

Using Disease Management and Market Reforms to Address the Adverse Economic Effects of Drug Budgets and Price and Reimbursement Regulations in Germany

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ABSTRACT

Objective: Germany spends the highest share (10.4%) of its gross domestic product on health care among European Union countries. The majority of this financing comes from an earmarked tax on labor earnings. Drug spending, as a share (12.7%), is relatively low, as is per-capita drug spending. Over the past decade, a number of specific budgeting initiatives were introduced to control drug spending—with some success, at least until the 11% increase in the first 6 months of 2001.

Methods: This article describes and analyzes these governmental initiatives as well as other market reforms.

Results: Germany has had a “drug budget silo mentality” throughout this period. But the focus of the mentality moved rapidly from the central budget to regional budgets and to drug budgets per physician based on historical data. These amounts do not correspond to either medical necessity or economic considerations. An analysis of the

health-care system as a whole shows that the efforts to constrain spending with budget in one area can lead to higher total costs. This article also considers the impact of introducing other actual or proposed reforms such as a positive list to replace the negative list, generic substitution, retail price competition among pharmacies, and E-health commerce. There is also a new national institute constructing a database of information on health technology assessments.

Conclusions: To overcome the strong segmentation of the health system in physician, drug, and hospital budgets, we recommend using this information from proper cost-effectiveness evaluations to develop clear guidelines for disease management programs, reinforced by appropriate financial incentives.

Keywords: drug budget, negative list, positive list, health technology assessment, disease management.

Introduction

Germany is one of the most important pharmaceutical markets in Europe with total spending of €30.2 billion in 2000 (total health expenditure, €240 billion) [1]. Much of the current political debate on health focuses on the rising costs of drugs. In the first 6 months of 2001, the drug expenditure of the sickness funds rose by 11%, while expenditures for other health services expenditure increased by only 2.5%. Furthermore, this disproportionate rise in drug expenditures accounted for a considerable part of the budget deficit of statutory health insurance (SHI) [2]. This was equal to an extra €2.5 billion.

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However, this development itself is not proof of an inefficient use of resources. Technical progress, elimination of care deficits from previously undersupplied areas, or the acceptance by citizens of good health as a superior good could be responsible for these rising costs [3,4]. Nonetheless, given these changes, it is important to examine both the growth and the efficiency of drug expenditures.

Pharmaceutical supply from producers occurs in Germany through two major channels—public pharmacies via wholesale and hospitals. For example, not including medical appliances from the pharmacy, the domestic sales at producer prices of drugs and surgical dressings in a broad sense accounted for €18.15 billion in 2000. Of this 85.9% (€15.6 billion) was to public pharmacies and 14.1% (€2.6 billion) to the hospital sector [1].

Of its total expenditures on health, Germany spends 12.7% on drugs. At this percentage, Germany is somewhat below the average of the

European Union (EU) countries (OECD average of about 16%). It should be remembered, first, that this proportion is in relation to entire national health spending and not only to the expenditures of social health insurances or national health services. Second, it must be taken into account that Germany in the EU comparison exhibits the highest health ratio (relation between health expenditures and GNP) and the highest health output per capita, measured in dollar purchasing power parity. This helps to explain this apparently modest proportion and explains, among other things, the relatively high proportion of the drug expenditure in Portugal (25.8%), Spain (20.5%), and the United Kingdom (16.3%), because of the comparatively low health ratios as well as smaller health spending per capita of these countries.

National drug spending can also be analyzed in terms of distribution channels. On average, the producers receive 56.4% of the pharmacy sale price, the wholesalers 4.1%, the pharmacists 25.7%, and the government 13.9% value added tax (VAT). Of the total pharmacy sales, prescribed drugs account for €23.9 billion (86.3%) and the self-medication for €3.8 billion (13.7%). With a drug that costs €100 in a public pharmacy, €30 on average accounts for distribution. A comprehensive analysis of efficiency and effectiveness of drug supply needs to consider the incentives for and impacts on all of these “stakeholders” and therefore should include price and quantity policies of the manufacturer, the prescription method of the doctors, the compliance or behavior of the patients, and the drug distribution incentives.

Possible health sector reforms under political discussion in Germany fall into two broad categories: 1) measures that concern the service catalog of national health insurance and the reimbursement system and 2) pharmaceutical-specific reforms. The first set of options from Sachverständigenrat [2] and Schulenburg and Schöffski [5] includes:

1. Budgeting of physician drug expenditures;
2. Establishing generally accepted positive and negative lists or lists of individual health insurance companies;
3. Controlling the national profits of the manufacturers;
4. Lowering of VAT;
5. Increasing and/or modifying patient copayment, for example, by transition to an indication-specific or proportional copayment.

