

Health Care Technology in Germany

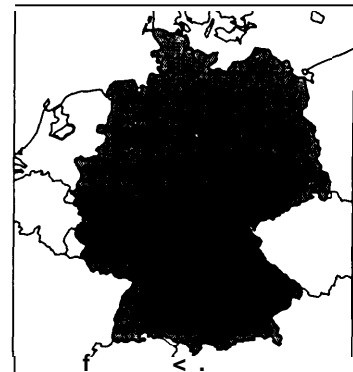
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OVERVIEW OF GERMANY

The Federal Republic of Germany (FRG) is a parliamentary democracy with 16 states (*Länder*). The legislative branch has two chambers: the parliament (*Bundestag*), whose members are elected by the people for four-year terms by proportionate representation, and the *Bundesrat*, whose members are nominated by the state governments. The Chancellor, elected by parliament, is the head of government. The President, elected by both federal legislative chambers and representatives of the 16 state parliaments, is the official head of state but may not interfere with political decisionmaking.

Since the reunification of the former German Democratic Republic (GDR, 16.4 million inhabitants in 1989) and the FRG on October 3, 1990, Germany has had about 80 million inhabitants living in an area of about 357,000 km². The average population density is about 225 persons per km². About 30 million individuals were employed in 1990 and 3.45 million were out of work in January 1992. A gross national product of 2,426 billion Deutschemarks (DM) (1990, West Germany only) made Germany the largest national economy within the European Community (EC). Since the reunification, the former East Germany has undergone a fundamental structural change. The economic collapse of the former socialist countries in Europe cost East German industry most of its exports. With only a few exceptions, the former state-owned industries did not survive under market conditions. Insufficient reinvestment and modernization during the time of the GDR ruined the majority of plants.



Because West German industry had enough production capacity to cover the East German market, there has been little West German investment in the east. As a result, most East German industrial enterprises have been closed down. Even a prestigious company like Carl Zeiss (Jena), which specialized in optics, was forced to cut its workforce from 29,000 to 7,900 and it is still not clear whether the company can survive.

Industrial decline has caused high unemployment—more than 40 percent in some regions. Within 18 months after reunification, more than 900,000 people aged 55 to 65 lost their jobs; most of them are living on social security funds. This sudden, irreversible termination of working life will no doubt cause increasing health problems, especially because unemployment was unknown in the former GDR (59).

The dramatic economic changes are reflected in the declining birth rate. At 12.9 births per 1,000 in 1988, the birth rate in the former GDR was slightly higher than in the old FRG (11.0) (60). Since reunification, the annual number of births in eastern Germany has fallen dramatically, from 200,000 to about 80,000 in 1992. Such a decline within less than three years occurred only once before, during the early years of the first world war. The decline is explained partly by the migration of about 1.5 million people from the east to the west from 1989 to 1992 (15). This migration, mostly of younger people worried about the future of East German industry, will cause considerable structural problems in the future.

HEALTH STATUS OF THE POPULATION

Since 1960, death rates have declined and life expectancy has increased in Germany. In West Germany, life expectancy at birth for women has risen from 72 in 1960/62 to 79 in 1987; and for men from 67 to 72 over that period. The lower life expectancy for men is due primarily to traffic and work accidents. There are no data concerning life expectancy by social status. The increase in life expectancy and the decline of death rates reflect a decrease in ischemic heart disease, cirrhosis of the

liver, and diseases of the respiratory tract (bronchitis, asthma, emphysema). In West Germany, infant mortality was a relatively low 6.98 per 1,000 in 1990.

Aside from life expectancy, useful data concerning the health status of the population are rare in Germany. Health statistics are extensive, but most have serious limitations. For example, there is only one regional survey with satisfactory data concerning the incidence of cancer in adults. But these data cannot be generalized to the rest of the country because the region (Saarland) and the incidence per age group are too small (60). Similarly, annual statistics published by the Federal Department of Defense showing the results of medical examinations of conscripts reveal little about the health of the general population because of constantly changing examination and classification criteria (60). Two surveys of hospital-based diagnoses also have serious limitations. One survey is regional and covers a mainly agrarian state with a low population density in the north of Germany. It cannot be projected to the entire FRG. The other survey covers the whole country, but it is not differentiated by medical departments and includes only those individuals insured by the local sickness funds. Even though about 40 percent of the population belongs to a local sickness fund, most are blue collar workers. Consequently, many biases exist in the data that make generalization risky.

The only representative information available concerning health status is an official government poll, including some questions about illness, of between 0.25 and 1 percent of the population that is done fairly regularly. Since 1974, about 15 percent of those interviewed have identified diseases from which they suffered. Most frequent were respiratory diseases, circulation disturbances, problems of the muscular and skeletal system, endocrinological and metabolic diseases, and digestive troubles. The questionnaire does not explicitly ask respondents to name the kind of disease they suffer from, and it concentrates on illnesses that have occurred within the past four weeks. The data

therefore must be interpreted cautiously. For example, one consequence of this survey method is that some diseases, such as cancer or psychiatric and nervous disturbances, are underreported.

There are also few useful data on the relationship between health status and socioeconomic status in Germany. The scarce research findings available indicate that differences in health are linked to working conditions and education (49). Myocardial infarction, cancer, and cirrhosis of the liver seem to occur significantly more often in the underprivileged classes. The literature stresses that there seem to be few differences by social status in the use of health services for treatment (60). But preventive services—prenatal care, screening for cancer, etc.—are used significantly more often by persons of higher socioeconomic status.

Germany has had virtually no disease-specific patient registries or reporting system, not (as claimed by some (39)), because people were reluctant after the Nazi experience to have their names placed on lists, but simply because for a long time no one (including physicians) was interested in these data. Extensive data are collected in many places in Germany, but they are collected only to answer very specific questions or to satisfy certain bureaucratic needs.

Health authorities and physicians engaged in health policy have been aware for a long time that the lack of data on health status and delivery impedes a rational discussion on the distribution of scarce health care resources (67). But this awareness has not resulted in better data. The reasons for this lack of action can be found in the structural peculiarities of the German health care system.

THE GERMAN HEALTH CARE SYSTEM

Legislation and Financing

Although the constitution of 1918 (*Weimarer Verfassung*) explicitly defined social rights (e.g., the right to work), the constitution of the Federal Republic of Germany (*Grundgesetz, GG*) only establishes a “democratic and social federal state” (article 20 GG), where “social” rights are to be defined by legislation. Except for prescribed areas of

federal interest, legislation is under the jurisdiction of the state parliaments. In those prescribed areas, however state legislation is subordinate to federal law. These include the areas of epidemics, university education in medicine, food and drug control, social security, and since 1972, financing of hospitals.

Between 1883 and 1889, the time of the German Empire, Germany enacted its basic social security laws: the Health Insurance Act (1883), the Accident Insurance Act (1884), and the Insurance for Disabled and the Pension Funds Act (1889) (75). The purpose of these laws was to ameliorate the social situation of the working class, thereby reducing the political influence of the Socialist Party. These laws were codified into one basic law, the *Reichsversicherungsordnung* (RVO), which came into force in January 1914. Overtime this law became very complex. Work began to reformulate it in a social code (*Sozialgesetzbuch, SGB*) in the 1970s, and in 1989, the reformulated health insurance law was enacted (SGB V).

The 1989 law determines who can become a member of a mandatory sickness fund and how contributions are to be paid. It specifies the entitlements of the insured and regulates the relations between sickness funds on the one hand and office-based doctors and hospitals on the other. The law also specifies the tasks of the so-called Concerted Action in Health Care (141 SGB V).

The Concerted Action in Health Care is a committee that advises government on health policy and health care financing. Created by law in 1977, it represents organizations “whose influence is so important that ignoring them would have miscarried political decision” (79). The committee consists of a total of more than 60 representatives of: the mandatory sickness funds (14), associations of the private insurance companies (2), physicians’ associations (11), the German Hospital Society (3), the federal association of pharmacists (1), the pharmaceutical industry (3), unions (6), employers’ associations (6), State governments (16) and experts (2 or more) from the federal departments involved.

The committee meets twice a year and makes recommendations on how to regulate the remuneration of sickness fund doctors and on cost-containment measures in hospital financing. It also discusses structural problems of hospital care delivery and possible solutions. The committee is too large to make decisions easily. It has been assisted by the Board of Experts for the Concerted Action in Health Care (*Sachverständigenrat für die Konzertierte Aktion im Gesundheitswesen-SVRKAiG*) since 1986. This board is made up of seven independent experts in medical science, economics, and social science. Its responsibility is to deliver an annual report analyzing developments in health care delivery and their medical and economic consequences. The board is also charged with recommending priorities for health care needs and the elimination of superfluous supply of health services, taking into account the economics of the health care situation. Because this task requires a good information base, the board has taken many initiatives to reorganize health statistics. The board's annual report is the best information source on German health care and its qualitative and financial problems.

The most important institutions in the German health care system are the approximately 1,100 mandatory sickness funds. In 1991, all employees in Germany who had a monthly income up to 5,100 DM were insured by a mandatory sickness fund. (This wage limit is modified annually. In certain cases, persons with higher salaries are also authorized to be insured by mandatory sickness funds.) Family members (spouses and children) of the insured who have no personal income are coinsured without making any contribution and are entitled to the same services. (This is the "solidarity principle" of social security: a member's sickness fund contribution remains the same whether he or she is single or has dependents or nonworking family members who are coinsured.) The employee's contribution, which is independent of individual, medical, or social risk factors, is a percentage of income. The contribution rate is fixed annually by each sickness fund according to

its financial needs. Most employees have limited or no options in deciding which sickness fund they want to join, leaving them with little choice concerning the level of contribution they have to pay. (This restriction will be canceled in 1996.) In 1992, the average contribution rate amounted to 12.6 percent, half taken from employees' gross wages and half contributed by employers.

About 90 percent of the population are obligatory or voluntary members (or coinsured family members) of mandatory sickness funds, which operate as nonprofit statutory corporations. In addition, 45 private insurance companies offer health insurance. About 6.8 million people are fully covered by private insurance, which offers more or less the same benefits as the sickness funds.

The services to be reimbursed by mandatory sickness funds are defined by law. They include medical and dental treatment, hospitalization, prescribed drugs and other remedies, prenatal care, and some preventive and screening measures. Most dental prostheses, eyeglasses, and other prosthetic equipment are reimbursed as well, with some limits. Table 5-1 shows the growth of expenditures by the mandatory sickness funds from 1970 to 1990 (not adjusted for inflation), and table 5-2 gives national spending broken down by source of payment for 1989 in West Germany. However, because there are no detailed statistics on total health care expenditures, some figures in table 5-2 ("employers health expenditures for their employees" and "private households") are estimated, so the total expenditure of 276 billion DM (about US\$153 billion) is also an estimated value.

Health Care Delivery

An essential feature of the German health care delivery system is the rigorous institutional separation of inpatient and outpatient care. Outpatient care is the task of about 75,000 office-based physicians, the gatekeepers to the hospital sector. With a few exceptions they have no opportunity to treat

TABLE 5-1: Expenditures of the Mandatory Sickness Funds (million DM)

Year	Office-based care	Dental care	Drugs	Hospital care	Others	Total
1970	5,458	1,708	4,226	6,009	6,448	23,849
1975	11,258	4,129	8,901	17,534	16,348	58,170
1980	15,358	5,517	12,572	25,465	27,044	85,956
1985	19,660	6,656	16,603	35,049	30,736	108,704
1990	24,371	8,172	21,841	44,595	35,295	134,238

SOURCE Sachverständigenrat für die Konzertierte Aktion im Gesundheitswesen (SVRKAiG), Jahresgutachten (Baden-Baden: Nomos Vlg., 1992)

patients in a hospital. Inpatient care is provided by 91,895 salaried hospital doctors, who, with a few exceptions, are not authorized for outpatient treatment.

