Government and Opposition, Vol. 51, No. 4, pp. 632–660, 2016
doi:10.1017/gov.2014.37
First published online 24 November 2014

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Strategic Institutional Design: Two Case Studies of Non-Majoritarian Agencies in Health Care Priority-Setting

Governments' decisions to delegate policy decisions to non-majoritarian agencies have been both criticized as attempts at blame avoidance or depoliticization and defended as enhancing the rationality and credibility of decisions. This article focuses not on the decision to delegate, but on the decisions of how and to whom to delegate. We argue that strategic motives are relevant not only in the decision to delegate, but equally, and perhaps more importantly, in the selection of the institutional properties of these non-majoritarian agencies. We present two case studies of health care priority-setting, in England and Germany, to illustrate how governments proceed strategically in institutional design choices and how their decisions affect outcomes.

THE DELEGATION OF POLICY DECISIONS FROM MAJORITARIAN INSTITUTIONS to independent agencies has become increasingly prevalent in political practice and an intensely researched subject in the last three decades (see, for example, Gilardi, 2008; Majone 1997; Thatcher and Stone Sweet, 2002, 2003; for a review article, see Flinders 2009). While some authors have defended or even appreciated delegation as a route to less myopic, more rational and more credible decisions, others have criticized it, pointing to problems of blame avoidance, depoliticization and an evolving 'expertocratic' regime. Early on in the discussion, Giandomenico Majone (1997: 152), in describing the shift from the 'positive' to the 'regulatory' state, argued that delegation was particularly appropriate for regulatory decisions, where 'expertise and reputation are the key to greater effectiveness' while redistributive decisions should remain under the control of elected governments.

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However, the distinction between regulatory and redistributive decisions was always one to be taken at the analytical rather than at the empirical level, and it is becoming increasingly blurred in the face of the growing complexity of the contexts in which policymaking takes place. To name but one example: apparently purely regulatory decisions to deregulate the American banking sector and trade with financial derivatives clearly seem to have had redistributive consequences when viewed in light of the financial crisis.

If we assume competing political parties to take different stances on the distribution of scarce resources in a society and to promote different interests, the decision to delegate policymaking to a non-majoritarian agency must clearly be viewed as having distributive aspects. Redistributive decisions can have high electoral costs, and as Kent Weaver (1986) has pointed out, these costs constitute a strong motive to delegate decision-making in order to avoid blame for unpopular decisions. As Sandra van Thiel (2004: 183) argues, 'benefits from reduced ministerial responsibility . . . will appeal to *all* politicians, irrespective of their ideological preferences'. However, governments are unlikely to give away too much control in any policy area and will keep agencies at arm's length in order to retain some control over their policy output. The easiest way to maintain such control is by building in a duty to obtain consent from the responsible ministry. Requiring ministerial consent, though, can undermine attempts at blame avoidance through delegation. We may therefore expect that governments (with strong incentives to delegate and depoliticize) will nonetheless tailor the set-up of non-majoritarian bodies in a way that furthers the governments' own policy goals.

The following section will provide a brief overview of the literature on delegation and institutional design choice and will formulate some expectations of why, when and how governments will manipulate the institutional design of non-majoritarian agencies in order to further specific policy goals. Following a brief description of our case selection and methodology, we present case studies of the development of institutions in health care priority-setting in two countries: England and Germany. As highly industrialized democracies, the two countries face very similar challenges in controlling health care expenses but display quite different institutional designs. We will show that the changes in government that each of the two countries has experienced in the last decade has led to increased reform activity with regard to the institutional design of these

agencies, resulting in structures that – to different degrees – further the policy goals of the respective governments. The discussion compares the results and analyses differences and similarities before the conclusion winds up the argument.

THEORY: STRATEGIC MOTIVES IN DELEGATION

Since the 1990s, governments in highly developed democracies have increasingly chosen to delegate tasks to specialized agencies. These agencies enjoy only indirect democratic legitimacy as they are not elected, and they are placed at arm's length (Taylor 1997) from governments and not subject to administrative hierarchies. The increasing significance of these agencies has led to a growing body of academic literature on the subject of delegation, with authors labelling them 'non-majoritarian institutions' (Majone 1996), 'independent regulatory agencies' (Thatcher 2002) or 'quangos' – quasi-non-governmental agencies (van Thiel 2001). The positive view on delegation that is expressed by Thatcher and Stone Sweet (2003), in Majone's earlier writings (1996, 1997) or, from a background in democratic theory, by Pettit (2003) has in recent years more frequently been countered with arguments that present delegation as a trend towards a post-democratic political order (Crouch 2004), towards depoliticization (Flinders and Buller 2006; Wood and Flinders 2014) or as a symptom of the crisis of representation and party democracy (Mair 2013). Despite undeniable legitimacy problems, non-majoritarian agencies in nation states operate within the 'shadow of politics' (Schmidt 2013: 10). At the supranational European level, however, things are even more complex, with the evaluation increasingly moving from a positive perspective that depicts committees as forums of inclusive and rational deliberation (Joerges and Neyer 1997) towards a more balanced (Groenleer 2009) or even highly critical one, with Peter Mair (2013: 126) going so far as to argue that the EU with its committees and agencies has been deliberately built by elites as a house 'without any substantial room for either politics or parties'.

How can governments' decisions to delegate substantial tasks to non-majoritarian agencies be accounted for? Two hypotheses are dominant in the literature: the complexity hypothesis views delegation as a reaction to increasing complexity and information

requirements, while the temporal consistency or credibility hypothesis argues that non-majoritarian agencies enable governments to make credible commitments in the face of electoral pressures and the temptations that come with these (see Majone 1996). Elgie (2006; see also Gilardi 2002) finds accumulating empirical support for these hypotheses but concedes that they are more suitable for quantitative testing than competing ones that entail strategic motives – although his own qualitative work also confirms them. Apart from such methodological biases, however, there may be a more fundamental reason behind the positive perspective on delegation that connects with these hypotheses, to which Terry M. Moe (2005) draws our attention: in the dominant tradition of rational choice institutionalism, institutions are viewed as structures of voluntary cooperation that enable Pareto-efficient solutions. This view ignores the fact that institutions are also structures of power and that those in power 'can legitimately use public authority to impose bureaucratic institutions that are structurally stacked in their own favour, and that make the losers worse off, perhaps by a lot' (Moe 2005: 218; see also Knight 1992).

