7.
Technology Assessment and Diffusion in the Health Care Sector in West Germany

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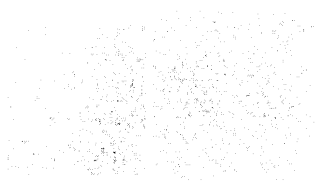

Contents

LIST OF TABLES

7. Technology Assessment and Diffusion in the Health Care Sector in West Germany

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WEST GERMANY: COUNTRY DESCRIPTION

Population

In 1977, approximately 61.4 million people lived in West Germany (including West Berlin). Of these, roughly 48 percent were males. About 54 percent of all males and 29 percent of all females were employed. The vast majority of workers, roughly 97 percent of them, were not self-employed, but working for an employer or a relative (l).

The population pyramid reflects a very low birth rate. As a result of this birth rate, the population of West Germany has declined slightly since 1974, and so has the number of people in the labor force. The government estimates that in 1979 about 20 percent of the population was over 65 years of age and this percentage is expected to remain constant for the next 5 years. The male/female population ratio for those over 55 years of age shows a substantial surplus of females, resulting from two World Wars, In terms of health care services requirements, increasing utilization of services by the aging, predominantly female population is expected to continue in the future.

Form of Government

West Germany is a federal republic with 10 States (Lander) and West Berlin. These 10 States and West Berlin have a fair amount of autonomy in terms of educational and health policies. Health care policy is determined more by sickness funds (Krankenkassen), which are nongovernmental associations, however, than by the Federal and State governments.

Social Democrats and Free Democrats, by forming an alliance and thus creating a slight majority in Parliament, have run the country jointly since 1969. The Social Democrats usually draw more than 40 percent of the votes, and the Free Democrats tend to garner slightly more than 5 percent. The counterbalancing voting block in this democracy are the Christian Democrats. Although they outpolled the Social Democrats in the last election, the Christian Democrats could not get the Free Democrats to aline themselves with their party. The influence of other political parties (except for a new alliance of environmentalist splinter-groups and parties popularly referred to as the "Green Party") has slowly diminished, partially as a result of the requirement that any party that wishes to take part in the governmental process obtain a minimum of 5 percent of the votes in the proportional election system.

Nature of the Economy

The two major political parties have similar views about the Federal Government's role in the economy. Starting with Erhardt's postwar direction toward a "free market economy," Ministers of Finance have attempted to create favorable conditions for economic growth and development, as well as a supportive social policy to shield the individual from the effects of

illness, disability, and unemployment. Serious thought has been given over time to the displacement of labor that can be caused by structural economic changes, such as technology or changes in trading policies. Such thought, for example, was given to the social and labor legislation that accompanied the treaty that created the European Economic Community (EEC).

To generalize, there is broad political support for a Federal economic policy that aims to develop a solid economic and social infrastructure, and for Federal intervention in the market to achieve these policy objectives. Thus, the Federal Government subscribes to a policy of support for technological growth, and even some State and local governments have commissioned research to determine how they might achieve a technological advantage for their State or local economy.

In 1978, government R&D expenditures constituted over 3 percent of the gross national product (GNP), and more than 6 percent of all Federal, State, and municipal expenditures (3). Paraphrasing the words of Volker Hauff, the Federal Minister of Research and Technology, these expenditures on research and technology are considered necessary to the West German economy and to its social fabric, because they (9):

- expand the understanding of basic science,
- improve productivity and enhance the ability of the West German economy to compete on world markets,
- conserve resources, and
- improve living and working conditions.

THE HEALTH CARE SYSTEM

Health Care Institutions and Providers

There are 3,416 hospitals in West Germany, which in 1977 discharged 10 million inpatients. Of these hospitals, 36.8 percent are public, 33.4 percent are voluntary institutions, and 29.8 percent are proprietary hospitals (l). With about 12 hospital beds per 1,000 population, West Germany has more beds per capita than any other country in the Western world, with the possible exception of Sweden.

In 1977, the average length of stay in all hospitals was *20.8* days; in an average acute care hospital, it was 15.8 days. In a sample survey by the German Hospital Association (Deutsche Krankenhausgesellschaf t), the average length of stay in 1978 was 15.5 days, with a range from 13 days in Hessen to 21 days in West Berlin. This customary long length of stay is not discouraged by an occupancy rate of 84.8 percent in 1978, down from 93.2 percent in 1960 and 88.5 percent in 1970 (1,7). Because there is a separation between physicians who are permitted to treat patients inside of hospitals and physicians who practice outside of hospitals, hospitals generally do not have outpatient clinics. (The exceptions are teaching hospitals, which sometimes have clinics for teaching purposes.) As a result, patients who in other countries might be treated as outpatients are often hospitalized.

In 1977, West Germany had 125,274 doctors, for a physician-per-population ratio of 1 per 490, one of the highest in the world. There were 32,121 dentists, 26,811 pharmacists, and 235,598 nurses, nurses aides, or midwives (l). of the physicians, 56,334 were based in hospitals, 58,222 in private practice, and 10,718 in administration and research. In 1977, 53.1 percent were general practitioners, and 46.9 percent specialists (l).

Health Insurance

West Germany has a system of social insurance which was established in 1883 and now covers more than 99 percent of the population with virtually full service benefits. In 1978, 1,360 semiautonomous sickness funds (Krankenkassen) administered the decentralized program, under the general supervision of the

Federal Ministry of Labor (Bundesministerium fur Arbeit) (1).

The statutory health insurance program mandates a wide range of benefits, including service benefits for medical and dental diagnosis and treatment, for preventive examinations, and for drugs. Sickness cash benefits are also provided to cover periods of unemployment due to illness. Sickness funds may expand on the basic benefits.

Employers and employees make equal contributions to the program in fixed amounts ranging from 10 to 13 percent of insurable earnings up to 20,600 deutsche marks (DM) ($10,842)1 income per year, and averaging 11.3 percent in 1979 (2). Contributions on behalf of retired and disabled pensioners are made by the Social Pensions Insurance Fund (Sozialversickerung), and contributions for persons receiving unemployment benefits or assistance and maintenance allowances are made by the Ministry of Labor.

Administration

The 1,360 sickness funds are organized on communal, regional, State, and Federal levels. These funds are organizationally and financially autonomous, i.e., independent of government and responsible for balancing their own income and expenditures. On the national level, they organize themselves into associations of sickness funds (Krankenkassenverbande) to safeguard their common interests.

Many sickness funds are organized around occupational groups (e.g., agriculture, large enterprises, small firms, seamen, miners), and membership, except for persons with high incomes, is obligatory. Those with high incomes may belong to Ersatzkasse, a voluntary sickness fund that frequently offers higher benefits at lower rates because of low loss experience. For all those who do not fit into one of the specific occupational groups, or who are not exempt by virtue of their high incomes from having to join a particular sickness fund, membership in the largest sickness fund, the Allgemeine Ortskrankenkasse (AOK, or general local sickness fund) is mandatory. In 1977, AOKS covered 44 percent of the working population and 57 percent of the retired (1). The large proportion of elderly members with high utilization rates in AOKS explains why these sickness funds charge generally higher premiums than do Ersatzkassen.

The Federal Government establishes broad legislative guidelines with respect to the operation of the health insurance system. Agreements on contract, payment, and benefit packages of the various sickness funds may not violate these guidelines. In all other matters, the government may not interfere in the decisions negotiated between the sickness funds and the State Associations of Insurance Doctors (Arzteverbande).

