Delegation and Institutional Design in Health-Care Rationing

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The delegation of decision-making powers to nonmajoritarian, independent agencies has become a significant phenomenon in more and more policy areas. One of these is the health-care sector, where decisions on the range of services covered within public systems have, in most developed countries, been delegated to specialized bodies. This article offers an analytical framework that seeks to grasp the empirical variety and complexity of delegative processes and appointed institutions. The framework is used to describe decision-making processes and institutions in six countries: Austria, Germany, Norway, Sweden, New Zealand, and the United Kingdom. We find that, although constrained by preexisting institutional structures and traditions, delegators enjoy a considerable degree of discretion in their institutional design choices and engage in strategic design and redesign of appointed bodies.

Introduction

One of the most significant developments in public policymaking in the last decades has been the increasing delegation of regulatory and decision-making powers to nonmajoritarian, more or less independent agencies. This trend has reached the health-care sector later than other policy areas, possibly because delegation seems more appropriate for regulatory than for redistributive tasks (cf. Majone 1997a, 162). However, constantly growing expenses are increasingly confronting governments with a new challenge: the challenge to set limits to public service provision and thus to ration health care. A major cause behind the increasing cost pressure is that more and more spending is going into patent-protected high-tech drugs and devices.

Rationing decisions are highly problematic for governments: To ration health care means to deny claims to treatment and to remove services that formerly would have been covered from the "health basket"—the package of services provided without charges. Limiting claims to medical services is politically dangerous in that it has the potential to erode popular support and trust. Moreover, decisions in this field require a high degree of specialized knowledge on the effects and costs of treatments. And

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Governance: An International Journal of Policy, Administration, and Institutions, Vol. 24, No. 4, October 2011 (pp. 665–688).

finally, the sheer number of decisions required in considering each medical drug, device, or service separately is likely to overtax legislative institutions and administration alike.

Most Organisation for Economic Co-operation and Development (OECD) countries have accordingly set up specialized bodies to evaluate medical services and have provided them with more or less far-reaching competences in the allocation of health care. These appointed bodies consider the costs and benefits of concrete medical services and technologies, and issue recommendations or even take immediately binding coverage decisions. While both the challenge of explicitly rationing health care and the strategy of delegating decisions to specialized, appointed agencies seem universal among the high-income democracies, the newly established decision-making structures and institutions display a great deal of variation when compared.

Although the design of institutions to which decisions in the allocation of health care are delegated has been discussed fruitfully from a normative perspective of democratic legitimacy and procedural fairness,[1] a systematic overview of institutional design choices as well as a set of empirical, rather than normative, categories for comparison is so far lacking. As institutional design is likely to display the way politicians think about the rationing challenge and will affect decisions and outcomes, an empirical comparison of institutional solutions therefore is a desideratum.

Our article seeks to explore the ways in which governments in different countries address the rationing challenge in the setup of appointed bodies. In how far is the institutional design of such bodies a matter of strategic considerations and in how far is the set of options available to politicians constrained by the existing structure of the health-care system of which it is part? What are the relevant properties that distinguish procedures and institutions in different countries, and what explanations for their selection suggest themselves?

Aiming at a better understanding of the logics of delegation and institutional design choice in the field, we present a possible analytical framework for the comparison of processes and appointed bodies in health-care rationing (next section), which we use to describe and analyze institutional solutions in six countries (later section). The final section suggests possible explanations for institutional design choices and concludes that while these take place under the constraints of preexisting institutional structures and traditions, governments enjoy considerable discretion in the delegation of competences.

Grasping Variety and Complexity: An Analytical Framework

Priorities in health care, as well as the processes used to determine them, have in recent years become subject to both public and academic debates. A number of studies have analyzed priority setting and health-care

rationing in international comparison. Volumes edited by Coulter and Ham (2000) and Ham and Robert (2003) have become classics in the rationing discussion; another one, edited by Schulenburg and Blanke (2004) provides information on rationing in Europe.[2] While rich in empirical information, a problem with these multiauthor studies is that they do not employ a singular analytical framework for the description of processes in different countries.[3] An article by Sabik and Lie (2008) describes processes in eight countries but employs normative rather than analytical criteria for comparison and evaluation.[4]

While drawing on previous comparative research on the definition of health baskets and the institutions involved in this process, we consider the subject from a perspective of institutional and regulation theory, focusing on the delegation of decision-making power to nonmajoritarian institutions, and considering competing explanations for institutional design choices. The delegation of regulatory tasks, but increasingly also of more or less binding decisions, to institutions outside the parliament and state bureaucracy has been a research topic in political science and public administration for more than 50 years (see Flinders 2009). While a strong tradition studies delegation from an empirical perspective using formal models and quantitative data (e.g., Epstein and O'Halloran 1999), a second one is more qualitative and normative (e.g., Skelcher 1998). Throughout this literature, we find the expectation that majoritarian institutions will increasingly delegate competences to nonmajoritarian ones, a trend that is further enhanced under conditions of financial crisis and rapidly increasing fiscal pressures.

Institutional delegation can be viewed as one among several tactics available to politicians seeking to remove a conflict from the political agenda and thus to depoliticize it (Flinders and Buller 2006). The hopes and fears with which the phenomena of delegation and depoliticization are described vary greatly: While some hope that it will enhance the credibility of policymaking (Majone 1999) and help democratic institutions to deal with complex decisions and political overload, others stress the dangers of blame avoidance and loss of accountability (Boggs 2000).

The complex and multifaceted body of research on delegation and depoliticization is united not only by the interest in their effects but also by a remarkable neglect of the logics behind delegation (Flinders 2009). The present article seeks to draw attention to the range of choices available to governments delegating decisions and suggests a framework of five variables to describe processes and institutions in health-care rationing that can serve as a reference point for international comparisons. Although they are certainly not exhaustive for the description of processes and institutions, we think that the following criteria enable us to reduce complexity and grasp central aspects of delegation, and thus help to better describe and assess decision making in health-care rationing.