A revived focus on power in the context of delegation and institutional design brings another hypothesis to the fore, which Elgie (2006: 208) terms the 'uncertainty hypothesis': in the knowledge that they may not be re-elected, governments may choose to delegate in order to 'prevent their political opponents from controlling the policy-making process when they take power'. As Wonka and Rittberger (2010: 737) argue, the establishment of non-majoritarian agencies 'enables ruling coalitions to institutionally "freeze" or lock in their preferred policy status quo and cater for their constituencies' interests beyond their term in office'. Following Moe's argument (2005: 221) that in systems with multiple veto players institutions are more easily created than removed, the decision to delegate thus becomes a strategic move.

Although quantitative studies by Gilardi (2005) and Wonka and Rittberger (2010) find considerable support for the uncertainty hypothesis in quantitative studies of national and EU agencies, respectively, and Elgie (2006) finds at least limited support in a qualitative analysis of two French agencies, the uncertainty hypothesis remains under-researched in comparison to the more prominent complexity and credibility hypotheses, in particular where the institutional design of non-majoritarian agencies rather than the decision to delegate is concerned. As noted before, this is probably due to the biased view of institutions as cooperative structures in rational-choice

institutionalism (Moe 2005) and to a methodological bias that results from the fact that an assessment of the uncertainty hypothesis requires more in-depth qualitative analysis of political actors' preferences and details of institutional design. We therefore intend to add to the literature by spelling out more specific expectations for strategic institutional design choices on the basis of the uncertainty hypothesis. In the second part of the article we undertake a qualitative analysis of non-majoritarian institutions in the same policy area (health care priority-setting) in two countries (England/Wales and Germany), thus seeking to explore the moderating effect of different institutional contexts and political systems on strategic institutional design choices.

Assuming that political uncertainty provides a motive for governments to lock their policy preferences into institutional structures, which institutional properties and procedural regulations of non-majoritarian institutions may be subject to strategic manipulation? The following list may still be incomplete, but in our eyes substantially widens the focus on institutional design:[1]

Default Setting

As Elinor Ostrom (1986) and Fritz Scharpf (1989) have pointed out, the way the default is set has significant consequences on negotiations and resulting outcomes. The default outcome is the outcome if no decision is taken. Accordingly, changing the default outcome of the decision-making procedure within an agency may practically reverse its entire logic. Examples that will be elaborated on in the case studies below are positive and negative lists of reimbursed drugs and medical services. Positive lists comprise all drugs or services that will be reimbursed, while negative lists define drugs or services that are not covered by the public health care system. In the case of positive lists, the default is negative: a drug or service will not be covered unless a positive decision is taken. With negative lists, the default is positive: the particular item is reimbursed if no decision is taken. The default will obviously have an effect on the range of drugs and services covered: if it is negative (a positive list), the range covered will be wider than if it is positive (a negative list). For an agency and for its public perception, it clearly makes a major difference whether it is to decide on the exclusion of a drug from the health basket or on its inclusion. For appointing governments, changing the default seems an attractive option to reprogramme institutions; its

significance is far from self-evident, which is why public opinion may fail to recognize it. Unless transaction costs are considered, it may not seem to make much of a difference whether positive or negative decisions are required. On a closer look, however, it becomes clear that changes (particularly from a negative to a positive list) can be rather costly and path dependencies difficult to overcome (for example, physicians used to a high degree of discretion in the choice of treatments might try to undermine restrictive positive lists).

Transaction Costs

The desire to limit transaction costs for decisions in systems with multiple veto players has been discussed as a central motive for the establishment of non-majoritarian agencies (Majone 2001; see also North 1990). However, transaction costs are also a central aspect of the institutional design of agencies themselves. Transaction costs for decisions within an agency will be higher if the group that is to take a decision is larger and if the interests and perspectives represented in it are heterogeneous. They will also be higher if the decision rule stipulated in the internal rules of procedure demands unanimous decisions or super-majorities. Transaction costs can be manipulated by appointing new members to a decision-making body or by reducing the number of members, or they can be manipulated by increasing or reducing the number/share of votes required to take a decision. The outcome effects of transaction costs clearly depend on the default setting, which is why these aspects must be viewed as interdependent.

Appointment of Chair and Board Members

If the appointing government maintains the authority to appoint agency staff, the selection of an agency's chair and board members is perhaps the most obvious strategy for the government to influence its policy decisions. Chair and board members can be chosen with regard to their known or secret party affiliation and policy preferences or, especially in expert committees, with regard to their belonging to a particular discipline or school of thought. However, replacing a chair already in office can be tricky for governments. A replacement that is obviously politically motivated can undermine

an agency's credibility and calls its independence into question. Incoming governments may thus be expected to refrain from too early replacements and to engage in negative campaigning behind closed doors rather than direct challenges.

Independence

Non-majoritarian bodies may be more or less independent from the government that appoints them and from their regulatees. The more independent an agency is, both statutorily and in its resources and discretion over its own organization and rules of procedure, the smaller is the government's ability to influence decisions. At the same time, delegation to an independent agency provides more opportunities for blame avoidance. In general, it seems more likely for an incoming government to restrict than to increase the independence of an agency: if a highly independent agency was set up by a previous government with different policy goals, it is likely to be programmed towards those policy goals and more or less beyond the new government's control. However, restrictions to the independence of an agency are likely to meet with resistance from the agency itself, and agency members might mobilize veto players successfully. If a government seeks to enhance the credibility of policy decisions and/or opportunities for blame avoidance through delegation, the most rewarding strategy thus seems to be to establish a new agency.[2]

Competences

If a government chooses to delegate tasks to a more or less independent agency, it can equip this agency with more or fewer competences, ranging from mere recommendations to immediately binding decisions. When a new agency is granted specific competences or an existing agency is deprived of competences or even completely abolished, respective decisions will be comparatively noticeable to the public and open to challenges from opposition parties. Nonetheless, incoming governments may try to pursue their particular policy goals by re-tailoring the competences of appointed agencies. In particular, competences of an obstinate but popular agency are likely to be restricted, while competences of a partisan agency may be extended, especially if the agency provides opportunities for blame avoidance in a 'thorny' policy area.