Reimbursement

Of the DM 69.8 billion ($36.7 billion) spent by sickness funds in 1977, 29.3 percent was paid to hospitals for inpatient care, 17.9 percent to physicians for ambulatory care, 6.6 percent to dentists, 7.7 percent for dentures, 14.1 percent for drugs, 4.8 percent for other products, 7.0 percent for sickness cash benefits, 1.4 percent for prevention, 2.5 percent for prenatal care, and 4.1 percent for other services (1).

Using a cost-finding formula set by the Federal Government, hospitals determine the per diem rate to be charged for hospitalization. The hospitals are then paid by the insured patient's sickness fund. Although in theory, per diem payments are to cover the entire cost of the hospitalization, in practice, they do not. Until 1972, the cost of hospital care was subsidized by community tax revenues and charitable contributions, but the low level of reimbursement led to inadequate reserves for maintenance, modernization, and replacement of buildings and equipment. Concern about the rapidly deteriorating capital stock of hospitals led to the enactment by the Federal Parliament in 1972 of a law on capital investments by hospitals, the hospital financing law (Krankenhausfinanzierungsge-

[1]For conversion of deutsche marks (DM) to U.S. dollars the exchange rate used throughout this chapter was DM 1.90 = $1.00 (U.S.). The reader should bear in mind, however, that the actual exchange rate has not remained constant over the years. According to the International Monetary Fund, between *1963* and 1968, the rate was DM 4.00 = $1.00 (U.S.), in 1969, it dropped to DM 3.9433; in 1970, to DM 3.6600; in 1971, to DM 3.4908; in 1972, to DM 3.1886; in 1973, to DM 2.6726; in 1974, to DM 2.5878; in 1975, to DM 2.4603; in 1976, to DM 2.5180; in 1977, to DM 2,3218; in 1978, to DM 2.0086; and in 1979, to DM 1.8329.

setz) of 1972. (That law is discussed in a separate section below.)

Hospital physicians are generally salaried employees whose services are included in the hospital's bill. Almost all physicians practicing outside of hospitals participate in the health insurance scheme. These physicians are reimbursed by fee-for-service based on the number of patients they have seen. Each patient gives the physician a sickness fund form (Krankenschein) each quarter. For reimbursement, physicians forward these forms to the State Association of Insurance Doctors. Fee schedules are negotiated by a Federal commission representing the doctors, sickness insurance funds, government, and other interested parties. The schedules include more than 5,000 separate procedures for which a physician may charge.

Review of physicians' services is done for purposes of economic control. Only recently have physicians been considering quality controls. Physicians who abuse the system are disciplined by their Association of Insurance Doctors.

Expenditures

According to the Federal Center for Statistics (Statistisches Bundesamt), West Germany spent 3.7 percent of its GNP on health care in 1970 and 5.8 percent in 1977 (18).[2] Expenditures of West German sickness funds, GNP, and expenditures of sickness funds as a percentage of GNP for the years 1970 through 1977 are shown in table 1. These data cannot be compared directly with the expenditures on health care in the United States, however, because they do not include the same costs. The major difference is that cash benefits for lost income during sickness were included in the expenditures of sickness funds until 1975 in West Germany.

What may be more telling than these data is the rapid rise of expenditures by sickness funds. As shown in table 2, between 1971 and 1977, total expenditures by sickness funds increased annually by the following percentages: 1971 (23.7 percent), 1972 (16.9 percent), 1973 (19.1 percent), 1974 (19.5 percent), 1975 (17.7 percent), and 1976 (9.1 percent), and 1977 (4.9 percent) (1). Only when cash payments were no longer included, and when hospital capital expenditures were covered by the government rather than by the sickness funds, did this yearly increase drop to 9.1 percent in 1976, and to an estimated 4.9 percent in 1977 (1). (As a yardstick, the consumer price index increased by between 5 and 7 percent per year between 1971 and 1975; between 1977 and 1978, it increased by a mere 2.6 percent per year.)

[2] There are other sources of data which estimate that the country spends a far higher proportion of its GNP on health care than the data on sickness funds would indicate. Thus, a 1979 Time survey came to the conclusion that West Germany had overtaken the United States in the proportion of GNP spent on health, spending *128* percent of GNP on health care in *1978.* Data obtained from the U.S. Social Security Administration in Washington indicate similar proportions *(8, 16, 17).*

Table 1.—Expenditures of Sickness Funds in West Germany as a Percentage of GNP[a] (1970-77)

Year	Expenditures of sickness funds (in millions of DM/dollars)		GNP (in billions of DM/dollars)		Expenditures of sickness funds as percentage of GNP
	DM	U.S. dollars	DM	U.S dollars	
1970	25,179.1	$13,252.2	679.0	$357.3	3.7%
1971	31,140.1	16,389.5	759.0	399.5	4.1
1972	36,400.6	19,158.2	827.2	435.4	4.4
1973	43,365.3	22,823.8	920.1	484.3	4.7
1974	51,808.5	27,267.6	986.9	519.4	5.2
1975	60,989.6	32,099.8	1,032.9	543.6	5.9
1976	66,563.5	35,033.4	1,127.9	593.6	5.9
1977	69,823.3	36,749.1	1,198.7	630.9	5.8

[a] For conversion of deutsche marks (DM) to U.S. dollars in this table, the exchange rate used was DM 1.90 = $1.00 U.S. The actual exchange rate, however, has fluctuated over the years.
[b] Preliminary estimates.

SOURCE: Statistisches Bundesamt (Federal Center for Statistics), 1979 (18).

Table 2.—Annual Percentage Increases in Total Expenditures by Sickness Funds in West Germany (1971-77)

Year	Percentage increase over previous year
1971	+ 23.7 %
1972	+ 16.9
1973	+19.1
1974	+19.5
1975	+17.7
1976?	+9.1
1977?	+4.9

[a]Preliminary estimates

SOURCE Statistisches Bundesamt (Federal Center for StatisticsL 1979(18)

Hospital expenditures increased faster than expenditures for ambulatory care. From 1970 to 1971, for example, hospital expenditures increased 27.3 percent, while ambulatory expenditures increased 24.4 percent (1). For subsequent years, the annual percentage increases forhospital and ambulatory expenditures were as follows: 1972, hospitals (22.3 percent), ambulatory care (ll.4 percent); 1973, hospitals (25 percent), ambulatory care (13.4 percent); 1974, hospitals (30.3 percent), ambulatory care (15,4 percent); 1975, hospitals (15.0 percent), ambulatory care (13.4 percent) (l).

Federal Financing of Capital investments in Hospitals

By 1971, there was cause for concern that sickness fund expenditures were increasing at too rapid a rate to keep up with increased productivity and salaries in the labor market, so sickness fund members werecharged higherpremiums. Despite the additional funds, the per diem rates paid by sickness funds were too low to permit hospitals to keep buildings and equipment up to date and to provide technically and qualitatively superior care.