In 1990, 71,700 office-based physicians, mostly solo practitioners, were providing mandatory sickness fund-covered services. (Only about 3,300 office-based physicians were exclusively treating privately insured patients.) Sickness fund doctors must be members of a regional association of sickness fund doctors (*Kassenärztliche Vereinigungen*).

These associations, not the individual doctors, contract with the sickness funds and negotiate remuneration. The associations provide information about the services rendered by their members to the sickness funds and distribute fees to each doctor proportional to the amount of services he or she has rendered. The physicians' associations hold the monopoly on outpatient care and have to guarantee a sufficient supply.

Besides physicians, in 1990 there were about 43,000 practicing dentists in West Germany who are organized in a similar way. The Federal Association of Sickness Fund Dentists negotiates contracts with the sickness funds and distributes the fees proportional to the amount of services rendered. In 1990, mandatory sickness funds and private health insurance companies spent 10.14 billion DM—more than 161 DM per inhabitant, the highest per capita dental expenditures in the world.

The number of office-based physicians has grown rapidly within the past 20 years, especially the number of specialists (see table 5-3). This increase has caused great debate over how many

doctors are necessary to provide outpatient care. Until 1960, the mandatory sickness funds were authorized to limit the number of contracting doctors. But in 1960, the Federal Constitutional Court (*Bundesverfassungsgericht*) found that this regulation was in conflict with the constitutionally guaranteed freedom of occupation. Balancing individual constitutional rights against the social interest in securing the financial stability of mandatory sickness funds, the Court saw no difficulty in entitling each doctor to obtain a license to contract with these funds, particularly since the number of uncontracted doctors was small. Mandatory sickness funds have had to contract with every office-based doctor who wants to do so; consequently, the number of office-based doctors has more than doubled. In addition, about 10,000 physicians a year have wanted to become sickness fund doctors since the early 1980s. In 1992, the government enacted a law that will again try to limit the number of sickness fund doctors in the coming years.

In 1989, there were 1,735 hospitals with about 452,000 beds for acute care and 1,311 hospitals with 217,000 beds for chronic diseases (e.g., rheumatism and some psychiatric illnesses) or rehabilitation. More than 11 million people were referred to a hospital that year with an average hospital stay of 11.9 days (not including psychiatric departments).

Three different types of hospital ownership exist: public, private nonprofit, and private. Public hospitals are owned by cities and municipalities, by counties, and, particularly in the case of psychiatric hospitals, by the states. Some public hos-

TABLE 5-2: Total Health Expenditures in West Germany, 1989 (million DM)

1. Federal and state budgets	37,891
Reimbursement for medical treatment of civil servants ^a and medical education	
2. Mandatory sickness funds	127,579
3. Social pension funds	19,606
Pensions for disabled persons DM13,084	
Medical rehabilitation: DM4,356	
4. Social accident insurance	8,559
Inpatient and outpatient care for workplace accidents and occupational diseases	
5. Private health insurance	15,866
6. Employers' health expenditures for their employees	46,907
Wages and salaries for sick workers: DM31,620	
7. Private households	20,339
Drugs and dental prostheses not reimbursed by mandatory sickness funds	
TOTAL	276,807

^a Civil servants are reimbursed for about 60% of their health care expenditures by the state and by private insurance for the rest

SOURCE Statistisches Bundesamt, *Statistisches Jahrbuch* 7992 für die Bundesrepublik Deutschland (Wiesbaden, 1992).

pitals (e.g., military hospitals) are run by federal authorities. Public hospitals account for 51 percent of all beds. Private nonprofit hospitals, most run by religious denominations, account for 35 percent of beds. The remainder are private proprietary hospitals, often owned by doctors.

The Hospital Financing Act of 1972 (*Krankenhausfinanzierungsgesetz* KHG) made legislation on hospital supply and financing a federal task. The planning of hospital supply was delegated to the states, which enact an annual hospital need plan. Except for rehabilitation hospitals and university clinics, which have other resources, a hospital must be admitted to this need plan if it is to survive financially. Other than initial ownership expenses, all investments (building construction, expensive medical equipment, etc.) in these hospitals are funded by the states, and operational costs are reimbursed by the mandatory sickness funds. The sickness funds reimburse the operating costs on the basis of a per diem rate that the hospital receives for each day of each patients' hospital stay. Because hospital income is directly related to the number of patients and the average length-of-

stay per patient, an economic incentive to extend hospital stays and to treat patients longer than medically necessary exists. This led to a change in the financing formula in 1993.

In 1989, about 878,000 persons were employed in hospitals. Of the 92,000 hospital-based physicians, more than 86,000 (94 percent) were salaried employees, 28 percent of them in the leading positions of medical director or assistant medical director. Another 47,000 (54 percent) were furthering their education working as assistant physicians to obtain specialist licenses. There also are 5,531 *Belegärzte*, or office-based physicians who lease hospital beds to provide their outpatient clients with inpatient treatment. (Small hospitals that want to offer a particular medical treatment but have too few patients to establish a special department are especially interested in leasing beds to office-based specialists. Some private for-profit hospitals engage only a few salaried physicians and nurses to provide basic services and to run the hospital; the remaining work is done by office-based physicians.)

TABLE 5-3: Office-Based Sickness Fund Doctors (West Germany)

Year	General						
	All doctors	practitioners	Internists	Gynecologists	Orthopedists	Radiologists	Urologists
1970	46,302	25,539	5,226	2,613	1,139	878	529
1975	49,928	24,757	6,760	3,534	1,573	988	833
1980	56,138	24,980	8,795	4,808	2,102	1,129	1,208
1985	63,694	27,405	10,203	5,610	2,604	1,216	1,386
1990	71,711	29,834	10,964	6,341	3,135	1,298	1,578

SOURCE Sachverständigenrat für die Konzertierte Aktion im Gesundheitswesen (SVRKAIG), *Jahresgutachten* (Baden-Baden Nomos Vlg., 1992)

The Medical Market

To understand Germany's health care system and its financing problems, it is necessary to examine the German medical industry. With about 10 percent of worldwide sales, Germany is the third largest market for medical equipment after the United States and Japan, and the largest national market in Europe (table 5-4). In 1991, Biomedical Business International estimated medical equipment sales in Germany to be about US\$10.6 billion. A sales increase of 6 percent over the previous year was due to reunification and the investment needs of the former GDR.

Germany is also one of the most important producers of medical goods. It is difficult to find useful data on production and sales of medical equipment because the statistics in question are not sufficiently detailed (e.g., they do not discriminate between lasers used in industrial production and in medical care). Total sales of the German electromedical industry in 1991 amounted to 5,854 million DM. Some 3,226 million DM worth of products were exported and more than 25,000 people were engaged in the production of major electromedical devices. In addition to the big firms, mostly organized in the Central Association of Electromedical Industry (*Zentralverband der Elektromedizinischen Industrie, ZVEI*), a considerable number of smaller firms produce other medical devices, such as endoscopes, hemodialysis equipment, and surgical instruments.

In 1990, world sales in diagnostics—i.e., reagents and instrumentation—amounted to about

22 billion DM. The sales of the German diagnostics industry accounted for approximately 25 percent of this total. German firms had about 900 million DM worth of sales to the German market, earning another 1.9 billion DM through exports. German imports of diagnostics from abroad were approximately 1.75 billion DM (77). That year the German health care system consumed about 2.65 billion DM of diagnostics—more than 12 percent of worldwide production.

There are some striking aspects to Germany's consumption pattern. The most obvious is in dental equipment and supplies: Germany spends 4.4 times more money per capita than the United States, about US\$17.30, 15.4 percent of total consumption of medical devices and diagnostic products. The differences in per-capita expenditure for

TABLE 5-4: European Medical Equipment Market

Country	Projected 1991 sales (US\$ billions)	Change from 1990 (%)
Germany	10.6	+6
France	5.4	-1
United Kingdom	4.3	0
Italy	3.9	+1
Benelux	2.7	0
Scandinavia	2.3	0
Spain	2.1	-4
Others	2.7	-1
Total	34.0	

SOURCE Biomedical Business International Newsletter 14 : 51 1991

TABLE 5-5: Gross National Product and Sickness Funds' Budget

Year	Sickness Funds' budget		
	GNP b on DM	B on DM	GNP
1970	675.7	24.411	3.6
1972	824.6	35.461	4.3
1974	983.7	51.015	5.2
1976	1,123.8	65.517	5.8
1978	1,289.4	73.550	5.7
1980	1,477.4	88.424	6.0
1982	1,590.3	95.754	6.0
1984	1,763.3	06.427	6.0
1986	1,936.1	17.194	6.0
1988	2,108.0	31.735	6.2
1990	2,425.5	41.864	5.8

SOURCE: Sachverständigenrat die Konzertierte Aktion im Gesundheitswesen (SVRKAIG), *Jahresgutachten* (Baden-Baden Nomos Verlag, 1992)

x-ray apparatus and tubes are no less striking: Germany spends US\$12.90, less than Japan at US\$16.50, but well ahead of the United States and Canada, with US\$8.70 and US\$8.90, respectively. The United Kingdom, with US\$4.30 per capita, spends only one-third as much as Germany. These differences in consumption may reflect differences in the structure of health care delivery.

Finally, the German chemical industry is one of the world's most important producers of pharmaceuticals. With US\$4 billion, Germany was the world's leading exporter of pharmaceutical products in 1988. In 1992, about 1,100 firms in Germany with more than 117,000 employees produced pharmaceuticals valued at 31.16 billion DM. From this total, drugs valued at about 12.82 billion DM were exported.

In sum, production and consumption of medical devices and drugs are important economic factors in Germany, which must be taken into account when analyzing health policy or cost containment measures.

THE COST CONTAINMENT DEBATE

In 1989, total health care expenditure in Germany amounted to 8.2 percent of gross national product

(US\$1,232 per capita), placing Germany seventh place among OECD countries. The share of gross national product spent on health care has been almost stable since the middle of the 1970s (60). (See table 5-5.) Nevertheless, since the end of the 1960s German politicians have talked about the urgency of cost containment in view of a perceived "cost-explosion" in health care (see e.g., 66). This dramatic phrase refers to the mandatory sickness funds' expenses.

The sickness funds' budgets as a percentage of gross national product have remained relatively stable since 1976, between about 5.6 and 6.4 percent. An increase between 1970 and 1976 was caused primarily by new social laws that focused on the sickness funds' budget (e.g., the Hospital Financing Act of 1972). The political problem is caused not by the actual increase in sickness fund expenditures, but by the increase of the contribution rate as a percentage of income. Industry complains that the costs of social benefits for the German labor force are the highest in Europe. This may be true, but the rise in the contribution rate is due to a multitude of factors, only some of which can be traced to growing health care costs.

Modernization, rising health care expenditures, and even a slow and moderate increase in the contribution rates seemed politically tolerable as long as they coincided with a growing economy and full employment. But as the share of total wages relative to the gross national product diminished, the resulting rises in contribution rates became a central political issue. An all-embracing coalition of industry, unions, and political parties advocated limiting or stabilizing contribution rates.

