Int J Health Care Finance Econ (2007) 7:185–200
DOI 10.1007/s10754-007-9020-0

International study of health care organization and financing: development of renal replacement therapy in Germany

Werner Kleophas · Helmut Reichel

Published online: 15 August 2007

Abstract The German health system represents the case of a global budget with negotiated fees and competing medical insurance companies. Physicians in private practice and non-profit dialysis provider associations provide most dialysis therapy. End-stage renal disease (ESRD) modalities are well integrated into the overall health care system. Dialysis therapy, independent of the mode of treatment, is reimbursed at a weekly flat rate. Mandatory health insurance covers health expenses, including those related to ESRD, for more than 90% of the population. Both employees and employers contribute to the premium for this insurance. Private medical insurance covers the remainder of the population. Access to treatment, including dialysis therapy, is uniformly available.

Keywords End-stage renal disease · Dialysis · Health care financing · Incentives · Medical costs · Reimbursement · Germany

JEL Classification I10 · I11 · I12 · 118

Introduction

The German health care system provides near-universal coverage, including the costs of chronic kidney disease treatment. In the last decade, the country's social insurance system, funded primarily by employer and employee contributions, has weathered both German reunification and the addition of comprehensive long-term care insurance; however, the system has been forced to change under pressure from rising health expenditures that have been outpacing wage growth. This pressure forced a restructuring of certain key elements of the system and the introduction of regulations that limit payments to health care providers and

W. Kleophas (✉)
Dialysis Center Karlstrasse, Karlstr. 17–19, Duesseldorf, 40210, Germany
e-mail: kleophas@nierenpraxis.de

H. Reichel
Nephrological Center, Villingen-Schwenningen, Germany

increase copayments by users. In 2005, pharmaceutical costs and costs for hospital treatment rose at an unexpectedly high rate, which could result in further policy adjustments to the health care system.

The prevalence and incidence rates for end-stage renal disease (ESRD) in Germany are among the highest in the European ISHCOF countries (Dor, Pauly, Eichleay, & Held, 2007). Like other European ISHCOF countries, it has relatively low transplantation rates (data not shown, and the lack of donor organs is its most significant barrier to transplantation, as in most other countries. When treating ESRD, German physicians have substantial freedom in determining treatment practices and modalities. Patients have benefited from generous insurance benefits, which quickly cover new technologies, a high physician-to-patient ratio, which makes it easy to obtain physician care, and a choice of service providers. Recent changes in the health care system, however, include incentives to limit modality choices, and the establishment of strict service provision guidelines. They also introduce limitations on coverage, including the adoption of pharmaceutical formularies.

German reforms have kept the growth of health care spending to a relatively low level compared with other developed nations, assisted, perhaps, by the relatively low growth in the German gross domestic product (GDP) per capita. However, as spending on services and pharmaceuticals continues to outpace the growth in salaries, cost-cutting measures will likely continue to affect services. A number of measures to reduce costs have been introduced:

(1) The reimbursement rate for dialysis procedures was reduced in 2002 and 2003. Before 2002, every single standard dialysis treatment was paid with an average of €170–180 (US$174-184; PPP 2001). In addition, there was an extra charge for more sophisticated treatment procedures, like hemofiltration. Since 2002, reimbursement for individual dialysis treatments has been changed to a weekly flat rate independent of the mode of dialysis procedure and the frequency of dialysis treatments. This flat rate was reduced from €580 in 2002 to €550 in 2003 (US$605 and $580, respectively; PPP 2002, 2003). In January 2004, the weekly flat rate was further reduced to €520 (US$558; PPP 2004) per week.
(2) A new reimbursement for system outpatient services (Einheitlicher Bewertungsmaßstab or standardized system for reimbursement) was introduced in April 2005. As a result, the number of prophylactic, diagnostic, and therapeutic measures conducted by private-practice physicians were further regulated. For example, restrictions were placed on the number of procedures performed per year and the minimum time taken per procedure.
(3) A moratorium on drug spending was introduced in 2004 but was partially relaxed in 2005. In 2004, the pharmaceutical industry had to give health care insurance companies a 16% discount for all drugs. Fixed prices for certain drug groups were introduced in 2005. For all other drugs, the industry discount was reduced to 6%. Upper-limit policies for the cost of certain drug groups were also expanded to more types of drugs. A new law on drug spending was expected in 2006 because expenditures continued to rise despite the moratorium; however, the law had not yet been implemented at the time of this publication.
(4) A health reform introduced in January 2004 resulted in a practice fee of €10 (US$10.73; PPP 2004), to be paid by each patient in each quarter, and higher patient copayments for drugs (a maximum of €10 for each prescription). Chronically ill patients, such as those with kidney disease, have a lower copayment due to the restriction of copayments to a maximum of 1% of the yearly income of the patient. For those patients who are not chronically ill, the annual copayment is limited to 2% of yearly income.

(5) The hospital sector switched to a diagnosis-related group (DRG) system for reimbursement in 2006.
(6) To limit the costs of ESRD treatment, the number of dialysis centers has been regulated and limited. The expectation is that this will increase the volume of dialysis treatments per center and, thus, spread fixed costs among more patients, resulting in better economic efficiency. However, although medical insurance companies estimate that ESRD costs are rising sharply, there is no evidence that having fewer but larger dialysis facilities in Germany increases cost-effectiveness.

Methods

The International Study of Health Care Organization and Financing (ISHCOF) is a substudy of the Dialysis Outcomes and Practice Patterns Study (DOPPS) aiming to characterize economic structures and their impact on the delivery of dialysis care. The ISHCOF is based primarily on one-time commissioned surveys (2004–2005) and subsequent papers by authors from each of the 12 DOPPS countries: Australia, Belgium, Canada, France, Germany, Italy, Japan, New Zealand, Spain, Sweden, the United Kingdom, and the United States. Details of the methods are described in Dor et al. (2007).