Deciding that hospital care was a public good, that there should be no underserved areas, and that the government had an obligation to make high-quality hospital care accessible to all citizens, Parliament enacted the hospital financing law (Krankenhausfinanzierungsgesetz) of 1972. Studies by the Federal Government had estimated the annual operating deficits of hospitals between 1966 and 1969 to be DMl billion ($526 million), and had also found that aging hospital plant and equipmentled to high personnel costs and inadequate medical care for patients(5). Many proposals to ensure adequate hospital facilities had been discussed, but two received the most attention. One was that the Federal Government require that the per diem fees paid by sickness funds cover both operational and capital costs. The other was to have the sickness funds cover hospitals' operational costs and Federal and local governments finance capital improvements.

The Federal Parliament opted for the latter, i.e., having the sickness funds cover hospitals' operational costs and the Federal Government pay for capital improvements. The reasoning was that an optimal distribution of services could not be achieved with each sickness fund deciding on a per diem fee, without central coordination (at least on a statewide basis) of capital expenditures by hospitals. The legislators believed that the widely divergent financial capacity of the different funds would have resulted in a system with services that were not geared to the needs of the population in a geographical area, but instead were dependent on the revenues of each area's sickness funds.

The 1972 hospital financing law provided for the financial requirements of hospitals as follows.

Operating Expenditures.—Operating expenditures and supplies and equipment with a lifespan of up to 3 years are financed through the per diem payments from sickness funds. The hospitals complete uniform cost reports (Selbstkostenblatter) on a line-item basis. Eventually, as reporting becomes more uniform, per diem comparisons of cost centers will provide useful information about comparative efficiency. The major deterrent to using this comparative information at present, apart from nonuniform reporting, is the inadequate detail which can be obtained on patient mix. Although several associations of sickness funds produce side-by-side comparisons of hospitals within a State, therefore, these data are not being used for planning or reimbursement purposes. Thus, the purchase of supplies and equipment with a lifespan of up to 3 years is not controlled.

Short-Term Capital Investment .—Short-term capital investment in capital goods with a lifespan of 3 to 15 years is financed with the so-called Zehnerpauschale (or par. 10, regarding lump sum payments, of the hospital financing law). The Federal Government contributes one-third of 8.33 percent of the basic replacement value of each hospital bed. The replacement value is lower for beds installed before January 1, 1951. It also varies by institutional category as determined by numbers of hospital beds: 1, up to *250* beds; II, 250 to 349 beds; III, 350 to 649 beds; IV, 650 or more beds. Thus, for example, the replacement value of a bed installed prior to January 1, 1951, in a level I hospital is DM 13,072 ($6,880); in a level II hospital, DM 15,351 ($8,079); III, DM 17,802 ($9,369); IV, DM 22,704 ($11,949); whereas the replacement value of a bed installed after this date in a level I hospital is DM 15,200 ($8,000); II, DM 17,850 ($9,394); III, DM 20,700 ($10,895); IV, DM 26,400 ($13,895).

The Federal Government has no direct control over how these funds are being spent. It is within this category of funding that equipment that has a long lifespan will be replaced, and just as with the per diem funds, there is only an indirect incentive to spend these funds so that comparable services are available in all the regions. (That incentive is provided through the State plans of need (Bedarfsplane), which are discussed in the next section of this chapter.)

Medium-Term Capital Investment. — Medium-term capital investment required to finance replacement or additions to existing capital stock with a 15- to 30-year lifespan is completely financed by the Federal Government (par. 9 of the hospital financing law). Applications for these funds must contain proof that the funds will be used to equalize access to care and that they will contribute to the cost effectiveness of the system.

Long-Term Capital Investment.—Long-term capital investment for buildings is completely financed by the Federal Government if the buildings are expected to have a lifespan exceeding 30 years. New hospital construction falls into this category of funding. In no case, however, will the Federal Government subsidize the purchase of land.

The amount of Federal funds made available under the hospital financing law for capital investment in 1972 was DM 465 million ($245 million). This amount increased to DM 915 million ($482 million) in 1977. Hospitals are not allowed to make capital investments outside of this system, except with funds obtained from philanthropic sources or public fundraising campaigns. Operating expenditures continue to be funded by the insurance system, which paid about DM 20.5 million ($10.8 million) to hospitals in 1977.

State Planning for Hospital Services

Two major objectives of the 1972 hospital financing law, to ensure the financial viability Of hospitals and to achieve acceptable levels of sickness fund premiums, had been achieved by 1977. The third objective, to provide an equitable distribution of hospital services, has still not been achieved, but all States have been working on plans of need (Bedarfsplane).

The hospital financing law was based on the idea that the physical plant of hospitals needed to be improved, that costs in hospitals had to be controlled, and that a system of incentives that would stimulate hospitals to economize had to be created. Past experience with reimbursement to physicians had taught everyone concerned that new funding without planning and evaluation would simply lead to higher expenditures—not to more cost-effective services.

Under the 1972 law, all States were required to produce plans for beds and services, and a Federal/State task force was established to discuss uniform terminologies and time frames for the State plans. The legislation emphasized the necessity of developing alternative modes of care and of fostering cooperation between those planning medical schools in the Federal Ministry of Education and Science (Bundesministerium fur Bildung und Wissenschaft), and even military establishments in the Ministry of Defense, and those planning hospitals in the Ministry of Labor and Social Affairs (Bundesministerium fur Arbeit und Sozialordnung).

States must comply with the planning requirements of the hospital financing law, and hospitals have to be "needed," according to the State bed need plan, in order to qualify for Federal capital subsidies. The plans of individual States vary greatly. The 1972 hospital financing law requires only that each State have a regionalized hospital system, and that the levels of care a hospital can provide correspond to criteria established by the State and be consistent with the hospital financing law. The Federal law suggested four levels of care, which would depend on the size of hospitals: The least complex level of care, level I, would be provided by hospitals with up to 250 beds; level II, by hospitals with between 250 and 350 beds; level III, by hospitals with between 350 and 650 beds; and level. IV, by those with more than 650 beds. Only one State used the suggested classification scheme alone; the other States established additional criteria for planning, such as the services provided and the departments providing care.

The need for beds is determined on the basis of population growth, the rate of admissions, average length of stay, and occupancy rates. Planners have experienced the usual difficulties in determining appropriate bed need indicators. The population data are imprecise because of the inadequate information on population movement from one census period to another. The use rate per 1,000 population differs greatly by State, and although factors that contribute to regional differences have been identified (e.g., the age and sex distribution of the population, the incidence and prevalence of disease, traffic patterns, occupational and socioeconomic characteristics, and the supply of hospital beds and medical services), they are difficult to quantify. Average length of stay and occupancy rates also differ greatly from one State to another.[3]

Despite the difficulties, however, the States are now at the point where they have some experience with bed need methodology, and some States are now preparing their fifth-generation State hospital bed need plan. Furthermore, the sickness funds are starting to collect more adequate data that will allow them and the State planners to become more sophisticated. Some of the issues that are beginning to be discussed are adjusting for patient mix, comparing line-item expenditures by type of patient and by type of hospital, and planning for new medical technology such as computed tomography (CT) scanners. If the plans become more sophisticated, and their present emphasis on beds and facilities is shifted to the types of patients a hospital should admit or to the types of services it should offer, State hospital plans will become the instruments through which the Federal and State governments will be able to influence spending on new technology.

'Much research was carried out between 1972 and 1976 to analyze the variables that affect hospital admissions and stays. See, e.g., H. Ehlers, Krankenhaushauf igkeit, 1976 (7).