The idea of easing the financial burden of social benefits by limiting the contribution rate was uttered first during a time of economic growth. In 1977, the Federal Minister of Labor and Social Affairs (a Social Democrat), called for the stabilization of contribution rates as part of a cost containment bill. He argued that even with a fixed contribution rate, revenues of mandatory sickness funds would rise in proportion to increases in wages. These annual rises in revenue would enable financing of investments in medical technol-

ogy as well as rising wages and incomes of health care personnel. This suggested rate stabilization was popular with conservative politicians as well, and it converged with the ideas of an influential group of economists who called for creating more market-oriented health care by privatizing some risks of illness. At the same time, a broad discussion began on the uneconomic structures of health care delivery and the oversupply of health services that caused a considerable amount of unnecessary care to be delivered. One implication of their discussion was that costs could be reduced without lowering quality or limiting accessibility.

The discussion of how to contain medical costs continued during the late 1970s and 1980s. Although there was unanimous agreement that contribution rates should be stabilized, the parties involved did not agree either on the measures to be taken or on the desired outcome. This was due in large part to the fact that the argument about the health care system providing unnecessary services encompassed two different criticisms. Some critics believe certain kinds of services should not be reimbursed at all by mandatory sickness funds, because they go beyond the role of social insurance. Others claim that the amount of diagnostic and therapeutic activities has expanded not for justifiable medical reasons, but to serve certain economic interests. Both of these issues needed to be addressed.

The political argument about the first issue is between those who want to reduce the catalogue of services covered by Social Security by eliminating some minor or traditional services, such as burial allowances or pharmaceuticals which are not proven to be therapeutically effective, and those who want to reduce social security to a level covering only "basic health care." Those who take the former position believe strongly that a social and democratic state should guarantee every citizen comprehensive health care according to his needs. The other opinion, enunciated by a prominent health politician, is that state-organized social security should be limited to those services that are unaffordable for middle class people, i.e., high-technology medicine for "severe diseases." In the case of hospitalization, patients should pay

a percentage on the level of hotel accommodation, so that they (if they cannot afford additional insurance premiums) will be encouraged to leave the hospital as soon as possible. Only pharmaceuticals "with strong and scientifically unquestioned effects, in particular those with vital indications" should be covered by mandatory sickness funds (2). The main idea behind such statements is that those services that have incremental effects (providing somewhat more care, etc.) and may be bought by those with more money or a higher level of additional insurance should be privatized.

Reducing the amount of medically unnecessary procedures is also controversial. While one side argues that the introduction of market structures and competition would be the only effective way to eliminate medically unnecessary procedures, the other side is convinced that the lack of consumer autonomy in health care requires strict regulation and administrative control instead of a reliance on market mechanisms.

The idea of basing more health care delivery on market forces has been stimulated by the American debate on "deregulation." The German discussion, however, has detached the idea of deregulation from its original context of eliminating monopolistic pricing by internal subsidy. German deregulators now want to eliminate all equalization of financial burdens hampering the establishment of market mechanisms. According to this view, the Association of Sickness Fund Doctors prevents price competition in outpatient care, and the mandatory sickness funds do the same through income-based contributions that limit the expansion of private insurance markets (30,76).

These and other viewpoints characterize the cost containment debate. For several years, budgeting or other economic restrictions seemed to be the only way to contain costs, but all the economic restrictions that have been attempted were effective only for a short time. In 1992, therefore, with the explicit agreement of the Social Democratic opposition, the government enacted a law that for the first time cautiously mandated a different tactic. The Health Care Act (*Gesundheitsstrukturgesetz, GSG*), which came into effect in 1993, does

contain rigorous budgeting measures, but most of them are explicitly provisional, put in place only for a few years until the intended structural changes become effective.

I Budgeting Measures in the 1993 Health Care Act

The budgeting measures in the 1993 Health Care Act are meant to be an “emergency brake” applied in the midst of economic recession and costly reconstruction of East Germany. An immediate and serious cut in health expenditure seemed inevitable to the coalition of Christian Democrats and Liberals as well as to the Social Democratic opposition. The legislature subsequently required that mandatory sickness funds’ expenses could not exceed actual receipts for three years. No matter what services were rendered or what drugs were prescribed, contribution rates had to remain unchanged. Up to the end of 1995, hospitals, which had been reimbursed for their actual costs will receive only a fixed annual budget, and they face the possibility that their costs will not be covered for the first time since 1972. The sickness funds doctors’ budget for the years 1993 to 1995 is limited to an increase of the revenue base of members of the mandatory sickness funds. Furthermore, the law requires that the amount of money available for prescription pharmaceuticals in 1993 will be no greater than 1991 expenditures.

The law includes strong incentives for office-based physicians not to exceed their budgets. If they do exceed it in one year, the total amount of physicians’ fees will be cut the next year. Doctors are not authorized to make patients bear the costs of drugs, however. If drugs are prescribed, the patient has the right to reimbursement by the mandatory sickness funds. Doctors are forced to reduce the number of prescriptions for “medically unnecessary drugs.” This regulation appears to have resulted in a substantial decrease of prescribed drugs. Finally, because pharmaceuticals in Germany are very expensive (60) compared to other European countries, manufacturers’ drug prices (except those drugs for which a reimbursement

rate had already been fixed) had to be lowered by five percent.

Interventions in Health Care Delivery Structure

The 1993 Health Care Act also makes some far-reaching changes in the traditional structures of health care delivery, affecting the roles of general practitioners (GPs) and specialists, the role of the hospital, hospital financing, and use of pharmaceuticals.

Germany’s traditional freedom of choice of doctor meant that people were free to consult any office-based physician, either GP or specialist. Specialists, most of whom have more sophisticated medical equipment, cost more than GPs. Experience has suggested that use of this equipment may be stimulated by economic motives. The last 20 years saw a continuous growth in the number of office-based specialists. While in 1970 about 25,000 GPs and 21,000 specialists offered outpatient care, the ratio was reversed by 1990: 30,000 GPs and 42,000 specialists.

The family doctor has lost much of his importance. Many experts agree that this has caused not only higher costs, but possibly lower quality of care. To remedy this situation, beginning in 1996, the law requires sickness fund patients to consult a general practitioner before they can be referred to a specialist. The GP will regain a central role as a gatekeeper, similar to his colleagues in the United Kingdom and the Netherlands. To support this policy change, the remuneration system will be modified; family doctors will receive a flat rate per patient and separate fees only in case of special services.

A longstanding problem in health policy has been the steadily growing number of office-based physicians (discussed earlier). Physicians have compensated for the resulting decline in the number of patients per physician by increasing the amount of service per patient. In response, the government decided to limit the number of physicians through the 1993 law. Beginning in 1999, the number of sickness fund doctors will be lim-

ited to a proportion of the number of insured individuals. The license to be a sickness fund doctor will be terminated when the doctor reaches age 65. This regulation will be paralleled by a reform of medical education aimed at reducing the number of medical students and improving the quality of the education itself. In 1989, the number of slots for medical students in West Germany was reduced from 11,600 to 9,300. A further reduction to about 8,000 in both parts of Germany is envisaged by the 1993 law.

The 1993 law authorizes hospitals to perform pre-admission testing for three days on an outpatient basis and to continue to treat a patient no longer confined to bed for up to seven days. Hospitals had asked for such authorizations for several years. Hospitals may also carry out certain surgical procedures on an outpatient basis. Patients will be able to choose whether to have these procedures at a hospital or at a physician's office (remuneration will be the same). While hospitals hesitated to approve this new regulation, mandatory sickness funds were enthusiastic with the idea of "fair competition" between office-based surgeons and hospitals in this field.

The most important component of the 1993 law is the change in the reimbursement of hospitals. A hospital's prime cost will no longer be reimbursed on the basis of per diem charges. For two years beginning in 1993, there will be a fixed budget for reimbursement of hospitals' prime costs that will rise only in proportion to the receipts of mandatory sickness funds. Beginning in 1996, a differentiated system of basic compensation, fixed prices for special services, and lump sums for the treatment of certain diseases will be enacted. The prices will be fixed and calculated by region; the particular circumstances of the individual hospital will no longer be considered. This regulation aims at rationalizing the working process of hospitals and ending outmoded and ineffective working structures. The idea is that more competition among service providers will ensure that money is spent more effectively.

On the pharmaceutical front, the government will establish an institute to develop a catalog of drugs that will be paid for by mandatory sickness

funds (*Positivliste*). The aim is to exclude from reimbursement those drugs that have no or very limited scientific support, drugs with ingredients not necessary for either therapy or the reduction of risks, drugs with so many components that their therapeutic effect cannot be accurately judged, and drugs that are used only in treating minor health troubles. The catalog will permit the comparison of pharmaceuticals with the same biochemically active substances and indications on the basis of costs per average daily dose so reimbursement amounts can be fixed. The catalog is to be published in 1996 and revised regularly.

CONTROLLING HEALTH CARE TECHNOLOGY

Technology Assessment

Until the end of the 1960s, German society believed strongly in technological progress as an essential basis of economic and social welfare. There was agreement on the need to close the technological gap with other industrial countries, particularly the United States. All political parties agreed that promoting technological research and development should be central task of government. This belief changed rapidly in the 1970s.

Certain consequences of new technologies became obvious and increasingly dominated public discussion: new technologies were jeopardizing job security; unforeseen stress factors inherent in new work environments promoted new health risks; and, perhaps most important, the ecological consequences of certain technologies became alarming. Such misgivings were voiced by new social movements, citizen committees, and unions. They initiated a wide range of technology assessment studies and claimed governmental subsidies for technology assessment research.

Since 1973, there has been an active discussion in Germany on whether technology assessment should be institutionalized in a way similar to the United States. Several declarations of intent have been published, and members of parliament and expert delegations from universities and research institutes repeatedly visited the U.S. Congressional Office of Technology Assessment (OTA).

But there was a growing gap between these intentions and the willingness to realize them. At the beginning of the 1970s, the Germans talked about establishing an advisory committee to parliament comparable to OTA in size and aims. In the following years, however, the tasks proposed for the new organization were continuously enlarged while the manpower and money envisaged were considerably diminished. So in 1978, some members of parliament proposed establishing a committee of five experts with an annual budget of 1 million DM, less than 0.015 percent of the federal government direct subsidies to the research and development of technology. A prominent social scientist remarked that the “discussion on technology assessment in German parliament tended to be more and more ridiculous” (21). Technology assessment was the hobby of a few members of parliament while the majority remained more or less disinterested.

In 1985, the federal parliament established an official inquiry commission that submitted its report in 1986. The commission agreed on the necessity of establishing technology assessment for advising parliament and proposed creating a commission with 15 permanent members and a budget of 10 million DM. The *Buro Technikfolgenabschätzung beim Deutschen Bundestag* was established in 1993 (after a three year probation period) with a budget of “at least 4 million DM” per year. It has initiated assessments of medical expert systems and the risks and benefits of genetic analysis in diagnostic testing.

In general, technology assessment is not afield of programmatic or systematic research in Germany. On the federal level, for example, the Department of Research and Technology has funded a clinical and economic evaluation of magnetic resonance imaging (MRI), an assessment of the introduction of mammographic screening, and an assessment of care for arthritic persons at home. But the Department concentrates its activities on promoting technology development—technology assessment remains marginal.

Another singular example is an inquiry commission on genetic technologies initiated by the federal parliament (23). Some federal states have

funded studies on special technology assessment questions, e.g., an assessment of gallstone lithotripsy (43). But compared to other countries, these remain minor activities. It is no surprise that the Swedish report on “Health Care Technology Assessment Programs” does not even mention Germany (74).

