Health Care Technology and Its Assessment in Eight Countries

February 1995

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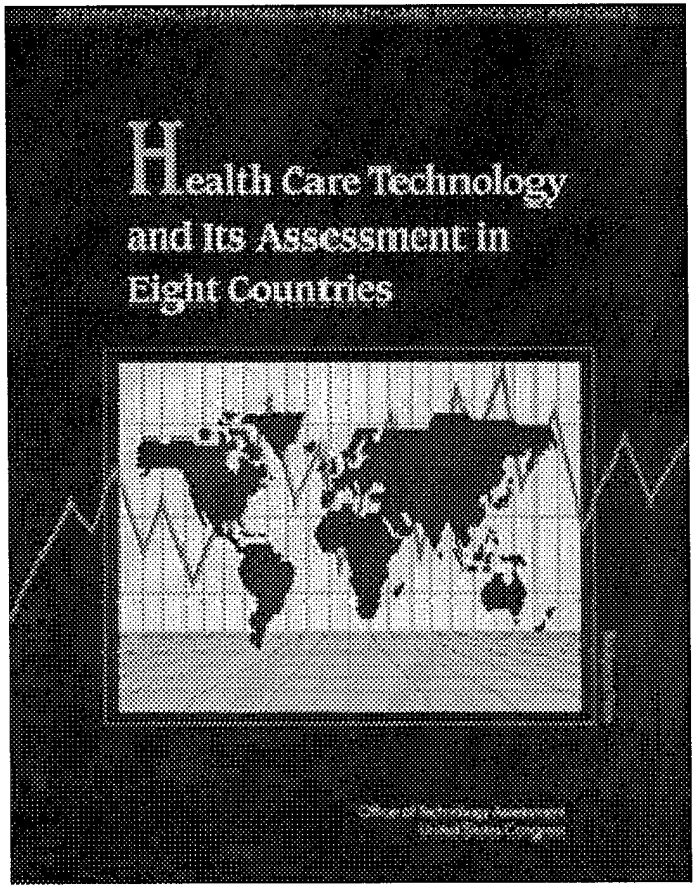

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Foreword

In 1980, when OTA examined the management of health care technology in 10 countries, we stated that "international literature in the area of evaluating and managing medical technologies is sparse. " The richness and variety of experiences in 1994, captured for eight countries in this background paper, is evidence that major changes have occurred. Technology assessment in health care was just emerging in the United States at the earlier date, and in other countries it was largely a new concept whose role had not yet been defined. Today, it would take a volume bigger than this one to fully describe technology assessment just in the United States. In each of the other countries studied—Australia, Canada, France, Germany, the Netherlands, Sweden, and the United Kingdom—technology assessment organizations also have become part of the health care landscape.

It is easy to catalog health care technology assessment organizations and their work in each country but difficult to discern how the adoption and use of technology has been affected by those efforts. In this background paper the experiences of each country with six technologies (or sets of technologies)—inincluding evaluation and management efforts and how the technologies diffused—are presented and compared. The six areas are: 1) treatments for coronary artery disease, 2) imaging technologies (CT and MRI scanning), 3) laparoscopic surgery, 4) treatments for end–stage renal disease, 5) neonatal intensive care and 6) breast cancer screening.

This background paper is part of a larger study on International Differences in Health Care Technology and Spending, which consists of a series of background papers. *International Health Statistics: What the Numbers Mean for the United States* was published in November 1993, and *International Comparisons ofAdministrative Costs in Health Care* appeared in September 1994. An additional background paper will report on lessons for the United States from a comparison of hospital financing and spending in seven countries.

The country chapters of this background paper were written by experts in those countries, and the entire effort was guided by David Banta of the Netherlands. It was greatly assisted by the advisory panel for the overall study, chaired by Rosemary Stevens of the University of Pennsylvania. In addition, many other individuals helped in various ways and OTA acknowledges gratefully the contribution of each one. As with all OTA documents, the final responsibility for the content rests with OTA.

ROGER C. HERDMAN
Director

Advisory Panel

Rosemary Stevens, Chair
University of Pennsylvania
Philadelphia, PA

Stuart Altman
Brandeis University
Waltham, MA

Jan E. Blanpain
Leuven University, Belgium
Leuven, Belgium

Harry P. Cain II
Blue Cross and Blue Shield Association
Washington, DC

Thomas W. Chapman
The Greater Southeast Healthhcare System
Washington, DC

Louis P. Garrison, Jr.
Syntex Development Research
Palo Alto, CA

Annetine Gelijns
Columbia University
New York, NY

John Iglehart
Health Affairs
Bethesda, MD

Ellen Immergut
Massachusetts Institute of Technology
Boston, MA

Lynn E. Jensen
American Medical Association
Chicago, IL

Bengt Jonsson
Stockholm School of Economics
Stockholm, Sweden

Kenneth G. Manton
Duke University
Durham, NC

Edward Neuschler
Health Insurance Association of America
Washington, DC

Jean-Pierre Poullier
Organisation for Economic Co-operation and Development
Paris, France

Mark Schlesinger
Yale University
New Haven, CT

Note: OTA appreciates and is grateful for the valuable assistance and thoughtful critiques provided by the advisory panel members. The panel does not, however, necessarily approve, disapprove, or endorse this background paper. OTA assumes full responsibility for the background paper and the accuracy of its contents.

Project Staff

Hellen Gelband
Project Director

Clyde J. Behney
Assistant Director
Health, Education, and Environment

Sean R. Tunis
Health Program Director

ADMINISTRATIVE STAFF

Beckie Erickson[1]
Health Program Office Administrator

Louise Staley[2]
Health Program Office Administrator

Charlotte Brown
Word Processing Specialist

Daniel B. Carson
PC Specialist

Carolyn Martin
Word Processing Specialist

Carolyn Swarm
PC Specialist

CONTRACTORS

Martha Cooley
Washington, DC

A. Mark Fendrick
University of Michigan
Ann Arbor, MI

Claudia Steiner
Johns Hopkins University
Baltimore, MD

1 Until September 1994
2 From September 1994

Contributors

H. David Banta
Netherlands Organization for Applied Scientific Research
Leiden. The Netherlands

Renaldo N. Battista
Conseil devaluation des Technologies de la Sante' du Quebec and
McGill University
Montreal, Canada

Michael Bos
Health Council of the Netherlands
The Hague, The Netherlands

Hellen Gelband
Office of Technology Assessment
U.S. Congress
Washington, DC

David Hailey
Australian Institute of Health and Welfare
Canberra, Australia

Matthew J. Hedge
Montreal General Hospital
Montreal. Canada

Robert Jacob
Quebec Ministry of Health and Social Services
Quebec, Canada

Egon Jonsson
Karolinska Institute and
Swedish Council on Technology Assessment in Health Care
Stockholm, Sweden

Stefan Kirchberger
Landesversicherungsanstalt Sachsen and University of Muenster
Leipzig, Germany

Jackie Spiby
Bromley Health
Hayes, Kent, United Kingdom

Sean R. Tunis
Office of Technology Assessment
U.S. Congress
Washington, DC

Caroline Weill
National School of Public Health
Saint-Maurice, France

Acknowledgments

Rob Carter
National Centre for Health Program Evaluation
Melbourne, Australia

Bernard Cohen
Eurotransplant Foundation
Leiden, The Netherlands

Dell Cowley
Australian Institute of Health and Welfare
Canberra, Australia

Bernard Crowe
Australian Institute of Health and Welfare
Canberra, Australia

Wolodja Dankiw
Australian Institute of Health and Welfare
Canberra, Australia

Yvonne van Duivenboden
Health Council of the Netherlands
The Hague, The Netherlands

Naarilla Hirsch
Australian Institute of Health and Welfare
Canberra, Australia

Guido Persijn
Eurotransplant Foundation
Leiden, The Netherlands

Diane Telrnosse
Conseil devaluation des Technologies de la Sante
du Que'bec
Montreal, Canada

Gabriel ten Velden
Health Council of the Netherlands
The Hague, The Netherlands

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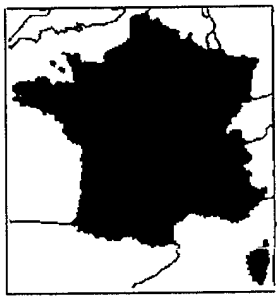

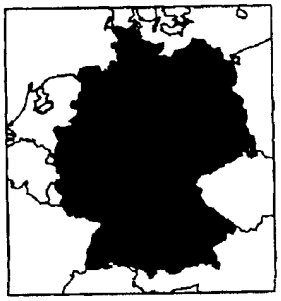

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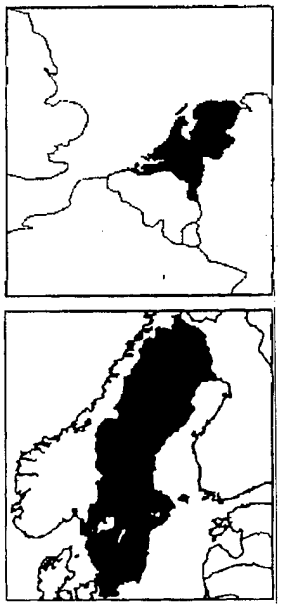

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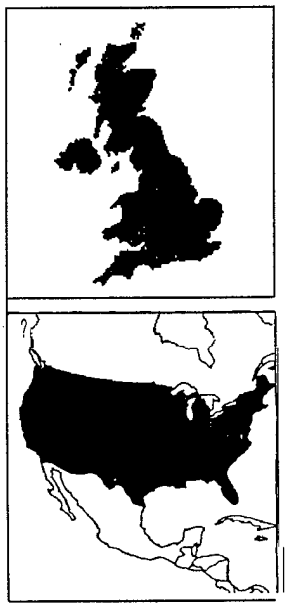

Health Care Technology as a Policy Issue

by H. David Banta

The rapidly rising costs of health care became the most important health policy issue in many countries during the 1980s and early 1990s. These costs are now threatening the prospects for providing higher quality services to broader population groups, especially in the United States. The reasons for rising costs clearly include the aging of the population, with associated increasing rates of chronic diseases and disabling conditions. Another critical factor is the rate at which resources are used in health care-which in turn is linked with the rapidity of technological change.

Apart from inflation and its effects on wages and the costs of goods, the increase in resource use is the primary reason for rising health care costs. Nations seeking to control these costs must control the growth and/or use of resources—an effort that inevitably has involved trying to control the processes by which health care technologies are developed, evaluated, adopted, and used.

Yet even without rising costs, controlling technology seems necessary. Choices among technologies have to be made—this occurs at different levels of health care systems. Some choices are made at the national or regional policy level, as when laws and regulations prevent the purchase of equipment or the provision of certain services. Most choices, however, are at the operational level of clinical practice: made by hospital administrators, heads of clinical departments, and health care providers working day to day. The ability to influence these choices, and the means through which that influence is exerted, are prominent health policy issues.

One means of positively influencing choice is through the application of health care technology assessment. Now about 20 years old, the assessment field developed as a tool for policy-

TABLE 1-1: Population, GDP Per Capita, and Health Care Spending in Eight Countries

Country	Population (millions)	GDP per capita ($US)[a]	% GDP on health care	% public spending[b]	Spending per capita[c] ($ US)
Australia	17.3	17,038	8.6	67.8	1,409
Canada	27.0	21,537	10.0	72.2	1,915
France	56.4	21,022	9.1	73.9	1,605
Germany	78.0[d]	24,585	8.5	71,8	1,659
Netherlands	14.9	19,298	8.3	73,1	1,360
Sweden	8.5	27,498	8.6	78.0	1,443
United Kingdom	57.5	17,596	6.6	83.3	1,035
United States	251.4	22,204	13.4	43.8	2,867

[a] Average GDP per capita for Organisation for Economic Co-operation and Development countries $US20,305
b percentage of health spending from public Sources
[c] Made comparable through purchasing power parity, in $US
[d] Germany West, 61 3; Germany East, 16.7

SOURCE Organasation for Economic Co-operation and Development, OECD Health Data A Software Package for the International Comparison of Health Care Systems (Paris, France Organsation for Economic Cooperation and Development, 1993)

makers to help shape the course of technological change in health care. One major focus of this report is the relationship between policy and operational levels and the field of health care technology assessment.

THE DIFFUSION OF HEALTH CARE TECHNOLOGY

Influencing technological change in health care means developing policies that affect basic research, applied research, clinical investigation and testing, and diffusion of technologies. *Basic research* produces new knowledge about the biological mechanisms underlying the normal functioning of the human body and its malfunctions in disease. Public policies definitely can affect this stage of technological change, as public funds support most of the world's health-related basic research. However, basic research is rather far from clinical technology. The paths by which technology develops are not well understood. Interventions at the basic research stage that might change the course of knowledge development would have unknown effects on later technology development. For these reasons, intervening in basic research has not been very promising as a policy tool.

Applied research uses information from basic research and other sources to generate new solutions to problems of disease prevention, treatment, or cure. Policy interventions at this stage could have greater effects on technological change; however, little is known about these processes. Attempts to direct the course of technological change by undertaking applied research are hampered by the fact that such research related to pharmaceuticals and equipment is carried out by industry, which means that much of the information concerning both these processes and their results cannot be easily obtained. Governments at various levels can, of course, fund applied research aimed at certain ends, but governments have been reluctant to invest heavily in applied research.

Clinical investigation and testing involves testing new health care technologies in human subjects. This stage encompasses a range of activities, from first human use to large-scale clinical trials and demonstration projects to determine efficacy and effectiveness (i.e., health benefit) and safety. Many of these activities are closely associated with technology assessment, as they form an essential part of the evidentiary basis for the field.

Diffsion is the stage of adoption and use of technology. As a new technology appears to be of value, clinicians begin to use it and patients begin to ask for it. Diffusion may culminate with the technology's attainment of an appropriate level of use or with the technology's abandonment, either

TABLE 1-2: Total Health Care Expenditures as Percentages of GDP (by year)

Country	1981	1988	1990	1991
Australia	7,5	8.0	8.2	8.6
Canada	7,5	8.8	9.5	10.0
France	79	8.5	8.8	9,1
Germany	8.7	8.6	8.3	8.5
Netherlands	8.2	8.1	8.2	8.3
Sweden	9.5	8.5	8.6	8.6
United Kingdom	6.1	6.1	6.2	6.6
United States	9.6	10,8	12.4	13.4

SOURCE Organisation for Economic Co-operation and Development, OECD Health Data A Software Package for the International Comparison of Health Care Systems (Pans, France Organisation for Economic Cooperation and Development, 1993)

because it was of no value or because a more effective technology has been developed. The technology also may be used too much or too little, as often seems to be the case.

In recent years a great deal of attention has been paid to the possibility of assessing the benefits, risks, and costs of technologies before they come into general use and employing the results of these assessments to guide technology adoption and use. The way in which such technology assessments have developed in eight countries is the major theme of this report.

For various reasons the effect of technology assessment has been limited in these nations, especially when the forces of th health care system lead to behavior that differs from what is seemingly desirable. Consider the powerful incentives embodied in payment for health care. Physicians may be paid highly for doing endoscopies, and studies showing that endoscopy is overused will probably have little effect on practice as long as use is well rewarded. This situation underlines the importance of the structure of the health care system and the nature of policies on technology adoption and use. These factors are discussed in the chapters that follow.

CONTENT OF THIS REPORT

Industrialized countries have begun to intervene with mechanisms to influence the development, diffusion, and use of health care technologies. The general and specific public policies that affect these processes in eight industrialized countries are discussed in chapters two through nine of this volume, which cover Australia, Canada, France, Germany, the Netherlands, Sweden, the United Kingdom, and the United States. Each chapter also presents that country's experience with a number of specific technologies: treatment for coronary artery disease (mainly coronary artery bypass grafting and percutaneous transluminal coronary angioplasty); medical imaging; laparoscopic surgery; treatment of end stage re al disease (including dialysis, renal transplant, and erythropoietin); neonatal intensive care (including extracorporeal membrane oxygenation); and screening for breast cancer.

The eight countries are all at similar levels of socioeconomic development. Their populations vary from 8.5 million to 251 million and their gross domestic product per capita varies from about $17,000 to about $27,000 (table 1-1). In 1991, the percentage of Gross Domestic Product (GDP) going to health care ranged from 6.6 in the United Kingdom to 13.4 in the United States (table 1-2). The health levels of the selected countries are generally similar (tables 1-3 and 1-4). One must be aware, however, that health status is related to many factors besides health care and health care technology (88).

TABLE 1-3: Infant Mortality Rate (infant deaths per 1,000 live births) Selected Years, 1981–91

Country	1981	1986	1990	1991
Australia	10.0	8.8	8.2	7.1
Canada	9.6	7.9	6.8	—
France	9.6	8.0	7.2	8.3
Germany	11.6	8.7	7.1	—
Netherlands	8.3	7.8	7.1	6.5
Sweden	6.9	5.9	6.0	6.1
United Kingdom	11.2	9.5	7.9	7,4
United States	11.9	10,4	9.1	8.9

SOURCE Organisation for Economic Co-operation and Development, OECD Health Data A Software Package for the International Comparison of Health Care Systems (Paris, France Organisation for Economic Cooperation and Development, 1993)

TABLE 1-4: Life Expectancy at Birth, Selected Years, 1981-91

	1981		1986		1990		1991	
Country	Women	Men	Women	Men	Women	Men	Women	Men
Australia	78,4	71,4	79,2	72.9	80.0	73.9	NA	NA
Canada	79.1	71.9	79,7	73.0	80.4	73.8	NA	NA
France	78.5	70,4	79.7	71.5	80.9	72.7	81,1	73,0
Germany	76.9	70.2	78.4	71.8	NA	NA	NA	NA
Netherlands	79.3	72.7	79.6	73,1	80.1	73.8	80.3	74,0
Sweden	79,1	73.1	80.0	74.0	80.4	74.8	NA	NA
United Kingdom	76,8	70,8	77.6	71,9	78.5	73.0	78.6	72.0
United States	77.8	70.4	78.3	71.3	78.9	72.0	NA	NA

NOTES 1990 and 1991 figures for US and UK are not confirmed: NA = not available

SOURCE Organisation for Economic Co-operation and Development, OECD Health Data. A Software Package for the International Comparison of Health Care Systems (Pares France Organisation for Economic Cooperation and Development, 1993)

Each of these chapters introduces the country's form of government and economy and then describes the country's health care system. Policies concerning research and development (R&D), evaluation, diffusion, regulation, and payment for technologies are discussed, and the chapters end with the case studies mentioned above showing how these policies have been applied.

The final chapter of the report draws general lessons from the eight countries. As background for the policy discussions in the remaining chapters of this volume, the technologies featured in the case studies are defined below and their uses, efficacy, and costs briefly described.

Case studies

TREATMENTS FOR CORONARY ARTERY DISEASE-CABG AND PTCA

Coronary artery disease, the most frequent cause of death in the industrialized world, is caused by narrowing and blocking of one or more of the arteries that supply blood to the heart. Coronary artery bypass grafting (CABG) is a surgical procedure in which a grafted vessel is placed between the aorta and a coronary artery to bypass a contracted portion of the artery, improving blood supply to the heart muscle.

A number of surgical procedures were tried in the past to improve the blood supply to the heart, but CABG is now the standard procedure. The American surgeon Michael DeBakey performed the first CABG in 1964, using a vein from the patient leg as a graft to bypass the occlusion in the coronary artery. After its introduction CABG spread rapidly into practice. In 1991 more than 400,000 CABG procedures were done in the eight countries discussed in this report.

The first randomized clinical trials to evaluate CABG took place in the early 1970s. It was clear early on that the operation effectively relieved angina pain, but the impact on survival was less clear. A recent overview of the trials, in which CABG was compared with medical therapy, shows the following results (93): significantly improved survival in patients with left main coronary artery disease, and in patients with single- or double-vessel disease; a non significant trend toward improved survival at five years, but no difference at 10 years (68).

During the 1960s and 1970s, the use of a catheter to dilate arterial stenosis (narrowing) was investigated. In 1964 Dotter and Judkins (22)

al vascular system, noting substantial improvement in health status and avoidance of amputation of the limbs when used for peripheral blockage. This technique continues to be used in Europe but never gained adherents in America (40).

In 1974 Gruentzig and his colleagues (36) used a catheter with a modified distensible tip to dilate renal and peripheral arteries. Two years later a similar but smaller tip was used to dilate coronary arteries in animals, and the technique was then used in humans. This procedure, percutaneous transluminal coronary angioplasty (PTCA), is now the standard n-ninvasi - (minimally invasive) procedure for cardiovascular disease. PTCA is done under local anesthesia and does not require an operating room, although emergency backup is necessary in case of cardiac arrest or other life-threatening complications.

PTCA involves penetrating the skin (percutaneous), crossing the inner space of the blood vessel (transluminal), and affecting the vessel constriction (angioplasty). It uses a guide catheter that can travel to the constricted area and a balloon threaded by wire through the catheter and across the stenosis. When the balloon is in the appropriate location, it is inflated repeatedly with a mixture of saline and contrast material. As the balloon presses against the artery wall, fluid is expelled from the plaque, which then splits at its weakest point. Over time, healing -curs. Immediate success rates for stenosis are above 90 percent, depending on the characteristics of the stenosis, the patient's clinical status, and the skill of the clinicians (39,48). Success rates for total blockage are considerably lower. PTCA is particularly indicated for short, segmental, and high-grade (more than 50 percent) blockages. Although restenosis occurs in 25 to 35 percent of patients, usually within six months of the procedure (46), PTCA has excellent later results, with few recurrences after six months.

PTCA was not tested in randomized controlled trials in its early diffusion. Trials comparing PTCA and CABG are only now underway in both the United States and Europe.

The evaluation of outcomes in the case of procedures on the coronary arteries is difficult. Cure cannot be expected. The patient generally continues to have the disease, and symptoms are often progressive. Cardiologists favor PTCA primarily because it delays the need for CABG, a much more invasive procedure. An issue of increasingly visibility in the United States and some other countries is the possible inappropriate use of CABG and PTCA (92).

In recent years a number of new technologies have come into development, including laser treatment, stents, rotary devices, and others (89). In general these have not proved (yet) to have better results that PTCA (74). One prominent alternative used increasingly in a number of countries is excimer laser angioplasty (6). Excimer laser angioplasty is being tested in a randomized clinical trial in the Netherlands.

The cost-effectiveness of PTCA versus CABG has been analyzed, but results the are not entirely convincing because of the lack of definitive information on the effectiveness of the procedures. Comparing PTCA with CABG (without a previous attempt at PTCA), the costs for a year of care (in 1984) averaged $US11 ,472 for PTCA and $US13,262 for CABG (70). A major expense in the PTCA group was the treatment of restenosis, seen in 33 percent of patients. These U.S. results might not necessary transfer readily to other coun - tries.

Comparing 100 patients with PTCA for at least two vessels to a matched group of controls undergoing CABG, in one year of followup, one repeat PTCA was required in 10 patients, two were repeated in one patient, and three PTCA patients underwent a CABG. The average costs for a year of care in this case were $US1 1,100 for the PTCA group and $US22,862 for the CABG patients (in the mid- 1980s) (9). More recently, RAND Corp., using data from the Framingham heart study and expert judgment, estimated five-year costs at about $US33,000 for PTCA and $US40,000 for CABG (50).

A 1991 study estimated the cost per quality adjusted life year (QALY) for CABG in patients with left main disease with severe angina pectoris at 2,090 British pounds, compared to 18,830 pounds for patients with one-vessel disease with moderate angina pectoris.

MEDICAL IMAGING (CT AND MRI)

Medical imaging was born with the discovery of x-rays in 1895 by Roentgen in Germany. By 1900, x-rays were being used to diagnose fractures, gallstones and kidney stones, foreign objects in the body, and lung disease. Bismuth was used beginning in 1896 to allow x-ray pictures of the gastrointestinal tract (71).

The innovation of x-rays forced changes in health care organization in all countries. Departments of radiology were established in the early decades of this century, and they expanded rapidly in the 1920s (79,80). The specialty of radiology was formally established in the 1930s. Physicians thereby gained complete control of the medical uses of x-rays.

Medical imaging remained relatively unchanged until the computed tomography (CT) scanner was introduced to the market by the EMI Co. in 1972. The CT scanner is a diagnostic device that combines x-ray equipment with a computer and a cathode-ray tube (a television-like device) to produce images of cross-sections of the human body. The principle of CT scanning was developed by the English physicist Hounsfield; he succeeded in producing the first scan of an object in 1967, and in 1971 he was able to scan the head of a live patient. Commercialization of the CT scanner in 1972 initiated a revolution in the field of diagnostic imaging (86). The first machines were "head scanners," designed to produce images of abnormalities within the skull (e.g., brain tumors). "Body scanners" able to scan the entire body were then developed.

CT scanning was rapidly and enthusiastically accepted by the medical community. Despite concerns about its high cost—up to and more than **$US1 million—it** diffused extraordinarily rapidly and came into widespread use throughout the world. A number of companies developed CT scanners; the international market is now dominated by such companies as General Electric, Philips, and Siemens. Although no randomized studies of the value of CT scanning were done in its early years, clinical experience gradually accumulated that indicated its usefulness in many conditions. It is now a fully accepted diagnostic technology.

Magnetic resonance imaging (MRI) is a more recent innovation in the field of medical imaging, based on nuclear magnetic resonance (NMR). NMR images are formed without the use of ionizing radiation and reflect the proton density of the tissues being imaged, as well as the velocity with which fluid is flowing through the structures being imaged and the rate at which tissue hydrogen atoms return to their equilibrium states after being excited by radiofrequency energy. The first NMR image was published by Lauterbur of the State University of New York in 1973 (49). Prototype MRI units were developed in the United States, England, and the Netherlands in the late 1970s (87).

MRI produces images of cross-sections of the human body similar to those produced by CT scanning (86), with some important differences. A CT scanner depicts the x-ray opacity of body structure. MRI images depict the density or even the chemical environment of hydrogen atoms (42). These various properties are not necessarily correlated.

MRI has several advantages. It gives a high-contrast sensitivity in its images, and it can distinguish between various normal and abnormal tissues. Blood flow, circulation of the cerebrospinal fluid, and contraction and relaxation of organs can be assessed. Tissues surrounded by bone can be represented. Also, MRI does not employ potentially dangerous ionizing radiation, as do CT scanning and other imaging methods. It is not necessary to inject toxic contrast agents, as is often done with CT scanning (although contrast agents are being used more and more frequently with MRI scanning). MRI allows for a choice of different imaging planes without moving the pa-

tient; CT scanning can produce an image of only one plane at a time, and some planes are not scannable. Finally, images can be obtained from areas of the body where CT scanning fails to produce clear images.

Despite its potential, the initial diffusion of MRI in most countries was less rapid than had been the case with CT scanners. Introduction and diffusion were slowed because of the economic recession in the early 1980s. At the same time health authorities were unwilling to invest heavily in MRI before any thorough evaluation had taken place Questions such as these were asked: Is present MRI an advance in imaging technology as compared with CT scanning? Does it produce useful information at a reasonable cost? Does it produce diagnostic information not otherwise available?

MRI has been repeatedly and formally assessed since its introduction (1 ,24,35,45,60,61,62,82, 86). An early issue of the *International Journal of Technology Assessment in Health Care* examined many aspects of MRI (72). These assessments agree that MRI is a reliable diagnostic device that produces information that can be quite useful. However, evaluation of MRI scanning has been far from optimal. For example, a literature review published in 1988 (18) found that 54 evaluations did poorly when rated by commonly accepted scientific standards, such as use of a "gold standard" comparison of blinded readers of the images (i.e., the expert doing the reading does not know the status of the patient). Only one evaluation had a prospective design. Also, over the period examined there was no improvement in quality of research over time, and this problem continued in later years (44,45).

Literature shows that MRI is probably superior to CT, its main competitor, for detection and characterization of posterior fossa (brain) lesions and spinal cord myelopathies, imaging in multiple sclerosis, detecting lesions in patients with refractory partial seizures, and detailed display for guiding complex therapy, as for brain tumors (44,45). In other diseases the efficacy of MRI is similar to that of CT. In fact, the best designed study, carried out in a heterogeneous group of patients in neuroradiology studied in a matched pair design, found that the sensitivity and specificity of CT scanning were somewhat better than those of MRI (38).

As for the diagnostic or therapeutic impact, little information is available. Investigators in Norway found that 33 percent of patients had their main diagnosis changed by MRI scanning (67). Plans for surgery changed in 20 percent of the patients, and plans for radiotherapy changed in 8 percent.

Although most MRI scans are of the brain(11), a specific advantage of MRI lies in diagnosis of spinal cord problems, where MRI may replace myelography, an x-ray procedure involving injection of a potentially dangerous dye. In the spinal cord two studies have examined the relative accuracy of MRI in relation to myelography and CT (57,58). The studies found that MRI and CT were roughly equivalent in terms of true positive results but that both were superior to myelography. MRI is gradually replacing both CT scanning and myelography (8,58). In one study the percentage of physicians ordering myelography prior to MRI dropped from 15 percent to zero during the two-year study period (67).

Another area in which MRI could be quite useful is in imaging joints (19,53). A common problem is torn or damaged menisci (cartilages) of the knee. The standard diagnostic procedure is either arthroscopy by scope or arthrogram; an x-ray procedure. Both are invasive in that the scope must be inserted into the joint or a contrast material must be injected. MRI is not invasive. However, the advantage of arthroscopy is that a therapeutic procedure can be done if an abnormality is found. Another common problem for which MRI may eventually be useful is herniated nucleus palposis ("ruptured disc").

The capital cost of an MRI scanner varies greatly, depending particularly on the strength of the magnets. A basic unit costs at least $US1 million. Operating an MRI facility in the United States costs between $US840,000 and $US1, 115,000 per year in the mid-1980s (1 1,3 1). Only about one-third of this operating cost is accounted for by the capital investment in the scanner itself. Other expenses include space, personnel, equipment,

and maintenance. The cost per scan in one mid- 1980s study was between $US370 and $US550, and the fee paid for the scan was **$US500.** (The costs apparently do not include payment to the physician.) Other studies have demonstrated that the costs of an MRI scan are considerably more than those of a CT scan (45). With increased throughput, MRI units have done well financially (32).

MRI costs maybe offset by replacement of other diagnostic procedures, particularly myelography (1 1). Although myelography requires hospitalization of at least one day, MRI can be done on an outpatient basis. It does not appear to have replaced other modalities, such as CT scanning in the brain, except that it is used preferentially in suspected posterior fossa tumors (84). In general, however, replacement of other procedures by MRI has not been demonstrated. The result is a considerable increase in costs (7,66).

The basic issue with CT scanning and MRI scanning is that they provide similar information. It has been difficult to demonstrate much advantage with MRI.

LAPAROSCOPIC SURGERY

Laparoscopic surgery is part of what has become known as "minimally invasive therapy" (MIT) or "minimally invasive surgery," a new and rapidly growing area of medical treatment that causes substantially reduced trauma to patients. MIT is truly a new field in medical technology, depending in most cases on new, advanced technologies-specially endoscopes, vascular catheters, and imaging devices.

In some respects, however, MIT is not completely new. Physicians and surgeons have always used the orifices of the body to observe internal structures. The first workable endoscope was developed by Desorrneaux in 1853. The laryngoscope, which made it possible to look at the larynx and the vocal chords, was developed in 1857. The benefits of the ophthalmoscope and laryngoscope stimulated the development of devices to explore other body cavities, such as the vagina, rectum, and stomach (1860). Visual scopes, such as the hysteroscope (1869) and the gastroscope (1870), came into use later; however, these procedures became truly widespread with the introduction of the flexible fiberoptic endoscope in the mid-1950s. Endoscopy then became a routine diagnostic tool. The movement toward surgery came as instruments were gradually incorporated into the scopes; they included miniature forceps, scissors, and (more recently) lasers, heat probes, electrocoagulation devices, and cryotherapy devices.

The first endoscopic examination of the abdominal cavity was carried out by Ott in 1901 in a procedure he named "ventroscopy." Kelling also carried out this procedure in 1901 and published a paper in which he described the entire procedure and its future possibilities (37). Nevertheless, the procedure was not often used, probably because of limitations of the technology. Introduction of the flexible fiberoptic endoscope in 1957 solved many of the technical problems and led to the widespread use of diagnostic laparoscopy.

The laparoscope was first used therapeutically in gynecology during the 1960s. The first International Symposium of Gynecological Endoscopy was held in 1964, and tubal sterilization by laparoscope was done with increasing frequency by 1969 (37). By 1974, a few treatments of endometriosis through the laparoscope by fulguration had already been reported (52).

Appendectomy is among the commonest surgical procedures in most countries. Appendectomy removes an inflamed appendix, which may perforate and spread infection. Appendectomy by laparoscope has now been done by Semm (73) in Germany for more than 10 years with good success. A gynecologist, Semm observed that during diagnostic laparoscopy for pelvic pain in young women, he sometimes found an unexpected inflamed appendix. He developed instruments to allow removal of the appendix through the laparoscope. The procedure is gradually gaining favor in the United States and Europe.

Laparoscopic cholecystectomy is the most dramatic case of laparoscopic surgery. Cholecystectomy, removal of the gallbladder, has been done since 1882. It is one of the most frequent surgical

procedures in industrialized societies. The standard treatment for symptomatic gallbladder disease (e.g., inflammation, stones) has been surgical removal, a procedure associated with ileus, pain, and a slow return to normal functioning (21) and a hospital stay averaging five days (90).

The first successful cholecystectomy via laparoscope was done by Mouret in France, in 1987. The procedure spread in France, and in 1988, particularly after publication of the experience of the group headed by Dubois (23), it began to spread internationally, particularly rapidly in North America (12). The first procedure was done in the United States in 1988 (69), but most of the spread has occured in the 1990s. In late 1990 more than two-thirds of 29 Canadian hospitals responding to a survey were already in the laparoscopic cholecystectomy business (13), Surgeons in the United States and elsewhere were skeptical initially, but patients began demanding the less invasive procedure and surgeons have acquiesced (5, 12).

Laparoscopic cholecystectomy was not evaluated initially by randomized controlled trials (5). In fact, evaluations of laparoscopic cholecystectomy played little part in its diffusion. Nonetheless, a number of uncontrolled studies give clear evidence of the superiority of this procedure in skilled hands (41 ,78). Other applications of laparoscopic surgery (in general surgery and gynecology) have not yet been well evaluated. These applications include hernia repair, bowel resection, treatment of colorectal cancer, removal of kidney stones, and a number of gynecological procedures, such as hysterectomy and removal of ovarian cysts (5).

Laparoscopic procedures are assumed to be more cost effective than the corresponding open surgeries, but few good analyses have been performed. The assumption of cost-effectiveness is based on a shorter length of hospital stay and an earlier return to normal activities. A comparative study of Australia and Canada estimated that the change to this procedure from open surgery could potentially reduce the health care costs of cholecystectomy in Canada from $C271 million to $C215 million and in Australia from $A124 million to $A1OO million (54). One can readily observe that the potential total savings from the 100 or so procedures included in MIT could be enormous. However, the number of cholecystectomies actually rose 15 to 20 percent after introduction of the laparoscopic technique in Canada and Australia (54). The actual health system savings achieved were only 56 percent of the potential savings in Canada and only 13 percent of those in Australia.

TREATMENTS FOR END-STAGE RENAL DISEASE (ESRD)

Hemodialysis and renal transplantation are two life-extending therapies developed in the early 1960s for victims of ESRD, 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. In hemodialysis toxic waste products are removed from the blood by means of an artificial kidney. The first dialysis machine was built in the Netherlands by physician and bioengineer Kolff in 1943. His machine was the basis for dialysis treatment as provided today. In the beginning the dialysis machine could be used only for patients with acute renal failure because the cannulas inserted into the patient arteries caused serious damage and could be used only for a short time (a matter of days). This changed around 1960 when Scribner and Quinton invented a new shunt system linking an artery to a vein and making use of teflon and silicone rubber cannulas, which prevent blood clotting and damage to the arteries and allow the shunt to stay in place permanently. Since then, patients have been able to live on "chronic intermittent dialysis," usually about three times a week.

In renal transplantation a healthy kidney from a living person or from someone who has just died is substituted for an individual's nonfunctioning kidney. Kidneys were the first successfully transplanted organs and remain the prototypic transplant. The Russian surgeon Voronoy attempted the first kidney transplantation in a human being in 1933; however, this and other attempts inevitably ended in rejection of the organ and death of the patient.

After the Second World War, new attempts were undertaken. A great step forward was made through the work of Peter Medawar, an Oxford zoologist who studied the immune response and found ways to manipulate it and induce immunological tolerance. On the basis of this work, immunosuppressive therapy using different drugs was developed. Medawar's finding that the immune response was not present in closely related individuals gave doctors the courage to try kidney transplantation between identical twins. In December 1954 Murray performed the first successful kidney transplant in Boston between the twin brothers Richard and Ronald Herrick. Richard survived for eight years with a functioning donor organ.

In 1962 the first successful kidney transplantation using the kidney of a deceased, genetically unrelated donor took place, following the discovery of the effective immunosuppressive drug 6-mercaptopurine. In 1958 the French immunologist Dausset discovered the role of human leukocyte antigens in graft rejection, and this became the basis for tissue typing and matching, making possible the matching of organs from deceased unrelated donors to recipients. Kidney transplantation on a large scale thus became a reality.

Steroidal hormones were used in conjunction with antimetabolites beginning about 1962, producing better results. Antilymphocyte serum joined the other two types of drugs around 1966, further improving results. In the 1970s cyclosporin, a particularly effective drug that acts by suppressing certain T-lymphocytes, was discovered and began to be used clinically. (In addition to their benefits, these drugs have significant toxic effects.)

With these improvements, kidney transplantation spread into use around the world, beginning in the 1960s. Kidney transplants are performed for ESRD associated with all major causes—mostly in people under 65 years old but increasingly in elderly people as well. Transplants are considered a fully established medical intervention.

The current rate of kidney survival is about 65 percent survival for five years after one transplant and 45 percent after a second transplant (if the first one fails). The five-year rate of survival from live donors (about five percent of the total) is about 85 percent: for patients in the age group up to 45 years, it is about 95 percent, and in the age group 45 to 65, about 80 percent (34).

Kidney transplant and different forms of renal and peritoneal dialysis comprise the treatment mix of ESRD programs. Without dialysis, patients with ESRD would die if an organ did not become available in time. After irreversible rejection of a donor kidney, the patient would die without a second transplant or dialysis. In practice, kidney transplant is a substitute for dialysis; therefore, the effects of kidney transplant as well as financial costs must be considered in comparison with the outcomes of dialysis. In general, quality of life following kidney transplant is nearly equal to that of the general population and is considerably higher than that of people on dialysis treatment (29,43,77). (An increased number of kidney transplants does not lead to a gain in years of life because of the availability of dialysis, however.)

An exemplary study from the Netherlands illustrates the financial savings to be gained by transplant (20). The yearly cost of renal dialysis carried out in a dialysis center was found to be Dfl 77,000 (about $US40,000). Renal transplant was found to cost Dfl. 69,000 (about $US38,000) in the first year and Dfl. 6,000 (about $US3,300) in every succeeding year.

The cost per QALY has been estimated for different ESRD treatments (55). Hospital hemodialysis costs 21,970 British pounds per QALY, compared with 19,870 pounds for continuous ambulatory peritoneal dialysis, 17,260 pounds for home hemodialysis, and 4,710 pounds for kidney transplant.

A new technology frequently used as part of renal dialysis is erythropoietin (EPO), licensed in the United States in June 1989. EPO is a substance produced through biotechnology that stimulates the bone marrow to make red blood cells. The most frequent use of EPO is inpatients on chronic hemodialysis for ESRD, as such patients suffer from a depressed bone marrow leading to frequent blood transfusions. EPO can make transfusions

unnecessary or much less frequent. In clinical trials EPO has been found to reverse uncomplicated anemia of renal failure within months (16,47,91).

Several clinical trials have examined the efficacy of EPO. Evans and colleagues (30) examined the quality of life in 300 patients before and after treatment with EPO and found it was improved in various respects. Patients reported increased energy, activity levels, functional ability, sleep and eating behavior, disease symptoms, health status, satisfaction with health, sex life, wellbeing psychological affect, life satisfaction, and happiness. The Canadian EPO Group reported similar findings.

EPO is very expensive, however. In the United States, it costs about $US 10,000 per year per patient on chronic dialysis. Because patients apparently do not return to work, there is no financial offset for this expenditure, raising serious questions about the cost-effectiveness of EPO in the setting of chronic renal failure.

Maynard (55) found that the estimated cost per QALY gained by EPO for dialysis anemia, assuming a 10-percent reduction in mortality, was 54,380 British pounds. Assuming no increase in survival, the cost per QALY was 126,290 pounds. McNamee and colleagues (56) estimated that the cost per QALY gained at Df1374,000 (about **$US210,000).**

NEONATAL INTENSIVE CARE

Neonatal intensive care involves the constant and continuous care of the critically ill newborn. The origin of "modem" neonatal intensive care technology can be traced to the first incubators developed by the obstetrician Tarnier in Paris in 1880. He took the idea from a chicken incubator that he had seen at an agricultural fair. The scientific development of medical care for the premature child started with Pierre Budin, a pupil of Tarnier, who published a treatise on the care of the premature newborn in 1890. In the years up to 1950, the Tamier prototype was improved. The "Lion incubator," introduced in 1896 (at the Berlin World Exhibition) by Couney, had a metal frame with glass doors, and air, temperature, and moisture could be regulated. Through Couney's promotional activities, specialized care for premature babies became established in the United States.

Another development was the Auvard incubator, a less sophisticated device made of wood in which hot-water bottles were placed. This machine became very widely used because it was relatively cheap. (Some hospitals used it up to the 1950s.) The most significant technological developments have occurred since World War II.

Most babies with severe problems weigh less than 2,500 grams at birth. During the late 1940s and 1950s, babies began regularly to be fed with indwelling tubes and to be given high concentrations of oxygen (15). Subsequently, the use of respirators, electronic monitoring, analysis of small blood samples, and the development of specialized staffs of highly trained nurses have become part of neonatal intensive care. Regional networks have been organized to coordinate services for obstetrical and newborn care in many countries. Regional tertiary-care centers have been developed to specialize in high-risk births and the care of sick infants.

Beginning about 1980, there has been concern about both the effectiveness and costs of neonatal intensive care. However, most studies (as in the case of prenatal care) consider the effectiveness (and/or costs) of a package of care given to high risk and very low weight infants, and it is difficult to isolate either the effective or the ineffective parts of this care (1 5).

There is evidence of falling mortality among populations of babies born weighing less than 1,500 g during the period of introduction of neonatal intensive care methods; evidence that low-weight babies born in institutions with neonatal intensive care units (NICUS) have a lower mortality rate than similar babies born in other institutions (65): and evidence in geographically based populations of better outcomes for low birthweight babies with access to NICUS (4,33). The mprovements in outcome have been seen in the group weighing from 750 to 1.000 g (26).

More than 700 randomized controlled trials of aspects of neonatal care have been identified (59). These trials do not help much in gaining an impression of what works in NICU and what does not. They deal with quite varied subjects, such as the effect of supplementary feeding on neonatal jaundice or the value of red blood cell transfusion for infants with low hemoglobin levels. The numbers in these trials are generally small. For the most part, the trials give little guidance on best practice because of these problems and a general lack of relevance (59).

An increasing rate of handicap among the population might have been expected from the growth in NICUS, but it has not been seen (26). *(Numbers* of handicapped children have, however, increased.)

The most comprehensive evaluation of neonatal intensive care was carried out in Canada (10), in a study in which the economic aspects of neonatal intensive care of very -low-birthweight infants were evaluated using costs and outcomes before and after the introduction of a regional neonatal intensive care program. The two periods compared were 1964 to 1969 and 1973 to 1977. Information on health state was collected from parents and used to calculate outcomes in QALYs. The overall results show an apparently good outcome in the group weighing from 1,000 to 1,499 g as compared with the 500 to 999 g group. The economic cost per QALY gained in the first group is $Cl ,000, compared with $C17,500 for the other group (expressed in 1978 Canadian dollars). There seems little doubt that NICU, as a package, is effective. It is also an expensive intervention.

Technology development has been rapid in neonatal intensive care. This has resulted in a proliferation of untested technologies in a situation in which effectiveness already is not well understood (15). Although randomized trials of new interventions would be desirable, clinicians feel that they cannot withhold possibly effective treatments. The result is that "many interventions become part of the armamentarium of the practicing professional without ever having been proven to be effective" (15).

An example of such a technology is extracorporeal membrane oxygenation (ECMO), developed in the United States in the early 1970s. This technique is used to improve oxygenation and lower mortality in certain serious diseases (81). It is an expensive and invasive technique that is potentially both effective and hazardous. ECMO entails diverting part of the blood circulation through a device that permits gas exchange across a permeable membrane (51) and involves ligating (tying) the carotid artery of the infant (although a newer technique uses a catheter connecting two veins). Some feel that only a few infants could benefit from this treatment, as compared with conventional treatments such as supports for respiration and oxygen (3). Only one small randomized trial (19 babies) was done before widespread diffusion of ECMO in the United States (64) All other studies have been much less rigorous. Yet although ECMO is not proved to be of benefit, it has been stated that randomized trials are no longer possible in the United States (28). A multicenter randomized controlled trial is currently under way in the United Kingdom, coordinated by the National Perinatal Epidemiology Unit in Oxford. A trial using historical controls in the Netherlands, incorporating a cost-effectiveness analysis as part of the study, reported preliminary results in 1994 favoring ECMO over conventional treatment for neonates with severe respiratory distress (at a cost of DF153,500 per infant).

A recent development is the use of nitric oxide (NO) as an alternative to ECMO in the United States. The use of ECMO has begun to decline following experience with an apparently effective and less invasive modality. However, careful evaluations of NO have not yet been carried out.

SCREENING FOR BREAST CANCER

Screening for breast cancer was developed during the late 1960s and early 1970s. The key event in this case was a large, well-designed randomized trial carried out in the Health Insurance Plan (HIP) of Greater New York during the 1970s, showing clear benefits from routine screening in terms of

mortality from breast cancer in women over the age of 50 (75).

Two procedures are used in organized breast cancer screening programs (25): breast physical examination by a trained practitioner and x-ray mammography. Other methods, such as thermography, ultrasonography, CT, and photoluminescence, have also been proposed for screening, but have not proved effective. Breast self-examination has also been promoted and may be of benefit.

The HIP randomized trial offered the interventional group, approximately 31,000 women aged 40 to 64 years, four successive annual screenings with two-view mammography and breast physical examination. About 67 percent of the women accepted, and approximately 50 percent of those received at least three screenings (76). The trial showed a statistically significant reduction in mortality in women who were over 50 years of age at entry into the study. Five years after entry, the reduction in mortality was about 50 percent, falling to about *20* percent at 18 years after entry. For women 40 to 50 years of age at entry, the reduction in mortality was small (about 5 percent at five years, and not statistically significant) (17).

These studies have been followed up by two randomized studies in Sweden (2,83), one in the United Kingdom (85), and a number of nonrandomized studies. These studies in total seem to demonstrate benefit from screening but leave a number of unanswered questions. One problem is that each one has used a different screening regimen, so the independent contribution of the two methods of examination cannot be estimated. (Despite this, most articles reporting on the studies refer to "mammography screening.") Another problem is that the studies have been done at different times with different x-ray technologies; the question of the usefulness of modern technology cannot then be answered. Nonetheless, it is widely assumed that modern x-ray mammography screening alone is of benefit.

A contentious issue is the question of screening women under the age of 50 years. In the United States some groups do not recommend screening women under 50 years of age (25), but others do. In Canada the Task Force on the Periodic Health Examination does not recommend screening younger women (14), but the province of British Columbia does support this practice.

A number of cost-effectiveness analyses of breast screening have been carried out. For illustrative purposes the results of one study from the United States will be presented. Using a number of assumptions, Eddy (25) estimated that a program that screened 25 percent of American women between the ages of 40 and 75 would cost $US4.2 billion for annual breast physical examination alone and $US15 billion for examination plus mammography. Using outcomes from the HIP study, the marginal cost of adding a year of life with both examination and mammography would be $US 134,081 in the age group from 40 to 50 years; $US83,830 in the age group from 55 to 65 years; and $US92,412 in the 65 to 75 year-old group. Other studies have found lower costs per year of life added with breast cancer screening. Typical figures range between $US13,2000 and $US28,000 per year of life saved (27). Maynard (55) found that the cost for a QALY gained through breast cancer screening was 5,780 British pounds. All of these analyses embody certain assumptions about benefit that might not be true.

INTERPRETATION OF THE CASES

Each country has dealt with these technologies, and information on their benefits and costs, in different ways that reveal various forces at work in technological diffusion. The chapters that follow will examine them from each country's perspective.

In chapter 10, these technologies are revisited. Differences and similarities in how they have been treated in each country are highlighted in that chapter.

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Health Care Technology in Australia

2

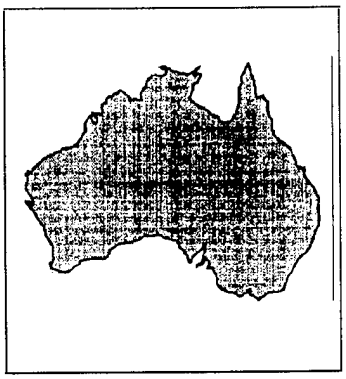
by David Hailey

OVERVIEW OF AUSTRALIA

Australia, which lies southeast of Asia between the Indian and Pacific oceans, consists of the smallest continent (and the world's largest island—approximately 4,000 km from east to west and 2,000 km from north to south) as well as the island of Tasmania. About a third of the continent is uninhabitable; in another third the rainfall is too low to permit close settlement. The climate varies from tropical to alpine, with very limited rainfall in the deserts in the center of Australia.