Positive and Negative Defaults

The effects of interaction within a decision-making system, and thus of delegation, depend to a considerable extent on how defaults are set (see Ostrom 1986). A default outcome is the outcome effected if no decision is taken or achieved. Regarding the allocation of health services, the existence of "positive" or "negative" lists of services (or health baskets) is central. If a list of services is defined positively, the default is negative: No service is funded unless it is explicitly included in the list. If a list is defined negatively, the default is positive: Any service will be funded unless it has explicitly been excluded.

The decision whether to define defaults positively or negatively is not itself an act of delegation but constitutes an important initial condition for the decision-making processes in which appointed bodies are to be involved and affects the kind of tasks and competences that can be delegated. Where the default is positive (i.e., where only a negative list of services exists), the decisions that are delegated will be decisions to exclude services. Such decisions tend to be highly unpopular, which is why delegation could in this case be accounted for as an attempt of blame avoidance (Weaver 1986) and depoliticization (Flinders and Buller 2006).

Where the default is negative (i.e., lists of services are defined positively), a much higher number of decisions can and has to be delegated as the number of candidates for inclusion will be higher than that of candidates for exclusion. Moreover, a decision to fund an expensive new technology for a large patient population can have significant impact on the health budget and lead to serious opportunity costs. Assuming that the prior decision to set a negative default is driven by the goal of limiting expenses, governments retain incentives to keep hands on "arm's length" bodies charged with decisions on which services to include in health baskets.

Degree of Independence and Delegation

While delegation to nonmajoritarian bodies seems inevitable given the number, complexity, and informational requirements of coverage decisions, two central parameters in the design of decision-making processes and institutions remain subject to the discretion of delegators. The first concerns the design of appointed bodies as more or less independent from the government and its regulatees. The second concerns the exact tasks and competences appointed bodies are equipped with and thus the degree to which decision making is in fact delegated.

Regarding the independence of institutions to which decision making is delegated, governments can decide whether to incorporate new bodies and decision-making processes within existing ministerial and administrative structures or whether to set up an independent institution with its own legal personality, budget, and secretariat. The chairperson(s) of any

such institution will typically be appointed hierarchically, but it makes a difference whether all members are appointed by the government or ministry, or whether the chairperson(s) have discretion to nominate further members themselves. Moreover, independence is not only an aspect of the appointed body's relationship with the government but also of the relationship with its regulatees, in this case health funds, service providers, and manufacturers. Where such groups are assigned rights to nominate members, a body may be more independent from the government but less independent from those it is supposed to regulate.[5]

Regarding the tasks and competences in the appraisal of technologies assigned to appointed bodies, and thus the degree to which decision making is delegated, bodies can be purely advisory, produce explicit recommendations (which still require the government's or parliament's consent to be put into practice), or be commissioned with immediately binding decisions. The appointed body can also be given responsibility for allocating at least a part of the health budget. Only in this case, benefits of one service have to be weighed against the benefits of others, whereas typically, services will be assessed in a case-by-case manner.

The independence of nonmajoritarian bodies and the degree to which competences are delegated to these are central issues in regulation theory and research. They are also important categories for the description of decision-making processes in health-care rationing, as they reveal possible motives for delegation and have the potential to significantly affect decisions and outcomes. Principal–agent theory, as a dominant approach in the study of regulation and delegation, assumes that governments appoint independent regulators because they seek to enhance the credibility of decisions, shift blame, and increase efficiency (cf. Coen and Thatcher 2005, 332). These motives conflict with the desire to maintain control—in our case, over the health budget and over a policy area in which conflicts are potentially explosive. High degrees of independence and delegation enhance credibility and the potential for blame avoidance or depoliticization only at the price of a loss of control. However, attempts to keep "hands on" are likely to result first in a loss of efficiency and eventually of credibility and potential blame avoidance. Strategies that suggest themselves from the perspective of delegators are thus ones that enhance either independence or delegation while keeping the other low.

Degree of Inclusiveness

A further important parameter in the setup of appointed bodies is their inclusiveness. By inclusiveness, we mean, first and foremost, their composition: Who are the members, what is their personal and professional background, which stakeholder groups are involved? Commissions staffed mainly with experts or bureaucrats are less inclusive, particularly where they are dominated by a small number of disciplines or "schools" of thought. Corporatist bodies staffed (in our case) with representatives of

health funds and service providers are somewhat more inclusive, as at least two parties, with typically opposing views, are represented. Maximally inclusive bodies would be large, involving not only all potential stakeholders, such as representatives of manufacturers, patient advocates, clerics, representatives of minorities, and different regions, but also lay citizens. However, the inclusiveness of a decision-making forum depends not only on its composition but also on its size and on the decision rule applied: A higher number of members expand the range of perspectives considered, and a consensus requirement equips members with the power to veto decisions that run counter to their interests or opinions.

As in determining the degree of independence and delegation, the motives of delegators are likely to conflict where decisions on the inclusiveness of appointed bodies are concerned. The higher the degree of inclusiveness, the higher transaction costs and the more difficult the decisions will be, which is why governments have incentives to set up less inclusive bodies in order to ensure efficiency. At the same time, involving stakeholder groups is important to ensure "input legitimacy" (Scharpf 2001) of the decision-making process, to reduce dangers of implementation failure, and to gain popular support for decisions. Finally, it is important to note that inclusiveness through stakeholder involvement reduces a body's independence from its regulatees and entails the risk of "capture" by vested interests (Coen and Thatcher 2005, 337). By increasing inclusiveness, governments may thus sacrifice goals of efficiency *and* credibility for (perceived) legitimacy and effective implementation.