This neglect of technology assessment in health care stems from the fact that German health care delivery is organized on a corporate basis. Except for areas that are regulated by law, such as the premarket control of drugs or medical devices, technology assessment is primarily understood as a task for the organizations involved. But this corporate structure, with its carefully defined responsibilities and widely diverging interests, has hampered the establishment of technology assessment as an independent scientific pursuit.

Mandatory sickness funds are primarily financial institutions, with little interest in research questions, even those with practical consequences. For example, the decision regarding whether a new form of therapy in outpatient care should be paid for by mandatory sickness funds (e.g., acupuncture or MRI diagnostics) has been delegated to a commission of representatives of physicians’ associations and mandatory sickness funds (*Bundesausschub Ärzte und Krankenkassen*). That commission does not require cost-effectiveness analysis or other specific types of evaluation in making their decisions. If a diagnostic or therapeutic item has any proven benefit, mandatory sickness funds must pay for it, regardless of its cost. This may explain why mandatory sickness funds in general do not know how much they spend for a certain therapy.

Mandatory sickness funds’ associations on the state and the federal level are more interested in comprehensive health policy questions. But except for the Scientific Institute of the Federal Association of Local Sickness Funds, which has concentrated its recent research activity on the analysis of drug prescriptions (*Wissenschaftliches Institut der Ortskrankenkassen* (WIdO)), there is no assessment activity.

The association of sickness fund doctors representing office-based physicians are financing a

research institute on the federal level (*Zentralinstitut für die Kassenärztliche Versorgung in der Bundesrepublik Deutschland*) that is promoting quality research in ambulatory care. The chambers of physicians (representing all physicians) are promoting research on quality assurance in hospital care. But here too, technology assessment seems to be of no concern. It seems doubtful that systematic technology assessment will become a part of German health care anytime soon.

Drug Regulation

Pre-Market Approval

Drug production and marketing in Germany have been regulated by law since the end of the 1970s. Before that time, drugs only had to be registered before they could be marketed. The 1976 Drug Law (*Gesetz zur Neuordnung des Arzneimittelrechts*, AMG), in force since 1978, required the premarket testing and control of pharmaceutical safety and efficacy. The reasons for new regulation were threefold:

1. After 1968, the FRG had become the second biggest exporter of pharmaceuticals worldwide (14). The lack of premarket safety controls had begun to hamper exports more and more. Export-oriented firms were interested in developing regulations similar to those in other European countries.
2. Public discussion over drug safety had been spurred by the thalidomide affair and its long lasting legal ramifications. It was reinforced by another dangerous incident with an appetite depressant, which was removed from the market in 1968.
3. In 1969, the new coalition of Social Democrats and Liberals wanted to put in place anew health policy. The Social Democrats in particular saw the chance to enact a strict consumer-oriented drug law.

The first bill on drug safety proposed by the government provoked a fierce discussion. Its strict regulation of drug evaluation and safety was not acceptable to industry. After five years of debate, a law reflecting the pharmaceutical indus-

try's interests much more was enacted. The law had to resolve two problems: how to regulate the safety and efficacy of new drugs, and how to regulate some 140,000 drugs already on the market.

A mandatory licensing procedure was instituted for new drugs, requiring the manufacturer to document its quality (chemical composition), efficacy, and safety. Information from clinical trials that can be evaluated by the Federal Office of Health (*Bundesgesundheitsamt*) must be presented. If the Office of Health accepts the drug, its decision is reviewed by an expert commission of the Federal Department of Health. If the Department of Health also accepts the drug, a five-year license is granted. Licenses are renewed on request; in certain cases, renewal requires the manufacturer to prove that characteristics of the drug have not been changed. (Homeopathic drugs need only be registered, not licensed).

There have been two problems with the licensing procedures. First, clinical trials remain the sole responsibility of industry—the Federal Office of Health has no role. In the course of the parliamentary debates on the law, industry objected to the planned standards of efficacy that the government first proposed, arguing that these standards would prove so expensive that Germany would become less attractive to industry, innovation would be impeded, and smaller firms would be ruined. They then proposed less strict standards, which became part of the law. The law states that “lack of therapeutic efficacy is indicated only when there are no therapeutic results at all” (Art. 1 25 (2) Nr.4 AMG). Critics of this part of the law point out that it shifted the burden of proof to the Federal Office of Health, which must prove the *inefficacy* of a drug. In addition, the government may not insist on double-blind clinical trials, even in the case of new ingredients (56).

Second, post-market control by the Federal Office of Health is weak because of work overload, faulty organization, lack of expertise, and a lack of political support in the face of industry pressure against gathering this information (38). The Drug Law itself leaves key judgments to industry and medical professionals—industry is obliged only to report “hitherto unknown” or “severe” adverse

drug reactions. Unlike in other European countries, such as the United Kingdom, physicians and other medical professionals in Germany are not obliged to report adverse drug reactions or side effects. As a result, they report these events infrequently (38).

About 12,000 new drugs were licensed between 1978 and 1993. The problem of how to proceed with the 140,000 drugs already on the German market in 1978, however, proved virtually insoluble. Effective control of safety and efficacy would have required not only an immense staff of trained personnel but also a considerable amount of money. So the federal legislature passed an interim regulation: drugs registered before 1978 could be marketed for 12 years during which a medical expert committee of the Federal Department of Health was charged with gathering information on these drugs in order to prepare a simplified licensing procedure. At the beginning of 1993, when the interim regulation and a three-year extension had expired, about 45,000 “old” drugs remained in the licensing procedure. This included 9,000 homeopathic drugs, which need to be registered, and about 5,000 drugs from the former GDR (28). About 70,000 drugs disappeared from the market, mostly because the producer did not ask for approval.

Regulation of Drug Prices and Consumption

Unlike most other European countries, in Germany there is practically no regulation of producer prices for pharmaceuticals. But the profit margin in the retail drug business is set by the Federal Department of Economy. As a result, all drugs sold only by pharmacists (and these alone are paid for by mandatory sickness funds) have standardized prices. German pharmacies have traditionally shunned competition.

With no way to regulate prices or control the quantity of prescriptions written for patients, pharmaceuticals are very expensive in Germany. Mandatory sickness funds cannot negotiate prices and neither physicians nor patients have an interest in doing so. Price competition has become somewhat more important only since the early

1980s, as the patents for many drugs expired and generics came on the market. In 1988, about 20 percent of all prescribed drugs were generics (13). The first attempt to introduce indirect price regulation took place in 1988 (35 SGB V) when a law was passed decreeing that a fixed reimbursement for certain drugs should be determined by the government. The law’s intent was to standardize and reduce the amount of reimbursement for certain drugs that had the same or similar biochemically active substances. Industry could still choose to set a price for its product above the federally set reimbursement, but if a patient chose to buy the more expensive drug, he would have to pay the difference between the manufacturer’s price and the reimbursement amount.

In 1989, a fixed amount of reimbursement was determined for the first 10 biochemically active substances, covering about 1,400 drugs. Most manufacturers reacted with considerable price cuts, as most of those insured were not willing to pay more simply for a name brand drug product. Manufacturers who did not reduce their prices bore a substantial decrease in sales (13). By the beginning of 1991, the reimbursement level had been fixed for about 6,400 drugs. The success of this price-setting measure in lowering drug costs is not possible to determine because the prices of most unregulated drugs increased as the measure was implemented.

Since 1981, the consumption of prescribed drugs has been analyzed annually by the *Arznei-erordnungsreport*, a joint research project of mandatory sickness funds, doctors, and pharmacists. It offers comprehensive information on sales and the prescription habits of doctors and covers about 2,000 drugs, roughly 90 percent of all prescriptions.

Medical Device Regulation

Except for technical safety regulations, which were instituted in 1986, there are no restrictions on the marketing of medical devices. A series of radiotherapy accidents caused by technical defects in the late 1970s is what prompted parliament to discuss extending laws on workers’ protection

and the safety of machines to cover medical equipment. The ruling coalition, however, could not reach consensus on how to proceed, and safety regulations did not appear until 1985. The *Medizingerateverordnung* states that every new type of medical equipment needs to be licensed. The license is to protect users and patients from safety hazards, but is not meant to ensure medical efficacy. Industry may ask government to conduct clinical trials with a prototype before granting a license.

REGULATION OF PLACEMENT OF SERVICES AND QUALITY ASSURANCE

German policy regarding the distribution of expensive, cutting-edge equipment can best be understood against the background of the rigorous institutional separation of ambulatory and inpatient care in the German health care system. This characteristic feature means that ambulatory care is virtually the monopoly of office-based physicians and that hospitals—apart from training medical students—are prohibited from offering outpatient care even when the patient has previously been hospitalized. The institutional separation of the two sectors was made law through an emergency decree enacted by Chancellor Bruning in 1932, passed after a long, fierce debate between hospitals and office-based physicians.

What would seem to be a reasonable idea—treating patients in an ambulatory manner whenever possible and confining them to bed only when unavoidable—has become an arena for competition between the two sectors in which equipment plays a major role. In contrast to the United Kingdom and other countries, both GPs and specialists work as office-based practitioners without any hospital privileges. About 60 percent of all specialists are office-based, and less than 8 percent of them (the *Belegärzte*) are allowed to treat patients in hospitals.

The amount of inpatient care is determined to a large degree by the technological equipment that the outpatient sector has, especially diagnostic equipment. Hospitals, of course, have the whole range of medical technology, but hospital special-

ists are allowed to treat outpatients only when there are not enough office-based specialists. For example, if there are not enough CT scanners installed in physicians' offices, a hospital radiologist may obtain authorization to perform ambulatory CT scanning. This authorization is given or refused by the Association of the Sickness Fund Doctors and can be canceled at any time.

Since the 1932 decree (confirmed by legislation in 1934 and 1955), the lack of integration between private practice and hospital medicine has been criticized for lowering the quality of the German health care system while raising its costs. But until the 1993 Health Care Act, all attempts to open the hospitals for outpatient care and to allow the use of hospital equipment for office-based physicians had failed (34,46). Since most hospitals are public or nonprofit organizations, office-based physicians had argued that opening these institutions for ambulatory care would be a step towards the socialization of care or even, in a more ideological formulation, the first step towards socialism.

(The former GDR had integrated outpatient and inpatient care by establishing clinics and ambulatory services in close cooperation with hospitals. However, the Socialist government had eliminated nearly all private office-based medical services. After reunification, most of the clinics and outpatient services were closed, and the formerly salaried physicians are now working as private practitioners. Some health policy analysts question whether this was a wise solution.)

The Debate On Regulating the Proliferation of Expensive Equipment

The amount, nature, and placement of acute care inpatient services are defined by the 1972 hospital plan of the states. The plan gives the states responsibility for providing a sufficient supply of inpatient care facilities. Therefore, they must develop and execute an annual regional plan. All hospitals designated as "necessary" in this plan (including private hospitals) are entitled to an annual budget allocation from the states for investments. (Except for some special hospitals, such as army and uni-

versity hospitals, the federal government has no role in hospital financing.) Mandatory sickness funds reimburse the operating costs. Sometimes the states delay their grants because of scarce funds, which leads to lobbying and public pressure by various interested parties.

Because high-technology equipment, especially for diagnosis, can be used in both inpatient and outpatient settings, regulating only equipment for the inpatient sector is ineffective at controlling the supply. Despite legally fixed prices for equipment, the prohibition of advertising, and other restrictions, a sole-practitioner physician is engaged in private enterprise. While hospitals often wait for the approval and purchase of costly equipment, office-based physicians had been free to make their own investment decisions. Both the Physicians' Associations and the Hospital Societies pointed out that in times of cost containment it was obviously not rational to procure the same equipment twice. But they could not agree on how to share equipment or how to coordinate investments. Some states and especially the mandatory sickness funds wanted to end duplication, but they had no legal basis for interfering with private investment. Federal regulation was not only politically controversial but constitutionally delicate when it intervened with private investment.

