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What explains 'generosity' in the public financing of high-tech drugs?

An empirical investigation of 25 OECD countries and 11 controversial drugs

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Abstract

In times of increasing cost pressures, public healthcare systems in Organisation for Economic Cooperation and Development (OECD) countries face the question of whether and to which extent new high-tech drugs are to be financed within their public healthcare systems. Systematic empirical research that explains across-country variation in these decisions is, however, almost non-existent. We analyse an original dataset that contains coverage decisions for 11 controversial drugs in 25 OECD countries using multilevel modelling. Our results indicate that the 'generosity' with which controversial new drugs are publicly financed is unrelated to a country's wealth and general expenditure levels for healthcare. However, healthcare systems financed through social insurance contributions tend to be more generous than tax-financed ones. Moreover, we uncover evidence suggesting that the institutional characteristics of the decision-making process matter systematically for decisions on whether to finance controversial drugs.

Introduction

One of the many challenges facing healthcare systems in developed democracies is the increase in costs for high-tech drugs. Hundreds of patented and often very expensive new pharmaceuticals enter the market every year and are demanded by patients. However, public healthcare systems in most countries have difficulties financing all drugs that are demanded, and perhaps also required, by patients. Where no limits to the public financing of high-tech drugs are set, costs are likely to burst the budgets for pharmaceuticals and produce other costs elsewhere inside and outside the healthcare system. In 2008 pharmaceuticals accounted for 16.9 percent of total health expenses in Organisation for

Economic Co-operation and Development (OECD) countries, compared with an average of 13.5 percent in 1980 (Organisation for Economic Co-operation and Development, 2011).

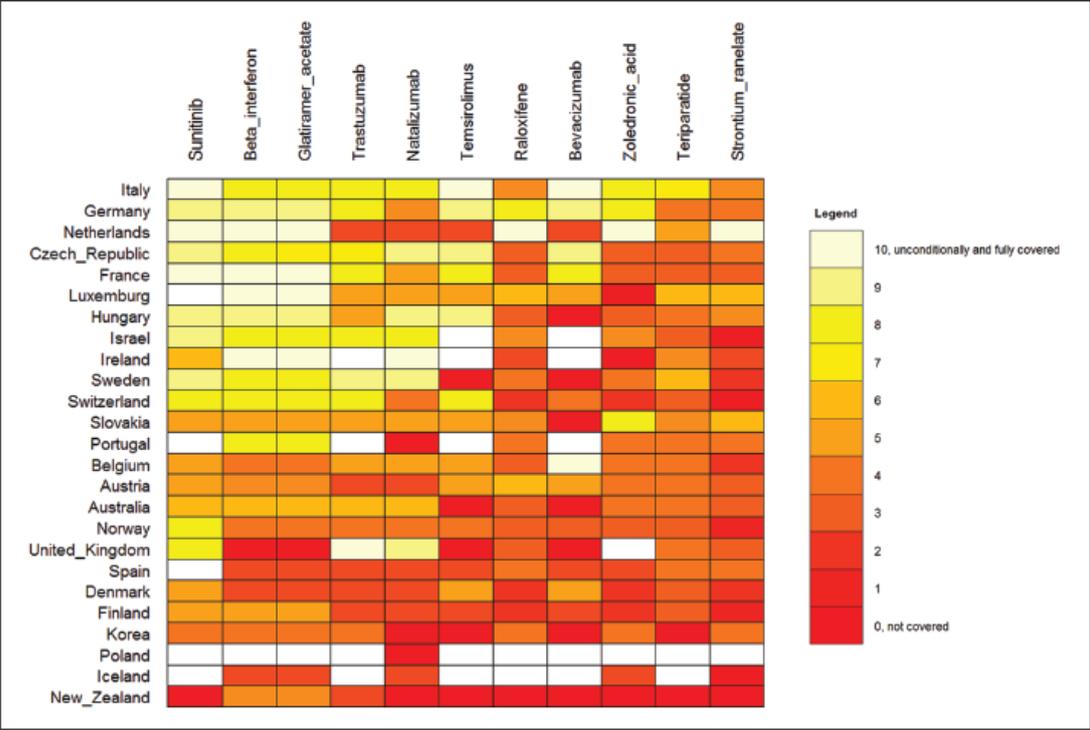


Figure 1. Public coverage of high-tech drugs by country and pharmaceutical.
 Note: Public coverage is measured by the conditionality and share of public coverage with an index that varies from zero ('not covered') to ten ('unconditionally' and 'fully covered'). The details of the index construction are discussed below. Countries are sorted in descending order of generosity from top to bottom; pharmaceuticals are sorted in descending order of generosity from left to right. More specifically, countries and drugs are ordered by estimated intercepts obtained from an 'empty' non-nested multilevel model. The model estimated is structurally similar to the specification described in the text. The model is, however, 'empty' in the sense of containing no explanatory variables. Blank (white) cells indicate missing values.

In order to limit public expenditure on drugs, most OECD countries have – to a greater or lesser extent – restricted the public coverage of new drugs. In this paper, we use public coverage as a synonym for the generosity of public healthcare systems in granting free access to a particular drug. In our use, the term 'public coverage' encompasses two dimensions: the share of costs that is borne by the public healthcare systems (share of coverage) and the conditions which regulate free access (conditions of coverage) and which can be more or less restrictive [1]. Figure 1 displays the extremely heterogeneous picture that is found when comparing the public coverage of a set of controversial drugs across OECD countries. The figure plots the extent to which these controversial drugs are publicly financed in a colour grid structured by countries (vertical axis) and pharmaceuticals (horizontal axis). To ease interpretation, countries are sorted in descending order of coverage from top to bottom and pharmaceuticals are sorted in descending order of

coverage from left to right. Given differences in price and effectiveness, it is hardly surprising that some drugs are more likely to be covered than others. What is striking, however, is that different countries cover different drugs and that some countries are generally more 'generous' than others in that they cover more controversial drugs than others do. According to our estimates, Italy is the most generous country in our sample, whereas New Zealand is the least generous.