MECHANISMS FOR MANAGING MEDICAL TECHNOLOGY

One effect of financing capital goods with Federal support was that between 1972 and 1979 many hospitals were able to update their plant and equipment. Since hospitals with fewer than 100 beds received no Federal support to acquire capital goods, between 1970 and 1977, the average hospital size increased from 190 to 212 beds.[4] A number of hospitals closed or consolidated, and there was a trend toward centralization and regionalization of highly sophisticated technology, such as open-heart operations, because only a level IV per diem rate would give a hospital the necessary funds to staff and equip such a service. Teaching hospitals, which are financed concurrently with medical faculties of universities by the Federal and State governments, were exempt from the planning requirements. The need for integrating teaching hospitals into the overall plan for hospital beck was first expressed as a concern after the passage of the law designed to decelerate cost increases (Kostendampfungsgesetz) in June 1977.

'Unexplained is the increase in private beds during that time. Private beds constituted 8.9 percent of all beds in 1970, but had Increased their share to 12.2 percent in 1977 (10).

The 1972 hospital financing law's initial emphasis on financing increased the funds available to hospitals for renovation, new buildings, and medical technology, but it also led to fears that these investments would not lead to cost-effective delivery of care. In addition to more systematic efforts at planning, a uniform accounting system to permit evaluation of the cost effectiveness of capital investments and of planning measures was proposed. Implementation of a new uniform accounting system was required starting in the spring of 1978. This new information system eventually is expected to provide the basic data for government-sponsored research into the levels of care required, personnel needs, optimal operations, duplicate tests, and shared and purchased services.

Research and Development

Because the emphasis has been on upgrading the capital stock and equipment of hospitals, until recently, very little thought has been given in West Germany to the effect of medical technology on the health of the population or the health care system. The period immediately after enactment of the hospital financing law of 1972 in West Germany, therefore, is somewhat comparable to the period following the Hill-Burton legislation in the United States.

The medium-term program of the Ministry of Research and Technology (Bundesministerium fur Forschung und Technologies) provides overall direction for technological development by establishing priority areas for subsidies. In 1974, the Ministry of Research and Technology commissioned a baseline study of medical technology in West Germany, which could be used to develop a strategy for future support of research activities and of new products (13). The Ministry's primary concern initially was to promote R&D of medical technology as one area where West German industry could compete effectively on world markets. A secondary concern was to use this technology to improve the health of the West German labor forces

'Maintaining the productivity of West German workers in the face of labor shortages has been said to have been Bismarck's primary reason for advocating national health insurance in the 1890's. Fiscal and social policy makers have since continued to view social welfare legislation as an investment in the productive capacity of the worker.

The rapid increases in expenditures on health care services after 1975 affected the Ministry's policy. In 1978, the Ministry published its *Program on Promoting Research and Development in the Service of Health,* which was to "increase the capacity and economic efficiency of medical care and also to facilitate making judicious decisions on health policy" (4). The emphasis shifted from the development of new technology to improve the competitive edge of West German manufacturers of medical supplies and equipment toward research to improve the health of the population. In the Ministry's 1978 report, major sections are devoted to health prevention, as well as to improving the cost effectiveness of the health delivery system through research into the structure of the system and possible changes.

Thus, West Germany is now establishing structures and procedures to develop a health care services and research policy and to assess all new medical technology and manage its dissemination. It has identified the following as main areas for research (4):

- Prevention
  - —identification of risk factors (cancer, heart disease, rheumatism, mental health),
  - —behavior modification, and
  - —development of health status indicators and measures of cost effectiveness of interventions.
- **Diagnosis, therapy, and rehabilitation**
  - **—automatic laboratory testing of Pap smears and other specimens,**
  - **—surgery with laser beams,**
  - **—improved optical instruments,**
  - **—reducing the exposure to X-rays,**
  - **—development of artificial kidneys,**
  - **—development** of instruments that permit the blind to read and paraplegics to function,
  - —development of artificial limbs, bones, etc., and
  - —applications of automated data processing to diagnosis and therapy.
- **Structure of the health care delivery system**
  - **—data base development on utilization, costs, expenditures,**

—effectiveness and efficiency of procedures,
—development of a planning process,
—evaluation of the health insurance system,
—development of strategies for payment of providers,
—examining the demand for diagnostic and other preventive measures, and
—applications of data processing to the delivery system.

Most medical research in the past was carried out in universities and teaching hospitals. Since the principle of academic freedom in West German universities guarantees the researcher virtual autonomy both in selecting a subject for investigation and in determining what type of research to conduct, research at these publicly financed institutions was not subject to any review. University research today continues to be funded primarily by the State governments, and no strings are attached to the moneys they provide. Similarly, no strings are attached to research funds that the Federal Ministry of Education and Science makes available to the States. In recent years, quasi-autonomous research institutes have gained in importance, partly because they have been able to attract funding from foundations, and partly because they have received contracts for research from manufacturers of equipment and supplies.

Since 1976, Federal funding of R&D has increased. The four Federal Ministries that support R&D are the Ministry of Research and Technology, which has the largest budget, the Ministry of Labor and Social Affairs, the Ministry of Youth, Family Affairs, and Health (Bundesministerium fur Jugend, Familie, und Gesundheit), and the Ministry of Education and Science. A Federal program for the years from 1978 to 1981 was outlined by the Ministries of Labor and Social Affairs, of Research and Technology, and of Youth, Family Affairs, and Health (4). Areas of emphasis and funding for biomedical and health services research are shown in table 3. Two major institutes were

Table 3.—Federal Grants and Contracts in the Areas of Biomedical and Health Services Research in West Germany (1978-81)

Ministry and area of promotion	Annual expenditures (in millions of DM/dollars)a								Total expenditures 1978-81	
	1978		1979		1980		1981			
	DM	U.S. dollars	DM	U.S. dollars	DM	U.S. dollars	DM	U.S. dollars	In millions of DM	In millions of U.S. dollars
Federal Ministry of Labor and Social Affairs										
Promotion of research and its application to areas of structural improvement in public health, preventive and early-detection schemes in statutory health insurance, and medical rehabilitation	4.2	$2.3	6.0	$3.1	5.5	$2.9	4.2	$2.2	19.9	$10.5
Promotion of research on hospitals pursuant to article 26 of law on hospital financing	4.25	2.24	4.0	2.1	4.0	2.1	4.25	2.24	16.5	8.7
Federal Ministry of Research and Technology										
Promotion of R&D projects in public health, medical research, and medical techniques	55.0	28.9	62.0	32.6	69.0	36.3	78.0	41.1	264.0	138.9
Data-processing applications in public health . . .	28.0	14.7	29.5	15.5	32.0	16.8	34.0	17.9	123.5	65.0
Federal Ministry of Youth, Family Affairs, and Health										
Public health, safety in the use of medicaments. .	5.0	2.6	5.7	3.0	6.6	35	7.1	3.7	24.4	12.8
Cancer research, cancer registers	0.2	0.1	0.3	0.15	0.3	0.15	0.4	0.2	1.2	0.6
Commissions	0.2	0.1	0.3	0.15	0.3	0.15	0.3	0.15	1.1	0.5
Statistical surveys on health questions.	0.2	0.1	0.2	0.1	0.2	0.1	0.2	0.1	0.8	
Total (rounded off)	97.0	$51.0	108.0	$56.8	117.9	$62.1	128.5	$67.6	451.8	$237.8

[a]For conversion of deutsche marks (DM) to U.S. dollars in this table, the exchange rate used was DM 1.90 = $1.00 (U.S.). The actual exchange rate, however, has fluctuated over the years.