I Population Characteristics

The country's population in 1992 was 17.4 million (17). The population is highly urbanized; 85 percent of Australians live in urban areas, and 65 percent live in the six state capitals. The main concentration is in the southeast, predominantly in the coastal zone. The crude fertility rate is 15.4 births per 1,000 population. Since the establishment of New South Wales as a British Colony in 1788, Australia's population growth has been dominated by European settlement, with immigration from Asian countries becoming more significant in recent years. Aborigines and Torres Strait Islanders (descendants of the country's inhabitants prior to European settlement) make up 1.4 percent of the population.



Government and Political Structure

The current political structure follows the federation of the former colonies into the commonwealth in 1901 and the basis for government is set out in the Constitution. Legislative power of the commonwealth is vested in a Parliament consisting of the Queen, a Senate, and a House of Representatives. The system of government follows the Westminster system; Australia's Parliament was modeled on the six state Parliaments, which were in-

turn modeled on the British House of Commons. Parliaments of all states except Queensland are bicameral. The two major territories in the country-the Northern Territory and the Australian Capital Territory-are self-governing and unicameral.

The relative powers of the commonwealth and states have evolved considerably since federation through "cooperative federalism" and interpretations of the Constitution by the High Court of Australia (96). In its development of governmental relationships through the High Court, Australia has followed a pattern that is closer to the United States than to the British experience; many features of the commonwealth Constitution are based on the U.S. Constitution.

The Economy

Primary production plays an important role in Australia's economy, and the country is a major exporter of food and minerals. The Gross Domestic Product (GDP) in 1991/92[1] was $386 billion,[2] and the average annual growth rate of the GDP was 3.4 percent from 1981 to 1990, with declining or lower growth since then.

Japan is Australia's major trading partner, and trade links with other Asian countries are strengthening. In 1991/92, the value of exported goods and services was $68.8 billion, of which 23 percent was composed of agricultural and related products and 57 percent of nonrural exports (3). Manufactured goods constituted 55 percent of exports, of which 14 percent comprised food, beverages, and tobacco; 21 percent, basic metal products; and 8 percent, machinery and equipment. Foreign exchange earnings from tourism totaled $7.2 billion. Imports are dominated by manufactured goods.

HEALTH STATUS OF THE POPULATION

The marked decline in death rates in Australia since the late 1960s continued up to 1990 (13). Life expectancy at birth increased, and the difference in life expectancy between males and females narrowed slightly to 6.1 years. The life expectancy for females was 80 years; for males, 73.9 years (in 1990).

These trends largely reflect declines in death rates from diseases of the circulatory system. This group of diseases remains the leading cause of death, however, and was responsible for 45 percent of all deaths in 1990. Death rates for injuries also continued to decline steadily. Deaths and incidence rates for cancers, responsible for 26 percent of deaths in 1990, have been steady for some years. In 1990 the infant mortality rate was 8.2 per 1,000 live births (13).

In 1988 there was slightly more than one hospital admission for every five people. For males the highest admission rate was for the category of "diseases of the digestive system," followed by "injury and poisoning." Complications of pregnancy and childbirth were the leading cause for admission for females, followed by diseases of the genito-urinary system. For children up to 14 years old, the leading causes were diseases of the respiratory system, injury and poisoning, and diseases of the digestive system. For the older age groups (65 years and over), diseases of the circulatory system, neoplasms, and diseases of the digestive and respiratory systems were the most common reasons for hospitalization (13).

According to the 1989/90 health survey conducted by the Australian Bureau of Statistics (ABS), 30 percent of males and 29 percent of females aged 18 or over reported excellent health status, with a further 50 percent considering their health good; only 20 percent of males and 21 percent of females reported their health status as fair or poor (2). Sixty-four percent of males and 60 percent of females reported one or more long-term health conditions—most commonly eye sight disorders, arthritis, hay fever, back trouble, asthma, hypertension, deafness and eczema or dermatitis.

1 1991/92 (and similar references to years) refer to the Australian fiscal year, which runs from July 1 through June 30.

2 Dollar figures in this paper are Australia dollars. In early 1994, the value of the Australian dollar was about $USO.7.

In 1988 one or more disabilities were reported by 16 percent of Australians, with 13 percent reporting being handicapped in some way by their disability (13). Most frequently, disabling conditions were those of the musculoskeletal system and connective tissue, hearing loss, and conditions of the circulatory system.

Some of Australia's major health concerns are common to those in other developed countries, including the major causes of illness and death—heart disease, stroke, and cancer. Efforts have been made through health promotion strategies to reduce the prevalence of risk factors for those diseases. A recent estimate of the cost of diet-related disease is $3.6 billion a year, with premature deaths due to poor diet contributing 36,600 potential years of life lost in 1989 (27).

Various concerns regarding women's health are being addressed through a series of initiatives, including cancer screening programs and strategies to manage osteoporosis. Substantial government programs have been put in place to assist the prevention and treatment of HIV infection.

Some problems that are more specific to Australia include high rates of skin cancer, including malignant melanoma (associated with exposure to high levels of sunlight) and asthma. Asthma deaths in Australia have continued to increase, with mortality rates higher than those in England and Wales, Canada, and the United States (13). The reasons for this high prevalence remain uncertain (91).

Like other countries, Australia has experienced differentials in health status that are strongly linked to employment and socioeconomic status. Amongst employed males, those whose occupations are classified as professional or technical have the lowest death rate, whereas those in occupations classified as transport/communications have the highest—with a differential of 87 percent. Most major causes of death show strong occupational linkages. In addition, the numbers of serious chronic and recent illnesses and average days of reduced activity reported by men and women rise as family income decreases (13). There are also concerns regarding the health status of certain migrant groups and their use of health services—particularly migrants with significant cultural differences from most Australians and those with poor English skills.

Yet another concern is the very large differential between the health of Aborigines and Torres Strait Islanders and that of other Australians. Aboriginal health has improved over the last two decades but remains substantially worse than that of other Australians. Overall life expectancy at birth is 15 to 17 years less than that for the total Australian population. Considerably higher mortality levels are experienced by young and middle-aged adults, and the infant mortality rate is three times that for all Australians. Diseases of the respiratory system, complications of pregnancy and childbirth, and injury and poisoning have been the most frequent causes of hospitalization for Aborigines.

THE AUSTRALIAN HEALTH CARE SYSTEM

Organization and Funding

The health care system in Australia is pluralistic, complex, and only loosely organized (13). It involves all levels of government as well as public and private providers. Government has been playing an increasing role in financing health services, but most medical and dental care and some other professional services are provided by private practitioners on a fee-for-service basis.

After an amendment of the Constitution in 1946, the commonwealth was empowered to make laws on pharmaceutical, hospital, and sickness benefits and on medical and dental services. These powers and the extension of conditional specific-purpose grants under section 96 of the Constitution have enabled the commonwealth to expand its role in the health care system. The commonwealth government is primarily concerned with funding programs and the development of broad policies. It influences policymaking and health services through financial arrangements with state and territory governments, provision of benefits and grants, and regulation of health insurance. State and territory governments are responsible for providing most health services, including public hospital systems, mental health services.

public health regulation, and licensing. The main responsibilities of local governments are in environmental control and a range of personal, preventive, and home care services.

Since 1956 the commonwealth has introduced benefits schemes covering medical, pharmaceutical, hospital, and nursing home services funded through government budgets. Many other programs, including health promotion, control of alcohol and drug abuse, and the campaign against AIDS, have involved conditional grants to the states and territories. A universal health insurance plan—Medicare—has been in operation since 1984, administered by the commonwealth government.

The structures of the various commonwealth, state, and territory health authorities have undergone frequent changes. At the commonwealth level, the Department of Health became the Department of Community Services and Health in 1987 and subsequently expanded further to include housing and then local government. At the end of 1993, the name of the agency changed to the Department of Human Services and Health (DHSH)(used throughout this chapter for both the current department and its predecessors). A separate statutory authority, the Health Insurance Commission (HIC), administers the Medicare program of universal health insurance and the Pharmaceutical Benefits Scheme.

At the state and territory level, some jurisdictions have combined health and community services functions. The momentum has been toward creating central agencies that delegate responsibilities in varying degrees to regional or area authorities (13). Because of each state's separate political development and the significant distances between major population centers, state governments have tended to take distinctive approaches to the provision and support of health care technologies (50). Differences between the states reflect varying philosophies on the level and organization of hospital and other services, population distribution, and development of centers of excellence.

In 1991/92, health care expenditure in Australia was $33.2 billion, an average of $1,900 per person (18). The commonwealth government provided $13.3 billion; state and local governments, $8.1 billion; and the private sector, $9.5 billion. Since 1984/85, the proportion of total expenditure funded by governments has declined from 72 to 68 percent, with the private sector proportion rising correspondingly.

The government contribution is funded from general taxation revenues and a Medicare levy on taxable incomes. General distribution of funds from the commonwealth to the states and territories occurs through financial assistance grants whose amounts are determined by the Commonwealth Grants Commission. The states decide the proportion of those grants that are allocated to health services. Hospital funding grants, which totaled $3.9 billion in 1992/93, are the main form of direct commonwealth assistance to the states and territories for health purposes (39).

For each health care technology included on the Medical Benefits Schedule, Medicare reimburses a proportion of the cost. If a technology is not included on the schedule, costs are typicall y paid by the patient; private insurance coverage is relatively limited. (For some high-cost technologies, funding has been provided through government grants with very limited private sector involvement.) Availability of Medicare benefits often has a major effect on a particular technology's diffusion. Once a technology is on the Medical Benefits Schedule, private providers are more likely to obtain it, knowing that payment for its use will be covered by insurance.

Capital grants that fund the acquisition of high-cost technologies are a means for government to achieve controlled introduction and distribution of health care technologies, which have remained largely in the public sector; to some extent this has also applied to lower-unit-cost technologies within the public hospital system, where the allocation of resources (including additional commonwealth grants) is determined by the state governments.

Medical Research and Policy Coordination

Coordination of medical research at a national level is largely the responsibility of the National Health and Medical Research Council (NHMRC). Its principal committees are concerned with medical research, health care, public health, public health research and development, and health ethics. The Council, which obtains funding through the federal budget, is the major funding source for medical research in Australia.

In 1991/92 the NHMRC provided $105 million in basic research funding through its Medical Research Committee, including $67 million in project and program grants and nearly $18 million in block grants to research institutes. About $5 million was provided for projects through the Council's Public Health Research and Development Committee.

Other research, particularly related to health services and health promotion, is supported by DHSH. Some states and the Northern Territory provide infrastructural support for medical research institutes established in association with universities and teaching hospitals. In some cases (notably in Victoria), revenue from tobacco taxes has been used to support health research and health promotion activities.

There have been relatively few attempts to channel research toward the development of new or modified health care technologies. The NHMRC's funding tends to support basic research projects in particular areas; specific downstream products are relatively uncommon. The NHMRC also channels research funds to defined areas of public health need (e.g., research on asthma). Evaluation research (through requests for proposals on specific topics) is also funded by NHMRC and DHSH.

Some research on potential commercial products has been supported by the commonwealth's Department of Industry, Technology and Regional Development. Many of its programs have, however, been directed toward assessing specific proposals rather than focusing research on particular types of technology. An interesting recent initiative has been the development of cooperative research centers (CRCS) in various fields of science and technology. A CRC, typically a consortium of research and commercial agencies, undertakes basic and applied research with a view to developing commercial products; matching funds are provided by the commonwealth government. Some of the CRCs cover areas of health care, including eye research and technology, insulin and cellular growth factors, vaccine technology, cardiac technology, tissue growth and repair, and cochlear implant, speech, and hearing research.

Responsibility for the development of national health statistics lies largely with the Australian Institute of Health and Welfare (AIHW), the ABS, Worksafe Australia, and the DHSH. The first three are statutory bodies and their functions, responsibilities, and constraints are defined by their enabling legislation.

One mechanism for Australian governments to discuss matters of mutual interest concerning health policies and programs is provided by the Australian Health Ministers' Conference (AHMC) and its advisory body, the Australian Health Ministers' Advisory Council (AHMAC). AHMAC includes commonwealth, state, and territory health ministers; New Zealand and Papua New Guinea health ministers attend meetings as observers. AHMAC consists of the heads o Australian health authorities and the chair of the NHMRC. It is concerned with health services coordination across the nation. Some of its standing committees deal with organ registries and donation, women's health, and communicable diseases. Recently, additional coordination has been achieved through joint meetings with the Standing Committee of Social Welfare Administrators.

Health Expenditures and Health Services

In real terms, health expenditures are continuing to grow at a relatively steady rate. As a proportion of GDP, health expenditure in 1991/92 was 8.6 percent; the increase from the previous year's proportion of 8.2 percent was largely the result of low

growth in real GDP during the recession (17). For the six years from 1984/85 onwards, health expenditure as a proportion of GDP was almost constant at around 7.8 percent.

The largest component of recurrent health expenditure (43 percent) is attributed to hospitals. Most personal health care is paid for through Medicare, and all residents of Australia (except foreign diplomats and dependents) are eligible for Medicare benefits. The amounts that a patient can claim for general practitioner services are set at 85 percent of the schedule fee for each item on the benefits schedule. Diagnostic services entail higher out-of-pocket expenses for patients.

Doctors are not obliged to abide by schedule fees, but if they bill the Health Insurance Commission directly for a service, the amount payable is the Medicare benefit and the patient is not required to pay any additional amount. The proportion of all services direct billed in this way increased from 45 percent in 1984/85 to 60 percent in 1990/91 (13).

Agreements among governments enable all patients covered by Medicare to obtain free care at public hospitals from appointed doctors. Private insurance can be purchased to cover the charges of private hospitals and for private status in public hospitals. Private insurance funds also sell coverage for services not covered by Medicare (particularly private dentistry, physiotherapy, chiropractic services, and appliances) and for prescribed medicines not covered by pharmaceutical benefits.

For private patients in hospitals, the Medicare benefit is 75 percent of the schedule fee, and the gap between the benefits obtainable by the patients and the fees charged is insurable. In other circumstances, the gaps between fees and the amount that can be claimed by patients cannot be covered by private insurance. Patients who receive social security are not usually required to pay the gap between schedule fees and Medicare benefits. A safety-net "threshold" above which full schedule fees are reimbursed applies to all patients.

Pharmaceutical benefits are provided for prescribed items purchased at retail pharmacies; items are listed on a schedule. Unsubsidized prescribed items can also be purchased in pharmacies, and many drugs are available without a prescription. When listed prescribed items are supplied, the pharmacist recoups the cost through a patient contribution and a commonwealth subsidy. Safety-net arrangements limit the amount to be paid by a patient in any calendar year.

In 1990/91, the total cost of drugs was about $1.8 billion. This included $985 million through the Pharmaceutical Benefits Scheme (PBS) and other commonwealth programs, $127 million for private prescriptions, and $200 million for hospital drug use (13).

Some tension exists between the commonwealth policies and programs and those of the states and territories. Areas of debate include the level of grant funding to be provided by the commonwealth for state-operated programs and whether certain services provided through state institutions are reimbursable under Medicare (and therefore a charge on the commonwealth). The AHMAC has helped resolve some of these difficulties, but negotiations on the funding of services and division of responsibilities can still be protracted. Tension also exists between health authorities generally and medical and other health care professions regarding the degree of support provided through Medicare and other mechanisms for particular services and technologies. A major focus of debate is the perceived pressure on the public hospital system because of the limited availability of certain technologies.

Proposals for Change

In recent years the commonwealth, states, and territories and the private sector have collaborated to improve hospital information and financial systems, hence to increase the effective use of hospital resources. This collaboration has entailed the development of "casemix systems." A Casemix Development Program, introduced in 1988, provided approximately $30 million in funding over five years (13). Activities funded to date have been directed toward developing patient record information systems in hospitals, examining ways in which different types of patients can be classi-

fled in casemix groups, developing suitable computer software, improving the understanding of relative costs of treating different types of patients in hospitals (diagnosis-related group cost weights), and using casemix information to examine the appropriateness and quality of hospital care. The health ministers agreed in 1992 that the adoption of uniform national casemix classifications and of cost and service weights should be addressed so as to advance structural reforms within the Australian health care system.

In 1991 the commonwealth government put in place a national health strategy. Over a two-year period the strategy was intended to focus on institutional, community, and personal health services primarily concerned with treating and caring for the ill, and also to consider activities that foster good health (66). The strategy project released a series of about 20 papers on a wide range of issues; their substance and recommendations have provided input for further consideration of changes to the health care system.

CONTROLLING HEALTH CARE TECHNOLOGY

The introduction and diffusion of health care technologies in Australia is determined by a complex interaction of market forces, public funding, and regulation (12). Nongovernmental parties, including professional groups, equipment suppliers, consumer organizations, third-party payers, local service administrations, and medical specialists all exert significant influence, and the introduction of a particular technology may not always be consistent with health care priorities. (For example, the establishment of laser comeal sculpting services was a result of decisions made by individual specialists without the involvement of health policy makers.) In some areas, such as the introduction of pharmaceuticals, there have been strong legislative provisions and regulatory control. More commonly, however, the major method of control is financial.

Regulation of Pharmaceuticals

Major changes to the way drugs are regulated have been introduced in the 1990s, updating a system developed largely in the 1970s. The first comprehensive program for appraising the safety and efficacy of pharmaceuticals was developed by the commonwealth during the early 1970s, with some additional regulatory measures imposed by the states of New South Wales and Victoria. The federal controls applied to imported pharmaceuticals and to products registered under the PBS. For these categories of product, the Therapeutic Goods Act and the Customs (Prohibited Imports) Regulations could be applied, requiring assessment of safety and efficacy (compliance with label claim).

Until recently, much weaker controls existed for pharmaceuticals manufactured in Australia that were not registered under the PBS, including over-the-counter preparations. Control of these was to some extent effected by state regulations, which included provisions for joint commonwealth-state inspections of manufacturing premises. The control of locally manufactured products has now been strengthened by an amendment to the Therapeutic Goods Act.

The approach to evaluating new products paralleled that used by the United States and Sweden. Pharmaceuticals were evaluated in accordance with a New Drug Formulation document developed by the commonwealth; chemistry and quality control, animal and human safety, and efficacy for each preparation were to be described by manufacturers. Following a detailed assessment by the DHSH, which included some chemical and pharmacological testing of new products, pharmaceuticals that met the evaluation requirements were certified for use by the Australian Drug Evaluation Committee (ADEC). An Adverse Drug Reactions Advisory Committee coordinated postmarketing surveillance.

Long-standing concerns within the pharmaceutical industry about the slowness of the evaluation

procedure generated pressure for streamlining. This pressure was increased by such issues as the perceived needfor''fasttracking" of approvals for newdrugs fortreatingAIDS. The pharmaceutical industry had also expressed concern about the rate of government reimbursement available through the PBS and had suggested that commonwealth policies were unduly restrictive on industry in the prices they could charge for drugs covered by the PBS.

These concerns eventually led to an inquiry regarding the drug evaluation system (20), including extensive informal discussion and bargaining as well as formal hearings (29). An important issue identified by the inquiry was a perceived overemphasis on safety and efficacy over timeliness. Recommendations included the adoption of strict target deadlines for evaluation and easier access to experimental drugs. The review also suggested greater use of evaluation reports from other countries, building on programs that had already been started in Sweden and Canada.

Proposed administrative reforms included reduction of "dead time" while drug applications were pending and a decrease in the need to reformat data by accepting European Community data formats. It was further recommended that routine evaluation of all individual patient data be discontinued to reduce the costs to industry and the Department and to facilitate the use of evaluations undertaken abroad. Preparation of product information after marketing approval was to be speeded up. The ADEC was to cease its involvement with more routine matters and to return to providing expert advice on difficult clinical issues and considering appeals of rejected applications. The findings of the inquiry were accepted by the government and have led to substantial changes in the drug evaluation program.

Availability of drugs subsidized by the commonwealth under the PBS is achieved through the Pharmaceutical Benefits Advisory Committee (PBAC), which makes recommendations on which products should be listed on the schedule. The PBAC is required to take into account the cost-effectiveness of drugs when making such recommendations. Since 1993, industry applications for listing under the PBS have had to include formal evidence of cost- effectiveness (34). The guidelines for industry to follow in preparing their applications are intended to be flexible and pragmatic while remaining linked to theoretical foundations. They do, however, pose challenges to industry and to government officials (31). Some emerging issues are the shortage of analytical expertise, selection of comparative therapies, degree of accuracy of estimates of incremental health benefits, and consistency of levels of evidence (69).

Despite the control exercised by the commonwealth government over pharmaceuticals' distribution and use, information about most aspects of their use is poor (13). Information from DHSH indicates that between 1980/8 1 and 1990/91, the real price per prescription issued through pharmacies increased by 34 percent. Average expenditures per person on prescription drugs increased by almost 240 percent—about twice the increase in the Consumer Price Index. The number of prescriptions per person increased by 16 percent and the price per prescription increased even more. Much of the increase in prices was due to the switch to newer, more costly drugs. Expenditures on drugs by public hospitals have decreased since the mid-1 980s, essentially through the transfer of costs to the commonwealth (PBS) by reducing the supply of drugs to patients on discharge.

I Regulation of Medical Devices

Systematic assessment of the safety and efficacy of medical devices is less well developed than is the program for pharmaceuticals. A formal process of evaluation of medical devices by DHSH was implemented in the mid- 1980s (under the Therapeutic Goods Act). The most comprehensive component of this program has been the establishment of a national register. Companies marketing medical devices in Australia must register their name and description with DHSH, which triggers an appraisal of product labeling. A Therapeutic Devices Evaluation Committee appointed by the commonwealth minister provides

recommendations on the import, export, and production of devices.

Beyond this, more detailed evaluation is undertaken for a limited number of categories of device that are prescribed by regulation. This list now extends to drug infusion systems, cardiac valve prostheses, cardiac pacemakers and accessories, intrauterine devices, intraocular lenses, intraocular viscoelastic fluids, and biomaterials of human and animal origin. For such products, departmental evaluations look at evidence of safety, efficacy, and the manufacturer's quality control process. Because such appraisals are resource-intensive, DHSH has moved to establish priorities to take account of major areas of need (22).

Financial Controls for Health Care Technology

As noted earlier, the main avenues open to governments for controlling the use of health care technologies (including procedures) have been financial-either through budgets for hospitals and clinic services (at the state level), through rate-setting for procedures funded through the Medicare and PBS programs, or through the allocation of grants for specific technologies or services. It is generally recognized that these are crude and imperfect ways of influencing the diffusion of technology and that control by regulation can only be partial (12).

Inclusion of items on the Medical Benefits Schedule is dominant in any consideration of payment for medical services, including technologies. Toward the end of the 1980s, 75 percent of all medical services in Australia were eligible for Medicare benefits, which covered a high proportion of the total costs. A further 18 percent of all medical services were provided to in-patients in public and repatriation general (i.e., Veterans') hospitals; the remainder was composed of veterans' services, workers' compensation, public laboratories, and community services (13).

Given the prominence of the Medicare program in recent years, the listing of new technologies on the Medical Benefits Schedule and reimbursement policies for technologies already in place are of major significance. Listing on the schedule is gained after submissions from professional groups to DHSH, which considers in detail both cost and efficacy data.

To date there has been no systematic linking of Medicare Benefits Schedule appraisals with health care technology assessment. Similarly, reviews of older technologies on the schedule have not drawn systematically on data from Australian assessments. From time to time recommendations in reviews of particular technologies by Australian assessment bodies have influenced subsequent decisions for listing. For example, computed visual perimetry was included on the schedule following an assessment (76), and reimbursement for use of a portable fluoroscope was not supported after the national assessment body expressed concerns about it (75).

Variations in technology use by different practitioners have concerned the commonwealth government for many years. Although there will always be some variation among medical practitioners, some appear to be overusing services as judged by data obtained by the HIC (which is responsible for administering the payment of Medicare Benefits). Pursuit of such practitioners through the courts has had limited success. The HIC has more recently begun providing feedback to practitioners whose level of use of technologies is considerably above average. This appears to be having some success as an educational process, although the long-term effects remain to be seen.

Governments can control the introduction of certain technologies that have high capital costs by funding their purchase in limited numbers. Commonly, costs are shared by the commonwealth and one or more state governments. Such approaches appear to be successful in the short to medium term and have been undertaken, for example, in the introduction of renal lithotripsy services, where initial restriction of government support to two sites prevented early diffusion of the technology (8). Such approaches seem to be essentially stopgap arrangements prior to the wider diffusion of technologies under Medicare funding, through health program grants from the

commonwealth, or public hospital funding provided by the states.

9 Regulation of the Placement of Services

Regulation of the placement of services has generally been the responsibility of state governments and has typically been associated with some financial control over public sector facilities. States have at times followed the suggestions and recommendations offered by guidelines on specialty services but often have reacted more to local pressures and imperatives. The placement of very specialized services has in recent years been directed by a policy on nationally funded centers adopted by AHMAC (discussed later).

Some control over the use of medical devices is exerted at the state level, particularly under radiation health legislation, which is used by some states to license various sites to operate technology such as radiotherapy equipment. In Victoria the introduction of certain new technologies was effectively controlled for several years by certificate of need (CON) provisions under the State Health (Radiation Safety) Act. State approval was required before certain equipment could be installed and operated. This legislation was applied to the introduction of new diagnostic scanners (particularly computed tomography (CT) and magnetic resonance imaging (MRI)) and to restrict lithotripsy introduction. No other state has adopted CON legislation and the Victorian use of this approach now appears to be at an end.

The background to the Victorian initiative has been described by Duckett (33), who commented that at that time, commonwealth and state incentives worked in opposite directions. For CT scanning, for example, commonwealth incentives for both capital and recurrent expenditure were covered by the Medical Benefits Schedule fee, thereby encouraging installation of scanners (as all costs were covered). State incentives were an attempt to regulate CT scanner acquisition.

Quality Control and Accreditation

Quality control requirements for health care technology services funded by governments are not mandatory in most areas, and standards and practice in this area are still evolving. A survey of hospitals in 1987 found that hospital quality assurance programs were embryonic and that although peer review was fairly common, its effectiveness had not been assessed (90).

A significant force in hospital and other institutional quality assurance has been the Australian Council on Health Care Standards (ACHS), established in 1974 by the Australian Hospital Association and the Australian Medical Association as an independent body to promote and encourage the efficient provision of best quality health care. It develops and implements national standards of care through an accreditation program in cooperation with professional bodies.

ACHS policy requires that health care facilities evaluate the care and services they provide in order to be eligible for full accreditation. This formal evaluation involves medical, nursing, allied health, and administrative staff. If granted, accreditation may be for one or three years, depending on the degree of compliance with guidelines.

As of April 1993,379 hospitals were accredited by ACHS, accounting for 73 percent of private hospital beds and 59 percent of public hospital beds in all states and territories. Accreditation of hospitals is perceived as a useful means of raising and maintaining standards, but it does not necessarily reflect an institution's access to funding for the use of a particular technology or service. ACHS is in an early stage of widening its activities to cover extended care and day procedure facilities. Results of follow-up surveys published by ACHS suggest that accredited hospitals are active in responding to recommendations made by surveyors. Some areas, notably medical record content, continue to be resistant to change, however.

In 1989 ACHS, in collaboration with medical colleges and other professional bodies, began the Care Evaluation Program, which involves the development of objective clinical indicators that reflect the process and outcomes of patient care. Development of the indicators stemmed in part from the medical colleges' requirement for a greater clinical component in the accreditation process and ACHS' wish to have greater clinical

involvement in quality assurance and a more defined role for clinician surveyors. National standards are to be established that are specific for disciplines and facilities but that account for case-mix and illness severity. Hospital-wide medical indicators have been developed by the Royal Australian College of Medical Administrators in conjunction with ACHS. Their use became a formal requirement for accreditation in 1993, and they are being phased in gradually.

The ACHS programs have given Australia a coherent framework for improving the quality of its health care institutions. However, even with the Council's effort, there are limits to what has been achieved even for those hospitals that are accredited. Coverage of ACHS accreditation is far from complete, and participation in the program is not mandatory.

National pathology laboratory accreditation came into being with amendments to the Federal National Health Act. Accreditation is awarded on the basis of laboratory inspections by the National Association of Testing Authorities using standards developed by the National Pathology Accreditation Advisory Council. Only those premises that provide pathology services to be reimbursed through Medicare are obliged to become accredited (outside of Victoria), but in practice, a large majority of laboratories are accredited, including all significant public sector facilities. One of the requirements for accreditation is that laboratories participate in appropriate quality assurance programs, typically those offered by the Royal College of Pathologists of Australasia and the Australian Association of Clinical Biochemists. Pathology laboratory accreditation has generally been regarded as successful in raising the standards of pathology services. While accreditation has had no obvious effect on levels of use of pathology testing, it has, in association with licensing costs, been one factor in restricting to a very low level all norlaboratory pathology use in Australia.

HEALTH CARE TECHNOLOGY ASSESSMENT

Health care technology assessment in Australia is undertaken by university groups, private consultants, and health authorities, but its major direction for over a decade has been set by national advisory bodies established by governments with secretariats provided by health authorities. Assessments from other sources have at times been influential, but the work of the national committees has had the most obvious effects on health authorities' opinions about health care technologies and on the formulation of policy.

Interest in health care technology assessment outside the context of the regulatory appraisal of pharmaceuticals developed during the late 1970s. A number of concerns and options were addressed in the report of the Committee on Applications and Costs of Modem Technology in Medical Practice (97), which was established to address the increasing costs of medical investigations and patient care. It considered various effects of technological developments on medical benefits and public hospital costs, with some emphasis on diagnostic methods that were then emerging as a significant area of concern. Certain key issues relating to technology assessment were clearly identified in this committee's report:

> Modem technology has increased the diagnostic capability and therapeutic effectiveness of doctors. It has made significant contributions to improvements in . . . health and . . . quality of life . . . . However, it has been suggested that the extra resources consumed through further increases in the use of modem technology may have only marginal benefits in terms of further improvements in health . . . . Both [doctors and patients] now tend to be less willing to accept diagnoses that have been arrived at solely on the basis of clinical examinations.

The report viewed technology assessment as one of several long-term measures to improve the effectiveness of technological services in the

TABLE 2-1: Australian National Health Technology Assessment Agencies: Terms of Reference

Australian Health Technology Advisory Committee (AHTAC)
Identify, gather data on, and assess new and emerging health technologies and highly specialized services, Including their safety, efficacy, effectiveness, cost, equity, accessibility, and social impact in the context of the Australian health care system.
Assess and develop guidelines for established health technologies and highly specialized services in light of their history of use.
Determine methods of and priorities for assessment of health technologies.
Advise the Australian Health Minister's Advisory Council (AHMAC) on requests relating to the assessment of technologies in the context of AHMAC'S nationally funded centers policy,
National Health Technology Advisory Panel (NHTAP)
Identify, gather data on and, where appropriate, assess new and emerging health technologies, including their safety, efficacy, effectiveness, cost, accessibility, and social impact In the context of the Australian health care system.
Review and assess established health technologies in light of their history of use,
Determine methods of and priorities for assessment of health technologies, and issue guidelines on these topics.
Make recommendations on appropriate areas of research into health technologies.
Make recommendations on educational measures for promoting the appropriate use of health technologies,
AHMAC Superspecialty Services Subcommittee (SSS)
Develop guidelines for superspecialty services, defined as highly specialized services for relatively rare diseases or which are unusually complex and costly. Guidelines should include the potential for integration, coordination, and rationalization of superspecialty services. Guidelines are submitted through AHMAC to the Australian Health Ministers' Conference for approval.

SOURCE D M Halley, 1994

health care system. The committee recommended that an expert national panel be established to advise on the scope of new technology; whether medical benefits should be paid for its use and, if so, whether it should be restricted to specific locations; and likely changes in patterns of use of related technology.

D The Formation and Operation of National Advisory Bodies

A National Health Technology Advisory Panel (NHTAP) was established by the commonwealth in mid-1982 (table 2-1). As envisaged by the Sax Committee, its membership balanced various interests and included representatives of the medical profession, hospitals, the health insurance industry, and manufacturing, as well as technical specialists. The DHSH chaired and provided a secretariat for the Panel, which reported to the federal minister for health and had broad terms of reference.

The Panel selected MR1 as its first topic and produced its first report in 1983. This influential assessment was a major input to policy on MRI. The MRI report established a process used by the Panel in later work: detailed consideration of available literature plus consultation with professional bodies, manufacturers, and health authorities, culminating in a synthesis of available information. Particular focuses were on clinical, technical, safety, and utilization data (cost data were also included but without duplicating activities undertaken by the DHSH). The Panel was also involved in two major assessments involving primary data collection: the MRI study that followed from the first report and one on dry chemistry pathology analyzers. Both were coordinated by technical committees that included representatives from appropriate professional bodies.

The Panel produced numerous assessment reports as administrative arrangements evolved.

TABLE 2-2: Technologies Assessed by the National Health Technology Advisory Panel (NHTAP)

Year	Topic	Originator of request
1983-90	MRI, MR spectroscopy	NHTAP
1984	Medical Cycloton Facilities	Federal Minister
1985	Lasers in medicine	NHMRC
1985, 1987	Renal extracorporeal shock wave lithotripsy	DHSH
1986, 1989	Bone mineral assessment	DHSH
1986	Digital subtraction angiography	DHSH
	Vestibular function testing	DHSH
	Surgical stapling	Industry
	Lasers in gynecology	Professional body
	Oxygen concentrators	NHTAP
1987-90	Nonlaboratory pathology testing	AHMAC
1987	Endoscopy	Professional body
1988	Digital radiology	NHTAP
	CT scanning	NHTAP
	Portable fluoroscope	DHSH
	Screening Mammography	AHMAC
	Billary extracorporeal shock wave lithotripsy	NHTAP
	Dynamometry for low back pain	Accident Compensation Org
1989	Coronary angioplasty	NHTAP
	High energy radiotherapy equipment	State Health Authority
	Computerized perimetry	DHSH
1990	Extracorporeal Membrane Oxygenation	AH MAC
	Cerebrovascular embolizatlon	AHMAC
	Positron emission tomography	DHSH

KEY AHMAC = Australian Health Mlnlsters Advisory Council, DHSH = Department of Human Serwces and Health, NHMRC = Nahonal Health and Medical Research Council

SOURCE D M Halley, 1994

During 1987/88 support for the Panel was transferred to the Australian Institute of Health (AIH) which had recently been created as a statutory authority. A review of NHTAP in 1988/89 endorsed the concept of an impartial and independent Panel and the continued operation of a health technology unit within the AIH (98). The unit's primary function would be to support the work of the Panel, but it also would conduct reviews of existing and significant emerging technologies, act as a reference center, and maintain a database, including primary data on health care technologies in Australia. The Institute continued to provide research and secretariat support to the Panel until it was subsumed by the Australian Health Technology Advisory Committee (AHTAC) in 1990.

NHTAP faced realities and problems common to other medical and health technology assessment agencies (44). These include the time taken to collect and analyze information and occasional tensions with policy makers seeking prompt advice; difficulties in securing resources to support data collection on a range of technologies; restrictions on time for meetings and the relatively few technologies that could be considered in detail; and the tendency to focus on "big-ticket" items.

NHTAP produced 41 reports covering the technologies listed in table 2-2. The Panel secretariat undertook most of the research and drafting tasks. The quality of the reports was enhanced by an ongoing dialogue with health professional groups and with industry; the Panel sometimes was able to follow up on technologies after the initial report and provide updated advice.

In a number of assessments, resource allocation was considered in some detail, although this did

not always include economic analysis. The more common approach undertaken by the Panel was to include cost analyses without proceeding to full economic evaluation. However, in these and other reports, many of the concepts embedded in models of economic assessment of health care technologies were taken into account (32).

Health authorities were major targets for NHTAP assessments—particularly DHSH with respect to technologies that were potential candidates for funding through Medicare. About half the referrals received by the Panel came from health authorities, but in some cases NHTAP initiated work on its own to provide early warning of potentially significant developments.

Although many of its recommendations were concerned with the adoption of technology and guidance on appropriate, phased introductions, in various instances the Panel also offered suggestions to professional bodies on the appropriate use of medical devices or procedures.

Another initiative in the early 1980s was the creation by the AHMAC predecessor of a Superspecialty Services Subcommittee. It developed guidelines for highly specialized services catering to relatively rare diseases or those that entailed unusually costly or complex forms of treatment. This initiative was motivated by increasing pressures on state health authorities to organize and fund more complex services within their hospitals. The Subcommittee, which was composed of commonwealth and state officials, relied on individual health departments to provide research support as resources became available.

Aided by professional bodies and other centers of expertise, the Subcommittee compiled information on the use, demand, distribution, and appropriate operation of various health services. Its publications provide general background descriptions of services followed by guidelines on such issues as bed requirements, sizes of units, geographic distribution, design of facilities, equipment requirements, and relationships with other services and staffing. The development of these guidelines proved to be demanding. Needed data were hard to obtain, and there were problems in achieving consensus on what were effectively aset of standards for specialized health services throughout the country (44).

TABLE 2-3: Guidelines by Superspecialty Services Subcommittee (AHMAC)

Year	Topic
1982	Burn treatment
1983	Cardiac surgery
	Level 3 neonatal intensive care (updated 1990)
1985	Bone marrow transplant services
	Genetic disorders
1987	Cancer treatment services
1988	Major plastic and reconstructive surgery
1989	Acute spinal cord injury services
1990	Refractory epilepsy centers

SOURCE D M Halley, 1994

The Subcommittee prepared nine guidelines with one major update (table 2-3). Most of the guidelines are valuable resource documents and continue to be widely regarded, although their recommendations are not necessarily followed by all jurisdictions.

Current Structure of Assessment Entities

In 1990 both the Panel and the Subcommittee were subsumed by a new body, the Australian Health Technology Advisory Committee (AHTAC) which was to report to the Health Care Committee of the National Health and Medical Research Council (NHMRC). This change was in line with a move to establish stronger links between AHMAC and NHMRC and to involve NHMRC more closely in advising health authorities on health services and technology.

Still in its early stages of development, AHTAC retains some of the characteristics of NHTAP. Its membership provides a range of expertise and is drawn from diverse sectors. AHTAC will be regarded as a source of advice to AH MAC

and DHSH on various matters, and may also receive requests for advice through the Health Care Committee. AHTAC is tending to follow the NHMRC practice of convening a working party for each project.

AHTAC'S work to date has been dominated by references on Nationally Funded Centers passed to it by AHMAC. The Committee is also continuing with the Subcommittee's work on guidelines preparation, which seems likely to be a significant ongoing function. Another likely undertaking is the preparation of brief statements on technologies, particularly for patients and the general public; the Committee's place within the NHMRC structure may provide a particular advantage in drawing on networks and achieving publicity. The Committee's reports are issued through the NHMRC system, and all are endorsed by this body (table 2-4 lists AHTAC'S publications to date).

AIHW undertakes health technology assessments in addition to its work in support of AHTAC, following the general directions recommended in the review of the earlier Panel. This work includes assessments initiated by the Institute or requested by other agencies, including DHSH; collation and publication of statistics on health care technologies in Australia; and participation in collaborative work with hospitals and other centers. (Assessments published by the Institute are listed in table 2-5.) In addition, on behalf of AHMAC the Institute undertook a major assessment project on screening for breast and cervical cancer.

Following a project undertaken for DHSH, in 1991 the Institute started a series of emerging technology briefs intended to provide prompt advice to health authorities and managers on new medical devices and procedures that seemed likely to have a significant impact on the health care system (table 2-6). There has been some collaboration with Canadian agencies in the preparation of these briefs. Briefs on current issues dealing with more established technologies have also been developed.

In some cases assessments that have been undertaken by the Institute have formed the basis for subsequent evaluation by AHTAC or other groups. For example, the statement on laser corneal sculpting followed an emerging technology brief and then a discussion paper by the Institute, which were in turn followed up by AHTAC. In other areas—for example, in a discussion paper on telemedicine (25)—the Institute has undertaken broader reviews that have served as resource documents for health authorities and other interested parties.

The National Center for Health Program Evaluation, which is partly funded through NHMRC and is part of Monash University in Melbourne, has had some involvement with health technology assessment matters. Its work has included cost-utility analysis of treatments for biliary disease, evaluation of whole body protein monitors, and assessment of laser treatment of benign prostatic hyperplasia.

TABLE 2-4: Publications of the Australian Health Technology Advisory Committee

Year	Topic
1991	Consensus statement on clinical efficacy of MRI
1992	Renal stone therapy
	Liver transplantation programs
	Statement on sleep disorders
	Guidelines for renal dialysis and transplantation
1993	Liver transplantation programs--2nd review
	Treatment of sleep apnea
	Statement on laser corneal sculpting
	Renal lithotripsy
	Heart and lung transplantation programs
1994	Low power lasers in medicine
	Treatment options for benign prostatic hyperplasia
Briefs (Nationally Funded Center Assessments)	
1990	Alfred Hospital, Melbourne cardiac transplantation unit
1991	Pediatric cardiac transplantation
	Stereotactic radiosurgery
1992	Craniofacial surgery
	Bone marrow transplantation using unmatched donors
1993	Queensland cardiac transplantation service

SOURCE D M Halley, 1994

TABLE 2-5: Assessments by Australian Institute of Health and Welfare

Year	Short title	Origin and use by advisory bodies
1989	Angioplasty and Other Percutaneous Interventions	Source material for NHTAP and SSS evaluations
1990	Tinted Lenses in Reading Disability	Follow-up to preliminary work in DHSH
	Options for Stereotactic Radiosurgery	Source material for NHTAP and AHTAC
	Screening Mammography Technology	Referred from AHMAC committee
	Gadolinium Contrast Agents in MRI	Referred from DHSH
	Developments in PACS	Follow-up to NHTAP assessment
	Medical Thermography	Follow-up to preliminary NHTAP work
	Laparoscopic cholecystectomy	AIH
1991	Implantable Cardiac Defibrillator	AIH
	Biliary Lithotripsy (also 1992, 1993)	Trial funded by Commonwealth and Victoria
	Boron Neutron Capture Therapy	Inquiry from NHMRC
	Laser Corneal Sculpting	Source material for AHTAC
	Assessing MRI in Australia	Position paper on national assessment
1992	Lasers in Angioplasty	AIH
	Minimal Access Surgery	Source material for AHTAC
	Cochlear Implants	Referred by industry
	Peripheral Angioplasty	Suggested to NHTAP
	Products for Office Pathology Testing	Referred from DHSH
	Cardiac Imaging	Interest from State authorities
1993	Telemedicine	AIHW
	Lasers in Medicine	Follow-up of NHTAP review
	New Technologies for Cervical Cancer Screening and Treatment	Referred from DHSH
	Treatment of Menorrhagia and Uterine Myomas	AIHW, source material for AHTAC
	Treatment of Benign Prostatic Hyperplasia	AIHW, source material for AHTAC
	Health Technology and the Older Person	Australian Science and Technology Council
	Technologies for Incontinence	AIHW, source material for AHTAC
	Social Impact of Echocardiography	Study by La Trobe University/St. Vincent's Hospital, Melbourne
1994	Hip Prostheses	
	Minimal Access Surgery--Update	Source material for AHTAC
	Intraoperative Radiotherapy	Referred from State health authority
	Laparoscopic Cholecystectomy in Canada and Australia	Joint studies with CCOHTA
	Magnetic Resonance Imaging at the Knee	Follow-up from earlier AHTAC discussion
	Pap Smear Examinations Under Medicare	Referred from DHSH

SOURCE D M Halley, 1994

Funding for Health Care Technology Assessments

Core funding for the national advisory body (NHTAP and now AHTAC) and AIHW has mainly been provided via annual appropriations of the commonwealth's health portfolio. The level of funding has been about the same for some years. In 1994AHTAC received direct annual funding of about $80,000, plus $90,000 provided by AHMAC for work related to Nationally Funded Centers, superspecialty services guidelines, and other referrals from the Council. Direct salary-related and administrative funding for the AIHW technol ogy assessment function is roughly $400,000 per year.

TABLE 2-6: AIHW Health Technology Briefs

Year	Topic
1991	Laser corneal sculpting
	Radiofrequency catheter ablation
	Cervical loop diathermy
	New laparoscopic procedures
1992	Endovascular coronary stents
	Helium lasers in corneal sculpting
	Cardiomyoplasty
	Collagen Implant therapy for treatment of stress incontinence
	Excimer lasers in coronary angloplasty
	Technologies for treating benign prostatic hyperplasia
	Cerebral oximetry
	Magnetoencephalography (MEG)
	Cultured skin
	Magnetic resonance anglography
	Laparscopically assisted hysterectomy
	Transurenthral lithotnpsy
1993	Lasers in dentistry
	Coronary atherectomy
	Radiolabeled monocolonal antibodies in diagnostic Imaging
	Fall oposcopy
	Focused extra corporeal pyrotherapy
	Levonorgestrel IUD for menorrhagia
1994	Digital mammography
	Dedicated MRI extremly scanners
	Stereotactic Image-guided surgery
Health technology issues	
1993	Carotid endarterectomy
	Diagnostic hysteroscopy
	Prostheses for total hip replacement
	Implantable defibrillators
	Hellcal CT scanners
	Cholesterol screening and associated Interventions

SOURCE D M Hailey, 1994

In practice, other funding has generally become available on a short-term basis for the national advisory body, and the Institute receives grants from DHSH and other sources. In 1990,$200,000 was made available by DHSH for specific small projects under the auspices of NHTAP, which were administered by AIH. The Department continues to provide evaluation funding for projects that are broadly related to current policy—including, for instance, support for a randomized trial of laparoscopic cholecystectomy, work by AHTAC on minimal access surgery, and a review of technologies for cervical cancer screening undertaken by AIHW.

In general, over the last decade the level of funding for the health technology assessment provided some assurance of continuity, but it remains at a modest level, limiting what can be achieved. Additional resources would permit more detailed economic studies, more consistent follow-up of technologies after their initial evaluation, wider coverage of technologies, and greater focus on patient perspectives.

Impacts of Health Care Technology Assessment

The early studies of MRI and dry chemistry pathology testing (where local primary data collection was being undertaken) and assessments of medical cyclotrons and renal lithotripsy, all were prompted by policy considerations and the results were used in the decisionmaking process (40,41).

Possible measures of impact and the conditions for these to occur were described and applied to a review of 24 technologies assessed by NHTAP (43). The Panel's reports appeared to have had a significant influence in the short to medium term for 11 of 20 technologies assessed through 1988; major recommendations were accepted, and subsequent governmental or other action was taken. Sixteen reports proved useful as source and educational materials, as judged by requests and literature citations. As an indirect indicator of impact, there was a steady growth in the number of requests for reports, and some publications were used in university courses.

The influence of Australian assessments of 10 health technologies (by NHTAP, AU-I and AHTAC) was discussed in more detail by Drummond and coworkers (32), who felt that the assessments met important criteria (e.g., whether evaluation questions were clearly specified, alternatives ad-

dressed, follow-up studies undertaken, and policy and practice influenced). The evaluations were influential, although the impacts of some of them had yet to be fully established given the interval between receipt of advice and policy formulation. As in other countries, the most obvious successes, in terms of policy being informed by assessment, have been linked to the possible introduction of a technology. The evaluation mechanisms available and their influence on the actual use of technologies become less certain after diffusion.

A further analysis noted that the impact of assessments by advisory bodies was greatest when local primary data were collected and the technology was not yet available or had just been introduced (42). The data generated by the various assessments was important, but perhaps equally significant was the commitment made by governments to support data collection in the first place. Each of the assessed technologies was seen as significant in policy terms so that evaluation funding was made available to hospitals and other institutions.

Assessments of eight technologies considered under the Nationally Funded Centers policy faced difficulties because of limited data and time for analysis but were nonetheless very successful: almost all the recommendations were accepted by AHMAC. In these cases the influence on policy is more obvious and direct, given the relatively narrow focus (i.e., to fund or not fund from a particular pool of money under set criteria) and the clear wish of health authorities for advice. Of 18 assessments undertaken by AIHW, five were used as input for subsequent NHTAP and AHTAC evaluations, all but two seemed to provide significant source material, and eight appeared to significantly influence policy or further research.

A survey undertaken by AHTAC of government agencies and other recipients of assessment reports showed that many considered the background information, the data on use, caseload, effectiveness, and cost, and the recommendations to be generally useful. The background information seemed of rather more immediate help to some policy makers than the cost/economic analyses. The scope of the assessments in most cases was seen as generally relevant or (less often) very relevant; to some extent this probably reflected the difficulty of capturing the immediate policy interest of the moment. Although the reports were seen as generally timely by a most survey respondents, only a small proportion thought they were "very timely."

The impact of health care technology assessment has been most readily visible in the decisions of health authorities and other funding sources. The effects on patterns of clinical practice is less certain; they have probably been more limited, but detailed studies have yet to be undertaken. The review of the impact of NHTAP assessments drew attention to the probable increased acceptance by professional bodies of the need for evaluation and critical consideration of health technologies (43). Changes to clinical practice maybe slow, however: some influences of health technology assessment will be felt only over the long term. The further review of 10 technologies suggested that in five cases, assessment had probably affected clinical practice; it was too early to make such a judgment for another two cases (32).

In some areas there maybe reluctance to accept new evidence. An Australian randomized trial was among several studies that demonstrated that antenatal fetal heart rate monitoring had no detectable effect on mortality or morbidity in high-risk cases (65). However, during the year after the trial ended, use of the technology in the hospital increased 16-fold, and it extended to less and less appropriate groups (64). This technology continues to be widely applied some years later.

A recent initiative of NHMRC has been the formation of a Quality of Health Care Committee that is responsible for preparing clinical practice guidelines. Three guidelines currently under development cover treatment of breast cancer, ischemic heart disease, and depression in adolescents. This approach offers the potential to strengthen the impact of assessment by providing a further channel for the results of individual evaluations.