The data in this report are based on secondary sources, including the QuaSi-Niere Annual Reports of Renal Replacement Therapy in Germany, the German Federal Statistical Office, and published articles. All monetary estimates were provided in national currency units and converted into U.S. dollars with Organization for Economic Co-operation and Development (OECD) purchasing power parities (PPP) from the year of each figure (OECD, 2006). Because of the small number of economic investigators and countries in this study, all international comparisons reported here are informal and qualitative, unless otherwise noted.

The gross epidemiology of kidney disease and the provision of care in Germany

Prevalence, incidence, and trends

While Germany's prevalence and incidence of ESRD remain well below those of the United States and Japan, Europe's most populous country has the highest incidence (194 per million in 2004) of the European ISHCOF countries (Dor et al., 2007). ESRD prevalence in Germany (998 per million in 2004) is also very high for ISHCOF countries and ties with Spain for the highest in Europe (Dor et al., 2007). The trends over 5 years reflect a growth in ESRD population worldwide. Germany's ESRD population is both growing and growing older. Data from the QuaSi-Niere show a dramatic rise in the mean age of incident and prevalent ESRD patients between 1996 and 2004 (Frei & Schober-Halstenberg, 2004). The median age of incident dialysis patients was 63 years in 1996 and 69 years in 2004. In 2003, 64% of incident ESRD patients were older than 65 years. The median age of prevalent ESRD patients rose to 64 years in 2003, compared with 59 years in 1996. This is due to a general aging of the population and a shift from primary and hereditary kidney diseases to secondary kidney diseases, such as diabetic nephropathy in patients with diabetes mellitus type 2. In addition, terminal renal failure is probably delayed due to the better treatment of hypertension and diabetes available today (Frei & Schober-Halstenberg, 2004).

Further data show that the percentage of incident ESRD patients between 70 and 79 years was 23% in 1996 and 32% in 2002. The percentage of incident ESRD patients aged 80 years

and older was 6% in 1996 and more than doubled to 13% in 2003. Preliminary data from 2004 suggest that the trend toward older ESRD patients has further increased. In parallel, there is a clear decrease in incident ESRD patients younger than 60 years. From 1996 to 2002, the incidence of younger ESRD patients decreased (those 30–39 years from 6 to 4%; those 40–49 years from 11 to 7%; and those 50–59 years from 19 to 13%). In the same period, the incidence of ESRD in patients aged 60–69 years remained constant (29%) and increased in elderly patients (those 70–79 years from 23 to 32%; those older than 80 years from 6 to 13%). (Frei & Schober-Halstenberg, 2004).

A decrease in the percentage of peritoneal dialysis (PD) patients in relation to the ESRD population has occurred in the last 5–7 years, but the absolute number of PD patients has remained somewhat stable (7.3% in 1996 with 3,140 patients; 4.6% in 2004 with 2,824 patients) (Frei & Schober-Halstenberg, 2004). Since 2002, the payment rates for PD and hemodialysis (HD) have been equivalent; the weekly flat rate, as of April 2007, is €520 for both dialysis procedures.

It is interesting to note that the number of prevalent dialysis patients rose considerably between 1995 and 2001 (from 41,350 to 57,188) (Frei & Schober-Halstenberg, 2004). This corresponds to a 37% increase in the prevalence rate of dialysis and an average annual increase of 5.4%. However, the increase in prevalence has slowed since 2001; between 2001 and 2004, the average annual increase in dialysis prevalence was only 1.1% (58,579 dialysis patients in 2003; 60,992 dialysis patients in 2004).[1] The reasons for this change are not clear. The general aging of the dialysis population and the high comorbidity may contribute to the slowed increase.

The increase in ESRD patient life expectancy is accompanied by an increase in comorbidity, which, in turn, causes an increase in treatment costs.

As mentioned above, the increase in the incidence of ESRD patients has slowed considerably since 2001. As compared with the United States, the incidence in Germany is low (186 per million population [pmp] compared to 340 pmp in the United States in 2003) (Frei & Schober-Halstenberg, 2004). Though the 5-year (1999–2003) prevalence trend for German ESRD patients was 31.3%, or an average of 7.04% per year, the 3-year prevalence trend for ESRD patients between 2001 (919 pmp) and 2003 (949 pmp) was only 1.01%. Over the same 5-year period in the United States, ESRD incidence increased less than in Germany, by an average of 1.60% per year (320 pmp in 1999 to 341 pmp in 2003); however, over the last 3 years of that period (2001–2003), the rate of increase in the United States, 1.02%, exceeded that in Germany (USRDS, 2004). Taken together, current data do not suggest a higher incidence trend for Germany compared with the United States.

Demographic and socioeconomic effects of the reunification of Germany in 1990 might have considerably influenced the ESRD incidence rate in Germany. To respond to a growing number of ESRD patients, the number of dialysis facilities in Germany increased by 45.4%, from 809 in 1995 to 1,176 in 2002; however, very little change was observed in 2003 (when there were 1,173 dialysis facilities) (Frei & Schober-Halstenberg, 2004). The numbers of dialysis centers probably rose more in the East than in the West since 1990, but definitive data do not exist.

Transplantation rates in Germany, like those in most other European countries studied, have remained low. The waiting list for kidney transplants increased in the 1990s as a result of the shortage of available organs. However, in the few last years, there has been no further increase in the waiting list (Table 1).

[1] It is important to note that the numbers given are not exact but are based on an approximately 90% reporting rate of German dialysis centers (Frei & Schober-Halstenberg, 2002;Frei & Schober-Halstenberg, 2004).