SOURCE: Bundesministerium für Forshung and Technolgie (Ministry for Research and Technology), *The Federal Government's Program on Promoting Research and Development in the Service of Health, 1978-1981* (Bonn, English version undated, German version 1978) (4).

singled out to receive funding for medical research, the Max Planck Society (Max Planck Gesellschaft) and the German Research Association (Deutsche Forschungsgesellschaf t). These two institutes are routinely funded by up to *50*-percent Federal moneys, and for special projects may receive even larger Federal contributions. Together, they carry out much of the important medical / biological research in West Germany.

Federal financing is also provided to several centers that conduct research of societal importance (Grossforschungsanlagen), for example, in the areas of cancer, radiation, and environmental issues. These centers receive up to 90 percent of their funding from the Federal Government, and 10 percent from the States. Other organizations that receive Federal funding for all or some of their activities are the Federal Public Health Department (Bundesgesundheitsamt, BGA), the German Institute for Medical Documentation and Information (Deutsches Institut fur Medizinische Dokumention und Information, DIMDI), and the Paul Ehrlich Institute (Paul Ehrlich Institut).

In recent years, the Federal Government has increasingly let contracts to consulting firms, to the research arm of the German Hospital Association (Deutsche Krankenhausgesellschaft), and to similar organizations. Letting contracts, however, is a rather new process, which is not yet at all standardized. Thus, as many or more unsolicited proposals submitted by research institutes and consulting firms to contracting Federal agencies are funded as are proposals solicited by Federal agencies through requests for proposals. A comparison with the history of grants in the United States in the 1950's and 1960's comes to mind.

The observer gets the impression that the Ministry of Research and Technology is not only the largest source of funds for R&D, but that it is also taking the lead in letting contracts for research and in developing coordinated research plans. **As target areas for R&D of new technology, this Ministry has identified new diagnostic tests, laboratory equipment, and radiotherapy.** In September of 1976, it also concluded a research agreement with the U.S. Department of Health, Education, and Welfare in the area of biomedical research.

The stated objective of the Ministry for Research and Technology is to develop technology that will improve patient care, reduce side effects, and be more cost effective. As was suggested earlier, the West German Government also is interested in developing R&D programs that will help give West German manufacturers a technological advantage over manufacturers in other exporting nations.

Support for Evaluation Studies

Perhaps as a result of the lack of baseline information in many areas in the health care field in West Germany, much of the research effort in health services is descriptive and enumerative. This characterization is somewhat applicable even to medical research. Efficacy studies of therapies, such as clinical trials, and cost-effectiveness studies of new technologies are still rare.

The Ministry of Research and Technology has been very supportive of conferences for physicians to discuss methodological approaches to evaluating medical technology and practice. One conference it supported resulted in a manual on methodology for evaluation; another resulted in a summary of how to mount a study of new therapies for cancer, heart disease, and arthritis. Such conferences are only one way in which the Ministry hopes to awaken interest in the medical community in evaluating its work.

One major bottleneck the West German research community has to confront is a shortage of analytically trained researchers, such as statisticians, epidemiologists, and operations researchers. The Ministry of Research and Technology is aware of the problem and has set aside substantial resources to develop analytical capabilities in universities and to train young researchers.

A major critic of the system of developing new therapies and new equipment without cost-effectiveness analyses is Professor Manfred Pflanz, a sociologist at the University of Hannever. His major themes are that there is too

much surgery in West Germany compared to the United States and *other* countries and that no one ever has discussed what types of medical care contribute to patient health (12). Professor Pflanz has influenced the opinion of the educated public on the subject of the need for evaluations, and it is to be expected that not only professionals, but the general public as well, will demand more evaluation studies in the future.

Regulation for Safety and Efficacy

Drugs have been regulated in West Germany for some years, but the regulations, which focused on assuring safety, have not been very rigorous. A new law to strengthen drug regulation was passed in 1976, to become active on January 1, 1978 (6). Reportedly modeled after U.S. requirements, the new law requires Federal Government approval of drugs to be sold in West Germany. Prior to marketing a new drug, the manufacturer is required to submit to the Federal Government the results of clinical trials testing the drug's effectiveness, dosage, contraindications, and side effects. The 1976 law states that the Federal Government may decline to allow the drug to be sold if ", . . the therapeutic efficacy attributed to the drug by the admission applicant is lacking or is insufficiently substantiated by the scientific knowledge currently recognized (or) there is reason to suspect that, under correct use, the drug has harmful effects which exceed the bounds considered justifiable . . . ." That law is now being implemented.

Since many West German firms do business with the United States or other countries that have laws regulating drugs and medical devices, they already follow U.S. or similar regulations. In addition, many of the drugs and devices used in West Germany are produced in the United States, and are therefore subject to U.S. regulations.

There is a growing awareness in West Germany that some governmental review of the safety and efficacy of new equipment is in order, that the training of technical personnel by manufacturers should be discussed, and that all equipment should be checked on a regular basis once it is installed in a clinical setting. The following types of equipment, failures of which have been identified as life-threatening, have become prime candidates for regulation: anesthesia equipment, dialyzers, infusion pumps, and heart pacemakers.

The Technical Surveillance Service (Technischer Ubernachungsdienst, TUV), a voluntary, quasi-governmental organization now primarily checking the road-worthiness of passenger cars, has advocated in the Ministry of Labor and Social Affairs that such equipment be surveyed on a regular basis and that TUV be given responsibility for this function. The Professional Association for Health and Social Welfare Services (Berufsgenossenschaft fur Gesundheitsdienst und Wohlfahrtspflege), a professional organization not unlike the American Public Health Association, has suggested examinations of all equipment and supplies that affect patients through energy (e. g., electricity, heat, pressure, ultrasound, radiation, and drugs).

Two basic approaches have been discussed. One is to have an organization that develops minimal criteria for new equipment. The other is to have a second organization that checks to see that these criteria are met, even when the equipment is installed. No review processes have been legislated yet, but government officials and equipment manufacturers believe that some regulation is imminent.

Health Planning

The health planning approach as far as hospital beds and investment are concerned has already been discussed. Suffice it to reiterate here that present planning legislation is still in its infancy, and that a methodology that would give direction to new investment in the development of new medical procedures or technology simply does not exist.

One of the problems faced by health planners in West Germany is the absence of an ongoing national data collection effort. There are national data on kidney dialysis because the manufacturers of the equipment have commissioned a survey, but these data are not publicly avail-

'Appendectomies in particular.

able. No data are available through the government on the number of CT scanners, on the extent of coronary bypass surgery, on cobalt therapy, on clinical laboratory testing, or any other new technology.

It is clear, however, that the Ministry of Labor feels compelled to obtain better information, so that more rational decisions can be made about allocating funds for equipment. This Ministry seems to have singled out CT scanning as one of the first technologies which needs to be examined, whose use needs to be surveyed, and whose benefits need to be documented. Likewise, the Ministry of Technology and Research is outlining a program for research and evaluation which may produce some baseline data within the next few years.