The appraisals of impact indicate a need for improved dialogue among concerned parties, the desirability of timely advice, and the need for

realistic linkages with the policy processes and methods of practice. There is an unmet need for systematic appraisal of a greater range of technologies and for follow-up after their introduction. This in turn points to the need for a wider constituency in health care technology assessment, with input from hospitals and other organizations.

Both NHTAP and AHTAC have involved clinicians (as well as other experts) in the assessment process, both through consultation during development and through comment and debate on drafts at the review stage. Public involvement in the work of the national advisory bodies has so far been limited, although NHTAP included a consumer representative; such representation is standard practice with NHMRC committees, including AHTAC. If there are significant moves toward organizing consensus conferences, a form of assessment that has not been widely used in Australia, public involvement may increase. Further development of advisory statements by AHTAC (making use of the NHMRC distribution process) might also increase public involvement.

Health technology assessment is well established in Australia and has influenced health policy. However, limitations on resources, the degree of coverage of technologies, and the extent to which initial assessments can be followed up are concerns that need addressing as technology assessment proceeds in Australia. It would also be desirable to achieve better coordination of evaluation groups and to complement existing successful patterns of assessment with further use of more formal methods, such as detailed cost-effectiveness studies and meta-analyses. Finally, greater use could be made of health technology assessment by policy makers, health care providers, and funders.

Policies on Specific Technologies and Pharmaceuticals

Nationally Funded Centers

In 1989, Australia's health ministers agreed to a policy supporting certain highly specialized or high-cost technologies that typically only one or two centers in the country might provide. This policy, applied by AHMAC, is aimed at ensuring access for all Australians to approved high-cost, low-demand services and avoiding unnecessary duplication. Support is provided on a relatively short-term basis; renewal of funding is subject to a review of the technology and of the centers that are providing it. The expectation is that in many cases, Nationally Funded Center status will be discontinued as technologies diffuse further.

Support for Nationally Funded Centers is provided through a special fund created by a portion of each state's Medicare grant. The policy rests on agreements reached between governments, rather than on legislation. Proposals for funding are made by individual states, with submissions prepared by the hospitals that intend to establish or develop the technology. Most of the funding has so far been applied to transplantation services.

Proposals for support under this policy are referred by AHMAC to AHTAC for evaluation against two sets of criteria. The first set is designed to establish the suitability of the technology as judged by measures of safety, efficacy, national demand, and need to concentrate services for cost-efficiency and best performance. The second set of criteria relates to the suitability of the proposed site in terms of established expertise, research programs, and support services. Each technology funded is eventually reviewed by AHTAC to determine whether support should continue or if the technology should be regarded as a superspecialty service funded by individual states.

Application of the policy to new proposals can be illustrated by the evaluation of technologies for treatment of arteriovenous malformations (AVMs) and other cerebral lesions. Evaluation of cerebrovascular embolization was carried out by NHTAP and completed by AHTAC (80). Proposals were assessed from a center in Perth with a long record of research in this technique and from hospitals in Sydney and Melbourne. It was accepted that embolization demanded high levels of skill and integration of specialties, that technology development continued to be significant, and that it was a useful approach to managing small

numbers of patients at significant risk of major neurological deficit or death. In view of the estimated national caseload and the developing expertise in the eastern states, the establishment of two national centers was recommended—in Perth and in Sydney. After AHMAC accepted this recommendation, a budget was developed on the basis of assessment data. Both centers will collect clinical and cost data for subsequent review by officials and evaluation by AHTAC.

Initial interest in establishing stereotactic radiosurgery, also used in the treatment of AVMS and certain types of cerebral tumor, related to introduction of the gamma knife, a focused array of gamma radiation from cobalt 60 sources. However, it became apparent that there had been significant developments in the alternative approach of the focused linear accelerator (linac). The technology was assessed by AHTAC in 1992 in response to applications for funding from centers in Perth and Sydney. AHTAC took the view that the focused linac option was more realistic and that because of the probable diffusion of this approach and the comparatively limited additional expertise required (compared with that found in major radiotherapy units), the technology would not be appropriate for Nationally Funded Center status (8). This position was accepted by AHMAC. Funding of radiosurgery units is therefore a matter for individual state governments.

The ongoing review process for Nationally Funded Centers can be illustrated by assessments of programs for liver transplantation services that were supported at three centers—in Sydney, Brisbane, and Melbourne. AHTAC considered liver transplantation in terms of criteria specified under the policy: whether the technology was continuing to evolve, whether further diffusion would lead to additional costs and inefficiencies, and whether the move to superspecialty status would adversely affect access to such services. In an initial review the Committee considered that technical development was still significant, further diffusion was not appropriate (particularly to smaller centers of population), and the situation should be reviewed again in two years (7). The follow-up review concluded that technical development had plateaued, further proliferation would be unlikely to generate significant inefficiencies, and a move to superspecialty status would not adversely affect access. The recommendation was for discontinuation of Nationally Funded Center status for the centers (10); it was accepted by AHMAC.

Highly Specialized Drugs

Following the states' concerns over rapid growth in the use of expensive specialized drugs provided through the public hospital system, discussions by AHMC and AHMAC led to an agreement on funding for such services and the establishment of a Highly Specialized Drugs Working Party (HSDWP). This entity selects drugs for inclusion in funding arrangements, monitors new highly specialized drugs that are potential candidates for inclusion, and monitors the way in which drugs supplied under the program are used. Decisions on listing drugs are made by the Pharmaceutical Benefits Advisory Committee. The criteria for selection of a drug for funding specify that ongoing medical supervision is required; the drug is for treatment of chronic medical conditions, not acute inpatient episodes; the drug is highly specialized, is subject to marketing approval by the commonwealth, and has a high unit cost; and there is an identifiable patient target group.

In addition to erythropoietin (discussed later in the case study on end-stage renal disease), the program was also initially applied to the supply of cyclosporine to patients through public hospitals, with grants of $25.1 million being made to states and territories in 1991/92. Subsequently, the HSDWP has focused especially on drugs for management of AIDS. Forward estimates for commonwealth funding of zidovudine (AZT) in 1992/93 were $12.9 million. Recommendations have been made on listings and prices for didanosine, desferoxamine, and ganciclovir. In each case supply of the drugs is handled by the public hospitals. States provide funding for an initial period, after which the commonwealth meets all subsequent costs subject to receipt of usage data based on individual patient records.

Case studies

TREATMENTS FOR CORONARY ARTERY DISEASE

Coronary Artery Bypass Grafting (CABG)

CABG commenced in Australia in 1970, and usage rates have increased steadily ever since. The status of CABG was considered briefly in guidelines prepared by the Superspecialty Services Subcommittee (100). At that stage, CABG procedures accounted for about 75 percent of all cardiac surgery caseloads in some states, after a period of rapid growth in use of the technique. The Subcommittee predicted that CABG caseloads would stabilize at about 500 procedures per million people. Recommendations did not address CABG per se but included minimum caseload levels for a cardiac surgery service of 200 adult patients per year within two years of inception, with a longer term goal of at least 1,000 patients per year. The Subcommittee's guidelines helped the New South Wales Health Department make a decision to limit the number of centers for such surgery; the guidelines were less influential in other states.

In 1991 there were 12,694 operations for coronary artery disease (CAD), all but 45 involving bypass grafting—an increase of 11 percent over 1990 (85). This amounts to 669 operations per million, which is substantially above the original Subcommittee estimate even after the diffusion of coronary angioplasty. Of these operations, 11,586 were without concomitant procedures. Mortality nationally was 2 percent (6 percent for the 7 percent of all bypass procedures that were reoperations). The number of grafts per patient in 1990 stabilized over the previous six years at just over three.

There was no national evaluation of CABG, although the National Heart Foundation has monitored the use and diffusion of the technology for many years. Published accounts of Australian work appear to be limited to descriptions of experience and outcomes for small series of patients. Diffusion of the technology has been determined largely by decisions of individual hospitals and state health authorities and by the availability of reimbursement through Medicare benefits. The initial growth of bypass surgery was particularly rapid in South Australia and Western Australia; there is now a more even coverage. Rates of surgery continue to increase in all states; in 1991 they ranged from 834 per million in New South Wales to 548 per million in Queensland.

Percutaneous Transluminal Coronary Angioplasty (PTCA)

PTCA was introduced in Australia in 1980. In 1991, 5,726 procedures were undertaken at 20 units (18 percent were repeat procedures), a 17 percent increase over 1990. The number of procedures per unit averaged 286 (ranging from 11 to 656), performed by 81 physicians (84). The overwhelming majority of procedures were for single vessel disease; procedures for double-vessel disease decreased from 10.2 to 8.1 percent between 1989 and 1991. Procedures on more than two vessels are still uncommon.

The primary success rate in 1990 was 91 percent, an increase of about 3 percent over five years. In 91 percent of all cases, indications for PTCA were stable or unstable angina, with acute myocardial infarction (AM I) accounting for 4 percent and prognostic reasons for 2 percent; 9 percent of procedures were performed on patients with CABG grafts. In 1991, 127 patients (2.2 percent) required CABG after PTCA during the same hospital admission, about three-quarters within 24 hours as emergency operations for complications. Over a 10-year period the rate of CABG

post-PTCA has fallen from initial values of 11 to 12 percent. The overall rate for AMI following PTCA is 2 percent over a 10-year period, with no clear trends over the last seven. The mortality rate for PTCA was about 0.4 percent between 1980 and 1991.

Coronary angioplasty was assessed by NHTAP, drawing on a review commissioned by AIH (79,93). The Panel's assessment looked in some detail at the indications for PTCA, efficacy, complications, and cost in comparison with bypass surgery and medical therapy; distribution of services in Australia; and institutional requirements. The Panel commented that each form of therapy (CABG, PTCA, and medical) had its own range of indications but that these overlapped substantially. It recommended the development of guidelines for PTCA, noting that these would need to be reviewed as results emerged from trials comparing CABG and PTCA for treating multi vessel disease.

NHTAP also noted that there was a potential for substantially increased use of PTCA in Australia, with replacement of some CABG procedures, increased use after AMI, and use for patients considered too frail for CABG or whose condition was not considered serious enough for surgery. The danger of overuse was also flagged-for example, for patients whose angina was satisfactorily controlled by medication, asymptomatic patients, and those for whom the cause of symptoms was uncertain. The Panel also saw a possibility of underuse, particularly in the public sector, as the result of funding constraints on public hospitals. This could lead to loss of productivity y, unnecessary use of CABG, and inadequate medical treatment with costs that could have been avoided if PTCA were more readily available. A possible reason for the modest growth of PTCA use in Australia (which has eased since preparation of the NHTAP report) is the limited capacity of cardiac catheterization laboratories.

There was no formal training program for PTCA in Australia, although all practitioners had in fact been trained under supervision (largely in the United States). Because peer review processes in Australia are strong, hospitals would be unlikely to award angioplasty privileges unless the practitioner had adequate experience. The Panel found no apparent immediate need for the introduction of credentialing for Australian users of PTCA.

Costs of PTCA and CABG

NHTAP estimated a cost for a single PTCA procedure of approximately $7,100, including an angiogram and other tests. Average cost per patient to the health care system, which also included CABG for a proportion of cases including later elective procedures, was $9,400. In comparison, the estimated cost of CABG was $10,500, rising to$11 ,700 in average cost per patient if complications were taken into account. No allowance was made for repeat CABG or PTCA, which would be required by many patients within 10 years of the first CABG procedure. In comparison, the costs of medical treatment of angina would vary widely, perhaps between $1,500 and $10,600 over a 10-year period.

The Panel recommended further analysis of the costs and benefits of PTCA by AIH in consultation with professional and government bodies. It also urged that appropriate professional bodies (in consultation with health authorities) consider the desirability of an accreditation system for institutions providing PTCA services.

Recent Developments

PTCA services have continued to grow, but although the Cardiac Society of Australia and New Zealand has developed guidelines, accreditation provisions have not yet been applied further to institutions and specialists. Because of funding constraints and other priorities for assessment, the proposed analysis of costs and benefits has yet to be undertaken. The question of more comprehensive guidelines for cardiac interventions is now being addressed by AHTAC, in part as a follow-up to the original cardiac surgery guidelines produced by the Subcommittee. The NHMRC's Quality of Health Care Committee is addressing the question of practice standards in this area.

It might have been expected that as PTCA became more accepted, possible CABG cases that

would have required only one or two grafts would be increasingly referred to angioplasty and that simple bypass procedures would make up a smaller proportion of the total (79). In fact, the proportion of CABG procedures requiring one or two distal anastomoses has fallen only slightly since PTCA was introduced, suggesting that PTCA might not be substituting for CABG to any major extent in Australia. International developments in this area have been followed with interest in Australia, but the use of CABG and PTCA has been determined largely by funding and organizational priorities and, to some extent, by assessment input from NHTAP and AIH.

Statistics collected by the National Heart Foundation show that the application of newer technology as an extension of PTCA and CABG has so far been quite modest. Thrombolytic therapy was used prior to angioplasty in 7.4 percent of all cases in 1991. Until recently, atherectomy was performed by only a few centers, and its level of use is low (42 cases in 1991). It seems to be regarded as an extension of PTCA, especially for application to extensively calcified or occluded lesions.

Use of coronary stents is increasing slowly (used in 50 PTCA procedures in 1990 and 78 in 1991), leading to increased costs (14). There are also issues related to patient selection criteria, appropriate training, and the need for appraisal of new stent designs and their use in Australia. The Institute saw coronary stents as a developing, additive technology that would find a useful but limited niche in algorithms for management of CAD.

The application of lasers for coronary artery disease has not yet occurred in Australia except for a brief trial in Perth. A review of lasers in angioplasty concluded that there was no evidence that laser treatment could replace balloon angioplasty, although lasers might play a limited role in the recanalization of complete or nearly complete obstructions (25). At that stage none of the lasers being evaluated overseas looked so promising as to make the case for evaluation in Australia particularly attractive. A more recent Australian review has concluded that laser coronary angioplasty is still a developing technology and that cost-effectiveness has not yet been established (28). On the basis of expected potential caseload, use of an excimer laser would cost $50,000 to $60,000 per year per hospital, with no clear indication at this stage of benefits or of complication rates (15)

Proven methods for treatment of CAD are well established in Australia, and access to them is generally good. Waiting list data are at present not generally available, but there are some indications for Western Australia. According to recent information for elective procedures in that state, median waiting times are about one week for PTCA and about one month for cardiothoracic surgery. The numbers of cases on the cardiology and cardiothoracic lists were halved between June 1992 and June 1993 (55).

Areas for consideration are achieving suitable balance between the different methods and resolving any problems of coverage in the public sector. A specific concern is the continuing growth of both CABG and PTCA despite earlier expectations that angioplasty might replace the surgical procedure to a large extent.

A further issue, identified in the NHTAP assessment, is the pressure placed on public hospital budgets by demand for PTCA services. Many public hospitals have imposed severe rationing on the number of PTCA procedures that they perform. Their costs are significant, and the benefits have accrued to the patient and the commonwealth rather than the state and the hospital (because of decreased commonwealth-funded medication and quicker return to normal activity). The situation has changed somewhat since a Medicare schedule benefits item for PTCA became available. This problem illustrates the type of funding debate that can occur between commonwealth and state governments.

The influence of technology assessment on this area has been relatively modest. The early Subcommittee report was helpful to some state governments, but although later assessments have been considered by policy makers and professional bodies, there is no evidence that they have exerted any major influence. Other factors have proved more significant.

MEDICAL IMAGING (CT AND MRI)

I Computed Tomography (CT)

CT scanning was introduced into Australia in the mid- 1970s with the acquisition of head scanners by private radiology practices. There appears to have been no systematic early evaluation of CT scanning. Opit and Dunt (89) analyzed the level of need for CT head scanning in a defined population and were among the first to express reservations about the number of machines that would realistically be needed for this new technique.

The private sector dominated the early stages of CT diffusion; the only governmental control was imposed by certain state authorities in terms of various units installed in public hospitals under their jurisdiction. Reimbursement for CT examinations rapidly became available through Medicare.

In early 1984 the Royal Australasian College of Radiologists (RACR) issued a statement on CT scanning that outlined suggested uses for the technology and gave details and suggestions for its distribution. An overview of health care technology assessment at that time noted that although the statement contained useful data, further appraisal involving other organizations in the health care system was now needed (44).

A synthesis report by NHTAP considered patterns of use of CT in Australia and its clinical role, costs, safety aspects, and clinical value (77). By mid- 1987 there were at least 170 CT units in Australia, 118 in the private sector and 52 in the public sector; at that stage, installation of public hospital units had become more widespread. It appeared that on a per capita basis, Australia offered higher levels of CT services (10.8 scanners per million residents) than any European country, but lower than the United States and Japan.

Although CT services were widely disseminated in Australia, there appeared to be room for improving the pattern of distribution, including keeping public hospital facilities under review and perhaps widening coverage to include smaller population centers. However, even taking into account the earlier methods that CT had replaced and widening indications for its use, it was not possible to account for the very large increase in numbers of examinations in recent years.

The Panel also drew attention to studies in other countries that suggested that use of CT scanners was unrewarding for patients with headaches and normal neurological findings, and to a Western Australian study that evaluated the use of CT in private neurological practice (52). Sixty patients had a CT scan before consultation, and 95 percent of those were normal. Of the 83 patients referred for CT after neurological consultation, 91 percent had normal CT findings. The Panel questioned the possible overuse of CT in this area.

Concern about certain applications of CT continues. In a series of 100 CT exams on 87 consecutive patients with low back pain or sciatica referred for specialist orthopedic opinion, 36 exams could be justified (of which 16 influenced management of the condition); 47 unnecessary exams were abnormal, but the abnormal findings were irrelevant. Some 75 percent of unnecessary scans would have been eliminated if somatic pain had been recognized and if the fact that CT does not contribute to an evaluation of such cases had been appreciated (94).

While accepting the technique's diagnostic excellence NHTAP noted that little quantitative information was available on how CT was being used in Australia or its effect on patient management, particularly outside major public hospitals. It recommended that a study be undertaken to determine the contribution of CT to patient care and the cost savings achieved through its use. It also recommended that professional bodies consider the development of guidelines for medical practitioners on the use of CT, including advice on appropriate indications for procedures, examination risks, costs, and expected benefits.

The first recommendation was considered in detail and a proposal for a study discussed by AHMAC. However, support for such an assessment was not approved largely because of disagreement between governments as to responsibilities for funding. The second recommendation (on guidelines) was taken up by NHMRC's Health Care Committee. Guidelines were subsequently pub-

lished (71) that drew on broader imaging guidelines developed by the Victorian Post-Graduate Foundation and the RACR (63) as well as on input from individual radiologists. The impact of these guidelines will probably not be apparent for some time and will depend on the degree of reinforcement by professional bodies.

The NHTAP report has been used as a source document by health authorities and has provided input for discussions on levels of reimbursement under Medicare. Medicare fees for CT have decreased in recent years, and the CT examinations eligible for payment under Medicare are specified in considerable detail in the benefits schedule. At the state level, replacement of older generation scanners has occurred in a number of public hospitals.

By November 1992 the total number of Australian CT scanners had reached 292, or 17 per million people (16), and in early 1994 it was approaching 350 (19). It appears probable that this increase will continue, given the comparatively lower numbers in Victoria following the earlier CON strategy in that state. On a per capita basis, numbers of services have increased by 115 percent over the last five years, and Medicare Benefits payments by 54 percent. There are still no quantitative data on how most CT services are being used and to what effect. The continuing proliferation of CT services maybe due to a combination of factors, including the availability of reimbursement under Medicare, support through the public hospital system, competition among hospitals and practices, and pressure from requests by referring physicians.

Magnetic Resonance Imaging (MRI)

The introduction and diffusion of MRI in Australia has followed a different pattern than that of CT because of technology assessment, related policy decisions, and investment judgments by private radiology practices in the early 1980s.

Australia's program for introducing and evaluating MRI (45) had its origins in a synthesis report by NHTAP (73). MRI was regarded as an expensive, rapidly evolving, and promising diagnostic imaging method that should be assessed before any widespread diffusion within Australia was contemplated. The report recommendations were accepted by the commonwealth government, which acted with the states to implement an assessment of MRI. This support for the rational introduction of MRI was prompted to some extent by concerns at the level of use of CT scanning. Issues for the governments included the likely cost of the new technology, its realistic range of application, likely benefits when compared with existing methods, technical performance, and areas of weakness.

At the start of the Australian evaluation, little was known about the performance and clinical use of MRI. Information from other countries was of limited use in the Australian context. Many early studies were poorly done and, in any case, applicable to different health care systems. The Australian governments sought a broad assessment of the overall place of the new technology, meaning that a wide range of possible examinations and disease states had to be considered.

The study was carried out at radiology departments in five public hospitals with general direction by a technical committee of NHTAP and collation and monitoring of data by the Panel's Secretariat. Each MRI unit collected cost data according to a defined protocol; a minimum data set, completed for every patient, which provided information on demographics, history, MRI findings, and radiologists' assessment of the benefit of MRI at the time of examination; and 71 more detailed follow-up studies on selected groups of patients to assess the usefulness of MRI in the diagnosis and management of specific conditions. No government funding for MRI was available outside the program.

One specific study reported on 2,810 consecutive examinations at the Royal North Shore Hospital in Sydney, which provided follow-up data on 2,100 cases (99). The accuracy of MRI in a number of conditions was considered in detail, and clinical impact was assessed on the basis referring clinicians' opinions. The impact of the technique was apparent in 104 cases where surgery was avoided; in 55 where invasive procedures were avoided: in 151 where MRI led to surgery or im-

proved surgical planning; and in 175 where a correct diagnosis was established after incorrect results from CT or other tests.

Another study considered the follow-up of 1,119 cionsecutive patients examined at the Sir Charles Gairdner Hospital in Perth who had been referred by specialists for imaging of brain or spine (47). MRI made a dominant contribution to the final diagnosis with neoplasia and vascular disorders but was less significant for white matter disease, including multiple sclerosis. In a high proportion of cases, other types of examination also influenced final diagnosis. MRI affected patient management in a high proportion of spinal examinations and in cases of cerebral neoplasm, with a lesser contribution to cases of cerebral vascular disorder and white matter disease. Although MRI was seen to be generally superior to other imaging methods, in practice it was often only one input to diagnostic and management decisions. For some cases, such as pituitary neoplasm and suspected acoustic neuroma, MRI replaced older tests and was not additive.

Following recommendations of NHTAP at the end of the assessment (82), the governments agreed on a policy to develop a network of teaching-hospital MRI units, with 18 to be placed in centers with major neurosurgical responsibilities. Government funding continues to be channeled only to such units, and reimbursement is not available for further services provided by private radiology practices except for limited numbers of "overflow" cases from public hospitals to designated private units. Decisions on levels of funding for the public MRI units have drawn on the cost data obtained in the assessment. The limited numbers of government-funded examinations at private units have had to comply with the MRI guidelines of a consensus statement developed during the assessment (6).

Despite this policy on limited government funding of services, the number of private radiology MRI scanners has increased substantially since the assessment (46). For most private units the caseload has been limited and dominated by workers' compensation cases. By early 1992 there were seven public and 16 private units in Australia, or 1.3 per million people—a somewhat lower proportion than in several European countries but now increasing to a projected 41 units by the end of 1994 (or 2.3 per million). There is concern that the proliferation of I may eventually lead to provision of services that are not cost effective and that much of the spread of the technology will have occurred outside the immediate influence of health authorities.

Influence of Technology Assessment

The introduction and use of MRI were strongly influenced by the assessments undertaken by NHTAP (similarly, assessments have influenced the more recent introduction of positron emission tomography (PET) (74,83). In contrast, assessment effect on the use of CT have been 1 imited to date, and it is too early to say whether the NHMRC guidelines developed following the Panel's report will have a major influence.

LAPAROSCOPIC SURGERY

The most common of the well-established laparoscopic procedures (based on Medicare data) include laparoscopy for treatment of ovarian cysts, endometriosis and adhesions, and arthroscopic operations on the knee. These widely established techniques were introduced in the 1970s. Arthroscopic surgery to the elbow, wrist, shoulder, and ankle was added to the Medical Benefits Schedule in 1990 and 1991. The numbers of these newer arthroscopic procedures are still quite small. Therapeutic thoracoscopy, esophagoscopy, and uteroscopy have also been established for many years, but their numbers also are small (less than 1,200 per year for each) but increasing. Most of these laparoscopic procedures have replaced older more invasive procedures, although the number of additional knee arthroscopes has risen substantially (60).

Use of diagnostic hysteroscopy has increased considerably in recent years (from 1,000 payments under Medicare benefits in 1985/86 to almost 28,000 in 1991/92). Over the same period, payments for dilatation and curettage (D&C) have declined. Some replacement of the older tech-

nique may have occurred, although the Royal Australian College of Obstetricians and Gynecologists (RACOG) advises that diagnostic hysteroscopy is usually an adjunct to, rather than a replacement for, D&C. It is also regarded by the College as complementary to the radiological technique of hysterosalpingography rather than as an alternative. Since 1989/90 there has been increasing use of outpatient endometrial sampling, which is being seen by RACOG as less invasive and cheaper than hysteroscopy and probably as effective. The trend toward office-based procedures, with further reduction in hospital admissions for D&C, seems likely to continue.

Laparoscopic Cholecystectomy

The more recent introduction of minimal-access surgical procedures has been dominated by developments and debate on laparoscopic cholecystectomy. The technique was assessed by AIH in 1990 following its introduction into Australia that year (58). Its early use was undertaken within major teaching hospitals. Diffusion within Australia has been rapid because of the acceptable up-front costs to hospitals, early eligibility for government reimbursement under Medicare, and public awareness and demand for a less invasive procedure. At present the benefits schedule fee for laparoscopic cholecystectomy higher than that for the open procedure.

The early experience of teaching hospital units is illustrated by the results obtained as part of the Australian biliary lithotripsy evaluation (95). When compared with open cholecystectomy, a series of laparoscopic cases at the hospital showed decreased length of hospital stay and down time for the patient before returning to normal activities, and substantially decreased requirements for analgesia following the operation. Estimated costs of the laparoscopic procedure were lower than for open surgery, largely reflecting the decreased hospital stay. Such estimates of savings, however, do not necessarily take into account the full costs to a hospital of introducing such a procedure and the associated infrastructural changes.

A cost-utility analysis showed that the outcome of laparoscopic cholecystectomy was superior to both the open procedure and lithotripsy, unless subsequent evidence indicated a very high incidence of common bile duct damage (24). This study included an assessment of costs to patients associated with both forms of cholecystectomy and lithotripsy. The costs to patients per case were estimated at between $1,800 and $2,500 less for laparoscopic cholecystectomy than for open cholecystectomy (101). A further study has confirmed shorter hospital stays, lower costs, and faster recovery for laparoscopic cholecystectomy as compared to open surgery (53).

Diffusion of laparoscopic cholecystectomy has continued rapidly. In early 1993 the Royal Australasian College of Surgeons (RACS) advised that the technique was in place in all teaching hospitals and inmost smaller surgical centers. The spread of the technique has been associated with an increase in total numbers of cholecystectomies.

An early estimate was that there had been a 26 percent increase in the rates of cholecystectomy in the first two years after introduction of the laparoscopic method, following a period of several years where rates for gallbladder removal were almost constant (68). Conversion rates for laparoscopic to open surgery were high during the first two years of use: Health Insurance Commission data indicated a level of over 14 percent. At that stage only an estimated 13 percent of potential savings to health program costs through use of the new method were being realized. Decreased costs per case for laparoscopic surgery appeared to be largely offset by the increased numbers of procedures.

The increase in the rate of cholecystectomies has subsequently slowed, although the number of procedures per year remains considerably higher than the levels prior to introduction of the laparoscopic method (49). The conversion rate has fallen with increasing experience with the procedure, to 8.4percent in 1992/93. Possible reasons for the increase in surgery rates include extension of services to frailer patients, a wish to resolve symptomatic cases rather than watchful waiting,

application to asymptomatic cases, and applications to misdiagnosed cases (68).

Concerns remain regarding standards of performance of laparoscopic cholecystectomy in smaller centers, and in response, the RACS has developed accreditation and training procedures. There have been anecdotal accounts of serious complications following performance of laparoscopic procedures at smaller centers. Routine intraoperative cholangiography has declined by 66 percent since the introduction of laparoscopic cholecystectomy. It has been suggested that routine laparoscopic exploration of the bile duct should be adopted as a standard practice to permit treatment of common duct calculi at the time of laparoscopic surgery (37).

Other Laparoscopic Procedures

Data on the other recently developed laparoscopic procedures are more limited. Laparoscopic appendectomy was first performed in Australia in the early 1980s (36). Since then its use has been restricted primarily to gynecologists treating chronic recurring lower abdominal pain in women. Although laparoscopic appendectomy is increasing in Australia, its uptake is likely to be slower than for laparoscopic cholecystectomy because training in the technique has not been widespread and because of the undesirability y of applying laparoscopic procedure in an emergency situation (60). There is also some feeling that the laparoscopic procedure may offer limited advantages for hospitals and surgical staff and that there would be little improvement in recovery time for patients as compared with the open procedure.

The major impact of laparoscopic surgery on hysterectomy is expected to be through use of laparoscopically assisted vaginal hysterectomy (LAH) rather than the full laparoscopic procedure (59,67). Neither LAH nor laparoscopic myomectomy are yet in general use in Australia. The RACOG is developing training and accreditation protocols for LAH.

LAH offers uncertain advantages to service providers over abdominal or vaginal hysterectomy as cost estimates are sensitive to lengths of stay, substitution rates, and instrument costs (59). However, if half of the abdominal hysterectomies performed for myomas were replaced by LAH, annual savings to the health care system could be on the order of $2 million. Future attention may focus on options for reducing the costs of disposable instruments (currently about $1,200 per case).

In terms of societal costs, LAH offers potential major benefits through considerable reduction in post-operative recovery (by four weeks) and probably in the cost of complications. Such factors are likely to increase the pressure for diffusion of LAH. A counterforce will be the availability of competing, minimally invasive approaches, including endometrial ablation or resection using diathermy. Endometrial ablation/resection is well established, with over 4,000 procedures funded through Medicare benefits in 1991/92 (59). During this period the rate of hysterectomy for menorrhagia in public hospitals declined by one-third.

Laparoscopic hernia repair was introduced into Australia in 1990 (21). This procedure's impact is expected to increase, although some centers do not regard the immediate advantages of the laparoscopic approach over a short-stay open repair to be clearcut, particularly in view of the experimental nature of the technology. If laparoscopic approaches for hernia repair ultimately result in faster recovery, decreased pain, and overall reduced costs, they are likely to be popular with both patients and organizations responsible for compensation payments, despite uncertainties about long-term recurrence (60).

Laparoscopic vagotomy has been performed in Australia (88), although its level of use is currently low; most patients are now treated with drugs. There still appears to be some uncertainty as to the appropriate technique for this procedure. Laparoscopically assisted bowel resection was introduced in 1991 at the Sydney Hospital, with the mobilized bowel taken out of the body via a laparotomy excision to perform the resection and form the anastomosis (102). At least some centers in Aus-

tralia appear to be moving toward the use of the full laparoscopic approach for this application.

Unanswered questions surrounding newer laparoscopic procedures relate particularly to assurance of appropriate training, availability of adequate caseload, mechanisms for appropriate follow-up of patients after laparoscopic surgery, and costs to hospitals through changes to infrastructure (48). Up-front costs of disposable instruments, which are preferred on technical grounds, are a chronic problem for hospital administrators. In a number of cases public hospitals have been using reusable equipment, accepting the less obvious cost of cleaning and sterilization plus the consequences for patients if these procedures are not performed adequately.

The Impact of Technology Assessment

The impact of technology assessment on the use of laparoscopic procedures is uncertain. Several assessments have provided information to health authorities and professional bodies, but there has been no discernible influence in the short term on the use and organization of services. For example, the trends in use of laparoscopic cholecystectomy and diagnostic hysteroscopy have largely occurred as a result of influences other than formal evaluation. Possibly assessment may be more significant in the longer term as data from the initial phase of some techniques are more closely considered and guidelines are established. AHTAC is developing a report on minimal-access surgery that may provide further focus and help set directions for the future.

TREATMENTS FOR END-STAGE RENAL DISEASE (ESRD)

Rates of ESRD treatment continue to rise in Australia. The Australia and New Zealand Dialysis and Transplant Registry has accumulated records on over 10,000 patients who have begun treatment for ESRD in Australia (30). In 1989 the treatment rate was 34.4 per 100,000 population.

These rates are rising largely because of an increase in the number of people over 60 years beginning dialysis. Diabetic nephropathy appears to be involved in an increasing proportion of cases of renal failure treated by dialysis and transplantation. Compared with many other nations, Australia has a high level of a nephropathy caused by analgesic medicines, although new cases are declining (9). Recent data indicate that Aborigines may have a more extensive requirement for renal dialysis. The rate at which Aborigines began treatment was over three times that for all Australians, and there still may be much untreated disease.

Guidelines for renal dialysis and transplantation have been prepared by AHTAC (9). There appears to be little scope for identifying preventive strategies to lower the incidence of renal failure. Although renal transplantation is recognized as the preferred method of managing ESRD, dialysis remains the dominant treatment method. The transplantation rate has remained at about the same level for the last decade; in 1990 only 12 percent of dialysis patients received a transplant.

During the 1980s the number of home dialysis patients grew slowly, and the proportion relative to population has been declining. In 1989 there were 798 home continuous ambulatory peritoneal dialysis (CAPD) patients (4.6 per 100,000), 582 (3.5 per 100,000) home hemodialysis patients and 18 (O. 1 per 100,000) home intraperitoneal dialysis (IPD) patients. Overall there were 16.3 dialysis patients per 100,000 population.

The overall median survival rate for patients with ESRD after five years of treatment is 61 percent; outcomes become poorer with increasing age. Variations in survival among different centers is substantial. For primary cadaver grafts after 12 months, there is a 22 percent variation in terms of patient survival and a 36 percent difference in graft survival between the best and the worst centers, AHTAC has recommended that every effort be made to elevate those units with poor results to an acceptable standard.

With regard to current service provision and expertise and the efficient use of staff and facilities. AHTAC considered a minimum of 30 transplant operations per year at each center to be desirable and recommended that centers that are not performing 20 operations per year should either cease transplantation altogether or increase their com-

mitment. All dialysis units should be linked organizationally to a renal transplantation program (9).

Transplantation is the preferred treatment on cost grounds, with hospital hemodialysis the most expensive of the alternative approaches. Opportunities for home dialysis appear to be lacking. AHTAC recommended that new facility development be promoted in the following order of priority: transplantation facilities, home dialysis (including CAPD), satellite dialysis, and hospital dialysis. In addition, efforts should be made to minimize maintenance dialysis in hospitals. Renal treatment programs should review their policies on dialysis location for patients with a view to relocating suitable patients to satellite and home dialysis.

Major themes of the AHTAC guidelines document were the need to increase the rate of organ donations for transplants and to decrease the proportion of dialysis patients treated in hospitals. Changing community and professional attitudes toward organ donation have the greatest potential to alter ESRD'S impacts and to affect cost allocation. According to the Australian Coordination Committee on Organ Registries and Donation (ACCORD), the current donation rate is 13.5 organs per million per year. If all suitable potential donors were to become actual donors, this rate could be nearly doubled.

Insufficient kidney donation is a major problem in overcoming the backlog of patients awaiting transplantation (40 to 45 percent of dialysis patients). ACCORD is addressing organ acquisition difficulties and promoting improvements to infrastructure and financial support.

Living related donor transplantation accounts for 10 to 12 percent of renal transplants in Australia and New Zealand. Increased use of this approach would be desirable because of the excellent results compared with cadaver transplants and the shortage of cadaver organs. In a series from a Melbourne hospital, the living related donor approach was associated with shorter waiting times for transplantation (38). Pancreas transplantation in association with renal transplantation is being undertaken on small numbers of type 1 diabetic patients with renal failure. The service is offered at a hospital in Sydney under the Nationally Funded Centers policy, after its consideration by the Health Care Committee of NHMRC and AHTAC.

Erythropoietin (EPO)

Recombinant EPO for management of anemia due to renal failure has been used in Australia since 1990, initially on a restricted basis because of its cost. It was suggested that treatment might need to be limited to patients in whom anemia causes serious disability unrelieved by other measures (35).

Various centers have adopted measures to reduce the EPO dose to the lowest level suitable for maintaining benefits in each patient. Experience at the Queen Elizabeth Hospital, Adelaide, has suggested that the cost per patient per year might fall to $6,000. At the Royal Adelaide Hospital, the annual cost for EPO given subcutaneously maybe as low as $2,000 to $3,000 per patient (9). A study at Westmead Hospital, Sydney, reported the successful use of low-dose EPO at a yearly per-patient drug cost of $3,681 (54).

The question of financial support for EPO was subsequently considered by HSDWP. Following its recommendations, funding was provided in the 1991 commonwealth budget to support the drug's use for treatment of anemia requiring transfusion associated with ESRD, where treatment is initiated in a hospital with a renal dialysis unit. (Any application outside these indications is not covered by the commonwealth.)

The states are responsible for meeting the drug costs of the in-hospital phase (taken to be three months from the initiation of treatment); the commonwealth meets subsequent costs. commonwealth grants to the states and territories for EPO in 1991/92 totaled just under $7.5 million (57), and the drug is now being used by all major centers. Evaluation procedures must still be developed.

The Impact of Technology Assessment

The impact of technology assessment in this area has been limited to date. The AHTAC guidelines

summarize current statistics, concerns, and possible future directions. Their influence will depend on how the suggested targets are viewed by state health authorities and professional groups.

NEONATAL INTENSIVE CARE

Like many other countries, Australia has accepted the concept of regionalization for perinatal services as a means of improving access to secondary and tertiary levels of care. A paper on organization of perinatal services, which drew on Canadian experience, defined three levels of neonatal care: level 1 (suitable for uncomplicated situations), level 2 (generally located in larger or suburban hospitals with obstetric services), and level 3 (sophisticated services based in major general maternity or children's hospitals) (70).

State guidelines for the numbers of beds in level 2 units vary considerably, from 1 to 2 per 1,000 live births in Queensland to 4.25 in New South Wales. Infants admitted to a level 2 unit are generally over 32 weeks in gestation and over 1,500 g in birthweight. Most level 3 units have obstetric services and accept many high-risk pregnancies referred in from the region in which they are located; they also handle the management of normal pregnancies in their immediate area.

Guidelines for level 3 neonatal intensive care were developed by the Superspecialty Services Subcommittee in 1983 and updated in 1991 (5). Apart from an increase in the recommended number of ventilator beds from 0.6 to 0.7 per 1,000 live births, no substantial changes were made to recommendations in the guidelines during that period. Other major specifications are that level 3 units should have 10 to 20 level 3 beds (1.1 per 1,000 live births) and nurse-to-patient ratios of 1 to 1 for ventilator beds and 1 to 2 for other level 3 beds. The guidelines also outline the need for level 3 units to provide support for parents, to have a well-defined role in staff and public education, and to monitor data and outcomes on a long-term basis. The need for control of nosocomial infection is stressed, although infection is not currently a major cause of neonatal death.

In 1990, 20 hospitals in Australia had level 3 neonatal intensive care units (NICUS) and full-time neonatologists; these had a total of 160 ventilator beds. A further 14 ventilator beds were planned for New South Wales and Victoria.

In 1983 the average cost per baby from the time of admission to the NICU to the time of discharge home, transfer to another hospital, or death was estimated at $13,952 (based on a hospital in Sydney): the average cost per survivor was $16,415 (61). In 1988/89 the average cost per baby had fallen to $10,279, and the average cost per survivor to $10,953 (62). The cost to the community of neonatal intensive care averaged $13,857 per surviving baby, with a range of $4,064 for a birthweight of more than 2,000 g to almost $138,000 for those less than 750 g (62).

The survival rate for very immature infants rose from 20 to 61 percent, associated with the introduction of positive pressure-assisted ventilation. Between the 1977-83 and 1984-86 periods, survival increased by 9 percent while the cost per additional survivor rose by 60 percent.

Both outcomes and costs for each individual baby are variable and difficult to predict (4). Those making decisions about withholding intensive care for individual babies are essentially making value judgments. Cost and economic data can only be one component of these judgments. The Subcommittee's guidelines point to statements on ethical issues in intensive care and to other guidelines for very -low-birthweight babies developed at consensus conferences at Westmead Hospital, Sydney.

Concern has been expressed about the increased need for NICU services that may result from births following in-vitro fertilization (IVF) and gamete intrafallopian transfer (GIFT) techniques. Assisted conception by IVF and GIFT in 1991 resulted in 2,009 live births up to September 1992, with overall totals of 6,932 and 3,794, respectively, since these techniques were introduced (86). About 1 in 200 births in Australia now result from these new reproductive technologies. These births are more likely to result in low birthweights, to be multiple, and to require neonatal intensive care. Over one-third of IVF/GIFT babies are of low birthweight, and about 23 percent of these births are multiple. Some NICUS report that

the IVF/GIFT cases consume up to 7 percent of bed days.

Extracorporeal Membrane Oxygenation (ECMO)

ECMO was introduced in Australia in mid-1988 at the Royal Children's Hospital, Melbourne, and about a year later at the Prince of Wales Children Hospital, Sydney (51). The decision to develop an ECMO program was made by the hospitals, and costs were met from their own budgets. Early results for neonates and other children were excellent. Different approaches were adopted at the two Australian centers. In Melbourne ECMO was offered to all neonates who met specified entry criteria. In Sydney high-frequency ventilation was tried first and ECMO was used only when it failed.

Following the units' initial experience, a consensus conference organized by the Australian Association of Pediatric Teaching Centres and NHMRC was held to define the role of ECMO as well as resource and research requirements. It was apparent that local clinical and cost data were limited and that a strong minority opinion held that satisfactory results were obtainable using conventional treatment.

The improvement in conventional treatment over recent years suggested the need for a critical comparison of ECMO with alternative approaches. Local evaluation was seen as necessary because of differences between Australia and other countries both in patient population and in standards of obstetric and neonatal care. For example, perhaps 40 percent of neonatal cases treated with ECMO in the U.S. have a primary diagnosis of meconium aspiration syndrome, which is comparatively rare in Australia. Also, the small national caseload would make it difficult to design and conduct a randomized controlled trial that could produce definitive results.

It was recommended that a panel be set up to explore the feasibility of a trial and that AHMAC be approached for funding and agreement to restrict ECMO units to two centers (1,92). AHMAC in turn referred to NHTAP the question of the costs and financial benefits of limiting ECMO to not more than two centers. NHMRC was to give further consideration to the feasibility of conducting a controlled trial of the technology.

The assessment of costs and financial benefits drew on information from the consensus conference, further opinions from the hospitals concerned, and relevant literature (81). It emerged that the marginal costs of ECMO were relatively modest ($5,800 to $8,400 per patient). Although NHTAP found that there was little difference in cost terms between the different options for numbers of ECMO centers, there appeared to be compelling reasons to limit the number of centers. The technology was still evolving and was in some senses experimental, and an appropriate minimum caseload was seen as necessary to maintain expertise and achieve efficiencies of scale.

Various issues needed to be considered by health authorities with regard to the future use of the technology. ECMO appeared to be a useful method of last resort in treating neonates and older children with severe respiratory distress; however, the data on its efficacy were limited, and pediatric use data were not conclusive. Future selection criteria used by ECMO centers would strongly influence caseload, cost per case, and the rate and quality of survival. The efficacy of ECMO in comparison with conventional therapy was deemed to need further critical review given the apparent shifts in practice, possible improvements in conventional therapy, and the perceived low sensitivity and specificity of selection criteria. NHTAP suggested that it would be wise for any future research on ECMO in Australia to include appraisal of alternative therapies.

AHMAC subsequently accepted the recommendation that there be not more than two ECMO centers but did not consider additional support under the Nationally Funded Center policy appropriate, in light of the limited impact of the specialized service on hospital budgets when marginal costs were taken into account. The issue of the controlled trial remains unresolved. The NHMRC has considered the question, but the fact is that many clinicians and nurses using ECMO have become convinced of its usefulness and will not accept al-

location of at-risk neonates to a control group. Efforts are being made to include one of the Australian centers in the British randomized trial of this technology.

The Impact of Technology Assessment

The impact of technology assessment on neonatal intensive care has been variable. The original guidelines produced by the Superspecialty Services Subcommittee were probably influential because of the consultation process that took place during their preparation. When they were updated, much of the material prepared some six years earlier was considered still current. Policy on support for ECMO was clearly influenced by a consensus conference and subsequent assessment by an advisory body, although the effect on patterns of practice probably was more limited.

SCREENING FOR BREAST CANCER

Breast cancer is the most common cancer and the most common cause of death from cancer among Australian women (4). Small-scale breast cancer screening services were established in the mid- 1980s but fell well short of a national program. They were limited in coverage, not subject to accreditation or other controls, and not designed to recruit and screen those women most likely to benefit from screening.

Use of mammography services increased in all age groups between 1984 and 1988, but women over 65 made least use of them, although the death rate associated with the disease was highest in that group (4). Data from the 1988-90 National Health Survey conducted by the Australia Bureau of Statistics indicated that only 22 percent of women aged 40 to 64 had had a mammogram in the previous three years, with the highest proportion (25 percent) in the 45-to 49-year age group (2). Poor awareness appeared to be a contributing factor, influenced by education level, family income, place of residence, and whether women spoke English at home.

Evaluation of Breast Cancer Screening

Two of the targets set in 1987 by an AHMAC committee were to reduce the death rate from breast cancer by 25 percent or more by the year 2000 and to increase participation in breast cancer screening to 70 percent or more of eligible women by 1995 (56).

In 1988, Australian health authorities established a National Breast Cancer Screening Evaluation. The evaluation, coordinated by a unit at AIH, reported in mid-1990 (4). It drew on a number of pilot projects based on some of the already established screening services and included a detailed economic assessment. Technical aspects of screening mammography were considered by NHTAP as input to the national evaluation (79). The Panel supported proposals by RACR to accredit clinics for mammography screening and summarized specifications for mammography units, film processing and quality control. Brief consideration was also given to personnel requirements, the need for follow-up facilities, and a national database.

The NHTAP report was followed up by AIH at the request of the AHMAC Steering Committee (11). The AIH report confirmed that mammography was the only proven technique suitable for breast cancer screening, gave detailed specifications for mammography units, and recommended adoption of quality control guidelines prepared by the Australasian College of Physical Scientists and Engineers in Medicine. According to a survey by the Australian Radiation Laboratory, there were about 300 mammography units in Australia in 1989, but it was not known how many of these would be available for screening work.

The Steering Committee's report supported introduction of a national screening program for all eligible women on both scientific and economic grounds. Cost per life year gained was estimated to be in the range of $6.600 to $11,000 (4). It was recommended that the program select women on the basis of age alone. The Committee also urged that mammographic screening be made available and publicized for women aged 40 years and older but that recruitment strategies should be targeted at women from 50 to 69 years old.

Screening should be made available as widely as possible to all eligible women in the target group with the intent of rescreening every two years.

Important practical and ethical issues arise in addition to cost-effectiveness considerations. The introduction of a mammography screening program that excluded women from 40 to 49 years old would encounter a practical difficulty: women in this age group would obtain mammography outside the screening program. Because such mammography would lack many of the features required of a national program, it would be likely to be less effective, with variable quality control, and seriously undermine the conduct of a national screening program.

Economic aspects of breast cancer screening have subsequently been considered by Carter and co-workers (23), whose analysis suggested that screening all women aged 50 to 69 every two to three years is reasonable value for money. For women from 40 to 49 mortality benefits and cost-effectiveness are less clear. It was suggested that screening in this age group be allowed but not actively pursued until further evidence is available.

This series of assessments addressed major issues in screening mammography, including the degree of benefit of the technology compared with other approaches, expected gains in quality of life, and problems caused by false positive results. These matters were taken into account during the development of a national program.

Establishment of a National Program

In March 1990 the commonwealth announced that it would contribute $64 million over three years toward the establishment of a National Program for the Detection of Breast Cancer. The earlier AHMAC report formed the basis for this program's development. By 1993 all states and territories had made commitments to population-based screening programs for eligible women.

The national program fully funds the provision of screening and assessment services through to confirmed diagnosis of breast cancer. Funding is independent of the Medical Benefits Schedule. Services funded under the program must be accredited.

Proposals in the AIH report regarding machine specifications and quality control were adopted in the National Accreditation Guidelines issued as part of the national program (87). The guidelines cover recruitment, services, and facilities for screening and assessment, data collection, training activities, and program management. Other topics covered include performance objectives and acceptable process, the timeframe for the national program, technical items to be evaluated in a quality assurance program, and suggested specifications for mammography units.

Under the national program, each screening unit will be linked to an assessment center. The assessment center will function with multidisciplinary teams and have primary responsibility for quality control and for management of screening and assessment procedures, including counseling and diagnostic workups.

Coordination units in each state or territory will have primary responsibility for liaison and negotiation with the commonwealth and implementation of the national program. This responsibility includes making recommendations on the location, type, and number of screening units and assessment centers; recruitment; accreditation; monitoring and evaluation; financial management; and data management. The national coordination unit (located within DHSH) is responsible for data collection and analysis and program monitoring and evaluation.

The national program has given detailed consideration to the role of general practitioners in the primary health care of women who are eligible for screening. General practitioners should be kept informed of the results of screening and any further workups required unless a woman directs otherwise. However, a doctor's referral is not a prerequisite for attendance at a screening service.

The current intention is to rescreen women every two years subject to revision as new data become available. Screening will be made available at minimal or no cost and will be free to eligible women who would not attend if there was a charge. Comprehensive and easily understood information, emotional support, and counseling will be provided. Women will be advised on the

effectiveness and risks of mammography and on the maintenance of a regime of breast care, such as breast self-examination, to reinforce the message that a negative mammographic screen does not preclude the diagnosis of breast cancer prior to the next screening.