In 1983, alarmed by the rapid diffusion of CT scanners and the introduction of MRI, the Social Democratic government of Hessen proposed a bill in the *Bundesrat*. According to this bill the diffusion of costly equipment in the outpatient sector would be regulated by planning the supply and harmonizing it with the hospital plans of the *Länder*. This initiative and a modified one of the Christian-Democratic government of Baden-Württemberg provoked a three-year discussion and very strong rejection of the idea by the physicians and their associations—in their view this was the first step to a “socialist planning economy.” The government was obviously interested in finding a way to regulate the diffusion of costly technology, but at the same time it hesitated to intervene in decisions of private enterprise.

Surprisingly, three years later the Federal Association of Sickness Fund Doctors took the

initiative and proposed a measure based on self-regulation. The Association proposed that Regional Associations of Sickness Fund Doctors and Regional Associations of Mandatory Sickness Funds should set out an annual plan detailing how much expensive equipment in outpatient care was needed. This plan would be binding for all sickness fund doctors. The sickness funds would not reimburse any spending on equipment that exceeded the limits set in the plan. In March 1986, this decree came into force.

Why this sudden willingness on the part of the Physicians Associations to cooperate? There seem to have been two reasons. First, the differences in income among various office-based physicians are extraordinary. This was not really a problem, as long as the total payment the Mandatory Sickness Funds provided to all physicians was growing rapidly. Even the rapid growth of income realized by the small group of radiologists operating CT and MRI or by cardiologists with catheterization labs was not seriously discussed. But in the 1980s, the government not only stressed the need to stabilize the contribution rates for the sickness funds, but also decreed that the total remuneration for all physicians would not grow faster than the total revenue of the mandatory sickness funds. The conflict between the small group of high-income doctors and those whose income was stagnating increased. The second reason seemed to be the rapidly growing number of office-based physicians. The more physicians who had to share a stagnating budget, the less income each could expect. By limiting the numbers of costly machines, the Physicians Association hoped to reduce potential conflicts.

This decree, however, was effective for only about three years. Some physicians who had purchased medical equipment without the permission of the Association of Sickness Fund Doctors, and therefore did not get any reimbursement, went to court. In October 1990, the Federal Social Court decided that the decree was a severe limitation on the constitutionally guaranteed freedom of pursuit of profession which should not be based on an agreement between two self-administered associations, but on a law that can be interpreted by the

Federal Constitutional Court. The Court's decision made the decree unlawful.

The 1993 Health Care Act seems to have solved the problem. Each state now has to form a commission composed of representatives of hospitals, sickness fund doctors, mandatory sickness funds, and state government. The commissions are legally authorized to decide how much costly high-level technology is necessary and where the devices should be located, whether in a hospital or in a physician's office. If the members of the commission do not agree, the state administration must decide (§ 122 (revised version) SGB V). It is too early to judge whether this regulation will remain in force.

Quality Assurance

At present, quality assurance has almost no place in German health care except for the laws concerning medical equipment and pharmaceutical products (discussed earlier), and some regulations and guidelines concerning structural measures (60).¹

Regulation of medical education is a federal task. Once licensed, physicians' postgraduate education is assigned to the General Medical Councils. In 1990, the German *Arztetag*, the parliament of the medical profession, confirmed anew its unwillingness to accept government quality assurance of postgraduate training. No recertification for specialists or updating of knowledge is required in Germany.

The Board of Experts for the Concerted Action in Health Care (SVRKAiG) has repeatedly called for better information concerning the real quality of physicians' work, saying it is the highest priority for assuring quality in German health care (60). In a 1989 report, the Board criticized the lack of

means to assure quality in the processes and results of medical treatment, especially in hospitals. It also produced a catalog of desired reforms (60).

Some quality assurance activities do exist for hospitals. Since 1976, a program has been developed for some special problems in general surgery (63,64) and perinatology; and since 1987, the Federal Ministry of Research and Technology has been financing a study of quality assurance in cardiac surgery (discussed later). But these initiatives remained optional for the clinics, and their consequences have never been analyzed.

In 1989, a requirement for the systematic quality assurance of inpatient care was established by law (§137 SGB V). Hospitals now have to participate in quality assurance measures related to treatment processes and the results of care. Treatment procedures must be standardized to enable quality control. According to the law, state associations of the mandatory sickness funds and the regional hospital societies are supposed to agree on how to standardize treatment. But the societies concerned have so far only agreed on which activities need quality standards. The divergent interests of the parties involved has prohibited the consensus necessary to make further decisions. Physicians say they fear the end of the anonymity of data and the possibility of lawsuits in cases of treatment failure (8).²

Physicians are interested in better outcomes, but in general they are not convinced that quality assurance measures will help. They also do not favor public discussion of the results of a quality evaluation. Hospitals fear a one-sided emphasis on economy by the sickness funds. Because any advertisements concerning the quality of care are strictly prohibited, hospitals do not understand

¹These include controls on the quality of laboratory performance in outpatient care (II) and on technical requirements and standards regarding the use of x-rays.

²This seems to be a spurious argument because quality assurance is not judged on the basis of individual patients' results. Furthermore, data protection and the right of control of the individual's records are well determined by German law. In particular, the anonymity of patients' treatment data is assured: nobody may look into hospital records except the treating physician. Research using hospital records requires the explicit consent of each individual patient and the treating physician. A study on quality assurance in American and German hospitals points out that comparable restrictions do not exist in the United States (26).

what they could gain by cooperating. While they recommend the implementation of quality assurance measures, they want the results communicated only to the senior physician and the hospital owner (*Deutsche Krankenhausgesellschaft*). The mandatory sickness funds, however, have to pay for these quality assurance measures, so they are quite interested in the results. In their view, economy and quality are two sides of the same coin. They want information. One cannot accurately

predict whether there will be agreement on this subject in the near future.

The discussion of quality assurance remains largely limited to a few experts in Germany. There are no consumer organizations able to bring this problem into the political debate, and the media discuss little more than malpractice problems. Nevertheless, with the 1993 Health Care Act, quality assurance has become critically important.

Case studies

TREATMENTS FOR CORONARY ARTERY DISEASE

In 1985, there were 70 catheterization laboratories for adults and 15 for children in Germany. Although they had no waiting lists, they regularly reported that the pressure of patients seeking treatment urged some laboratories to do more diagnostic procedures per year than were medically justifiable (31). Although data to support this are scant, it appears that the need for Coronary Artery Bypass Grafting (CABG) in the mid-1980s was twice as high as the number of procedures performed. At that time, medical journals and other news media reported stories of patients who were forced to seek an operation elsewhere, especially in the United States (1,41).

The number of catheterization labs is determined by the state hospital plans. Of the 222 catheterization labs installed in West Germany in 1991, 211 were operated by hospitals. The number of diagnostic and therapeutic facilities has grown rapidly since 1986. The current capacity for percutaneous transluminal coronary angioplasty (PTCA) now seems to be sufficient. Nevertheless, cardiologists claimed that the high incidence of coronary artery disease necessitates adding more facilities (31).

(See table 5-6 for trends in the use of CABG and PTCA.)

For both diagnostic cardiac catheterization and PTCA, some sites are much busier than others. In 1990, nearly half of the diagnostic procedures were performed in about one-quarter of the clinics, and about 20 percent of the laboratories carried out less than 500 catheterizations per year. The figures for PTCA are similar.

Apparently, the site of diagnosis can influence whether a patient eventually gets CABG or PTCA. Patients diagnosed in centers without PTCA equipment are more likely to get CABG than PTCA as a therapeutic intervention, while patients diagnosed at centers with PTCA equipment have an equal likelihood of being referred for CABG and PTCA.

Percutaneous balloon valvuloplasty was introduced in 1986. Between September 1986 and July 1988, the university clinic GroLBadern (Munich) performed aortic valvuloplasty on 110 patients (25). In 1990, 473 valvuloplastic interventions were performed within the FRG (32). In general, this method does not seem to be in widespread use.

TABLE 5-6: Frequency of CABG and PTCA

	1978	1980	1982	1984	1986	1988	1990	1991a
CABG	3,042	4,887	7,287	10,458	17,489	21,363	26,137	31,338
PTCA	200	500	1,387	2,809	7,999	16,923	32,459	44,050

^a1991 data include the former GDR

KEY CABG = coronary artery bypass grafting, PTCA = percutaneous transluminal coronary angioplasty

SOURCES E Bruckenberger, Dauerpatient Krankenhaus—Diagnosen und Heilungsansätze (Frelburg Lambertus Vlg, 1989), U Gleichmann, H Mannemach, and P Lichtlen, "Bericht über Struktur und Leistungszahlen der Herzkatheterlabors in der Bundesrepublik Deutschland," *Zeitschrift für Kardiologie* 82:46-50, 1993, E Bruckenberger, Bericht des Krankenhauschusses der Arbeitsgemeinschaft der Leitenden Medizinal beamten (AGLMB) zur Situation der Herzchirurgie in Deutschland (Hannover: Niedersächsisches Sozialministerium, 1992)

Cardiac surgery is one of the areas where quality assurance has gained some importance. In 1984, the German Society for Thoracic and Cardiovascular Surgery began to investigate quality assurance in this field. The aim was to develop guidelines that could help control quality within cardiovascular surgery facilities (73). Interested clinicians in eight facilities discussed and agreed on a catalog of measurable, quality-relevant items. More than 480 of these variables describing preoperative, intraoperative, and postoperative situations should allow a self-evaluation by the hospital as well as external comparisons for quality control. Variables concerning the treatment process included loss of drainage blood, new postoperative arrhythmias, number of days of intensive care, number of infections, etc. On the basis of the data collected within the first three years, the commission defined quality standards. One recent report said, "The comparison of characteristics in one's own hospital at various times and above all with the broad-based multicentric item can disclose conspicuous features to such an extent that they give rise to interventions demanded by quality assurance" (73). Organizing an active follow-up to the development of these standards seems to be an important and unsolved problem.

MEDICAL IMAGING (CT AND MRI)

As in other countries, CT and MRI have become prominent in Germany, but traditional x-ray imaging and sonography have maintained a higher rate of use than in most other countries. In 1990, the more than 50,000 x-ray machines in West Germa-

ny were used for 88.2 million examinations—more than 1.4 per inhabitant in that year. More than half of these examinations were of the thorax, at least partly explainable by the traditional fear of tuberculosis.

Computed Tomography (CT)

Compared to most other countries, German health authorities and sickness funds were caught unawares by the rapid proliferation of CT scanners during the 1970s. The diagnostic capacity of the new technology was evident, but at first it seemed to apply only to neurological problems. Nevertheless, by 1979, 68 cranial CTS were operating in Germany, a ratio of 1:900,000 inhabitants. The first body scanner was installed early in 1976 by the German Center for Cancer Research (Heidelberg), apparently the first one in Europe (27). Ninety percent of the investment cost (1.8 million DM) was financed by the Federal Ministry of Research and Technology, the remainder by the *Land Baden-Wurtemberg*. The number of body scanners increased even more rapidly than the head scanners (see table 5-7). Most devices are in the big cities (Hamburg, Bremen, Munchen, Koln, etc. (33)), though surprisingly, not in West Berlin, and most are in the largest hospitals and in the offices of radiologists and neurologists (see table 5-8).