Table 1 Renal transplantations in Germany, 1994–2003

Year	Total Renal transplantations*	Living-donor transplantations (%)	Active waiting list
1994	1,972	78 (4.0)	7,446
1995	2,128	83 (3.9)	7,673
1996	2,016	129 (6.4)	8,112
1997	2,249	279 (12.4)	8,546
1998	2,340	343 (14.7)	9,067
1999	2,275	380 (16.7)	9,474
2000	2,219	346 (15.6)	9,633
2001	2,352	388 (16.5)	9,547
2002	2,325	443 (19.1)	9,623
2003	2,516	405 (16.1)	9,479

* Deceased-donor and living-donor transplantations
Source: Deutsche Stiftung Organtransplantation, www.dso.de

Table 1 also shows the number of renal transplantation procedures performed in Germany between 1994 and 2003. Thus, the overall number of renal transplantations in Germany has not dramatically changed over the last 10 years despite the increase in the number of patients who could benefit from transplants.

It is important, however, to emphasize that the number of living-donor renal transplantations has greatly increased. The data from Table 1 also show that the number of deceased-donor renal transplantations has actually decreased and was compensated by living-donor transplantation (related and non-related). The introduction of blood group—incompatible kidney transplantation in Germany has furthered efforts to increase the living-donor pool.

The "old-for-old" transplant program was introduced in 1998. It is designed for recipients over 65 years of age, who are matched to deceased-donor kidney donors who are also over 65 years. Thus, the absolute number of renal transplant recipients over 65 years has increased. The relative percentage of ESRD patients between 65 and 70 years who received a kidney transplant in 2003 was approximately 7% (which was much higher than in other age groups).

Treatment facilities

In 2004, Germany had 1,192 dialysis and kidney transplantation facilities (USRDS, 2004). Of the 1,192 facilities offering HD treatment to the country's 60,992 dialysis patients, 861 were freestanding outpatient facilities. Most dialysis centers in Germany are privately owned. Dialysis units in hospitals (teilstationär, stationär) treat 11.2% of HD patients. Most of those hospitals are publicly owned facilities. In 2004, approximately 55% of the dialysis units were for-profit (serving approximately 57% of the private-sector patients), while the remainder were not-for-profit.

In 2005, around 94 (7.8%) of all German dialysis units offered night dialysis. Night dialysis provides higher treatment comfort and higher treatment efficacy, mostly to younger dialysis patients who are still working. However, the higher costs of nightly dialysis, mostly due to nurse salaries, are not covered by medical insurance (public or private) and dialysis centers are largely unwilling to pay them. These factors somewhat limit the application of this dialysis modality.

Less than 1% of ESRD patients in Germany use home HD, which provides the opportunity for more frequent (up to daily) short dialysis sessions.

Transplantation services are provided, with few exceptions (e.g., large municipal hospitals), in university hospital facilities.

The reimbursement situation for patients treated in outpatient facilities differs substantially from the situation for patients treated in inpatient hospital facilities. Outpatient dialysis services are reimbursed at a capitation-like weekly flat rate (which was reduced by more than 10% between July 2002 and January 2004). Hospital-based dialysis services for chronic ESRD patients are reimbursed per dialysis procedure. Those rates are usually higher than the rate received by outpatient facilities. Outpatient facilities are legally obliged to adhere to a number of quality measures associated with the dialysis procedure. Comparable measures have not yet been defined for in-hospital facilities. Hospital-based facilities are supposed to treat ESRD patients who have more comorbidities.

Dialysis facilities are more or less evenly located throughout Germany. In terms of access to dialysis treatment, availability of dialysis modalities, and access to renal transplantation, there is no real difference between urban and rural areas or between the types of dialysis provider. A law aiming to increase the economic strength of a given dialysis center regulates and limits the number of dialysis facilities. (See the description above of the health law implemented in 2002.)

ESRD staffing

Germany has the highest number of primary care physicians per inhabitant of all ISHCOF countries — at one physician for every 600 people, it is almost twice the average (data not shown). The ratio of nephrologists to ESRD patients, however, conforms more closely to other countries, with one nephrologist per 45 patients (Ashton & Marshall, 2007; Durand-Zaleski et al., 2007; Hirth 2007; Luño, 2007; Nicholson & Roderick, 2007; Pontoriero, Pozzoni, Del Vecchio, & Locatelli, 2007; Van Biesen, Lameire, Peeters, & Vanholder, 2007; Wikström, Fored, Eichleay & Jacobson, 2007). Historically, some physicians without board certification in nephrology have obtained licenses to treat ESRD patients. The number of those physicians is not known. In 2002, a law was introduced limiting licenses for dialysis treatments to nephrologists. In the same year, a law aiming to increase treatment quality limited the number of ESRD patients that a nephrologist may treat to, on average, no more than 50.

The number of renal transplant centers in Germany, 40, has remained stable over the last 10 years. The number of medical practitioners performing transplantations is not known. While the number of transplant surgeons is adequate for the number of kidney transplantations performed, patient demand cannot be met due to a lack of available organ donors, a problem that is common around the world.

Transplant coordinators who are also involved in organ procurement have been installed in all hospitals with an intensive care ward.

In 2003, the reimbursement rate for most dialysis facilities decreased from the 2002 weekly flat rate of €580 (US$613; PPP 2002) to €550 (US$580; PPP 2003). There is no difference in reimbursement for the various dialysis modalities. The weekly rate is based on a minimum number of two weekly treatments in the same unit and is calculated on an average of 3.2 treatments per week. In January 2004, the weekly reimbursement rate was further reduced to an average of €520 (US$549; PPP 2003). The weekly rates differ for patients younger than 60 years (€504 or US$532; PPP 2003), for patients 60 years and older (€520 or US$549; PPP 2003), and for diabetic ESRD patients (€538 or US$568; PPP 2003). A further decrease was introduced in July 2005 for diabetic ESRD patients (€530 or US$564; PPP 2004). Because of this development, the income of nephrologists, nurses, and technicians most

likely has not risen in the last several years**.** It can be assumed that the income decreased for most professionals involved in the care of ESRD patients. Though exact numbers are not available, employed nephrologist incomes are estimated to be between €75,000 and €130,000 (US$82,000 and US$142,000; PPP 2004) per year.

