Scientific evidence, politics and law – the case of regulating hospital minimum volumes in Germany

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Abstract

Inspired by scientific studies of volume and outcome relationships for complex surgery in the United States, minimum volumes were attractive to German policy-makers in the early 2000s as both 'evidence based' and intuitively plausible. This paper examines how scientific evidence to support minimum volumes was influential at different stages of the policy process, specifically (1) parliamentary policy making, (2) policy specification in the health self-administration (Federal Joint Committee), and (3) adjudication by the Federal Social Court. The analysis starts from the premise that each arena has developed, and it governed by, a distinct set of rules that shape how scientific evidence is interpreted and related to policy. Federal policy-makers, for example, were under no obligation to use scientific evidence to substantiate their decisions. For the Federal Joint Committee supporting decisions through evidence claims was a crucial mark of legitimacy. Legal adjudication involved translating scientific probability into legal plausibility to construct a justification of specific minimum volumes. The institutional rules on health policy making in Germany thus led to a situation in which scientific evidence is equally used to promote, contest and justify policy decisions, with different institutional arenas arriving at different settlements between the interests involved in health policy-making.

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In Germany, the idea of evidence-based policy as a model of modern policy-making has not engendered as much enthusiasm as it does in other, mostly Anglo-Saxon countries (Jun and Grabow 2008, Knieps 2009). German policy-makers and researchers are broadly in agreement that scientific evidence has become more relevant to policy-making over time to address increasingly complex policy problems and to provide legitimacy for potentially unpopular decisions (Renn 1995). There is an ever growing demand for expertise met by an array of scientific advisory committees, research institutes, expert commissions and expert networks providing advice to government (Jun and Grabow 2008, Siefken 2007, Kloten 2006). In the health care sector, with its proximity to evidence-based medicine, scientific evidence use has become institutionally established, for example, through the creation of the Institute for Quality and Efficiency in Health Care (*Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen,* IQWiG) (IQWiG 2015). This is broadly reflective of international trends.

However, scepticism prevails when it comes to the role of scientific evidence outside the narrow confines of health technology assessment, with some saying that reference to evidence is mostly made for the purpose of 'scientifically cloaked lobbyism' (Knieps 2009). The argument is that the complexity of the policy process in Germany – with its multitude of actors involved brought about by federalism and corporatism, and the dominance of legislation over other forms of policy-making – does not lend itself to support notions of straight forward evidence use in policy-making. German scholars in fact tend to speak about 'policy advice' (*Politikberatung*) rather than 'evidence-based policy', indicating a perceived primacy of policy and politics over evidence use (Siefken 2007, Kloten 2006, Falk et al. 2006, Brede 2006, Mayntz 2009). Others have argued that politics and science are interrelated public spheres which have become increasingly reliant on each other for status and legitimacy, with Weingart pointing to the paradoxical co-existence of the 'scientification of politics' and the 'politicisation of science' (Weingart 1999).

This paper will explore the role of scientific evidence in German health policy-making using the case of minimum volumes as a pertinent example. Based on the idea that quality improves with greater experience in a given procedure ('practice makes perfect'), minimum volumes have been introduced for a number of highly specialised hospital services as a measure of improving quality of care. The paper will examine the role of evidence at different stages of the policy process using the concept of *institutional arenas* to understand better the specific rules and practices associated with each arena and how these interact with notions of evidence use. In the case of minimum volumes these arenas are:

- The federal legislature comprising two chambers of parliament, the Federal Assembly (*Bundestag*) and Federal Council (*Bundesrat*);
- The 'corporatist' self-administration, represented by the Federal Joint Committee (*Gemeinsamer Bundesausschuss,* GBA) as the highest decision-making body of the self-administration of organised interests in health care; and
- Social courts, charged with legal adjudication.

The idea of regulating minimum volumes was initially inspired by research: Studies in the United States suggested that hospitals that performed a larger number of highly complex surgeries produced better outcomes for patients than hospitals that provided these services less often (e.g. Birkmeyer et al. 1999). The idea of turning volume-outcome relationships into a policy proposal has been credited to health economist and university professor Karl Lauterbach who, at the time, was an influential policy advisory to the Federal Minister of Health Ulla Schmidt (*Interview*)[1]. Minimum volumes were passed into law in 2002 and have been specified and operationalised in the years that followed, attracting much controversy as well as legal challenge from hospitals.

This paper focuses on a single case study to analyse the process of national health policy-making in Germany. Hospital minimum volumes have been chosen as a topical case because of the complexity of the regulatory issue at stake which allows for an analysis of policy-making in three institutional arenas. These arenas reflect stages in the policy process as well as the division of power within the federal state of Germany as they relate to health policy:

[1] This study has used interviews as a method of data collection (see Methods). Material used in this study gained from interviews will be identified as such (see brackets) but will not be attributed to individuals or their professional roles.

legislative power vested in the parliamentary process; executive power as delegated to, and exercised by, corporatist actors; and judicial power exercised by state and federal courts. This threefold distinction forms the analytical framework that will guide this analysis.