In 1977, prices of cranial CT scanners ranged from 800,000 to 1.5 million DM and that of body-scanners from 1.8 to 2.3 million DM. At that time mandatory sickness funds paid 300 to 415 DM for a cranial scan, depending on the specifics of the

TABLE 5-7: CT Scanners in the FRG (1979)

Region	Cranial CT	Whole body CT	CT per million population
Schleswig-Holstein	4	3	2.71
Hamburg	3	12	8.89
Bremen	3		4.24
Niedersachsen	9	11	2.78
Berlin (West)	2	2	2.06
Hessen	3	5	1.44
Nordrhein-Westfalen	23	27	2.93
Rheinland-Pfalz		3	1.10
Saarland		1	0.92
Baden-Wuerttemberg	9	9	1.98
Bayern	11	9	1.85
Total	68	82	2.44

SOURCE. W Pietzsch, and G Hinz, "Erhebungen zur Durchfuehrung der Computertomographie," *Strahlenschutz in Forschung und Praxis* 20152-157, 1980

examination. This sum covered material, depreciation costs, and physicians' fees. Three years later, in 1980, reimbursement for a cranial tomography had fallen to 250 to 271 DM and a body-CT examination was reimbursed 300 to 434 DM (66). In spite of inflation, this amount has remained nearly unchanged for more than 10 years.

The proliferation of new costly technology had especially alarmed the states, which were confronted with demands from the hospitals for funds to invest in new machines. The states passed laws aimed at establishing a certificate-of-need system (16). They organized several conferences and discussions, but the states had as much trouble dealing with this new technology as other countries did. They defined the "necessary" number of examinations and devices arbitrarily. Rather than define the problem as a political one, politicians demanded "objective" measures of need. But using epidemiological data to find a criterion to limit the number of "necessary diagnostic examinations" (3,35) did not lead to a solution. There have, of course, been studies defining appropriate indications for CT scanning, but these studies are not suitable for determining the number of devices needed. Consequently, there has been no realistic effort to discuss the cost-effectiveness of CT scan-

ning in the health care system and no systematic assessment of the new technology.

One attempt to regulate the quantity of CT examinations is worth reporting. As mentioned earlier, the Associations of Sickness Fund Doctors was interested in limiting the continuous rise of costly radiological examinations. In 1986, some of these associations informed their members that for each referral to CT (and MRI) diagnostics they would have to document the diagnosis and the foregoing examinations and findings. The goal was to help improve the quality of diagnosis. But at the same time, the associations made explicit the fact that, in view of the limited budget for sickness funds doctors, unnecessary examinations would reduce the income of all office-based physicians (41,44).

Between 1982 and 1986, the number of CT examinations increased by about the same percentage in both the North Rhine and Westphalia regions. (See figure 5-1.) After Westphalia required the documentation of referrals for CT diagnostics, there was a significant change in the two regions' patterns. While in North Rhine the number of referrals rose by about 22,000, it leveled off in Westphalia. In 1987, the rule continued to be

TABLE 5-8: CT Scanners in the FRG (1978)

Hospitals and physicians	Number of hospitals/offices	Number of CTS (installed or on order)
Acute care hospitals		
<300 beds	1,900	2
300-600 beds	410	20
600-800 beds	65	10
> 800 beds	75	50
Long-term care hospitals	1,250	30
Office based physicians (radiologists/neurologists)	2,400	48
		Total 160

SOURCE G Rau, "Aktuelle Versorgungslage," *Wirtschaftliche Aspekte der Computerfotographie/CT-Symposium* am 11-12 January 1979 an der Deutschen Klinik für Diagnostik, Hessisches Sozialministerium (Wiesbaden) and Bundesministerium für Arbeit und Sozialordnung (Bonn) (eds) (Münster, 1979)

effective in Westphalia, but the number of examinations in North Rhine rose again. By 1988, the obligation to document CT examinations seems to have become a bureaucratic routine in Westphalia—the number jumps and continues a “normal” increase in the following years. It is important to mention that the doctors’ association only asked for a detailed report and not for a decrease in the number of examinations. One might reasonably conclude, however, that at least for two years some unnecessary examinations were avoided.

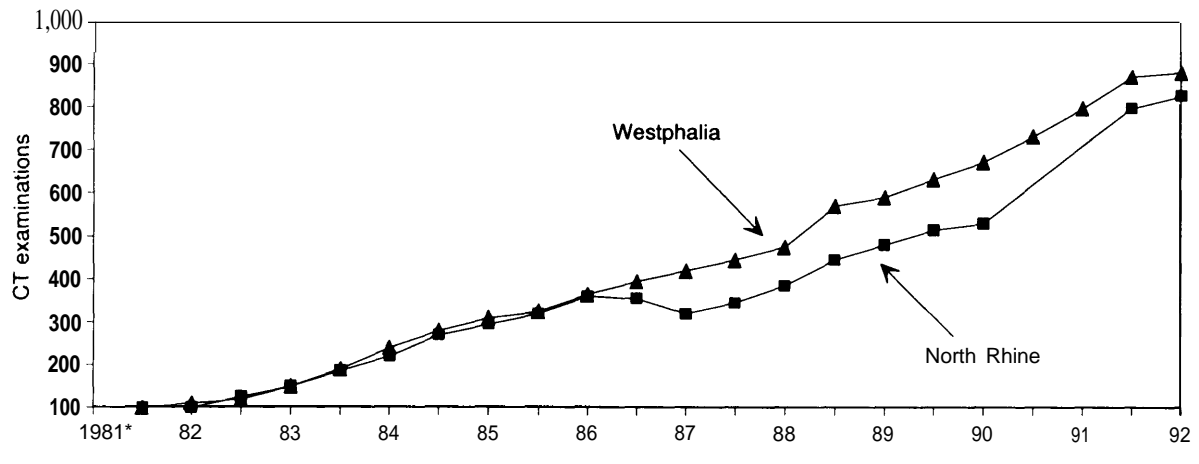
Magnetic Resonance Imaging (MRI)

MRI diffused somewhat more slowly than did CT, which may be due to its diagnostic value not being as clear as that of the well-known x-ray technology. It is difficult to determine the exact number of MRI scanners in operation at a particular time, however. State ministries and mandatory sickness funds have published discrepant data on this point. There are no records of when a machine is retired from service and data published by the industry do not discriminate between ordered and installed devices. Nevertheless, table 5-9 provides an approximate overview of the trends. Nine years after the installation of the first CT there was already one machine for every 189,000 inhabitants; in the case of MRI, the ratio was 1:357,000.

In 1986, four years after installation of the first MRI, 46 MRI scanners were in operation, more than half run by office-based radiologists. This is surprising because office-based radiologists depend on patient referrals from other physicians. In addition, mandatory sickness funds approved reimbursements for MRI diagnostics only in cases of suspected brain tumor, multiple sclerosis, epilepsy, and tumor in the spinal cord, or syringomyelia—a very small list of conditions. With a reimbursement of only 470 to 536 DM per examination, physicians could not possibly recover their investment costs. Obviously, other incentives existed to encourage investment in this prestigious new technology (48). Hospitals, on the other hand, have not been confronted with the problem of profitability. As already mentioned, hospitals’ investment costs are paid by the state, and operating costs are paid by the sickness funds as part of the per diem charges. The Board of Experts for the Concerted Action in Health Care stated in its 1991 report that oversupply was causing MRI devices in Germany to be used below capacity (60).

Because of the anticipated benefits to diagnosis, the Federal Ministry of Research and Technology has financed several medical and technical research projects on MRI since 1978 (12,17,20). In particular, it supported a multicenter study from

FIGURE 5-1: CT Examinations in North Rhine and Westphalia



*First six months in 1981 *100

SOURCE S Kirchberger, "Überlegungen zu Diffusion und Nutzung der Computertomographie in Nordrhein Westfalen," *Medizin Mensch Gesellschaft* 14:87-95, 1994

1987 to 1989 to evaluate the clinical and economic benefits of this technology (18,19). This document remains the only example of a systematic technology assessment in Germany.

The MRI study consists of three parts:

1. An evaluation of MRI as a clinical procedure, analyzing the whole technical range of devices in operation in Germany (0.15- 1.5 tesla) and the different institutional settings (university hospital, general hospital, office-based radiologist).
2. An analysis of the economic aspects of running an MRI within an individual enterprise.
3. An examination of the effects of MRI diagnosis on health outcomes to determine some of the overall costs and benefits to the health care system.

The empirical base for this research consisted of the records of 21,000 MRI examinations and much operational data (including personnel involved, transportation costs, time management, etc.) from 25 different institutions. In addition, the Federal Ministry did a controlled study of the neurological use of MRI by arranging follow-up examinations of 900 patients one year after their initial diagnosis.

LAPAROSCOPIC SURGERY

Laparoscopic surgery is among the procedures that make up minimally invasive surgery (MIS), which includes: endoscopic papillotomy, percutaneous nephrolithotomy, laparoscopic treatment of ectopic pregnancy or endometriosis and removal of ovarian cysts, arthroscopic meniscectomy, laparoscopic appendectomy, colecystectomy, etc. All have been performed in Germany for several years.

In 1973, two internists at Munich University Hospital introduced the endoscopic removal of bile duct stones in Germany. Percutaneous nephrolithotomy was first practiced at the University of Mainz in the early 1980s. A gynecologist at the University Clinic of Kiel has treated tubal pregnancy and ovarian cysts by endoscope since 1970; in 1982, he carried out the first laparoscopic appendectomy. A practitioner in Boblingen published a record of his first experience with laparoscopic cholecystectomy in 1986 (50). In 1991, he reported on a follow-up study on his first 94 patients, treated between September 1985 and March 1987, and compared the outcome with 136 patients treated with conventional surgery within the same period (51).

TABLE 5-9: CT and MRI Installations in Germany by Site^a

Year	CT		MRI	
	Medical office	Hospital	Medical Office	Hospital
1974	—	3 ^b	—	—
1975	3 ^b	15 ^b	—	—
1976	10 ^b	30 ^b	—	—
1977	20 ^b	60 ^b	—	—
1978	30 ^b	80 ^b	—	—
1979	40 ^b	110 ^b	—	—
1980	50 ^b	140 ^b	—	—
1981	65 ^b	180 ^b	—	—
1982	85	232	—	—
1983	115	250	4	4
1984	140	270	13	8
1985	195	310	21	14
1986	220	315	26	20
1987	235	320	27	29
1988	253	352	34	34
1989	280	370	45	48
1990	334	457	62	58
1991	427	499	112	56
1993	455	590	171	125

^aThe table shows the number of devices sold. Since some are replacements the number of devices in operation is somewhat lower.
^bInstallations for 1974-1981 are extrapolated from 1982-status in line with CT-market growth Worldwide.

SOURCES: Siemens, personal communication, 1994; E Bruckenberger, personal communication, 1994.

Unlike the diffusion of certain expensive technologies, the spread of new procedures with low costs and routine outcomes is difficult to document in Germany because such procedures require no special reimbursement or licensing regulations. Nevertheless, endoscopic therapy seems to have had a considerable impact on German health care.

Used primarily by internists or other specialists equally familiar with diagnostic endoscopy, MIS has given rise to a struggle between different medical disciplines. Surgeons interested in endoscopic therapy were often opposed by their surgical colleagues. Until the end of the 1980s, most surgeons rejected the new methods and condemned them as risky and even unethical (42). The long-lasting hostility of the majority of surgeons is understandable in view of the fact that the new

methods not only required new skills but also made familiar manual and tactile abilities superfluous.