What explains these differences in public generosity where the coverage of high-tech drugs is concerned? Is generosity merely a function of economic wealth, as expressed in the gross national product (GNP)? Does it depend on a society's across-the-board generosity for healthcare, as expressed in public health expenses per capita? Do we need to consider institutional factors such as the history and structure of the respective healthcare system? Finally, given that decisions on the coverage of new drugs are in nearly all OECD countries delegated to specialized bodies or agencies (see Landwehr and Böhm, 2011), we need to address the structure of the decisionmaking process and institutions involved in it.

To answer these questions, we draw on data we have gathered on the public financing of 11 controversial drugs in 25 OECD countries. Although all these drugs have market-authorization for the countries studied, the public financing of these drugs is controversial, as their efficiency is either unclear or contested. We consider both the conditions under which these drugs are available to patients and the share to which their price is covered by the public systems (leaving the difference between reimbursed cost and the actual price to be paid out-of-pocket by the patient). As explanatory factors, we consider the wealth of a country and its level of public health expenditure as well as the organization of the healthcare system and institutional parameters of the decision-making process used to decide on the coverage of drugs. The larger questions behind our analysis are whether it is eventually economy or politics that drives distributive decisions on the coverage of health services, and more specifically, what difference the institutional design of healthcare systems and decision-making processes within them make for the availability of more or less essential services.

This paper presents a multilevel analysis of coverage decisions in the OECD world. Our analysis is based on OECD health data as well as a novel dataset for both coverage decisions and decisionmaking processes in 25 OECD countries containing data that we collected in a research project in 2010. We come to the surprising result that neither

economic wealth nor expense levels significantly affect generosity. Instead, explanations need to consider the institutional set-up of the healthcare system and, what is more important, the structure of processes in which decisions about whether to publicly finance a drug or not are made. Put briefly, the explanations for generosity in the public financing of high-tech drugs are not economic, but political ones. We conclude that if institutional design affects financing decisions, institutional design is a matter not only of procedural, but also of distributive justice.

Coverage decisions in healthcare: existing research, theories and hypotheses

Coverage decisions on expensive pharmaceuticals are a central aspect of a more general problem: the need to set limits to healthcare spending in face of increasing costs and decreasing public revenues. Healthcare priority-setting, or, put more crudely, healthcare rationing, has in recent decades increasingly become a hot issue in public and academic debates. The 1980s and early 1990s were characterized by a search for something like 'objectively fair' allocation principles from which single coverage decisions could simply be derived. However, empirical experience with participatory and expert bodies has shown that principles of distributive justice are too abstract to guide concrete coverage decisions and that consensus on allocation criteria remains out of reach. The debate has hence taken a 'procedural turn' (Holm, 2000), thus focusing on desiderata for a fair decision-making process rather than on substantial coverage decisions. A seminal contribution in this regard has been Norman Daniels and James E. Sabin's model 'accountability for reasonableness', in which the authors outline conditions bodies charged with coverage decisions need to fulfil in order to guarantee procedural justice (Daniels and Sabin, 2002).

Until recently, most research on healthcare priority setting focused on the fundamental ethical questions involved, using the case as an example to discuss implications of different theories of justice or outlining ideal decision-making procedures. In the last few years, however, more empirical literature has emerged. A major European project has analysed the content of health baskets in numerous countries (Schulenburg and Blanke, 2004), and several studies have compared decision-making processes in smaller sets of countries (for example, Ham and Robert, 2003; Landwehr and Böhm, 2011; Sabik and Lie, 2008). None of these contributions, however, has tried to account for differences in coverage decisions and resulting health baskets, and none has studied effects of decision-

making procedures on resulting decisions. This is the research gap that this paper seeks to address by asking which variables can account for differences in coverage decisions and by explicitly taking into account the effect of institutional factors (that is, properties of decision-making processes) on resulting decisions.

In examining the relationship between institutional characteristics and decision outcomes, we focus on high tech drugs because these are one of the main forces that drive the growth of health budgets. Furthermore, the coverage of drugs is well specified in most countries, while the coverage of other health benefits is often only vaguely defined. An examination of a wider range of drugs (for example, bestsellers) was not possible because we had to make sure that coverage decisions were made by the particular committee for which data on institutional parameters were available. These data were for most countries available only for currently serving committees.

What might explain differences in generosity in the public funding of high tech drugs? The first explanations that suggest themselves almost selfevidently are the economic wealth of a country and its general expenditure levels in the healthcare sector. Wealthier countries, according to the apparently obvious explanation, can afford higher public health expenses and can cover more, and more expensive, drugs. Similarly, a society that can afford to spend a higher total amount per capita on healthcare than another and decides to do so within a public healthcare system seems likely to cover more, and more expensive, drugs. In a first step, we thus assess the effects of economic wealth and healthcare expenditure on coverage decisions for our 11 controversial high-tech drugs for the treatment of four different diseases. The hypotheses to be tested here are straightforward:

H1: The wealthier a country is (measured by GNP per capita (p.c.)), the more 'generous' is the public funding of controversial drugs (that is, the less restrictive are conditions and the higher the share that is publicly funded).

H2: The higher overall spending on healthcare (p.c.) is, the more 'generous' is the public funding of controversial drugs.

H3: The higher public spending on healthcare (p.c.) is, the more 'generous' is the public funding of controversial drugs.

In a second step, we assess whether the broader institutional context within which coverage decisions are made affects the extent to and conditions under which controversial high-tech drugs will be publicly financed. To begin with, the healthcare system as a whole could clearly be a significant contextual variable. Each healthcare system is a unique sample of different institutional characteristics. In order to be able to compare healthcare systems, researchers have developed various classifications of healthcare systems in the past (for an overview see Freeman and Frisina, 2010; Wendt et al., 2009). The best established is probably the typology developed by the OECD in 1987 that groups OECD healthcare systems according to the three features (population coverage, funding and ownership) into three categories: national health systems (universal population coverage, tax funded, state ownership of provision), social insurance systems (universal population coverage, financed by social insurance contributions, public and/or private ownership) and private insurance systems (voluntary private insurance, private insurance contributions, private ownership). As our sample does not include any private systems, we concentrate on differences between national healthcare systems and social insurance systems. Both types are equally characterized by universal population coverage, which is why we do not address this issue here. We also disregard the aspect of ownership as healthcare in almost all OECD countries today is provided by a mix of public and private providers (Böhm et al., 2012). Instead, we concentrate on how the system is financed. Regarding the effects of the type of financing of a healthcare system on generosity in coverage decisions, we theorize that social contribution financed systems are more generous in financing controversial treatments than tax-financed systems for two reasons. First, social insurance systems constitute an enforceable legal right to services, which is based on an individual insurance contract and legitimated by contribution payments. Most state systems, in contrast, are based on a social contract that constitutes a general right to treatment but does not imply an individual right to particular services, meaning that the scope of coverage can be modified according to changing social and economic conditions (Wendt, 2003: 49–51). Second, the budget of social health insurance systems is (in most cases) separated from the general state budget and might thus be less subject to budget constraints. Our hypothesis is thus:

H4: In tax-financed healthcare systems public funding of controversial drugs is less generous.