The following section introduces the concept of institutional arenas and the three arenas in question, followed by a description of the study methods and a summary of the scientific evidence base for minimum volumes. The middle section of the paper is devoted to the analysis of the role of scientific evidence in the three institutional arenas and the different ways the rules and practices of each arena shape the relationship between evidence and policy. The paper finishes with a discussion and conclusion.

Institutional arenas

This paper takes an institutional perspective to analyse the three main arenas in which scientific evidence interacts with the health policy process: 1. The political arena of law-making in parliament; 2. the corporatist arena of the self-administration in health care, mandated with operationalising minimum volumes; and 3. the judiciary arena of social courts that adjudicate in cases of legal disputes between policy actors (e.g. public authorities, corporatist actors), individuals (e.g. citizens, doctors) and organisations (e.g. hospitals, sickness funds) insofar as they relate to social welfare.

This paper uses the concept of institutional arenas to highlight the differences in rules and practices of decision-making between these three arenas. Arenas are defined by a specific, in German health policy mostly legally codified, constellation of policy actors and the procedural rules applying to their role in policy-making. A focus on institutional arenas has been applied to the analysis of various sectors of society, including the bureaucratic state, markets and professions (e.g. Thornton and Ocasio 2008). Such analyses tend to emphasise the simultaneous existence of multiple 'logics' associated with different arenas and the contradictions they entail for individuals and organisations (Friedland and Alford 1991).

The paper argues that each institutional arena has developed its own rules and practices of using, or relating to, scientific evidence. A similar observation was made by Jasanoff who, comparing Britain, Germany and the United States, noted that countries had developed

their own 'civic epistemologies' in how they dealt with science and uncertainty in regulatory decisions, for example, relating to the regulation of carcinogens or stem cell research (Jasanoff 2002, 2005). In a similar vein, Renn distinguishes cultural styles in national policy-making (e.g. adversarial, fiduciary/patronage, consensual, corporatist), which he associates with different 'styles of scientific evidence use' (Renn 1995). These styles then differ in how rules apply to the selection of evidence considered relevant; to the processing of scientific information (e.g. via individual expertise or systematic reviews); to the mixing of scientific evidence and other forms of knowledge used for strategic purposes; and to legitimation of policy decisions with the public (e.g. whether studies are quoted in policy documents). Instead of comparing 'styles' between countries this paper argues that such differences also exist between institutional arenas involved in policy-making in a single country and a single policy process. The following analysis specifically looks at Germany, a country in which health policy processes tend to be highly institutionalised, and organised around developing, operationalising and interpreting legislation.

The parliamentary arena

In Germany, national health policy is usually made through legislation which, for social health insurance, is brought together in Social Code Book V (SGB 5). Consequently; it almost always requires approval from parliament. Parliament is bicameral, with the *Bundestag* composed of the political parties elected by the populace, and the *Bundesrat* representing the 16 federal states (*Länder*). Members of the *Bundesrat* are delegated by the state governments. States have constitutionally enshrined rights and responsibilities, including for hospital planning and investment. Legislation passed by the *Bundestag* that affects the rights and responsibilities of the states always require approval by the *Bundesrat*. In consequence, legislation relating to minimum volumes involves decisions in both chambers of parliament. Such decisions are typically prepared by parliamentary committees. In the case of minimum volumes, the Health Committee (*Gesundheitsausschuss*) was the place in which differences between the positions of the parties in the *Bundestag* were deliberated and a consensus negotiated in view of gaining a majority to pass the bill. A second committee – the Mediation Committee (*Vermittlungsausschuss*) – arbitrates between the *Bundestag* and the *Bundesrat*, aiming to reconcile the interests of the federal level and the

states. In the case of minimum volumes, both committees had a substantial influence on the specific wording of the final bill that was passed into law.

The corporatist arena

Passed in 2002, the resulting Act on the Introduction of Diagnosis-related Groups for Hospitals (*Gesetz zur Einführung des diagnose-orientierten Fallpauschalensystems für Krankenhäuser*) delegated the responsibility for operationalising minimum volumes to the corporatist sector that constitutes what is termed the 'self-administration' in health care. At federal level, the self-administration brings together key corporatist actors representing payers and providers of health care, notably the top association of sickness funds, the federal association of ambulatory doctors and the German Hospital Association.

These groups jointly form the Federal Joint Committee (GBA), the top decision-making body of the self-administration. The GBA was created in 2004 through a merger of a number of existing committees including the Hospital Committee, through which associations of hospitals and sickness funds jointly developed regulation for the hospital sector (GBA 2014). The mandate for minimum volumes preceded the GBA and has been part of its organisational development ever since. The mandate of the GBA has grown substantially with almost every health care reform adding new responsibilities which now include tasks as diverse as approving medical procedures and pharmaceuticals for reimbursement, developing guidelines for capacity planning in the ambulatory sector, and developing and implementing quality assurance measures, including setting minimum volumes for hospital services.

