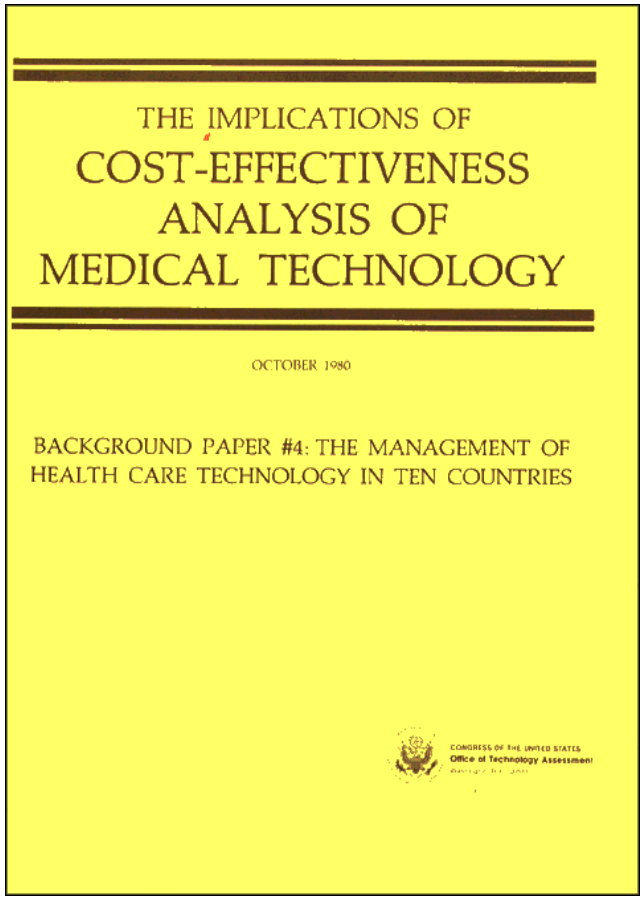
The Management of Health Care Technology in Ten Countries

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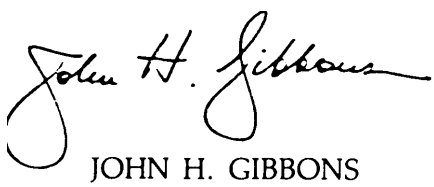
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Foreword

This report was developed as part of OTA'S study on the use of cost-effectiveness analysis to evaluate medical technologies. Recognizing a common international concern about the costs and benefits of medical technologies, OTA commissioned papers describing the health care systems of nine countries and the mechanisms these countries use for managing the diffusion and use of medical technologies. Whenever possible, the authors included data on five specific medical technologies: the computed tomography scanner, renal dialysis, coronary bypass surgery, cobalt therapy, and automated clinical laboratory services. Equivalent information for the United States is presented and compared to that for the nine other countries in the summary and analysis (ch. 11), which was prepared by OTA staff and Louise Russell, Ph. D., of The Brookings Institution.

Initial drafts of the nine papers on the management of medical technologies in other countries were reviewed by Dr. Russell and OTA staff. Helpful comments were also provided by Henry Aaron, Ph. D., of The Brookings Institution. On November 1, 1979, most of the authors met for a l-day workshop in Washington, D. C., to discuss their papers and the implications of their findings. In the following weeks, they completed their revisions. Helpful comments on the Japan paper were given to OTA by Dr. John Bowers of the Macy Foundation and Professor Daizo Ushiba of the International Medical Information Center, Tokyo. Dr. Irv Asher of the Food and Drug Administration furnished specific information on drug and device regulation in several countries, and Dr. Peter Frommer of the National Heart, Lung, and Blood Institute provided helpful comments on coronary bypass surgery. A draft of the entire volume was reviewed by two OTA advisory bodies: the Health Program Advisory Committee and the Advisory Panel on the Implications of Cost-Effectiveness Analysis of Medical Technology. OTA is grateful for the many contributions of all these individuals.

As a background study, this volume does not include policy options. It should be noted that since international literature in the area of evaluating and managing medical technologies is sparse, firm conclusions are difficult to reach—only a few conclusions are stated in chapter 11. The many different approaches to medical technology in other countries do offer a fruitful testing ground for new ideas, however, and OTA hopes that this report will stimulate further activity, including comparative research.



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Introduction;

RISING MEDICAL CARE EXPENDITURES

The rapidly escalating costs of medical care have become an important political issue in a number of countries. In the United States, the costs have been rising at the rate of 10 to 15 percent annually for the last 10 years. As shown in table 1, other industrialized countries have experienced rises as rapid or even more rapid. Between 1967 and 1976, for example, annual health expenditures rose 18.4 percent in the Netherlands, 20.5 percent in Australia, and 1.7 percent in West Germany (3). What accounts for these rapidly rising costs? It appears that one contributing factor is medical technology.

Economists have estimated that new resources account for up to half of the rise in the cost of hospital care in the United States (2). Clearly, substantial amounts of the new resources are being used to provide new medical technologies. Some new technologies provide no benefit for the patient.[1] That finding, apart from stimulating interest in the scientific evaluation of the efficacy and safety of medical technologies, has raised the hope among some that the rapid rate of growth in health expenditures can be stemmed simply by eliminating technologies and services that do not provide any benefit. Unfortunately, however, this is not an adequate solution to the problem of rising costs. The reason is that most new technologies do appear to have at least some benefit, however small or costly. Examples of technologies that fall into this category are "halfway" technologies such as organ transplantation, artificial organs, many cancer therapies, and current treatment for coronary artery disease (11).

Since the growth of resources used for medical care, over and above the effects of economywide inflation, is the primary reason for rapidly rising costs, nations seeking to control health care costs must effectively control the growth and/or use of new resources. Inevitably, this effort will involve them in controlling the processes by which technologies are developed, evaluated, adopted, and used. And fundamentally, this means that they will be forced to choose among beneficial technologies, providing some to the fullest extent, others to a limited extent, and still others not at all.

[1] An example is gastric freezing for peptic ulcers (4).

Table 1.—Annual Percentage Increase in the Consumer Price Index (CPI) and Health Care Expenditures in Eight Industrialized Countries (1960-76)

	Percentage increase			
	1970-76		1969-76	
Country[a]	CPI	Health care expenditures	CPI	Health care expenditures
Australia	5.62	14.15	9.87	20.46
The Netherlands	5.80	17.35	7.94	18.37
United Kingdom	7.63	13.00	13.77	18.15
West Germany	3.81	14.45	5.78	17.74
France[b]	3.81	14.45	5.78	17.74
Sweden[c]	6.21	14.42	7.82	14.63
Canada	4.46	12.18	6.76	14.29
United States	4.21	10.86	6.52	12.64

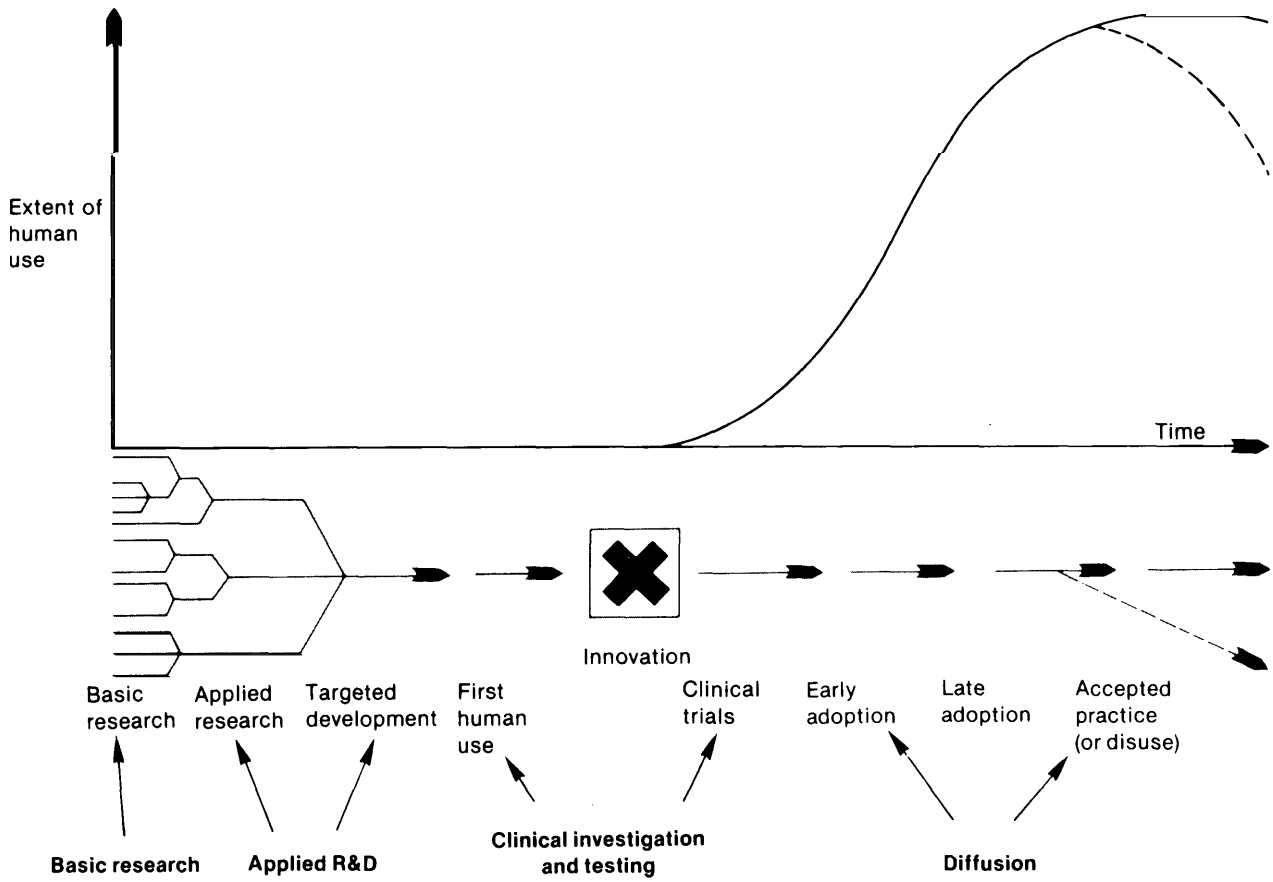
[a] Ranked by 1969-76 health care expenditures.
[b] Data for 1960-75 and 1969-75.
[c] Data for 1965-75 and 1969-75.

SOURCE: J. G. Simanis, and J. R. Coleman, "Health Care Expenditures in Nine Industrialized Countries, 1960-1976," *Social Security Bulletin* 43:3, 1980 (10).

THE DIFFUSION OF MEDICAL TECHNOLOGIES

Public intervention to control the diffusion and use of specific technologies is likely to be related to one or another of the four theoretical stages in the process of development and diffusion of medical technologies shown in figure 1. The first stage, *basic research,* produces new knowledge about the biological mechanisms underlying the normal functioning of the human body and its malfunction in disease ***(6).*** In the second stage, *applied R&D,* this basic information is used to create new solutions to problems in the prevention, treatment, or cure of disease. The next stage, *clinical investigation and testing,* involves the testing of new medical technologies in human subjects. This stage encompasses a range of activities from first human use to large-scale clinical trials and demonstration projects to demonstrate efficacy and safety (s). Efficacy is the benefit from use of a technology; safety is a measure of the risk of a technology. Finally, as a new technology appears to be of value, clinicians begin to use it and patients begin to ask for it. As more and more physicians use the technology on more and more patients, the extent of its use increases. This is the process of *diffusion,* Diffusion may end with the technology's attainment of an appropriate level of use. Alternatively, it may end with the technology's being abandoned, either because it was of no value or because a more effective technology

Figure 1.—Stages in the Development and Diffusion of Medical Technologies



SOURCE. Office of Technology Assessment, U S Congress, *Development of Medical* Technology *Opportunities for Assessment* (Washington, D C U S Government Printing Office, 1976) (6)

has been developed, or with its being used too much or too little.

The model sequence depicted in figure 1 is attractive because it offers a way to understand the process of development and diffusion of medical technologies such as drugs, devices, and procedures. In reality, however, medical technologies emerge from a process that is far less systematic than the model implies. In the ideal model of diffusion, for example, scientific evaluation of efficacy and safety is an integral part of the diffusion process. In the real world of medical care and health care policy, however, such evaluation is often not done (5). Epidemiological and statistical methods have been developed to measure scientifically the benefits and risks of a technology under controlled conditions. Increasingly, these methods, and especially the controlled clinical trial, have been proposed as the basis for decisions concerning medical technology.

DESCRIPTION OF THIS VOLUME

All industrialized countries have begun to experiment with the kinds of mechanisms that will be necessary to effect changes in development, diffusion, and use of medical technologies. The general and specific public policies that affect the development and diffusion of medical technologies in nine industrialized countries are discussed in chapters 2 through 10 of this volume: the United Kingdom (ch. 2), Canada (ch. 3), Australia (ch. 4), Japan (ch. 5), France (ch. 6), West Germany (ch. 7), the Netherlands (ch. 8), Iceland (ch. ***9),*** and Sweden (ch. 10). In chapter 11, U.S. policies pertaining to the development and diffusion of medical technologies are compared to the policies of the other nine countries. Also compared are the United States' and other countries' experience with five specific technologies: 1) computed tomography scanners,2) renal dialysis, 3) coronary bypass surgery, 4) cobalt therapy, and 5) automated clinical laboratories.

Generally, each chapter begins with an introductory section in which the author briefly describes the country's form of government and economy. Following this is a section in which the country's medical care system is discussed. In the third section of each chapter, the country's policies concerning the R&D, evaluation, and regulation of medical technologies are examined. Along with institutions for biomedical research, government funding of research, and priority areas of research, government policies toward and support of the evaluation of medical technologies are discussed. Also covered are safety and efficacy regulation, health planning and related investment controls, utilization review, and both general health care financing arrangements and financing arrangements specific to technologies.

To help illustrate the application of the country's general policies, in the fourth section of each chapter the country's treatment of five specific technologies is examined. As background for the policy discussions in the remaining chapters of this volume, these five technologies are defined below, and their uses and costs briefly identified.

DESCRIPTION OF FIVE MEDICAL TECHNOLOGIES

Computed tomography (CT) scanners.—The CT scanner is a diagnostic device that combines X-ray equipment with a computer and a cathode ray tube (television-like device) to produce images of cross-sections of the human body (7). The first machines were "head scanners, " designed to produce images of abnormalities within the skull (e. g., brain tumors). These machines were developed in Britain in the late 1960's. "Body scanners" able to scan the rest of the body as well as the head have been developed more recently.

Following its development, the CT scanner was quickly hailed as the greatest advance in radiology since the discovery of X-rays. CT scanning was rapidly and enthusiastically accepted by the medical community. More recently, however, three factors—the rapid spread of CT scanners, the frequency of their use, and the expenditures associated with them—have combined to focus attention on the contribution of CT and other diagnostic medical technologies to the recent growth of medical care expenditures. The concern over expenditures has also caused decisionmakers to examine policies pertaining to other medical technologies. In ***1979,*** a CT scanner cost, on average, more than ***$500,000*** to buy and *$400,000* to *$500,000* a year to operate. That year, the United States had more than *1,200* scanners, so the cost of scanning in *1979* **was** more than *$500* million.

Renal dialysis.—Hemodialysis and renal transplantation are two life-extending therapies that were developed in the early 1960's for victims of end-stage renal disease. End-stage renal disease is a clinical condition reached when a person has such a degree of deterioration of kidney function that without treatment he or she will soon die.

Hemodialysis is the process of removing toxic waste products from the blood by means of an artificial kidney. The first dialysis machine was built in Holland in the early 1940's, but could be used only for short periods of time (6). Long-term dialysis became possible when Scribner and his colleagues developed the "Scribner shunt." This device, a semipermanent apparatus that linked an artery to a vein, could be used to connect a patient to a dialysis machine, without surgery for each session of dialysis. A patient generally requires dialysis about three times a week.

Renal transplantation is a surgical procedure whereby a healthy kidney from a living person or a person who has recently died is substituted for an individual's nonfunctioning kidney. Transplantation has become more and more reliable, but is still in a somewhat experimental stage. The recipient's body tends to reject the kidney graft, and drugs are necessary to suppress this rejection.

Concerns about the treatment of end-stage renal disease in both the United States and other countries have focused on costs. In the United States, it was estimated in 1975 that the average annual charge for dialysis received in a hospital was $30,500; $27,500 for nonhospital dialysis; $14,000 for the first year of dialysis at home, and $7,000 for successive years (8). Transplantation charges averaged about $12,000. The treatment of end-stage renal disease has been covered under the medicaid program since 1972, and cost the program $573 million in 1976. Costs in 1979 were expected to exceed $1 billion.

Coronary bypass surgery.—Coronary bypass surgery is a surgical procedure in which a graft is placed between the aorta and a coronary artery to bypass a constricted portion of the artery and thus improve oxygen supply to the heart muscle (5). The surgery is used as a treatment of coronary artery disease, a disease caused by narrowing and blocking of the arteries that supply blood to the heart. This disease is the number one cause of death in the United States. In 1975, it caused 642,719 deaths.

Coronary bypass surgery came into practice in the early *1970's.* Approximately *25,000* operations were performed in the United States in 1973, and perhaps 100,000 in 1978. In 1977, the total cost of coronary bypass surgery in the United States averaged ***$15,000*** per patient. If 100,000 operations were performed in 1978, the aggregate costs to the Nation were more than $1.5 billion.

The benefits of coronary bypass surgery for all classes of patients with coronary artery disease have not been clearly demonstrated.

Cobalt therapy.—Cobalt therapy is a form of radiation therapy (9). Radiation therapy is used almost exclusively for the treatment of cancer, either to cure it or to alleviate its symptoms. In the United States, there are approximately 300 new cases of cancer per 100,000 population each year. Including both new and previously discovered cases, 430 people per 100,000 population are treated for cancer each year.

About 70 percent of those who are treated for cancer receive radiation therapy at some point

during their illness. It is difficult to evaluate the benefits of radiation therapy. Not only is it generally used in combination with other therapies, but its benefits must be weighed against sometimes serious side effects. Furthermore, the therapeutic goal is often to alleviate rather than to cure.

In 1975, the cost of purchasing a cobalt therapy unit was about $90,000 to $125,000. Construction costs are high because of the need to shield staff and the surrounding population from dangerous radiation.

The issue with cobalt therapy, as with many other large and expensive technologies, concerns the number and distribution of units. Most experts believe that, like many expensive technologies, cobalt therapy should be centrally located to ensure access and located in a specialized medical center to permit optimal use.

Automated clinical laboratories.—The primary function of the clinical laboratory is to analyze and provide data on samples of body tissues or fluids. By correlating these data with firsthand observations and results of other tests, physicians are better able to make accurate diagnoses and to determine the proper therapy for their patients. Appropriate and reliable data from clinical laboratories are essential for current medical practice.

The automation of clinical laboratories began in the late 1950's with the marketing of the continuous-flow blood analyzer, a machine that performs multiple tests on a single sample of blood. Newer machines have improved on the original blood analyzer, and clinical laboratory functions in addition to blood analysis have since been automated. By 1972, more than 50 percent of U.S. hospitals had automated their hematology and/or chemis try laboratories.

Automating clinical laboratory functions has both lowered unit costs for laboratory tests and improved the reliability and validit, of the test results. At the same time, however, the ready availability of automated equipment has stimulated the use of laboratory tests and increased the total volume of tests performed—to such an extent, in fact, that the value of much of this testing is now in question.

In 1975, 5 billion laboratory tests were done in the United States at an estimated cost of $15 billion ***(6).*** The number of tests was increasing both for hospitalized and ambulatory patients. Between 1969 and 1976, the average number of tests provided per patient per day in the hospital rose from 2.3 to 5,0, an average annual increase of 11.1 percent (1). During the same period, the average cost per test rose by $0.22, from $1.34 to $1.56. In 1976, it was projected that the total volume of laboratory tests nationally would rise at the rate of 11 percent a year ***(6).***

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2.

The Management of Medical Technology in the United Kingdom

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2.

The Management of Medical Technology in the United Kingdom

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THE UNITED KINGDOM: COUNTRY DESCRIPTION

The United Kingdom, with a total population of ***55.5*** million ***(23),*** consists of four countries: England, Scotland, Wales, and Northern Ireland. It has a constitutional monarchy with government by a two-tier Parliament (the House of Commons and the House of Lords). All four countries are directly governed by Parliament at Westminster, though Northern Ireland has, in the past, had its own Parliament. Despite direct rule, a certain amount of power has been devolved to the separate countries, producing some differences, for example, in how the health services are managed. In recent years, both Scottish and Welsh nationalism have increased and will almost certainly lead to further devolution of power. The idea of separate assemblies for these countries, however, was rejected in a recent referendum.

The two major political parties in the United Kingdom are Labour and Conservative, although a number of other parties (e.g., the Liberals, the Scottish Nationalist Party, etc.) are represented in Parliament. Members of the House of Commons are elected democratically, with each Member representing a particular constituency. The government is formed by the party with the majority of Members of Parliament in the House. The Prime Minister is the leader of that party, and he/she forms the Cabinet from the Members of that party in the Houses of Parliament. The various government departments and ministries are headed by Secretaries of State or Ministers, a subset of whom form the Cabinet. All departments and ministries are led by individuals from the majority party in Parliament, so there is no separation of the executive and legislative branches of government.

The House of Lords is composed of hereditary peers, as well as peers appointed for life. It is the privilege of the Prime Minister to select a certain number of individuals for life peerages each year; those selected tend to be individuals who have had distinguished careers in various walks of public life. The House of Lords is of less importance than the House of Commons, but does provide a useful check on parliamentary legislation and can initiate bills itself. There is agreement from both major parties, however, that some reform of this body is due.

The economy of the United Kingdom is mixed. A number of major services and industries are nationalized (e. g., British Rail, the British Steel Corp., etc.). In many cases, these industries are managed, not directly by Parliament, but by independent corporations whose leadership, composition, and powers are laid down by Parliament. The National Health Service (NHS) is an exception in that a Secretary of State for Social Services in Parliament does head the corresponding government department, i.e., the Department of Health and Social Security (DHSS). ' In recent years, particuiar]y under Labour governments, the number of na-

'The Ministry of Health was combined with the Ministry of Social Security in *1968,* when it became DHSS.

tionalized industries has increased. In addition, where industries have particular importance to the economy, the government has stepped in to support firms in the free enterprise sector (e. g., Rolls Royce, Chrysler).

Britain's relative lack of productivity, as compared to its European, American, and Japanese competitors, has been blamed on a number of factors. The management side of industry is blamed for not modernizing its equipment and for not being willing to risk involvement in new ventures. These problems are, in turn, blamed on the government, which is said to have produced a lack of incentives for investment or for entrepreneurial activity. On the workers' side, the unions are blamed for strikes, for enforcing rigid demarcation rules, and for overmanning. There would seem to be truth in the statements that each of these factors has contributed. Nevertheless, the sum of all of these factors, not any particular one, has caused Britain's decline relative to other countries.

The problems of British industry give some insight into the attitudes towards technology. New technology is often rejected by the unions, not for itself, but because it will lead to a reduction in jobs. Management may be fearful of a confrontation with the unions or may not be willing to invest in innovations. The result is a fairly conservative attitude towards technology in Britain, despite the very high quality of science and technology research carried out in British universities and research institutions.

In discussing British attitudes towards technology, a somewhat different point should also be made. Although science and academic research in Britain are of high status, technology has for a long time been considered somewhat second rate. This attitude, perhaps, can best be exemplified by the status of engineers. Engineers in the United Kingdom do not receive the same respect as other professionals; in comparison to the status of engineers in other countries, their status is low, The large gap between the development of inventions and innovations in research institutions and their actual implementation or production by industry very likely reflects the predominant attitude toward technology.

Recently, concern over Britain's declining economy has led to a slow recognition that industry, technology, and innovation must be given increased status and more incentives. In particular, the previous Labour government took steps to ensure that Britain would not get left behind in the microprocessor revolution. Whether these steps are adequate and whether more fundamental attitudes towards technology can be changed remains to be seen.

THE HEALTH CARE SYSTEM

A national insurance system that covered the health care of most of the working population was initiated early in the century, but it was not until 1948 that Britain established its NHS. World War II changed many public attitudes and fostered the belief that a postwar social order should be created that 'would include health care as a right for all. Although the Beveridge plan for NHS was drawn up during the war, legislation creating NHS was not passed until 1946, and the Service was not finally begun until 1948. Funds for NHS come from national insurance contributions and from general taxation. All health care is provided to patients free of charge (apart from small payments for drugs, spectacles, etc.).

The basic tenets of the 1946 Act creating NHS still hold, although the Service, particularly its organization, has been modified by various laws passed since. The most major change came in 1974 with the reorganization of NHS. Until that time, hospitals had been managed by regional hospital boards responsible to DHSS and ultimately to the Secretary of State in Parliament; community care, including district nurses, school health services, etc., however, had been the responsibility of local government

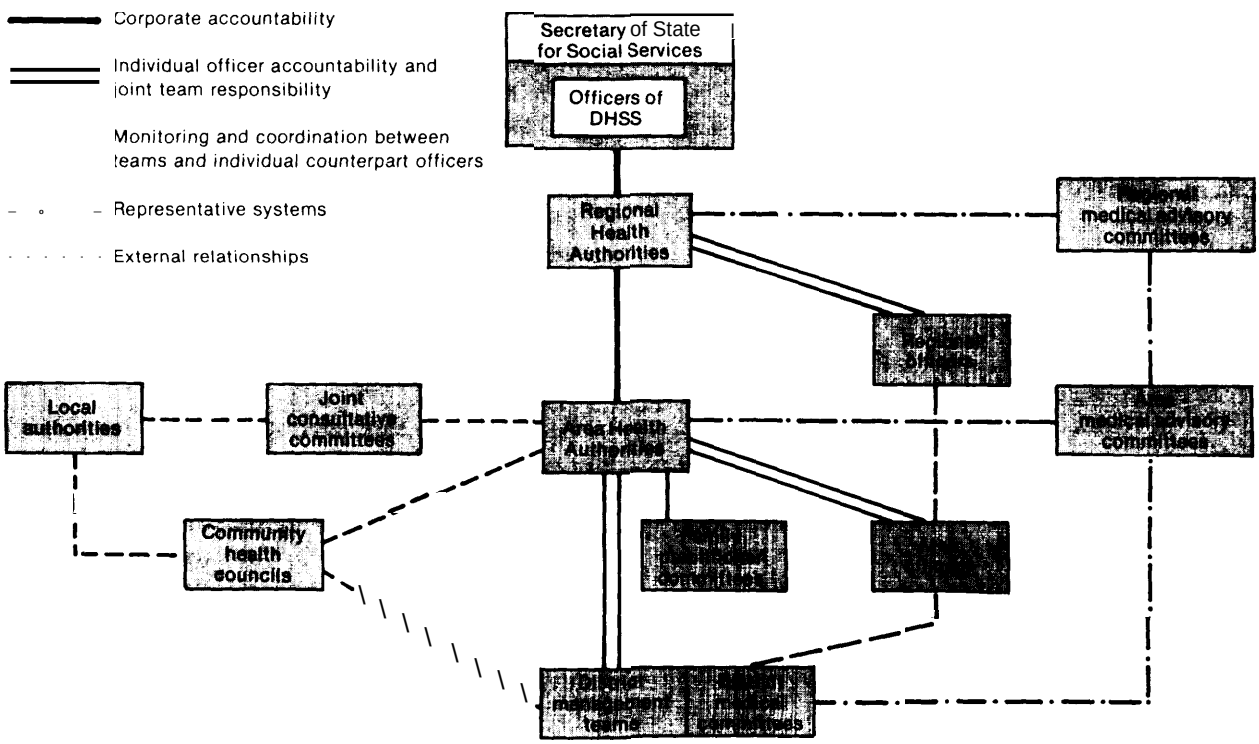
authorities. In 1974, the various facets of health care were unified under one authority.

Currently, the unified NHS in England is organized in a number of tiers. (See figure 1.) The bottom tier is the "district," serving perhaps a quarter of a million population. All hospital and community services are the responsibility of a district management team. The district is part of a larger "area" (although some areas contain only one district). The area has a team of officers who are actually employed by the Service but who are responsible to an Area Health Authority appointed by the Secretary of State for Social Services. The areas are overseen by "regions."[2] A regional team of officers carries out the day-to-day activities, but is responsible to a Regional Health Authority. Statutory authority for NHS is vested in the Area and Regional Health Authorities (all of whose members, apart from the chairmen, serve unpaid). In Scotland, although the organization of NHS is similar, there are three tiers.

One or two points need to be made about the structure of NHS. It is envisaged that actual management of health services should take place at the lower levels, with the upper levels providing a coordinating and policymaking function. There have been considerable difficulties in the Service about the role of each of the tiers, however, and there is some consensus

[2]There are 14 regions in England, The other three countries in the United Kingdom are comparable in size to an English region and are therefore organized slightly differently: Scotland has 15 Area Health Boards; Wales has 8 Area Health Authorities; Northern Ireland has 4 Health and Social Service Boards. Northern Ireland is different from the other countries in that health and social services are combined,

Figure 1.—Framework of the NHS Structure in England



SOURCE Office of Health Economics, The *Reorganised* NHS (London White Crescent Press. 1977) (19)

that there is probably one tier too many. Because much upheaval resulted from the 1974 reorganization of the Service, however, further disruption is not likely to be undertaken lightly.

Despite the position of DHSS at the top of the hierarchy, it is repeatedly pointed out that, subject to conforming with general policy, the regions and areas are free to manage NHS as they see fit, and in particular, to allocate resources according to their own judgment. Nevertheless, there is some confusion about how binding DHSS' advice is—confusion that is seen both in the purchase of medical equipment and in other activities. In one sense, DHSS is quite outside the Service in that it is the Regional and Area Health Authorities rather than the Department who actually employ NHS staff. Since DHSS holds the purse strings and distributes money to the regions, however, it obviously has considerable powers of persuasion.

According to DHSS, NHS spending for fiscal year 1979-80 (excluding central services) was 18.1 billion ($17.8 billion). ' The Office of Health Economics estimated that in calendar year *1978,* NHS expenditures were running at 5.7 percent of the gross national product (GNP).[4] Apart from government expenditure on health, an additional small but increasing amount of money is spent on private health services. There is also separate funding for biomedical research through the Medical Research Council (MRC).

How NHS funds should be distributed is a topic that has recently come in for considerable scrutiny. Concern about inequality in the provision of health services led to the setting up of the Resource Allocation Working Party (RAWP). RAWP recommended that resource allocation should not be based on existing facilities per se, since these tend to generate their own demand; instead, money should be allocated to regions on a population basis modified by various factors that might indicate the need for health care, such as standardized mortality ratios (11). The formula RAWP recommended is quite complex and has generated much controversy, not least because full implementation of the recommendations would lead to a decrease in funds for the Thames regions (which cover the whole of London) to provide for increases elsewhere. In fact, the previous Secretary of State for Social Services, in office until 1979, took more of a middle road, giving increases in funds to all regions but with the amount of growth proportional to each region's relative under- or over-provision. It remains to be seen how the present Conservative Secretary of State will handle this problem.

The resource allocation problem has highlighted the difficulties likely to be faced in the next few years. As in other developed countries, health care costs in the United Kingdom have risen (although here they have been comparatively well restrained, perhaps at the expense of the quality of the Service). Since it is clear that this situation of rising costs cannot go on indefinitely, NHS is in for a period of little or no growth. During that period, it will be hard to remove inequalities.

Finally, on NHS funding, it should be pointed out that the Health Authorities operate on a system of cash limits. Each year they must remain within these limits, though some allowance is made subsequently for inflation. Major salary increases negotiated at the national level and taking effect in the budget year in progress make it difficult for Authorities to plan their budgets to remain within these limits. In some cases, this difficulty has led Authorities to underspend during the year, and then at the end of the year to use their surplus funds for major purchases such as medical equipment.

To complete this section, a brief summary should be given of some of the other descriptors of NHS. Unfortunately, in government documents, some figures are given for England and Wales, some for Great Britain (which includes Scotland but not Northern Ireland), and some for the United Kingdom (including all four countries). This should be kept in mind when reading this section.[5] In 1976, there were

[3]For conversion of British pounds to U.S. dollars, the exchange rate used throughout this paper was £1 (British) = $2.20 (U.S.).

[4]Based on an estimated GNP of £1,286 billion ($3,049.2 billion).

[5]The information in this section is taken from two publications of DHSS, Annual *Report 1977 (4)* and *Health* and *Personal Social Services for England (s).*

479,359 hospital beds in Great Britain, of which about *300,000* were nonpsychiatric and the rest psychiatric beds.

The latest figures available on staff are for 1975, when a total work force of 914,068 was given for Great Britain, with something under half of this total being nursing and midwifery staff. For 1976, a full-time equivalent figure of 37,257 medical staff was given for hospital and community services. General practitioners (GPs), who provide the bulk of medical staff in the community, are not included in this figure, since they are not NHS employees but work on contract to the Service through family practitioner committees. (See figure 1.) Since GPs act as the front line for much of the Service and are responsible for referrals to hospitals, consultants, etc., they play a major role in Britain. There were 26,418 GPs in Great Britain in 1976.

To give some idea of the utilization of NHS, some figures for 1977 can be cited. In England, 5.3 million inpatients were treated in the country's approximately 376,000 hospital beds. The average length of stay was *20.9* days, but reduces to 9.2 days if pyschiatric, geriatric, and younger disabled units are excluded. The total attendancies of outpatients at consultant clinics was 33 million, not including accident and emergency departments, and there are also active day patient programs in psychiatric and geriatric units. On the average, a patient visits his or her GP three times a year.

MECHANISMS FOR MANAGING MEDICAL TECHNOLOGY

Research, Development, and Evaluation

In Britain, much technological innovation in medicine has stemmed from university and medical school research, particularly in bioengineering or medical physics departments. The pharmaceutical industries have always undertaken their own research, but the medical equipment industries have tended to develop inventions and ideas from academia. As more medical industries, particularly those in diagnostic equipment, are setting up their own research laboratories, however, this situation may be changing.

Funds for research in academia may come from a variety of sources—from university overheads, from government-funded research councils, and quite commonly in the medical field, from a number of trusts and foundations. At the development stage, a number of routes can be taken: The invention may be taken up by industry; the National Research and Development Corporation may provide funds for development work or may find a suitable firm to take up the idea; *or* DHSS, through its Scientific and Technical Branch, may provide "pump-priming" funds for inventions which it feels may be especially useful to NHS.

The processes for the evaluation of medical technology are generally more haphazard. For new drugs, however, a rigorous code of practice is followed. Trials of new drugs are usually sponsored by the drug manufacturer after animal trials have been completed and found acceptable by the Committee on Safety of Medicines. The clinical trials tend to take place in the NHS setting, although doctors are not paid for their involvement. Before a drug may be marketed, approval by the Committee on Safety of Medicines is required.

There are no formal procedures for the evaluation of medical devices. Two agencies, however, do exert some oversight: 1) the Scientific and Technical Branch of DHSS, and 2) MRC. MRC is responsible for most of the clinical trials of new procedures in the United Kingdom (apart from trials sponsored by pharmaceutical manufacturers). MRC has a well-earned reputation for the quality of its clinical trials, but does not evaluate all new procedures and treatments. Evaluation of a particular procedure or piece of equipment may be suggested by the committees, units, *or* council of MRC, may be suggested independently by a particular researcher in a grant application, or may be requested by DHSS. How many of these triaIs actually take

place depends on their importance in comparison to other uses of MRC funds; there is no fixed budget for clinical trials. Britain is in a very favorable position for carrying out clinical trials, however, because the costs of patient care (including salaries of staff, etc.) are already being borne by NHS. The actual costs of a clinical trial, then, are low, "particularly in comparison to the costs of trials in the United States. MRC tends to emphasize randomized trials of new or existing treatments rather than the evaluation of diagnostic or other procedures, or on medical equipment more generally.

The Scientific and Technical Branch of DHSS exerts a more general overview of the field than MRC. The evaluation activities of this branch tend to focus on the safety of equipment and its performance and reliability in clinical settings. Although the branch may provide funds for purchase of machines to be tested in the clinical environment, it is not involved in randomized clinical trials. It may suggest to MRC, however, that such trials are needed.

Thus, clinical performance, and to some extent clinical trials, of medical technology are the major facets of evaluation in Britain. There is virtually no emphasis on evaluating the more general social and economic impacts of innovations. Any such work that does take place probably arises independently in universities around the country, although it may be supported by DHSS-controlled research funds or perhaps by the Social Science Research Council.

The Purchase of Equipment[6]

The structure of NHS was discussed earlier, but it perhaps needs to be reiterated here that it is Regional and Area Health Authorities who decide how money should be spent, and it is up to them to decide what equipment is needed and which make should be purchased.[7] Thus, although there is a nationalized health service in Britain, there is much more scope for variability than one might at first suspect. Consequently, too, the introduction and diffusion of medical technology are not so well managed as might be thought.

The main reason that Britain has not had the pressures for more control which are in evidence in the United States is not so much that technologies are well managed as that NHS budgets are very tight and there are many competing claims on a Health Authority's funds. Through the NHS budgetary system, Britain has had some protection from the cost explosion of new technologies seen in other countries.

The controls over medical equipment purchasing are quite variable in NHS. Some equipment (e. g., X-ray apparatus, renal dialysis machines, and automated laboratory equipment) is purchased under central contracting arrangements. DHSS—again Scientific and Technical Branch or its counterpart in Wales, Scotland, or Northern Ireland—negotiates contracts with the supplying firms, and this equipment is produced to DHSS specifications and evaluated. Since DHSS does not directly place orders for equipment, however, there is no guarantee to a manufacturer that its equipment will be purchased by Health Authorities. Purchase will depend on whether an Authority decides it needs new equipment, and even if an Authority decides that it does, it may buy from another manufacturer (although the fact that the equipment has been built to certain standards and specifications is an incentive to use the firm with the DHSS contract).

Even within the central contracting arrangements, there is some variability according to the type of equipment. Orders for X-ray and radiotherapy equipment are placed through DHSS. With other equipment, such as automatic analyzers, the central contracting is for a base price, and individual Authorities negotiate with and purchase equipment from the firms directly. There have been complaints about the central contracting arrangements both from manufacturers, who have no guarantee of a number of sales and yet are selling at prices favorable to NHS, and from Health Authorities, who would like more freedom to negotiate with firms.

[6] "Much of the information in this section was taken from "Medical and Scientific Equipment in the NHS, " *Brit, Meal, J. 1(6120):* 1160, *1978 (16).*

[7] This is apart from the small amount of equipment purchased directly by DHSS for evaluation.

Apart from the central contracting arrangements, supplies, including medical equipment, are in the hands of the Health Authorities themselves. The cheaper equipment (under 15,000 ($11,000)) comes out of revenue expenditure and is handled through hospital budgets. If it costs more than 5,000, equipment is considered a capital expenditure and may be handled in a variety of ways depending on the area or regional policy. In some regions, a budget is set aside for equipment and there are committees set up at the regional level to decide on equipment (e.g., for radiology, for pathology, etc.). This system may have advantages in that the supply of equipment is rationalized throughout the region and the actual purchase decided on by specialists who understand the highly complex machinery.

In other regions, there may be no special budget for equipment; instead, areas may be allowed to decide how much of their minor capital allowance to spend on it. Devolving the decision downwards in this way has the advantage that money is not automatically spent on equipment, i.e., without comparison of that need to other needs for capital. On the other hand, the region may lose out on discounts for bulk buying and there may be other problems such as duplication of equipment. It should be pointed out that requests for equipment in these various systems tend to originate with clinicians; whether requests are successful will depend to some extent on clinicians' ability to argue their case in the face of other competing claims on resources.

Clearly, there is great variability in how NHS handles the purchase of medical technology. The general question of supplies for NHS, of which medical equipment is one facet, has been under examination recently by the Salmon Working Party. There is agreement that all is not well with the current mechanisms, and the working party recommended setting up a Supply Council to set policy, including policy for the evaluation of medical equipment (6). How far the working party's recommendations are implemented and how they will affect NHS await to be seen under the new government.

Planning

To complete this section on medical technology management, something must be said about the NHS planning system. Since the *1974* reorganization of NHS, a highly complex planning system has been initiated. Under this planning system, the lowest tier (i.e., the district) prepares a 3-year operational plan which is passed up to the higher tiers and incorporated (with appropriate discussion and modification) into the higher tiers' larger operational plan. In addition, areas prepare 10-year strategic plans which are incorporated into regional strategic plans. These strategic plans are revised every 4 years. In theory, by a process of passing down information about policy from the top and receiving these plans upwards from the bottom, it is hoped that a region, and ultimately DHSS and the Secretary of State for Social Services, can guide NHS in appropriate directions. Although this planning system is in its early stages and is having teething troubles, it is necessary to mention it, particularly in the context of capital expenditure. Since capital will form an important part of a regional strategy for modifying its service provision, it should be through these plans that modifications of capital stock are approved.

Capital budgets are allocated to regions in a way similar to that described for resource allocation of revenue costs (i. e., the RAWP formula discussed above) (11). Although regions— and also areas, if decisionmaking is devolved downwards—are free to decide on how capital funds should be spent, it is likely that major capital developments (e.g., new hospitals) will have been thoroughly discussed with DHSS and approved by the Secretary of State. As an interesting aside, it is noteworthy that hospital bed closures cannot be made without the approval of community health councils, the community "watchdogs" of NHS. When these councils and a Health Authority disagree, the final decision is made by the Secretary of State.

SPECIFIC TECHNOLOGIES

CT Scanners[9]

In 1967, G. N. Hounsfield, working on pattern recognition studies at British manufacturer EMI's central research laboratory, built a crude scanning device which produced pictures of inanimate objects. Although similar devices had been produced by others, particularly, W. H. Oldendorf and A. M. Cormack in the United States, their ideas had not been taken up by industry. It was Hounsfield's success in persuading EMI of the medical importance of his invention which led to the manufacture of the first computed tomographic (CT) scanner.

DHSS was involved from a very early stage. EMI approached DHSS about the usefulness of Hounsfield's idea, and as a result, DHSS provided funds for the first prototype brain scanner. The Department also arranged in 1971 for this scanner's clinical evaluation at Atkinson Morley's Hospital in London (1). During *1973,* two additional first-production machines were purchased out of the Department's R&D funds and sited in well-known hospitals. Subsequently, DHSS purchased three more machines for further evaluation.

Early on, it became obvious that CT brain scanning was a remarkable breakthrough. The results of evaluation studies furnished to DHSS in *1976* by the six institutions with scanners led to the Department's recommendation that each region purchase at least one brain scanner. By August 1978, 33 brain scanners had been installed or were on order in England and Wales. The number did not increase greatly thereafter, because of Authorities' tendency to buy body scanners for both brain and body purposes. By January 1, 1979, there were 39 head scanners, and 1 more was added during 1979.

Meanwhile, EMI had succeeded in decreasing the scan time from 5 minutes to about *20 seconds,* thereby making body scanning a possibility. DHSS was much less involved with the development of body scanners, and EMI provided its own funds for the first prototype. This machine was installed in Northwick Park Hospital in 1975. Although DHSS did not take part in the evaluation of the machine, it did advise Health Authorities to be cautious about purchasing scanners until the evaluation was further advanced.

In fact, events overtook the evaluation. With resistance to purchase of body scanners in official channels, other sources of funds for such scanners were apparently sought. In a number of areas, various philanthropists donated scanners to NHS; in other areas, appeals were set up to raise the necessary funds. Table 1 shows the

Table 1.—CT Body Scanners Installed or on Order in the United Kingdom (October 1979)a

Location	Source of funds for machine
England and Wales	
Northwick Park	DHSS
Brighton	Donor
Manchester (Medical School)	University and NHSb
Birmingham	Donor
Bristol	Donor agency
Royal Marsden, Sutton	Cancer research campaign and additional sources
London (St. Thomas')	Endowment funds
London (University College)	Donor
London (St. Bartholomew's)	Endowment funds
London (Middlesex)	Endowment funds
Leeds	Appeal
Conventry	Appeal
London (National Hospital)	DHSS, donors, and additional sources
London (Great Ormond St.)	Appeal
London (Charing Cross)	Donor
Manchester (Christie)	Appeal
Guild ford	DHSS and NHS
Scotland	
Edinburgh	NHS
Glasgow	NHS
Northern Ireland	
Belfast	NHS
Outside NHS	
BUPA	Donor
Midhurst	Donor

[a]This table first appeared in *New Scientist,* London, the weekly review of science and technology.
[b]Source of funds may be through Health Authority or Board of Governors.
SOURCE: B. Stocking, "X-Rays Highlight the Doctor's Dilemma," *New Scientist* 81(1137): 84, 1979 (21).

[a]Much of the information for these case studies was derived from particular individuals. These sources are given, but the individuals concerned are not responsible for any mistakes or misinterpretations.

[9]A fuller discussion of CT scanning in Britain is given in B. M. Stocking and S. L. Morrison, The Image *and* the *Reality: A Case Study* of *Medical Technology, 1978 (22).*

sources of funds for the capital costs of all body scanners installed or on order in October 1978. Eighteen body scanners were operational by January 1, 1979, and another five became operational during 1979.

Early on, DHSS had set up a committee to monitor the body scanner's evaluation, but it was not until August 1978, when a large number of body scanners were already in use, that DHSS issued a paper saying that whole-body scanning did have a place in diagnostic radiology (7). This letter went on to say: "In a few centres it is likely that general purpose scanners will need to be provided primarily for the body role. "

Whole-body CT scanning has raised a number of important questions in the United Kingdom. The central issue concerns how new technologies should be evaluated. A number of diagnostic techniques have been tried out in clinical settings before large-scale diffusion; CT scanning is unique in that questions have been raised about the usefulness of this as compared to other techniques and the need for randomized clinical trials of diagnostic equipment has been recognized.

The important issue of the role of philanthropy in NHS has also been raised. In a number of cases, Health Authorities have been put into an embarrassing position. Scanners have been offered to them, but individual Area Health Authorities have had to provide the operating costs (and probably eventually the funds for replacement machines). Operating costs are estimated at 50,000 ***($110,000)*** per annum, and given current tight budgets, these Authorities might prefer to use their funds for other purposes.

There are also other consequences of philanthropic gestures. Because local consultants have usually been the stimulus behind appeals and the local community itself has raised the funds, the local community expects to benefit by having the scanner in its own hospital. This may or may not be the best location for it. It is certain that some of the early scanners donated by philanthropists did not go into the most appropriate locations for a proper clinical evaluation. Even now, DHSS recommends that priority for body scanners should be given "to those centres prepared to undertake further clinical evaluation" (11). The hospitals that are getting scanners as a result of appeals, though, are not necessarily the most capable of evaluating them. Thus, although it is accepted that philanthropy can provide a very useful source of funds for NHS, in the case of CT scanners, philanthropy has produced a number of difficulties.

Renal Dialysis[10]

For patients with chronic renal failure, treatment by dialysis or the receipt of a transplant may be alternatives or may be complementary. Thus, in the following discussion, figures are given for both dialysis and transplant services.

Britain became involved in the provision of renal dialysis for chronic renal failure in the mid-1960's. The British Government, through the then Ministry of Health, became directly involved in establishing dialysis units and in evaluating the technique. By the end of the decade, the current network of dialysis centers was established, and Britain was leading the way in Europe in the provision of this service. (Britain no longer holds this lead.)

The Ministry of Health was also involved in setting up the network of transplantation units alongside the dialysis units after a working party on the subject had reported in the early *1960's.* Finally, central funds were used to setup the National Organ Matching and Distribution Service and the National Tissue Typing Reference Laboratory (referred to jointly as "UK Transplant").

After these early initiatives, the Ministry of Health handed over the responsibility for financing the now 49 dialysis and transplant units in England and Wales to the Regional Authorities. Particularly since reorganization of NHS in 1974, DHSS has emphasized that resource allocation decisions are in the hands of the Regional and Area Health Authorities.

[10]Much of the information for this case study was taken from a *1978* publication of the Office of Health Economics, Renal Failure: *A Priority in Health? (18)* and from discussion with author William Laing (15).

Despite this devolution of responsibility, renal dialysis has reached sufficient prominence in public debate for the British Government to become involved again. In particular, in late 1977, funds were provided through the special medical development (SMD) earmarking system for extra dialysis machines for children. The SMD money is for the initial stages of new programs. The conditions set are that the object of expenditure should be just emerging from the experimental stage and that the period of direct financial support should be short term. No provision was made for recurring revenue costs with the pediatric dialysis machines. Thus, Regional Authorities already battling with very tight budgets were not enthusiastic about the offer of machines. In fact, in some cases, the machines were not accepted.

More recently, in the 1978 budget, the British Government again entered the scene, this time quite outside its stated policy of minimal intervention in resource allocation. In the budget, 3.5 s million ($7.7 million) was allocated to cover the costs of treating ***400*** extra patients, with provision for the running costs for at least 2 years. It is unclear whether these machines were ever purchased, and if so, whether they are in fact in use.

The British Government has always been involved in the transplant service, because this service is a nationally based system. In particular, DHSS has taken initiatives to increase the numbers of cadaver kidneys available for transplant through the use of kidney donor cards. In current law, in the absence of any clear statement of the potential donor's wishes, the person lawfully in possession of the body must make reasonable inquiry to ascertain whether the deceased, the spouse, or any surviving relative objects to the organ donation (with all the attendant problems of securing their approval). Kidney donor cards signed by the potential donor, if carried by a large number of the population, would therefore be expected to increase the number of kidneys for transplantation. In 1978, DHSS intensified its campaign to bring the existing donor card system to the public's attention, hoping to increase the number of cards carried.

There has, then, been considerable British Government intervention in renal dialysis and transplant services. To understand why the British Government has felt obliged to take specific action, it is necessary to look at the figures for the service provision with estimates of need. In the late 1960's, three major surveys were undertaken in the United Kingdom to estimate the levels of chronic renal failure in the population. From these surveys resulted the often quoted figure that 40 new patients per 1 million population aged 5 to 60 years would need treatment per year. Even this must be considered an underestimate, since it is now accepted that people who were excluded from the treatable category because of associated conditions (e.g., diabetes) could now be treated. Also, there are obviously many individuals over the age of 60 who need treatment, and it is a matter of priorities about whether and at what age treatment should no longer be offered.

The figures reported for the United Kingdom for 1978 (2) show that 2,946 patients were alive on dialysis machines (about two-thirds of whom were on home dialysis). For the same year, ***820*** live or cadaver transplants were reported. The transplant rate of 15.3 per 1 million population per year compares well with the 4.7 per 1 million population average for Europe as a whole. The overall rate for all patients being treated by dialysis or with a functioning transplant in the United Kingdom in 1978 was 92.3 per 1 million population. The number of new patients accepted for either form of treatment in 1978 was 19 per 1 million population. If this figure of 19 patients per 1 million population is compared to the survey figures of an estimated 40 new patients per 1 million population per year, a serious shortfall in the number of patients who are receiving treatment compared to the estimated number of patients who could benefit is apparent. These figures, linked to the publicity there has been on the subject, are clearly reasons why the British Government has felt obliged to step in.

The questions raised by by the situation regarding the treatment of patients with kidney failure are quite unusual, because it is one of the few instances in which a directly lifesaving pro-

cedure is not being provided to individuals whose lives are threatened. Whether an increase in the number of dialysis machines would solve the problem, however, is another question. It appears that it is not so much a shortage of machines as an inability to recruit enough nurses, coupled with a lack of money to pay them, which results in machines' not being used as fully as possible (15). Even this, it is suggested, is not the whole story, since most dialysis units could in fact take more patients. It seems that patients are probably being turned away at an earlier stage, perhaps when they are seeing general medical consultants before even reaching dialysis units.

Although no new renal dialysis units are planned, a number of them are undergoing expansion; that is, the number of beds, including machines and the necessary staff, are being increased. If the numbers of patients on dialysis are to increase substantially, however, it would seem that these units would have to make it clear to doctors in their referral areas that treatment is in fact available.

Given the improving life expectancy of patients on dialysis, the constant input of new patients, and the easing of criteria for patient acceptance for treatment, then, it is certain that treatment of all patients by dialysis will never be feasible. The government's attempts to increase the number of kidneys for transplant, therefore, can be seen as an important means to resolve the current dilemma.

Coronary Bypass Surgery[11]

Coronary bypass surgery began to be carried out in various centers in Britain in 1969. Since a number of centers were equipped for open-heart surgery, no new technology as such was required. At the time, however, these centers were dealing with a backlog of valve operations. This backlog, coupled with the fairly conservative attitude of GPs in referring patients with angina to cardiac specialists for possible surgery, resulted in fairly slow growth in the number of operations performed.

[11]Dr. Celia Oakley, Hammersmith Hospital, London, provided much of the information for this case study (17).

With more widespread acceptance of the apparent benefits of the procedure for relieving angina symptomatically, pressure to increase facilities grew. Health Authority budgets were becoming increasingly constrained, however, and according to central policy, acute services were to be given lower priority.[12] From 1972, the European Coronary Bypass Study was underway to look at the effects of coronary bypass surgery on mortality, and this provided a suitable reason for saying that increased facilities would not be made available until more was known about the effectiveness of the procedure. In 1977, there were 2,532 bypass operations in NHS hospitals in England and Wales (operations in private hospitals are not included) (13).

The number of centers involved is based on the number able to perform open-heart surgery. As in the United States, guidelines have been proposed for how many operations should be carried out in each center. The Cardiology Committee of the Royal College of Physicians suggested that each center should do a minimum of 300 operations per year, with each surgeon performing at least 200 operations per year.

Cobalt Therapy[13]

Radiation therapy had been used to treat cancer for some time, but it was only after World War II that cobalt isotopes, producing the high energy radiation suitable for treatment of deep tumors, became available. The first commercial cobalt machines were produced in the 1950's, and the first cobalt machine in Britain was purchased with NHS regional hospital board funds from Atomic Energy of Canada (AEC) and placed in the Mount Vernon Hospital. Subsequently, three British firms, AEC, Hunslett, and

[12]This policy was explicitly stated in two documents issued by DHSS, *Priorities for Health and Social Services in England* (9) and *The Way Forward* (12). The increased priority to be given to long-term care of the elderly, mentally ill, handicapped, etc., and decreased priority for acute care services obviously has implications for all the technologies described here. It has never been clear, however, the extent to which Health Authorities should be constrained by this stated policy. Certainly, it was not intended to be an overnight change, but with tight budgets and alterations in resource allocation policy, Health Authorities have found it extremely difficult to make any change in the relative priorities of acute and "cinderella" services.

[13]Much of the information on cobalt therapy was obtained from D. Kidney, DHSS (14).

Nuclear Energy (now incorporated in TEM Instruments) sold machines in Britain, and these machines, too, were purchased with NHS regional hospital board funds, although the then Ministry of Health was involved in central contracting arrangements. Central R&D funds were not used to develop equipment and purchase early machines for clinical evaluation. 1[4]

At the time, there were *50* radiotherapy centers in England and Wales—a number of them in the London teaching hospitals, others in major cities around the country. Each of these centers purchased a cobalt therapy machine; some, depending on their patient load, purchased more than one. The decision to purchase machines was in the hands of the hospitals designated as radiotherapy centers, and there seems to have been little call from other hospitals for these machines.

In April 1979, there were ***105*** cobalt machines in Great Britain, almost all of them of British manufacture. This figure probably represents a peak. Even though patient loads may increase, and in addition replacement machines will have to be purchased, there is a tendency to replace cobalt machines with linear accelerators. The advantages of linear accelerators are that: 1) patient throughput is faster, and 2) these machines are easier to use, because the size of the source is smaller and can be more readily pinpointed to reach a tumor.

It is unlikely that linear accelerators will replace all cobalt machines. Cobalt therapy may be more suitable for some treatments, and cobalt machines are less complex to maintain and also considerably cheaper than linear accelerators. At present, a cobalt machine costs about 4100,000 *($220,000),* a linear accelerator about double that price. Cobalt machines do require purchase of new cobalt sources about every 4 to 5 years, however, and these cost about *15,000* **($33,000).**

Both types of machines are bought through central contracting arrangements, but there is no policy on whether accelerators or cobalt machines should be purchased. The current policy guidelines (8) state only that each designated radiotherapy center should have a minimum of two megavoltage machines. In fact, the centers are quite variable. Four of the five Scottish centers, for example, have chosen accelerators, whereas the fifth has decided to use only cobalt machines.

Clinical Laboratory Testing: Laboratory Automation [5]

The first single-channel automated laboratory analyzers became available at a time when there was much concern about the increasing workloads in pathology laboratories in the United Kingdom. The then Ministry of Health's response to the first commercially available machine, the Technicon system, was to ask hospitals not to buy these analyzers. Because of the pressure of the workloads, a number of teaching hospitals and regional hospital boards did go ahead and buy machines in the early 1960's, despite the Ministry's request. Meanwhile, by providing funds for development and offering guarantees of purchase as an inducement, the Ministry of Health attempted to encourage British manufacturers. The one machine that resulted from this encouragement was not very successful.

By the mid-1960's, two-channel and then multichannel machines were becoming available, and it was at this time that the Ministry of Health began working with Vickers to produce a multichannel analyzer. It was already being suggested that laboratory services should be centralized, and it was with this aim in mind that the Vickers development was supported. Vickers did produce a satisfactory machine. The Ministry of Health purchased 22 Vickers machines for NHS, and Health Authorities then paid their running costs. Health Authorities subsequently purchased additional Vickers machines, as well as analyzers produced by other manufacturers. The figures on exactly how many single-channel and multichannel analyz-

[14] with DHS now commonly involved in the development of equipment and purchase of early machines for clinical evaluation, current practice represents a departure from this.

[15] The information on laboratory testing was obtained from Dr. C. Riley, Royal Sussex County Hospital, Brighton (20) and Dr. C. Connally, Regional Scientific Officer, South-East Thames Regional Health Authority, Croydon, England (3).

ers are in NHS are probably not known. A reasonable estimate is that there are about 19 to 20 multichannel machines in each English region, making a total of perhaps 280 for England alone.

DHSS is still involved in automated analyzers in that it negotiates central contracts with manufacturers. As described earlier, however, this negotiation does not guarantee any sales; it merely sets a base price. Health Authorities are then able to negotiate directly with manufacturers for a particular machine and purchase it directly.

One major policy that has affected the number of machines purchased is the centralization of laboratories, a policy set out in a health circular in 1970. The aim is that each district (the lowest tier in NHS, serving about a quarter of a million population) should **have** only one laboratory for clinical chemistry. Again, because of the potential for automation, hematology is also centralized. Histology and microbiology have been centralized to some extent, but since they are much less machine-oriented, there has been less pressure on these branches of NHS.

Some concerns have been raised about the implications of the increased volumes of data produced by automatic analyzers, and DHSS funded a study to investigate the question. [16] This study indicated that the increased information was marginally beneficial, but the issue is still frequently raised.

Another question concerns the reliability and safety of machines and the accuracy and reproducibility of the data they produce. DHSS-funded evaluations of new automated equipment address these questions, as well as the total costs of purchasing, operating, maintaining, and manning the machines in relation to laboratory workload (10).

[16]The results of the study can be found in T. P. Whitehead and I. D. P. Wootton, "Biochemical Profiles for Hospital Patients," *Lancet* 2:1439, 1974 (24).

CONCLUDING REMARKS

Britain's fairly conservative attitude towards technology has been noted; notwithstanding this attitude, in the health sector, calls for the latest equipment are common from the public and doctors alike. In fact, a certain amount of dissatisfaction is felt by health workers because they do not have the latest technologies available to them. The reasons for the lack of availability throughout the country of the newest generation of each technology have already been described: NHS operates on a budget set by Parliament, and choices between one technology and another or between equipment and other uses of the funds must be made in the context of this overall budget. Because these choices are rarely stated explicitly, however, there is a sense in some quarters that technology gets priority funding over some of the less glamorous NHS activities, particularly, the so-called "Cinderella" services such as care of the elderly, the handicapped, etc. The relatively slow growth of NHS in the next few years is likely to sharpen the whole debate on technology and its role in British health care.

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3.
The Management of Medical Technology in Canada

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3.

The Management of Medical Technology in Canada

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CANADA: COUNTRY DESCRIPTION

Canada has a population of 23 million people.[2] Although its land area is second only to that of the Soviet Union, it is basically an urban country, with *56* percent of its population in metropolitan areas of over 100,000 population. Most of Canada's population lives along the "fourth North American coastline," the Saint Lawrence River and Great Lakes, and on the Pacific coast, and much of the prairie population lives fairly close to the Canadian / U.S. border.

Settled initially by both the French and British, Canada in the 18th century was an arena of imperial competition between them. The country continues to have separate French- and English-speaking communities, each with its own educational, social, and religious institutions, and is officially bilingual. For many years, the English-speaking community has dominated the national economy. Even in Quebec, where the French community is concentrated (approximately 80 percent of the population is francophone), the English were economically dominant until recently. There has been extensive immigration to Canada and the country is ethnically diverse, but the split between the English- and French-speaking communities remains a central factor in Canadian society. It has been accentuated in recent years by the growth of the Quebec separatist movement and election of a separatist government in that Province.

Canada is a confederation made up of 10 Provinces and 2 Territories. Confederation, agreed to in 1867 and embodied in the British North America Act, was an essential compromise necessary to address the political conflict between the French and English communities and to pave the way for independence from England.[3] Governments at both the Federal and Provincial levels are parliamentary in form. Compared to the constitutional division of responsibilities in the United States, the constitutional division between the Federal Government and the Provinces in Canada is more clearly defined and more strictly observed. In addition to the formal wording of the British North America Act, social and political factors create continued pressures to maintain this separation.

Social programs, including health programs for the general population, fall within the sphere of activities reserved for the Provinces.[4] In order to overcome the constitutional bar to Federal administration and bring Federal resources to bear on social problems, a pattern has developed in Canada in which the Federal Govern-

[1]The author gratefully acknowledges the invaluable assistance of Roger LeCompte of Lewin and Associates, Inc.

[2]According to Statistics Canada (14), the estimated population of Canada in 1974 was 2,334,000. The two largest Provinces were Ontario, with a population of 8,063,000, and Quebec, with 6,119,000. The next largest Province was British Columbia, with only 2,382,000. The smallest was Prince Edward Island, with 116,000. Two territories—the Yukon and Northwest Territories—combined had an estimated population of 56,000.

[3]Canada is an independent nation, but its constitutional ties to the United Kingdom are still strong. For example, the Queen of England is formally head of state and appoints a Governor-General to represent her. The constitution, the British North America Act, is at Westminster.

[4]Formal Federal responsibility for health care is limited to such public protection activities as food and drug regulation, regulation of radioactive materials, quarantine, and providing health services to special groups such as Indians and Eskimos.

ment shares the costs of many provincially administered social programs. Federal legislation defines the services for which costs will be shared, the population that must be covered, other conditions of participation, and the cost-sharing formula. Provincial legislation is enacted consistent with the Federal conditions.

The Canadian economy is a diversified private enterprise economy, with manufacturing, finance, farming, trade, and extractive industries comprising major areas of economic activity. Within the private enterprise economy, there is acceptance of government ownership at both the Federal and Provincial levels. In general, there is greater public acceptance of government efforts to direct economic activity in Canada than there is in the United States.

THE HEALTH CARE SYSTEM[5]

The Canadian health care system—with both private and public components, in which private providers of care and public financing predominate—is similar to that of the United States. In 1975, personal health expenditures in Canada were *$452* per capita (14). Of this amount, 46 percent went to the country's approximately 1,200 hospitals, and 18.5 percent went to the country's approximately 35,000 physicians (157 per 100,000 population). Expenditures on personal health care were 6.2 percent of the gross national product (GNP), compared to 7.6 percent for the United States in the same year.