Hesitation in adopting the new methods seemed all the more appropriate because per diem charges provided no economic incentive for changing conventional practice, although in some cases, especially at university hospitals, there was pressure from patients who demanded the endoscopic procedure (42). When surgeons became aware that more and more MIS procedures were going to be performed by physicians in other disciplines, their opinions began to change. (With about 70,000 operations per year, cholecystectomy is one of the most frequently performed procedures in the FRG. Together with appendectomy and inguinal hernia, it accounts for nearly 50 percent of all general surgery cases.)

In 1991, one of the main themes of the 108th Congress of the German Society of Surgery was “gentle surgery,” a subject the President of the Congress characterized as “somewhat fashionable.” At a 1992 meeting on minimally invasive surgery, it was claimed endoscopic surgery was a genuine activity of surgeons “because only a surgeon will be able to skillfully control all possible complications” (78).

The competition between surgeons and other medical specialists is obvious, as is the lack of communication between them. For example, the Department for Internal Medicine in a university hospital with more than 1,000 beds had been practicing endoscopic papillotomy for several years when it was astonished to learn that the surgical department was also performing the same procedure.

The standards of postgraduate training, especially in the case of a new technology, take time to define. In the case of endoscopic procedures, surgeons and internists have to reach a consensus on the training necessary. Because endoscopic instruments and even the necessary imaging technology are generally affordable for most hospitals, there are no financial barriers limiting their proliferation. Many training centers now provide workshops on MIS, but demand still seems much higher than supply. The media recently began to report not only on the advantages of MIS, but also on its risks and failures. After performing about 100 endoscopic appendectomies, a hospital in North Rhine-Westphalia abandoned the method and returned to conventional surgery because the outcomes seemed better with the older method (78).

Along with training, the frequency of use of endoscopic therapy is an important indicator of quality. Physicians trained to perform percutaneous nephrolithotomy (PCN), for example, must practice it routinely in order to retain their proficiency. Because the technology associated with PCN is less expensive than that for lithotripsy, the use of PCN as a surgical treatment has spread rapidly. In 1987, 85 of 112 urological departments in North Rhine-Westphalia were using it. But because so many centers now offer the treatment, the number of procedures per hospital has diminished. This

development suggests that to promote quality, centralizing certain services will be necessary. But at present, neither political nor economic means exist to cause such a change. Beginning in 1995, other modalities of hospital financing together with quality assurance measures might eliminate some redundancies in the system.

TREATMENTS FOR END-STAGE RENAL DISEASE (ESRD)

Until the late 1960s, only a few hospitals in Germany offered renal dialysis. Although the number of patients with renal failure was rising by more than 2,000 every year (30 to 40 per million inhabitants), only 745 patients received this lifesaving treatment in 1970. Ten years later the federal parliament stated that the network of dialysis facilities in Germany was sufficient to treat everybody in need.

Faced with the poor supply of dialysis facilities in hospitals, Klaus Ketzler, an economist, decided in 1969 to establish a nonprofit organization, the *Kuratorium für Heimdialyse* (KfH), the purpose of which was to improve the care of patients with renal failure. The rapid spread of home dialysis and dialysis in hospital-associated centers in Germany is largely due to the initiative of the KfH.

In September 1970, the mandatory sickness funds, which until then had reimbursed dialysis treatment only in hospitals, were confronted with a patient claim for compensation for the cost of a home dialysis machine. The Court of Social Affairs in Berlin found that the mandatory sickness funds had to pay because the scarcity of dialysis machines in hospitals allowed only two dialysis sessions per week, which was insufficient. The Court argued that:

... since technical progress has brought about a situation where the physician is substituted for by technical equipment, a new interpretation of the existing code is required ... care does not solely mean physician's treatment and nursing ... but also the availability of an apparatus that partially substitutes for a physician's activity (71).

In other words, dialysis was no longer bound to hospitals.

Furthermore, the court decision made it possible to purchase the machines at the expense of mandatory sickness funds. The KfH began to organize an infrastructure of independent centers for dialysis. Soon afterward, other nonprofit organizations were founded for the same purpose. Today, the *Patinten- Heimversorgung (PHV)* and the *Dialyse Trainingszentren (DTZ)*, nonprofit organizations founded by firms engaged in the dialysis market together with the KfH treat about 50 percent of all dialysis patients in more than 200 centers. About 250 office-based physicians care for about 30 percent of the ESRD patients. Only about 5 percent of patients receive home dialysis.

In 1992, the mandatory sickness funds in Western Germany had to pay more than 1.7 billion DM (about 50,000 DM per patient/per year) for equipment and other costs of dialysis treatment, not including physicians' fees, travel expenses for the patients, additional pharmaceuticals, and hospital treatment, which amount to 170 to 200 million DM. Germany is by far the biggest market for dialysis products in Europe with about 24.6 percent of the total, followed by Italy with 16.8 percent and France with 14.3 percent.

The spread of dialysis has been accompanied by much discussion of its costs. In 1984, a report prepared on behalf of the Federal Department of Labor and Social Affairs discussed cost-saving possibilities (29). Cost-saving was taken up again by the Board of Experts of the Concerted Action in Health Care. In its 1988 report, it cast doubt on the way hospitals calculated the special per diem charges for dialysis and raised questions about the considerable variations in cost from hospital to hospital. In 1987, the cost of hospital dialysis ranged from 408 to 694 DM, depending on the region and hospital (60). The Board criticized the dwindling number of patients on home dialysis and the under-utilization of continuous ambulatory peritoneal dialysis (CAPD), the least expensive treatment method (60). The most recent discussion of the problem, a 1992 study, stressed that there are organizational deficits and practically no competition in dialysis supply (45).

TABLE 5-10: Trends in Renal Transplantation

Year	Number of transplants
1977	277
1979	587
1981	762
1983	1,027
1985	1,275
1986	1,627
1987	1,711
1988	1,778
1989	1,960
1 1990a	2,358
1 1991a	2,255

*Including East Germany

SOURCE Kuratorium für Dialyse und Nierentransplantation, Jahresbericht, Neu-Isenburg, 1992

Unlike dialysis, the rate of transplants is relatively low (see table 5-10). With 29 renal transplants per million inhabitants in 1988, Germany ranked eighth in Europe (45). It is not clear why Germany does not have a higher transplant rate. Certainly, no lack of surgical capacity exists. However, unlike other countries, kidney transplants in Germany come almost exclusively from cadavers (in 1991, there were only 58 living donors), although even this resource is not fully utilized; in a recent year, Germany had more than 8,000 accidental deaths, but only 1,000 pairs of kidneys were transplanted.

The lack of a law on transplants has been criticized (52), and it is argued that the legal uncertainty hinders hospitals' decisions about whether to perform transplants. The usefulness of enacting a transplant law has been discussed since the end of the 1960s. Proponents favor a law that would increase the frequency of "donation" by assuming that every patient who has not explicitly refused to donate organs has agreed to make them available for transplantation. But media reports on the criminal procurement of organs have obviously influenced public opinion. It seems inevitable that

Year	Total viable births	Deaths within the first seven days	Death rate per 100,000
1975	600,512	6,967	1,160
1980	620,657	3,904	629
1985	586,155	2,217	378
1990	727,199	1,904	262

SOURCE Statistisches Bundesamt, *Statistisches Jahrbuch 1992 für die Bundesrepublik Deutschland* (Wiesbaden, 1992)

relatives will be asked about the intentions of the deceased potential donor. Finally, the lack of transplants has been traced to the fact that hospitals with an emergency station but no transplant facility are not interested in procuring organs because of lack of personnel. (Transplantation is reimbursed by the sickness fund of the patient who receives the transplant.)

The fact that the former GDR had a transplant law that prohibited the removal of organs only when the deceased had explicitly objected recently revived the discussion. The Federal Department of Justice, however, holds the opinion that this regulation could not be adopted in the FRG for political reasons. When the Federal Department of Justice did not enact a transplant law, the health departments of the *Länder* organized a conference in 1992. In April 1993, they reached agreement on a bill that will be enacted soon (24). In all probability, the Federal Department of Justice will enact a measure in this legislative term that will prohibit organ sales.

The low transplant rate means that a growing population needs dialysis. In 1988, the Board of Experts for the Concerted Action in Health Care stated that the number of dialysis patients might equal the number of transplants in 1992 (60). This balance did not occur. In 1991, the net growth of patients with ESRD was 54 per million, but there were only 29 transplants per million. While the exact number of dialysis patients is unknown, it appears to have been about 33,000 in 1991.

Erythropoietin (EPO), developed by Genetics Institute in Cambridge, Massachusetts, in cooperation with the German firm Boehringer (Mannheim), was first used in Germany in 1987. In

March 1987, Boehringer initiated two multicenter clinical studies to test the value of the drug (6,62), and since 1988, EPO has been available for use. Mandatory sickness funds do not know how many patients are treated with EPO because the costs for the drug are generally included in the lump sum paid for dialysis treatment. The official number registered by the European Dialysis and Transplant Association (EDTA) seems by far too low. EDTA statistics show that about 45 percent of the hemodialysis patients receive EPO. According to the KfH, which treats more than 12,000 patients with ESRD, costs of EPO treatment amounted to about 39 million DM in 1992.

NEONATAL INTENSIVE CARE

Starting in the mid- 1970s, perinatal mortality in Germany diminished considerably (see table 5-11). The rate of newborns dying within the first seven days decreased from 1,160 to 261 per 100,000 births between 1975 and 1990. The reasons for this decline include the systematic quality control of hospital care in this field and the continuous expansion of neonatal intensive care units (NICUs).

The 12,828 obstetric hospital beds in Germany are found mostly in small facilities close to families' residences. This in turn means that the average number of births per year per hospital, 500, is relatively low—much lower than in Sweden or the United Kingdom, for example. Only 15 percent of obstetrical departments have more than 900 births per year. This system of widely scattered small facilities is supplemented by a well-organized transportation system that transfers high-risk newborns to special centers.

During the 1970s, obstetricians established a regionally organized neonatal emergency service system, based on five areas of cooperation between neonatology and obstetrics departments (36):

1. consulting visits to the gynecological department on request;
2. regular medical care by a neonatologist (visits, consultations, etc.);
3. a neonatologist presence in the gynecological hospital during regular working hours, with the neonatologist on continuous emergency call;
4. intensive neonatal observations; and
5. neonatal intensive care.

For various reasons, the organization and location of the intensive care units has remained controversial. Obstetricians are skeptical about the early transfer of high-risk pregnancies to these centers, and pediatricians are strongly opposed to the separation of neonatal intensive care units from the children's hospital. Transporting gravely ill children can be dangerous, and separating a mother and child is not at all desirable. On the other hand, in order to operate efficiently, NICUS must be restricted to relatively few large institutions with large numbers of births. The exact number of NICUS is unknown because there is no official definition of regular care, intensive observation, intensive care, or clinical supply. Nevertheless, a 1990 survey of all pediatric clinics in West Germany identified between 170 and 219 NICUS, employing more than 3,300 people. (54).

Of the 1,904 newborns who died during their first seven days of life in 1990, half weighed less than 1,800 g. About 36 percent had incurable cardiac defects, congenital malformations, or chromosomal aberrations. The remainder had serious respiratory problems which might have been successfully treated by extracorporeal membrane oxygenation (ECMO). However, before 1990, only the University Clinic of Mannheim had introduced ECMO. Between 1987 and 1990, the Clinic used the new technology on 13 neonates. In 1990, it organized the first German symposium on this subject (40). It was stated that ECMO is no more expensive than more common therapies, which

made its slow rate of use hard to understand. By **August 1993**, ECMO was being performed at two additional clinics (in Lubeck and Berlin) (54).