As a corporatist body, the GBA has two faces: The outward looking face presents the GBA in its role as decision-maker charged with a significant amount of statutory tasks, which otherwise (i.e. in other countries) would be executed by the state. Its decisions are binding on all actors in the health system, including payers, providers and patients/citizens, and its directives have legal status as subsidiary norms. The GBA thus has substantial authority. The inward looking face sees decisions arrived at through negotiations between its member organisations, each representing its own interests and vested with significant power arising from its membership (i.e. hundreds of sickness funds, thousands of hospitals, and tens of thousands of doctors).

The judicial arena

In Germany, jurisdiction relating to social welfare is exercised by a separate judiciary branch, the social courts, which are hierarchically organised at municipal, state and federal level. Some disputes require social courts to review decisions of parliament (i.e. legislation) or of the GBA (i.e. its directives). The role of courts in reviewing and potentially rejecting or changing legislation (i.e. by requesting parliament or the GBA to amend their decisions) has been criticized by some as inefficient and can make for a lengthy policy process (*Interview*), as the case of minimum volumes demonstrates.

Scientific evidence has played a role at each stage of the process of legislating, specifying, and adjudicating on minimum volumes in hospitals. However, the ways in which policy-makers, politicians and judges have engaged with scientific evidence has differed vastly between institutional arenas. This paper will examine how scientific evidence was used at different stages of this process and how the rules of each institutional arena influenced the relationship between evidence, policy and politics.

Methods

The case study is informed by documentary analysis and interviews. Documents include published protocols of parliamentary committees; published records of court decisions; selected articles from several broadsheet newspapers reporting on minimum volumes such as *Der Spiegel*, *Frankfurter Allgemeine Zeitung* and *Die Zeit* and from professional journals such as *Deutsches Ärzteblatt*; scientific reports published by IQWIG and by researchers commissioned to undertake evidence reviews; materials from websites such as policy documents relating to minimum volumes published by the GBA and by corporatist organisations, as well as press releases published by these organisations.

The documentary analysis has been supplemented by a number of interviews with key individuals (n=9), representing various types of policy-makers (government bureaucracy; corporatist organisations) and researchers. Interviewees were selected because of their knowledge of, and/or known involvement in, the process of developing minimum volumes

policy. The roles of individual interviewees will not be identified in the following analysis to ensure the level of anonymity and confidentiality agreed at interview.

Minimum volumes in hospital – policy idea and scientific evidence

Since the 1970s, health services research in the United States and elsewhere suggested that for certain services, typically complex surgery, hospitals that provided the service to a larger number of patients achieved better outcomes for patient (i.e. lower mortality and morbidity) than hospitals that provided the same service to a smaller number of patients (Luft, Bunker, and Enthoven 1979). Interviewees suggested that studies published by Birkmeyer and colleagues in the 1990s and early 2000s were particularly influential in turning a statistically observed association of volume and outcomes into a policy idea (Birkmeyer et al. 1999, Birkmeyer et al. 2002, Birkmeyer et al. 2003, Finlayson, Goodney, and Birkmeyer 2003). The idea also appealed to policy-makers as it resonated with the common sense notion that 'practice makes perfect'. Minimum volumes had already been ubiquitously used in medical training and accreditation, although they had not been used before to exclude hospitals from providing a service.

In Germany, regulating minimum volumes also fit with the wider reform agenda for hospitals at the time. There were two concerns specifically: the perceived inefficiency and comparative costliness of hospital care compared to other countries and emerging concerns about variation in the quality and outcomes of care. The first concern was to be addressed by the introduction of activity-based payments as the main method of funding hospitals (Busse and Blümel 2014). Minimum volumes promised to speak to the second concern and to counter perceived risks to quality associated with the first.

However, despite being a policy idea inspired by scientific research, the scientific evidence base for operationalising the policy proved challenging. Evidence reviews suggested that there was a statistically significant relationship between higher volumes and improved outcomes for a number of complex surgical interventions such as pancreatic resection or oesophagectomy (IQWiG 2008, Geraedts 2002, Rathmann and Windeler 2002, IQWiG 2005). These studies were typically observational (i.e. non-experimental) and were not considered as providing ultimate proof of causality. There were also limitations with regard to the data

used in these studies, which typically relied on routinely collected information and were limited to certain populations or countries or groups of hospitals (e.g. in the US), raising questions on the transferability of their findings.

A further challenge was the difficulty of using studies indicating statistical correlations to support or set precise minimum volumes for specific procedures. Studies typically used definitions of 'high' and 'low' volumes of service provisions, but these were set by researchers and reflected the data available. In addition, most studies originated in the US with studies using German data only emerging over time. But analyses of German data were also difficult to interpret and almost impossible to use to inform minimum volumes. For example, in 2006, IQWIG, the research institute associated with the GBA, published an analysis of data on volumes and outcomes of total knee replacement surgery, using two indicators of outcome quality (postsurgical mobility and infection) that produced conflicting findings (IQWiG 2006).