Almost all hospitals are nonprofit institutions. A substantial number of the hospitals have been established by local governments, under separate board of trustees, with local responsibility for budget deficits. In 1975, there were 6.8 beds per thousand population, 5.2 acute care beds, 1.5 long-term beds (3). Average length of stay was 11.5 days overall, 8.8 days in acute care units. Admissions to acute care units were 162.4 per thousand population, and total days of care in these units were 1,445 per thousand. Average acute bed occupancy was 76.1 percent.

The development of national health insurance and the organization of Provincial activities to manage the health care system are briefly reviewed in the discussion that follows. Each Province exercises considerable autonomy in the health area, and in the remainder of this chapter, Ontario and Quebec are used as principal examples. [b]

National Health Insurance

Over the past 25 years, the major change in the Canadian health care system has been the introduction of national health insurance. National health insurance was debated immediately after the Second World War, but no action was taken at the time. A program of national health grants for health facility construction and manpower training was enacted in 1948, however, and it is likely that this program helped create pressure for health insurance by developing a supply of health care resources which the private insurance programs could not adequately finance.

Health insurance was enacted piecemeal—hospital insurance was enacted first in 1957 and

[5]Much of the overall presentation on the Canadian health care system that appears here is based on the following study conducted by the author and others: Lewin and Associates, Inc., *Government Controls on the Health Care System: The Canadian Experience, 1976 (11).* The information from that study has been updated to reflect changes in financing and other events since the study was completed. Extensive interviews were conducted in several Provinces for the 1976 study. For the paper presented here, Ontario and Quebec were revisited to assess changes in patterns of technology management and to review specific technologies.

[b]The use of Ontario and Quebec as principal examples is not meant to imply that their experience is typical. Those familiar with Canada have indicated since the first draft of this paper that the experience of other Provinces has been different both because of their smaller, more manageable health care systems and the availability of more complete data. Ontario and Quebec were selected for focused study because of the author's previous work (11) and because they are the largest Provinces. (Their combined 14 million population constitutes over 60 percent of the total population of Canada (l),) It was also believed that Ontario and Quebec would have the most complex technology issues and be applying more resources than other Provinces to their resolution.

medical insurance a decade later in 1966. In both cases, rising costs were critical factors in the decisions to develop government programs. Several economists have noted that the major increase in supply of hospital beds and physicians occurred before the programs were enacted (1).

The patterns of development of the hospital and medical insurance programs were similar. In the period from 1945 to 1950, after proposals for a national health insurance program had been shelved, three Provinces, Saskatchewan, British Columbia, and Alberta, independently developed their own hospital insurance programs. A fourth, Newfoundland, had a partial insurance program. By 1955, a consensus for hospital insurance had developed, and discussion of the topic at a Federal-Provincial conference being held at the time was requested by the Provinces.

In 1956, the Federal Government made a concrete proposal for a phased-in insurance program, beginning with insurance for hospital care. This proposal received the general support of the Provinces, and the Hospital Insurance and Diagnostic Service Act was enacted in 1957. Five Provinces entered into the program at its inauguration in 1958, the four with existing programs and Manitoba. Prince Edward Island, Nova Scotia, and Ontario entered in 1959, and Quebec in 1961.

Medical insurance developed in a similar manner, alhough there appears to have been less consensus among the Provinces to take this next step in the phased-in program that the Federal Government had proposed in *1956.* In 1961, a Royal Commission on Health Services (the Hall Commission) was appointed to review the medical insurance situation. Several Provinces acted on their own before the Hall Commission reported. Saskatchewan introduced compulsory Provincial medical insurance in 1962, and although this led to a physicians' strike, a compromise that retained the public program was reached, In 1963, Alberta increased the regulation of the contents of medical insurance contracts and provided premium subsidies for those unable to pay. This program covered 70 percent of the population. The Government of British Columbia began making nongroup medical coverage available in 1965, when the only nonprofit carrier providing this type of coverage failed.

In 1965, the Hall Commission released its *re*port calling for the establishment of a Federal program. The Medical Care Act was passed in 1966 for implementation in 1968. In July 1968, only two Provinces—Saskatchewan and British Columbia—were prepared to enter the Federal program. In 1969, five more entered—Newfoundland, Nova Scotia, Manitoba, Alberta, and Ontario. Quebec and Prince Edward Island joined in 1970, and New Brunswick in 1971.

Both the hospital and medical insurance programs follow the general Canadian policy of establishing minimum standards to make a Provincial program eligible for cost sharing but leaving the actual administration of the program to the Provinces. Compared with the detailed programmatic and administrative requirements that are imposed in U.S. Federal-State programs such as medicaid or aid to families with dependent children, the conditions imposed for cost sharing in Canada are limited and general. The Hospital Insurance Act and regulations combined are only 19 pages; the Medical Insurance Act is 9 pages. Although there are requirements that specific administrative functions (such as setting payment rates, licensing and inspection of hospitals, planning and development of hospital resources) be performed, and that the agreement with the Federal *Govern*ment describe the arrangements for them, the Federal regulations do not specify or place conditions on how these activities are to be carried out. The greatest detail is in the sections detailing the costs that would be eligible or excluded from Federal cost sharing, which in each program were to be approximately 50 percent of the Provincial costs. ' Beyond establishing the general framework of the programs and cost-sharing formula, Federal involvement has been limited to establishing mechanisms for coordination and joint Federal-Provincial program review, and to providing technical assistance to Provinces when they request it.

[7]The cost-sharing formula for both programs involved some redistribution of costs to the poorer Provinces, with the medical insurance formula more favorable than the hospital insurance formula.

During the rapid inflation in health care costs in the late 1960's and early 1970's, the Federal Government became increasingly uneasy over its fiscal exposure in a program whose costs it could not control. After several years of negotiation and considerable conflicts with the Provinces, the cost-sharing formula was changed. Beginning in 1977, the basis of Federal contributions to the hospital and medical insurance programs was shifted so that Federal contributions effectively were indexed to the rate of growth in GNP.[a] These arrangements have increased the flexibility of the Provinces in allocating medical care funds among services, but also put the Provinces completely at risk for expenditure increases higher than the growth of the Federal contribution.

Several other general trends have developed with respect to Federal involvement in the health care system over the past several years. One is a growing concern over manpower issues, particularly increases in physicians, which has led to substantial changes in immigration policy. A second trend has been toward major emphasis on health promotion and disease prevention activities. The rationale for this emphasis was outlined in a 1974 report by the Minister of Health Marc Lalonde (10).

Provincial Management of the Health Care System

Provincial involvement in the Canadian health care system is extensive. Provincial responsibilities include manpower licensure, public health activities, and direct provision of some health services. In terms of expenditures, the Province's primary involvement is in administering the hospital and medical insurance programs.

Organization for Health Systems Management

Largely as a result of the hospital insurance program, the Provinces play a large number of roles for institutional providers of health care. They are regulators and inspectors, providers of consultant services, and health system planners. There are nine major functions that the Provinces perform:

- budget review and financial management consultation;
- administrative consultation to improve general management and performance in special areas such as dietary, nursing, and laboratory;
- inspection of facilities;
- institutional bed need planning;
- other health services planning and project review;
- review of construction plans and supervision of construction;
- research and statistical analysis;
- medical review of the appropriateness of institutional care; and
- health sector labor relations.'

Most commonly, a Province groups the functions of budgeting, administrative consultation, planning, and inspection into an institutional or hospitals division. This is what Ontario has done. Under this type of arrangement, the research and statistics functions and medical consultation office are outside the institutional division as general service and support activities for the entire health department program.

Quebec has a radically different arrangement from Ontario's. The Quebec Ministry of Social Affairs is a combined health and social services department. A functional organization was adopted in a reorganization of activities in 1970. Health and social service orientations were to be integrated within each function. Thus, the major divisions for both health and social programs were planning, operations and programing, finance, labor relations, and inspection. A more recent reorganization has modified this slightly, establishing separate units for the areas of health, social programs, and income security, along with separate planning, programing, fi-

[a]The mechanisms to introduce this indexing involve transfers to the Provinces of Federal income tax credits, with equalization among the Provinces and some cash payments. Additional cash contributions to the Provinces are to be made to contribute to Provincial programs for nursing home care, adult residential care, the conversion of mental hospitals, home care, and ambulatory services.

'Most Provinces have only recently become involved in labor relations issues, and the situation in this area is in flux. In Ontario, for example, the Ministry's personnel unit has been involved with the issues, but has not sat at the negotiatin, table.

nance, labor relations, and capital budgeting functions for each.

Despite considerable variation among Provinces in the administration of the hospital insurance, medical insurance, and nursing home benefit programs, in each Province there initially was substantial decentralization. As the Provinces have begun viewing their individual health activities as elements of a general strategy toward ensuring adequate health services, however, they have attempted to bring the units administering these activities into greater proximity.

The degree of integration of these activities within each Province reflects in part the degree of acceptance within the Province of the concept of the Provincial government as medical system administrator. In Quebec, this concept has been eagerly embraced. In Ontario, the concept has been generally accepted, but Provincial responsibility is viewed as being shared with the medical community and public. Indeed, since extensive political pressure forced the Ontario Ministry of Health to back away from ordered bed closings in 1974 and 197s,[10] the Ministry has hesitated to take actions to direct the development of the hospital system, relying instead on general budgetary and fiscal constraints to control institutional demand for new beds and services, and on its consulting process to encourage change.

The key to the programs of institutional control with respect both to overall expenditures and service levels and investment in new or upgraded services and equipment is the Provincial system for reimbursement.

Hospital Budgeting Arrangements

The Canadian Provinces have been administering hospital insurance programs for approximately 20 years. At the start of the hospital insurance program, the intent was to leave the hospitals privately managed and free to make independent decisions about administration and services they would offer. Hospital budget review by Provincial governments was designed only to forecast the costs of the hospital insurance program and to exclude costs not covered by the Hospital Insurance Act.

This arrangement proved unstable. Provincial governments quickly came to review every detail of administration to assure that Provincial moneys were to be well spent. Budgets were reviewed and set on a line-by-line basis. Each staff position had to be justified in the operating budget, and the basic operation of any department was subject to review. In the capital budget, the purchase of a new wing, a sterilizer, or a desk might require Provincial approval. Hospitals could not deviate from the approved budget without Provincial authorization.

To administer the wide range of oversight responsibilities, Provincial hospital insurance programs recruited staffs with expertise on each phase of hospital administration. Provincial staffs included financial experts and accountants, general administrators, nurses, and dietitians. These individuals, generally called “consultants” by the Provincial governments, served as budget review personnel, as health service planners, as consultants to hospitals on operations, and as Provincial licensing inspectors.

In the late 1960’s, many Provinces began to feel that the existing budgeting systems were awkward to administer and unduly restrictive to hospital management. Efforts were made to develop systems that would allow hospital administrators and boards greater flexibility in running their institutions. The systems that were developed have been called generically “global budgeting.” Under global budgeting, an institution can shift funds among categories of expenses, so long as its overall budget is not exceeded. In some Provinces, the initial global budget or parts of it are still fixed by detailed line-by-line review; in others, flat percentage increases are applied to previous budgets or costs.

In the 1960’s, Provincial governments generally made funds readily available for hospitals. Hospital programs were popular, because hospitals were visible and could serve as

[10] This was done in such a way that some of the projected savings accrued to the Province. In some cases, beds were closed. In others, beds remained open, but an amount estimated to equal the savings was taken from institutional budgets. In still other cases, the closings were canceled.

sources of local employment, and the Federal Government paid half the costs. Since funds were readily available, if an institution could make a reasonable case for new staff or a remodeled wing or some other expenses, the request was usually granted. Budgets were determined prospectively, but it was understood that funds would generally be available at the end of the year if difficulties were encountered; risk, therefore, was minimal. This decade was also a period of catchup for hospital employees' wages, a process in which few Provinces interfered.

A growing concern over the costs and effectiveness of hospitals and health care began to emerge in the late 1960's. The health insurance plans had become the largest component of the Provincial budgets, and the rapid inflation in the health sector burdened Provincial revenues and hindered initiatives in other areas. In response to these problems, the Federal Government initiated a study of the costs of health services in Canada. The report of the Task Force on the Costs of Health Services in Canada, completed in 1969, discussed a wide range of issues, including the dispersion and utilization of new technology (8). Almost every Province did comparable studies, examples being the study of the Commission of Inquiry on Health and Social Welfare (Castonguay-Nepveu Commission) in Quebec, the Manitoba White Paper, the Llewelyn-Davies-Weeks Studies in New Brunswick, the report of the Health Planning Task Force in Ontario, and the Foulkes report of the Health Security Program Project in British Columbia.

Beginning about 1970, partly as a result of these studies and partly concurrently with them, Provinces began implementing hospital constraint programs. The introduction of global budgeting was accelerated by the concern over costs. By applying an overall increase to budgets that matched or was lower than the projected inflation rate, Provinces could avoid debating individual line-item cuts. They could encourage greater efficiency without being required to identify areas where it could be achieved. Generally, the inflation estimates were tight but realistic. The hospital constraint programs the Provinces introduced appear to have had a substantial impact on the rate at which resources float into the health care system. As table 1 demonstrates, the percentage of GNP directed toward personal health services in Canada has declined slightly since peaking in 1971.

Each Province developed its own constraints, but Ontario's mechanisms are typical of the range of approaches available. Introduced over a period of 4 to 5 years, these controls have included:

- refusing to budget for inpatient volume increases, except in areas of rapid population growth;
- refusing to budget for additional laboratory and radiology services for inpatients;
- refusing to budget for increases in outpatient volume;
- imposing a moratorium on physical plant construction and renovation;
- requiring hospitals to find the funds for new, approved services within their existing global budget;
- mandating bed closings; [11]
- limiting the amount of a salary and pension increase that would be funded by the Province; [12]
- reducing each hospital's budget in 1 year by an amount equal to 60 percent of depreciation and in another year imposing a 2-percent reduction in the base; 13 and
- manipulating the inflation projection .14

Some Provinces, including Alberta (which has extensive oil revenues), have continued to fund extensive hospital programs. In other Provinces, including Ontario and Quebec, how-

[11]Not all beds ordered closed in Ontario were actually eliminated. Political pressures kept some open and funded. In other cases, the hospital agreed to have an amount equal to the estimated cost of operation removed from its budget base if it would be allowed to operate the beds within its reduced budget. Other beds were closed voluntarily in an effort to meet the budget limits imposed.

[12]In one labor dispute, however, the Province pressured the hospital to grant a larger increase than the hospital wished to.

[13]Provincewide general decreases were requested by the Ontario Hospital Association rather than increases targeted at individual hospitals.

[14]In 1974, the Ontario Treasury Board required the Ministry of Health to utilize an inflation estimate below any realistic projection. At year's end, the Province was required to provide supplemental funds to cover major deficits.

Table I.— Percent of GNP Directed to Personal Health Care in Canada and the United States (1960-76)

	Personal health care		Hospitals		Physicians	
Year	Canada[a]	United States[b]	Canada	United States	Canada	United States
1960. . . .	4.62	4.69	1.65	1.80	0.93	1.12
1965. . . .	5.13	5.44	2.04	2.03	0.98	1.24
1970. . . .	6.16	6.69	2.65	2.83	1.20	1.46
1971. . . .	6.37	6.83	2.70	2.92	1.31	1.51
1972. . . .	6.27	6.91	2.57	3.03	1.31	1.49
1973. . . .	5.96	6.87	2.57	3.00	1.19	1.48
1974. . . .	5.84	7.14	2.62	3.17	1.12	1.50
1975. . . .	6.21	7.61	2.85	3.41	1.15	1.63
1976[c] . . .	6.21	7.78	2.89	3.52	1.09	1.63

[a]Institutional care, professional services, drugs, and appliances.
[b]Hospital care, nursing home care, professional services, eyeglasses, appliances, drugs and drug sundries, other health services.
[c]Preliminary estimates for Canada.

SOURCES: Canada: Health and Welfare Canada, *Review of Health Services in Canada, 1974*, 1974 (7). Updated by personal communication, 1979 (6).
United States: R. M. Gibson, "National Health Expenditures, 1978," *Health Care Financing Review* 1(1), summer 1979 (2)

ever, hospitals have confronted a decline in the amount of real dollars available for public programs. It is in this more restrictive context that most discussions of expanded technology have occurred.

The specific trends in capital financing and service development show similar patterns. In the 1960's, capital investment by the Provinces was heavy, [15] with most of this investment going into renovations or bed construction to match population growth. There was little effort to improve the efficiency of capital use by limiting construction to increase occupancy levels. It is difficult to judge whether specialized services were expanded to the point of oversupply, because there are no general inventories of units or overall assessments of their efficiency. Discussions with Provincial authorities and hospital administrators, however, suggest that efforts within individual Provinces to avoid extensive duplication were generally successful, although there was some duplication of highly prestigious services.

As part of the more recent effort to constrain costs, the Canadian Provinces have begun looking much more critically at capital expansion. Construction has been curtailed, in some cases sharply.[16] Provinces that had previously routinely approved all capital funds requested have had either partial reductions, or in some years, all new projects cut from the budget. Hospitals have been told no funds would be available for new services-and that such services would have to be begun within the global budget. In the capital budgeting process, the Provinces are trying to move from single-year to multiple-year projections, Some of these trends and the management of capital investment in technology are discussed further in the next major section of this chapter.

Physician Reimbursement

The primary mode of physician reimbursement in Canada is fee-for-service payment. Initially, the Provinces adopted a modification of the existing fee schedule established by the medical societies and generally used for Blue Cross reimbursement. In all Provinces but Quebec, increases in overall fee levels and other conditions of participation are negotiated between the Province and medical associations. In Quebec, physicians are represented by three unions, one for general practitioners, one for specialists, and

[15]The Federal Government did not share the cost of construction or fixed equipment as part of the hospital insurance program. It did establish some direct grant programs for construction of hospitals, medical education, and research facilities, however, and did share the cost of movable equipment.

[16]In Quebec, for example, the new Minister of Social Affairs entered office in 1970 and ordered all health construction—with a total value in excess of $400 million—halted. After a lengthy review, a limited number of projects were allowed to continue.

one for residents and interns. The negotiations have been marked by varying degrees of conflict from Province to Province and year to year:

The size of fees for individual procedures are generally developed by the Provincial medical association, although this too can vary. The treatment of new procedures is discussed in the context of regulation and reimbursement in the next section of this chapter.

MECHANISMS FOR MANAGING MEDICAL TECHNOLOGY

Canada has a large and well-trained medical community, and the medicine practiced is technically advanced. The major issue in the management of medical technology in Canada is the speed of diffusion of cost-increasing technology that appears to offer some potential benefit to patients. Although fiscal constraints introduced over the last several years have made this issue more acute, nowhere in Canada have medical services been withheld because the associated expense would be too high.

In reviewing Canada's experience with regard to managing medical technology, four points are critical to providing a context for understanding the operation of the system:

- The Provinces' protection of their authority against Federal encroachment has left almost all decisions in this area at the Provincial level. Even in the area of technical assistance, Federal activity is limited and conducted cooperatively with the Provinces.
- Most technology management decisions related to the diffusion of technology are made in the context of the hospital budgeting process. Indeed, for the hospitals, the technology issues are subordinate to the budgeting process. In recent years, because of economic conditions, most Provinces have introduced considerable fiscal constraints into their programs. Thus, unlike supply controls in the United States, which operate independently of the financing system in an environment in which funding is relatively easy to obtain, supply controls in Canada are initially linked to fiscal control, and—particularly in Ontario and Quebec—have recently operated within an environment of extremely limited resources.
- Canadian hospitals have basically accepted the legitimacy of Provincial controls and constraints on resources. The hospitals generally accept that these decisions are political, so any challenges they mount are usually political.[17] Furthermore, the hospitals have accepted the responsibility for rationing services that is implicit in the fiscal constraint programs and have begun developing an internal capacity for such rationing.
- Decisionmaking is informal, closely tied to budgeting, and often involves interested parties. Standard-setting and planning are closely related to current decisions and do not generally take place apart from and prior to such decisions. There are few requirements regarding formal procedures or public access to the decisionmaking process.

The management of medical technology in Canada is reviewed in three subsections below. The first reviews R&D efforts by the Federal and Provincial governments and by national voluntary agencies. The second examines the guidelines and procedures used to evaluate new medical technology. The third and largest subsection examines the operation of regulation and reimbursement as they influence medical technology.

Research and Development

In 1973, an estimated $94 million was spent on health sciences research[18] in Canada, representing 5 percent of total health expenditures

[17]Ontario's hospitals sued and won a decision on provincially mandated bed closings, but no such legal challenge was made in Quebec, and there have been no lawsuits over the tight budgets.

[18]Actually, $94 million is an underestimation of total spending, because it does not include research by pharmaceutical companies and may exclude university- or hospital-provided overhead.

(5). Federal expenditures accounted for approximately $69 million. Over half of these Federal health research funds were spent through the Medical Research Council, an independent body reporting to Parliament through the Department of National Health and Welfare. Most of the remaining Federal funds were directly provided by the Department of National Health and Welfare, and a substantial portion of these went to manpower development and construction of research facilities.

The other Federal support for extramural medical research came from the Department of Veterans Affairs for support of research on chronic diseases, the National Research Council, and the Defense Research Board. The Department of National Health and Welfare also pursued a modest intramural research program in areas including pharmacology and pharmaceutical chemistry, nutrition, pesticides, food additives, clinical laboratory procedures, epidemiology, and physical fitness. In recent years, Federal support for medical research has declined because of a general tightening of Federal spending that has affected all Federal research activities.

In addition to the Federal Government, some Provinces support medical research. The most stable Provincial support is in Quebec. The Quebec Medical Research Council receives much of its revenue from the Quebec Medical Insurance Board, which is mandated to pay the Research Council 0.2 percent of the total amount paid Provincial physicians.

Another major *source* of medical research funds in Canada are national voluntary agencies, These include the National Cancer Institute, Canadian Arthritis and Rheumatism Society, Canadian Cystic Fibrosis Foundation, Canadian Association for the Mentally Retarded, Muscular Dystrophy Association of Canada, and Multiple Sclerosis Society of Canada. Such voluntary agencies attend meetings of the Interdepartmental Committee on Medical Research, which provide a forum for sharing information on medical research support (7).

Evaluation

The evaluation of new medical technology in Canada, like that in the United States, is substantially a matter of independent clinical research and experience reported through the professional literature and discussed at professional meetings. Indeed, Canadian clinical evaluation activities are integrated with U.S. activities through the literature and professional meetings, and because of the difference in size between the U.S. and Canadian medical systems and research efforts, Canada draws substantially on research done in the United States. For the most part, work has focused on assessments of efficacy. An increasing but still limited amount of work, however, is focusing on cost-effectiveness and cost-benefit assessments.

Two types of evaluations that are particularly important in terms of the decisions that Provinces address on a daily basis are discussed below. First are assessments of the appropriate rate and degree of diffusion of medical technology. Second are evaluations of the appropriateness of individual pieces of equipment,

Guidelines for Special Services

Provinces have felt a need for Federal assistance in developing guidelines for reviewing proposals for new and expanded services in hospitals. Their primary need has been for guidance on the appropriate organization and physical space and equipment needs for a new service. Their second need has been a basis for assessing how many units are needed in an area.

In accord with the general pattern of developing a joint Federal-Provincial committee or working party to address these types of issues, a working party on special services was created in 1972. This group had representation from the Federal and Provincial agencies administering the hospital and medical insurance programs.

The first guidelines prepared by the Working Party on Special Care Units in Hospitals were published in 1975 and covered nine units or programs—intensive care, coronary care, dialysis,

cardiac surgery, nuclear medicine, physical rehabilitation medicine, narcotic addition treatment, patient hostel, and burn (9). Guidelines have since been developed for additional services, and some of the original guidelines have been revised. A list of the guidelines currently available is presented in table 2.

For the development of guidelines on a specific service, a task force of several Federal officials, several Provincial officials, and medical consultants is formed. A typical guideline has 10 components:

1. patient load;
2. bed requirements;
3. recommended distribution on of units;
4. administrative policy, procedures, and control;
5. staff establishment and coverage;
6. staff training and qualifications;
7. specific supporting departments and services;
8. space allocation, utilization, and specific design features;
9. equipment; and
10. relationship with other departments and services.

As this list makes clear, considerable emphasis is given to issues of organization, staffing, and program quality. Planning guidance is usually contained in the discussion of patient loads and recommended distribution of units. In some cases, the recommendation is quite specific. 19 In other cases, the guideline is more general. None of the guidelines explicitly considers the economics of alternative configurations of services.

Once the Federal-Provincial guidelines are developed, the Provinces are free to adopt or modify them as they see fit. Ontario and Quebec have both made many changes in individual guidelines, and such changes have served as the basis for subsequent revision by the Federal-Provincial working party.

The introduction to the Ontario guidelines, published in 1976, describes the process used in the Province (13):

> In considering the means by which the guidelines might be reviewed, it was evident that a conventional task force approach would repeat much of the work done by the federal-provincial working party. It was decided that the ideal situation would be evaluation and modification based on the comments of all those directly involved—clinically or administratively—in the operation of the units throughout the province, If this could be achieved, the degree of multidisciplinary involvement would be maximal and

[19] The original nuclear medicine guideline, for example, called for a three-tiered system of centers, with the highest tier serving a population of 1 million.

Table 2.—Guidelines for Special Services in Hospitals

The following guidelines have been prepared by the Federal-Provincial Working Group on Special Services in Hospitals. These guidelines were requested by the Federal-Provincial Advisory Committee on Health Insurance, Ottawa. Some of the guidelines are updated versions of guidelines previously published by the Working Group.

Expected publication date—November/December 1979
- burn unit
- Day surgery unit
- Dental care units in hospitals
- Detoxification unit
- Diabetic day care unit
- Narcotic day addict ion treatment unit
- Nuclear medicine in hospitals
- Patient hostel unit
- Rehabilitation medicine unit
- Respiratory technology services unit

Expected publication date—December/January, 1979-80
- Diagnostic ultrasound facilities in hospitals
- Geriatric day hospital
- Geriatric unit in a hospital
- Intensive care unit
- Total parenteral nutrition

Expected publication date—April/May 1980
- Adult psychiatric services provided by general hospitals
- Child and adolescent psychiatric services provided by general hospitals
- Cardiac care facilit ies and services:
  - —Ambulatory elect rocardiography monitoring
  - —Cardiac care
  - —Cardiac catheterization
  - —Cardiac surgery
  - —Cardiovascular nuclear medicine
  - —Cardiac pacemaker
  - —Cardiac stress testing
  - —Echocardiography
  - —Intermediate cardiac care
  - —Noninvasive laboratories
  - —Phonocardiography
- Perinatal intensive care unit
- Regional renal failure program
- Spinal cord injury unit

NOTE. A report on emergency services in Canada IS also available.

SOURCE: Health and Welfare Canada, Ottawa, personal communication, 1979, (6)

province-wide participation would be assured. A questionnaire was devised to evaluate the guidelines for each unit. With the endorsement of both the Ontario Hospital Association and the Ontario Medical Association, all of the active treatment hospitals in Ontario were invited to participate in the evaluation process. The acceptability of the approach was indicated by a response rate which ranged from 88 percent up to 100 percent for the various types of units.

The task force used the responses as the basis for modification of the guidelines. A provincially acceptable adaption—not a rewrite—was the intended goal. The degree of acceptability of the guidelines varied according to the unit. For some, only minor changes were required. In the case of nuclear medicine, the responses indicated that the guidelines would require major revision for use in Ontario; therefore the Task Force sought the assistance of the OMA. The section on nuclear medicine appointed an ad hoc committee which, guided by responses of **46** departments of nuclear medicine, drafted a new set of proposed guidelines. These were then recirculated to the hospitals and the resulting comments were used in preparing the final version.

To adapt the Federal-Provincial guidelines or to assess appropriate service distribution independently, a Province will often establish a study committee. Such committees are usually expert professional panels charged to address specific planning or operational issues (e. g., the appropriate distribution of units for a given service) or to conduct an assessment of existing hospital programs and recommendations on programs to be closed,

The performance of these study committees has been mixed. In Quebec, for example, a committee comprised of nuclear medicine specialists (a separate specialty from radiologists in Canada) concluded that nuclear medicine was an established, proven, and basic diagnostic service that should be available in all institutions with over 100 beds and with adequate staff, and that 80 to 100 new cameras should be added within the Province.

The Quebec Government had strong reservations about the committee's findings. Provincial officials felt that, although the committee had been charged with assessing whether nuclear medicine was a basic diagnostic service or a referral service, the committee had given this question short shift. The Province had also wanted an assessment of the relative efficiency of nuclear medicine vis-a-vis other imaging services, but that assessment was not provided.

Currently, there is a freeze on the expansion of nuclear medicine in Quebec, although existing units have been allowed to upgrade equipment on the basis of the recommendation of a separate committee. The Provincial government would like to resolve the issue and allow more diffusion if it is appropriate, however, and will probably take several steps in this direction.

First, it will probably form another study committee, this one including radiologists, internists, and surgeons, that is, representatives of alternative specialty services and of the principal "consumers" of these services. One clear lesson of the earlier experience is that advisory committees should be organized in such a way that conflicts and differences in professional judgment are surfaced rather than hidden.

Second, it will probably tie approval of a new nuclear medicine unit to the creation within the hospital of an imaging department that will combine the radiology, nuclear medicine, and ultrasound capacities. The creation of imaging departments that combine these capacities, coupled with the continued fiscal pressures that force hospitals to budget more tightly, is seen as one way of moderating the competition among specialties and encouraging the development of an appropriate mix of service capacities by making the tradeoffs and overlaps among alternative techniques clearer.

Third, Quebec will probably require the creation of a formal evaluation protocol for the nuclear medicine service to provide information on the appropriate use of the service and its role relative to other services. This was an idea that was suggested 4 years ago, but never implemented. The expressed view of the Provincial planning officials was that a formal evaluation process as was originally conceived is almost impractical for a new technology such as nuclear medicine, because the technology itself is undergoing development and change, and because physicians using the technology are learning

and continually modifying their practice patterns. Provincial officials believe that evaluation for purposes of assessing the extent of appropriate diffusion is possible, but that it should be limited in scope, geared to incremental assessment (of the impact of the procedure and judgments on diffusion), and repeated as appropriate over time. Critical to the process of evaluation is framing the questions to ensure that the right issues are addressed at the proper level of detail.

Selection of Specific Equipment

Somewhat removed from the question of overall services distribution or rate of diffusion is the question of the specific equipment that should be purchased for a unit. This becomes an issue, because since a Province reimburses capital expenditures, it must approve the specific selection.

Most Provinces have an equipment specialist whose primary responsibility is to review individual equipment requests. These individuals are often quite knowledgeable and may also have access to technical experts in such areas as radiology or laboratory; however, the information they have about the relative operational performance of different equipment may be limited.

One advantage of the development in some Provinces of regional bodies to review capital budget requests (which is discussed in the next section of this chapter) has been the provision of additional information to hospitals making equipment decisions. In Ontario, for example, the Province requires all laboratory equipment purchases over $5,000 and all general equipment purchases over $20,000 to be reviewed by local organizations. These local organizations have generally set up provider advisory committees to review the requests, and the experts on these committees will often share their experiences and discuss alternative equipment choices as part of the review. Comparable discussions take place in Quebec.

Several years ago, a proposal was circulated calling for the establishment of a Federal unit to compile information on the performance of alternative equipment and to serve as a referral center for questions from individual Provinces. Such a unit was never developed. In part, that was because of a lack of funds and a general retreat by the Federal Government from the operational details of the insurance programs when the cost-sharing formula was changed. Also, questions have been raised about the ability of such a unit to provide accurate, current assessments in a market in which upgrading and product modification occur at rapid rates.

Regulation and Reimbursement

As noted above, most direct controls on the health care system are imposed at the Provincial level, and these controls generally operate as part of the reimbursement system. For this reason, the concepts of regulation and reimbursement are linked in the discussion below. The process and content of health planning at the Provincial level, the budgeting process and its impact, controls on physicians relative to new technology, and utilization controls are described following a brief review of regulation at the Federal level.

Federal Regulation of Drugs, Medical Devices, and Nuclear Materials

Direct Federal regulation is limited to three areas—drugs, medical devices, and nuclear materials. The Federal Government regulates both the manufacture and distribution of drugs in Canada.[20] The conditions under which drugs are to be manufactured are described in the manufacturing facilities and control regulations. The regulations pertain to facilities, employment of qualified personnel, quality control procedures, maintenance of records, and maintenance of a suitable system to enable a complete and rapid recall of any batch of drugs from the market. Plants manufacturing biologicals such as serums and vaccines must be licensed according to specifications of the Health Protection Branch, whether they are located in Canada or abroad. Pharmaceutical plants are regularly visited by inspectors.

[20]This description is adopted from Health and Welfare Canada, Health Economics and Statistics Division, *Review of Health Services in Canada, 1974*, 1974 (4).

When a new drug is to be placed on the market, the manufacturer is required by law to provide specified information, including a quantitative list of all ingredients, evidence of clinical effectiveness, the formulation of dosage forms, and reports of any adverse effects. This information is evaluated by the Health Protection Branch to assess whether the drug is safe and effective.

Once a new drug is on the market, its sale can be banned by the Health Protection Branch if the adverse drug reaction program indicates that the drug is unsafe and injurious to health. The drug quality assessment program aims at producing objective evidence on the quality of drugs already on the Canadian market and disseminating this information to members of the health professions, governments, and the general public.

Another major activity of the Health Protection Branch is designed to allow greater price competition for drugs. This activity involves inspecting manufacturing facilities, assessing claims and clinical equivalency of competing brands, and providing information to concerned professionals and to the general public.

Also, the Health Protection Branch has a Bureau of Medical Devices that conducts a program for medical devices analogous to that of the U.S. Food and Drug Administration (FDA). Unlike the U.S. program, which includes an extensive premarketing approval process, however, the Canadian program is principally a postmarketing effort. The difference between the two countries' programs in part reflects the fact that the United States is a manufacturing country, whereas Canada is an importing country.

The postmarketing system in Canada is judged by those operating it to function well. It involves responding to user concerns, some literature review, and contact with U.S. regulators, since problems generally appear in both countries. The program is not bound by specific procedures, and when problems are identified, the Canadian Government may require modification or withdrawal of the product. Hospitals are generally alerted to identified problems.

Program administrators feel that a strict postmarketing approach may be inappropriate with respect to new technology. For certain types of new products, they are requesting voluntary participation of manufacturers in monitoring the scope of diffusion and identifying clinical investigators studying these products. The products subject to this premarketing review include implants, cardiac pacemakers, intrauterine devices, intraocular lenses, and long-wear contact lenses.

All Canadian applications of radioactive isotopes are controlled and licensed by the Atomic Energy Control Board (AECB).[21] The Radiation Protection Bureau of the Department of National Health and Welfare serves as a health and safety advisor to AECB. Medical approval of license applications is required from the Bureau. The physician named on the license is personally responsible for the use of particular radionuclides. Each license is set out for the physician, specifying—on the basis of AECB'S assessment of the training and qualifications of the individual physician—the types of radionuclides the physician can use, their application, and their dosage.

Provincial Health Planning Processes

The Canadian Provinces have not invested resources in health services planning separate from the regulatory processes. Most efforts to develop bed need projections, criteria for special care units, or statements of Provincial goals with respect to the organization and distribution of specific services have been made in response to project applications. As has happened frequently with U.S. health planning agencies, the first request in a given area triggers the process of developing standards and criteria and a Provincial plan for the service.

The standards development process, as noted above in the section on guidelines for special services, involved both joint Federal-Provincial efforts and strictly Provincial activities. It also tended to be informal and to involve Provincial

[21] The description that follows is adopted from Health and Welfare Canada, Working Party on Special Care Units in Hospitals, Special *Cure Units in Hospitals,* 1975 (9).

officials and selected medical consultants. The general public has had little opportunity for participation or comment, but that situation is changing somewhat. The three largest Provinces—British Columbia, Quebec, and Ontario—all have some local regional organizations that are involved in both planning and review of specific project requests. The organizations' level of activity and degree of involvement vary in each Province.

British Columbia was divided into regional districts in 1957, and regional planning boards (essentially councils of municipal government) were established in each. One subfunction of these regional planning boards was health. In 1967, "regional hospital districts" coterminus with the general planning districts were created as administrative mechanisms to authorize bonds to support hospital construction and establish taxes to repay the bonds. (A separate organization was required constitutionally to allow for taxing authority.) The regional hospital district boards and the regional planning boards are identical, although most districts have established advisory committees of hospital representatives and, in some cases, laypeople.

The net effect of the establishment of these boards in British Columbia appears to be that greater attention is devoted to regional health planning. The districts have been developing regional plans specifying the role of individual institutions, and in the absence of a Provincial health plan, these serve as key planning documents. Most boards have little independent health planning capacity and rely heavily on Provincial government staff for advice and support. Only two districts have their own staffs and are particularly active. One of these, Greater Vancouver, has reported some conflict with the Province over specific projects.

The Province of Quebec has been divided into 12 regions, and each region has a regional health and social services council (CRSSS). The regional councils began operation in 1972, their first responsibility being to oversee the elections for a provincially mandated reorganization of hospital boards. The responsiblities of the councils are conceived as evolving to include considerable authority over the regional medical and social service system.

Initially, the councils were involved in planning for emergency medical services, handling consumer complaints about health services, assisting institutions to establish common services and group purchasing, and reviewing and commenting on individual institutional projects and Department of Social Affairs' statements of regional and Provincial health and social service priorities.

Beginning in 1976, the regional councils' scope of authority **was** dramatically increased. Quebec changed the basis for financing capital (discussed below) and gave the councils authority over the expenditure of substantial funds. Several of the councils, most notably that in Montreal, have responded not only by reviewing specific project requests, but also by developing more general mechanisms for reviewing patterns of service delivery and encouraging change. These efforts have generally been dominated by hospital representatives sitting on a separate commission within the council structure. The program of fiscal constraints and the potential cost savings associated with consolidating services, however, have helped the councils achieve some restructuring.[22]

Quebec's regional councils are currently involved in a major planning initiative mandated by the Provincial legislature. This is an examination of the distribution of medical staff expertise and activities among teaching hospitals, a two-phase project in which the councils are working with the hospitals and universities and in which the Quebec Ministry by law cannot participate. The first phase has required the university-affiliated hospitals to specify a medical staff organization and identify the range of services and expertise they have available. During the second phase, these plans will be reviewed and recommendations will be made concerning adjustments to the distribution of

[22]In Montreal, for example, where the council employs three biomedical engineers, obstetric and pediatric services were realined and consolidated. Hospitals and the council resisted public demonstrations and picketing to keep the closed units open, which were held for a year-and-a-half following these decisions.

medical expertise and services, with concomitant proposals for shifting staff.

The planning initiative in Quebec is being pursued deliberately and with extensive participation from all parties. Such an effort is virtually inconceivable in any other Province. Apart from the integrating effect of the medical schools, one factor that makes this planning initiative possible in Quebec—and unlikely in other Provinces—is the legal domination of hospitals by the Quebec government. The passage of legislation mandating a complete restructuring of hospital governance in Quebec reflects a level of acceptance of Provincial control that is unmatched in other Provinces. Furthermore, in Quebec, there has developed general acceptance by both physicians and government of the legitimacy of negotiations between them regarding not only insurance payment rates, but other conditions of work. In other Provinces, the legitimate scope of negotiation is often viewed as more limited.

It should be noted that the initial development of 12 councils with advisory power in Quebec represented a weakening of a more extensive decentralization proposal. The original proposal was for three regions with extensive authority to determine institutional operating and capital budgets. After considerable debate about whether Provincial authority should be delegated, a legislative compromise was reached. Since then, the Provincial government has delegated authority on an administrative basis.

A similar debate occurred in Ontario, where district health councils are currently being organized. In 1972, the Ontario Ministry of Health was reorganized to achieve one goal—the development of a capacity to develop integrated community health delivery systems and planning capacity. Central to the development of such a capacity was the concept of local bodies with extensive health planning and health systems management responsibility that would receive staff support and expertise from the Provincial level. This concept became enmeshed in a general Provincial debate on regional government. Because the local organizations were not established, the Ministry was reorganized again that same year to reestablish centralized centers of activity. Since then, efforts have been underway to establish district health councils with advisory responsibilities. The first district council was established in January 1974, and approximately 20 district councils have now been formed.

There is no district health council established in Toronto. Two hospital organizations share what would be the council's responsibilities—the University Teaching Hospital Association for university-affiliated hospitals, and the Hospital Council of Metropolitan Toronto for community hospitals. These organizations share an executive director and staff. That hospital associations are playing the role of district health councils in the largest Provincial metropolitan area, although not a comment on the quality of work done by these organizations, is indicative of Ontario's attitude regarding the importance of public participation (as well as Toronto politics regarding the selection of appropriate public representatives).

The district health councils in Ontario were conceived of as providing advice in the areas of personal health and hospital services, community health services, mental health, environmental health, and linkages to social services. Their potential role as managers of the local health system was left undefined, but they were to be given considerable authority to review local capital spending plans.

The Ontario Ministry of Health did not want the councils to become bureaucratic, so it attempted to avoid the development of extensive staffs in each district. Each council has an executive director. To provide technical staff support and to provide contact points within the Provincial government, the Ministry established area planning coordinators and created area health teams. The area teams consist of individual members of the staffs of each Ministry division who have been assigned responsibilities for specific districts or groups of hospitals.

Because of their involvement in other functions, area planning coordinators have not served as an effective bridge between the district health councils and area health teams. The area teams appear to have been effectively estab-

lished, however, and are a major source of formal organizational linkage across functional lines. One effect of this has been to facilitate hospitals' access to the Ministry on the operational level by establishing clear contact points.

Ontario's district health councils have not yet assumed the full range of activities or role in the system originally contemplated for them. They are doing almost no planning separate from reviewing and making recommendations on service and capital expenditure requests. Although the Province has approved many of the changes developed for Windsor, approving not only the perinatal unit, but also development of two chronic care units and the purchase of a new computed tomography (CT) scanner, the guidance the district health councils have received from the Ministry on reviewing service and capital expenditure requests has been late—and because of the fiscal constraints, no action has been taken on the councils' recommendations.

Hospital Budgeting and the Diffusion of Technology

As noted above, the hospital budgeting process is the central process in which resource allocation decisions are made. This process has two components. One is establishing the operating budget for the hospital, which may contain an adjustment to provide additional operating funds for new services or to staff new equipment. The second is establishing the capital budget, with provision for spending on plant, fixed equipment, and movable equipment.

There is enormous variation in the methods different Provinces use to provide funds for capital investment. Part of the reason for this variation is that the Federal Government has not shared the cost of construction and fixed equipment through the hospital insurance program. Although separate funds have been available from the Federal Government for hospital construction and construction to support medical education, the costs of plant and fixed equipment have generally been Provincial responsibilities. Movable equipment has been eligible for cost sharing, and Provincial governments have had the option of expensing grants each year or paying depreciation.

Each of the two Provinces that have been the focus of this study, Ontario and Quebec, uses a unique approach to capital financing.[23] Ontario provides two-thirds of the approved capital cost of new construction or renovations of a community hospital or health care facility.[24] Health science centers and university teaching hospitals are paid Provincial grants of 100 percent of approved capital costs.

Hospitals in Ontario may fund a project totally, using the hospital's capital funds, provided that additional operating costs will not result from it. There are several possible sources of these funds: philanthropy, local government, operating surpluses, endowment, endorsement, and contributions are the most important. The two-thirds/one-third split historically has been the relative value of plant and land, so a new facility essentially has had to have the land contributed to obtain the funds for a new plant. With this method of funding, the Ministry's planning procedures must still be adhered to, with plans approved by the Ministry. Funds for movable equipment are provided through depreciation, but the hospital must provide the initial purchase funds itself. These are often generated from public or private contributions or operating surpluses.

Over the last several years, the Ontario Ministry has provided only limited capital funds to the hospitals in Ontario. In 1973, the Province agreed to a 10-year development program for teaching hospitals, pledging $95 million in real dollars over that period. Teaching hospital projects have been approved under that program, but in many cases, capital funds have not been allocated during the year of approval. Instead, the Province has authorized the hospitals to borrow the funds and pledged to reimburse them for the loans and interest. Hospital construction has been authorized in rapidly growing areas and to address safety issues, but under few other circumstances.

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[23]For a full description of Provincial approaches to financing, see Lewin and Associates, Inc., *Government Controls on the Health Care System: The Canadian Experience*, 1976 (11).

[24]If the hospital or health care facility is located in northern Ontario, and the population of the municipality is not more than 12,000, the Ontario Ministry's share increases to five-sixths of the approved capital cost of new construction or renovation.

Almost no funds have been provided for equipment projects and new services in Ontario. The Province has approved acquisitions but told hospitals that they will not have their depreciation or operating expenses increased to reflect the addition, a situation characterized as "approved but not funded. " Of the seven approved CT scanners in metropolitan Toronto, for example, only two were funded by the Ministry. The remainder had to be funded out of global budgets or philanthropy.

One exception, in terms of the provision of capital funds, has been a program under which the Ontario Ministry will provide 100 percent of the capital funds for projects that will recover their costs in operating fund savings within 5 years. The hospital's operating budget, however, is reduced by the savings. To make it more attractive, the program will be changed so that if a hospital provides the initial capital funds, it will be allowed to recover these plus interest, and subsequent operating savings will be shared on an equal basis between the hospital and the Province.

In Quebec, until 1976, all capital funds were provided directly by the Province. As part of the 1976 delegation of authority to the regional health and social services councils, there was major restructuring of capital financing that shifted some financing to the regional councils and hospitals themselves. Until 1976, hospitals had been reimbursed by the insurance program at a standard ward rate. When patients voluntarily sought semiprivate or private rooms, they would be charged separately for them.[25] In establishing hospital budgets, Quebec had used the revenues from preferred accommodation charges to offset the amount needed from the Provincial hospital insurance program. Under the restructured system, hospitals were required to place 45 percent of these funds into a special fund for capital expenditures. Another 45 percent was to go to the regional council, and 10 percent went to the Provincial government to redistribute to regions with less of this revenue.

Hospitals in Quebec are expected to finance minor equipment purchases out of the funds generated by those preferred accommodation charges or contributions. Construction and other renovations under $1 million and purchases of specialized equipment are to be reviewed by the regional council, and approved requests are funded jointly out of the council funds and hospital funds. The council can contribute no more than 80 percent of the cost of renovation of equipment and may in fact contribute less, requiring the hospital to fund up to the entire amount of the project itself.

Certain types of equipment purchases, although they will be funded through the council, must be approved by the Province. Included in this category at one time were purchases of diagnostic radiology, therapeutic radiology, nuclear medicine, data processing, laboratory automation, and anesthesia and recovery equipment. The category now includes only purchases of computer applications and data processing equipment.

Construction projects over $1 million in Quebec are funded entirely by the Province. These projects must be reviewed by the regional council and approved by the Province. Funds needed for the operating expenses associated with new capital or service charges are also reviewed and could be added to the global budget by the Provincial government. Over the past 4 years, however, no additional funds were added.

General construction funds have been tight in Quebec over the last several years. In 1975-76, they *were $42* million. The accommodation charge generated an additional $20 million. When the new financing system was put into place, the Province estimated the amount that was being spent on equipment and renovation under $1 million (the expenditure classes to be funded by these charges) and set the charges to realize this level of revenue. The charges have since been increased but there has been no systematic analysis of whether current changes provide a sufficient level of funding.

Discussions with individuals in Quebec suggest that the accommodation charge is providing only a marginal amount of funds. The 10-

[25] Blue Cross and other insurers remain active in a market for insurance covering these charges and other medical charges not covered by the insurance program.

percent fund for reallocation has been inadequate and the Provincial government has augmented it. The Montreal Council estimated that it received $40 million per year in requests, divided evenly between renovations and equipment, of which it authorized $15 million and directly contributed $6 million to $7 million. It is receiving $3 of special equipment requests for every dollar it authorizes.

Limited funds have required Provinces and regional bodies to establish priorities among projects. A variety of mechanisms have been employed. In Ontario, beginning with fiscal year 1978, hospitals were asked to submit their proposed capital projects and proposed new and expanded services to the district health councils. No guidance was provided to the councils on the priorities they should employ for their review.[26] In addition to this lack of guidance on priorities, the councils received no information from the Province specifying which projects from the previous year, if any, had been funded and which should be reconsidered in the current year. Because of these problems, for fiscal year 1981, the University Teaching Hospital Association refused to carry out a priority-ranking process for new and expanded programs.

The Province of Ontario has expressed conflicting attitudes on the degree of autonomy the district health councils will have. On the one hand, it has reserved the right to change the priorities coming from the district councils. Along this line, Provincial staff indicate they have developed their own priority-ranking system, including a set of numerical weights that applies to project ranking. This system has not been shared with the district councils or Provincial hospitals, but its general shape can be surmised from the guidance the Province has given the districts. The guidance on capital spending established 10 project categories: 1) correction of hazards, 2) conversion from active treatment to chronic care, 3) regional bed shortage, 4) improvements in services, 5) consolidation in services, 6) investments that reduce operating costs, 7) cancer treatment services, 8) crippled children's services, 9) energy-saving investments, and 10) other. Priority was to be given to projects in the first, third, and sixth categories.

Although the Province has reserved the right to change district health councils' priorities and has established its own ranking system, however, Provincial staff indicate that, in reviewing the councils' priorities for funding in 1979-80, they selected the top three to five projects from each council in order to assure that the top priorities from each would be represented, and then established a ranking among these. Indeed, no one contacted in the Ministry or hospital community cites any case in which district council priorities have been modified. There is, however, one footnote to this priority-setting exercise. For 1979-80, no new funds were made available for new or expanded services, so all projects approved in that year, regardless of rank, had to be funded out of individual institutions' global budgets.

In Quebec, because of the local council funding and institutional autonomy over spending on specific activities, the arrangements for establishing priorities are different from those in Ontario, but their effect is comparable. Having received guidance from the regional council on its funding priorities, hospitals submit their equipment and renovation priority lists to the council. In Montreal, the lists are initially reviewed by a commission within the council consisting of two representatives each of the medical schools, teaching hospitals, community hospitals and chronic hospitals, and one representative of the psychiatric hospitals. This commission makes the final decisions within the council on projects under $100,000. For projects over $100,000, the commission makes recommendations, but the council makes the final decisions.

The commission within the Montreal council has conducted or sponsored studies on a variety of issues. These have ranged from mundane but economically costly issues of storm window replacement in hospitals to a review of regional nuclear medicine facilities to determine which departments would be allowed to update their

[26] In the first year, guidelines were issued only 2 months before submissions from the district councils were due, a time when the process was well underway and after many councils had established their own priorities. This timing led to considerable complaints from the councils. The next year, this situation was similar.

equipment. (Following the nuclear medicine study, the council arranged for group purchase of equipment at a discount.) The priority-setting process during the first 2 years of its operation was reported by some participants to be extremely disordered and inequitable, in part because of council weaknesses, in part because the hospitals failed to set priorities effectively. There was a feeling that the process had improved, however, and that despite the low proportion of funded projects to total requests, the hospitals were substantially satisfied with the results.

As in Ontario, the Quebec government reserves the right to change recommendations from the regional councils. There have been only a few cases in which it has exercised its right, partly because the councils have participated in the process by which the planning parameters were set.

In closing this discussion, two outstanding issues should be noted. The first is that the lack of new program funds has been a major problem for Provincial hospitals. Despite discussion of changes in the reimbursement system, the global budgets of most hospitals have remained substantially unadjusted for several years, and in real terms, the base has in fact declined. This, more than the capital limits, has affected the institutions' capacities to mount new programs. Although the lack of funds has encouraged internal economies, service adjustments, and consolidation of service as a means of coping with tight resources, it has also prevented some consolidations by not providing a structure for shifting resources to hospitals that have received the consolidated programs.

The second issue is that the Provinces have not developed a long-term basis for determining the level of resources in health care. Indeed, a global approach to this problem is not necessary. Some Canadians, for example, decided that, in light of perceived excess capacity and inefficiencies and in view of other Provincial priorities, funds to the health system would be restricted. They did not attempt to determine the optimal level, but instead began reducing services at the margin. Although this approach is reasonable, as implemented it suffers from the lack of any assessment of the marginal impact of these decisions.

Those in Canada regularly point out that decisions concerning the health system, particularly resource decisions, are political. The introduction of assessment methods would not change this. By highlighting the effect of the current decisions, however, it might inform judgments concerning how these decisions should be modified in the future. There is the risk for government that such evaluations, if public, would fuel pressures for higher spending. The Provincial governments are sensitive to constituent pressures on these issues, and several individuals in Ontario and Quebec reported increasing public pressure to expand resources in the health sector .27

If decisions are made to increase the capital funds available to the health sector, the formal systems for establishing priorities to allocate these funds appear to be in place in these Provinces. Until now, however, especially in Ontario, constraints have been so tight that choices among priorities have been more formal than substantive. One question confronting these systems is whether they can in fact operate in an environment of real allocation decisions, or whether the increased funds and greater relevance decisions would generate a higher level of conflict than the systems could absorb. Related to this, a second question is whether Provinces can marginally increase the level of investment and cost growth, or whether, unable to do this, they will move from famine to feast as they moved from feast to famine in the early 1970's.

Hospitals' Responses to Investment and Service Constraints

The fiscal constraints in general, and capital and service constraints in particular, have significantly changed the environment in which hospitals operate. Hospitals have reacted to this in a wide variety of ways, some supporting public policy, some attempting to undercut it. Five

[27] The front page headline in the July *24, 1979* Toronto Star, for example, played to public concerns by announcing "Our Hospital Nightmare: You Could Die Waiting. " The next day, the Health Minister's response was headlined "I'll Fight for Needy Hospitals—Timbrell. "

aspects of hospitals' responses in the technology area are particularly notable.

First, in addition to attempting to achieve greater efficiencies to adjust to the constraints and create internal funds for capital and service expansion, hospitals have tightened the management of their capital and operational budgeting system. To respond both to the overall constraints on available funds for capital and new operating expenses and to the requirement that they present formal lists of priorities to regional bodies, hospitals have had to define their priorities clearly.

One approach that hospitals have used to define priorities has been to establish budgeting committees that include physicians from the major departments, such as medicine, surgery, radiology, and pathology. Such committees change the decisionmaking process from one in which the hospital's administrators must respond to departmental requests individually to one in which the competing claims on limited resources are reviewed and resolved in discussions that include physicians representing the different interests. Thus, the establishment of hospital budgeting committees represents a major reordering of decisionmaking in these institutions. Among its effects are to reduce staff alienation from the budgeting process, to broaden the range of the expertise and perspectives brought to bear in assessing relative priorities, to enable more effective challenge of planning assumptions and project justifications, and sometimes to generate unexpected solutions to problems. A main force assuring the effectiveness of such committees, however, is the reality of the external constraints.

A second element in the hospital response has been an increasing acceptance of service consolidations and shared-service arrangements. The obstetrics and pediatrics consolidation in Montreal and Windsor have already been noted. Other examples that are cited by Canadians are arrangements for the shared use of a CT scanner by radiologists at Toronto General Hospital and Mount Sinai Hospital (these facilities are across the street from each other) and a similar shared-use arrangement between the anglophone McGill-affiliated Jewish General Hospital and francophone University -of-Montreal-affiliated Hotel de Notre-Dame. Also cited is a growing interest among hospitals in referring highly specialized laboratory tests to other hospitals rather than duplicating the capacity. Efforts in Hamilton, Ontario, where hospitals have developed an in-common laboratory and agreed to consolidate special services such as neurosurgery, cardiac surgery, and burn treatment at individual institutions, represent a notable example of this.

Within this small but growing movement toward consolidation, the medical schools have played mixed roles. There is general acceptance in Canada that highly specialized services should be centralized at teaching hospitals, but the medical schools have varied significantly in the degree to which they have acted to try to achieve coordination of services among their teaching affiliates. McGill and Laval in Quebec were cited as examples of schools which had actively promoted coordination and consolidation. The University of Toronto and University of Montreal were noted to be far less involved. An area of fruitful future inquiry would be to understand the factors that have led to these differences.

A third element that can be noted among some Canadian hospitals is a renewed growth in philanthropy and private development campaigns. Several hospital administrators view efforts in these areas as increasingly important; they consider it a major need and challenge to explain to the public why, even with a government insurance program, private contributions are necessary. Philanthropy has made acquisitions possible when government funds were not available. In Quebec, for example, funds for all CT scanners in the Province were made available either by private philanthropists or from hospital endowments. Purchases in Quebec were all made with Provincial approval. In Ontario, by contrast, not only approved scanners were purchased with philanthropic funds, but several unapproved scanners, as well.

The fourth notable element of hospital response is the acquisition of unauthorized equipment. Such acquisition has occurred primarily in Ontario, where in Toronto, for example,

there are three unauthorized CT scanners. Similarly, it was reported that when this Province delayed decisions on ultrasound equipment, many hospitals simply purchased it. The situation in Ontario in part reflects the fact that since hospitals *were* being asked in most cases to fund such purchases out of their global budgets with no increase in funds, obtaining approval offered no financial advantage. It also reflects hospitals' belief that certain services are critical to maintaining quality and staff. (The hospitals with the unauthorized CT scanners have referral neurology and neurosurgery services.) Finally, it reflects their belief that the Province will not attempt to discipline or penalize the hospitals that make unauthorized purchases. The Province of Ontario has never ordered a hospital to sell off or discontinue an unapproved service, and political pressures might make such an order infeasible. Furthermore, the Province continues to pay radiologists the professional component of their fees, and this practice further undermines belief in the Province's will to crack down.

Individuals in Quebec indicated that in that Province a similar situation involving the acquisition of unauthorized equipment was extremely unlikely, because the Provincial government has previously demonstrated considerable willingness to deal aggressively with hospitals, and because regional councils' control over renovation and equipment funds provides a clear disciplinary mechanism.

Finally, a fifth element of hospitals' response is represented by hospitals' attempting to shift expenses from their global budget outside to other aspects of the health insurance system. As part of their constraint programs, Ontario and Quebec stopped adjusting hospital outpatient budgets for higher volume. (In Ontario, however, the Province has given slightly higher across-the-board budget increases to the outpatient budget than the inpatient budget. This is intended to encourage and promote shifts from inpatient to outpatient care.) One institutional reaction has been to refer ambulatory patients to nearby private physicians for tests that will be covered under the medical insurance program, These referrals have generated some interest among physicians in developing noninstitutional nuclear medicine facilities. Efforts to expand the reimbursement in the medical insurance program to cover these facilities have been resisted.

Professional Fees and the Issue of Freestanding Units

The process by which professional fees are set was described in the section on the health care system in Canada. Several people involved in the fee-setting process were sensitive to the issue that fees can create incentives for higher utilization or abuse of services. To some extent, this pressure is countered by the general concern within the medical societies that incomes by specialty be equalized, and by the existence of one interspecialty group that reviews the relative fees for new procedures.

The Ontario Medical Association indicated that, as a general rule, it tries to set an initial fee that is based on the recognition that as the procedures become more routine, there will be less physician effort. It also identified some procedures, such as chronic dialysis, for which the original fee was reduced, and others for which the fee increases were kept below average until a more appropriate relative value was reached.

As noted above, the fiscal constraint program has led to some interest among Canadian physicians in developing freestanding units for such services as CT scanning, nuclear medicine, and ultrasound. The principal Provincial control over this private proliferation of high technology is the fee system, since unless there is a technical component to the fee as well as a professional component, the Provinces will not reimburse equipment and technician costs. In general, Provinces have held the line against such freestanding units.

It can be argued that the development of freestanding units should not be resisted because such units can better respond to outpatient needs and may operate more efficiently. For the Provinces to allow this development, however, they would have to be assured that inappropriate utilization could be prevented and that the insurance programs would realize some of the

financial benefits of a shift of diagnostic services to an outpatient setting.

Utilization Controls

Utilization controls in the Provincial insurance system are limited. Most focus on outpatient care and are designed to identify fraud or high-billing physicians. Similarly, the in-hospital review systems run by the Provinces are limited. Despite the fact that the global budget incentive is to reduce length of stay and unnecessary admissions, many Canadians believe that current hospital utilization is unnecessarily high, and some hospitals have therefore begun implementing internal review programs.

SPECIFIC TECHNOLOGIES

The preceding sections of this chapter have attempted to present an overview of the management of medical technology in Canada, including the issues being addressed in the system and the formal and informal processes involved in making the technology decisions. In this section, an effort is made to shed additional light on the earlier discussion through examinations of specific technologies. The reviews presented are not comprehensive, but do provide information on the number of units, basic planning approaches, and Provincial experiences that illuminate the technology management process.

CT Scanners

The original Federal-Provincial guidelines for special care units did not address CT scanners. In March 1977, a member of the Federal-Provincial working party drafted a report on CT scanning citing the EMI standard of one unit per 500,000 population. A definitive standard was not attempted, however, because it was felt that changes in the technology would quickly outdate it. Although an interim report was prepared, the working group recommended that, because CT scanning technology had raised **a** number of issues in radiology and nuclear medicine, the report not be issued and that a national symposium on diagnostic imaging be held. A symposium took place in October 1978. Since that conference, a group has been working on a draft guideline on CT scanning, and it was scheduled to complete this work in May 1980.

The delay in Federal-Provincial guidelines left the Provinces to address the issue of diffusion. Most Provinces adopted an initial standard of one unit per 1 million population or one per 100,000 population. In 1978, there were 20 to 25 units in Canada. Among the major unresolved issues for the Provinces in addressing the diffusion of the technology are: 1) how to reconcile the population and volume-based projections of units with patterns of neurological and neurosurgery practice and the demands for scanners at hospitals providing these services, 2) how to assess the relative utility of this CT equipment vis-a-vis other services, and 3) how to assess the utility of a whole-body scanner relative to a head scanner. In general, while attempting to obtain answers for these questions, most Provinces have moved conservatively, but not dogmatically, in limiting CT scanner services.

Ontario had 17 authorized scanners as of January 1, 1979. As of that date, three had not been installed. The pattern of authorized expansion of scanner services was as follows:

	Total authorized scanners
1974 ....., ... ,	1
1975	2
1976 ..., ... , ...	6
1977	8
1978	10
1979	17

Recently, a joint Ministry / Ontario-Medical-Association committee revised the criterion to one per 500,000 population and recommended adding several additional scanners. Five of the approved scanners are located in Metropolitan Toronto. Two of these have restricted use—one at the Hospital for Sick Children, the other at the Princess Margaret Hospital, which is the Provincial cancer center. As noted above, in some cases, patterns of sharing CT scanners have developed.

In addition to the approved scanners operating in the Toronto area, there are three unauthorized scanners. Unauthorized scanners have developed in Ontario for several reasons:

- Only two of the approved scanners in the Toronto area were funded by the Ontario Ministry; the others had to be financed out of global budgets, The hospitals that installed unauthorized scanners were therefore at no more financial risk than the hospitals that installed approved scanners. Furthermore, one unauthorized scanner was donated and the benefactor guaranteed that operating expenses would be met; a second scanner was purchased used, therefore at reduced cost.
- Hospitals expect that at some point the Ontario Ministry will pick up the operating expenses on the unapproved scanners.
- With the Ministry considering hospital closings or definitions of hospital roles, possession of a scanner is viewed as important in terms of allowing an institution to remain in the forefront, Hospitals believe their position in a restructured system will be based on the equipment and services they offer—regardless of whether the equipment and services have been approved.
- Ontario continues to reimburse radiologists for the professional component of their fees for CT scanning even at unapproved scanners, thereby making use of these scanners attractive to radiologists.
- Scanners are attractive to hospitals in terms of maintaining physician staff loyalty. Unlike cardiac surgery, a service which requires a cardiac surgeon, scanning is a basic diagnostic technique that many physicians want to have available.