A second potentially important contextual variable is the way the default is set. The default is the outcome that is effected if no decision is taken. Its significance for actor constellations and resulting decisions has been pointed out impressively by Elinor Ostrom (1986). With a positive default, all pharmaceuticals are reimbursed until a contrary decision is made. In this case decisions merely to exclude a drug need to be taken. More common are negative defaults, where pharmaceuticals are funded after a positive decision only. We expect the default to have significant predictive power for generosity with a positive default rendering regulations more generous. This expectation is in accordance with game-theoretic work that emphasizes the crucial role default regulations play in shaping the power of individual actors with diverging preferences in individual decision problems (see Tsebelis, 2002). Roughly speaking, in the case of a positive default, an actor preferring full coverage just needs to block any decision to the contrary. [2] We thus expect:

H5: Where the default is negative, public funding of controversial drugs is less generous.

Most important, however, we also expect the properties of the decision-making process itself to affect coverage decisions. All OECD countries have set up specialized bodies to deal with the challenge of healthcare priority-setting, but have chosen very different institutional designs for these (see Landwehr and Böhm, 2011). In order to be able to compare the various and often complex processes we suggest a set of categories that grasp the main institutional characteristics we theorize to have effects on resulting decisions (see Landwehr and Böhm, 2011).

The first categories are the degree of delegation of decision-making power from government to nongovernmental bodies and the independence of these bodies from the influence of the government on the one hand and their regulatees on the other. Our theoretical expectation is that delegation and independence render public funding less generous: delegation to independent bodies constitutes a strategy of 'depoliticization' and possibly also 'blame avoidance' (Weaver, 1986) with which elected governments evade responsibility for unpopular decisions. Opportunistic politicians have incentives to not restrict the funding of certain drugs if this is expected to prove electorally costly. The general expectation from the welfare state literature is that social policy retrenchment is indeed

associated with negative consequences at the ballot box, especially to the extent that losses are concentrated and potential gains diffuse (Giger, 2011: 19). Where independent bodies enjoy much leeway, electoral costs are thus likely to be less relevant for the final decision. At the same time, governments that seek to avoid electoral costs through delegation are under pressure to limit expenses and have incentives to choose an institutional design that promotes this goal. For example, they may staff respective bodies with experts who have a background in evidence-based medicine or health economics and who take a sceptical view on new drugs with (yet) unproven effectiveness. With more delegation and independence, less generous decisions are, therefore, to be expected.

Furthermore, we suppose that the inclusiveness of the committee, namely its composition and size, affects decision-making. Transaction cost and negotiation theory (the most seminal being Coase, 1937) has shown that the larger and more heterogeneous, and thus more inclusive, a committee is, the more costly and difficult, and thus eventually unlikely, decision-making becomes. A higher number of different actors (or actor groups) means that a higher number of divergent interests and points of view have to be coordinated, which affects the probability and content of decisions. However, it must also be noted that heterogeneity in the composition of a forum enlarges the argument pool actors can draw on and might thus improve the quality and acceptability of decisions. As to the degree of generosity to be expected from composition and size, our weak theoretical prior is that inclusiveness generally leads to more generous financing schemes. As experts are involved in nearly all of the bodies considered, inclusiveness is to a considerable degree determined by whether patients, laypersons and industry representatives take part in decision-making. We expect that these actors push the decision towards more generous public funding: patient organizations are nowadays well-informed on innovative treatments and often supported by the pharmaceutical industry, thus fuelling the demand for new drugs with unproven benefits. The industry's interest in generous funding for controversial drugs is self-evident. The general public, as well as lay members of appraisal bodies, may be expected to sympathize with patients and discard accruing opportunity costs in favour of a duty to help.

Apart from the composition of a forum and the number of members, the decision rule applied is a central aspect of its inclusiveness. Consensus requirements obviously render decisions more difficult, while the availability of majority decisions (and hierarchical

decisions even more so) reduces transaction costs and thus increases the probability that a decision will be reached at all. How this affects generosity should be contingent on the default regulation in place. When the default is negative (as is true for 23 out of the 25 countries under investigation), more inclusive decision rules should lead to less public funding. Considered from a game-theoretic perspective, under a consensus rule and a negative default the final decision should reflect the preferences of the actor who is most strongly opposed to public funding as this actor can simply block any decision that is more generous than his ideal point (Scharpf, 1989; Tsebelis, 2002).

Finally, the transparency of the decision-making process might have an impact on the generosity of decisions. Transparency is marked as a central desideratum in the normative debate on procedural justice of distributive decisions because it is believed to increase accountability (Daniels and Sabin, 2002). However, we also expect the degree to which a decision-making process is publicly accessible and transparent to have effects on resulting decisions, although the direction of these effects is less clear. On the one hand, publicity and transparency increase opportunities for public scrutiny and may thus make unpopular decisions (that is, ones not to cover a drug) more difficult. On the other hand, publicity and transparency may provide decision-makers with opportunities to justify tough decisions, thus eventually facilitating these. To summarize, the following hypotheses on the effects of institutional characteristics of the decision-making process follow from our theoretical considerations:

H6: Where the degree of delegation and independence of an appointed body are high, public funding of controversial drugs is less generous.

H7: The more inclusive an appointed body, the more generous is the public funding of controversial drugs.

H8: The higher the majority requirements for decisions (maximum: consensus), the less generous is the public funding of controversial drugs.

