Social values and health priority setting in Germany

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Abstract

Purpose – The purpose of this paper is to provide an overview of health priority setting structures in Germany. It reflects on how and which social values may influence decision making, and in particular investigates the role of the Institute for Quality and Efficiency in Health Care (IQWiG) in integrating evidence-based decision making into the German system.

Design/methodology/approach – The paper applies Clark and Weale's framework of analysis for Social Values and Health Priority Setting to the German context. Placing German health care decision making into Clark and Weale's framework allows for an analysis of the role and content of social values in different dimensions of decision making.

Findings – Germany has witnessed significant changes in its health care decision-making procedures in recent decades. The establishment of the Institute of Quality and Efficiency in Health Care (IQWiG) represents an effort to introduce health technology assessment (HTA) as a formal element of decision making in health care. In doing so, Germany has made unique methodological and structural choices that reflect the social values and institutional traditions that underpin its self-governing statutory health insurance (SHI) system. The empirical evidence suggests that the principle of solidarity is upheld as a core value in health priority setting in Germany.

Originality/value – The German case of health priority setting highlights some of the challenges involved when introducing centralised HTA structures to a self-governing SHI system. As such, this paper contributes to an understanding of the different forms that HTA can take, what social values they embody and how they can affect health priority setting in different ways.

Keywords Germany, Health care, Social values, Health priority setting, IQWiG, Health technology assessment

Paper type Case study

Introduction

This paper aims to provide a reflection on how and which social values may influence health priority setting in Germany. Discussions of social values in health priority setting need to take into account the political and institutional context within which decisions are made. The relationship between values and institutions is complex and values rooted in the political and national traditions of a country affect the organisational form that institutions take (Hall, 1989); vice versa social values and ideas may be subject to gradual change as institutions develop (ibid.). This is why, in order to achieve its aims, this paper gives an overview of the health priority setting structures in Germany and how they operate within the German Statutory Health Insurance (SHI) system. In doing so, the paper takes the view that the establishment of the Institute for Quality and Efficiency in Health Care (IQWiG) in 2004 can be seen as an effort by policy-makers to integrate evidence-based decision-making in the form of health technology assessments (HTA) into the German system. The uniqueness of Germany's methodological and structural choices, which will be outlined within the paper, serves to highlight some of the challenges involved when introducing centralised HTA structures to a self-governing SHI system. The following discussion

Journal of Health Organization and Management
Vol. 26 No. 3, 2012
pp. 374-383

1477-7266
DOI 10.1108/14777261211239016

of social values and health priority setting in Germany can thus be seen as an illustration of the challenges involved when considering social values against the backdrop of the institutional specifics of a given country, thereby contributing to an understanding of the different forms that HTA can take and what social values these forms might embody.

Health priority setting decisions in SHI systems such as the German one can be difficult to disentangle as self-governing bodies of health insurers and providers choose how to provide the level and quality of health care that is mandated by the given legislative framework (Giaimo and Manow, 1999, p. 976). As long as the statutory level and quality of care are provided by the self-governing institutions in SHI systems, questions of transparency of decision-making processes and accountability of decision-makers to the general public seem to be secondary in these systems, especially when compared with tax-based systems in which the state is both the payer and the provider of health care. Investigating the role of social values adds an additional layer of complexity to the question of how health priority setting is carried out in SHI systems as there is frequently little to resort to other than the principles laid out in the legislative framework. While this a worthwhile starting point for an empirical investigation it does not suffice if one is interested in what drives health priority setting in SHI systems; this necessitates a closer look at the procedures of and publications by the main health care decision-making bodies in Germany.

The situation in Germany is further complicated by the fact that it is a federal, and as such a de-centralised political system. The nature of a federal system which is based on a frequently contested division of responsibilities between the federal, regional and local governments implies that the introduction of centralised decision-making procedures and institutions is likely to be met with considerable resistance by self-governing bodies. The health care self-governing bodies consisting of the statutory sickness funds and the provider associations (general practitioners, physicians, dentists and hospitals) do not just function on a federal level, but also on a regional level in every "Bundesland" to negotiate the provision and pricing of health care services with each other and with third parties such as pharmaceutical manufacturers (Simon, 2010). It is therefore likely that health priority setting takes place in a variety of different ways and at multiple levels of the German health care state. However, the last decade has witnessed a number of legislative developments that have introduced more formalised structures to govern health care decision-making – and by extension health priority setting – in Germany. Specifically, the creation of IQWiG under the Statutory Health Insurance Modernisation Act 2004 represents an attempt by policy-makers to establish HTA as a more integrated feature of decision-making in health care in Germany.