Transparency and Publicity

Ensuring accountability through publicity and transparency is first and foremost a normative requirement of democratic legitimacy. Apparently, the more politically salient the issues an agency deals with are, the higher accountability has to be in order to make its decisions publicly acceptable (Koop 2011). With regard to the institutional design of non-majoritarian bodies, though, the selection of procedures and mechanisms that increase or decrease the degree of transparency and publicity that is realized also has strategic implications. In general, publicity may be assumed to make compromises more difficult and to draw public attention to pending unpopular decisions, thus increasing transaction costs. If an incoming government seeks to restrict the power of an existing agency, increasing its transparency and publicity can be a comparatively easy way to prevent unwanted decisions.

As delegation is hardly a new phenomenon these days, incoming governments will in most cases be confronted with existing delegative institutional structures. Although reversing delegation is always an option, it is not so much the decision to delegate itself that is at stake. Rather, the new government may be expected to assess existing delegative structures for their effects and revise them in accordance with its own policy goals. However, having listed potential working points for strategic institutional design, we should be careful not to deny that governments may have non-strategic and more reputable motives altogether. To begin with, it is important to note that the effects of institutional design are themselves subject to much uncertainty. To some extent, uncertainties may be reduced by experience or academic research, but to a significant degree they will persist: interaction effects not only between institutional parameters of appointed bodies, but also between these parameters and the surrounding institutional structure and regulatory context can make effects unpredictable. Moreover, as Anthony Bertelli (2006) has shown, governments have conceptions of what good and credible government amounts to that they may seek to realize through institutional design. As these conceptions vary between different political parties, the question of who is in power makes a difference for institutional design without rendering choices strategic in the narrow sense. Finally, it would be cynical to assume that governments always and only assess institutions for their outcome effects.

Procedural values, such as transparency or accountability, are likely to be of importance as well. Even if they do not outweigh strategic considerations, the popular support they enjoy will restrict governments' scope for action. Under conditions of uncertainty in particular, normative reasons for institutional design choices (such as enhancing accountability and transparency) may win the day, as their categorical logic makes decisions easier.

In light of these different potential motives for institutional design choices, our strategy will be to link the competing complexity and credibility hypotheses to a null hypothesis, namely that governments select institutional parameters of non-majoritarian agencies under purely functional considerations, seeking to find the best solution to a given governance problem. In so far as our case studies reject the null hypothesis, we may assume that other, possibly strategic, considerations play a role in institutional design choices.

CASE SELECTION AND METHODOLOGY

In order to explore strategic institutional design choices in the set-up of non-majoritarian agencies, we conduct in-depth qualitative case studies of agencies within the same policy area, but in different countries. The agencies we will look at are engaged in the appraisal of new medical technologies (drugs and treatments) for funding in public health care systems: the National Institute for Health and Care Excellence (NICE)[3] in England and Wales and the Federal Joint Committee (FJC) in Germany.[4] Agencies of this type have been set up in most OECD countries in the past two decades, with their establishment commonly interpreted as a reaction to rising cost pressures caused by progress in medical research and technology (see, for example, Ham and Robert 2003; Landwehr and Böhm 2011; Sabik and Lie 2008). Both the National Institute for Health and Care Excellence and the Federal Joint Committee are formally independent in their day-to-day business, but the ministry (in England until 2012) or the parliament (in Germany, and England since 2012) can change the institutional set-up of the bodies (for example, their composition, task, funding) at any time.

By choosing agencies that deal with the same tasks, we keep the functional requirements (managing complexity and enabling credibility) stable. Our independent variable in the assessment of strategic

institutional design choices is the governments' policy preferences, which come to bear when elections result in new majorities. Both countries have seen changes in government during the period of observation, with a centre-right government succeeding a centre-left government in the UK as well as in Germany. Our dependent variable is changes in the institutional design of the respective agencies initiated by governments. If strategic intentions and choices can be established and the null hypothesis can thus be rejected, a further and equally interesting question concerns the moderating effect of the institutional context on strategic institutional design: are some political systems more vulnerable to strategic motives in institutional design than others? The study involves two quite different political systems, with the British Westminster system being characterized by strong governmental sovereignty and few veto points, while the German system is veto ridden and reforms are not easily realized. How far these different institutional contexts affect the possibility and direction of strategic institutional design choices will be addressed in the discussion.

The case studies presented below describe institutional reforms and ministerial interventions into the work of the particular committees from the year of their establishment (1999 and 2004) until 2013. The case studies are based on a comprehensive analysis of relevant regulations and legal reforms, and on several interviews with members of the particular committees conducted by the authors during 2011 (Germany) and 2012 (England). The interviews were conducted in the context of a larger research project that examines the influence of the institutional design of agencies on resulting decisions.

CASE STUDY ONE: THE NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE, ENGLAND

The National Institute for Health and Care Excellence was set up in 1999 by Tony Blair's Labour government, which had come into office in 1997. Improving service standards in the National Health Service (NHS) had been a central theme in Blair's election campaign: although and partly *because* the National Health Service was and is extremely popular with the British public, dissatisfaction with its performance was also extreme. The National Health Service was not

only underfunded but, in consequence of its decentralized organization, the level and quality of services varied widely between areas. 'Postcode rationing', as this is known, was not a new problem, but the new government was no longer willing to live with these differences (Klein 2010: 197). The National Institute for Health and Care Excellence was therefore given the mission of improving standards of service provision through clinical guidelines and to set a national standard of services local authorities (primary care trusts, PCTs) had to provide. In particular, the statutory instrument SI 1999/260 demands that the National Institute for Health and Care Excellence set up a Technology Appraisal Committee (TAC) whose task it is 'to advise the Institute on such matters relating to the use of new and existing technology in the health service' (reg. 9(1)(b) SI 1999/260).[5] To do so, the National Institute for Health and Care Excellence is 'to appraise the clinical benefits and the costs of such health care interventions as may be notified by the Secretary of State or the National Assembly for Wales and to make recommendations' (reg. 2(1)(a) 1999 Directions).[6]