The program follows earlier recommendations of the AH MAC Steering Committee in specifying requirements for screening services. Film-screen mammography alone is the principal screening method, using two-view mammography with one view at rescreening if previous mammograms have indicated that two views are not required. All mammograms will be taken by a radiographer appropriately trained in screening mammography, and read and reported independently by two or more specially trained readers, at least one of whom is a radiologist. Reports will be combined into a single recommendation and results provided to patients promptly and directly.

In 1990, 10 screening and assessment services were offered in five states that had been pilot projects in the National Screening Evaluation. Screening services under the national policy are now established in all states and the Australian Capital Territory (with the Northern Territory to follow in shortly), for a total of 21 centers in place. Areas where coverage is poor are being reached by mobile mammography units in order to increase acceptance of the technology before establishing permanent facilities. Participation rates are rising, although they remain considerably below target.

Current NHMRC policy on mammography screening for women under 50 years of age is that there is insufficient evidence to advise women under 50 years to have routine mammography (72). Women from 40 to 49 should not be excluded from screening programs if they request it but should be counseled on current evidence of benefits; women at higher-than-average risk should have the option of attending a screening program. There is no evidence of benefits from screening women under 40 years old.

Now that substantial resources have been committed by governments to the national program, concerns are to ensure an appropriately high rate of recruitment, adequate minimum technical standards, and effective reporting and follow-up procedures. The program will be subject to ongoing evaluation coordinated by a national advisory committee. It is hoped that this concerted effort will lead in the medium term to a significant improvement in one aspect of women's health.

Technology assessment has strongly influenced the development of screening mammography services. The substantial evaluation program funded by AHMAC set directions for the current national program, and the brief assessments by NHTAP and AIH assisted this process. Assessment will continue with formal reviews of the performance and impacts of the program.

CHAPTER SUMMARY

Substantial changes in approaches taken to health care technologies in Australia have occurred in the past two decades. Medical benefits remain an important factor in the funding and use of health care technologies: however, other mechanisms, such as government grants and the Nationally Funded Centers program, have become significant. Health care technology mechanisms has been put in place, and quality assurance programs have been developed. The availability and quality of data have improved. Debate continues on how much should be spent on high-technology medicine as opposed to preventive and community programs.

Overall, the Australian population's access to a wide and appropriate range of health care technol - ogies is good, and an effective level of support has been delivered within expenditures that have remained at or below 8 percent of GDP for a number of years. Concerns typically arise regarding whether some technologies (notably diagnostic techniques) are overused. delays in providing services to some patients. appropriate levels of reim-

bursement for use of technologies, and whether both superspecialty and more routine services are consistently provided cost-effectively and to appropriate standards.

In Australia significant segments of the population will always be geographically remote from some technologies and services. Most specialist medical practitioners with expertise in new health care technologies are based close to metropolitan areas or to university teaching hospitals, not easily accessible for many Australians. The inconvenience and expense to some patients is unlikely to change in the short term. Certain health care technologies will continue to be sited in large population centers because of high costs and limited demand.

Although there are areas of dissatisfaction, including pressure on public hospitals and the level of out-of-pocket expenses for some services under current insurance arrangements, the level of public acceptance of the health care system seems quite high. Notably, the Medicare insurance scheme continues to be popular. In early 1994 only 38.4 percent of Australians had hospital insurance coverage through private funds.

Australia's relative success in controlling technologies—taking account of introduction, diffusion, level of use, societal costs and benefits, and equity of access—has been mixed. As described earlier, legislative provisions to control most types of health technology are limited. Both health authorities and health professionals have to live with the realities of operating within a system with a complex mix of government responsibilities and political and professional imperatives. The control and use of health technologies in Australia will be strongly influenced by intergovernmental relationships, the size and distribution of budgets for health care, and funding mechanisms. Major programs that have been put in place in recent years, such as the casemix development and cancer screening initiatives, are likely to significantly affect government and professional relationships and patterns of provision of health services.

The control of pharmaceuticals with regard to safety and efficacy has been generally successful, with changes seen as necessary to ensure that evaluation is timely. Close consideration of cost-effectiveness is a recent development. Control of medical devices has been less certain, and even less direct influence has been possible with regard to procedures.

The Nationally Funded Centers policy has provided defined mechanisms for support of very specialized technologies in their early stages of use and review to determine when this type of intergovernmental support is no longer justifiable. Linking government grants conditionally to assessment of new types of medical devices has been a useful approach. The shortcomings of such initiatives have been the limited assessment and monitoring of technologies after diffusion. Accreditation procedures for pathology services have worked effectively, although they provide only a narrow focus of control, and the Superspecialty Services Subcommittee and AHTAC guidelines have been successful in providing a framework for discussion and planning of health care services.

The Australian experiment of linking the introduction and support of health care technologies to assessment is now in its second decade. There have been some significant successes in informing policy through appropriately targeted, well-timed assessments. Recommendations and data from the assessments have influenced policy on whether to fund technologies, levels of funding, indications for use, and placement of services, but only in a minority of cases. Practice, too, has been influenced, but the data here are more limited.

Despite "islands" of assessment and fully informed policy, the mainstream of health technology has been deployed through less formal mechanisms (42). This is perhaps inevitable until assessment is linked more systematically to decisions on resource allocation and is undertaken more widely within hospitals and other institu-

(ions. Further progress is likely though more systematic linking of funding decisions with formal assessment, application of practice guidelines, and longer term educational initiatives.

Reports from Australia's national advisory bodies have been influential and well regarded and have contributed to policy formulation and to the wider education of health technology providers and purchasers. A major factor in the success of these assessments has been the expertise and continuity provided by a permanent group of evaluators who have supported the national committees.

Some assessments, notably those involving collection of primary data, have to some extent been opportunistic, depending on the level of support obtainable from staff in hospitals and other institutions. The emerging databases and assessments undertaken by AIHW (some in support of AHTAC) have also worked well.

The involvement of professional bodies and industry in the work of the national health technology assessment groups, and the practices of inviting comment and being willing to update reports and recommendations in the light of experience and new data, have helped considerably in broadening the base of assessments and their acceptance. One possibly undervalued aspect of the assessments has been the provision of general descriptions of technologies to policy makers, administrators, and the media, which have helped to demystify technical terms and concepts.

Information from agencies in other countries has been a valuable input to many assessments. However, local appraisal of a health technology is often highly desirable because of limitations in the data from other countries and the need to take into account local characteristics (98).

Conducting primary research locally is often desirable, even if studies are not entirely definitive: counsels of perfection need not impede clinical trials of new technologies. Several Australian trials have provided rich information on costs, effectiveness, and process even though pragmatic decisions had to be made on limiting the power of particular studies.

Health authorities and professional groups face constraints in controlling technologies and ensuring their appropriate use. The timing of assessments and the prompt provision of results remain major issues, and evaluators need to be aware of the pressures on policymaking areas. Mechanisms are needed to link the introduction and diffusion of new services and procedures to the assurance of efficacy and to the collection and provision of data by the new methods' sponsors. This will not be easily achieved without legislative changes and close cooperation between Australian governments and professional groups.

Australia has achieved a realistic balance between the coverage of technologies, rigor and depth of evaluation, speed of assessment and available resources. However, changes in the administrative arrangements for national advisory bodies in recent years have caused some loss of momentum. A period of stability would be desirable to permit consolidation of achievements and stronger links between different evaluation groups—all of which seek increases in funding. It must be said that assessment output has probably reached its limits with the current level of resources.

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Health Care Technology in Canada

(with special reference to Quebec)

3

by Renaldo N. Battista, Robert Jacob, Matthew S. Hedge

OVERVIEW OF CANADA

Canada is a sparsely populated northern landmass of approximately 10 million km^2. Created in 1867 after French and then British colonization, the Canadian federation currently consists of 10 provinces and two territories. Provincial populations in 1991 (table 3-1) make apparent the rather imbalance distribution of Canadians across the country (119). Compounding this imbalance is the population's north-south distribution; 80 percent of Canadians are clustered within 320 km of the border with the United States. Providing services to the remaining 20 percent living in remote areas has been a key issue throughout Canada's development.

Despite the logic of north-south transport links between Canadian regions and adjacent regions of the United States, domestic east-west links have been heavily emphasized. This historical pattern arose from the central location of the four founding provinces—Ontario, Quebec, New Brunswick, and Nova Scotia—combined with a mistrust of their southern neighbor, the United States, in the aftermath of the U.S. Civil War and apparent territorial designs on what was, until 1867, British North America. East-west links also clearly benefited English mercantilist trade during the 1800s. Recent free-trade agreements between Canada and the United States as well as among Canada, the United States, and Mexico suggest that Canada now wishes to consolidate and expand its north-south links.

Government and Political Structure

In light of the strong ties, both economic and historical, to Great Britain, it is not surprising that until 1982, Canada's constitution consisted of the British North America (BNA) Act of 1867 and

TABLE 3-1: Provincial Populations, 1991

Province	Year joining confederation	Population (1991)
Newfoundland	1949	568,475
Prince Edward Island	1873	129,765
Nova Scotia	1867	899,945
New Brunswick	1867	723,900
Quebec	1867	6,895,960
Ontario	1867	10,084,885
Manitoba	1870	1,091,940
Saskatchewan	1905	988,930
Alberta	1905	2,545,550
British Columbia	1871	282,065
CANADA	(excluding Yukon and Northwest Territories)	27,211,415

SOURCE Statistics Canada, The *Nation Age, Sex, and Marital Status,* Statistics Canada Pub No 93-310 (Ottawa 1993)

subsequent amendments. This act of the British parliament established governmental structures and jurisdictional divisions between federal and provincial governments, and amendments required the assent of the House of Commons in England. Despite the distance between the BNA Act and the people it governed, this process worked reasonably well.

In 1982, however, the Constitution Act was passed by the Canadian parliament, effectively repatriating the BNA Act and enshrining a Canadian Charter of Rights and Freedoms in a new Canadian constitution. Repatriation was supported by all provinces but Quebec. To gather sufficient support for repatriation from the other nine provincial governments, the federal government provided a "notwithstanding clause" allowing provincial governments to pursue legislative goals that might impinge on the guarantees of the Charter of Rights and Freedoms.

Canada's federal legislature is a bicameral parliamentary system with 295 Members elected to the House of Commons and 104 Senators appointed by the Prime Minister for terms until age 75. Legislative power resides almost entirely in the House of Commons; the Senate only rarely intervenes to reject legislation. Executive power resides in the cabinet, which is composed of the prime minister and ministers—nearly all of whom are also members of the legislative branch by virtue of their being elected to the House of Commons.

The provincial legislatures operate in a similar fashion but without provincial equivalents of the Senate. Three essentially national political parties are active in both federal and provincial politics. The Progressive Conservative Party espouses a right-leaning, centrist philosophy, and the Liberal Party advocates a more clearly centrist philosophy. The New Democratic Party (NDP) has traditional links to organized labor but is most similar to the centrist social democratic parties found in several European countries. The NDP has been the source of virtually all major social policy initiatives in Canada, particularly in health care. During the 1960s the federal Liberal Party established the Medicare system of national health insurance along the lines established by the NDP in Saskatchewan and in NDP position papers.

Jurisdictional tension between federal and provincial governments has encouraged the growth of several parties with peculiarly regional support and agendas generally stressing more autonomy for their region. In the western provinces these have been particularly strong, often also advancing a conservative social agenda. In addition, the *Parti Que'be'cois* in the predominantly French-

speaking province of Quebec has advocated various measures that would markedly diminish federal jurisdiction there.

Issues of language and ethnicity are a staple of Canadian political life. Both English and French are considered official languages, and federal services are ostensibly available in both languages across the country. Roughly 24 percent of Canadians state that French is their first language, and of these, 88 percent live in Quebec (118). Treaties signed with aboriginal peoples have created "status" Amerindians, who constitute approximately 2 percent of the population.

Population Characteristics

Apart from the small aboriginal population, Canadais a country of recent immigrants, initially from northern Europe and the British Isles but (after World War II) increasing y from other parts of Europe and Asia. According to the 1991 census, 19 percent of Canadians were born outside Canada (11 7). The federal government has adopted an official policy of multiculturalism, encouraging recently arrived Canadians to maintain features of their places and cultures of origin. Immigrants to Canada have tended overwhelmingly to settle in Canada's three largest cities: Vancouver, Toronto, and Montreal.

The Economy

In addition to ethnic and language differences among regions, important regional economic differences exist. British Columbia, Alberta, Ontario, and Quebec account for 84 percent of the population and have traditionally been seen as the "have" provinces. Their economies are the most diversified and integrated with North American and world markets. The four Atlantic provinces, by virtue of their small size, remote location, and dependence on fishing and lumbering are.the weaker siblings in the Canadian family.

The central prairie provinces, the birthplace of many of Canada's social welfare programs, are heavily dependent on agriculture and resource extraction. With Canada's national capital located in Ottawa and the financial capital in Toronto, Ontario has often been perceived, particularly by provinces more distant from central Canada as having a stranglehold on power in Canadian society. This perception, accentuated by the relatively large populations of Ontario and Quebec, has spurred repeated attempts to recast Canadian political institutions, particularly the Senate, along regional or provincial lines.

Background on Quebec

Because much of the data for this chapter are drawn from the province of Quebec, a few words on its history are in order. Originally colonized as New France by French farmers, fishermen, and fur traders, Quebec was lost to the British in 1759 at the Battle of the Plains of Abraham. Despite several halfhearted attempts to assimilate the French into an emerging English society, the British were seemingly content to govern a colony with a predominantly English-speaking, Protestant urban center and a French-speaking, Catholic countryside. The Roman Catholic church controlled many of the social structures, including health care and education, and encouraged the embrace of a simple, pastoral life.

As pressure for change built during the late nineteenth and early twentieth centuries, this fundamental linguistic and geographical division remained intact, despite rapidly increasing francophone urbanization. By the middle of the twentieth century, forces of social change had ushered in secular social services and public education in both English and French and had supplanted the power of both the Catholic church and English-speaking business elites in the province. This "quiet revolution" represented a wholesale transfer of power and influence from these former pillars to a newly dynamic provincial government and an array of secular nongovernmental bodies.

Concomitantly, historical expressions of concern about the future of Quebec in Canada and of the desirability of independence resurfaced with broader support. In 1980 the ruling *Parti Que'be' cois* lost a referendum seeking a mandate to negotiate some form of "sovereignty-association" with the rest of Canada. Since that time, popular

support in Quebec for sovereignty has remained at approximately 30 to 45 percent of poll respondents. In keeping with a desire for increased autonomy, Quebec chose not to consent to the Constitution Act of 1982. The decade since then has seen the failure of two major, federally initiated constitutional proposals designed in part to satisfy Quebec's agenda. Neither has received sufficient support from the constitutionally required combination of provinces and population.

HEALTH STATUS OF THE POPULATION

The health of Canadians has improved immensely throughout the twentieth century; life expectancy is now 81 years for women and 74 years for men (126). Reflecting a general pattern among Organization for Economic Cooperation and Development (OECD) countries, ischemic heart disease and cancer are the two main causes of death. Tobacco appears to be a major contributor to these tolls, despite heavy taxation of tobacco products.

Among Canadian men, ischemic heart disease accounts for 24 percent of deaths, and lung cancer for 9 percent (1990 figures) (114). Among Canadian women, ischemic heart disease accounts for 22 percent of deaths, followed by breast cancer (5 percent) and lung cancer (5 percent). Motor vehicle accidents account for 3 percent of male deaths and 1 percent of female deaths, with much larger percentages among young men.

The Canadian population continues to grow from both immigration and natural increase. In 1990 the birth rate was 15 per 1,000 population and the rate of natural increase was 8 per 1,000. Birth rates are highest in the Atlantic provinces. Infant mortality was 6.8 per 1,000 live births, of which 68 percent occurred in the first month (neonatal mortality) (11 6). These rates were highest in Newfoundland and the Northwest Territories, the parts of the country with lowest average incomes. Circulatory anomalies were the largest single cause of infant deaths (14.3 percent of female deaths and 11.8 percent of male deaths). Obstetrical complications accounted for about 10 percent of infant deaths (115).

Data on overall morbidity are not routinely gathered; however, accurate data are available on hospital use. Overall rates of use (excluding pregnancy-related admissions) indicate that men and women are equal users with a national rateof117 admissions per 1,000 population in 1990. For men the three greatest causes of hospitalization were diseases of the circulatory system (18.4 per 1,000), gastrointestinal conditions (16.1 per 1,000), and respiratory disease (15.7 per 1,000). Pregnancy and related care was the main reason for female admissions to hospitals (40.7 per 1,000), followed by gastrointestinal conditions (15.1 per 1,000) and diseases of the circulatory system (14. 1 per 1,000) (1 14). In general, lengths of stay have decreased throughout the last decade, although a growing proportion of beds in acute care hospitals are occupied by long-term residents, in part because of increasing numbers of very old people.

THE CANADIAN HEALTH CARE SYSTEM

Under the Canadian constitution, health care is a provincial responsibility; the federal role is limited to health care financing, health protection, and environmental health. Although all Canadians are insured for health services, 13 different health care systems exist, one in each of the provinces and territories and a federally managed one for aboriginal peoples.

The current system of universal health insurance grew from concerns at both federal and provincial levels that insurance, particularly for hospital services, was needed to improve the lives of Canadians. In the aftermath of the Second World War, a federally subsidized program was offered to the provinces in return for their ceding the collection of personal and corporate income taxes to the federal government. Not surprisingly, the provinces rejected this plan. Nonetheless, high public expectations led to the creation of provincially administered plans in several western provinces and the growth of private sector Blue Cross/Blue Shield plans in several other provinces. Wrangling continued until 1956, when the

two levels of government agreed to a financing scheme based on equal federal and provincial shares. By 1958 a federally subsidized, provincially administered program of hospital insurance was in place.

This program, coupled with public pressure, led the government of Saskatchewan to establish a program of comprehensive, publicly funded medical insurance in 1961. Physician-sponsored insurance carriers, alarmed at the support for and success of government-managed insurance, were instrumental in the 1961 federal decision to form the Royal Commission on Health Services, directed to address the issue of national health insurance (3, 122).

The Commission's report, released in 1964, called for a federally subsidized, provincially administered system of comprehensive medical insurance. The newly elected federal Liberal administration, having campaigned on a promise to establish a national health insurance system, provided a receptive policy environment. Canada's comprehensive Medicare system was thus created, with federal contributions conditioned on four criteria: services were to be comprehensive, benefits were to be universally available, coverage was to be portable from province to province, and the system of insurance was to be publicly administered (66). Despite some initial resistance from physicians, including job actions in several provinces, all provinces had joined the scheme by January 1, 1971. Since then, support for national health insurance has remained high among both physicians and the public.

Recently, several provinces have reviewed their health care systems comprehensively. These reviews include the Commission d'enquete sur les services de Sante' et les Services Sociaux in Quebec, and groups in Ontario and British Columbia (56, 102, 106). All of these have been generally oriented to prevention and regionalization and, more recently, to quality assurance, technology assessment, and cost control. The multiplicity of planning reports underscores the fact that each province designs its own approach consistent with the goals and conditions for federal financing. Although all provinces need to slow the growth of expenditures, the controls in place and available policy options differ among them.

Despite provincial variation, Canada's current health care system represents a balance among government direction, consumer choice, and provider autonomy. Universal health insurance, administered by provincial governments on a shared-cost basis with the federal government, covers inpatient and outpatient care in hospitals, ambulatory care and, in some provinces, prescribed medications and appliances. All provinces also provide some coverage for long-term care. Hospitals are autonomous corporate bodies administered by boards of directors. Patients are free to consult the physician of their choice as often as they desire. Physicians are reimbursed on a fee-for-service basis, with fee schedules determined by negotiations between provincial medical associations and ministries of health. When the system was first introduced, physician incomes increased from the levels of the pre- insurance era.

Over the last decade, federal health care financing has fallen in real terms, and several provincial governments have considered introducing copayments, deductibles, or other revenue sources that might simultaneously limit the demand for services. Provincial options are, however, limited by provisions of the Canada Health Act. Promulgated in 1984, this federal legislation sought to reaffirm the principle of universality by banning user fees and "extra billing" by which physicians would charge patients directly for services at rates higher than those of the fee schedules negotiated between medical associations and governments (71). The bill received broad public support but was viewed by several provinces as unwarranted federal interference in a clearly provincial jurisdiction.

In spring 1993, candidates for the leadership of the federal Progressive Conservative Party stated publicly that user fees may have a place in the Canadian health care system. It remains to be seen how provinces will respond to increasing health care expenditures in light of decreasing federal contributions coupled with the revenue restrictions mandated by the Canada Health Act. Despite increasingly fragile fiscal health, provincial gov-

emments have shown little interest in moving away from a single-payer system.

In addition to the administrative efficiency of having one payer for all services, the provincial governments exercise a fair degree of control over facilities construction and technology diffusion. Hospitals generally receive an annual, prospective global budget to cover operating expenses, and some provincial health ministries administer separate capital budgets for facilities construction and equipment. This centralized resource allocation scheme, coupled with a degree of power to determine which services in which locations will be deemed reimbursable, has led to less technology uptake than in the United States (24,107).

Control over physician numbers has been rather more problematic. Primary care physicians and specialists are approximately equal in number, but the total numbers of both are perceived in some quarters to be excessive. During the 1960s overly generous predictions of the growth rate in Canada's population and in the number of doctors who would leave Canada after Medicare was introduced led to an increase in the number of places in Canada's 16 medical schools. A generation later, provincial governments are trying various schemes to limit the number of practicing physicians and, more directly, expenditures for physician services. Recognizing the need for national coordination, the Conference of Deputy Ministers of Health commissioned a report to examine the state of medical personnel in Canada. The report made a number of recommendations that, in the absence of a national framework for action, have been variably adopted by provincial governments (10).

Despite an increase in the number of physicians per capita, a geographic maldistribution has persisted, leaving urban areas overstaffed and rural areas understaffed. In the province of Nova Scotia, for example, roughly 900 of the province's 2,000 physicians practice in the Halifax-Dartmouth area, home to 36 percent of the population.

The provinces have developed a variety of policies to address maldistribution and contain the cost of physicians' services. Quebec appears to have been the most effective, establishing caps on gross revenues for family physicians and specialists. Accompanying these caps is a fee differential such that recently qualified physicians practicing in one of the province's three urban areas receive only 70 percent of the mandated fees, whereas those in underserved areas receive 115 percent if they are family physicians and 120 percent if specialists. British Columbia, the province with the most physicians per capita, sought to limit the number in the Vancouver area by tying new billing numbers to specific locations outside Vancouver. The courts, however, deemed this restriction an unconstitutional limit of rights to mobility.

Perhaps mindful of the experience in British Columbia, in 1993 Ontario announced that family physicians, pediatricians, and psychiatrists establishing practices in all but a few locations designated as underserviced would receive only 75 percent of mandated fees. This plan appears to be an attempt to circumvent legal challenges based on limitations to mobility rights while not explicitly invoking the "notwithstanding" clause of the Canadian constitution. This clause has not yet been used to address physician distribution but may become increasingly attractive as provincial governments perceive that physicians are maldistributed and a cause of rising health care expenditures.

Given the particular reference to Quebec in this chapter, two features of that province's health care system deserve mention. The first is the integration of health and social services, which are managed by single bodies at the provincial and regional levels. Quebec has established a province-wide network of *Centres Locaux de Services Communautaires* (CLSCs), intended to be the front-line point of service. CLSCS have been most successful in rural areas but less so in urban areas, where they face competition from physicians in private offices.

The second distinctive feature of Quebec's system is regionalization. The province is divided into 18 administrative regions, each under a regional authority, the *Re'gie Re'gionale de la Sante' et des Services Sociaux* (RRSSS). Although these RRSSSS have been involved for some years in management of the health system and particularly,

responsible for a portion of the budgets for technology acquisition, their role has been greatly enhanced by recent reforms giving them broad powers over planning and organization of services and the allocation of resources.

One final point is the importance of the frame of reference from which one examines the Canadian health care system. The United States, by virtue of its size and power and its proximity to Canada (both geographically and culturally), looms large as a standard of comparison in any examination of the Canadian way of doing things. From this vantage point, Canada appears to be doing everything right, spending 30 percent less per capita on health care than the United States and having better experience in both infant mortality and life expectancy (108). However, a more global view reveals that Canada spends more per capita on health care than any other country in the world except the United States. In 1989 Canadian per capita spending was 36 percent higher than that of Germany and more than double that of the United Kingdom (108). From this point of view, Canadian decisionmakers are increasingly concerned about the future health of Canada's health care system and are turning for help to a number of tools, including technology assessment.

CONTROLLING HEALTH CARE TECHNOLOGY

Macro-Mechanisms for Fiscal Management

In Canada the diffusion of health care technology is determined largely by the health care system's overall structure. Factors promoting or limiting the system's expansion have significant effects on technology diffusion. Among these structural factors, autonomy of both hospitals and physicians is the main force favoring technology acquisition and use. Fee-for-service remuneration, making the physician a quasi-entrepreneur in a publicly funded system, often creates incentives for practitioners to adopt and use technology. Hospitals' pursuit of institutional development and physicians" pursuit of professional development combine to favor the rapid uptake and diffusion of innovative health care technologies.

Countering these expansive forces are several funding and management mechanisms, the most important of which is the global budget formula used to fund hospitals. Under this system hospitals are provided with annual budgets for the basket of services they provide. Hospitals retain a fair degree of latitude in choosing which services they will offer, but they must address specified health needs.

By limiting the resources available for hospital services, the global budget constrains the ability of hospitals both to acquire expensive technologies and to expand services. This restriction applies not only to inpatient services but also to a large number of outpatient services, such as laboratory tests and radiological examinations, most of which are dispensed by hospitals. Global budgeting at the hospital level thus offsets the expansive incentives of fee-for-service remuneration of physicians. In several provinces, incentives for technology use are further tempered by measures to cap physician billings.

Rules governing the management and financing of capital expenditures constrain hospital autonomy in developing new services, particularly those requiring expensive technological innovations. In Quebec, hospital capital budgets are separate from operating budgets, and depreciation is not a recognized component of the global budget. Because institutions have limited internal funds for financing capital spending, they must obtain subsidies from regional authorities or the provincial government for all but small projects. Even if a hospital manages to obtain private donations to finance some of its capital projects, authorization by regional authorities or provincial governments is still required by law in most cases. Thus, regional and provincial planning and financing act to restrain the development of new services.

Public funding and management of medical and hospital services with the provincial government as sole payer for health services is the key factor in modulating the forces and incentives that determine technology diffusion and use (47). By

collectivizing health care financing through taxation and subsequent public funding, the public has both a right to health care services and an obligation to assume the burden of their costs through taxation. Regulation seeks to balance the citizen as taxpayer and as health care consumer. Government, both as the overall manager of the health care system and as a body of elected representatives, must try to minimize the tension between these two perspectives.

Recent Policy Reports and Decisions

Given minimal federal jurisdiction over the health care system, national policy reports or decisions are limited to particular, generally narrow issues. Throughout the 1980s, attempts to establish a national technology assessment council or body ran aground on the shoals of provincial discomfort with what were perceived to be federal incursions into perhaps their most critical area of jurisdiction. As a result, national-level policy, data, and reports on technology have generally appeared sporadically and have had minimal impact. In 1993 the newly elected Liberal government promised a national inquiry into Canada's health system with a view to identifying opportunities for reform.

In Quebec the Commission of Inquiry on Health and Social Services reviewed the health care system from 1985 to 1988 (56). The commission's report led in December 1990 to a complete overhaul of legislation governing health and social services, redefining the system's organizational and functional features (69). Despite strong protests from the medical profession, the new legislation was enacted in the fall of 1991 with slight modifications.

With regard to health care technologies, the Commission identified three major problems: obsolescent equipment and a technological lag, haphazard diffusion of certain technologies, and a need for technology assessment. Addressing obsolescent equipment and the technological lag, the Commission noted that the lag perceived in relation to the United States vanished when European countries were compared with Quebec. Haphazard technology diffusion occurred when diffusion did not follow the priorities dictated by hospital size and expertise—for instance, when a region's first magnetic resonance imaging (MRI) device was placed in a hospital other than the one responsible for neurological and neurosurgical services. Regarding the effectiveness and efficiency of health care technologies, the Commission called attention to the frequent lack of solid data that could guide decisionmaking.

In response to perceived technological lags, the annual investment in new technologies was increased (from $15 to $25 million a year).] To rationalize the diffusion of expensive and sophisticated technologies, increased powers were granted to the Minister of Health and Social Services to control the organization and deployment of highly specialized services. Two additional steps were recommended: 1) adding health care technology assessment to teaching, research, and dispensing of specialized services as a mission of Quebec's university hospitals and institutes, and 2) establishing a body to assess health care technologies for Quebec. The government created the *Conseild' evaluation des Technologies de la Sante'* (CETS) a few weeks before the Commission's report was published.

Research Policy

Canada has historically ranked near the bottom of the OECD countries in terms of per capita government spending on research (74). Both federal and provincial governments support various types of research through funding councils responding primarily to investigator-initiated proposals as well as through other programs of more directed funding.

1 All dollar figures are given in current canadian dollars. The value of the Canadian dollar against other currenices has fluctuated but has generally been in the range of $1 CAN = $0.74 U.S. to $0.82 U.S. over the last decade.

Most government spending on health-related research is through the Medical Research Council (MRC) annual budget of approximately $250 million. Most of this amount funds laboratory-based basic science research, although the MRC recently unveiled a strategic plan calling for greater efforts in health services research. Currently, most government-funded research relevant to technology assessment and health policy is supported by the federal National Health Research and Development Program (NHRDP) and provincial funding bodies in Alberta, British Columbia, Manitoba, Ontario, Quebec, and Saskatchewan.

Measuring the actual amounts spent on such research is difficult, as almost all funding bodies give money to an array of projects ranging from laboratory basic science to clinical epidemiology and psychosocial research. In addition, significant amounts of funding are allocated to career awards, which provide salaries for university-based researchers. Universities are expected to cover overhead costs, although biomedical research is shifting increasingly toward hospital-affiliated and -based research institutes that free scientists from teaching and other university obligations. In addition to public sector support of research, philanthropic organizations, particularly those focused on a given condition (e.g., the Canadian Cancer Society, the Heart and Stroke Foundation), are important funding sources for investigator-initiated research.

Industry also funds research, but the level of spending is nearly impossible to measure for proprietary reasons. The promise of increased corporate research spending was one of the justifications for recent federal legislation extending patent protection on pharmaceutical products. To date, industry has favored channeling funds to established university-based researchers rather than investing in "bricks and mortar" to build free-standing research institutes.

Technology assessment organizations are another source of funds for research. Recent directed grant competitions in Quebec and British Columbia, operating through requests for proposals limited to technology assessment, indicate that technology assessment is an area of growing importance for research funding bodies. The national body, the Canadian Coordinating Office for Health Technology Assessment (CCOHTA), was established with a fairly rudimentary budget for research; however, it has recently been directed by the Conference of Deputy Ministers to strengthen its research efforts. In addition, several provincial bodies, including CETS in Quebec, have allocated some of their budgets to generate information of particular relevance to ongoing or impending assessments. The Ontario and Manitoba governments have funded university-based research groups with the understanding that some portion of their efforts will be directed to policy-relevant research.

Although Canada lags in government-funded research, Canadian scientists have managed to produce valuable advances, both in the laboratory and in addressing policy issues. Given the great need for health services research and the availability of administrative and other data sources in the universal health insurance system, research pertinent to technology assessment appears poised to take over a greater share of Canadian spending on biomedical research.

Control of Pharmaceuticals

Pharmaceuticals are the most formally regulated of technologies in the Canadian health care system, and have been increasingly targeted for systematic assessment. Several vehicles have been proposed for this task, including a federal-provincial undertaking to establish a stand-alone body for assessing pharmaceuticals (50). Part of the tension surrounding the creation of such a body stems from concern over the degree of likely duplication of activities already underway at CCOHTA and in provincial drug and technology assessment bodies. Regardless of who ends up doing the work, systematic assessment of pharmaceuticals can only grow in importance over the next decade.

Marketing Authorization and Patent Protection

The Food and Drug Act requires that before a pharmaceutical can be authorized for marketing in Canada, its safety and efficacy must be demon-

strated. Authorization is the responsibility of the Health Protection Branch of Health and Welfare Canada. Implementing post-marketing surveillance mechanisms is a recognized need but remains a largely unfinished project.

Over the past few years, pharmaceutical patent protection, which falls under federal jurisdiction, has been a prominent issue in Canada. Legislation in effect in the early 1980s was said to provide the weakest patent protection among industrialized nations. In 1987, following commitments of the pharmaceutical industry to increase research and development investment in Canada, the federal government adopted Bill C-22, which increased the patent duration for pharmaceuticals and essentially ended a system of compulsory licensing that had benefited manufacturers of generic drugs.

Early in 1993 the Canadian parliament adopted a new act increasing patent protection from 17 to 20 years. Given the strong likelihood that longer patent protection would increase pharmaceutical prices and thus provincial expenditures, several provinces protested the legislation. However, Quebec, home to roughly half of Canada's patented medicine industry, supported the change. According to the Pharmaceutical Manufacturers Association of Canada, the proportion of sales revenue allocated by its members to research and development increased from 3 percent in 1979 to 10 percent in 1992. The legislation extending patent duration contains neither a provision for independent assessment of the degree to which the pharmaceutical industry meets its promises to increase research spending in Canada, nor penalties for shortfalls.

Of concern to Canadian policy makers has been evidence regarding the prices of patented medicines in Canada. According to a recent study produced by the Patented Medicine Prices Review Board (a federal surveillance organization established as part of the C-22 provisions) prices in Canada are higher than in other countries. Drugs with the highest sales volumes were reported to be priced an average 20 percent higher than the median international price, and launch prices of new products were similarly elevated.

Authorized Drugs and Prices

Most provinces prepare formularies (lists of authorized drugs) to manage their pharmaceutical services programs. In Quebec, the government body charged with advising the minister in this regard is the *Conseil Consultatif de Pharmacologic* (CCP). The Council's recommendations must, by legislation, consider the therapeutic value of pharmaceuticals and the fairness of their price. The CCP has also recently commissioned a user's guide for certain expensive drugs whose indications are controversial, such as thrombolytics, erythropoietin, and colony-stimulating factors. There are two regularly updated formularies, one for pharmaceuticals provided in health care facilities and the other for those provided outside such facilities to welfare recipients and all persons over age 65. (These are the only ambulatory patients whose prescription drug costs are insured by public programs in Quebec.) Other provinces generally have similar programs with the exception of Saskatchewan, which insures prescription drug costs for all citizens.

For services to hospitalized patients, drugs are limited to those on the formulary. However, exception mechanisms are provided and widely used. The formulary does not set the prices paid for drugs; their cost is covered directly by the global budget of the relevant institution. To minimize drug expenses, most drugs are purchased in bulk.

The formulary for services to eligible elderly and indigent ambulatory patients includes not only the drugs covered but also the price reimbursed by the provincial health insurance plan (RAMQ). This program covers only drugs prescribed by a doctor or dentist. Until recently, a median-price policy was used, setting the maximum allowable reimbursement for a drug at the median price for that category of drug. For more expensive drugs, the patient pays the cost difference (unless it is assumed by the pharmacist).

Changes implemented early in 1993 established guaranteed sales prices. Under this scheme, manufacturers agree to firm prices for their products for a period of six months, and wholesalers agree to a set percentage for distribution charges.

These promises form the basis of the price appearing in the formulary; however, the price must not be higher than it is in other Canadian provinces.

This drug program for ambulatory patients accounts for about 4 percent of public health care expenditures. Its cost increases have been the fastest and the most difficult to control. From 1987 to 1991, drug expenditures rose an average of 16 percent annually, resulting equally from higher costs per drug and higher numbers of prescriptions (65). In 1992 the government imposed a $2 user fee per prescription for elderly patients not receiving a guaranteed income supplement. This change was perceived by some as a first breach of free access to services guaranteed by the Canada Health Act, hence as the first step toward widespread user fees to control costs.

Control of Medical Equipment

Marketing Controls

Current regulatory mechanisms for medical devices are much less developed than those for pharmaceuticals. Regulation of medical devices is a federal responsibility and aims to make manufacturers or importers responsible for safety and effectiveness. Manufacturers or importers are required to register devices marketed in Canada with Health and Welfare Canada and to comply with labeling standards specifying (among other things) who is responsible for the products. A small number of explicit standards apply to specific products.

Users of medical devices are urged to inform the federal Health Protection Branch's Bureau of Radiation and Medical Devices (BRMD) of any problem they encounter with these products, especially regarding safety. Nevertheless, device regulation is not an obstacle to the introduction of innovative medical devices in Canada. The relative lack of regulatory requirements for certification and disclosure of devices as compared with pharmaceuticals has recently created controversy, particularly regarding breast implants. This situation may shift with recent changes in device evaluation requirements by the federal BRMD and an increased focus on devices with particularly high risks (67).

Capital Expenditures by Hospitals

In Quebec rules governing hospital acquisition and funding of medical equipment differ for replacing equipment and for developing new services. If an acquisition does not entail an increase in operating costs, the institution may finance the purchase with a line of credit granted to it by the Quebec Ministry of Health and Social Services (MSSS) for capital and equipment expenditures. However, the regional authority's authorization is required if the purchase falls into one of the following categories:

- medical imaging,
- radioisotopes and laboratory automation,
- electronic patient monitoring,
- radiation therapy,
- anesthesia and resuscitation,
- hemodialysis, or
- pacemaker implantation.

If one of these projects is authorized, the regional authority may help finance the purchase through a line of credit allocated to the region by the ministry. Half of available capital funds for a given region are managed by the regional authorities; this gives them considerable influence and planning power over the distribution of medical equipment.

If the project entails an increase in operating expenses or will provide new, so-called superspecialized services, the institution must obtain written authorization from the minister, who consults the regional authority before making a decision. Superspecialized services include:

- cardiac surgery,
- neonatal surgery,
- neurosurgery,
- organ transplants,
- bone marrow transplants,
- neonatal intensive care and bum units, hemodialysis,
- high-risk pregnancy units,
- radiation therapy,

- computed tomography (CT) scanning,
- magnetic resonance imaging (MRI),
- photon- or positron-emission tomography, and
- extracorporeal shock wave lithotripsy.

If a project is authorized, MSSS funds are approved for capital expenditures and a negotiated portion of operating expenses. In recent years this funding has tended not to coverall the costs, leaving a large gap to be filled by other sources—in particular, hospital fundraising campaigns. Government funding for these services usually covers half of capital costs.

Placement of Services

Planning

For superspecialized services, centralized review and funding of new services are the main regulatory mechanisms controlling their placement. In Quebec the MSSS has established committees of medical experts; local, regional, and provincial administrators; and, in some cases, representatives from patient associations who recommend how to orient the organization and development of these services. This planning, which is open to considerations of health care technology assessment, has had a major impact on service placement.

Permits for Private Laboratories

In Quebec anyone wishing to operate a private medical laboratory or diagnostic x-ray facility must obtain a permit from the MSSS. The Public Health Protection Act stipulates that such a permit may be denied if the needs of the region do not justify it. The Act provides some control over the organization of services outside hospitals. As a result, most laboratory services are dispensed by hospitals.

The private sector's share of medical laboratory output is less than 5 percent as only services provided in hospitals are insured. (In contrast, in Ontario about half of all medical laboratory services are provided outside hospitals in privately owned laboratories.) Unlike medical laboratory services, diagnostic X-ray services provided by private facilities are insured in Quebec. For the most part these facilities are located in large urban centers, and their output represents about a third of all x-ray services.

Decisions on Coverage

Decisions on insurance coverage shape service placement, as a given service maybe covered only in hospitals. Such is the case with obstetrical ultrasound in Quebec so as to prevent duplication of services by hospitals and private clinics and to limit overutilization. Additionally, by limiting coverage to hospitals, obstetrical ultrasound falls under the global budget, which promotes substitution of services. These administrative decisions, although not explicitly limiting the amount of a technology in place, have a general uptake-retarding effect when combined with global hospital budgets. Services may also be insured only in specific locations; an example is extracorporeal biliary lithotripsy, for which agreements administered by the provincial health insurance plan state that the service is covered only in three hospitals designated by the minister.

Control of Health Care Providers

Medical Personnel

One way to control the use of health care technology is by regulating the numbers and training of medical personnel. Several provinces have attempted to limit the growth in the number of physicians. In the 1980s Quebec used quotas for residency and internship positions but despite this, the number of doctors increased two to three times more quickly than the population. The government has recently announced firmer action with regard to medical school enrollments to make growth in the number of physicians more congruent with demographic changes (60).

TABLE 3-2: Breast Thermography in Quebec, 1972–1980

Year	Number of examinations	Total costs ($ Canada)	Proportion in private clinics (in percent)
1972	4,695	$ 134,295	77%
1973	11,791	349,965	79
1974	25,256	752,772	86
1975	61,070	1,820,012	98
1976	89,141	2,659,608	96
1977	12,693	380,415	99
1978	5	25	0
1979	0	0	0
1980	4	20	0

SOURCE R Jacob Quebec Ministry of Health and Social Services, personal communication 1994

Ceilings on Physician Revenue

Regulated ceilings on gross revenue earned by doctors have been instituted to counter incentives for expansion inherent in fee-for-service remuneration. In Quebec the limits are individual for general practitioners and collective for specialists. For general practitioners a quarterly revenue ceiling is set above which there is a 75 percent reduction in fees paid for services rendered. For specialists an average annual target revenue is negotiated between the MSSS and the Federation of Medical Specialists (FMSQ) for the entire group. Targets for each specialty practice are then negotiated within the FMSQ. If, during a given year, the average target revenue is exceeded, fee adjustments are negotiated downward for the following year to compensate for overages.

In addition, activit y ceilings for certain services and practice revenue ceilings for some specialties are set out in agreements with physician organizations. For example, in 1992 any radiologist performing more than 25,000 examinations and receiving more than $214,000 in practice revenue would have his or her fees above these limits reduced by 75 percent for the remainder of the calendar year.

Conditions for Coverage of Services

Fee schedules and locations for insurable services can be used to regulate volumes for specific services. For instance, in Quebec the soaring use of injections of sclerosing agents to treat varicose veins from 1970 to 1974 was both curtailed and redirected toward specialists by fee schedule changes (54).

Limiting the locations where the service was insured was used to regulate use of breast thermography. From 1972 to 1976, thermography use skyrocketed in Quebec as the annual number of examinations increased from 4,500 to about 90,000 (table 3-2). More than 95 percent of these examinations were performed in private x-ray laboratories. A generous fee for a technology requiring no major investment and involving few risks made this procedure an attractive opportunity for some radiologists. However, rapid increases in output and expenditures led the MSSS and the FMSQ to review the data on thermography's effectiveness. The procedure is not very sensitive (a conclusion that was later reached at a U.S. National Institutes of Health consensus conference as well) and should not be used routinely in breast cancer screening programs (123). In 1976, following negotiations with the FMSQ, the government deinsured the service in private laboratories. Despite continued coverage in hospitals, thermography was completely discontinued by 1978.

Control of Provider Locations

In Quebec the government has implemented several policies to ensure an equitable distribution of physicians in the province. These include:

- scholarships to medical students who agree to practice in areas short of physicians
  isolation bonuses for doctors in remote areas;
- differential remuneration for new physicians: reduced (70 percent) in regions where there is an adequate supply and increased (for general practitioners, 115 percent, specialists, 120 percent) in designated areas; and
- incentives for establishing and remaining in practice in remote areas, minimum revenue guarantees, and grants for specialized training for doctors in designated areas.

The distribution of general practitioners is generally agreed to be satisfactory, but that of specialists is still suboptimal, with heavy concentrations in the three urban regions where faculties of medicine are located. Some basic specialties, including general surgery, internal medicine, psychiatry, obstetrics, anesthesia, and radiology, continue to be unevenly distributed. The implications of this imbalance are unclear, as CETS recently reported that rural residence does not appear to be associated with decreased rates of any of nine common surgeries (36). Nevertheless, legislation requiring the definition and implementation of medical staffing plans for each region was recently enacted to address physician distribution.

Efficacy of Control Mechanisms

Cost Control

With 8.7 percent of its gross national product going to health care in 1989, Canada ranked second in the world in per capita health spending after the United States (109). Growth in health care spending is generally considered under control in Canada, in contrast to the situation in the United States (48,49). Canada's universal public health insurance plan, permitting the collective purchase of health care services, appears to be the main factor responsible for these differences.

Given strict control over the number of hospital beds available, Quebec's experience suggests that growth in hospital spending has been successfully limited by global budgeting limiting the volume of resources utilized in the hospital sector (40). For physician services, costs were initially controlled by slowing price growth through contractual negotiation and, more recently, by controlling the volumes of services provided by physicians.

The question of underfunding arises frequently. As noted earlier, obsolescent equipment and technological lag are concerns often raised by observers of the Canadian experience and are taken as indications that the system is underfunded (73). In the case of obsolescent equipment, the Quebec experience with medical imaging suggests that use of this technology is high and that the equipment pool is constantly growing. Data comparing Canada and the United States indicate a 20 percent higher rate of exams per population in Canada (75). However, a clear preference for using available funds for new equipment rather than consolidating and upgrading existing equipment means that older, serviceable equipment may well continue to be used.

Technological lag is striking only in relation to the United States. In the case of capital-intensive equipment, financial and regulatory control mechanisms clearly slow diffusion. Less capital-intensive technologies not subject to these mechanisms, such as ultrasound, usually diffuse at a rapid pace, as illustrated by the data in table 3-3. In any case, evidence of obsolescence or technological lag leading to suboptimal health outcomes is difficult to find.

Equal Access to Services

In Canada the publicly funded, universal health insurance plan guarantees the entire population access to health services. Care whose cost is not reimbursed, personal financial disasters linked to illness, and uninsured patients are eliminated. At least for hospital services, the data show that the volume of services used is largely determined by need, not personal income (86).

TABLE 3-3: Diffusion of Ultrasound in Quebec, 1977–1984

Year	Hospitals reporting use	Annual rate of increase	Specialized hospitals as proportion of users
Before 1977	13	—	16,9%
1977	16	23.1%	18.8
1978	22	375	27.3
1979	30	36.4	46,7
1980	43	43,3	44.2
1981	54	25,5	51.8
1982	63	16.6	58,7
1983	71	12,7	549
1984	76	7,0	56.6

SOURCE R Jacob, Quebec Ministry of Health and Social Services, personal communication, 1994

In Quebec proximity to resources is still variable, reflecting the nonuniform distribution of the population. People living in areas far from large urban centers continue to travel to receive many services, even in cases where it would be reasonable to provide these services closer by. Although steps are being taken to address this situation, studies analyzing geographic variations in utilization rates of certain services in Quebec have not demonstrated a lower level of use in remote areas than in areas where resources are concentrated. On the contrary, for elective surgery, utilization seems to be higher in remote areas (36).

Efficiency

In Quebec resource limitations imposed by global budgeting are forcing hospitals to consider efficiency in decisionmaking, creating a context favorable to health care technology assessment. The combination of pressure exerted by the global budget and the production of timely, pertinent assessment data has resulted in efficient choices in such cases as the use of contrast media in radiology, thrombolytics, and the reuse of hemodialyzer filters (32).

Organizing superspecialized services efficiently remains difficult, however. In these sectors, particularly tertiary cardiology and organ transplantation, resources are suboptimally dispersed, for these services are dispensed in a large number of hospitals—several of which have low volumes of activity. Various studies have shown that health outcomes improve and average costs fall as volumes of activity increase in superspecialized services (33).

Individual hospitals, however, tend to approve projects proposed by their physicians aimed at developing high-tech services. Resource dispersion then results when the hospitals' individual global budgets prevent their achieving levels of activity generally recognized as sufficient to guarantee good performance. External review mechanisms for these projects have not been very effective. Superspecialized services are currently being examined by planning committees with a broad representation of experts and managers, and their restructuring is an MSSS priority.

HEALTH CARE TECHNOLOGY ASSESSMENT

The Canadian Task Force on the Periodic Health Examination (CTFPHE) is an early example of organized technology assessment in Canada. Established by the Conference of Deputy Ministers of Health in 1976, the CTFPHE was mandated to summarize scientific information on clinical preventive services in order to make recommendations to practicing physicians. The CTFPHE was established soon after the Lalonde report appeared in 1975 (83).

This report (published under the auspices of then-Minister of National Health and Welfare Marc Lalonde) argued for a reorientation of Canada's health care system and spending toward pre-

ventive services and practices. In this climate the CTFPHE was seen as a logical step toward preventive health care.

Members of the CTFPHE were chosen on the basis of their credibility as scientists. The CTFPHE began by establishing systems for grading scientific evidence based on methodological quality (an exercise that broke new ground in this area). Recommendations were then to be published on whether decisions to implement specific interventions were supported by scientific evidence. The first report was released in 1979. The CTFPHE is currently revising all of its recommendations for re-release in 1994 (21).

In addition, there have been several consensus conferences in Canada addressing clinical decisionmaking and targeting their findings to practicing physicians (e.g., 1988 Consensus Conference on Cholesterol). Despite some minor differences in organization, scope of final reports, and the actual conference process, consensus conferences in Canada are broadly similar to those in other countries (89). The impact of consensus reports in Canada has been generally weak. Systematic investigation of the effects of a consensus statement recommending reduced rates of cesarean section led to a conclusion that statements had had little effect in the absence of specific incentives or disincentives for their adoption (85).

The measurable impact of CTFPHE recommendations on practice has been similarly weak. Initial dissemination strategies, focusing on publication of recommendations in the *Canadian Medical Association Journal* and *L' Union Me'dicale du Canada,* appear to have been less effective than had been expected. The growing recognition of the importance of actively targeting such information to practitioners as part of a comprehensive dissemination strategy bodes well for increased impact of CTFPHE recommendations in the future.