Despite the establishment of an HTA organisation policy-makers and practitioners have divergent views on whether health priority setting is already or indeed should be a part of the German health care system. In what has become a landmark speech on the issues of priority setting and rationing in Germany, the late President of the Federal Association of Physicians, Prof. Dr Joerg-Dietrich Hoppe, called for an honest and public debate on health care prioritisation in Germany (Hoppe, 2009). Such calls have been met with an apparent reluctance by German policy-makers to address issues of health priority setting, a common view being that stability in the financing of and efficiency improvements within the German health care system can make debates on

rationing and prioritisation unnecessary (Aerzteblatt.de, 2011). Tensions between reports of over-supply in some areas (Lisac *et al.*, 2010), i.e. in the provision of hospital beds, and under-supply leading to implicit rationing in others (Marckmann, 2010) exacerbate the challenge of assessing the status of the health priority setting debate in Germany. Whilst recognising that the discussion over health priority setting in Germany remains controversial, the establishment of IQWiG can be seen as a conscious effort by policy-makers to introduce evidence-based decision-making in the form of a HTA institution to the German health care system; "[. . .] the use of evidence to improve policy making is on the rise" (Pfaff, 2009, p. 99). As HTA is considered a technique for determining priorities (Coulter and Ham, 2000), it is appropriate to examine IQWiG's tasks and functions in order to assess how and indeed which social values underlie health care decisions in Germany.

The Institute of Quality and Efficiency in Health Care (IQWiG)

IQWiG was established under the SHI Modernisation Act in 2004 and it is financed through a levy on SHI contributions (IQWiG, 2012); its tasks and functions are laid out in the Social Code Book V, especially § 139 a-c and § 35 a-b (Sozialgesetzbuch V – SGB V, 2012). It currently produces 6 types of evaluations and assessments: reports, rapid reports, dossier assessments, addendums, health information and working papers (IQWiG, 2011). For the purpose of this paper the reports, rapid reports and dossier assessments are especially relevant as they are produced to aid decision-making in the main decision-making body of the SHI system in Germany, the Federal Joint Committee (FJC).

Clark's (2010) framework divides health priority setting into two dimensions, namely the processes of decision-making (institutional setting, rules of decision-making, accountability for decisions, participation in decision making) on the one hand and the content of decision-making (cost and clinical effectiveness, social values judgements, cost-sharing) on the other.

Dimension 1: the processes of decision-making

A. Institutional setting

The decisions for or against the inclusion of medical interventions are made in the FJC in Germany (Fricke and Dauben, 2009); the FJC consists of five representatives of the payer (the statutory sickness funds) and provider associations (physicians, dentists and hospitals) respectively and three impartial members (Gemeinsamer Bundesausschuss, 2012). The FJC is the main decision-making body of the self-governing SHI system in Germany and as such it is one of the most important institutions of the self-governing structures (Fricke and Dauben, 2009). Approximately 70 million German citizens are currently covered by statutory sickness funds, the remaining German citizens are primarily covered by private insurance schemes (Bundesministerium fuer Gesundheit, 2009).

Both the FJC as well as the Federal Ministry of Health (BMG) can commission IQWiG to carry out benefit assessments of new and/or existing medical interventions (IQWiG, 2011). The results of the assessments and evaluations that IQWiG produces serve as recommendations for decisions of the FJC (ibid.). This means that IQWiG does not have a direct decision-making mandate and primarily supplies the FJC with assessments of scientific evidence on a given medical intervention when commissioned

to do so, thereby acting as an advisory rather than a regulatory body in the German SHI system.

B. Rules of decision-making

The rules of decision-making can be found in the relevant paragraphs on IQWiG in the Social Code Book V. One rule is consistently highlighted both in the Social Code Book V and in the documents on IQWiG's methods: IQWiG is to carry out its assessments according to currently recognised international standards of evidence-based medicine (EBM) and health economy (IQWiG, 2011). In practice this rule gets translated into IQWiG's search of all available scientific evidence on given interventions compared with other interventions, with studies that offer the most reliability in terms of their results being prioritised (ibid.). Randomised controlled trials (RCTs) are given priority over other forms of studies which are recognised as reliable evidence in exceptional cases only and with detailed justification. This suggests that clinical effectiveness is a core value in health priority setting in Germany.