In the area of drug market regulation, the following options could be considered:

1. Promoting low priced import drugs as well as reimported and parallel imported goods;
2. Suspending or loosening the law prohibiting multiple and foreign pharmacy ownership;
3. Terminating so-called resale price maintenance;
4. Modifying drug price regulation;
5. Removing “*aut idem* delivery” or the drug substitution by the pharmacist using preparations with identical active ingredients (i.e., generic substitution);
6. Allowing pharmacies the option to separate drugs from economically priced larger packs;
7. Allowing the operation of mail-order companies and E-health commerce.

This list runs the risk of double counting, because some reforms would affect others. For example, a reduction of the resale prices in the fixed retail pharmacy price system reduces the saving potential for the relief of an *aut idem* delivery [2]. Currently, the foundations are not even in place to support decentralized price negotiations between the producer and the health insurance companies, several positive lists among individual insurance companies, and national profit control of the companies. Also a lowering of VAT will not be discussed here, because it would lead to a reallocation between the treasury and the national health insurance.

The aim of this article is to describe the rationing measures either implemented or under consideration in Germany and their actual or likely effects on health system performance. In addition, a proposal is described that would lead to higher quality care at a lower cost. The financing of health care in Germany and the mechanisms for and effects of health-care budgeting in Germany will be discussed and analyzed. To understand these measures as a whole, it is helpful to present complementary budgeting measures, which have either already been introduced or are still in preparation. They all aim at reducing distribution costs by limiting the number of drugs on the market. Furthermore, we will give some examples of how the budgeting process affects the allocation of medical resources, recommend an integrated concept of cost regulation in the health sector, and summarize the main results of this investigation.

Health-Care Financing

The German system can be seen as a third alternative for financing health care, situated between a governmental system, like the United Kingdom and the Sweden, and a primarily market-based system,

as in the United States. In Germany, the SHI is compulsory for employees with a gross monthly income between €325 and €3375. The qualifying income level is adjusted each year to match salary growth. White-collar workers and blue-collar workers who earn more than €3375 have the choice to stay voluntarily within the SHI or to opt out and join a private health insurer. Currently, 88.5% of the population are members of the SHI, and 8.9% are members of private health insurers. Approximately 2% are members of special forms of national health insurance system (e.g., state-financed health care for policemen), and approximately 0.3% are not insured [6]. The insurance premiums of the SHI are income-related, and they are paid half by the employee and half by the employer. Up to the above-mentioned income level the payments are calculated as a percentage of gross income, and above this level a maximum premium is applied, calculated as a percentage of the income level.

In 2002 the SHI was organized into 356 sickness insurance companies among which the employee can choose, and 95% of the covered medical services are determined by law. The coverage of the sickness insurance companies only differs in a few services, for example, mother-child regimens. The payment to the sickness funds depends not only on the employees' income but also on the sickness fund itself as each fund calculates its own percentage. This ranges from 8.5% to 15.3%, with an average of 14.0% in 2001. The average premium percentage for the different types of sickness funds increased from 1970 to 2002 from 8.2% to 14% of gross salary. Unemployed spouses and children in education up to the age of 25 are covered by the insurance free of charge. One-third of all people in the SHI are insured as family members for free. The Federal Insurance Office supervises a countrywide risk-structure compensation scheme between these insurance companies. This reinsurance scheme compensates funds according to the socioeconomic composition of the members in terms of income, age, sex, and the number of family members.

Because the premiums are not calculated according to individual risk, the SHI practices a system of redistribution and social transfers to the poor and to families and older people. The rationale of these transfer payments is the principle of solidarity within the health-care system. Thus, the access to health care does not vary because of socioeconomic circumstances within the SHI. The German Social Security Act (Sozialgesetzbuch V—SGB V) establishes the stability of contributions by ensuring that increases in health-care expenditure occur only once

in accordance with wage increases. These pre-planned constraints are justified by the particular characteristics of a health-care market with full insurance protection, without deductibles and co-insurance to reduce moral hazard. Because there is no rationing through market prices of the direct demand for health services, cost containment by the government is necessary. Otherwise, price and volume of services could expand without bound [7].

Office-based physicians or dentists who want to treat SHI-insured citizens must be members of the responsible Insurance Doctors Association of SHI (Kassenärztliche Vereinigung). The sickness fund patient may choose freely among physicians and dentists. Physicians can increase their income by increasing their volume of services per patient. Because, in many regions, there exists an upper limit of the number of patients per physician for whom the health insurer will reimburse, increasing income by increasing the number of patients is limited.