Regarding the *default*, primary care trusts used to be free to decide which services to provide. Given the shortage of resources, however, primary care trusts were and still are unlikely to fund high-cost medical services unless required to do so. The default for the coverage of these services must therefore be regarded as negative. In 2001 in Blair's second term in office, primary care trusts became obliged to fund health care interventions that are recommended by the National Institute for Health and Care Excellence in a Technology Appraisal Guideline within three months of publication of the respective recommendation. While establishing a positive entitlement to specified services, this new regulation also (at least implicitly) rendered the negative default explicit. While thus strengthening the role of the National Institute for Health and Care Excellence, the government repeatedly bypassed negative recommendations – for example, through establishing risk-sharing schemes with manufacturers for drugs used in the treatment of multiple sclerosis. The newly elected Conservative/Liberal Democrat coalition government under David Cameron was even more radical in bypassing recommendations by the National Institute for Health and Care Excellence. In particular, it established a cancer drug fund to provide patients with access to high-cost cancer drugs even if these were not recommended by the National Institute for Health and Care Excellence and not funded

by the respective primary care trusts. Accordingly, the negative default for high-cost cancer drugs has been softened considerably.

The high number of 506 (as of September 2013) technology appraisals produced by the National Institute for Health and Care Excellence committees since 2000 indicates that transaction costs in the committees are reasonably low. With up to 30 members each, the (now four) committees are large and heterogeneous, representing different societal and interest groups. The possibility of majority voting enables decisions even when the committee is split. According to Technology Appraisal Committee members, however, majority decisions are rarely necessary, as informal pressures typically enable consensual decisions.[7] The fact that final decisions are taken behind closed doors may contribute to making speedy and expedient assessments possible.

The secretary of state is responsible for the appointment of the National Institute for Health and Care Excellence chairman and those board members who are not employed by the institute, and also determines their term of office. The National Institute for Health and Care Excellence officers and Technology Appraisal Committee members are appointed by the National Institute for Health and Care Excellence. Remarkably, both the Labour and the subsequent Conservative/Liberal Democrat governments have evidently chosen not to employ their considerable powers in the appointment process strategically. The governments' reluctance to do this is in keeping with a general increase in competences that the National Institute for Health and Care Excellence has experienced since 1999. Not only have primary care trusts become obliged to fund treatments and drugs recommended by the National Institute for Health and Care Excellence Technology Appraisal Committees, but Labour also extended the National Institute for Health and Care Excellence's role to provide advice on public health issues in 2005 (reg. 3(b) SI 1999/220 as amended by SI 2005/497). The coalition government continued expanding the institute's competences and commissioned it to provide guidance on social care in 2013 (Health and Social Care Act 2012).

Furthermore, the National Institute for Health and Care Excellence was to play a central role in establishing a value-based pricing process that Secretary of State Andrew Lansley intended to introduce. The new government wanted to abolish the obligation for primary care trusts to fund treatments and drugs positively appraised

by the National Institute for Health and Care Excellence Technology Appraisal Committees. The Health and Social Care Bill allowed for the newly established general-practitioner-led clinical commissioning groups to decide locally which services to provide for their patients. During the consultation process, however, it became clear that general practitioners did not want to be involved in funding decisions because they did not want to be responsible for denying patients access to treatment (Gulland 2013). A further obstacle to the abolition of compulsory funding seems to have been the National Health Service constitution, which grants every patient the right to receive drugs and treatments recommended by the National Institute for Health and Care Excellence. Not only have the National Institute for Health and Care Excellence Technology Appraisal Committee recommendations remained binding, but the government even further expanded the institute's competences in defining National Health Service services: it was additionally charged with assessing medicines targeted at treating rare diseases that involve complex needs and for this purpose established a Highly Specialized Technologies Evaluation Committee (HSTEC). Positive recommendations by this committee must be funded centrally by the National Health Service Commissioning Board, now called NHS England, within three months (reg. 8 SI 2013/259).

The strong status of the National Institute for Health and Care Excellence within the National Health Service is supported by its high degree of statutorily and practical independence both from the government and from its regulatees. The National Institute for Health and Care Excellence could, from the beginning, make its own standing orders for the regulation of its proceedings and business (reg. 11(2) SI 1999/260). Subject to these standing orders, any subcommittees, including the Technology Appraisal Committees, can make their own regulations concerning, for example, the quorum, proceedings and place of meeting. Originally, topics for guidance were determined by the Department of Health (DoH), although the National Institute for Health and Care Excellence could propose topics (National Institute for Clinical Excellence 2000: Annex C, Annex B no. 3). The Department of Health can also ask the National Institute for Health and Care Excellence to review guidelines (National Institute for Clinical Excellence 2000: Annex B no. 6). Subsequent reform[8] under the second Blair government further strengthened the institute's independence: since 2005, publication of

recommendations and guidelines no longer requires the approval of the secretary of state, and since 2006 the first part of the topic-selection process is carried out by the National Institute for Health and Care Excellence and only the second part remains with the ministry.

In a strongly majoritarian and centralist political system such as the British one, which provides limited opportunities for blame shifting, governments apparently value the existence of a widely recognized independent agency and thus have motives to refrain from strategic interference. As one board member notes:

> They [the government] are aware that it's helpful to have an independent body taking these decisions on their behalf and that to start trying to interfere is going to backfire – if you like – on them. They benefit from having an organization like NICE that takes the decisions. So in the headlines in the press, it's about NICE's decision and it's not about the government's decision that nobody likes. So it is to everybody's benefit to ensure that it is NICE operating independently.[9]

Since 2013, political influence is even explicitly prohibited by a statutory instrument which states that '[t]he Secretary of State must not give a direction . . . about the substance of a technology appraisal recommendation' (reg. 7(14) SI 2013/259). Interestingly, the Cameron government has further increased the National Institute for Health and Care Excellence's independence by changing its status from a National Health Service Special Health Authority into a non-departmental government body. With the Health and Social Care Act 2012, any substantial reform of the National Institute for Health and Care Excellence, including its abolition, is no longer at the discretion of the secretary of state but needs parliamentary approval.

The status of the National Institute for Health and Care Excellence is also supported by the considerable degree of external credibility that it has gained through low-threshold interaction with patients and the public and by making its recommendations accessible and comprehensible. Transparency has always been a particular focus of the National Institute for Health and Care Excellence, with part of the Technology Appraisal Committee meetings being opened to the public soon after its establishment. Although it must be noted that transparency and stakeholder involvement can also be employed strategically to divert attention from actual decisions and to gain public acquiescence, there is no evidence that changes in the degree of transparency realized by the National Institute for Health and Care Excellence have been undertaken with strategic intentions.