Utilization Review

The sickness funds have the capability of doing only rudimentary comparisons of utilization. They code only three digits of the International Classification of Disease (ICDA-8) code and have little capability to check for the accuracy in the coding of discharge abstracts. The major difficulty in carrying out utilization review, apart from the lack of comparable data, stems from the lack of trained personnel and the independence of physicians. Both at the micro- and macro-levels, there exist shortages of personnel, such as record librarians, utilization review coordinators, biostatisticians, epidemiologists, and computer experts.

Fee and Ratesetting

Little thought has been given to ways of regulating the diffusion of medical technology through the fee structure and ratesetting, even though these mechanisms clearly do affect this diffusion. Since hospitals have to forward plans for special services and equipment with a 3- to 15-year lifespan to the State, and the States forward their plans to the Federal Government, perhaps eventually a national plan can be developed for technology, and reinforced through financial incentives.

Reimbursement of Hospitals

The reimbursement of hospitals has already been described. Since there are virtually no deductibles and coinsurance for medical care, there are no disincentives for individual patients to command the use of special services, advanced technology, or ultraspecialized medical centers and personnel.

Use of Evaluation Results in Managing Medical Technology

As discussed earlier, evaluation studies are still in their infancy in West Germany. Many such studies have been commissioned by policymakers in the Federal or State governments to provide information for policy decisions. It seems likely, therefore, that the results of research will be used in developing policy in R&D of medical technology, in the delivery of services, and in the incentives and disincentives provided by reimbursement, planning, and regulation.

Another important recent development is the so-called “Konzertierte Aktion im Gesundheitswesen” or “coordinated action in the health care system” *(8)*. Since its inception early in 1979, the Minister of Labor and Social Welfare has attempted to develop medical and economic baseline data in cooperation with representatives of all umbrella organizations, such as the German Hospital Association, associations of sickness funds, and physicians. The objective of this effort that the Minister of Labor is coordinating is to increase the effectiveness and efficiency of the health care delivery system,

SPECIFIC TECHNOLOGIES

Some of the information that is available concerning West Germany’s experience with five specific medical technologies—CT scanners, renal dialysis, coronary bypass surgery, cobalt therapy, and clinical automation—is presented below.

Of these five, only coronary bypass surgery is directly affected by bed-planning parameters, Teaching hospitals and level IV hospitals are the only hospitals that get high enough capital subsidies and per diems to be able to provide open-heart surgery. Since few hospitals can afford to become highly specialized centers, it is fairly noncontroversial when a State planning agency designates only those few as ultraspecialized centers that receive funding to carry out specialized work.

CT Scanners[7]

CT scanners are the most contested new equipment in the West German health care system. As medium-term purchases with a 15- to 30-year lifespan, CT scanners are regulated under paragraph 9 of the 1972 hospital financing law and are completely financed by the Federal Government. Hospitals seeking to acquire a CT scanner must submit an application to their State ministry, and the State ministry then requests funding from the Federal Ministry of Labor and Social Welfare.

In theory, therefore, CT scanners in hospitals should be very closely regulated, and up-to-date information on their distribution and use should exist. In practice, however, there is still some room for "slippage," because some hospitals are able to obtain CT scanners by having a fundraising campaign or by having a private physician purchase the equipment. There are no restrictions on the purchase of a CT scanner for a physician's office, Private financing is obtainable on the basis of the reimbursement rate paid by the sickness funds. This rate is DM 480 to DM 500 ($252 to $263) for a body scan and DM **300 ($158)** for a head scan, with an added DM 115 ($61) for additional work.

There has been some discussion by sickness funds and by physicians' associations about restricting reimbursement for CT scanning services to physicians who are specialists in radiology and have special technical training. According to confidential information from one executive of the association of physicians who accept sickness fund patients (Kassenarztlichen Bundesvereinigung), guidelines will be developed for reimbursement of head and body scanning services. These will include criteria establishing the need for equipment, a limited list of symptoms for which CT scanning will be considered appropriate, proof of competence by the physician, a limit on who can refer a patient for a scan, and a fee schedule for appropriate and equitable reimbursement.

At the end of 1978, according to one source, 160 CT scanners were reportedly in operation or on order in West Germany. Physicians' offices had 48, or 30 percent of these, 82, or 51 percent, were in acute care hospitals, and 30, or 19 percent were in long-term care and rehabilitation hospitals (14). (See table 4.) A survey in April 1979 carried out by the Federal Public Health Department (Bundesgesundheitsamt) counted 120 scanners in operation at the end of 1978 (19). One issue that has been raised is the possible maldistribution of CT scanners and the concentration of this equipment in urban areas of the country. The Ministry of Labor and Social Welfare is examining the problem, but still has to gather data to see where scanners are located.

A CT scanner "needs assessment" conducted by one radiology facility, the Diagnostic Radiology with Computer Tomography Institute (Diagnostisches Rontgeninstitut Mit Computer-

Table 4.—Distribution of CT Scanners in West Germany (1978)

Type of facility	Total number of facilities	Number of CT scanners[a]	Percentage of all CT scanners
Acute care hospitals			
Up to 300 beds.	1,900	2	1.070
300 to 600 beds	410	20	12.5
600 to 800.	65	10	6.5
Over 800 beds	75	50	31.0
Long-term hospitals .	1,250	30	19.0
Offices of **physicians in private practiceb .**	2,400	48	**30.0**
Total	6,100	160	100.0%

[a]Installed or on order.
[b]Radiologists or neurologists.

SOURCE: Adapted from G. Rau, remarks at CT Symposium at Deutsch Klinik für Diagnostik (German Clinic for Diagnosis), Weisbaden, Jan. 11-12, 1979 (14).

[7]The information for this case was gathered in meetings with the Federal Ministry for Labor and Social Welfare, with State ministries, with sickness funds, and from proceedings of a symposium on CT scanners on Jan. 11-12, 1979, at the West German Clinic for Diagnostics at Wiesbaden.

Tomographic) at Dietzenbach derives a "need" for West Germany of between 120 and 300 scanners, depending on the proportion of the population who will need a scan per year and on the number of scans that can be done on one CT scanner (14). Almost accepted is a standard of 0.5 percent of the population needing a head scan per year and another 0.5 percent needing a body scan. If an average 200 working days per year and 15 scans per day per machine are assumed, then a total of 200 CT scanners would be required. If the working day can be extended to more than *8* hours, or the number of working days per year or the number of scans per day can be increased, then the 160 CT scanners West Germany already has are enough for the country as a whole.

In applying any standards when awarding grants to States for the purchase of CT scanners in hospitals, the Ministry of Labor and Social Welfare has to take into account the need for CTS based in physicians' offices (with lower utilization), because of the separation between private practice and hospital privileges, and the geographic distribution of the equipment. Eventually, therefore, the Ministry will not only have to plan for the distribution of scanners in hospitals, but it will have to look at the availability of all CT equipment.

When CT scanners were initially introduced in West Germany 3 to 4 years ago, they were produced only by EMI, the British firm that first developed the equipment. At present, many other firms are in the market, such as Siemens (a West German firm), General Electric, and CHF Muller. The peak in sales seems to have been reached, unless better and less expensive equipment can be developed and new applications can be found. Because of the training requirements, technical manpower may contribute to a temporary bottleneck in terms of further expansion of CT scanning.

CT scanning is a new medical technology which has been singularly well studied in West Germany within 3 years of its first being used. Such study is quite unusual and may signal a complete change in how West Germany will examine new medical technologies. The Ministry of Labor and Social Welfare believes that CT scanners constitute more than 1 percent of all capital expenditures in hospitals, however, and it is possible that CT is an atypical new technology.