The Ontario Ministry's actions toward unauthorized scanners in Toronto have been inconsistent. The three hospitals with unauthorized scanners were ordered to set up a separate cost center for the scanner and segregate the costs associated with it; the hospitals complied. Reportedly, CT scanner expenses are being excluded from their global budgets. (One hospital with an unauthorized scanner announced that it would make referral scans from other regional hospitals available free of charge. Since the hospitals with approved scanners in the city are charging for referral scans, this was seen as one way of creating pressure on the Ministry.) When one hospital with an approved scanner had to close its scanner for several months and contracted with a hospital with an unapproved scanner to provide scanning services, however, the Ministry sought an amendment to the Provincial law establishing scanners at specific hospitals to permit reimbursement to the hospital with the unapproved scanner for the provision of scanning services of the approved hospitals.

There is reported to be a 2-month backlog for outpatient referral scans in Ontario. One observer thought that this backlog was an artifact resulting from inadequate operating funds for the scanners. Noting that many scanners are operating only 8 hours a day because of staff limitations, that observer suggested that the backlog could be significantly reduced or eliminated if the scanners were operating for longer periods.

Quebec has maintained tight control over scanners. There are only seven units in the Province, with two on order. The Montreal Neurological Institute has two—one head, one body. Of the remaining units, all are body scanners. There are procedures for referral and sharing among hospitals. The pattern of scanner expansion in Quebec has been as follows:

	Head	Body	Total scanners in use
1973 . . .	1	0	1
1974	***1***	**0**	**1**
1975	1	0	1
1976	1	2	3
1977	1	4	5
1978	1	6	7

After receiving requests for three additional scanners, the Province conducted a general review of its policy. Officials felt particularly uneasy regarding two questions—the relationship of scanning to other diagnostic services and the true utility of the whole-body scanner. Quebec has therefore decided to limit the scanners in the Province to the current units and will not consider adding to these units until the six have an average annual volume of 2,800 examina-

tions each, and a rigorous evaluation of scanning from both a health and economic perspective is completed, either in Quebec or some other location. Both Ontario and Quebec are considering sponsoring such an evaluation.

Renal Dialysis

Federal-Provincial guidelines and assessments of renal dialysis place it in the overall context of treatment of end-stage renal disease. Those documents place an emphasis on home dialysis to maximize autonomy, and on kidney transplants as a major service that should be available.

The Federal and Ontario planning guidelines call for a hospital-based unit to support 25 to 50 new patients a year, a planning estimate that requires approximately six beds (9). The original Federal guidelines state that the program should be based on a population of no less than 1 million and that "depending upon criteria for selection and the aggressiveness of the case-finding programs, this population base may be expected to yield at least 25 new **cases** per year, and possibly many more" (9). The guidelines further note (9):

> If the treatment were wholly successful, the program would obviously grow until patients began to die of old age, or other causes. Assuming a death rate of 10 percent per annum of those at risk, a program based on 25 new patients per annum would increase to a total of more than 200 patients in 15 years and would not stabilize until 250 patients were on treatment.

A revised Federal-Provincial Guideline on Regional Renal Failure Programs has been completed and is awaiting publication. The revised guideline expands the discussion of renal transplantation and organ retrieval requirements.

In 1979, Ontario had 10 hospitals with inpatient dialysis units. Sixteen hospitals, including some with important programs, provided home dialysis. In the period from April 1, 1978 to March 31, 1979, 9,394 outpatients and 1,854 inpatients received dialysis services. There were 201 transplants.

The Quebec planning documents analyze the current dialysis and transplant programs in the Province and call for specific changes (12). In 1978, there were 16 hospital-based chronic dialysis units, with 97 dialysis machines. There were three acute dialysis units in other hospitals. All of these were inpatient based; there were no outpatient dialysis units (12). Three other centers provided for home dialysis and had 52 dialysis stands. There are six hospitals in Quebec doing approximately 125 transplants a year.

Quebec's dialysis goal established in 1978 was to increase the proportion of home dialysis from 20 percent to 30 to 40 percent by 1981, a figure comparable to rates in Ontario, the United States, and Europe. This was to be done by expanding the efforts of the three centers for home dialysis. Outpatient dialysis was to be substituted for inpatient dialysis, with one center serving as a pilot project. The existing hospital units were viewed as sufficient, particularly if home dialysis and outpatient dialysis were developed. Transplants in Quebec were projected to increase to 145 in 1981; the six transplant units were viewed as sufficient to meet this demand. Indeed, by some planning standards, that is more than the number of transplant facilities needed, but the Province announced as policy a decision not to seek a regrouping of the current centers. In short, the Provincial plan called for shifts in the modes of treatment for end-stage renal disease, but no regrouping of the hospitals providing these services.

Since Quebec's planning was completed, the demand for dialysis services has increased. Current facilities are, by general agreement, saturated. The Province has not yet determined whether the prevalence of end-stage renal disease is increasing or if indications for dialysis have changed. It seems prepared to meet the needs imposed by the unexpectedly high demand, but views home dialysis and outpatient dialysis as the areas to emphasize.

Cardiac Surgery

Coronary bypass surgery has been increasing in both Ontario and Quebec. In Ontario, in 1977, there were 1,675 reported cardiac revascularization procedures; in 1978, this number grew to 1,947. In Quebec, in 1977, there were 1,678 bypass procedures and 2,412 other open-

heart procedures; in 1978, there were 1,891 and 2,690, respectively. A study of the effect of the surgery in Quebec showed that of those receiving the surgery, 55 percent returned to activity but 45 percent did not. The increase in this surgery was noted in both Provinces, but in neither Ontario nor Quebec was the increase viewed as a major problem.

More concern was expressed over the appropriateness of the distribution of cardiac surgery units and the quality of care they render. Implicitly, it is assumed that appropriate controls on the proliferation of units will control marginal surgery. The appropriateness of care at established units has been the subject of several studies in each Province.

In Ontario, the problem has been treated primarily as a quality issue. Along this line, guidelines have been established for a minimum of 150 operations per year per unit; a staff of two surgeons, two cardiologists, and 24-hour coverage by residents or others; and affiliation with a health sciences center. The guidelines in use were reviewed and revised by a 1973 task force on cardiovascular surgery. The task force consisted of three surgeons, two internists, a pediatrician, and three Ministry of Health staff. It recommended the closing of one unit in Windsor and the establishment of a second unit in London. Both these recommendations were followed,

Currently, there are 10 hospitals in Ontario at which cardiac surgery is performed; 4 are in Toronto. Only one, at Sudbury, is not a teaching hospital. The Sudbury unit was established in 1967, and its performance has been closely monitored. A 1976 task force reviewed its performance, complication and mortality rates, and approved the continuation of surgery there for 2 years, but recommended that the team stop elective valve surgery. Several other units with low volumes are also examining the referral of elective valve surgery.

A task force on cardiovascular surgery in Toronto that will soon complete its work is expected to report that facilities there need to be upgraded. If this task force follows the pattern set by others, it will also have specific recommendations for each unit concerning the deficiencies that should be addressed. A conclusion by this task force that services need to be expanded or upgraded will create pressures in the Province for additional spending.

In Quebec, there are currently 11 cardiac surgery units. Cardiac surgery has been the subject of three task force reports by the Province. The first task force, consisting of cardiac surgeons, was appointed in 1970 or 1971. Its report justified the existence of each cardiac surgery unit in the Province, including two with workloads well under 100 operations per year. One impact of this report was to increase the Ministry of Social Affairs' distrust of the medical community, discouraging for several years the use of practicing Provincial physicians on government studies of medical services.

The most recent study was completed by a task force chaired by a McGill University cardiologist and former dean of the medical faculty. That report set out criteria for evaluating units, but made no recommendations on whether specific units should be closed. On the basis of that report, the Quebec Ministry sent letters to two hospitals requesting that they terminate their cardiac surgery activities. One hospital terminated this service. At the other, two additional surgeons were recruited, and the rate of surgeries went up over the 100-per-year level.

Radiotherapy

The situations regarding radiotherapy are substantially different in Ontario and Quebec. In Ontario, the expansion of radiotherapy has been strictly controlled. The Canadian Cancer Treatment Foundation, a nonprofit organization with Federal, Provincial, and voluntary support, conducts a cancer research program and has been given responsibility for coordinating treatment within the Province. In the treatment area, it operates seven treatment centers in the Province. Radiotherapy and implants are centralized at five centers. Other hospitals may do chemotherapy, surgery, and limited implants.

The Canadian Cancer Treatment Foundation has always budgeted its own centers, including

selecting and purchasing equipment, and is not reimbursed on a fee-for-service basis by the insurance programs. The foundation has usually had a tight limited budget, so it has tended to impose internal budgeting constraints. The Ontario Ministry is not involved in reviewing its budget, but is convinced that the foundation has handled its resources well. The Canadian Cancer Treatment Foundation has been a major coordinator of cancer treatment facilities in Ontario.

In Quebec, as of March 1977, there were nine hospitals with megavoltage radiotherapy services (most with orthovoltage equipment as well) and one hospital with orthovoltage equipment only. Three of the hospitals offering megavoltage services were outside the Montreal region, the rest within it. Of the megavoltage equipment, 19 of 25 pieces of equipment were cobalt 60 units. There were eight linear accelerators. After reviewing the number and quality of radiotherapy units in the Province, the Quebec Ministry 'concluded that there was sufficient capacity in the area outside of Montreal to meet the projected needs of new patients there. No additional centers or equipment were to be authorized there. (Subsequent to arriving at this conclusion, the Ministry reconsidered the assumptions it had made regarding the utility of existing orthovoltage equipment; it has not yet published a modification of its conclusions.)

In Montreal, the Ministry concluded 'that some units were underutilized, others operating at full capacity. It called for a reorganization of radiotherapy units to consolidate them into units that would be able to better handle the service demands and to regroup staff medical resources to upgrade both medical education and treatments. The plan for this reorganization was to be developed in consultation with the regional council and the universities, and a survey and analysis by the regional council are underway.

Clinical Laboratory Equipment and Automation

Detailed information was not available on the number and distribution of automated laboratory equipment in either Ontario or Quebec. Neither Province has formal policies regarding the appropriate equipment levels in laboratories or points at which automation should be allowed. Prior to the creation of regional review bodies, decisions regarding both were made by the equipment specialists in the institutional units of the Provincial Ministries and were influenced by the relative availability of funds. As a result, until the fiscal constraint program was introduced, most projects that were even marginally justified were approved. One study done in Quebec estimates that laboratory facilities are used at approximately *64* percent of capacity.

The fiscal constraint program has introduced additional discipline into the system, although noneconomic decisions continue to be made. With few new funds available to pay for additional equipment, facilities have been reviewing their needs more closely. The equipment specialist in Ontario reported that hospitals have slowed their purchases of new equipment and have been retrofitting or replacing modules in autoanalyzers to upgrade the equipment. The limited budgets encourage automation where it is less expensive, and in Quebec, unions are becoming concerned with the threat of automation and job reductions encouraged by the constraint program.

Another accommodation that has emerged is the development of in-common laboratories, in which hospitals share the expense of joint facilities for some tasks. The lab in Hamilton has been held out as a successful model. The Toronto in-common laboratory, however, has not been a success. This laboratory was reported to have management difficulties. In addition, a major function the Toronto laboratory was serving was to identify laboratory capacity for specific procedures in individual hospitals and to arrange for transportation of samples from other hospitals that needed those tests; once the network was established, the laboratory organization was not necessary to manage the process. In both Quebec and Ontario, there is resistance to the network concept, and activities to develop networks remain limited.

The introduction of the regional councils into decisionmaking on this equipment has added another element to hospital decisionmaking. In

Ontario, the Province requires requests for all pieces of laboratory equipment over $5,000 to be reviewed by the local council. In Toronto, this requirement has led to the creation of an Advisory Committee on Laboratory Services made up of pathologists from each of the major hospitals. The committee has functioned reasonably well, in part, because it has also become a source of consulting expertise to the individual hospitals. Pathologists are able to share their experiences with specific equipment and to direct individual hospitals away from equipment with which they have been dissatisfied or which does not really meet their need. There has been some opportunity to review programmatic needs, but this has been less systematic and effective than the sharing of experience on specific equipment. The consultation is not completely successful. A survey of hospitals in the Toronto area revealed that these hospitals purchased many items of equipment whose purchase had been recommended against.

In Quebec, although final approval of laboratory equipment is at the Provincial level, the regional councils review and advise on purchases. As **a** result, and given the involvement of hospital administrators in this review, comparable opportunities for commenting on equipment choices and programmatic needs exist. Respondents could cite only one case in which a piece of equipment was obtained after a negative recommendation.

CONCLUDING REMARKS

This review of the management of medical technology in Canada underscores several aspects of this issue as it has developed in that country. The first is that there is no separate medical technology policy. The factor that has influenced the introduction and expansion of technology is the overall level of funding of hospital services. The funding level, in turn, has been determined in a political context in which health services have been in competition for resources with other government programs and with the private sector. Capital spending has been limited and new technology rationed, but only because of these general constraints—not because of programs specifically designed to limit new investments.

A second aspect of the experience of Ontario and Quebec is the general acceptance of the legitimacy of resource decisions being made in the public sector. There is conflict over the level of funding, but for the most part hospitals and the public accept the government's role in determining it. There are exceptions to this, however. The most notable example is evidenced by the existence of unapproved CT scanners in Toronto. Another is evidenced by hospitals' increasing efforts to review and expand philanthropy. Significant constraints on hospital financing have been introduced only over the past 7 to 8 years, and it remains to be seen whether augmentation of government funding represents a permanent new feature of the financing system or is a short-term reaction that is part of a period of adjustment from times of generous to times of more restrictive levels of public funding.

A third aspect of the Canadian experience is the role that medical schools have played as integrating forces in consolidating services. That role has been facilitated by the apparent acceptance in Canada of a hierarchical relationship among university-affiliated hospitals and between university-affiliated and community hospitals. In the United States, where similar hierarchies do not exist, community hospitals are often in competition with teaching hospitals for new technology and sophisticated services.

Finally, it should be noted that the fiscal constraint program has had an influence on the decisionmaking processes in hospitals, a situation that must exist if any long-term changes in the hospital system are to occur. Among the most notable changes is the structured involvement of key members of the medical staff in the internal review and evaluation of alternative uses of capital funds. The medical community is increasingly participating in establishing priorities for

capital spending by hospitals and appears to be accepting responsibility for the impact of these choices on medical practice and the availability of medical services.

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4.

Australian Health Care System and Medical Technology

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Australian Health Care Systems and Medical Technology

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AUSTRALIA: COUNTRY DESCRIPTION

Australia is an island continent with a population of 14. s million and an area close to 3 million square miles. Its greatest east-west mainland distance is 2,400 miles, and its north-south spread is almost as great. With an overall population density of 3.5 persons per square mile, large areas of Australia are sparsely populated. Huge, dry inland areas carry little, if any, population. More than 80 percent of the people live in urban environments, which lie mainly along the coastal fringe. Large and prosperous cities along the southern and eastern shores of the country are major ports of entry. These include Sydney, with a population of 3.2 million, and Melbourne, with 2.7 million.

Six States have been federated under the name of the Commonwealth of Australia. The Commonwealth also includes two mainland Territories, one of which is self-governing. At the time of federation in 1901, all governmental powers other than those exclusively vested in the Parliament of the Commonwealth by the Constitution were retained by the States.

THE HEALTH CARE SYSTEM'

The Australian health care system is pluralistic, complex, and not tightly organized. It involves three levels of government (Federal, State, and municipal), as well as public and private providers and institutions. In spite of the increasing role for government in the financing of health services, most medical and dental care is provided by private practitioners on a fee-for-service basis. This has been—and will continue to be—an important feature of Australian health services.

Prior to 1946, most major health functions were retained by the States, and the primary health functions of the Commonwealth pertained to quarantine and the health needs of veterans. consequent upon a 1946 constitutional amendment, however, the Commonwealth was given powers to make laws about pharmaceutical, hospital, and sickness benefits, and medical and dental services. In addition to these powers, the Commonwealth also has used its constitutional powers to make grants for health purposes to the States and nongovernment organizations.

State governments have the major responsibilities with respect to the public provision of health services. These governments are responsible for the public hospital systems, mental health services, public health regulation, and licensing. The statutory obligations of local governments vary from State to State, but the

'Much of the descriptive information pertaining to the Australian health care system in this chapter is based on personal conversations with Australian health authorities or unpublished, confidential documents to which the author has access in his capacity as Special Adviser on Social Welfare Policy for the Commonwealth. For this information, specific references are generally not cited.

major health responsibilities of these governments are in the area of environmental control and in the provision of a limited range of personal preventive services.

Public hospitals in Australia are very heavily subsidized by State governments. These, in turn, are assisted by the Commonwealth, which meets half of the approved aggregate net operating costs of public hospitals in each State. Public hospitals accommodate both private patients and public patients. Private patients are treated by their own doctors on a fee-for-service basis and charged inclusively (at subsidized rates) by the hospital for accommodation and nonmedical services. Public patients are not charged at all and are cared for by doctors engaged by the hospital. Any patient who is not insured can elect to be treated as a public (or "hospital") patient.

Private hospitals, established during the 19th century for those who did not want to be admitted to the public hospitals, are run both commercially and by religious and charitable organizations. Patients at private hospitals are treated by their own private doctors on a fee-for-service basis.

The 790 public and 340 private hospitals in Australia provide approximately 71,000 and 21,600 beds, respectively, totaling 6.5 beds per 1,000 population (11). In addition, 1,190 nursing homes supply 58,000 beds, or 4.1 beds per 1,000 population. In 1978, the Commonwealth's 10 medical schools graduated 1,260 persons with a first medical degree. The total number of medical practitioners in Australia was 23,600, yielding a ratio of 1 doctor to 600 persons. It is predicted that by 1990 the ratio will have increased to 1 doctor to 500 persons (9).

Commonwealth medical and hospital benefits schemes were introduced in the 1950's. Since 1972, the Commonwealth Government has made frequent and major revisions in health care financing arrangements. The development of Commonwealth benefits schemes prior to 1972 and the changes that have been made since 1972 are described in the next two sections of this chapter.

Development of Commonwealth Health Benefit Schemes (1950=72)

From 1950 to 1972, four major Commonwealth benefits schemes were introduced to assist patients to purchase health care. They concerned: 1) pharmaceutical benefits, 2) medical benefits, 3) pensioner medical services (PMS), and 4) hospital benefits. These schemes, along with mental health services, health benefits for veterans, and the Commonwealth Department of Social Security, are discussed below.

Pharmaceutical Benefits

A pharmaceutical benefits scheme was introduced in the early 1950's. Currently, about 1,000 items are listed in a Commonwealth pharmaceutical benefits schedule. Australian doctors may prescribe items other than those listed on the schedule, but government benefits on these items will not be paid. For items on the schedule, ordinary patients contribute only $2.75 per item, and pensioner patients pay nothing. Pharmacists bill the Commonwealth Department of Health for the balance of their charges, which are fixed in agreements.

There is no separate charge for pharmaceutical items supplied through public hospitals, because the public hospital's bill is an inclusive one that covers the costs of accommodation, nursing, and pharmaceutical supplies. For pharmaceuticals in private hospitals, however, patients pay separately. Federal Government payments for pharmaceutical services and benefits at present amount to approximately $320 million per year (10).

Therapeutic substances in Australia are subject to close surveillance by the Commonwealth Department of Health, which administers the pharmaceutical benefits scheme.[2] Drugs and medicinal preparations are added to or deleted from the schedule of pharmaceutical benefits following recommendations from the Pharma-

[2]Therapeutic substances of various kinds are subject to controlled clinical trials in the major Australian medical centers. Comparatively few prospective, controlled trials of surgical therapy, however, have been done. The same might be said of changing technologies in diagnostic mediums.

ceutical Benefits Advisory Committee. The Commonwealth Department of Health, which provides technical services to the advisory committee, evaluates applications for listing. In order to exert some control over the cost of the pharmaceutical benefits scheme, the Department also negotiates with manufacturers on the prices of products listed as pharmaceutical benefits.

Responsibility for ensuring that therapeutic goods comply with standards of safety and effectiveness rests with the National Biological Standards Laboratory, which tests samples for compliance with standards, evaluates manufacturers' protocols, and inspects manufacturing plants. In addition, the Commonwealth Department of Health exercises control over the importation of therapeutic goods with regard to quality, safety, and efficacy. It maintains a register of adverse drug reactions from reports received from the professions in Australia and from overseas. It also provides technical services for the Australian Drug Evaluation Committee. This committee is an independent group established to evaluate specific drugs referred to it and other drugs which it thinks require evaluations beyond that normally undertaken prior to listing as a subsidized pharmaceutical benefit. Reports concerning adverse reactions suspected to be caused by prescribed medications are sent to the Adverse Drug Reactions Advisory Committee, which examines the reports and assesses the likelihood that a prescribed medicine was responsible for the observed symptoms. All doctors are promptly advised of the committee's findings.

Medical Benefits

A voluntary insurance scheme introduced in the early 1950's was intended to provide broad coverage for medical expenses, while at the same time preserving the traditional doctor-patient relationship. Payment of Commonwealth medical benefits under this scheme was made contingent on the patient's membership in a registered medical insurance fund. Insured patients chose their own doctors and were charged whatever fees these doctors thought appropriate. A Commonwealth benefit was payable for each item of doctor's service. Having settled the doctor's account, the patient submitted the receipt of the bill to his or her insurance fund. The insurance fund paid the fund benefit and also paid, as agent for the Commonwealth, the Commonwealth benefit. For reimbursement of the latter, the fund subsequently claimed on the Commonwealth Department of Health.

A matter of concern to those who believed in full coverage was the size of the copayment that patients had to meet out-of-pocket under this scheme. Originally, it had been intended that the copayment would amount to about 10 percent of the bill. Although there were fluctuations, however, the amount did not fall below 30 percent until the medical benefits scheme was amended in 1970.

The new scale of benefits introduced in 1970 was directly related to the fees most commonly charged for specified medical services. Each benefit was set so that the common fee for the item of service would not exceed the total benefits by more than $5.00. In respect of general practitioners' services, the patient was expected to meet very small amounts out of pocket.

Pensioner Medical Service

PMS commenced in 1951. It paid for medical attention by general practitioners, without any charge to the patients, for all recipients of age, invalid, widow's, and war service pensions, and their dependents. The Commonwealth Government entered into an agreement with the Australian Medical Association (AMA) under which doctors were paid reduced fees by the government for services provided to eligible pensioners and their dependents.

Because the AMA repeatedly expressed dissatisfaction regarding the levels of reduced fees and the enrollment in the PMS of pensioners for whom the pensions means test had been progressively relaxed, after 1969 individuals who qualified for pensions solely because of some specified liberalization of means tests were excluded from automatic eligibility for PMS membership, pensioner pharmaceutical benefits, and free treatment at public hospitals.

Hospital Benefits

A hospital benefits scheme was introduced in 1952. This enabled public hospitals, in State public hospital systems, to introduce charges for accommodation in public beds and to utilize means tests to determine patients' eligibility for treatment in public beds. The Commonwealth paid a small basic benefit ("ordinary benefit") for all public hospital patients, whether insured or not, an "additional hospital benefit" for subscribers to voluntary hospital insurance schemes, and a benefit at or above the ordinary rate for patients covered by PMS.[3]

Initially, the benefits paid from Commonwealth funds under this scheme made a substantial contribution towards the cost of maintaining patients in public hospitals. In 1958, the cash benefits the Commonwealth paid in respect of insured patients amounted to some *20* percent of the total share for public ward accommodation in all States. Because Commonwealth hospital benefits did not keep pace with increases in hospital costs, however, State governments had to pay increasingly larger subsidies to their public hospital systems, and voluntary insurance funds progressively raised their subscription rates to provide coverage against higher charges.

When the hospital insurance scheme was first established, insurance funds set subscription rates at levels that were sufficiently low to be attractive to most people. They were able to set such rates, because benefits were not payable for chronic illnesses, for hospital treatment exceeding a certain period each year, or for ailments existing at the time a member joined a fund. Since these exclusions debarred from benefit some of those who were most in need, in 1959 the Commonwealth introduced a "special accounts" system, enabling registered funds to offer benefits for subscribers in respect of claims that otherwise would have been disallowed under the exclusion rules. Deficits incurred by organizations operating special accounts were covered by the Commonwealth. Initially, the special account benefit scales were, in many instances, less than the charges levied. In 1966, however, the special accounts system was amended so that hospital insurance subscribers were guaranteed the payment of hospital benefit at the full rates for which they were insured, up to the amount of the hospital bill, irrespective of the length of hospital stay.

In the original hospital benefits scheme, patients in approved and licensed nursing homes were entitled to hospital benefits. In the early 1960's, separate provision was made for the payment of a Commonwealth nursing home benefit.' This benefit was paid without means test on behalf of any person, whether insured or not, accommodated in an approved public or private nursing home. No insurance fund benefit was payable to nursing home patients, but patients who had been contributing to a hospital insurance fund now could receive the Commonwealth nursing home benefit. In 1969, a supplementary extensive care benefit was introduced for those nursing home patients who were deemed to require more extensive nursing care than others.

Mental Health Services

Apart from some minor exceptions, services for the mentally ill were originally provided by State governments. Although psychiatric services have become better integrated with other types of health care over the past 20 years or so, the largest part of inpatient psychiatric care is still provided in State mental hospitals. There are some 90 State psychiatric hospitals in Australia, with about 25,000 available beds. These hospitals treat a total of approximately 70,000 inpatients each year and also provide substantial outpatient and domiciliary care services. More than 85 percent of these hospitals' costs are met from State funds. In two States, patients in State mental hospitals may be charged for the accommodation and services that they receive; hospital charges to patients incapable of managing their own affairs may be met from the pa-

[3] Only patients who satisfied a means test at the hospital were treated free in public hospitals; all others were required to pay. The additional "hospital benefit" was intended to encourage people to buy insurance.

[4] The Commonwealth also entered a new field in the early 1960's, namely, the institutional care of physically and mentally handicapped children. A handicapped children's benefit subsidized the costs of accommodating handicapped children in homes maintained by religious or charitable organizations that employed nursing and special staff.

tients' estates. In other States, there are no charges.

When insurance-based schemes of hospital benefits were being introduced in the 1905's, mental hospital patients tended to be long-term cases and were not recognized as good insurance risks. Largely because of this, there was little likelihood of their becoming subscribers to insurance funds; these patients, therefore, were not generally eligible for insurance fund hospital or nursing home benefits. More recently, however, there has been a sharp decline in the average length of stay in State mental institutions, and mentally ill patients are being viewed as better risks. In addition, an increasing number of public general hospitals and also some private hospitals are providing psychiatric care. Mentally ill patients in public and private hospitals, and in nursing homes, may receive Commonwealth and insurance fund benefits in the same way as other patients in these institutions.

Health Benefits for Veterans

The Commonwealth Department of Veterans' Affairs has major responsibilities in the health field. It provides a wide range of cash benefits and personal health services to those who have served in war and to dependents of such exservice personnel, Treatment is provided free of charge, either through departmental institutions or through the general facilities available in the community, for all disabilities that have been recognized as due to war service.

The Department of Veterans' Affairs administers six large general hospitals that provide care for virtually all types of cases, excluding obstetrics. These hospitals are concerned mainly with the management of acute episodes of illness. Patients who do not require the facilities of a fully equipped general hospital are accommodated in the Department's five auxiliary hospitals. There are 3,100 beds in veterans' hospitals. At these hospitals, undergraduate and postgraduate medical education is conducted in association with university medical schools and professional colleges.

The armed forces run six hospitals that are maintained at the expense of the Commonwealth Government and staffed by service personnel. The peacetime bed complement of each of these institutions is between 100 and 120. Limited medical facilities also are available at other service centers.

Commonwealth Department of Social Security

The Department of Social Security plays an important role in the disbursement of a wide variety of cash benefits. It also makes grants to approved nonprofit organizations for a large portion of the capital costs of residential and nursing home type accommodations for the aged and infirm, and for the provision of sheltered workshops and accommodations for the disabled. In addition, the Department subsidizes the States for the provision of home help services, senior citizen centers, and welfare officers, and it runs the Commonwealth Rehabilitation Service, which provides treatment and training for selected disabled persons who are deemed potentially able to work. Fourteen Commonwealth rehabilitation centers provide work preparation and work adjustment services to about 4,500 clients annually.

Changes in Health Care Financing Since 1972

Since 1972, there have been major and frequent revisions of the medical and hospital benefits schemes previously described. The history of changes in arrangements for financing health care in Australia since *1972* illustrates the difficulties faced by Australian Governments in seeking to provide universal health insurance coverage, while also attempting to limit government outlays and inflation.

Introduction of Medibank by the Labor Government (1972-76)

In December 1972, a reforming Labor government came to office, and the following year, legislated for a new health insurance scheme known as Medibank.[5] This scheme, which came

[5] In addition to Medibank, a community health program was introduced by the Labor government in 1973 to provide capital and recurrent financial assistance to the States and nongovernment organizations to: 1) establish and improve community health and health-related services, 2) promote disease prevention, health maintenance, and rehabilitation, and 3) improve coordination of health services in the community and their links with other health and welfare services. Approximately 700 projects involved a Commonwealth expenditure of some $70 million in 1976-77 (1).

into operation on July 1, 1975,[6] was financed out of general revenues. It provided for universal coverage entitling all Australian residents to specified medical and hospital benefits. A Health Insurance Commission was established to operate the plan.

Medical benefits to all residents (including pensioners who previously had had restricted entitlements, and individuals who were covered by workers' compensation and third-party motor vehicle insurance) were paid at 85 percent of schedule fees, subject to a maximum copayment of $5 for any item of service. Coverage was extended to consultation involving eye refractions, whether performed by doctors or optometrists.

The basic hospital benefit under Medibank was a universal entitlement—without any means test—to free standard ward care, including medical treatment, in recognized public hospitals. Provision of this benefit involved the negotiation of agreements between the Commonwealth and individual States.

Under these agreements, the Commonwealth undertook to meet so percent of the aggregate net operating costs of the public hospitals in States that agreed to provide free medical treatment for "hospital patients" (public inpatients and outpatients) at their public hospitals. Treatment for "hospital patients" was to be provided free of charge by staff employed by public hospitals on a salaried or contractual basis. Patients who chose to be admitted to public hospitals as private patients were to be charged agreed on daily fees. For patients in private hospitals, the Commonwealth paid a daily benefit of $16 directly to the hospital.

Benefits available from the government could be supplemented by private insurance, especially for private status in hospitals. Private insurance contributions in respect of supplementary service remained tax deductible.

Reform of Medibank by the Conservative Government (1976-77)

At the end of 1975, the Labor government lost office. The newly elected conservative government was committed to the reduction of inflation, which at the time was running at very high levels. In pursuit of its objective, it aimed to reduce Commonwealth expenditures so that budget deficits could be contained. In the area of health, the new government sought to maintain universal health insurance, but to concentrate government expenditures on the needy.

An important feature of the new Medibank health insurance plan which the conservative government introduced in October 1976 was a levy on taxable income at an annual rate of 2.5 percent, with ceilings of $150 for taxpayers without spouses or dependents and $300 for families. Exemptions were provided for persons at the lower end of the income scale and for certain pensioners and veterans. Individuals and families not otherwise exempt could "opt out" of Medibank coverage and gain exemption from the levy by buying private medical and hospital insurance (both) to an approved level.

Levy payers and those exempted from the levy (for reasons other than the purchase of private insurance) received medical benefits under Medibank in the same way **as** they had under the previous scheme. They also had the right to accommodation and treatment as "hospital patients" free of charge in recognized public hospitals without being means-tested. An additional right to purchase supplementary "hospital only" coverage privately at subsidized rates enabled persons with little income to insure for hospital benefits equal to the minimum fees charged to private patients in public hospitals. Persons so-insured could be treated at public hospitals by their own doctors (rather than as "hospital patients" treated by doctors engaged by the hospitals). The assistance also helped them to choose care in private hospitals.

The conservative government also introduced new Commonwealth/State cost-sharing agreements on public hospital costs. Previously, the Commonwealth had paid 50 percent of the net operating costs of public hospitals in each State, whatever these costs turned out to be. It now came to exert leverage over public hospital costs by paying 50 percent of only those operating costs in each State which it had previously approved in the State's aggregate budgets.

[b]Medibank came into operation on July 1, 1975, but agreements with all the States were not completed until several months later.

A compulsory reinsurance pool replaced the "special accounts" system for hospital care, and the Commonwealth contributed a flat $50 million annually to that pool. This subsidy was far less than the special account outlay would have been and also imposed a firm ceiling on the Commonwealth's liability. The reinsurance subsidy was available only on objectively determined grounds: hospitalization for more than 35 days in a year. Special accounts in relation to medical services ceased.

The regulation of private health insurance funds was strengthened. Individuals who opted out of Medibank had to be covered unconditionally, at least for levels of benefit equivalent to those provided by Medibank. Private funds could not reject or discontinue the insurance of any subscriber; nor could they limit the payment of benefits from the basic tables. All tables to which the funds could apply limitations and exclusions had to be expressed as supplementary tables. This requirement ensured that contributors to higher tables participate in the basic tables and so share the risks of all other basic contributors.

In 1977, the Commonwealth Government agreed upon an insurable nursing home benefit. This benefit was payable in each State at a level which—when combined with a specified compulsory out-of-pocket patient contribution[7]—would cover fully the Commonwealth-approved controlled fees charged to *70* percent of patients in private ("nongovernment") nursing homes in each State. Hospital insurance organizations became liable for payment of the full amount of nursing home benefits in respect of their standard (basic) hospital benefit table contributors. The amount of benefit payable by the private insurers in such cases was the Commonwealth basic benefit (about $25 a day) plus, where appropriate, an extensive care benefit (which was raised from $3 a day to *$6* a day). Uninsured nursing home patients, who were not entitled to benefits from hospital benefits organizations, continued to receive both the basic and extensive care benefit from the Commonwealth Department of Health.

[7]The out-of-pocket contribution amounted to about 90 percent of the age pension.

Additional Reforms by the Conservative Government (1978-79)

With the 1976 and 1977 health care financing arrangements, the conservative Commonwealth Government had gone some way towards achieving its objective of reducing the proportion of expenditures from the Commonwealth's budget. It was still not satisfied, however, and introduced new arrangements in November 1978. By this time, the government was concerned about the effect of health insurance arrangements on the consumer price index. It also believed that the existing insurance arrangements were too complex.

The new scheme the government introduced in 1978 was less complex than the previous one. It abolished the health insurance levy and provided for the Commonwealth to pay a new universal medical benefit from general revenue. The new medical benefit covered *40* percent of schedule medical fees, subject to a maximum patient contribution of *$20* for any one item for which the schedule fee was charged, and was paid through private insurance health funds, Although additional coverage was not compulsory, private health insurance funds were permitted to offer supplementary medical benefits. They also continued to provide hospital benefits. Funds were given considerable freedom and flexibility to devise attractive benefit packages.

Accommodation in standard wards of public hospitals with treatment by doctors engaged by the hospitals continued to be made available free of charge to those who were not privately insured for hospital care.

For pensioners and their dependents who were not privately insured, doctors continued to accept reduced payments of 85 percent of schedule fees from the Commonwealth. People who were unable to pay their medical bills could be classified by their doctors as "disadvantaged." For individuals in this new group, doctors billed the Commonwealth Department of Health and received 75 percent of the schedule fee in full settlement; they were not permitted to seek any additional payments from the patients themselves.

All these new arrangements were estimated to add $305 million a year to Commonwealth budget outlays and to reduce receipts from the health insurance levy by about $320 million in a full year (2). Because the arrangements were largely tax financed, their effect on the consumer price index was favorable.

Hardly *6* months had elapsed before the Commonwealth Government announced yet another change. In May 1979, it decided to pay no universal Commonwealth benefit at all on small bills up to $20 for any item of service, and to pay the full amount in excess of $20 in respect of the schedule medical fee for each item. Arrangements for pensioners and the disadvantaged were continued. Because some 80 percent of medical services attract a schedule fee of less than $20, the upshot of this arrangement should be a savings to the Commonwealth of approximately $200 million a year and a reduction in the number of claims processed by the private health insurance funds.

Rising Health Care Costs (1974-78)

For some time, but particularly during and after the financial year 1974-75, Australian health care costs had been rising rapidly. Total public and private expenditures on health increased from $4.19 billion in 1974-75 to $7.15 billion in 1977-78 (7,8). As a percentage of gross national product, they rose from about 4 percent in the mid-1950's to 7.89 percent in 1977-78 (7,8). The rate of growth in expenditures has been declining since 1976.

Health care has always been financed to a large extent by the public sector in Australia. With the introduction of Medibank in 1975, however, the public sector's share of expenditures rose from 62 percent in 1974-75 to 72 percent in 1975-76 (7,8). By far the largest share of the increase in public sector expenditure was borne by the Commonwealth Government. The Commonwealth's share of total health expenditures rose from 30 percent in 1974-75 to 48 percent in 1975-76, while the States' percentage fell from 32 to 24 percent.

The changes the conservative government made in health care financing in 1976 resulted in a reduction in the Commonwealth Government's share of total health expenditures to 42.6 percent in 1976-77 (7,8). The States' share remained reasonably consistent at *23.6* percent for both fiscal years 1975-76 and 1976-77, and private sector spending rose to over 35 percent after the change. The share of health costs borne by individuals has now returned to about the same level it was at prior to the introduction of Medibank.

Nearly 58 percent of all health expenditures in *1976-77* was for institutional care (7,8). Public hospital costs continue to account for over one-third of all current expenditures on health care, and other institutional care accounts for an additional one-fifth of health expenditures. By far the largest share of institutional care, 70 percent in 1974-75 and about 76 percent in the next 2 years, is financed by the public sector.

PUBLIC POLICIES THAT AFFECT MEDICAL TECHNOLOGIES

The arrangements for financing health care in Australia, described in the previous section of this chapter, exert a considerable influence on the supply and utilization of medical technology. These arrangements, a discussed below, exert their effects through 1) hospitals' cost-sharing agreements, which affect the supply of public hospital facilities and staff and provide opportunities for rationalization; 2) regulation of charges in hospitals; 3) negotiation of fees and salaries; and 4) regulation of private health insurance. Major policy decisions on these matters are made by the Commonwealth Government on the basis of recommendations submitted by the Minister for Health (5,13,14).

Hospitals' Cost= Sharing Arrangements

Cost-sharing arrangements for public hospitals, since July 1, 1975, have been elaborated in agreements between the Commonwealth and individual States. These bilateral agreements pre-

scribe hospital services to be provided and cost shared, categories of patients to be charged, and processes for agreeing to hospital budgets and rates of charges. Commonwealth and State officials meet formally twice each year in bilateral negotiating sessions. At these sessions, they discuss estimates of income and expenditures, formulate budgets, and review experience in the light of known revenue shortfalls or overexpenditures in relation to approved budgets, The officials' recommendations are submitted to the Commonwealth Minister for Health and the State Minister responsible for the particular State's health portfolio for their approval.

Negotiations take place in an atmosphere in which there is no agreed on absolute ceiling on the level of expenditure for medical care and hospital services that the country can afford, but in which there is doubt that marginal increases in the hospital budget will produce benefits comparable to those that will result from similar outlays in other sectors. The Commonwealth need not approve the full level of subsidy required to meet 50 percent of the aggregate net operating costs experienced by one or more States, and in the context of national budget-framing, when the Commonwealth decides how much it is prepared to allocate to the public hospital system, it has repeatedly rejected budgets prepared by officials. Commonwealth expenditures under the arrangements in 1978-79 are estimated at about $1,040 million. (Commonwealth subsidies to private hospitals totaled $73 million (7).)

The formulation and development of hospital cost-sharing policies, which are subject to ministerial endorsement, is undertaken by a National Standing Committee comprised of senior health officials from the Commonwealth and from each of the States and Territories, and by State standing committees established under Commonwealth/State administrative arrangements. These standing committees provide a forum for the exchange of views on budgetary matters and on a range of hospital and related health policies which the Commonwealth and the States use to seek effectiveness, efficiency, and cost containment in the delivery of public hospital services. These objectives are sought through continuing review of hospital resources, standards, methods, and procedures; rationalization of existing facilities and services; and evaluation of proposals for the upgrading or expansion of public hospital services, including the introduction of high-cost technology.

Rationalization of Existing Hospital Facilities and Services

In recent years, as government and insurers have covered large proportions of incurred costs, there have been few financial inhibitions on the use of medical services. Knowing that the marketplace is no longer effective as a rationing process, State and Commonwealth officials aim to replace it by conscious planning or the imposition of controls to change the behavior of health professionals and the community.

HOSPITAL BEDS/DAYS

Because there is a generous overall supply of beds in public hospitals, there is no need to add to the pool. When new facilities are provided, they arise not because of shortages, but because of the age or geographic or functional maldistribution of existing hospital facilities. Without making any commitment, the Commonwealth Government has proposed that public hospital services should be reduced by the application of two principles (11):

- as additional staffed beds are opened, every effort should be made to achieve offsetting closures of other staffed beds wherever that may be feasible, and
- public hospital patient days should be reduced within 4 years from approximately 1,300 to approximately 1,100 days per 1,000 population per annum.

It is considered important that the rationalization program should cover all hospitals (public, private, and veterans) and related facilities (such as nursing homes and mental hospitals); otherwise, contraction in one area could lead to expansion in another. In the nongovernment nursing homes area, growth control already applies. A guideline now used on a State or regional basis is that there should be not more than *50* nursing homes beds per 1,000 population aged *65* years or more. It is not thought to

be necessary for the Commonwealth Government to take steps to discourage the transfer of patients from recognized hospitals to mental hospitals, because the States now carry the major burden in regard to mental hospitals and can be expected to take whatever action is necessary to avoid their expansion.

HOSPITAL UTILIZATION

Hospital utilization rates are high in Australia, with annual utilization approximating 1,600 patient days (about 1,300 patient days in public hospitals and 300 in private hospitals) per 1,000 population (11). Some States provide satisfactory levels of care with far lower rates of hospital use. Evidence exists that many patients are in hospitals because hospitalization is the most convenient answer to a problem which may be as much social, domestic, or financial as it is medical (11).

There are large differences in length of stay for the same illnesses and operations. These differences can be only partially explained by social and geographical factors. Surveys of customary practice also have shown large variations in surgery rates between different areas—even after allowing for difference in age composition. For example, the highest rate for tonsillectomy is five times the lowest rate, the rates for appendectomy and gallbladder removal both show a threefold variation; and the rates for hysterectomy show an almost fivefold variation *(4,6).*

Commonwealth and State Health Authorities agree that hospitals should be influenced to reduce inappropriate inpatient utilization. Unnecessary inpatient care generates staff and technology costs almost as great as those generated by essential care. The admission of patients who could be treated at lower cost elsewhere contributes to excessive use of hospitals and of their associated technologies.

It is generally agreed that, to monitor customary practice, it is necessary to have good medical record systems, prompt analyses of records, and displaying of the results for consideration. Attempts are being made by Health Authorities to upgrade present record practices and procedures and to organize medical staff in hospitals so that they can participate in reviews of hospital utilization.

Evaluation of Proposals for Expansion of Public Hospital Services

Eighty percent of short-term acute hospital care is delivered in public hospitals, which must comply with conditions of subsidy determined by State Health Authorities. These conditions are increasingly likely to reflect the arrangements agreed to in Commonwealth/State discussions and negotiations with respect to the hospitals' cost-sharing arrangements.

In public hospitals, an item of new equipment valued up to $50,000 can be treated as "expendable" and the cost of its purchase be regarded as an operating cost. Thus, a good deal of medical technology can be introduced and expanded without being subjected to the acquisition scrutiny described below. All investments exceeding $50,000, however, are treated as capital, and State governments are the sources of funds. Consequential growth in operating costs is taken into account before State facilities are expanded, because there can be no assurance that the Commonwealth Government will agree to share these costs unless they have been specifically approved.[8]

STATE EVALUATIONS OF TECHNOLOGIES

Australian Health Authorities agree that the most specialized facilities and services should be concentrated in large units rather than dispersed haphazardly because:

. large populations are required to support specialist units of economic size, especially in neurosurgery, thoracic surgery, radiotherapy, and plastic surgery (some of the expensively equipped diagnostic technologies should be included in this group of services);

[8] In private hospitals, all capital charges are borne by the owners. Private hospitals, therefore, tend to invest in facilities and equipment that assure a quick and good return. They tend to keep away both from investment in training and emergency care facilities which require generous staffing and from investment in the most sophisticated and expensive technologies. A high proportion of private hospital work consists of common forms of elective surgery and of obstetrics.

. specialists require a regular and adequate flow of patients to maintain their skills; and
- the provision of a comprehensive range of specialists in a single site assists in the cross referral of patients between specialists.

State Health Authorities discourage the provision by local or district hospitals of more than a limited range of services (e. g., general medicine, relatively minor surgery, minor trauma, physical and psychiatric rehabilitation, uncomplicated obstetrics, and outpatient consultations). Because these hospitals provide ready access for local communities, however, the Authorities support their staffing and provision.

In most States, advisory committees help the State Health Authority determine criteria for the provision of sophisticated services in public hospitals. These advisory committees have been particularly helpful in the process of rationing sophisticated new technologies in a public hospital system subject to increasingly firm cost controls.

In New South Wales, for instance, the assessment of a request for equipment to be purchased by a particular hospital will take into account factors which include:

- guidelines for the provision of specialized services,
- the hospital's capacity to make effective use of the equipment,
- the extent and state of existing equipment in the hospital, and
- the availability of similar facilities in other hospitals in the area.

The hospital's capacity to make effective use of equipment will depend on the availability of accommodations, the presence of enough trained staff to manage the technology, and a sufficient workload to justify the purchase of new equipment. Policy guidelines for the provision of cancer services, open-heart surgery, neurosurgery, and other highly specialized services have been published and widely distributed by the Health Commission of New South Wales.

Similar activities in other States have resulted in the establishment of the following 11 stages for the acquisition of technology equipment by public hospitals:

1. initiation of a request to the State Health Authority,
2. justification of the proposal,
3. technical assessment,
4. allocation of funds,
5. preparation of specification,
6. invitation of tenders or quotation,
7. technical evaluation of tenders,
8. financial evaluation of tenders,
9. approval of funds,
10. acceptance of tenders, and
11. evaluation of practice.

Public hospitals are generally under the immediate administrative control of boards of directors incorporated under State laws. Public hospital boards consist of both elected and appointed members, several of whom wield considerable influence in their communities. They see their task partly in terms of determining policies for the management of hospitals in accordance with the conditions of subsidy determined by State Health Authorities and partly in terms of acquiring resources. [g]

In pursuing 'resources, the boards frequently find allies among the doctors using the public hospitals. Jointly with these doctors—and usually supported by the medical and local communities seeking the best and the brightest in an environment in which taxpayers foot most of the bill—public hospital boards are able to exert strong pressures on governments. With public hospital charges fixed at uniform rates, the acquisition of additional facilities and staff will not be reflected in a particular hospital's bill, but such facilities will attract better qualified specialists and add to the prestige of the hospital's board of directors. In this atmosphere, guidelines for the rationalization of medical technology are subjected to political processes and may be set aside, particularly as the earn-

[g] In some States, approval for the acquisition and installation of expensive new equipment in a public hospital is conditional on the hospital's raising a substantial share of the capital by voluntary local effort. This system operates to the advantage of affluent communities, however, and is therefore in the process of being discarded.

ings derived from the technology by doctors using it will come largely from the Commonwealth and health insurance funds.

NATIONAL EVALUATION OF TECHNOLOGIES

Awareness of the need for some national system of evaluation, in addition to the technology assessment procedures that are now applied to technologies used in the public hospital systems of individual States, has grown.

In 1978, the Commonwealth Committee on Applications and Costs of Modern Technology in Medical Practice identified the folIowing as issues needing examination in the development of criteria for the location and use of technology services (3):

- whether the current availability of the various technologies is appropriate;
- whether essential resources or support services are available to ensure adequate standards in the provision of a particular technological service;
- whether it is possible to determine optimum sizes of population services by highly specialized technologies;
- whether it is possible to indicate the patient throughput per year that is desirable to maintain professional expertise and an efficient service; and
- whether limits should be imposed on the provision of any technology. ‘

This committee suggested that policy guidelines for rationalizing technologies should be developed by consultative advisory committees in each State and that these committees should have a formal link to a national advisory committee in order to achieve uniformity throughout Australia. It further suggested that duplication of resources in any specialty should be avoided unless need could be demonstrated and the cost justified.

The Commonwealth Committee on Applications and Costs of Modern Technology in Medical Practice recommended both the establishment of an expert national advisory panel on medical technology and the creation of a central repository of technical information (3).

The expert national advisory panel would advise on questions pertaining to new technologies, such as (3):

- whether a new technology is for broad general use or for use by specific types of patients;
- whether medical benefits should be paid for the new technology, and if so, whether the technology should be restricted to specific locations;
- whether benefits should be paid for use of the technology in an extended experimental evaluation period (if there are doubts about its efficacy);
- whether the introduction of the new technology into the benefits schedule might affect national health expenditures in significant ways; and
- whether there is likely to be a change in the patterns of use of related technolog=s.

The central repository of technical information would (3):

- receive reports from the expert national panel;
- collect information on:
  —the effects of technological services on patient outcomes,
  —the economic effects of technical services on the health system and the public, and
  —the winding down of displaced or ineffective technologies; and
- supply information to the States or other interested bodies as required.

The Committee on Applications and Costs of Modern Technology in Medical Practice has proposed a sequential process for using the R&D process as a method of regulation. The main components of the proposal are (3):

- modification of the operation of the medical benefits schedule in such a way that the experimental nature of and doubts about the effectiveness of some technologies are recognized;
- initiation of carefully designed evaluation studies of all new medical technologies; and
- establishment of a system to oversee and monitor the development, introduction, and diffusion of new technologies.

The first stage of the evaluation of a new technology, to determine its effectiveness, would be an experimental phase during which the payment of a medical benefit would be limited to those services provided at pilot locations.[10] The second stage would be an extended experimental period or a period of extended use during which evaluation would be aimed at assessing the impact of the technology on the use and cost of health services. The main focus of the second stage would be not so much on efficacy as on technology use rates and on the costs and quality of care.

Regulation of Charges in Hospitals

The average gross operating costs per occupied bed in public hospitals in different States vary from $125 to $175 a day. Yet inclusive charges to private patients in these hospitals are fixed uniformly throughout Australia at $50 a day for a shared room and a $75 a day for a private room. Patients who are not insured are treated free of charge by doctors engaged by the hospital. Commonwealth and State governments contribute equally to make up the hospitals' deficits (approved net operating costs).

Patients who are insured against hospital cost usually carry enough coverage to meet the full charge for the type of public hospital accommodation that they prefer, and the same level of coverage applies in the event of their admission to a private hospital. Charges in private hospitals, however, are not inclusive, i.e., fees for use of operating theaters, labor rooms, pharmaceutical, and toilet items may be additional. The Commonwealth Government subsidy in private hospitals is limited to $16 per patient per day. To the extent that private hospitals are influenced not to raise charges much higher than the levels for which patients are covered by private room insurance, charges generally do not greatly exceed $100 a day plus extras. Individuals can purchase supplementary insurance to cover the cost of extras, however, and a few private hospitals have much higher charges for high standards of amenity.

As some 50 percent of the beds in public hospitals are used for treating private patients, the comparatively low charges for private care in public hospitals have an indirect effect on charges in private hospitals. To maintain their competitive position, private hospitals have to hold their charges down. Another indirect effect is to hold down the cost of hospital insurance subscriptions; this, in turn, holds down potential rises in the general consumer price index, which is seen by the Commonwealth Government as a desirable objective, because wages are indexed. A perverse effect of artificially low charges in private hospitals, however, is the stimulus such charges offer entrepreneurs who own the hospitals to generate revenue by expanding their technological equipment to take advantage of leasing and hiring arrangements with doctors who are paid by fees for services rendered through use of that equipment.

Medical Fees and Third-Party Coverage

With the high levels of third-party coverage that Australia has experienced since 1970, the price elasticity of demand at the margin has been negligible. The medical profession has strenuously protected this position by advocating that fee increases should always be followed by increases in subsidized insurance benefits, and at the same time by insisting that it has the sole authority to determine fees. This does not mean that fees have ever been determined at the national level by AMA. Representatives of local AMA branches and specialist societies have shared in the function of recommending fees. The recommendations of these groups ultimately led to the adoption of a schedule of "recommended" fees in each State, but individual doctors were not bound to follow this schedule.

In recent years, AMA has used a formula for adjusting fees in accordance with changes in unit costs. This has guaranteed gains from any growth in productivity (e.g., achieved by reducing home visits and so providing more office services per day, or by technological advances in diagnostic procedures) or from extensions in the capacity to earn income (e.g., by abolition

[10]A new technology has been accepted for medical benefits purposes until now on the basis of advice from the Medical Benefits Advisory Committee that the technology is in use, reputable practitioners are using it, and it is not in conflict with any current legislation or safety standards.

of the honorary system in public hospitals) .11 Furthermore, in issuing their fee recommendations, State branches have usually gone beyond the formula-indicated percentage changes by rounding off upwards or by seizing opportunities related to foreshadowed increases in insurance benefits. All these factors have combined to establish systematic and consistent fee variations between States.

Prior to 1970, specialist fees were not the subject of AMA's recommendations. Some specialist bodies circulated fee lists, but these did not enjoy the same authority as the recommendations for general practitioners published by AMA. Individualism in fee setting was particularly blatant in the field of surgery, where, for example, in April 1967, the insured charges for appendectomy ranged from $35 to $180, the most common fee being $60 (14). This dispersion of specialist fees, while possibly increasing the price elasticity of demand, was inconsistent with the objectives of those who believed that the central purpose of health insurance was to remove random fluctuations in consumers' disposable incomes caused by medical care expenditures.

With absence of a proper relationship between doctors' fees and medical benefits being seen as the "fundamental deficiency in the medical benefits scheme" (14), the concept of a schedule of common fees for all items of service evolved. The intention was that variance around the central fee would diminish; the dominant issue, therefore, became the amount of the central fee. Related to this were questions about who would determine the central fee and by what process, as well as about what sanctions would ensure the fee's application.

Under threat in *1970* that the Commonwealth Government would introduce a "participating doctor scheme," under which only the fees of doctors who agreed to charge the "common fee" would attract insurance benefits, the profession agreed to formal mechanisms for determining fees for benefits purposes. An independent arbitral body, recently headed by a judge, has reviewed and determined these fees ever since. The price that the doctors—particularly the specialists—exacted for conceding to the government on this matter was acceptance of their fee proposals unchanged. Before agreement was reached, they were promised a maximum copayment of $5, provided the common fee was charged. The rise in fees and benefits resulted in the immediate growth of Commonwealth medical benefits from $54.9 million in 1969-70 to $127.1 million in 1971-72 (14).

The increase in the amount being paid to doctors was not accompanied by any assurances about the effective level of coverage that insured people could expect, because the government, the professional associations, and the insurance organizations were given no authority over individual doctors' fees. A parliamentary committee's previous proposal that doctors should agree to inform their patients of their own fees and of the established common fee was rejected. In 1975, an attempt was made under Medibank to induce doctors' adherence to common fees by making available to patients the alternative of receiving free treatment from public hospitals (for both inpatient and ambulatory care). Doctors engaged by the hospitals on a salaried, sessional, or contractual basis to provide such treatment, however, were not at any time appointed in sufficient number to have much impact, and the policy was not pursued with any vigor after the demise of the Labor government in 1975.

So the country was left with a system in which there **was** no effective power countervailing that of the doctors and no built-in control of usage, but in which there was a high level of subsidized underwriting of private medical fees through health insurance. This system stimulus was sure to give impetus to the growth of expenditures. Neither patient nor doctor had

[11] prior to 1975, Australia had an honorary system for providing hospital care to public patients. Originally, it arose from association between charity to the sick poor and medical education (14). The teaching hospitals were staffed at senior levels by leaders of the profession who spent part of their time in unpaid teaching and in caring for indigent patients. Similar arrangements were adopted in other hospitals, despite the appointment of increasing numbers of salaried specialists and resident medical officers. The honorary staff derived benefit by treating their private patients in public hospitals on a fee-for-service basis and by coming to the notice of referring practitioners.

reason to base treatment decisions on the cost of services rendered, so doctors increasingly tended to perform or request any procedure that had diagnostic or therapeutic possibilities irrespective of its cost. Medical technology was set to diffuse rapidly in such an environment, and this it did.

The situation has been aggravated by the granting of rights of private practice to salaried public hospital specialists. The salaries and conditions of service of these doctors are determined by industrial courts[12] and are generous. Rights of private practice are usually allowed on the basis that up to about one-fifth of the specialist's hospital salary can be earned in private practice as an additional personal income. Any amount in excess of that portion is paid into a trust fund which finances travel, study, and research activities of the specialist group at each hospital.

When expensive hospital equipment and staff are used by the salaried specialists exercising their rights of private practice, the hospital is paid a share of the fees earned. Thus, in radiology and pathology, it is not unusual for the public hospital to take 60 percent of the fees earned by its salaried specialists in private practice. There can be no sharper conflict of interests for a hospital management wishing to limit excessive utilization of diagnostic tests and procedures than that which arises when the hospital is paid a substantial portion of the fees that are earned from them—especially when the management knows that increased utilization will generate income for the hospital without making any real call on patients' disposable resources.

Recent changes in health insurance arrangements were aimed at restoring price as a factor to be taken into account. The abolition of Commonwealth medical benefits for fees up to $20 for any item will apply to all persons who are not pensioners or designated "disadvantaged." The disincentive to excessive provision for pensioners and disadvantaged persons is that the benefits paid by the Commonwealth on their behalf amount, respectively, to 85 and 75 percent of the common fee. All other persons pay the copayment out of pocket or insure to cover it. Because a high proportion of these individuals do insure, expensive, excessive, and inefficient use of technology is likely to persist.

Administration of the medical benefits scheme, however, can be used to influence the costs, utilization, and quality of medical services. One mechanism that is infrequently used, although its availability may exert influence, is a system of Medical Services Committees of Inquiry. Committees are set up under law to inquire into the practice of doctors who are believed to provide excessive and unnecessary services in private fee-for-service practice.

Rules can be devised by the Minister to modify the level of fees, and accordingly, the benefits payable, under various circumstances depending on the type and nature of the service. The Commonwealth Medical Benefits Schedule Revision Committee makes recommendations in regard to the inclusion of new items into the benefits schedule, the deletion of items, amendments of the description of items, and the combination or grouping of items of service. It also recommends appropriate fees for benefits purposes for new items and investigates anomalies in fees.

The Commonwealth Medical Benefits Advisory Committee considers claims for increased fees in cases in which a service is of unusual length or complexity. It also considers whether professional services rendered in specified circumstances should be excluded from payment of medical benefits. Medical benefits for tomography, for example, have been restricted to services rendered in the management of glaucoma. Medical benefits for health screening services are not authorized unless the Minister for Health directs otherwise. Medical consultations for medical checkups in the course of normal practice do qualify for benefits. Benefits are not payable for mammography unless the patient has been referred to a specialist radiologist and the referring doctor has reason to suspect the presence of malignancy.

[12] Industrial courts have been established for all industries in Australia and are concerned with the salaries and conditions of service of employees.

The fee level for an item is intended to provide a fair and reasonable return to the doctor for the rendering of that service in most circumstances. Adjustments to common fees are made regularly. Factors which have a direct bearing on the need to review and restructure items include evidence of the reduced capital cost of equipment, cheaper alternative equipment, and increased throughput. As a result of recommendations made recently by the Committee on Medical Technology (3), fee levels are being examined in accordance with the concept that they should reflect efficient use of facilities.

Special arrangements have been made for pathology services. A new schedule of services and fees for pathology services has reduced the number of individual pathology items, adjusted fees to stimulate the reasonable use of modern cost-saving technology, and generally improved the rules relating to multiple testing of the pathology specimens. Requests for pathology services must be in writing and the requesting practitioner must be clearly identified. Providers of services must retain the requests for a specified period to enable examination in connection with Medical Services Committees of Inquiry. Medical benefits for most pathology services will not be payable unless the practitioner providing the service has been approved as a provider by the Minister for Health, and before approval is granted, the provider is required to give an undertaking to abide by a code of conduct prohibiting fee-splitting and other undesirable practices.

It is not yet clear to what extent patients will cover themselves by insurance to meet their bill; nor is it clear whether the recent health insurance amendments will have any effect on the use of technology. Nevertheless, total health expenditures in Australia, which had been growing very rapidly during the brief period when tax-financed universal coverage was provided, did show progressively lower rates of growth as the proportion of public sector expenditure dropped. For instance, in 1975-76, when a basic level of universal coverage was provided out of tax revenues, total expenditures on health rose by 36.6 percent over the previous year (9).[13] In the next year, the rise was only 14 percent and in 1977-78 it was 10.7 percent (12).

Education and Research

Material related to the value and utility of specific diagnostic procedures has been prepared by the Commonwealth Department of Health for circulation to medical colleges and societies to generate discussion concerning the cost effectiveness of the related technological services. In a similar vein, officers of the Department of Health and AMA have approached the Australian medical schools with a view to having medical students exposed to some information about the cost effectiveness of technological services.

AMA has been awarded specific grants to develop and implement peer review systems throughout the nation. A period of some 2 years was taken up in informing the profession at the grassroots level about the concept. A resource center has now been established, and peer review (including utilization review of work done in the hospital) is slowly becoming accepted as a formal goal by the medical profession.[14] Informal review activity has always been undertaken at the larger teaching hospitals.

The Commonwealth Department of Health has approximately $1.5 million a year available to it to fund health services research studies and health service development projects. In addition, health services research funds are available in the States and to a limited extent at universities. Some examples of current studies and projects are:

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[13] "Other factors were involved when overall cost rises were so steep. These included a very rapid escalation in labor costs in hospitals at a time of sharp inflation. Population growth accounted for only a small proportion of this rise in expenditures (12).

[14] Peer review of medical services was requested by the Commonwealth Government at the time of introducing health insurance amendments in October 1976. The Australian Medical Association was subsidized to set up voluntary systems, and was advised that failure to respond satisfactorily within 3 years could result in some kind of compulsory program. Both peer review and hospital accreditation had been resisted in Australia, although numerous informal review activities were common. Hospital accreditation was not seen to be necessary by State Authorities, who, in fact, maintained close supervision of most hospitals through their conditions of subsidy of public hospitals and licensing of private hospitals.

- *Accreditation of Australian hospitals.* —To develop standards of accreditation for Australian hospitals, including a series of pilot studies to refine the methodology.
- *Medical administrative standards in hospitals.* —To develop medical administrative standards by conducting a survey of the formal organization of medical staff in Australian hospitals, and analyzing the effectiveness of the organizational patterns.
- *Cost effectiveness of treatment of end-stage renal disease.* —To analyze the treatment of end-stage renal disease with special emphasis on the available alternative methods of treatment.
- *Evaluation* of *the role* of *specialist medical units in a teaching hospital.* —To compare and evaluate the treatment received by patients with similar disorders who are admitted either to specialist units or general medical wards at random.
- *Prospective evaluation of coronary care in two* States. —To undertake a pilot study involving selected hospitals in Queensland and New South Wales on the effectiveness of a range of facilities in treating certain coronary conditions.
- *The autopsy in quality insurance in hospital practice.* —To use autopsy data to examine the effectiveness and quality of care and services.
- *An evaluation of the cost effectiveness* of *surgical and related hospital services.* —To develop a cost accounting system which will identify and analyze the cost differentials between the surgery units at two Melbourne hospitals.
- *Retrospective evaluation* of *coronary care in Queensland.* —To study various levels of intensity of coronary care with respect to intrahospital survival and cost to the community.
- *The impact of computed tomography (CT) in Australia.* —To evaluate CT services, with particular attention to cost effectiveness and cost efficiency, and to develop guidelines for patient selection.
- *Evaluation* of *CT and ultrasound.* —A prospective clinical evaluation of the parallel and complementary use of CT and ultrasound in diagnostic imaging of the body, excluding intracranial examinations.
- *An educational program to reduce excessive use of clinical biochemistry laboratory tests within hospitals.* —To reduce the overuse of pathology tests in hospitals by the use of an educational program aimed at influencing doctors responsible for ordering tests.
- *Evaluation of a large-scale screening programs.* –To evaluate a multiphasic health testing service (study completed under the auspices of the University of New South Wales).