CASE STUDY TWO: INSTITUTIONS IN HEALTH CARE PRIORITY-SETTING IN GERMANY

In the German social insurance health care system, priority-setting or rationing of medical services have long been less significant topics. In 1998, however, after Helmut Kohl's centre-right government had been voted out of office after 16 years, the new centre-left government led by Gerhard Schröder approached the health care sector with ambitious plans and undertook a number of institutional reforms. Influenced by the example of the National Institute for Health and Care Excellence in England, the Schröder government set up an expert institute that was to provide reports on controversial medical services in 2004: the Institute for Quality and Efficiency in Health Care (IQWiG). Originally, the institute was designed to be independent from the self-governance bodies of the social health insurance which were obliged to take the recommendations of the new institute into account when deciding on the coverage of services (Bundestag-Drucksache 15/1170: 29ff.). The resistance of providers, manufacturers, health funds and the parliamentary opposition, however, caused a complete restructuring of the institute's design and functions. The new institute now was to advise a corporatist body with responsibility for coverage decisions, the Federal Joint Committee. The Federal Joint Committee was founded in 2004, joining four separate forums in which health funds and service providers had been engaged in specifying the public health care basket which is only generally defined by the Social Code Book V.

Regarding the provision and reimbursement of medical services, the default has traditionally been positive in Germany. Up until the 1990s, new technologies rarely underwent critical assessment before being made accessible to patients. For in-patient services, hospital doctors still have discretion to make use of any technology available on the market unless it has explicitly been excluded from coverage. Since 2003, however, hospitals operate under the restrictions of diagnosis-related groups (DRGs), meaning that limited budgets raise pressures to engage in implicit rationing. For out-patient services (provided both by general practitioners and specialists), new therapies can be provided only after a positive decision of the Federal Joint Committee, so that the default is negative in the field of ambulatory medical care. A major reform package in 1992 entailed the introduction of a positive list for pharmaceuticals, which would have

rendered the default negative. Although the respective law[10] passed both chambers of parliament, it was never implemented by Kohl's conservative government.

After winning the 1998 elections, the new red–green government coalition brought the positive list for drugs back on to the agenda. Regulations concerning the introduction of a positive list were legislated in 1999. The concrete positive list passed the German Bundestag in 2003 (Bundestag-Drucksache 15/800). By then, however, the government had lost its majority in the Bundesrat (the federal chamber), where an opposing majority blocked the law. In 2005, Chancellor Schröder called snap elections, leading to a grand coalition government led by Angela Merkel. Given that the social and Christian democratic parties in the grand coalition were deeply divided over health policy, and that it had been a hotly debated point of dissent in the election campaigns, the new government did not include the controversial issues in its reforms.

Merkel's Christian Democrats won the 2009 elections and could form a coalition with an unusually strong Liberal Party that had won nearly 15 per cent of the votes. The traditionally pharma-friendly Liberal Party had little incentive to change the status quo. In face of the financial and economic crisis since 2007 and the rising costs of drugs, however, the debate on priority- and limit-setting gained some momentum even in Germany. In 2010, the government made an apparently surprising move. The Ministry of Health, led by Philipp Rösler of the Liberal Party, worked out a law on the regulation of the market for pharmaceuticals (Arzneimittelneuordnungsgesetz, AMNOG)[11] that seemed seriously to violate the interests of the pharmaceutical industry. According to the new law, any new pharmaceutical is subjected to an assessment process that is to determine the additional benefit of the new drug. Following the assessment, manufacturers – for the first time in German history – have to engage in price negotiations with the health funds. If negotiated prices fall short of manufacturers' expectations, the low price will have adverse consequences even beyond the German market, as the German market price serves as the reference for negotiations (or prices) in most other countries. At a second glance, though, the introduction of value-based pricing for drugs through the regulation is less surprising. At the time the law was drafted, the centre-right government had lost support, with polls showing a majority for the red–green opposition. With economic crisis still looming, fears that a future government

would take more decided steps towards explicit rationing by introducing a positive list were thus justified. The pharmaceutical industry's extraordinarily diffident criticism of the law on the regulation of the market for pharmaceuticals further indicates that this strong lobbying power was not fundamentally opposed to the law but rather preferred it to the alternative of introducing a positive list. If at least moderately successful in controlling expenses for drugs, the value-based pricing scheme would be unlikely to be removed by any subsequent government.

The establishment of the Federal Joint Committee in 2004 by the red–green government had reduced transaction costs in negotiations between health funds and service providers by breaking the tie of votes with an uneven number of members in committees and by having them chaired by three experts. Given the antagonistic interests of the two 'benches' (the health funds and providers), a tie of votes had before rendered transaction costs high. In 2007, the grand coalition significantly expanded the scope of functions of the Federal Joint Committee and at the same time restructured its institutional set-up in order to 'achieve a more efficient use of staff and tangible means as well as faster decision-making' (Bundestag-Drucksache 16/3100: 178, authors' translation). The formerly four decision-making committees were abolished and decision-making power was concentrated within a central committee. In addition, the number of members with voting rights was reduced from 21 to 13, and meetings were opened to the public. Under the new centre-right government that had come into office in 2009, however, a fundamental reform of the decision rule was passed in 2011,[12] requiring decisions to exclude a drug to win a majority of nine out of 13 votes – meaning that they have to be supported by members of both benches (service providers *and* health funds). The new rule increases transaction costs to a degree that decisions to exclude a medical service or drug from coverage become highly unlikely. In this case, the government may have foreseen that protests against increasing majority requirements would be comparatively unlikely to occur.

