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SCIENTIFIC CONTRIBUTION

Priority-setting, rationing and cost-effectiveness in the German health care system

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Abstract Germany has just started a public debate on priority-setting, rationing and cost-effectiveness due to the cost explosion within the German health care system. To date, the costs for German health care run at 11,6 % of its Gross Domestic Product (GDP, 278,3 billion €) that represents a significant increase from the 5,9 % levels present in 1970. In response, the German Parliament has enacted several major and minor legal reforms over the last three decades for the sake of cost containment and maintaining stability of the health care system. The Statutory Health Insurance—SHI (Gesetzliche Krankenversicherung—GKV) is based on the fundamental principle of solidarity and provides an ethical and legal framework for implementing equity, comprehensiveness and setting the principles and rules for financing and providing health care services and benefits. Within the SHI system, several major actors can be identified: the Federal Ministry of Health, the 16 state ministries of health, the Federal Joint Committee (G-BA), the physicians (with their associations) and the hospitals (with their organizations) on the provider side, and the sickness funds with their associations on the purchasers' side. This article reviews the structure and complexities of the German health care system with its major players and participants. The focus will be put on relevant ethical, legal and economic aspects for prioritization, rationalization, rationing and cost-effectiveness of medical benefits and services. In conclusion, this article pleads for open discussion on the challenging subject of priority-setting instead of accepting the implicit and non-transparent rationing of medical services that currently occurs at many different levels within the health care system, as it stands today.

Keywords Cost-effectiveness analysis · German health care · Prioritization · Priority-setting · Rationalization · Rationing · Solidarity · Statutory health insurance

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Introduction

Many countries are confronted with controversial debates on health care expenditures and the limits to the medical services and treatments by the national health care systems. In Germany, this debate has started anew due to the scarcity of resources that is accompanied with an increasing demand for expensive medical services. Although until now, every person has been assured of getting all the necessary treatment he or she needs to treat a serious illness, many experts expect significant restrictions on care provision to occur soon due to the uncontrollable cost explosion in the health care sector. To date, equity, comprehensiveness and the setting of principles and rules for financing and providing medical services is regulated by the Statutory Health Insurance (SHI) (Gesetzliche Krankenversicherung—GKV). Oversight of SHI comprises of a big and highly complicated network with several major players charged with the central goal of cost containment. To achieve this goal, a number of different legal reforms have already been passed by the German Parliament under the different governments over the last 30 years.

SHI covers care for about 70 million insured people, which is about 90 % of the German population. The other 10 % are covered through private insurance (Private Krankenversicherung—PKV). The legal structure of SHI is

based on the fundamental principle of solidarity that provides the legal and ethical framework for providing and financing health care services. Due to the setting of self-governance and self-regulation, several major players can be identified to be working within the SHI framework: the Federal Ministry of Health, the 16 state ministries of health, the physicians (with their associations) and the hospitals (with their organizations) on the provider side, and the sickness funds with their associations on the purchasers' side. The selection of medical services within the so-called benefit package (Leistungskatalog) and the reimbursement by SHI is regulated by the Federal Joint Committee (Gemeinsamer Bundesausschuss—G-BA). In 2007, another institution, the so-called Institute for Quality and Efficiency in Healthcare (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen—IQWiG) was introduced and charged by law with the provision of performing cost-benefit-effectiveness analyses as an instrument to increase efficiency and savings (Oduncu 2012a, b).

All of the above mentioned players as well as others perform negotiations within the SHI framework to provide equal, fair, necessary, useful and efficient health care services to their patients and the German citizenry. Thus, SHI practice strongly relies on issues of distributive social justice in its application in health care and medicine. The legal framework for implementing this kind of criteria is set by the Social Code Book V (Sozialgesetzbuch V—SGB V) which itself refers to the German Constitution (Grundgesetz).

The following article will discuss the reasons for soaring cost in the German healthcare system and describe the structure and complexities of the SHI system. After a short introduction about the attitudes of the German public on priority-setting, the terms of rationalization, rationing and prioritization will be defined. Following this, basic principles concerning the provision of medical services of the SHI will be analyzed. Finally, a potential framework for a future model of priority-setting will be outlined.

Reasons for soaring health care cost ("cost explosion")

Germany is concerned about the increasing share of national income devoted to health care costs. In attempts to control soaring health care costs, the German Parliament has enacted a number of major and minor legal reforms over the past three decades. Among the most recent reforms, the so-called Arzneimittelmarktneuordnungsgesetz (AMNOG) for cost-effectiveness analysis and the GKV-Finanzierungsgesetz (GKV-FinG) for cost-containment were enacted on January 1st 2011, as measures to incorporate cost-effectiveness in the analysis of health care treatment.

Germany like many other countries is starting to struggle to control its soaring health care costs (Figs. 1,2). Currently, Germany spends some 11.6 % of its Gross Domestic Product (GDP) on health care, that places it fourth in the world after the USA (17.4 %), the Netherlands (12 %), and France (11.8 %) in expenditure. In Germany, costs for medical services have been continuously growing over the past decades, e.g. from 186.3 billion € in 1995 to 278.3 billion € in 2009.[1] In 1970, Germany spent only 5.9 % of its GDP on health care, compared to 7.4 % witnessed by the USA (Schieber et al. 1992).

The reasons for these soaring health care costs are in part due to demographic and epidemiological changes, accompanied by the increasing costs of medicines and use of technological advances.[2] In industrial countries, longevity is constantly increasing. Concomitantly, the burden of disease is changing with a shift towards chronification of diseases, including increases in multi- and co-morbidities, functional impairments, and psychiatric conditions of old age. As a consequence of living longer, people will experience more illness, which in turn cause more cost burden to health care programs (currently 47 % of the total cost of illness is accounted for by patients over the age of 65) (Deutscher Ethikrat 2011, p. 16).

At the same time, the birth rate in Germany is constantly decreasing, which enhances the disbalance between those who pay in contributions to the health care system and those who receive medical care from it. This imbalance has been characterized as "double ageing" (Bauch 2000, p. 31). Hence, in the long run on its current course, the burden to be carried by the young and working generations for the constantly increasing share of elderly needing special medical care will run the public system into a huge financial deficit and will inevitably result in higher premiums being demanded.[3]

In addition, advances in diagnostic, therapeutic, preventive and rehabilitative services and benefit demands will also cause tremendous cost pressures for an ever increasing patient population. To compensate for these projected cost increases, society will have to be willing to pay higher insurance premiums and Parliament will have to legislate more funding for the SHI system from taxation.