H9a: The higher the transparency of the decisionmaking process, the more generous is the public funding of controversial drugs.

H9b: The higher the transparency of the decisionmaking process, the less generous is the public funding of controversial drugs.

Study design and data

Our study addresses coverage decisions for high-tech drugs in 25 developed democracies. We consider the OECD member countries as of 2009, including Israel, which acceded in 2010, and excluding Mexico, Turkey and Greece for which the quality of available data is too poor, as well as the United States and Canada, where the decentralized character of the public healthcare system does not allow claims on the public coverage of single drugs for the national level and resource constraints and kept us from collecting data at lower levels. We also had to exclude Japan due to problems with data availability and translation. Although our sample thus includes mainly European countries, we think that the right analytical level for comparison is the entirety of developed industrial nations because these all face the same problems concerning the financing of high-tech drugs. Moreover, the influence of the European Union in this area is marginal, as coverage decisions fully remain within the responsibility of the member states (Böhm and Landwehr, 2013).

Our dependent variable is the ‘generosity’ public healthcare systems display in financing decisions on controversial drugs. We describe a system as generous when it meets patients’ demands for funding at a time when the effectiveness of a drug has not yet been proven – so that the payer does not know what value is derived from the investment. More specifically, we have chosen 11 pharmaceuticals for the treatment of four different diseases. This choice is the result of a two-stage selection process that was guided by the search for variance in decision-outcomes and the wish to include drugs for different kinds of diseases. In a first step, we scanned reimbursement decisions and assessment reports for a smaller country sample to find high-tech drugs for which reimbursement was contested due to controversial efficiency and for which coverage decisions varied between countries. In a second step, we selected condition-treatment pairs in order to represent a range of different diseases, including a ‘normal’ age-related medical condition (osteoporosis), a severe but non-fatal illness (multiple sclerosis) and two types of cancers, one of which is very common but treatable (breast cancer) while the other is rather rare but highly lethal (renal cell carcinoma). For three of the conditions (osteoporosis, multiple sclerosis, renal cell carcinoma) for which treatments were considered, our sample contains several controversial treatments, which may in some cases substitute for one another. In order to get full information on generosity, we thus considered all available and controversial treatments for a given condition.

Zoledronic acid, teriparatide, strontium ranelate and raloxifene are used for the treatment of osteoporosis. All four drugs are very much more expensive than standard therapy without securely proven better effectiveness. Beta-interferon, glatiramer acetate and natalizumab are immune-modulating substances for the treatment of relapse-remitting multiple sclerosis (MS). Trastuzumab (Herceptin) is a monoclonal antibody for the adjuvant therapy of a certain type of non-metastatic breast cancer that is given after initial treatment (for example, chemotherapy) to improve long-term prognosis. In the case of trastuzumab, the required duration of treatment is contested. Sunitinib, temsirolimus and bevacizumab have market authorization in the countries studied for the first-line treatment of metastatic renal cell carcinoma.

To measure the generosity of public reimbursement, we have developed two indices that contain information about the conditions of coverage and the share of coverage pertaining to the individual country- drug cases, which we then combine into one summary measure of generosity. To be able to compare conditionality of reimbursement between countries, we have first collected data on the constraints that financing of these pharmaceuticals are subject to and which are not named in its market authorization. In a second step, we compared single conditions and classified them according to their potential to restrict coverage. We then categorized each pharmaceutical according to restrictions on coverage into five levels of conditionality, ranging from unconditionally covered to not covered at all (see online appendix for a description of the index and conditions categories). The resulting conditions of coverage index ranges from zero to one, with zero indicating 'not covered' and one reflecting 'unconditionally covered'. The share of coverage index displays what share of a drug's price is to be borne by the patient. If the particular drug is not covered, the index takes the value zero, and it takes the value one if it is fully reimbursed without co-payments for the patient. In between, we distinguish four different levels of copayment (for a detailed description of the index values and the calculation of co-payment, see online appendix).

To reflect the fact that the generosity of public coverage depends clearly on both aspects, we combine the two indices into one overall *generosityindex* [3]. In our view, the most sensible way to combine this information is by computing the product of the two individual indices with equal weights attached to the two components. A multiplicative index has the advantage that, in contrast to an additive index, it does not allow for full

compensation (see Nardo et al., 2005: 79), that is, it is not possible for a country to compensate for very strict conditionality restrictions with a high share of coverage. We rescale the resulting generosity index so that it takes a maximum value of ten (when pharmaceuticals are unconditionally and fully covered) and a minimum value of zero (when a drug is not covered at all) by multiplying the product of the two sub-indices with the factor ten in order to facilitate the description in the empirical analyses.[4]

All data on the institutional parameters of decision-making processes and the dependent variables were collected in an observation period in the first half of 2010. Thus, neither coverage decisions nor changes in the institutional design after June 2010 were considered. Data on institutional characteristics of the decision-making process and on coverage decisions were gathered from official documents (legal texts, rules of procedures) as well as web pages of the respective committees or other official web pages from ministries or public health administration. This information was supplemented by information from secondary literature and confirmed by experts from the respective systems (academics or committee members). Data on GNP per capita and public health expenses as well as on the financing of healthcare systems (all data are for 2008) were drawn from OECD health data 2011 (Organisation for Economic Co-operation and Development, 2011). In order to operationalize the properties of the decision-making processes, we have developed indices that translate qualitative information on the particular institutional characteristics into numerical values between zero and one. Information on the default is included as a dummy variable. Drawing on an independence index for regulatory agencies suggested by Gilardi (2002), we have established a delegation and independence index that considers the members' status, the body's financial and organizational autonomy, the competences of the committee and that asks who takes the final and binding decision. The inclusiveness of the involved committee is mapped by an index that contains information about the members, the number of members and involved stakeholders. Due to its relative importance (see above), we have not included the decision-rule into the inclusiveness index but have given it an own value. And finally, we have used information on the public availability of proceedings, meetings and reports to build the transparency index. Table 1 gives an overview over the institutional characteristics of the decision-making process and the construction of the indices. Details on the construction of the indices can be

found in the online appendix accompanying this article, where we also list the data on the independent variables and their pairwise correlations with each other.