Degree of Publicity and Transparency

Publicity and transparency are important normative demands on processes and institutions that produce explicit and binding decisions, especially in the allocation of health care (see Daniels and Sabin 2002). But at the same time, they are important aspects of institutional design choice where decision-making powers are delegated. In the literature on the regulatory state, it has been argued that independent regulatory agencies can, contrary to the fears of democratic theorists, render policymaking more transparent and thus more accountable in comparison with decision-making processes within the state bureaucracy (Majone 1999), and Thatcher (2002) sees at least some empirical evidence for improved transparency.

The mandate and rules of procedure of an appointed body determine the degree to which meetings and proceedings, relevant documents, and reports are accessible to outsiders. This kind of formal publicity and transparency has to be distinguished from public attention and media coverage, which are not entirely in the hands of delegators. We describe a body or decision-making process as minimally transparent or public where only its decisions are public and accessible. A medium degree of transparency and publicity is achieved where, in addition, the criteria and

information decisions are based on and more or less comprehensive reports that explain and justify decisions are published. A high degree of transparency and publicity is achieved where meetings are public and where all (or nearly all) relevant documents and reports are accessible.

As with the four central parameters of institutional design discussed earlier, motives for choosing the degree of publicity and transparency are likely to be mixed. On the one hand, publicity and transparency are important instruments to ensure "downward accountability" toward the addressees of decisions (Scott 2000), which complements "upward accountability" toward the delegators and promotes credibility and public acceptance of the appointed body and its decisions. On the other hand, unpopular decisions attract more attention and are more likely to lead to protests if they take place in public, so that publicity and transparency can also make decisions more difficult and reduce efficiency. Given that decisions to exclude services are most likely to meet with resistance, they can also undermine the goal of controlling expenses.

Processes and Institutions in Health-Care Rationing: Six Solutions

In this section, we want to illustrate the potential of our analytical framework for the description and comparison of appointed agencies and decision-making processes in health-care priority setting by applying our criteria in the analysis of six cases. Moreover, we want to explore potential ways of thinking about how governments make institutional design choices, three of which can be derived from the literature.

1. *Institutional context and traditions*: Historical institutionalism and comparative welfare state theory claim that the setup of new institutions has to take into account preexisting institutional structures and traditions (see, e.g., Peters, Pierre, and King 2005; Yesilkagit and Christensen 2009). According to this view, delegators are at not free in their design choices but are constrained by the context in which these are taken. In the context of health-care rationing, the organization of the health-care system constitutes a central determinant. Health-care systems in most OECD countries can be described either as social insurance systems (the Bismarck model), as public systems (the Beveridge model), or as a mix between the two.[6] Social insurance systems and public health services provide incentives and resources for different groups of actors and entail different preexisting institutional structures that regulators can employ for new purposes but that also constrain the design of new bodies.

2. *Political conflict, credibility, and uncertainty*: Alternative explanations for the institutional design of independent agencies include the level of political conflict faced by regulators and the resulting need to improve credibility of regulation, as well as the degree of political

uncertainty, which depends on the number of veto players involved in decision making and the frequency of changes in government. Common hypotheses are that a high level of conflict and (corresponding) need to demonstrate credibility, as well as a high degree of political uncertainty, enhances the probability of delegation to agencies with a high degree of independence (see Gilardi 2005; Majone 1997b).

3. *Institutional transfer and transnational policy learning*: The transnational transfer and convergence of policies among interdependent states with open markets and societies has long been an issue in political science. The same factors that enhance transfer and convergence of policies may also affect institutional design choice when regulators learn from one another (Gilardi 2005, 2008). Gilardi (2005) finds that the most de facto independent regulators are those that participate intensely in European networks of regulators, which are well developed in the fields of health care and priority setting. Moreover, institutional solutions that are perceived as particularly successful may serve as a blueprint for the design of institutions in other countries.

The explanatory approaches focusing on political conflict, credibility, and uncertainty, but also the ones that assume policy learning, tend to assume governments to be equipped with a higher degree of self-determination, and thus capability for rational and strategic decision making in institutional design choice, than the institutionalist approaches that focus on contextual constraints and institutional traditions.

In our case selection, we regard preexisting institutional contexts and traditions as the main explanatory variable. From the group of high-income democracies, in which challenges of health-care rationing and the trend toward delegation are most notable, we have thus chosen three sets of countries in which this variable assumes different values: two countries with social insurance health-care systems (Austria and Germany), two countries with state health-care systems and a strong redistributive tradition (Norway and Sweden), and two countries with state health-care systems but a more residual welfare state tradition (New Zealand and the United Kingdom). Looking at two cases for each value of the main explanatory variable for institutional design allows us to consider to what degree this variable has an apparently constant effect and to what degree other explanatory factors suggest themselves—including the degree of political conflict and uncertainty, and requirements of credibility as well as institutional transfer and learning. While the countries studied are similar in many respects (high-income stable democracies with comparable health-care spending per capita), ceteris paribus conditions obviously cannot be assumed. Given this and the small number of countries studied, any inferences drawn must inevitably remain tentative and, while

supporting one of the competing accounts found in the literature more than the others, predominantly point toward roads for further research.

The data on properties of decision-making processes and institutions in health-care priority setting used in the case studies are drawn from secondary literature (including Health Systems in Transition [HiT] and Pharmaceutical Pricing and Reimbursement Information [PPRI] country profiles) and official documents (legal texts and rules of procedure, where available, as well as Web sites of the respective bodies studied), and confirmed by at least two experts (academic experts and members of the respective bodies) for each country.[7] While these data only allow us to assess some properties, such as independence, at a formal rather than de facto level, we regard them as sufficiently reliable for our purposes.

Austria

Austria has a social insurance health-care system with nearly 30% tax financing and over 20% private spending; in sum, Austrians spend 10.5% of their gross domestic product (GDP) for health (OECD 2011). Despite steadily growing health expenses over the last decades, rationing has never been an issue of public and political debate in Austria (and has not been dealt with by a principles commission).