In conclusion, many experts express their dissatisfaction with the current public insurance system based on budgeted health care expenditures. Accordingly, it seems inevitable

[1] Federal Ministry of Health: www.bmg.bund.de/fileadmin/dateien/Publikationen/Ministerium/Broschueren/Broschuere_Daten_Gesundheit_2011_Internet_110818.pdf (Accessed 17 Feb 2012).

[2] Federal Ministry of Health: www.bmg.bund.de/fileadmin/dateien/Publikationen/Ministerium/Broschueren/Broschuere_Daten_Gesundheit_2011_Internet_110818.pdf (Accessed 17 Feb 2012).

[3] www.wikipedia.org/wiki/Health_in_Germany (Accessed 12 Feb 2012).

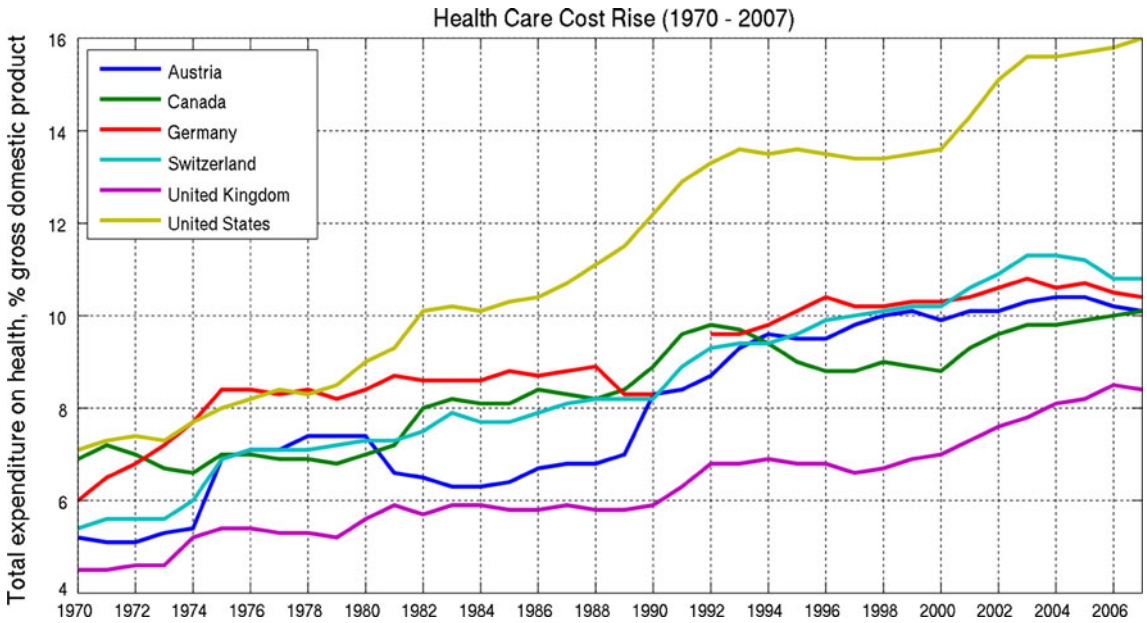

Fig. 1 Health care cost rise (1970–2007) http://en.wikipedia.org/wiki/File:Health_care_cost_rise.svg#file (Accessed 17 Feb 2012)

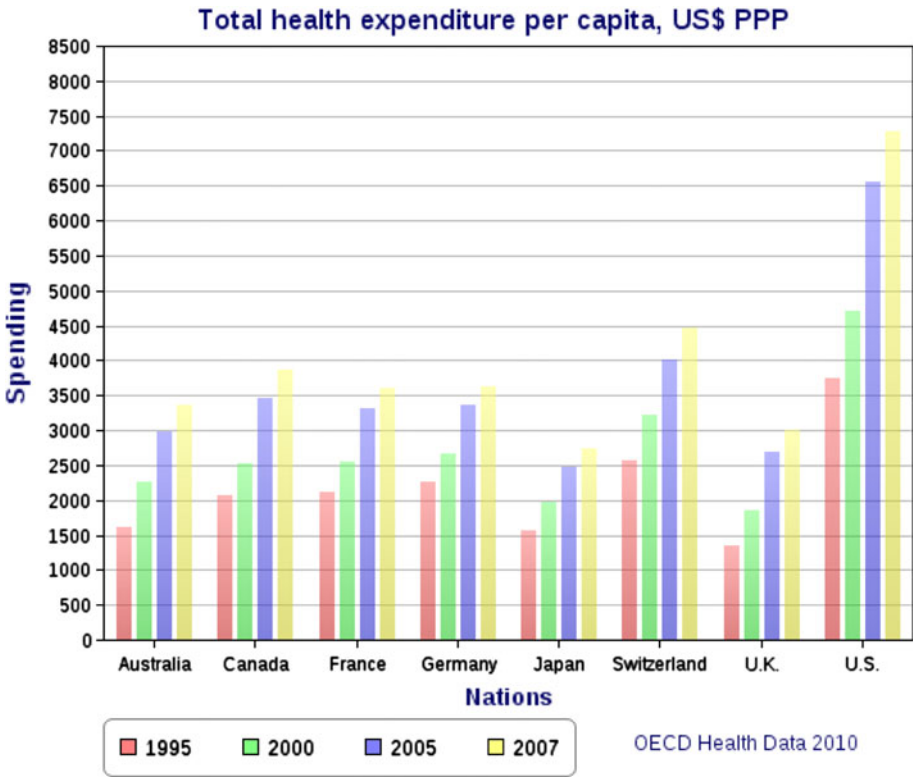

Fig. 2 Total health expenditure per capita, US$ PPP http://wikimedia.org/wikipedia/commons/8/80/Total_health_expenditure_per_capita%2C_US_Dollars_PPP.png (Accessed 17 Feb 2012)

that cuts in the provision of necessary health care services will be necessitated in the solidarity-based funded health care system. We propose that these cost cutting measures be based on rational priority-based-rationing within the German health care system (Oduncu 2012a).

Structure of the German Health Care System

The German health care system was established in the late 1800's by Otto von Bismarck's Social legislation that included the Health Insurance Bill of 1883, the Accident

Insurance Bill of 1884, and the Old Age and Disability Insurance Bill of 1889.[4] In Germany, accident insurance (Arbeitsunfallversicherung) is covered solely by the employer which secures the employee against all risks for commuting to work and at the workplace, whereas long-term care insurance (Pflegeversicherung) is co-financed by both the employer and employee and covers all needs and facilities that a person may need to manage his or her daily life. In addition, health insurance in Germany has two main types: the public Statutory Health Insurance (SHI) (Gesetzliche Krankenversicherung—GKV) and the private insurance (Private Krankenversicherung—PKV).