Experience with Regional and Physician Drug Budgets

Regional Drug Budgets

Overview. As a part of the Health Care Structure Act 1993, the legislation introduced a nationwide drug budget including all prescribed drugs in ambulatory care distributed over 23 regions. Each region has its own separate drug budget, and a surplus in one region cannot be used to compensate for a deficit in another region. From 1993 to 1995 the budget was fixed under law. The initial level was equivalent to the 1991 level adjusted for inflation and population growth. After 1995 it had to be negotiated between sickness funds and physician associations. It was decided that the regional insurance doctors association would pay for any deficit. But for political reasons, this was never been carried out. First, the negotiating parties agreed that the doctors would have the opportunity to compensate for the deficit in the following year [8], but this has never been achieved because of technical problems described below. In February 2001 these regional drug budgets were abolished altogether [9].

Effects. In 1993, because of the threat to physicians of this compensation, the number of prescriptions dropped below that of 1991. Subsequently, the expenditures for drugs increased again [10,11], and in 1995 the expenditures for drugs were higher in 9 of the 23 regions than the budgets. This illustrates a weakness of the German health system. On the one

hand, it has never been established how to distribute the compensation for overspending among the physicians. If all physicians in one region were required to pay the same amount, those who prescribe little medication or who prescribe economically would have to pay the same as those actually responsible for inappropriately exceeding their budget. However, if the latter had to pay the compensation single-handedly, their practices would reach the verge of bankruptcy. On the other hand, because of the information lag, physicians never know how much of the budget has been spent in the current year. They only receive this information in the middle of the following year. Consequently, they would have little time left to compensate for the exceeding budget in the previous year. In addition to these problems, there is one important external and probably unanticipated effect of a drug budget on other sectors of the health system. After the introduction of the drug budget, the number of referrals and hospital admissions has grown significantly [5,8]. Because of those substitution processes, the total costs of the health system can be higher with regional drug budgets than without them.

Drug Budgets per Physician

Overview. The Reform Act of the SHI in 2000 introduced a drug and remedy budget per physician based on the number of patients registered with the physician in a quarter. The whole of the existing budget available for drugs and surgical dressings, on the one hand, and remedies, on the other, is distributed among the doctor groups based on the number of prescriptions in 1999 (paragraphs 2 and 3 of the agreement between the associations of statutory health insurance fund and the physicians' association) [12]. At the same time, the costs of certain drugs (e.g., antibiotics and antiepileptic drugs) are subject to the budget. Every group of specialists has its own budget. Self-medication has increased compared to the situation before the budgets (paragraphs 31 and 32 SGB V) as well as the discount, which the insurance company receives from the pharmacy, according to paragraph 130 SGB V. The discount was 5% of the pharmacies sales prices in the past and 6% since 2001. Should prescription behavior change significantly between the doctor groups, a recalculation of the drug budget will occur to the next possible quarter, according to paragraph 6 of the agreement. If an office-based physician exceeds his drug budget by more than 5% for reasons not caused by special circumstances, that is, that he could not control, an inquiry must be

made, according to paragraph 10. Exceeding the budget by more than 15% results in the office-based physician having to reimburse the additional expenses that occur for reasons than other special circumstances.

Effects. The drug budgets per physician are externally determined and based on past data. Therefore, the amounts do not correspond to either medical necessity or to economic considerations. Thus, doctor groups that have overprescribed in the past have an advantage because the current drug budget is based on past prescription behavior. In contrast, doctor groups who have behaved economically in the past receive lower budgets now. A variation downward, that is, current year saving, does not produce any benefits to the physician or patients, but will be considerably penalized with a lower budget the following year.

Achieving the saving targets through given budgets depends mostly on the participation and compliance of the patients. A study commissioned by the federal association of the German pharmaceutical industry found that 29% of the persons who were not prescribed a drug by their doctor for economic reasons sought out other doctors. More than 19% considered this reason enough to change doctors completely [13]. On the one hand, this indicates that the foundation of trust between the doctor and patient has been broken. On the other hand, an analysis of the health system as a whole shows that the efforts to constraint spending with budget in one area can produce evasive responses that can lead to higher total costs than in a system without budgeting.