Austria has a positive list only for pharmaceuticals ("Erstattungskodex"); the content of the health basket regarding other medical services is not defined. The *default* for the coverage of pharmaceuticals is thus negative, meaning that a decision is required to include new drugs into the health basket. This decision is taken by the main Association of Austrian Social Security Institutions (ASSI)[8] on the basis of a recommendation given by a drug evaluation commission (DEC). As an advisory committee to the ASSI, the DEC is concerned with the evaluation of drugs and thus constitutes the central institution in the technology appraisal process. It consists of representatives of the health funds, experts (pharmacologists), members from each side of labor relations, and representatives of medical and pharmaceutical associations.

The definition of the pharmaceutical health-care basket lies fully within the hands of social security organizations in Austria, so that the *degree of delegation* must be classified as high. At the same time, the *degree of independence* of both the ASSI and the DEC is lower. While comparatively independent from the ministry and government, they are, as essentially corporatist bodies, less independent from their regulatees—in this case, the health funds and medical associations. Moreover, experience shows that the Austrian government has incentives and opportunity to keep hands on by modifying institutional design to change majorities and reallocate veto power: In 2001, the new conservative government coalition enforced a comprehensive organizational reform of ASSI, which abolished the trade unions' majority in favor of the employers' side and thus

strengthened the power of pro-government members (Talos and Obinger 2006).

The *inclusiveness* of the decision-making process is classified as medium. The ASSI, which takes the eventual decision, is staffed with social security bureaucrats and is therefore less inclusive. The DEC, as the central body in the appraisal process, is much more inclusive: Apart from patient representatives, five different stakeholder groups are involved, and the committee is chaired by the independent expert members. However, given the fact that representatives of the social insurance still account for half of the committee members, the inclusiveness nonetheless remains only medium. Neither DEC nor ASSI management meetings are open for the public, and only the results of the decision-making process are published. Only in case of a negative result, the DEC as well as the ASSI are bound to justify their decisions. *Publicity and transparency* of the decision-making process must hence be categorized as low.

In sum, Austria's strong corporatist culture and its social insurance system can account for the main features of processes and institutions employed for the appraisal of new drugs. Existing negotiation structures between health funds and service providers could be employed for the new purpose of priority setting and were assigned considerable competences—in keeping with strong traditions of self-administration that characterize corporatist systems. The low degree of publicity and transparency is also in keeping with corporatist modes of decision making, where negotiations typically take place behind closed doors. As the government has little alternative to involving the health funds and medical associations, which constitute central veto players within the corporatist system, in the decision-making processes, its main strategy to influence outputs is through modifications of institutional design.

Germany

Germany exemplifies the Bismarck model of a social insurance system and spends 10.5% of its GDP on health (OECD 2011). Although German health policy has moved from expansion to retrenchment since the 1970s, topics of prioritization and rationing come close to being taboos in the public debate. While a parliamentary study commission and the German Ethics Council published rather vague and hardly noticed reports, the rationing issue still remains to be politicized.

Defaults in the coverage of services are predominantly positive in Germany: For drugs and hospital services, only negative lists exist, while for outpatient services (both primary and specialist), the range of services covered is restricted by a list of reimbursable items. The body that is in charge of defining all three lists is the Federal Joint Committee (FJC), which was set up in 2004.[9] The FJC joins several preexisting committees in

which health funds negotiated remuneration and service provision with contracted doctors and hospitals under a single roof and in a new institutional structure.

The *degree of delegation* in the definition of health baskets is high in Germany. The FJC is a statutory independent body with its own budget and secretariat, taking immediately binding decisions. Its members, including the three expert chairpersons and patient representatives, are nominated in collaboration by the health funds, the contracted doctors' association, and the hospital association, which jointly constitute the FJC. As in the Austrian case, the FJC is less independent from its regulatees than from the government, so that its *degree of independence* can only be classified as medium. Another similarity with the Austrian case is that the FJC's institutional structure and internal rules of procedure have been hierarchically defined and redefined by consecutive governments in the apparent hope to influence its outputs.[10]

The FJC's main committee consists of five representatives of the health funds and five representatives of the service providers (doctors, hospitals, dentists), and is chaired by three expert members. Patient advocates are members of the committee but only in an advisory function without voting rights. Decisions are taken by simple majority vote. On the whole, we therefore classify the FJC's *degree of inclusiveness* as medium. *Publicity and transparency* of the FJC were—in keeping with corporatist traditions and similar to the Austrian case—originally low, with the committee's meetings and proceedings being more or less inaccessible to outsiders. A reform in 2008, however, has opened all meetings of the main committee to the public. Nonetheless, the committee itself remains unknown beyond a small expert community.

In several respects, the German case resembles the Austrian one: Corporatist actors dominate the decision-making process and are assigned considerable competences in the definition of health baskets. Accordingly, decision makers are less independent from their regulatees than from the government, and governments seek to influence outputs with regard to their respective policy preferences through changes in institutional design. Two aspects distinguish the German from the Austrian case, however. First, Germany stands out as the only OECD country that does not possesses a positive list for drugs and has only recently begun to engage in rather low-key price negotiations with manufacturers. This particularity is typically accounted for by the successful lobbying strategies of drug manufacturers based in Germany, and thus by political rather than institutional factors. Second, the high degree of publicity that was enforced upon a corporatist decision-making system is remarkable. Besides government intentions to influence outputs through institutional design, the British National Institute of Health and Clinical Excellence (NICE) (discussed below), with its outstanding transparency, is likely to have played a role as a reference institution here.[11]

Norway

Norway has, since the 1980s, following the discovery of huge oil resources on its coastline, ranged among the highest income economies in the world. It has a national health service that is predominantly tax funded and spends 8.5% of its GDP on health care (OECD 2011). Considering the huge resources available, it seems surprising that Norway was the first country to politicize the need to set limits in health care by setting up a respective expert commission in 1985 (see Holm 2000). In fact, however, the sudden availability of large resources was the main reason to discuss limit setting: In order to protect non-oil-related domestic industries by avoiding revaluation of its currency, Norway had to keep public spending at a reasonable level. The "Lønning Commission" originally aimed at an explicit prioritization of services but eventually produced only a set of abstract principles to guide allocation.