Although the CTFPHE was created relatively easily by the Conference of Deputy Ministers, various proposals for a national technology assessment body went unrealized, perhaps reflecting a lack of consensus on the broader role of technology assessment in the Canadian health care system **(51).** Throughout the 1980s, the federal government's ability to spearhead a national technology assessment effort was increasingly weakened by federal attempts to shift health care financing to the provincial governments. With decreased federal financial leverage and a climate of federal-provincial tension, activity shifted to the provinces.

Canada's first operational technology assessment body was established in Quebec in 1988. CETS was mandated to promote, support, and produce assessments of health care technologies; to counsel the Minister of Health and Social Services, and to disseminate its syntheses and summaries of available knowledge to all the key constituencies of Quebec's health care system (28). Operationally, CETS draws on the skills of a permanent secretariat complemented by a scientific panel and outside experts retained for specific projects.

In 1991 CETS' 11 reports were examined and their impacts determined by an independent consulting firm. The consultant concluded that 9 of the 11 reports had measurable impact and that CETS' performance compared favorably with that of the Swedish Council for Health Care Technology Assessment (46). Estimated efficiency gains as a result of policy decisions that implemented CETS conclusions amounted to $24.9 million (77).

In evaluating the overall performance of CETS, the consultant noted that the Council had succeeded in establishing its credibility and in developing the appropriate scope and quality for its products. The consultant recommended that CETS promote awareness of its mandate and activities much more vigorously (46). This need for increased attention to dissemination parallels that found with the CTFPHE.

At the national level, unanimity among the provinces remained elusive despite awareness of Quebec's activities and calls for a national effort in health care technology assessment. In 1989, shortly after CETS' creation, an interprovincial symposium on technology assessment was organized to bring together federal and provincial officials and academics. At this meeting federal and pro-

vincial governments agreed to establish and fund jointly the Canadian Coordinating Office for Health Technology Assessment (CCOHTA).

In 1990 CCOHTA was formally created with a modest annual budget of approximately $500,000. This appears to have represented a compromise between provincial interests in a coordinating and clearinghouse role for a national body, and concern that a body fully equipped to assess technologies might lead to federally mandated national standards. To put this budget into perspective, CETS in Quebec began with an annual budget of $800,000, which increased in 1992-93 to $1 million. Emerging from these tentative beginnings, CCOHTA was established as a nonprofit corporation whose board of directors includes the 13 Deputy Ministers of Health or their designates.

CCOHTA'S mandate includes the following six tasks:

- to establish a clearinghouse for information on health care technology assessment;
- to analyze, synthesize, and disseminate health technology information;
- to perform an "early warning" function regarding emerging technologies in the health care system;
- to pursue opportunities for cooperative ventures with technology assessment agencies in Canadian provinces and in other countries;
- to establish links with health care organizations, professional associations, health care providers, and provincial and territorial health departments; and
- to identify areas where information vital to decisionmaking on health technologies is lacking and to stimulate research in these areas (22).

Initially granted a three-year term, CCOHTA has recently been reviewed and will continue to receive financial support from the provincial and federal governments while also pursuing an expanded role in assessing pharmaceuticals. In the review CCOHTA was generally commended for its work to date; as with the CTFPHE, its dissemination efforts were highlighted for attention (14).

By 1992 four provinces had established a technology assessment body or group. In 1991 British Columbia established the British Columbia Office of Health Technology Assessment (BCOHTA), with an annual budget of $350,000. The BCOHTA is located within the University of British Columbia and is mandated "to promote and encourage the use of assessment research in policy and planning activities at the government level and in policy, acquisition, and utilization decisions at the clinical, operation, and government levels" (15). The provinces of Alberta and Saskatchewan are also establishing technology assessment efforts.

In addition to formal technology assessment bodies, provincial governments, particularly in Ontario, have turned to university-based centers for information relevant to policy. In Ontario the Center for Health Economics and Policy Analysis (CHEPA) at McMaster University is funded by the provincial government, the university, and other sources. In 1992 the Institute for Clinical Evaluative Sciences (ICES) was established at the University of Toronto as a joint venture of the provincial government and the Ontario Medical Association (OMA). ICES is intended to provide information relevant for decisionmaking to the joint management committee established by the provincial health ministry and the OMA. Similarly, in Manitoba the provincial government funds a university -aftlliated health services research center at the University of Manitoba.

Further complementing these groups is Canada's expertise in clinical epidemiology and health services research. Extensive university-based training programs exist at a number of Canadian universities, including McMaster, McGill, and the universities of Montreal, Ottawa, and Toronto. These programs not only provide training but have also raised consciousness about the evaluation of health services in medical curricula across the country and have fostered practitioner recep-

tiveness to the products of health services research and technology assessment.

The growing network of technology assessment bodies in Canada parallels a growing demand for such information from a variety of stakeholders in the health care system. Provincial governments, faced with rapidly rising health care expenditures, are interested in anything that can improve decisionmaking. Despite the politically charged nature of decisionmaking on health care in Canada, most parties have accepted that there is a role for a more dispassionate consideration of the effects of technologies. The relative freedom of Canadian technology assessment bodies from bureaucratic direction and control has made their products increasingly palatable to both policymakers and stakeholders.

Increasingly, too, the Canadian public is demanding more information on health technologies. Under the single-payer, publicly administered system of health insurance, increased expenditures on health care are perceived less as a transfer from consumers to suppliers than as a transfer from one area of governmental responsibility to another. Faced with information needs and public pressure to act, decisionmakers have frequently turned to technology assessment bodies for input and recommendations.

Physician and health professional organizations, however, have been somewhat wary of coordinated technology assessment activities. Although individual physicians are involved in technology assessment as academics, reviewers, or employees of technology assessment bodies, professional organizations have only recently begun to see technology assessment as meriting attention. There are signs that this may change with a growing interest in quality assessment and assurance in a general climate of cost concerns. Quality issues have spawned growing interest in clinical practice guidelines, extending the CTFPHE model beyond preventive services. In 1992 the Canadian Medical Association (CMA), as a leader of the National Partnership for Quality in Health (NAPAQH) organized a workshop to develop "guidelines for guideline developers." Despite misgivings about national-level efforts, participants identified four "action items":

- develop a definition of quality reflecting both process and outcomes of care,
- hold a national workshop to develop a manual outlining practical methods for guideline development,
  establish a network of guideline developers to foster standardized methods and avoid duplication, and
- maintain an updated database of clinical practice guidelines that would be available to practitioners and patients (19,42).

While different from quality assessment, technology assessment shares a need for information, for synthesis of evidence, and for dissemination (45,82). Potential cooperation between technology assessment and quality-of-care initiatives may bring physicians more centrally into decisionmaking on the optimal use of health care technologies.

Technology assessment has not been simply an active choice on the part of policy makers; rather, the Canadian health care system has become conducive to incorporating the results of technology assessment in decisionmaking. Canada's one-payer system of universal health insurance allows for rationality in planning and decisionmaking about health technologies, as provincial governments can exercise a fair degree of control over budgets and insurable services. In addition, the public character of the system creates a receptiveness among political decisionmakers for technical information that can help them avoid the appearance of making difficult allocation decisions solely on political grounds. This receptiveness should continue to grow in Canada as provincial governments increasingly try to curtail expenditure growth that results from mounting demands for health services from an aging population, compounded by poor economic conditions.

Case studies

TREATMENTS FOR CORONARY ARTERY DISEASE

In Canada coronary artery disease is a significant cause of mortality and morbidity. Nevertheless, despite an aging population, death rates fell throughout the 1980s, as shown in table 3-4 (1 12,1 13). Increasing numbers of hospital admissions for these conditions (and decreased lengths of stay per admission) suggest that hospital-based intervention is the major therapy for coronary artery disease.

Canada's first cardiac catheterization was performed in 1946 and was followed by the first open heart surgery in 1968. Percutaneous transluminal coronary angioplasty (PTCA) was introduced during the 1980s and has spread rapidly. By 1993, 37 centers were offering open heart surgery—including correction of congenital abnormalities, valve surgery, and coronary artery bypass grafting (CABG)—and 78 centers had cardiac catheterization facilities (25). All provinces except Prince Edward Island have at least one hospital performing CABG and at least one with catheterization facilities. In the smaller provinces these are usually the same facility.

In contrast, the number of procedures performed in the United States is proportionately three times greater. The average annual number of procedures per facility in Canada is roughly 500, as compared with 200 in the United States, which has many more facilities for catheterization (24). Similarly, population rates of CABG are markedly higher in the United States than in Canada. CABG rates in New York and California were consistently 25 to 80 percent higher than those in Ontario, Manitoba, and British Columbia between 1983 and 1989. Three-quarters of the difference between California and the three Canadian provinces was attributable to higher rates among elderly Californians, particularly those over 75. CABG rates were lowest for Americans living in low-income areas and highest for Canadians living in low-income areas suggesting that Canada's universal health insurance reduces the influence of income on access to services (2).

In Ontario, Canada's largest province, the number of CABG procedures increased 52 percent between 1979 and 1985. The increase was due in part to the rapidly increasing proportion of older CABG patients (aged 65 and up). This expansion occurred in the absence of data on efficacy or cost-effectiveness in this age group. A randomized trial of this therapy among older patients was advocated (1). Despite these and other studies examining the effects of regionalization and queuing, rapid diffusion of these therapies, particularly CABG and PTCA, has occurred with lesser emphasis on scientific data addressing efficacy or effectiveness and with greater emphasis on consumer and provider demand in light of the perceived efficacy of CABG and PTCA (79,98,101).

National utilization data are difficult to gather because of provincial jurisdictions, but utilization data and projections from the province of Quebec illustrate clearly the rapid expansion of volume of procedures (table 3-5) (58,63). Angioplasty use has grown especially rapidly and does not appear to have led to any clear, stable substitution for CABG.

In Quebec a number of working groups and reports have studied tertiary cardiac services. In 1977 the government commissioned a report from a group of physicians that recommended a series of minimum standards and resources for cardiac catheterization facilities (90). In 1986 the federal government drew upon utilization data to estimate that 1,000 cardiac catheterization procedures

TABLE 3-4: Mortality and Morbidity Due to Coronary Artery Disease, 1980 and 1989

	1980	1989
Death rate (per 100,000) due to ischemic heart disease (ICD 410-41 4)		
Female	166	*147*
Male	245	200
Hospital admission rate (per 100,000) for acute myocardial infarction (ICD 41 O)		
Female	128	139
Male	*272*	*269*
Average length of stay for admissions for acute myocardial infarction (days)		
Female	*21.4*	*14.9*
Male	15.7	11.7
Hospital admission rate (per 100,000) for other ischemic heart disease (ICD 411 -414)		
Female	*303*	*286*
Male	*472*	*515*
Average length of stay for admissions for other Ischemic heart disease (days)		
Female	*22.7*	13.4
Male	*13.4*	*8.8*

SOURCE Statistics Canada, Institutional Care Statistica Division, HospitalMorbidity 1981, 1989, Statistics Canada Pub No 82-206 (Ottawa 1983 and 1991), Statistics Canada, Vital Statistics and Disease Registries Section, Causes *of Death,* 1981, 1989, Statistics Canada Pub No 84-203 (Ottawa 1983 and 1991)

would be performed annually per 500,000 persons; it then established norms for establishing new cardiac catheterization facilities (96). In Quebec this federal initiative was felt to require supplementation by the provincial government, particularly in light of the growing role of PTCA and the desire to ensure both an optimal distribution of resources and equitable access to tertiary services.

In considering various frameworks for optimizing resource distribution, the government placed great importance on the availability of cardiac surgery services in facilities offering cardiac catheterization. This was deemed essential because of 1) the logical synergy resulting from having diagnostic cardiac catheterization and cardiac surgery in the same facility and 2) the potential need for emergency surgery following cardiac catheterization.

A working document (published in 1988 and revised in January 1989) proposed a framework for ensuring access to high-quality cardiac catheterization services while optimizing resources (57). This framework included a model for projecting future years' volumes as well as the assumptions that maximal use of a cardiac catheterization facility would be 1,500 hours annually and that optimal use would be deemed to be 85 percent of this time, or 1,275 hours. Furthermore, diagnostic cardiac catheterization was assumed to require one hour of cardiac catheterization facility time; angioplasty, two hours. The report concluded with a series of short- and medium- to long-term recommendations regarding the optimal distribution of new services and assignment of responsibility for certain geographic regions to existing facilities.

Shortly after the 1989 revision was published, public pressure on the MSSS over waiting lists for elective cardiac surgery led to the creation of a working group to address the entire tertiary cardiac care sector comprising both diagnosis and

TABLE 3-5: Use of Catheterization, Angioplasty, and CABG in Quebec, 1979–1990

Year	Diagnostic catheterization	Angioplasty (PTCA)	Coronary artery bypass grafting
1979	7,314	0	1,780
1980	8,377	0	2,166
1981	8,665	0	2,171
1982	9,221	0	2,364
1983	10,366	0	2,940
1984	10,362	351	2,868
1985	10,781	1,033	2,988
1986	11,538	1,589	2,719
1987	12,907	2,195	3,337
1988	13,790	2,812	3,582
1989	13,718	3,110	4,308
1990	15,268	3,681	3,642
*994-95	17,607	5,590	5,282

*Projected

SOURCE Gouvernement du Que'bec, Ministe're de la Sante' et des Services sociaux, "Les Services Tertiaires en Cardiologies, " rapport du groupe de travail sur la revascularisahon coronarlenne, Quebec, June 1990), Gouvernement du Quebec, Ministere de la Sante' et des Services soclaux, "Gestion de l Accessibilite aux Services de Cardiologie Tertiaire, " rapport du groupe de travail - document de travail, Quebec, May 1992

treatment of ischemic heart disease (58). After considering epidemiologic data, projections of future requirements, and available resources for cardiac catheterization, the report reaffirmed the centrality of the goal of ensuring access to high-quality services while optimizing resources committed to this sector. The working group specifically recognized the "major problem" of waiting lists for elective cardiac services and noted that their elimination should be an important consideration in resource allocation. Specific recommendations regarding optimal resource allocation included 1) offering four new cardiac surgery services, 2) establishing angioplasty only where cardiac surgery facilities were already in place, and 3) creating a provincial coordination mechanism to establish priorities for waiting lists coupled with improving the coordination of services to reduce average waiting time (58).

Following the release of this report, the Minister announced a three-year plan for addressing the report's recommendations. This process included a working group to recommend ways to improve administration of these services. This group's preliminary report (issued in May 1992) identified three solutions to the waiting list problem:

- an increase in resources to more closely approximate demand for these services,
- a system of four "supraregional" waiting lists to which persons would be added only after evaluation and assignment of priority, and
- formalizing "interregional corridors" for transferring persons on waiting lists to centers with resources (63).

The report also included a seven-level priority scheme for diagnostic cardiac catheterization, angioplasty, and CABG. This scheme is based largely on a classification of angina and left ventricle ejection fraction combined with results from non-invasive tests to diagnose reversible ischemia. In addition, the report suggested that waiting list

TABLE 3-6: CT and MRI Scanners in Canada, 1993

Province	CT scanners		MRI scanners	
	Number	Number per million	Number	Number per million
Newfoundland	6	10.6	1	1.76
prince Edward Island	1	7.7	0	0
Nova Scotia	8	8.9	1	1.11
New Brunswick	7	9.7	0	0
Quebec	60	8.7	5	0.73
Ontario	72	7.1	11	1.09
Manitoba	9	8.2	1	0.92
Saskatchewan	6	6.1	1	1,01
Alberta	24	9.4	5	1,96
British Columbia	23	7.0	5	1.52
Canada	**216**	**7.9**	30	**1.10**

SOURCE Canadian Coordinating Office for Health Technology Assessment, Technology Brief, No 53 (Ottawa 1994)

times for lowest priority, elective coronary angiography should not exceed six months.

CETS also reported on the optimal distribution of cardiac catheterization laboratories (27). Published in 1989, its report stated that centralizing cardiac catheterization facilities in hospitals with active cardiac surgery programs would be desirable. Furthermore, the report stated that angioplasty should be used only in hospitals with cardiac surgery facilities. This report was produced at the request of the Minister for the working group addressing the distribution of tertiary cardiac services. The findings were retained by the working group and have had an important influence on its recommendations.

Throughout the 1980s, Quebec faced increasing demand for both diagnostic and therapeutic cardiac intervention services. Political pressure on the provincial government led to consultation and studies and a subsequent series of budgetary and administrative solutions designed to meet these increasing demands. Because the government is the sole payer for health services, solutions are proposed with the expectation that the government will implement them. In this climate the pressure both to recognize a problem and to do something about it fosters a demand for rationality in decisionmaking and, consequently, for technology assessment.

MEDICAL IMAGING (CT AND MRI)

Medical imaging technologies have been particularly prominent in Canadian debates and policymaking on health technologies. Part of this is undoubtedly due to the capital investment required to acquire and operate these facilities, particularly in the case of CT and MRI. These two diagnostic modalities draw particular attention in Canada because of the explicit budgeting undertaken by provincial governments for capital expenditures in the health sector. Each province has its own version of cost thresholds or categories of services that require hospitals seeking to introduce a new service to apply to the provincial government for funds explicitly tied to the new service. Even the most efficient hospitals would be hard pressed to generate sufficient surplus operating funds to acquire CT or MRI equipment and to cover the operating costs (see table 3-6) (25).

Computed Tomography (CT)

The first CT scanner was installed in Canada in 1973 at the Montreal Neurological Institute. This technology diffused rather rapidly, and 216 scanners were reported to be operating in 186 Canadian hospitals in 1993 (25). The story of CT diffusion in Canada's two largest provinces, On-

tario and Quebec, provides a number of lessons for considering expensive new technologies.

The general pattern in Ontario has been summarized as a cycle of reactive, ineffective policymaking by governments punctuated by continued efforts by hospitals to circumvent policies perceived to be limiting acquisition or diffusion of CT scanners (41). Responding to requests for funds for CT scanners in 1973, the provincial government established a Provincial Program Advisory Committee (PPAC) to consider policy on CT in Ontario. A year later the province first scanner was installed in Toronto and was treated as any other capital purchase with depreciation over five years and operating expenses to be met from the hospital's existing budget. Shortly thereafter, PPAC recommended that the province fund five scanners, one at each university center. The rapid development of technology for body scanners further fueled demand for this service among Ontario hospitals and led to "illegal scanners" as hospitals affiliated with medical schools purchased scanners without government approval.

Part of the explanation for this appears to be Ontario's lack of penalties for hospitals that acquired scanners without approval. The only sanction applied to such hospitals was the government refusal to allow depreciation allowances or operating costs to be included in the offending hospitals' annual budgets.

Pressured to legitimize these "illegal" CT scanners, Ontario's Ministry of Health developed a three-phase plan for CT services. Phase one covered placement of the initially planned five scanners in university centers. Phase two envisioned a total of 17 scanners, one for every 500,000 persons. Needs of areas beyond the catchment of the province's university centers were to be addressed during phase three (68).

A succession of policies followed, all quickly circumvented by hospitals and having little effect on CT scanner diffusion in Ontario. In 1981 the province revised its target upward to one scanner per 300,000 persons. By 1986.42 scanners were operating, and funding for an additional five had been approved—surpassing the government's revised target with one scanner for every 192,000 persons. By 1993 the number of scanners had reached 72 units and, perhaps, some stability; scanners are now found in every hospital with at least 300 acute care beds and a growing number with fewer (25). The U.S. experience of CT services in private offices beyond the reach of government regulation did not occur to a significant degree in Canada (9).

Ontario's experience with CT scanners provides a lesson in how not to establish policies on technology diffusion and utilization. First, the experts consulted by the governments overwhelmingly represented university-based providers with a particularly strong interest in acquiring the technology. This interest (which is perhaps not altogether unreasonable) appears attributable to the "cutting-edge" mentality of university medical centers and their differential ion. on the basis of access to technology, from hospitals not affiliated with university centers. This differentiation is revealed explicitly in the government's notion that the five university centers were to have been the primary target for diffusion of CT scanners.

Second, a consistently reactive policy focus is insufficient in the face of concerted demand from hospital administrators and providers for a given technology. Through the mid- 1970s. minority governments in Ontario, needing the support of opposition parties to rule and faced with sluggish economic growth, may have had limited ability to establish and enforce policy. The experience suggests, however, that weak policy is of minimal value.

Last, the diffusion of CT scanners in Ontario points to the allure of "big-ticket" items for hospital administrators and other stakeholders. A combination of sufficient autonomy and marketing savvy enabled several institutions to purchase CT scanners with funds from nongovernment sources. Nevertheless, community support, both financial and political, for technology acquisition left the government unwilling to continue refusing to cover operating costs.

Unfortunately, debate and decisions on CT scanners relied rarely, if at all, on scientific data

TABLE 3-7: CT Diffusion and Use in Quebec, 1977–1984

Year	Number of scanners	Examinations per scanner	Examinations per 100,000 people
1977	3	3014	144.4
1979	6	4368	414.1
1981	10	3999	625.0
1983	14	4520	978.2
1985	21	4267	1230,9
1987	35	3553	1872.7
1989	44a	3745a	2460.3*
1991	54a	3788*	3034.9a

*Estimates

SOURCE Gouvernement du Que'bec, Ministe're de la Sante' et des Services sociaux, "L'imagerie Me'dicale au Quebec, " rapport d'une recherche sur le phe'nome'ne de deffusion des technologies medicales, Que'bec, 1986.

regarding the technology's efficacy or cost-effectiveness. Aside from initial attempts to decide on a target level of access, the ensuing experience in Ontario had far more to do with politics, marketing and the clout of University of Toronto teaching hospitals.

The process of diffusion of CT scanning was slower and perhaps more orderly in Quebec, where Canada's first scanner was installed, than in Ontario. From 1977 to 1985 both the number of facilities performing CT scans and the number of scans per facility increased (table 3-7) (55).

The key determinant of the initial diffusion of CT scanners in Quebec appears to have been the fact that any such machines would have to be acquired from funds raised by the hospitals themselves, a diffusion policy based on philanthropy (55). Radiologists would be reimbursed by the government-run health insurance system, but until 1984/85, the government provided no funds for equipment acquisition.

The decision to provide such funds in 1984/85 led to the authorization of eight new facilities. These were distributed so as to offset the concentration of scanners in metropolitan Montreal and particularly in the teaching hospitals affiliated with McGill University, which had been most active in community-based fundraising. The goal was to ensure that CT services would be available in all university centers and in any region with a population greater than 200,000. As CT scanning increasingly became a standard technique, its diffusion accelerated such that scanners are now installed in almost all hospitals with more than 200 beds. The fiscal attractiveness of a philanthropy-based diffusion policy eventually gave way to a role for government to address what was perceived to be an increasing lack of equity in access.

Magnetic Resonance Imaging (MRI)

MRI was initially introduced in Canada as a research tool in 1982/83. At that time two units were installed in academic centers in Ontario and one in a similar center in British Columbia. The first clinical uses of MRI began in 1985; since then, 28 additional units have been installed with at least one now in all but two provinces. An additional six units are in various stages of installation (24). In contrast, there are currently over 1,500 MRI units in the United States—a diffusion rate that is roughly sixfold higher on a population basis.

Among the MRI units currently operating, three are notable for their location in private clinics in the western provinces of Alberta and British Columbia. Both have been financed by consortia of private individuals, including physicians who are theoretically referring persons to these facilities. In Calgary, Alberta, private ownership appears to be due in part to the existence of a waiting list of about 1,000 persons with nonacute work-

and sports-related injuries for the one MRI scanner currently in place there (26).

In Quebec a 1991 internal planning report to the MSSS, noting that MRI's "diagnostic superiority" remained unproven, considered MRI a service appropriate to university centers (59). Projected demand was estimated to require eight units in the province, of which three were operating and three were under construction as of the report's publication. This view was supported by a subsequent report of CETS on MRI in Quebec (30). This report, noting that MRI technology was rapidly evolving and that its superiority remained unproven, recommended that priority for acquisition be given to university centers with significant caseloads in neurology and neurosurgery.

CETS identified 55 specific cases in which MRI's diagnostic superiority was largely accepted by the professional community. This tempered view has contributed strongly to the relatively slow diffusion of MRI in Quebec. Although some commentators are troubled by the private clinics about to open in Alberta, the Canadian experience with MRI has been generally more orderly than that with CT scanners. To say that lessons learned from the CT experience were applied to MRI would be dangerously optimistic, but several issues deserve comment. First, MRI became available for clinical use in Canada at a time when the level of concern about health care spending, particularly on technology, was higher than at the time CT scanners were introduced. In addition, fairly early in the technology's life cycle, downward revisions of its promise and advantages over CT scanning occurred. As cost concerns throughout the health care system increased in importance, this critical reevaluation of MRI's capabilities served to temper demand.

Second, just as widespread diffusion might have been expected during the late 1980s, Canada's economy plunged into a severe recession, and apolitical consensus began to emerge that the level of government indebtedness was fast becoming intolerable. In such an economic and political environment, government receptiveness to high-profile, capital-intensive health technologies that were not directly life saving was likely to be minimal.

Last, over the past 20 years, a sharper sense of limits has emerged. In addition to the social and economic conditions noted above, Canadian expertise and facility with methods for determining the effectiveness of medical interventions have grown markedly. This has had both direct and indirect effects on policymaking but would generally appear to have contributed to an environment in which scientific data have become an increasingly greater input to policymaking. In the case of MRI, scientific data on effectiveness have remained sufficiently open to interpretation that they have limited widespread diffusion.

Overall Experience With CT and MRI

Canada's experiences with both CT and MRI are similar in that the technologies were first introduced in tertiary-care, university teaching hospitals in large metropolitan areas and then extended to other university centers in smaller urban areas and finally to regional-level community hospitals. With MRI, diffusion beyond university teaching hospitals has yet to occur. The overall pattern occurred, however, with rather less governmental control in the case of CT than for MRI.

Clearly, too, a philanthropy-based diffusion policy requiring no decisions on budgets, locations, or contracts is rather more easily maintained by a provincial government than a series of reactive, lukewarm policy efforts. Nevertheless, equity concerns are likely eventually to require a more active stance regardless of initial postures.

Although predicting the arrival of new, capital-intensive technologies is difficult, the Canadian experience with MRI suggests that there is now a greater role for technology assessment in decisionmaking (at least for such high-profile, big-ticket items) than was the case 20 years ago, when CT scanners first appeared. Whether this policy activism can be applied to other technologies in the health care system remains to be seen.

LAPAROSCOPIC SURGERY

Laparoscopic surgery differs quite markedly from the other technologies surveyed in this book in that it is relatively less capital intensive and requires little new infrastructure. In Canada the recent explosive growth in use of laparoscopic cholecystectomies has occurred with little or no input from the provincial governments that administer the health care system. To date most laparoscopic surgery has been cholecystectomies, although rapid expansion in laparoscopic hernia operations, appendectomies, and thoracic and orthopedic procedures is expected as expertise with laparoscopic techniques spreads. In the absence of utilization data for laparoscopic surgery or administrative records as to its diffusion, this section will focus on laparoscopic cholecystectomy, which has been the subject of much scrutiny in Canada.

The first laparoscopic cholecystectomy in Canada was performed in 1990 as a result of a community surgeon's exposure to the technique in Europe (104). Within two and a half years, all hospitals with more than 500 beds, 97 percent of those with 200 to 499 beds, and 78 percent of those with less than 200 beds had adopted this technology (91). Teaching hospitals were earlier adopters than community hospitals, but this may simply reflect bed size, as few community hospitals have more than 500 beds.

By March 1993 at least two-thirds of the hospitals in all regions of the country were using this technology. Preliminary cost data suggest that the average cost per case, based on 1988/89 data, is $3,437 and **$2,605** for open and laparoscopic procedures, respectively. Using these figures and assuming that 88 percent of open cholecystectomies would be replaced by laparoscopic procedures, total annual savings to Canadian health care systems are estimated at $36 million (88).

An assessment of laparoscopic cholecystectomy completed in Saskatchewan considered substitution rates of 30 and 70 percent of open cholecystectomies with laparoscopic procedures. Both scenarios yielded estimated savings of approximately $1,000 per laparoscopic procedure (72). A more recent report using carefully collected prospective study data from a randomized trial of laparoscopic versus minicholecystectomy produced average per-patient costs of $3,169 for minicholecystectomy and $2,889 for laparoscopic cholecystectomy—a savings of approximately 10 percent for the laparoscopic procedure, which is far more modest than previously estimated (35). Furthermore, total savings may be reduced if the number of cholecystectomies increases because of the diffusion of laparoscopic methods (87). Anecdotal observations suggest that indications are expanding and that biliary tract injuries represent a growing source of complications in some community hospitals.

It would be comforting to identify a pivotal role for scientific data on efficacy or effectiveness in this rapid diffusion, but the Canadian experience suggests that this diffusion was well under way before any efficacy data from controlled studies became available. At a symposium on laparoscopic cholecystectomy in September 1991 (53,84, 100,104,105) only one presenter reported patient data, a case series of 2,201 patients undergoing laparoscopic cholecystectomy from centers across the country (84). Another article in the June 1992 issue of the *Canadian Journal of Surgery* (in which the symposium papers were published) reported a smaller case series of 258 patients from a single center (44), including 60 cases reported in an earlier report (43). All three series stressed the rarity of complications and concluded that laparoscopic cholecystectomy had become the therapy of choice.

In November 1992a Canadian group published the results of a randomized clinical trial comparing laparoscopic cholecystectomy to mini-cholecystectomy (12). Their data demonstrated shorter hospital stays and convalescence among patients undergoing laparoscopic cholecystectomy. In addition, patients undergoing this procedure returned to normal activities earlier than those in the comparison group and had more rapid improvements in post-operative quality of life scores. Nevertheless, the diffusion of laparoscopic chole-

cystectomy was well underway at the time of this study's publication.

In the Canadian health care system, technology diffusion is commonly thought to be under the control of provincial governments, in view of their single-payer role. Nevertheless, a fair degree of flexibility and autonomy remains, particularly regarding the uptake of so-called medium and low technologies. Laparoscopic surgery does not require extensive financial or human resources, and although the instrumentation itself is the product of intensive technological development, its use requires little in the way of support structures additional to those already in place for conventional surgery.

As a result, laparoscopic cholecystectomy's rapid diffusion has occurred in the absence of specific incentives or disincentives offered by provincial governments. Nevertheless, a general desire to reduce bed-days and length of stay, coupled with waiting lists for some forms of surgery, have created a climate in which both physicians and hospital administrators face strong pressures to adopt laparoscopic technology. In addition, factors acting at physician and patient levels accord with administrative interests and have been collectively responsible for the rapid uptake, consistent with the general experience with medium and low technologies (13). Foremost among these factors would appear to be a synergy between a redefinition of general surgery in the face of continuing pressure to specialize, and a demand among consumers for innovative therapies that decrease hospital stays and pain. Some commentators have heralded this confluence, noting with apparent approval the refusal of patients to enter randomized trials comparing treatments, both surgical and otherwise, for symptomatic gallstones (52).

Within surgical practice the increasing role for minimally invasive therapies performed by non-surgeons has been a cause of concern. Extracorporeal shock wave lithotripsy (ESWL) had been touted as a non-surgical treatment for symptomatic gallstones. Recent data show costs of lithotripsy are greater than for laparoscopic removal and recurrence rates are more than 50 percent after ESWL (35). Laparoscopic cholecystectomy's rapid diffusion, due in part to its relatively rapid learning phase, may be interpreted as an attempt by surgeons to reposition themselves within an increasingly competitive therapeutic arena.

Strengthening this view, the Canadian Association of General Surgeons (CAGS) proposed guidelines for laparoscopic cholecystectomy in 1990, two years before the publication of data from the Canadian randomized trial and concurrently with the first reported Canadian case series. The CAGS has a structured relationship with the Royal College of Physicians and Surgeons, and these guidelines were proposed with a view to influencing training programs and certification. The guidelines stressed three points:

1. Only general surgeons experienced with traditional, open cholecystectomy should perform laparoscopic cholecystectomy.
2. Training in laparoscopy should be provided to all interested general surgeons through "appropriate instruction."
3. Training programs should be located in university centers across Canada and developed in coordination with the CAGS to ensure that supervised instruction and practice are part of all such programs (80).

The Canadian experience with laparoscopic cholecystectomy indicates that in the absence of procedure- or technology-specific funding or remuneration features, new technologies diffuse relatively unhindered and in accord with models of medical technology diffusion (91). In addition, receptiveness to stay-reducing technologies among hospital administrators has favored rapid diffusion. Finally, the impact of consumer preference appears to be more important in the case of laparoscopic cholecystectomy than in imaging technologies because of morbidity and aesthetic considerations. In the absence of extensive, well-controlled studies, evaluating the long-term impact of laparoscopic cholecystectomy on the Canadian health care system will be a challenge.

TREATMENTS FOR END-STAGE RENAL DISEASE (ESRD)

Therapies for ESRD include dialysis and renal transplantation; in addition, erythropoietin (EPO) is marketed in Canada. Both dialysis and transplantation are well established, and Canadian health researchers have been quite active in investigating these therapies and their consequences.

This work has been facilitated by the Canadian Organ Replacement Registry (CORR), established in 1981, which has provided valuable information on the natural history of renal failure treated with various therapies (78). The number of people with ESRD has more than doubled over the last decade. In 1991, prevalence of ESRD was 488 per million people, having increased at an average annual rate of 6.8 percent since 1981. Incidence appears to be rising in step with the aging of Canada's population. Between 1981 and 1991, the annual number of newly diagnosed cases increased from 1,197 to 2,568, outstripping population growth over the same interval (20).

Across Canada, the distribution of primary disease leading to ESRD is relatively consistent. In 1991,2,568 new cases of ESRD were added to the CORR. The primary diseases causing ESRD among new cases are shown in table 3-8.

Applying recent prevalence estimates to the entire country yields approximately 13,000 Canadian cases of ESRD. Incidence rates among aboriginal Canadians have been estimated to be 2.5 to 4 times greater than those among nonaboriginal Canadians, in part because of higher risks of diabetes, glomerulonephritis, and pyelonephritis (127).

TABLE 3-8: Causes of New Cases of ESRD, 1991

Primary disease	Proportion of cases (in percent)
Diabetes	23.8%
Glomerulonephritis	18,3
Renal vascular disease	17.2
Pyelonephritis	7.9
Polycystic kidney disease	5.3
Analgesic abuse	1.4
Others	13.4
Unknown	12.6

SOURCE Canadian Organ Replacement Register, 1991 *Annual Report* (Don Mills, 1993)

Dialysis

Just over half of Canadians with ESRD are treated with dialysis, and just under half of those use some form of home dialysis, a proportion that has increased over the last decade because of the increasing use of peritoneal dialysis. Among those using home dialysis, the proportion using peritoneal dialysis varies from 44 percent in Manitoba to over 90 percent in the Atlantic provinces; the national average is approximately 75 percent. Overall, 62 percent of people in dialysis use hemodialysis and the remainder use peritoneal dialysis (62). The proportion of persons with ESRD receiving dialysis has been decreasing (table 3-9), coincident with an increase in the number of transplantations (20).

CETS has produced two reports relevant to ESRD treatment in Quebec. The first of these addressed the reuse of hemodialyzers and concluded that reuse, if done according to prevailing standards, does not increase the risks associated with dialysis and presents a valuable opportunity for more efficient provision of services. This report served to validate this practice and influence its continuation. Moreover, significant savings would result if reuse rates in Canada rose from approximately 12 percent toward the 72 percent seen in the United States. Savings for Canada as a whole were estimated to be between $5.8 and $5.9 million annually, while reuse for all patients in Quebec would save $2.0 to $2.7 million annually (1 1,32).

I Transplantation

Renal transplantation is increasingly used in treating ESRD-the number of transplants increased from 103 in 1981 to 789 in 1991. In 1991,24 centers offered renal transplantation (20). In that same year the proportion of persons with ESRD in the three largest provinces with functioning trans-

TABLE 3-9: Therapies for ESRD, 1981–1991

Year	Number of persons with ESRD	Percentage on dialysis	Number of renal transplants
1981	5,576	59%	103
1982	5,916	59	286
1983	6,640	57	422
1984	7,305	55	489
1985	7,804	55	592
1986	8,637	51	749
1987	9,303	51	705
1988	10,381	50	815
1989	11,282	50	789
1990	12,067	51	763
1991	13,190	52	789

SOURCE Canadian Organ Replacement Register, 1991 *Annual Report* (Don Mills, 1993)

plants was 53 percent in British Columbia, 46 percent in Ontario, and 45 percent in Quebec.

Advances in immunosuppressive drugs have improved patient survival and graft survival through the 1980s (78). The five-year recipient survival rate is estimated at 93 percent for haplotype-matched organs from living related donors and 83 percent for organs from cadaveric donors. Five-year graft survival rates are 80 and 65 percent for organs from related and cadaveric donors, respectively (62). While renal transplantation is perceived to be superior to dialysis, expanding transplantation services is constrained by donor kidney supply.

In Quebec the first renal transplant was performed in 1958; up through 1990, 2,676 renal transplantations were completed. Approximately 20 percent of these were performed at one urban university teaching hospital (62). Waiting lists and access for persons living in remote areas continue to challenge policy makers.

In 1990 the average waiting time for a cadaveric kidney was 300 days; of 368 persons on the waiting list, 31 percent had been waiting for more than 24 months. Waiting times for transplantation are determined jointly by available resources and immunocompatibility; hence, most of this group are waiting for relatively rare, compatible donors (62).

The second ESRD-relevant report of CETS addressed renal transplantation as part of its overall examination of organ transplantation. The report noted that renal transplantation was both an established therapy and the therapy of choice for ESRD. On the basis of expert opinion, CETS suggested that efficiency and effectiveness would be best served by requiring that centers offering renal transplantation perform a minimum of 20 to 25 transplants annually. Recognizing that transplantation services in Quebec are widely distributed, CETS concluded that although centralization might be advantageous, many of its advantages could be gained from better coordination. Quebec Transplant, the provincial organ procurement organization, was proposed as the best choice for this coordination role, particularly with respect to organ retrieval and distribution and clinical research (33).

Erythropoietin

Erythropoietin (EPO) became available in Canada coincident with its introduction elsewhere. Canadian investigators staged a multicenter trial of EPO and have published several other studies on this technology (18,8 1,99). A study of the cost implications of EPO, published in 1992, used data gathered from the previously reported clinical trial (11 1).

EPO yielded a net increase in costs of $3,425 per patient-year of therapy. Varying assumptions produced a range from a net cost of $8,320 to a net savings of $1,775 per person year. Costs included $10,OOO annually for therapy and an additional $200 for antihypertensive medication; cost offsets were identified from reduced transfusions, reduced numbers of hospital days for EPO-treated persons, and reduced months of dialysis treatment because of increased renal graft survival (111).

In Quebec, EPO'S role in ESRD began with its manufacturer providing the drug free of charge to persons with ESRD, thus generating a market and (in light of its impact) strong demand from recipi -

TABLE 3-10: Formulary Pricing for EPO in Quebec, 1991–1993

Dose	July 1991	January 1992	July 1992	January 1993
4,000 units	$62.13	$62.13	$62.13	$57.00
10,000	146.01	146.01	146.01	133,95

SOURCE Gouvernement du Quebec, Re'gie del'Assurance-Maladie, *Liste de Me'dicaments* (Quebec, 1991)

ents. Once this program ended, nephrologists and persons with ESRD appeared in the media, requesting that the government provide this drug. The government then turned to the *Conseil Consultatif de Pharmacologic* (CCP) for advice.

In 1991, shortly after pressure had been exerted on the Minister, budget supplements totaling $3.2 million were announced for hospitals treating ESRD to defray the cost of EPO. Each center received an amount based on the number of persons treated there who required the drug.

Prices of EPO are difficult to ascertain, but insured prices in the provincial formulary for EPO in the treatment of zidovudine-related anemia among persons infected with human immunodeficiency virus (HIV) are shown in table 3-10 (61).

Overview of ESRD Policy

The treatment of ESRD has been an important focus of policy makers' attention, but management of these programs continues to elude a one-time "master stroke." New technologies, particularly pharmaceuticals (including EPO and new immunosuppressive agents), make long-range planning problematic. More importantly, the "life-and-death" nature of ESRD has prompted micromanagement of resources by the ministry in recognition of the fact that the rapid growth in numbers of affected individuals is not manageable by rigid global budgeting. Although limits exist, particularly in renal transplantation (because of the vagaries of donor supply), accommodation mechanisms have been adopted by the health care system to optimize access to treatment. Yet, given the increasing incidence of ESRD along with increasing rates of survival, planning and managing treatments for ESRD will continue to demand the attention of policy makers.

NEONATAL INTENSIVE CARE

Neonatal intensive care services are distributed across Canada in rough proportion to the nation's 16 medical schools. The country's geography has dictated the regionalization of neonatal intensive care services, and several provinces have an explicit regional, tiered structure of centers providing various levels of obstetric and neonatal care. In Quebec five levels of perinatal care are recognized (table 3-11).

A working group addressing neonatology services in Quebec provided recommendations to the government in a 1992 report (64). The working group was established as a result of the health minister's concern regarding a shortage of neonatology services in Montreal. The group was charged with responsibility for developing a framework for decisionmaking on neonatology services in the province.

The working group noted that vast improvements had been made in care of the newborn but that demand for increasingly specialized intensive care was being driven by the need to care for an increasing number of infants with birthweights between 500 and 750 g. After considering existing services and their utilization, recommendations were made for additional beds and personnel and for followup clinics for high-risk newborns. These were adopted by the ministry.

The working group recognized the difficulty of estimating future demand for neonatal care, particularly in light of technological advances. A prime example of such a technology is extracorporeal membrane oxygenation (ECMO). Examining the decisionmaking surrounding the ECMO center in Quebec offers insights into the role of technology assessment in policy choices.

TABLE 3-11: Neonatal Intensive Care Unit (NICV) Services in Quebec

Level	Number of centers with obstetrical services	Number of NICU beds	Services provided
Primary	**58**	**0**	Provides services for low-risk deliveries, neither obstetrician nor pediatrician services necessarily available.
Secondary	24	0	Services available for moderate-risk deliveries, including an obstetrician or pediatrician, links to tertiary centers exist.
Secondary-modified	3	11	Most tertiary care services offered in a hospital with neither research nor teaching roles.
Tertiary	6	45	Resources for high-risk deliveries and neonatology subspecialty care.
Tertiary - modified	3	41	Tertiary services plus neonatal surgery and additional subspecialties.

SOURCE Gouvernemen du Quebec, Ministere de la Sante et des Services sociaux, "La Neonatalogie au Qu'ebec, " Rapport du groupe de travail, Quebec, 1992

Three Canadian centers offer ECMO services, located in university hospitals in Montreal, Toronto, and Edmonton. (A fourth, in British Columbia may be established shortly.) Each center has pursued a slightly different strategy to finance the equipment, training, and infrastructure support necessary to establish ECMO services.

Given the not insubstantial resources required for ECMO services, a request for funds to establish a new service was initially forwarded to the Quebec Ministry of Health and Social Services (MSSS) in 1988. The proposal identified an opportunity to reduce neonatal mortality and morbidity resulting from persistent pulmonary hypertension of the newborn (PPHN)—and also to reduce both short-term costs, by shortening intensive care stays; and long-term costs, by reducing morbidity and risks of cerebral and pulmonary injury (97).

The program's advocates estimated the potential annual demand to be 30 to 40 newborns in the province of Quebec. The MSSS responded with an initial grant of $50,000 for equipment purchase. In 1990 the hospital submitted a further request for funds to establish the clinical service that was 50 percent lower than the original amount. This reduction was attributed to a staff reorganization, a lowering of the estimated number of patients, and reduced equipment expenses, as some of the equipment had already been acquired.

To build support for the ECMO program, officials at the hospital needed to balance the need for sufficient publicity to further their cause with the need to avoid offending Montreal's other children's hospital, whose staff was not convinced of ECMO'S value. This became particularly important with respect to the issue of treating congenital diaphragmatic hernias (CDH). Advocates of ECMO point to its usefulness in newborns with CDH, arguing that respiratory stabilization prior to surgery should increase survival. Opinions regarding ECMO were not, however, uniform; physicians at other children hospitals made efforts to alert key government decisionmakers to the results of treating CDH with immediate surgery (37).

Further input to the decisionmaking process came from a CETS report entitled "ECMO: Efficacy and Potential Need in Quebec" (29). Given uncertain estimates of potential demand, the ministry asked CETS to investigate this technology and its potential role in the provincial health care system. The report advised the MSSS on criteria to use, should the decision be made to establish an ECMO unit in Quebec. The criteria addressed four key issues:

1. If ECMO services were to be provided, no more than one center should be opened.
2. This center should be located in a university teaching hospital with demonstrated research capability.
3. Prior to establishment, the designated center should submit a research proposal to provide policy-relevant information for decisionmaking on ECMO'S future in Quebec.
4. The designated center's program should be considered provisional, with continued operation conditional both on satisfactory functioning and on regular provision of the information identified above.

Ongoing uncertainty regarding potential demand in Quebec led CETS to conclude that ECMO, if brought into Quebec, should be introduced for the purpose of evaluation. In this way, needs for further information and advocates' desires to establish the service could be addressed by a single decision.

These efforts culminated in the June 1991 announcement of a budget supplement of $100,000 for the ECMO program at the Montreal Children's Hospital. In the first year, 18 children were treated with ECMO; 11 survived, and one was being treated at the time of data collection. Evaluation of the service is currently under way for submission to the MSSS.

In reconstructing the decisionmaking process, the role played by a strong incentive to act—namely, the cost of sending infants to the United States for ECMO treatment—looms large. In the year preceding the CETS report, this cost was said to have reached $700,000 for four children. The CETS report notes that "the transfer of as few as 3 patients per year for treatment outside the province...would be a significant financial outlay" (29). Cost estimates vary, but costs concerned all parties to the decisionmaking process.

The Quebec experience with ECMO reveals several key themes. First, the role of the technology assessment body appears to have been driven primarily by uncertainty about demand, efficacy, and economic concerns about alternatives to ECMO; establishing an ECMO service in Quebec offered the chance both to evaluate a new technology and to reduce overall expenditures on neonatal intensive care (through elimination of out-of-province transfers). Second, the conditions of the government's decision to implement a new service suggest strong influence by the CETS report. Third, the timeframe of decisionmaking was such that multiple consultations and iterations occurred between the government and the hospital involved.

As ECMO use increases in Canada, addressing quality-of-life issues for treated individuals and their families will become more important. More generally, a key issue for policymakers in Quebec and Canada will be the extent to which resources should be allocated to saving babies with ever-lower birthweights through technology-intensive care versus using those resources to prevent prematurity and low birthweight.

SCREENING FOR BREAST CANCER

Screening for breast cancer, primarily involving mammography and breast self-examination, has been and continues to be a high-profile issue in Canada. Both federal and provincial governments have developed policies and programs and several reports and resource documents have attempted to bring scientific data into decisionmaking.

A useful point of departure for investigating Canadian approaches to breast cancer screening is the National Breast Screening Study (NBSS). This multicenter, randomized trial began in 1980 (95); despite some initial difficulties, 89,835 women were enrolled (4). In 1992, the investigators reported their results for women from 40 to 49 years old at enrollment and for women from 50 to 59 at enrollment (92,93). Previous publications had addressed the operating characteristics of first-screening mammography and of physical examination, improvements in technical quality, and the role of nurse-examiners in breast cancer screening (5,6,7,94). Among the women enrolled in the NBSS at ages 40 to 49, the strategies compared were usual care and the screening combination of annual mammography and physical examination. After a mean followup of 8.5 years,

no difference in death rates from breast cancer was found. The investigators reported increased numbers of node-negative, small tumors in the screened women compared to the women receiving usual care (92).

Women aged 50 to 59 at enrollment were randomized to either annual mammography and physical examination or annual physical examination alone. After a mean followup of 8.3 years, no difference in death rates from breast cancer was found; however, as with women aged 40 to 49, increased numbers of small, node-negative tumors were reported among the women undergoing annual mammography (93).

The NBSS will continue to provide valuable data for scientists and policymakers. However, political pressure has required Canadian provincial governments to act prior to the NBSS data becoming available. Breast cancer screening was discussed at several meetings of the Conference of Deputy Ministers of Health and led to the publication of a federal report in 1986 outlining desirable standards for screening mammography, a 1988 federal-provincial workshop, and a December 1988 implementation report in which all provinces agreed to make breast cancer screening a priority (16,39,70,125).

British Columbia was the first province to establish a formal screening mammography program. Other provinces soon followed suit with variations on a general pattern of pilot-phase projects with provision for expansion to province-wide programs. Although scientific data clearly played a significant role in policy formation, technology assessment of breast cancer screening approaches in Canada had been fairly small scale. The 1988 workshop report had provided an preview of the scientific data including the HIP study and studies in Sweden, Haly, The Netherlands, and preliminary results from the NBSS (38,103,1 10,121 ,124).

To date, two technology assessment bodies have addressed screening for breast cancer. The Canadian Coordinating Office for Health Technology Assessment published a brief commentary on a selection of trials of breast cancer screening programs in 1992 (23). This appears to have been prompted by a request for information from one or more provinces. Despite general agreement on the efficacy and political importance of mammography programs, much heated debate has continued on the question of who should be screened and at what frequency.

In Quebec CETS published a report in 1990 entitled "Screening for Breast Cancer in Quebec: Estimates of Health Effects and of Costs." Drawing on efficacy data from a number of trials of breast cancer screening programs, the report concluded that "there is solid evidence that it is possible to prolong the life of women with breast cancer through early detection by periodic screening using mammography, with or without physical examination" (31). The report estimated that universal participation among women aged 50 to 69 in a biennial screening program would cost approximately $27 million annually. More realistic estimates of 75 and 60 percent participation would yield annual direct costs of $20 million and $16 million, respectively. Estimates of expenditures per life-year gained ranged from $3,400 to $5,700, depending on participation levels required to realize projected aggregate increases in life expectancy. Recognizing that mammography was already in widespread use in Quebec, the report also recommended steps to optimize screening activities already under way, including possible targeting of mammography to women of selected ages.