It is now apparent in Germany that both the GKV and PKV are struggling to control the increasing costs of medical services due to the changing patient demography. To date, about 90 % of the population in Germany are covered by GKV with the remaining 10 % covered by PKV. In general, people with incomes above the mandatory GKV level may opt out of the standard plan, in favour of PKV. Whereas the GKV's premiums are linked to income level, the PKV's premiums are linked to health status and risks of the insured. The GKV provides a standard level of care and coverage, while the PKV offers additional benefits. GKV insured people currently pay a legally mandated premium of 15,5 % of their income, which is co-covered by the employee (8,2 %) and the remaining 7,3 % by the employer (Oduncu 2012b).

In the following sections, the roles and competencies of some of the major players within the SHI system will be described. A flow chart detailing GKV group interactions is shown in Fig. 3.

SHI at the Federal level and the Federal Ministry of Health (Bundesgesundheitsministerium—BMG)

The actions and rules within the SHI are based on the principle of *self-regulation* and *self-government* set under the legislation of the German Social Code Book (Sozialgesetzbuch— SGB), with statutory health insurance being covered in Book V (SGB V). The principle of self-governance means that the responsibility of financing and the provision of health care services is delegated to self-governing and self-regulating institutions, like the sickness funds and the provider organizations (physicians, hospitals), with the German Parliament setting the legislative framework as guidance. In the SHI's structure the premium is set by the Federal Ministry of Health, for covering a fixed panel of medical services described in the German Social Code Book (SGB V) which limits all medical services and benefits to be "sufficient, fit for purpose, economically efficient and necessary" (§§ 12, 70 SGB V).

The basic feature of SHI is to supply medical care in a strongly regulated environment with the principal financial goal of cost containment and a principal ethical goal of maintaining social solidarity (Oduncu 2012a). To translate this notion into practice, redistribution represents an inherent feature of the SHI, with both life-cycle and cross-sectional redistribution processes taking place: "Specifically, those with higher incomes pay for part of the services received by those with lower incomes. Those who are fully employed help pay for those who are not yet or no longer employed. Younger and healthier individuals help pay for part of the services received by those who are older and less healthy. Those who are single and childless pay for some of the services received by those with families and children and finally, males help pay for some of the services received by females because of their higher gender-specific risks" (Henke et al. 1994, p. 255).

SGB V regulates many different major players within the public health insurance sector (Fig. 3). At the federal level, the German Parliament defines the set of rules and legislation on health care. The Federal Ministry of Health in turn is responsible for supervising the National Associations of SHI Physicians and Sickness Funds.

In particular, SGB V regulates the following (Busse 1999, p. 72):

- Mandatory and voluntary membership in sickness funds;
- the contents of sickness funds' benefits packages;
- the organizational structure of sickness funds and their associations;
- the goals and scope of negotiations between the sickness funds and providers of health care, most notably the physicians' associations; and
- financing mechanisms.

The so-called *benefit package* of SHI (Leistungskatolog der GKV) encompasses prevention of disease, screening for disease, diagnostic and treatment services and patient transportation. Moreover, employed patients receive cash sickness benefits after the first 6 weeks from the initiation of their illness. Sickness funds will pay 80 % of income for up to 78 weeks per period of illness. During the first 6 weeks, insured patients receive cash benefits from their employers covering 100 % of their current income. When this period of time expires, the beneficiary is still entitled to either get a pension based on disability or to receive social welfare assistance.

The German SHI has no gate-keeping system like that in the US or other countries. In Germany, patients are free to select a sickness fund and a sickness fund affiliated doctor of their choice, and to select the hospital of their convenience

[4] www.wikipedia.org/wiki/Health_in_Germany (Accessed 17 Feb 2012).

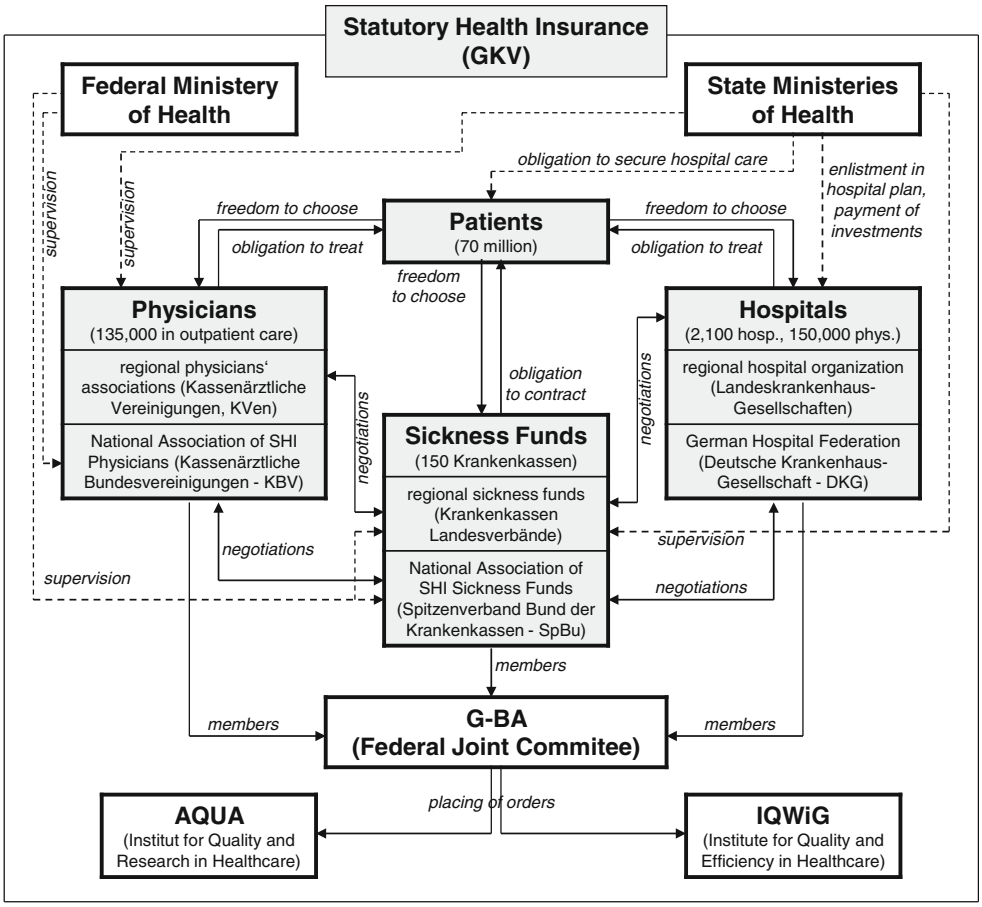

Fig. 3 The German Statutory Health Insurance (GKV) (following Busse 1999, p. 79; Oduncu 2012b)

for their treatment. Furthermore, patients can directly choose an office-based specialist without first contacting their family practitioner or GP.

