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Summary and Analysis

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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):

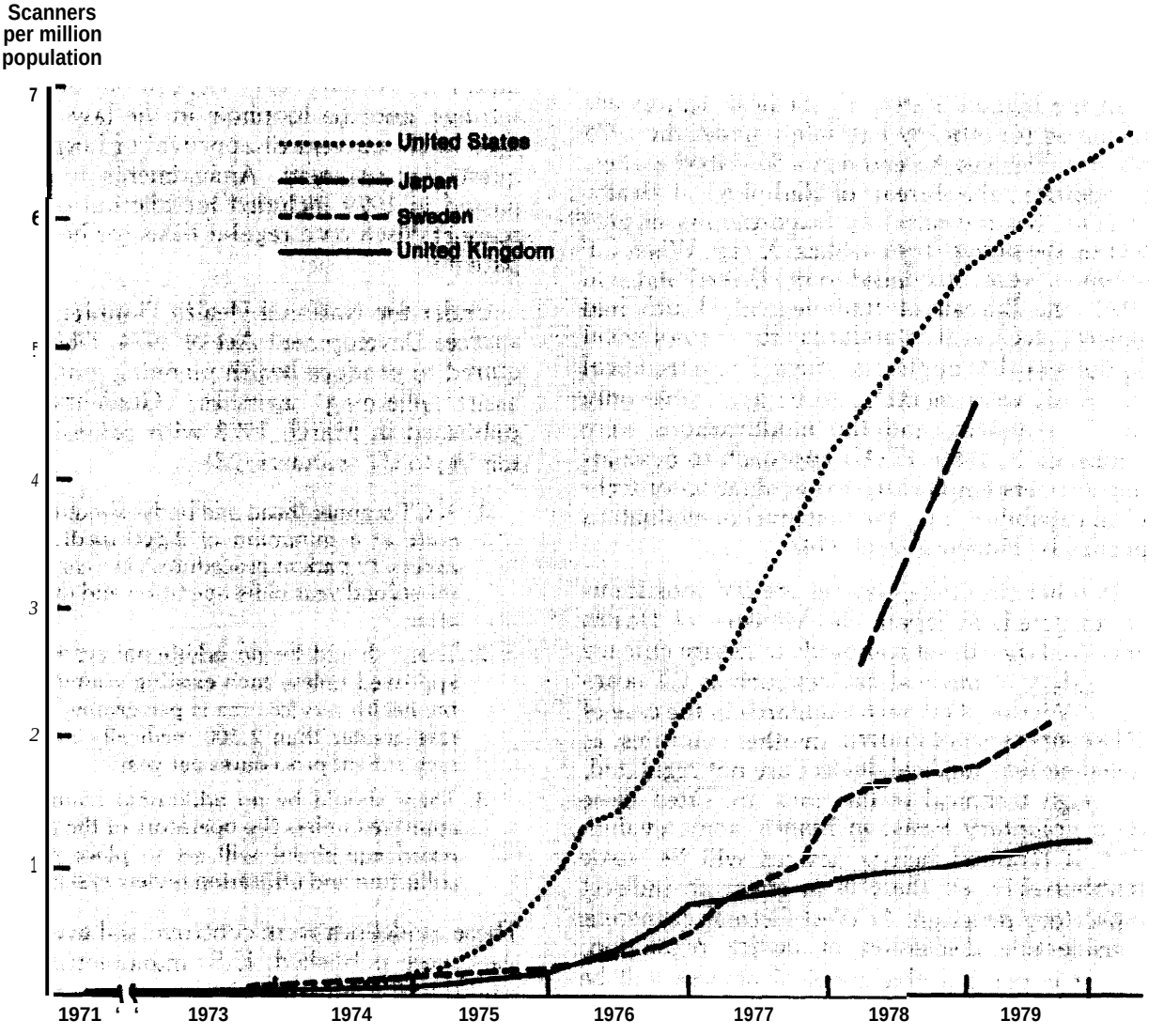
1. ACT scanner (head and body) should operate at a minimum of 2,500 medically necessary patient procedures per year, for the second year of its operation and thereafter.
2. There shouId be no additional scanners approved unless each existing scanner in the health service area is performing at a rate 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).

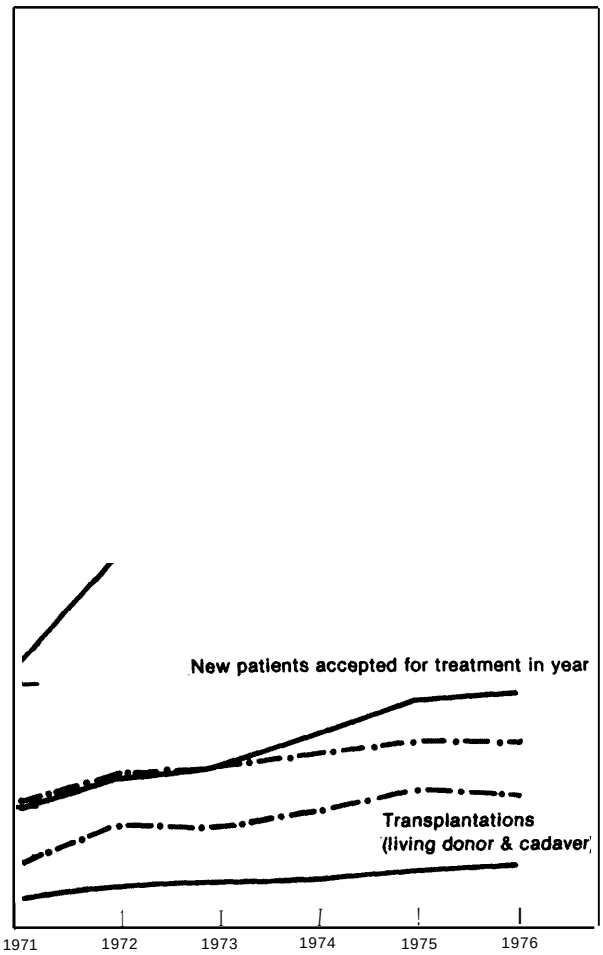
Dialysis will continue to be a major cost problem as long as it is the primary form of treatment for chronic kidney failure. In every country, the number of dialysis patients is growing as new patients are brought in for treatment and a much smaller number die each year—and the number of patients will 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.

CHAPTER 11 REFERENCES

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Appendix