Furthermore, patient-relevant outcomes are highlighted as a major criterion in the evaluation of scientific evidence:

> The decisive criteria are outcomes that are important for patients. It is not enough for a drug to simply alter the results of a lab test: It should enable people to live longer, reduce their symptoms or complications, or improve their quality of life (IQWiG, 2012).

These patient-relevant outcomes are also outlined in § 35b Social Code Book V (SGB V § 35b) with regards to cost-benefit assessments of pharmaceutical products. Thus, the rules of clinical effectiveness with an emphasis on evidence-based medicine and patient-relevant outcomes carry more weight than the costs of an intervention when health care decisions are made in Germany.

C. Accountability for decisions

Since the responsibility of decision-making lies with the FJC, the FJC is accountable to the general public. The decision documents are made available on the FJC's homepage and include reasons for given decisions. These reasons frequently include a reference to the legislative framework that the FJC works within as well as an outline of the assessment of the scientific evidence of a specific intervention, the combination of which leads to the decision of the FJC. However, these documentations are not easily understood by the general public which raises questions about what Clark refers to as the current "[. . .] mechanisms [. . .] by which decision-makers are required to justify their decisions" (Clark, 2010, p. 2). Since the nature of a self-governing corporatist health care system is such that the self-governing bodies decide on how to provide the level and quality of statutory health care as it is legislated (Giaimo and Manow, 1999), the formal requirements for how they justify their decisions are limited. As a result, the courts in Germany play a comparatively important role when it comes to appeals against decisions by the FJC, especially since "[. . .] no appeals procedure exists [. . .]" within the FJC (Landwehr, 2009, p. 597). The disadvantage of court appeals is that they can be lengthy in time which is one of the reasons why representatives of the pharmaceutical industry have been calling for the introduction of an independent ombuds-structure to settle disputes over FJC decisions (Pharmazeutische Zeitung, 2011).

D. Participation in decision-making

There is a statutory requirement for IQWiG to invite and consider opinions and comments by pharmaceutical manufacturers and patient groups as part of its assessment procedures (IQWiG, 2011). Opinions and comments take a written format, with an oral hearing being an option but not a formal requirement (ibid.). The assessment meetings of IQWiG are not open to the public. However, the appraisal meetings of the FJC in which decisions are made based on the evaluations of IQWiG are open to the public. To date no structural element exists in IQWiG or the FJC that is comparable to the deliberative-democratic structure of the Citizens Council at NICE in which members of the public are consulted about difficult decisions, especially as and when they pertain to a careful deliberation on what the public values with regards to difficult health priority setting issues. While the perspective of the statutory insurants in Germany is frequently mentioned as being of primary importance in producing assessments in IQWiG's documentations (Caro *et al.*, 2010), it remains unclear how this perspective is ascertained during the assessment procedures. Having said that, the SHI Provision – Structure Act (GKV-Versorgungsstrukturgesetz) which is currently undergoing the legislative process includes proposals to improve the transparency of and participation in decision-making in the FJC (Bundesministerium fuer Gesundheit, 2012).

Dimension 2: content of decision-making

A. Cost and clinical effectiveness

As mentioned previously cost effectiveness considerations play a secondary role in health priority setting in Germany. This reflects the legislative framework that was given to IQWiG by policy-makers: IQWiG's primary function is to assess a medical intervention with regards to its benefits and, in the case of new medical interventions or pharmaceutical products, with regards to its additional benefits as compared to existing interventions (IQWiG, 2011). Thus, the goal of IQWiG's assessments as laid out by the legislator is not the in- or exclusion of an intervention in the health benefit basket or indeed the prioritisation thereof within the SHI system (Caro *et al.*, 2010), but rather to provide an independent assessment of the scientific evidence available which can be used by the FJC to make judgements on the potential harms, benefits and/or additional benefits of an intervention.