Statistical model

We explore the predictive power of the factors discussed above within a non-nested (or ‘cross-classified’) multilevel model where individual regulations are simultaneously nested within countries as well as pharmaceuticals. Given that our observations are structured along these two dimensions the natural way of analysing this data is to directly specify this grouping structure in the statistical model. In contrast to usual multilevel applications in political science that employ strictly hierarchical models (see Steenbergen and Jones, 2002) our grouping structure is non-nested. In our data each individual observation simultaneously relates to a specific pharmaceutical and a specific country. In addition to the level of the individual observations (level 1), we thus have two group levels (level 2) that are not hierarchically related to each other. Hence, we specify distributions

Table 1. Institutional characteristics of decision-making processes.

Indices	Single independent variables
Default [<i>dummy variable</i>]	<i>Explicit decision necessary for inclusion</i>
Independence and delegation	
Independence	Member status: <i>appointment; status</i> Financial and organizational autonomy: <i>own budget and secretariat; formal independence; internal organisation; agenda setting</i>
Delegation	Relationship with government/parliament: <i>actor taking binding decisions; competences of the committee</i>
Inclusiveness	<i>Members; stakeholder participation; number of members</i>
Decision rule	<i>Decision rule</i>
Transparency	<i>Openness to the public</i>

for the individual level, for the country-intercepts and the therapy-intercepts. Formalizing this discussion, our statistical model takes the following form (our notation builds on Gelman and Hill, 2007):

$$y_i = \alpha + \mu_j + \delta_k + \varepsilon_i$$

$$\text{for } i = 1, \dots, N$$

$$\mu_j \sim N(\beta X_j, \sigma_\mu^2)$$

$$\text{for } j = 1, \dots, J$$

$$\delta_k \sim N(\omega Z_k, \sigma_\delta^2)$$

$$\text{for } k = 1, \dots, K(1)$$

In the individual level model (first row of model 1), the generosity of the regulation (y_i) is regressed on an overall intercept (α), on (j) country-specific intercepts (μ) and on (k) drug-specific intercepts (δ). The second row of model 1 specifies a distribution for the country intercepts; it is this part of the model in which we are substantially interested. We assume a normal distribution with variance (δ_μ^2) estimated from the data and a mean that is specified as the product of country specific vectors of predictors (X_j) and a vector of corresponding coefficients (β) to be estimated from the data. In the matrix of countrylevel predictors we include the explanatory factors discussed above. The third row of model 1 specifies a distribution for the pharmaceutical intercepts. Again, we assume a normal distribution with variance (δ_δ^2) to be estimated from the data. Rather than just assuming a mean of zero, we directly model the fact that the 11 pharmaceuticals relate to four different diseases. In order to do that, we specify the mean of the distribution to be the product of drug-specific vectors of predictors (Z_k) and a vector of corresponding coefficients (ω). The columns of the matrix of drug level predictors are dummy variables for three of the four diseases (with the remaining one building the reference category). The vector ω is thus of length three and contains the coefficients for these three dummy variables.

We estimate this multilevel model via Winbugs (version 1.4.3), a statistical software program that allows for Bayesian analysis using Markov Chain Monte Carlo (MCMC) methods. In doing so, we follow the advice of Gelman and Hill (2007: chapter 16) who advocate the use of Bayesian MCMC methods in fitting multilevel models in case of more complex grouping structures such as non-nested ones. More generally, Bayesian estimation tends to produce more accurate and conservative results (than alternative maximum likelihood estimation) in cases where the number of level-two units is small (for example, Stegmüller, 2013). We use non-informative priors for coefficients and variances, again following the usual practice as presented in Gelman and Hill (2007). Convergence is checked via the potential scale reduction factor \hat{R} that assesses convergences via the mixture of different chains (see Gelman and Hill, 2007: 358). All reported results are based on results from a sufficiently large number of iterations such that $\hat{R} < 1.1$

In the results section, we present posterior means and lower and upper bounds of the corresponding 90 percent credible intervals for our parameters of interest. For readers more familiar with standard regression approaches, we note that these can be interpreted

analogously to estimated coefficients and corresponding 90 percent confidence intervals from standard regression outputs. Likewise, a coefficient can be interpreted as being statistically significantly different from zero with $p < 0.10$ if zero is not contained in the 90 percent credible interval. We present R^2 measures of explained variance at the different levels (data level, country level and pharmaceutical level) following Gelman and Pardoe (2006). These can be interpreted analogously to the classical (adjusted) R^2 .

Results

In the estimation of our models, we proceeded in an explorative and stepwise fashion given the limited prior knowledge on our subject matter and to save degrees of freedom. This section presents the empirical findings. It follows the structure laid out above in that we first consider the economic wealth and general expenditure levels in the healthcare sector. We then turn to the institutional context within which coverage decisions are made. Finally, institutional parameters of decision-making processes and involved bodies are taken into account. Our approach is theory-guided in that we move from less proximate to more proximate factors in a manner that allows us to eliminate potential explanatory factors in turn [5]. This way it becomes possible to estimate reasonable reduced models that do not contain all possible explanatory factors at once; such a 'garbage-can' (Achen, 2005) approach would be unwise given the limited information in our data.

Table 2 investigates into the predictive power of the first group of explanatory variables. Overall it presents the results from four different specifications that differ (only) in regard to the country-level predictors that are included. In the first three models only one predictor is included in turn. The first model introduces the GNP per capita in thousand US\$, the second model total health expenditure per capita in thousand US\$ and the third model public health expenditure per capita, again, in thousand US\$. These variables are strongly correlated to each other such that it would be problematic in terms of multicollinearity to include them in one model at once. For none of these three variables do we observe any noteworthy association with our dependent variable. The posterior means indicate small effects in all cases: for example, a move from the poorest country in our sample to the richest one corresponds to an expected increase in generosity of about only 0.5 [6]. Further, as indicated by the credible intervals, in none of the cases can we have any confidence that the effects are different from zero. The low predictive power of the three predictors is also

evident by the poor model fit as indicated by the measure of explained variance at the country level: it is negative across these three models meaning that the estimated error variance is larger than the estimated variance of the country intercepts in these models.