Today, Norway does not have an explicitly defined health basket for nonpharmaceutical medical services. For drugs, an explicit positive list exists, rendering the *default* negative: New drugs are not covered without a positive appraisal. The Norwegian appraisal process for drugs is complex: The Norwegian Medicines Agency (NoMA),[12] a regulatory entity within the public health system also responsible for market authorizations and monitoring of drugs, assesses coverage applications from manufacturers. The NoMA takes advice from an expert committee and can decline coverage for a new product. Positive coverage decisions only fall within the responsibility of NoMA if their budget impact does not exceed a limit of 5 million NOK per year. Where this "bagatelle limit" is exceeded, the NoMA passes the decision, along with its recommendations, to the Ministry of Health. The ministry can consult the "National Council for Health Care Priorities," set up in 2007. If the ministry decides that an expensive new drug is to be covered, the parliament has to approve the decision through a budget bill (cf. Festöy et al. 2008).

In international comparison, the *degree of delegation* is remarkably low in the Norwegian prioritization process, at least with regard to the definition of its positive drug list. For decisions with a considerable budget impact, the parliament retains full authority and accountability. What is interesting in the Norwegian case is that decision-making power is retained for positive coverage decisions, while the power to refuse coverage is delegated to the NoMA. However, this fits Norway's goal of controlling public spending. The *degree of independence* of the institutions involved in the decision-making processes is comparatively low as well. Although the experts serving in its advisory committee are independent, the NoMA itself, which takes the majority of decisions, is part of the bureaucratic structure and is controlled by the ministry.

Regarding the *inclusiveness* of the process, the Norwegian case is interesting in that a large-scale public and relatively inclusive debate

about prioritization did not result in respective institutions to deal with the everyday challenges of prioritization and rationing. The processes both within NoMA and within the Ministry of Health have a bureaucratic-technocratic character. The Council for Health Care Priorities includes a number of patient advocates among its members but has so far issued only a small number of merely advisory recommendations. While the council holds public meetings and the advisory committee (from which NoMA takes advice) publishes minutes of meetings, the decision-making processes within NoMA and within the ministry lack *transparency and publicity*—as is to be expected from a bureaucratic process. Only when decisions reach the stage of a budget bill and are dealt with by the parliament, can they become subject of public scrutiny. We thus classify the Norwegian process as "medium-low" on this point.

On the whole, the Norwegian drug appraisal process and institutions involved in priority setting can be characterized as bureaucratic-technocratic: The degree of delegation and independence is low, as are levels of inclusiveness and publicity/transparency. This character is in keeping with the traditions of the redistributive welfare state and a centrally administered health-care system. More recently, the establishment of the Council for Health Care Priorities speaks of a wish to improve the transparency and legitimacy of the priority-setting process, especially where decisions on treatments for severe and chronic diseases are concerned. While its inclusive and transparent setup—apparently inspired by the procedural turn in the priority-setting debate and reference institutions like NICE—is less typical with regard to Norwegian bureaucratic tradition, the council's main function remains that of an advisory body *within* the bureaucracy.

Sweden

Sweden has a tax-funded public health-care system and spends 9.4% of its GDP on health (OECD 2011). The topic of priority setting and rationing in health care reached the political agenda in Sweden early: In 1992, the "Parliamentary Priorities Commission," consisting of representatives of the five largest parliamentary parties, the government and administration, as well as a group of experts, set out to define fundamental ethical principles to serve as an "ethical platform" for concrete allocation decisions. In 1993, the commission published a consensual report, which was approved by the parliament and thus turned into a set of legalized guidelines.[13]

Concrete allocation decisions on medical services are decentralized in Sweden and are taken at the level of county councils, while a national positive list of drugs is determined by a board within the Dental and Pharmaceutical Benefits Agency (Tanvards-och Läkemedelsförmansverket, TLV). The *default* for the coverage of pharmaceuticals is thus negative,

meaning that all new drugs have to be approved by the board consisting of seven members, of which three are health service directors from different county councils and two are academic experts (one pharmacologist and one health economist). The board is also authorized to undertake a step-by-step revision of the complete positive list of pharmaceuticals, reassessing older drugs and removing them from the list if coverage is no longer regarded as justified.

The majority of the board's members are representatives of the Swedish public health administration, and its rules of procedure are determined by the ministry alone, meaning that the board's *independence* from government and administration is comparatively low. However, the board enjoys considerable competences: Its decisions are immediately binding (without approval from the ministry), and it is at least to some degree free to set its own agenda. This relatively high *degree of delegation* is further promoted by the fact that the TLV (of which the board is part) has its own secretariat and budget.

In keeping with the mainly administrative character of the TLV, the *inclusiveness* of the board must be classified as only low-medium. Bureaucrats constitute the majority of members, and the only stakeholder involved is a patient representative from the Swedish blood cancer association. With only seven members, the board is small and uses simple majority voting to take decisions—meaning that the patient representative can, even together with the two expert members, always be outvoted. Sweden resembles Norway in that while the public debate on fundamental principles for priority setting in the 1990s was lively and inclusive, the *publicity and transparency* of the process and bodies in which concrete coverage decisions on drugs are taken are low. While the positive list itself is easily accessible via the Internet, no background information on the evidence base or normative reasons for decisions is provided, and board meetings are not open to the public.