What was somewhat more startling to the public than the changes in decision rules were strategic appointment decisions taken by the centre-right government in 2009/10. Since its establishment in 2004, the Institute for Quality and Efficiency in Health Care (charged with preparing assessments of controversial drugs) had been chaired by Peter Sawicki, a specialist in internal medicine who was known to be

sceptical of pharmaceutical innovations and influenced by the Cochrane Foundation's approach on evidence-based medicine. Under Sawicki's chairmanship, the Institute for Quality and Efficiency in Health Care had published several reports that recommended not covering particular new drugs; among these were several drugs for patients with diabetes. According to many newspaper reports, an internal paper under the title 'Key Demands for Black and Yellow [the colours of the Christian Democrat and Liberal parties in Germany] Health Policy' asked that Sawicki was replaced as chair of the institute. Sawicki's term in office was due to end in 2010, but his contract was expected to be renewed. Allegedly, the new health minister, Philipp Rösler of the Liberal Party, commissioned an auditing firm with a critical assessment of Sawicki's expenses (Sieber 2010). The auditors found irregularities with regard to Sawicki's company car, and these served as justification for his contract not to be renewed, although a legal opinion did not confirm the accusations. In September 2010 Jürgen Windeler was appointed as the new chair of the Institute for Quality and Efficiency in Health Care. According to newspaper sources, even the chancellor's offices were involved in Sawicki's dismissal.[13] It must be noted, however, that although less distinguished in this regard than Sawicki, the new chair Windeler was not uncritical of the pharmaceutical industry either.

Changes also took place at the top of the Federal Joint Committee (the committee in charge of taking actual coverage decisions) after the centre-right government had come into office. In 2012, Josef Hecken succeeded Rainer Hess, who had chaired the committee since its establishment and was, after two terms in office, stepping down at the age of 71. The new chair, Hecken, was a career politician and member of the Christian Democrats. Although his appointment was certainly in keeping with the centre-right government's preferences, it remains to be seen whether it will have significant effects on the Federal Joint Committee's decisions, in particular given the increased majority requirements (see above). What is remarkable is the fact that shortly before Hess's term of office drew to a close, the government changed the appointment procedure for the Federal Joint Committee's expert members. Formerly, providers' associations and health fund associations had the right to appoint new expert members jointly, and the task was only passed on to the ministry if the two benches could not reach an agreement on a candidate. Under the new regulation, provider and health fund associations are still

allowed to nominate candidates, but the independence of the candidates is to be confirmed by the health committee of the German Bundestag.

The Federal Joint Committee's competences seem to have steadily increased since its establishment in 2004. In particular, the committee's role in limiting the range of services covered by the health funds was extended. The law that established the Federal Joint Committee[14] determines that the committee can exclude services from coverage if clinical effectiveness, medical necessity or cost effectiveness are not confirmed (§ 92(1) SGB V). Since 2006,[15] the Federal Joint Committee may exclude pharmaceuticals from coverage if they are 'inexpedient or if another, more cost-effective, treatment with comparable diagnostic and clinical utility is available' (§ 92(1) SGB V 2006, authors' translation). The law on the regulation of the market for pharmaceuticals passed under the centre-right government in 2010, however, significantly restricts the Federal Joint Committee's competences in limit- and priority-setting decisions. At the same time, the committee has gained new and different competences in the value-based pricing scheme introduced by the law on the regulation of the market for pharmaceuticals. Competences were thus altered rather than simply retrenched after the change in government.

Even after the restrictions through the law on the regulation of the market for pharmaceuticals, the Federal Joint Committee's competences are remarkable in that the committee can take immediately binding decisions. In this sense, the committee is not an arm's-length institution in relation to the government, but enjoys a level of discretion that limits the government's capacity to determine the range of health services available to citizens. It is accordingly hardly surprising that over the years governments have repeatedly tried to stop Federal Joint Committee decisions not to cover specific drugs and services and have even gone so far as to have a legal dispute with the Federal Joint Committee.[16] The committee eventually gained a legal confirmation of its competences and independence – possibly at the price of having them severely restricted by a new law in 2011.[17]

As the ministry's influence on the Federal Joint Committee is restricted to legal supervision and commissioning it with decisions on specified issues, the committee enjoys great independence from government. Unlike the National Institute for Health and Care Excellence in England, however, it is not at all independent from those it is to regulate. The members of the Federal Joint Committee,

the Association of Statutory Health Insurance Physicians, German Hospital Federation and the National Association of Statutory Health Insurance Funds have their own and particular, rather than collective interests. The impression that the Federal Joint Committee might be at risk of being 'captured' (Laffont and Tirole 1991) by what are effectively, in Olson's sense (1982), distributive coalitions may have been what motivated governments' repeated, but ultimately unsuccessful, attempts to decrease the influence of provider and health fund associations on coverage decisions. In 2004, the red–green government intended to install an independent expert committee to provide recommendations on coverage decisions, which the Federal Joint Committee would have had to follow (the Institute for Quality and Efficiency in Health Care, see above). In 2007, a Federal Joint Committee reform envisaged staffing the entire committee plenum with experts employed by the committee. Opposition from the committee's member associations stalled the plan and hence only the three existing independent members became employed by the Federal Joint Committee.[18] In 2011, the centre-right government finally managed to increase the likelihood of the Federal Joint Committee's expert members being independent of regulatees by demanding a verification of their independence through the health committee of the Bundestag and by restricting their tenure to a maximum of six years.[19]

While the institutional reforms of priority- and limit-setting institutions in Germany discussed so far can easily be explained by strategic motives of reformers, a final set of institutional changes is more likely to be motivated by normative considerations of accountability and procedural justice. Up until 2007, the Federal Joint Committee was, like its predecessor institutions, highly secretive and hardly known beyond a small community of health care experts. A law passed under the grand coalition in 2007[20] rendered all meetings of the main committee open to the public, and a subsequent law in 2008[21] further required reports and advice provided by experts to be made available to the public. Given the profound controversy and balance of powers over health policy under the grand coalition, either party in the coalition would have blocked institutional changes with adverse consequences on their own interests beyond the term of office. This situation opened up the space for reforms that strengthened the Federal Joint Committee's accountability and transparency. The effect of transparency on the resulting decisions is unclear (see above), but possibly only small. Moreover, there are

strong normative arguments in favour of transparency and publicity, and respective reforms are likely to meet voters' approval. In this particular case, reforms towards more transparency were probably initiated by actors within the Institute for Quality and Efficiency in Health Care and Federal Joint Committee who had gained confidence after the lawsuit with the Ministry of Health had been decided in their favour, and who were influenced by the National Institute for Health and Care Excellence's experience in England with transparency and citizen involvement. In sum, however, reforms to increase transparency have not made the Federal Joint Committee more publicly visible and failed to establish anything like public scrutiny over its decision-making processes and eventual decisions.