Complementary Pharmaceutical Policies

Regulations in the Pharmaceutical Market

Copayments. With the Health Care Reform Act in 1989, fixed global budgets for drugs were introduced and copayments for drugs without a reference price were increased. Reference prices for all drugs with the exception of patent protected drugs. In 1993, within the scope of the Health Care Structure Act, the copayment for drugs and surgical dressings depended on the price and since 1994, on the pack size. In 1997 this copayment had been increased twice, namely, through the Health Insurance Contribution Rate Exoneration Act and the First and Second Health Insurance Restructuring Acts. Currently, copayment depends on the pack size and varies between €4 and €5 [14]. The copy-

ment and its dependence on the pack size are chosen to discourage patients from wasting drugs. A comprehensive evaluation of the impact of copayment by the patients can only be accurately discussed in relation to the financing problem as a whole.

Pharmacy price maintenance. Regarding the retail sales price of the drugs, there is a fixed price system that includes all drugs sold in the pharmacy, that is, also those not requiring a prescription. The markups of pharmacies are regulated by law and depend for each drug on the wholesale purchase price of pharmaceuticals, which the pharmacist pays to the wholesaler. The higher the purchase price, the less is the additional charge in percentage of the purchase price, for example, €10 purchase price—plus 48%; €40 purchase price—plus 30%. This results in uniform pharmacy sales prices across pharmacies. Therefore, Germany has no price competition among pharmacies. From an economic perspective, the arguments for a general fixed sales price for drugs are not persuasive. The pharmacy's stock risk and capital commitment are limited and therefore would not support the case against price competition. The stock risk and the capital commitment are mostly borne by the wholesaler, so in this respect the pharmacies no longer have a special position which would justify an exception from free market competition. To argue that it is unreasonable to compare prices may be justified in the case of serious medical indications, as the patient is limited in his or her ability to make these complex decisions, but if the patients themselves demand or obtain a drug, as in the case of nonprescription drugs, the argument is less convincing.

It is estimated that the abolition of the fixed retail price system for nonprescription drugs would induce an average reduction of pharmacy sales prices of these drugs by 15%, which is rather a conservative estimate and would imply savings of €500 million for SHI. As in the policies encouraging the acquisition of good value drugs from abroad, an incentive problem occurs here. With the effective additional cost rule, the patient has no incentive to obtaining lower cost drugs, because nearly all drugs exceed the copayment. A possible solution would be a transition to proportional copayment, with income-dependent limits.

Modification of the drug price regulation and aut idem. The regulations for pharmaceutical pricing set a high distribution surcharge on high-priced drugs and surcharges that do not cover costs on low-priced preparations. Therefore, within the SHI

approximately 10% of the packs with a sales price of over €50 account for 50% of the revenues for pharmacies, whereas additional costs among prices of up to €10 do not cover the costs. This distribution surcharge system produces a subsidization of low-priced drugs by high-priced drugs, and because the latter are overproportionally found in the SHI, these pricing regulations subsidize the over-the-counter (OTC) market in effect.

A cost-oriented, but neutral surcharge under this pharmaceutical price regulation could save the SHI €0.25 to €0.5 billion. In contrast, of course, the prices of the OTC preparations must increase in total by the same amount. Because the impact on the SHI is only through the high-priced market segment, barely any financial overlaps or double counting would occur if second-hand price maintenance of nonprescription drugs were abolished. Combining both proposals would have an estimated saving potential of €0.75 to €1.5 billion [2].

Using their specialized knowledge, the pharmacists could, in addition, contribute to increase the use of cheaper registered products in the generic drug market without a loss in quality. The *aut idem* delivery provision (generic substitution) has been in effect since October 25, 2002, under which the pharmacies are obliged to sell lower-cost, equivalent drugs, as long as the doctor does not explicitly prohibit a brand name drug to be substituted with one containing the same ingredients [15].

As long the pharmacy's revenues depend on the sales price, there is unlikely to be a strong financial interest in the substituting of lower cost drugs, because this would lead to a conscious reduction in their own income. To solve this inducement problem, the price-dependent reimbursement would have to be replaced by a quantity-oriented payment and without revenue loss by the pharmacy. For example, a dispensing charge could be charged as a fixed extra cost on individual packs, on prescriptions, or in the act of sale. A further problem is that the *aut idem* regulation abolishes the liability of the manufacturer, because in the past one could always fall back on the medical documentation of the doctor to assess possible damage from a drug. To reach conclusions about the prescribed drug, as done previously, the pharmacies must also be committed to increased documentation. A price-independent reimbursement of the sale of drugs through the pharmacist could also increase the doctors' trust in the competence and selection of the pharmacist and is necessary for an improvement in the patient's compliance. In contrast, it is important that the patients are informed of the ingredient similarities;

that is, the patients must be able to trust this regulation [16].