In keeping with respective traditions, many properties of the Swedish process and institutions are bureaucratic-technocratic ones. However, the degree of delegation is remarkably high (in contrast to Norway), a result that may be accounted for by the higher degree of devolution in the Swedish health-care system, which is commonly assumed to favor delegation to nonmajoritarian bodies (Hoggett 1996). In addition, budgetary austerity is more notable in Sweden than in Norway. Independent expert bodies, like the National Center for Setting Priorities (PrioriteringsCentrum) and a Council for Health Technology Assessment (SBU), while not charged with concrete coverage decisions, have become important actors in the public debate focusing on the necessity of limit setting. In Sweden, institutional design in health-care rationing thus seems to be characterized by a tension between the redistributive welfare state tradition, suggesting bureaucratic control, and the wish to ensure policy credibility through delegation and independent expert bodies.

New Zealand

New Zealand has a fully tax-funded national health service and spends 9.8% of its GDP on health care. In contrast to other countries, the reform debates in New Zealand have involved the questions of what items a basket of core services should include and how services should be prioritized. In 1992, New Zealand was one of the first countries to politicize these issues by setting up the "National Advisory Committee," which was to base its decisions on a number of public hearings. While the necessity to set limits in health care was thus explicitly communicated to the public, the committee eventually failed to define the basket of core services and instead named a number of principles to serve as guidelines for allocation (see Gauld 2004).

Although the attempt to define a complete positive list for all medical services was not successful in New Zealand, a new body, Pharmac, was set up in 1993 to decide which drugs are to be covered. The *default* for nonpharmaceutical services thus remains positive, while the default for drugs is negative—no drug is covered unless it has been listed by Pharmac. Pharmac decisions are taken by the board, which takes advice from an expert committee (Pharmacology and Therapeutics Advisory Committee [PTAC]) and are immediately binding. Although members of the board and the committee are hierarchically appointed by the ministry, Pharmac enjoys a high *degree of independence*, given that it has its own legal personality, budget, and over 60 employees. What is remarkable is the fact that Pharmac does not assess drugs on a case-by-case basis but has to allocate a given budget and is thus forced to engage in a comparative assessment of different treatments for different conditions. The *degree of delegation* for coverage decisions on drugs is thus particularly high in New Zealand.

As in the Norwegian and Swedish cases, the high degree of public involvement and politicization in New Zealand's priority-setting debate is contrasted by comparatively low levels of both *inclusiveness* and *publicity/transparency* in the processes and institutions for actual coverage decisions. The Pharmac board members have careers as consultants or senior public servants, mainly in the health sector, behind them, and an educational background in finance/economics (five of six) or medicine (one). PTAC members are practicing physicians. The Pharmac board takes consensual decisions, whereas PTAC rules of procedure enable majority votes. A consumer advisory committee that is to provide input from a patient perspective is not involved in the assessment of funding applications, which is why we classify Pharmac's inclusiveness as low. Despite New Zealand's strong tradition in administrative transparency, the degree of publicity and transparency offered by Pharmac can only be described as low-medium, too: While minutes of PTAC meetings are available from the Pharmac Web site, board meetings are entirely inaccessible to the public. It must be noted, however, that the decision-making process for coverage

decisions is more politicized in New Zealand than elsewhere and that Pharmac is much better known to the public than respective institutions elsewhere.

Summarizing the results for New Zealand, Pharmac's high degrees of independence and delegation, as well as the low inclusiveness of an expert body, seem to be typical features of the "regulatory state" (Majone 1997a), which is thought to be particularly advanced in residual welfare states. The decision to delegate responsibility for the entire pharmaceutical budget to an independent agency is unprecedented and remarkable, however. While fiscal pressures (New Zealand's GDP and public health spending per capita are only half those of Norway) offer some explanation here, we view this decision as an instance of particularly consistent institutional design: Where health-care services are to be prioritized in order to cut expenses, they must be subject to comparative evaluation rather than assessment on a case-by-case basis.

United Kingdom

The British National Health Service (NHS) constitutes the classical model of a tax-funded universal health-care system—the Beveridge model, which is commonly contrasted with Bismarck's social insurance model that characterizes countries like Germany and Austria. In line with its tradition as a rather residual welfare state, the United Kingdom spends a comparatively small proportion of its GDP on health care—8.7% in 2008. While the United Kingdom is one of the few countries that has, under the Labour government from 1997 to 2010, intentionally and significantly increased its health-care spending in an attempt to improve the quality of service provision, resources remain scarce and pressures for implicit rationing high.

Given the tradition of implicit rationing, which in many places used to surface in waiting lists, overcharged medical staff, and run-down facilities, the quality of services and allocation of resources within the NHS have long been subjects of public debates in the United Kingdom. A number of citizen hearings at the local level have addressed these issues, and the discussion surrounding the foundation of NICE has politicized questions of priority setting and rationing. Moreover, a "citizens council" advises NICE on ethical matters, although its actual influence on decision-making processes is controversial (Gulland 2002).

In the United Kingdom, most decisions on the provision and coverage of services are taken at the level of local primary care trusts (PCTs), that is, smaller administrative units within the NHS. Given the unequal geographical distribution of wealth and morbidity, as well as disparities in management qualities of the PCTs, this system has led to regional inequalities that have been described as "postcode rationing." NICE was set up in an attempt to reduce inequalities and improve the quality of service provision. While the United Kingdom does not use comprehensive positive lists of services, NICE decisions define authoritative claims to

specific medical services and fit PCTs with a justification to refuse the provision of less essential or effective services.

Given that explicit lists for drugs and medical services do not exist in the United Kingdom, the *default* for coverage appears to be positive at first glance. However, the contrary is the case: As PCTs are chronically short of resources, expensive and controversial services are most likely not to be provided unless a NICE decision has assigned respective claims to patients. While NICE is commonly regarded as an institution set up to ration health care, it does in fact fulfill a somewhat different function within the British context: It establishes standards the PCTs have to comply with. Nonetheless, its task, the assessment and appraisal of medical technologies, is the same as that of the other bodies discussed in this article.