These studies raise a number of questions. Should all technologies be evaluated? If that is our belief, there are substantial resource implications. Even when evaluations are well done, a remaining question is this: Will anybody be influenced by the results?

SPECIFIC TECHNOLOGIES

Sophisticated and expensive new technologies have had their diffusion in public hospitals controlled primarily by the overall cost caps applied by State and Commonwealth Governments (12). These controls have slowed growth of public hospital operating costs in real terms from 11.2 percent in 1975-76 to 8.8 percent in 1976/77, 6.2 percent in 1977-78, and 3.4 percent in 1978-79.[15] Similar success has not been achieved outside the public hospital system, in private office practice, or in private hospitals.

Against the background of intention and practice outlined in the preceding section of this

[15]Even during the 4 years prior to 1975, when cost-growth in the health services generally was rapid, however, 8 percent of it was estimated to be due to population changes, about 60 percent to higher prices and wages, and 32 percent to increased volume and intensity of usage. Most of this growing volume and intensity of usage is attributable to the comparatively less sophisticated technologies, such as chest X-rays, audiometry, electrocardiography, electro-encephalography, respirometry, and endoscopy.

chapter, Australia's experience with specific medical technologies is presented below.

CT Scanners

CT scanners were introduced to Australia in the mid-1970s. By December 1978, there were 28 in use and 1 on order. They were distributed among the States in public and private facilities as listed in table 1. Scanners are identified as "head" and "general purpose" scanners (rather than "head" and "body" scanners), because 75 to 85 percent of examinations carried out on the body scanners in Australia are head scans.

With 29 scanners, there will be approximately 1 CT scanner per 500,000 population. Since 15 of the scanners are located in Sydney and Melbourne, the peripheral populations of large States have difficulties of access. Government-subsidized aerial ambulance services and other subsidized transport schemes for those living in remote areas are designed to overcome these problems.

As a noninvasive technique with high diagnostic accuracy, CT scanning has caught the imagination of Australia's medical profession. Nevertheless, in recent years, special concern has been shown about the effectiveness and economics of CT scanning. Its role in patient management and its advantages and effects on other neuroradiological investigations have been under review in all States. Because improvement in patient outcome and advantages over isotope scanning have not been satisfactorily demonstrated, State Health Authorities have rigidly curtailed the introduction of CT scanners into public hospitals and do not support an expansion of this technology at present. In addition, the New South Wales Health Commission has determined that referrals of patients for CT scanning in public hospitals should be restricted to those made by clinical specialists in disciplines relevant to the examinations being conducted.

In the private sector, these direct restraints are not possible. Private installations are not regulated. Medical benefit arrangements have been reviewed recently, however, and as a result of the review, fees have been reduced so that profits will not be so high as to encourage a rapid expansion of CT scanning in the private sector.

Renal Dialysis

Renal dialysis maintenance programs were instituted in 1964, 1 year before the first successful renal transplant. Since then, the capacity to treat patients with renal failure has been progressively expanded. A total of 1,124 patients are alive with functioning kidney grafts, a rate of 78 per 1 million population. The rate for patients on dialysis is 77 per 1 million population.

A national policy for the management of chronic renal insufficiency was developed by the National Health and Medical Research Council, and this policy has been accepted and implemented on a voluntary basis. Transplantation is seen as the objective for all potentially suitable recipients, but both dialysis and transplantation

Table I.–Number and Distribution of CT Scanners in Australia (1979)

State/territory	Number of scanners by type		Distribution of scanners in public and private facilities		Total number of scanners/facilities
	Head	General purpose	Public	Private	
New South Wales	1	9	5		10
Victoria	2	3	2	3	5
Queensland	2	2	2	2	4
South Australia	1	2	2	1	3
Western Australia	1	3	2	2	4
Australian Capital Territory	—	1	1	—	1
Tasmania	—	1	1	—	1
Northern Territory	—	1a	1a	—	1
Total	7	22	16	13	29

[a]On order.

are used in an integrated combined approach to the management of renal insufficiency.

Renal dialysis units are located exclusively in the public hospital system, where they are subject to controls on expansion and where State Health Authorities are committed to a policy of rationalization. Home dialysis is coordinated and supervised at major hospital units. Cooperation and coordination among dialysis units has been remarkably close.

Coronary Artery Bypass Surgery

Coronary artery bypass surgery was introduced in 1971 and has been limited to nine public teaching hospital units which are subject to the rationalization policies of State Health Authorities. As the following figures for annual operations show, the controlled diffusion of this technology in Australia has been quite rapid.

Year	Number of operations
1971	158
1972	283
1973	366
1974	621
1975	1,070
1976	1,506
1977	1,978

At this stage, further diffusion to additional units in public hospitals is not proposed. There are indications, however, that a private hospital may enter the field; this entry cannot be controlled under present legislation.

Cobalt Therapy

Cobalt therapy was introduced to Australia in 1959. It is centralized in each State at selected teaching public hospitals; and State policies are to maintain their principles of regionalized radiotherapy facilities. In New South Wales, an effort is being made to include cobalt therapy in an integrated and planned oncology program based in public hospital units.

Laboratory Automation

Laboratory automation has quite a different character from the technologies discussed above. Major laboratory automation was introduced to Australia in 1960, and its acquisition by public hospitals is subject to the general rules for equipment purchases previously described.

Rationalization of some services occurs without formal government intervention through the use by several hospitals and private practitioners of particular services provided by large public hospital laboratories. All State Health Authorities promote and facilitate cooperative arrangements, and these Authorities have established some major regional biochemistry services. In all cases, participation in regional or area services is optional. Technical advisory committees assist the Authorities in planning integrated or cooperative arrangements.

Outside public hospital and government laboratories, automation has been very widely diffused. It is found in private hospitals, in university laboratories, in both single and group private medical practices of pathologists, and in large commercial laboratories. In these situations, the major influence on the amount of testing is that exerted by specially designed codes of conduct that supplement the influence of health insurance arrangements.

CONCLUDING REMARKS

In conclusion, it must be said that there are being heard in Australia some voices that question medicine's extravagant support of lives of suffering and torment. The major question is whether society should not dispute the proposition that life should be maintained regardless of other factors. Some claim that resources should be diverted to other pressing, and possibly more rewarding, efforts aimed at improving the organization and coordination of services and the prevention of disease and disability.

A large proportion of patients suffer chronic diseases, disabilities, discomforts, and worries that will seldom go away quickly. These patients endure more and more encounters with

specialists, technical personnel, and machines, while perceiving less and less continuity of care and coordination of interests on their behalf. They often leave the technical services disillusioned—with little change in their problems—to find themselves in a community served by splintered sources of help that leave unbridged gaps between the health and social services that the patients require.

What about, for example, the thousands of handicapped children in remote areas of Australia who do not receive sufficient help? Can a clear case not be made for studies in communication and transport technology which would be of assistance to such children? To take another example, is the prevalence of child abuse in our society not an indictment of our inept handling of a problem which could be eradicated? What about the 3 percent of Australian children who are born with a serious disability? While few of them can be cured now, is there not clearly scope for the application of modern technology to their problems? As the result of an intensive and comprehensive genetic counseling program, Perth is said to have one of the lowest incidence of muscular dystrophy in the world.

It may be appropriate to end this discussion with the following comment. Stimulus to the social sciences and their technology may yield greater benefits than the mindless multiplication of diagnostic and therapeutic technologies in hospitals. If Henry Sigerist was right in asserting that the target of medicine is to keep people adjusted to their environment, or to help them readjust when they have dropped out because of illness or injury, then we have a social goal.

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5.
Medical Technology in Japan

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5.
Medical Technology in Japan

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JAPAN: COUNTRY DESCRIPTION

Civilization in the Japanese Archipelago began several thousand years ago in the neolithic age (17). Japan is made up of 4 main islands and more than 3,000 smaller islands, covering a land mass of over 377,000km^2. Over 111 million persons reside on less than 3 percent of the land. Nearly 70 percent of the land is covered by mountains and forests, and 27 percent is used for farming and industry.

The Meiji Restoration in the mid-1800's marked the beginning of the modernization of Japan. At that time, Japan opened its doors to the rest of the world and took steps to modify and update its industries, political institutions, and the pattern of society. Today, the government is a parliamentary system with three branches: legislative (the Diet), executive (Prime Minister and Cabinet), and judicial. National policies are administered at the local level by governments in each of the country's 47 Prefectures (States).

Buddhism, introduced to Japan from China and Korea, and Shinto, a religion native to Japan, are the primary religions. Japan has a rich cultural history ranging from the theatrical arts, including Noh and Kabuki, to significant literature and poetry. Other forms of art and music from the past still hold a prominent place in today's society.

Japan is essentially ethnically homogeneous and has one language. In order to be able to read the daily newspaper, one must have a working knowledge of three different alphabets, the principal alphabet (Kanji), which is made up of several thousand characters; and two other alphabets (Hiragana and Katakana), each of which has 46 letters. The literacy level in Japan is extremely high and education is an important societal goal.

The economy of the past was labor intensive and had many, many small industries. Japan, of necessity, entered into international trade because of the lack of raw materials needed in manufacturing processes. Much of Japan's rapid economic progress has occurred in the post-World War II recovery period, after the country and its productive capacity had become almost totally inoperative. Accomplished primarily because of a focused effort, the country's achievement has been rather remarkable.

In recent years, there has been **a** massive shift to high technology. Industries in Japan, through the guidance and support of government agencies, have concentrated on developing high levels of productivity for a limited number of manufactured products. Marketing methods for the distribution and sale of these products, furthermore, have helped make these industries highly competitive in world markets.

The tradition of lifetime employment security has played no small part in the success of Japanese industry. In addition, Japan has a rather elaborate social security system. This system, which provides for medical, annuity, industrial accident, and unemployment insurance, has undoubtedly had an impact on the lifestyle of the Japanese people.

THE HEALTH CARE SYSTEM

The days of acknowledgment that "illness was God's punishment" went out to sea when Western medicine was introduced to Japan in the 1740's by Dutch and German physicians (20). Isei, the medical law, was adopted during the Meiji Restoration in 1873 and established medical schools for the education of physicians. Japanese physicians were and are today primarily concerned with ". . . affairs to protect people's health, to cure their illnesses, and to foster medical science. " Japan's Constitution states that "in order that all the people may lead a healthy and decent life worthy of man, the right to life and the pursuit of happiness shall be respected" (20).

A series of questions come to mind when one wishes to explore and understand the medical care system within the milieu of a country like Japan. What is the state of the art in Japan with respect to health and medical care? What kind of financing system is there? Who administers and plans for the health sector? Finally, what problems seem to be emerging and how are programs evaluated? Answering these questions in brief will provide at least an overview of a health and medical care system that is both "alive and dynamic. "

At the outset, it is important to realize that Japan ranks as a modern postindustrial society and has an advanced medical care system. Most observers in the United States turn to the East—that is, to Western Europe—for information about their medical experience, but rarely go West— to the Orient—to learn from centuries of experience. When seeking to add to the body of knowledge for future decisionmaking, observations in all directions might be more appropriate.

Japan scores high in the health indicator arena, with an infant mortality rate of 8.9 infant deaths per 1,000 live births for 1977 (12). At the other end of the lifecycle, Japan boasts about its life expectancy achievements, namely, 77.95 years for females and 72.69 years for males (12). With the newly developing health promotion centers, the use of selective health screening programs, emphasis on physical fitness, and the use of feet and bicycles for transportation, these measures will probably continue to move in the same positive direction.

General Organization of the System

Medical care in Japan has been, and continues to be, dominated by solo general practitioners in clinic (office) settings. There are 1.18 physicians per 1,000 population, but the distribution of physicians varies markedly by Prefecture, from a high of 1.8 to a low of 0.5 physicians per 1,000 persons (4). Operating parallel with, but separate from, clinic practice is a "closed-staff" hospital system. Clinic physicians rarely have hospital privileges and hospital specialists seldom conduct part-time private practices. A situation in which hospital specialists are salaried at substantially lower incomes than clinic physicians, who practice on a fee-for-service basis, has caused some abandonment of hospital specialty practice for lucrative solo general practice.

Nearly 43 percent of the solo practitioner clinics possess 1 to 20 short-term (72 hours or less) holding beds. These units, although not officially classified or regulated as hospitals, account for 18.7 percent of the short-term beds in Japan. In 1975, Japan had 8,294 hospitals with 1,164,098 beds, or 10.4 beds per 1,000 population (4). When the clinic and specialty beds are added to this complement, the bed/population ratio is estimated to be 12.8 beds per 1,000 population, or 70 percent higher than the ratio in the United States (4).

Hospitals are owned and managed under many auspiccs throughout Japan. Some are owned by private physicians, whereas others are owned and administered by insurance plans, unions, industries, churches, and various levels of government. The private sector owns between 70 and 75 percent of the general hospitals (50 percent of the beds) and 95 percent of the psychiatric hospitals (9,27). Private ownership has had a definite impact on use patterns and expenditures for medical care, as evidenced by the

reported 33-day average length of stay in the short-term general hospitals (9). This length of stay has been explained in two ways. First, because of limited housing space and a paucity of nursing homes, patients have nowhere other than hospitals to convalesce. Second, the average cost per day in the hospital is rather low, and a significant portion of this cost is covered by sickness insurance.

Traditional public health and environmental health programs (i.e., institutional inspections, food and water supply inspections, etc.) are administered by the 852 Prefectural and local health centers (4). These health centers also provide preventive services to the population as a whole. Preventive services, which are not included as covered benefits in the insurance program but are provided on a large scale through these centers, include screening (early detection) programs for selected conditions (e.g., hypertension, stomach cancer, diabetes), immunizations and physical exams for infants and school age children, plus special categorical programs for maternal health, hypertension, etc. It is obvious from visiting the health centers that persons from all socioeconomic strata frequent them. These facilities truly function as public centers.

Financing

Nearly the entire Japanese population possesses health insurance coverage which has evolved over the 40-year period since passage of the basic Health Insurance Act of 1922. The original Act was a broad law covering the working population. By compelling employers to offer health insurance to their employees, this statute set the stage for the development of various health insurance plans. Amendments added subsequently required the plans to provide coverage to dependents of workers, the poor, and the aged. Most recently, benefits were added to provide special coverage for persons with high-cost (catastrophic) illnesses.

Six health insurance plans have developed since passage of the 1922 Act, and these plans collectively cover the entire population: Seikan Kempo, which is government-managed; Kyosai Kumiai, which is administered by the Ministry of Finance; Kokuho, which is administered by Prefectural and local governments; and three other plans which function independently. (See table 1.) All six plans have been set up as nonprofit organizations.

The compulsory health insurance system in Japan has been financed by two methods: 1) employer-employee contributions, and 2) subsidies derived from general tax revenues. Employer-employee contributions are in actuality insurance premiums derived from a specified percent (8.3 percent) of the employee's basic salary. The employer, by law, contributes at least 50 percent of the premium and the employee pays the remainder.

Table I.—Japanese Health Insurance Plans, Beneficiaries, and Enrollments"

Plan and year established	Beneficiaries	Number of persons insured	Percent of all insured persons
Seikan Kempo, 1926	Employees off firms having 5 to 1,000 persons	27,721,000	25.1 %
Kumiai Kempo, 1926	Employees of firms having more than 1,000 persons	25,573,000	23.1
Hiyatoi Kempo, 1953	Day laborers	752,000	0.7
Senin Hoken, 1940	Seamen	753,000	0.7
Kyosai Kumiai, 1962	National and local government employees; public corporations; private school teachers and staff	11,969,000	10.8
Kokuho, 1938	Employees of firms having fewer than 5 persons; persons who are self-employed, retired, aged, and others not covered by employees insurance	43,853,000	39.6
Total		110,631,000	100.0%/0

[a]Over 99 percent of the population in Japan is covered by one of the six insurance plans; the remainder is covered under special categorical programs. The distribution is as follows:

Total population	–	*Total insured persons*	=	*Persons covered by special programs*
111,275,000	–	110,621,000	=	654,000
100 percent	–	99.4 percent	=	0.6 percent

SOURCE: National Federation of Health Insurance Societies (Kemporan), *Health Insurance and Health Insurance Societies in Japan* (Tokyo, September 1977) (16).

Over the past several years, the Government of Japan has been called on to subsidize five of the six health insurance plans to cover unexpected, and in some cases continuing, deficits. Only one of the plans (Kumiai Kempo) has consistently shown a surplus, and surplus funds are passed on to the enrollees in various forms (i.e., premium reduction, extra benefits, recreation facilities, hospital facilities).

On the consumer side, in addition to the insurance premium paid to their respective insurance plan, insured persons (workers) pay a small, fixed amount out of pocket for care, whereas their dependents (family) pay *30* percent out of pocket up to a 39,000 yen ($108) I maximum liability during a calendar month (2).[2] In late 1973, an amendment (Kogaku Ryoyohi) was added to the basic insurance law as a means to meet high-cost illness (catastrophic) expenses for dependents beyond the *39,000* yen threshold. This program, administered by each insurance plan, was designed to prevent economic catastrophes that heretofore had resulted from high-cost illness. Patients in Japan have the right to seek care from any provider, and the provider in turn is able to bill any of the appropriate health insurance plans for the services rendered.

Reimbursement

Physicians, dentists, other health providers, and medical care institutions are reimbursed for care by the insurance plans under a standardized set of fee schedules. Lists of fees for each item of service (consultation, teaching, lab by test, drug by generic class, specific surgical procedure, X-ray by type, etc.) are published, and all claims for reimbursement must be submitted by medical care providers on standard forms. Clinics and hospitals have a choice (annually) to elect the use of "fee-for-(each) service" or an "all-inclusive rate. " In general, hospitals select the "all-inclusive rate" scheme, and solo practitioners choose the "fee-for-service" method.

Fees for each service that is provided in a medical care settings are negotiated on an annual basis. The Bureau of Insurance of the Ministry of Health and Welfare is charged with the development of a fee reimbursement scheme proposal for the providers and medical facilities (14). Under a system adopted in 1943, each item of medical service is assigned a certain number of points, depending on such things as the item's relative complexity. The actual medical fee for a particular item is then calculated by multiplying the respective points by a certain unit cost, which was set at 10 yen *($0.027)* per point in 1977. Proposed changes in fees are presented, debated, and negotiated within the Central Social Insurance Medical Council, an advisory body to the Ministry of Health and Welfare that is made up of representatives from medicine, dentistry, the insurance plans, and so forth. The specific tariff schedule for drugs, for example, is reviewed annually and in recent years has also been revised annually. The strongest body in the policymaking process of fee-schedule development is probably the Japanese Medical Association.

Administration and Planning

The Ministry of Health and Welfare has the primary responsibility for the regulation, administration, and conduct of public health programs. This Ministry regulates the health insurance plans, but generally delegates the responsibility for day-to-day administration to each plan. For insurance plans that are government-sponsored, however, the Ministry retains this administrative responsibility.

Health planning has traditionally been from the bottom up (local to national) through committee consensus. In the past, national health planning was categorical in nature. Early in the 1960's, the concept of comprehensive planning became more practical, particularly since there had been rapid socioeconomic changes in the country as a whole (4). Today, it has been noted, the Ministry of Health, on an ad hoc basis, calls on and utilizes input from various institutes and university experts on substantive planning issues, and also solicits citizen participation (the latter having become rather popular in re-

[1] For conversion of Japanese yen to U.S. dollars, the exchange rate used throughout this paper was Y360 = $1.00 (U.S.).

[2] For the legally poor and the elderly (persons over 70 years old), no copayment is required.

cent times). In this manner, it develops both short- and long-range health plans and updates these as changes are needed.

As part of the Ministry's medical manpower development plan, the policy of establishing new medical schools (one per Prefecture) has been implemented since ***1970.*** This effort will be terminated in a few years. The Ministry is planning to improve postgraduate medical education in primary care by training doctors for education technology or sending trainees to the United States.

The Ministry of Health and Welfare recently became actively involved in a newly formed World Health Organization/Pan American Health Organization (WHO/PAHO) health planning consortium that will serve as a continuing forum for the exchange of methodologies and program experience in health planning. Some WHO-collaborating health planning centers have been established. In addition, the Ministry has a plan to establish an International Medical Care Cooperation Center to promote medical care cooperation, particularly with developing countries.

POLICIES TOWARD MEDICAL TECHNOLOGY

The introduction and adoption of a significant volume of new forms of medical technology in Japan is similar to that in other well-developed industrialized countries. Over the past two decades, vast amounts of sophisticated new medical technologies have been developed and used to augment the provision of medical care in hospitals, as well as in private solo practitioners' clinics. The function of these technologies is to prevent, detect, or treat illnesses once thought to be the cause of "unnecessary disease, disability and untimely death" (21).

The devices industry has grown rapidly in Japan. In 1974, receipts totaled 254.3 billion yen ($706 million), an increase of 26 percent over the year before (14). Electronic equipment in general has shown very rapid growth, rising from *21.6* billion yen ($60 million) in 1971 to 35.7 billion yen ($99 million) in 1974 (14). Patient monitoring and diagnostic equipment sales increased from 1.9 billion yen ($5.4 million) in 1971 to 5.5 billion yen ($15 million) in 1974 (14). Drugs account for annual sales for the industry of 2,161 billion yen ($6 billion), a figure that rose about 15 percent from 1975 to 1976 (14).

Because of the rapid development and dissemination of new medical technology in Japan, the evaluation phase in many cases has been ignored or set aside for future action. Today, particularly with the ever increasing costs of the delivery of health and medical care in Japan, there is not only a consciousness of increased costs, but a concerted effort to carefully allocate scarce funds and resources. It may be that this effort will provide some impetus to a more thorough evaluation of medical technology.

Research and Development

The Japanese Medical Association functions prominently in the promotion, development, and support of research, and in the introduction of new technology (25). This has been particularly true in the past for historical reasons. Prior to 1955, the vast majority of physicians continued their training 6 to 10 years beyond the Doctor of Medicine degree to attain the higher Doctor of Medical Science degree (Igaku-Hakase) (4,26). In 1955, postgraduate training was reconstructed into a 4-year program in research, completion of which resulted in the granting of the same higher degree. Some of the physicians who completed their training in these programs became and continue to be the nucleus of the technological innovators in Japan. In 1968, a number of medical students challenged the new process, reportedly because they believed that too much emphasis was being placed on research and not enough on clinical medicine (25). The immediate impact of the change that resulted was a decrease in clinical research and widespread inability of medical schools to attract new faculty interested in and/or with ex-

pertise in research. Currently, the impact of this turn of events is being tempered by government and private foundation sponsorship of research fellowship programs abroad. The long-range effects of the change are not yet being felt.

The development and introduction of new medical technologies in Japan—whether these be in the form of instrumentation, procedures for patient management, or drugs—follows a common pathway. In general, a new technology is developed by researchers and clinicians from the leading medical schools, sometimes with the aid of technical specialists from industry. The quasi-governmental Science and Technology Agency often provides grants-in-aid to support the research, as do the Ministry of Health and Welfare and the Ministry of International Trade and Technology (MITI).

In recent years, the major focus for the development of medical technology in Japan has been to find the means to change the tide of the three leading causes of death: 1) cerebrovascular disease (stroke), 2) cancer, particularly stomach cancer, and 3) heart and other vascular diseases, with special emphasis on chronic renal disease (12). Basic scientific research on cerebrovascular disease is currently being carried out at the Japan Stroke Prevention Center, Institute of Health Science in Shimane, in cooperation with the U.S. National Institutes of Health. Animal model studies, which it is hoped are transferable to man, have been concentrated on the development of stroke-resistant strains of rats and on the means of the treatment of persons who have been found to be stroke-prone (5,28).

Also being carried out are clinical studies with scanning devices to detect persons with vascular changes. A limited number of experimental stroke intensive care units, some with hyperbaric chambers, have been set up by private hospitals in an effort to reduce mortality of persons who have had cerebral hemorrhages. Other modalities for the prevention and treatment of stroke, including diet modification, drugs for the treatment of hypertensive disease, and neurosurgical procedures, are being explored. None of these modalities, however, have been introduced on a broad scale; nor have any of them been fully evaluated or received sufficient endorsement from the medical community to warrant general use.

Much more technology has been developed for the early detection of cancer, particularly stomach cancer, than for detection of cerebrovascular disease. A great deal of research is currently underway in Japan to increase the speed of diagnosis with the so-called automated cytology process using optical scanning technology. Research for this and a series of related projects has been supported for several years by funds from the Ministry of Health and Welfare and MITI. Before there is any diffusion and dissemination of the new technology, however, researchers want to perfect it to the level at which there will be no sacrifice of accuracy for speed.

Evaluation of Medical Technology

The use of a new medical technology in Japan is dependent on its introduction by an eminent professor or clinician and its subsequent endorsement by peers or professional groups. The process of peer evaluation applies to all forms of medical technologies—drugs, devices, and procedures—whether they are developed within Japan or are imported.

Once the original investigator's coworkers and peers feel the technology has promise, the investigator usually publishes the findings in technical scientific or medical journals. If and when the investigator's peers recognize the potential and value of the technology, they replicate the work and often make improvements on the basic idea. Subsequent publication of their findings is recognized as **a** positive sign to the original investigator, who then with his peers formally introduces the technology for review and approval by the Pharmaceutical Affairs Bureau of the Ministry of Health and Welfare.

Regulation of Drugs and Medical Devices

Drugs and medical devices are currently regulated in Japan under the Pharmaceutical Affairs Law (15), which passed the Japanese Diet

on August 10, 1960. Products intended for use in humans are controlled by the Ministry of Health and Welfare, through its Bureau of Pharmaceutical Affairs. The Bureau of Pharmaceutical Affairs is assisted in implementing the Pharmaceutical Affairs Law by the Pharmaceutical Affairs Council, an advisory group with 13 committees and 55 subcommittees. The committees and subcommittees of the Pharmaceutical Affairs Council deal with such matters as the approval of manufacture and import of new drugs (Committee on Drugs), the establishment of quality standards for medical devices (Committee on Medical Devices), measures to assure the safety of drugs (Committee on Safety of Drugs), and review of drugs already on the market for effectiveness and safety (Committee on Drug Efficacy Re-Evaluation).

Whenever a new drug is proposed for marketing, data concerning its safety and efficacy must be submitted to the Bureau of Pharmaceutical Affairs. The Committee on Drugs of the Pharmaceutical Affairs Council reviews the data and makes a recommendation, but the final decision on market approval is made by the Bureau of Pharmaceutical Affairs. Of interest is the fact that drugs already marketed in other countries apparently are approved more readily than totally new drugs.

Once the drug is approved, it is entered in the Japanese Pharmacopoeia and may be marketed. In addition, the Bureau of Pharmaceutical Affairs requires good manufacturing practices to assure quality products. Because of their exposure to a series of manmade tragedies resulting from environmental contaminants, the Japanese are especially sensitive to the issue of safety. A national drug monitoring system of *465* hospitals that report adverse drug reactions is administered by the Bureau of Pharmaceutical Affairs (14). A surveillance system is also operated by the Bureau of Insurance through its Division of Medical Affairs.

Although medical devices are regulated under the pharmaceutical affairs law, any medical device that is in conformance with standards promulgated under the industrial standard law, may be manufactured or imported without a product license. Regulation under the industrial standard law focuses on safety, in particular, the safety of electrical instruments and apparatus. Performance standards have been established for ***140*** devices, including electrocardiographs, gastroscopes, and blood pressure meters. The law also requires manufacturers to register their products.

Reimbursement and Medical Technology

As was mentioned earlier, when a new service is proposed for a fee in Japan, it must first be debated by the Central Social Insurance Council, In its informal evaluation, the Council considers what is known about the benefits and risks of the proposed technology at that time. The fee established is intended to cover the price of the service. Thus, for example, the fee for a drug should be the actual purchase price. In practice, however, these purchase prices vary considerably in different institutions and different parts of the country, so the Minister of Health and Welfare establishes one fee.

The fees for drugs have been consistently lowered in recent years, reflecting market prices. The lowering of fees discouraged excessive drug use in the early *1970's,* and the reduction of market prices probably results from competition in the Japanese drug industry. In 1974, a new free medical treatment system for the aged "brought about a tendency to excessive dependence on drug therapy and eventually resulted in great increase in drug consumption" (14).

Cost-Containment Efforts

A rather dramatic increase in medical care demands following the introduction of new technology has been documented by the ongoing Medical Care Survey for Social Insurance (Shakai Iryo Chosa) (19) of the Ministry of Health and Welfare's Information and Statistics Department. In the period from *1964-74,* for example, it was observed that new technology increased the frequency of visits *2.4* times and the level of expenditures 6.9 times (19). These increases have been attributed, in part, to the increase in the variety of available laboratory tests and the increased testing capacity of laboratories resulting from automation.

In general, it is thought that the new technology has contributed to better diagnostic ability and therapy, and subsequently has had a positive influence by the improvement of the quality of care (19). Some people, however, feel that at least part of the observed increases in use of the technology maybe due to provider incentives in the fee-for-service payment system, which may result in duplication and possible abuse or excess service (19). Although the increases themselves have been documented through the Medical Care Survey, their causes remain to be demonstrated empirically before any attempts are made to modify public policy. Because there is now a great deal of concern about the rising costs of medical care, the Ministry has been conducting a variety of studies to pinpoint the underlying causes and is attempting to develop methods to contain medical care costs.

SPECIFIC TECHNOLOGIES

The use in Japan of medical technologies like radioisotopes, radiotherapy, computed tomography (CT) scanners, renal dialysis, premature incubators, and drug therapy has shown rapid growth in recent years. Specific technologies are discussed below.

CT Scanners

CT scanners were first introduced in Japan in 1975. At that time, the device used was the EMI scan imported from England. Since then, similar devices have been developed and manufactured in Japan for domestic use. Initially, the CT scanner was used primarily as a diagnostic instrument, but over time it has come to serve also as an adjunct and guide for radiation therapy for cancer.

In 1978, a survey **was** conducted to determine the number and type of CT scanners that were in place in a number of industrialized countries. In this inventory, Japan, with 180 head scanners and 112 body scanners, ranked second out of 8 industrialized countries (10). There were 2.6 scanners per 1 million persons in the population (10). As of April 1979, Japan had an estimated 516 (304 head, 212 body) scanners in operation, or approximately 4.6 per 1 million persons (23,24).

Japanese researchers and clinicians have continued to develop and evaluate scanners since the introduction of this new technology. In particular, Japanese researchers have compared CT scanners with other forms of diagnostic methodologies, e.g., radionuclide imaging and angiography (11). Conclusions from some of their studies (11) indicate that the medical profession in Japan has not fully accepted the CT scanner as a single, foolproof diagnostic tool. The use by some practitioners of both CT scanning and its diagnostic predecessors, however, may be duplicative, resulting in an unnecessary added expenditure in the delivery of medical care. Any unnecessary expenditure is being absorbed by society through the health insurance premium-reimbursement system.

Renal Dialysis

The introduction of hemodialysis in Japan, almost 25 years ago in 1955, marked the beginning of an era for the treatment of persons with acute renal failure (8). Therapy for those with chronic renal failure was made available about 10 years later.

For the first 10 to 15 years, the diffusion and distribution of renal dialysis units in Japan were rather limited. In 1972, however, this form of therapy was introduced as a reimbursable benefit through all of the six major health insurance plans that collectively cover the entire Japanese population. From December of 1966 to mid-1978, the number of hemodialysis units in Japan reportedly increased from 48 to 11,671 (8). Table 2 illustrates a nearly 50-percent increase in the number of units from 1976 to 1978.

The number of patients receiving dialysis has been increasing annually at a rather rapid rate. There are now over 200 renal dialysis cases per 1 million population now receiving dialysis in

Table 2.—Number of Hemodialysis Units in Japan (1976-78)

Dialyser	June 30, 1976	June 30, 1977	Dec. 31, 1977	June 30, 1978
Coil	—	4,720	5,228	5,514
Patient stations	—	4,728	5,317	6,157
Total	7,822	9,448	10,545	11,671

SOURCES: T. Inou and M. Odaka, "The Situation of Dialysis in Japan," *Proceedings of the Seventh International Congress of Nephrology,* Montreal, Canada, 1978 (8); T. Inou, "Current Status of Artificial Organs in Japan," *Artificial Organs (Japan)* 1(1):19, 1977 (6); and T. Inou, "Current Status of Artificial Organs in Japan," *Artificial Organs (Japan)* 2(Suppl.):1, 1978 (7).

Japan, which is probably the highest rate in the world (8). This is not to say that the prevalence of kidney disease in Japan is necessarily higher than is reported in other countries, but that dialysis therapy is quite accessible and available. Health insurance is probably a rather significant "enabling factor" in this context.

As of July 1978, 99 percent of patients requiring renal dialysis in Japan received their treatment in the hospital or at specialized hospital-affiliated centers; less than 1 percent of Japanese patients who require dialysis had home dialysis, which is used more commonly in other countries (1,3,6,7,8,17). (See tables 3 and 4.) There are several reasons for the lack of use of home dialysis in Japan. First of all, the vast majority of the families live in one- or two-room apartments. The installation of a dialysis unit would crowd the already limited quarters and might require special plumbing facilities. Secondly, the administration of dialysis is considered by physicians to be a medical treatment which, because of its specialized nature, can be provided

Table 4.—Percent of Chronic Renal Disease Patients Receiving Home Dialysis in Selected Countries and Areas

Country (or area)	Percent of patients receiving home dialysis
Japan (1976)	0.6%
United States (1976)	23.7
Washington State	75.0
Indiana	60.0
Northeast United States	15.0
United Kingdom (1977)	66.0

SOURCES: E. Friedman, et al., "Pragmatic Realities In Uremia Therapy, " N. .Errg J. *Med.* 298(7):368, 1978 (3); and C Blagg, "Incidence and Prevalence of Home Dialysis," *Journal of* Dialysls 1"475, 1977 (1)

only in a medical care setting by physicians. Lastly, Japanese health insurance plans pay the physicians higher fees for dialysis in the hospital and clinical settings than in home settings. By exerting a stronger influence on the physicians' choice of treatment site, this last reason probably overshadows the others.

Along with the number of patients, the costs for the provision of renal dialysis treatment have been rapidly escalating. The equipment in *1976* dollars averages about $5,000 for the apparatus (coil type $5,120, plate type $4,200, and hollow fiber type $6,420) and $70 per treatment for the disposable parts (8). Each treatment costs $200 in the outpatient setting, or $31,200 per year per patient (8). The cost across the nation for Japan for the year 1976-77 for 20,000 patients was estimated at $624 million (8).

A number of promising avenues (e.g., the development of reusabIe filters) to stem the cost tide are being approached and explored by universities. In addition, concerted efforts are being

Table 3.—Number and Percent of Chronic Renal Disease Patients Receiving Different Types of Hemodialysis in Japan (1976-78)

Type and location of treatment	June 30, 1976	Dec. 31, 1976 Number/percent	June 30,1977 Number/percent	Dec. 31, 1977 Number/percent	June 30, 1978 Number/percent
Hospital in the daytime	—	13,864/77.0%	16,037/75.9%	17,317/76.7%	19,184/76.0%
Hospital at night	—	3,721/20.6	4,693/22.2	4,847/21.5	5,766/22.8
Home dialysis	—	103/0.6	111/0.5	156/0.7	115/0.5
Peritoneal dialysis	—	322/1.8	299/1.4	259/1.0	185/0.7
Total	15,675	18,010/100.0%	21,140/100.0%	21,140/100.0%	25,250/100.0%
Cases per million population	140	160.9	188.9	199.4	222[a]

[a]Estimate.

SOURCES: T. Inou and M. Odaka, "The Situation of Dialysis in Japan," *Proceedings of the Seventh International Congress of Nephrology,* Montreal, Canada, 1978 (8); T. Inou, "Current Status of Artificial Organs in Japan," *Artificial Organs (Japan)* 1(1):19, 1977 (6); T. Inou, "Current Status of Artificial Organs in Japan," *Artificial Organs* (Japan) 2(Suppl.):1, 1978 (7); and M. Odaka, "Current Status of Dialysis Patients in Japan," *Artificial Organs (Japan)* 2(Suppl.):7, 1978 (17).

made by physicians to increase patients' survival rates, and just as importantly, to improve the quality of their survival. When appropriate, for example, kidney transplantation is being recommended to more candidates. Today, fewer than 200 kidney transplantations are performed in Japan per year (8). It has been reported that 8 to 10 percent of the kidneys are obtained from cadaver donors and that the remaining 90 percent are obtained from related donors (8). There is also a drive to promote night hospital dialysis and home dialysis. Finally, basic research projects supported by the government and foundations are well underway to develop an effective low-cost artificial kidney.

Radiation Therapy

Radiation therapy or teletherapy for cancer in Japan has taken, and continues to take, several forms. Initially, the treatment of choice was with X-radiation referred to as orthovoltage. During the past two decades, other forms of radiation therapy have been added to the cancer treatment armamentarium. A more potent treatment source that followed X-radiation was cesium (^{137}Cs), and this source was then superseded by the "super-voltage" modality cobalt (^{60}CO). More recently, Japan has developed even more advanced technology to augment cobalt therapy, by the introduction of electronically generated therapeutic impulses, with cyclotrons, betatrons, and linear accelerators. These new radiation methods, along with cobalt therapy, are often combined with surgery, chemotherapy, immunotherapy, and hyperbaric oxygen.

The predominant source of teletherapy used in Japan today is cobalt therapy. The other "super-voltage" sources are limited in number, and in many cases still under development. Cobalt units that emit over the 1,000-curie range have been shown to be most effective and are more commonly found in hospital teletherapy units. (See table 5.) A 1978 survey conducted by the Science and Technology Agency's Bureau of Nuclear Safety indicated that there were 589 cobalt and 10 cesium units in use in Japan (22). These units ranged in power from less than **100** to over *5,000* curies. Almost half (48.1 percent) of the cobalt units and 70 percent of the cesium units are in the over 2,000-curie class, which appears to be the treatment of choice (22,29).

Table 5.—Number and Distribution of Teletherapeutic Apparatus in Use in Japanese Hospitals and Clinics (March 1978)

Power of apparatus (in curies)[c]	Number of hospitals with apparatus in use	Cobalt units[a]		Cesium units[b]	
		Number	Percent distribution	Number	Percent distribution
Less than 100 Ci	60	75	12.7%	1	10.0%
100 Ci to less than 200 Ci	10	12	2.0	—	—
200 Ci to less than 500 Ci	47	48	8.1	—	—
500 Ci to less than 1,000 Ci	60	60	10.2	—	—
1,000 Ci to less than 2,000	110	111	18.8	2	20.0
2,000 Ci to less than 3,000 Ci	123	124	21.1	6	60.0
3,000 Ci to less than 5,000 Ci	152	152	25.8	—	—
5,000 Ci and over	7	7	1.2	1	10.0
Total	569	589	100.0%	10	100.0%

[a]Cobalt = ^{60}Co.
[b]Cesium = ^{137}Cs.
[c]Curies (Ci) = a unit of radioactivity equal to 3.7×10^{10} disintegrations per second.

SOURCE: Science and Technology Agency (Japan), Nuclear Safety Bureau, "Statistics on the Use of Radiation in Japan" (Tokyo, 1979) (22).

CONCLUDING REMARKS

No country, including Japan, has been able to provide a problem-free health care program to its people. Japan's major problem now is dealing with chronic disease. Once a country conquers its basic communicable disease and sanitation problems, it enters an era in which the challenges come from chronic illness, environmental and industrial hazards, and other similar threats to mankind. The leading causes of death shift from infectious diseases like tuberculosis, typhus, and smallpox to cerebrovascular disease, cancer, and other similar conditions. As inflation, recession, and unemployment affect the general economy, they also affect the health sector—and their impact makes the combating of these chronic conditions of postindustrial society especially difficult.

A second area of concern in Japan is the rising costs of medical care. National medical care expenditures (NMCE) have risen over 20 percent per year for the past several years (e.g., from 1970 to 1975, NMCE increased by a total of 154 percent, from 2,553 billion yen ($7,091,667) in 1970 to 6,478 billion yen ($17,994,444) in 1975) (4). At the present time, approaches to modify the insurance program are under serious discussion. In June of 1978, the Ministry of Health and Welfare submitted to the Diet a proposal to reform the health insurance program (i.e., to increase the premium, increase the out-of-pocket payment for outpatient drugs, equalize insurer and dependent out-of-pocket liability, etc.). This proposal, primarily a cost-containment measure, was introduced at the end of the legislative session of the Diet and was tabled for further study. Since that time, elements of the proposal have been debated by organized medicine, industry, unions, and the general public. The debate and exchange of ideas is a healthy sign, but unless action on this measure is taken soon, the Ministry of Finance will be unable to continue to cope with the deficits of the health insurance plans.

A third problem that is being anticipated in Japan is the potential impact of the country's increased life expectancy achievement. It is estimated that by the year *2025,* more than 18 percent of the population will be over the age of 65 (13). This important segment of the population will require special health services, health facilities, housing, income maintenance, and other specialized services. These services must be planned for and financed by today's working population for a period of 40 years hence in order to avert future problems. The emphasis, therefore, has been on planning and program development for the aged population to prevent future problems. If this activity proceeds at its projected pace, there will be few if any problems. Only time and experience will reveal the success of this preventive action.

The fourth and final set of problems pertain to medical manpower distribution and health care technology. A visit to a physician's clinic will reveal a well-trained physician who probably has specialty training. Unfortunately, some of the physician's skills are underutilized because of the closed-staff hospital system. Relaxation of this barrier would alleviate at least part of the problem. In the clinic setting, it is clear that medical technology permeates the air. One will probably find a rather large variety of sophisticated diagnostic and therapeutic equipment. That is, technology can be observed as the rule rather than the exception. Technology assessment, on the other hand, has not kept pace with the introduction of new modalities. Because of the recent recognition of the need for cost savings and cost-containment measures to stem the tide of spending during these inflationary times, however, it is anticipated that more assessment will be done in the future to determine the use, benefits, risks, and costs of technology to society.

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6.

Policy for Medical Technology in France

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6.
Policy for Medical Technology in France

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FRANCE: COUNTRY DESCRIPTION

Physically the largest country in Western Europe, France has approximately 53 million inhabitants. Almost 75 percent of the population lives in urban areas, and 16 percent lives in the Paris metropolitan region. The average population density is 97 inhabitants per square kilometer, with a range from 44 inhabitants in the Limousin Region to 821 in the Paris area.

The active working population includes approximately 21.7 million people, of whom 13.3 million are men and **8.4** million women. Life expectancy at birth is 69.1 years for men and **77.2** years for women (41). The birth rate, which in recent years has been declining, is now 14 births per 1,000 inhabitants; the mortality rate is about 10.1 deaths per 1,000 inhabitants (41). As in other Western countries, the proportion of persons over the age of 65 has been increasing. In 1977, they represented 13.8 percent of the population. A summary of basic demographic data for France is presented in table 1.

Table 1.—Basic Demographic Statistics for France[a]

Population	52,973,000
Males	25,949,106
Females	27,023,887
Population density	97 inhabitants per km^2
Urban population	75 percent
Birth rate	14.0 per 1,000 inhabitants
Death rate	10.1 per 1,000 inhabitants
Life expectancy at birth	
Males	69.1 years[b]
Females	77.2 years[b]
Infant mortality rate	12.3 per 1,000 live births
Active working population	21,756,000

[a]1976 data from the Institut National de la Statistique et des Etudes Economiques (INSEE).
[b]1976 data from the United Nations.
SOURCE: Ministère de la Santé (Ministry of Health), *Annuaire Statistique de la Santé et de l'Action Sociale*, 1979 (41).

Like other countries in Western Europe, France has a parliamentary democracy. The present form of government was adopted in 1958 following a referendum which established the Fifth Republic. Executive power is exercised by the President, who is elected for 7 years and appoints the Prime Minister. The Prime Minister leads the government and makes recommendations concerning presidential appointments to other Cabinet positions.

The Prime Minister and the Cabinet are responsible to Parliament. Parliament, consisting of the National Assembly and the Senate, has legislative power. Deputies to the National Assembly are elected directly by their constituencies for periods of 5 years. Senators, whose term of office is 9 years, are elected indirectly by Deputies to the National Assembly, Departmental General Councilors, and delegates from municipal councils.

Most legislation is initiated by the Prime Minister.[1] The Prime Minister not only proposes new laws to Parliament, but, he/she has the exclusive right to initiate governmental expenditures. Parliament has censuring power over the Prime Minister's government, by its vote on the budget and 4- or 5-year economic and social development plans. Once laws have been approved by Parliament, the Prime Minister is responsible for ensuring their execution.

Government administration, with Ministries providing the infrastructure, is very centralized in Paris. France is divided into 95 Departments, each of which functions both as an administra-

1 The Prime Minister initiates about 95 percent of proposed legislation. Parliament itself initiates only about 5 percent.

tive unit of the Central Government and as a local unit administering its own concerns. In each Department, a Departmental Prefect is appointed by and represents the Central Government and all the Ministries. The Departmental Prefect is also responsible for executing policies established by the Departmental General Council, a directly elected body in each Department. Local units of governmental jurisdiction in France are the communes. Each commune has an elected municipal council and a mayor that the council elects.

Regions in France were given explicit new powers and functions by the Regional reform **law** of 1972, which became effective in late 1973.[2] The aim of Regional reform was decentralization, especially in the domain of economic and social development, so as to facilitate better response to Regional needs and more effective utilization of available resources. Economic and social development plans have guided major national development concerns since 1947. France is now in its seventh economic and social development plan and is working on goals for the eighth. In the past decade, plans have been increasingly oriented towards a Regional perspective.

There are 22 Regions, consisting of two to eight Departments each. Each Region is administered by a public corporation consisting of the Regional Prefect (the Departmental Prefect of the Department in which the Region's capital is located), the Regional Council, and an Economic and Social Commission. Advised by the Economic and Social Commission, the Regional Council is the policymaking body. Its decisions are executed by the Regional Prefect.

The French economy is a free enterprise system in which the State and public sector (i.e., industries and commercial establishments under State control)[3] play very important roles. Economic growth has been very rapid since World War II. In recent years, the gross national product (GNP) has continued to increase, although the inflation rate has been very high since 1974 (I5 percent in 1975), and unemployment, especially among the young, is a serious concern. Of salaried workers in France, about 10 percent are employed in the agricultural sector, 39 percent in the industrial sector, and the remaining 51 percent in the commercial and services sector.

[2]Unlike the Department, the Region is neither an administrative subdivision of the Central Government nor an independent administrative unit. It therefore has no authority other than that delegated by the Government.

[3]The public sector is comprised of: 1) government monopolies in industries such as transportation and energy, and 2) nationalized banks, insurance companies, automobile manufacturers, and oil companies that compete in the private sector.

THE HEALTH CARE SYSTEM

Brief History of the System

A dominating principle in the evolution and growth of the French health care system has been the continuing respect for the practice of "medicine liberale" (liberal medicine). Four basic principles, though somewhat modified in practice, still dominate the functioning of the French health care system: 1) the physician is free to prescribe as he/she wishes, 2) medical confidentiality is maintained, 3) the patient is free to choose his or her physician, and 4) the patient pays the physician directly.

Historically, French physicians cared for patients in their homes. Public hospitals were established by the church as centers for lodging the poor. Hospital services were free, and resources—human and material—were gifts. After the French Revolution of 1789, the hospitals' were accorded a civic rather than religious status, but their function and resources were not altered. In 1851, the civic responsibility was enforced explicitly, and each commune or municipality had to support its own hospital.[4]

The private hospital sector really developed along two different tracks. First, small, private "cliniques," for-profit hospitals offering limited

[4]In some cities, e.g., Marseilles and Paris, public hospitals today are still called "public assistance hospitals."

services to privately paying patients, most often were started by physicians. Second, private, nonprofit hospitals for workers were started by some large industries. Care at these institutions was free and physicians were reimbursed by the enterprise. Other private, nonprofit institutions were established to address specific health problems (e.g., tuberculosis, cancer, mental health).

Medical care in France today continues to be provided by both the private and public sectors. (See table 2.) Most ambulatory care is furnished by private practitioners. Some ambulatory care, however, is furnished by outpatient departments associated with large public hospital centers, by mutual fund societies run by industries or unions, and by neighborhood health centers.

Table 2.—Public and Private Health Care Providers in France (1979)

Provider	Public	Private
Physicians	30 %	70 %
General practitioners	(32)	(68)
Specialists	(28)	(72)
Institutions		73c
Beds	(72)	(28)d

[a]Physicians in public practice includes only full-time salaried practitioners (e.g., school physicians, industry-employed physicians, Social Security physicians).
[b]Physicians in private practice includes those who may have a part-time appointment in a public institution.
[c]Private nonprofit institutions constitute 23 percent; private for-profit institutions constitute 50 percent.
[d]Private nonprofit institutions constitute 11 percent; private for-profit institutions constitute 17 percent.

SOURCES: D. Ceccaldi, *Les Institutions Sanitaires et Sociales*, 1979 (15); and Ministère de la Santé (Ministry of Health), *Annuaire Statistique de la Santé et de l'Action Sociale*, 1979 (41).

Institutional care is provided by: 1) public institutions (including public hospitals) that are sponsored by the Department or commune, but are subject to administrative authority of the Ministry of Health (Ministere de la Sante); 2) private, nonprofit industry-related or special purpose facilities; and 3) private, for-profit, hospitals (called "cliniques") which usually offer surgical, medical, and/or obstetrical services. Most psychiatric hospitals, although originally private nonprofit or for-profit institutions, are now public facilities.

National health care expenditures' in France account for 7.36 percent of the country's GNP (42). In 1976, public and private hospitals consumed 43.8 percent of national health expenditures (42).

Health Policy, Administration, and Planning

Although government administration in France is highly centralized, along with efforts to decentralize economic and social development, there have been increasing efforts to decentralize the administration of health and social services.[6] Health policy is established nationally by the Ministry of Health.[7]

In each Department, there is a Departmental Directorate of Health and Social Services (Direction Departementale de l'Action Sanitaire et Sociale, DDASS), which serves as an external unit of the Ministry of Health (44). Heading the DDASS is the Departmental director of health and social services, who is directly responsible to the Departmental Prefect. He/she is assisted by various specialists (e.g., the Departmental medical officer, who is responsible for ensuring that institutions adhere to the decisions of the Prefect).

DDASS enforces both the regulations of the Ministry and the regulations of the local authorities. It has administrative authority over public hospitals in the Department, must approve the hospitals' budget and help establish the prix de

'National health expenditures includes only operating expenditures (not capital expenditures). Two categories of operating expenditures comprise national health expenditures: 1) medical care expenditures (i.e., expenditures for hospital care, ambulatory and home health care, routine and preventive medicine, affiliated medical activities such as industrial medicine, medical goods and devices); and 2) health expenditures (i. e., expenditures for medical research, medical education, administration of the health care delivery system, and community health).

[6]The organizational and administrative structure of the French health system is very complex. Full understanding of this structure is not needed to examine issues related to medical technology. Readers interested in other details, however, are referred to D. Ceccaldi, Les Institutions *Sanitaires et Sociales*, 1979 (15).

'The exact name of the Ministry concerned with health can change when a new Minister assumes power, or when the existing Minister feels that a socially relevant problem is of considerable importance that it should be included in the ministerial title. Since the establishment of the Fifth Republic in 1958, the name has changed numerous times. For the purpose of simplicity, though, the term Ministry of Health is used throughout this chapter.

journée[8] for the Departmental Prefect's approval, and has administrative control over technical standards for public and private institutions. DDASS also administers the various agencies responsible for numerous public health programs. It shares with the Regional Directorate (discussed below) some of the responsibilities related to Social Security.

Health facilities planning, coordination, and technical supervision are conducted at the Regional level. Responsibility for decisionmaking rests in each Region with the Regional Prefect, who is advised by the Regional director of health and social services, a Regional inspector-general, and a Regional hospital commission. The Regional director of health and services, who is responsible to the Regional Prefect, administers the Regional Directorate of Health and Social Services (Direction Régionale de l'Action Sanitaire et Sociale, DRASS) a coordinating body in each Region. This body performs management advisory functions for DDASS. It also has responsibility for enforcing Social Security regulations. (The Regional director of health and social services does provide consulting services, with technical input from the Regional medical officer, but has no authority over the Departmental director. With some exceptions, the Regional director does not have control over the institutions in the Region.)

Public and Private Hospitals

The Hospital Reform Acts of 1958 and 1970 (35,37,38) were enacted to foster coordinated planning of health facilities on a Regional basis.[9] Under these acts, France was divided into 280 health services districts (secteurs sanitaires) and 22 health services regions (régions sanitaires), corresponding to the Economic Development Regions. Each health services district is supposed to be able to meet the primary and secondary care needs of a defined geographic area and population (50,000 to 150,000 inhabitants); each health services region is supposed to be able to provide tertiary care.

The two hospital reform acts led to the expansion of the functions of the public and private hospital sectors, classified public hospitals according to the services they were prepared to render, and created a public hospital service. Although a description of ways in which the public and private hospital sectors can be integrated to form a public health service is contained in the 1970 Hospital Reform Act, the concept of an integrated service has been implemented slowly.[10]

Public hospitals throughout the country function in a fairly uniform manner, largely because they are subject to detailed Central Government laws, decrees, and regulations (arrêtés), which control and govern many of their fiscal procedures. Public hospitals are under the administrative authority of the Departmental Prefect, but receive recommendations from the Regional Directorate of Health and Social Services. They are public corporations with financial autonomy, which are administered locally or municipally. Each has a management committee (conseil d'administration), similar to a board of directors, and a hospital director, who is appointed by the Departmental Prefect.[11]

For the purposes of planning, the Ministry of Health classifies public hospitals on the basis of size and types of services they provide. Thus there are (classification revised in 1978 (33) but not yet applied):

- *Local hospitals (hôpitaux locaux).*—Local hospitals largely provide long-term and residential care, especially to the elderly. They also provide basic medical care, occasionally with limited maternity services. These hospitals, which do not have salaried medical personnel (i.e., physicians or midwives), allow local practitioners to care for their patients at the hospital.

[8]Prix de journée, the French term for a public service hospital's daily hospital charge, is used throughout the text. The manner in which the prix de journée is established is discussed in the section of this chapter entitled "Hospital Charges and Reimbursement."

[9]These laws, along with other regulations, decrees, etc., cited in this chapter can be found in D. Comet, *Legislation des Hôpitaux Publics*, 1974 (17).

[10]All nonprofit private hospitals can be accorded public service status. For-profit hospitals can provide agreed on services for the public service, but seldom do this because the procedure for obtaining agreement is rather complicated.

[11]The hospital director's responsibilities include ensuring the application of laws and regulations; the management committee's functions are primarily advisory and supervisory.

- *"Hospitals" ("hopitaux") or second category hospitals (hopitaux de deuxieme categorie).* — "Hospitals" are usually affiliated with hospital centers (see below) and collaborate in providing for the health care needs of a health care district. These institutions are supposed to provide at least one unit for each of the following: general medicine, general surgical, maternity, chronic care, pediatric, and infectious disease. They are also to have outpatient services, a clinical laboratory for basic analyses, and electroradiology. Medical personnel are salaried and are usually part-time employees.
- *Hospital centers (centres hospitaliers).* — Hospital centers are one jurisdictional entity, but may consist of several institutions. They are usually located in the capital city of the Department and are supposed to be able to provide for all the primary and secondary care needs of the health care district. Hospital centers offer a larger variety of specialty services than "hospitals" do. They also have more full-time medical personnel, especially in radiology, clinical laboratory, and anesthesiology. They sometimes participate in medical training and are often the base for a nursing school. *Specialized hospital centers (centres hospital iers specialises)* provide specialized care within a single medical area, e.g., psychiatry, tuberculosis.
- *Regional hospital centers (centres hospital iers regionaux, CHR),* called *university hospital centers (centres hospitaliers universitaires, CHU),* when they are in the same city as a medical school. The CHR is usually in the Regior's capital city. Not only must the CHR have the facilities to meet the basic needs of its health care district, but it must have the highly specialized facilities to provide the tertiary care for the entire Region. CHUS play a significant *role* in medical education and research.

Table 3 lists the number of different types of public hospitals (classified prior to 1978 revisions) and beds for France. Table 4 summarizes the distribution of types of beds for the public and private sectors.

Table 3.—Number of Public Hospitals and Beds in France (1975)

Type of facility	Number	Number of beds
General hospitals		
CHRs[a] (including CHUs[b])	28	120,601[c]
Hospital centers	99	105,513
Hospitals	400	156,626
Local hospitals	364	53,068
Total	891	435,808
Specialized hospitals		
Psychiatric hospitals[d]	89	83,954
Tuberculosis hospitals	55	9,163
Total	144	93,117

[a]CHRs—Centres hospitaliers régionaux (regional hospital centers).
[b]CHUs—Centres hospitaliers universitaires (university hospital centers).
[c]One CHR, Public Assistance Hospitals of Paris, has 38,547 beds.
[d]Most but not all psychiatric hospitals are public hospitals.

SOURCE: Centre d'Etude des Revenus et des Coûts (Center for the Study of Revenue and Costs), *Le Coût de Hospitalisation,* 1977-78 (16).

Physicians and Nurses

As shown in table 5, in 1977, there were some 91,000 physicians in France, or roughly 172 per 100,000 inhabitants. Of the total, one-third were private practitioners. 12 The number of nurses totaled 219,000, or 412 per 100,000 inhabitants.

Just as they do in the United States, physicians in France tend to cluster in urban areas, especially around university hospital centers. There is a 5:3 ratio of generalists to specialists, and the distribution of physicians throughout the country reflects and parallels this ratio.

In the period 1967-79, the number of physicians in France increased by approximately 80 percent (41,46). To stem this rapid growth, the government has instituted more restrictive medical school selection procedures.

The rapid increase in the number of physicians is affecting the number of physicians seeking salaried positions in order to guarantee a minimum level of income for themselves. In recent years, the number of salaried physicians in France has been increasing. Furthermore, an ever increasing number of salaried physicians

[12] When hospitals and universities started to collaboratein medical education, a university-hospital career track was created. The prestige associated with this career has made it competitive with private practice.

Table 4.–Number and Distribution of Facilities and Beds in Public and Private Institutions in France (1975)

Type of facility/bed	Public institutions			Private institutions			Total		
	Number of facilities	Number of beds	Beds per 1,000 population	Number of facilities	Number of beds	Beds per 1,000 population	Number of facilities	Number of beds	Beds per 1,000 population
Medicine/medical specialties	852	145,850[a]	2.8	680	29,262	0.6	1,532	175,112	3.4
Surgery/surgical specialties	489	70,569[b]	1.3	1,265	66,249	1.2	1,754	136,818	2.5
Obstetrics	614	16,374	0.3	716	14,695	0.3	1,330	31,069	0.6
Convalescent/rest.	218	7,099	0.1	452	21,217	0.4	670	28,316	0.5
Functional rehabilitation	53	3,426	0.1	134	12,007	0.2	187	15,433	0.3
Other: long stay.	24	2,314	0.1	–	–	–	24	2,314	0.1
Tuberculosis	55	9,163[c]	0.2	195	15,038	0.3	250	24,201	0.5
Psychiatry	78[d]	16,913	0.3	222	15,103	0.3	414	137,535	2.6
	114[e]	105,519	2.0						
Total	1,044[f]	377,227	7.2	2,534[f]	173,571	3.3	3,578[f]	550,798	10.5

[a]Including chronic beds.
[b]Including gynecology.
[c]Autonomous public institutions.
[d]Psychiatric units within general hospitals.
[e]Public psychiatric hospitals and private psychiatric hospitals in the public hospital service
[f]Does not represent the sum because there are beds that have a variable classification.

SOURCE: Ministère de la Santé (Ministry of Health), *Annuaire Statistique de la Santé et de l'Action Sociale*, 1978 (40)

Table 5.—Number of Physicians and Nurses in France (1977)

Profession	Number	Number per 100,000 inhabitants
Physicians		
Private practitioners~	63,531	119.4
General practitioners	39,262	73,8
Specialists.	24,269	45,6
Salaried physicians.	**27,911**	**52.5**
General practitioners	18,453	34.7
Specialist.	9,458	17.8
Subtotal—general practitioners	57,715	108.5
Subtotal—specialists.	33,727	63.4
Total	91,442	171.9
Nurses		
Registered nurses.	152,575	286.9
Nurses aides, nurses auxiliaries, nurses in sanatoriums.	17,364	32.6
Psychiatric nurses	49,143	92.4
Total	219,082	411.9
Midwives	**8,899**	**16.7**

[a]This includes both full- and part-time private practitioners.
[b]This includes only physicians who are salaried exclusively, i.e., it does not include part-time private practitioners.

SOURCE: Ministère de la Santé (Ministry of Health), *Annuaire Statistique de la Santé et de l'Action Sociale*, 1979 (41).

are working full time. The increase is especially impressive in the public hospital sector. In 1965, only 3.3 percent of all physicians were full-time salaried employees in public hospitals, compared to 13.6 percent in 1977 (15,46).

The nursing population has not increased to meet hospital staffing needs. Although the Government has made efforts to attract people to nursing by increasing salaries and career opportunities, results have not yet been observed. It may be that the low status of the nursing profession, combined with difficult working conditions, is retarding change.

Health Insurance

France has a comprehensive Social Security system (Securite Sociale), with a highly elaborate sickness insurance mechanism[13] that covers virtually the entire population. Between 99 and 100 percent of the French population is now

[13]The term health insurance would be a partial misnomer, because the orientation is definitely toward curative rather than preventive care. Only limited coverage for screening and periodic checkups is mandated by national policy. A national system for preventive services for mothers and children is established under systems not discussed in this chapter.

covered by one form of sickness insurance or another. The country's Social Security system had its formal origin in the law of April 5, 1928 (22), which was revised and became operational in 1930. At first, insurance was mandatory for certain groups of workers, but was administered through private social insurance and mutual aid funds. Reforms of 1945 and 1967 reorganized the administration of the Social Security system and also created a national health insurance system (3,22,48).

Administration and Financing

Because there was resistance on the part of the different worker groups to having one administrative system, different administrative "r%-gimes" were established under the Ministry of Health to cover different categories of workers. Currently, there are four large regimes within the Social Security system. These regimes and the workers for whom they offer health insurance coverage are:

1. *General Regime* (Regime *Generale).–All* salaried workers in industry, commerce, etc., not covered by "special regimes" (see below).
2. *Special Regimes (Regimes Speciaux).* — Salaried workers in special industries such as railroads, mines, electric and gas companies, and in the civil service.
3. *Nonagricultural Independent Professions (Professions Independents Nonagricoles).* —Autonomous, nonsalaried workers, including craftspeople, small business owners, private practitioners in medicine and law.
4. *Agricultural Regime (Regime Agricole).* — Salaried agricultural workers and independent farmers.

Social Security contributions are slightly different for each regime, but over the years have tended to move in the direction of increasing uniformity. Although contributions are the shared responsibility of the employer and employee, the employer pays by far the larger share (78 percent **(48)** or more) of the subscription rate. Social Security policy is set by the Ministry of Health, but the sickness funds administer independently.

All four regimes have similar hierarchical structures to facilitate service at levels close to the insured. In the General Regime, which covers approximately two-thirds of the population (and is expanding), the reimbursement system is operated by 122 primary sickness insurance funds (caisse primaire d'assurance maladie). These 122 funds—there is usually one such fund per Department—are fiscal intermediaries that provide reimbursement to hospitals or patients, as appropriate. A Regional sickness insurance fund (caisse reionale d'assurance maladie) operates in each Region, and is responsible for, among other things, developing and coordinating prevention activities in the area of occupational health and accidents. At the national lvel is the National Sickness Insurance Fund (Caisse Nationale d'Assurance Maladie, CNAM), a public institution under the trusteeship of the Ministry of Health and the Ministry of Economics and Finance. The National Sickness Insurance Fund receives insurance fund contributions from employers and employees and then disburses endowments to the primary and Regional funds. It ensures on a national level the fiscal solvency of the primary sickness insurance funds with regard to the provision of coverage for the two groups of risks: 1) sickness, maternity, disability, death; and 2) work-related accidents and occupational health (15).