Throughout the last decade, the number of mammograms performed in Quebec increased, reaching 337,050 in 1991; however, fully 53 percent of these were for women less than 50 or more than 69 years of age. Approximately two-thirds of these examinations were done in clinics and the remainder in hospitals. Despite this growth, pressure to establish dedicated breast cancer screening centers rose with the end of enrollment in the NBSS and the subsequent closure of study centers in 1987. The health Minister at the time announced that no decision would be made until the results of the NBSS were available, expected to be in 1990. Meanwhile, pressure for action grew and was mirrored by the high priority given to screen-

ing mammography at the 1988 federal-provincial conference.

In July 1989 a proposal was made to the government for 37 designated screening centers across the province to establish a biennial mammography program for women aged 50 to 69. Costs were estimated at $9 million but would be offset by savings in breast cancer treatment costs resulting from early detection and the ending of screening mammograms described as "unnecessary" in women under 50 years of age. Part of this proposal directed CETS to examine the evidence on the efficacy of screening programs for breast cancer.

CETS released its report in January 1991, making recommendations on reimbursement for mammography, guidelines for screening programs, and data collection for program evaluation. During the following two months, the government endorsed the CETS recommendations, and the health Minister, expressing reservations about dedicated screening centers, advocated optimization of existing services.

A year later the provincial association of radiologists argued that screening mammograms should be available to women from 40 to 49 years old. This position generated a great deal of editorial comment, as it contradicted the views of the ministry and CETS. In June 1992, pressure on the health Minister increased with the presentation of a petition from Breast Cancer Action of Montreal calling for the reimbursement of physicians for screening mammograms in women 40 to 49 years old; however, by October this group had agreed with the idea of focusing on women aged 50 to 69. In May 1993 CETS published a report on breast cancer screening in women under 50 years of age and noted that data supporting a benefit of screening in this group were indirect and weak (34). However, CETS stated that technological advancements might well shift the balance in favor of screening women aged 40 to 49, and for this reason the case should not be considered closed. CETS concluded its report with an urgent call for policy on screening mammography in light of the not insignificant health and financial effects of the current situation.

Current government policy is to provide a universal mammography screening program for women from 50 to 59 years old. Younger women at higher risk because of family history of breast cancer will have access to screening following medical referral. This policy essentially follows the recommendations of CETS and includes provisions for optimization of existing resources, together with coordination and quality assurance mechanisms.

The Quebec experience with breast cancer provides insights into how technology assessment fits into a highly politicized health issue. With a visible and well-organized target constituency, policy development on breast cancer screening is far more delicate than on items such as MRI scanners. Various actors in the debate have used media sources to attempt to strengthen their positions, thrusting technology assessment into the glare of public attention.

Technology assessment seems to have weathered this quite well in Quebec, but in a largely reactive fashion. As technology assessment matures in Canada and is brought to bear on issues of increasing political importance, its practitioners may have to ask whether they will need to become more skilled in media relations and communications and if this will threaten scientific rigor and credibility. These demands may herald the formation of dedicated communication units or an important role for communications professionals within technology assessment organizations.

CETS also appears to have played an important role as an arbiter of sorts, providing the government with advice for policy and political breathing room. As difficult a balance as this role requires, it is likely to become more frequent as technology assessment matures.

CHAPTER SUMMARY

A decade ago OTA reviewed health technology management in a number of countries (8). At that time in Canada, management was marked by a rigid separation of roles: providers stated their needs and payers (provincial governments) decided whether to provide the requisite funds. Technology assessment was largely a theoretical proposition.

A decade later, much has changed. Cost concerns have broadened the focus of both groups, with payers increasingly interested in the effects of interventions and programs, and providers more concerned with costs. Evaluation has thus emerged as a common basis for sharing decisionmaking. Health technology assessment is now established, and its development has been further encouraged by information needs arising from a management framework in which providers and payers both increasingly demand the results of evaluation.

Several prominent themes emerge from our survey of health technology in Canada. The first is that diffusion patterns of technologies within the Canadian health care system are determined by the system's overall characteristics. Provider autonomy and fee-for-service remuneration have created a system responsive to emerging needs and emerging technologies, and central control and global budgeting provide levers for rational planning. Finally, public financing holds regulation increasingly accountable through the democratic process. Effective control of diffusion occurs rarely by "magic bullet" but rather by creating a macro-level environment that acts to constrain micro-level choices.

For example, limiting funds available for acquiring expensive technologies is a macro-level decision effectively limiting the supply of these technologies at the provider level. The government does not bar physicians or hospitals from acquiring or using such technologies; rather, it creates boundaries within which acquisition or use occurs. In the case of CT scanners, a philanthropy-based macro-level policy acting to slow acquisition has had the intended effect of slowing diffusion in Quebec as compared with Ontario.

The Canadian experience demonstrates that there is nothing magic or sacred about health care technologies that makes them more or less amenable to regulation than other elements of the system. Instead, the system's structure creates decisionmaking schemes and incentives that collectively shape technology diffusion. Only at this macro level has the Canadian health system been able to influence diffusion, with greater influence as the resource intensity of the technology increases. In contrast, the rapid spread of laparoscopic cholecystectomy indicates that the system offers a great deal of flexibility for adopting less resource-intensive technologies. By not challenging the boundaries set at the macro level, these technologies have been free to diffuse unchecked by measures explicitly directed at them.

Given the need for and impact of a comprehensive strategy, a basic question arises: how did this framework come to be? The levers of control of the Canadian health care system have been in place for over 20 years but have only recently been used firmly. The spur to action comes from increasing demands for more resource-intensive services from an increasingly older population, creating both the need and the incentive to curtail costs.

In the face of this pressure, a comprehensive strategy was not implemented all at once; existing elements of the system including global budgets and bed controls for hospitals, policies regarding physician numbers and remuneration, regionalization, capital expenditures, and insured services provided policymakers with a series of complementary levers. With cost concerns, preexisting synergies simply became apparent and were more effectively deployed.

In this vein Quebec may have been slightly ahead of the rest of the country. A cultural receptiveness to systems planning exists in Quebec that is less evident in predominantly English-speaking provinces. Given the strong ties of culture and language among the people of Quebec, the threshold

for widespread physician resistance may be higher there than in the rest of the country, where physician migration appears more likely.

Turning to the technologies considered in this chapter, the ability of the system to temper diffusion may well have been helped by the lack of evidence of adverse outcomes attributable to a limited supply of health care technologies such as MRI. For life-saving technologies (e.g., therapies for ESRD) a hands-off, macro-level approach is less possible, and specific and sporadic adjustments are made in light of changing needs.

More troubling, the system has also been free from accountability for the quality of care dispensed. The Canadian model of using system features as levers to control technology diffusion has been reasonably successful at the macro level, particularly regarding "high-tech" acquisitions, but does not necessarily result in the greatest efficiency. Thus, a final theme is the challenge, in the face of continued cost pressure, to design and implement effective mechanisms that will optimize use and address practice.

The fundamental principles of the Canadian health care system—universality, portability, and comprehensiveness—are coming under increasing scrutiny. Global budgeting and acquisition controls have limited aggregate expenditures, but some combination of regulation, incentives, information, and education will be necessary to ensure appropriate utilization of technologies. Addressing this micro level will require new approaches to complement existing mechanisms and may well include clinical practice guidelines for practitioners and scrutiny of existing incentives favoring adoption, diffusion, and use of technologies at the practitioner level.

To date, physician organizations, particularly the Canadian Medical Association, have attempted to claim guidelines as a matter to be developed within the profession. This appears consistent with the system's traditional role definitions. The patience of governments, in their role as payers, may soon be tested if actual guidelines continue to diffuse at their current slow rate. Nevertheless, an increasing role for practice-focused technology assessment appears inevitable. Changing perceptions of the role of the physician, coupled with increasing demands by citizens for both efficiency and high-quality care, cannot help but promote technology assessment as a vehicle for resolving the inherent conflict between these two demands. In this light, technology assess: ment's task of bridging science and policy remains paramount; however, increasing emphasis on communication—particularly new methods of intervention and incentives for information use, may well expand current notions of what a technology assessment body does.

Despite this potential for expansion, practice-focused technology assessment will share with its procurement-focused counterpart needs for rigorous methods and ongoing vigilance to ensure that policy-relevant information is produced. As with procurement, there will be no "magic bullet" to improve quality of care and user satisfaction; rather, the structural features of the system within which care is delivered will bean important determinant of its quality. The challenge for technology assessment in Canada is to deliver information that enhances efficiency and quality in a system that is based on a balance among fiscal control, consumer choice, and provider autonomy.

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Health Care Technology in France

4

by Caroline Weill

OVERVIEW OF FRANCE

France is an industrialized country with a large agricultural sector. Its population in 1991 totaled 57 million. According to the Constitution of 1958, France is organized as a parliamentary democratic republic. Separation of legislative and executive powers, multiplicity of political parties, and respect for the Constitution and the Human Rights Declaration are the guaranties of democracy.

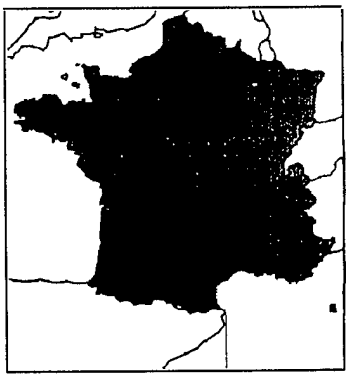
The French Constitution refers to health as a fundamental right. According to this document, France guarantees to everyone, "especially to the child, the mother and the aging worker," health protection.

Government and Political Structure

The main French powers are the *President de la Re'publique,* the Parliament, the government *(Conseil des Ministres),* and the Prime Minister. The President, who serves as the head of the French state, represents the French nation. He is also the chief of foreign policy and the commander in chief of the French army. The President is elected through universal franchise (all citizens vote) for seven years and can be reelected.

The French Parliament is divided into two chambers: the *Se'nat* and the *Assemblee Nationale.* Senators are elected by elected members of local assemblies for nine years. Members of the *Assemblee Nationale,* called *deputes,* are elected through universal franchise for five years.

The *Conseil des Ministres* executes the laws passed by the Parliament. The Prime Minister is the leader of the government; he is nominated by the President. The government is responsible to the Parliament for its policy and programs.



Metropolitan France is divided geographically into 95 *departments* (departments) including four overseas departments. Under the authority of prefects, the departments administer the local services of most of the ministries. The departments are grouped in 22 *regions,* whose prefectural authorities are responsible for implementing the government's regional economic development policy. A total of 37,000 local administrative units *(communes)* have wide powers for managing major public services, including health services.

The 1982 and 1983 Decentralization Acts were intended to confer greater decisionmaking powers on the lower echelons of local government; general policymaking was to remain the responsibility of the central government. These acts distinguish between two types of authorities in each administrative unit: the appointed representatives of the central government and the elected representatives of the local communities. The former are the *prefets* (prefects), of whom one grade has responsibility for the departmental level and another for the regional level.

The elected representatives of the local communities *(communes)* are headed by the president of the assembly, an elected local representative. The elected councils are the *Conseils Municipaux* for the towns, the *Conseils Generaux* for the departments (i.e., several towns), and the *Conseils Regionaux* for the regions (grouping several departments).

The Decentralization Acts transferred to local elected authorities various functions formerly performed by the central government. Each community is fully responsible for its functions, for which it raises taxes, and each acts freely without control from other communities. Generally, the localities are responsible for public services; the *departements* are in charge of social aid, health, and welfare; and the *regions* carry out economic responsibilities, including planning.

Departmental councils are in charge of maternal and child health, immunization activities, and medical assistance for the uninsured. These councils can issue regulations for the services and residential establishments they supervise. Communal health services, under the authority of each town's mayor, comprise the Communal Hygiene Service and community health centers and dispensaries that carry out primary local health care activities and preventive work.

The central government, through its regional directorates and coordinated by the regional prefects, establishes and implements rules for public hygiene. The central government is also directly in charge of policies concerning mental illness, drug addiction, and alcoholism. It establishes regulations for social welfare and health insurance, controls the finances and activities of public hospitals, and is in charge of health planning.

Population Characteristics and Health Status

In 1991, 27 percent of the French population was under 20 years of age and 14 percent was over 65 years. The crude birth rate—which has been decreasing over the past 20 years—was 13.3 per 1,000 inhabitants in 1991 (31).

Since 1980, life expectancy at birth has continued to improve, reaching 77 years in 1991 (for females, 81.1 years, for males, 73 years). Infant mortality decreased from 10.1 deaths per 1,000 births in 1980 to 7.3 per 1,000 in 1991. The death rate (standardized) for the entire population fell to 9.2 per 100,000 in 1991, compared with 10.0 in 1985 and 10.6 in 1970.

Five major categories of causes of death account for more than 80 percent of all deaths in France: diseases of the circulatory system (37 percent), cancer (24 percent), injuries and poisoning (9 percent), diseases of the digestive system (6 percent) and respiratory diseases (6.5 percent) (31). In France, mortality differentials among males indifferent social strata exceed the differentials between men and women (31). The categories of people most likely to die prematurely are (in decreasing order): manual workers, skilled workers, service personnel, and unskilled workers. The same general relationship is apparent in mortality differentials among females but is less marked. Mortality and morbidity also differ

among geographical regions; rates are generally higher in the northern and eastern regions of France.

The incidence of infectious diseases (e.g.tetanus, diphtheria, poliomyelitis, and tuberculosis) is verylow. AIDS,on the otherhand, has become a very serious problem in France, which has the third-highest incidence and the highest prevalence in Europe. There were 3584 new cases in 1991 (0.32 per 100,000), and a total of 18,508 cases registered. Disabilities among the elderly are becoming more and r ore serious problems, given the increase in the number of people who are more than 80 years old.

Certain behavioral factors cause health problems (31). Smoking rates, for instance, increased for some time but have now stabilized. A 1991 law strongly limited propaganda and advertising for tobacco and has prohibited smoking in public areas. Fat consumption has increased, but alcohol consumption (still very high in France) has decreased from 16.2 liters per person in 1983 to 12 liters in 1990. Alcohol-related mortality rates are significant: the estimated number of deaths due to cirrhosis and alcoholic psychoses was 14,000 in 1992 and" another 14,000 deaths are attributed to cancers of the respiratory and digestive systems. Alcohol-related accidents are estimated at roughly 21 per 100,000 people, more than twice the rate in the United Kingdom.

THE FRENCH HEALTH CARE SYSTEM

The health care system in France combines freedom of medical practice with nationwide social security. Every employed person or student, individuals on welfare or retired, and both French citizens and foreign residents benefit from the system, in which participation is compulsory. Health care is provided by a range of institutions, both public and private, and patients have free access to any physician. Patients' expenses are paid directly either to the hospital or to the practitioner by the social security insurance system, or they are paid by the patient and then refunded.

Universal availability of health care is guaranteed largely by the national health insurance system. In addition, the Social Aid Scheme provides benefits for individuals not enjoying full social securit y coverage (i.e., people who have been unemployed more than one year and who cannot benefit from a parent's coverage). This corresponded to 390,000 persons in 1986, and 550,000 persons (1 percent of the total population) in 1992.

That said, the funding of health-related expenses is a chronic social policy problem in France. The principle of providing a high standard of care for the entire population, set against a background of rising costs and, more recently, decreasing income (due to increasing unemployment), is causing a financial gap that the government is struggling to close. Health-related expenditures rose from 6.1 percent of Gross Domestic Product (GDP) in 1970 to 8.9 percent in 1991. More than 75 percent of health expenses are covered by public-sector mechanisms; the remainder is covered by private individuals or complementary private insurance schemes.

General Administration

In the field of health care and welfare, treatment continues to be a central government responsibility. Accommodating the elderly and the handicapped is now the responsibility of the departments (4). Public and private treatment facilities are opened, expanded, or merged on the basis of a planning tool known as the "health map" *(carte sanitaire),* drawn up by the Ministry of Health in accordance with a 1970 law (modified in 1991). For the major disciplines of medicine, surgery, and gynecology and obstetrics, this map is based on a list of health care facilities by region and, within the regions, by "health sector." Using requirements expressed in terms of bed-to-population or equipment-to-population ratios, the map quantifies the needed numbers of beds and of equipment considered costly (or "heavy") relative to calculated theoretical levels.

The 1991 revision of the law transferred to the regional representatives of the central government the main responsibility for the health care facility panning process. (This planning process and the definition of "needs" are discussed in more detail

below.) The process does not concern private office-based practice; physicians may establish practices wherever they choose.

In each department, public hospitals and private facilities operating within the public sector are administered by the Departmental Directorate for Health and Welfare *(Direction Departementale des Affaires Sanitaires et Sociales)* under the authority of the prefect. The elected president of each departmental council supervises the day-to-day administration of the Departmental Directorate for Health and Welfare. At the next level, the prefect for the region supervises the Regional Directorate of Health and Welfare, which has responsibility for (among other things) regional health and welfare planning, inspection and management audits of facilities, and regional investment policy.

The Hospital System

The hospital system is composed of public hospitals as well as commercial and nonprofit private hospitals. The public and nonprofit private institutions participate in the Public Hospital Service and operate for the general welfare of the population. Through this service, all patients are accepted into public hospitals at all times (27). Public hospital management is undertaken by both elected local authorities and the Ministry of Health. Public hospitals are run by a board of directors chaired by the mayor; members include representatives of local communities, Sickness Fund, and medical and nonmedical staff.

The Ministry of Health is responsible for the administrative and budgetary supervision of all hospitals. The Ministry's departmental representative must concur with every decision of the board of every public hospital. This is, understandably, a source of constant tension between local and national views. Public hospitals are generally hospital centers comprising treatment units (e.g., medical, surgical, obstetric), "medium-stay" centers for patients needing convalescent care, curative care units (e.g., spas, addiction centers), centers for rehabilitation or treatment of mental illness, and long-term medical centers for elderly people who can no longer live independently.

Public hospitals are legally classified in terms of the size of the populations they serve and the types of services they provide. The main categories are general hospital centers, specialized hospital centers, regional (teaching) hospital centers, specialized psychiatric hospital centers, cancer treatment centers, medium-stay centers (for convalescence therapy and rehabilitation), long-stay centers, and local hospitals, where local private physicians have access to beds for their own patients or may treat them there. Regional hospital centers (27 percent of all public hospital beds) provide regional coverage and undergraduate teaching and bring together a large proportion of specialist care and medical services.

Public hospitals are funded by a lump sum grant from the central government determined in agreement with the Social Security bodies under the supervision of the state (see the section on Coverage of Health Expenses). But the Social Security entities and not the state provide most of the financing for hospitals by covering the costs of their insured. In addition, a hospital may, for its investments, receive grants from the state or from a local community, and it may takeout financial and bank loans.

Private hospitals play a major role in the health care system and account for one-third of all hospital care in France. Some are commercial, others nonprofit. Private hospitals are particularly important in certain fields, such as obstetrics and digestive surgery. Physicians in such settings usually work as private practitioners and are paid by patients on a fee-for-service basis. Like public facilities, private hospitals are controlled by the health map.

Since 1980, the number of hospital beds and stays has decreased, and the rate of admissions has slowed. Present policies favor development of the long-stay and medium-stay sectors and a reduction in the short-stay sector. The total number of

beds is still considered too high (247,813 in 1991, two-thirds of which were in the public sector).

Physicians practicing in public hospitals are paid a salary, but to a certain extent they can carry on part-time private practices outside a hospital.

Other Medical Services

Most doctors practicing in communities provide their services on a private basis, as do dentists, ophthalmologists, pharmacists, and allied health professionals (e.g., nurses, physiotherapists, pediatricians, hearing-aid specialists). Some, however, are employed by the health insurance system, friendly societies, or official authorities—for instance, health centers whose main function is to provide health care for people on low incomes. A large network of public and nonprofit private establishments operate facilities offering specific services, such as special services for mothers and children.

Health Care Professionals

Between 1981 and 1992, the number of physicians in France increased dramatically, from 108,000 to 155,896 (259 per 100,000 population) with a disproportionate increase in the number of specialists. In 1992, specialists accounted for 49 percent of all physicians, compared with 39 percent in 1981. Physicians in private practice represent 80 percent of the total. Since 1985, to limit the number of physicians, the number of students admitted to medical schools has regularly decreased (going from 8,500 in 1970 to 3,500 in 1993). Nevertheless, the total number of practicing physicians in France will increase until the year 2010.

Restrictions on medical practice are not straightforward under the French system. Even if some of the rising costs of health care may be related to an excess of medical activity, some young physicians now experience difficulties in seeing enough patients to make a living. In 1991 a report of INS ERM *(Institut National de la Sante' de la Recherche Me'dicale,* the French equivalent of the U.S. National Institutes of Health) to the Minister of Health suggested that some medical practitioners might receive complementary training to become epidemiologists, lawyers, economists, statisticians, or prevention officers in a renovated prevention system. This idea has not, however, been put into action on a large scale.

The number of nurses also increased, from 246,000 to 294,000 between 1979 and 1986, with a trend toward private-sector employment. A high turnover rate in nursing stems from increasing dissatisfaction with jobs, position, status, and income (especially in the public sector).

Health care personnel are unevenly distributed geographically, with a disproportionate representation of medical and allied professions in private practice in the south of France and the Paris region. Regional differences are greater in the most specialized professions.

Payment for Health Care

Health costs totaled more than 573.4 billion francs in 1991, representing an average of 10,000 francs ($US1,800) per capita and 8.9 percent of the Gross National Product (GNP). France leads the European Economic Community in its health expenses, which have risen 7 percent annually in recent years (see table 1- 1). Nearly 97 percent of this total is spent on medical goods and services; 3 percent is spent on preventive medicine (e.g., industrial medicine, school health services, mother-and-child protection).

Hospital care and treatment account for almost half of the total expenditure, office practitioners for 30 percent, and medical supplies (e.g., drugs, spectacles, orthopedic appliances) for 20 percent. Finally, costs are concentrated on a relatively small number of people: 10 percent of all patients account for 75 percent of total expenditures.

The Social Security System

Most of France's health care expenditures are paid for through a system of compulsory health insurance within the nation's general social security scheme. Health insurance is funded by contributions of both employers and employees. The system is directly managed (under State supervision) by employers and trade union representatives.

Contributions are calculated as a percentage of employees' salaries and cover the health care expenses of any member of that individual's family. In July 1992 the percentages paid by the employer and the employee were 12.8 percent and 6.8 percent, respectively, of the employee's salary. Typically the Parliament has not been involved in payments for health care. Nevertheless, in 1990a small percentage (3 percent) of the employee's contribution (the *contribution sociale ge'ne'rali-s&e,* or CSG) was added to the salary-based contribution. The CSG, being a tax voted by the Parliament, gives the Parliament the right to discuss health and social security issues.

Since 1988 the National Sickness Fund *(Caisse Nationale d'Assurance Maladie des Travailleurs Salarie's,* CNAMTS), has covered 73.4 percent of all insured persons' health expenses. In the event of hospitalization, whether public or private, the fund reimburses the hospital directly on behalf of the insured.

When consulting a doctor, however, each patient must generally pay the fees and then obtain reimbursement from the National Sickness Fund. The patient himself is responsible for about 25 percent of the total and is reimbursed for the rest according to a tariff fixed by agreement between the CNAMTS and the doctors' professional associations. The cost of prescription drugs also is reimbursed to the patient.

An increasing number of physicians (18 percent in 1985, 28 percent in 1990) have been allowed by the agreement to charge more than the tariff *(de'passement),* and a few (3 percent) with high qualifications have chosen to practice outside the agreement. The latter can charge what they want, and the reimbursement is close to nothing: however, the patient may receive a partial refund from private insurance. Confronted with a notable increase in the number of physicians choosing to overcharge, the government decided in March 1990 to "freeze" the number of physicians able to do so. After negotiation, this decision was accepted by the physicians' representatives.

The costs for which the insured remains personally liable (i.e., the *ticket mode'ateur)* can be covered by a private insurance scheme or by a nonprofit organization directly managed by its members who traditionally play an important role in this regard. These organizations are usually structured to cover individuals in certain jobs or professions.

The Social Aid Scheme is organized by local authorities to meet the needs of people of inadequate means. It can either act in lieu of Social Security or complement the latter's benefits. The role of Social Aid is now greatly reduced.

Price Setting

Prices for ambulatory care are determined by a governmental decree after negotiations between the National Sickness Fund and the national trade union of physicians. Price setting is based on a list of medical procedures. The private practitioner must give the patient a file to be sent to the National Sickness Fund in order to claim reimbursement. To protect medical confidentiality, medical procedures are not registered individually but expressed through "key letters" (C for a consultation, Z for radiology, B for biology, K for surgery, etc.) combined with a coefficient; the key letter corresponds to a certain price, and the coefficient is a multiplier. The key letter is unrelated to any diagnosis. Unfortunately, one consequence of this system is that it is difficult to ascertain what medical practices are actually performed on a routine basis; they can be classified only in aggregate (e.g., several procedures have the same "290" code).

More than 4,000 procedures are classified under 50 key letters. The list is not frequently or regularly modified, so the valuation of the procedures is approximate and usually does not represent real costs. New technologies are classified through "assimilation" to older, comparable procedures; which may lead to some highly profitable technologies and other highly under-reimbursed ones. Updating this list appears to be quite difficult because of the multiple and contradictory goals involved (e.g., health benefits, cost containment, support of the medical industry). The seeming impossibility of updating the list has been one of the most evident limits of French health policy since the beginning of the 1980s.

Private physicians' activities and prescriptions account for 50 percent of total health care expenditures. The annual growth rate of private office practice in France was 8.5 percent in 1989 and 7.2 percent in 1990, in contrast with 6.8 percent from 1980 to 1988. Because physicians are paid on a fee-for-service basis and prices are set by a legal tariff, it is clear that physicians must increase their activity in order to increase their personal income; moreover, overall activity increases as a result of an increase in the number of physicians. A law passed in January 199[illegible] was aimed at allowing a negotiated limitation of this increase. This law defined the principle of an annual financial goal for the profession as a whole (enveloppe)-which, according to the law, is to be based on "national medical references" of practice, taking in to account several factors (e.g., general population characteristics, the state of medical technology, the knowledge base in epidemiology, and the state of medical supplies). The law stresses the responsibility of the National Sickness Fund for the control of rising health costs.

The annual agreement signed at the end of 1993 between the National Sickness Fund and the private office practitioners' trade unions included several important clauses, including the use of treatment protocols, based on fully assessed scientific literature as rules of practice for private office practitioners. During the summer of 1993, the medical board of the National Sickness Fund devised such rules for 80 well-documented conditions. These drafts were reviewed by experts nominated by the physicians' unions, and by the Agency for the Development of Medical Evaluation (ANDEM). These protocols will be used to evaluate statistically the activity of practitioners. Practitioners who treat more than 20 percent of their patients not in accordance with the protocols risk financial penalties.

To implement these rules, physicians will have to report (anonymously) details of their activities. A new database will be created in two steps: first, prescriptions will be registered openly; later, the database will include diagnosis-related prescriptions in private office practice. A medical record *(carnet de liaison)* will be established for each patient by general practitioners. This file will become the center of a medical information network, and all patients will carry a summary of their medical records that they will have to show every time they see a doctor in order to be reimbursed. (Every physician attending a patient as well as the medical board of the National Sickness Fund will be allowed to review the patient's medical record.) At first, only patients over 70 will be involved in this reform.

Until 1985, hospitals were reimbursed by the National Sickness Fund on a fee-for-service basis. For each day spent by a patient in a hospital bed, the hospital received an amount that was to cover the average cost for a given medical specialty. As a result, the hospital's income was automatically adjusted for expenses. This method had dangerous inflationary consequences. Since 1984, anew payment system has been established by the government (initially for the public sector only) based on an annual global grant for each hospital defined by the Ministry of Health and allocated to each public hospital every year for the following year.

The basis for each hospital's budget has been, for year 1 (i.e., 1985), the level of its income for year O; thus, at the start, the most efficient hospitals were penalized. Every year the budget of a given hospital may increase after a negotiation between the hospital, local Social Security representatives, and state representatives. The budget reflects the hospital's activity at the end of the fiscal year plus an amount of money determined through the application of a "national rate of acceptable increase in expenses" established by the government after overall prices and wages in the industry are reviewed.

Each hospital's annual budget is then submitted by the director in accordance with government rules and either approved or rejected by the board of directors (although rejection is of no particular consequence if the government representative—the prefect—approves it). One-twelfth of this allocation is paid to the hospital each month by a "lead fund" *(caisse-pivot),* usually the local branch of the National Sickness Fund. Financial reparation is made to the different funds involved.

Since 1991 this procedure of payment has been extended to the private hospitals. Every year, a "national quantitative goal" is determined according to national agreement; it expresses a level of activity not to be exceeded during the following year. In 1992, a maximum, agreed-upon level of expenses was negotiated as well with representatives of laboratory physicians; negotiations are ongoing with representatives of radiologists.

Pharmaceutical prices are set by the government after extensive negotiations with representatives of the industry *(Syndicat National de l'Industrie Pharmaceutique,* or SNIP). A general agreement with SNIP is followed by specific contracts with each firm or laboratory. The negotiations focus on several goals, including rationalization of the use of drugs in France (which is considered too high), cost containment, and protection of the French pharmaceutical industry, which is highly competitive (with 80,000 employees and annual sales of 90 billion francs).

Financing the introduction of new technologies in hospitals is differently regulated for private and public hospitals. For private hospitals a specific procedure called the interministerial tariff for health devices *(Tarif interministe'riel des prestations sanitaires,* or TIPS) determines the conditions under which hospitals may be reimbursed following the acquisition of medical equipment or drugs for individual care. This procedure, based on a list of prices, is implemented by the Ministry of Health with input from other officials in other ministries involved in the setting of prices. Public Hospitals, in contrast, invest in needed equipment and drugs by using requests for proposals (when the amount is over 100,000 francs).

If the equipment to be procured is subject to premarketing approval, the hospital must go through this procedure in order to be reimbursed. In any case, three other conditions must be fulfilled: 1) registration with the pricing list *(nomenclature), 2)* conformity to legal manufacturing standards, and 3) an existing set fee for the medical procedure involved. For certain equipment considered especially costly or of nationwide interest, advance purchasing authorization by the Ministry of Health is also required (see below).

CONTROLLING HEALTH CARE TECHNOLOGY

The regulation of health care technology in France is different with respect to pharmaceuticals and equipment or devices. The regulation of pharmaceuticals is based on a time-tested, pre-marketing approval approach designed to assess the safety and efficacy of drugs. The regulation of equipment entails approval of the location of services and pre-market approval of the equipment itself—two distinct processes. Since 1970, placement of services have been decided by a planning system for hospital beds and major equipment that is aimed largely at guaranteeing equal coverage across the country. The pre-market approval procedure, which was reinforced in the 1980s, remains weak.

Regulation of Pharmaceuticals

Control of pharmaceuticals is based on a procedure of "authorization to market" *(autorisation de mise sur le marche',* or AMM). Created in 1972, the AMM procedure controls verification of the therapeutic value of pharmaceutical products and their correct use. The companies bear the major responsibility for testing products for efficacy and safety in fulfillment of the authorization requirements. Until 1992, the AMM process was administered by the Ministry of Health; the minister himself signed each AMM after reading the findings of the *Commission de 1'AMM.* After the AMM is signed, cost-effectiveness is considered (along with conditions for placing a drug on the pricing list for reimbursement) by another committee, the *Commission de la Transparence.*

Since 1980, surveillance of adverse effects of pharmaceuticals has been part of drug regulation. Physicians and pharmacists are supposed to report any unexpected and harmful effects of medications to a network of "pharmaco-vigilance" centers. Warnings and even the withdrawal of a medication by the Ministry of Health can ensue after advice from the National Pharmaco-Vigilance Commission. Up to now, however, only a few drugs have been reported to this Commission.

Despite some red tape, the system for assessing medication has been considered a model system. Recently, several experts have pointed out that there are insufficient funds and staff for implementing the AMM procedure. To solve this problem, in 1992 the government decided to create a new body, the Agency for Medicine *(l' Agence du medicament),* an independent agency financed by grants from the government and industry oversee the AMM procedure. The agency may also receive private funding. The Agency of Medicine has a staff of 320 experts, one-third of whom are physicians and chemists. During its first year, this agency dealt with more than 1,000 authorization requests. Its board of directors includes, together with Ministry of Health representatives, individuals from the Ministries of Research, Industry, and Finance and from Social Security, along with seven experts (including a representative of industry).

The agency's director, not the Minister of Health, signs the AMM for drugs. It is expected that this new procedure, which involves all the players, will be more consensual. One of its main goals is to define the ways and means of its cooperation with the European agency created by the European Union in London.

Pre-Marketing Approval Process

The pre-marketing approval process *(homologation)* aims at assuring safety for patients as well as machinery operators and at assessing new technologies' technical and clinical efficacy (25). (Efficiency prospects, comparisons, or cost evaluations are not part of this procedure.) A manufacturer applies for pre-marketing approval by submitting results of tests carried out by one of the official laboratories listed by the Ministry of Health, as well as clinical trials. The procedure takes six months on average. Until 1990, the pre-marketing approval process affected only public hospitals. Like private clinics, private hospitals were free to buy any equipment of their choosing.

Since the decree of October 1990, manufacturers have been held responsible for the marketing of any new technology. As a consequence. pre-marketing approval is now required for both public and private medical practice. Only about 70 technologies have in fact been governed by this procedure to date. These are listed on an official decree as "technologies implying a risk for the patient or for the user of the machine."

A National Pre-Marketing Approval Commission advises the Ministry of Health. The 30 members of this commission include 12 representatives from the concerned ministries (e.g., Health, Industry, International Trade, Defense, Consumer Interests, Research) representatives from Social Security, nine representatives of stakeholders (e.g., representatives of public and private hospital associations, industry, insurance companies), and nine individuals personally nominated by the Minister of Health.

Extension of the pre-marketing approval process to private hospitals and local practitioners, combined with the temporary consequences of internal administrative organization, has caused dramatic delays in the system. The National Commission as well as the bureau in charge of the process at the Ministry of Health appeared initially unable to handle the volume of requests, even though less than 10 percent of all technologies were governed by the process. The logistics remain problematic, and manufacturers complain about the costs and delays involved.

Post-Marketing Quality Control

Since July 1986 a post-marketing procedure has been established for medical equipment, aimed at observing the conditions of use and modification of equipment in order to detect any risk, incidents, or accidents and, ultimately, to minimize risks. Users of approved equipment must fill out a form when taking possession of the equipment and whenever an incident occurs or may be foreseen. Inquiries are then held when incidents are reported, with various possible consequences: canceling approval of the equipment either temporarily or permanently; definition of new directions for use, modification of norms, setting up of new trials, etc.

Although theoretically significant, the system is of little practical use. Only about 50 forms were completed in the first year and even fewer thereafter. In 1991 only 19 forms went through the entire procedure, and half were rejected by the National Commission.

ii9 Health Care Planning

As noted earlier, the French health care planning system, based on a national health map, was setup in 1970 (4,28). The system was modified by the 1991 law on hospitalization to consider the qualitative aspects of medical services. In every region the health map quantifies equipment and beds required in the future, as evaluated by "need indexes." In addition, the "regional scheme of health organization" (SROSS), which is defined through an extensive negotiation process, is established in every region and qualitatively describe various common goals for health care and health equipment supply.

Definition of needs is technically very complex. The definition of needs for beds and heavy equipment is the technical base for health care mapping; until 1991, this was the task of the Ministry of Health (though it involved groups of experts at different levels). In its conception, this procedure aimed at stimulating the reorganization and equal distribution of health care facilities and services. It was intended to guarantee the availability of resources for all geographic areas and population groups during a period when facilities were being built and technological innovation was strong.

National bed-to-population ratios for medicine, surgery, and obstetrics, as well as equipment-to-population ratios for some heavy equipment listed in a national decree, were established as reference points (mostly guided by existing capacities in 1973). A reference health map was then drawn that described desirable health care facilities for the entire territory. The document was finalized in 1977 and revised once (in 1980).

In each health sector, the calculation of a needs index makes it possible to ascertain whether health care facilities are adequate. When the needs index shows an excess in existing local capacity, creation of a new facility is deemed legally impossible.

This process has suffered from a lack of expertise and funding. The reference ratios have remained inexact, having taken little account of epidemiologic, demographic, and local characteristics. In the case of diagnostic equipment, such as computed tomography (CT) scanners or magnetic resonance imaging (MRI) equipment, establishing an appropriate reference ratio based on objective assessments or data has been especially difficult. The temptation to politicize the process---either by allowing perceived "needs" to drive the purchase of new equipment or by increasing the size of the population considered in the equipment-to-population ratio in order to restrict equipment capacities—has apparently been a problem. Although the system was designed to guarantee equitable health care across the entire population, other criteria—such as the balance between the public and private sectors, competition with other countries, industrial motivations, or cost containment—have entered into the picture. Moreover, the intended universality of the approach did not in fact come to pass, as authorization processes differed with respect to requests by public versus private hospitals.

Ultimately, it became clear that most of the health sectors were overequipped and that the health map system was operating strictly as a quantitative limitation tool. Not only increases in the number of hospital beds but also the restructuring and reorganizing of existing facilities became impossible. As a result, the law was revised to allow a more evolutionary approach. In 1991 the health map was extended to cover every technology and setting necessary to meet the population needs. For example, same-day care (e.g., at-home hospitalization and ambulatory surgery), costly medical activities, and other activities 'of special importance to public health are now covered by the health map. Moreover, the authorization process is now the same for private and public hospitals. The list of activities and procedures

governed under the agreement system (hence requiring a specific governmental license) includes the following:

- implementation of services (e.g., opening of new departments as well as extensions, reorganizations, or conversions) in one of the basic disciplines, including medicine, surgery, obstetrics, psychiatry, rehabilitation or convalescence care, and long-term care;
- heavy equipment, including extra-corporeal heart-lung machines, hyperbaric chambers, hemodialysis apparatus, blood product separators, centrifuges, cyclotron, nuclear medical devices, CT scanners, digitalized angiography, MRI, radioactive monitoring, lithotripsy, and imaging networks; and
- major care, including organ and bone-marrow transplants, bum treatment, cardiac surgery, neurosurgery, emergency care and trauma centers, intensive care, radiotherapy, nuclear medicine treatment for cancer, neonatal centers, chronic renal failure treatment, reproduction treatment and research centers, and rehabilitation.

The law requires that the Ministry of Health determine national goals for the health system as well as national need indexes for each program and each piece of equipment or group of activities, after being advised by a national committee *(Comite' National de l'Orgunisution Sanitaire et Sociale).* This committee has 40 members, including representatives of the Ministry of Health, two Congressmen, one representative from each type of local assembly, and representatives of the different Social Security funds, public and private hospital unions, various unions of physicians, patients, and health professionals' unions.

Regional mapping is undertaken by regional authorities for each of the 247 "health zones" (which are different from the administrative regions), and SROSS (health and social organization scheme) is designed prospectively for every zone. (Zones are intended to be internally coherent with regard to medical facilities, economic and social activities. geography. transportation facilities, and cultural traits.) Regional committees of representatives work as advisers to the regional directorates; members are comparable to those of the national committee at the regional level. According to the law, the SROSS and health map are designed to fulfill the needs of the population while taking into consideration local disease patterns, demographic trends, improvements in medical technology, and present available supply.

The 1991 law concerning the authorization process has six main characteristics:

- unification of processes for the private and public sectors;
- compatibility of individual authorizations with the goals of the SROSS;
- requests for authorization must include a commitment from the applicant regarding the level of activity involved and future costs to insurance funds;
- permits are given for a limited period of time, and can be revoked;
- regular assessments for all permits; and
- permitting by the regional prefect, with the exception of permits for certain equipment and health care facilities listed by special decree, including extracorporeal heart-lung machines, centrifuges, cyclotrons, nuclear diagnostic equipment, MRI, organ and bone marrow transplants, treatment for serious bums, cardiac surgery, neurosurgery, nuclear treatment for cancer, and reproduction treatment centers.

Permits are issued by the local representative of the government for a period of five years or less. Renewal is subject to the same conditions, including that of evaluation. If fully used by the government, this mechanism might have important consequences for future technology assessment—because evaluation is involved at every stage of the planning process—and for general health care regulation in France. The system remains quite new, however. It is too early to evaluate the future impact of the 1991 law, although it is obvious that a major attempt to rationalize the health care system and to make it more responsive to the needs of

the population has been launched, and an important negotiation process has begun at local levels.

HEALTH CARE TECHNOLOGY ASSESSMENT

Concerns about the quality of health care began appearing in France in the 1970s (21,32). At the same time, efficiency issues became central for the health care financing system due to increases in health care costs. The deficiency of medical technology assessment was stressed by the Minister of Health in 1983. At that time, only the director of the Hospitals of Paris benefited from the advice of a proper, permanent group of experts (the CEDIT) with respect to purchasing and siting new technologies. To plan, set tariffs, and perform quality control responsibilities, neither the Ministry of Health nor the CNAMTS had any means of evaluating medical practice or medical technology; thus, decisionmaking relied mainly on negotiations or arbitrary evaluations. A leading university physician was commissioned by the Minister of Health to investigate ways of implementing a system that would allow for the development of medical technology assessment at the national level. His 1985 report recommended the creation of a multipartner, financially self-sufficient foundation to hold consensus conferences. The report was accepted, and a contract was signed by all the partners for the creation of this foundation. Unfortunately, a change of majority in the Parliament occurred, and the project was canceled by the new government. Nevertheless, in 1987 the government set up an institution called the National Committee for Medical Evaluation in Health Care. This committee involved leading personalities and offlcial representatives of the health care system, but had neither a budget nor an official schedule. Its task was mainly to discuss ethical issues and methods of evaluation in health care and to develop priorities.

In 1989, after the return of a socialist majority in the Parliament, a leader of the continuing medical education association was commissioned by the Minister of Health to undertake another study. His report involved most of the experts in the field of medical technology assessment. It led to the creating a national agency to launch medical technology evaluation as a national project.

The emphasis on technology assessment must be placed in the wider context of the French government's concern about a lack of evaluation of public programs in general during a time of economic difficulties. The need to assess public policies and programs was indicated by several reports as a much-needed goal. Specific bodies, including a National Evaluation Committee *(Comite' National de l'Evaluation)* and a Scientific Board *(Conseil Scientifique de l'Evaluation),* were created close to the Prime Minister, and some grants were allocated for starting evaluation projects. (Fifteen projects have been financed by the National Evaluation Committee, none of them dealing with health policy.)

This concern about evaluating public programs reached its zenith in 1990, when reform of the law on hospitalization was discussed by the Parliament. The new 1991 law finally included not less than 14 articles treating evaluation as a major theme—thus lending medical technology evaluation the status of a legal requirement for every hospital manager and for every health care professional.

This entirely new situation is to be realized through a new set of norms and practices in the health care system. Yet this field must be created, as the law has expressed requirements and goals but has not defined ways and means. The concept of evaluation itself remains undefined and health professionals recognize the need for expert help. Expertise and training are in major demand. Professional training and seminars offered through the National School of Public Health, university courses, use of private experts, and cooperation with public researchers for specific evaluation programs are all growing. The years to come will show if this approach has been successful in building greater expertise into the decisionmaking process.

In 1994, the main bodies involved in health care technology assessments are as follows:

1. the Department of Evaluation of the Hospitals of Paris, which includes the CEDIT, the oldest and the most experienced French technology assessment program, and a new bureau in charge of evaluation of health care;
2. ANDEM, a recently created national agency financed equally by the Ministry of Health and the National Sickness Fund, in charge of developing medical technology evaluation in France, building adequate methods, assessing medical practice, and training students and practitioners; and
3. a group of institutions inside the Ministry of Health or close to it at the national or local level, created by the 1991 law to use the concepts and tools of evaluation as a way of regulating health care.

9 Committee for Evaluation and Diffusion of Medical Technology (CEDIT)

CEDIT is part of the Department of Evaluation of the Hospitals of Paris, which also includes a new bureau in charge of evaluation of health care. CEDIT was established in 1982 as an advisory board for the General Director, mainly to help the Director buy and site new and costly medical technologies.

The General Director, the president of the Medical Council, and any chief physician of a clinical department or hospital director may ask CEDIT to investigate implementation of a new technology. The staff will study the case and present its conclusions to the scientific board, which will make recommendations to the General Director regarding diffusion, placement, financing, and assessment of the technology.

The staff of the committee includes 10 experts from various disciplines. Also involved are physicians trained in economics, a hospital manager, and an engineer. The Scientific Board has 18 members; half are top physicians, and the other half represent hospital managers of the Hospitals of Paris.

Methods of assessment include synthesis of relevant medical literature, consultation with experts, and economic evaluations. Roughly 50 technologies have been investigated by CEDIT the past 10 years (see appendix table 4-1).

In 1991, CEDIT became a branch of the new Department of Health Care Evaluation of the Hospitals of Paris. The other branch of this department is dedicated to the evaluation of health care. Its first missions have included:

- conceiving follow-up tools for topics selected as indicators of malfunction (e.g., waiting time in emergency care departments or for outpatient care; drug delivery; surveillance of falls of patients; surveillance of nosocomial infections; followup of complaints, etc.);
- launching multicenter studies on the quality of health care; and
- cooperating on evaluations of the management of planned and integrated care.

The department also has built a network of medical practitioners specializing in medical evaluation. An assessment of its activities will be carried out after three years.

Agency for the Development of Medical Evaluation (ANDEM)

Generally speaking, ANDEM is in charge of leading any program of technology and health care assessment with an impact on public health (with the exception of pharmaceuticals). ANDEM was established by law in 1989 as a nonprofit, independent association with the following goals:

- to develop internal projects in technology assessment,
- to validate the methods and means of external projects,
- to disseminate the results of assessments, in cooperation with concerned professionals,

TABLE 4-1: Guidelines Issued by CEDIT

Year	Topic
1990	▪ Implantable insulin pumps
	Cochlear implants
	▪ Treatment with intravenous polyvalent immunoglobulins
	• Treatment of prostatic adenoma by hypothermia
1991	• Stereotaxic radiotherapy with gamma rays
	• High-resolution digitalization of angiographic images and reducing use of film
	• The digital system for transmission of digital images
1992	Endovascular treatment of intracranial aneurysms by platinum microcoils
	Measuring the attenuation of ultrasound by bone
	▪ Novacor Phase II
	▪ Chronographic diagnosis of endotoxinemia
1993	• Ventriculocysternostomy under endoscopic control
	• High-speed rotational coronary angioplasty (Rotablator)
	▪ The treatment of tremors by thalamic stimulation
	• Extracorporeal photochemotherapy
	▪ Endovascular hepatic echography
	• Digital echography
	▪ Minitransplants of bone marrow
	▪ Applications of the Charpak wire chamber in radiology

SOURCE C Weill, 1994

- to build a resource center of documentation on French and foreign assessments,
- to build a network of assessment specialists,
- to develop a proper curriculum for the training of medical evaluation specialists, and
- to measure the impact of specific assessments on health professionals and laypeople.

ANDEM is assisted by a scientific council and is supervised by a board of directors. Its budget, originally $US1.5 million in 1990, was raised to $5US million in 1992. (Funds come equally from the Ministry of Health and the CNAMTS.) The agency has a full-time staff of 24 people, mostly physicians, who work with the help of many scientific experts and health professionals. The board of directors (whose chairperson is a civil servant) comprises representatives of the ministries of Health, Education, Research, and Agriculture. Other members are appointed from the CNAMTS, the National Insurance Fund for nonsalaried physicians, and the complementary insurance Fund. The National Committee for Medical Evaluation is also represented. Scientific council members (18 in total) are commissioned by the Minister of Health and are nominated personally on the basis of their expertise.

Topics for assessment may be suggested to ANDEM by the board of directors, the scientific council, or any other partner or professional group. Selecting and launching an assessment requires the consultation of the scientific council and the board of directors. ANDEM has produced syntheses of scientific knowledge on various technologies and a booklet on the methodology of consensus conferences. Its resource center for documentation has become very efficient. Many expert teams are working in parallel on diverse fields and topics. A network is being built that connects private office practitioners interested in medical evaluation. This network develops methods and research studies in collaboration with university experts. A guide to the methodology of technology assessment is being prepared for publication.

The topics and technologies studied by ANDEM are shown in table 4-2.

TABLE 4-2: Topics and Technologies Studied by ANDEM

Year	Topic
1 990/91	▪ Prevention of hepatitis C
	▪ Heat treatment of prostatic adenoma
	▪ Osteodensitometry
	▪ Screening blood with p24 antigen to reduce transfusion-related AIDS
1992	▪ Pre-operative routine testing
	▪ Bone marrow transplants
	▪ Blood transfusions
	▪ Lasers in ophthalmology
	▪ Vascular angioplasty
	▪ Dental implants
	▪ Fetal telemonitoring
1993	▪ Oral Implants
	▪ Bone marrow transplants
	▪ Endoluminal revascularization of lower limb arteries
	▪ Digestive echoendoscopy
	▪ Gynecologic laparoscopy

SOURCE C Weill, 1994

Consensus conferences have always been a major ANDEM concern. A 1985 attempt to create a federal foundation to promote a national program of consensus conferences was unsuccessful. Nevertheless, the concept of such conferences quickly created interest among various specialist societies and public health professionals. Many such conferences have been held in France with many different sponsors, such as scientific associations, the National Sickness Fund, the Complementary Insurance Fund, hospital physicians, and so forth. "Consensus conferences" came to refer to any grouping of experts expressing a common point of view, regardless of their methodologies. This resulted in some confusion between scientific consensus based on a proper methodology and other types of consensus. Taking as one of its priorities the need for clearer definitions and guidelines, in its first year ANDEM published a guidebook used for validating consensus conferences. It has also helped organize (and has assisted financially) a limited number of conferences each year, selected by the scientific council. ANDEM participates by collecting scientific references, defining major issues or questions referred to the consensus panel, disseminating recommendations, and assessing relevant medical practices and the impacts of conferences. It can also work as an advisor, or review various methodological aspects of the process. In 1991, 1992, and 1993, ANDEM was involved in eight consensus conferences, and it has allowed its name to be used in connection with eight others (see table 4-3).

