominance of medical expertise quality and efficiency assessment were progressively introduced in German health policies.

3. The incremental integration of quality and efficiency assessment in German health policies

Since the beginning of the external quality assessment of hospitals, the quality indicators have taken a more and more compulsory character. At the same time, the goals of the usage of quality indicators have not changed for a very long time. New goals have appeared only very recently.

The first projects of quality assessment in hospitals using quality indicators, as the project of the surgery wards in Hamburg, were voluntary. The project of the surgery wards was conceived as peer review and the results of the comparisons had no binding consequences for the participants. The ambition of the surgeons to belong to the best ones of their discipline pushed them to take part in the project and to improve the quality of care in the surgery ward of their hospital.

With the legal obligation to install a quality management for hospitals, the use of quality indicators has become compulsory for hospitals. Nevertheless, the quality assessment of healthcare did not lose the character of a peer review. Between 2003 and 2008, the BQS developed the necessary instruments for the compulsory external quality management of hospitals. The healthcare professionals in the hospitals collected the data and the regional points of quality assurance and the BQS compared them with the data of other hospitals and presented the results of the comparison (benchmarking) and their temporal evolution (monitoring). The quality reports of the BQS permitted to detect the reasons for quality flaws and they provided indicators for quality flaws in other fields as well. The reports allowed also to estimate the costs caused by the quality flaws. The BQS considered

the first effects of the compulsory external quality assessment of hospitals as encouraging. The BQS established in 2007, that 3.5 million of data have been collected in 1 600 hospitals for the quality assessment. In 2008, the BQS observed an improvement for 80 percent of the quality indicators in comparison with the years before.

Since 2005, the use of quality indicators has little by little lost its character of a peer review. The hospitals got the legal obligation to publish their quality reports periodically. After a decision of the Federal Joint Committee, those reports must contain some quality indicators. However, those quality reports present principally some quality indicators of structural quality as the number of beds, technical equipping, etc. Some of the quality indicators of the BQS have also been considered as suitable for a publication in the quality reports. For the hospitals, the quality report can be an instrument to show the quality of care. It is considered as important to improve the transparency and the competition between hospitals (§ 137 SGB V). The BQS has developed the contents and the methods for a comparative external quality assessment in healthcare. The regional points of quality assurance assisted the BQS to put them into practice. The organization of those regional points of quality assurance varies from one German state to another (interview with a representative of a regional point of quality assurance).

The transfer of the compulsory external quality assessment of hospitals from the BQS to the AQUA-Institute did not entail major changes in terms of the quality indicators that were used for the quality assessment. Nevertheless, the use of the quality indicators partly varies. In the new quality report, one chapter summarizes the results of a structured quality dialogue in order to point out the necessities to act. There is a chapter about the risk adjustment, too. The AQUA-Institute did not continue the monitoring in order to show the temporary evolution of the quality indicators. There were many new experts working on the quality report made by the AQUA-Institute. The comparison with the former reports made by the BQS could have led to biases. However, the AQUA-Institute has a structured dialogue with hospitals that met the same problems within several years (AUQA 2009). Even after the transfer of the compulsory external quality assessment of hospitals from the BQS to the AQUA-Institute, the regional points of quality assurance contributed at the operative level to the quality assessment process. In some German states, they are still in charge of the data collection for the quality assessment. They also collaborate with the working-group on the development of the external quality assessment (interview with a representative of a regional point of quality assurance).

The quality indicators of the BQS/AQUA-Institute are also used in other projects of quality assessment. Since 2009, the German Hospital Association (DKG) provides an online register of hospitals that shall help patients to find a hospital in their region. Patients can find information about the structure, the array of services and the quality of a hospital. The quality indicators presented on

this website come from the quality reports of the AUQA-Institute. Since 2010, the website www.qualitätskliniken.de also provides information about the quality of 136 hospitals. The website presents 400 quality indicators. Most of those indicators come from the BQS, too. They shall provide information about the care quality, patient security, patient satisfaction and the satisfaction of office-based doctors sending patients to the hospitals.

The German health ministry never intervened directly in the external quality assessment of hospitals. It wielded its authority by changing the framework legislation (interview with a civil servant of the government of Social Democrats and Greens). However, that was not the case of the Federal Joint Committee. The advisory board of the BQS was placed under the oversight of the Federal Joint Committee that defined the disciplines and the medical interventions subjected to the compulsory external quality assessment (interview with a representative of the BQS). But this situation could be dramatically changed by the hospital reform announced by the government early June 2015. Quality is the main orientation of the reform, which aims to link the hospital budgets to quality assessment.

The evolution is less obvious for efficiency assessment. The main aspect is the introduction of early assessments of new drugs, based on the dossiers submitted by the drug manufacturer to the G-BA, in the Act on the Reform of the Market for Medicinal Products (AMNOG), passed in 2010. These benefit assessments, based on EBM methods, 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.

Conclusion: what convergence of evidence-based bureaucracies in Europe?

The new institutions created in Germany clearly share organizational patterns of evidence-based bureaucracies: separation of (scientific) assessment from (political) management, association of executive and deliberative tasks, technical directorates working according to administrative principle (neutrality, permanent staff, hierarchical principle, public bodies…), committees and working groups with external experts (permanent or ad hoc committees…). Another convergent dimension is the high level of formalization of the work performed through protocolization based on EBM.

Nevertheless the German case shows the importance of governance traditions: quality and efficiency assessment have been embedded in the institutions of the self-government of healthcare services. And if international and Anglo-Saxon quality indicators in healthcare served as a source of inspiration, the German experts didn't just copied them. They were rather translated (Campbell, 2004) to the existing institutional context in their content and their usages.

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