Coverage

Although there are several health insurance administrations or sickness funds covering different categories of workers, the coverage the various funds provide is similar. Reimbursement coverage for the following is provided (3):

- fees for general and special medical care;
- fees for dental care;
- cost of drugs, prosthetics, medical devices or appliances, biological and radiological exams;
- cost of hospitalization in all public and private nonprofit health institutions, and in all private for-profit health institutions that have made an agreement with the national sickness funds and meet basic technical requirements (accreditation);

. cost of transportation by ambulance and other means; and
• cost of surgical operations.

The patient's copayment varies with the type of care received. Although there are minor insurance fund differences for the rate of reimbursement, the following percentages are the responsibility of patients covered by the General Regime (3):

- 10 percent of expensive and essential drugs;
- 20 percent of medical and paramedical fees and laboratory procedures in public or private nonprofit hospitals or hospital outpatient departments;
- 20 percent of hospital costs during the first 30 days;
- 25 percent of medical and paramedical fees for care provided at the physician's private office or for a home visit; and
- 30 percent of other expenditures, such as laboratory expenditures outside the hospital, drugs other than essential ones, outpatient dental care, eyeglasses, and small medical devices-or appliances.

The copayment often can be eliminated through various exceptions recognized by the social insurance system. For certain procedures and tests that are considered "high cost, " for example, computed tomography (CT) scans, the patient is fully covered and the sickness insurance fund reimburses at 100 percent.

Many individuals belong to independent mutual aid funds or purchase private insurance to cover copayment costs.[14] If the patient is a member of a mutual aid fund, care is provided by the mutual aid society or reimbursement for the copayment is provided through the mutual aid fund.

Hospital **Charges and Reimbursement**

It is important to note the continued impact in France of the principle of liberal medicine. Hospital charges in both the public and private sectors are calculated along two primary axes: 1) a daily hospital charge for institutional service, and 2) the quantity of different "medical actions" performed at the hospital by or under the supervision of a physician. Compensation for medical actions is provided in the form of honorariums for specific types of actions, either directly to the individual physician or indirectly through the institution.[15] (Honorariums are discussed in more detail in the section on physician reimbursement.)

The prix de journe (daily hospital charge) for each public hospital and private nonprofit hospital in the public service is fixed in each Department by the Departmental Prefect, who is advised on this matter by the Departmental director of health and social services. The prix de journe is calculated for each hospital by dividing the sum of the institution's real costs for the previous year plus its deficit by the number of bed days in that year, and then multiplying this figure by the inflation-related index recommended by the Ministry of Health.

$$\text{Prix de journee for year N + 1} = \frac{\text{(Real costs of year N + Deficit of year N)}}{\text{Number of bed days in year N}} \times \text{Inflation-related index}$$

The reimbursable daily hospital charge for each private for-profit hospital is based on an agreement or "convention" between the individual institution and the Regional sickness fund. If a hospital is not conventioned, its reimbursable daily charge is set by the Departmental Prefect, and the charge is considerably lower than it would be if the hospital were conventioned.

For the past few years, there has been an increasing interest in prospective reimbursement as a method for cost containment. Several public service hospitals are now using prospective reimbursement on an experimental basis.

[14] In 1975, there were more than 8,000 mutual aid societies with a membership of approximately 33 million. The number of societies is constantly decreasing, but total membership is constantly increasing.

[15] In the case of salaried physicians working for public hospitals (or in some nonprofit private hospitals), the principle of liberal medicine that the patient pays the physician directly is not fully respected. Honorariums for the physicians' actions are paid to the hospital, but the physicians themselves receive a set salary. Recent legislation allows full-time salaried physicians to have a ver, limited number of private beds, or perform certain medical acts on a private patient basis. For these acts, they are directly reimbursed.

Physician Fees and Reimbursement

Fees for medical care provided by or under the supervision of physicians are based on a system of valuation of medical actions. Assisted by the Permanent Commission on the General Nomenclature of Professional Acts (Commission Permanence de la Nomenclature Generale des Acts Professionnels), the Ministry assigns a key letter (i.e., C for consultation, K for medical manipulation, B for laboratory, Z for radiology) and a coefficient or relative weight to every medical action that must be done by or under the supervision of a physician (16). Thus, for example, an appendectomy is worth 50K, whereas an EKG is worth 12K (36). Monetary values are assigned to the key letters, and these can and do change over the years; the coefficients for specific medical actions, which presumably reflect the action's relative complexity, however, usually remain constant.

Upper limits on physicians' fees for office visits and medical actions—the monetary values assigned to the key letters—are determined either by conventions between physician groups or individual physicians and the national sickness funds, or if no agreement is reached, by an interministerial committee. As shown in table 6, fees for physicians' acts vary depending on whether services are rendered through private practice, private institutions, or public institutions. The key letters are assigned higher values for physicians' services provided in the public sector than they are for services provided in the public sector. The higher values in the private sector reflect the inclusion in the physician's honorarium of certain material costs, which for the public sector are included in the hospital's prix de journee.

Most private practitioners are conventioned with the sickness funds.[16] Physicians who are conventional are not supposed to charge more than the conventional fees.[17] In certain situations, specified below, the conventioned fees are waived:

1. the physician holds certain categories of university or hospital titles (e. g., the

[16] Those who are not are reimbursed at a much lower fee that is set by the Departmental Prefect.

[17] There are no data to indicate whether conventioned physicians violate this regulation.

Table 6.—Key Letters and Unit Values of Honorariums for Medical Actions Performed by Physicians in the Public and Private Sectors in France (1977)

	Unit values of physicians' honorariums (in francs)[a] [b]			
	In public hospitals		In private practice, private establishments	
Key letter and type of medical action	CHUs[c]	Other public hospitals[d]	Agreed tarification[e]	Authorized tarification[f]
Hospitalized patients				
C—Consultation	5.64	5.13	33.00	4.00
K—Medical intervention	2.06	1.88	7.40	2.00
Z—Radiology	1.84	1.77	5.90	1.60
B—Laboratory	0.22	0.20	—	1.15
Maternity care	148.00	135.00	450.00	96.00
Outpatients				
C—Consultation	16.15	16.15		
K—Medical intervention	4.34	4.34	Same as	Same as
Z—Radiology	3.06	3.06	above	above
B—Laboratory	0.77	0.77		

[a] 4.25 francs = $1.00 (United States).
[b] In specified instances involving certain patient characteristics, provider characteristics, or hospital stay, the unit values of honorariums that are shown may be modified.
[c] CHUs—Centres hospitaliers universitaires (university hospital centers).
[d] Excluding local public hospitals.
[e] Based on agreements (conventions) between private practitioners or establishments and the sickness funds.
[f] Set by the Departmental Prefect and applied when the private practitioner or establishment has not entered into agreement with the sickness funds.

SOURCE: Centre d'Etude des Revenus et des Coûts (Center for the Study of Revenue and Costs), *Le Coût de l'Hospitalisation*, 1977-78 (16).

equivalent of assistant, associate, or full professor, or clinical department head) or has passed highly competitive specialty exams;
2. the physician possesses medical authority accrued through research, publications, seniority, etc; or
3. a visit is excessively long or special treatment is provided.

For physicians who are in the first category, a waiver is granted automatically if requested. For those in the second category, a panel of peers and representatives of the sickness funds makes a judgment, which once attributed, is not rescinded. Waivers for long visits or special treatment are judged on a case by case basis. As of January 1, 1979, 15 percent of conventioned physicians had waivers for conventioned rates, 5 percent of general practitioners had waivers, and 29 percent of specialists had waivers. The fees of conventioned physicians who have waivers are not to be excessive and are to be set "with good measure and tact" (25).

POLICIES TOWARD MEDICAL TECHNOLOGY

France is a country with a highly traditional culture, and perhaps because of that, some ambivalence and skepticism underlie the attraction of modern medical technology. For the most part, however, technological innovation is greatly appreciated and sought after. Furthermore, with the economic growth of recent decades, medical technology has diffused very rapidly. There is strong national interest in—and financial support for—the development of French-produced technology for domestic and export use.

Numerous policies regulate the introduction, diffusion, and utilization of medical technologies in France. Discussed below are government policies in the areas of R&D, regulation of drugs and medical devices, health facilities and equipment planning, and reimbursement.

Research and Development

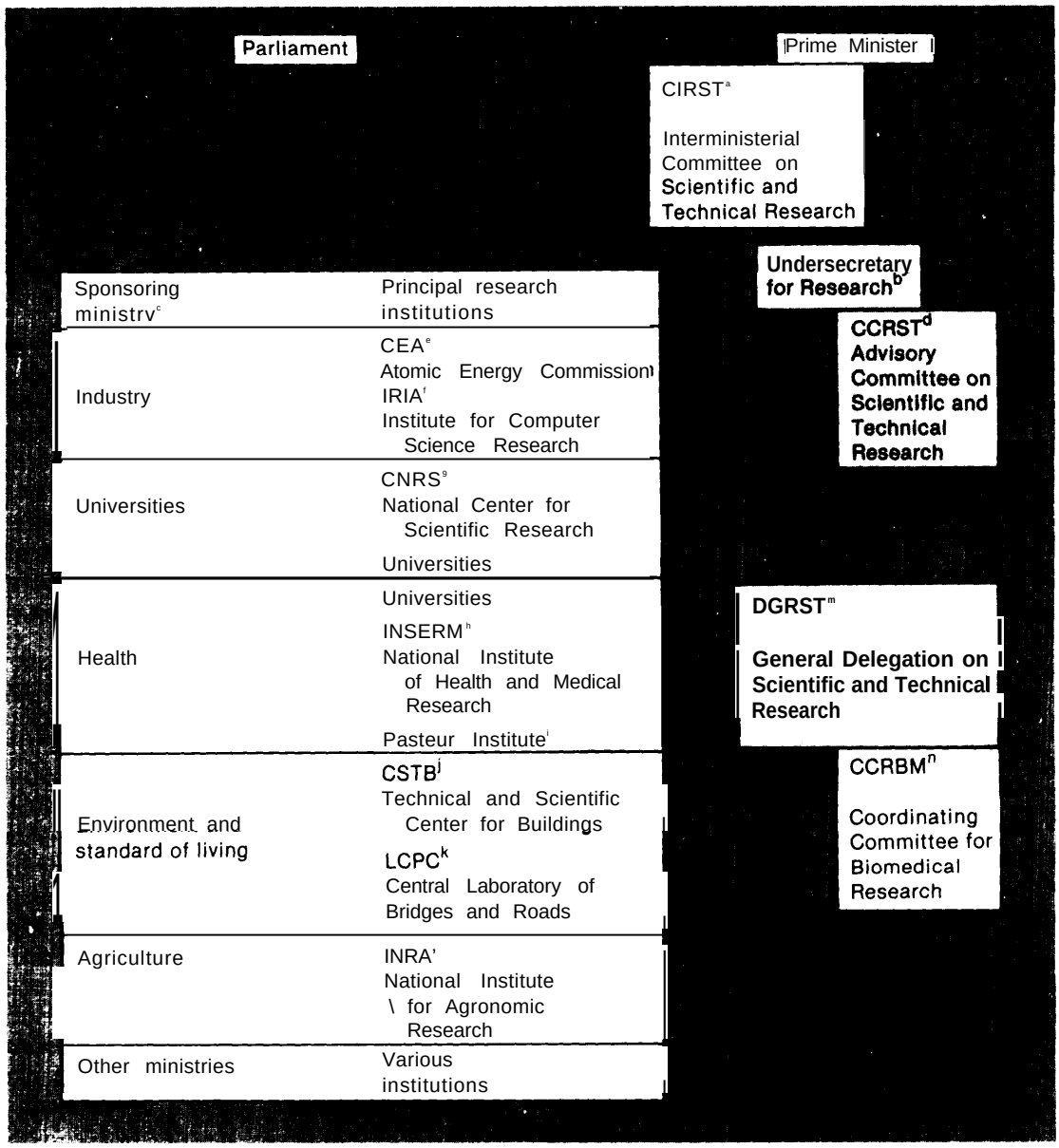
An Undersecretary for Research, attached to the Prime Minister's office, is responsible for the national publicly funded research budget. This research budget, or research envelope (envelope recherch~), includes the budgets of individual public research institutions.[18] Each public research institution is sponsored by the Ministry most closely alined to the subject area of research, and each institution's research funds come primarily from the state's budget to the sponsoring Ministry. (See figure 1.)

Responsibility for coordinating, stimulating, and monitoring all publicly funded scientific and technical research rests with the General Delegation for Scientific and Technical Research (Delegation Generale a la Recherche Scientifique et Technique, DGRST), which operates under the authority of the Undersecretary for Research. Advised by the Advisory Committee for Scientific and Technical Research (Comite Consultatif de la Recherche Scientifique et Technique), which is comprised of 16 prominent scientists from the public and private sectors, DGRST defines and implements, either directly or indirectly, any specific research policy in France (2,14). Its basic purpose is to ensure that short-term research goals are in accord with the longer term objectives of the economic and social development plan and national priority areas of interest.

DGRST attempts to coordinate collaboration between public and industrial research groups. In 1977, public funds accounted for 57 percent of R&D expenditures in France, but 61 percent of total R&D expenditures **was** utilized by private industry. The National Agency for the Promotion of Applied Research and Development (Agence Nationale de Valorisation de la Recherche), a recently expanded agency under the Ministry of Industry, stimulates innovation by partially subsidizing prototypes and by assisting in the subsequent development phase.

[18] The research envelop does not include all public research funds. For example, it does not include military research and telecommunications research. The research envelope coordinated by DGRST in 1977 represented 52 percent of all public research funds.

Figure I.–Simplified Organizational Chart **for** Public Research **Efforts in France (1978)**



[a]CIRST—Comité Interministeriel de la Recherche Scientifique et Technique (Interministerial Committee on Scientific and Technical Research).
[b]There is no Ministry for Research.
[c]Only the Ministries and institutions that do a fairly large amount of research related to health are shown.
[d]CCRST—Comité Consultatif de la Recherche Scientifique et Technique (Advisory Committee on Scientific and Technical Research).
[e]CEA—Commissariat a l'Energie Atomique (Atomic Energy Commission).
[f]IRIA—Institut de Recherche d'Informatique et d'Automatique (Research Institution for Computerization and Automation).
[g]CNRS—Centre National de la Recherche Scientifique (National Center for Scientific Research).
[h]INSERM—Institut National de la Santé et de la Recherche Médicale (National Institute of Health and Medical Research).
[i]The Pasteur Institute is a private, nonprofit foundation that receives government funding.
[j]CSTB—Centre Scientifique et Technique du Batiment (Technical and Scientific Center for Buildings).
[k]LCPC—Laboratorie Centrale des Ponts et Chaussees (Central Laboratory of Bridges and Roads).
[l]INRA—Institut National de la Recherche Agronomique (National Institute for Agronomic Research).
[m]DGRST—Délégation Générale a la Recherche Scientifique et Technique (General Delegation on Scientific and Technical Research).
[n]CCRBM—*Comité de Coordination de la Recherche Biomédicale (Coordinating Committee for Biomedical Research).*

SOURCE: Délégation Générale a la Recherche Scientifique et Technique, DGRST (General Delegation on Scientific and Technical Research), "France Recherche et Industrie," 1975 (20). (Modified by personal communication, May 1979.) (Reproduced with permission of DGRST.)

DGRST reviews and makes recommendations concerning all public research institutions' budgets to be presented to the Prime Minister and the Interministerial Committee on Scientific and Technical Research (Comite Interministerial de la Recherche Scientifique et Technique, CIRST) for annual budgetary approval. In addition to the budgets of individual public research institutions, the research envelope includes funds for DGRST to allocate to concerted actions (actions concertees) in areas of research which DGRST has identified as having priority (e.g., biomedical engineering, biology and myocardial function, computers and social sciences, reproductive and developmental biology, nutritional and agricultural technology, immunology, organ transplants). Funds for concerted actions are given to university research groups, research units of the research institutes, and to industry (18).

The Coordinating Committee for Biomedical Research (Comitee de Coordination a la Recherche Biomedicale, CCRBM) of DGRST supervises the activities of the various organizations that conduct or sponsor biomedical research. As shown in figure 1, the principal public institutions are: 1) the National Institute of Health and Medical Research (Institut National de la Sante et de la Recherche Medicale, INSERM), 2) National Center for Scientific Research (Centre National de la Recherche Scientifique, CNRS), and 3) the universities. The Pasteur Institute, a private, nonprofit foundation that also does biomedical research, is partially subsidized by the state.

INSERM and CNRS both allocate research funds to their own in-house research laboratories and to research units at the universities; both can also identify priority areas for research and request research proposals that are called programed thematic actions (actions thematique programme, ATPs). ATPs are 3-year contracts to support the operating expenses, equipment, and temporary personnel for assistance with items such as data collection or interviewing. [19]

[19]The salaries of reseachers at public institutions, who after a 4-year probationary period are tenured employees, must be paid with general research funds and cannot be met with funds for ATPs.

The scientific merit of research proposals is judged by different advisory commissions within INSERM and CNRS, depending on whether the proposals are self-generated grant proposals or are submitted in response to ATPs. INSERM receives a certain amount of money to help subsidize ATPs from the National Sickness Insurance Fund. INSERM judges the proposals for scientific merit, but if the ATP is based on a priority area of the National Sickness Fund, the Fund makes the final decision about whether to allocate funds.

Evaluation studies have been subsidized by ATPs, concerted actions, and the sickness funds. Most evaluation studies conducted are either clinical trials or efficacy studies of one form or another. A recent reorientation to include cost effectiveness is illustrated both by the inclusion of cost-effectiveness studies as an INSERM research priority and by the allocation of ATP funds to evaluate radiologic examination methods and determine their cost-effectiveness ratios (20).[20]

The state and its central policy guidelines have played an important role in scientific development since the creation of the Fifth Republic. A 10-year research policy (1980-90) has been proposed and is now (January 1980) being refined and elaborated by scientists. Among the various long-term priority areas that have been identified are biomedical technologies (microbiology, genetics, biomedical engineering), medical care evaluation research (nutrition, medication), and health economics (19). For the past few years, France's total public and private investment in R&D has been 1.8 percent of the gross domestic product. There is a plan to increase the public sector's investment in R&D

[20]In the late 1960's and early 1970's, cost-benefit analyses were very much in vogue within the Ministry of Health. For example, the maternal and child health program was implemented after a cost-benefit study (rationalisation des choix budgetaires, RCB). A similar study was conducted for deciding whether psychiatric catchment areas were advantageous or not. It is difficult to ascertain whether the psychiatric study had an impact on the decision-making process or was used to justify a decision already made. In both cases, the studies were coordinated by the Ministry with substantive input from experts in the specific medical area. In more recent years, there has been growing disenchantment with this approach, and no such studies appear to be underway at the present time.

during the 1980's, so that the country's total public and private investment in R&D amount to 2.2 percent of the gross domestic product—the same percent as in West Germany and Japan at present.

Evaluation and Regulation of Drugs and Medical Devices

Medical technology in France is regulated directly, indirectly, or not at all, depending on the technology in question. New medical procedures are not regulated at all, because one of the principles of liberal medicine which is still respected in France is that the physician is free to prescribe or treat as he/she wishes. If a new procedure is not in the nomenclature of medical acts reimbursed by the sickness funds, however, reimbursement to the patient for the procedure may not be provided. (In some cases, though, a new procedure can be integrated into an existing category of acts for which reimbursement is provided.)

Medications are regulated both directly and indirectly. Decisions regarding which drugs can be sold in France are made with the assistance of expert commissions by the Directorate of Pharmacy and Medications (Direction de la Pharmacie et du Medicament) at the Ministry of Health. Drugs to be sold in France are required to meet fairly stringent standards of experimentally demonstrated efficacy, safety, etc. A recent legislative change by the European Economic Council (EEC) may eventually provide an alternative for market approval: If a drug has been approved for sale in any two EEC countries, then the other EEC countries are expected to grant permission fairly automatically (26,33, 34). This legislative change will not actually be enforced for a few years.

Although there are no advertising or price restrictions on drugs that have been approved for sale (including most over-the-counter drugs), such restrictions are imposed on drugs that are included on the reimbursable list of the Social Security System. In order to be placed on this formulary, a new drug must be shown to be more efficacious, have fewer side effects, or cost less than another drug which is already on the formulary. Once the drug has met these criteria and been placed on the formulary, its price is set by the Ministry, and advertising must conform to certain restrictions. At the same time, however, the market for the drug is greatly expanded.

Medical devices are not regulated for efficacy before being placed on the market. Sometimes, however, the evaluation of a new medical device is stimulated by the National Sickness Insurance Fund. Since the Fund provides reimbursement for medical devices, it can decide to provide reimbursement for a limited quantity of a new device on the condition that INSERM or a university group be permitted to evaluate the new device's efficacy. This evaluation provides information that can be used in deciding whether or not the device should be placed on the list of devices for which reimbursement will be provided (47). To obtain reimbursable status, a device must be shown to be efficacious. The evaluation of medical devices that is required by Social Security can be considered an indirect form of regulation.

Health Facilities and Equipment Planning: The Carte Sanitaire[21]

The carte sanitaire, the system of health facilities and services charts that is used for health planning, was created by the Hospital Reform Act of 1970 (35). Since 1972, various decrees and circulars have detailed how the system should function (see, e.g., 4,5,6,7,8,10,26,27, 28,29,30,31,34,35). Creation of the carte sanitaire was aimed at stimulating reorganization and equalization of the distribution of health care facilities and services. By regulating their expansion and redistribution, the carte sanitaire regulates the availability of resources for geographic areas and population groups. Expansion or creation of services must be approved regionally or nationally to ensure that growth relates to need.

[21]*Carte sanitaire, the French term for the system of health facilities and equipment charts that are used for health planning, is the term used to refer to that system throughout the remainder of this chapter.

A method for needs determination is established nationally. The Ministry of Health, advised by the National Commission on Medical Equipment (Commission Nationale de l'Equipment Sanitaire), recommends norms for equipment/population ratios. [22] The charts that constitute the carte sanitaire are prepared on either a population or specific equipment basis by the Regional Prefect, and they list existing and authorized-for-purchase equipment and locations, population projections, and where applicable, the discrepancy between actual supply and projected supply and projected need.

The Ministry of Health reviews and approves the charts prepared regionally; except in specified cases, however, he/she leaves actual needs determination (and the local request and approval process) to the Regional and Departmental authorities. Health facilities planning for individual Regions and districts within the Region is coordinated by the Regional Prefect, who is assisted by the sectorial interhospital group, the Regional interhospital group, and the Regional Commission on Medical Equipment (Commission Regionale de l'Equipment Sanitaire). [23] Interregional planning and decisionmaking for certain facilities or equipment that are considered to be assessed best from a national perspective are the responsibility of the Ministry of Health advised by the National Commission on Medical Equipment. The carte sanitaire must be reviewed by the Ministry each time a new economic and social development plan is being prepared, about every 5 years. At the initiative of the Ministry or Regional Prefect, it can be reviewed at other times, as well.

The Ministry of Health has issued a list of "heavy equipment" (equipements lourds), and each of the specific medical technologies on this list has its own chart, and usually an index of need. Authorization for acquisition from the Minister of Health, the Regional Prefect, or the Departmental Prefect, depending on the technology and type of facility, is required for any item on the list. [24] In the case of a public institution, if authorization for purchase of an item is granted, the state may—but is not obliged to—subsidize part of the purchase cost. If authorization is not granted, purchase by a public or private institution would be illegal .25 The cost of unauthorized equipment could not be included in a public or private hospital's capital or operating costs, nor could it be included in calculating a public hospital's prix de journee,

At the present time, there are 11 technologies on the "heavy equipment" list of the carte sanitaire that applies to both public and private institutions. [25] [26] They are (modified May 1976) (31):

1. autoanalyzers,
2. heart-lung machines,
3. hyperbaric chambers,
4. linear accelerators with sources greater than 10 MeV (million electron volts),
5. radiotherapy machines: cobalt bombs and linear accelerators with sources less than or equal to 10 MeV,
6. scintillation cameras,
7. radioisotope scanners,
8. artificial kidneys,
9. information-processing equipment whose cost exceeds 150,000 francs (13,530) [27] for purchase, or 5,000 francs ($1,175) per month for rental and operation,
10. laser photocoagulators, and
11. CT scanners.

[22] These have been established for surgical, medical, obstetrical, and extended-care-facility beds, and also for certain medical technologies.

[23] The members of the Regional Commission on Medical Equipment are recommended by the Ministry and include representatives from various organizations and institutions who are directly or indirectly involved with hospital care. These include representatives from the Regional and Departmental government agencies, from elected representatives, from private practitioners, from both the public and private hospital sectors, from the medical university, from the sickness funds, etc. The membership of the National Commission on Medical Equipment is analogous to that of the Regional Commission.

[24] The approval process for private for-profit hospitals is different from that for institutions in the public hospital service. When a private sector institution requests approval for equipment acquisition, replacement, or expansion, the appropriate approval body must respond within *6* months of the demand. Otherwise, approval is granted by default. Public service hospitals are granted a *6*-year authorization, whereas for-profit hospitals are granted a *2*-year authorization.

[25] Enforcement of th, prefect's decisions is the responsibility of the Departmental or Regional medical officer.

[26] Additional technologies are included on the heavy equipment list that applies to the private sector.

[27] For conversion of French francs to U.S. dollars, the exchange rate used throughout this chapter was *4.25* francs = $1.00 (U.S.).

The Regional Prefect has jurisdiction for autoanalyzers, heart-lung machines, hyperbaric chambers, artificial kidneys to be used only for acute kidney failure, and information-processing equipment in private facilities. All equipment in public facilities, [28] excluding CHRS and CHUS, are in the jurisdiction of the Departmental Prefect. The remaining items are the responsibility of the Minister. The Minister is advised with respect to items in the private sector by the National Commission on Medical Equipment.

Indexes of need are recommended by the National Commission on Medical Equipment. To help determine an index, the Commission may call on experts, including physicians and manufacturers, in the specific area of interest. Given the diverse representation and expertise of the National and Regional Commissions, indexes of need are presumably unbiased or balanced and based on the latest available information and methodology for needs determination. If the indexes are perceived by the General Directorate of Health or others at the Ministry of Health to be inadequate or inappropriate, however, efforts to revise them are initiated.

The carte sanitaire can affect the capital expenditures of an institution and determine the availability of specialty units and beds, and indirectly, personnel. By explicitly indicating that certain districts are "underequipped" the carte sanitaire can and has induced health costs. The system also brings to light the fact that certain districts are "overequipped. " Until December 1979, the carte sanitaire regulations allowed the appropriate authorities to close down "unneeded" beds and heavy equipment—for the private sector. In practice, however, little if anything, was done to redistribute equipment from "overequipped" districts.[29] The power to close down unneeded facilities has now been extended to public hospitals. Individuals responsible for the carte sanitaire at the Ministry anticipate that this change, combined with the present emphasis on health care cost containment, will provide the impetus to enforce this regulation.

The Hospital Reform Act creating the carte sanitaire was passed in 1970. In a circular on July 13, 1976, however, the Minister indicated that the carte sanitaire's regulations were not being taken seriously and were therefore having no apparent impact (12). At the time of the circular, the carte sanitaire system had been functioning for only 3 years, and its work had been mostly descriptive and hardly at all normative. Since then, the situation has been improved by more concerted efforts. The latest available data for the private sector 1977 (43) indicate that not only are fewer beds being requested, but that a lower proportion of the requests are being authorized. What is important to observe, however, is the lag between the declaration of policy, the presumed implementation of policy via regulatory mechanisms, and the expected impact of the policy.

Reimbursement and Medical Technology

Reimbursement for professional fees and technology charges is provided for differently in the public and private sectors. For public service institutions, technology capital and operating costs are included in the hospital's prix de journee. For private facilities and practitioners, part of these costs is included in the reimbursable daily hospital charge and part is included in the honorarium fee.

As has already been mentioned, the percentage of reimbursement to the patient depends on the technology in question. More complex technological procedures engender a higher rate of reimbursement, i.e., the patient pays less or nothing at all. Prior to the use of certain high-cost procedures, authorization should be obtained from the sickness funds. If authorization is denied, the patient is liable for the cost. (The mechanism of prior authorization is discussed below in conjunction with cobalt therapy.)

[28] Except dialysis machines for chronic kidney failure.

[29] Thus, for example, although there are districts that do not have a cobalt machine that they "need," France as a whole has more machines than the cobalt/small-linear-accelerators total population index specifies.

SPECIFIC TECHNOLOGIES

As described in the preceding section of this chapter, France **has** numerous policies that regulate the introduction, diffusion, and utilization of medical technologies. Some of these policies are fairly recent, and it is too early to assess their impact. The following examples of experience with specific medical technologies, however, provide insights into the existing relationship between the policies and the technologies.

CT Scanners

A highly expensive capital investment, the CT scanner was subject to regulation by the carte sanitaire even before it was specifically added to the list of heavy equipment by the decree of September 1975 (31). Because of the computer component of the machine, the CT scanner was regulated as technology in the category of information-processing equipment exceeding specified cost limitations. This category was in the jurisdiction of the Prefect. As soon as the Minister placed the CT scanner on the list of heavy equipment, however, she indicated her intention to obtain ministerial jurisdiction for this technology. Ministerial jurisdiction for CT scanners in the private sector was obtained shortly thereafter (32).

The first CT scanner in France was purchased with assistance from the Ministry of Health by the Public Assistance Hospital of Marseilles. That purchase was made in March of 1975, before a CT scanner facilities chart and government-recommended indexes of need had been issued.

The current index of need, one CT scanner per 1 million inhabitants, is a combined index that includes both head and total body scanners. This index was agreed on by an expert committee of renowned physicians, researchers, and manufacturers called together by the National Commission on Medical Equipment. The committee recommended that scanners be approved only for institutions associated with research units; it also recommended that brain scanners be approved only for those facilities with neurosurgery departments and that body scanners be approved only for facilities with clinical oncology departments.

The rate of diffusion of CT technology, as controlled by the index of need, was affected by an important factor—the desire to foster the development of a French-fabricated scanner. The scanner had been included in a priority area for development identified by DGRST: computer science technology. In addition, government subsidies for developing CT equipment had been provided to the French manufacturer CGR. The index of one scanner per million inhabitants was chosen so that there would not be a rapid saturation of the CT market and room would be left for CGR to compete. The index was not medically restrictive, because the relative diagnostic value of the scanner had not been fully established. The first perfected CGR scanner was installed in January 1977.

Using the current index of need, France should have 54 CT scanners by 1983. As of January 1, 1979, 30 CT scanners (20 head, 10 body) were installed in France, and 26 more (13 head, 13 body) have been authorized (43).[30] Nine of the twenty-two Regions do not have scanners, although they have been authorized, and Corsica's population size does not justify one. Other Regions have attained their limit and would like more.

The high level of interest in the diagnostic value of the scanner has stimulated the awarding of grants and contracts through INSERM, the National Sickness Fund, and DGRST for research on the value of this technology to medical decisionmaking. The impetus and efforts to evaluate a medical technology in terms of the impact of the information it provides are a rather new phenomenon in France, but one which has persisted. When the National Commission on Medical Equipment was requested to reassess the index of need in light of the in-

[30] Fifteen scanners (5 head, 10 body) purchased without government subsidies have been installed since *1975 (43)*, Most of these scanners are in private (for-profit and nonprofit) establishments; some are prototype machines for evaluation, All 15 were authorized.

production of body scanners, researchers working on the subject of diagnostic value of the scanner were also invited to participate. Further evidence of the persistence of the phenomenon was the recommendation that total body scanners be installed where research could be conducted to evaluate the machine. Requests for proposals (ATPs) from INSERM followed this requirement. In addition, the National Sickness Fund is currently supporting several scanner evaluation projects.

Requests for scanner purchase authorizations have been coming in more slowly than expected by the Ministry and CGR. The supposition is that the political problems involved in determining which radiology service in a Region or hospital center gets a machine have slowed down the process. In the United States, each hospital within a medical or hospital center that includes several hospitals usually has independent administrative authority; in France, though, a hospital center is one jurisdictional entity. Since each hospital can have its own radiology department, or several smaller departments, each of which is headed by a chief of radiology, reaching agreement as to which radiology department within the hospital center will get the machine can sometimes be difficult. This problem is thought to have affected the requesting process.

The CT scanners that have been installed are operating at capacity. Inpatients have an average delay of 3 to 4 days between the request for a scan and the performance of the procedure. For outpatients, the delay is closer to 4 weeks. All scans are reimbursed by Social Security at 100 percent, because they are considered high-cost procedures.

Whether the scanner is being utilized appropriately is not known. Most physicians perceive a need for more installations, however, and this perception, combined with CGR'S capacity to supply the demands, fosters the expectation that the present index will be revised with the next 3 or 4 years.

Renal Dialysis

Research on renal dialysis apparatus was going on in France in the late 1940's, but the clinical use of hemodialysis machines did not begin until 1965. Since kidney disease fell into the category of chronic diseases, Social Security funds covered the entire cost related to the treatment. Considerations of the patient's ability to pay, therefore, were not a determinant of the choice of patients for treatment. This choice was left—and remains—entirely up to the clinician.

The very early indicators of need for dialysis equipment, which affected the diffusion of this technology, were based on the availability of trained professionals and the purchase of equipment, as well as the increasing prevalence of kidney failure. These early indicators came from a group of experts representing INSERM, specialists in nephrology, and the Ministry of Health. The goal in the mid- to late 1960's was to have enough renal dialysis facilities to treat 10 new cases per 1 million inhabitants. The treatment goal was revised in 1968, for the sixth economic and social development plan (1971-75), to 30 cases per million. The current goal, 50 new cases per 1 million inhabitants, has been achieved in practice, and the present intention is not to increase the number of facilities. The demand for facilities should start leveling off by 1985 because of advances in nephrology that are expected to prevent chronic renal failure (39).

The carte sanitaire includes renal dialysis machines as heavy equipment that must meet interregional planning objectives (11). The Ministry of Health has jurisdiction for the carte sanitaire for dialysis machines used for chronic renal failure in hemodialysis centers; and the Regional or Departmental Prefect has jurisdiction for machines used in such centers to treat acute renal failure. The current carte sanitaire index prescribes 30 dialysis machines per 1 million inhabitants for chronic renal failure (24). (This includes machines to train people for home dialysis, and surveillance to ensure that machines are being used for this purpose is called for.) That index is qualified by an additional index that guarantees at least five machines for each CHR. This means a possible in-

dex of 35 machines per 1 million inhabitants. The directives specify the desired minimum number of machines per center (eight), and they assign the power to the Region to determine the locale so that patient convenience is planned for. Each machine is supposed to be used to treat four patients.

Although the carte sanitaire does not include home dialysis machines, present policy is to encourage the expansion of home dialysis and kidney transplants when medically and socially appropriate. The expectation is that stopping the expansion of dialysis machines in centers will increase the use of home dialysis and transplants. The goal is to treat approximately 50 percent of new cases at centers and to treat the other 50 percent by other methods (e.g., home dialysis, peritoneal dialysis, transplants, etc.) (39). A ministerial circular in January 1977 specified a goal of 25 percent home-dialyzed patients among chronic renal disease patients (13).

Statistics on the prevalence of dialysis use and related information are maintained by the Division of Hemodialysis and Transplantation within the General Directorate of Health at the Ministry. This Division is advised about hemodialysis equipment by the Commission on Hemodialysis and Transplantation. There are 151 hemodialysis centers in France (9,13,43). As of 1977, there were 7,096 individuals with chronic renal failure on dialysis (9,13,43). Within this group, 83.4 percent (5,920 persons) were treated at the 151 dialysis centers, and 16.6 percent (1,176) were on home dialysis. The percentage of patients on home dialysis tends to vary inversely with the rate of transplant operations. Furthermore, this percentage varies in different parts of the country: In the Paris Region, for example, 38 percent of dialyzed patients are on home dialysis, whereas in the Rhones-Alpes Region, only 9.8 percent are. Approximately 650 kidney transplants were performed in 1978 (39). Data on the number of machines to treat acute renal failure were not available.

INSERM supports several research projects on the subject of the treatment of chronic renal failure. One collaborative venture, originally supported by the Ministry of Health, the National and Paris Region Sickness Insurance Funds, the Association for Artificial Kidney Utilization (Association pour l'Utilisation du Rein Artificiel), and the National Commission on Hemodialysis (Commission Nationale d'Hemodialyse), is now completely supported by participating dialysis centers. This project involves the development and operation of a computerized data bank on dialysis patients (at present in 40 centers). Data from the project are being used to evaluate the effectiveness, impact, and epidemiology of hemodialysis.

Coronary Bypass Surgery

Coronary bypass surgery was first performed in France in 1969. Since then (up to 1979), approximately 5,000 bypass procedures have been done, 1,000 of them in 1978 alone (21).[31] Only cardiac surgery departments can perform bypass surgery, because only they have the necessary equipment. At present, 23 active cardiac (open-heart) surgery units in CHRs and CHUs and several (5 or 6) private institutions perform this procedure.

The carte sanitaire for the authorization of heart-lung machines does place some indirect limitations on the surgery rate, but because the government has no jurisdiction in the area of regulating individual physicians' decisions concerning the use of medical interventions, it cannot regulate physicians' use of coronary bypass surgery. The initial response of French physicians to this new procedure was rather skeptical. Practitioners wanted more evidence of its effectiveness. Because of ethical objections, the French have not conducted, and do not plan to conduct, their own randomized trials of the procedure. When French physicians make therapeutic decisions, however, they do use the results of trials conducted elsewhere.

When coronary bypass surgery was introduced in 1969, it did not have to be specifically added to the nomenclature of medical acts with an associated K-coefficient (medical manipulation), because it could be subsumed under the existing category of open-heart surgery. Thus, neither the government nor Social Security was involved in the introduction of this technology.

[31] Subjective estimates provided by informed sources.

Since the charges for coronary bypass surgery are the physician's honorarium as reflected by the total number of K's, in fact, neither the Ministry nor the sickness funds can even provide accurate data on the number of procedures performed.

The general belief among physicians seems to be that coronary bypass surgery is used cautiously, and the rate of coronary bypass surgery seems to support that belief. The rate of coronary bypass surgery in France, about 19 procedures per million inhabitants, is far lower than that in the United States, about 370 per million inhabitants (21). One possible reason for the lower rate in France is the channeled access to the surgery there. Referrals for surgery are made by cardiologists only after treatment failure with medications. Generally, surgery is prescribed only for those patients, usually fairly young (35 to 45 age group), who have had certain types of myocardial infarctions or for whom medications have not been effective in treating cardiac pains. The rate of surgery has been increasing (21), however, and one cannot predict if the rate has reached a plateau or will continue to increase.

Cobalt Therapy

The first cobalt treatment machine was installed in France in 1955. In the beginning, cobalt machines were mostly in the private sector. Figure 2 illustrates the rate of diffusion of radiotherapy equipment (i.e., cobalt bombs and small linear accelerators combined).

The carte sanitaire specifically lists linear accelerators and cobalt bombs as heavy equipment needing special approval (31). Both are subject to approval of the Ministry of Health. The first indexes of need were one linear accelerator and five cobalt treatment machines per 1 million population. In May of 1976, these were revised to reflect utilization patterns. The present indexes are one large linear accelerator (capable of more than 10 MeV) and five cobalt bombs and/or small linear accelerators (capable of 10 MeV or less) per 1 million inhabitants.

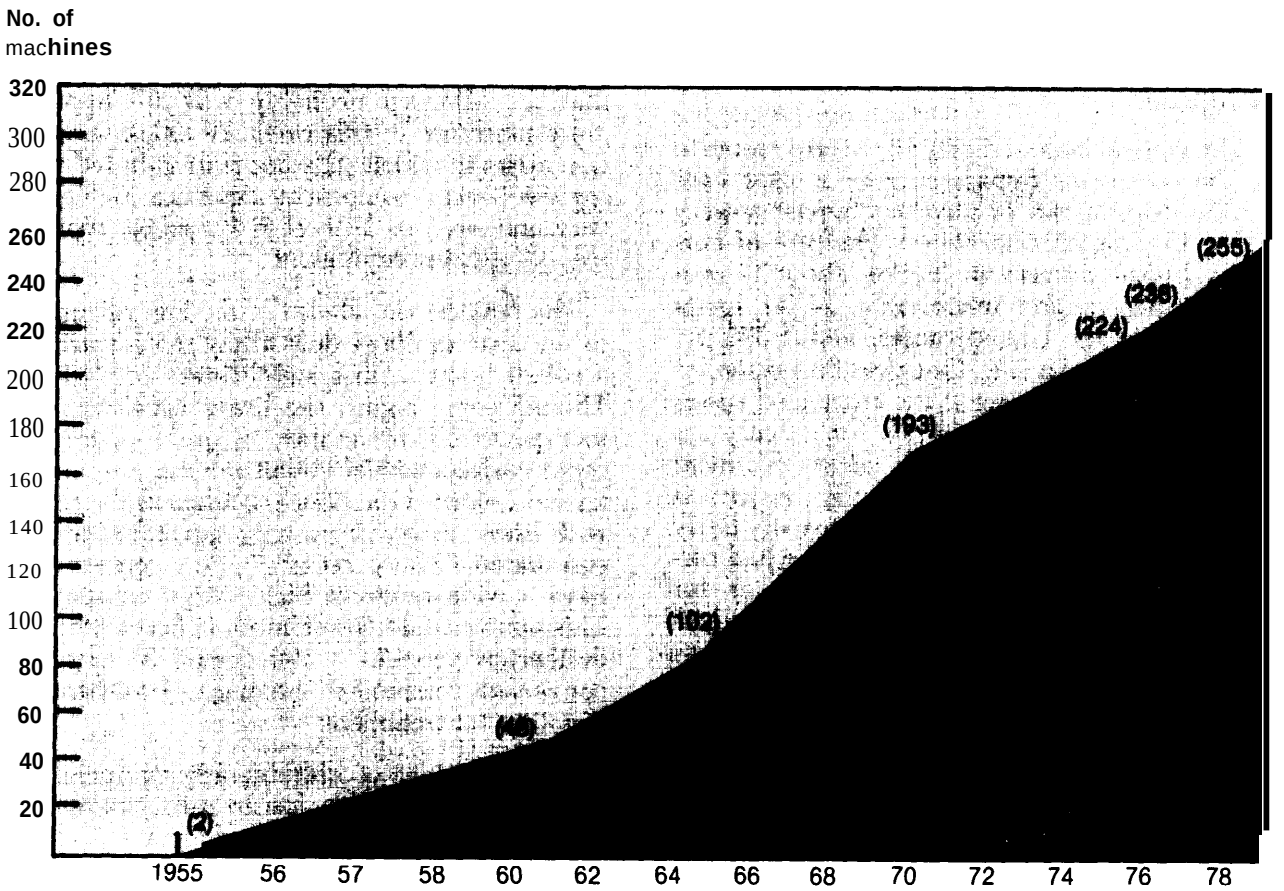
The carte sanitaire for radiation therapy made explicit in three Regions the unmet need for the large linear accelerators. With the reclassification of small linear accelerators into the cobalt bomb category, there is a small excess of this category of equipment (278 authorized machines instead of 263) (43). This excess means that the Ministry probably will not approve more machines in this category unless a situation arises in which: 1) a population-based need for additional equipment develops (which is very unlikely), or 2) there is a need for replacement of existing equipment.

The replacement clause of the law pertaining to the carte sanitaire does allow replacement of a cobalt bomb with a small linear accelerator. Though some regard the linear accelerator as therapeutically preferable, in order to impede rapid replacement of cobalt bombs, the Ministry has qualified the clause to allow replacement with linear accelerators only in establishments considered "heavy centers, " i.e., centers that have a wide range of high-energy equipment. This action could foster more concentrated radiotherapy services, which would be more inconvenient for patients having to travel longer distances for treatment.

For each piece of radiotherapy equipment it possesses, every facility has an authorization for ownership from the Ministry of Health. If an institution does not really use its machine, or uses it infrequently, as may be the case for some private clinics that had cobalt machines early, it sells its machine and associated authorization to another institution within the health services region or Department. This procedure is not one that the Ministry recommends, but it is not really illegal and is tacitly accepted.

In addition to the aforementioned measures for regulating the acquisition and existence of this technology through the carte sanitaire, there does exist a Social Security System mechanism which presumably is intended to regulate its use. When radiation treatment is prescribed, a request for prior authorization of the treatment is submitted to the sickness fund. If a response is not provided within 10 days, tacit approval is implied. (Although prior authorization is supposed to be granted before treatment is provided, in practice it is often granted after

Figure 2.—Diffusion Curve for Installed Cobalt Machines and Linear Accelerators < 10 MeV in France (1955-78)



SOURCE: F. Bachelot, *Cancer et Radiothérapie* (Paris: Firmim-Didot, 1977) (1). Updated by the Ministère de la Santé (Ministry of Health), 1979 (43).

treatment.) In the event that authorization is denied, the patient who has received treatment is liable for the cost and there is no reimbursement. It was not possible to obtain data on how frequently reimbursement is denied. Few documents discuss the procedures for prior authorization, and the procedures are not often mentioned by physicians as being part of the treatment/reimbursement process. This suggests that prior authorization is not widely perceived as a powerful regulatory mechanism. Whether its weakness results from inadequate staff at Social Security to fully review authorization requests, or from a small proportion of inappropriate requests, cannot be determined on the basis of available data.

Several years ago a study commissioned by the Ministry produced results that indicated to the Ministry that the coefficients for radiotherapy (Z key-letter) were inflated (45). Despite criticisms of this study, the coefficients were reduced. Radiotherapy is considered a high cost therapeutic mode, and the sickness insurance funds cover the cost completely.

At the present time, possible changes of the carte sanitaire indexes for radiotherapy equipment are under discussion. The discussion has arisen for two reasons. First, preparation of the eighth economic and social development plan requires review of the carte. Second, the experience of using the linear accelerators, large and

small, for several years has changed the treatment protocols again and may have altered the equipment needs.

Automated Clinical Laboratories

The first autoanalyzer installed in France was a Technicon product installed in 1959-60. Since 1972, autoanalyzers have been included on the heavy equipment list of the carte sanitaire. This equipment is under the jurisdiction of the Regional or Departmental Prefect. For the carte sanitaire, autoanalyzers are defined as bioassay equipment capable of performing 250 analyses or exams per hour, or more than 5 analyses or exams simultaneously. The equipment can be one apparatus or an assembled apparatus of several components.

The index for determination of need is not based on population, but based on the volume of tests performed by the laboratory. A clinical laboratory must perform a total number of tests valued at a minimum of **2** million B (key-letter category for laboratory honorariums) in order to purchase automated equipment. This carte sanitaire index is for public and private hospital laboratories, as well as for freestanding laboratories.

Following the 1972 decrees identifying heavy equipment, the Ministry of Health requested an inventory of existing equipment. Data concerning the distribution of autoanalyzers in 1973 should therefore be fairly accurate. Any subsequent figures, however, underestimate the number of autoanalyzers. This is because the Prefect's approval for purchase is required only if a laboratory wants to purchase a large machine, or wants to obtain *several* small ones simultaneously for integration into a unified apparatus. It is not uncommon—and according to some, it is quite frequent—for a laboratory to build up sophisticated apparatus by purchasing small independent components in a sequential and planned fashion. In this manner, a laboratory is able to obtain a more sophisticated and powerful machine, while avoiding government regulation and thereby not having its equipment appear in the Ministry's statistics. Even when a technology's diffusion is closely regulated, it appears, ingenuity can sometimes circumvent the regulatory process in a very legal fashion.

CONCLUDING REMARKS

The carte sanitaire system has been operational for close to a decade. Experience has improved judgment and clarified the problem issues. With the present preparations for the eighth economic and social development plan, and the concomitant review of the carte sanitaire, two major issues are being raised at the Ministry of Health.

One issue is revision of the authorization process. The **1970** law establishing the carte sanitaire and the many decrees and circulars that describe, define, and redefine its procedures have created a system that is bureaucratically heavy, confusing, and at times counterproductive. Under the existing authorization process, for example, a private institution and a public institution (other than a CHR or CHU) that want a heart-lung machine would submit their requests to, respectively, the Regional Prefect and Departmental Prefect. Each Prefect could make a decision independent of the other's, thereby undermining the intended coordination of the carte sanitaire. To improve overall coordination, some individuals at the Ministry want to have one decisionmaker for a given type of equipment in both private and public institutions.

The second major issue being raised at the Ministry is revision of the carte sanitaire indexes. Health care providers consider many of the indexes overly restrictive. Individuals with responsibility for the carte sanitaire at the Ministry of Health consider it advantageous not to revise the population-based indexes for equipment,[32] however, until there is better information about the use and the utility of the equipment.

[32] Other than the scintillation camera.

The carte sanitaire system has the potential for ensuring that the French population's health needs are being met and that health care facilities are not overabundant. Its early effects are now being observed, but it is too soon to say whether the system will be effective over a longer period. As noted above, because of the sanctioning process, the carte sanitaire system does have loopholes. Further, it appears that stricter enforcement of the carte sanitaire authority is necessary to the correct the system's functioning. Finally, it should be noted that although the carte sanitaire was introduced to foster coherent health services planning and to redistribute services so that the needs of local populations are met, in some cases the carte sanitaire can be counterproductive. The concentration of facilities at technology heavy centers that have evolved in part because of some of the criteria for authorization, for example, may limit some patients' access to these facilities by necessitating their having to travel farther for treatment. It is too early to say whether the carte sanitaire system has had an impact on health care costs. These costs have been rising at the rate of 17 to 20 percent each year for the past few years. Whether efforts to limit the supply of available technology resources will stem the increases, however, is still not known.

The carte sanitaire is a good example of French social laws. The policy is simple, clear, and flexible: Regionalization of health services planning, indexes of need based on the consensus judgments of experts, required review of the indexes. The regulations, by contrast, are both very detailed and subject to frequent modifications and additions, which often makes their implementation complex bureaucratically. As the carte sanitaire illustrates, the legislative system's flexibility in terms of permitting frequent changes can at times lead to a situation that is confusing and somewhat less rational than the rational policy which fostered the legislation. The result is a system that has many positive attributes that are counterbalanced by defects and other problems.

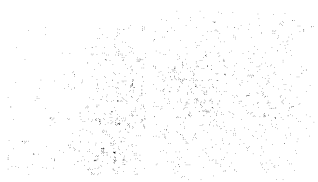
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7.
Technology Assessment and Diffusion in the Health Care Sector in West Germany

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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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Medical Technology in the Health Care System of the Netherlands

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8.

Medical Technology in the Health Care System of the Netherlands

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THE NETHERLANDS: COUNTRY DESCRIPTION

The Netherlands is a small country divided into 11 Provinces, a district called the IJsselmeerpolders, and *850* municipalities. With about *(400* inhabitants per square kilometer (1978), the Netherlands is one of the most densely populated areas of the world. In 1976, there were 13.9 million inhabitants. The percentage of the age group 65 and older was 11 percent, an increase of 5 percent since 1889 (2).

Form of Government

The Netherlands is a kingdom with a parliamentary democracy. The head of state is Queen Juliana of the House of Orange-Nassau. The Parliament (Staten Generaal) consists of two chambers. The Second Chamber (De Tweede Kamer), which is the more important one, has 150 members. As there are no electoral districts in the Netherlands, members of this chamber are chosen directly by the population under a system of proportional representation. This method of election leads to the presence in Parliament of a number of political parties. Since no one party has a majority, a coalition of several parties is necessary to form a government. In 1979, the government consisted of Ministers of the Christian Democratic and Liberal Parties. The major role of the Second Chamber of Parliament is to amend and approve drafts of laws put forward by the government. Only rarely does this chamber exercise its authority to develop laws on its own. The First Chamber (De Eerste Kamer), which is elected from and by Provincial councils, can only approve or reject laws that the Second Chamber has passed. Ordinarily, the First Chamber does approve these laws.

Provincial councils are elected in each of the 11 Provinces and manage the policies of individual Provinces. Each Province is headed by a Royal Commissioner (Commissaries der Koningin), who is appointed by the Queen after she is advised by the Cabinet. The main task of the Provinces is the supervision of the municipalities. Each municipality has an elected council and a mayor appointed by the Queen advised by the Cabinet (for larger cities) or by the Minister of Internal Affairs (for smaller towns).

Nature of the Economy

The Netherlands' location at the mouth of the great rivers Rijn and Maas has made the country a leader in international trade. Rotterdam has the largest harbor in the world. The Dutch economy is based on free enterprise, but the government's influence is growing in response to the weak economic situation and the imminent failure of a number of private enterprises.

Overall, the working population is divided into the following sectors (2):

Agriculture and mining	1.9%
Industry	38.0
Services (for-profit)	31.8
Government and nonprofit	28.3

Wage costs have risen tremendously in recent years, creating problems in selling the country's products internationally. Labor-intensive industries, in particular, have had a very difficult time. Because of the importance of the problem

of unemployment, the Government has sought to encourage the development of industries that make use of sophisticated techniques and know-how.

The production of medical technology is discussed in this context as a partial solution to the nation's economic problems. About 60 enterprises in the Netherlands are active in the manufacture and trading of medical instruments internationally. These include large companies, such as Philips, which have a broad range of articles, and many small companies, which are more specialized. The Dutch industry in medical technology takes care of 18 percent of the world market (1). Ninety percent of medical technology produced in the Netherlands is exported, which accounts for the importance of the medical technology industry to the national economy.

Overall, the Netherlands is a pluralistic country. With people of different backgrounds and different religions, tolerance is essential. Government is viewed not in a negative light, but as a solution to societal problems. Ordinarily, the public and the private sectors work hand-in-hand; but if the private sector is unable to deal with a problem, the Government will generally step in. The traditions of the Netherlands encourage the incorporation of the new, including the adoption of new models of social action.

THE HEALTH CARE SYSTEM

Fully describing the health care system of the Netherlands is a difficult task. Because the system has emerged with no systematic plan from the Netherlands' tradition of pluralism, in fact, some people call it a "nonsystem."

Immediately after World War II, the Government of the Netherlands sought to restore the country's social and economic life through various formal policies. As wartime regulations were abolished and freedom restored, specific laws regulating the health care system were passed. The two most important were the hospital tariffs law (Wet Ziekenhuistarieven) of 1965, which regulates price setting for all intramural institutions, and the Hospital Provisions Act (Wet Ziekenhuisvoorziening) of 1971, which regulates the building and renovation of intramural institutions. Notwithstanding this post-war government intervention, however, the health care system of the Netherlands remains largely private. Proposals to strengthen the government's regulatory powers have recently been sent to Parliament.

The government's role in health care is administered through the Ministry of Health and Environmental Protection (Ministerie van Volksgezondheid en Milieuhygiene) Ultimate responsibility for the entire Ministry rests with the Minister, but health care, specifically, is under the direction of a State Secretary. Both these officials are politicians.

A number of important advisory councils and boards at the national level seek to ensure the full cooperation of doctors, hospitals, sick funds, private insurance organizations, and others affected by national health care policies. These advisory boards include: 1) the Health Council (Gezondheidsraad), which advises the government about the state of the art in applied medical sciences and plays a central role in the application of new technologies; 2) the Central Council for Public Health (Centrale Raad voor de Volksgezondheid), which fosters cooperation between the government and private organizations and institutions working in the health care system and advises the government on all issues in curative and preventive health (16); 3) the Central Board for Hospital Tariffs (Centraal Orgaan Ziekenhuistarieven), which plays an important role in the pricing of services of intramural institutions on the basis of the 1965 hospital tariffs law; and 4) the Central Board for Hospital Provisions (College voor Ziekenhuisenvoorzieningen), which advises the government on the building of intramural institutions

[1]Intramural institutions are institutions that receive patients as inpatients. This law applies to general hospitals, categorical hospitals (hospitals for specific diseases), psychiatric hospitals, nursing homes, homes for the mentally retarded, homes for handicapped children, etc.

in accordance with the 1971 Hopital Provisions Act .

The government's most important role in the health care system is in the area of preventive medicine. Preventive services, which amounted to 3 percent of total costs of health care in 1977, are financed out of general revenues. Some preventive services are provided by the organizations for home care (Kruisorganisaties), private organizations that receive government subsidies. In addition, municipal health services provide preventive care and ambulance services. Industry provides some preventive services as required by law.

In general, the government's role in curative health care is very modest, involving only a few government institutions. Basically, it is to guide the curative system to help ensure the availability y and accessibility of high-quality care at reasonable costs. The government has a special responsibility for the quality of care, which is entrusted to National Inspectorates (Staatstoezicht op de Volksgezondheid) and their Provincial offices (16).

Hospitals

A number of hospitals in the Netherlands were founded and administered by Catholic or Protestant religious orders, but most of these institutions have now been turned over to private foundations administered by lay people. Though most of the hospitals in the Netherlands are private, there are also public institutions. Some large cities, for example, have their own municipal hospitals. Originally, these facilities were established to treat poor patients, as required by the national poor laws. In addition to municipal hospitals, some psychiatric hospitals are public. With the exception of the Province of North Holland, however, most Provinces meet their legal obligation to provide psychiatric services by making arrangements with private hospitals.

There are seven university teaching hospitals in the Netherlands, which are under the control of the Ministry of Education and Sciences (Ministerie van Onderwijs en Wetenschappen). These hospitals, which have traditionally had an important role in conducting medical research, are gradually being transferred to the health care system and are increasingly emphasizing patient care.

A breakdown of hospitals in the Netherlands by type is presented in table 1.

Table 1 .—Intramural Health Care Institutions in the Netherlands (1976)'

Types of institutions	Number of institutions	Number of beds	Beds per 1,000 inhabitants
General hospitals	185	61,038	4.4
Categorical hospitals[b]	54	7,012	0.5
University teaching hospitals	7	6,776	0.5
Psychiatric hospitals	73	25,940	1.9
Institutions for mentally retarded	127	26.947	2.0
Institutions for sensory handicapped	13	1,795	0.1
Nursing homes	304	42,034	3.0
Total.	763	171.542	12.4

[a]Intramural institutions are institutions that receive patients as inpatients.
[b]Categorical hospitals are hospitals for specific diseases.

SOURCE: Nationaal Ziekenhuisinstituut (National Hospital Institute). *Financiele Statistiek 1976 in de Instellingen van Intramurale Gezondheidszorg* (Utrecht, 1977) (11).

Health Care Providers

Medical specialists and pharmacists in the Netherlands work mostly on a fee-for-service basis. They work either in private practice in the community or under an arrangement with hospitals to provide services. Generally, physicians work independently. Only in psychiatric hospitals, university teaching hospitais, and large municipal hospitals are doctors on salary.

Data on the numbers and types of personnel in the Dutch system are presented in tables 2 and 3. Table 4 shows the increases in specific types of hospital staff that occurred between 1973 and 1978.

Levels of Care

The health care system of the Netherlands is generally considered to have three levels of care. The first level, public health, includes the provision of preventive services. Some preventive services are offered to the entire population, and

Table 2.—Number of Personnel Employed by Intramural Health Care Institutions in the Netherlands (1978)

Types of institutions	Number of personnel
General hospitals	94,293
Categorical hospitals (including university teaching hospitals)	31,434
Psychiatric hospitals	23,254
Homes for mentally retarded	24,099
Institutions for sensory handicapped	1,133
Nursing homes	43,191
Total	217,404

SOURCE: National Ziekenhuisinstituut (National Hospital Institute), *Statistiek Personeelssterkte 1978 in de Instellingen van Intramurale Gezondheidszorg*, 79.165 (Utrecht, 1979) (14).

Table 3.—Number of Physicians and Other Health Care Personnel in the Netherlands (1976)

Types of personnel	Number	Number per 100,000 inhabitants
Physicians		
General practitioners	4,937a	36
Specialists	7,223	53
Doctors in public health	1,158	8.4
Other doctors	8,574	62
Total	21,892	159.4
Nonphysicians		
Dentists	4,462	32
Pharmacists	1,197	9
Midwives	850	6.2
Home nurses	3,721	27
Maternity aides	2,718	20
Total	12,948	94.2

[a]General practitioners with own pharmacy: 1,298.

SOURCE: Centraal Bureau voor de Statistiek (Central Bureau of Statistics), *Vademecum Gezondheidsstatistiek Nederland 1977* (The Hague, 1977) (3).

Table 4.—increase in Hospital Staffing in the Netherlands (1973-78)

Type of staff	Number in 1973	Number in 1978	Average yearly increase
Nursing staff	53,390	55,852	+ 0.9%
Medical and paramedical staff	18,190	24,385	+ 6.0
General staff	36,620	42,173	+ 2.9
Other	4,430	3,316	– 5.6
Total	112,630	125,726	+ 2.2%

SOURCE: Ministerie van Volksgezondheid en Milieuhygiëne (Ministry of Health and Environmental Protection), *Financieel Overzicht van de Gezondheidszorg, Waarin Opgenomen een Raming van de Kosten tot 1984* (The Hague, September 1979) (7).

others are offered to specific groups (e. g., children, diabetics, employees, and elderly people).

The second level of care, so-called "first-line care," is immediately accessible to the patient. This includes home care provided by nurses, as well as care provided by general practitioners working in solo practice, in group practice with other general practitioners, or in health centers with other professionals such as nurses, physiotherapists, and social workers. Both the government and sick funds want to encourage the development of health centers.

"Second-line care," the third level in the system, is generally, except for emergencies, provided on referral by the first-line practitioners. Second-line care includes outpatient care by specialists (provided mostly through outpatient departments of general hospitals) and inpatient care in acute care hospitals. It also includes care in nursing homes and homes for the mentally retarded.

Administration of the System

The Netherlands' health system depends very heavily on private institutions and independent practitioners. Individual patients are free to choose their own physician, whether generalist or specialist. Professionals are free to select treatment for their patients. Physicians are also free to settle and practice where they like, although in order to practice in a particular hospital, they are required to obtain a license from the hospital board.

With the government taking the steps to be described below, the openness of the health system in the Netherlands is generally decreasing. The possibility of restraining cost rises by restricting the number of health care personnel is now much discussed.

Financing

As mentioned previously, preventive care is financed by the government out of general revenue. Curative health care is financed by insurance and out-of-pocket payments; only a small part of it is subsidized by the government.

The following sections describe how the insurance system is divided.

National Sick Fund Insurance

A compulsory insurance scheme dating to 1941 was legalized in the Sick Fund Act (De Ziekenfondswet), social security legislation passed in 1966. Sick fund insurance (Zeikenfondsverzekeving) covers about 70 percent of the population, Members of the scheme include employees whose income falls below a certain level (36,200 florins in 1978—$19,053),[2] self-employed persons whose income falls below this same level, and those over the age of 65 with incomes below a certain level (20,600 florins in 1978-$10,842). Each group is subsidized by the government in a slightly different way.

National sick fund insurance finances all acute health care, including that provided by general practitioners, specialists, and hospitals. Generally, all costs, including drug costs, are covered, and the patient pays only for incidentals such as appliances and transportation.

The national sick fund insurance scheme is executed by 65 independent sick funds. All of these funds are members of the Society of Dutch Sick Funds (Vereniging Nederlandse Ziekenfondsen, VNZ), which plays an important role in shaping health care policy in the Netherlands. The sick funds are supervised by the Sick Fund Council (Ziekenfondsraad), representing government, employers, employees, sick funds, institutions, and professionals working in the health system. The Sick Fund Council approves arrangements between sick funds and providers of medical care. It also advises the Ministers of Social Affairs and Health Care concerning the premiums of the insurance schemes, which the Ministers have to fix.