In parallel, ANDEM, together with concerned professionals, has begun working on developing clinical practice guidelines. So far, three have been completed. At the beginning of 1994, the ANDEM was asked by CNAMTS and the Ministry of Health to validate the "medical references" in the context of the national agreement with private practitioners' representatives—a task assumed by the organization's scientific board.

The 1991 Law on Hospitalization

The new law is based on the need for evaluation, respect for patients' rights, and the concept of universal health care. Evaluation, an important yet undefined concept, has become through this law a leading channel for health care regulation, management, and planning in France. New institutions have been set up to implement evaluation methods in health care management at various levels: regional evaluation committees and an evaluation bureau in the Department of Hospitalization of the Ministry of Health.

Regional Committees for Medical Evacuation of Hospitals (CREMES)

The 1991 law requires all public and private hospitals, "in order to deliver quality care," to evaluate its activity. This mandate includes evaluation of medical practices, hospital management, nursing care, and "any activity aiming at providing patients with total care particularly in order to guarantee its quality and efficiency."

This new requirement is monitored at the administrative regional level. The CREMES established by law as methodological resources, advise local authorities on:

TABLE 4-3: Consensus Conferences: ANDEM

Year	Topic
	Direct involvement of ANDEM
1991	▪ Medicalizing the menopause
	▪ Urinary lithasis. therapeutic strategies
1992	▪ Monitoring the extension of non-small-cell bronchial cancer
	▪ Prophylaxis of endocardial infections
1993	▪ Diagnosis, prognosis, treatment and surveillance of polyglobulinemia
	• Indications for hepatic transplant
	• Use of red blood cells to compensate for blood loss during adult surgery
1994	▪ Long-term therapeutic strategies for schizophrenia
	Methodology endorsed by ANDEM
1991	▪ Stopping mechanical ventilation in the adult patient
	▪ Dealing with infertility For whom? How? For what results?
	• Selective digestive decontamination during resuscitation
1992	▪ Evaluation of adult ventricular function at the sick bed
	▪ Digestive cleaning during severe intoxication
1993	▪ Sedation and resucitation, concept and practice
	▪ Sexually transmissible disease in the woman, the mother, and the child
	• Predicting outcome in ICU patients

SOURCE C Weill, 1994

medical and technical implications of the planning process;
- methods and results of medical evaluations of hospital management, technologies, and practices in health care; and
- "any question concerning medical evaluation and databases run by public and private hospitals."

These committees have not been set up as permanent organizations. They do not have autonomous agendas, permanent staff, or means of operating routinely. According to the law, CREMES intervene only if requested by the prefect or the hospitals; they are not supposed to develop independent projects. Thus, their efficacy in disseminating proper technology assessment methodologies is unpredictable.

Each CREME comprises 11 members nominated by the local government representative (i.e., the prefect) "according to their expertise in the field of medical evaluation and technology assessment." CREME members must include two hospital practitioners (one of them from a university hospital), one physician from a private clinic, one matron, one public hospital director, one biomedical engineer, and two other individuals commissioned in consultation with ANDEM. CREMEs are not legally coordinated at the national level (although such coordination could in theory be provided by the Ministry of Health to bring about coherence in methods and projects). A National College of Experts has, however, been set up for national issues concerning health care evaluations. In this context, the law has given a more official role to ANDEM, which has a legal mandate to validate evaluation methods in the planning process.

ANDEM is thus the methodological support of the entire system, but its tasks are huge, and it is hard to predict if and how this system will actually work. As it stands, each CREME is trying to find its own way toward fulfilling an imprecise mission; no specific resources, human or financial, have been dedicated to this task. Moreover, CREME members are typically local representatives rather than experts in evaluation. Their activity appears to be legally dependent on other local institutions, as the CREMEs have to be asked by these groups to work with them.

Evaluation Bureau of the Department of Hospitals

To implement the 1991 law, a new bureau was created as part of the Branch of Planning of the Ministry of Health under the Hospitals Department. This bureau has a large assignment but limited staff, with one public health physician as a permanent member of the team. The bureau is in

charge of defining "adequate and acceptable methods" for the following:

- evaluating health care organizations policies with reference to public health goals (to be defined by the National Committee of Public Health in concert with the Minister);
- assessing the health care system performance prior to planning at various levels: local, regional, inter-regional, and national;
- stimulating the hospitals to set up programs for quality assurance with the help of assessment specialists (partly through the definition of guidelines).

In June 1993 another bureau dedicated to health care evaluation was created in the Ministry of Health under the general director of Public Health. This bureau is in charge of defining the goals of a policy of evaluation of medical practice. The staff is now working on developing its first projects.

Other Activities

With the new law, a wide field of activity has now opened for experts. Several groups including researchers, clinical physicians, medical-school public health departments, and private consultants compete for evaluation markets.

The *Researchers*

INSERM, the French national research institute specializing in biomedical and public health research, established in 1990 a special (but temporary) multidisciplinary committee to undertake research in health care prevention and evaluation. This committee may provide grants and contracts, using research funding or with the financial support of the National Sickness Fund. Epidemiologists, economists, and social scientists are involved more than ever before in evaluation projects. A new research unit dedicated to health care economics has been created in Paris and another unit that evaluates innovation and technologies has been created in Marseille. The National School of Public Health, until now dedicated chiefly to management and legal topics, has begun developing research activities in hospital management and economics, and the quality of health care assessment.

Physicians

The French Society for Evaluation in Health Care and Technology Assessment (SOFESTEC) was created in 1986 as a French version of the International Society for Quality Assurance. Its main goal is to gather experts in the field from various institutions to disseminate the methods and results of both French and foreign assessments.

Private Consultants

A number of private consulting companies (especially audit firms) have "applied physicians" trained in economics, statistics, or informatics and have set up specialized departments for health care and hospital management evacuation. They establish databases, audit hospitals, and report on medical projects for establishments made legal by the 1991 law.

Two consulting firms are of special interest: the Centre National de l'Equipement Hospitalier (CNEH) and SANESCO. CNEH was until 1990a semi-public organization with governmental duties in the field of medical informatics and technology assessment. It has now become an independent, private association whose main clients are the Ministry of Health and public hospitals. SANESCO was created in 1989 by the former director of the Hospitalization Department of the Ministry of Health. Its activities cover technology assessment, databases, auditing, and prospective studies. SANESCO also handles logistics for consensus conferences run by the main complementary insurance Fund *(Mutualite Francaise).*

The Departments of Public Health of the Medical Schools

Departments in various universities are now creating courses in evaluation. More physicians are now trained in such subjects as informatics, statistics, and economics, and they are obtaining postgraduate degrees in health care evaluation. At the same time, hospital informatics and statistics departments have started developing quality-of-care assessment projects in connection with clini-

cians. It appears that the level of expertise in evaluation methods will increase rapidly in the health care system.

CNAMTS Medical Board

The medical officers of the National Sickness Fund (CNAMTS) are now working to change traditionally control-oriented activities and to develop evaluation projects based on the construction of a medico-economic database. In 1992 the medical board of CNAMTS carried out a huge survey of obstetrics; future possible projects include a comprehensive study of anesthesia. In September 1993 CNAMTS started working on the establishment of reference protocols (re'fe'-*rences me'dicales)* in the context of the annual agreement with physicians' representatives. This project includes reviews of published scientific literature and negotiations with medical representatives.

It is not easy to evaluate the future developments and impacts of this type of activity for CNAMTS. This body has been extensively criticized in the past for its preference for control rather than evaluation methods. Considering the importance of this group of public health physicians in the management of health care in France, it will be very interesting to see if it can adapt to new conditions.

Case studies[1]

TREATMENTS FOR CORONARY ARTERY DISEASE

A national survey carried out by the National Society of Cardiologists, published in 1991, along with a report to the Ministry of Health by the General Inspectorate of Social Affairs *(Inspection G'e-ne'rale des Affaires Sociales* or IGAS) in 1988, provide an assessment of the diffusion of coronary artery bypass grafting (CABG), percutaneous transluminal coronary angioplasty (PTCA), and other methods (20). Some of the data, especially in the IGAS report, are now as old as 1986, and only some can be updated using the 1990 census of the Ministry of Health. Anew survey by the National Society of Cardiologists and a CNAMTS study were carried out in 1992 and 1993, respectively. These studies are part of the negotiation process for new pricing of cardiology procedures, however, and their results are not available to the public.

PTCA was introduced into France in 1978, but not fully developed until after 1983, when the guided coaxial system was introduced. PTCA diffused first in teaching hospitals and then mostly in the private sector, which now appears very active, despite general dissatisfaction with rate of payment for PTCA. Media coverage was considerable, and patients immediately demanded this technique-as they still do.

The 1988 IGAS report noted the following:

> The treatment of coronary artery diseases has benefited greatly due to the improvement of drug treatments, of heart-lung machines, of improvements in surgical strategies and, above all, of the introduction of PTCA. Treatment using beta-blockers and calcium inhibitors has now been improved and is better mastered. Intensive care through the veins allows for a better response from the patient. Emergency revascularization surgery in the different stages of

[1] The case studies, with the exception of the one on neonatal intensive care, are based on previously published literature. As a result, some of the information may be outdated. More recent data were unavailable when this report was prepared.

> unstable angina does not exist any more. Now, surgery is in most cases postponed for scheduled surgery, and takes advantage of the possibility of using a membrane oxygenator for extracorporal blood circulation. ... before, coronary investigations were restricted by the fear of possible incidents with no other possible conclusion than surgery. Today, PTCA offers a possible treatment to patients over 70, chronically ill patients, or younger adults with an early diagnosis of coronary stenosis.

As a result, the patient population for PTCA has increased amatically, including older anc sicker patients. In addition, coronary artery surgery rates have increased, as has the mortality rate after bypass surgery (from 1.5 to 2 percent in 1970 to 4-6 percent in 1987). The existing studies show that the development of PTCA in particular has led to more angiographic investigations and to major qualitative changes in cardiac surgery. Thus, rather than substitution of a new procedure for an old one, cardiac surgery has been extended (33).

A Ministry of Health census established that in 1990, there were 73 authorized cardiac surgery units, 49 in public hospitals and 24 in private clinics. The growth in these units is significant; there were 44 units in 1979 and 63 in 1987. In 1990, the total number of centers perforn ng PTCA was estimated at 145 and included 55 private centers, which revealed a number of PTCA centers outside cardiovascular surgery units. Hospitals in the south, southwest, and Paris regions are overequipped, whereas those in the west and north appear underequipped.

In 1986, 27,000 cardiac surgeries were performed; of these, 24,334 involved extracorporal blood circulation (EBC) and about half of these (1 1,675) were coronary artery surgeries. In 1990, according to the Ministry of Health census, 32,702 EBC procedures were performed, an increase of 30 percent.

According to the Society of Cardiologists, about 20,000 PTCAS were carried out in France in 1990, and 30,000 were performed in 1991. Half were carried out in the private sector. The procedure is now available to all potential patients. apparently with no waiting list in most regions. PTCA has replaced conventional bypass surgery in about half of all cases, but the expansion of indications for the conventional procedure has led to the general extension of cardiac surgery.

The indications for PTCA have expanded since 1980. Coronary artery dilatation was initially restricted to single, noncalcified proximal lesions but is now performed in multiarterial lesions, arterial bifurcations, tandem or distal stenoses, and stenotic bypasses. PTCA also may be offered by some operators for the elderly or children, but there is no complete consensus in France on these patients.

Today, PTCA is considered established; various techniques are available, the "gold standard" being the balloon. PTCA with the balloon is a perfected technique, involving tools considered completely reliable. After five years, the results for single-lesions PTCA are the same as those for conventional surgery.

Concerns with the Technology

A high restenosis rate with PTCA remains a problem. Researchers are now investigating the possibility of finding drugs to treat cell proliferation. They are also working to develop intercoronary support springs, rotary probes to dislodge atheroma plaque, and laser treatment (2).

In 1987, according to IGAS, eight out of 56 surveyed centers had performed more than 30 percent of the total PTCAS in France. More recently, a higher level of dissemination has been observed in smaller centers and in institutions with no in-house cardiovascular surgery, which has been considered problematic. This points up the fact that as the technique is developed, the concept of "surgical cover" has become followed less rig idly.

Government Policy

Cardiac surgery units are subject to authorization by the Ministry of Health, whose policy implies that every university hospital must have one such department. Moreover, EBC machines are considered heavy equipment requiring ministerial authorization.

The needs index for cardiac surgery identifies the need as one department for every 850,000 inhabitants. However, PTCA is freely diffused, with no government license or specific price setting. In particular, there has been no administrative requirement or control to limit PTCA to, or close to, cardiac surgery units. Setting global policy vis-a-vis cardiac surgery is not straightforward. Today, the pricing of PTCA appears problematic; providers believe that the actual price does not take in account the real cost of the procedure. Negotiations between cardiologists and the Ministry of Health have been difficult during a time when cost containment receives top priority.

MEDICAL IMAGING (CT AND MRI)

Regulation

Acquisition of CT and MRI scanners, which are classified as heavy equipment, is dependent entirely on authorization from the Ministry of Health or its local representatives. Need for these devices is evaluated on the basis of an equipment-to-population ratio; if there appears to be no need in a given area, then no hospital in that area, either public or private, can buy such equipment.

Under the 1991 law, the need for CT scanners is evaluated locally, whereas for MRI scanners, it is evaluated nationally (24)—probably because of the high cost of MRI, which means that government financial support is required to purchase MRI equipment. Many experts have stressed that this situation will pose a major obstacle in the event that a particular region seeks to develop a coherent policy for medical imaging.

There are no data on the numbers of CT and MRI scanners in place in France, but only on the numbers authorized, which may not reflect the actual situation. For example, the purchase of a scanner may have been authorized, yet for some reason the purchase was never made. It also is possible (even though this would be hard to prove) that some machines that should be replaced by a new, approved one are being kept in use by hospitals.

Needs for and Distribution of CT and MRI Scanners

According to the first needs index for CT scanners, one machine was needed for every million inhabitants. At that time, the ratio was 1:250,000 in the United States and 1:450,000 in West Germany. A modified needs index was published in 1981 allowing one machine per 600,000 to 900,000 inhabitants.

Between 1976 and 1981 the main goal of the Ministry of Health was to delay the introduction of foreign CT scanners in France. In fact, the *Compagnie Francaise de Radiologie* (CRG) was working on a prototype French CT scanner. In 1976 and 1977 CRG distributed two cranial scanners, but the company underestimated the demand for CT scanners. The French total body scanner was ready for marketing only in 1981, which is when the needs index was modified allowing more equipment (15).

The distribution of CT scanners accelerated through annual public programs after 1984, including subsidies from the government to public hospitals for their purchase. By 1987a new needs index allowed one machine for every 140,000 to 250,000 inhabitants. By 1992, the authorized ratio was 1: 122,000. Since the introduction of CT scanning technology in France in 1976, 476 licenses have been granted: 63 percent to public hospitals, 9 percent to nonprofit hospitals, and 28 percent to private for-profit clinics. As a result, France has now attained the population to machine ratio of other European countries.

The national (authorized) stock of MRI equipment in 1989 was of one for every 850,000 inhabitants, which represented the sixth-highest density among the industrialized countries. Sixty-six new imagers were authorized between 1983 and 1989, 74 percent to the public sector. This shows an accelerating trend, confirmed by the current number of authorizations (103, or one MRI for an average population of 564,000 inhabitants).

Since 1984, CT scanning has become accessible to the entire French population without waiting. Every teaching hospital has been equipped

with MRI. Remaining disparities among regions reflect no more than existing disparities in the numbers of hospital beds and of other equipment in the different regions. The Centre and Pays de la Loire regions have been for a long time the least equipped with regard to CT scanners: one machine for every 188,000 people in the Centre region and one for every 225,000 in the Pays de Loire. For MRI, the Centre region has one machine for every 2,264,000 inhabitants; Picardie has one machine for every 1,740,000. Conversely, the Ile de France, Provence-Alpes-Cote-d' Azur, and Midi-Pyrenees regions are the best equipped in terms of MRI and CT scanners, as well as all other facilities. These are also the regions where the equipment rates at private, for-profit facilities are the highest.

The private for-profit sector's equipment rates (for CT and MRI scanners) appeared after 1986 to be somewhat higher than this sector's level of hospital beds. Indeed, 70 percent of the licenses given after 1986 for CT scanners and 42 percent of those for MRI were for facilities in the private for-profit sector. Recently, traditional private x-ray centers have begun to transform into autonomous diagnostic centers. This may now be the case for one-quarter of those centers that own CT scanners.

The private sector can take advantage of easier loan conditions (private hospitals do not have to wait for government agreement) as well as the fee-for-service pricing system, which allows for quicker profitability. Generally, the greater flexibility of the private sector has become evident since the 1980s, especially regarding adoption of new technology. Moreover, after 10 years of cost containment, the public sector suffers from an increasing lack of skilled medical imaging professionals.

Concerns with the Technologies

Even if knowledge of medical imaging activity remains incomplete, most experts feel that use of imaging is excessive in France (16). According to the Ministry of Health, in the mid- 1980s the private for-profit sector performed 8.500 scans per year, as opposed to 4,350 yearly in the public sector. According to the INSERM survey, the private sector in the Provence-Alpes-Cote d'Azur region performs more than 10,000 scans per year. A CNAMTS survey of one day of imaging activity has shown that the private sector, which owns 28 percent of all CT scanners in France, performs 33.5 percent of the procedures. (The reimbursement rate for the procedure was considered too profitable and was revised downward.)

Medical imaging activity in the public sector has also increased greatly over the past decade. At facilities of the Hospitals of Paris, the total number of radiological procedures (key letter Z) increased 13.7 percent between 1982 and 1988, while payments for these services increased 21 percent. Use of each Hospitals of Paris scanner increased 18.5 percent per year between 1985 and 1988; at the same time the number of machines increased from 10 to 17. Some experts have raised the possibility of inappropriate use.

New need indexes published in February 1993 greatly increased the allowable number of CT scanners and MRI in France. After years of restriction (due mostly to the cost containment priority), this step was taken after intensive negotiations among the Ministry of Health, CNAMTS, equipment makers, and hospitals. The date of the decision, very close to the elections of May 1993, can be interpreted as a sign that political rather than health goals were key.

For CT scanners, the new need index authorizes one machine per 110,000 persons in each health sector, plus one machine for every 1,500 university hospital acute beds. As a result, 72 new CT scanners could be purchased in the years to come, thereby allowing under-equipped regions to reach the levels of the others (which, with the saturated needs index, cannot acquire any new equipment).

Ten regions are now fully equipped for MRI, but others are waiting for machines. The February 1993 needs index authorizes one MRI for every 600,000 inhabitants, which would allow 18 new imagers.

Government Policy

The policy of the Ministry of Health concerning CT scanners and MRI has been characterized by a desire for a rather slow diffusion for several reasons: 1) the technical complexity of defining needs for diagnostic equipment; 2) the long-range cost implications; and 3) the duration of the learning curve. The desire to promote French industry was involved, too, in choices to distribute CT scanners between 1976 and 1981. The rather slow equipping of French hospitals was harshly criticized by professionals and the media. Waiting lists in France were very long, and the more fortunate patients were for a time sent to foreign hospitals, especially in Belgium or Switzerland. It was seemingly very difficult for France to maintain a level of equipment that was notably inferior to the level of its nearest European neighborsven if at that time the French government could legitimately deem the technology not yet fully assessed. Indeed, this situation illustrates one of the limits of an independent national approach to the diffusion of medical technology. Although currently the number and distribution of CT scanners is considered quantitatively satisfactory and possibly overused, medical professionals emphasize that the quality of the French equipment maybe poor and en route to obsolescence.

LAPAROSCOPIC SURGERY

The leading role of French physicians in the major innovative field of coelioscopy (laparoscopy) is well known in scientific and clinical communities, and is a source of national pride (33). The first pelvic coelioscopy was attempted in 1943 by Dr. Raoul Palmer in Paris. In 1973, Professor Bruhat of the teaching hospital of Clermont-Ferrand carried out the first treatment of an abscess of the fallopian tubes through a coelioscope. The same year, Bruhat performed the first coelioscopy for the treatment of an extra-uterine (ectopic) pregnancy. The first treatment of an ovarian cyst was published by Bruhat in 1976.

In 1980 the first appendectomy using a laparoscope was carried out successfully in Germany. The "French first" was performed in Lyon in 1983 in the private Clinique de la Sauvegarde. In 1981 Professor Bruhat was the first to attempt use of a laser in coelioscopic gynecological surgery.

Arthroscopy, a technique imported to France in 1969 remained unusual for many years and was carried out only by rheumatologists. Orthopedic surgeons gradually adopted the technique from 1980 on, and it became widely available (especially in the private sector) after 1986. In 1987, a French doctor carried out the first cholecystectomy through a laparoscope, and the first hyperselective vagotomy for duodenal ulceration was carried out by Professor Dubois at the Clinique de la Porte de Choisy in Paris in 1989.

Coelioscopy in Gynecology

The diffusion of this technique was stimulated by Professor Bruhat and his medical team at the teaching hospital of Clermont-Ferrand (17,19). Numerous international symposia were held there, as was the World Congress of Gynecological Coelioscopy in 1989. Clermont-Ferrand took the lead as a training center, with the creation of a European certificate and an international training center for endoscopic surgery. According to the equipment manufacturers, virtually all public and private gynecologists, whether or not they are surgeons, are now equipped with endoscopes. Forty percent are said to undertake surgical laparoscopy.

Gynecological laparoscopic surgery was studied between January 1987 and December 1991 by seven leading French centers (30). The 17,521 procedures followed fall into three categories of celioscopy:

1. "traditional coelioscopy," which includes the current indications: diagnostic; and "minor laparoscopic surgery" such as minor adhesiolyses, destruction of first-stage endometriosis, biopsies and treatment of ovarian cysts, tubal sterilization, and reproduction treatment;
2. "major laparoscopic surgery," which includes procedures that have become "classical:" major adhesiolyses, destruction of ovarian cysts, and treatment of extra-uterine pregnancy; and
3. "advanced laparoscopic surgery," which defines a field of new procedures: including hys-

terectomy, myomectomy, ovariectomy, treatment of prolapsus, cure of incontinence, and pelvic and para-pelvic ganglion curettage. (This is the field of "research and future possibility for practice.")

Activity inlaparoscopic surgery has increased in the seven centers studied; 52.5 percent of the 17,521 procedures studied were performedduring the three first years of thesurvey, and 47.5 percent during the last two years. Advanced surgery accounts for most of this increase,comprising 1 percent of the indications in 1989 and 10 percent in December 1991. The rate of incidents leading to an emergency laparotomy was 3.25 per thousand (1.7 for diagnostic procedures and 5.3 for surgery). One death occurred during the five years of the survey.

No administrative obstacle has either hindered or promoted dissemination of the technique, which has taken place in departments already equipped for diagnostic coelioscopy. There has been no specific reimbursement rate for performing a coelioscopy rather than classical surgery; the financial scaling incorporates no incentive to carry out one procedure over another.

According to the experts, a small proportion of coelioscopic surgery may be performed in ambulatory care facilities, but there are many obstacles with respect to the internal organization of hospitals, and CNAMTS as well as the Ministry of Health appear to be reluctant to endorse this practice. They fear that it would result in more procedures with possibly debatable indications and increasing costs, rather than leading to a substitution of practice.

In the past, gynecological laparoscopic surgery faced strong hostility from cancer treatment centers and from many academics. The method was denigrated as a "blind" procedure that could not provide gynecologists with a proper pelvic and histological assessment. Recently, however, coelioscopic surgery in gynecology has become quite fashionable. More surgeons came to this technique after the diffusion of the laparoscopic cholecystectomy technique. French gynecology is therefore entering a new learning phase that, according to observers, may result in increased surgical risk (although no figures are available to support this observation).

Laparoscopic surgery in gynecology is a field of ongoing diffusion. Its indications are increasing, and there is strong acceptance by patients. With "advanced laparoscopic surgery," a new area has now opened, following the developments of digestive laparoscopic surgery. This has fueled a need for risk-benefit evaluations.

Digestive Laparoscopic Surgery

This technology (6,33) has been strikingly quick to spread and has also been the subject of a major media campaign. (Some media have even called for'' the end of surgery.") *The American Journal of Surgery* has called the spread of this technique the "second French revolution" (9). Interestingly, laparoscopic surgery did not appear first in university hospitals but in two private clinics in Paris (11).

According to digestive surgeons, laparoscopic cholecystectomy is a consumer-driven technology; some patients are now refusing the classical invasive procedure. The competition between digestive surgeons and gastro-enterologists has also played an important role: digestive surgeons may regain some of the patients who are drawn toward physicians because of new drug therapies and, to a certain extent, lithotripsy.

Laparoscopic appendectomy was first performed in France in 1983. Although this procedure is considered efficient, its diffusion remains rather slow. The classical procedure is considered satisfactory by both surgeons and patients.

A 1992 unpublished survey exhaustively described the practice of laparoscopic digestive surgery (6). Two-thirds of the relevant facilities in the public sector and three-quarters in the private sector now perform laparoscopic surgery. The Hospitals of Paris appeared to be slightly behind; in public hospitals, diffusion of the technique appears greater in university hospitals than in others. Diffusion occurred particularly early in private for-profit hospitals, and the smallest of these were the pioneers; nevertheless, only 55 percent performed coelioscopies by the end of 1992. The

public sector reached the same level of **activity as** the private sector in late 1989. The public sector nonetheless proved less dynamic, and the lead continues to be held by the private sector.

In January 1992 laparoscopic surgery in the public sector accounted for 53 percent of the total number of cholecystectomies, with a higher concentration in the university hospitals compared to other public hospitals. A tendency to expand referrals toward treatment of asymptomatic stones was noticeable. (In December 1991, a European consensus conference stated that cholecystectomy is not justified in the absence of specific symptoms.)

By the end 1992, 79 percent of the digestive surgeons in public hospitals had performed laparoscopic surgery; in one-quarter of the departments, residents could be trained on a routine basis. Thirty-two percent of the nonuniversity and 46 percent of the university ones were involved in some trial or register. Seven ongoing studies were registered by the survey.

In university hospitals, 35 percent of the departments perform laparoscopic appendectomy; 46 percent treat perforating ulcers; 32 percent treat hiatal hernias; 27 percent perform abdominal vagotomy; and 23 percent perform colectomies (at least once).

Concerns with the Technology

For hospitals, the diffusion of laparoscopic surgery creates significant problems because of new working conditions (6,33). Patients' stay in the intensive care units is shorter, but the entire stay is more costly because it involves more procedures. The large patient turnover creates a burdensome task for the personnel. Moreover, the equipment is delicate and carries high maintenance costs. Finally, defining indications, evaluating procedural risks, and training operating personnel are major challenges with this technology.

The economic advantages of the technology for French society at large are linked to the simplicity of post-operative sequelae, the reduction in hospitalization time, and the more rapid recovery of activity experienced by patients. However, these benefits are arguably more theoretical than real. There has been a noticeable increase in tests prior to actual operations, especially in the areas of cholangiography and ultrasound endoscopy, which are especially invasive and costly. The widening of the indications for cholecystectomy is also a source of increased costs.

Since 1990, laparoscopic cholecystectomies have been registered by the French Society of Digestive Surgery. Of 1,200 procedures reported during one year by 67 surgeons, the figures show that 8 percent of patients had peri-operative cholangiographies, 8 percent had laparotomies, 6 percent had post-operative complications, 2 percent had early re operations, and 0.1 percent died (14). As in gynecology, the method has been diffused freely without administrative controls or pricing processes. There were no financial limits, either, as the endoscope is moderately priced, and can be easily borrowed by digestive surgeons from gynecologists (or even from manufacturers). Moreover, the equipment has not been subject to pre-marketing approval. In less than two years, laparoscopic cholecystectomy has become a standard technique. Nevertheless, concerns have been raised about the quality of the training of surgeons performing coelioscopies; many surgeons learn while actually performing the operation.

In 1993 CNAMTS asked ANDEM to study the risk-benefit ratios of coelioscopy, both in gynecology and in digestive surgery, to help define proper pricing for the procedures. This assessment is ongoing.

TREATMENTS FOR END-STAGE RENAL DISEASE (ESRD)

Since 1990, a national register has been maintained by the National Society of Nephrology with the support of the Ministry of Health. This register extended to all of France for the first time in 1991, and comprises more than 20,000 patients treated either by dialysis or by renal transplant. Of the 240 existing facilities that provide the treatment, 210 have reported information on their patients.

Fifty-nine percent of ESRD patients are male and 41 percent are female. Thirty-two percent of

the patients were living with a functional transplant, 56 percent had been treated by he modialysis at a center or by auto dialysis, 7 percent by hemodialysis at home, and 6 percent by peritoneal dialysis. Nearly 40 percent of all patients are retirees; 20 percent are disabled, 20 percent are jobless and on welfare, 8 percent have full-time jobs, and 4 percent have part-time work. Statistics indicate an aging population in this program.

The prevalence of patients treated for chronic renal failure at the end of 1991 was 355 per million inhabitants; 46 new patients per million inhabitants were treated for the first time. Glomerulonephritis now represents 25 percent of all of ESRD; renal polycystic disease, 10 percent; and diabetic renal disease, 7 percent.

"Chronic nephropathy and the pure primitive nephropathic syndrome" as well as "post-transplant surveillance" are on the list of ailments said to be "long-term afflictions" for which care is 100 percent reimbursed by the National Sickness Fund. Moreover, a sick individual can benefit from state welfare revenues if his or her physical status leaves him or her unemployable.

Renal Dialysis

The first French renal experiments date from September 1960. These first trial experiments took place in high-technology hospitals. The first experiments in at-home dialysis were carried out in 1967 in Lyon. The placement and maintenance of patients in their homes proved more difficult; thus, at the beginning of the 1980s, auto-dialysis was developed for autonomous patients aided by nurses. As at home, with this technique patients are responsible for maintaining their own personal material. This formula rapidly developed, and the number of patients quickly increased from 760 in 1985 to 2,374 in 1990 (10,34). In 1991 around 4,300 new patients (77 per million inhabitants) were cared for using the entire gamut of available techniques; about half were treated outside of centers.

Renal dialysis equipment requires authorization from the Ministry of Health. Theoretical needs were established in 1984 at 40 to 45 stations per million inhabitants. However, the rules have never clearly fixed actual limits on the zones of the health map, nor has dialysis outside a center been considered. Also not considered is the technical evolution of handling patients (e.g., the wider diffusion of renal transplants due to the use of cyclosporine). In the technical arena, moreover, nothing determines the working rules of the public sector nor of dialysis outside the established centers. As a result, the rules today appear to be singularly obsolete, making any attempt at global policy inefficient. Experts are calling for their modification.

The current state of dialysis in centers is virtually unknown. No precise inventory has been made of this practice or of patients in residence; an official census exists only for public establishments. In 1989 there were 116 public centers at which 937,770 dialysis sessions took place (for 6,011 full-time patients). The situation in the private sector is even less well known. The number of patients using private establishments is around **9,000** (10,34).

Renal Transplant

Renal transplants were successfully performed in France in 1951; a year later, the first renal transplant involving a living donor was performed at Necker Hospital in Paris (5,7). French doctors continued to be pioneers in this domain: a successful transplant operation was performed on identical twins in 1955, and attempts made with related nontwin donors multiplied until 1970. Transplants were then practiced by means of initial grafting, with organs taken from subjects in a state of brain death; between 1970 and 1986, approximately 13,000 renal grafts were performed. By 1980, France was fifth in Europe with regard to the number of grafts accomplished, having slowed somewhat in its advances with this technology.

As of 1984, the use of the immunosuppressive drug cyclosporine (undertaken in France as early as 1981 and diffused by 1984 to all clinical research teams) prompted considerable progress. Increased activity and interest were supported by specifically y defined concessions provided by pub-

lic budgetary allocations for transplants (as of 1986). Surgery and followup care benefits of 100 percent were provided by the Sickness Fund. Studies have established the cost of this surgery in France at between $US3,515 and $US3,630, and the cost of the followup care for an individual between $US6, 150 and $US9,000, depending on the hospital and region (28).

Between 1977 and 1983, the number of medico-surgical groups practicing transplants (for all organs) remained at about 35 teams. However, after the diffusion of cyclosporine and the allocation of public funding, this number rose. There were 44 teams in 1984 and 104 in 1988. Simultaneously, the steadily improving rise in the numbers of grafts performed was remarkable within every category of transplant. Between 1984 and 1988, 1,808 renal transplants were performed.

To match donors and recipients, French transplant surgeons have created an interesting organization (13). *France Transplant is* a nonprofit association founded in 1969 to:

) Develop the deduced organs by their number and quality; [promote] the use of all those available; promote and coordinate the extraction of multiple organs; 2) . . . perfect the necessary skill of extraction of all the various organs; [and] 3) Organize the distribution of the organs according to ethical and scientific norms, as well as the modes of distribution proper to each organ on the local, regional and national level.

This association cooperates with teams receiving authorization to perform transplants as well as with histocompatibility laboratories. The association functions in a decentralized manner in seven regions, each of which has a coordinator who informs both professionals and the public at large of the need for organs and designates local coordinators.

The power of *France* Transplant remains, however, limited. When an organ is removed from a subject in a state of brain death, only one kidney is furnished to the association; the other is assigned to the team that has removed it. *France Transplant,* unlike UNOS (its American equivalent), does not have the legal right to claim the second kidney. Moreover, some teams have felt that the system has favored the major Parisian teams. This has led to discord between the medical groups and to the creation of regional independent associations *(Paris-Transplant and Rhone-Mediterra - nean Transplant).*

The rate of renal transplants remained at about 35 per million inhabitants from 1989 to 1991. Waiting lists are lengthening; an estimated 4,886 patients were waiting in 1991. (Average waiting time is estimated at three years.) Long waiting lists are the result of several factors, including reduced numbers of transplantable organs because of a reduction in road accident traumas; a seeming recent reluctance on the part of the French people with regard to donating organs; and more restrictive ethical rules resulting from various donation scandals reported by the press.

Erythropoietin (EPO)

No French company produces EPO, which first became available in France in January 1989. After its introduction, public authorities, considering EPO too costly, sought to restrain its use (the annual cost per dialyzed individual is as high as the minimum legal income). Nephrologists protested publicly, as did those doing transplants; and the public authorities ended up overturning previous restrictions.

According to the national register of chronic renal failure, EPO was used at the end of 1991 in 38 percent of patients treated by hemodialysis in centers or by autodialysis. There are important regional variations, with more than 45 percent of patients benefiting from EPO in Ile de France and Aquitaine, as opposed to 16 percent in Rhone-Alps. EPO seems to be markedly less frequently used for patients having peritoneal dialysis (only 22 percent).

Government Policy

The Ministry of Health is responsible for guaranteeing the equity and general balance of the system, using legal requirements and conditional financial support to accomplish those ends (26). By 1986, confronting an increase in transplant activity and rising costs, the Ministry took excep-

tional administrative steps to coordinate diffusion of transplant activity throughout the country. That year, a ministerial instruction defined (for certain categories of grafts) national, quantified objectives as well as a methodology for their implementation. Each transplant unit was to define a medical goal that integrated an analysis of the current situation, a definition of therapeutic protocol, and the modes of evaluation to be put into practice. By 1987, a quantitative "balance sheet" and annual financial scheduling were required from each transplant unit.

Although newly formed teams were in theory free to undertake transplants, only the pilot centers or some of the more "encouraged" centers (i.e., the allo-graft centers) could benefit from public funding (14 renal grafting centers benefited). The pilot centers were selected by the Ministry of Health from among the oldest and most prestigious transplant teams. Their role is now to set norms of practice that can be transferred to the other centers, which must compete in order to improve their practice and become pilot centers themselves (as determined by the Ministry of Health).

As of 1988, organ transplants, in both the public and the private sector were subject to ministerial authorization; any hospital unit that had not begun a program of organ grafting as of this date could not begin without authorization.

In 1992, reform of the system of organ and tissue transplants was initiated. Its aims were rationalization, published guidelines, and security. The *Comite de Transparence* was formed by a legal order in 1992 to develop requirements for different associations in the field, to counsel the Minister of Health, and to identify all cases of malfunction. The committee chairperson is a state counselor (civil servant), not a specialized doctor.

Active transplant units (fixed at 40 for renal units) are defined by a 1992 health map, and health norms are established for the centers, which are now required to declare any organizations involved in imports, conservation, and transformation of organs and tissues and to guarantee the highest quality of technical and human know-how. Reports from the general inspectorate and the committee cover the scheduling of transplant activity as well as financial guidelines (e.g., setting of payment rates and payment of costs).

NEONATAL INTENSIVE CARE

Little information exists on neonatal intensive care in France as it relates to demographic, equipment-related, or technological issues, despite the fact that Neonatal Intensive Care Units (NICU) require a Ministerial license. Neonatology itself does not exist in France as a formal specialty, but pediatricians who specialize in neonatology are grouped together in a Neonatal Study Group *(Groupe d'EtudesNkonatales,* or GEN). Information in this case study derives from private interviews with two leaders in the field and from GEN.

In the Ile de France region, GEN uses its unpublished census on various neonatal services to organize summer shifts of services on a permanent basis. Thus, the GEN figures give an accurate assessment of the number of beds and units in the Paris area. In the permanent summer-shift organization, GEN accounts for 196 beds in 15 units. Only three hospitals have wards exclusively for neonatology. There is one unit in a private hospital. Most of the beds are in NICUS, but some are part of general pediatrics.

Most units are costly in terms of both equipment and personnel. The situation has become more tense recently, particularly in relation to problems with nursing personnel, which has meant that beds are unavailable at certain times of the year, and experts feel that the situation may worsen in the near future. The NICU population is now growing as a result of several factors (mostly connected with improvements in the technologies):

- increases in birth rates of radically premature infants (delivery between 33 and 37 weeks) whose survival was previously impossible;
- the consequences of medical interventions in procreation, which lead to an increase in multiple pregnancies (3 percent triple pregnancies after medical intervention) and ultimately to very low birthweight premature infants;

- the consequences of prenatal diagnosis, leading to therapeutic in utero care and continued care in NICUS; and
- complications in pregnancy (e.g., low fetal growth) leading to fetal problems during birth, and neonatal emergencies of term infants who are systematically placed under surveillance and quasi-systematically resuscitated.

Concerns with the Technology

Experts emphasize a great disparity in the ways and means of neonatal services as well as in medical and nursing staffs. The high level of technical skill, heavy equipment, and burden of care for the nursing staff in NICUS implies that such units should be restricted to university hospitals and carefully assessed by ministerial authorities. Lack of proper beds for NICUS in university hospitals, combined with the lack of specific qualifications for personnel, has meant that new wards are being created in general hospitals (the smallest with only three or four beds). Even though GEN experts find these small units insufficient to satisfy safety criteria and lacking in specialized services with the proper environment, technology, and staff, they cannot be closed.

According to GEN experts, the main problem of the NICUS (other than the absolute lack of beds) is linked to nursing jobs. NICU nursing is very demanding and not socially rewarding. Nurses working in the NICUS do not receive career or salary advantages or professional recognition. These units must expend increasing energy on maintaining their nursing personnel, and they rotate shifts excessively.

In May 1991 one expert submitted to the Prime Minister a report on French problems in bioethics. One chapter and several appendixes of that report discuss the question of neonatal intensive care. The report underlines questionable areas as well as positive aspects of neonatal resuscitation, and it raises several ethical questions (23). On the positive side, the report points out that France has a strong tradition of organizing specialized services for newborn infant care. Such services are closely coordinated with centers for prenatal diagnosis, which can thus anticipate and prepare to receive newborns with problems. However, on the negative side, France's infant mortality rate is 7.3 per 1,000, which places it eleventh in the world. Moreover, although the frequency of premature births in France has been diminishing (from 7 percent in 1981 to 5 percent in 1991), the rate is not negligible. The rate of highly premature births (i.e., delivery after less than 33 weeks) is 0.7 percent of the births, or 5,000 per year, which raises immense problems for localities treating these infants.

Ethical questions concern, on the one hand, the problem of resuscitating newborns, and on the other, the harvesting of organs from brain-dead infants for transplantation. The decision to abstain from therapy or to pursue resuscitation lies mostly with physicians rather than parents. Proponents of resuscitation feel that newborns must be systematically resuscitated if this is possible—a position that has been a focus of criticism, particularly because the criteria used for deciding on whether to resuscitate vary with different proponents.

Demand for grafts from newborns-heart and lungs in particular-has been increasing, and both harvesting of organs and transplantation require NICU services. If a baby is alive, it is theoretically and ethically possible to extract bone marrow for transplantation to a sibling, but only with the consent of parents and of three doctors not involved in the operation. Removal of an organ from a deceased child (covered by the Cavaillet Law of 1976) is subject to parental consent as well as that of the recipient. Above all, the law calls for doctors to take all precautionary measures for the benefit of the recipient.

Extracorporeal Blood Circulation

The French technique of extracorporeal blood circulation and artificial lungs in newborns was first undertaken in 1987. The American technique (extracorporeal membrane oxygenation, or ECMO), which requires two nurses per patient, appeared overly burdensome, and the hospital that first used the technology therefore developed a less invasive technique: the AREC, a "veino-venous" tech-

nique permitting the ward to perform AREC with three units for 14 beds using only five nurses (8). An association known as GRAREC was created to ensure the dissemination of this particular technique in France and Europe (3). Five centers now function in France: two in Paris (one with three machines and one with one machine); one in Line with one machine: one center and one machine in Dijon; and two machines in Marseille.

AREC is not subject to specific regulations, reimbursement rates, or analytical accounting. As a technology within neonatology, AREC receives financing from relevant administrations (e.g., the CEDIT in Paris) as a technological innovation. At present a l the French centers use the AREC technique rather than ECMO. This technique is connected to the use of a French invention, a pump developed by Rhone-Poulenc, readapted, and now produced by other, smaller companies.

Around 200 French newborns with an estimated 80 percent risk of mortality have been placed on AREC: the average duration of treatment is five days. A followup of results over two years demonstrates that 86 percent of the infants are normal. A frequent complication can be intracranial hemorrhaging due to heparin (1 2).

The AREC technique is less invasive than ECMO. It uses only the jugular vein and does not suppress natural circulation inside the lungs. It also permits much less intensive surveillance. The expense compared to that of maintaining an average patient in an intensive care unit is estimated to beslightly lower. An estimate of potential need for this technique was made by CEDIT and GRAREC (held to be 40 cases annually in the Paris region, or about 200 overall in France).

AREC is not considered by all French neonatologists to be a priority but rather one technology among others. Currently, GEN gives most of its attention to the ethical issues of neonatal intensive care, to problems of the burden of care in the units, and especially to the status and position of NICU nurses.

SCREENING FOR BREAST CANCER

In 1982, early screening for breast cancer by mammography was virtually nonexistent in France. Mammographies were exclusively a diagnostic activity undertaken after the appearance of a symptom or as a surveillance practice. Between 1982 and 1988, the use of mammography increased rapidly (there were 650 machines in 1982 and about 1,700 in 1988), and the field underwent a veritable explosion—from 350,000 to nearly 1,890,000 annual tests (about 90 percent of which were done by the private sector) (22).

In 1988, 60 percent of mammography were medically prescribed for the purpose of early detection, but outside organized screening programs, and a considerable number of mammograms still are done outside of formal programs.

In recent years, about 1.15 million exams have been done annually. Unfortunately, the percentage of the population screened is only around 8 percent of women aged 45 to 54 and 10 percent for those between 55 and 64-age ranges for which epidemiologic studies show that screening is the most beneficial. A structured national system of early detection thus appears necessary.

Government Policy

In 1988 the Ministry of Health entrusted the National Sickness Fund with the responsibility of setting up and evaluating programs of prevention and health education. A new financial tool was founded for the promotion of this mission, with a specific fund *(Fends National de Prevention, d' Education et d'Inforrnation Sanitaires,* or FNPEIS) managed by CNAMTS. Programs to be funded are selected by the CNAMTS board of directors and annually approved by the Minister of Health (1,29). Some of these grants were dedicated in 1989 to the organization and evaluation of departmental campaigns to reinforce screening for breast and colorectal cancer in several research *departements.*

Programs for breast cancer screening have only lately seen the light in France. In 1988, before financial action from FNPEIS, eight structured programs were being set up and eight others were well established. These programs are characterized by enormous diversity within the institutional and financial framework. reflecting the

organization provided for by the 1983 Law of Decentralization that gives responsibility for cancer screening and for post-treatment surveillance to the departments. In conformity with the law, the screening program provided for and supported by FNPEIS was organized by departments; local hospitals and local Sickness Funds did not take the lead but were associated as full partners. A total of 48.5 million francs ($US8 million) or 5 percent of the FNPEIS budget was dedicated to cancer screening in 1990. The Ministry of Health intervenes principally to give a technical endorsement to provide the legal basis for disbursing funds, and it participates in program followups.

The CNAMTS prevention program is aimed at women 50 to 69 years old. The strategy is based on sensitizing practitioners; advertising campaigns; drafting contracts with radiologists responsible for examining mammograms; creating contracts with a center for "secondary x-ray readings;" making contacts with local partners (e.g., departmental leagues for the fight against cancer); and developing mailing lists.

Women are invited to be screened in a letter from the local Health Insurance Fund. After the x-ray is completed, the fee is directly paid by the local fund to the radiologist ($US40 per examination), so that the service is free to the patient. The radiologist sends the results to a center for secondary x-ray readings.

Financing is budgeted by size of the populations targeted by each department, which means (for breast cancer exams) that about 2 million francs are allocated for every 50,000 people. The cost of the entire program is estimated at 234 million francs per year, around 100 million francs less than the estimated cost of the actual (predominantly spontaneous) exams conducted in France (22).

This program still is defined as "experimental," and a "medical, social and economic" evaluation is required to change its status. In 1992, 20 or so departments were receiving financing for screening; mass screening, however, has not yet been carried out.

CHAPTER SUMMARY

Compared with the situation at the beginning of the 1980s (18), the assessment of health care technology in France has achieved the status of a major concern. The 1991 law made extensive use of the concept of evaluation, associated with notions of quality, management, planning, and cost-effectiveness assessment. For decades, French experts have stressed the lack of basic studies of the decisionmaking process. It is striking that now legal requirements, specific institutions, and public grants dedicated to evaluation exist at every level of the health care system and the government.

Public health care managers are learning how to deal with the new requirements, which are based on a demand for greater expertise as well as improved communication and cooperation among the different actors. Nevertheless, needs for consensus and guidelines on medical strategies as well as for primary data on diagnosis-related medical activities and prescriptions remain the stumbling block. This is not news to the experts, but it seems to be widely publicized and accepted now—in particular by physicians, which makes a great difference.

Experts feel that medical representatives (if not the entire medical community) have now become less reluctant to accept the concept of medical technology evaluation. Many groups of professionals have for some years been involved in consensus processes or in assessments of some sort. However, the main change derives from the fact that physicians' representatives have negotiated contracts with the Ministry of Health and the National Sickness Fund that involve medical evaluations and medical guidelines stipulating possible sanctions for physicians who infringe these rules—a situation that would have seemed impossible 10 years ago.

It is thus fair to say that the need for cost containment (because of the dramatic increase in health care costs), rather than objective interest in improving health care quality, has played the major role in pushing technology assessment in health care into the spotlight. Successive Ministers of Health, calling for reduced health care expenses, have promoted the concept of "medicalized management of health care," which implies that improvement of quality and cost containment can go hand in hand. The public at large is now well informed about this concept. Moreover, the possibility of drastic changes in the health insurance and welfare system is also generally grasped. The medical community thus cannot remain outside this national debate. Evaluation in health care is beginning to be viewed by every professional involved as the key to a stronger position at the inevitable negotiating table.

It must be said too that this now familiar technical debate took center stage at the very moment when important national debates were occurring in France about medical ethics and about governmental and physicians' responsibilities in ensuring health care security and quality after the recent tainted blood scandal (which led four top physicians and administrators to court and two to jail). The responsibilities of experts, medical advisors, practitioners, industry, and the government have been publicly and dramatically discussed. It is hard to forecast the historical consequences of these events, yet it is possible to speculate that the blood scandal may have opened a new era in which experts, journalists, and the courts might play an increased role.

As for the experts, it has been widely noted (especially during the blood scandal) that their knowledge has not played and generally does not play (as far as health policy is concerned) the role it should. Lack of expertise has been pointed out for many years by different observers of public health policy. Proposing solutions to this problem was one of the goals of successive missions on the development of medical evaluation in the 1980s. One of the consequences of the blood scandal has been to drive the government itself toward a better understanding of the need for expertise to assist the Ministry of Health. Money and positions have become available, and a number of new experts have now started to work in various teams close to the Ministry of Health.

As for the various media, they had mostly (until the 1990s) intervened to praise and promote medical innovation and had frequently promoted technologies that were not yet fully assessed. Journalists are now appearing in a different role, as protectors of patients against the high risks of medical technology and poor quality health care. Apart from the transfusion issue, other medical and health care issues have been highlighted by the press (e.g., the unequal and generally poor situation of emergency care).