Physician income levels, at four times the average population's (International Reform Monitor, 2005), are an incentive in a labor market that places no restrictions on the numbers of training or practicing health providers. In an effort to limit costs, however, the Reform Act of SHI 2000 stipulated that, starting in 2003, the number of physicians involved in the care of ESRD patients would be linked to the number of ESRD patients treated at each center (International Reform Monitor, 2005). These changes have been in effect since July 2002 and have resulted in a somewhat higher demand for nephrologists. Patient services have not been directly affected.

Expenditures

Germany's health care spending

Total health care expenditure in Germany as a percentage of GDP (11%) is the highest of European ISHCOF countries, and nearly two full percentage points above the average of all non-US countries studied (Huber & Lafortune, 2003). While the total amount, well over US$100 billion, is high in absolute terms, it translates to just over US$2,800 (PPP 2001) per capita. This is within the range of the other countries with similar incomes surveyed with the exception of the United States (Huber & Lafortune, 2003).

Since the country's reunification, German health expenditure growth has been substantially lower than that of other industrialized nations (2% between 1992 and 2001) (Huber & Lafortune, 2003), despite the fact that comprehensive long-term care insurance was added in 1995–1996. The slower growth is attributed to active cost-control measures, including budget and spending caps, and regulated competition among sickness funds (Busse, 2003).

The health insurance reform was implemented in January 2004. As a result, the large deficit of German medical insurance in 2003 changed into a budget surplus in 2004, when, in some cases, insurance premiums exceeded costs by several billion euros. Politicians now expect sickness funds to reduce insurance rates below what they would otherwise have been. But the expectation is for continued growth in premiums in absolute terms and at rates that exceed the payroll tax base used to finance the bulk of medical spending in Germany.

The treatment cost of each ESRD patient in Germany, at US$57,354, is comparable to other European ISHCOF nations (Dor et al. 2007). This sum comprises the reimbursement for dialysis procedures (weekly flat rate), the physician's fees for dialysis treatment, hospitalization costs, all drug costs, and costs for other medical care received by ESRD patients. For details on the estimation of this expenditure, see the appendix.

As pointed out earlier, the reimbursement rates have decreased through the introduction of a flat rate. Because the flat rate varies by patient age and health status, changes in the total ESRD expenditure will relect changes in patient case-mix more than what is provided during the dialysis procedure.

Public/private financing

The public sector funds the majority of general health care in the ISHCOF countries, with the exception of the United States, and virtually all ESRD care in all countries. In Germany, 85%

of the population is covered by public social insurance**,** while almost all others are covered by private insurance (International Reform Monitor, 2005). The public sector provides three-quarters of total health care funding. Of the public funding, 87% comes from the country's compulsory social insurance system (which, in turn, is funded through equal contributions by employers and employees) and the remainder comes from general government subsidies (i.e., for the unemployed, disabled, and pensioners) (International Reform Monitor, 2005). On the private funding side, almost all patients are covered by private insurance (available to the high-income population and some groups, like the self-employed). A small number of people have no medical insurance; those persons are usually above the wage level at which sickness fund contributions are mandatory, but they have stopped buying private insurance. If they drop to the wage level at which mandatory insurance by the sickness fund is effective, they would not be allowed to return into public insurance.

Social insurance contributions flow through statutory sickness funds in each of Germany's regions. The funds negotiate with, and pay, regional hospital and physician associations, which, in turn, pay hospitals for inpatient care and physicians for outpatient services. Physicians and specialists are paid on a fee-for-service basis, while hospitals are funded through prospective payments. As part of ongoing efforts to control cost increases, the Reform Act of SHI 2000 introduced case fees (based on DRGs) for hospitals in 2003 (International Reform Monitor, 2005).

The DRG system is being progressively introduced to all hospitals and DRG rates are exprected to by synchronized in 2007. Most estimates predict a reduction in the number of hospital beds, but no facts are available at times of publication.

Social insurance covers 85% of the population, while private insurance covers almost all others (International Reform Monitor, 2005). Public system benefits include unlimited visits to physicians and specialists, most pharmaceutical costs, lost wages, and dental care. Copayments are charged for inpatient care, dental care, and pharmaceuticals, among others services. However, they are limited to 2% of gross income (and do not apply to some groups, like children and low-income population). The Reform Act of SHI 2000, among other initiatives, set incentives to limit direct access to specialists and limited pharmaceutical costs by introducing a list of covered drugs.

The current health care structure supports ESRD patients through free access to specialists as well as compensation for lost wages. An employer must pay 100% of a patient's salary for the first 6 weeks of illness. Thereafter, medical insurance companies in the public health system pay 80%. Privately insured patients must insure the compensation of lost wages individually. In the case of long-term unemployment due to chronic disease, many patients are transferred into the retirement insurance system.

The health care system extends extra financial protection to the chronically ill by limiting copayments if patients spend at least 1% of their annual gross income to treat their illness. This refers to all health costs. The 1% limit for chronically ill patients applies each year. Insurance provides full coverage for iron, vitamin D, multivitamin supplements, epoetin, and anti-rejection drugs for transplant patients. In addition, public health covers costs for Doppler sonography studies. The changes enacted in 2000 do not affect access to specialists and pharmaceutical coverage. This limit probably means that, at the margin, most ESRD patients are not subject to out-of-pocket payments.