In sum, while there was scientific evidence to support the selection of services which could benefit from minimum volumes, there was limited evidence to guide selection of the specific volumes to be set in these cases. This substantially reduced the potential for explicit "evidence based" decision-making when it came to setting volumes.

Parliamentary arena – turning an evidence-inspired policy idea into law

In 2001, the Federal Government – then composed of Social Democrats and the Green Party – brought a proposal for major reform of hospital funding before parliament. The proposal involved replacing the previous method of paying hospitals via budgets and per diems (payments per day of hospital stay) through a funding approach predominantly based on activity-based payments using diagnosis-related groups. The aim of this reform was to reduce perceived inefficiencies in hospital funding and to reduce the length of stay of hospital inpatients, which were one of the longest in Europe. Minimum volumes were introduced on the back of these reforms, as a counter measure to known risks to quality associated with activity-based funding. They had the added attraction – especially for sickness funds and Social Democrats – of excluding hospitals with lower volumes from

providing certain services, thus providing a lever for facilitating structural change in the (difficult to reform) hospital market.

Although the idea of regulating volumes of complex hospital services is likely to have been inspired by research studies hinting at a volume-outcome relationship, scientific evidence, unsurprisingly, did not feature widely in the parliamentary discussion where the legal framework for minimum volumes was developed. Instead, the procedural rules of parliamentary decision-making show a much clearer imprint on the resulting legislation, published as part of the 2002 Act on Case-Based Payment (*Fallpauschalengesetz*). In relation to minimum volumes, the 2002 Act stipulated that the relevant decision-making body of the self-administration (at that time the Hospital Committee and, from 2004, the GBA) should identify hospital services for which "the quality of outcomes particularly depended on the volume of services provided" and set minimum volumes for such services (Bundestag 2002b). The Act has since been integrated into Social Code Book V, now forming part of paragraph 137.

As the bill concerned hospital funding it directly touched on the legal responsibilities of the states and therefore required approval of both chambers of parliament. In the *Bundestag*, the bill was discussed in the Health Committee, which introduced a number of amendments including that minimum volumes should only be applied to 'planable' services (*planbar*), thus excluding urgent or emergency services. The Health Committee also requested transitional arrangements for hospitals that wanted to invest in expanding or creating new services, for example, by employing a new specialist (Bundestag 2001a, b). While seemingly reducing the scope of minimum volumes, the Health Committee also sharpened the bill by making minimum volumes binding on hospitals (instead of using them as guidelines as an earlier version suggested) and by preventing sickness funds from reimbursing services if hospitals continued to provide them in insufficient numbers. Taken together, the changes introduced by the Health Committee both suited the agenda of sickness funds and, to some extent, may have mollified hospitals by limiting minimum volumes to elective services.

The states, represented in the *Bundesrat*, also made amendments to the bill as the documents of the Mediating Committee suggests. Specifically, the Committee made provisions that allowed states to exempt individual hospitals from minimum volumes if they found access to services at risk within a given geographic area (Bundestag 2002a).

There is no indication in the documents examined that parliamentary committees concerned themselves with an interpretation of the scientific evidence available in support of minimum volumes. However, the resulting legislation included a clause where the specific wording lends itself to being interpreted as stipulating that specific minimum volumes had to be supported by scientific evidence. Specifically, the Act stated that "the quality of outcomes *particularly* depended on the volume of services provided" [emphasis added]. This clause had significant influence on how the law was subsequently interpreted and applied both by corporatist decision-makers and by social courts.

Corporatist arena – using evidence to inform, legitimise and contest decisions

With the passage of the Act, federal legislators mandated the self-administration to identify hospital services suitable for minimum volumes and to set volume thresholds. This task fell initially to the Hospital Committee (*Ausschuss Krankenhaus*), formed by the top associations of sickness funds, the German Hospital Association and the Medical Association (*Ärztekammer*), and, from 2004, to the newly formed GBA.

The legal mandate required associations of sickness funds and hospitals (with participation from a number of other organisations such as private health insurers) to jointly identify the 'catalogue of planable services' and to set minimum volumes for these services (MMV 2002). However, both (groups of) associations also brought their own positions and interests of their members to the negotiating table. Sickness funds, as noted above, were keen to establish minimum volumes as a policy instrument for quality assurance and structural change.

The hospital association, in contrast, wanted to prevent the introduction of minimum volumes and, as this had failed, to limit the number of services they would apply to and keep volume thresholds low. Introducing minimum volumes had the potential (or the risk, depending on perspective) to exclude low-volume hospitals from service provision and to shift services to hospitals that already had higher volumes. The policy thus created new winners and losers both groups being represented by the German Hospital Association.