Model 4 investigates the question of whether any visible pattern emerges when accounting for wealth, total and public health expenditure simultaneously. In order to do that we look at total health expenditure in percent of GDP and public health expenditure in percent of total health expenditure, that is, we reconstruct these measures in such a way that collinearity is reduced. Our conclusions remain unchanged: to our surprise, the data do not support the hypotheses, that more wealthy states are more generous with regard to the public financing of high-tech drugs (H1); nor is there any evidence to support the seemingly obvious conclusion that the generosity in the public financing of high-tech drugs consistently corresponds to general expenditure levels for overall (H2) or public healthcare (H3). As all the considered variables do not seem to be consequential for generosity, we do not include them in the following models.[7]

Table 2. Wealth, health expenditure levels and generosity of public coverage of high-tech pharmaceuticals.

	(1)	(2)	(3)	(4)
Variables: country level				
GNP p.c. (in thousands)	0.007 [-0.025; 0.040]			0.010 [-0.026; 0.046]
Total health expenditure p.c. (in thousands)		0.108 [-0.215; 0.438]		
Public health expenditure p.c. (in thousands)			-0.011 [-0.460; 0.407]	
Total health expenditure in % of GDP				0.149 [-0.371; 0.691]
Public health expenditure in % of total health expenditure				-0.030 [-0.117; 0.053]
Variables: therapy level				
Breast cancer	1.77 [-0.42; 3.90]	1.81 [-0.66; 4.16]	1.81 [-0.48; 4.13]	1.79 [-0.59; 4.14]
Multiple sclerosis	2.14 [0.53; 3.70]	2.12 [0.56; 3.70]	2.10 [0.51; 3.55]	2.12 [0.52; 3.65]
Renal cell carcinoma	1.50 [-0.05; 3.12]	1.50 [-0.05; 3.05]	1.47 [-0.17; 3.05]	1.48 [-0.16; 3.12]
Standard deviation				
Country level intercepts (σ_{μ})	1.75 [1.26; 2.34]	1.75 [1.23; 2.29]	1.73 [1.26; 2.31]	1.83 [1.32; 2.48]
Pharmaceutical level intercepts (σ_{ϕ})	1.09 [0.54; 2.01]	1.11 [0.53; 2.01]	1.10 [0.53; 1.99]	1.09 [0.54; 1.98]
Explained variance				
Overall	0.42	0.42	0.42	0.42
Country level	-0.03	-0.02	-0.04	-0.09
Pharmaceutical level	0.36	0.34	0.35	0.35
Number				
Of observations	247	247	247	247
Of countries	25	25	25	25
Of pharmaceuticals	11	11	11	11

Note: Bayesian non-nested multilevel models; dependent variable is the generosity of public coverage of pharmaceuticals; listed are posterior means for coefficients with 90 percent credible intervals given in brackets below the coefficients (that is, values for the 5th and 95th percentile of the posterior distribution); constant and country and pharmaceutical level intercepts not shown.

Table 3 thus concentrates on the remaining two groups of explanatory variables. Model 5 in Table 3 introduces two variables that relate to the broader institutional context in which coverage decisions are made: the type of the healthcare system, that is, whether it is predominantly societally or state funded, and a dummy variable that captures whether the default is positive or negative. Both variables seem to be clearly associated with generosity in the expected direction. The point estimates for the posterior means indicate that generosity is higher by 2.1 in countries with a positive default and 1.4 in countries with a societal healthcare system. These effects correspond to substantial differences in generosity given the range from zero to ten. Moreover, the 90 percent credible intervals do not contain zero in both cases such that we can reject the nil hypotheses with reasonable confidence. The model explains 28 percent of the variance across countries: a substantial

improvement over the previous models. Initial support for the hypotheses that associate state funded healthcare systems with less generosity (H4) and positive defaults with more generosity is thus obtained (H5). Given their predictive power we keep these variables in the subsequent models that introduce the variables that relate to institutional features of decision-making processes and delegative bodies.

Table 3. Healthcare system structure, delegative institutions and generosity of public coverage of high-tech pharmaceuticals.

	(5)	(6)	(7)	(8)
Variables: country level				
Healthcare system societal	1.39 [0.32; 2.42]	0.84 [-0.46; 2.16]	0.80 [-0.40; 1.92]	
Positive default	2.13 [0.13; 4.00]	2.37 [0.28; 4.48]	2.34 [0.22; 4.38]	2.45 [0.34; 4.57]
Delegation and independence		-1.95 [-4.62; 0.87]	-2.30 [-4.94; 0.15]	-3.10 [-5.49; -0.49]
Transparency		1.36 [-0.50; 3.12]	1.45 [-0.23; 3.12]	1.75 [0.24; 3.40]
Inclusiveness		0.29 [-2.52; 3.05]		
Decision rule		-1.98 [-3.95; -0.06]	-2.08 [-3.99; -0.26]	-2.27 [-4.05; -0.33]
Variables: therapy level				
Breast cancer	1.81 [-0.64; 4.18]	1.73 [-0.69; 3.96]	1.77 [-0.73; 4.26]	1.80 [-0.34; 4.08]
Multiple sclerosis	2.13 [0.55; 3.74]	2.15 [0.52; 3.78]	2.12 [0.49; 3.76]	2.20 [0.68; 3.90]
Renal cell carcinoma	1.48 [-0.23; 3.15]	1.44 [-0.06; 2.98]	1.47 [-0.13; 3.10]	1.51 [-0.01; 3.05]
Standard deviation				
Country level intercepts (σ_{μ})	1.43 [1.00; 1.97]	1.42 [0.93; 2.04]	1.36 [0.90; 1.94]	1.40 [0.99; 1.97]
Pharmaceutical level intercepts (σ_{ξ})	1.12 [0.53; 2.04]	1.11 [0.53; 1.96]	1.12 [0.55; 2.02]	1.08 [0.47; 2.00]
Explained variance				
Data level	0.42	0.42	0.42	0.42
Country level	0.28	0.34	0.38	0.35
Pharmaceutical level	0.32	0.35	0.32	0.36
Number				
Of observations	247	247	247	247
Of countries	25	25	25	25
Of pharmaceuticals	11	11	11	11

Note: Bayesian non-nested multilevel models; dependent variable is the generosity of public coverage of pharmaceuticals; listed are posterior means for coefficients with 90 percent credible intervals given in brackets below the coefficients (that is, values for the 5th and 95th percentile of the posterior distribution); constant and country and pharmaceutical level intercepts not shown.