SHI at the state level and the State Ministries of Health (Länder Level, Landesgesundheitsministerium)

The 16 German States (Bundesländer) with their State Ministries of Health (Landesgesundheitsministerien) have the duty and responsibility to provide and maintain hospital infrastructure according to so-called "hospital plans" (Krankenhausplan) (Fig. 3). Those hospital plans, outline the financing of the necessary investments required for each hospital. Furthermore, the State Ministries of Health are responsible for the prevention and monitoring of communicable diseases as well as for supervising all pharmaceuticals and drugs. Along with these duties to hospitals, the German States are responsible for commercial activities involving food, environmental hygiene, medical, dental and pharmaceutical education. In addition, the States are responsible for the supervision of the sickness funds and the regional physicians' associations that represent the physicians affiliated with the sickness funds (Busse 1999, p. 73).

The sickness funds (Krankenkassen)

Overall, the German health care system is highly decentralized and consists of about 150 autonomous statutory sickness funds (Krankenkassen) that covers 90 % of the country's population. Only 10 years ago, the number of sickness funds was higher than 2000, but due to competition grew smaller in number and is constantly decreasing. Through the combination of freedom to choose and *risk structure equalization* (Risikostrukturausgleich—RSA), inequities of the system should be removed and efficiency enhanced by competition. Because most of the sickness funds had only a limited capacity to compete due to their mandatorily determined benefit structure, the consequence was to produce an ongoing movement towards a larger more uniform system and a continuous decrease in the overall number of sickness funds. Thus, it appears that "economies of scale will further force small sickness funds to merge with larger ones, until eventually only a few or perhaps even one sickness fund remains" (Henke et al. 1994, p. 260).

In Germany, membership in the sickness funds is mandatory, and coverage of the population with adequate, efficient and necessary (SGB V) health care services is guaranteed regardless of an individual's ability to pay.

Sickness funds also cover family dependents and children until the ages 18 or 25, if they attend university. In addition, each person can freely choose among a variety of sickness funds, and any selected sickness fund is obliged to offer a health insurance contract. In their mode of operation, the sickness funds generate their revenues from payroll deductions taken from their employed members, with total payments being divided between the employee and employer and calculated as a percentage of gross income. The current deduction rate for individuals averages 15.5 %. Sickness funds cover a broad range of health care services such as hospital care, office-based/ambulatory/outpatient physicians and dentists, pharmaceuticals, physiotherapy, medical appliances, medical services for rehabilitation, maternity benefits, and family planning services.

Importantly, sickness funds also provide benefits in cash for sickness, maternity allowances (6 weeks before and 8 weeks after delivery), and lump sum payments for confinement. However in the past, some co-payments from the patients were introduced for various services. As such, co-payments are currently charged for hospitals stays (calculated in days), for rehabilitation, for pharmaceuticals (depending on the prices), and for certain medical appliances (Henke et al. 1994, p. 255).

In cases where there are doubts about the necessity of treatments, the sickness funds can engage their Medical Review Board (Medizinischer Dienst der Krankenkassen—MDK), a joint institution of the sickness funds, to provide expert opinion on the medical necessity of the treatment and its adequacy.

Hospitals (Krankenhäuser)

Under SHI, hospitals are obligated to treat patients, and patients are free to choose any hospital for their treatment. At present, there are about 2,100 hospitals and about 150,000 physicians working in them. The hospital sector is the largest sector in the German health care system and manifests one third of the total sickness fund expenditures. Due to a continuous shift to ambulatory medicine, the number of hospitals is continuously decreasing, e.g. from more than 3,000 in 1990 to about 2,100 in 2011. Among those present today, there are public hospitals (owned by cities, municipalities, or states), private voluntary hospitals (owned by churches or other charitable institutions, and private proprietary hospitals (owned by private enterprises).

The former methods used for reimbursement that were base on per diem rates and made payments regardless of the intensity of care, length of stay, or diagnosis, have now been exchanged by the introduction of the so-called DRG-System in 2004. In the *diagnosis-related grouping (DRG-) system,* the reimbursement unit is no longer based on per diem, but by the specifics of each disease's case (Fig. 4). The aims of this newer DRG-System include: achieving more appropriate and fair allocation of resources, facilitating precise and transparent measurement of services delivered by hospitals, and increasing efficiency and quality of services through improved documentation of all internal processes (Busse 2011, p. 35).

At present there are now more than 1,000 different DRGs for specific diseases and procedures. Each DRG is generated by a specific case mix index (CMI), which multiplied with the general base-rate (at present about 3,000 €) provides the DRG-fixed rate amount of money. However, there are apparent shortcomings showing in these DRG systems such as missing quality adjustments in reimbursements, lack of reflection on different input prices, uniform accounting systems that ignore the different categories of hospitals and of their different rate of expenditures (university hospital vs. small local hospital), and overall increased complexity due to the number of DRGs (Busse 2011, 44):

Hospitals within the hospital plan negotiate DRG budgets every year with the statutory sickness funds: whereby the sum of case mix points × base rate + supplementary fees = hospital budget. In case of budget over-runs, adjustments must take place with hospitals having to pay back the over-expenditures. In case of budget under-funding, adjustments are required for hospital compensation.

Kassenärztliche Bundesvereinigung—KVB (National Association of Statutory Health Insurance Physicians)

During the past decades, the total number of physicians in hospitals (at present about 150,000), but especially physicians in ambulatory/office-based care (135,000) have increased steadily. Among SHI physicians, corporate institutions on the provider side are represented by the regional and national physicians' and dental physicians' associations (Kassenärztliche Vereinigung—KV, Kassenärztliche Bundesverinigung—KVB). These associations have somewhat of a "Corporate Monopoly and Mission to Secure Ambulatory Care" (Busse 1999, p. 74). This means that only physicians, who are registered in their regional associations, are permitted to provide ambulatory medical care, i.e. office-based care, whereas hospitals, communities and sickness funds are not allowed to do so. The regional physicians' associations negotiate budgets from the sickness funds and distribute it only amongst their members. All of these physicians' associations have the primary mission and duty to meet the health needs of the population as defined in the benefit catalogue of the SHI.