DISCUSSION

Our analysis indicates that in Germany governments have engaged in strategic institutional design of non-majoritarian bodies in health care limit- and priority-setting much more than in England. What accounts for this difference? Did UK governments have fewer motives to engage in strategic design choices and refrain deliberately from interfering with the National Institute for Health and Care Excellence's decision-making and autonomy? Or does the British political system provide fewer opportunities for strategic action in institutional design choices? Our findings indicate that both may be the case.

There is one general difference between the German and English health care systems: in England, the financial responsibility for the National Health Service finally rests with the government, while in Germany health funds are responsible for expenditure and contributions. Resulting from this difference, governments in both countries face different pressures with regard to coverage decisions. Pressure on German governments to restrict service coverage is generally lower because it is the health funds that are blamed for increases in contributions. The UK government, by contrast, must keep taxes low and hence has a stronger interest in limiting expansion of the National Health Service benefit package.

A further difference between the two cases is that the National Institute for Health and Care Excellence and the Federal Joint Committee/Institute for Quality and Efficiency in Health Care were set up for similar purposes, but under very different conditions.

Although the National Institute for Health and Care Excellence can make recommendations to primary care trusts not to cover drugs and services, it was set up at a time when the National Health Service was underfunded and when implicit rationing was an everyday occurrence in many primary care trusts. The National Institute for Health and Care Excellence served the Labour government's goal of establishing a minimal standard across primary care trusts rather well, not only allowing the government to avoid blame for less popular decisions, but also winning support for the National Health Service and its performance as a whole. Independent expert agencies have a strong tradition in UK public administration (Silberman 1993) and tend to be valued by governments and the public. Having established a successful agency, the Labour governments (under both Tony Blair and Gordon Brown) had little reason to interfere in its decision-making and thus damage its independence. Moreover, the centralist character of the UK political system means that institutional reforms of independent agencies are, like these agencies themselves, much more publicly visible and more likely to become the subject of public debates and be challenged.

When the Labour government was succeeded by a Conservative/Liberal Democrat coalition in 2010, no significant changes were to be expected. Under Margaret Thatcher in the 1980s the Conservatives had tried to liberalize the market for health services in Britain and introduced internal markets to the National Health Service. Public health care spending was far below the average of developed democracies, and the resulting poor condition and low performance of the National Health Service had helped Labour win the 1997 elections. Even under Thatcher, however, the Conservatives shrank from more severe retrenchments of the National Health Service, which despite its poor condition remained highly popular with the public. Fiscal austerity in the aftermath of the financial crisis induced the Cameron government to cut back social spending, although the National Health Service has so far been spared significant cut-backs. Even though we can assume that the Cameron government nonetheless sought to control health care expenses, it would be unwise of it to challenge a successful priority-setting institution. The former plan to restrict the National Institute for Health and Care Excellence's competences with regard to its compulsory recommendations might have been motivated by hopes of replacing explicit priority setting with the less explicit cost-control instrument of value-based pricing, but the

government quickly realized that rights (and responsibilities) once established are not easily abolished. All British governments seem to have had a strong interest in the independence of the National Institute for Health and Care Excellence or at least feared to attack it directly. Instead of intervening in the institute's decision-making or amending relevant institutional characteristics of the committee as their German colleagues have, they resort to alternative measures (such as risk-sharing schemes or Cameron's cancer drug fund) that bypass the National Institute for Health and Care Excellence decisions.

In Germany, by contrast, both motives and opportunities for strategic institutional design were stronger. The profound controversy over the future of the German health care system that has characterized the last two decades makes it inevitable that the set-up and direction of the Federal Joint Committee and the Institute for Quality and Efficiency in Health Care have strategic relevance. The Social Democratic Party holds a traditionally strong alliance with the public health funds and seeks to strengthen their position within the system. At the same time, it is critical of service providers in general and the pharmaceutical industry in particular as cost drivers. The project of introducing a positive list for drugs has been on its agenda since the 1990s, but timing was invidious as its adoption fell in the period when the red–green coalition had lost its majority in the second chamber. The Christian Democratic Party has always been more protective of the private service providers' interests, although not as decidedly as the Liberal Party, with whom it entered a coalition government in 2009. The Christian Democrats and Liberals not only undertook strategic appointments at the top of both the Federal Joint Committee and the Institute for Quality and Efficiency in Health Care but also used the short period in which they held majorities in both houses to pass a law that significantly undermined the Federal Joint Committee's role in priority setting – thus promoting their interests beyond their own term in office. The more decentralized and power-sharing character of the German political system and the strong position of the Bundesrat in legislation strengthen motives for strategic institutional design. Given that majorities in the two chambers are more often than not opposed, governments tend to enjoy far less sovereignty in Germany than in the UK. Controversial social reforms can therefore only be approached in grand coalitions (either formal or informal) or in rare periods with identical majorities in both chambers. Since 1998, reforms have frequently been reversed

when a new government comes into office, showing that long-term policymaking has become difficult. Under these conditions, the institutional design of independent agencies (still in place after the politicians' own term in office has ended) becomes a viable strategy to pursue long-term goals in health policy.

Moreover, the German political system appears to offer more opportunities for strategic institutional design. Both the public pension scheme and the public health funds have a corporatist administrative structure, being managed by representatives of employers and employees. Representatives enjoy some legitimacy as they are elected in 'social elections', although these typically have a very low voter turnout. The way in which assemblies and managing boards constitute themselves and take decisions is hardly known by the public. On the whole, decision-making in German social insurance schemes is opaque and largely beyond democratic control, but still enjoys diffuse public support. The same seems true for the system of collective contracting between providers and health funds. The Federal Joint Committee, being built on pre-existing corporatist and negotiation structures, was thus hardly in the public focus. To the public, it was probably one of the many corporatist bodies that 'was just there' without ever being either challenged or justified. Under these conditions, strategic manipulations could easily go unnoticed. The Institute for Quality and Efficiency in Health Care, although its competences remained small in comparison with the Federal Joint Committee, has been subject to more public attention. As an expert body, it was set up from scratch and was in some conflict with the corporatist tradition in the German health care system. The moderate but audible protests following Sawicki's dismissal as chair of the institute indicate that strategic institutional design and appointment are more difficult in this case without risking an institution's credibility and public support. On the whole, the corporatist German system is thus more vulnerable to strategic institutional design, with the decentralized power-sharing character of the political system providing incentives to engage in it.