NICE is a statutory independent agency that has considerable control over its own organization and rules of procedure. It is equipped with a considerable budget and has around 500 employees. Its guidelines and technology appraisals originally had to be approved by the ministry. Since 2005, however, positive decisions on new technologies are immediately binding for PCTs. Both the *degree of independence* and that of *delegation* are thus high in the case of NICE, with a single limiting factor: NICE has no control over its own agenda, as guidelines and appraisals remain to be commissioned by the ministry.

Regarding the *inclusiveness* of decision-making process, a closer look at the "technology appraisal committees" within NICE, which draft recommendations on the coverage of new technologies, makes sense.[14] Each of the four committees consists of 33 members, including experts, service providers (doctors and nurses), and representatives of the NHS administration, as well as representatives of patient groups, and the pharmaceutical industry and lay members. The committees seek consensual decisions but can resort to majority voting if necessary. Although bureaucrats and experts constitute the majority in these committees, the high number of members from different backgrounds, the involvement of several stakeholder groups, and the effort to achieve consensus render inclusiveness relatively high. Meetings and minutes of the appraisal committees are accessible to the public, and decisions are extensively justified, including a comprehensive description of the evidence considered. The degree of *publicity and transparency* can thus be classified as high—indeed as exceptionally high in comparison with the other bodies discussed here.

The institutional setup of NICE with its high degrees of independence and delegation can be seen as a typical case of regulation through delegation, which is particularly characteristic of the British public service tradition (Dargie and Locke 1999; Silberman 1993). At the same time, the high degrees of inclusiveness and publicity that NICE displays are remarkable and support the claim that delegation to independent agencies can, compared with bureaucratic decision making, actually enhance transparency and accountability (Majone 1999). A remarkable recent development is the

fact that the conservative-liberal government that came into office in 2010 is apparently planning to modify NICE's tasks and limit its competences (Boseley 2010). While a reversal of the decision to delegate competences appears difficult and would run counter to tradition, this move illustrates how delegators do try to engage in strategic institutional design (Table 1).

Discussion and Conclusions

Considering the different solutions to the challenges of health-care prioritization in the six countries described earlier, the variation in processes and institutions is striking. What appears to be the same problem is addressed in very different ways. Is this variation in institutional design choices best accounted for by different preexisting institutional structures and traditions in different health-care systems and welfare state regimes? Or do delegators enjoy the discretion to set up processes and institutions according to their strategic preferences? And finally, does the variation we find with regard to our criteria merely hide trends toward convergence which could be explained by policy learning and transfer in response to universal challenges?

Regarding the way *defaults* are set, a positive list for drugs appears to be the standard solution, from which only Germany and the United Kingdom deviate. The causes of this deviation are different ones, however. In Germany, the threats of manufacturers to shift production and jobs to other countries have successfully prevented the introduction of a positive list. In the United Kingdom, by contrast, the default for the coverage of controversial drugs is, despite the lack of a positive list, negative, given the shortage of resources within the PCTs. Although variation is low in this respect, the way defaults are set is important to understand decision-making processes and institutions: The German FJC takes decisions to exclude drugs from coverage, while comparable institutions in other countries are concerned with decisions to include drugs in health baskets.

Regarding the kind of competences that are delegated to more or less independent bodies, we find that the *degree of delegation* is high in all countries in our sample except Norway. By contrast, the *degree of independence* is subject to more variation: Only the two more residual state systems, which also share the British public service tradition within which independent agencies have always played a more central role in regulation than elsewhere, employ bodies with a high degree of independence. In the other countries, degrees of independence are lower, albeit for different reasons. In the redistributive state systems, hierarchical control is stronger, meaning that the degree of independence from the ministry and government is reduced. In the social insurance systems, independence from the delegators is high, but independence from regulatees is reduced within the corporatist decision-making structure.

The *inclusiveness* of appointed bodies, too, appears to be partly determined by preexisting structures: In our sample, the countries with social

TABLE 1
Institutional Design Choices Compared

Country	GDP (PPP) per Capita/ Health Spending in % of GDP/ Public Health Spending per Capita[a]	Institution(s) in Charge of Appraisal for New Drugs	Defaults	Degree of Independence	Degree of Delegation	Degree of Inclusion	Publicity and Transparency
Austria	37,873/ 10.5/ 3,053	Drug Evaluation Commission/ ASSI	Positive list for drugs	Medium	High	Medium	Low
Germany	35,436/ 10.5/ 2,869	Federal Joint Committee	Negative lists for drugs and hospital services, positive list for ambulatory services	Medium	High	Medium	High
Norway	58,596/ 8.5/ 4,213	Norwegian Medicines Agency, Ministry of Health, National Council	Positive list for drugs	Low-medium	Low	Low-medium	Low-medium
Sweden	36,946/ 9.4/ 2,841	Pharmaceutical Benefits Board (part of TLV)	Positive list for drugs	Medium	High	Low-medium	Low
New Zealand	27,245/ 9.8/ 2,158	Pharmac	Positive list for drugs, positive and negative lists for some medical services	High	High	Low	Medium
United Kingdom	36,128/ 8.7/ 2,585	National Institute of Health and Clinical Excellence (NICE)	Negative and positive decisions on drugs and medical services (no explicit list)	High	High	Medium-high	High

[a]OECD Health Data for 2008 (OECD 2011).
GDP, gross domestic product; PPP, purchasing power parity; ASSI, main Association of Austrian Social Security Institutions; TLV, Tanvards-och Läkemedelsförmansverket.

insurance systems employ corporatist bodies, those with redistributive state systems bureaucratic bodies and those with more residual state systems expertocratic bodies. While governments are clearly constrained by the need to include veto players in the composition of decision-making forums, the contrast between New Zealand (low inclusiveness) and the United Kingdom (medium-high inclusiveness) shows that where the involvement of additional stakeholders is concerned, delegators do enjoy discretion in institutional design. The same is true for *publicity and transparency*. While we find them to be lower in the redistributive state systems (in keeping with the rather bureaucratic character of the entire processes), there is no stable pattern if we regard the two other sets of countries. Apparently, publicity and transparency are features of institutional design that can quite easily be enforced upon institutions or introduced at the initiative of institutions themselves, as they are central requirements of democratic accountability against which few arguments can successfully be made in public.

