
Let's Talk About Health Economic Evaluation: Relevant Contextual Factors for the German "Sonderweg"

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1 Introduction

The starting point of the chapter provided by Williams and Bryan (see chapter "Using Economic Evaluation in Priority Setting: What Do We Know and What Can We Do?") is the observation that the usage of economic evaluation as a criterion for priority setting differs tremendously between countries and between national and local levels of decision making. In the following, I will first briefly comment on some aspects raised by Williams and Bryan's elaborations of what is known about typical barriers to the usage of health economic information (Sect. 2). One of their main observations is that context is often neglected as a central explanation for differences observed. Hence, in Sect. 3, the notably limited role played by economic evaluations in the context of the German statutory health insurance (SHI) system, which serves almost nine out of ten Germans, will be sketched. Also, the special evaluation methods developed by the German "Institute for Quality and Efficiency in Health Care" (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, IQWiG) will be described. Potential reasons for these German-specific limitations and regulations will be collected in Sect. 4 by summarizing especially findings of some qualitative studies. Section 5 concludes.

"Sonderweg" might be translated as "unique path." See Wahler (2009) for the usage of this term with respect to health economic evaluations in Germany.

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2 General Comments

Healthcare systems all over the world face growing financial pressure and higher need for healthcare services, which are caused by rapid medical-technical progress, demographic shifts, and epidemiological changes. Probably not only from a health economist's perspective, this should foster interest of decision makers in the usage of economic evaluations in priority setting. Is economics not *the* discipline that focuses on resource scarcity? And is the primary aim of health economic analysis not to assist decision makers when tackling problems arising from scarcities (Bryan et al. 2007)?

When using the term “priority setting,” Williams and Bryan (see chapter “Using Economic Evaluation”) adopt the well-established definition summarized by Klein (2010, p. 389) who describes it as “decisions about the allocation of resources between the competing claims of different services, different patient groups or different elements of care.” Resource scarcity and the discrepancy between supply and demand lead to this competition of claims. Also according to Klein, the term “rationing” then “describes the effect of those decisions on individual patients, that is, the extent to which patients receive less than the best possible treatment as a result.” Consequently, rationing is understood as the actual consequences of priority setting for patient care (see Williams et al. 2012). These authors also point out that alternatives to “explicit priority setting” exist, including rationing by delay or by ability to pay, and implicit (“bedside”) rationing, as well as increasing the overall health care budget, eliminating system inefficiencies, or strengthening preventive public health. However, they argue that each of these alternatives is problematic and, whenever applied, has been unable to decisively reduce the gap between demand and supply. In the present paper, this interpretation of the terms “priority setting” and “rationing,” and the distinction between them are adopted, as they are helpful to describe the specific characteristics of the discussion about the acquisition and potential usage of health economic information in Germany.

In the literature, various normative arguments are raised for or against the inclusion of cost-effectiveness analysis as one criterion for priority setting. However, instead of providing a further account of the discussion about such normative claims, Williams and Bryan (see chapter “Using Economic Evaluation”) draw our attention to the steadily growing number of quantitative and qualitative studies, which aim at identifying reservations raised by decision makers. They are the natural target group for health economic analyses as soon as one agrees with Gaertner and Schokkaert (2012, p. 8) that the “ultimate aim of any normative theory” must be to have an impact on practice (see also Bryan et al. 2007; Bryan and Williams 2014). It should be noted that quantitative studies facilitate investigating the frequency and, thereby, the overall relevance of obstacles of the usage of economic evaluations among the participating groups of individuals. However, qualitative investigations have demonstrated that interview techniques might be better able to identify potential barriers in the first instance. As Strech et al. (2008) point out, this is partly due to complex notions of central terms, methods, and conceptions, which are more difficult to present unambiguously in surveys or closed questions. Hence, in Sect. 4, the main focus will be on qualitative findings.

As a first result, Williams and Bryan (see chapter “Using Economic Evaluation”) report different intensities of usage of health economic evaluations along two dimensions: on the one hand, at local level decision makers are rarely found to incorporate health economic information into their processes, while several national priority setters are even mandated to include such evaluations (see Eddama and Coast 2008, for a comprehensive review). On the other hand, at national level, significant variations between countries are also apparent. For example, in the UK, the National Institute for Health and Care Excellence (NICE) has to explicitly include results of health economic evaluations into the decision on coverage of medical interventions by the National Health Service (NHS), while such evaluations have played virtually no role in the German SHI system until now (Gerber-Grote et al. 2014). Williams and Bryan (see chapter “Using Economic Evaluation”) provide an overview of various factors, which deter the application of health economic methods and, furthermore, categorize them either as accessibility or as acceptability barriers. They explain that aspects of the latter category are regularly found to be more severe but less often addressed especially by responses of health economists.