While unable to openly reject quality assurance as an objective, the main strategy of the hospital association was to highlight the risks to patients potentially arising from minimum volumes. These risks came in two flavours: The first argument was that minimum volumes would endanger access to care for patients by reducing the geographic coverage of services:

> 'In addition, the proposed bill suggests minimum volumes for hospitals. Yet the application of minimum volumes can exclude hospitals [from service provision] in an unjustified way, which would endanger access to services for patients.' [DKG, Press release, 1 Feb 02]

A second line of argument of the hospital association was that minimum volumes were insufficiently supported by scientific evidence and were 'unfair' to low-volume hospitals that would produce good outcomes (*Interview*). Legislators had pre-empted the first line of argument by allowing state authorities to grant exemptions on a case-by-case basis on the grounds of geographic equity. However, the second argument – insufficient evidence – was more successful in challenging the appropriateness of minimum volumes and obstructing their implementation.

A first list of complex surgical procedures was agreed in 2003, comprising liver transplants, kidney transplants, complex surgery of the oesophageal system and the pancreatic system, and stem cell transplantation. For these services, thresholds were set between 5 and 20 per hospital per year (liver transplantation 10; kidney translation 20; oesophageal surgery 5, pancreatic surgery 5, stem cell transplantation 10-14) (MMV 2002).

Interviewees commented that these procedures had been considered as relative uncontroversial, as their relative share in service delivery and potential financial impact on hospitals was small and volume thresholds low (*Interview*). They were also reflective of the services analysed in existing studies (Geraedts 2002, Rathmann and Windeler 2002). The limited selection of services and the low thresholds thus suggests compromise between hospital and sickness fund associations. In contrast, minimum volumes proposed by sickness funds (e.g. the *Verband der Angestellten-Krankenkassen*) were more ambitious, for example, for oesophageal and pancreatic surgery (both 10), coronary surgery (100), carotid surgery (20), percutaneous transluminal coronary angioplasty (150), breast cancer surgery (150) (Geraedts 2002). In 2004, two further procedures were added to the list: total knee replacement and coronary surgery (BMGS 2004). However, no volumes were set at the time and coronary surgery – arguably a high volume service – would not be pursued any further.

More controversially, in 2005, a threshold of 50 cases per hospital and year was set for total knee replacements (BMGS 2005). Neonatal services for babies with very low birth weight were added in 2009 (GBA 2009). These two decisions involving services with high volumes (knee replacement) and high costs (neonatal care) proved highly contested and were both challenged in court.

At the time, two 'evidence reports' – one commissioned by sickness funds and authored by Rathmann and Windeler (2002) and the other commissioned by the Federal Chamber of Physicians and authored by Geraedts (2002) – appeared to have influenced the selection of services for minimum volumes. Both reports were able to identify procedures such as complex surgery of oesophageal tumours for which evidence of a robust volume-outcome relationship existed. However, as these studies were observational and relied on routine data, they did not lend themselves to suggesting volume thresholds. They also did not identify the mechanisms, or factors, that would explain why higher volumes produced better outcomes. In other words, while these reviews established the problem and provided a rationale for action, they were unable to suggest specific solutions.

However, despite the known limitations of the evidence base, the 2003 agreement stipulated that future minimum volumes should be based on scientific evidence. Specifically, it stated that decisions should be taken based on 'epidemiological and empirical knowledge' and applied in 'a transparent and rule-based process' (MMV 2002: 1). Not only should future minimum volumes require evidence of a causal relationship between volume and outcomes, they also required proof that improved outcomes were *predominantly* caused by higher volumes ('*im überwiegenden Teil*'). Thus the 2003 agreement suggested that minimum volumes should only be set if volume was proven to be the decisive factor for variation in outcomes. This wording echoed similar terminology in the law ('*in besonderem Maße*') but further raised the bar as to which types of evidence were regarded sufficient. However, evidence of volume being more influential than other factors, was difficult to come by for practical reasons (i.e. such studies did not exist) and scientific reasons (i.e. volume is a proxy for other factors thus can never be decisive).

Unsurprisingly, this move towards evidence-based medicine in justifying minimum volumes was celebrated by the hospital association:

> ‘Paragraph 3 of the agreement includes a procedural rule that stipulates that the setting of minimum volumes for certain services require an evidence-based process and scientific evaluation‘ [DKV, 4 Dec 03]

In 2004, having replaced the Hospital Committee, the GBA asked its research institute, IQWiG, to examine systematically the evidence of a volume-outcome relationship and to identify thresholds for total knee replacement (IQWiG 2005). Published in 2005, the IQWiG report noted that a volume-outcome relationship was plausible, but could not be proven in the absence of experimental studies (IQWiG 2005). In addition, the analysis of hospital data on volumes and outcomes for total knee replacement (using the outcome measures ‘post-surgical mobility’ and ‘infection after surgery’) resulted in conflicting findings, with one indicator showing a decline in desired outcomes at higher volumes and the other showing steady improvement. Individually and jointly the analyses of these indicators did not indicate that there is an ideal volume threshold. A later report by IQWiG relating to the treatment of very premature babies with very low birth weight also concluded that a causal relationship between volume and outcomes was likely, but could not be regarded as proven due to the absence of experimental studies (IQWiG 2008).

