
1 Introduction

Contents

	<i>Page</i>
Rising Medical Care Expenditures	3
The Diffusion of Medical Technologies.	4
Description of This Volume	5
Description of Five Medical Technologies	5
Chapter I References	7

TABLE

<i>Table No.</i>	<i>Page</i>
1. Annual Percentage Increase in the Consumer Price Index and Health Care Expenditures in Eight Industrialized Countries	3

FIGURE

<i>Figure No.</i>	<i>Page</i>
1. Stages in the Development and Diffusion of Medical Technologies.	4

Introduction;

RISING MEDICAL CARE EXPENDITURES

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

Economists have estimated that new resources account for up to half of the rise in the cost of hospital care in the United States (2). Clearly, substantial amounts of the new resources are being used to provide new medical technologies. Some new technologies provide no benefit for the patient.¹ That finding, apart from stimulating interest in the scientific evaluation of the efficacy and safety of medical technologies, has raised the hope among some that

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

the rapid rate of growth in health expenditures can be stemmed simply by eliminating technologies and services that do not provide any benefit. Unfortunately, however, this is not an adequate solution to the problem of rising costs. The reason is that most new technologies do appear to have at least some benefit, however small or costly. Examples of technologies that fall into this category are "halfway" technologies such as organ transplantation, artificial organs, many cancer therapies, and current treatment for coronary artery disease (11).

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

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

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

^aRanked by 1969-76 health care expenditures.

^bData for 1960-75 and 1969-75.

^cData for 1965-75 and 1969-75.

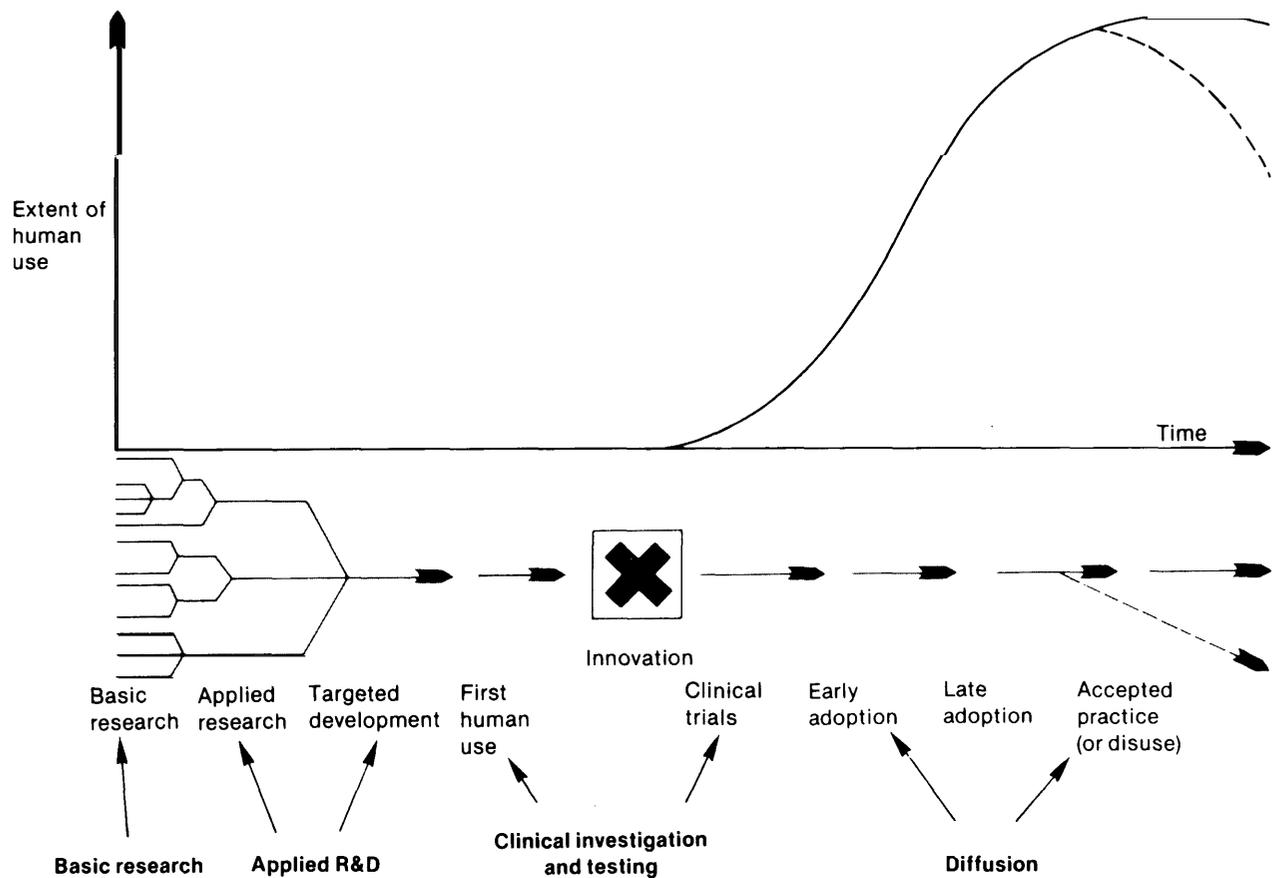
SOURCE: J. G. Simanis, and J. R. Coleman. "Health Care Expenditures in Nine Industrialized Countries, 1960-1976." *Social Security Bulletin* 43:3, 1980 (10).