While six cases surely do not allow for too much extrapolation, our sample suggests some inferences that could be scrutinized in studies considering a higher number of cases—respective institutions in further countries and appointed bodies in other policy areas.

To begin with, governments in our sample are clearly constrained in their institutional design choices and display preferences for solutions with deep roots in institutional and administrative traditions. Nonetheless, they also appear to enjoy a considerable degree of discretion in the setup of independent agencies charged with coverage decisions. Existing structures, for example, corporatist structures for remuneration negotiations in social insurance systems or agencies for market authorization and price negotiations with manufacturers in state health-care systems, are strategically employed and modified. In particular, in the social insurance systems, where governments are bound by strong traditions of self-administration, we observe attempts to influence outputs by modifying the institutional design of appointed bodies.

Moreover, processes of policy learning and institutional convergence certainly play a role as formalized "fourth hurdle" processes in the appraisal of new drugs spread across the world. European Union legislation is a central factor here. A council directive from 1988 (89/150/EEC) requires member states to set up formalized appraisal processes through which decisions on the listing of new drugs are taken within 90 days and negative decisions justified. In addition, the British NICE plays a strong role both as a blueprint for the setup of respective institutions and as a producer of reference decisions. While institutional design is unlikely to be transferred in a one-to-one style, NICE is not unlikely to become a growing source of convergence in the future. If participation in international networks of regulators, which all bodies discussed here engage in, does promote agencies' de facto independence from governments (as argued by Magetti 2007), the general role of independent

regulators in health-care priority setting is likely to increase in the future.

On the whole, what we observe in our six cases is best described as strategic institutional design under the significant conditions of given institutional structures and international organizations and networks. These context conditions define the set of options available and are thus not only constraining but also enabling, offering, for example, structures that can be employed for new purposes. What is remarkable is that strategic institutional design that runs counter to institutional traditions seems more easily possible for some institutional properties, such as delegation and transparency, than for others, such as defaults and independence. This result promotes our claim that a comparison of institutional solutions in different countries benefits from a framework of categories that enable the systematic description of design choices.

Given that governments have incentives and opportunities to manipulate the institutional design of appointed bodies according to partisan preferences in order to achieve strategic goals, an important focus for future research on delegation are the distributive effects of institutional design choices. Decision-making procedures and institutions are, especially where the allocation of essential goods like health care is concerned, never entirely neutral but always promote the values and interests of some groups more than those of others. In this sense, institutional design choices are at least in part distributive decisions themselves. This is why the choices that lie ahead should be intently observed with regard to the motives behind them and the effects that follow from them not only by researchers but also by a critical and informed democratic public.

Notes

1. For the most influential account, see Daniels and Sabin (1997).
2. Furthermore, a large European Union-funded project called *Health*BASKET compiled data on how European countries define health baskets. An article by Schreyögg et al. (2005) summarizes the main results.
3. A report by the Austrian Institute for Health Technology Assessment (Breyer 2008) and reports from the Pharmaceutical Pricing and Reimbursement Information project (see http://www.ppri.oebig.at) are further useful sources of empirical information on the definition of health baskets in international comparison.
4. A number of other articles compare smaller sets of countries (e.g., Gress et al. 2005; Holm 2000; Landwehr 2009; Schwarzer and Siebert 2009).
5. Thatcher (2002) uses a set of six indicators in a discussion of independent regulatory agencies for market competition. Several of these indicators are equivalent to the ones we use; others are not suitable in our context. Gilardi (2002) suggests an index to assess the independence of regulatory agencies. This index could, properly adjusted, provide a formal measure for what we, in this qualitative survey, describe as the degree of independence and delegation.
6. The United States constitutes the only case of a predominantly private health-care system within the OECD world, which is not further considered here.

Wendt, Frisina, and Rothgang (2009) suggest to classify health-care systems with regard to three dimensions: financing, organization, and service provision, each of which can be either public, societal, or private. Few systems are pure (taking the same value in all dimensions), but in most cases, one mode of regulation is dominant in at least two dimensions, thus enabling classification.

7. Names and functions of experts who confirmed the data are available from the authors on request.
8. Hauptverband der österreichischen Sozialversicherungsträger.
9. Gemeinsamer Bundesausschuss (GBA).
10. In 2010, the parliamentary majority of the Christian democrats and the liberal party (FDP) introduced a novel price-setting mechanism for innovative pharmaceuticals, thereby redesigning the process of coverage decision making for pharmaceuticals. From 2011 onward, every new drug must be assessed by an independent Health Technology Assessment (HTA) institute. On the basis of this assessment, the FJC negotiates the price with the manufacturer. If no agreement is achieved, an arbitration body will set the price.
11. The governing coalition between the social democrats and the greens (1998–2005) explicitly referred to the British NICE when it set up the FJC (on the basis of several preexisting committees) along with an advisory expert body (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen) in 2004. In 2008, a new grand coalition (between social democrats and Christian democrats) was in office, but the FJC reform was devised by the same minister as the previous reform (Ulla Schmidt, SPD).
12. Statens legemiddelverk.
13. On the parliamentary priorities commission in comparison with the Norwegian Lonning commission, see Calltorp (1999).
14. The composition of guidance committees, which develop nonbinding recommendations on the coverage and provision of nonpharmaceutical medical services, is rather similar: They consist of 10–20 members and involve different stakeholders, too. Appraisals and guidance developed within the committees have to be approved by the guidance executive, the senior management unit within NICE, before they are published and become binding.

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