It must be noted that the new *aut idem* provision is simply a reversal of the previous rule–exception relation. In the past, the doctor had to make a cross when he or she allowed a substitution; now he or she must clearly state that he forbids this [17]. The size of the savings depends not only on the extent to which doctors allow substitutions, but also whether pharmacies' remuneration is adjusted to this new regulation.

Allowance for mail-order companies and E-health commerce. Although paragraph 43 Arzneimittelgesetz (AMG—pharmaceutical law) forbids the mail-order sale of pharmaceutical products and according to paragraph 95 AMG such practices can be penalized, certain legal possibilities exist in this area that might allow this method for obtaining low-price products. Foreign contractors can sell pharmaceutical products on the Internet and German users, that is, patients, may, according to paragraph 73 AMG, order drugs from EU countries by mail order as long as they are for noncommercial, nonprofessional use and of a quantity conventional for personal use. The prohibition of commercial mail order is enforced in that the customers collect the drugs themselves or use a delivery service.

An argument against this type of mail-order pharmacy is potential insufficient service quality and the concentration on particularly high-yield, that is, expensive drugs, as product profitability is highest here. However, from a patient perspective, there are no arguments that mail order should be restricted. But regulations should ensure high quality of mail-order pharmacies. The valid accusation of “cream skimming” in the current reimbursement system loses its economic foundation when, as suggested above, the pharmacies' refunds would no longer be based on the price of a drug but rather oriented to quantity.

Which Drugs Should Be Reimbursed? Negative and Positive Lists

Description. Two additional instruments for control of drug expenditures are the negative and positive list. While the former has been in use in Germany since 1983, the latter is planned for 2003. The negative list, which excludes certain drugs from reimbursement, aims to reduce the excessive provision and thereby associated inappropriate therapeutic use, and at the same time supporting the cost-effective use of the drugs.

Based on paragraph 182 of the Imperial Insurance Regulation, drugs in the following application areas have been excluded from the sickness funds' benefit scheme since 1983 among others: 1) drugs for colds and endemic influenza; 2) mouth and throat therapy; 3) laxatives; and 4) medicine for travel sicknesses.

The aim of the Health Care Reform Act in 1989 was mainly to reduce drug expenditures. In addition to excluding certain drugs, certain indication areas were excluded from reimbursement.

In contrast to the negative list, the positive list does not exclude certain drugs, which shall be deemed not to be cost-effective, but it includes only certain drugs. The difference is that for the negative list the proof of cost-ineffectiveness had to be made and for the positive list the proof of cost-effectiveness must be made. The positive list will replace the negative list. Requirements for the acceptance of a drug on the positive list are based, according to paragraph 33a Sozialgesetzbuch V (SGB V—Social Code Book V), on more than just marginal therapeutic benefit, as measured by the extent of the attainable therapeutic effect. After the three existing hurdles of product quality, clinical effectiveness, and a relative low risk factor of serious side effects from paragraph 24 of the AMG, it is planned to introduce cost-effectiveness as a fourth hurdle. Drugs would not be on the positive list if they are for minor health problems, have elements unnecessary for the therapy target, have insufficient risk reduction, or have effects that cannot be assessed with sufficient certainty because of the number of active ingredients contained.

To apply these criteria, a therapy must be examined first for its effectiveness and then for its economic efficiency. This application concerns the typical patient who would be treated and not the individual treatment case where it may not work. It is worth noting that an ineffective therapy is always uneconomic, whereas an uneconomic therapy is not always ineffective. An initial version of such a list in Germany was planned for January 2003.

Effects. The exclusion of entire indication areas leaves two possible strategies open for the patient, who still seeks for treatment. First, patients and their physicians can avoid this service exclusion by, for example, creating an “acute bronchitis” out of “a cold.” Consequently, instead of a cough medicine (antitussive), antibiotics as well as sulfonamide and chemotherapeutic agents are prescribed. Such a response is not unproblematic even from a political point of view. This is understandable, as the doctor

does not want to lose his or her patient as a customer. In addition, there is not a uniform acceptance or application of the definition “negligible health problem” [18].

Second, the exclusion of drugs from the benefit scheme of the sickness funds encourages lawfully provided self-medication in the area of OTC drugs. This may be justifiable and desirable as long as comprehensive information on the pharmaceutical market is available to the patients, who will have to deal with a very complex market in the field of nonprescription drugs.