Since its inception the GBA has been committed to more stringent evidence use, especially in relation to (typically controversial) decisions on the reimbursement of pharmaceuticals and medical procedures. There was a notable effort to apply similarly robust approaches to decisions on minimum volumes, resulting in the commissioning of reviews and additional data analyses prepared by IQWiG. In commissioning these studies the GBA followed established best practices, including the publication of protocols and peer review. The GBA is also bound by its by-laws to provide explicit rationales for its decisions, to make such information publicly available and to give due consideration to reports commissioned from its research institute (GBA 2008). However, despite this emphasis on procedural robustness the GBA found itself in a position in which it was impossible to base minimum volume decisions on evidence alone. This happened because the scientific evidence in support of specific threshold was inconclusive. In addition, being a membership organisation, the GBA continued to be exposed to partisan interests, in one instance rejecting a study brought in by the hospital association which aimed to demonstrate that a volume-outcome

relationship was inexistent (GBA 2010). There was thus substantial tension between two procedural rules, those set out in by-laws which aim at ensuring transparency and due process and those associated with the corporatist nature of the GBA and the practice of negotiating consensus between the organised interests in health care.

Judiciary arena –scientific evidence in legal argumentation

Scientific evidence also played a key role in legal adjudication on minimum volumes, in which the courts used evidence from research to substantiate claims about the potential effects of minimum volume regulation on hospitals and patients. These effects were typically framed as the balance of 'risks' and 'benefits'.

Following the introduction of minimum volumes for total knee replacement at a level of 50 per hospital and year and of increasing existing volumes for very premature babies from 14 to 30 (GBA 2013), several hospitals took legal action against sickness funds which had refused to pay for services delivered at lower numbers than required. Both cases led to a judicial review of the GBA decisions at state level (the Social Court of the Land Berlin-Brandenburg, here referred to as 'state court'), and, subsequently, at federal level (by the Federal Social Court, here the 'federal court').

Three questions were considered in the courts specifically: 1. Whether the GBA was entitled to set minimum volumes that are binding on hospitals; 2. whether the selection of services to apply minimum volumes to was in compliance with the law (i.e. SGB 5), especially whether these services were 'planable' (in the case of services for preterm babies) and whether there was sufficient evidence of a 'particular' causal relationship between volume and outcome; and 3. whether specific minimum volumes set were sufficiently justified by the GBA.

On the first question, the state and federal courts upheld consistently that the GBA was entitled and mandated by parliament to set binding minimum volumes; however, the courts emphasised that the GBA had to explain and justify such decisions, as do other bodies of the public administration (BSG 2012a).

On the second question, the federal court ruled that services are legitimately selected if they are 'planable' in the sense that they can be accessed without posing additional risks to patients, arising, for example, from longer journeys to (fewer) hospitals. In relation to care for very premature babies, the court argued, referencing national and international studies, that the benefits for mothers-to-be outweighed the risks associated with longer travel (BSG 2012a: para 43). The court thus rejected an interpretation of 'planable' as 'elective' or 'predictable', as both terms would not consider the balance of risks and benefits to patients (BSG 2012a: para 30).

The courts also referred to research to clarify the meaning of the law with regard to the 'particular' causal relationship between volumes and outcomes required by law to justify specific minimum volumes. In 2011, the state court ruled that a causal relationship could only be regarded as 'particular' if 'controlled studies' suggested a statistical relationship (LSG 2011: para 87). The state court thus aligned the wording of the law with the concept of the 'hierarchy of evidence' used in evidence-based medicine, which considers RCTs as the strongest research design to establish claims of causality.

This ruling was rejected by the federal court in 2012. The federal court argued that the law should not be interpreted as giving preference to particularly types of studies, especially since in the case of minimum volumes RCTs were neither practical nor ethical. Evidence from scientific studies would suffice if a causal relationship was 'probable and plausible' (BSG 2012b: para 31). However, such decisions would require additional support in the form of 'medical experience' (*medizinische Erfahrungssaetze*) (BSG 2012b: 39). Professional expertise is often used in court decisions. For example, courts can invite 'experts' (*Sachverständige*) to help establish 'the facts' or ask for written comment from organisations (*Stellungnahme*). The expectation is that experts, such as members of the medical profession, can bring together the collective wisdom of their profession, which includes knowledge from research as well as practical knowledge (Hase 2012). It is also seen as legitimate that courts assume that there is such collective wisdom without recourse to specific individuals or studies. In this respect the court deviated substantially from the earlier reference to the hierarchy of evidence, in which expert opinion would rank low (Evans 2003).