Early in the beginning of the statutory health system, individual sickness funds made contracts with individual physicians. This later changed to where individual sickness

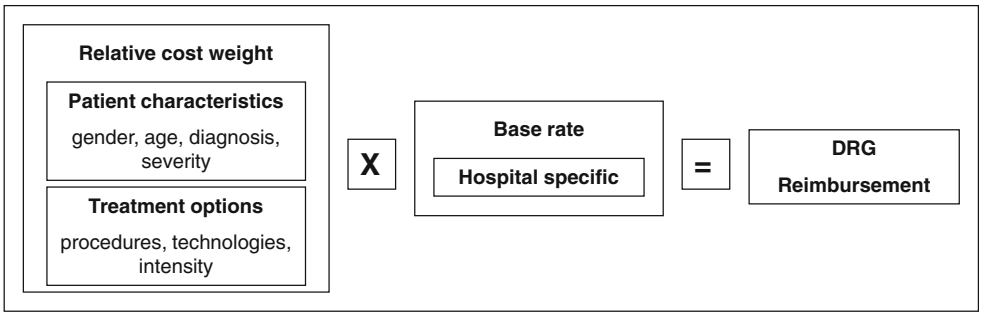

Fig. 4 The DRG reimbursement system (Busse 2011, p. 44)

funds contracted only with physicians' associations which is the current practice. Hence, negotiations only take place between the physicians' associations and the sickness funds. However, this system of contracting between these large organizations also revealed inconsistencies and problems. In order to address problems and imbalancies between these two major players of the SHI, additional collective negotiation committees have been established.

Gemeinsamer Bundesausschuss—G-BA (Federal Joint Committee)

The G-BA, is a body formed by members from the *Kassenärztliche Bundesvereinigung—KBV* (National Association of Statutory Health Insurance Physicians), the *Deutsche Krankenhausgesellschaft*—DKG (German Hospital Federation), the *Spitzenverband Bund der Krankenkassen*—SpBu (National Association of Statutory Health Insurance Funds), and patient representatives. The G-BA is the supreme decision-making institution of the self-governing and self-regulating system of the statutory GKV in Germany (§§ 91 and 92 SGB V). It defines the contents of the benefits catalogue and issues norms and rules which are binding to physicians, hospitals and sickness funds within the GKV, including guidelines to regulate the prescription of pharmaceuticals, medical care, medical aids by physiotherapists, the inclusion of new technologies and diagnostic and therapeutic procedures into the benefits catalogue of ambulatory (outpatient) care. Moreover, the G-BA also issues the so-called "need-based" planning (Bedarfsplan) of physician-distribution within private practice over the country.

In order to manage the financing and provision of health care, the G-BA has created several sub-committees to address the different tasks. Among these, one committee deals with the cost-effectiveness of new diagnostic and therapeutic procedures, ensuring that standardized procedures are followed founded on the principles of evidence-based medicine. Hence, not only does the IQWiG (see below) conduct assessments, but also the G-BA as well. Based on the current state of the art medicine, the effectiveness, quality, and economic viability of various treatment methods under examination are assessed. These assessments are critical in the establishment of the benefits catalogue including medical services but not pharmaceuticals (Fricke and Dauben 2009, p. S20).

Another G-BA sub-commission makes proposals to determine the relative weight of all health care services provided in the benefits catalogue which is called the "Uniform Value Scale" (Einheitlicher Bewertungsmaßstab—EBM) for physicians' reimbursement. Very similar to the Medicare Resource-Based Relative Value Scale in the United States, the German physician reimbursement system for payments of ambulatory care is also awarded according to a point value scale. Like the Medicare Resource Evaluation Standard, the German EBM defines the schedule of charges for health care services and their point value relative to one another (Henke et al. 1994, p. 256). The German EBM is used both by the GKV and the PKV for setting fees. However, the PKV has a different set of conversion factors that converts the point values into a Euro-valued schedule of charges. This means, that PKV pays e.g. 3,5 times the amount in Euros which the GKV pays for exactly the same medical services.

Criteria for the assessment of any new diagnostic and therapeutic procedure by the G-BA includes "efficacy, benefit-risk ratio, outcomes, additional benefit of an option compared to the alternative, cost-benefit assessment, budget impact, and evidence levels of the evidence collected or submitted" (Fricke and Dauben 2009, p. S22). These evaluations were originally based on the three criteria defined in the Social Code Book V (§§ 12, 70 SGB V): "sufficient", "necessary" and "economically viable". All assessments are based on the G-BA's rules of procedure (Verfahrensordnung) (G-BA 2006). As a usual practice, the G-BA commissions the IQWiG for assessments. The decisions made from this benefit assessment can be divided up into three categories (Fricke and Dauben 2009, p. S23):

(1) Permission or confirmation as service for the SHI care
(2) Exclusion as service for the SHI care
(3) Suspension of assessment-procedure until new evidence is provided ("Modellvorhaben").

Arzneimittelmarktneuordnungsgesetz—AMNOG (Act on the Reform of the Market for Medicinal Products)

On January 1st 2011, the new law *AMNOG* was enacted for the evaluation of pharmaceuticals due to soaring cost for drugs within the GKV (AMNOG 2011). The aim of this law and its updated evaluation process was to control the prices of medicinal products and to remove benefits that lacked any evidence of benefit and as a result produce negative cost-effectiveness under solidarity-based GKV criteria (Oduncu 2012b). Thus, current pricing must now be justified based on comparative evaluations. In 2009, the GKV spent 32,4 billion € for pharmaceuticals, which represented 19 % of total GKV expenditure (170,8 billion €). To put this into comparison, in 1999, pharmaceutical costs were 18,5 billion € and represented just 15,6 % of total GKV expenditures (130,9 billion €) (BMG 2010).