German ESRD patients have little need for private insurance. Private insurance includes direct access to specialists (mostly located in hospitals) who do not participate in the public outpatient system. Private insurance also can cover the costs of extra comforts during hospital stays (e.g., private rooms).

Funding system incentives and effects

The German health care system is based on a "solidarity principle," which does not link contributions to risk factors or need. Rather, it sets them in proportion to salaries. There is no salary tax for incomes lower than €15,000 per year. For those with very high wages, there is a limit about which contribution to sick funds no longer rise with rising income.

Despite cost-control measures, the system has been strained by growing health care costs, which increased by 2.0% of GDP between 1992 and 2001 (a lower rate compared with the 3.4% average for OECD countries, but a higher rate than the growth of the wage base) (Huber & Lafortune, 2003). The above-mentioned reforms, instituted to control rising costs, have affected the provision of services, their cost-effectiveness, and the incentive structure.

Competition among insurance providers, for instance, might be able to improve the quality of services and reduce costs, but its effects are limited by the fact that the benefits of sickness funds are required to be uniform, making differentiation difficult. Competition among physicians is strictly controlled by their associations.

Since 1997, the treatment quality of a dialysis facility is regulated by law. As mentioned above, one physician may treat, on average, only 50 ESRD patients. Each facility must cooperate with a renal transplant center, and all dialysis modalities must be offered to patients. A number of technical quality standards must be met (e.g., water treatment, hygienic measures, and emergency procedures). A quality assessment system has been legally required since 2004.

Free-standing units, but not hospital HD centers, will be required to report medical quality parameters for all ESRD patients starting in the second half of 2007. All dialysis facilities will have to participate in a quarterly benchmarking and reporting system. If certain quality criteria are not met, sanctions will be implemented. Committees including nephrologists, official members of the semi-public physicians' associations, and medical insurance companies will analyze the quality data. If severe problems with medical quality occur, the license to treat ESRD patients may be discontinued.

The mandatory ESRD quality assessment system will include the length of dialysis treatments (hours per dialysis session), the frequency of weekly treatments, and the hemoglobin concentration and dialysis efficacy (for HD and PD, as measured by dialysis dose [Kt/V]). If one or several of those parameters do not match a certain standard in the benchmarking system, sanctions may occur.

The insurance-based system removes one of the barriers to care potentially faced by ESRD patients—namely, out-of-pocket costs. Comprehensive insurance (including preventive care), freedom of choice, and limits on copayments all enable patients to seek whatever care they prefer. From a provider perspective, care is enhanced by the fact that pharmaceuticals are paid for independently of dialysis reimbursements. However, there is also a tendency to reduce reimbursement for dialysis treatment itself, due to overall increasing costs of the health system.

Other factors that potentially enhance the quality of care for ESRD patients in Germany are those mentioned above: (1) the physician/patient ratio in ESRD treatment, (2) implementation of a quality assurance and benchmarking system, and (3) availability of all dialysis modalities, including home dialysis, for the same price.

Specific aspects of treatment and financing

Pharmaceuticals

Pharmaceuticals are covered by public insurance with minor contributions by patients (International Reform Monitor, 2005). The maximum financial contribution to health costs within the public insurance system is 2% of yearly income and 1% for chronically ill patients. However, given the efforts to control costs and the fact that pharmaceuticals are the fastest-growing health-care-related expense in the country, Germany's Reform Act of SHI 2000 introduced formularies of covered pharmaceuticals (International Reform Monitor, 2005). Insurance companies have excluded several pharmaceuticals from coverage. A number of exceptions (e.g., phosphate binders, vitamins, laxatives, and others) have been made for ESRD patients so that insurance companies still cover those drugs important for their care.

Individual physicians determine the use of pharmaceuticals and pharmaceutical therapies for ESRD patients, although they are subject to benchmarks for erythropoietin (EPO). Physicians are generally given freedom in prescribing pharmaceuticals (including EPO, iron, vitamin D, and multivitamins) as well as in assessing hematocrit/hemoglobin levels. However, if the average spending on drugs prescribed by comparable dialysis facilities and nephrological practices is grossly exceeded, responsible physicians are made liable and forced to pay the additional costs. Pharmacies, which must be licensed by the government, generally dispense pharmaceuticals.

In Germany, medical societies recommend that physicians follow the clinical practice guidelines outlined in the Dialysestandard (introduced by the Deutsche Arbeitsgemeinschaft für Klinische Nephrologie) or those published by the Robert Koch Institut. However, as mentioned above, quality measures corresponding to these scientific guidelines will not become mandatory until the second half of 2007.

Public insurance currently funds 100% of all pharmaceuticals for ESRD patients (with the exception of the patients copayment. Payments for EPO are based on reimbursement by dose, independent of the mode of administration. Physicians prescribe EPO, while pharmacists handle and reimburse the prescriptions. The cost of a 1,000 unit dose of EPO (or an equivalent dose of an erythropoietin stimulating agent) is approximately €16–18 (US$17–19; PPP 2004).

There is no restriction with respect to the brand of EPO. Scientific guidelines are recommended.

Access to prescription pharmaceuticals is not limited by administrative rules or protocols, or lack of funding. This situation, though, is in the process of changing, and the introduction of formularies limits the access patients have to some necessary pharmaceuticals. However, this does not affect ESRD patients. The total cost for medications prescribed by the physician every three months is benchmarked in each dialysis unit, except hospital HD centers. If a unit's costs are markedly higher than the average for all regional centers, the nephrologists may have to refund partial costs to the sick funds.