In contrast to several earlier contributions, the argument of Williams and Bryan (see chapter “Using Economic Evaluation”) does not end at this point by “simply” proposing to reduce accessibility barriers by health economic training of decision makers. Instead, they indicate that in particular contextual factors, including especially the organizational and political environment of decision making, determine the demand for health economic information. Hence, their main point is that context is often neglected although it may help to explain the different extents of usage of economic evaluation in priority setting observed. However, as will be explained in the next sections, also the selection of the specific evaluation methods applied may depend on contextual aspects.

3 Health Economic Evaluation at the National Level in Germany

This section offers a brief sketch of the minor role played by health economic evaluation in the German SHI system up to now (see, e.g., Gerber-Grote et al. 2014, for a more comprehensive overview). Furthermore, the special evaluation methods developed are described. The central body for decision making about the benefit catalog of the SHI is the “Federal Joint Committee” (Gemeinsamer Bundesausschuss, G-BA). Its main committee comprises representatives of both health insurance companies and healthcare providers, while patient advocates only have an advisory function. Hence, although the G-BA is formally independent from the government, it displays less independence from its regulatees (Landwehr and Böhm 2011). In 2004, IQWiG was established as a scientific agency to support the G-BA by conducting health technology assessments and improving evidence-based health policy making. In particular, rising prices of drugs led to a healthcare reform in 2007. A new law explicitly introduced health economic evaluation as the tool to set a reasonable maximum reimbursement for pharmaceuticals, but not to make general

reimbursement decisions or to determine funding priorities of society (Gerber-Grote et al. 2014; Sandmann et al. 2013). Accordingly, IQWiG should perform full benefit assessments and health economic evaluations. However, in 2011, a further reform led to a reduction of the relevance of health economic assessments for the decision-making process in the case of drugs with new active ingredients. Now, price negotiations are implemented between the “National Association of Statutory Health Insurance Funds” (GKV-Spitzenverband) and the pharmaceutical manufacturer of the drug. They are based on a dossier provided by the manufacturer, which contains information on patient-based benefits and forecasts of annual drug costs, but no health economic evaluations. This dossier has to be evaluated by IQWiG. Only if added benefit compared to an appropriate existing therapy is acknowledged but price negotiations fail, the G-BA can commission IQWiG to perform a health economic evaluation to provide a (further) evidence-based reimbursement price. Gerber-Grote et al. (2014) review the impact of health economic information on the setting of reimbursement prices for new drugs. They conclude that despite the fact that the legal regulations of the German SHI system have allowed for cost-effectiveness analysis for many years, “the current impact (as of mid-2014) of health economic evaluations for statutory decision making in Germany has been factually non-existent” (p. 5). In contrast, other regulations, including global budgets, efficiency checks, and reference values for prescriptions, are used in Germany, which has led to less explicit rationing mainly delegated to local levels (Breyer 2013).

Furthermore, because the method which IQWiG (2009) is going to apply if a health economic evaluation is commissioned makes the German case so special compared to other healthcare systems; Wahler (2009) has named it the German “Sonderweg.” It was updated in 2011 due to legal changes, but the basic procedure has remained unchanged since 2009 and is equally applicable to drug and non-drug interventions (Caro et al. 2010; Gerber-Grote et al. 2014). The so-called Efficiency Frontier describes the efficient interventions currently available within *one* therapeutic area. To determine this frontier, all existing interventions for a therapeutic area are plotted in a diagram with costs per patient to be borne by the community of all citizens insured by SHI on the horizontal axis and clinical benefit per patient on the vertical axis (Caro et al. 2010). The connecting line between the origin of the diagram, which denotes the case without treatment and costs, and those interventions which are not dominated either by a single therapy or a combination of existing interventions (“extended dominance”), form the Efficiency Frontier at increasing levels of benefit. Due to the additional constraint in Germany that a new intervention has to be more effective than the currently best one, two remaining situations have to be distinguished. The case of a more effective and less expensive new intervention compared to the currently most effective therapy is certainly unproblematic. However, for the alternative case of a more effective and more expensive intervention, the last segment of the Efficiency Frontier is extrapolated. Hence, the extension of this line denotes the same ratio of costs and clinical benefits as for the currently most effective therapy relative to the second most effective therapy (Gerber-Grote et al. 2014). It forms an “ad hoc cost-per-effect threshold” (Klingler et al. 2013). New interventions above the extrapolated Efficiency Frontier should then be fully reimbursed, whereas those below the line receive a price cap so that the

intervention lies exactly on the (extrapolated) Efficiency Frontier from the perspective of the German SHI.