THE DIFFUSION OF MEDICAL TECHNOLOGIES

Public intervention to control the diffusion and use of specific technologies is likely to be related to one or another of the four theoretical stages in the process of development and diffusion of medical technologies shown in figure 1. The first stage, *basic research*, produces new knowledge about the biological mechanisms underlying the normal functioning of the human body and its malfunction in disease (6). In the second stage, *applied R&D*, this basic information is used to create new solutions to problems in the prevention, treatment, or cure of disease. The next stage, *clinical investigation and testing*, involves the testing of new medical technologies in human subjects. This stage encompasses

a range of activities from first human use to large-scale clinical trials and demonstration projects to demonstrate efficacy and safety (s). Efficacy is the benefit from use of a technology; safety is a measure of the risk of a technology. Finally, as a new technology appears to be of value, clinicians begin to use it and patients begin to ask for it. As more and more physicians use the technology on more and more patients, the extent of its use increases. This is the process of *diffusion*. Diffusion may end with the technology's attainment of an appropriate level of use. Alternatively, it may end with the technology's being abandoned, either because it was of no value or because a more effective technology

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



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

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

The model sequence depicted in figure 1 is attractive because it offers a way to understand the process of development and diffusion of medical technologies such as drugs, devices, and procedures. In reality, however, medical technologies emerge from a process that is far less systematic than the model implies. In the ideal model of diffusion, for example, scientific evaluation of efficacy and safety is an integral part

of the diffusion process. In the real world of medical care and health care policy, however, such evaluation is often not done (5). Epidemiological and statistical methods have been developed to measure scientifically the benefits and risks of a technology under controlled conditions. Increasingly, these methods, and especially the controlled clinical trial, have been proposed as the basis for decisions concerning medical technology.

DESCRIPTION OF THIS VOLUME

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

Generally, each chapter begins with an introductory section in which the author briefly describes the country's form of government and

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

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

DESCRIPTION OF FIVE MEDICAL TECHNOLOGIES

Computed tomography (CT) scanners.—The CT scanner is a diagnostic device that combines X-ray equipment with a computer and a cathode ray tube (television-like device) to produce images of cross-sections of the human body (7). The first machines were "head scanners," de-

signed to produce images of abnormalities within the skull (e. g., brain tumors). These machines were developed in Britain in the late 1960's. "Body scanners" able to scan the rest of the body as well as the head have been developed more recently.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In 1975, 5 billion laboratory tests were done in the United States at an estimated cost of \$15 billion (6). The number of tests was increasing both for hospitalized and ambulatory patients. Between 1969 and 1976, the average number of tests provided per patient per day in the hospital rose from 2.3 to 5.0, an average annual increase of 11.1 percent (1). During the same period, the average cost per test rose by \$0.22, from \$1.34 to \$1.56. In 1976, it was projected that the total volume of laboratory tests nationally would rise at the rate of 11 percent a year (6).

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