CONCLUSION

Strategic institutional design, or the strategic choice of institutional properties of non-majoritarian bodies to which decision-making

competences are delegated, seems to be a significant empirical phenomenon in both countries studied in this article, although it is more prevalent in Germany than in England. We can thus reject the 'null hypothesis' that institutional design is driven by functional considerations alone and establish that governments do employ opportunities to shape decision-making structures in a way that advances their policy goals beyond their own term of office. We thus think that it is time to move the discussion about motives for delegation, in which some stress more honourable motives such as the quest for credibility and expertise while others highlight the dangers of depoliticization, one step further. We should explore not only the motives for delegating decisions, but also the motives behind decisions on how and to whom to delegate. While our hypotheses remain to be tested in different policy areas and countries, the expectation that governments will manipulate transaction costs, membership and competences of decision-making bodies could be made plausible. For transaction costs in particular, this expectation is in keeping with our own higher-N quantitative research that has indicated that the decision rule has significant outcome effects (Böhm et al. 2014).

In light of these findings, it is important to remain aware of the fact that delegation to non-majoritarian agencies per se is problematic with regard to democratic legitimacy. Where strategic institutional design comes into play, decisions to delegate central competences can no longer be justified by pointing to the advantages of a division of epistemic and political labour. Institutional design choices are procedural decisions that have the potential to perpetually disadvantage losers and therefore require a particularly strong democratic mandate. Only if strategic institutional design can be replaced with democratic institutional design can delegation be defended as potentially compatible with democratic legitimization. What seems to be in order is thus a theory and practice of democratic institutional design which presupposes a public and academic interest in the strategic implications of institutional design.

NOTES

[1] This is a revised version of a set of criteria for the comparison of independent agencies that we have suggested in Landwehr and Böhm (2011).

[2] Gilardi (2005) and Wonka and Rittberger (2010) study agency independence as an independent variable, finding that independence is higher in some policy areas than in others. However, they do not consider changes in the degree of independence that might be accounted for by strategic institutional design.

[3] The name of the institute was changed twice: from National Institute of Clinical Excellence to National Institute for Health and Clinical Excellence in 2007 and to National Institute for Health and Care Excellence in 2013.

[4] Decisions by the National Institute for Health and Clinical Excellence apply to the English and the Welsh National Health Service, but not to the National Health Service Scotland and Health and Social Care in Northern Ireland.

[5] Legislation on the National Institute for Health and Clinical Excellence referred to here is available from: www.legislation.gov.uk.

[6] Directions to the National Institute for Clinical Excellence, given by the Secretary of State for Health, dated August 1999.

[7] Interview with National Institute for Health and Clinical Excellence Technology Appraisal Committee member, 2 and 3 April 2013.

[8] Directions and Consolidating Directions to the National Institute for Health and Clinical Excellence 2005, given by the Secretary of State for Health, dated 31 March 2005.

[9] Interview with National Institute for Health and Clinical Excellence board member, 18 May 2012.

[10] Gesetz zur Sicherung und Strukturverbesserung der gesetzlichen Krankenversicherung (Gesundheitsstrukturgesetz), passed 21 December 1992, BGBl. I, p. 2266.

[11] Gesetz zur Neuordnung des Arzneimittelmarktes in der Gesetzlichen Krankenversicherung (Arzneimittelmarktneuordnungsgesetz), passed 22 December 2010, BGBl. I, p. 2262.

[12] Gesetz zur Verbesserung der Versorgungsstrukturen in der gesetzlichen Krankenversicherung (Versorgungsstrukturgesetz), passed 22 December 2011, BGBl. I, p. 2983.

[13] Neither the existence of the internal paper nor the events leading to Sawicki's dismissal can be confirmed beyond doubt. Information provided here is based on newspaper articles collected on Sawicki's German Wikipedia profile (http://de.wikipedia.org/wiki/Peter_Sawicki, as at 28 October 2013). The discussion on the Wikipedia site and the number of times the Sawicki entry has been changed indicate the controversy over the evaluation of the events.

[14] Gesetz zur Modernisierung der gesetzlichen Krankenversicherung (GKV-Modernisierungsgesetz), passed 14 November 2003, BGBl. I, p. 2190.

[15] The respective reform law is the Gesetz zur Verbesserung der Wirtschaftlichkeit in der Arzneimittelversorgung, passed 26 April 2006, BGBl. I, p. 984.

[16] The Ministry of Health rejected a directive issued by the Federal Joint Committee that excluded artificial nutrition from the benefit basket and issued an alternative directive with contrary content. The Federal Joint Committee took legal action against the ministry and the social court decided in favour of the Federal Joint Committee, arguing that the ministry had exceeded its competences, which are restricted to legal supervision (correctness of decision-making process) and do not

include the content of decisions (Social Court Cologne, 21 March 2007, S 19 KA 27/05) Similar judgments of the Federal Social Court confirmed the role of the ministry to be limited to legal supervision (Federal Social Court, 6 May 2009, B 6 A 1/08 R; Federal Social Court, 11 May 2011, B 6 KA 25/10 R).

[17] Interview with Federal Joint Committee member, 30 August 2011. The law referred to is the Versorgungsstrukturgesetz.

[18] The first draft of the GKV-Wettbewerbsstaft of the GK (Bundestag-Drucksache 16/3100) allowed for the employment of all members by the Federal Joint Committee, this plan was abandoned in the second draft (Bundestag-Drucksache 16/4200).

[19] Versorgungsstrukturgesetz 2011.

[20] Gesetz zur Strukturgesetz 2011.erbs in der gesetzlichen Krankenversicherung (GKV-Wettbewerbsstärbs in der gesetzlich 26 March 2007, BGBl. I, p. 378).

[21] Gesetz zur Weiterentwicklung der Organisationsstrukturen in der gesetzlichen Krankenversicherung, passed 15 December 2008, BGBl. I, p. 2426.

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