All four concerned variables are introduced in model 6. With the introduction of these variables the healthcare type dummy loses in predictive power: the mean coefficient is cut in half and the 90 percent credible interval now also contains negative values. The results for the positive default remain largely unchanged. Coming to the newly introduced variables, we observe the clearest effect for the decision rule. Where decision rules are more inclusive stipulating a consensus among the participant actors, generosity tends to be lower by about

2 points (compared with hierarchical) and 1.5 points (compared with majority decision rules), and the effect is reliably estimated to be negative. This supports H8. In contrast, inclusiveness is not related to generosity: the posterior distribution is wide with a mean close to zero. Thus, we do not obtain support for the proposition that inclusive committees will produce more generous regulations for the public financing of high-tech drugs (H7). Our results remain inconclusive with regard to delegation and independence as well as transparency. The posterior mean points to a substantial negative effect of delegation and independence which suggests that delegation and independence facilitate rationing decisions and more restrictive regulations as expected by H6. However, the coefficient for delegation and independence is imprecisely estimated with a large credible interval that is mainly in the negative range but also contains values above zero. A similar pattern emerges for transparency: the point estimate suggests a substantial positive effect with more transparency being associated with more generous regulations (as suggested by H9a). Again, however, the coefficient is imprecisely estimated and the 90 percent credible interval also marginally contains negative values. The data thus point to both delegation and independence and transparency (as far as H9a is concerned) in the expected direction, but the confidence in these associations remains limited. Model 7 eliminates inclusiveness from the set of country-level predictors. The estimation results for the remaining variables stay similar in comparison to model 6. As indicated by the explained variance at the country level in both models 6 and 7, the introduction of the institutional features of decision-making processes and delegative bodies further helps to improve the predictive accuracy of the model.

Finally, model 8 excludes the healthcare dummy. While this is partly problematic given the predictive value of this variable (especially in model 5), the exclusion is based on the rationale that some of the features of the delegative institutions are to some extent related to the overall type of the healthcare system for reasons elaborated upon elsewhere (Landwehr and Böhm, 2011). For this reason, it might be hard to statistically reliably distinguish effects of the healthcare system from those of these institutional features. Therefore, model 8 explores how the exclusion of the healthcare type changes the estimation results. The results for the default regulation and decision rule remain roughly unchanged with substantial and reliable associations in the theoretically expected directions. In case of delegation and independence as well as transparency, we also observe only slight

modifications, which, however, would lead to different conclusions from the perspective of statistical significance testing. Both posterior means are larger in absolute value compared with models 6 and 7. What is more, the credible intervals do contain only negative values for delegation and independence and only positive ones for transparency. Accordingly, the nil hypothesis could be rejected with $p < 0.10$ in both cases. Overall, there are considerable hints that these two variables are reliably associated with generosity in the respective directions. However, our results also make it clear that it is hard to establish this definitively and to distinguish this association statistically from effects of the healthcare system type on the basis of the data at hand.

Discussion

The first and rather surprising finding of our study is the fact that neither the wealth of a country nor the level of public health expenditure affects the extent to which high-tech drugs are covered within public systems. Clearly, our study is limited to explicit regulations on particularly controversial drugs and does not assess whether access to these is limited through mechanisms of implicit rationing. Governments may choose to avoid explicit decisions, which are politically explosive, and instead try to limit expenses by way of tight budgets for hospitals and doctors. Nonetheless, our results indicate that political and societal attitudes towards the coverage of high-tech drugs are at least not predominantly driven by wealth and expenditure patterns.

Results have also confirmed our hypotheses that the financing of the healthcare system – through taxes or social insurance contributions – affects its generosity: in countries with social insurance systems, high-tech drugs are significantly more likely to be covered. As noted in section 2, this difference may be accounted for by the different quality of claims to health services. In social insurance systems, claims are addressed at health funds and backed by previous contributions, whereas in taxfunded systems, claims are addressed at the community of tax-payers and more likely to be made dependent upon the fiscal situation. This difference between contribution-based and tax-funded healthcare systems also accounts for the fact that the discussion on limit-setting and rationing in healthcare has reached the European welfare states with social insurance systems decades after it came up in the Anglo-American and Scandinavian countries. Only quite recently, the costs associated with the public coverage of expensive, patent-protected drugs have become an issue in

continental Europe, and attempts at limit-setting are so far faltering in countries such as Germany and France.

Given that the institutional properties of the healthcare system seem to have significant effects on the coverage of high tech drugs, it made sense to take a closer look at the decision-making processes that are employed to take coverage decisions. Our results confirm hypotheses from a literature that highlight the significance of the way the default is set (Ostrom, 1986; Scharpf, 1989; Tsebelis, 2002). We show that a negative default for drugs reduces the probability that controversial products are funded. Countries with a negative default usually keep a 'positive list' that contains all pharmaceuticals that are reimbursed by the particular public healthcare system. Unless an explicit decision to include a controversial drug in this positive list is taken, the drug will not be funded. By contrast, in countries where the default is positive and where only a negative list exists, the explicit decision required is the politically much more precarious one to exclude controversial drugs from funding.

Only three countries in our sample do not apply positive lists: Germany, the UK and Ireland. The default for the UK must be regarded as negative, though, as primary care trusts are unlikely to cover an expensive drug that has not been appraised by the National Institute for Health and Care Excellence (NICE), whose decisions we have been considering here. Germany and Ireland, by contrast, have a positive default that clearly contributes to their comparative generosity in the funding of controversial drugs.[8]

Not only the default, but also properties of the appointed bodies charged with coverage decisions are associated with the generosity of resulting decisions. Finding that the decision rule is the most significant factor confirms rationales drawn from transaction cost and negotiation theory. It may seem surprising, though, that consensus requirements render positive, and thus popular, decisions less likely. However, this may be accounted for by the fact that in the majority of our cases, the default is negative. This implies that the decision at stake, which is rendered difficult by consensus requirements, would be one to cover, rather than to exclude a service. For the other institutional properties of bodies charged with coverage decisions, the results are not robustly significant, but point into the hypothesized direction. More specifically, we obtain indication that delegation and independence are associated with less generous regulations, whereas transparency is associated with more generosity. The corresponding coefficients, however, are only statistically significant in one of the models.