An advantage of a positive list is that the political decision makers are now responsible for the exclusion of explicit services, and this implicit rationing decision is no longer forced on treating physicians. Because of this change, a positive list for drugs can ease the relations between doctor and patient and thereby improve the compliance. In addition, the number of possible cases of drug intolerance and interactions falls more than proportionally with a decline in the total number of preparations. Consequently, the reduction in the total volume of pharmaceutical use by eliminating less effective medicines can reduce the probability of “medical errors” because doctors can more easily manage with a smaller number of drugs.

Nonetheless, the hope that the positive list as an isolated instrument, if it is ever truly implemented, would produce substantial cost savings by reducing use of ineffective drugs is unrealistic for the following reasons: While a negative list does not allow any exceptions, paragraph 33a SGB V allows the prescription of drugs in individual cases that are not on the positive list. One can only wait to see how physicians take advantage of this exception to the rule.

If the patients require a noncovered medication, the doctor could feel forced to prescribe expensive substitutes, which have severe side effects. Many of the so-called ineffective pharmaceutical drugs are preparations whose prices do not considerably exceed the additional cost limit of the copayments. Relevant savings only occur for those insurance companies where the patients have previously been exempt from the copayments, such as extreme cases, children, or pregnant women or because of excessive demands.

A frequent argument raised in support of limiting the number of pharmaceuticals is that a much higher number of drugs are available on the federal German pharmaceutical market compared to other countries. The list of drugs on the German market (Rote Liste 2001) comprises listings of 9684 compounds [19].

It should be noted, however, that in Germany the effective number of drugs included in these counts also reflects the various dosage and formulations that are available, which may not be true in other countries.

The “fourth hurdle” of cost-effectiveness can be viewed, from a political economy perspective, as supporting a market system approach. The structures and conditions of the suppliers of health-care services correspond in principle to market-economy conditions, but this does not apply to demand. The doctor as demander and the patient as consumer of drugs do not replace the price for the drug financed by the sickness fund and therefore need not reveal their individual willingness to pay, which would result—in a market system—in economically efficient decisions. The function of the fourth hurdle in this context is to show the benefit from aspects of the overall economic efficiency.

To evaluate the cost-effectiveness of pharmaceuticals, methods such as cost analysis, cost-effectiveness analysis, and cost-utility analysis must be employed [20]. In practice, however, problems can arise even in the measurement of effectiveness. The decisive factor for the patient in drug therapy is the quality of the result, avoiding a stroke, for example. These events occur rarely and sometimes only after a relatively long time period. To overcome this limitation, the studies often investigate risk factors or intermediate end points, which are assumed to have a close relationship with the final result. In the case of a stroke, this could be the lowering of blood pressure, subsequently termed a “surrogate end point.” In a study, it can be seen within a relatively short time whether the drug lowers the blood pressure. From this, we can project the long-term impact in lowering the risk of stroke.

The limitations of modeling in projecting long-term cost-effectiveness are well known. First, the relationship between the surrogate and the quality of the result can frequently not be strictly proven; second, side effects occurring in the long term may not be recognized; and third, the use of a medicine in clinical practice cannot be considered appropriately, for example, because of the interaction with other drugs. A final point is the influence of other drugs that produce unfavorable effects. Therefore, a drug must have a long-term, positive effect on the quality of the clinical outcome and not only affect selected surrogate variables (short term) [2].

An example that illustrates that often the efficiency of drugs can only be proven on a long-term basis is the treatment with statins. Statins were developed and employed in practice in the hope that

a reduction of a high cholesterol level would lead to a reduction of the cardiovascular morbidity and mortality risk. It was not until the final extensive studies were made, such as “4S,” “LIPID,” and “CARE,” that a positive effect on plaque buildup, cardiac infarction risk and in particular mortality as a whole could be demonstrated. On the basis of the final studies, a comprehensive appraisal of cost-effectiveness was more possible than on previous application in practice [21].

On the allowance of drugs, paragraph 24 AMG states that when the therapeutic effectiveness of a drug as denoted by the supplier is nonexistent, the federal authority responsible may refuse its admission according to paragraph 25 AMG. With the current criteria of the cost effectiveness (paragraph 33a SGB V) it is not easy lawfully to deny drugs a place on the positive list if they satisfy these AMG demands particularly with regard to clinical effectiveness.

From a general theoretical point of view, a positive list does not have any differential advantages under these circumstances compared to an extended negative list, which at least creates the more legal protection for doctors. The main problems of inefficiency and ineffectiveness in drug therapy are not so much the overly large spectrum of drugs, but rather the incorrect use of this variety. Limiting of this spectrum by several thousand preparations as an isolated measure is of little help in promoting cost-effective drug therapy.