In 1975, 26 obstetrical departments joined together to launch a regular survey of quality in perinatology, the *Munchener Perinatalstudie* (69). In 1986, 826 clinics representing 76 percent of the total number of births took part. The cooperating clinics decided to use a standardized procedure to document all births, based on the assumption that poor quality care is primarily a problem of insufficient information. This standardized procedure made it possible to compare the hospitals, as well as providing a detailed description of the state of perinatology as a whole. Each cooperating clinic receives data from all the others, although the clinics are not identified by name in the data. Peculiarities are regularly discussed during meetings and workshops. This survey has done a great deal to improve the quality of perinatal care.

For several years an increasing number of publications has raised questions about neonatal intensive care. This followed a long period in which the prospects for a newborn surviving, the likelihood of handicaps, and their quality of life as well as the fate of the mother or the family were rarely discussed. Because of the history of Germany's National Socialist "euthanasia program" (killing "socially useless" life), nobody dared to discuss whether there were limits to saving lives in neonatal intensive medicine. This outlook changed only in the early 1980s. At the 12th German Congress of Perinatology in 1985, a pediatrician reported that about 40 percent of the surviving premature babies who weighed less than 1,000 g at birth had severe neurological handicaps. He raised the question of whether the doctor should use all medical means to save these children, and whether parents should have the right to share in the decision. He stated that doctors should have some guidelines in this field. One year later, a workshop of the German Society of Medical Law, a society of lawyers and doctors, formulated guidelines, the *Einbecker Empfehlung* (22,37). These guidelines were the first attempt to define situations in which the doctor was not obliged to take all lifesaving measures: premature and handicapped newborns

who were unable to survive outside the NICU or who would never be able to communicate (e.g., severe microcephaly, severe brain damage). Beyond that, there is scope for decisionmaking in cases of newborns with, for example, severe neurological failures or multiple damages which, in general, severely impair the quality of life. Parents must be informed of their child's fate and should be integrated into the decision process, but they cannot prevent the doctor from taking lifesaving measures.

SCREENING FOR BREAST CANCER

One of the legally prescribed tasks of mandatory sickness funds is to prevent disease by providing information, medical advice, checkups, and early diagnosis (§20 SGB V). A program of early diagnosis and prevention of cancer was established in 1970 authorizing mandatory sickness funds for the first time to pay not only for treatment, but also for prevention. They did not define precisely which diagnostic procedures were to be covered, however. A catalog of procedures was compiled, and has been modified in succeeding years.

Breast cancer is the second most frequent cause of death for German women (after myocardial infarction), at 44.1 deaths per 100,000 inhabitants in 1990 (West Germany). The breast cancer screening program consists only of physical breast examination, not mammography. It does not seem to be very successful, as only 31 percent of the eligible women participate (60), varying by age and education. Rates have not changed substantially since 1981. (See table 5-12). Women with more formal education have a higher participation rate than those with less.

A 1983 study by a survey institute suggests that the most important impediment to regular participation in the screening program is lack of interest by office-based physicians. The survey found that if physicians offered annual screening to patients who asked for other services, participation would probably increase to more than 50 percent.

Mammographic screening is still not part of the screening program, although mandatory sickness

TABLE 5-12: Age-Specific Participation Rates in Breast Cancer Screening (1981)

Age	Percent of eligible women participating
30-34	41.9
35-39	43.0
40-44	45.8
45-49	44.6
50-54	38.1
55-59	31.4
60-64	27.8
65-69	18.5
70-74	12.8
75 +	5.2
30 +	30.9

SOURCE: P. Robra, "Ergebnisse und Probleme des 'Gesetzlichen' Krebs Früherkennungsprogrammes in der Bundesrepublik Deutschland," *Die Krankenversicherung* 37:65-69, 1985

funds do have to pay for clinical mammography when the results of a physical examination are unclear or worrisome. There are between 1,700 (58) and 1,900 (70) x-ray mammography machines in Germany. About 40 to 50 percent of mammographic examinations charged to the mandatory sickness funds' account are, in fact, not clinical but screening measures (5). Industry's estimate of the sales of x-ray film suggests about 2.5 million mammographic examinations (clinical and preventive) each year (59).

In the 1980s, many radiologists and clinicians advocated integrating mammography into the screening program, but evidence on the usefulness of unselective screening was considered to be lacking. The fact that some screening programs had detected more cases of breast cancer than became manifest within the lifetime of the population was a critical point in considering the risks and benefits of mammography. As a result, health authorities hesitated. In 1980, the Federal Chamber of Physicians recommended periodic mammography only for women 50 to 60 years old in the absence of risk factors (68). Health authorities later argued that it would be preferable to delay

unselective mammographic screening until the findings from different foreign studies had been published (57).

Since 1989, the Federal Ministry of Research and Technology has been financing a study to define the conditions for integrating mammography into the cancer screening program. The study is expected to:

1. recommend ways to ensure the quality of devices and procedures, including standardized documentation of diagnostic findings that would make them suitable for regular evaluation,
2. develop an education program,
3. recommend measures to encourage women to undergo mammographic screening, and
4. analyze the economic consequences of the program.

Based on this study, the Federal Commission of Physicians and Mandatory Sickness Funds will decide whether to integrate mammography into the screening program. A pilot study with four gynecological institutions has developed criteria for

judging technical quality, interpretation of the pictures, and organizational structures for quality assurance. In 1990, the *Deutsche Mammographie-Studie* started a regionally limited mammographic screening program for women over 39 (the mean age of participants was 53). Within 18 months, about 22,000 women were examined. Each mammogram was evaluated twice. Discrepancies in findings seemed to depend on physicians' experience and equipment.

Forty-four office-based physicians participated in the program. Reviewing the technical quality of the exams revealed that about half of the x-ray devices use tubes that, although still meeting standard specifications, should have been replaced. (Each tube costs about 30,000 DM.) At the beginning of the study, a number of physicians were given a course where they were asked to inspect images and present biopsy recommendations. The course showed that physicians needed further education and that further education led to improvements. The current problem is how to develop these findings into a strategy that can be implemented on the federal level.

CHAPTER SUMMARY

Germany has developed a comprehensive health care financing system based on the Social Security legislation of 1883 to 1889. The basic goal of the German health care system has been equal access to all medical services for all citizens, regardless of their financial situation. About 90 percent of the population is insured by mandatory sickness funds, and the rest (mainly self-employed persons, employees with high income, and civil servants) are insured privately. Contributions to mandatory sickness funds are based on income. The health care package contains most necessary services except for long-term care.

The federal government sets the legal framework for mandatory sickness funds, determining who is subject to compulsory insurance, which categories of services have to be reimbursed, and what percentage of excess charges are to be paid

by patients. Within this legal framework, most specific regulations are defined by sickness funds organizations and physicians' associations. The different actors are brought together financially by the budget of the mandatory sickness funds and organizationally by the self-governing bodies of physicians, hospitals, and sickness funds. This structure means that most health policy decisions are made through bargaining between large organizations within a legal framework. The limited integration of the different sectors and the diverging interests of the groups result in a considerable lack of suitable data for health reporting and evaluation of health services. Growing financial pressures on health care have been accompanied by many initiatives to improve the information base, but they have yet to be very successful.

The strict separation of inpatient and outpatient care has led to competition between the two sec-

tors, including competition based on the acquisition of medical technology. Self-employed office-based doctors are free to purchase items as they choose (except for some of the most costly cutting-edge technology) because their costs are reimbursed by sickness funds. Hospital investments are financed by the states, however, which wield some control over what technologies hospitals may acquire, always under conditions of limited funds. This difference, and the separation of inpatient from outpatient care itself, is the source of possibly great inefficiency in the system.

German health policy has gone through three stages since the late 1960s. For a short time, social and health policy was dominated by the belief in modernization by state intervention and regulation. This period began with the Hospital Financing Act of 1972, which first established public responsibility for a sufficient hospital supply; it came to an end with the 1976 Drug Law. In 1976, the sociopolitical cooperation of the ruling coalition of Social Democrats and Liberals was exhausted. Moreover, economic difficulties reduced the government's means of financial intervention, and finally, administrative courts restricted the government's ability to regulate, and different interest groups tried to defend their autonomy from regulators.

As a result, the federal government withdrew from the field of health policy and reduced its legislative activities to a minimum, leaving most decisions to the self-governing corporations of physicians' associations, mandatory sickness funds' associations, hospital societies, pharmacists, the drug industry, etc. Laws passed between 1977 and 1992 were aimed primarily at cost reduction, without an accompanying change in health care delivery structures. Hospitals, however, had no strong representation in the bargaining process between health care organizations, while becoming identified more and more as the essential cause of rising health costs. They became the focus of the cost containment debate.

The 1993 Health Care Act marks the third stage of the health policy process. Decisionmakers now realize that budgeting and other cost containing restrictions may be insufficient to successfully re-

duce the growth of health care expenditures. The 1993 law's modifications of the health care delivery structure may fix some obvious deficiencies.

One provision of the 1993 Health Care Act is to limit the contribution rates of employers and employees to mandatory sickness funds, requiring cuts in sickness fund budgets. In view of the fact that all previous cost containment measures were only successful in the short term, this law is trying to affect health care and financing structures in ways that have never been done before in Germany. The 1993 Health Care Act is trying to foster a market-oriented system by encouraging hospitals to provide ambulatory surgery and developing a new hospital reimbursement plan that creates incentives for price competition. (Yet it also introduces obviously restrictive measures by limiting the number of sickness fund doctors and the amount of reimbursement for prescribed drugs.)

It is too early to judge what the final result will be, but clearly the German health care system is at a crossroads, where the principle of equal access to services for all citizens maybe sacrificed on industrial and economic policy grounds. In the last 50 years, health care has become an essential field of industrial activity. Germany is not only a important market, but also an important producer of medical goods. Federal economic policy is primarily concerned with the well-being and growth of industry and much less in the quality of health care. In times of recession and unemployment, steady contribution rates and an open and growing health care market are incompatible aims. Equal access and stable contribution rates require regulating (though not necessarily rationing) medical services. Such regulation would necessarily delimit the growth in purchases of medical technology. Unregulated growth would be possible only by privatizing payment for some medical services.

The idea of restricting compulsory insurance to what is called "basic health care for severe diseases" excludes many needed services and opens the market for private insurance, which not everyone would be able to afford. Seen against this background the restrictive measures of the 1993 Health Care Act become comprehensible. In 1960 the Federal Constitutional Court argued that being

licensed as a sickness fund doctor was a precondition for survival as an office-based physician; therefore, it found that limiting the number of sickness fund doctors was unconstitutional. A reduction of compulsory insurance to "basic health care" could provide a source of patients to physicians not licensed by mandatory sickness funds. So limiting the number of sickness fund doctors could be brought in line with constitutionally guaranteed rights.

Limitations on purchases of high-technology equipment (and drugs) apply only to reimbursement by mandatory sickness funds. Private insurance may expand sales for the medical device and pharmaceutical industries by removing the existing impediments, thus favoring industry. Ultimately, what may emerge is a two-class health care delivery system.

Medical technology assessment has almost no role in the German health care system, despite the recent establishment of a commission to advise the Parliament on technology assessment. Even some of the most basic medical and economic data needed for technology assessment are not collected in Germany. The number of major assessments that have been done (on a case-by-case basis) can be counted on the fingers of one hand.

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