Given the comparatively small number of countries, more robustly significant results were unlikely to occur. The confidence in the theoretical significance of our results has to remain limited to some extent. Definitive conclusions on all possible explanatory variables are ruled out. Nonetheless, our findings strongly suggest focusing on institutional rather than monetary factors when trying to explain countries' generosity in the funding of high-tech drugs. A deeper understanding of the causal relationships between institutional properties, especially those of the bodies charged with decision-making, would require in-depth case studies and qualitative analysis. This remains a clear desideratum for future research.

Conclusion

The wealth of a country and its level of public healthcare spending do not affect the extent to which expensive high-tech drugs are funded within a public healthcare system. As previous research indicates, wealth and spending do not affect health outcomes, measured, for example, by healthy life expectancy, either (Kotzian, 2009). What matters, by contrast, is the institutional set-up of the healthcare system as a whole as well as the institutions chosen to deal with the thorny issue of coverage decisions and their design. Both express underlying traditions and power structures as well as dominant conceptions of solidarity and distributive justice. We therefore come to the conclusion that 'generosity' in the public financing of advanced medical technologies is eventually a matter of interest constellations and 'social value judgements' (Weale and Clarke, 2012). These affect decisions, among other things, by being inscribed into the structure of the healthcare system as such as well as into decision-making processes and the institutional design of bodies appointed to take coverage decisions. All this said, we want to emphasize that our findings refer only to industrialized nations with advanced public healthcare systems. The conditions under which developing and newly industrializing countries have to make coverage decisions are completely different and the factors influencing those decisions are not comparable to the ones that influence decision-making in OECD countries.

What implications do these results have for comparative welfare state research and theory? Apparently, politics and institutions do matter for the allocation of scarce goods and services, and they matter more than wealth and fiscal constraints. A further exploration of the causal links between institutional parameters, decision outputs and distributive

outcomes in health politics and other areas of social policy therefore seems to be a clear desideratum. Normatively speaking, institutional design in the healthcare system and elsewhere should thus not only be addressed as a matter of procedural, but also as a matter of distributive justice: if institutional parameters have effects on distributive decisions, their choice amounts to distributive decision in itself.

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Notes

[1]. Our concept of public coverage is a modified version of the concept developed by Busse et al. (2007). Busse and colleagues assume three dimensions in the coverage of public healthcare systems: first the population coverage (who is covered), second the service coverage (what is covered) and third, the cost coverage (how much of costs is covered). As in OECD countries the total population (or at least the vast majority) is covered by the public healthcare system, we have replaced the first dimension by the conditions of coverage, which, in our view, better reflect restrictions to access in developed countries. Furthermore, we have merged the second and third dimension into one (share of coverage).

[2]. A further refinement of this argument is the hypothesis that there might be some interaction between the default regulation and the decision rule, specifically whether decisions are taken by consensus or some other rule. The limitations of our data with only two empirical cases of a positive default prevent us from specifying such an interaction in our statistical models.

[3]. A similar logic has been regularly employed in the construction of generosity or decommodification indices of welfare state programmes in the tradition of Esping-Andersen (1990) that combine information on ‘replacement rates’, on the one hand, and ‘qualifying conditions’, on the other (for example, Scruggs and Allan, 2006).

[4]. The combined index thus also contains the missing values of both indices. Hence, missing values result from either missing information on the share of coverage or on the conditionality of coverage or both. In some cases (Ireland, Iceland) we did not include decisions that were taken by the precursor committee because institutional characteristics

of the old committees differed widely from those of the new committee. In Poland, we had no access to the positive list and thus could only include information from secondary sources. The resulting index can take 17 unique values (of which 15 are observed in our data; see online appendix for more description on the dependent variable) and it seems legitimate to treat it as an interval-scaled measure in the empirical analyses thereby imposing a linearity assumption. Specifying an ordered logit model would not be feasible in terms of costs in degrees of freedom given our data and the 15 observed unique values in our dependent variable. Note that our dependent variable is bounded to the range from zero to ten. The linear model might potentially produce predictions beyond these permissible bounds. Given the observed distribution of the dependent variable with little skewness and no strong clustering at the bounds, we believe that the linear model provides a good approximation to our data nonetheless. Empirically, the models essentially produce no predictions beyond the permissible bounds (see online appendix for details). To nonetheless probe the robustness of our findings, we applied a logistic transformation to the dependent variable and re-estimated all models. We obtain qualitatively similar results that lead to the same substantive conclusions (see online appendix for detailed estimation results). We report results for the untransformed dependent variable here also because they are easier to interpret: with the logistic transformation, the effects are harder to interpret as the effects of the independent variables on the untransformed dependent variable are not constant by assumption.

[5]. By more proximate factors we refer to explanatory variables that can be thought of as being causally prior to other explanatory variables in the model and, in addition, seem, at first sight, to provide obvious explanation for different degrees of generosity as suggested earlier. In more concrete terms, we first test for effects of the explanatory variables suggested by H1, H2 and H3 before moving, in a second step, to the remaining variables.

[6]. To help with the interpretation of effect sizes, note that the observed range of the dependent variables lies between zero and ten. The dependent variable has a standard deviation of about 2.95. To further facilitate the interpretation, we relegate the interested reader to the accompanying online appendix that provides more details on our dependent variable (that is, more details on the construction of the index as well as the raw data and frequency distributions in tabular and graphical form).

[7]. Nonetheless, we have checked this strategy by reintroducing (each variable in turn) the three explanatory variables from models 1 to 3 from Table 2 into our preferred model 3 from Table 3 to be discussed below. None of the wealth and expenditure variables emerges as substantially or statistically significant with these other explanatory variables included. Moreover, the results for the other variables remain reasonably similar.

[8]. For a detailed description of the British and German case as well as of four other countries (Austria, Norway, Sweden, and New Zealand) see Landwehr and Böhm (2011).

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