The third question discussed by the courts was whether specific minimum volumes determined by the GBA were sufficiently justified. The review of such justifications drew heavily on scientific evidence, although courts came to different conclusions about the level of justification needed for minimum volumes to be considered legal. For the state court in 2011, evidence was insufficient in the absence of experimental studies, which meant that the minimum volumes in question were unjustified (LSG 2011). Rejecting this ruling, the federal court argued – in line with its earlier reasoning – that minimum volumes were sufficiently justified if they were likely to improve outcomes, if the statistical association would be supported by 'medical experience' and if potential risks arising from minimum volumes (e.g. longer distances) would be outweighed by the potential benefits (BSG 2012b, 2014).

This weighing of risks and benefits led the federal court to come to different conclusions when considering specific minimum volumes. It argued that minimum volumes of 14 cases of very preterm babies per year were justified noting that 14 cases (roughly one per month) were sufficient to require the presence of a specialist team in a hospital. The existence of such a team would make quality improvements plausible. In a similar vein, it argued that 50 total knee replacements (roughly one per week on average) would be sufficient to require the hospital to employ a specialist team (BSG 2014, 2012b).

Using the same rationale, the federal court rejected minimum volumes of 30 per year for very preterm babies on the grounds that the higher threshold would increase the risks to those babies by excluding hospitals with lower volumes (but potentially providing good quality services) without increasing the benefits (BSG 2012b: para 60-61). It specifically cited four studies in support of this suggestion, one of which had been included in an earlier systematic review (i.e. by IQWiG) and another one had been rejected by the GBA in an earlier version and was co-funded by the hospital association (Kutschmann et al. 2012, GBA 2010). While these studies made valid points about the limited ability of minimum volumes to separate high from low performing hospitals entirely accurately, the ruling gave prominence to a few selected studies while disregarding all the others included in previous scientific reviews.

Both courts built their decisions on the legality of minimum volumes on considerations of the scientific evidence. However, they did so in different ways: The state court (initially)

argued for applying a model of evidence use based on the hierarchy of evidence, while the federal court stipulated that a combination of scientific plausibility and 'medical experience' were sufficient to justify minimum volumes. The latter reflects established legal practice applied in other rulings in which courts rely on a broad range of inputs, including from experts or organisations, to help them assess risks and benefits resulting from a decision. This way the court acknowledged the uncertainty that remained after considering the scientific evidence available, by bringing in other sources of legal evidence.

Courts also deviated from the rules on scientific evidence use in the way they used evidence systematically. While the overall approach to legal argumentation was highly systematic, the recourse to scientific evidence was in part selective, especially as this related to picking individual studies in support of a point (which is particularly relevant if this study turns out to be co-funded by a party with an interest in the case). On other occasions, in contrast, the use of evidence was highly generalised. For example, evidence reviews provided by IQWiG were are automatically considered valid under the 'legal presumption of correctness' (*Rechtsvermutung der Richtigkeit*) applied to public research bodies.

In sum, the analysis of court decisions suggests that scientific evidence was of key relevance to the legal adjudication on minimum volumes and to establishing whether specific minimum volumes set by the GBA were sufficiently justified in the eyes of the law. However, the methods applied by the courts in dealing with scientific evidence substantially differed from those suggested by proponents of evidence-based medicine (Evans 2003). Firstly, courts used existing evidence reviews but also drew on other sources of knowledge to assess the risks and benefits of minimum volumes. They thus acknowledged that the evidence base was too limited to justify specific minimum volumes. Secondly, they tended to use scientific evidence both by selectively picking individual studies and generically by relying on the presumption of correctness of reviews published by IQWiG. Both approaches differ significantly from the principles of systematic reviewing established in evidence-based medicine to which models of evidence based policy aspire.

Discussion and conclusion

This paper examined how the use of scientific evidence is influenced by the rules and practices associated with different institutional arenas, including parliament, the corporatist self-administration and the judiciary, using the introduction of minimum volumes in hospitals in Germany as a case study.

The analysis above shows that the role played by scientific evidence is complex, and varies between arenas. In the parliamentary arena, scientific evidence relating to minimum volumes seemed to have largely played the part of agenda-setter and idea-giver. Law-making, in contrast, was dominated by procedural concerns that mediated the influences of policy actors on legislation and provided democratic legitimacy.

In the corporatist arena, the formation of the GBA and IQWiG in 2004, changed the rules of the game significantly, with new procedures developed for, and applied to, scientific evidence use. Engagement with research had previously been dominated by the consensual arrangements characteristic of corporatist decision-making, with actors bringing research to the negotiating table they had commissioned themselves. Consensual arrangements have principally been maintained in the GBA, yet processes have become more rule-based, including as they relate to commissioning, conducting and using review of scientific evidence. This suggests that the use of scientific evidence has become a substantial aspect of the GBA's approach to legitimising its decisions in relation to minimum volumes.