The approach developed by IQWiG together with external experts and IQWiG's Scientific Advisory Board has proved to be very controversial (see the literature cited by Gerber-Grote et al. 2014; Kifmann 2010; Klingler et al. 2013). Critics have pointed out that prices depend on the efficiency prevailing in the therapeutic area concerned, which regularly differs from other therapeutic areas and, therefore, lead to inconsistencies due to different reimbursements of similar health benefits. Also, Drummond and Rutten (2008) remarked that efficiency standards may differ between therapeutic areas leading to increased inefficiencies due to the extrapolation of the Efficiency Frontier. Furthermore, the current restriction to one-dimensional clinical outcome measures for determining health benefits has been criticized. Quality-adjusted life years (QALYs), which are used, for example, by NICE to quantify the impact of a therapy on survival and health-related quality of life (NICE 2013), are criticized by IQWiG (2009), but alternative multidimensional concepts have not been developed, yet.

Nevertheless, it is often pointed out that both the ignorance of health economic information and the development of the Efficiency Frontier approach have been induced by specific German circumstances (Caro et al. 2010; Gerber-Grote et al. 2014). According to Williams and Bryan (see chapter "Using Economic Evaluation"), these are contextual factors, which may help to explain differences in both health economic evaluation methods and the extent of their usage in decision making at the national level.

4 Contextual Reasons for the German "Sonderweg": Some Insights

Williams and Bryan (see chapter "Using Economic Evaluation") not only claim that acceptability barriers are relatively unaddressed in the health economic literature, but that they are reduced to ethical concerns while organizational and political factors are regularly ignored. For example, in an interview study with key healthcare decision makers in Australia on the usage of economic evaluation, Ross (1995) collected typical barriers but also identified "other factors" which influence allocation decisions in health care. Based on an earlier classification by Sax (1990), these factors included political aspects such as the "philosophy of the Government," "the climate of opinion in society and pressure groups," and values and attitudes held by decision makers (Ross 1995, p. 107).

Several of these factors are also relevant for the German context. Gerber-Grote et al. (2014) summarize major challenges during the implementation of health economic evaluation in Germany. Besides several ethical concerns, experiences during the Nazi regime are often said to influence these discussions, since parts of the population were identified as "life unworthy of life" ("lebensunwertes Leben") in the Third Reich. Furthermore, the authors mention an extraordinary reluctance of many Germans to explicitly determine a concrete and fixed threshold value for reimbursement of costs for medical interventions. In fact, decision makers regularly claim that "the German public" is not prepared to link health to costs (Breyer 2013;

Klingler et al. 2013). However, although this observation might be true as a general and more abstract statement, empirical evidence is less clear-cut. In a series of four representative surveys conducted between 2012 and 2014 among adult Germans, Ahlert et al. (2014) revealed that, at least in their specific settings, Germans displayed no higher willingness to pay for health improvements or life extensions compared to respondents from several other European countries. Also, the ambiguity of public opinion in Germany can be inferred by the results of a representative survey reported by Diederich and Schreier (2010). In one question, about 70 % of respondents were opposed to the statement that (the amount of) costs should play a role if it had to be decided whether a medical treatment should be financed by the SHI. In contrast, only about 31 % of the same sample agreed that the treatment of a cancer patient, which costs €15,000 and extends the patient's life by a short period of time (e.g., 11 days), should be financed by the SHI, whereas 54 % disagreed. Hence, it seems that many participants rejected the consideration of costs for health improvements in general, but were less reluctant when they faced a more concrete case.

It has already been explained that the main decision-making body on the inclusion of new interventions in the benefit package of the SHI system in Germany is the G-BA, which comprises representatives of health insurance funds, health service providers, and patient advocates. Thus, the qualitative studies reported by Schreier et al. (2011) and Klingler et al. (2013) with members of these groups are particularly suitable to shed further light on contextual reasons for the minor role played by health economic evaluations in the German healthcare system and for the development of the Efficiency Frontier as a specific tool. In the first study, 45 members of relevant stakeholder groups including physicians, nursing personnel, and health insurance administrators, as well as healthy individuals, patients, and politicians, participated in semi-standardized interviews on different topic areas concerning prioritizing in health care. Here, I will only focus on one particular question, which is aimed at eliciting the acceptance of a "guideline adopted in the UK according to which the costs of cancer therapy must not exceed 30,000 Euro per life year gained by administering the therapy" (Schreier et al. 2011, p. 3).¹ To start with, 19 participants were in favor of adopting the guideline in the German SHI system, while 22 respondents opposed this proposal (seven individuals were undecided). When asked for reasons for their decision, the former group stated two major aspects: while 67 % thought that the German SHI funds were already under enormous financial pressure, 33 % argued that such a guideline would finally provide a clear regulation. Thus, the second reason also indicates a desire to avoid (further) bedside rationing within the healthcare system, which is a growing matter of concern for many physicians and other healthcare professionals (see, e.g., Strech et al.