Economic Evaluation: Health Technology Assessment (HTA)

Since the Reform Act of the SHI in 2000 (article 19), the German Institute for Medical Documentation and Information (DIMDI) established and operates a database-supported information system for the evaluation of the effectiveness as well as the costs of medical procedures and technologies in HTA reports. The information system gives access to the relevant data for national and international research within the area of the technology evaluation in the medical sector. Also, on the basis of the Reform Act, a scientific council was created within the DIMDI. Its main task is to generate a methodical procedure for developing and disseminating HTA reports. The council also initiates evaluations of medical procedures and technologies and assists in topic identification: assignment of research contracts in the area of HTA and priority setting for the handling and assignment of research contracts. The scope of these HTAs is broad, addressing the following areas: 1) experimental effi-

cacy; 2) effectiveness in everyday life conditions; 3) comparative effectiveness; and 4) health economic considerations (efficiency), social, legal, and ethical implications.

The results of HTA reports in Germany have until now been noncommittal rather than making a strong recommendation. It is intended over time that these guidelines result in a higher level of transparency. As a consequence, they would enable a more efficient use of drugs in the treatment. This increase in economic efficiency could be enhanced, if these guidelines were to become more binding. In the current systems of drug budgeting, doctors have no incentive to take cost-effectiveness into account. In contrast, considerations of cost-effectiveness may lead to higher drug costs than alternative treatments. For these reasons in the fifth part of this article we recommend disease management as a strategy by which guidelines can be implemented in an organizational framework.

Impact of the Drug Budget Mentality on Prescription Behavior and Total Costs—An Example

In this section, we will describe how drug budgeting can lead to unanticipated, negative impacts on the efficiency of resource allocation. As an example, we consider the treatment of schizophrenic patients, who in industrial countries generate 1.6% to 2.5% of the total health expenditures. Besides the conventional neuroleptics, there can be an “atypical” neuroleptic lasting for several years, which when treated leads to approximately seven times more medication costs. The total cost of a therapy is influenced by many other factors in addition to the actual drug cost, such as the cost of treatment for long-term results or side effects. In a pharmacoeconomic study, a time period of 5 years with a hypothetical patient collective was simulated using a Markov process [22]. The probabilities are derived from international studies on the course of schizophrenic patients, for example, Palmer et al. [23].

Because in the case of a relapse considerably more resources (e.g., hospital stay, rehabilitation) are used than in a positive course, the alternative therapies create comparable total costs. In general, the atypical neuroleptic leads to a relatively low relapse rate, so that a clearly better cost-effectiveness than the conventional neuroleptic can be shown. From pure consideration of a drug budget, however, the atypical neuroleptic will be withheld from the patients. This is because those responsible for the drug budgeting do not have to consider and

represent the total cost of the treatment. Nevertheless, as the total costs are practically identical, there is no reason not to administer atypical neuroleptic, regarding patients or their relatives because of the higher effectiveness and, thus, improved quality of life.

Atypical neuroleptics are much less prescribed in Germany than, for example, in the United States. One important reason for this different prescription behavior is the existence of overall and personal drug budgets, because long-term savings in inpatient care cannot compensate for the short-term higher drug costs in the segmented German health system.

On being asked by the Advisory Council of the German Ministry of Health on the undersupply of innovative drugs, the physician organizations stated the following as in short supply:

1. New antidepressants with weak side effects;
2. Cholinesterase inhibitor for Morbus Alzheimer;
3. Interferon for hepatitis C;
4. Glucoprotein and ADP-receptor antagonistic drugs for acute coronary syndromes and cardiological interventions.

Sometimes physicians' insufficient knowledge of pharmacotherapy can be a problem because they diverge in practice from the recommendations of evidence-based guidelines and use inadequate diagnostic tools. Because of drug budgeting, this hinders the prescribing of necessary but expensive drugs and is responsible for an underuse in certain indications. Patients were at times not administered a drug even though a good cost-utility relationship existed from an overall economic perspective.

Reform Option: Disease Management

Studies indicate that physicians have responded to attempts to control their drug spending by developing "side-stepping" strategies, such as referrals to specialists and admissions to hospitals, that lead to more costs in total. Thus, the savings in the regulated area are not automatically the same for the whole health system. Furthermore, because of the partial nature of previous approaches, treatment may sometimes be withheld from patients even when they have a general benefit or even lower total costs than the alternative treatment. In addition, the current system has the danger of producing inefficient treatment because of the doctors' insufficient knowledge of current pharmacotherapy.