The role of scientific evidence in legitimising decisions and, by extension, organisations mandated with decision-making chimes with earlier studies on the functions of scientific knowledge in policy and advisory organisations. Boswell (2008), for example, argued that scientific knowledge plays a key role in substantiating and legitimating the role of the European Commission in immigration policy, a field that is considered highly contested. A similar observation was made by Bijker and colleagues (2009) in their study of the *Gezondheidsraad* in the Netherlands. This transfer of authority from science to policy works (somewhat paradoxically) despite the fact that society has become increasingly sceptical of the ability of research to reduce risks and uncertainty (Weingart 1999). The analysis of the role of the GBA also echoes findings that emphasise the negotiated nature of decisions (Etgeton 2009), with findings from this case study suggesting that policy actors that are constituent members of the GBA also engage in strategic uses of evidence to support their claims and promote their interests.

Some have argued that corporatist bodies such as the GBA are particularly well placed for taking potentially unpopular decisions in contested policy fields, for example, service exclusions from the public benefits package (Gerlinger 2010). However, these decisions often end up in court with much of the legal argument concerning the validity of scientific evidence (e.g. on pharmaceutical effectiveness). This analysis has shown that evoking the authority of scientific evidence is unlikely to make substantive disagreements disappear. It also suggests that the policy process – traditionally assumed as being orientated towards corporatist consensus – has evolved and become more adversarial when actors affected by decisions (e.g. hospitals) take the corporatist decision-maker to court.

Social courts developed their own approaches to engaging with the scientific evidence relating to minimum volumes. For example, they presumed evidence reports by IQWiG to be correct wholesale and stretched the limits of evidence by invoking the support of general but unspecified 'medical experience'. The courts thus transformed scientific evidence into legal evidence by unquestioningly reducing studies to their findings, ignoring the methodological limits and debates associated with them.

Courts also reframed the case of minimum volumes as an assessment of the balance of risks and benefits to decide on their legality and legitimacy. However, by doing so courts brought two principles of evidence use into collision, with systematic approaches to reviewing evidence (provided by IQWiG) that tended to suggest benefits of minimum volumes(through improving outcomes) being overturned by a selective use of single studies emphasising potential risks (arising from longer travel distances). Jasanoff, in her early work, already pointed to the limits of judicial ability to judge complex scientific cases (Jasanoff and Nelkin 1981). Specifically, she argued that claims to scientific objectivity evoked by courts can run into problems if decisions are characterised by substantial uncertainty about risks and benefits. The case of minimum volumes, with its incomplete and ultimately inconclusive evidence base, demonstrates again that conflicts between policy actors in areas of uncertainty cannot be resolved by scientific evidence alone.

The above analysis has shown that each institutional arena has different rules of using (or not using) scientific evidence. Scientific evidence has been used to promote, contest and justify decisions, with little suggestion of a single (national) style of evidence use. Scientific support was crucial for decisions of the GBA and has become more important over time,

although it is argued here that this only applies to specific (clinical or similar) decisions within its remit. A similar transfer of scientific authority was undertaken by courts, although this was tempered by other (legal) constructs of evidence and expertise used to assess risks and benefits associated with minimum volumes. This is somewhat in contrast with observations of evidence as agenda-setter in the parliamentary process and the demand for evidentiary support for the purpose of promoting organised interests.

The policy process analysed here arguably does not tell the entire story of minimum volumes, as it focuses on three specific stages of decision-making while largely ignoring the dynamics of agenda-setting prior to the parliamentary debate, and the actual impact of minimum volumes in practice (de Cruppé, Malik, and Geraedts 2014, Peschke, Nimptsch, and Mansky 2014). The boundary drawn between arenas is also in part artificial as feedback loops exist between arenas, which means that processes may not always be sequentially aligned. Court decisions, for example, tend directly affect how the GBA goes about making decisions in future. Meanwhile, sickness funds have asked parliament to change the wording of the law to reduce the requirement on evidentiary support for minimum volumes (Leber 2014). It is also unclear how the principles developed by the courts – i.e. justifying a certain volume by its potential for requiring the presence of a specialist team – can be applied to minimum volumes of other services.

Given the complexity of these rules and procedures the policy process as a whole has been lengthy and arduous, and is likely to perform better against measures of democratic accountability than procedural efficiency. The case of minimum volumes also provides a cautionary tale of the challenges of scientific evidence use in institutionally complex environments such as health policy-making in Germany.

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Table of key organisations and committees

German	English	Function
Ausschuss Krankenhaus	Hospital Committee	Committee representing hospitals and sickness funds, mandated with decision-making for the hospital sector before 2004
Bundesrat	Federal Council	Chamber of parliament representing elected political parties
Bundestag	Federal Assembly	Chamber of parliament representing the governments of the states (*Länder*)
Deutsche Krankenhausgesellschaft	German Hospital Association	Federal-level association of hospitals
Gemeinsamer Bundesausschuss (GBA)	Federal Joint Committee	Top decision-making body of the corporatist self-administration in health care, since 2004
Gesundheitsausschuss	Health Committee	Parliamentary committee, preparing health related legislation for the *Bundestag*
Vermittungsausschuss	Mediation Committee	Parliamentary committing, mediating between *Bundestag* and *Bundesrat*