Private Insurance

Approximately 30 percent of the population is not insured under the national sick fund insurance scheme described above. Individuals in this group finance their own health care, usually by buying private insurance. Private insurance premiums and health care expenses are tax deductible by the patient.

Although private insurance policies vary, generally the costs of more expensive items, such as hospital and specialist care, are completely covered. The costs of general practitioner care and drugs, however, are usually not covered. Deductibles and coinsurance are common.

In Government councils that play an important role in the system, private insurance companies are represented by their own society, the National Society of Private Insurers for Health Care Costs (Kontaktcommissie Landelijke Organisaties van Ziektekostenverzekeraars, KLOZ).

National Catastrophic Illness Insurance

In 1968, Parliament passed a general law on costs of catastrophic illness (Algemene Wet Bijzondere Ziektekosten), establishing a new catastrophic insurance scheme under social security. This scheme is known as “insurance for the population” (Volksverzekering), because all citizens are required to be members. The scheme is financed out of premiums, which are levied by fiscal authorities. There is no income limit for membership, but the premium (2.86 percent) is levied on those whose incomes exceed a specified maximum (41,750 florins in 1978–$21,974; 43,950 florins in 1979–$23,131).

This insurance finances the most expensive forms of care, including long-term care in general hospitals, nursing homes, homes for the mentally retarded, and ambulatory care for mental health. Beginning in 1980, the catastrophic scheme will also finance home care, previously financed through general revenues and patient contributions. This change is intended to reinforce first-line health care.

Reimbursement

Payment to Hospitals and Other Institutions

Tariffs for hospitals and other institutions are set by the Central Board for Hospital Tariffs, the national advisory board mentioned earlier. This body is made up of representatives of hospitals, sick funds, private insurance systems, and independent members. The Central Board for Hospital Tariffs evaluates costs prospective-

[2]For conversion of Dutch florins and guilders to U.S. dollars, the exchange rate used throughout this chapter was 1.90 florins or guilders = $1.00 (U.S.).

ly and sets rates following guidelines that it has developed and that the Sick Fund Council and the Minister concerned have approved. The guidelines are very clearly defined and applied with individual circumstances taken into consideration.

Payment to Physicians

General practitioners are paid on a cavitation basis for sick fund patients and on a fee-for-service basis by private patients. Specialists are paid exclusively on a fee-for-service basis for all patients. Fees from the sick funds are set in negotiations between the organization of physicians, the Royal Netherlands Medical Association (De Koninklijke Maatschappij ter Bevordering der Geneeskunst), and the sick funds. General practitioners' fees for private patients are comparable to their fees for sick fund patients. Specialists' fees for private patients, however, are much higher. On the average, a specialist can earn 50 percent of his/her income from private patients, who make up only 30 percent of the population. Technical specialties such as radiology are the best paid.

Fees for all physicians can be changed only with the approval of the Minister of Economic Affairs, who is attempting to implement a general incomes policy for social and political reasons. Recently, the government has set up a Commission on the Structure of Medical Specialists' Fees (Commissie Structuur Honorering Medische) to revise fees. The government is also developing an incomes policy to bring the incomes of specialists and other professionals into line with incomes of comparable government officials.

Cost Containment

Because the curative health care system is largely private and financed by insurance, the government's influence on the system can only be indirect. Many items of the health care system are open ended. More services generate more money for the providers. Furthermore, since the health care costs are not part of the government budget, health care expenditures do not compete with other social needs such as education.

Figures demonstrating the rise in the costs of care during the period from 1973 to 1977 are shown in table 5. As can be seen from these figures, overall cost rises have been in the range of between 11.2 and 18 percent each year for the past several years. There does, however, seem to be a decreasing trend in the rise of costs. The percentage of gross national product consumed

Table 5.—Overview of Health Care Costs in the Netherlands (1973-77)

	Cost per year (in millions of florins/dollars)[a]					Percent increase in relation to past year			
Category of expenditures	1971	1974	1975	1976	1977	1974	1975	1976	1977
Intramural care	6,663	8,060	9,749	11,222	12,519	21.0%	21.0%	15.1%	11.6%
	$3,506	$4,242	$5,131	$5,906	$6,589				
Specialists	970	1,110	1,261	1,346	1,484	14.4	13.6	6.8	10.2
	$510	$584	$664	$708	$781				
Drugs	1,500	1,640	1,855	2,025	2,174	9.3	13.1	9.2	7.4
	$789	$863	$976	$1,066	$1,144				
Extramural care	1,961	2,293	2,668	3,076	3,486	17.0	16.4	15.2	13.3
	$1,032	$1,206	$1,404	$1,619	$1,835				
Preventive care	323	372	431	530	581	15.2	15.9	23.0	9.6
	$170	$195	$227	$279	$306				
Administration and other	778	912	1,028	1,149	1,273	17.2	12.7	11.8	10.8
	$409	$480	$541	$605	$670				
Total	12,195	14,387	16,992	19,348	21,517	18.0%	18.1%	13.9%	11.2%
	$6,418	$7,572	$8,943	$10,183	$11,325				
Percent of GNP	7.2	6.5	8.2	8.2	8.2				

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

SOURCE: Ministerie van Volksgezondheid en Milieuhygiëne (Ministry of Health and Environmental Protection), *Financieel Overzicht van de Gezondheidszorg, Waarin Opgenomen een Raming van de Kosten tot 1984* (The Hague, September 1979) (7).

by health care expenditures was 7,2 percent in 1973 and 8.2 percent in 1977 (6).

Since 1976, the government has tried to bring down collective spending, that is, spending on items financed by taxation and social security premiums. Since these items are financed out of wages, increased expenditures contribute to unemployment. The government expects that implementation of its cost-containment policy will save 2 billion florins ($1.052 billion) in 1981 (15). It has already submitted two important proposals to Parliament. One is the law on tariffs in health care (Wet Tarieven Gezondheidszorg), which would give the government full authority to regulate all tariffs and fees. The second proposal is the law on health care provisions (Wet Gezondheidszorgvoorzieningen), which would allow regulation of the development of all health care facilities, including doctors' practices. These proposals would broaden and replace existing laws.

Although these proposed laws could be enacted within 2 years, past experience with the Hospital Provisions Act of 1971 suggests that the types of policies which they embody are difficult to implement. Under the Hospital Provisions Act of 1971 (which the pending legislation would strengthen), the government's policy is to decrease the number of general hospital beds to four beds per 1,080 inhabitants. Implementation of this policy has been difficult, because the general population, patients, and hospital employees resist the closing of their hospitals. Furthermore, because of its policy of full employment, the government approved an increase in guidelines for nursing personnel in intramural institutions this year, despite the predicted negative impact on costs.

POLICIES TOWARD MEDICAL TECHNOLOGY

The general impression in the Netherlands is that medical technology is a significant contributor to rising health care costs, but little specific information is available. Econometric analyses by the author give indirect indications that technological innovation is an important contributor to costs (10,12). In an analysis of price rises in institutional health care, Van Montfort reported that costs for medical and nursing materials rose from 323 million florins ($170 million) in 1972 to 497 million florins ($262 million) in 1975, an increase of 53.9 percent (17). Of the 53.9-percent increase, 16.9 percent was due to price increases and 37 percent to real changes in services. Technical innovation also increases costs by increasing staff size in hospitals (5). Further, technology requires space. About 20 percent of total space in hospitals is taken up by selected departments with technology, such as X-ray equipment, laboratories, and operating rooms (9).

From the standpoint of outputs, technical innovation appears to be a stronger influence in the diagnostic area than in the therapeutic. Between 1960 and 1974, the number of diagnostic procedures performed rose from 9.84 per 1,000 insured patients to 45.75 per 1,000 (13). The number of therapeutic procedures performed rose during the same period from 50.5 per 1,000 in 1960 to 94.09 per 1,000 in 1974 (13). Increases within the area of diagnosis can also be documented. For example, laboratory production per 100 admissions increased about 11 percent per year from 1973 to 1975 (13). The incidence of X-ray use also rose slightly, from 401.8 per 1,000 admissions in 1973 to 413.7 in 1975, an increase of 3 percent (13). Therapies increased 31 percent over the same interval (13).

Research and Development Efforts

Research related to medical technology is conducted by industry, by research organizations, and by universities. University research is generally funded by government.

The two important government organizations that fund research are: 1) the Dutch Organization for Fundamental Scientific Research (Nederlandse Organisatie Zuiver Wetenschappelik Ondezock, ZWO), and 2) the Dutch Organization of Applied Scientific Research (Nederlandse Organisatie voor Toegepaste Natuur-

wetenschappelijk Onderzoek, TNO). The research of ZWO is basic research that has little to do directly with medical technology. TNO, however, has a special department for health care, the Health Organization TNO (Gezondheidsorganisatie TNO), which spends about 50 million florins ($26.3 million) a year on research related to patient care. Some of this research is conducted in a few prominent general hospitals, but most of it is conducted in university teaching hospitals.

R&D in the health area is primarily the task of the university teaching hospitals, which are reimbursed by the social security system and patients on the basis of a uniform tariff. This tariff is based on the output of the average university teaching hospital, with the guidelines applied to the bigger general hospitals taken into consideration. Reimbursement is not sufficient to cover university teaching hospitals' costs, however, and the government covers their deficits. The deficits amount to about 30 percent of the hospitals' budgets, and some of the deficits are attributable to research and teaching. According to the Ministry of Education and Sciences, the total deficit in 1977 was 496 million florins ($261 million).

At this time, there is a special commission on the tariffs for these university teaching hospitals which is to solve the problem of reimbursement. As a method of furnishing the resources needed for new developments in patient care, the policy will be to fund new techniques at the marginal cost of the technique. The guidelines for reimbursement, however, do not contain space for research. Research is to be directly funded by special funds.

Evaluation of Medical Technology

Few evaluation studies of medical technology have been conducted in the Netherlands. New technologies in heaIth care, including new diagnostic and therapeutic devices, however, are evaluated by the Health Council, before they are accepted into medical care. The advice of this group guides the decisions of other bodies, such as the Sick Fund Council and the Central Board for Hospital Provisions, which are responsible for planning heaIth services.

The Health Council's evaluations are mostly of a technical nature. Only recently has the council considered costs and benefits in making its recommendations. Before it made its recent recommendation about the number of kidney transplants, for example, it considered the economic benefits of transplantation versus dialysis (4), Similarly, it considered some cost issues prior to advising on renal dialysis.

A working party on the evaluation of medical instruments with regard to safety and efficacy has been founded in cooperation with the Health Organization TNO and the National Hospital Institute (Nationaal Ziekenhuisinstituut), a research institute founded by the National Hospital Council (Nationale Ziekenhuisraad). So far, the working party has published eight papers on items including heart monitoring systems, EKG apparatus, defibrilators, electrical thermometers, electrical beds, external pacemakers, and blood pressure monitors. Reports in preparation concern EEG instruments, fetal monitoring instruments, and heart monitoring instruments.

Regulation of Medical Technology

The only medical technology that is directly regulated in the Netherlands, based on legislation of 1958, is drugs. Drugs can be prepared only by pharmacists, general practitioners with their own pharmacy, or assistants working under the supervision of pharmacists or general practitioners with their own pharmacy.

Industrial production and distribution of drugs by drug companies must be approved by the government. The Commission on Drugs (Geneesmiddelencommissie) advises the Minister of Health on drugs, and only those drugs which have been registered can be distributed to the public. Prior to registration, a special board evaluates the drug's composition, efficacy, and side effects. This board critically examines the producer's claim regarding the drug's efficacy.

Planning of Medical Technology

The Hospital Provisions Act of 1971, which regulates the building and renovation of institutions such as hospitals, is the only law that can

contain the expansion of technology in the Netherlands. Under this law, a hospital that wants to make a capital investment for renovation exceeding a certain amount of money must apply for a license with the Central Board for Hospital Provisions. The Board can also limit the size of, for example, the hospital's X-ray department. Recently introduced legislation would give the government the authority to close down hospitals or part of them.

Article 18 of the Hospital Provisions Act of 1971 gives the government the authority to regulate very "advanced" technologies on the basis of a national plan. This national plan contains an inventory of existing facilities and gives indications as to where these facilities should be changed. The planning process has not been fully applied to all facilities, because there is some fear that a national plan may favor the expansion of existing facilities and thereby increase costs.

So far, regulations have been issued for both renal dialysis for chronic kidney failure and megavolt therapy. Preparations are currently under way to issue regulations to cover cytogenetic laboratories, nuclear medicine (both diagnostic and therapeutic), and diagnostic facilities for angiocardiography and heart catheterization. Guidelines for open-heart surgery and computed tomograpy (CT) scanners are in operation, also.

Many technologies, however, do not need building arrangements and can be expanded without government regulation. In some instances, the government has asked hospitals not to invest in new instruments without the approval of the Ministry of Health. It has done this, for example, in the case of diagnostic devices that use radioactive isotopes, such as gamma cameras. (The automation of laboratory equipment is a special case described in the next major section of this chapter.)

The Central Board for Hospital Tariffs is considering the development of special guidelines with respect to investments in medical instruments and the number of paramedical personnel. General hospitals following the guidelines would be able to expand these investments and personnel by a limited amount each year. It is hoped that a policy of restricting this infrastructure will make doctors more critical with respect to their utilization of facilities.

There are technological innovations that the government has not dealt with and over which it has no authority. The government is considering a system of restraining expansions by a new law to limit tariffs in the health care sector. This law, the law on tariffs in health care, may avoid a proliferation of bureaucracy and allow for a flexible policy. Recently, the government has stressed the importance of negotiations between hospitals and reimbursers of care. These regional contacts could provide an important forum for discussion, out of which a sensible policy toward the deployment of medical technology may evolve.

Reimbursement and Medical Technology

The reimbursement system, as described previously, favors the expansion of medical technology, The structure of tariffs varies between hospitals, and such services as drugs and laboratory tests can be included or not in the charge per day. Pharmacists and clinical chemists, who are responsible for the chemical analyses done in the hospital, are on the hospital's payroll, and their salaries are included in the hospital tariff. A few physicians also perform these tests, however, and they can be paid on a fee-for-service basis. Most specialists work on the basis of fee for service, which encourages giving service. The surgeon and the anesthetist bill the patient for their services, for example. The radiologist bills for a fee.

The hospital bills separately for its services and is reimbursed at cost. Costs for the use of an operating room (including the cost of personnel, instruments, and appliances), for example, are not included in the hospital tariff. X-rays are not included either. These services are billed for separately and are reimbursed at cost. The tariffs for medical ancillary services such as laboratory and X-ray are set uniformly for the whole country by the Central Board for Hospital Tariffs. These tariffs, which are based on costs for per-

sonnel, materials, and costs of other investments and include a small addition for overhead costs, are revised every 3 years.

Under this hospital reimbursement system, the more services that are performed, the more money that is generated. In technical departments, the costs are more or less constant, so an increase of services above the budgeted level generates surpluses of revenue above costs. These surpluses allow expansion. They also lead to lower rates for patient days when the Central Board for Hospital Tariffs has to revise the hospital budget. Hospital budget revisions are made whenever the hospital applies for a tariff increase, otherwise at the end of 4 years.

The direct relation of services and income for physicians is criticized by government, the sick funds, and patients. Because of these criticisms, radiologists recently made a new agreement with the sick funds, under which radiologists' fees for tests in excess of 15,000 are lowered by a percentage. The government is also urging hospitals to include more items in the day rate to mitigate expansion in certain services.

Several health economists are studying the possibilities of stricter budgeting in hospitals, or perhaps replacing hospital rates by a system of budget financing under which there would be a more direct relationship between output and costs (lo, 12).

Utilization Review

There has not been much utilization review in the Netherlands. In Utrecht, however, the Foundation of Medical Registration (Stichting Medische Registratie) assembles data about patients admitted to hospitals, diagnoses, average length of stay, operations performed, and so forth. This foundation covers almost 90 percent of hospital beds in the Netherlands and is financed by member hospitals, i.e., voluntary members, The data the foundation generates are very important, because they are used by medical staff to evaluate their work and are also used for hospital planning.

A separate data bank has been established by the sick fund organizations to collect data on their patients admitted to hospitals. The data collected concern such things as the referral policies of general practitioners and acts performed by specialists, they also include data on hospitalizations (e.g., average length of hospital stay). Some individual private insurance companies have also begun to collect important data about their patients admitted to hospitals.

Recently, a new foundation called the National Organization for Quality Assurance in Hospitals (Centraal BegeIeidingsorgaan voor Intercollegiate Toetsing in Ziekenhuizen) was established. This new organization is financed by hospitals, which are licensed by the Central Board for Hospital Tariffs to include their contribution as part of their reimbursement costs. The new organization is expected to foster medical audit and utilization review in hospitals, particularly in cooperation with the medical societies.

SPECIFIC TECHNOLOGIES

As noted previously, article 18 of the hospital provisions law allows the government to issue guidelines and regulate advanced medical technologies on the basis of a national plan. Only some medical technologies have been brought under this article to date.

CT Scanners

At the present time, there are 32 CT scanners installed in the Netherlands. There is no definitive regulation of CT scanners by article 18, but the Secretary of State and the hospitals have agreed not to install additional facilities without allowances from the government.

In existing CT scanner guidelines, a distinction is made between brain scanners and total body scanners. For brain scanners, the guideline is one scanner per 500,000 inhabitants. Brain scanners are to be installed in hospitals that have teaching facilities in neurology and a

department of neurosurgery, and hospitals with scanners are to work in regional cooperation with other hospitals, On the basis of the existing guideline and population, about 30 brain scanners can be installed. These scanners will be placed in the near future.

Total body scanners are to be placed in those university teaching hospitals which have a center for cancer patients, teaching facilities for X-ray diagnostic and therapeutic procedures, expertise in radiation physics, a radiation therapy simulator and treatment planning system, and the capacity for evaluating the results of CT body scanning with those of other radiological diagnostic methods, nuclear medicine, echography, and clinical neurophysiology. Since a preponderant motivation is research, spreading CT body scanners throughout the country is not deemed necessary. About eight total body scanners are to be installed.

Renal Dialysis and Kidney Transplants

There has been a "gliding standard" of an absolute limit of a minimum of 71 and a maximum of 111 dialysis units per 1 million inhabitants. This gliding standard was made dependent on the number of kidney transplants performed. The guideline for kidney transplants has been 32 transplants per 1 million inhabitants, and the Health Council urged the government to aim at 400 kidney transplants per year. This goal has not been reached, however, because there have not been enough kidneys available.

The existing renal dialysis guideline applies for patients older than 15 years. As dialysis is being used for people over 60 years old, and more people are applying for treatment, however, the need for dialysis equipment is growing. The government has recently increased the guideline to 100 dialysis units per 1 million inhabitants. This would bring the number of dialysis units, not including home dialysis units, to 1,407 in 1980.

Cardiac Surgery

Cardiac surgery is a very hot political issue in the Netherlands. The supply of existing facilities is not sufficient to meet the ever growing demand for coronary bypass surgery. Notably, the Society of Heart Patients (Nederlandse Hartpatientenvereniging) deployed lobbying activities in government and Parliament to increase the facilities and get permission for patients to have operations in other countries such as the United States, Switzerland, and England (8). As a result, patients may now be reimbursed by sick funds and other private insurance for bypass operations performed in foreign countries.

According to the Sick Fund Council, in 1978 there were 1,079 operations for open cardiac surgery performed abroad as follows (18):

Houston, Tex., United States	268
Genolier Swiss, Switzerland	501
London-St. Anthony's Hospital, England	218
London Middlesex Princess Grace Hospital, England	92
Total	1,079

In 1977, the total number of operations performed abroad was 965.

Planning for cardiac surgery is based on the following guidelines: 300 operations for open coronary surgery per 1 million inhabitants (i.e., 4,200 operations per year), 50 operations for closed cardiac surgery (i. e., 720 operations per year). The total capacity in **1976 was 2,095** open- and 388 closed-heart surgery operations. The target at the moment is set at 6,000 operations a year. The specified guidelines are to be realized after 1980.

The government has designated six teaching university hospitals and three general hospitals as cardiac centers where these cardiac surgery operations can be performed. Each center is to aim towards a production of 400 operations a year. Currently, the Antonius Hospital at Utrecht is performing 700 operations a year. In addition, very recently, the government designated a sanatorium for tuberculosis to function, in cooperation with a nearby general hospital, as a center for 1,000 operations per year.

Megavolt Radiation Therapy

For planning these facilities on the basis of article 18, the concept of a "radiation unit" is used. A radiation unit is a megavolt apparatus, with supplementary provisions, which has suffi-

cient capacity to treat 250 new patients a year. The capacity of telecobalt apparatus with a range of 2,000 to 3,000 curies is one radiation unit. The capacity of telecobalt apparatus with 6,000 to 9,000 curies is two radiation units. A linear accelerator can be counted as two radiation units.

Currently, there are 49 radiation units in 20 general, university teaching, and categorical (special purpose) hospitals in the Netherlands. The number of cancer patients in the Netherlands is estimated at 3,250 patients per 1 million inhabitants, about 1,450 of whom need radiation therapy. Given its population of 13.9 million inhabitants, the country needs radiation capacity for 20,155 new patients, i.e., 80 units. The existing 49 units, therefore, may have to be enlarged in the near future. Since 20 of the 1,450 patients are treated by orthovolt units, however, the need for megavolt apparatus may be less. For this reason, the government intends to follow a prudent policy in enlarging the existing facilities. Very recently, there have been indications that the need for radiation therapy may increase. The government will ask the Health Council to advise on this matter. The guidelines may have to revised.

CONCLUDING REMARKS

The proliferation of medical technology is of great concern to the government of the Netherlands, which is confronted with ever increasing costs of medical care. In an effort to restrain costs, the government is seeking to control specific elements of the health care system, especially hospital beds. There are many conflicting interests to be considered. Patients and doctors want the most modern technology. The medical technology industry, with its importance in R&D and the general economy, is another important force. Although a full employment policy favors the expansion of health care personnel, the rising costs of the health care system may jeopardize the general economic system.

In light of these conflicting interests, the evaluation of medical technology could play an important role in the effort to find solutions to the difficult and delicate problems which surround the diffusion of medical technology. In the area of technology assessment, the Netherlands has as yet made very few contributions. The need for technology assessment, however, is likely to be increasingly felt in the future. The problems are international, so perhaps technology assessments could be performed on a European basis. I would hope that the European community will be able to make a contribution in this area.

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9. Medical Technology in the Health System of Iceland

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ICELAND: COUNTRY DESCRIPTION

Iceland is a Scandinavian republic of 224,000 population (1978) located in the North Atlantic near the Arctic Circle. It is a country of almost no trees and has a rugged volcanic landscape.

Iceland has one of the world's lowest population growth rates, lowest infant mortality rates (11.3 per 1,000 live births, 1978; 9.5 per 1,000 live births, 1977), and longest life expectancy (male 73.0 years, female 79.0 years, 1975-76). Demographic trends between 1850 and 1975 are shown in figure 1. The proportion of the total population of males and females in 5-year age groups is shown in figure 2.

The population is spread along the coast, with 100,000 people living in the capital city of Reykjavik and surroundings. (See table 1.) Reykjavik has the same growth of population as other Scandinavian capitals do. The proportion of persons over the age of 67 is growing faster in Reykjavik than in other parts of the country. (See table 2.)

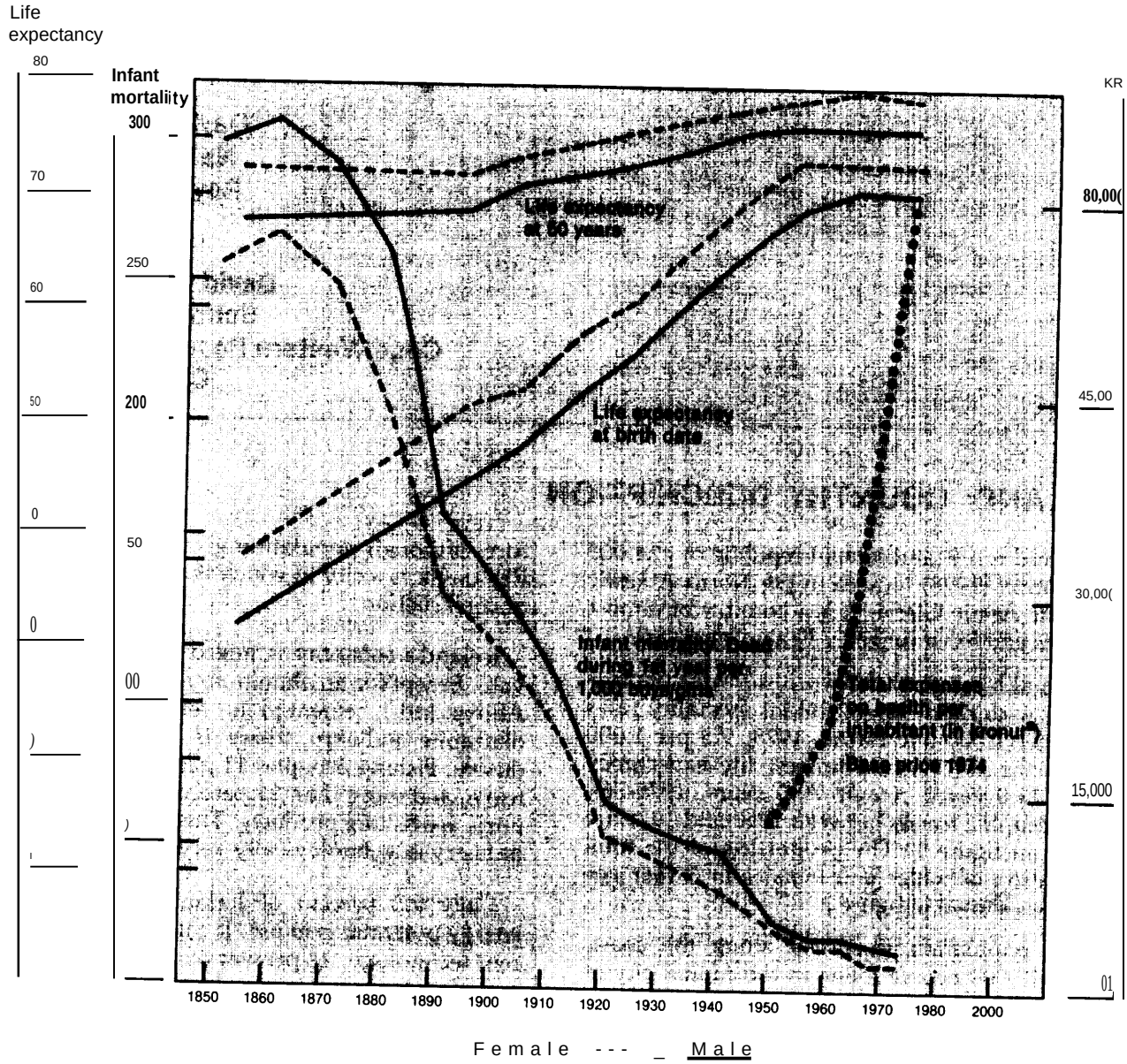
Iceland has a high per capita gross national product (GNP) and a per capita income of $9,470 (1978). There are no very rich and no very poor. Inflation, which in past years has averaged 30 percent, was up to 69 percent in November 1979. Because of this high inflation, people tend not to save money but to invest immediately in houses and automobiles. Therefore, although population growth is not great, Reykjavik is a city in which there is a great deal of construction.

Iceland's economy is mixed—public and private. Except for an aluminum refinery (Icelandic Alloys, Ltd.), cement plant, fertilizer plant, and diatomite industry, there is little heavy industry. Fishing occupies 11 percent of the labor force, and more than 75 percent of Iceland's exports are fishing products. The country's fishing industry is technologically very advanced.

Only 9.5 percent of Iceland's hydroelectric energy potential is in use. If calculated with current technology, 12 percent of the profitable potential is being realized. Geothermal energy is used to heat all of Reykjavik and many other places.

Iceland is a republic. It has the oldest parliament in continuous existence and no fewer than 224 elected municipal councils. Parliament (Al thing) is divided into an Upper Chamber and a Lower Chamber. The chief of state is an elected President without political power. The political parties are the Independence Party, the Progressive Party, the Peoples Alliance, and the Social Democratic Party. In foreign policy, the major issue on which these parties disagree is that regarding the continued presence of an

Figure 1.–Demographic Trends in Iceland (1850.1975)



*400 Icelandic kronur = $1.00 (U. S.)

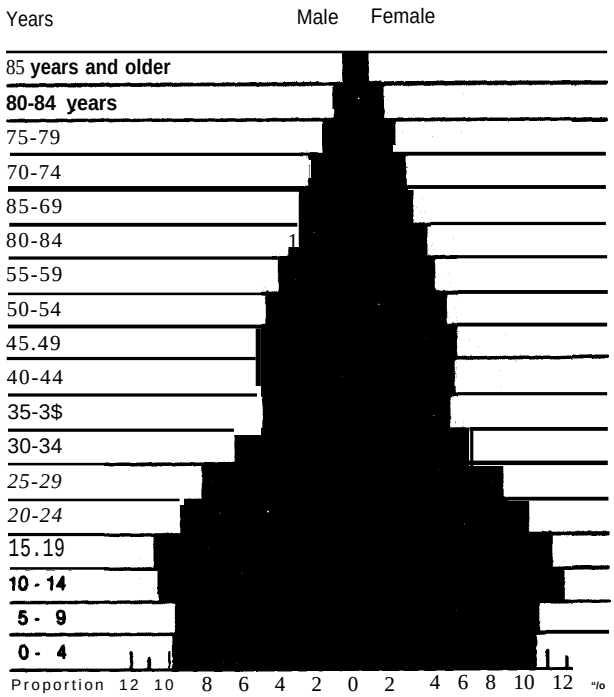
SOURCE: Framkvaemdastofnun Rikisins (Economic Development Institute), *Mannfjöldi, mannafli og tekjur* (Reykjavik, 1979) (2)

American air base an hour's drive from Reykjavik. Iceland has no army.

National funds come from a 22-percent sales tax, export/import duties, and from income tax. The highest income tax rate is 50 percent. Municipal funds come from a 10- to 12-percent income tax and real estate taxes.

Family ties in Iceland are still very strong, and as a rule, primary social assistance is rendered by the family. Iceland's few inhabitants, the country's distance from other countries, and the homogeneity of its population result in close personal contacts across occupations and work places.

Figure 2. —Proportion of Iceland's Total Population of Males and Females in 5-Year Age Groups (1977)



SOURCE: Framkvaemdastofnun Rikisins (Economic Development Institute), *Mannfjoldi, mannafli og tekjur* (Reykjavik, 1979) (2).

Table I.— Distribution and Growth of Iceland's Population (1970-78)

Year	Iceland Total population	Reykjavik Number of inhabitants	Reykjavik Percent of total population	Reykjavik area Number of inhabitants	Reykjavik area Percent of total population
1978	224,384	83;092	37.2%	119,054	53.00/0
1977	222,470	83,387	37.7	118,422	53.2
1976	220,918	84.493	38.3	118.241	535
1975	219,033	84,856	38.7	117,736	53.8
1974	216,628	84,772	39.1	116.410	53.7
1973	213.499	84,333	39.5	114,453	53.7
1972	210,775	83,977	39.8	113,276	53.7
1971	207,174	82,892	40.0	108.770	53.5
1970	204.344	81,561	39.9	—	—

SOURCES: Hagfraeoideild Reykjavikur (Economic Department of the City of Reykjavik), *Arbok Reykjavikurborgar 1979* (Reykjavik, 1979) (4); Hagstofa Islands (Statistical Bureau of Iceland), *Hagtioindi 71-79* (Reykjavik, 1979) (5); and Seolabanki Islands (Central Bank of Iceland), *Hagtolur manaoarins 74-79* (Reykjavik, 1979) (10).

Table 2.—Distribution and Growth of Iceland's Population Over Age 67(1970.78)

Year	Percent of population over age 67	
	Iceland	Reykjavik
1978	8.5%	10.7%
1977	8.3	10.3
1976	8.0	10.0
1975	7.9	9.5
1974	7.9	9.3
1973	7.9	9.1
1972	7.8	8.8
1971	—	8.5
1970	7.6	8.3

SOURCES: Hagfraeðideild Reykjavíkur (Economic Department of the City of Reykjavík), *Árbók Reykjavíkurborgar 1979* (Reykjavík, 1979) (4); Hagstofa Íslands (Statistical Bureau of Iceland), *Hagtíðindi 71-79* (Reykjavík, 1979) (5); and Seðlabanki Íslands (Central Bank of Iceland), *Hagtölur manaðarins 74-79* (Reykjavík, 1979) (10).

HEALTH SERVICES

In **1978,** Iceland spent about 7 percent of its GNP on health—a little less than the percent of GNP spent by Sweden or the United States (8,9). Iceland's health service is almost entirely funded within the government sector. In 1974, a new health law was issued in Iceland. The law's main emphasis is on advancing outpatient and community services.

The Minister of Health is a member of the government and is usually a Member of Parliament. The Secretary General is the senior civil servant for health. The Chief Medical Officer is the next most senior post. The country is divided into eight local health government areas, and local health governments are appointed by the municipal councils and boards of institutions in each area.

Key decisions in the Ministry of Health are: 1) hospitals' per diem rate, 2) physicians' cavitation and fee rates, and 3) patient payments. Patient payments for outpatient visits do not change often and are not a major issue. The per diem funding rate for municipal hospitals is decided by a joint committee composed of both national and municipal authorities.

Since the patient day charge is based on the costs of salaries, positions, and supplies for the previous 3-month period, a snowball effect tends to increase costs. [1] All hospital workers, including physicians, are unionized. The unions, which are organized by occupation, negotiate with the Ministry of Finance for pay scales. [2] The National Government pays the municipality for hospital care on the basis of (0.92) times (patient days) times (agreed upon patient day charge). When a patient from one municipality is hospitalized in another, there is a transfer payment to the second municipality. If the patient is hospitalized at the National Hospital (discussed below), however, no transfer payment is made.

The municipal council, among other things, appoints the administrator of the local hospital and approves the hospital's budget. If major capital expenditures are being considered, National Government approval is sought to ensure that 85 percent of the investment funding is obtained this way. If the National Government refuses to approve a project and provide funding, however, the municipality can, if it chooses, finance the project itself.

Perhaps because of rising health care costs, the municipalities' central organization has asked for municipalities to be relieved from paying for their hospitals. There is now a political debate over whether the National Government

[1] Inflation, however, tends to keep spending down.

[2] Pay within job categories varies according to seniority, but not by performance. At one hospital in Reykjavík, Landakotsspítali, however, doctors are paid on the basis of their performance.

should take over the funding and management of all the hospitals.

Iceland has 21 general hospitals. The largest three are in Reykjavik. The National or University Hospital (Rikisspitalar) has a total of 1,082 beds and is the largest hospital in the country. The Rikisspitalar organization includes, for administrative purposes, a 238-bed psychiatric hospital (including beds for alcoholism), a 184-bed hospital for the mentally handicapped, a 76-bed hospital for chest disease, and a 76-bed nursing home (in the north of Iceland). The main hospital, Landspltal inn, has 508 acute care beds, including beds in maternity, gynecology, psychiatry, neurology, and pediatric departments. The National Hospital is the primary teaching hospital of the University Medical School. Unlike other hospitals, the National Hospital has a fixed budget and receives almost 100 percent of its funding from the National Government.

The second largest hospital in Iceland is the Reykjavik City Hospital. This institution, like all other local hospitals in Iceland, receives **92** percent of its operational funds from the National Government and 8 percent from the local government. The third largest hospital, Landakotsspitali, was founded by a Catholic Order of Sisters from East Germany. In **1976,** the National Government bought the hospital and handed it over to an independent board of trustees. Both these hospitals are funded by a per diem rate.

A number of health clinics are being built with 85-percent national funding and 15-percent local funding. These clinics are operated with both national and local funds.

Ambulatory care is largely provided outside of hospitals by private practitioners. Private practitioners receive most of their income from the National Government, partly by cavitation and partly per visit. The patient pays 2,000 Icelandic kronur ($4.30)' per visit. Pharmacy services are paid for by the National Government, and the patient pays about 2,000 Icelandic kronur ($4.30) per prescription. There are some small fees paid by ambulatory patients going to hospitals for X-rays or other procedures unavailable in physicians' offices, but there is no charge to patients for inpatient care.

Iceland is probably educating more doctors per capita than any other country in the world. For the years 1975 to 1979, Iceland graduated an average of 21.6 doctors per 100,000 inhabitants each year (6), As of January 1, 1979, Iceland had 651 licensed medical doctors, or 290 doctors per 100,000 inhabitants (1,6).

Physicians who work 75 percent or less of their time in a hospital may pursue private practice as much as they wish. Physicians who spend more time in the hospital are limited to **6** hours of work per week outside the hospital. Nearly all Icelandic physicians do some private practice, so a sharp separation between hospital and nonhospital doctors does not really exist.

'For conversion of Icelandic kronur to U.S. dollars, the exchange rate used was 430 Icelandic kronur = $1.00 (U.S.).

MEDICAL TECHNOLOGY

Being a small country, Iceland has no medical technology industry of its own. The country's close contacts with other Scandinavian countries, the United States, and England, however, guarantee that medical technology know-how gets to Iceland fast. At any one time, about one-third of Icelandic physicians are abroad, some of whom are obtaining medical specialization in specialties unavailable in Iceland.

Because of Iceland's excellent population records, which go back **150** years, medical research often relies more on those and clinical population studies than on elaborate laboratories with expensive technology. Research outside the University is funded by the Cancer and Heart Societies, which obtain some money for research from the National Government and some from yearly lotteries and donations. The

University Medical School does not provide research funds, but faculty may use spare time in the National Hospital for clinical research. Most of the teaching facilities and equipment for medical research are provided by the National Hospital. The major source of funds for construction of the University Medical School is the University lottery.

Studies in health economics are becoming increasingly common and are gaining interest among Iceland's decisionmakers. A number of senior doctors in Iceland are interested in cost-effectiveness studies of health care programs. Excellent evaluations of some programs have already been conducted. A program to reduce smoking by high school youths, for example, received a careful evaluation (7). An evaluation of the cost of automobile accidents and their prevention has also been done (3). Decisions about programs and new technology that are based on analysis of costs and effectiveness are well received. As in other countries, however, decisions in these areas are generally influenced by political forces.

Consistent with the informality of a small country, there are no detailed regulations pertaining to the safety and efficacy of medical technology, quality of medical care, etc. There are strict regulations for electrical equipment in general, however, and medical equipment must adhere to these. At the National Hospital there is a physical technical department, which most of the other hospitals consult when choosing or approving apparatus. There is a national drug formulary, but a hospital may obtain other drugs and special drugs for research. The list of approved drugs in Iceland is maintained by a committee of the Ministry of Health.

Health planning at the national level is the responsibility of the Ministry of Health. For major decisions, however, local involvement results in formal negotiation. Such decisions include capital expenditures and the addition of hospital beds. If a technology requires special expenditures, the matter will be debated and decided upon through the budgetary process—first with approval at the hospital level, then at the level of the Ministry of Health, and then by review of the Ministry of Finance and approval by Parliament. It would not be unusual for a local hospital administrator or doctor to discuss the subject with the local parliamentary member, who might be a neighbor, former schoolmate, second cousin, or all three.

During the years, it seems, the National Government has had difficulties" in controlling both capital and operational expenditures. The building of health centers in the south of Iceland is an example. Initially, there were plans to build only four centers. When the politicians in Parliament had had their say, however, there were seven, three of which had no permanent doctors.

There is no utilization review. Hospitals employ chiefs of service who are responsible to the Chief Medical Officer. These individuals are responsible for assuring efficient utilization and quality of care in their service as are chiefs of service in Sweden or England. This control mechanism is better developed in the larger hospitals.

SPECIFIC TECHNOLOGIES

Given Iceland's small population, the country's medical care technology is modern and extensive. Most specific technologies have been established as soon as technological knowledge has become available in the country.

CT Scanners

As of September 1979, Iceland does not have a computed tomography (CT) scanner. Doctors at both the National Hospital and at the Reykjavik City Hospital, however, believe there is an urgent need for one.

The two matters at issue are the location and type of scanner. Doctors at each of these institutions have been developing their justification for having a scanner at their own hospital. Part of the problem is that neurology is at the City

Hospital and neurosurger-y is at the National Hospital.

Reykjavik City Hospital doctors argue that they need a scanner there because they run the major emergency service for the city, and some trauma cases need a head scan as soon as possible. Doctors at the National Hospital argue that they need a body scanner there because they have neurology, oncology, and radiation therapy departments, and doctors in these departments do 200 tests per year (such as pneumoencephalography) which a body scanner would replace. Further, they suggest, an additional zoo to 400 tests that are not done now because doctor-s prefer to avoid the risky, unpleasant procedures available probably would be done if a CT scanner were available.

The National Hospital doctors worked through an analysis of the value of the body scanner. They argue that there are certain cancers which are detectable by body scanner only, retroperitoneal cancer being the primary example. They also argue that the body scanner, by more accurately locating a tumor, will increase the chances of radiating all the cancer and lower the chances of radiating noncancerous tissue.

The doctors at the National Hospital feel somewhat discouraged in pursuing their analysis, however, because they believe that political lobbying will determine which hospital gets a scanner. If the Reykjavik City Hospital gets a scanner, the city must pay 15 percent of the purchase cost; if the National Hospital gets it, all the costs will be paid through the National Government.

The final decision concerning the purchase of a CT scanner will be made by the Parliament during the budgeting process. Because of the high cost of buying a scanner, Parliament is interested in buying only one, and it is relying on the doctors and administrators in the two hospitals to cooperate.

In the meantime, the Icelandic Government does pay for some CT scanner examinations abroad. Some Icelanders go abroad and pay for this test themselves.

Renal Dialysis

At any given time, there are three or four patients needing dialysis. This number has reached a high of eight patients. There are four dialysis machines at the National Hospital in Reykjavik, and these have been available for several years.

Coronary Bypass Surgery

As of September 1979, coronary bypass surgery is not being performed in Iceland. Patients needing this procedure, about 35 a year, are sent abroad at the expense of the National Government. They generally go to Hammersmith or Bromton Hospital in London, institutions chosen because of personal contacts between Icelandic surgeons and the surgeons at these hospitals.

Whether bypass surgery should be performed in Iceland has been debated at some length over several years. A committee of doctors was appointed by the Ministry of Health to make a decision about it. It is recognized that the volume of patients would not be very large—perhaps double the current number. This volume might not be enough to maintain a high-quality service. One senior government official in the Ministry of Health, however, said the Ministry would be willing to accept a slightly higher operative mortality rate in order to achieve "medical independence. " Having bypass surgery in Iceland, it was argued, would eliminate the need for having Icelandic patients go for the procedure to a foreign country, where they would not feel as comfortable as they would at home. It was also argued that existence of capacity for this surgery would improve other aspects of the country's surgical and medical care.

The committee of doctors appointed by the Ministry produced a report with some analysis and decided that coronary bypass surgery should be started at the National Hospital. An Icelandic physician in Sweden is becoming proficient in this procedure and will return to Iceland to start it. An existing operating room is to be set aside for specific periods in the year for coronary bypass surgery. Experienced nurses and a surgeon are to come from abroad during these periods, at least during a transition period until proficiency is achieved locally.

The committee's analysis reflects careful thought given to fixed costs, capital expenditures, proficiency of the surgical team, and other effects of the committee's decision. Some Icelandic physicians, though, are still unsatisfied with the decision. They maintain that they themselves would prefer to go abroad for this procedure, If coronary bypass surgery is performed in Iceland, the National Government will no longer pay for this procedure abroad.

In February 1980, the Minister of Health decided that coronary bypass surgery will be started at the National Hospital in the beginning of 1981.

Cobalt Therapy

This procedure has been available since 1969 at the National Hospital. It was provided as a gift from the International Order of Odd Fellows, a men's benevolent organization, the Cancer Society, and several individual gifts.

Automated Laboratory Testing Equipment

High-volume testing machinery such as the SMA12 or SMA16 is not currently in use. The volume of tests seems sufficiently small at any one location, however, that there appears to be no pressing need for it.

CONCLUDING REMARKS

Perhaps the most striking feature of Icelandic health policy decisionmaking, the result of the small size of the country, is the frequency of contact between politicians, administrators, and doctors. A second notable feature is the implicit balancing, as in the case of coronary bypass surgery, of medical quality and medical independence.

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10.
Controlling Medical Technology in Sweden

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SWEDEN: COUNTRY DESCRIPTION

Sweden is a Scandinavian country of 8 million people. It is 1,500 miles in length and its northern part is above the Arctic Circle. Largely urban and highly industrialized, Sweden has one of the world's highest per capita incomes. The country's economy is mixed capitalist and socialist. Basic demographic data for Sweden and the United States are presented in table 1.

Sweden's internal development has occurred in an atmosphere of tranquility unknown to most Western nations. Except for an ultimately unsuccessful expansionary period during the 17th and 18th centuries, Sweden's history has largely been one of relative isolation, distinguished by neutrality since the Napoleonic Wars. The stability of this country is reflected in the continuity of Swedish politics. During this century, one party, the Social Democrats, ruled for 44 years with only a 3-month hiatus prior to their defeat in 1976 (65).

Like England, Sweden is a constitutional monarchy in which all Federal political power rests in an elected Parliament. Local units of government are the lans (counties), of which there are 25. Although Sweden has not fought in a war since 1812, it maintains a modern army with compulsory military service.

Sweden provides extensive health and welfare benefits for its citizens. Demographic data and information on health and medical care in Sweden and the United States are presented in tables 2 and 3, respectively. All 8,236,179 Swedes[1] are covered by compulsory health insurance. This pays for all physician care and hospital services, except for a modest copayment fee of about $4.50. Care for the chronically ill is provided in nursing homes or at the patient's residence at no extra charge. Drugs are free except for a modest

[1]By census as of Dec. 31, 1976 (56).

Table 1.—Demographic Characteristics of the United States and Sweden

	United States	Sweden
Population		
1960	180.68 million	7.48 million
1971	207.05 million	8.10 million
Population density (1971)	22 per km²	18 per km²
Percent of population in urban areas (1970)	74.1%	79.6%
Average annual compound growth rate (1960-71)	1.2%	0.7%
GNP per capita (1972)	$5,590	$4,480
Percent of labor force unemployed (1971)	5.4%	2.7%

SOURCE: R. Maxwell, *Health Care: The Growing Dilemma* (New York, N.Y.: McKinsey and Co., 1975) (37).

Table 2.—Data on Health in the United States and Sweden

	United States	Sweden
Life expectancy at age 1		
Male		
1958	67.8	71.9
1971	67.9	72.0
Percent change	+ 0.1	+ 0.1
Female		
1958	73.8	74.9
1971	75.2	77.3
Percent change	+ 1.9	+ 3.2
Infant mortality per 1,000 live births (1969)	20.7	11.7
Maternal mortality per 100,000 live births (1969)	24.5	10.2
Elderly (+ 65) as a percent of total population (1968)	9.6	13.5
Deaths from motor vehicle accidents per million population (1969)	275	169
Deaths from accidents, poisoning, and violence per million population (1969)	777	682
Annual number of cigarettes smoked per adult (1970)	3,670	1,620
Liters of alcohol consumed per person (1972)	5.9	5.7

SOURCE: R. Maxwell, *Health Care: The Growing Dilemma* (New York, N.Y.: McKinsey and Co., 1975) (37).

Table 3.—Dataon Medical Care Providers and Facilities in the United States and Sweden

	United States	Sweden
Health expenditures		
Percent of GNP spent on health services(1969)	*6.7%.*	6.4%
Annual health expenditures per person (U.S. dollars)(1969)	*$298*	$234
Physicians and nurses		
Dentists per l0,000 population (1970)	5.0	8.4
Doctors per l0,000 population (1970)	15.8	13.6
Nurses per 10,000 population(1969)	33.5	38.2
Percent of general medical practitioners in group practice(1971)	12.O%	20.0%
Hospitals		
All hospital beds per 1,000 population (1969)	81.0	164.0
Average number of beds in general hospitals(1969)	155.0	540.0
Average number of beds in psychiatric hospitals(1969)	1,174.0	146.0
Psychiatric beds per 1,000 population (1969)	30.3	62.8
Admissions to general hospitals per l,000 population(1969)	144.6	147.0
Average length of stay(days)	9.3	12.6

SOURCE: R. Maxwell, *Health Care: The Growing Dilemma* (New York, N.Y.: McKinsey and Co., 1975) (37).

basic charge, and prescriptions for such long-term conditions as diabetes or epilepsy require no copayment. Also provided in Sweden are maternity benefits, compensation for 90 percent of lost income during illness, and various types of pensions. All of these benefits, which maintain the citizen's health indirectly by providing for economic well-being, are part of the Swedish matrix that blends health and social welfare functions.[2]

Largely because of the cost of Sweden'scomprehensive health and social welfare benefits, which absorb almost three times as much of the budget as defense, Swedes pay among the highest taxes in the world (44). The magnitude of these taxes is a commentary on the Swedes' high priority for good health. In fact, in a 1975 survey, a representative sample of the population ages 18 to 70 years listed medical and dental care first among 29 potential uses of an increase in the nation's total revenues (11).

As a country that not only is actively trying to control the use of medical technology but has

[2]For a complete discussion of benefits, see pp. 27-64 in *Var Tryghet* (17). A similar discussion in English appears in *Information for Immigrants: Social Insurance in Sweden* (18).

had some success in doing so, Sweden is a fascinating case. The efforts of Swedish planners are aided by the Swedish bureaucracy's favorable relationship with the citizenry. They are greatly facilitated, as well, by the regionalized hierarchical structure of Sweden's health care system.

To understand the regionalized structure of Sweden's present health care system, it is necessary to gain some appreciation of the major forces in Swedish history that have affected its development. These are discussed in the next section of this chapter. In the following section, the general mechanisms that Swedish planners use to control the diffusion of medical technologies—the rationing of medical care, the education and employment of doctors by the state, and the evaluation of specific technologies and issuing of voluntary guidelines by the Swedish Planning and Rationalization Institute of the Health Services (SPRI)—are described. The section after that contains case studies of specific technologies to illustrate how Sweden's system operates in practice.

HISTORICAL ORIGINS AND DEVELOPMENT OF THE MEDICAL SYSTEM

Two aspects of the Swedish health care system, regionalization and socialization, are critical in understanding the manner in which Sweden controls medical technology. The origins of these features of this country's medical care structure are rooted in Sweden's political, economic, and cultural history.

The fiscal "socialization" of Swedish medicine did not occur until national health insurance was implemented in 1955, the regional system of medical services was not established until 1958, and the employment of doctors by the Swedish Government did not come about until the establishment of a national health service in 1969. As described below, however, events as early as the 16th century predisposed Sweden to develop the regionally organized and tractable medical system that facilitates controlling the diffusion of modern medical technologies.

The Swedish Bureaucracy

The effectiveness of the Swedish bureaucracy is partially rooted in the bureaucracy's historically favorable relations with the citizenry. The origins of the Swedish civil service date to medieval times. Unlike many other countries, Sweden failed to develop a feudal system, so rather than becoming feudal lords, Swedish nobles entered into the service of the king. The consequences of the nobles' playing the role of civil servants rather than feudal lords were twofold. First, friction between nobles and serfs in Sweden was inarguably less than it was on the continent, and Sweden's aristocratic civil servants did not have to bear the burden of citizen antagonism. Second, comprising an elite, selected from the well educated and capable, the Swedish civil service usually acquitted itself in a style worthy of the respect accorded it.

The result has been described by British historian Roland Huntford (24):

> The identification of aristocracy and civil service has conferred on the Swedish bureaucrat a unique supremacy and esteem. For centuries, he has been honored with deference and respect. He has never had to bear the scorn, dislike, and suspicion poured on the state functionary in so many other countries. He is considered greater than the politician, the lawyer, and the industrialist, The senior official remains, true to the figure of a mandarin, at the top of Swedish society . . . . The chief civil servant has more prestige than his minister.

State office was monopolized by the Swedish nobility until the late 19th century; at that time, highly competitive examinations were introduced to determine entrance to the "executive" guild, so the Swedish bureaucracy has remained a recognized elite (20).

Good bureaucrat-citizen relations are guarded in Sweden by special officials called "ombudsmen, " who have been active since

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1809. It is their duty to investigate complaints against the government and its agencies on behalf of the electorate. The diffusion of the Swedish word "ombudsman" into other languages is testimony to the longstanding responsiveness of the Swedish civil service, a responsiveness that is only beginning to be duplicated elsewhere.[3]

The effectiveness of the Swedish bureaucracy also stems from the bureaucracy's insulation from political tides. Even when governments turn over, as happened in 1976, the medical administration remains intact. This is because the chief health officer, the Director-General of the National Board of Health and Welfare (Socialstyrelsen), is not a Cabinet Minister, but a civil servant who works on a theoretically apolitical plane above the elective government. The continuity of the Swedish medical civil service has enormously facilitated health planning, because in some cases, as many as *20* years have elapsed between the issuing of a report and its implementation.

The Parish System of Decentralized Administration

The subjugation of the nobles to the state was not the only important source of qualified administrators for Swedish development. The Reformation, embraced by King Gustav Vasa in the 1530's, resulted in the establishment of a Lutheran State Church which exists to this day (45). Following the union of state and church, the clergy continued its task of keeping parish records of births, deaths, and population movements, but now this activity amounted to census taking on behalf of the state. This source of demographic information has proved to be invaluable to medical planners on many occasions.

The parish system also provided a geographic blueprint for administrative regions. This framework was exploited by the government as a basis for decentralized medical care responsibility when it ordered the church to provide rudimentary care for its parishioners in the 17th century.

State Secular Hospitals

Before the Reformation, the Catholic Church had established helgeandshuser (lit: holy ghost houses) for the care of the sick and the poor. When King Gustav Vasa de facto nationalized the church in 1527, he took pains to see that these salutary functions were continued. In a series of letters[4] to priests and taxmasters, King Gustav ordered that parish services to the indigent and ill be maintained, and authorized taxmasters to finance them (64). This royal initiative marks the beginning of the government takeover, or socialization, of medicine in Sweden.

The development of state hospitals was further spurred by the needs of the 17th century. Swedish troops, particularly during the Napoleonic Wars, were devasted by syphillis *(50).* For treating the soldiers, venereal disease hospitals called kurhus (lit: cure-house) were established, and government district doctors were appointed to staff them (22). These secular hospitals established a second channel for medical services, alongside the parish system, that eventually came to dominate.

When the last soldiers returned from the Napoleonic Wars to henceforth neutral Sweden, a third course of medical development, a civil one, was already being pursued. Military spending was being reduced, so to preserve the kurhus system, a head tax was levied. A number of hospitals independent of the original "holy ghost houses" had already been established in the major cities. These were more reassuringly named lasaretts,[5] after the biblical figure Lazarus who was raised from the dead. In the century preceding 1864, the landmark year when the lans

[3] Today, a special medical ombudsman plays a crucial role in arbitrating consumer complaints against the health care system. This ombudsman and the Medical Responsibility Board of the National Board of Health and Welfare usually settle what would be malpractice claims in the United States with far less litigation and lower awards *(70).* A frequent complaint in the United States is that the defensive medicine produced by malpractice claims leads to overuse of diagnostic procedures. It is interesting to note, therefore, that the volume of laboratory and X-ray tests ordered in Swedish hospitals is only one-half of that performed in American hospitals on similar patients (12,30).

[4] These letters were assembled and analyzed by Reformation historian Thyselius in 1841 (64).

[5] The first and most famous of these is the Serafimer lasarett in Stockholm, established in 1752 (67).

(counties) and landstinget (county councils) took over the hospitals, nearly 50 lasaretts were built, and the number of beds went from 200 to nearly 3,000 (67).

Counties and County Councils

Sweden was not politically organized in a highly centralized fashion until quite recently. In the 19th century Sweden's economy was based on loosely connected and geographically disparate clusters of industry, mining, and agriculture called bruks *(46).* The parishes and bruks were too small to deal directly with the Swedish Government, so for their dealings with the state, they had formed small clusters called lans, or counties. These lans eventually came to be used as the new administrative base for medical care delivery.

In the reforms of 1862, 25 counties (mostly rural areas with a central market town) and four self-standing cities were officially designated lans (40). A mere *2* years later, in 1864, the responsibility for health of citizens in each of these lans was invested in the landstinget (lit: county council) which had been formed to administer the Ian (58). At first exclusively devoted to providing for the hospitals, the county councils subsequently took on other responsibilities. Nevertheless, they continued to devote over two-thirds of their budget to medical care (33).

The state retained both fiscal and administrative control of the medical schools, and in 1878, it created a body to supervise them as well as the county councils. This organization was known as Medicinalstyrelsen (lit: Medical Steering) (59), and was a descendant of the Collegium Medicum, a principally academic and professional organization that had been founded in 1663.

The remaining events in the history of Swedish health care involved resolving the problems of financing and providing personnel for the costly and complex enterprise of state-operated hospitals. With the exception of the development of medical regions in 1958, few major structural changes have been made in Sweden's health system since the transfer of the administration of health care to the county councils in 1864.

National Health Insurance, Employment of Doctors by the State, and Medical Regions

The Social Democrats came to power in 1932, and it was during their 44-year tenure (1932-76) that Sweden's health care system evolved most of the features that facilitate its control of technology: 1) national health insurance, 2) the employment of doctors by the state, and 3) a regionalized, hierarchical system for the provision of medical services.

During the period 1862-1955, numerous voluntary insurance plans had evolved to replace patients' income, but the financing of outpatient care remained largely in private hands. Inpatient care was financed through a system of employer-financed sickness funds (sjukkassor) (35). In 1910, only 10.7 percent of Swedes were active members of the over 2,000 sickness funds; by 1930, this figure had grown only to 16.6 percent (57).

National health insurance covering outpatient care was not seriously debated until the 1920's (60). The National Health Insurance Act (Allman Sjukforsakring), covering physicians, outpatient services, and drugs, was finally passed by Parliament in 1947. Laws in Sweden, however, are implemented at the government's discretion, so a grace period is left during which the administrative framework can be ironed out to ensure their smooth implementation. In the case of the health insurance law, the major issue complicating implementation was whether physicians would remain independent under the new insurance scheme or instead would become civil servants (32).

In a 1948 report, Dr. Alex Hojer, a prominent socialist who served as Director-General of the National Board of Health from 1935 to 1952, recommended a reform of primary health care, based on salaried positions for all physicians (51). Hojer also suggested that Sweden should aim to improve its health system by coupling the development of decentralized ambulatory and preventive care services with that of more

centralized specialized services (51). The county appeared to be too small a unit to benefit from full efficiencies of scale in providing specialized services that required major investments of capital and training of personnel, Hojer said, so intercounty cooperation would be essential (51). To facilitate such cooperation, he suggested, large regional hospitals should be developed. Primary care services, however, should be decentralized to bring them as close to the people as possible. Small health centers, Hojer believed, were the ideal unit for blending both social welfare and medical services into "totalvard, " or total care on an ambulatory basis (51).

In 1955, 8 years after the National Insurance Act was passed, national health insurance was implemented. The history of the Swedish health system since then, with some minor exceptions, can be described as the development and systematic implementation of Director-General Hojer's principles by his successors Arthur Engel and Bror Rexed. Their systematic implementation of Hojer's ideas during the three decades following the publication of his 1948 report is compelling evidence of the importance of the continuity and power of the civil service as a factor in the development of Sweden's medical structure.

With the publication of the Engel report of 1958, the basis of Sweden's hierarchical hospital plan was laid (52). Under this plan, Swedish counties were organized into seven medical regions, creating the intercounty cooperative clusters that Hojer had envisioned as necessary for efficient delivery of specialized services. In 1961, a comprehensive plan was introduced to increase medical manpower by expanding medical education (53). Vast numbers of new hospital positions were created for medical school graduates, and by 1970, the center of gravity of the medical profession had shifted sufficiently toward salaried service that a reform making virtually all doctors employees of the state, unthinkable in 1948, was effected with fairly little ado (69).

The unification of medical and social welfare services became a reality when the two were combined into the Nation-al Board of Health and Welfare (Socialstyrelsen) in 1968. The decentralization of ambulatory health services, intended to foster small facilities for "total care, " was prompted when the government transferred responsibility for the district doctors and mental hospitals to the counties in 1961 and 1963, respectively.

MECHANISMS FOR CONTROLLING MEDICAL TECHNOLOGY

Swedish planners, have at their disposal three organizational levers for controlling medical technologies—patients, hospitals, and medical personnel. These levers and how Swedish health planners manipulate them in order to control the influx of medical technologies are described below.

Swedish Patients and Constraints on Consumer Demand

Sweden has a government-owned and operated medical care system. Except for a nominal charge for ambulatory care, the patient pays nothing for medical services. Price, therefore, is not a mechanism used to limit demand. As Swedish health economist Ingemar Stahl has pointed out (49):

> From the patient's viewpoint, there is hardly any reason to stop the individual demand at a point at which further costs for treatment will not be outweighed by benefits. Probably the patients will demand treatments up to a point where further treatment will be rather a nuisance and completely disregard the costs involved
>
> . . . . With zero user charges, rationing of health care becomes a necessity. Clinical freedom in its usual sense can no longer be accepted and different types of cost control and economic surveillance have to be introduced . . . . One and the same illness can often be treated in different ways and there will be no incentives for patients to select or prefer the most cost-effective treatment . . . . It is not at all clear that the basic incentives of the medical profession will act as a countervailing power.

Restraining consumer demand, therefore, is one method that—deliberately or otherwise—Swedish planners have used to limit the use of medical services and restrain the influx of medical technologies. What makes these restraints on supply of services successful in Sweden is not the brilliance of its planners but the compliance of Swedish consumers. This compliance appears to be rooted in the collectivist orientation of Swedish society.

The Swedish medical care system depends to an extent on consumers who not only place a high enough value on medical services to willingly pay the price, but who also have a "collectivism" rather than "individualistic" attitude toward the use of resources. Without Swedes' collectivism orientation, which in large measure accounts for their acceptance of the rationing of medical care, the efforts of Swedish planners could not succeed.

Before investigating collectivism further, certain constraints on consumer demand in Sweden must be described to show why they might be objectionable to those with individualistic values. An intentional mechanism for limiting demand for medical services in Sweden are modest copayments for consultations and prescriptions. These copayments, set at 7 Swedish crowns in 1970, rose to 20 crowns ($4.50 U. S.) by 1977. The copayments are loosely indexed to inflation, by being kept roughly equal to "the cost of a first run movie at a commercial theatre" *(68).* The parallel is deliberate. Not a significant source of revenue, these copayments are meant to discourage frivolous waste without inhibiting reasonable use of medical services.

A second, though unintended, constraint on the demand for medical services in Sweden is that patients are often forced to wait for services simply because the supply of services is insufficient. Since there are no appointments for preliminary consultations, patients have to form physical queues in reception areas. Patients also have to be put on waiting lists for specialist services after referrals have been made. The Swedish Medical Association has acknowledged that patients have average waits of over 60 days to see an internist, 82 days for a gynecologist, 146 days for an ophthalmologist, and 16 days for a routine X-ray (43). Although they are not pleased by the long waits, Swedish patients are surprisingly phlegmatic about them.

The difference between the values of Americans and Swedes was noted by American political scientist Steven Kelman in his comparison of worker safety regulation (31):

> In Sweden, deferent values were dominant, which encourage people to accept the wishes of the state. In America, dominant self-assertive values encouraged people to have it their way.

The deferent values that Swedes hold are reflected in their confidence in the civil service and respect for government policies. For example, Sweden has been able to pass and successfully enforce legislation mandating the use of vehicle seatbelts, a law that has proved unacceptable or unworkable in other countries. While it is difficult to argue against the benefits of seatbelt use, Swedish citizens have also complied with rules requiring daytime use of special headlights, which are at times expensive to install, a slight nuisance, and are only of debatable value. Other examples of how Kelman's so-called "deferent values" have facilitated social policy decisions abound. Extraordinarily high taxes on cigarettes and alcohol have not spawned widespread contempt of government monopolies and rampant smuggling as in other countries. In the medical sphere, studies requiring mass screening of mass populations—even entire counties—for asymptomatic disease have been successful largely because of citizen compliance. Planners' efforts to control the dissemination of medical technology are greatly assisted by this tendency of Swedish citizens to cooperate with their government.