Consequently, it is necessary to consider not only the cost of the provision of drugs but also of the

treatment as a whole. The reform option called "disease management" presented below covers all areas of the health industry, not just drugs. Disease management can be understood as an integrated care management during the course of an illness, covering prevention, diagnostics, therapy, rehabilitation, and care [24]. The focus is on good management of expensive and frequent treatments.

Disease management programs can be provided by health insurer, specialized companies, or both. They organize care for the patient according to his or her personal needs and type of illness on an adequate level of physician expertise (general practitioner, specialist, inpatient medical care, rehabilitation, or outpatient care) with the service necessary to achieve their target of treatment. With specific forms of organization, financing modalities, and controlling instruments, an economic supply of high-quality care can be achieved. How best to incorporate new disease management programs in the risk adjustment process of the German statutory health insurance system on the drug budgets is not yet clear. It can be anticipated that disease management may lead to higher drug expenditures, as evidence-based treatment guidelines often recommend more costly pharmaceutical treatment regimens than the current practice. Therefore, office-based physicians argue that a drug budget for patients enrolled to disease management programs may not be target-oriented. In negotiations with sickness funds, the physician associations aim to remove these drug budgets for such patients. It is also possible that drug budgets could be increased for enrolled patients, but this question is not yet decided.

The provider of a disease management program is responsible for the care of their insured, instead of the doctor or the hospital. In this system, office-based physicians would function as "gatekeepers," who in turn are monitored in terms of the necessity of hospital admissions for their patients. Usually under these disease management programs, office-based physicians would receive a fixed sum for each insured person per quarter of a year. Each such patient thus increases the income of the physician, but increased services do not increase physician's income. Nevertheless, the patient must be satisfied with the service so as not to feel compelled to change doctors or the "disease management provider" [25].

From the financing side, this system has the advantage that the doctors can be paid a per-capita amount for each registered patient, creating an incentive to manage total care economically.

Consequently, the problem of the supply-induced demand [3] in the health system is greatly lessened.

To help resolve the conflict between containing costs and improving medical care quality, the development and enforcement of treatment guidelines seems to be one solution. Their development could be an extremely economical, particularly for diagnostic services, where there is a high total health system costs, that is, in treatments that are used frequently or which are singly comparatively expensive [26]. These guidelines will be necessary in the future to assess all necessary therapeutic and diagnostic stages without creating preventable costs.

Within such a system, many more weak points in the German health-care system could be eliminated, including medically unsubstantiated diagnostic measures [26]. Furthermore, services for minor health problems can no longer be consumed on the expenses of SHI.

Conclusion

Before new rationing measures are enacted to control costs through a denial of treatments, it must be certain that all possibilities to improve efficiency have been exhausted. Only then should rationing measures be relied on, whereby it is to be guaranteed that the measures which indicate the best cost-utility relation are realized.

After eliminating the described regulation gaps on the liability of the manufacturer and shifting the pharmacy remuneration system from price-oriented to quantity-oriented, the *aut idem* delivery and a neutrally occurring cost-oriented change of the pharmaceutical price regulation is a complement to reduce costs. However, practice will have to show if the substitution possibility of the *aut idem* delivery will reduce the possibility of the health insurer to influence the drug budgets. With the additional abolition of the fixed prices of drugs in a simultaneous transition to higher coinsurance, potential savings can be realized of approximately €1.5 billion. The introduction of mail-order pharmacies will bring additional savings. These can be achieved without having “hard” rationing, that is, direct, explicit withholding of medical services.

Concerning the benefit scheme and the reimbursement regulations, the question arises as to how a waste of resources and an undersupply of services in particular areas of the health-care system can be avoided. Approaches that are only aimed at the outpatient areas are susceptible to possible sidestepping strategies. Both the negative and the positive lists can lead to extra costs through a change in the diag-

nosis or through prescription of high-priced drugs. The problem also arises in budgeting measures result in higher costs in other particular areas of the health-care system, as treatment is, for example, shifted to the inpatient department. It is also not guaranteed that the enacted measures will lead to the highest net utility for patients.

To avoid sidestepping strategies, we would consequently advocate clear guidelines for disease management programs. This can contribute to both an improvement in quality of care and providing a better manner to finance the health-care system, because they also soften the adverse impact of weak points such as moral hazard and supplier-induced demand. Thus, with simultaneous control of the doctors through the disease management programs, further drug budgeting measures by provider would be unnecessary, as the treatment method would follow guidelines under which the type of medication is fixed. Such a reform step must be well prepared as the doctors and the health insurance companies would adapt considerably.

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