With AMNOG now in place, the G-BA can assess in the context of "early evaluation of medical benefit" the incremental, i.e. additional, medical benefit compared to alternative options. The previous setting of just paying maximal reimbursement amounts has been replaced by AMNOG with a procedure that uses negotiation for payments to be based on the evaluation of medical benefits and cost-effectiveness (Deutscher Ethikrat 2011, p. 51). In practice, the G-BA must carry out their evaluations of medical benefit within a period of 3 months from the initial introduction of the new medical drug into the pharmaceutical market. This "early evaluation" is exclusively based on a dossier containing study data provided by the pharmaceutical company. The process could present bias in the evaluation. Therefore, the G-BA may additionally commission the IQWiG to evaluate for medical benefits based on international standards for evidence-based medicine and health economics (§ 35a SGB V).

In the case where an evaluation fails to show any incremental benefit for the alternative treatment, the new product is then assigned to a so-called *reference price* (§ 35a SGB V). Thus, reference prices set the maximum reimbursement allowed for medicines that possess equivalent therapeutic effect, and these values ensure an adequately effective medicine of guaranteed quality will be available at reasonable prices (Henke et al. 1994, 258). In 1989, the reference price scheme was first introduced as a system to handle reimbursement for pharmaceuticals in Germany in order to reduce the drug costs, which had been steadily increasing. Giuliani et al. conducted a thorough analysis on the German experience in its use of reference pricing (RP) and came to the conclusion that the reference pricing scheme was an effective tool for price control, but was not sufficient by itself to provide total cost containment. Conclusions from this study indicated further measures would be required: "Generally, RP systems suffer two main weaknesses: they cannot be applied to innovative drugs, and they imply clear-cut criteria for defining the therapeutic equivalence of drugs. On the other hand, when applied extensively, RP systems can improve market transparency by eliminating price gaps between therapeutically similar products" (1998, p. 84).

If, however, early evaluation within the AMNOG procedure demonstrates an incremental benefit, the SpBu will negotiate with the pharmaceutical manufacturer on what reimbursement amount is appropriate for its new medicinal product. Under the guidelines, the price for the new drug must be set up within 12 months, and if necessary the process expedited by involvement of a mediation committee. In conclusion, the manufacturer can set the price for its new drug for the first year after initial introduction into the market. After 12 months of positive evaluation, the new drug will get assigned its ultimate reimbursement price which is then valid from that time on. In accordance with the § 35b SGB V, medical benefit can be defined as: improvement of the patient's state of health, shortening of the duration of illness, prolongation of life, reduction of side-effects or improvement in the quality of life.

On the grounds of AMNOG standards and its assessment for medical benefit, the German Ethics Council concluded: "The exclusion of non-cost-effective medicinal products, a substantially more drastic measure that was at any rate not precluded by the law prior to the amendment, could in addition be introduced by the legislature at any time as a more far-reaching instrument of rationing. If the practice of cost-effectiveness analysis were then de facto to affect only 'spurious innovations' of no more than marginal medical benefit i.e. products for which licensing for market is applied for less on grounds of medical progress than with a view to extending patents nearing expiry and hence allowing high prices to continue to be charged—no significant issues of justice would be raised" (Deutscher Ethikrat 2011, p. 57).

Institute for Quality and Efficiency in Health Care (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen—IQWiG)

The IQWiG, which was established in 2004, also can carry out evaluations of medical benefits and cost-effectiveness analyses on behalf of the G-BA (§§ 139a—139c SGB V). It itself cannot make decisions, but instead provides recommendations for the decision-making G-BA body that commissions it. The IQWiG adheres to its own published "General methods" (2011) on benefit assessment ("Nutzenbewertung"), the "Draft method for evaluating the relation between cost and benefit in the German Statutory Health Insurance system" (2009), and the "Technical document cost estimation" (2008) in its evaluations. The

IQWiG accepts surrogate parameters with direct causal relationship to patient-relevant outcomes and focuses on randomized controlled trials (RCTs) with head-to-head comparisons of drugs as scientific standard for its recommendations.

Attitudes on priority-setting and rationing in the German public

In past years, several surveys have been conducted among the citizens in Germany to evaluate the public's attitudes on issues of rationalization, prioritization and the rationing of health care (Busse 1999; Müller and Gross 2009). It was found that the majority of the public actually favoured unlimited funding for health care services, that if necessary, soaring health care costs should be compensated for by the state (e.g. increased taxation or by saving resources in other government funded fields of public life). In addition, the public perception was that if priority-setting and rationing of medical services were unavoidable, then medical decisions should be decided primarily by doctors, patient organizations and ethics committees, but not by politicians or the sickness funds. Limiting the benefits catalogue to a core of essential services was rejected as an option as well as the idea of setting priorities based on age, chronic or incurable diseases. According to the surveys, the majority supported the solidarity-based system of GKV and demanded more active participation on decisions concerning public issues on limitations in the provision of health care (Diederich et al. 2009, p. A654).

Rationalization, rationing, and prioritization

In contrast to many other European countries where since the 1990s the issues of priority-setting have been extensively discussed and turned into publicly accepted concepts (Marckmann 2009; Preusker 2007), only in past few years has a public debate on priority-setting and rationing emerged in Germany. Since then various strategies and procedures attempting to address medical, ethical and legal aspects for prioritization and rationing have been introduced and extensively discussed (Buyx et al. 2009; Gross 2007; Huster 2006; Krämer 2007; Nida-Rümelin 2007; Oduncu 2012a, b; Rabatta et al. 2009; Raspe and Meyer 2009; Schöne-Seifert et al. 2006; ZEKO 2000, 2007; Zimmermann-Acklin and Halter 2007).

There are various instruments to limit the distribution of health care services and how to make tough decisions in the face of a scarcity of resources. Hence, an open debate on equitable and transparent criteria is unavoidable. In the following, three instruments—rationalization, prioritization, rationing—will be defined, which are often used in the framework of this debate. For clarification purposes, it is recommended to sharply differentiate between these three instruments, rather than use them in a synonymous way.

Rationalization

"Rationalization is generally understood to mean the complete utilization of economic efficiency reserves. It concerns the ratio of goal achievement to the use of resources. Either the current outcome must be improved with a given volume of resources (the maximization principle), or a defined outcome must be achieved while reducing the resources deployed (the minimization principle)" (Deutscher Ethikrat 2011, pp. 17–18).

In contrast to prioritization and rationing, rationalization is ethically unproblematic. Hence, wherever it is possible to reduce and avoid unnecessary and redundant administrative, structural or organizational services, this ought to be done. Goals of rationalization aim at increasing efficiency and productivity without withholding useful treatments from patients. In this sense, procedures of rationalization always precede procedures of prioritization and of rationing (Fuchs et al. 2009; Gosepath 2007; ZEKO 2007).