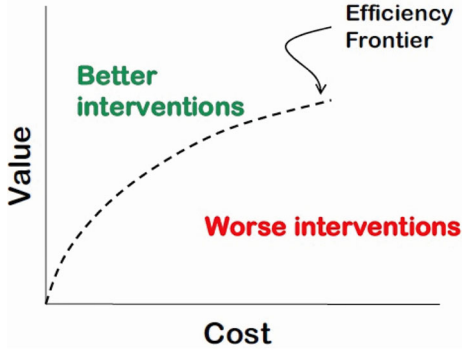
The secondary role of cost effectiveness to the benefit of a medical intervention in Germany is illustrated when referring to regulations in the *Arzneimittelmarktneuordnungsgesetz* (AMNOG), an Act of Parliament which introduced novelties with regards to the regulation of the pharmaceutical market in Germany and came into effect on 1 January 2011. The act created the so-called "early benefit assessment" which requires the manufacturer of a new pharmaceutical product to hand in a dossier with details about the new product, i.e. the medical indications it is used for, the patient population it targets, the results of clinical and other relevant trials and its expected benefits with regards to patient-relevant outcomes (IQWiG, 2011). When commissioned to do so by the FJC, IQWiG then proceeds to conduct an "early benefit assessment" in order to examine the product's potential benefits, harms and/or its additional benefits when compared with current therapy alternatives. A cost-benefit analysis, however, is not carried out automatically. On the contrary it needs to fulfil two prerequisites: a cost-benefit analysis is only carried out when IQWiG concludes –

on the basis of international standards of evidence-based medicine – that the product in question does indeed offer an additional benefit and is superior when compared with existing therapy alternatives and the FJC needs to commission IQWiG to produce a cost-benefit assessment (ibid.). Thus, even though the AMNOG has introduced a genuinely novel feature to the way health care decisions are made in Germany due to the required "early benefit assessment", the additional regulations for the conduct of cost-benefit-analysis seems to underline Joensson's point that "[...] economic evaluation in Germany is still not seen as a valuable instrument by decision makers" (Joensson, 2008, p. 206). This suggests that cost effectiveness is not a value that drives health priority setting in Germany.

B. Social value judgements

The social value judgements that are made by IQWiG are implicit in the sense that no formal document comparable to NICE's "Social Value Principles" exists. Furthermore, IQWiG's document on its General Methods repeatedly reiterates the point that value judgements cannot be made by IQWiG as they are seen to lie within the responsibility of the legislator and the policy-making institutions (IQWiG, 2011). However, despite this apparent lack of explicit social values that guide IQWiG's recommendations, one can argue that the institute has made at least one very important social value judgement that reflects the principle of solidarity which underpins the German SHI system ever since its introduction by Bismarck. The judgement I refer to is the decision for the use of the "efficiency frontier" method rather than other methods used in health economic evaluations such as the use of quality-adjusted life years (QALYs). While it may be correct that IQWiG had no choice other than to make this judgement because of the legislative framework it was given (Caro *et al.*, 2010), it is nevertheless a decision that carries considerable weight when investigating the role of social values and health priority setting in Germany.

The efficiency frontier is a method used for expressing the cost-benefit ratio of a given medical intervention. In the efficiency frontier method "[...] existing therapies in [...] [a] therapeutic area [are plotted] as points on [...] [a] graph" (Drummond and Rutten, 2008, p. 7) with the most efficient interventions forming the "efficiency frontier" in the graph as expressed by their cost-benefit ratios. This results in a diagram such as shown in Figure 1.



Source: IQWiG (2008, p. 14)

Figure 1.
Efficiency frontier

The exercise of plotting the different interventions on the graph aids the decision-maker to judge which interventions provide the best value for money. The most important characteristic of the efficiency frontier method is that it is indication-specific, meaning that only the benefits and costs of medical interventions used for the same indications are compared to each other (IQWiG, 2009a, b). Implied in this decision is a social value, even if it is not labelled as such. The conscious decision against the ability to compare the costs-benefit-ratios of pharmaceutical products in different disease categories suggests a belief that there is no objective measure that would adequately reflect the severity of one disease as compared to another (IQWiG, 2011), which is why the only way to measure whether a product provides good value for money is to compare its benefits and costs to its existing counterparts within the same indication. The content of this value judgement can be viewed as a reflection of the principle of solidarity that stipulates that access to health care in the SHI system should be granted equally according to individual need and not be based on how high an individual's SHI contributions are (Bundesministerium fuer Gesundheit, 2011). By extension, a comparison of benefits and costs across disease categories runs the risk of undermining the access of a medical intervention according to individual need if one disease is considered more or less severe than another, thus discriminating against patients with certain conditions.