Hospitalization

Hospitals in Germany are used to perform transplants and to serve dialysis patients. Historically, patients with high comorbidity have been treated in inpatient (hospital-based) facilities. It is not known if differences in comorbidity still exist between chronic ESRD patients treated in hospital-dialysis facilities rather than in outpatient facilities. Historically, reimbursement rates for hospital-based ESRD patients have been negotiated regionally between hospital

carriers and medical insurance companies. The reimbursement rates are also based on local salary levels and costs of local infrastructure. In general, reimbursement rates for hospital-based dialysis facilities are higher than for outpatient dialysis facilities.

German hospitals have been funded by a "dual financing" system, whereby the regional governments fund investment costs (and thus have power over planning, including which specialties will be housed) while sickness funds cover operating costs. This system places regional governments in a key decision-making role with regard to hospitals, which thus were slower to reform than other sectors of the health care system.

Operating costs used to be covered on a full-cost-cover principle, but the Health Care Structure Act of 1993 abolished this structure and allowed hospitals to make profits and incur deficits. Subsequently, the Reform Act of SHI 2000 stipulated that, starting in 2003, payments for all patients in hospitals would switch from a per-diem basis to a case-fee basis (using newly instituted DRGs). It is unlikely that this change affects the treatment of ESRD patients.

Physicians practicing in outpatient facilities make the decisions about hospitalization. Currently, no general data on hospitalization of ESRD patients are available. Benchmarking systems have been installed to prospectively obtain those data.

Transplantation

Just over 25.9% of German ESRD patients in 2004 were living with a functioning kidney transplant. As discussed earlier, the recent incident transplantation population shows a disproportionate number of older patients (>65 years), a result of the old-for-old program.

Public and private health insurance companies fund transplantation. There are no patient contributions, even for anti-rejection drugs.

Two percent of German hospitals perform kidney transplantations. Organ procurement and distribution occurs through the public organization Eurotransplant (www.eurotransplant.org), which is located in Leiden, Netherlands. Organs from deceased donors are distributed among the patients on the waiting list according to an algorithm including waiting time, tissue compatibility, and other factors.

There is a relatively dense net of transplant centers in Germany, so geography is not a barrier to access. The waiting list in Germany for kidney transplantation comprised 9,270 patients in 2004. It can be assumed that the vast majority of the patients not on the waiting list have medical contraindications.

As is the case worldwide, transplantation is severely restricted by the lack of organ availability. While the incidence of renal transplantation has grown very slightly in Germany over the past five years, the number of patients on the waiting list has remained stable. As mentioned above, living-donor renal transplantation has compensated for the reduction in deceased-donor transplantation.

Official studies of the cost-effectiveness of transplantation are, to our knowledge, not available in Germany. The pharmaceutical industry has carried out such studies on an international level with the introduction of new immunosuppressive drugs.

Dialysis

Eighty-three percent of Germany's 57,188 dialysis patients are treated in HD units, while 5.7% undergo home dialysis treatments (4.9% with PD and 0.8% with home HD). In addition, 11.4% of dialysis patients are treated in "limited care" centers. This refers to HD facilities where physicians are not always present during the dialysis procedure and the dialysis is

carried out by the nursing staff. Nephrologists make rounds at least once weekly. Limited care centers treat patients without significant comorbidity who are stable during HD and who cannot perform home HD because of social, personal, or familial reasons.

The profile of HD patients includes disproportionately high percentages of diabetics (36%) and elderly patients as compared with the general population.

Providers usually make decisions about dialysis, while unit staff make decisions about staffing levels, types of dialyzers, and Kt/V.

Although Germany has few standards or guidelines for Kt/V levels, the minimum acceptable level is 1.2 Kt/V. Furthermore, new regulations will set standards and require Kt/V level sampling; they also will include a system of sanctions for failure to meet the standards (see above).

There are currently no guidelines for an acceptable range of HD treatment time. A typical treatment, however, is estimated to last at least 240 min. The benchmarking system to be implemented will that 15% of all dialysis treatments to be shorter than 240 min and less frequent than 3 treatments per week. The availability of physicians and specialists, as well as the generous insurance system for ESRD patients, ensures that patients adhere to treatment schedules with little deviation.

Trends and outcomes, and conclusion

Germany is currently facing an increase in the incidence and the prevalence of ESRD. Moreover, there is a strong trend toward older patients and higher comorbidity. There has been a deep-reaching reform of the outpatient medical treatment of ESRD patients in Germany since 2002 to address these problems. The introduction of a weekly flat rate instead of a single-treatment reimbursement is expected to lead to a substantial cost saving in direct treatment costs. Another goal of the reform was to provide incentives for widespread use of lower-cost treatment procedures because this flat rate is paid regardless of the mode of dialysis procedure.

Nevertheless, there is no significant trend toward more self-treatment procedures like PD, indicating that the ESRD population in Germany is neither suitable for nor willing to undergo these procedures. Moreover, the introduction of a weekly flat rate has shifted some of the risk from insurance providers to treatment providers. For that reason, the law has introduced a quality management system, giving exact guidelines for basic care and procedure quality. Starting in 2007, authorities also check medical outcomes.

In conclusion, outpatient ESRD treatment has developed into one of Germany's first closed-loop quality-controlled medical services. The introduction of a weekly flat rate restructured the dialysis reimbursement system. Other ESRD costs are such as those for transportation and medication, are now under discussion. Different insurance providers are now introducing systems to manage patient transportation so that two to three patients will share one car to the dialysis center and back home. Medication costs could be cut by direct distribution of drugs to the centers.

Hospital-based ESRD treatments in Germany are still more expensive than outpatient treatments, although hospitals are not obliged to fulfill sophisticated quality guidelines. The reimbursement follows a DRG system.

In general, further reform of Germany's health care system is expected. Currently, the government is deciding on future financing of the health care system. The changes implemented over the last few years have led to more competition. Traditionally, medical treatment in Germany was divided into hospital and outpatients centers. There is now the opportunity

to provide integrated treatment and to treat patients in Medizinische Versorgungszentren (medical provision centers), which could be run not only by physicians and hospitals, but also by nonprofit or for-profit organizations. However, such centers are still rare.