However, rationalization will not by itself be sufficient to control health care costs due to coming demographic changes and more expensive implementation of advances in medicine and technology. In the long term, collective funding of the solidarity-based GKV will require even further means of prioritization and rationing.

Rationing

Rationing means controlling the allocation of rations of health care services. In a positive way, rationing means allocation of scarce resources to a certain patient or patient group. In a negative context, it could also mean the withholding of beneficial services from the patients in need (ZEKO 2000, p. A1019). The forms of rationing can be distinguished between "hard versus soft rationing", "explicit versus implicit rationing", or "direct versus indirect rationing" (Deutscher Ethikrat 2011, p. 21; Fuchs et al. 2009, p. A556).

Rationing means that tough decision-making should always be the means of last resort. And if rationing is necessary, it should always be done in an open, transparent and explicit manner so that those affected by the decision can follow the procedure and arguments involved. However, some authors have mentioned a number of examples where implicit and non-transparent rationing in the German

health care system has occurred and needs to be corrected (Strech et al. 2009, p. A1269; Wiesing 2009, p. 551).

Prioritization

The term "prioritization" is broadly used in literature and national legislations to address "to systematic consideration of scarcity-related limitation of treatments and services" (Deutscher Ethikrat 2011, p. 22). Prioritization is characterized by two elements: First, identification of relevant criteria and second, their ranking in relationship to each other (Oduncu 2012a, b).

Two forms of prioritization can be distinguished in practice: horizontal prioritization (ranking across different illnesses, conditions, patients, e.g. ranking treatment of cancer patients vs. HIV patients) and vertical prioritization (ranking within one category, e.g. ranking across different cancer patients or transplant patients) (Fuchs et al. 2009, p. A555). The transplantation list of patients waiting for organ donation is a prime example for prioritization of organ recipients who are ranked on the waiting list in accordance with defined criteria (Oduncu 2000; Oduncu et al. 2003).

In a number of countries, parliamentary and other institutional commissions have drawn up priority lists based on a variety of medical, ethical and economical criteria. In 1992, the Swedish Parliament defined 5 Priority Groups using the ethical principles of human dignity, need, solidarity, and cost-effectiveness (Preusker 2007). In the United Kingdom, the National Institute for Health and Clinical Excellence (NICE) defined in 1999 that health care services be evaluated in terms of both their clinical efficacy and cost-effectiveness. There, the benefit of a medical treatment is measured by QALYs (quality-adjusted life years) (NICE 2005). QALYs represent a measurement that combines life expectancy with the quality of life for a person into one single value. The NICE has defined a financial threshold for the provision and reimbursement of medical treatments between GBP 20,000 and GBP 30,000 (NICE 2005). From the State of Oregon in the USA, a list of horizontal prioritization was set up in 1990 and was based on only the single use of the criterion of cost-effectiveness (Marckmann 2009).

In Germany, however, we appear to be just at the beginning of this public debate on health care priorities and rationing, and there is no official model for this kind of priority-setting existing yet (Oduncu 2012a).

Priority-setting and the German Social Code Book (Sozialgesetzbuch V—SBG V)

As described above, on the international level the principles of evidence-based efficacy and clinical benefit of health care services using priority-setting and cost-effectiveness seem to be paramount measures in modernizing health care systems.

The German Social Code Book SGB V defines in a very similar way fundamental principles to guide the provision and reimbursement of medical services within the benefits catalogue of the solidarity-based GKV. These include that "Treatments must be adequate, fit for purpose and economically efficient; they must not exceed the dimension of the necessary" (§ 12 SGB V).[5] What is defined as *adequate* (German "ausreichend") care is outlined by the minimum level of care for the insured population under the statutory GKV. The intended benefit should provide sufficiently successful cure "in terms of its extent and quality". The prerequisite that treatments be *fit for purpose* (German "zweckmässig") means that treatments must be suitable for achieving a medical objective. Hence, medical services and treatments must be neither superfluous nor useless. The notion that treatments be economically efficient (German "wirtschaftlich") also has a fundamental requirement and means that the most favourable-cost alternative treatments among the various comparable alternative options must be applied. And finally, health care services and medical treatments must not exceed the dimension of the *necessary* (German "notwendig"), which in the case of the Federal Social Court (Bundessozialgericht) is defined as "unavoidably, imperatively and indispensably requisite"[6] (Deutscher Ethikrat 2011, p. 27–28).

In conclusion, the content of the terms "adequate, fit for purpose, necessary" (§§ 2 and 12 SGB V) refer to what can be accepted as the medical standard and good medical practice set by the community of medical science. The basic requirements for a medical standard include proven scientific evidence for efficacy and clinical benefit witnessed for the particular treatment. As soon as a specific health care service is accepted as a standard medical practice, it is also analyzed for cost-effectiveness by the G-BA and then included in the benefits catalogue for provision and reimbursement by the solidarity-based GKV.

A potential framework for use of priority-setting in the German SHI system (GKV)

The ethical and legal framework for identifying and ranking criteria that can be used in priority-setting and rationing is based on the GKV (Oduncu 2012a). The GKV itself is grounded on the basic principle of *solidarity* and *subsidiarity* (§ 1 SGB V, Kerber 1998). The ultimate goal

[5] This Section 12, sentence 1 of the SGB V is a translation by the Deutscher Ethikrat 2011, p. 27.

[6] Federal Social Court: BSG, SozR 2200, Section 182b RVO No. 25.

is to provide and guarantee *equity* and (distributive) *justice* for the provision and allocation of health care services and medical benefits within the collectively funded GKV. The ethical and legal foundations for applying the principles of solidarity and equity is itself set by the fundamental principle of maintaining human dignity (§ 1 Grundgesetz = Basic German Law, Vorländer 1965).

The concept of social health insurance (SHI) provides the organizing principle around which a preponderance of medical funding is applied across many European countries. The appropriate conceptual framework for assessing the complexities of SHI systems is captured in the *SHI pyramid* presented in Fig. 5 (Saltman 2004, p. 16–17): "In this conceptual approach, the lowest level serves as the essential foundation from which higher levels draw their character and legitimacy, and upon which these higher levels are thus integrally dependent. As Fig. 5 suggests, the base of the four-part SHI pyramid incorporates the national culture and historically-tied values found in the broad society. The second level—dependent on society but functioning independently—is the nation state, which constructs the legislative, regulatory and judicial arrangements for SHI systems. Built on these two lower levels are, at the third level of the pyramid, the actual organizational and administrative arrangements of each studied country's SHI system. Lastly—and therefore most contingent upon and least independent of the lower three levels of the pyramid—one finds issues of funding. Thus, discussions and analyses that focus exclusively on the funding level alone implicitly assume the existing configuration and activities of the three lower levels."