Why Swedish citizens are so accommodating is difficult to determine. In addition to the supply of medical services, the Swedish Government controls the supply of housing, capital on both the reserve and retail levels, education, and many other citizens' services. In a country where one must wait in line for an apartment, a loan, or a position in a university, waiting in line for health services is not so strange an experience. Swedish internist Lars Werko remarked on the phlegmatic nature of the Swedish

patient shortly after the "Seven Crowns reform" (69):

> The relative indifference demonstrated by most people toward the recent changes in medical practice, as judged from what is written in the newspapers or discussed on television, has always astonished me. The explanation I have arrived at is that the people rely upon the government and are confident that all is going to function as well tomorrow as it did yesterday.

Copayments and queues apparently do reduce the demand for services. In 1963, the average number of physician visits per person per year in Sweden was 2.5 (7). By 1974, 4 years after the "Seven Crowns Reform" significantly reduced costs to the patient, annual visits had risen only to 2.7 per capita (33). More visits per capita would have led to increased referrals and to greater demand for specialists and their technologies.

The Regionalized Hierarchy of Hospitals

In terms of expenditures, 87 percent of medical care in Sweden is delivered at hospitals, 88 percent of which are operated by the 26 county councils in the decentralized fashion set out by the reforms of 1864 (33). Thus, it is the counties who are the actual purchasers of medical equipment, and in a sense, it is the counties who decide whether a new technology is adopted.

The policymaking of the counties, however, is constrained by the" state, as is discussed below. The counties' freedom of choice is also limited by cooperative agreements with other counties to provide specialized services on a regional basis. The objective of the regional system of medical services introduced by Director-General Arthur Engel in 1958 (52) **was** to ensure that specific types of services were delivered at the level—local, county, or regional—on which they could be provided most efficiently.

This regionalized system of Swedish medical services is mirrored by Sweden's hospital system. There are four levels or categories in the hospital hierarchy: 1) health centers, 2) district hospitals, 3) central general hospitals, and 4) regional hospitals.

Outpatient services within each county are organized by primary care districts containing 10,000 to 20,000 inhabitants, and each of these districts usually has one or more health centers. Health centers in primary care districts, which form the lowest tier of the hierarchy, are usually staffed by general practitioners in charge of ambulatory and preventive practice. District nurses are active in home care and sometimes specialize as midwives or child care nurses.

At the second tier of the hospital hierarchy, above the health center, are district hospitals. These hospitals, which usually serve several primary care districts with a total population of 60,000 to 90,000, ordinarily provide four specialized services—medicine, surgery, radiology, and anesthesiology.

At the third tier of the hospital hierarchy are the central general hospitals. There is usually at least one such hospital per county, and each hospital serves a population of 250,000 to 300,000, Each central general hospital offers 15 to 20 specialized services.

At the fourth and top tier of the Swedish hospital hierarchy are the regional hospitals. There are seven regional hospitals throughout the country, each of which has an average population base of slightly over a million. All but one of these institutions are affiliated with medical schools and serve as centers for research and teaching. Among the specialized services that these institutions provide are neurology, radiation therapy, thoracic surgery, neurosurgery, pediatric surgery, and certain types of cardiac care. [b]

Sweden's four hospital tiers provide a clear "pecking order" for who receives sophisticated new technologies. The regional hospitals are the first in line, and the central general hospitals, district hospitals, and health centers follow. At each tier, a service is provided only if there is a sufficient population base for it to be as cost effective at that level as at a higher one.[7]

'Some of these services are actually provided on an interregional basis. Thoracic surgery departments, for example, are located only at the four largest regional hospitals.

'As an aside, it might be said that such a system is not only more economical but also tends to provide better care. The very rarely needed procedures are concentrated, and more experience with such procedures by medical practitioners brings better results.

County council members need not feel responsible for bringing a sophisticated new technology to their own county's central general hospital, because county residents may be referred from that hospital to the regional hospital that they subsidize. If a new technology is cost effective on the central hospital level, however, the county's council and taxpayers both have a role in deciding whether or not to acquire it. As Egon Jonsson, the SPRI planner responsible for the CT rationalization report, put it, "There is a clear link between the politician a Swedish citizen elects, the size of his taxes, and the medical services he has access to" (28). Because of the policy that, except under special circumstances, Swedish patients cannot use hospitals outside the county or region in which they reside, citizens as well as planners have a direct interest in seeing that necessary—but not excessive—equipment outlays are made in the central hospitals.

It should not be inferred, however, that cost-effective choices are always made. County pride occasionally dominates over pragmatism. Several central hospitals, for example, have begun to insert pacemakers, even though ideally this procedure should be performed at the regional level (68). Similarly, when technology-intensive advances in obstetrics and a decline in the birth rate recently mandated closing the lying-in ward of the Enkoping central hospital in favor of the regional department in Uppsala, local citizens filed a petition to block the closing. A senior planning official of the National Board of Health and Welfare, attributed the uproar solely to local fear that the city was becoming a backwater (68).[8]

This regionalized hierarchy of hospitals provides Swedish health planners with two separate strategies for optimizing the use of medical technologies. Highly sophisticated equipment and technology-intensive specialties can be concentrated at the regional hospitals and simpler inventions can be dispersed to the health centers. Often, the most cost-effective level for the provision of a service is that of the health center, because care at health centers is less expensive per patient than care at outpatient clinics at major hospitals (14). As Director-General Arthur Engel explained (14):

> For financial and manpower reasons, we have formulated the guiding principle that care should be provided on the lowest acceptable level of the organizational system.

Swedish planners foresee the health center as being the new basic unit for the decentralized provision of total care (totalvard), the combination of sick care (sjukvard) and preventive care (halsovard), and also the counseling and financial services of the social welfare system (34). Referrals to specialists at the central and regional hospitals will be made from the health centers, so that economies of scale for complex and unusual care will be preserved.

The American political scientist Arnold Heidenheimer concluded that the hierarchical structure of Swedish hospitals is deliberately being polarized (21):

> Centripetal forces here respond mainly to the location of highly specialized equipment and skills, while centrifugal forces are strengthened by political demands for care which is proximate both in terms of physical distance and in terms of its concerns with primary care.

This process of polarization leaves the district hospitals caught in the middle between the poles of specialization and decentralization. Swedish planners doubt that district hospitals are large enough to benefit fully from efficiencies of scale for many services, and aim to convert them to chronic care and old-age homes (15). The four specialties that these hospitals now house will then move up to the level of the central general hospitals. Currently, too much geriatric care is being delivered on an inappropriate technology-intensive level at the central and regional hospitals. The conversion of the district hospitals to long-term care facilities, therefore, should reduce the influx of technology not only at the district level, but at the county and regional levels as well.

[8] 'Citizens' opposition to the closing of the central hospital ward was certainly not based on medical grounds because the quality of care to be received by the mothers at the regional hospital was to improve significantly. Less than 10 percent of the Enkoping petitioners were women of childbearing age. When polled separately, the women who were potential mothers and likely to be the most affected by the change, were in favor of the move.

State Education and Employment of Medical Personnel

The external organization of Swedish hospitals provides only a partial picture of the mechanisms at the disposal of Swedish planners to restrain the influx of technologies. In addition, the internal mix of medical personnel and facilities must be analyzed. For the sake of brevity, the discussion of medical manpower here is limited to physicians and nurses.

As of 1977, Sweden had roughly 15,000 doctors, or a ratio of 1 physician per 515 population, quite similar to the ratio of 1 per 571 population in the United States (25,61). Most Swedish physicians are employed by the state. In 1977, only 6 percent of Swedish physicians were in private practice, and the average age of these physicians was considerably over the mean for their profession. The gradual disappearance of the private sector in Sweden has facilitated planning. In other countries, noninstitutional settings have been used to circumvent constraints on technology purchases (47).

The state not only employs but also educates virtually all medical personnel in Sweden. Thus, it is able to match training programs to anticipated and present needs. As Director-General Rexed succinctly put it, "Training policy (is) the most important contribution to future planning" (44). By 1985, the numbers of Swedish doctors specializing in long-term care and psychiatry are projected to increase by 130 percent and 60 percent, respectively. **The ranks** of physicians who use technology-intensive techniques, however, will be increased by only 28 percent (44). (Swedish policy toward the training of the latter is discussed in conjunction with specific technologies in the next major section of this chapter.)

Once doctors are educated in a predetermined fashion, the National Board of Health and Welfare also can decide to a large extent where these physicians will work, through its allocation of medical posts. This power facilitates planned assignment of doctors at various levels within the hospital hierarchy (from the regional hospital to the health center) and is also the basis for ensuring their proper geographical distribution. It should not be inferred, however, that Sweden has solved the nearly universal problem of supplying rural areas with physicians (13). An overall physician shortage in Sweden still allows for mobility.

Doctors are not the only human resource that is "rationalized" in Sweden. The same official goal of "giving the best care without undue demands on scarce resources" (44) applies to the use of nurses. Nurses comprise a much greater proportion of total hospital personnel in Sweden than in the United States. Nurses in Sweden perform a variety of tasks that in the United States are ordinarily reserved for doctors—delivering babies as midwives, and giving anesthesia and administering public health services as district nurses.

How does the "rationalization" of human resources through training and of capital resources by regionalization affect the overall plant-personnel mix at the Swedish hospitals? Cross-national comparisons show that Sweden has the highest per capita number of beds in the world, with 17 per 1,000 population, as compared to 10 per 1,000 in the United States (62).[9] Sweden has only one-half the personnel-to-bed ratio of the United States (29), though, and a higher proportion of Swedish workers are nurses. Sweden also has a longer mean length of stay than the United States, 30.9 days as opposed to 18 days. Much has been made over these differences as a manifestation of planning. The differences, however, can be largely explained by the older age of the Swedish hospital population. This population tends to be admitted to hospitals for chronic problems that require longer stays but less intensive care.[10]

Governmental Evaluation and Control of Medical Technology

The three governmental bodies that exercise control over the medical care system in Sweden are the Executive and Parliament, the National

[9]Figures from R. Maxwell, *Health Care: The Growing Dilemma* (37) that are cited in table 3 differ somewhat.

[10]The significance to planners of care for the elderly must not be underestimated: The life expectancy of Swedes is the highest in the world, and the proportion of the population over 65 years of age is 14 percent, compared to 11 percent in the United States (29).

Board of Health and Welfare, and the county councils.

The relationship of the state to the counties is like that of a rider to a horse—the rider can apply persuasive tactics, but in the final analysis, it is up to the animal to decide on its movements *(48)*. The steering role of the rider is played by the National Board of Health and Welfare, which sets standards for quality, conducts inspections, and allocates physicians (44). In addition, the Swedish Government uses its fiscal leverage by subsidizing hospital construction. Since *1884*, however, counties have had constitutional power to tax their citizens and to decide whether or not to build hospitals, so they control the amount of care available. In summary, the state tries to compel the counties to follow the desired path through regulation and subsidy.

The question persists, however, of how the state decides which course to adopt when a new technology becomes available. To answer this, it is useful to examine the information on which the "rider" depends. The National Board has three principal sources of information for evaluating new methods and instrumentation: 1) the National Bureau of Statistics (Statistiska Centralbyran), 2) physicians who serve as consultants to the National Board of Health and Welfare, and 3) the Swedish Planning and Rationalization Institution (SPRI).

The National Bureau of Statistics assembles data concerning all Swedish patients using their "social security" numbers. Since social security numbers are used for medical record identification, all medical services rendered to a given individual can be accounted for and used in tabulating national health statistics.

Once health needs and budgetary constraints are known, the strictly medical likelihood of **a** new technology's satisfying unmet needs must be evaluated. This general evaluation of biomedical innovations in Sweden is performed by selected physicians, prominent in their specialties, who serve as consultants to the National Board. Their task is to assess whether the technology "is consistent with proven scientific knowledge and good experience."[11] Unlike SPRI, these physicians do not appraise equipment on a brand-by-brand basis. Instead, they evaluate experimental techniques (such as transplantations) or diagnostic and therapeutic interventions without precedent in a general way.

If the likelihood of a new technology's fulfilling unmet medical needs is deemed adequate, planning to determine whether implementation is affordable and on what scale it should be undertaken can proceed. The panel of experts' opinion on the potential of the innovation from a medical standpoint is used by the National Board through SPRI (63). This administratively independent body is financed jointly by the National Board and the county councils. Combining the scientific evaluations of the panel of experts with the statistics for need and costs, SPRI attempts to formulate a coherent plan for implementing the new technology in the most "efficient" way.[12]

Summary of Mechanisms for Controlling Medical Technology

It is worth summarizing the mechanisms Swedish planners might have at their disposal to control the influx of innovations by matching them with the five basic strategies for restraining medical technologies. The first strategy, to oversee R&D so as to abort innovations that could consume inordinate amounts of resources, does not play a significant role in Swedish efforts to control technology. The Swedish Government does invest heavily in health R&D, but funds for R&D are not systematically identified in government budgets. Different parts of the government invest in R&D according to their general mandate and interests. Most of the funding is from the Ministry of Social Affairs and goes directly to university hospitals. Another major route is from the Ministry of Education to the Medical Research Council, which may fund research and has also

[11]Little useful literature has been published on the subject of expert evaluation panels. The discussion in this paper was based entirely on an interview with Gunnar Wennström (68).

[12]When SPRI was organized in the 1960's, the evaluation of medical technology was not one of its tasks. It was concerned with architectural design, staffing analysis, engineering, and research on medical care delivery problems.

funded research chairs in important areas. There are no special procedures for planning this R&D investment. Not only is it considered counterproductive to supervise basic science in Sweden, but it also would be impossible to extend control abroad, where innovations such as CT scanners and coronary artery bypass operations originated.

A second strategy Swedish planners could employ, adjusting manpower policy so as to reduce the number of technology-intensive specialists, is used. Favored by Sweden's manpower policy at present are doctors and nurses trained for chronic, geriatric, and primary care.

The third mechanism that could play a role in Sweden's socialized system is funding incentives. Financial pressure might be used to indirectly punish counties that acquired technologies that were uncalled for in the eyes of SPRI and the National Board. Swedish planning director Dr. Gunnar Wennstrom, however, although fully cognizant of this channel for technology control, insists that it is rarely used (68).

The fourth strategy, regulating technologies as rigidly as pharmaceuticals, is not appropriate for use in Sweden, because it goes against the "rider and horse" mentality of the Swedish medical structure. As previously noted, the counties in this context are free to make their own decisions concerning the purchase of medical technologies.

In light of Sweden's medical structure, issuing voluntary guidelines through a national information agency, the fifth strategy, is clearly preferred. It is therefore not surprising that SPRI has undertaken to fill this advisory role. The success of this purely advisory institute in planning technology in Sweden goes hand in hand with the regional organization of Sweden's hospital system, because planning the rational diffusion of a technology requires a clear hierarchy in order to prevent duplication.

In theory, therefore, Sweden is predisposed towards the second and fifth of the aforementioned containment strategies, i.e., the manpower and informational approaches. Only empirical evidence about the influx of specific technologies, however, can demonstrate whether these methods work. Presented in the next section of this chapter, therefore, is an analysis of the Swedish experience with CT scanners, coronary artery bypass operations, and other innovations.

SPECIFIC TECHNOLOGIES

CT Scanners

The first CT scanners became available in England in 1972 and were introduced in Sweden and the United States in 1973. As of May 1978, the United States had 4.8 scanners per million inhabitants (8). Sweden, however, had only 1.6 scanners per million population (54).

How did Sweden manage to stem CT's influx? In the case of CT scanners, manpower strategies did not play a role for two reasons. First, in the short period between the introduction of CT scanners in 1972 and 1978, no significant adjustment in the numbers of radiologists could have been made. Second, although the concentration of physicians per capita is about the same in Sweden as in the United States, 5.23 percent of Swedish doctors (compared to 2.81 percent of American physicians) are specialists in radiology (23).[13] Thus, Sweden has sufficient radiologists to equal if not exceed the U.S. level of CT use per capita.

It appears that what was responsible for restraining the influx of scanners in Sweden were timely coordinated planning and the regional hierarchy of services. SPRI began with the groundwork for plans to rationalize CT scanners in 1973, when the first head scanner

[13] Actually, for many years Sweden has been a leading country in radiology and radiotherapy. This preeminence is often attributed to the centralization of the hospital system, because centralization provides concentrated experience and permits greater specialization in the subsections of radiology. Indeed, the specialty of neuroradiology originated in Sweden (41,42).

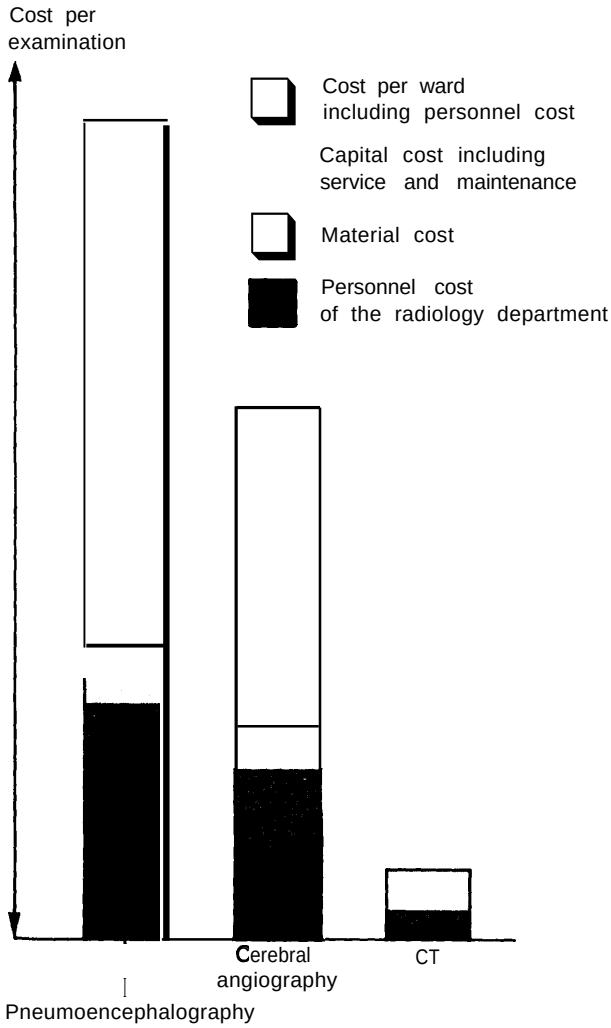
was purchased by the Karolinska Hospital in Stockholm. The introduction of CT scanning to Swedish hospitals was not viewed by planners as a simple case of adding another machine. CT was viewed as partially replacing the functions of other diagnostic modalities, which therefore could be allocated fewer resources. The problem facing Swedish planners, therefore, was to ensure that the CT scanners were not installed beyond the point of diminishing returns from the standpoint of the diagnostic examinations they replaced.

The basic question SPRI asked was: How many pneumoencephalographic and/or angiographic examinations have to be replaced at a given hospital by CT in order for the costs of the scanner to be justified? The costs of the CT head scanner were weighed against those of pneumoencephalography and cerebral angiography at various levels of examination.[14] The medical and psychological value of replacing an invasive procedure with a noninvasive one were deemed impossible to gauge, so only equipment, hospital, and manpower expenses were considered. (See figure 1.)

The cost-effective level for installation of CT scanners was determined to lie somewhere in between the regional and central hospitals, since some of the large central hospitals did almost as many brain examinations as the smallest regional hospital. SPRI did not specifically recommend, therefore, which institutions should acquire CT technology. Rather, it published charts that county councils could use to grid specific levels of usage of angiography and pneumoencephalography at any given hospital in order to determine if replacement of these modalities with a CT scanner would be cost effective. (See figure 2.)

Why was this seemingly unspectacular information probably responsible for restraining

Figure 1.—Relative Proportions of Different Cost Items in the Total Costs of Pneumoencephalographic, Cerebral Angiographic, and CT Examinations



As is evident from this figure, cerebral angiographic and pneumoencephalographic examinations are much more personnel demanding than CT examinations.

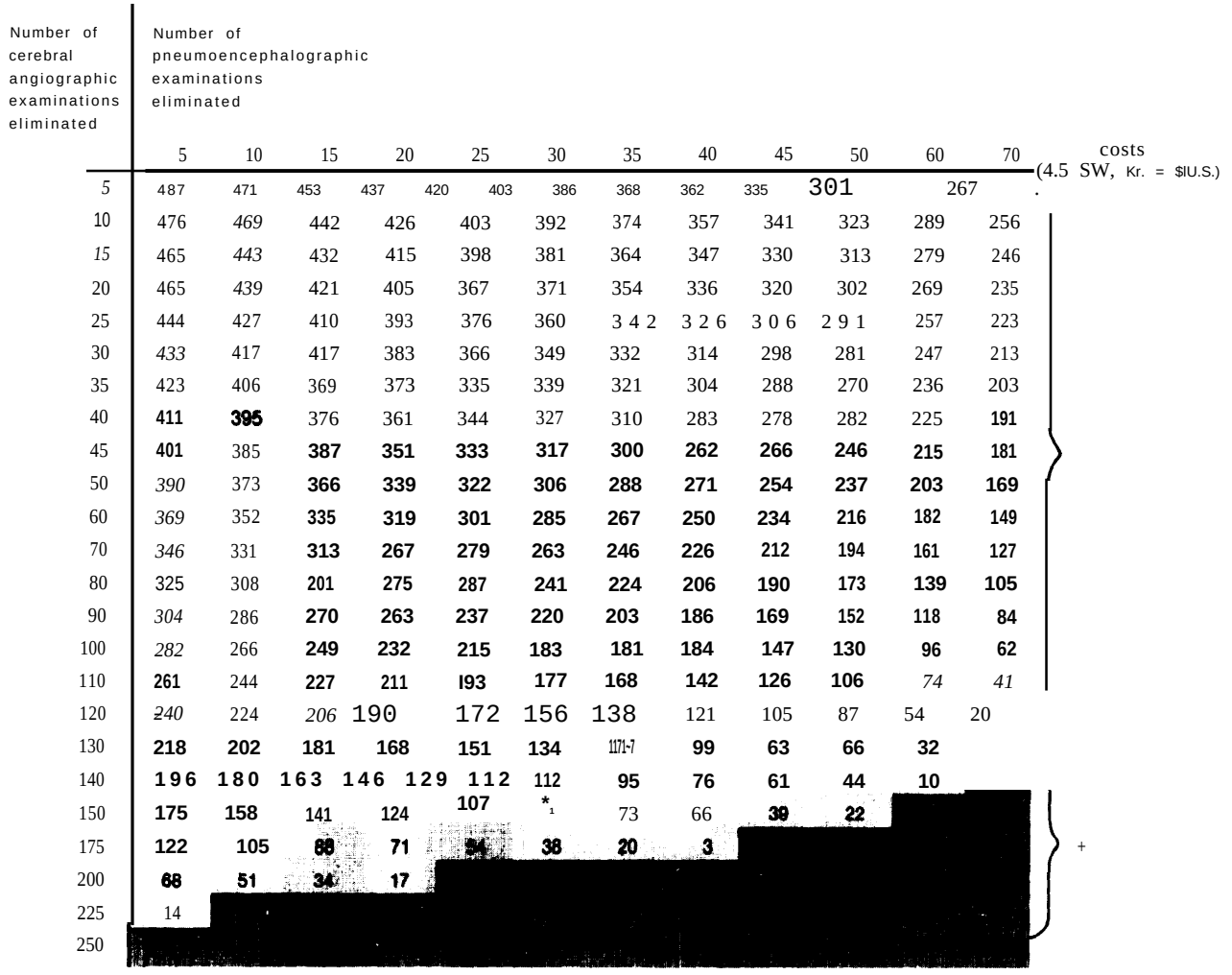
SOURCE: E. Jonsson and L. Å. Markē, "CAT Scanners: The Swedish Experience," *Health Care Mgt. Review* 2:37, 1977 (28).

CT? The answer lies partly in the timeliness of SPRI'S report. As the experience with the Enkoping hospital obstetrics unit showed, it is easier not to add a service than to eliminate it later on. Swedish health economist Edgar Borgenhammer stated (11):

> My experience is that it means a lot for the possibilities of cost containment that the admin-

[14]Two other methods used to detect cerebral lesions in Sweden, gamma- and echo-encephalography, did not figure prominently in CT planning for two reasons (28). First, their cost per investigation is only one-fifteenth the cost of angiography or pneumoencephalography. Thus, potential savings from replacing them with CT were not significant. Second, both gamma- and echo-encephalography give somewhat different types of information from the types of information given by pneumoencephalography, angiography, and CT.

Figure 2.—Projected Annual Cost Increase or Decrease Resulting From the Introduction of a CT Scanner (in thousands of Swedish kroners)



SOURCE: E. Jonsson and L. Å. Marké, "CAT Scanners: The Swedish Experience," *Health Care Mgt. Review* 2:37, 1977 (28)

> istrator can catch problems before they grow big. . . , Once resources have been allocated to an area it is very difficult to diminish or remove them,

The Swedish experience with CT is a case where planning was done before the situation grew too big. Most Swedish hospitals waited for the report and seemed to follow its recommendations. Only two scanners had been installed in Sweden at the time the SPRI report was released. By that date, *320* scanners were already in operation in the United States (8).

Although it is far from perfect in practice, Sweden's hierarchical hospital system did serve to arrest the diffusion of scanners. As of February 1979, Sweden had eight head scanners, all but one at regional hospitals, and six total body scanners, two of which were located at the largest central hospital (54). As of late 1979, Sweden had 17 scanners (27). They were installed on the following dates: October 1973 (1), November 1975 (1), November 1976 (l), January 1977 (l), February 1977 (l), March 1977 (I), July 1977 (1), September 1977 (l), November 1977 (1),

December 1977 (l), January 1978 (l), February 1978 (l), May 1978 (l), February 1979 (l), June 1979 (2), August 1979 (1).

How successful was the SPRI model in predicting the effect of the introduction of CT? The assumption that the usage of alternate modalities would drop off proved correct. A subsequent turn that has altered the results of CT implementation, however, is that scanners are used more frequently than was projected on the basis of the assumption that scans would replace angiographs and pneumoencephalographs (4). As a consequence, the introduction of CT may have lowered costs for given numbers of cerebral examinations, but raised total costs. The structure of the Swedish hospital, however, keeps these marginal costs at a minimum, an advantage Swedish planners Jonsson and Marke pointed out (28):

> It is conceivable that in the United States, 50 angiographs per year could be replaced by 800 CAT exams. This would result in a major net increase in third party expenses. The Swedish counties have less of a problem in this area. Once they decide on equipment purchase and staffing changes, that decision defines most of the difference in total costs. A much higher than expected volume of CAT scans will not create a financial crisis, perhaps until another budget year when a second CAT scanner is asked for.

In September 1979, SPRI organized an international conference to alert other countries to the need for evaluations similar to its evaluation of CT. The following features of SPRI'S approach are especially deserving of note:

- SPRI developed good working relationships with a number of senior physicians who provided medical expertise.
- The report SRRI issued was timely, Produced when the decisions were being made, the report synthesized existing knowledge and original information SPRI collected in areas such as costs and staffing. It was not the definitive study that might have consisted of **a** randomized trial with long-term followup. Such a study, however useful, would not have provided information until many years after the critical decisions had already been made.
- The report addressed the concerns of the decisionmakers. The lay county council members needed to understand the central issues. They needed this kind of information to respond to the perhaps overenthusiastic requests for scanners from their medical staff.
- The report did not give a simple yes or no answer with regard to CT scanners, but defined a set of tradeoffs related to the avoidance of other more risky procedures, volume of tests, and costs. It allowed play for local preferences in coming to a decision.
- SPRI performed a new analysis for body scanners when the matter of their possible purchase arose.
- SPRI organized a national conference on this topic drawing together physicians and administrators and lay county council members to present its analysis and allow for discussion. Swedish authorities presented their views on CT, and an American expert, Barbara McNeil, came to explain that the benefits of CT scanners were not yet at all well defined.
- SPRI staff continued contacts with medical decisionmakers to offer advice.
- To improve future medical technology assessments, SPRI is now conducting a followup interview study to see how, if at all, Swedish decisionmakers were influenced by the SPRI analysis.

The approach that SPRI used in its evaluation of CT scanners might well be used as a model for other countries.

Coronary Bypass Surgery

Although there were precedents for the treatment of coronary artery disease by surgery in Sweden, no procedure had been very successful or was in wide use when coronary bypass surgery was introduced. Beginning with Lindgren's stellate ganglion resection experiments in the late 1940's, Sweden had been on the forefront of experimental surgical techniques to relieve angina pectoris (36). Various techniques were developed and tested, but although in some cases the techniques did yield some relief from

pain, they did not appreciably change mortality statistics. As a result, there developed in Sweden skepticism toward each new "miracle" operation that emerged in that country or elsewhere.

According to Uppsala thoracic surgeon Torkel Åberg, skepticism toward innovations in heart surgery influenced Swedish decisionmaking on the bypass operation (1). Lending credence to Åberg's argument is Sweden's decision not to use heart transplantation. Subsequent to its introduction in South Africa in 1967, heart transplantation was attempted in almost every developed nation except Sweden. The consensus in Sweden, despite some heated dissent, was that heart transplantation was too experimental in nature to justify its use (9,10). In the case of coronary bypass surgery, Sweden exercised considerable restraint, but did not decide to avoid the procedure altogether. The experts on the medical evaluation board agreed that, unlike heart transplantation, the bypass procedure was consistent with proven scientific knowledge and good practice. Since the bypass surgery was felt to be potentially valuable, in 1973-74, it was instituted in Sweden on a small and experimental scale (68).

The Swedish experience with coronary bypass surgery differed from that with CT scanners because of the doubts concerning not only the economics of the surgery, but also its strictly medical worth. Once the decision to implement bypass surgery was made, however, its diffusion process paralleled that of CT. Once again the central question for Swedish planners was: How can this technology be implemented in the most cost-effective fashion? In other words, which tier of the hospital hierarchy is appropriate for coronary bypass surgery? In the case of CT, there was some dispute, since a scanner can be placed virtually anywhere, even in a doctor's office. Bypass surgery is fundamentally different from CT, however, in that it requires enormous ancillary support.

In order to perform this surgery, all the prerequisites for major cardiac surgery—intensive care units, heart-lung machines, blood gas monitoring—are necessary. Given these prerequisites, the sites at which coronary bypass surgery could be performed in Sweden were predetermined—by the location of departments of thoracic surgery, which had already assembled all these resources and equipment for other types of heart operations. These departments, as a result of a consolidation that took place in 1963, were located only at Sweden's four largest regional hospitals.

In designing the framework for the Swedish regional hospital network, Director-General Arthur Engel saw thoracic surgery departments as a special case, noting in his 1958 report that these departments required a "block" of supporting departments: pulmonary medicine, specially equipped cardiology and radiology clinics, and a physiology laboratory for respiratory and circulatory testing (52). At the time of that report, eight hospitals and two sanitoria were equipped for thoracic surgery. Referrals to these institutions from smaller hospitals were erratic. Furthermore, two of the departments had far greater operating loads than the others, some of which had only 10 beds. Engel felt that these inefficient units were best closed, as the minimum effective size for a thoracic surgery department was 25 beds, and the ideal unit was 50 beds (52). This judgment implied that a fifth, interregional tier of the hospital hierarchy would be necessary for thoracic surgery; otherwise if all seven regions were to outfit effective size units, there would be overcapacity. No immediate modifications were made to the newly created regional system, however, so as to ease the passage of the 1958 report.

As explained by Engel, the interregional system for advanced cardiac surgery departments was developed in 1963 (14):

> One amendment to the original plan was made in 1963. It was found inadvisable to carry out advanced cardiac surgery needing extracorporeal circulation and respiration by means of a heart-lung machine at all regional hospitals. This activity is therefore now located in the four largest regions only.

As a result of the 1963 consolidation of thoracic surgery departments, Swedish planners had only four possible sites to choose from for cor-

onary bypass surgery.[15] Thus, in the case of coronary artery surgery, an earlier consolidation of services played a dividend in restraining the diffusion of a then unforeseen innovation—the maxim being "past planning begets the success of future planning."

The decision that coronary bypass surgery was worthwhile and would be done only at select hospitals did not answer the question of how many operations should be performed. For the year 1977, only about 220 coronary bypass operations, or about 27 per million Swedes, were performed. (See table 4.) What limited

Table 4.—Estimated Number of Coronary Artery Bypass Operations Performed in Sweden (1977-79)

Year	Number of operations	Number of operations per million population
1977	**220**	**27**
1978	**300**	**37**
1979	400	50

SOURCE. T. Aberg, Professor of Thoraclc Surgery, The Academ!c Hospital, Uppsala, Sweden, personal communication, December 1979 (2)

Sweden to the relatively low figure of 27 operations per million citizens? Surgical candidates were plentiful. According to the World Health Organization (WHO), the theoretical need for bypass surgery is estimated to be *150* patients per million population (71). Medical manpower was not a limiting factor in Sweden, either. Swedish thoracic surgeons were doing far fewer coronary bypass procedures than the *50* procedures that WHO stated "are required per year per surgeon for adequate professional skill to be maintained" (71).

The immediate limiting factor was the number of intensive care beds available to the thoracic surgery clinics. A certain number of bed-days are allotted to each clinic, which can use them as it sees fit. This allowance was expanded to accommodate what planners saw as suitable numbers of bypass operations. Additional operations would have had to cut into resources for other types of thoracic surgery (l). Swedish thoracic surgeons' response to the Veterans Administration (VA) trial (38), given the limited resources they had, was to try to treat only the most promising candidates with coronary bypass surgery and handle the remainder of angina patients with drugs (26). Surgeons at Uppsala Academic Hospital, who handled roughly one-third of the bypass referrals in 1977, allotted resources for 72 operations. In deciding who received the operation, surgeons considered patients' medical conditions and ages (1).

The level of 27 coronary bypass operations per million population per year, achieved by 1977, was found to be insufficient to treat all the patients that had been selected for surgery. Plans were proposed to incrementally raise the number of bypass operations in Sweden closer to the optimal level of *150* per million per year suggested by WHO, if not beyond (3). At the same time, there was a call in the United States to reduce the amount of bypass surgery.

Viewing the discrepancy in coronary bypass surgery levels in the United States and Europe, Swedish internist Ed Varnauskas arrived at the following conclusion (66):

> With the given indications, the number of operations now performed is probably too high in the USA and too low in Europe. The truth lies somewhere in between.

There are two separate routes for reaching the "golden mean" between underutilization and overutilization of technology. The pattern in the United States seems to be overexpansion followed by contraction. The disadvantage of this path is that resources are wasted. Furthermore, reducing the share of resources allocated to an entrenched medical technology is more difficult than increasing the share allocated to an underutilized one.

Rather than following the pattern in United States, Sweden tends to adopt a "wait and see" approach.[16] In the case of coronary bypass surgery, Sweden's "wait and see" approach was

[15] Although no reliable figure for the number of centers for coronary bypass surgery in the entire United States is available, in 1975, in the State of California alone, 91 hospitals performed cardiac operations (16). California's population, five times that of Sweden's, does not account for the over 20 times greater diffusion of coronary bypass surgery in terms of operation centers.

[16] "The phrase used to describe this policy is "avvaktande hallning" *(54)*, which translates idiomatically as "wait and see."

cost effective but had one major drawback. During the "trial" period, triage was instituted, so many deserving candidates for coronary bypass surgery were not given treatment or put on waiting lists. The success of Sweden's limited approach to coronary bypass surgery, therefore, was very dependent on Swedish citizens' acceptance of rationalization. The "collectivism" orientation that underlies Swedes' willingness to wait their turn has already been noted previously in this chapter. The experience with coronary bypass surgery does not shed additional light on the roots of Swedes' "collectivism" orientation, but does demonstrate how it facilitates the efforts of Swedish planners. Had patients felt they were being denied a lifesaving service and rebelled, the "wait and see" approach might have failed.

Swedish citizens did not feel that a vital service was being denied to them for two reasons. First, the Swedish medical system previously had avoided implementing an innovation—namely, heart transplantation [17]—without disastrous results, perhaps establishing a precedent of good judgment in controlling the diffusion of new operations. Second, definitively lifesaving technologies have not been withheld from Swedish patients—only questionable ones have. A good example of a clearly vital innovation that was not restrained by Swedish planners is that of kidney dialysis.

Renal Dialysis

For examining the diffusion of an innovation, renal dialysis is not as good a specific case study as CT scanners and coronary bypass surgery. CT of the head and the coronary bypass surgery arrived as state-of-the-art technologies at definite times, and few fundamental theoretical improvements on these technologies have been made since. Renal dialysis evolved more slowly, and its gradual diffusion since the late 1940's has been controlled as much by advances in equipment as by specific policies and their effects (19).

Dialysis machines function as kidney substitutes in cases of chronic renal failure. This disorder, when untreated, quite predictably leads to death from uremic poisoning. Demand for dialysis is therefore linked more closely to urgent need and less to subjective medical referrals than are CT and coronary bypass surgery. As a lifesaving technology for which demand originates largely from objectively rather than subjectively determined need, renal dialysis is a valuable reference point.

Swedish planners made this technology readily available to individuals that needed it (5). The planners' policy of meeting the demand for this clearly lifesaving technology contributes to the confidence citizens have in their judgment. This faith in turn allows rationalization of more questionable technologies without major objections by Swedish patients.

Table 5 shows the number of Swedish patients receiving renal dialysis and kidney transplants by region in 1978. Reliable statistics on renal dialysis for identical years in the United States and Sweden are difficult to obtain, but during the year 1977, both countries had roughly 100 persons per 1 million population on dialysis (39,55). The fact that the rates for dialysis in the countries are comparable suggests that when Sweden does not make attempts to restrain technologies, dialysis being a case in point, they proliferate to a similar extent as in the United States. Using the dialysis baseline, it is justifiable to attribute at least some cross-national discrepancy in the levels of CT and coronary bypass surgery in Sweden and the United States to Swedish planners' success in actively seeking to restrain the influx of these two technologies.

Cobalt Therapy

Cobalt therapy units are rationalized in Sweden through the hospitaI regionalization planning mechanism. The decision to have such a unit requires national approval of the physician staffing at the hospital and local approval for construction and operating costs. This mechanism for rationalizing cobalt therapy fits well into the regionalized structure of hospital care in Sweden. There are 28 cobalt machines in Sweden, about 3 per 1 million population.

[17] It must be added that the decision against beginning with heart transplantation hinged on Sweden's definition of brain death (which is uniquely stringent), not on a socioeconomic opinion that the operation would be unrewarding.

Table 5.—Number of Renal Dialysis and Renal Transplant Patients in Sweden by Region (Oct. 31, 1978)

Region and population (in millions)	Renal dialysis patients		Kidney transplant patients	
	Number	Number per million population	Number	Number per million population
Stockholm (1.568)	137	87	180	115
Linköping (0.6)	86	136	41	65
Lund (1.524)	140	92	80	52
Malmö (0.250)	27	108	19	76
Göteborg .. Vanersborg (1.499)	57	38	116	77
Örebro (0.810)	43	53	36	44
Uppsala (1.075)	69	64	71	66
Umea (0.908)	43	47	75	83
Total	602	73	618	75

SOURCE: J. Allmén, Section of Nephrology, Medical Clinic I, Sahlgren's Hospital, University of Göteberg, Sweden, personal communication, January 1979 (6)

Automated Clinical Laboratories

Decisions regarding automated laboratory testing in Sweden have been left up to local county councils as part of the capital equipment budgeting process. There are no specific national guidelines.

CONCLUDING REMARKS

Unique features of Swedish culture, history, and the organization of medical care have set the stage for careful and systematic evaluation of new medical technology. The regionalization of hospital services, the respect for government planners, the county and national control of medical care costs, the homogeneity of Swedish culture, and the existence of SPRI, a central advisory group, make possible in Sweden the timely review of new medical technology.

Decisions concerning automated laboratory testing have been made at the local (county) level. The control of cobalt therapy and coronary bypass surgery was achieved through the regionalized hierarchy of hospitals. A new departure from the control of medical technologies through the budgetary, staffing, and regionalization processes was SPRI'S systematic and timely analysis of costs and benefits of the CT scanner. SPRI'S evaluation of that new medical technology provides an example worthy of emulation.

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11.

Summary and Analysis

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11.

Summary and Analysis

INTRODUCTION

The preceding chapters of this volume have described the po licies and mechanisms used to manage medical technology in nine industrialized countries: the United Kingdom, Canada, Australia, Japan France, West Germany, the Netherlands, celand, and Sweden. This chapter describes the policies and mechanisms used in the United States and then compares these with those of the other countries. (An overview of medical technology development and use in the United States appears in table 1.) The purpose of the analysis is twofold: first, to draw out

Table 1 .—Medical Technology Development and Use in the United States: Formal Programs of the U.S. Department of Health and Human Services[a]

Technology's stage of development	Policy area and Government activityb	Responsible agency or program
Research and development	Support, conduct, and plan basic research	National Institutes of Health, others[c]
	Support, conduct, and plan applied research	National Institutes of Health, other agencies and programs
Demonstrate ion of safety, efficacy, and cost effectiveness	Support or conduct clinical trials . test safety • test efficacy • protect human subjects	National Institutes of Health, others[c]
	Ensure efficacy and safety of drugs and devices • control of testing procedures . postmarketing surveillance	Food and Drug Administration
	Provide economic analyses • cost-benefit analysis • cost-effectiveness analysis	National Center for Health Care Technology National Institutes of Health[d]
	Evaluate social, ethical, political impacts . technology assessment	National Center for Health Services Research
Diffusion	Regulate market approval of drugs and devices	Food and Drug Administration
	Encourage distribution by information dissemination	National Institutes of Health[d]
	Control distribution through certificate of need, review of purchase	Health Resources Administration
Widespread use	Ensure appropriate use	Professional Standards Review Organization certification programs
	Monitor practice	Professional Standards Review Organizations
	Reimbursement for health services • define benefits package • set reimbursement levels	Medicare[f] Medicaid[g]

[a]Formerly the Department of Health, Education, and Welfare.
[b]The Federal Government's role in the development and use of medical technologies is generally strongest in the initial stages of a technology's development, becoming progressively weaker in the stages that follow.
[c]Agencies and programs other than the National Institutes of Health have limited responsibility in this area.
[d]The National Institutes of Health has limited responsibility in this area.
[e]Professional Standards Review Organizations have limited responsibility in this area.
[f]Medicare provides reimbursement for the elderly.
[g]Medicaid provides reimbursement for the poor.

SOURCE: Office of Technology Assessment.

common patterns in the various countries' appreaches to managing medical technology where such patterns exist; and second, to delineate differences in approach where there are interesting and important exceptions to the patterns.

The discussion is organized in five sections. The first four sections discuss, in turn, government policies toward 1) R&D, 2) evaluation, 3) safety and efficacy regulation, and 4) investment in and use of medical technologies. The fifth section examines the U.S. and other countries' policies toward five specific medical technologies: computed tomography (CT) scanners, renal dialysis, coronary bypass surgery, cobalt therapy, and automated clinical laboratory testing. Data concerning these technologies have been drawn from the chapters in this volume and from other sources. [1]

IThe chapters on individual countries in this volume are not referenced in this chapter. Unless otherwise noted, material is taken from these chapters.

RESEARCH AND DEVELOPMENT

In 1979, the world's total public and private R&D budget was estimated to be about $150 billion (31). About one-third of that amount was invested by the United States, and another third by Western Europe and Japan combined. Overall, from 7 to 10 percent of the total was spent on R&D related to health (2,31).

Since World War II, governments over the entire industrialized world have become deeply involved in supporting R&D of all kinds. In 1979, the U.S. Government spent almost $30 billion on R&D, making up about two-thirds of the country's total investment. Governments of other industrialized countries spend proportionately comparable amounts. In Britain and France, for example, more than half of the R&D effort is supported by public funds (31). Although government funds in Japan amount to less than 25 percent of the country's total investment in R&D (31), the special relationship between government and industry there gives government planners more power over R&D than that figure suggests. The actual amounts invested by different countries in R&D vary. In 1970, for example, the percentage of gross national product (GNP) invested in R&D ranged from 0.5 percent in Canada to 1.6 percent in the United States (36). The per capita expenditure on health R&D in 1969 ranged from more than $6 in the United States to less than $1 in the United Kingdom (36).

According to the Organization for Economic Cooperation and Development (OECD), despite substantial government support, R&D generally has been going through a difficult period (36). During the 1950's and 1960's, a preoccupation with economic growth led to an attitude on the part of the general public that almost all R&D should be encouraged. By the end of the 1960's, however, with heightening interest in the proper utilization of human and environmental resources, there emerged a desire on the part of the public for science to attack problems more directly related to the achievement of these goals. Since that time, governments of industrialized countries have attempted to exercise greater selectivity in making R&D investments and to bring about relative or absolute reductions in the amounts that they devote to R&D (30).

The increasing emphasis on social goals for R&D has helped to foster increasing support for health R&D (36). Numerous countries have declared health R&D to be one of their top priorities in coming years. In 1975, OECD found that among 12 OECD countries, including the United States and Japan,[2] health ranked number seven overall among priorities for R&D investment (36). Furthermore, among the new social objectives that became prominent during the 1970's— including public welfare, community services, and pollution abatement—health ranked number one. With health services taking a growing share of GNP, some countries are interested in the contribution that health R&D can

'The 12 OECD countries are Belgium, Canada, France, West Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden, the United Kingdom, and the United States.

make to strengthening the general economy. This is particularly true in the Netherlands, which exports 90 percent of its medical technology.

In the United States, health R&D represents about 11 percent of the total Federal R&D expenditure, a higher percentage than in most industrialized countries.[3] A number of U.S. Federal agencies fund R&D related to health, with a total budget of about $3.8 billion in 1978 (27). Of these, the National Institutes of Health (NIH) is predominant. With a 1978 budget of $2.6 billion, NIH supports about two-thirds of the entire Federal effort. Private industry in the United States also supports R&D related to health. In 1978, U.S. industry invested an estimated $1.8 billion in health-related R&D. Of this amount, $1.3 billion came from pharmaceutical companies, and the remainder from instrument and supply companies. Industry is also important internationally.

The allocation of moneys in Government research programs in the United States is essentially a political process, with Congress playing an active role in setting overall priorities. Biomedical research policies in the United States have been well described by Strickland (47), and more recently, by Rettig (40) and Springarn (46). During the second half of the 1970's, NIH came under pressure from many sources to fund nontraditional research more related to societal goals, such as epidemiological research, social science research, and nutritional research (49,50). Research to evaluate medical technology, described in the next section of this chapter, also falls into this category.

In countries other than the United States, central government agencies that support and carry out biomedical research do exist, but probably none of these agencies is as dominant and autonomous as NIH. Among the 12 OECD countries cited earlier, only half have a central government budgetary mechanism for biomedical research (36). Australia, Japan, France, and the Netherlands invest their public funds through a central mechanism, usually through the Ministry of Health or its equivalent. Most publicly funded biomedical research is done either in intramural institutions (i. e., government agencies or institutes) or in the higher education sector.

In the United Kingdom, Canada, and Sweden, independent medical research councils play an important role in funding biomedical research and insulate such research from direct government controls. West Germany has a particularly decentralized system, in which the State governments play an important role. Most federally funded research is carried out in quasi-autonomous research institutes. In all countries, much research is carried out by academicians in university hospitals who are funded by service moneys through health insurance. As in the Netherlands, university hospitals have higher tariffs than others, and this money subsidizes research.

How priorities are set in the government biomedical research programs of various countries has not been well described (40). Given the decentralized nature of the R&D system, the large private involvement, and the autonomy of academic teaching hospitals, the possibilities for control are limited. Furthermore, the scientists themselves play a large role in setting priorities through research councils or, as in France, by giving advice to the government. According to Klein, biomedical research priorities in Britain have tended to be shaped by the interests of the research community rather than by an appraisal of what type of research would yield the greatest dividend to the community at large (20).

In some countries, however, there are indications that the interests of the public are increasingly being considered in determining biomedical research priorities. France has perhaps gone the furthest in setting explicit priorities. In addition, the "war on cancer" in the United States resulted from public demands that research be addressed to specific needs (39). In Belgium, the government has been concerned with the effect of drugs (36). The stated objective of the Ministry of Research and Technology in West Germany is to develop medical technology that will improve patient care, reduce side effects, and be more cost effective. Finally, the development of

[3] Some industrialized countries spend considerably less. In 1972, for example, Japan spent only 1.8 percent of its public R&D funds on health; the comparable figure in the United Kingdom was 1.9 percent *(36)*.

the CT scanner was funded by the Department of Health and Social Security in the United Kingdom because of its promise for improving quality of care through better diagnosis.

Biomedical R&D, wherever it is carried out, has implications for all countries. The international impact of the CT scanner developed in Britain and of renal dialysis developed in the Netherlands clearly shows this. In many cases, therefore, the critical decision for policymakers will be how to react to a new medical technology developed elsewhere—not whether and when to develop it.

EVALUATION OF MEDICAL TECHNOLOGY

One type of health-related research that has been gaining visibility is the evaluation of the benefits, risks, and costs of medical technologies. In the United States, no Government agency has had a clear mandate to perform such evaluation until recently. Examining the situation in 1977, OTA found that there had been little research done on the efficacy and safety of medical technologies (33). In many cases, available evaluation methods had not been applied.

By far the largest of the U.S. Federal Government agencies that were performing some evaluative work, OTA found, was NIH, which supports such work as part of its general research mandate. In 1975, NIH supported about 755 clinical trials at a cost that year of about $100 million (33). In 1976, it spent $147 million on 926 clinical trials (29). The priorities of these NIH-sponsored studies, in terms of the types of technologies being evaluated, were heavily skewed toward cancer therapies, especially drugs. Few surgical procedures, diagnostic technologies, or preventive interventions were being evaluated. Noting the lack of knowledge about the efficacy and safety of many medical technologies, OTA suggested a mandated program to evaluate medical technology.

In October 1978, Congress passed legislation establishing the National Center for Health Care Technology (NCHCT). Besides carrying out and supporting evaluation studies, NCHCT has responsibility for coordinating research on medical technologies to ensure that important studies are funded. In particular, it is supposed to see that the information needs of programs such as the health planning program are met. NCHCT also has a statutory mandate to provide advice on the coverage of benefits to the medicare and medicaid programs, the major public health insurance programs that pay for medical care for the elderly and the poor. Since its inception, NCHCT has devoted **a** great deal of effort to performing this function, although its effect on the development, diffusion, and use of medical technology is unknown.

The issue of the need for more evaluation of medical technology is also becoming more visible in a number of countries other than the United States, but investments in this' type of research appear to be small. The highest priority for evaluation in other countries also seems to be drugs (33). A number of voluntary institutes evaluate medical devices in other countries, but the evaluations tend to be technical (i.e., they deal with such matters as safe design to prevent electrical shock, but not the question of health benefit from use of the device).

OTA was unable to identify **data on the amounts various countries spend on evaluation studies** in health care. Furthermore, such studies are not specifically budgeted and must compete with other types of health R&D. With respect to the performance of randomized clinical trials (RCTS) in various countries, Cochrane has commented (8):

> If some such index as the number of RCTS per 1,000 doctors per year for all countries were worked out and a map of the world shaded according to the level of the index (black being the highest), one would see the U.K. in black, and scattered black patches in Scandinavia, the U. S. A., and a few other countries; the rest would be nearly white.

As shown in table 2, Cochrane's observations concerning the unequal distribution of RCTS

Table 2.—Distribution of Randomized Clinical Trials of Gastrointestinal Therapies by Country (1964-74)

Country[a]	Number of trials	Percentage of total	Number of trials per million population	Country rank by number of trials per million population
United Kingdom	83	27.1 %	1.48	2
United States	75	24.5	0.34	6
Italy	16	5.2	0.28	
West Germany	15	4.9	0.24	8
Japan	13	4.2	0.11	10
Denmark	11	3.6	0.46	4
South Africa	10	3.3	0.38	5
Australia	9	2.9	0.64	
France	7	2.3	0.13	9
Norway	7	2.3	1.75	1
Other countries	52	16.9	—	—
International trials	8	2.6	—	—
Total	306	100.O%	—	—

[a]Ranked by absolute number of trials.

SOURCE: E. Juhl, et al., "The Epidemiology of the Gastrointestinal Randomized Clinical Trial," *N. Eng. J. Med.* 296:20, 1977 (19)

among nations have been generally confirmed with independent data on trials of gastrointestinal therapies. Although one should not overemphasize their generalizability,[4] the findings presented in this table are in accord with the reputation of different countries. In particular, the high ranking of the United Kingdom, both in numbers of trials and in trials by population, is consistent with Cochrane's statement. The low ranking of France and Japan, and the intermediate ranking of West Germany and the United States, are similarly in accord with anecdotal evidence.

Because their results are often used in countries other than the country of origin, controlled clinical trials obviously have international implications. It might be noted that, in terms of conducting clinical trials of gastrointestinal therapies, the United Kingdom is carrying a burden disproportionate to its size. The number of trials conducted in the United States is relatively large, although the number of U.S. trials per million population is small. The lack of Canadian trials of gastrointestinal therapies in table 2 may be attributable to Canada's dependence on data from trials conducted in the United States. Although the international importance of U.S. clinical trials may be an argument for expanding their funding, it also points to the need for other countries to begin sharing more of the burden of evaluating medical technologies. Smaller countries that might have problems producing a large enough sample for a study could make financial contributions to help ensure that important technologies are studied.

The small number of international trials in table 2 is also of interest. Currently, there is considerable discussion of expanding international studies (48). An international European study of coronary bypass surgery was carried out in the mid-1970's. In 1979, there were discussions about initiating a trial of electronic fetal monitoring coordinated by the European Common Market Commission.

On the basis of the information presented in the other chapters of this volume, it appears that few evaluative studies other than randomized controlled clinical trials are done in either the United States or other countries. Deserving of note, however, is that the French and Australian Governments have begun to fund cost-effectiveness studies for the purpose of influencing policymaking. A number of coun-

[4]Since the literature review that yielded the data in table 2 was done from the U.S. Medlars System, it may not have represented journals from all countries equally, but instead emphasized English-language journals.

tries have analyzed the role of CT scanning. An independent cost analysis by the Swedish Planning and Rationalization Institute apparently led county governments to approach the purchase of CT scanners with considerable caution. Some scanners in France have been approved only for institutions that have the capability to do evaluative studies.

Another important activity related to the evaluation of medical technology is synthesizing and drawing conclusions from existing knowledge. In the United States, where organizations such as insurance companies are increasingly involved in the delivery of health care, clear-cut conclusions about the benefits and risks of technologies are essential. Traditionally, syntheses of existing knowledge in the United States have been done in a very informal manner. Many different Federal Government programs do such syntheses. In an effort to make the synthesizing processes more formal and more open to public view, NIH has been experimenting for several years with a process that it calls "consensus exercises. " NIH brings together various experts and gives them the best scientific information that can be found; these experts then arrive at consensus recommendations concerning such matters as the appropriate use of specific technologies (e.g., electronic fetal monitoring and mammography). These consensus exercises, however, are still in an experimental stage.

In all the countries discussed in this volume, activities to synthesize existing knowledge about medical technologies, unlike formal experimental evaluations, are common. In England, physician consensus often substitutes for either scientific evaluation or public involvement in decisionmaking (20). In Canada, guidelines for new and expanded facilities in hospitals are frequently developed by special task forces comprised of Federal and Provincial officials and outside medical consultants. More or less the same situation has been noted in West Germany, France, Australia, and Sweden.

Although the countries in this volume have done little to assure the timely evaluation of medical technologies, the issue of the need for such evaluation has become visible in all of them. Furthermore, a number of countries, including France, West Germany, and the Netherlands, are considering expanding their evaluation activities. In Australia, a new system has been proposed that would include a national expert committee to give advice on medical technology and a central repository of information on medical technology. It seems certain that activities to evaluate medical technologies will continue to expand.

REGULATION OF DRUGS AND DEVICES FOR SAFETY AND EFFICACY

Virtually every country discussed in this volume has mechanisms to regulate the safety and efficacy of drugs. These regulatory mechanisms have evolved because the production and sale of drugs in capitalist countries is primarily the responsibility of private enterprise (41), and although the private enterprise system has led to many advances in modern medicine and has made high-quality drugs accessible to the general population, it has also resulted in harm. **A law** to regulate safety of drugs sold in the United States, the U.S. Food, Drug, and Cosmetic Act of 1938, was enacted in response to a 1937 disaster in which 358 people died from ingesting a drug ("elixir of sulfanilimide") that was sold in a solvent of diethylene glycol, which caused kidney damage. The law initiating the regulation of drugs for efficacy in the United States, the U.S. Food and Drug Amendments of 1962, also followed a disaster, this time involving serious birth defects caused by the drug thalidomide. The historic pattern of first regulating drugs for safety, and later for efficacy, has also apparently been followed by other countries.

The U.S. Government agency with responsibility for the regulation of drugs for safety and efficacy, along with the regulation of their man-

ufacture, is the Food and Drug Administration (FDA). When a drug company has a drug that it wishes to test in humans, it must submit data from preclinical testing in animals to FDA. If FDA agrees that the drug looks promising, it approves the sponsoring company's "investigational new drug" application to permit the drug to be tested in humans. When sufficient data have been accumulated from controlled clinical trials and other tests in humans to show that the drug is efficacious and safe, or that the benefit/risk ratio is favorable, the company submits a "new drug application" to FDA. If FDA finds the data convincing, it allows a drug to be marketed.

Once a drug is on the U.S. market, FDA has little control over its use or evaluation. Processes for collecting information on the safety (rare adverse reactions, long-term effects) and on the indications for use of drugs on the market are very limited and for the most part voluntary. It also should be noted that although drugs are usually tested for specific clinical indications, and their use is often approved only for those indications, such products are frequently used for other indications. Anesthetics used in childbirth, for example, have not been tested for that indication and are not explicitly approved by FDA for that use.

In countries other than the United States, controls of the marketing of drugs based on efficacy and safety are similar to controls in the United States, but are generally not as rigorous. Indirect controls are often more restrictive than direct ones. In France, for example, a decision must be made to place a specific drug on the reimbursable formulary of the Social Security System. To be placed on this list, a new drug must either be more efficacious, have fewer side effects, and/or cost less than another drug on the formulary. In Japan, fees to cover the prescribing of drugs are set yearly. In recent years, the fees have been reduced each year, perhaps in part in an attempt to lower the incentive for drug prescribing. In Australia, the pharmaceutical benefits scheme does not cover all drugs on the *market.*

Some countries do have postmarketing regulation of drugs. A system for collecting information on adverse reactions to drugs on the market has been set up in Japan, where there is great concern about safety. Canada also relies primarily on a postmarketing surveillance system to regulate drugs. Postmarketing surveillance, either in combination with premarketing controls or as a specific approach, has a number of advantages, One is that it allows the collection of data from the real-world setting where drugs are used. Another is that it enhances flexibility.

In recent years, there has been increasing discussion in the United States about relying more on postmarketing controls on drugs and relaxing the premarketing controls a bit. The drug approval process used in the United States since passage of the 1962 Food and Drug Amendments has demonstrably lengthened the time required for approval of a new drug. DeHaen studied the time required for a drug to move through the "pharmacology, clinical study, government review to marketing" pipeline in four European countries and the United States (11,12). Looking at 42 drugs, he found that the 12 drugs that became available before 1962 were marketed about as rapidly in the United States as they were in Britain, France, Italy, and West Germany. For the 30 drugs introduced since 1962, however, the story was quite different. The number of years required between introduction and marketing of these products was lowest in Britain, next lowest in France, third lowest in West Germany, higher in Italy, and highest in the United States. A1l post-1962 applications in Britain, France, and West Germany were approved within 2 years, but in the United States, only 17 of 23 drugs were approved in that span, and 4 of the 23 drugs took 4 years or longer to gain approval.

The basic findings that the United States tends to lag behind other countries in licensing of drugs and that the U.S. drug lag is in part attributable to FDA's regulatory program has been confirmed by a considerable body of literature (16,37,45,52,53), which has been summarized by Schifrin and Tayan (44). The following conclusions can be drawn. First, drug lag exists to some extent in every country. Second, drug innovation, as measured by the number of new chemical entities marketed per year, has de-

clined since 1960 in all countries. Third, the United States tends to lag somewhat behind other countries in its marketing of drugs, but it also **has** drugs that are marketed very early. Fourth, the United States has had the most productive private drug R&D effort in the world.

Peltzman used a broad framework to analyze the effects of the lag in drug marketing in the United States, and concluded that the negative effects of forgone health benefits and higher prices resulting from reduced competition caused by the lag outweighed the positive effect of reduced waste from purchases of ineffective drugs by $3oo million to $4oo million in 1970 alone (37). It is important to note, however, that Peltzman made no adjustment for the value of additional information gained about adverse reactions during the extended premarketing period. As Schifrin and Tayan observed (44):

> With some estimates of the annual hospital costs of drug reactions ranging into the billions of dollars, it is plausible to suppose that even fairly small percentage net reductions in new drug adverse reactions and interactions may have brought a benefit of large dollar magnitude, which . . . might change Peltzman's conclusion of a large net negative result to a smaller one, or even to a net positive balance.

Unfortunately, the literature on drug regulation that is available does not answer some of the most important questions. One is whether there is any relationship between the development of drug regulatory programs and the decline in drug innovation. It is not clear that there is. A second question concerns the overall impact of drug regulatory programs on the health of the public. That impact cannot be assessed. Deaths and disability that result from unsafe drugs are highly visible. Thus, the thalidomide disaster in Europe, which led to enactment of the 1962 U.S. Food and Drug Amendments, is often cited as evidence of the need for drug regulation to protect the public. On the basis of data from uncontrolled clinical trials, thalidomide was allowed to be marketed in West Germany in 1956 as a safe, effective, sleep-producing sedative drug. By the time the link between thalidomide and deformities in babies whose mothers had taken the drug while pregnant was established in 1961, an estimated 6,000 to 8,000 cases of deformity had occurred in West Germany (22).[5] Less visible, though no less important than deaths and disability that result from unsafe drugs, however, are deaths and disability that result from delaying the marketing of new and better drugs. Striking a reasonable balance between the two is a difficult task for policymakers.

Given the lack of data to answer the important questions concerning the impact of drug regulation, social policy must be based on wise judgment. At the moment, the international trend seems to be toward more rigorous regulation of drugs. In 1965, the Council of the European Economic Community (the European Common Market) issued a directive aimed at developing common procedures for drug regulation among its member countries (9). Although at that time, West Germany had a rather weak law, in 1976 it set up a structure similar to FDA's and began to require evidence of efficacy of drugs from well-controlled studies. (West Germany's new law was implemented beginning in 1978.) In the United States, FDA has attempted to cut down on the long periods of time required for approval of drugs and has participated in developing amendments to the Food, Drug, and Cosmetic Act that would expedite the approval processes. FDA is also seeking authority to expand its use of postmarketing drug evaluation mechanisms.

The regulation of medical devices in the United States, like the regulation of drugs, is primarily accomplished through premarketing controls. FDA is authorized to regulate medical devices under the Medical Devices Amendments of 1976. Since medical devices do not always come in contact with the human body, FDA's system for regulating devices is somewhat different from its system for regulating drugs. Devices are classified into three types, classes I, II, and 111. Class I devices are those that are not used to support or sustain human health (e.g., tongue depressors), and these are subject only to

[5] Although thalidomide was not approved by FDA for marketing in the United States, the drug was readily sold in the United Kingdom and Japan, and it was 1962 before it was withdrawn from the Japanese market (22).

general controls. Class II devices are those for which general controls are deemed insufficient to provide assurance of efficacy and safety (e.g., X-ray devices) and about which enough is known to establish performance standards. Class 111 devices are those that are used to support or sustain human health (e.g., cardiac pacemakers), and like drugs are required to be tested in clinical trials and to have premarket approval. (The 1976 medical devices law is still being implemented.)