Acknowledgements The International Study of Health Care Organization and Financing is supported by the Arbor Research Collaborative for Health. The Dialysis Outcomes and Practice Patterns Study is supported by research grants from Amgen and Kirin without restrictions on publications.

Appendix A: Estimating total annual expenditures for German ESRD patients

The total annual expenditure per ESRD patient in Germany was estimated at €44,982 (US$46,905; PPP 2002) in 2002. This estimation is based on a weighted average of modality-specific costs. Methods for both the modality-specific and overall expenditures are described below.

Expenditures for hemodialysis patients

The total annual expenditure per HD patient in Germany was estimated at €53,613 (US$55,905; PPP 2002) in 2002. This estimate is a sum of the components detailed below and shown in Table A.1.

Hemodialysis treatment costs

Using the 2002 flat rate reimbursement for hemodialysis (€580 per week) and adding nephrologist reimbursement for dialysis oversight, the annual payment for hemodialysis treatment in Germany was €33,507 (US$34,940; PPP 2002).

Hospitalizations

Data from the Dialysis Outcomes and Practice Patterns Study (DOPPS) show 1.07 hospitalizations per year per HD patient at an average length of stay of 14.7 days (Rayner et al., 2004). This yields 15.73 hospital days per HD patient per year.

According to the OECD (2005), an average German spent €1,018 for 0.2016 overnight hospital discharges per year in 2002 with an average length of stay of 11.6 days in 2001. Using these data, the cost per hospital day in Germany, was €435 (US$454; PPP 2002) for the general population (1018/(0.2016 × 11.6)).

Assuming that a hospital day for the general population costs as much as a hospital day for the HD population, the annual hospitalization cost for German HD patients in 2002 was €6,847 (US$7,140; PPP 2002).

Erythropoietin (EPO)

Pisoni et al. (2004) estimated that 86 percent of the HD patients in Germany received EPO at an average dose of 6,846 units/week. At 52 weeks per year, this is 306,000 units per year (0.86 × 6846 × 52). The government price of EPO in 2004 was €16.28 per 1,000 units (US$19.81; exchange rate, 2004). If we deflate this cost by 3% per year, the cost in 2002 was €15.32 per 1,000 units (US$18.64). Using the 2002 data, the total annual expenditure on EPO per German HD patient was €4,689 (US$5,704; PPP 2002).

Table A.1 Expenditures per Hemodialysis patient in Germany, 2002

Component	Expenditure per ESRD patient	
	€	US$ (PPP)
Hemodialysis and physician reimbursement	33,507	34,940
Hospitalizations	6,847	7,140
Erythropoietin	4,689	4,889
Other medications	4,041	4,214
Non-dialysis physician services	4,483	4,675
Total	53,613	55,905

Table A.2 Expenditure per ESRD patient in Germany, 2002

Modality	Expenditure per patient (€)	Weight	Weighted Expenditure per patient	
	€	US$, PPP	€	US$, PPP
Hemodialysis	53,613	0.71	38,295	39,932
Peritoneal dialysis	53,613	0.04	1,928	2,011
Year of transplant	88,932	0.03	2,733	92,734
Functioning transplant	9,250	0.22	2,026	9,645
Total		1.00	44,982	46,905

Other medications

In an ad-hoc conference involving 10 German dialysis facilities, an average for non-EPO costs was determined to be 40% of the total drug cost of HD care. Using this proportion of the HD cost, other drugs contribute €4,041 (US$4,214; PPP 2002).

Non-dialysis physicians

In the US, physician payments for services other than dialysis amount to 8.8% of total HD patient expenditures (USRDS, 2005). As no validated estimations for this cost component exist in Germany, we will assume that the US proportion also applies to German expenditures. Therefore, expenditures for non-dialysis physician services were €4,483 (US$4,675; PPP 2002) per patient per year.

Transportation

Transportation is an additional cost that is an increasingly important issue as the average age of dialysis patients increases. In Germany, many elderly patients take ambulances or taxis (€10–15) to and from treatment. If a patient's physician can explain why the patient cannot take public transportation (due to age, weakness after treatments, etc.), these costs

will be reimbursed by the insurance company. In some regions, the government is looking for ways to decrease transportation costs by initiating ride-share programs and by encouraging patients to start peritoneal dialysis, which does not entail such high transportation costs. Because other countries in this ISHCOF study have not included transportation costs in their estimates, these costs were excluded from this estimate.

Expenditure for peritoneal dialysis patients

In several countries, total spending for peritoneal dialysis per patient is less than the spending per HD patient (Cass et al., 2006; Lee et al., 2002; USRDS, 2002). However, in Germany, the weekly flat rate reimbursement for PD patients is the same as for HD patients. It was assumed that the other component costs (medications, non-dialysis physician services, and hospitalization) do not differ between HD and PD patients. Therefore, the total expenditure for PD in this estimation is equivalent to that for HD.

Expenditure for transplant patients

Techniker Krankenkasse (TK), a company that insures 6 million Germans, published an average cost of €50,000 – 65,000 per transplant operation and €6,000 – 12,500 for transplant maintenance each year after transplantation (Techniker Krankenkasse, 2006; personal communication, Dr. S. Holthausen and T. Brandes, March 2007). The midpoint of these ranges are used in the calculation below. Assuming that in the year of transplantation, a patient would be on dialysis for an average of 6 months, and assuming that 50% of the average annual post transplant cost is accrued in the first 6 months of transplant, the point-prevalent cost per incident transplant patient would be, (0.5)(53,613) + 57,500 + (0.5)(9,250) = €88,932 (US $92, 734; PPP 2002).