Following the recommendation by the Central Ethics Commission of the Federal Association of Physicians (ZEKO) in Germany, three major and two minor criteria of prioritization can be identified and proposed. The three major criteria include: "medical need" (in terms of severity and danger of disease, urgency for intervention), "proven benefit and fitness for purpose" (in terms of evidence basing), and "cost-benefit-effectiveness". The minor criteria include: "waiting list" and "drawing lots", if all other major criteria are equally fulfilled by this analysis in several patients (ZEKO 2000, 2007; Oduncu 2012a, b). On the basis of these criteria, a hierarchy of five potential priority groups can be classified, with priority group 1 being subdivided in subgroups 1a–1d (Table 1).

Beside these above regarded content criteria, various other formal criteria are also applied in terms of procedural justice for priority-setting that include: transparency, justification, consistency, legitimacy, and evidence basing (ZEKO 2007).

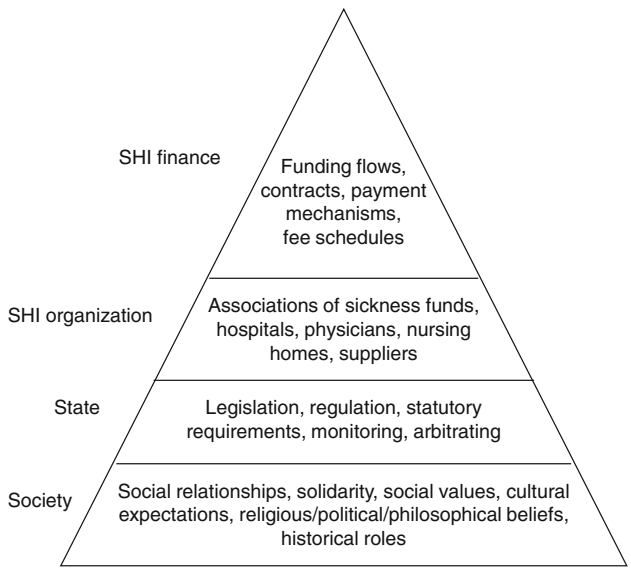

Fig. 5 Pyramid model of SHI systems (Saltman 2004, p. 17)

Conclusion

Germany is still at the beginning of a public debate on priority-setting, rationing, cost-benefit-effectiveness and distributive justice in health care. The demographic and epidemiological changes that are coming and the expenses associated with advances in medicine and medical technologies will cause soaring costs. This in turn, demands strategies and procedures for rationalization, prioritization and rationing in the health care system that will be needed in the near future. The German Statutory Health Insurance (SHI) (Gesetzliche Krankenversicherung—GKV) is based on the fundamental principle of solidarity, with the collective funding able so far to provide reimbursement of medical services for about 70 million people. A number of legislative reforms over the past three decades have been passed to contain costs within the SHI system.

The SHI system is characterized by self-governing and self-regulating agencies that include various major players and participants: patients/consumers, Federal Ministry of Health, 16 State Ministries of Health, National Association of SHI Physicians, National Association of SHI Sickness Funds, German Hospital Federation, Federal Joint Committee (G-BA), and IQWiG (Institute for Quality and Efficiency in Health Care).

To date, the SHI still manages to provide equal access to health care and coverage for all its insured people and patients regardless of their income, and continues to guarantee freedom for all participants in the complexities of the SHI framework. This reflects the specific concept that Germany has always viewed the issue of health care as society's overall responsibility. The SHI coverage is based on a minimum level of care laid down in the Social Code Book V (Sozialgesetzbuch—SGB V), stating that treatments must be adequate, fit for purpose, economically

Table 1 Proposal for defining criteria for priority-setting within the German statutory health care system (GKV) (following ZEKO 2007)

Socio-ethical framework: Human dignity, equity, justice, protection of life, solidarity, subsidiarity	
Priority Levels	Criteria
1	Medical need: severity and danger of disease, urgency for intervention (*Medizinische Bedürftigkeit: Schweregrad und Gefährlichkeit der Erkrankung, Dringlichkeit des Eingriffs*)
1a	Protection of life and protection against severe suffer and pain (*Lebensschutz und Schutz vor schwerem Leid und Schmerzen*)
1b	Protection against loss or impairment of crucial organs or bodily functions (*Schutz vor dem Ausfall oder der Beeinträchtigung wesentlicher Organe und Körperfunktionen*)
1c	Protection against less severe or temporary impairments of well-being (*Schutz vor weniger schwerwiegenden oder nur vorübergehenden Beeinträchtigungen des Wohlbefindens*)
1d	Enhancement und strengthen of bodily functions (*Verbesserung und Stärkung von Körperfunktionen*)
2	Proven benefit and fitness for purpose, evidence basing (*Nachgewiesener Nutzen und Zweckmäßigkeit: Evidenzbasierung (EBM)*)
3	Cost-benefit-effectiveness (Kosten-Nutzen-Effektivität)
4	Waiting time: if all other criteria are equally fulfilled in several patients a prioritization concerning waiting time is possible (*Wartezeit: Wenn alle Kriterien bei mehreren Patienten in gleicher Weise erfüllt sind, ist eine zeitliche Priorisierung möglich*)
5	Drawing lots: if all other criteria including waiting time are equally fulfilled in several patients a procedure of lottery can be used (*Losverfahren: Wenn alle Kriterien inkl. Wartezeit bei mehreren Patienten in gleicher Weise erfüllt sind, kann das Losverfahren eingesetzt werden*)

efficient, and must not exceed the dimension of the necessary (§ 12 SGB V). Using this minimum level of care under the solidarity-based funded SHI, the Central Ethics Committee of the Federal Association of Physicians (ZEKO) has formulated criteria that seem to be viable for the provision and ranking within a potential theoretical model of priority-setting in the future, including (1) medical need (2) evidence-based benefit and fitness for purpose, and (3) cost-benefit-effectiveness.

In conclusion, it appears that it is time that an open debate on the challenging subject of priority-setting should be expanded instead of providing implicit and non-transparent prioritization and rationing of health care services on the different levels of the publicly funded SHI system in Germany.

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