¹It should be noted that this question somewhat simplifies the method applied by NICE. More specifically, for a new technology with an "incremental cost-effectiveness ratio" (i.e., the ratio of expected additional total cost and expected additional QALYs compared with alternative treatment(s)), above £30,000, the provision by the NHS is not excluded immediately but requires "to identify an increasingly stronger case for supporting the technology as an effective use of NHS resources, with regard to [further] factors" (NICE 2013, p. 74).

2008). However, 12 different reasons have been mentioned by participants who opposed the guideline. Besides more general accessibility and acceptability concerns, context-specific obstacles have been mentioned. Some respondents expected that the German public would be strongly opposed to the implementation of a corresponding limitation, while others mentioned the comfortable financial situation of the German SHI system especially compared to the NHS, which prevents more dramatic measures (see Gerber-Grote et al. 2014, for a similar argument). Furthermore, several interviewees pointed out that financially better-off patients may also be better able to bear incurred treatment costs on their own and, thereby, undermine the principle of solidarity, which is thought to be one of the most fundamental principles of the German SHI system.

The study by Klingler et al. (2013) gives further insights into contextual factors relevant to the adoption of the Efficiency Frontier approach by IQWiG and into differences between the corresponding German and UK “regulatory spaces.” Hence, the authors confirm the context hypothesis of Williams and Bryan (see chapter “Using Economic Evaluation”) but without referring to their work. To investigate such factors, in summer 2011, Klingler et al. (2013) conducted semi-structured interviews with 11 representatives of institutions including IQWiG and G-BA, which are highly involved in the German discourse on health policy. Again, I will focus only on contextual factors, which reveal the specific situation in Germany.

The authors categorize results into two major groups: first, rejection of a fixed threshold and second, doubts regarding QALYs. With respect to the first category, many respondents pointed out strong reservations toward linking health benefits and costs, which led to the adoption of a less visible tool to set limits, viz., the ad hoc cost-per-effect threshold denoted by the Efficiency Frontier. Furthermore, several individuals argued that there is a German tradition of focusing only on (clinical) benefits, which makes rationing decisions “culturally unacceptable” (p. 275). Other respondents stressed an “all-inclusive mentality” of the German public and the conviction that “everything for everybody will be made available” (p. 276). This is backed by politicians and other decision makers, who have experienced a comfortable financial situation of SHI funds during the last years, despite several reforms of the healthcare system. They regularly assure German citizens that all beneficial therapies will be made available so that cost-effectiveness research is unnecessary (Breyer 2013). However, the results reported by Klingler et al. (2013) also reveal that policy makers are well aware that such statements shift rationing decisions toward the local level where physicians and other care providers are often forced to ration implicitly.

Regarding the second category of results, QALYs as a measure for health-related benefits are generally rejected for two reasons. First, methodological reservations are articulated especially by respondents who can be expected to “really” understand the underlying concept, i.e., members of IQWiG or the G-BA. Second, QALYs are refused because they are commonly associated with healthcare rationing especially in the UK, although QALYs do certainly not imply per se the application of thresholds or rationing decisions (see also the clarification by Klingler et al. 2013, or IQWiG 2009). However, it seems to be particularly this connotation combined

with the general objection of healthcare rationing that led to the refusal of QALYs and, more generally, other health economic tools.

5 Concluding Remarks

Williams and Bryan (see chapter “[Using Economic Evaluation](#)”) have argued that contextual factors are crucial, but often neglected, when it comes to explanations of the use of health economic information in priority setting. In the present contribution, I have related this general statement to the special situation of economic evaluations in the German SHI system. First, it is characterized by an overall absence of an explicit impact of economic evaluation on priority setting decisions at the national level. Second, the development of the Efficiency Frontier approach as a method of health economic evaluations has led to the conclusion that the German SHI system follows a “Sonderweg” (“unique path”). A combination of ethical, historical, and political or cultural factors seems to have created a general refusal of open discussions about healthcare rationing and, particularly, about health economic evaluations. This leads to a shift of responsibility to local decision makers and often results in implicit rationing. Although once in a while decision makers try to put these issues on the political agenda, one probably has to agree with Gerber-Grote et al. (2014) who conclude that the exceptionally comfortable financial situation of German SHI funds has avoided, and still avoids, stronger pressure to attain the “best value for money” and to take health economic information into consideration.

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