Renal Dialysis[8]

Renal dialysis was introduced on a large scale in West Germany relatively late, in comparison to the United States, and when one considers that Dr. Willem Kolff built the first kidney dialysis machine in Holland in the early *1940's.* The year 1960 was a landmark year in the history of dialysis because it was then that the "Scribner shunt" made long-term dialysis possible. Although that year also seemed to mark a turning point in the accessibility of this new therapy, however, dialysis was still relatively scarce in West Germany until the late 1960's.

Manufacturers of dialysis equipment through the European Dialysis and Transplant Association jointly purchase a yearly survey being conducted in all of Europe by a London firm, which provides up-to-date information on patients, centers, and types of equipment used. According to information from one of the largest manufacturers of dialysis equipment in West Germany, end-stage renal disease (ESRD) dialysis treatment was not introduced on a large scale until 1968. Up to 1970, waiting lists in West Germany were long. By 1973, however, patients could enter treatment without having to wait for a treatment place.

At the end of *1975,* West Germany treated 5,421 patients in ESRD dialysis programs. (The estimated population in ESRD dialysis programs in 1976 was 6,200 patients, and in 1978 was 7,000 patients; estimates for 1985 are between 12,500 and 13,500 patients.) In 1975, compared to other European countries, West Germany was in the middle in terms of number of patients on ESRD treatment per million population, with 87.7 patients per 1 million popula-

[8] "The data and information for this case were gathered with the help and from the files of one of the largest manufacturers of dialysis equipment in West Germany. The data were collected in surveys sponsored by a manufacturer. Additional information for the case was provided by a consulting firm and a consortium providing dialysis services.

tion. (In the same year, the comparable rate for Switzerland was 136.1 patients per million population; for Sweden, 85.4; and for Great Britain, 62.0. The comparable rate in the United States in 1975 was 95.2.) In 1975, 5,056 West German ESRD patients, the vast majority, were on hemodialysis, and 66 patients were on peritoneal dialysis.[9]

Dialysis is provided as one of the benefits of sickness funds. Centers and hospitals are reimbursed on the basis of cost per dialysis session, and the rates of dialysis include the costs of equipment and supplies. In 1976, about 70 percent of all West German ESRD patients were dialyzed in limited-care centers (33 centers), hospitals and clinics (181), or physicians' offices. At the end of 1975, there were 195 limited-care centers in West Germany; at the beginning of 1979, there were 220 centers with between 2,500 and 3,000 dialysis machines.

In 1975, 30 percent of all ESRD patients in West Germany were on home dialysis, compared to 19 percent of all European ESRD patients. The largest West German home dialysis center (Kuratorium für Heimdialyse, Neu-Isenburg) had 1,215 home dialysis patients in 1975 and was training 208 more. The emphasis on home dialysis in West Germany, beginning in the early 1970's, can be traced to policy decisions by sickness funds to pay for dialysis in home settings at cost, just as they pay for dialysis in freestanding or hospital-associated dialysis centers.[10] The decision to support home dialyis as much as center dialysis has not only proven to be of social value to the patient, but has also saved money. In 1976, the sickness funds paid DM 340 to DM 350 ($179 to $184) for each home dialysis session and DM 600 ($316) for a dialysis session in a hospital. This amounted to DM 50,000 to DM 60,000 ($26,31 to $31,579) per year for home dialysis and DM 90,000 to DM 100,000 ($47,368 to $52,631) for dialysis in a hospital. Dialysis in limited-care centers lies between home and hospital dialysis in terms of reimbursement rates. These centers are expected to become very successful in the more populated areas of the country.

In 1975, ESRD patients in West Germany were far less likely to receive a kidney transplant (4.8 percent of all patients with ESRD) than patients in the United States (31.7 percent), Australia (64.5 percent), Switzerland (47.7 percent), or Sweden (40.6 percent). At a one-time cost of DM 30,000 ($15,789), and providing that rejection rates are low, transplants are considered both by the government and by potential kidney transplant patients as an attractive alternative to dialysis. One problem in West Germany, however, is a serious shortage of donor kidneys. Of 19,000 fatal accidents, only 100 permit the donation of kidneys. Thus, in 1976, only 273 transplants in 24 centers were performed (an increase from 228 transplants in 1975). Eight hundred persons were on waiting lists for transplants. Only 10 percent of the 2,000 patients who could benefit from a kidney transplant get a donor kidney each year. West Germany belongs to the Eurotransplant Center in Leiden and also has been debating a law since 1977 which would facilitate donating kidneys.

States license dialysis centers. There is at present no contiguous planning by the Federal Government to coordinate the planning decisions of the States in this area. Furthermore, no certificate of need is required in order to establish a dialysis center. The distribution of dialysis stations depends on the demand by physicians of dialysis for their patients. Since each patient is covered for this service, private physicians, nonprofit kidney centers, public and religious organizations, as well as hospitals, all have established services. As in the United States, the startup capital may be provided by a voluntary organization, or may be borrowed from a bank. An implicit belief in West Germany is that the dialysis market will regulate itself and that an optimal distribution of centers will result.

There is no State regulation of dialysis equipment. New dialysis processes are quickly available, since equipment is either imported or produced within the country by a West German

[9]Hemofiltration, a new process that requires no dialysate which has been developed for the past 10 years by Professor Quellhorst at the University of Tubingen, has been used on an experimental basis only.

[10]This policy of the sickness funds in West Germany is somewhat in contrast to the policy of medicare in the United States. In the past, medicare has not reimbursed as fully for home dialysis as for center dialysis.

firm under license. Although major changes in the dialysis process are infrequently developed within the country, West German manufacturers and physicians are very aware of research in other countries and will try a new process almost as soon as it becomes available. New models are introduced by manufacturers, tested in a few centers, and then demonstrated at fairs and by salesmen. Equipment manufacturers often use the evaluations of "expert" users to sell equipment to other centers. In addition, they often develop new equipment jointly with physicians in a dialysis center or teaching hospital. Since there is no real financial restriction on the purchase of new equipment, nonprofit organizations have a strong incentive to get the latest equipment for their centers. The Federal or State government does not approve the production process and evaluate the safety and efficacy of equipment, as the U.S. Food and Drug Administration does under the 1976 medical devices legislation and the good manufacturing practices requirements. There is discussion, however, of having periodic testing of equipment, analogous to the rigorous annual testing of automobiles.

Dialyzers, monitors, pumps, and supplies produced in West Germany and other countries are used. Three types of dialyzers are being used: coil dialyzers, plate parallel flow, and hollow fiber parallel flow. The coil dialyzer is being phased out; the hollow fiber one is the newest. Much of the dialysis equipment, especially the dialyzers, is imported from the United States. Plate dialyzers are also imported from Sweden (Gambro), Japan (Cobe), and France (Rhone-Poulenc). Cuprophan, the most common membrane for dialyzers worldwide, is made by a West German firm (Bemberg, a subsidiary of Enka) in Wuppertal.

As noted in the previous section of this chapter, the Federal Government supports several institutions that carry out research that benefits society but may be too expensive to be undertaken by any one institution. In its 1978-81 program to support R&D, the Federal Government named as one objective the further development of transplant and dialysis technology. This is the first instance in which a concerted effort is being mounted to develop new technology in this area under government sponsorship.