Other countries do not ordinarily regulate medical devices directly. One exception is Japan, which has established performance standards for a number of medical devices through its industrial laws. Another is Canada, which has a program for postmarketing surveillance of devices that includes the power to require modification or withdrawal of a product. Even without direct regulation, however, evaluation of medical devices in other countries is common. In England, for example, the Medical Research Council often funds such evaluations. There also appears to be discussion in some countries about changing the situation with regard to the regulation of medical devices. In West Germany, for example, there is considerable interest in the U.S. devices law and in the possibility of legislating a similar program for West Germany.

CONTROLS ON INVESTMENT AND USE

When a new technology moves out of the laboratory and begins to enter everyday medical practice, the diffusion phase has begun in earnest, and institutions and practitioners must decide whether to invest in the technology and how extensively to use it. Most or all of the population in each of the countries discussed in this volume has extensive medical coverage provided through some sort of public program, through private insurance, or a combination of the two. As a result, decisions regarding the adoption and use of technology in the medical sector are not constrained—as they often are in other sectors—by the preferences and incomes of individuals. Collective constraints, however, have been introduced as a matter of public policy in every country—most often in response to the rising costs of medical care. In many cases, the policies are quite recent and have not yet had time to be fully worked out. Their efficacy and side effects, like those of some of the technologies they regulate, are not always known.

Collective constraints on the adoption and use of medical technologies can be generally characterized as either direct or indirect. Direct constraints come in the form of prohibitions against the adoption or use of a technology or detailed specification of the circumstances under which the technology may be adopted (e. g., a requirement that only hospitals with open-heart surgery units may have cardiac catheterization laboratories). Indirect constraints are most often financial. These come in the form of decisions by authorities external to the institution or practitioner, for example, a State government or an insurance fund, about the budget or fees to be permitted, Decisions about fees include whether to reimburse for the use of the technology at all, and, if so, how much. Fees can be coupled with conditions (e. g., that the use of the technology will be reimbursed only for patients with specified symptoms, or reimbursed only if the work is done by certain specialists) that make them little different from direct constraints. Another form of indirect constraint is offered by manpower policies. Through controls over the numbers of health professions students, the kind of training they receive, and the kinds of posts available for them when they graduate, governments can influence the climate for a new technology.

The United States has so far emphasized direct controls. Some of the controls grew out of the requirement that States draw up statewide plans for hospital construction in order to receive construction subsidies under the Hill-Burton program created by the Hospital Construction and Survey Act of 1946. In 1966, Federal

legislation created a network of comprehensive health planning agencies, voluntary agencies that were to draw up plans for the development of health resources in their areas. Initially, these agencies were given no power to carry out their plans. Over time, however, individual States legislated certificate-of-need laws requiring State approval of major capital investment by hospitals, and the planning agencies were often asked to give advice on applications from their areas. Three States passed such laws in the 1960's, and quite a few more did so in the early 1970's. Federal legislation passed in 1972 stipulated that medicare and medicaid would not reimburse the depreciation charges for any investment that had not been approved by the appropriate planning agency; this law strengthened the certificate-of-need process in those States that had one and was used to set up a review process in a number of other States as well.

These strands were brought together in the National Health Planning and Resources Development Act of 1974. That Act designates State health planning agencies and approximately 200 health systems agencies (HSAS) to replace the voluntary agencies created in 1966. Each of the new HSAS has responsibility for a relatively self-sufficient catchment area[b] and is required to develop a plan for health resources in that area. These plans form the basis for a statewide plan. The major power to implement these plans resides with the State: The 1974 Act requires that every State enact a certificate-of-need law. To guide the process, the U.S. Department of Health and Human Services (DHHS)[7] has set out the features that a State's certificate-of-need law must have and is responsible for publishing guidelines for the appropriate supply and distribution of health resources.

Although the U.S. health planning law was passed in 1974, its provisions are still being worked out. Some States have still not agreed on a certificate-of-need law, and Federal guidelines were first published March 1978 (28). The 1978 guidelines set the standard for non-Federal short-term hospital beds at a maximum of four per 1,000 persons, with an occupancy rate of at least 80 percent. They also set standards for the occupancy rates, or minimum caseloads, for a number of specialized facilities, such as neonatal intensive care units, radiation therapy, and renal dialysis. Planning laws often take a long time to put into practice, and the United States' experience with planning is similar in this respect to the experience of other countries.

Another form of direct control in the United States, aimed in this case at the use of technologies rather than at investment decisions, is the network of Professional Standards Review Organizations (PSROS). Created by the Social Security Amendments of 1972, PSRO'S are organizations — usually groups of physicians—designated by DHHS to review the care given medicare and medicaid patients for necessity and quality. Their first assignment has been hospital care. If a PSRO decides that a patient does not need to be in the hospital, medicare or medicaid refuses to pay. PSRO reviews could be directed at the use of particular technologies in the hospital, but so far they have not been.

Reviews of incoming bills are carried out by private insurers, of course, and also by medicare and medicaid. These reviews are usually for the purpose of trying to hold down costs by catching fraudulent claims and suspicious patterns of services by individual physicians or hospitals. In some cases, however, third-party payers have adopted reimbursement policies that have a bearing on the use of medical technologies, Perhaps the best example is the Blue Cross/Blue Shield "medical necessity" program, in which Blue Cross/Blue Shield determined that certain services would no longer be reimbursed because they are believed to be ineffective and that others would be reimbursed only in certain specific situations.

Interest in financial controls in the United States has been growing, but such controls have not been extensively used. DHHS has been cautious in using its power, legislated in 1972, to set hospital reimbursement rates for the medicare program, and has so far only regulated routine, or "hotel," costs. A few States have created

[b]The average HSA has jurisdiction over a population of about 1 million, but the range extends from less than 100, OOO to more than 7 million.

[7]Formerly the Department of Health, Education, and Welfare.

ratesetting commissions to review hospital budgets and establish reimbursement rates. But the major effort in this line, the Carter administration's hospital cost-containment bill, was rejected by Congress. That legislation would have specified a maximum rate of increase each year for the revenues of individual hospitals.

The only example of a manpower policy aimed at the diffusion of technologies in the United States is now a footnote in history. The regional medical program, passed in 1965, was supposed to promote the adoption and use of technologies for the treatment of heart disease, cancer, and stroke; renal dialysis was added to the list in 1970. The principal means available to the program was training; the regional agencies financed many short courses to train physicians and nurses in the use of specific technologies. (Intensive care received particular emphasis.) But as costs became a greater concern, the active promotion of technological diffusion began to seem out of place, and Congress terminated the program in 1975.

Policies in other countries follow a variety of patterns and have been in place for quite different lengths of time, but there are many points of overlap in both the types of controls used and the timing of their introduction. Direct controls on investment (usually referred to as regulation or planning) and budget constraints are the dominant policies. Direct controls are usually aimed at large items of expenditure (e. g., at investments involving more than $150,000 in the United States (less in some States), more than 5,000 ($11,000 to $12,000) in the United Kingdom, or with an expected life of more than 3 years in West Germany). Smaller items may be outside the system of controls altogether or may be subject to general constraints through limits on operating budgets.

Budget constraints may allow the planning process to be more informal, with fewer specific directions and sanctions from the top, because they limit the consequences for costs of whatever decisions are made. Strictly enforced budget limits force planners to trade off the costs of one proposal against another, These statements appear to apply, for example, to the United Kingdom. A national budget for the National Health Service (NHS) is allocated to the health service regions, and the regions are responsible for decisions about how the money is to be used. There seem to be few, if any, direct prohibitions from the Department of Health and Social Security (DHSS). As Stocking relates, DHSS does intervene—sometimes extensively—with information, advice, and occasionally, subsidies to encourage particular policies; this intervention has been unusually frequent and extensive in the case of dialysis. But the advice, and even the offered subsidies, can be and are ignored by the regions. There has apparently been some dissatisfaction with the informal process, however, and a more formal process of planning within each region was introduced along with the reorganization of NHS in 1974. That planning process, according to Stocking, is still not in place and is having "teething troubles. " More recently, the creation of a committee to set policies on equipment and supplies has been recommended.

The Canadian system also places first reliance on budgetary constraints. Because of Canada's Federal-State system, there is no nationally set budget, but the Provinces are encouraged to limit spending by the fact that the Federal share of costs, once 50 percent of whatever was spent, has since 1977 been allowed to grow only as fast as the GNP. The Provinces set operating budgets for hospitals, and provide capital funds separately; capital subsidies are available from the Federal Government, but not according to the same generous matching provisions as operating funds. The planning process that goes on within these budget constraints can be detailed—equipment specialists at the Provincial health department may determine which machine is finally bought—but Needleman describes it as informal. It is sometimes ignored. In Ontario, for example, Provincial approval of a project often does not bring extra money with it—the hospital is expected to finance the purchase out of its existing budget—and hospitals sometimes choose to go ahead with a project without getting approval.

Australia and West Germany appear to have elements of planning and budget controls, but in

these countries the policies are much more recent, and as a result, much less clear in their operation. Australia has the potential for control over the adoption of hospital technologies through its largely public hospital system. The system receives most of its funds from the States and the Commonwealth. The Commonwealth's share of these costs has been changed often and by large amounts during the 1970's; it was greatly increased under the national health program introduced in 1975, and has been greatly decreased since the reversal of that program a year or two later. The States provide capital funds and must approve proposals for capital expenditures. When operating funds were easily available through the Commonwealth subsidies, the capital planning process did not impose many limits on investment in new technologies. In the new, less affluent climate, that may be changing.

Planning was introduced in West Germany by a 1972 law under which the West German Government supplies the funds for long-lived capital equipment. The States are required to engage in planning, and hospitals' applications for funds are submitted to the States. Currently, the focus of the planning process is on hospital beds, but applications. also involve technologies, and planning can potentially include them. Dumbaugh states that a major stumbling block has been lack of information about even so much as the current distribution of particular technologies. The State governments have some financial control through their power to set hospital per diem rates to be reimbursed by the insurance funds. Until very recently, however, when costs began to rise very rapidly, the rate-setting process was not used to try to restrain costs. In 1977, financial controls were expanded by a law giving the government the power to set guidelines for the amounts that can be paid doctors and other health practitioners (15).

In the Netherlands, the national government has some control over investments in technologies through the Hospital Provisions Act of 1971. A good deal of investment falls outside the jurisdiction of this law, however, and the Netherlands Government has recently proposed legislation to extend its powers in this area and to give it greater power to set rates as well.

In France, the Hospital Reform Act of 1970 created a quite detailed system of planning and regulation of technologies. Under the law, the Ministry of Health prescribes the maximum ratio of equipment to population for specific items such as dialysis machines, linear accelerators, and CT scanners. This system of direct controls appears to be the major form of governmental intervention in the diffusion process, and like many planning systems, it is taking time to put in place. In the last few years, the French Government has become increasingly interested in financial controls as well, and it is experimenting in particular with global budgets.

Every country discussed in this volume uses some concept of regionalization— the idea that facilities should be planned for an entire region, or State, or Province in order to avoid needless duplication of highly specialized facilities. In Sweden, however, regionalization is the major component of policy toward medical technology. Institutions are designated as belonging to one of four ascending levels in a hierarchy—health centers, district hospitals, central hospitals, and regional hospitals—and the designation carries a certain weight when decisions are made about where to place new technologies. The counties finance the hospitals and have primary responsibility for making such decisions. The Swedish Government's influence over the process is exercised through its encouragement of regionalization, its emphasis on providing information relevant to the decisions in good time, and through its power to allocate staff positions in hospitals. The counties have not yet apparently felt any need to introduce the kinds of budget limits that are the rule in the United Kingdom and Canada and that have been proposed in other countries.

Mechanisms other than budget constraints and direct controls on investment play a much smaller part in most countries' policies toward medical technology. Except in Sweden, for example, relatively little use is made of manpower policies to influence technological diffusion.

Manpower policies are rather slow and uncertain and often too general an instrument to influence the course of a single technology. Changes in numbers of students and in curricula take a long time to reach the medical care system, by which time the technology is well established. Gaensler, Jonsson, and Neuhauser note that manpower policies could not be of much help in Sweden in controlling the diffusion of the CT scanner, because at the time the scanner appeared, Sweden already had an unusually high proportion of doctors in radiology—and such stocks of trained manpower are slow to change. To control CT's diffusion, Sweden relied instead on the regional hospital system and on the rapid dissemination of information about scanners and of rules of thumb for deciding about them. The potential of manpower policy as a more general cost-control device is reflected in the debate in the Netherlands over whether to restrict the numbers of people trained and in the decision in the United States to stop increasing them.

The setting of fees and conditions of reimbursement also seem to be used only occasionally as a way of influencing technological diffusion. In countries like the United Kingdom or Sweden, where few doctors or hospitals are paid fees, fees are not available to serve as an instrument of policy. This may also be true where private insurers are important and have the right to set reimbursement rates independently. But it may also reflect difficulties in choosing the level at which to set fees, and the fact that controlling the quantity of services, hence the total cost, by means of the fee is a more uncertain process than controlling the total cost directly through a budget. Fee policies can, however, be a useful addition to policy in specific cases: For example, West German insurers decided to reimburse home dialysis at cost in order to avoid creating financial incentives to choose center dialysis.

Formal utilization review is apparently part of national policy only in the United States, making the PSROS a unique institution. Insurers in other countries check bills in much the same way as U.S. insurers do, but again primarily for the purpose of spotting fraudulent claims. Utilization review programs are now being considered in several countries—the Netherlands, Australia, West Germany, and France, in particular.

Notwithstanding variations in the different countries' precise mix of policies, certain common themes run through the descriptions. One is the need for information about technologies. Planners and regulators set guidelines, and to do this, they need a great deal of information about the uses of the technology, the resources it requires, and the associated costs. Hospitals and doctors need information to make the decisions that are left to them, and to present their case when the decision is made by an outside authority. The information needs are enormous.

A second theme is that controls are never airtight. Probably they cannot be—and, in democratic countries, should not be. Some countries permit, or even encourage, local discretion. Even if they did not, public and professional pressures would produce deviations from any national plan. Regulated parties often try to evade the regulations. Hospitals in Canada, for example, as a way around their own limited budgets, have tried to spin off some of their activities in the form of freestanding centers, while physicians in the United States have bought CT scanners when their hospitals were denied approval for one. Private philanthropy has often allowed a community to go ahead with plans that were vetoed by a public authority.

Finally, the situation in nearly every country is changing. In most, the changes are quite obvious, as one new law is followed quickly by another to strengthen or reverse it. Countries are trying to figure out not only what works, but what balance of services and costs they want to achieve. This balance would not be easy to achieve in any event, but certainly not when new technologies must continually be factored into the problem.

CONTROLS ON FIVE SPECIFIC TECHNOLOGIES

To explore the way various controls have been applied in different countries, the author of each chapter on a specific country was asked to examine five specific technologies: 1) CT scanners, 2) renal dialysis, 3) coronary bypass surgery, 4) cobalt therapy, and 5) automated clinical laboratory equipment. These five were chosen because they are known to be of policy concern in the United States and in other countries.

In some instances, a positive decision has been made about the diffusion of a particular technology (e.g., about renal dialysis in France). In others, general constraints, such as certificate of need, have been applied to specific cases as they have arisen (e.g., certificate of need has been used to restrain the spread of open-heart surgery units in some States of the United States). In either situation, the fact of control requires that some standard of provision be set and that the government begin to formulate some idea of the optimal provision of resources considering both the costs and benefits of their use. The specific cases discussed below point to some of the stresses and strains that arise in trying to develop and apply these objectives.

CT Scanners

Determining the value of diagnostic technologies such as CT scanners is particularly difficult. In discussing the benefits of diagnostic technologies, Fineberg, et al., posited five levels at which these benefits could be examined (14):

1. *Technical capability.* —Does the device perform reliably and deliver accurate information?
2. *Diagnostic accuracy,* —Does use of the device permit accurate diagnoses?
3. *Diagnostic impact.* —Does use of the device replace other diagnostic procedures, including surgical exploration and biopsy?
4. *Therapeutic impact.—Do* results obtained from the device affect planning and delivery of therapy?
5. *Patient outcome.* —Does use of the device contribute to improved health of the patient?

If it is assumed that the function of a diagnostic technology, such as a CT scanner, is to make accurate diagnoses of individuals' illnesses, the evaluation of benefit concentrates on the second level. If the technology is expected to affect therapy or eventual patient outcome, then the fourth and fifth levels would be examined. Studies at the fourth and fifth levels are often difficult to conduct because long-term followup is required. In addition, health improvements may depend on better therapeutic tools.

As a result of the difficulties in defining the goals of diagnostic testing and the emphasis on diagnostic accuracy, evaluations of CT scanners in terms of therapeutic planning and patient outcome are infrequently performed. The scientific literature evaluating the efficacy of scanners in the United States is rather sparse. Although there are many articles on the use of CT scanners, almost all of them are uncontrolled case reports (34). Very few examine effects on patient therapy or health outcome. The same dearth of scientific literature generally obtains in other countries. Because of this dilemma, it is not possible to say what an appropriate number of CT scanners for a country or an area is. Policies toward placement of scanners and payment for scanner services have reflected that uncertain y.

In the United States, an early evaluation of CT scanners based on a synthesis of available knowledge was published by OTA (34). A first draft of OTA's evaluation was available and widely circulated in late 1976, but the diffusion of scanners during 1977 and 1978 was nevertheless very rapid. Another study, to determine indications for use of CT body scanners, was undertaken in 1976 and 1977 by a quasi-governmental agency, the Institute of Medicine of the National Academy of Sciences, at the request of the National Blue Cross Association (25). This study did have some impact, because a number of Blue Cross plans did not pay for CT body scans until after the report was published.

Similarly, some evaluation studies of CT scanners in other countries have affected policy. In Sweden, for example, an early evaluation by

the Swedish Planning and Rationalization Institute convinced the county councils to limit the number of CT scanners and to place them in regional hospitals. Sweden's model of waiting to make a decision until the results of an evaluation are completed is an interesting one. In the United Kingdom, early evaluations that were carried out on units that DHSS purchased partly for the purpose of assuring such evaluations were the basis for the government's decision to recommend that each region purchase a brain scanner. Evaluations in France, Australia, and West Germany have also had some effect on decisionmaking.

In the United States, all medical devices are regulated for efficacy and safety under the 1976 Medical Devices Amendments described earlier. In addition, the Bureau of Radiological Health of FDA, has the statutory responsibility of protecting the public from medical X-ray. When CT scanners were introduced to the United States in 1973, the Bureau of Radiological Health had general technical standards for radiological equipment that applied to them. These technical standards were modified to be applicable only to CT scanners, and the modifications were published in 1980. FDA's approach to evaluating scanners emphasizes the evaluation of technical capability, i.e., the first level of evaluation posited by Fineburg, et al. (14).

In other countries, devices are not consistently regulated. In Japan, the Ministry of Health and Welfare can set standards to assure efficacy and safety of medical devices such as CT scanners. Whether it set such standards in the case of CT scanners is not known. In other countries, as noted earlier, medical devices are not regulated, although technical evaluations are often done on a voluntary basis. In France, some evaluation is required before devices will be made reimbursable, so there is in effect an indirect regulatory program. In West Germany, there is considerable discussion of device regulation, and it is possible that medical devices will be regulated in the future.

The major program aimed at affecting the numbers and distribution of medical technologies in the United States is the health planning program and its provisions for certificate of need described earlier. CT scanners generally cost more than $5s0,000 and are therefore subject to certificate-of-need provisions. In fact, because of the development of head scanners costing less than $l50,000, in April 1979, regulations were published to cover CT scanners regardless of cost under a provision concerning significant new services. Generally, however, health planning agencies do not have jurisdiction over services in out-of-hospital settings or in Federal hospitals. In the case of CT scanners, the exclusion of physicians' offices in the health planning law is significant. Eighteen percent of the 1,254 scanners in the United States in February 1979 were in out-of-hospital settings, and the loophole in the law has been used to circumvent disapproval of hospitals' requests for scanners. Amendments to the law passed in 1979 included jurisdiction over such scanners used on a regular basis for hospital inpatients.

Under the National Health Planning and Resources Development Act of 1974, DHHS is required to produce health planning guidelines to assist planning agencies. Guidelines were published in March 1978 with provisions pertaining to CT scanners (28):

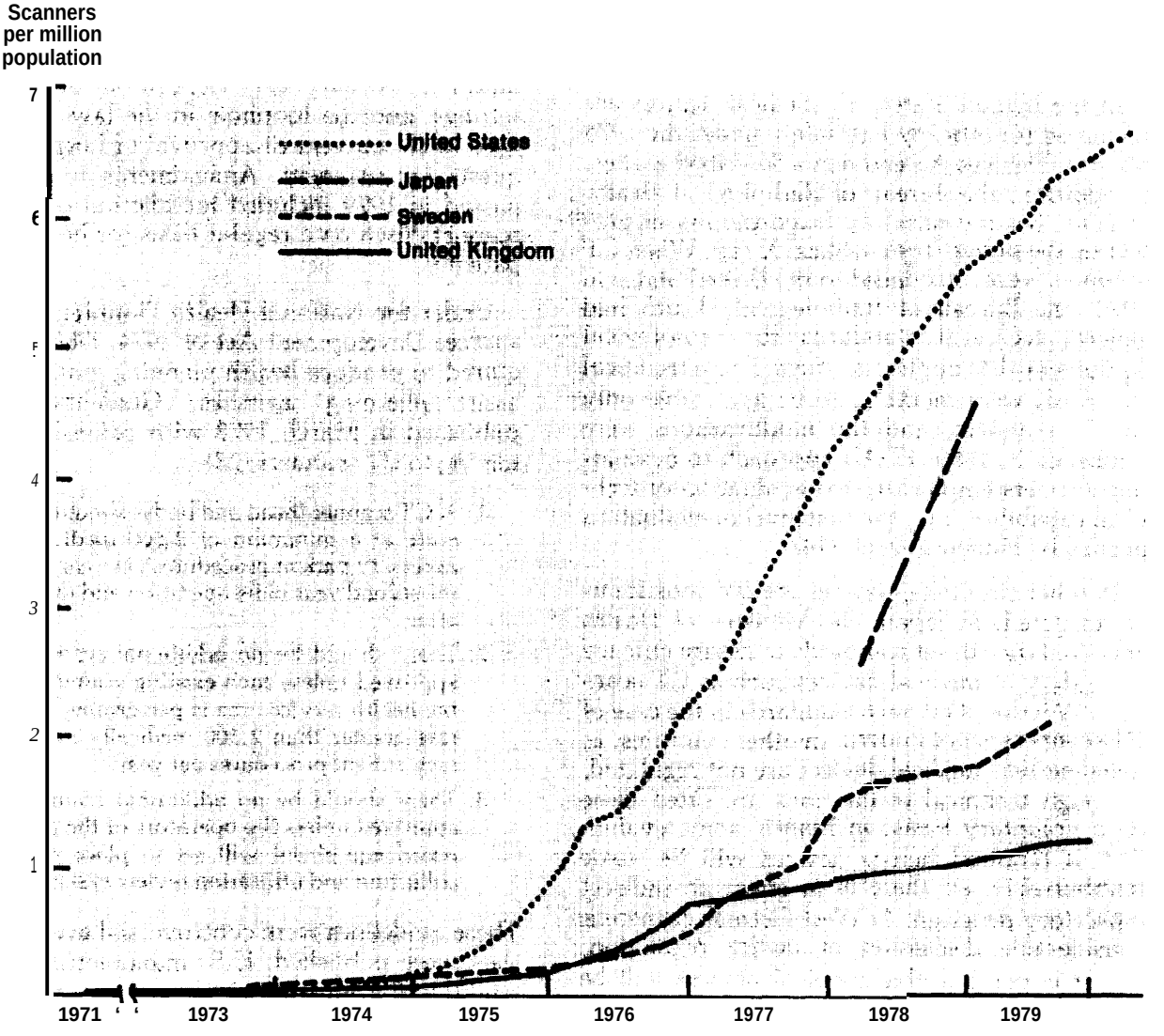
1. ACT scanner (head and body) should operate at a minimum of 2,500 medically necessary patient procedures per year, for the second year of its operation and thereafter.
2. There shouId be no additional scanners approved unless each existing scanner in the health service area is performing at a rate greater than **2,500** medically necessary patient procedures per year.
3. There should be no additional scanners approved unless the operators of the proposed equipment will set in place data collection and utilization *review* systems.

These guidelines were controversial even before they were published. U.S. manufacturers contend that the guidelines have prevented the purchase of scanners, thereby hurting the market and impeding the process of innovation. Actually, however, the situation is much more complex. The U.S. market for CT scanners is near saturation. More than 80 percent of hospitals

with more than 500 beds already have scanners (35).

The diffusion of scanners in the United States and other countries is illustrated in figure 1. As shown in table 3, by early 1978, the United States had significantly more CT scanners than any of the other nine industrialized countries examined in this volume. That situation continued during 1979, after the U.S. health planning guidelines had been issued, although Japan appeared to be catching up. A major factor influencing the diffusion of CT scanners in the United States is probably the medicare and medicaid programs. These programs, with their use of cost reimbursement to hospitals and fee-for-service payment of physicians, have in effect assumed an open-ended obligation to pay for

Figure I.— Diffusion of CT Scanners in the United States, Japan, Sweden, and the United Kingdom (1971=79)



SOURCES: U.S. data: Office of Technology Assessment, U.S. Congress, *Policy Implications of the Computed Tomography (CT) Scanner* (Washington, D. C.: US. Government Printing Office, August 1978) (34).
Office of Technology Assessment, U.S. Congress, *Policy /rep//cations of the Computed Tomography (CT) Scanner: An Update,* draft, Washington, D. C., 1980 (35).
Other data: Country papers in this volume

Table 3.–Distribution of Installed CT Scanners by Country (1978 and 1979)

	March 1978				1979			
	Number of scanners			Scanners per million	Number of scanners			Scanners per million
Country'	Head	Body	Total	population	Head	Body	Total	population
United States.	337	668	1,005	**4.6**	**400**	**854**	**1,254**	**5.7 (Feb.)**
Japan	**180**	**112**	**292**	**2.6**	**304**	**212**	**516**	**4,6 (Apr.)**
West Germany.	51	42	93	1.5	u	u	160	2,6 (July)
Australia.	u	u	u	u	7	21	28	1.9 (Jan.)
Canada.	u	u	u	u	9	29	38	1.7 (May)
Sweden.	8	5	13	1.6	8	6	14	1.7 (Feb.)
Netherlands.	u	u	u	u	u	u	20	1.4 (Jan.)
United Kingdom	36	16	52	0.9	39	18	57	1.0 (Jan.)
FranceC.	10	2	12	0.2	20	10	30	0.6 (Jan.)
Iceland	0	0	0	0.0	0	0	0	0.0 (Jan.)

Key to symbols: U = Unknown.
[a]Ranked by scanners per million population in 1979.
[b]The Netherlands has planned to install 30 head scanners and 8 body scanners.
[c]In France, an additional 21 scanners were authorized in July 1979.

SOURCES: ***March 1978 data:*** E. Jonsson, letter, *N. Eng. J. Med.* 299:665, 1978 (18).
United States 1979 data: Office of Technology Assessment, U.S. Congress, *Policy Implications of the Computed Tomography (CT) Scanner: An Update,* draft, Washington, D.C., 1980 (35).
Canadian 1979 data: Health and Welfare Canada, Ottawa, unpublished data, 1979 (17).
Netherlands 1979 data: Ministerie van Volksgezondheid en Milieuhygiëne (Ministry of Health and Environmental Protection), The Hague, 1980.
Other 1979 data: Country chapters In this volume.

medical care for their client groups. In the case of CT scanning, the Federal Government made an unprecedented decision to withhold reimbursement payments pending evidence of the new procedure's efficacy. CT scans of the head were paid for beginning in September 1976, but scans of the body were not paid for until August 1978. This policy does represent an instance of using the reimbursement system to affect use of technology, but probably had little effect on overall diffusion.

A number of countries other than the United States have used planning guidelines to indicate the number of scanners that would be acceptable. In France, for example, the standard is one CT scanner per 1 million population. Ontario, Canada, and the Netherlands set a guideline of one scanner per 500,000 population. In the Netherlands, scanners have not been regulated, but hospitals have agreed not to install them without government approval. Some countries, notably Iceland and Japan, do not regulate the distribution of CT scanners directly but do use direct or indirect budgetary controls. In Iceland, purchase of a CT scanner would have to be budgeted, so without the explicit approval of the national government, a scanner could not be purchased—and, in fact, has not been. Budget constraints have been specifically used to control the spread of CT scanners in Canada, the United Kingdom, Australia, and West Germany. In addition, France uses budget constraints to enforce its centrally developed guidelines for -planning. The global budgeting system in Canada is a direct attempt to limit the purchase and use of technology which deserves more scrutiny.

Although, superficially, it appears that the controls used in other countries have constrained the number of CT scanners, one should be cautious in reaching such a conclusion. First, it should be noted that Iceland, with no direct controls, has no scanners. Second, it should be noted that physicians and patients in Europe appear to be more conservative in adopting and using new medical technologies than those in the United States. This conservatism was apparent in the case of coronary bypass surgery, which is described in a separate section below (38). Furthermore, political pressures are certainly put on other countries' government programs to control medical technologies. In France, a restrictive policy was developed for CT, not only because of rational planning and cost-benefit considerations, but for the broader economy. The French company CGR did not have a scanner when the British firm EMI began to sell scanners in Europe, so it needed the pro-

tection of French law to have a chance to develop its own scanner. The restrictive law, however, apparently failed to prevent purchases and installations without subsidies from the central government: Five head and ten body scanners were installed without such subsidies. Likewise, in Ontario and the United Kingdom, restrictive policies led to the purchase of unauthorized scanners with private funds.

Table 3 indicates that most countries have focused on head scanners and continue to be cautious about body scanners. Most experts would feel that head scanners are much more established as an important part of the diagnostic armamentarium. Another interesting comparison that might be noted is the number of scanners in out-of-hospital settings. In most countries, the tradition is against the location of such technology in the physician's office. In West Germany, it apparently is not. Furthermore, just as there are no restrictions in the United States, there are none in West Germany on purchase of scanners by private out-of-hospital settings. Insurance readily pays for scans on these machines. The result is that 30 percent of CT scanners in West Germany are in physicians' offices.

The data on CT scanners are generally quite good. In the United States, OTA has a well-validated list of operational scanners that is updated about once a year. In other countries, because of the expense and visibility of the scanner, data on the numbers of scanners and their distribution are generally not hard to find and should be fairly reliable.

The irony of the situation with CT scanners is that after more than 3 years of controversy in the United States, little is known about the ultimate place of CT scanning in medicine. Guidelines for number of scanners per population are essentially based on minimum utilization standards and are often arbitrary. And without clear definition of the goals sought from diagnostic testing, it is unlikely that the situation will improve for other diagnostic technologies in the future.

Renal Dialysis

Renal dialysis is unlike many technologies in that its efficacy is not at issue. It clearly extends the lives of people who would otherwise die from the accumulation of metabolic wastes, which their own kidneys are no longer able to remove from their blood. Because of its known efficacy and high cost, questions about dialysis have focused with particular clarity on the issue of how extensively to provide it—that is, on when the gains in extra months or years of life and the quality of that life are great enough to justify the diversion of resources from other uses. In all of the countries described in this volume, there have been irresistible pressures to expand the provision of dialysis to all who can benefit from it.

In the 1960's, when the technology was new, the estimates of people who would need dialysis were based on rather conservative assumptions. Those assumptions rested in part on the fact that not enough machines, staff, or money were yet available to offer dialysis to everyone. In the United States, a National Committee on Chronic Kidney Disease convened in 1967 to draw up recommendations for the provision of dialysis. The committee recommended that treatment should go primarily to people between the ages of 15 and 45 who had no serious disease other than kidney disease; those criteria implied about 35 new patients per 1 million population each year. Similar criteria guided the major surveys carried out in the United Kingdom during the 1960's; those produced estimates that there would be 40 new patients between the ages of 5 and 60 per 1 million total population each year (32).

In most countries, treatment gradually became available to most or all of the people within these guidelines. In West Germany, for example, waiting lists had virtually disappeared by 1973. Beyond this, every country has felt pressure to broaden the criteria for treatment and to admit older people and people with other serious disease. In the late 1970's, in the United States, estimates of new patients had been revised upward to 60 per million population on the basis of the new criteria. A British source estimates that the number could rise as high as

150 new patients per million population (32). The incidence of chronic kidney failure appears to be similar in different countries, so all countries face similar problems of provision and cost .

Table 4 presents some data on the numbers of people on dialysis (or with a functioning transplant) in each of the countries discussed in this volume. It also gives data on the number of new patients admitted to treatment each year. These data suggest that many countries are now taking about 30 new patients per million population per year, with the exception of the United Kingdom. Stocking notes that although the United Kingdom was a leader in establishing dialysis and transplant services in the 1960's, dialysis has not grown as rapidly there as in other countries because of budget constraints. She describes the recurring debate in Britain that has accompanied this policy and the unusual degree of intervention by the British Government in an attempt to provide more resources specifically for dialysis. Most countries have reached levels of patients receiving treatment that are close to, or exceed, 100 per million population. The United States and Japan are far beyond this point, with the United States having something closer to 200 dialysis patients per million population and Japan exceeding 200.

There are some problems with the data, however, that suggest that the comparisons between countries are rough at best, and possibly misleading. The range of estimates given for the number of people on dialysis in the United States presents the clearest case. The low estimates are derived directly from surveys of dialysis facilities (3). The higher ones are based on enrollment records kept by the medicare program, which pays for most dialysis treatment in the United States (42). Since many people become eligible for medicare (because of age or disability) before they require dialysis, a special survey was taken in 1973, when dialysis was first included in medicare, in an attempt to identify the records of dialysis patients. This survey is known to have included by mistake some patients receiving short-term dialysis for acute kidney disease, but how many is not known. The upshot is that no one knows which set of

Table 4.—Treatment of Patients With End-Stage Renal Disease by Country and Year'

	New patients (on dialysis or with a functioning transplant)		Total patients (on dialysis or with a functioning transplant)			Transplant rates
Countryb	1975	1976	1975	1976	1978	1976
Japan	u	u	u	140	222	u
United States.	u	u	u	123-149*	164-206"	15.9
France	30.3	29.1	102.2	125.0	133* (1977)	6.8
Canada	30.3	31.4	u	121.1	u	15.1
West Germany	29.6	30.8	87.7	1.05e	114e	u
Netherlands	18.9	21.4	90.2	108.5	u	11.7
Sweden	28.7	28.7	85.4	99.3	73'	**20.0**
United Kingdom	**14.5**	**15.1**	**62.0**	**71.2**	**9 2**	**10.8**
Australia	**u**	**u**	**u**	**u**	**77***	**u**
Iceland	**u**	**u**	**41.5**	**50.0**	**u**	**u**

Key to symbols: U = unknown, * = dialysis only, e = estimate.
[a]All numbers given in this table are per million population.
[b]Ranked by total patients on dialysis or with a functioning transplant per million population.

SOURCES: ***Japanese data:*** Broida's paper.
U.S. data: Lower estimates, R. C. Brown, Chief, End-Stage Renal Disease Branch, Medicare Bureau, Health Care Financing Administration, Baltimore, Md. (3). Higher estimates, J. N. Romano, Actuary, Division of Medicare Cost Estimates, Office of Financial and Actuarial Analysis, Health Care Financing Administration, Baltimore, Md. (42).
French data: for 1977, Führer's paper; for 1975, Office of Health Economics (OHE), *Renal Failure: A Priority in Health*? (London, April 1978) (32) (OHE's data are taken from the European Dialysis and Transplant Association and will hereafter be cited as OHE/EDTA); for 1976, A. J. Wing, et al., "Combined Report on Regular Dialysis and Transplantation in Europe, VIII, 1977," *Proc. Eur. Dial. Transplant Assoc.* 14:4, 1978 (54).
Canadian data: Health and Welfare Canada, Ottawa, unpublished data, 1979 (17).
West German data: for 1975 and 1976, OHE/EDTA (32); for 1978, Dumbaugh's paper.
Netherlands data: OHE/EDTA (32).
Swedish data: for 1978, Gaensler, et al.'s paper; for 1975 and 1976, OHE/EDTA (32).
United Kingdom data: for 1978, Stocking's paper; for 1975 and 1976 OHE/EDTA (30).
Australian data: Sax's paper.
Icelandic data: for 1975, OHE/EDTA (32); for 1976 data, A. J. Wing, et al. (54).

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numbers is correct or what accounts for the differences between them.

The data for Europe come from the records of the European Dialysis and Transplant Association (EDTA) (32). No description of the method of collecting the records, or their probable completeness, was published with the data. There are some inconsistencies, however, that suggest problems with these data as well. In particular, the growth in number of patients on dialysis per million population from one year to the next should equal the number of new patients minus the number of patients who died during the year (approximately 10 percent of the total (32)). The numbers for the United Kingdom are consistent with this requirement, but those for France between 1976 and 1977, for example, are not. It is thus not clear how good the data are or how confidently one can draw international comparisons.

Most countries have tried to provide facilities and financing to make dialysis quite widely available. As noted, the United States extended medicare coverage to dialysis and transplant patients in 1973. The health planning guidelines require end-stage renal disease "network areas, " each serving a minimum population of 3.5 million, and define standards for the development and approval of facilities for treatment.[8] In West Germany and Japan, dialysis has been covered by the ordinary health insurance funds. The United Kingdom provides dialysis through NHS, but the technology has received an unusual amount of attention from the British Government from first to last, Although the usual policy is to allow the regions and districts to decide about resource allocation, the dialysis and transplant network resulted from national guidelines and special funds, the results of a national conference on dialysis policy.

The major response to the high and growing costs of dialysis (Medicare estimates, for example, that a year of dialysis in an outpatient center cost $22,000 in the mid-1970's (24)) has been that virtually all countries advocate treatment by transplant whenever possible, and the provision of dialysis at home, again whenever possible. If successful, a transplant eliminates the need for continuing expensive treatment. But the use of transplants is severely limited by the availability of kidney donors, so the extent to which governments can promote transplantation as a matter of policy is also limited.

The encouragement of home dialysis is a more amenable policy instrument than the encouragement of transplantation. Medicare estimated that after the first year, when the patient must be trained in the technique at a center, dialysis at home cost $12,000 per year in the mid-1970's (24). The experience of different countries in this respect varies over an extremely wide range, The percentage of dialysis patients receiving dialysis at home in different countries is shown in table 5. In the United Kingdom, two-thirds of all patients dialyze at home. In West Germany, the proportion is 28 percent, and in the Netherlands it is about 10 percent. In Japan, less than 1 percent of patients dialyze at home.

Table 5.—Percent of Dialysis Patients Receiving Treatment at Home by Country (1976)

Country	Percent
United Kingdom	66.570
Canada	33.4
West Germany	27.5
Sweden	25.6
United States	23.7
France	13.8
Netherlands	10.2
Japan	0.6
Iceland	0.0

SOURCES: ***European data:*** A. J. Wing, et al., "Combined Report on Regular Dialysis and Transplantation in Europe, VIII, 1977," *Proc. Eur. Dial. Transplant Assoc.* 14:4, 1978 (54).
Canadian data: Health and Welfare Canada, Ottawa, unpublished data, 1979 (17).
U.S. data: Broida's paper.
Japanese data: Broida's paper.

The different countries have various policies to try to encourage more home dialysis. In the United Kingdom, the government pays for special housing or plumbing requirements, over and above the more strictly medical components of the service (6). The United States recently revised its reimbursement policy, which had paid a larger proportion of the costs for center dialysis than home dialysis, in an attempt to remove financial reasons for favoring center

[8] *20* CFR, part 405, subpart U.

dialysis. West Germany's sickness funds decided in the early 1970's to pay the full costs of home dialysis for the same reason. France has guidelines for the maximum number of dialysis units that should be available in a Region; home units are specifically excluded from this limit to encourage their use (43).

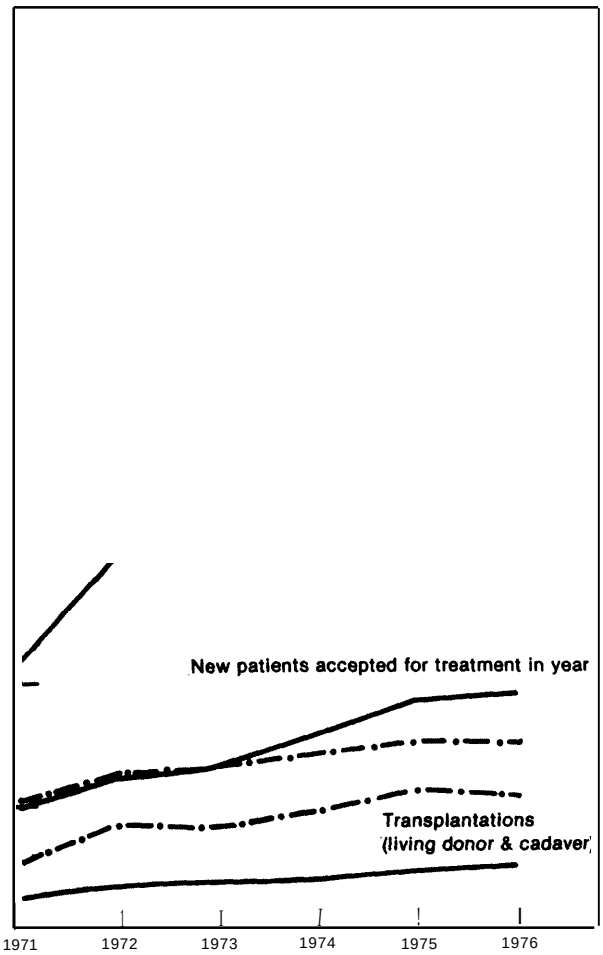
Dialysis will continue to be a major cost problem as long as it is the primary form of treatment for chronic kidney failure. In every country, the number of dialysis patients is growing as new patients are brought in for treatment and a much smaller number die each year—and the number of patients will continue to grow for many years. Figure 2 shows the rapid growth between 1971 and 1976 in the total number of patients on dialysis for Britain and for the other European countries belonging EDTA.

The equilibrium population of patients eventually reached by each country will depend on the criteria for selecting new patients and the death rate among existing patients. The more generous the former, and the lower the latter, the larger that population will be. EDTA estimates equilibrium levels for its member countries, assuming an upper limit of 40 new patients per year is eventually achieved. For the United Kingdom, for example, EDTA estimates that the dialysis population will reach 340 patients per million sometime after the year 2000, about five times its level in 1976 (32). With growth like this expected, each country will repeatedly face the question of an appropriate policy toward dialysis. It is undoubtedly with this in mind that the West German Government has taken the unusual step of establishing the treatment of kidney disease as a particular area of concentration for future medical research.

Coronary Bypass Surgery

The controversy concerning coronary bypass surgery encompasses its efficacy, safety, and costs. In the United States, the operation was introduced in the early 1970's and rapidly diffused. Approximately 25,000 operations were performed in 1973, at least 70,000 in 1977, and an estimated 100,000 in 1978 (21). The population rates corresponding to these figures are shown in table 6.

Figure 2.—Patients Treated for Chronic Renal Failure in Great Britain and Europe (1971-76) (rates per million population)



SOURCE: Office of Health Economics, *Renal Failure: A Priority in Health?* (London: White Crescent Press, April 1978) (32).

Coronary bypass surgery diffused in the United States on the basis of claims that it prevented premature death and relieved angina pectoris (a condition characterized by severe chest pain) in patients with coronary artery disease. Coronary bypass surgery gives symptomatic relief from angina pectoris. It is reported that 70 percent of patients evaluated 1 to 60 months after surgery was initially completely relieved of angina, but that this improvement diminished with time (23). Randomized controlled clinical trials of internal mammary artery ligation conducted in the 1950's, how-

Table 6.—Corona~ Artery Surgery per Million Population by Country and Year

Country	1975	1977	1978
United States	280	369	u
Netherlands	50	u	*78'*
Sweden	24	20	u
United Kingdom	25	55b	u
West Germany	14	20C	u
France	u	u	**19**
Australia	u	136	u
Iceland	u	u	*233d*

Key to symbols: U = unknown.
[a]Those sent abroad only.
[b]England and Wales.
[c]Approximate figures.
[d]All sent abroad; figure is estimated.

SOURCES: ***1975 data:*** T. Preston, *Coronary Artery Surgery: A Critical Review* (New York: Raven Press, 1977) (38).
U.S. data: National Center for Health Statistics, Hyattsville, Md., unpublished data, 1979 (26).
West German 1977 data: World Health Organization (WHO), *The Long-Term Effects of Coronary Bypass Surgery* (Copenhagen: WHO Regional Office for Europe, 1978) (53).
Other data: Country chapters in this volume.

ever, showed that a sham operation was associated with a high degree of relief of anginal pain, apparently as the result of placebo effect (7,13). Furthermore, medical treatment of angina pectoris is usually effective.

The efficacy of coronary bypass surgery in reducing mortality was examined in several important clinical trials. Perhaps the most important was carried out from 1970 to 1974 by the U.S. Veterans Administration (VA), which compared the efficacy of medical treatment to the efficacy of this surgery in reducing mortality among patients with stable angina pectoris (51). Only patients with significant narrowing of the left main coronary artery, about 11 percent of the total, were found to have improved mortality with surgery. Except for that relatively small group of patients, the efficacy of coronary bypass surgery in reducing mortality from coronary disease has not been shown. Furthermore, the risk of the surgery is significant, with mortality rates that average 1 to 2 percent. Many experts feel that coronary bypass surgery is overused. Braunwald states that many people are operated on because of the "hope, largely without objective supporting evidence at present, that CABG[9] prolongs life or diminishes the frequency of subsequent myocardial infarction (or accomplishes both)" (4).

'Coronary artery bypass graft,

In the United States, coronary bypass surgery is generally not subject to policies concerning medical technology. A number of trials were funded by U.S. Government agencies, including VA and NIH. No program regulates the surgery, and insurance programs (including medicare and medicaid) pay for it when a physician considers it to be medically necessary. With a cost per procedure of at least $15,000, coronary bypass surgery probably costs the country more than $1.5 billion in a given year.

As indicated by table 6, the coronary bypass surgery rates in other industrialized countries are considerably lower than those in the United States. Preston has speculated that European patients are less aggressive than Americans in seeking out the new treatment (38). He feels that the disparities in rates of coronary bypass surgery can be explained only by political and economic factors. A high degree of skepticism among physicians about the efficacy and cost effectiveness of the bypass procedure is mentioned as a factor in the chapters on the United Kingdom, Sweden, and France in this volume. Skepticism in Sweden, for example, initially led to the provision of the procedure on an experimental basis only. Furthermore, only four hospitals in Sweden's regionalized hospital system were equipped with the facilities necessary to perform the procedure—an open-heart machine and a team trained to use it, intensive care units, advanced anesthesia, blood gas monitoring, and so forth.

Facilities were also limited in the United Kingdom, the Netherlands, France, West Germany, and Iceland. In the Netherlands, capacity was so limited and the demand for the procedure so great that insurance companies sent patients to the United States to have surgery. In 1977, it was reported that one university surgical center had a contract with an American medical center to provide coronary bypass operations at $11,000 an operation (21). Patients in the Netherlands have lobbied for access to bypass operations. In Iceland, patients deemed to need the operation are also sent out of the country, usually to England.

In 1978, the World Health Organization convened a special meeting on coronary bypass

surgery, which concluded that the theoretical need for bypass surgery was about 150 patients per million in developed countries (55). That standard, though supposedly based on population rates and proven and expected efficacy of the procedure, was actually agreed upon without sufficient information. Furthermore, it has helped lead to attempts to increase capacity for coronary bypass surgery in various countries.

It should be noted that the figures given in table 6 are approximate. One source of data in the United States is the Hospital Discharge Survey, a random sample survey of hospitals carried out yearly by the National Center for Health Statistics (NCHS). The most recent data available from this NCHS source are from 1977. Another source of data is the Commission on Professional and Hospital Activities (CPHA), which estimates rates of certain procedures on the basis of a sample of data from its subscribing hospitals. The most recent data from this source are also from 1977. NCHS estimated 81,529 procedures in 1977 (27), while CPHA estimated 79,000 (10). The yearly totals from each source are given below:

	NCHS	*CPHA*
1972	31,380	17,000
1973	49,940	26,000
1974	52,168	42,000
1975	56,962	53,000
1976	73,700	63,000
1977	81,529	79,000

Although the orders of magnitude are similar, the figures obviously lack precision. The reliability and validity of the figures from other countries are not fully known. It is known that the figures from West Germany and France are only educated guesses. Except for the obviously top ranking of the United States, the relative ranking of countries shown in table 6 could be in reality quite different.

The important point to stress in the case of coronary bypass surgery is that the appropriate rate of use is not known. There does seem to be general agreement that the rates in most European countries are too low, and that the U.S. rates **are** probably too high, at least on the basis of what is now known. How does one reach the optimal level of use? Gaensler stated:

> The pattern in the United States seems to be overexpansion followed by contraction. The disadvantage of this path is that resources are wasted. Furthermore, reducing the share of resources allocated to an entrenched medical technology is more difficult than increasing the share allocated to an underutilized one . . . In the case of coronary bypass surgery, Sweden's "wait and see" approach was cost effective but had one major drawback. During the "trial" period, triage was instituted, and many deserving candidates for coronary bypass surgery were not given treatment or put on waiting lists.

This quote seems to sum up the difference in approach of the European countries and the United States to this technology.

Cobalt Therapy

Cobalt is the oldest of the five technologies specifically considered in this volume. It has also been stable in form for the longest time; there have been no major changes in the technology since it was first introduced in the early 1950's. As a result, this technology does not need or get as much attention as the other four from individuals concerned with policy. This observation is reflected in the very brief remarks about cobalt in most of the chapters.

Cobalt treatment units are major pieces of equipment, and where there are laws governing the acquisition of such equipment—as in the United States, France, and West Germany—cobalt is covered by the law. But applications for cobalt are not submitted very frequently. In the United States, for example, the adoption of cobalt by hospitals reached a plateau in the mid-1960's (43). The issues that do appear involve policies for replacing units and policies for the overall distribution of radiotherapy equipment in general, of which cobalt is only one kind. With respect to distribution, policies usually favor the regionalization of radiotherapy—through explicit planning or indirectly through a more general policy of regionalization such as Sweden' s—not only because of the expense but because of the expertise and backup facilities required for good treatment.

The question of replacing units brings up an issue that is not yet important for new technol-

ogies like the scanner or bypass surgery—the issue of whether and how to regulate the replacement of one technology by a newer one that is marginally better. The replacement of cobalt by the newer linear accelerators brings up issues that are mentioned in the chapters on the United Kingdom and France. In Britain, there is no policy favoring one over the other, and each radiotherapy center is free, within its budget constraint, to choose its own mix of equipment. The French system has not operated under budget constraints, and the planning guidelines are thus designed to try to slow the replacement of cobalt by the more expensive accelerators, by permitting such replacement only in centers that already have a wide range of high-energy radiotherapy equipment. The French can potentially control the use of cobalt radiation as well through the mechanism of prior authorization for treatment, which is necessary if the patient is to be reimbursed; but there is little evidence concerning the effectiveness of this mechanism. The fee schedule for reimbursement is another potential influence on use, and here the French recently reduced the fees paid for radiotherapy relative to other fees.

Automated Clinical Laboratory Testing

Describing the efficacy of clinical laboratory tests is difficult, just as it is in the case of other diagnostic technologies. Presumably, the ultimate goal of medical care is to improve the patient's health and functioning. The diagnostic test, however, cannot itself accomplish this goal. Its efficacy depends on the efficacy of a subsequent therapeutic intervention. For this reason, diagnostic technologies are generally evaluated for their precision in establishing a diagnosis. Occasionally, their contribution to therapeutic decisionmaking is also analyzed.

The importance of evaluating the efficacy of clinical laboratory tests is heightened by their enormous volume. The average laboratory now offers perhaps 600 specific tests (s). Some machines can automatically perform up to 20 distinct tests on one sample of blood.

To analyze efficacy completely requires knowing the contribution of each test to the diagnosis, therapy, and ultimate outcome of the patient. Because of the difficulties in determining this contribution, policies toward clinical laboratory tests in the United States have understandably focused on the technicalities of clinical laboratory testing. The machines themselves are regulated for efficacy and safety by FDA, as described earlier in this chapter. FDA also regulates the reagents and diagnostic products used in testing.

Responsibility for developing policy for the educational preparation, utilization, and credentialing of certain types of manpower employed in clinical laboratories in the United States rests with the Health Resources Administration of DHHS. In addition, the health planning system described earlier has authority over laboratory construction and renovation in hospitals for capital investments exceeding a "trigger" amount. It does not have such authority over independent commercial clinical laboratories, but under the 1979 amendments to the Health Planning Act, States are given the option to include independent laboratories under capital expenditure controls. And finally, the Center for Disease Control of DHHS administers a comprehensive laboratory improvement program through the provision of reference diagnostic services, research, consultation, proficiency testing, and licensing of laboratories engaged in interstate commerce.

Perhaps the most important policy toward clinical laboratories in the United States is that concerning payment. Since hospitals are generally reimbursed on the basis of costs, there is no economic check on laboratory testing. The PSRO program has done no direct reviews of clinical laboratory services, primarily because of the volume of tests involved. It has undertaken some educational activities. Programs of prospective reimbursement and other methods of limiting hospital expenditures might slow the growth in these services and their associated expense.

The situation in other countries described in this volume is rather similar to that in the United States. In most countries except Iceland, which does not yet have automated equipment, automation began during the 1960's. The number of tests and the expense of testing have since

risen to a level that is causing concern in most countries, but about which generally little is being done. The only policy that has been followed with any consistency is the policy of centralizing labs. Laboratory centralization is occurring in Sweden, Canada, the United Kingdom, and France. Another mechanism for controlling the number of automated machines is through budget constraint, as the United Kingdom and Canada.

It should be noted that few data are available on the volume or cost of laboratory services. In the United States, the data, based on surveys of hospitals, are of questionable quality. Numbers and types of laboratory tests done in physicians' offices are little more than estimates.

SUMMARY AND CONCLUSIONS

This study was undertaken because of the lack of literature about policies toward medical technologies in various countries and how such policies affect the distribution and use of specific technologies. The chapters in this volume show that it is seldom possible to make definitive statements about how technologies are evaluated and controlled in other countries. None of the chapters point the way to clearly desirable alternatives that might be adopted by the United States. In most of the countries described, policies to evaluate and control medical technologies are quite new, but even in those countries where the policies are of longer standing, changes are under consideration. Further, as the discussion of specific technologies in each country shows, the application of any given policy is altered by the circumstances surrounding a particular technology.

The chapters do show that a range of alternative policy mechanisms has been and is being used in the various countries to affect medical technology distribution and use: biomedical research policy, manpower policy, reimbursement methods and levels, direct regulation of investment and use, and information gathering and evaluation activities. Since each of these mechanisms can be directed at different policy objectives, the precise content of a specific policy will depend on which objective is chosen. The rapid changes in the laws and policies of the countries described in this volume thus reflect not just attempts to find effective policy mechanisms, but the difficulties of choosing a realistic policy objective.

The range of possible policy objectives is a wide one and might best be described in terms of a four-level hierarchy (43). At the first level, a national government *may actively promote a new technology's development and adoption.* To promote a technology's development, it might finance research; or to speed the diffusion process, it might pay for the equipment or train people to use the technology. When promoting a technology is the goal, costs are usually secondary. The rising costs of health care programs, though, have become a matter of concern to the governments in most of the countries described in this volume (1); thus, many of these governments have been led to the next level of the hierarchy.

At the second level, a government may concern itself with whether a new technology is being used efficiently. Without making judgments about the volume of use, it may ask whether that volume is being produced at the lowest possible cost, whether existing facilities are used to capacity, and whether there is "unnecessary" duplication. Once the government makes these determinations, it may *intervene to encourage greater efficiency in the production or use of a technology.*

At the first two levels of the hierarchy, a government generally takes as given that the technology is a good thing, that it is beneficial for patients and therefore worth having. Actual judgments about benefits are left implicitly to medical professionals (individually and collectively) and to patients. But in fact, the

value of many medical technologies has not been proven.

At the third level in the hierarchy, a government may begin to *question and test the benefits of medical technologies.* The simplest approach to determining the benefits of a technology is to ask the medical profession whether it thinks the technology is beneficial and for whom. This approach does make the previously implicit judgments of the medical profession explicit, but is based on the assumption that the steps the profession has taken to learn about the benefits of specific technologies support its judgments. Questioning or discarding that assumption, a government may instead adopt the approach of asking whether the technology has been proven beneficial by persuasive scientific evidence, particularly in the form of randomized controlled clinical trials. If the government establishes either by expert opinion or by controlled trials that a technology is not beneficial, it may use the information in the planning or reimbursement process in an effort to restrain the technology's use, or it may simply disseminate the information and let practitioners decide for themselves.

At the fourth level in the hierarchy, a government accepts the further possibility that it may not be realistic to provide every kind of care that is beneficial. Some benefits are too small or too costly. At this level, the question shifts from whether the technology is beneficial to how great its benefits are for different groups and how the benefits compare with the costs. The corresponding objective becomes to *limit the diffusion* of *technologies to a level that strikes a balance between the benefits to be gained and the costs of achieving them,*

It appears from the chapters in this volume that so far most of the countries discussed have concentrated on the goal of technical efficiency, that is, they have not moved beyond the second level of the hierarchy. Even in those countries that have a more rigorous planning process than the United States, the focus still seems to be on efficiency. The discussions do show, however, an increasing interest in the evaluation of medical technologies in many countries in addition to the United States. One or two countries have even adopted systems of budgetary constraints that clearly bring them to level 4 of the hierarchy. The United Kingdom, for example, has a limited national budget for medical care, which forces hospitals and physicians to limit the provision of some beneficial technologies, and is a clear exception to the generalization stated above. Canada is moving in a similar direction.

It is striking that in all 10 countries described in this volume there is so much new activity related to the evaluation of medical technology and so much discussion of the necessity for doing more evaluations and using them in decisionmaking. This activity and discussion seem to constitute a general movement to the third level of the hierarchy, and may presage further movement to level 4. Actually, it is possible, and perhaps even desirable, for policy to function at multiple levels. The objectives of the four levels are not mutually exclusive, and it is even fair to say that level 4 encompasses activities at all of the previous levels. Thus, for example, careful evaluation of technology (level 4) can indicate which technologies should be promoted (level 1). The promotion of technologies that bring benefits to patients at reasonable cost is as much a part of the objective of level 4 as is the limitation of other technologies.

Finally, and perhaps more importantly, the chapters in this volume show that the concern for medical technology and its use is a common one across country boundaries. The problems that surround the diffusion of medical technologies have some of the same dimensions in different countries. This suggests the potential value of doing further research in the international area. Now may be an excellent time to develop international efforts to evaluate the benefits, risks, and costs of medical technologies.

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Appendix



Appendix —Description of Other Volumes of the Assessment

The overall OTA assessment, The *Implications of Cost-Effectiveness Analysis of Medical Technology,* consists of a main, policy-oriented report plus five background papers. The present volume, *The Management of Health Care Technology in Ten Countries,* is one of the background papers. The main report and the other background efforts are briefly described below.

The main report, *The Implications of Cost- Effectiveness Analysis of Medical Technology,* examines three major issues: 1) the general usefulness of CEA/CBA in decisionmaking regarding medical technology, 2) the methodological strengths and shortcomings of the technique, and 3) the potential for initiating or expanding the use of CEA/CBA in six health care programs (reimbursement coverage, health planning, market approval for drugs and medical devices, Professional Standards Review Organizations, R&D activities, and health maintenance organizations), and most importantly, the implications of any expanded use.

The prime focus of the report is on the application of CEA/CBA to medical technology (i. e., the drugs, devices, and medical and surgical procedures used in medical care, and the organizational and support systems within which such care is provided). With the exception of a background paper *on* psychotherapy, the report does not address psychosocial medicine. Other aspects of health, such as the environment, are not directly covered either. The findings of the assessment, though, might very well apply to health care resource decisionmaking in general, and with modification, to other policy areas such as education, the environment, and occupational safety and health.

The main report contains chapters on methodology, general decisionmaking, each of the six health programs mentioned above, and the general usefulness of CEA/CBA. It contains appendixes covering a survey of current and past uses of CEA/CBA by agencies (primarily Federal), a survey of the resource costs involved in conducting CEA/CBAs, a discussion of ethical issues and CEA/CBA, and a brief discussion of legal issues.

In order to help examine the applicability of techniques to assess the costs and benefits of medical technology, 19 case studies were prepared. All **19 are available** individually. In addition, 17 of the cases are available collectively in a volume entitled *Background Paper #2:* Case *Studies* of *Medical Technologies.* Some of the cases represent formal CEAS (e.g., the case on bone marrow transplants), and some represent net cost or "least cost" analysis (e. g., the case on certain respiratory therapies). Other cases illustrate various issues such as the difficulty of conducting CEA in the absence of adequate efficacy and safety information (e. g., the case on breast cancer surgery), or the role and impact of formal analysis on policymaking (e.g., the case on end-stage renal disease interventions). The 17 case studies in *Background Paper #2* and their authors are:

Artificial Heart
- Deborah P. Lubeck
- John P. Bunker

Automated Multichannel Chemistry Analyzers
- Milton C. Weinstein
- Laurie A. Pearlman

Bone Marrow Transplants
- Stuart O. Schweitzer
- C. C. Scalzi

Breast Cancer Surgery
- Karen Schachter
- Duncan Neuhauser

Cardiac Radionuclide Imaging
- William B. Stason
- Eric Fortess

Cervical Cancer Screening
- Bryan R. Luce

Cimetidine and Peptic Ulcer Disease
- Harvey V. Fineberg
- Laurie A. Pearlman

Colon Cancer Screening
- David M. Eddy

CT Scanning
- Judith L. Wagner

Elective Hysterectomy
- Carol Korenbrot
- Ann B. Flood
- Michael Higgins
- Noralou Roos
- John P. Bunker

End-Stage Renal Disease Interventions
- Richard A. Rettig

Gastrointestinal Endoscopy
- Jonathan A. Showstack
- Steven A. Schroeder

Neonatal Intensive Care
- Peter Budetti
- Peggy McManus
- Nancy Barrand
- Lu Ann Heinen

Nurse Practitioners
- Lauren LeRoy

Orthopedic Joint Prosthetic Implants
Judith D. Bentkover
Philip G. Drew
Periodontal Disease Interventions
Richard M. Scheffler
Sheldon Rovin
Respiratory Therapy
Richard M. Scheffler
Morgan Delaney

The 18th case study is published separately as *Background Paper #3: The Efficacy and Cost-Effectiveness of Psychotherapy.* That study assesses methodological and substantive issues relating to the scope of psychotherapy, the evaluation of psychotherapeutic efficacy, and the applicability of CEA/CBA in assessing psychotherapy. It was prepared by Leonard Saxe on the basis of a report prepared for OTA by Brian Yates and Frederick Newman. The 19th case study was prepared by Judith Wagner and is published separately as *Background Paper #5: Assessment of Four Common X-Ray Procedures.*

A related report prepared by OTA and reviewed by the Advisory Panel to the overall assessment is *A Review* of *Selected Federal Vaccine and Immunization* Policies. That study, published in September of **1979, examined** vaccine research, development, and production; vaccine efficacy, safety, and cost-effectiveness; liability issues; and factors affecting the use of vaccines. Pneumococcal vaccine was used as a case study, and a CEA/CBA was performed.

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