C. Cost-sharing

Similarly to other countries, policy-makers in Germany have introduced various measures to contain health care spending in the recent decades. Amongst these cost containment efforts, policy-makers in Germany have introduced measures targeting the demand-side of health care by introducing cost-sharing arrangements (Pfaff, 2009). Cost-sharing arrangements in Germany include co-payments such as a flat-rate quarterly fee payable when visiting a GP or specialist practice although it is possible to get referrals from one physician to another in order to avoid paying the fee twice. Limits on the coverage of pharmaceuticals have also been a prominent area for cost-sharing arrangements in Germany. The so-called "aut-idem" rule requires pharmacists to hand out generic rather than brand pharmaceuticals unless specifically stated otherwise on the prescription. The patient may ask for the brand product, however, the price difference between the brand product and the generic has to be paid for by the patient in this case.

The issue of cost-sharing potentially becomes relevant to the question of how social values affect health priority setting in Germany when a cost-benefit-assessment of a pharmaceutical product is carried out. As mentioned previously such an assessment will only be conducted if it has already been established that the product in question provides an additional/superior therapeutic benefit in comparison with existing alternatives. However, the goal of this cost-benefit-assessment is not, as it is in other systems, to determine whether the intervention should be in- or excluded from the coverage but to provide an indication as to the maximum reimbursable price of the product which should reflect the additional therapeutic value gained from its use (IQWiG, 2009a, b); this is intended for cases of pharmaceuticals which do not fit into the existing reference price groups (ibid.). Since the maximum reimbursable price acts as a guideline for sickness funds in their negotiations with pharmaceutical manufacturers but is not binding for these manufacturers this could – in theory –

mean that a product gets reimbursed up to a certain price but that the individual patient might have to pay the difference in price if the manufacturer does not adjust the market price of the product accordingly (ibid.). This in turn could have possible negative implications for the social value of solidarity as only individuals who can afford to pay for the difference in price would get access to certain new pharmaceuticals. To what extent this is a real rather than a theoretical concern remains to be evaluated when IQWiG has carried out more cost-benefit-assessments than it has to date; a search on IQWiG's homepage showed only two cost-benefit assessments to this date (IQWiG, 2009a, b).

Conclusion

The above discussion has highlighted that it is comparatively more difficult to analyse how health priority setting decisions are influenced by a given set of social values in SHI systems. This is a direct result of what Giaimo and Manow (1999) label the autonomy in decision-making that the state grants the self-governing institutions in SHI systems as long as they implement the standards of provision that are laid out in the legislative framework. While the nature of a self-governing SHI system might be seen to present certain challenges to the implementation of health priority setting mechanisms based on social values, developments in Germany have shown that it is possible to integrate health priority setting organisations to improve the standing of evidence-based policy-making in health care (Pfaff, 2009). Evidence-based policy-making, however, is viewed as a tool to provide the best and most efficient quality of care to every patient in Germany; as such it overrides considerations of cost effectiveness. A slight caveat is, however, in order: these observations are based on the information that is made available to the public by IQWiG and the FJC. Both the transparency of and participation in health priority setting decisions in Germany are somewhat lagging behind other national contexts such as England (Landwehr, 2009). The improvement of both transparency and participation as envisaged by the SHI Provision-Structure Act might in future unveil considerations that guide health priority setting which have not been discussed in this paper.

To what extent the establishment of IQWiG as an advisory body to the FJC will lead to health priority setting in the sense that it provides the FJC with opportunities to prioritise certain interventions over others remains uncertain. Especially the emphasis on the principle of solidarity and its interpretation as an individualistic rather than an utilitarian value decreases the chances that medical interventions will be weighed against each other in Germany. However, as this paper has highlighted, that is not to say that social values do not underpin decision-making in health care in Germany; on the contrary social values such as the principle of solidarity and a trust in the self-governing structures form the guiding principles of the health care system and currently present a barrier to health priority setting as it is understood in other national settings.

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