In summary, the diffusion of new ESRD technology in West Germany is left to market mechanisms. Funding for each dialysis session leaves room for independent organizations or entrepreneurs to enter the market and to determine whether they can attract enough patients to break even. If in the future the sickness funds should determine that controls are necessary, the controls can be exercised through the reimbursement contracts the sickness funds develop with dialysis centers. The only other way in which the government may affect this market in the near future may be through a requirement to have periodic inspections of all equipment.

Coronary Bypass Surgery

Open-heart surgery has been performed on a large scale in West Germany for the past 5 to 6 years. Coronary bypass surgery is performed mostly at seven centers which are affiliated with medical schools. Since there are virtually no restrictions on what operations can be performed by surgeons, the only restrictions on coronary surgery are those on the equipment a hospital can acquire. The equipment for coronary bypass surgery has a short lifespan, so it has to be financed via the per diem rate paid to hospitals by the sickness funds. Only the large hospitals with tertiary services are paid a high enough rate to finance this equipment.

The sickness funds are comparing the costs of open-heart surgery in various settings. In the State Nordrhein/Westfalen, a coronary bypass operation costs DM 50,000 ($26,316) in Dusseldorf, but far less elsewhere. The sickness funds hope to negotiate the reimbursement for such operations with hospitals in that State, If no agreement can be reached, and if the State's Minister of Finance cannot act as mediator, it is anticipated that the funds may take court action. Similar developments can be expected in other States.

There have been no evaluations of rates of complications from this surgery or cost-benefit analyses, such as have been seen in the United States, but the results of analyses carried out elsewhere are being publicized and used by physicians at their discretion. The 1,000 to 1,500 pa-

tients who are waiting for this operation constitute an enormous political pressure group.

Cobalt Therapy

Cobalt therapy has become increasingly available in the past 10 to 15 years. Operating and capital funds have come from the per diem reimbursement provided to hospitals by the sickness funds, or from the sponsors of individual hospitals (community, private, etc.). At university teaching hospitals, which are well funded by the Federal Ministry of Education, the funds have come out of the general budget.

Little information about the distribution and utilization of radiation therapy equipment is available. The Government of Bavaria, for example, knows where such equipment is located only if the equipment is in a newly constructed facility that has been federally financed. One of the largest cancer treatment services in the country is at the City Hospital for Women in Nuremberg, which uses approximately 45 percent of its capacity (or 115 beds) for cancer patients. Since its establishment 12 years ago, it has treated 5,000 women, and this year is accepting approximately 400 new patients.

As long-term capital investment, cobalt and other radiation therapy equipment is paid for completely by the Federal Government. The sickness funds and the Federal Government have been encouraging hospitals to form consortia that share radiation equipment. Since the equipment is becoming more expensive and complex, further efforts to encourage this are likely to be made.

"Needs" for the equipment have not been projected. In one case, a State Ministry decided not to approve an application for a cobalt therapy unit, so the community and the hospital decided to carry out a fundraising campaign, and through this they were able to finance the purchase. The local sickness funds felt that they had no choice politically but to pay the higher per diem that resulted.

Cobalt therapy equipment is being checked for safety only by the Board of Trade Regulation (Gewerbeaufsicht), a branch of the Department of Commerce, which also checks equipment used in the operation of businesses and other public institutions.

Clinical Laboratory Testing and Automation

In 1975, approximately 1.3 billion laboratory tests were carried out in West Germany. Of these, 500 million tests were done in acute general hospitals, 105 million were done in specialty hospitals, and 530 million were done in physician practices (4). Physicians own roughly 90 percent of the country's 45,000 laboratories. Only a very small proportion of these laboratories are central, large-scale commercial labs or diagnostic centers (13).

For the past 20 years, the volume of laboratory tests has increased by about 20 percent per year. Similar trends are predicted for the future. Since all diagnostic tests are fully covered by the sickness funds, there is no disincentive to use on the part of the patient. In addition, the Federal Government has actively promoted "preventive screening programs" for cancer of the breast, uterus, cervix, prostrate, and colon. These programs, based in physician offices, have also contributed to the high volume of tests.

One might expect that the large volume of laboratory tests and a continued lack of qualified personnel in West Germany would precipitate automation of laboratory testing. Since physicians provide the lion's share of ambulatory services, however, most laboratory tests are still carried out in nonautomated, small-scale laboratories in physicians' offices.

In discussions with economists at consulting firms, with the Ministers of Labor and Technology, and with manufacturers of equipment, no clearcut process of the diffusion of automated equipment emerged. Further complicating research into this topic was the almost complete lack of data on specific equipment, and the fiercely competitive market in this area in West Germany. The information that emerged from the discussions was that multichannel analyzers were introduced on a large scale around 1973-74 and that analyzers produced by U.S. firms and by Coulter (U. K.) dominate the market. The total number of automated analyzers in 1974,

according to one source, **was 1,200.** With 300 analyzers that year, Technicon seemed to dominate the clinical chemistry market for automated enzyme analyzers and other similar automated equipment. Lack of centralization of laboratories was given as the major reason for the comparatively slow diffusion of automated equipment.

Laboratory equipment in hospitals is financed via the per diem allowance which hospitals get from the sickness funds. In physicians' offices, laboratory tests are billed for separately from physicians' services. From a purely financial point of view, therefore, there has been little incentive to consolidate laboratory services. Many obstacles would have to be overcome in order for hospital-based physicians and physicians in private practice to agree in principle to share laboratory services. Not surprisingly, one central laboratory has been hailed as exemplary (15). This, the so-called Lemgo model, is a cooperative laboratory that a general acute hospital with 634 beds founded in 1972 to be able to utilize multichannel analyzers in a cost-effective way.

Although there is much discussion of automated laboratory testing in West Germany, very little quantitative information seems to be available.11 This is one reason why cost-effectiveness studies in this area are not very common. [12] In sum although the planning, utilization, and financing of automated laboratory equipment is an area that generates much discussion in West Germany, it is relatively unexplored and unregulated.

[11]One exception is a report by the Ministry for Research and Technology on automating cancer screening laboratory tests, which I was told about, but could not obtain: Bundesministerium fur Forschung und Technologie (Ministry for Research and Technology), "Einsatzmoglichkeiten Automatisierter Diagnose auf dem Gebiet der Krebsfruherkennung bei frauen in der BRD," Bonn, 1978 or 1979.

[12]The only study I saw in the literature was H. A. Michael, et al., "Kosten und Investitionsplanung im Medizinischen Labor," 1978 (11). This study discussed how to furnish a laboratory, but was not concerned with single laboratory tests.

CONCLUDING REMARKS

Medical technology is easily obtained by West German physicians' offices and by teaching hospitals, because there are virtually no financial constraints or planning guidelines to limit the acquisition of new equipment. As much as 90 percent of all medical technology originates at West German medical schools, but the diffusion from university hospitals to community hospitals and private offices is rapid. Physicians who move from a university hospital to a community hospital often want the same equipment they had in the teaching hospital, and some physicians acquire new technology which they see at meetings or read about in the medical literature. Even where there are some constraints on the diffusion of new medical technology, for example, in community hospitals, political considerations still seem to outweigh the planning criteria that have been discussed and are being established at the State and Federal levels.

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