References

Ashton, T., & Marshall, M. R. (2007). The organization and financing of dialysis and kidney transplantation services in New Zealand. *International Journal of Health Care Finance and Economics*. DOI 10.1007/s10754-007-9023-x

Busse, R. (2003). Professor of Health Care Management, Technische Universität Berlin, lecture March 10, 2003, London, European Observatory on Health Care Systems : The German Healthcare System in a Nutshell.

Cass, A., Chadban, S., Craig, J., Howard, K., McDonald, S., Salkeld, G., & White S. (2006). *The economic impact of end stage kidney disease in Australia.* Sydney, Australia: The George Institute for International Health.

Dor, A., Pauly, M. V., Eichleay, M. A., & Held, P. J. (2007). End-stage renal disease and economic incentives: The Internaional Study of Health Care Organization and Financing (ISHCOF). *International Journal of Health Financing and Economics.* DOI 10.1007/s10754-007-9024-9

Durand-Zaleski, I., Combe, C., & Lang, P. (2007). International study of health care organization and financing for end-stage renal disease in France. *International Journal of Health Care Finance and Economics*. DOI 10.1007/s10754-007-9025-8

Frei, U., & Schober-Halstenberg, H.-J. (2002). *Annual Report on Dialysis Treatment and Renal Transplantation in Germany for 2001/2002.* Retrieved March 13, 2007, from http://www.quasi-niere.de/berichte/online/en/01/world.html.

Frei, U., & Schober-Halstenberg, H.-J. (2004). *Renal replacement therapy in Germany 2003/2004*. Retrieved March 13, 2007, from http://www.quasi-niere.de/berichte/online/en/03/world.html.

Hirth, R. A. (2007). The organization and financing of dialysis and kidney transplant care in the United States of America. *International Journal of Health Care Finance and Economics*. DOI 10.1007/s10754-007-9019-6

Huber, M., & Lafortune, G. (2003). *Health at a Glance–OECD Indicators 2003: Briefing Note (Germany)*. Retrieved November 1, 2005, from http://www.oecd.org/dataoecd/15/30/16782333.pdf.

International Reform Monitor (2005). *Health-care and long-term care (Germany).* Gütersloh: Bertelsmann Stiftung Foundation. Retrieved November 1, 2005, from http://www.bertelsmann-stiftung.org/downloads/health.

Lee, H., Manns, B. J., Taub, K., Ghali, W., Dean, S., Johnsom, D., & Donaldson, C. (2002). Cost analysis of ongoing care of patients with end-stage renal disease: The impact of dialysis modality and dialysis access. *American Journal of Kidney Diseases, 40,* 611–622.

Luño, J. (2007). The organization and financing of end-stage renal disease in Spain. *International Journal of Health Care Finance and Economics* DOI 10.1007/s10754-007-9021-z

Nicholson, T., & Roderick, P. (2007). International study of health care organization and financing of renal services in England and Wales. *International Journal of Health Care Finance and Economics*. DOI 10.1007/s10754-007-9015-x

OECD (2006). *Purchasing Power Parities (PPPs) for OECD Countries 1980–2005*. Retrieved April 28, 2006, from http://www.oecd.org/statisticsdata/0,2643,en_2649_34357_1_119656_1_1_1,00.html.

OECD (2005). *OECD in Figures – 2005 Edition: Health Spending and Resources.* Paris: Organization for Economic Cooperation and Development. CD Rom.

Pisoni, R. L., Bragg-Gresham, J. L., Young, E. W., Akizawa, T., Asano, Y., Locatelli, F., Bommer, J., Cruz, J. M., Kerr, P. G., Mendelssohn, D. C., Held, P. J., & Port, F. K. (2004). Anemia management and outcomes from 12 countries in the Dialysis Outcomes and Practice Patterns Study (DOPPS). *American Journal of Kidney Diseases, 44*(1), 94–111.

Pontoriero, G., Pozzoni, P., Del Vecchio, L., & Locatelli, F. (2007). International study of health care organization and financing of renal replacement therapy in Italy: An evolving reality.*International Journal of Health Care Finance and Economics*. DOI 10.1007/s10754-007-9016-9

Rayner, H., Pisoni, R. L., Bommer, J., Canaud, B., Hecking, E., Locatelli, F., Piera, L., Bragg-Gresham, J. L., Feldman, H. I., Goodkin, D. A., Gillespie, B., Wolfe, R. A., Held, P. J., & Port, F. K. (2004). Mortality and hospitalization in haemodialysis patients in five European countries: results from the Dialysis Outcomes and Practice Patterns Study (DOPPS). *Nephrology Dialysis and Transplantation, 19*, 108–120.

REIN Studie & Dialyse Fachtagung Symposium. http://www.kieler-nierenwoche.de/seiten/14.reinstudie.html.

Techniker Krankenkasse (2006). Retrieved October 16, 2006 from, www.tk-online.de/centaurus/generator/tk-online.de/dossiers/organspende/070-nierentransplantation/17.

U.S. Renal Data System (USRDS). (2002). *Annual Data Report: Atlas of end-stage renal disease in the United States. Bethesda* MD: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases.

USRDS (2004). *U.S. Renal Data System 2004 Annual Data Report: Atlas of End-Stage Renal Disease in the United States.* Bethesda: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases.

Van Biesen, W., Lameire, N., Peeters, P., & Vanholder, R. (2007). Belgium's mixed private/public health care system and its impact on the cost of end-stage renal disease. *International Journal of Health Care Finance and Economics*. DOI 10.1007/s10754-007-9013-z

Wikstöm, B., Fored, M., Eichleay, M. A., & Jacobson, S. H. (2007). The financing and organization of medical care for patients with end-stage renal disease in Sweden. *International Journal of Health Care Finance and Economics*. DOI: 10.1007/s10754-9013-y