As for judges and the courts, in 1993 three high-profile scientists and administrators were charged for bearing responsibility for the occurrence of 25 cases of Creuzfeld-Jacob disease among children treated by extractive growth hormone. This decision was publicized as a new blood scandal—an attempt by the press (and others) to go beyond the limits of the transfusion issue and to find a new and perhaps more demanding definition of medical and governmental responsibilities in the diffusion of medical innovations. This new attitude will probably have important consequences for the future of clinical research and the management of innovation.

Above all, the government now appears to consider cost containment its top priority. The reforms of the 1980s and the 1991 law strengthened the quality control processes for medical equipment and health care; now the focus at the central governmental level is on costs.

Compared to the 1970s and the 1980s, the French health care system is going through a crisis. The longstanding balance among the powers and parties involved (physicians, industry, Sickness Funds, government, courts, patients, and press) has become unstable. Quality of care and excessively rising costs have become open, urgent, and nationwide concerns, and technology assessment one of the key tools for addressing the problem.

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Health Care Technology in Germany

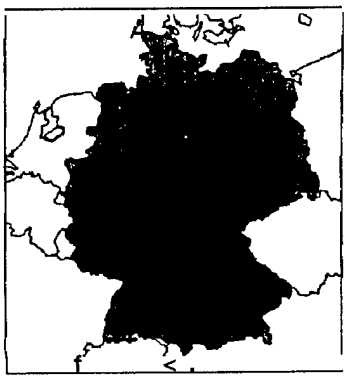
5

by Stefan Kirchberger

OVERVIEW OF GERMANY

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

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



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

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

The dramatic economic changes are reflected in the declining birth rate. At 12.9 births per 1,000 in 1988, the birth rate in the former GDR was slightly higher than in the old FRG (11 .0) (60). Since reunification, the annual number of births in eastern Germany has fallen dramatically, from 200,000 to about 80,000 in 1992. Such a decline within less than three years occurred only once before, during the early years of the first world war. The decline is explained partly by the migration of about 1.5 million people from the east to the west from 1989 to 1992 (15). This migration, mostly of younger people worried about the future of East German industry, will cause considerable structural problems in the future.

HEALTH STATUS OF THE POPULATION

Since 1960, death rates have declined and life expectancy has increased in Germany. In West Germany, life expectancy at birth for women has risen from 72 in 1960/62 to 79 in 1987; and for men from 67 to 72 over that period. The lower life expectancy for men is due primarily to traffic and work accidents. There are no data concerning life expectancy by social status. The increase in life expectancy and the decline of death rates reflect a decrease in ischemic heart disease, cirrhosis of the liver, and diseases of the respiratory tract (bronchitis, asthma, emphysema). In West Germany, infant mortality was a relatively low 6.98 per 1,000 in 1990.

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

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

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

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

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

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

THE GERMAN HEALTH CARE SYSTEM

Legislation and Financing

Although the constitution of 1918 *(Weimarer Verfassung)* explicitly defined social rights (e.g., the right to work), the constitution of the Federal Republic of Germany *(Grundgesetz, GG)* only establishes a "democratic and social federal state" (article 20 GG), where "social" rights are to be defined by legislation. Except for prescribed areas of federal interest, legislation is under the jurisdiction of the state parliaments. In those prescribed areas, however state legislation is subordinate to federal law. These include the areas of epidemics, university education in medicine, food and drug control, social security, and since 1972, financing of hospitals.

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

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

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

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

The most important institutions in the German health care system are the approximately 1,100 mandatory sickness funds. In 1991, all employees in Germany who had a monthly income up to 5,100 DM were insured by a mandatory sickness fund. (This wage limit is modified annually. In certain cases, persons with higher salaries are also authorized to be insured by mandatory sickness funds.) Family members (spouses and children) of the insured who have no personal income are coinsured without making any contribution and are entitled to the same services. (This is the "solidarity principle" of social security: a member's sickness fund contribution remains the same whether he or she is single or has dependents or nonworking family members who are coinsured.) The employee's contribution, which is independent of individual, medical, or social risk factors, is a percentage of income. The contribution rate is fixed annually by each sickness fund according to its financial needs. Most employees have limited or no options in deciding which sickness fund they want to join, leaving them with little choice concerning the level of contribution they have to pay. (This restriction will be canceled in 1996.) In 1992, the average contribution rate amounted to 12.6 percent, half taken from employees' gross wages and half contributed by employers.

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

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

Health Care Delivery

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

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

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

'SOURCE Sachverstandigenrat fur die Konzertierte Aktion im Gesundheitswesen (SVRKAiG), Jalvesgutachten (Baden-Baden: Nomos Vlg., 1992)

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

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

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

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

The number of office-based physicians has grown rapidly within the past 20 years, especially the number of specialists (see table 5-3). This increase has caused great debate over how many doctors are necessary to provide outpatient care. Until 1960, the mandatory sickness funds were authorized to limit the number of contracting doctors. But in 1960, the Federal Constitutional Court *(Bundesverfassungsgericht)* found that this regulation was in conflict with the constitutionally guaranteed freedom of occupation. Balancing individual constitutional rights against the social interest in securing the financial stability of mandatory sickness funds, the Court saw no difficulty in entitling each doctor to obtain a license to contract with these funds, particularly since the number of uncontracted doctors was small. Mandatory sickness funds have had to contract with every office-based doctor who wants to do so; consequently, the number of office-based doctors has more than doubled. In addition, about 10,000 physicians a year have wanted to become sickness fund doctors since the early 1980s. In 1992, the government enacted a law that will again try to limit the number of sickness fund doctors in the coming years.

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

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

TABLE 5-2: Total Health Expenditures in West Germany, 1989 (million DM)	
1. **Federal and state budgets**	37,891
Reimbursement for medical treatment of civil servants* and medical education	
2. **Mandatory sickness funds**	127,579
3. **Social pension funds**	19,606
Pensions for disabled persons DM13,084	
Medical rehabilitation: DM4,356	
4. **Social accident insurance**	8,559
Inpatient and outpatient care for workplace accidents and occupational diseases	
5. **Private health insurance**	15,866
6. **Employers' health expenditures for their employees**	46,907
Wages and salaries for sick workers: DM31 ,620	
7. **Private households**	20,339
Drugs and dental prostheses not reimbursed by mandatory sickness funds	
TOTAL	*276,807*

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

SOURCE Statistisches Bundesamt, *Statistisches Jahrbuch* 7992 fur die Bumdesreputdik Deutschland (Wiesbaden, 1992).

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

The Hospital Financing Act of 1972 *(Krankenhausfinanzierungsgestz* KHG) made legislation on hospital supply and financing a federal task. The planning of hospital supply was delegated to the states, which enact an annual hospital need plan. Except for rehabilitation hospitals and university clinics, which have other resources, a hospital must be admitted to this need plan if it is to survive financially. Other than initial ownership expenses, all investments (building construction, expensive medical equipment, etc.) in these hospitals are funded by the states, and operational costs are reimbursed by the mandatory sickness funds. The sickness funds reimburse the operating costs on the basis of a per diem rate that the hospital receives for each day of each patients' hospital stay. Because hospital income is directly related to the number of patients and the average length-of-stay per patient, an economic incentive to extend hospital stays and to treat patients longer than medically necessary exists. This led to a change in the financing formula in 1993.

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

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

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

SOURCE Sachverstandigenrat fur die Konzertierte Aktion im Gesundheitswesen (SVRKAIG), *Jahresgutachten*(Baden-Baden Nomos Vlg , 1992)

The Medical Market

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

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

In 1990, world sales in diagnostics—i.e., reagents and instrumentation—amounted to about 22 billion DM. The sales of the German diagnostics industry accounted for approximately 25 percent of this total. German firms had about 900 million DM worth of sales to the German market, earning another 1.9 billion DM through exports. German imports of diagnostics from abroad were approximately 1.75 billion DM (77). That year the German health care system consumed about 2.65 billion DM of diagnostics—more than 12 percent of worldwide production.

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

TABLE 5-4: European Medical Equipment Market

Country	Projected 1991 sales (US$ billions)	Change from 1990 (%)
Germany	10.6	+6
France	5,4	-1
United Kingdom	4.3	0
Italy	3.9	+1
Benelux	2,7	0
Scandinavia	2.3	0
Spain	21	-4
Others	2.7	-1
Total	34.0	

SOURCE Biomedical Business International Newsletter14 : 51 1991

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

Yea	GNP b on DM	Sickness Funds budge B on DM	GNP
1970	675.7	24.411	3.6
1972	824.6	35.461	4,3
1974	983.7	51.015	5.2
1976	1,123.8	65.517	5.8
1978	1,289,4	73.550	5,7
1980	1,477.4	88.424	6.0
1982	1,590.3	95.754	6.0
1984	1,763.3	06.427	6.0
1986	1,936.1	17.194	6.0
1988	2,108.0	31.735	6.2
1990	2,425.5	41.864	5.8

SOURCE: Sachverstandigenrat die Konzertierte Aktion im Gesundheitswesen (SVRKAiG), *Jahresgutachten* (Baden-Baden Nomos Vlg , 1992)

x-ray apparatus and tubes are no less striking: Germany spends US$12.90, less than Japan at US$l 6.50, but well ahead of the United States and Canada, with US$8.70 and US$8.90, respectively. The United Kingdom, with US$4.30 per capita, spends only one-third as much as Germany. These differences in consumption may reflect differences in the structure of health care delivery.

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

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

THE COST CONTAINMENT DEBATE

In 1989, total health care expenditure in Germany amounted to 8.2 percent of gross national product (US$1,232 per capita), placing Germany seventh place among OECD countries. The share of gross national product spent on health care has been almost stable since the middle of the 1970s (60). (See table 5-5.) Nevertheless, since the end of the 1960s German politicians have talked about the urgency of cost containment in view of a perceived "cost-explosion" in health care (see e.g., 66). This dramatic phrase refers to the mandatory sickness funds' expenses.

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

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

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

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

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

The political argument about the first issue is between those who want to reduce the catalogue of services covered by Social Security by eliminating some minor or traditional services, such as burial allowances or pharmaceuticals which are not proven to be therapeutically effective, and those who want to reduce social security to a level covering only "basic health care." Those who take the former position believe strongly that a social and democratic state should guarantee every citizen comprehensive health care according to his needs. The other opinion, enunciated by a prominent health politician, is that state-organized social security should be limited to those services that are unaffordable for middle class people, i.e., high-technology medicine for "severe diseases." In the case of hospitalization, patients should pay a percentage on the level of hotel accommodation, so that they (if they cannot afford additional insurance premiums) will be encouraged to leave the hospital as soon as possible. Only pharmaceuticals "with strong and scientifically unquestioned effects, in particular those with vital indications" should be covered by mandatory sickness funds (2). The main idea behind such statements is that those services that have incremental effects (providing somewhat more care, etc.) and may be bought by those with more money or a higher level of additional insurance should be privatized.

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

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

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

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

I Budgeting Measures in the 1993 Health Care Act

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

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

Interventions in Health Care Delivery Structure

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

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

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

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

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

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

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

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

CONTROLLING HEALTH CARE TECHNOLOGY

Technology Assessment

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

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

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

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

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

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

Another singular example is an inquiry commission on genetic technologies initiated by the federal parliament (23). Some federal states have funded studies on special technology assessment questions, e.g., an assessment of gallstone lithotripsy (43). But compared to other countries, these remain minor activities. It is no surprise that the Swedish report on "Health Care Technology Assessment Programs" does not even mention Germany (74).

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

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

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

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

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

Drug Regulation

Pre-Market Approval

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

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

The first bill on drug safety proposed by the government provoked a fierce discussion. Its strict regulation of drug evaluation and safety was not acceptable to industry. After five years of debate, a law reflecting the pharmaceutical industry's interests much more was enacted. The law had to resolve two problems: how to regulate the safety and efficacy of new drugs, and how to regulate some 140,000 drugs already on the market.

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

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

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

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

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

Regulation of Drug Prices and Consumption

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

With no way to regulate prices or control the quantity of prescriptions written for patients, pharmaceuticals are very expensive in Germany. Mandatory sickness funds cannot negotiate prices and neither physicians nor patients have an interest in doing so. Price competition has become somewhat more important only since the early 1980s, as the patents for many drugs expired and generics came on the market. In 1988, about 20 percent of all prescribed drugs were generics (13). The first attempt to introduce indirect price regulation took place in 1988 (35 SGB V) when a law was passed decreeing that a fixed reimbursement for certain drugs should be determined by the government. The law's intent was to standardize and reduce the amount of reimbursement for certain drugs that had the same or similar biochemically active substances. Industry could still choose to set a price for its product above the federally set reimbursement, but if a patient chose to buy the more expensive drug, he would have to pay the difference between the manufacturer's price and the reimbursement amount.

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

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

Medical Device Regulation

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

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

REGULATION OF PLACEMENT OF SERVICES AND QUALITY ASSURANCE

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

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

The amount of inpatient care is determined to a large degree by the technological equipment that the outpatient sector has, especially diagnostic equipment. Hospitals, of course, have the whole range of medical technology, but hospital specialists are allowed to treat outpatients only when there are not enough office-based specialists. For example, if there are not enough CT scanners installed in physicians' offices, a hospital radiologist may obtain authorization to perform ambulatory CT scanning. This authorization is given or refused by the Association of the Sickness Fund Doctors and can be canceled at any time.

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

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

The Debate On Regulating the Proliferation of Expensive Equipment

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

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

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

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

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

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

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

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

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

Quality Assurance

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

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

The Board of Experts for the Concerted Action in Health Care (SVRKAiG) has repeatedly called for better information concerning the real quality of physicians' work, saying it is the highest priority for assuring quality in German health care (60). In a 1989 report, the Board criticized the lack of means to assure quality in the processes and results of medical treatment, especially in hospitals. It also produced a catalog of desired reforms (60).

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

In 1989, a requirement for the systematic quality assurance of inpatient care was established by law (S137 SGB V). Hospitals now have to participate in quality assurance measures related to treatment processes and the results of care. Treatment procedures must be standardized to enable quality control. According to the law, state associations of the mandatory sickness funds and the regional hospital societies are supposed to agree on how to standardize treatment. But the societies concerned have so far only agreed on which activities need quality standards. The divergent interests of the parties involved has prohibited the consensus necessary to make further decisions. Physicians say they fear the end of the anonymity of data and the possibility of lawsuits in cases of treatment failure (8).[2]

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

[1] These include controls on the quality of laboratory performance in outpatient care (I I) and on technical requirements and standards regardi,, the use of x-rays.

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

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

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

Case studies

TREATMENTS FOR CORONARY ARTERY DISEASE

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

The number of catherization labs is determined by the state hospital plans. Of the 222 catheterization labs installed in West Germany in 1991, 211 were operated by hospitals. The number of diagnostic and therapeutic facilities has grown rapidly since 1986. The current capacity for percutaneous transluminal coronary angioplasty (PTCA) now seem to be sufficient. Nevertheless, cardiologists claimed that the high incidence of coronary artery disease necessitates adding more facilities (31). (See table 5-6 for trends in the use of CABG and PTCA.)

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

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

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

TABLE 5-6: Frequency of CABG and PTCA

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

*1991 data include the former GDR

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

SOURCES E Bruckenberger, Dauerpatient Krankenhaus—Diagnosenund Heilungsansatzeze (Frelburg Lambertus Vlg , 1989), U Gleichmann, H Mannemach, and P Lichtlen, "Bericht uber Struktur und Leistungszahlen der Herzkalheterlabors in der Bundesrepublik Deutschland, " Zeitschruft fur Kardiologie 82:46-50, 1993 , E Bruckenberger, Bericht des Krankenhauschusses der Arbeitsgemeinschaft der Leitenden Medizinal beamten (AGLMB) zur Situation der Herzchirurgie in Deutschland (Hannover: Niedersachsisches Sozlalministerlum, 1992)

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

MEDICAL IMAGING (CT AND MRI)

As in other countries, CT and MRI have become prominent in Germany, but traditional x-ray imaging and sonography have maintained a higher rate of use than in most other countries. In 1990, the more than 50,000 x-ray machines in West Germany were used for 88.2 million examinations—more than 1.4 per inhabitant in that year. More than half of these examinations were of the thorax, at least partly explainable by the traditional fear of tuberculosis.

Computed Tomography (CT)

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

In 1977, prices of cranial CT scanners ranged from 800,000 to 1.5 million DM and that of body-scanners from 1.8 to 2.3 million DM. At that time mandatory sickness funds paid 300 to415 DM for a cranial scan, depending on the specifics of the

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

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

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

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

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

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

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

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

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

SOURCE G Rau, "Aktuelle Versorgungslage, " Wirtchafilicbe *Aspekte der Computerfomograph/e,* CT-Symposium am 11-12 January 1979 an der Deutschen Kinik fur Diagnostik, Hessisches Sozial-mwusterlum (Wiesbaden) and Bundesminlsterium fur Arbeit und Sozlalordnung (Bonn) (eds) (lMesbaden, 1979)

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

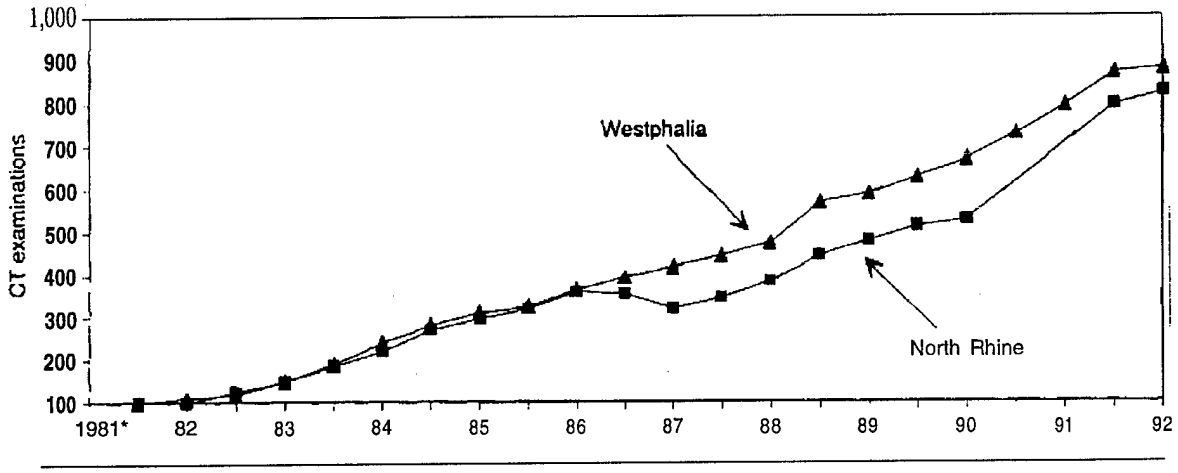
Magnetic Resonance Imaging (MRI)

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

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

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

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



*First six months in 1981 = 100

SOURCE S Kirchberger, "Uberlegungen zuDiffusion und Nutzung der Computertomographie Nordrhein Westfalen, *"Medizin Mensch Gesellschaft* 14:87-95, 1994

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

The MRI study consists of three parts:

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

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

LAPAROSCOPIC SURGERY

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

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

TABLE 5-0: CT and MRI Installations in Germany by Site[a]

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

[a]The table shows the number of devices sold Since some are replacements the number of devices in operation is somewhat lower
b Installations for 1974-1981 are extrapolated from 1982-status in line with CT-market growth Worldwide

SOURCES Siemens, personal communication, 1994, E Bruckenberger, personal communication, 1994

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

Used primarily by internists or other specialists equally familiar with diagnostic endoscopy, MIS has given rise to a struggle between different medical disciplines. Surgeons interested in endoscopic therapy were often opposed by their surgical colleagues. Until the end of the 1980s, most surgeons rejected the new methods and condemned them as risky and even unethical (42). The long-lasting hostility of the majority of surgeons is understandable in view of the fact that the new methods not only required new skills but also made familiar manual and tactile abilities superfluous.

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

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

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

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

Along with training, the frequency of use of endoscopic therapy is an important indicator of quality. Physicians trained to perform percutaneous nephrolithotomy (PCN), for example, must practice it routinely in order to retain their proficiency. Because the technology associated with PCN is less expensive than that for lithotripsy, the use of PCN as a surgical treatment has spread rapidly. In 1987, 85 of 112 urological departments in North Rhine-Westphalia were using it. But because so many centers now offer the treatment, the number of procedures per hospital has diminished. This development suggests that to promote quality, centralizing certain services will be necessary. But at present, neither political nor economic means exist to cause such a change. Beginning in 1995, other modalities of hospital financing together with quality assurance measures might eliminate some redundancies in the system.

TREATMENTS FOR END-STAGE RENAL DISEASE (ESRD)

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

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

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

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

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

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

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

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

TABLE 5-10: Trends in Renal Transplantation

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

aIncluding East Germany

SOURCE Kuratorium fur Dialyse und Nierentransplantallon, Jahresbericht, Neu-Isenburg, 1992

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

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

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

SOURCE Statistiches Bundesamt, *Statististisches Jahbuch 1992* fur *die Bundesrepublic Deutschland* (Wiesbaden, 1992)

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

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

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

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

NEONATAL INTENSIVE CARE

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

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

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

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

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

Of the 1,904 newborns who died during their first seven days of life in 1990, half weighed less than 1,800 g. About 36 percent had incurable cardiac defects, congenital malformations, or chromosomal aberrations. The remainder had serious respiratory problems which might have been successful] y treated by extracorporeal membrane oxygenation (ECMO). However, before 1990, only the University Clinic of Mannheim had introduced ECMO. Between 1987 and 1990, the Clinic used the new technology on 13 neonates. In 1990, it organized the first German symposium on this subject (40). It was stated that ECMO is no more expensive than more common therapies, which made its slow rate of use hard to understand. By August 1993, ECMO was being performed at two additional clinics (in Lubeck and Berlin) (54).

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

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

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

SCREENING FOR BREAST CANCER

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

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

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

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

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

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

Age	Percent of eligible women participating
30-34	**41.9**
35-39	**43.0**
40-44	45.8
45-49	44.6
50-54	38.1
55-59	31.4
60-64	**27.8**
65-69	**18.5**
70-74	12,8
75 +	5.2
30 +	**30.9**

SOURCE. P Robra, "Ergebnisse und Probleme des 'Gesetzlichen' Krebs Fruherkennungsprogrammes in der Bundesrepublik Deutschland," *Die Krankenversicherung* 3765-69, 1985

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

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

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

Based on this study, the Federal Commission of Physicians and Mandatory Sickness Funds will decide whether to integrate mammography into the screening program. A pilot study with four gynecological institutions has developed criteria for judging technical quality, interpretation of the pictures, and organizational structures for quality assurance. In 1990, the *Deutsche Mammographie-Sludie* started a regionally limited mammographic screening program for women over 39 (the mean age of participants was 53). Within 18 months, about 22,000 women were examined. Each mammogram was evaluated twice. Discrepancies in findings seemed to depend on physicians' experience and equipment.

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

CHAPTER SUMMARY

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

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

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

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

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

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

The 1993 Health Care Act marks the third stage of the health policy process. Decisionmakers now realize that budgeting and other cost containing restrictions may be insufficient to successfully reduce the growth of health care expenditures. The 1993 law's modifications of the health care delivery structure may fix some obvious deficiencies.

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

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

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

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

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

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

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Health Care Technology in the Netherlands

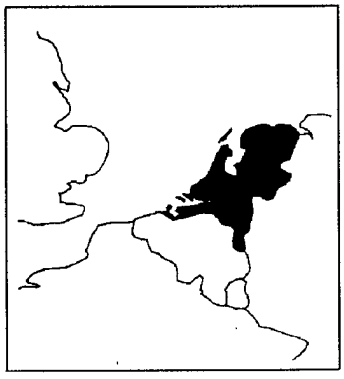
6

by Michael A. Bos

OVERVIEW OF THE NETHERLANDS

The Netherlands is a small country in Western Europe, located on the North Sea coastal area at the mouth of the rivers Rhine and Meuse, bordering Belgium and Germany. The territory of the Netherlands covers 41,574 km^2 of which 7,636 km^2 are water. About one-quarter of the country, especially the western part where land has been reclaimed from the sea since the 16th century, actually lies below sea level. In the south and the east, some hills rise to a maximum height of 321 m (above sea level).

In 1992, the Netherlands had a population of 15.1 million inhabitants (table 6-l). Due to high population growth during the 20th century, population density in the Netherlands is the highest in all Europe: 446 inhabitants per km^2 of land area in 1992. The western part of the country, with the three major cities (Amsterdam, Rotterdam, and the Hague), is the most densely populated. In 1992 there were 758,000 foreigners living in the Netherlands (5 percent of the population), plus another 650,000 people with a Dutch passport who were born in another country. Immigration (1 18,000 in 1992) has been increasing since 1985, and the number of refugees (22,000 in 1992) requesting asylum for political or humanitarian reasons is growing.



Government Structure

The Netherlands has been a kingdom since 1806, first as part of the French Bonaparte empire (1806-1 813) and afterwards as an independent state under the royal House of Orange-Nassau. The hereditary monarch is the constitutional head of state, but the governmental power is executed through a Parliamentary democracy. The Parliament *(Staten Generaal),* which represents the people,

TABLE 6-1: Netherlands Population Statistics

Total population (Jan. 1, 1992)	15,128,604
Males	7,480,111 (49.4%)
Females	7,648,493 (50.6%)
Age 65 years and older	1,960,474 (1 3%)
Net population growth in 1991	118,700
Population growth rate in 1991	0.79%

SOURCE Central Bureau of Statistics, *Statistical Yearbook of the Netherlands for* 7993 (The Hague SDU Publishers, 1993)

consists of two chambers. The Second Chamber *(Tweede Kamer),* which is politically the more important one, has 150 members who are elected directly by the people under a system of proportional representation (there are no electoral districts). As a result, in the Second Chamber the major national political parties are represented. Since no one party has a majority, a coalition of several parties is usually necessary to forma cabinet. The government consists of the Queen and the Cabinet Ministers (under a Prime Minister), who retain the executive power. The First Chamber (Senate) has 75 members who are elected by the Provincial Councils *(Provincial Stalen). The* two Chambers together with the government have the power to legislate. The major role of the Second Chamber is to amend and approve bills put forward by the government. The First Chamber can only approve or reject laws that have already been passed by the Second Chamber-it acts as a "second opinion."

Provincial Councils are elected in each of the 12 provinces. Each council implements central state policy on the provincial level and supervises the day-to-day municipal administration. Each of the 647 municipalities has an elected municipal council headed by a mayor. During the last decade, more and more executive administrative power has been handed over by the central government to the provincial authorities, and the four largest cities have been given more responsibility to govern their own internal affairs.

1 The Economy

The Dutch labor force consists of 6.6 million people (65 percent of all people 15 to 64 years old). This labor force is on the small side compared with other European countries (75 percent in United Kingdom, 71 percent in Germany, 66 percent in France, 81 percent in Denmark) due to the traditionally low percentage of employed women (about half of women age 15 to 64), but the number of employed women is now growing fast. Although the labor force is modest, average productivity per worker is very high.

In general, the Dutch economy is based on free enterprise, but there is a certain degree of control and influence from the government, especially in times of economic recession, when large private enterprises (sometimes with state participation) are threatened. In the last decade the economy has been influenced more and more by the regulations and forces of the European Community internal market. Under the current economic recession the Dutch economy has been weakened by high unemployment (600,000 workers in 1993), but the Dutch currency[1] is among the strongest and most stable in Europe.

Despite the small percentage of the population that is employed in agriculture (6 percent), this sector is of major importance for the Dutch economy. After the United States, the Netherlands is the second largest exporter of agricultural products.

Industrialization started in the Netherlands only after World War II, somewhat later than in the rest of Western Europe. The most important industries in 1993 include (petrochemicals, electronics, and food. They are located mainly in the south and west of the country. Industry employs over a quarter of the workforce.

Because of its location at the mouth of the rivers Rhine and Meuse, trade and transport have been important for the Dutch economy throughout history. The port of Rotterdam is the biggest in the world. In the last decades, an increasing propor-

[1]$US 1 = Dfl 1.90 in 1994.

TABLE 6-2: Health Status by Subjective Rating

Rating	1981	1985	1991
Excellent	—	32.1	27.2
Good	80.2	50.4	53.7
Reasonable	12.2	10,7	12.1
Precarious	5.6	4,8	4.7
Bad	1,9	1.9	2.2

SOURCE Central Bureau of Statistics, *Stistical Yearbook of the Netherlands for* 1993 (The Hague SDU Publishers, 1993)

(ion of the cargo is transported by air, and Schiphol International Airport (near Amsterdam) has become one of the busiest airports in Europe.

HEALTH STATUS OF THE POPULATION

The Dutch people have a very high standard of health, both according to their own subjective standards (table 6-2) and by objective data on vital health indicators. The good health status of the population is also reflected by the modest (in comparison to other countries) use that is made of medical services (see ch. 10).

The favorable figures for the Netherlands are the result of high standards of living, good nutrition, good sanitary and housing conditions, and the availability y of reliable drinking water for most people since the first decades of this century. And for the last 50 years, the Netherlands has also d an excellent health care serv . . As a result, illness and death are to a large degree influenced by factors related to the affluent society (overconsumption and degenerative disorders) (table 6-3). Heart disease predominates, but cancer is a close second. Cancer is expected to be the number one cause of death in the future because of the advancing age structure of the Dutch population.

Aging of the population is one of the main concerns of the health care authorities. The proportion of people over 75 years of age is predicted to grow from 5 percent now to almost 15 percent in 2010, increasing the demand for medical services. Although people can stay relatively healthy to an advanced age, the need for homes for the elderly and care for handicapped people and for psycho-geriatric cases w i 11 grow. Waiting lists are now becoming a visible problem in the Netherlands.

THE DUTCH HEALTH CARE SYSTEM

The Dutch health care system has been described as a "patchwork quilt"-it has no master plan at its base. Rather, it is a complicated system that has evolved from a constant adding and changing of institutions, regulations, and responsibilities. This method of evolution is in the best tradition of Dutch pluralism. Yet, what has emerged over the years is a system in which high quality health care is provided with reasonable efficiency, and is equally distributed over the population (12).

Every citizen in the Netherlands has an entitlement to health care. Since 1983 the Constitution has contained an article under which the central authorities are obliged to take measures to promote public health (Article 22). Authorities (central and regional) are assigned the responsibility of ensuring that the whole Dutch population has access to high-quality care at an affordable cost and provided through a system that operates throughout the country. However, this principle has not been translated into a "National Health Care System," as in the United Kingdom or the Scandinavian countries. Public health care, the control of infectious diseases, environmental protection, and the regulation and recognition of the health care professions have traditionally formed part of the activities of the central government. When it comes to the actual provision of care, the authorities have focused on creating favorable conditions in which the already existing private sector could expand in the fields of hospital care, nursing care, and social services. Thus, the Dutch health care system is a mix of public and private initiatives under the umbrella of the central government.

Brief History

Before World War II there was no true health care system in the Netherlands. All care was provided by private institutions, charities, or municipal organizations. There was no universal health insurance, but many private and public insurance agencies were operating throughout the country. In the late 1930s, progressive political and societal circles demanded reform of the health care

TABLE 6-3: Five Leading Causes of Death in Dutch Population, 1975–1990

Cause of death	1975		1980		1985		1990	
	Male	Female	Male	Female	Male	Female	Male	Female
Heart/vessels	43.5	46.2	43.4	46,7	43.2	45.6	38.9	41,4
Cancer	26,9	24.6	29.1	25.0	29.4	25.1	30.3	25.1
Accidents, violence and poisoning	6.2	5.5	5.7	4.8	5.1	3.9	4.6	3.6
Respiratory tract disease	7.6	4.8	7.0	5.1	8.4	6.2	9.4	7.1
Digestive tract disease	2.9	3.4	3.0	4,0	1.9	4.1	3.1	4.2

SOURCE Central Bureau of Statistics, *Statistics Yearbook of he Netherlands for* 1993 (The Hague' SDU Publishers, 1993).

system, but **action was** prevented by the outbreak of the war.

After the war the new conservative government, rejecting a national health care system, left the initiative with private institutions and organizations, and limited themselves to overall control and regulation of hospital building activities and reimbursement fees. In 1956 new legislation delegated the principal authority for coordinating health care to Provincial Health Councils (who were representatives of the regional private care organizations).

The 1960s were a period of economic and social expansion in the Netherlands. The private foundations and organizations that controlled inpatient and outpatient care increased the number of new facilities, beds, and personnel, but without any regional or national coordination. The cost increases associated with these developments (and the resulting disparities and inefficiencies) troubled the government. However, the government had virtually no instruments for controlling or guiding these activities. It became clear that there was a need for legislation and administrative provisions to control health care.

The Hospital Tariffs Act (Wet *Ziekenhuislarieven)* of 1965, which regulated price-setting for all intramural institutions, and the Hospital Provisions Act *(Wet Ziekenhuisvoorzieningen)* of 1971, which regulated all building and renovating of intramural institutions, were the first steps. The first real planning of health care started when the government (a coalition dominated by the Socialist Party) drew up a Memorandum on the Structure of Health Care *(Structuurnota Gezondheidszorg)* in 1974. This document described a coherent and coordinated regionalized system of health services, built up in stages, which could be directed and controlled. A major starting point was reform of the financing structure, under which the public health system as a whole would be financed out of general revenues and other facilities out of a separate health insurance scheme.

The strategy and the expectations of the policy outlined in the memorandum have not been completely fulfilled. The legislation required was introduced only partially, and was applied only to a limited extent. Nevertheless, the reforms started in 1974 did create a more coherent structure for the Dutch health care system and enabled the government to become a major player.

In the 1980s pressure on the health care system grew with rising costs, higher insurance premiums, new medical technologies, a growing range of services, and increasing administrative costs, all during an economic recession. It appeared that excessive demand for care combined with an oversupply of care could not be controlled with the existing system. The elaborate administrative system, inflexible through the large number of rules and regulations, proved incapable of checking the virtually autonomous growth of the health care sector.

In 1986 the government published a policy document, "Health **2000,"** which identified future health problems: aging of the population, growing dependency on care, consequences of alcohol and tobacco consumption, the social cost of accidents, and the predominance of cancer and cardiovascular disease alongside new infectious diseases. These future health problems could only be met with new, forward-looking policies, signaling the

need for yet another major reform of the health care system (described later).

Legal and Legislative Background

The legislative structure of the existing health care system in the Netherlands (until the recent reforms, described later) rests on four pillars: health care insurance, regulation of health care providers, control of health care costs, and accreditation of health care professionals.

Health Insurance

A compulsory national health insurance scheme (originating from a scheme introduced in 1941) was implemented in 1966, when the Sick Fund Act (Ziekenfondswet) was passed in Parliament. Part of the social security system, Sick Fund insurance covers about 62 percent of the population. Members of the scheme include employees and self-employed persons whose income falls below a certain level (US28,500 in 1992) and those over the age of 65 with no income of their own. Sick fund insurance covers all acute care provided by hospitals, general practitioners, and specialists; all costs of drugs and appliances; and transportation. For all public employees of provincial and municipal governmental bodies there is a similar insurance scheme (covering about 6 percent of the population). The remaining 32 percent of the population is insured through private schemes. Private insurance companies are represented by the National Society of Private Health Care Insurers (KLOZ), which participates in health care administration.

The national social insurance scheme is executed by independent sick funds. All of these are members of the Society of Dutch Sick Funds *(Vereniging van Nederlandse Ziekenfondsen* or VNZ), which plays a dominant role in shaping general health care policy. The sick fund scheme is supervised by the Sick Fund Council *(Ziekenfondsraad),* representing government, employers, employees, sick funds, care institutions, and health professionals. The Council approves arrangements between sick funds and health care providers, controls and defines the benefit package, and advises the Ministers of Health and of Social Affairs concerning the level of the insurance premium, which is fixed by the central government.

Neither the VNZ nor the KLOZ has a director legal role in health care administration or planning at the national level. However, they represent their members in the national negotiations over tariffs and budget guidelines that take place in the COTG (see below). They also participate in budget negotiations with each hospital, giving them potential influence over the introduction and utilization of health care technologies—for example, they may block a hospital's initiative to introduce a new technology by withholding financing.

In 1968 another social security law was passed to cover the costs of "exceptional medical expenses." This insurance scheme (AWBZ) covers the most expensive forms of care, including long-term care in hospitals, home care, nursing homes, homes for mentally and physically handicapped, and ambulatory mental care. It is compulsory for all Dutch citizens, and financed out of premiums under the fiscal system.

Regulation of Institutions

The provision of health care is regulated under the Hospital Provisions Act (1971), which covers acute care hospitals, nursing homes, mental health institutions, and institutions for the handicapped. Regulation includes the number and location of the institutions, building and renovation, the number of beds, certain equipment, number of specialists, etc. The capacity of the institutions is planned and approved by the provincial health authorities, but legal authorization is given by the central government. The central government provides guidelines to the provincial health authorities to assure equal distribution and access to care over the country. One of these guidelines concerns reductions in the number of hospital beds (table 6-4).

Health Care Costs

In 1965 the Hospital Tariffs Act (Wet *Ziekenhuistarieven)* was passed to control price-setting for all inpatient care institutions and was later ex-

TABLE 6-4: Hospital Care Data

Data	1988	1992
Number of hospitals	181	162
General	130	112
University clinic	9	9
Specialized/category 1	42	41
Total number of hospital beds	68,020	63,744
Hospital days (x 1,000)	18,164	16,986
Admissions (x 1,000)	1,531	1,547
Outpatient visits (x 1 ,000)	20,119	21,718
Average hospital stay in days	11.5	10.6

SOURCE Central Bureau of Statistics, *StatisticalYearbook of the Netherlands for 1993* (The Hague SDU Publishers, 1993)

TABLE 6-5: Health Care Spending, 1993

Sector	Expenditure (in million Dfl)	% of total
Hospital care	15,272	27.1
Medical specialists	2,435	4.4
Ambulance transportation	537	1,0
Mental health care	3,899	6.9
Care for handicapped	4,883	8.6
Care for the elderly	10,568	18,7
Extramural care (incl. GP's)	**9,664**	**17.1**
Pharmaceuticals	**5,466**	**9.7**
Preventive care	**763**	**1.4**
Administration	**2,845**	**5.0**
Total	**56,333**	**100.0**

SOURCE Ministry of Welfare, Health, and Culture, *Fiancial Reveiw for Health Care* 7993 (The Hague SDU Publishers, 1993)

tended to all health care sectors (see table 6-5 for a breakdown of health care spending by class). The law is executed by the Central Board of Health Care Tariffs (COTG). In 1984 a hospital budget system was introduced; these global budgets, which are negotiated between hospitals and health care financiers, also must be approved by the COTG.

In practice the COTG creates a formula for calculating global hospital budgets, which is used in local negotiations over hospital budgets in which the different payers participate. The complexity of this process is reduced by the fact that each region usually has one dominant social insurance agency. The private insurers that operate on a national scale are represented by a KLOZ negotiator. The COTG monitors the end results of each local negotiation to see that they are consistent with the general guidelines.

The Tariffs Act also regulates the total volume of capital investment in the health care sector. Hospitals organizations are, in principle, free to acquire the money they need for building or enlarging their hospital facilities through loans on the capital market. However, the resulting costs for interest and depreciation will only be included in the budget and in the per-day price of a hospital bed if the hospital can secure a "certificate of need" from the central authorities. Another form of control through this act is on the diffusion of health care technology. Both buying and use of expensive technology by hospital authorities is dependent on approval to accommodate the extra cost in the budget.

Certification of Health Professionals

Physicians and nurses must be certified by the government. A new system for enhancing professional standards and quality control in health care, a result of the 1994 Medical Professions Bill *(Wetsontwerp* BIG), is to be introduced over a period of four years: certification and registration of nurses and physicians, description of "restricted medical acts (i.e., restricted to qualified physicians only), and reform of the professional disciplinary law. The volume of physicians is regulated in two ways: enrollment in basic medical training is limited by a central government quota at the level of the medical schools; and specialist education is regulated by the professional specialist organizations.

Administering the System

Health care administration under the current system in the Netherlands is very complex. It is a combination of elaborate government regulation

and the provision of care by mainly private health institutions and practitioners. As of 1994 the government's agent is the Ministry of Health, Welfare, and Sports.

The government has ultimate control over the planning of care facilities, the pricing of provisions and the macroeconomy of health care expenditures. It is directly responsible for prevention, health promotion, health protection, and intersectoral action in the health field. More and more, the government is striving for a comprehensive health policy.

The daily provision of health care is mainly in the hands of hospitals and institutions that have a private legal status. They originate from private foundations, charities, etc. Although private they all function in a nonprofit setting since all reimbursement of health care provisions is centrally regulated. This means there are nationally uniform reimbursement fees and charges, leaving little room for free enterprise and market force competition.

Individual patients are in principle (on the basis of health care legislation) free to choose their own physicians and their own hospital; however, since all referral to specialist care is done by general practitioners, this choice is limited. Professionals are free to select treatment for their patients, within the limits set by the insurance packages. Physicians are also free to settle and practice where they like, although there is more and more regulation in this respect from regional and municipal authorities.

Reimbursement of Services

Charges for health care services are uniform throughout the country. COTG is an autonomous body that sets out guidelines for the composition and calculation of charges and tariffs. Representatives of the providers and insurance agencies use these guidelines as the basis for negotiating the actual charges, which must be approved by COTG.

Before 1984 the health care reimbursement system in the Netherlands was open-ended. As part of the cost-containment policy all hospitals are required to have a global annual budget, which is calculated prospectively. There is no possibility of recalculation or compensation afterwards if the hospital exceeds its budget.

General practitioners are paid on a cavitation basis for sick fund patients and on a fee-for-service basis by privately insured patients. In general their fees for sick fund patients and private patients are the same. Specialists are paid exclusively on a fee-for-service basis for all patients (except physicians in University Hospitals, who are salaried). Specialist fees for sick fund patients are negotiated between the representative organization of physicians and the sick funds. Specialist fees for private patients are negotiated with the insurance companies and are usually higher. All physicians' fees are controlled and approved by the Minister of Economic Affairs, as part of a general incomes policy.

Reform Proposals and Implementation

The introduction of global hospital budgeting in 1984 proved effective in containing the rising costs. Between 1984 and 1992 total health care expenditures remained stable at 8.3 percent of Gross Domestic Product (GDP). However, the Dutch government wanted to introduce further reforms to impose greater control over health care expenditures, to change the insurance system, and to enhance the efficiency of the system by introducing a competitive market system. In 1987 a special committee was asked to produce a blueprint for comprehensive health care reform and in 1988 it published its report, *Willingness to Change*. The central recommendations for reform were:

1. provision of health care and social care should be integrated;
2. the efficiency and flexibility of health care should be improved through the application of market forces, without sacrificing the principles of equality and equity; and
3. there should be a shift from government regulation to market regulation and self regulation.

The important innovative element was to be a central health insurance fund, covering the whole population and providing insurance against more

than 90 percent of health expenditures. The fund would receive income-related contributions from the population and would pay out risk-related premiums to competing sickness funds and private insurers. There would be sharing in the cost of premiums (no more than 15 percent of the cost) by consumers to encourage cost-conscious choice of insurers.

In 1990 the Dutch government started to implement these changes in a somewhat revised form with less emphasis on market orientation. The new proposal tries to integrate enhanced efficiency with a more regulated national insurance system based on solidarity. In this approach the differences between social and private insurance agencies would disappear and solidarity would be extended to all insured patients. This has been proposed because under the existing system the high financial burden on privately insured patients prevents market forces from acting. However, there is almost no place for competition between insurance agencies in the new scheme. Step-by-step introduction of the new system was planned over a period of four years beginning in 1991.

However, it is now becoming clear that such a system has significant effects on incomes and may be more costly in the long run; the medical associations are strongly opposed to measures directed at controlling and lowering the incomes of specialists. In late 1994 a new government decided not to go forward with all the reforms. There will not be a national health insurance scheme, but differences between social and private insurance schemes will be diminished. Priority will be given to moving consumer demand for and physician supply of care toward greater cost-effectiveness.

CONTROLLING HEALTH CARE TECHNOLOGY

Until the 1980s the Dutch health care authorities had no clearly defined philosophy of controlling the development and use of health care technology. In some areas (e.g., drugs) regulation had always been very strict, but in others, such as the licensing of new medical devices, control was almost lacking. Equipment could be introduced and become part of established practice without decisionmaking, evaluation, or cost-calculation. The resulting problems have led to a wide range of regulatory instruments, each developed for a specific sector, with different procedures and varying degrees of control. Compared to other European health care systems, the Dutch system is usually considered to have a high degree of regulation; coordination, however, is rather poor.

Research and Development Efforts

In the Netherlands, research and development (R&D) related to medical technology falls into four broad categories:

1. *University research:* basic, strategic, and applied research in all fields of biomedical science. University research in the field of biomedical science is mainly concentrated in the eight medical faculties, the university-related research institutes, and in some of the technical universities. Overall responsibility lies with the Ministry of Education and Science, which covers the cost of the research infrastructure (buildings, facilities, and equipment) and takes on a large part of the R&D funding. Universities are no longer completely free to choose their own research areas and priorities. Since the mid- 1980s the Minister of Education and Science has successfully implemented a policy of creating centers of excellence (zwaartepunten) to put an end to the considerable overlap in research efforts.
2. *Nonuniversity related research institutes within the public domain:* mainly applied research under contract to the government, industry, or societal organizations. Infrastructure and funding is mainly through the Ministry of Education and Science, and other ministries. The foremost institute with an interest in biomedical technology is the Netherlands Organization for Appiied Scientific Research (TNO; see below).
3. *[dependent research institutes (not-for-prof it):* basic, strategic, and applied research according to self-chosen mission. Infrastructure and funding is from their own sources, cover-

ing such topics as blood transfusion, mental health, and rehabilitation.

4. *Industrial R&D:* basic, strategic, and applied research according to self-chosen mission. Infrastructure and funding is from their own sources. Since 1986, the Ministry of Economic Affairs has implemented a policy to stimulate cooperation between research institutes and industry, with the aim of strengthening the position of the Dutch industry in this area internationally.

Total expenditure on biomedical R&D in the Netherlands was Df1975 million in 1991, excluding industrial spending (on which no data are available). Biomedical R&D is approximately 15 percent of all expenditure on R&D.

An important role in developing and implementing research policy is played by the Royal Dutch Academy of Sciences (KNAW), an organization with a longstanding tradition of advising the government and fostering cooperation and coordination between scientists and scientific institutes. The KNAW presents a periodic inventory of all biomedical research, judging the quality of the institutes and identifying future research areas *(Disciplineplan Geneeskunde).* Also important is the Dutch Organization for Scientific Research (NWO), which does ot conduct research itself, but supports efforts of the universities by coordination, priority-setting, and funding. NWO allocates research funds made available by the government and acts as an intermediary between the government and the universities. Finally, the Council for Health Research (RGO) advises the government on future health research priorities.

The structure for biomedical R&D the Netherlands has always been confusingly complex with many overlapping organizations and different funding arrangements. However, for several years the government has been implementing policies to coordinate the research efforts of the universities, the independent research institutes, and industry. Factors such as burden of disease in the Dutch population are used more and more in determining research priorities. Applied research (including technology assessment) has also been given a higher priority than in the past.

Regulation of Drugs and Biological Substances

Like other countries, the Netherlands regulates drugs and biologics for efficacy and safety. The Dutch program follows the usual system of requiring proof of efficacy and safety before the drug or biologic material can be marketed and used (pem- rketing approval).

From an international perspective, it is fair to say that the Dutch system for regulating drugs and biological substances is one o: the strictest in the world. The independent status of the organizations involved helps assure the integrity of these processes. The system works well in assuring safety and efficacy of the products on the market.

The Drugs Act of 1963 (Wet *op de Geneesmiddelen-voorziening)* is the legal basis for the premarket surveillance and approval of dregs. The pharmaceutical industry itself has the responsibility for establishing safety and efficacy of any new drug. The law requires them to submit these data to the Board for the Evaluation of Drugs (College *ter Beoordeling van Geneesmiddelen),* an independent body of experts appointed by the Minister of Health. The Board has autonomous authority to grant, refuse, or revoke drug marketing licenses, and its decision is binding. The Board considers evidence of efficacy, safety, and quality, but does not consider societal need for the drug. Admission of a new drug usually leads to reimbursement by the sick fund insurance agencies. Refusal means the drug cannot be sold or used in the Netherlands.

All pharmaceutical products, as defined by the European Community (EC), and pharmaceutical preparations (medical products marketed in bulk or without a brand name) are subject to the registration procedure. Since 1978, new drugs that already have been approved elsewhere may be imported under a simplified procedure ("parallel imports"). Specialized drugs on the market before 1963 and generic drugs on the market before 1978 usually have not been submitted to careful evalua-

tion. They are given temporary licenses and will be assessed during the coming years, mainly by post-marketing surveillance.

The establishment of the European single market will profoundly influence the drug registration policy in the Netherlands. Registration through the Brussels office will mean automatic registration in all member states.

The use of drugs is not regulated, but a committee formed by the Sick Fund Council issues guidelines for their appropriate use. Since 1982 the Sick Fund Council has published a prescription guide *(Farmacotherapeutisch Kompas)* that gives recommendations on the use of drugs based on comparisons of price and therapeutic efficacy of equivalent products. This guide has been very influential in changing prescribing patterns of general practitioners in the Netherlands, since the guidelines are linked with payment decisions.

Blood and blood-derived products are strictly controlled in the Netherlands, regulated by the Committee for the Regulation of Blood and Blood Products *(Commissie ex artikel 1, van het Besluit bloedplasma en bloedproducten).* Vaccines and sera are regulated by an independent committee *(Commissie ex arlikel 14 Sera- en Vaccinsbesluit)* that functions in a similar manner to the Drug Board. Vaccine trials in humans outside the laboratory must be approved by the Committee. As with drugs, vaccines are monitored after they are approved for use.

Regulation of Medical Devices

The introduction of biomedical devices and medical appliances in the Netherlands is poorly regulated. There is no systematic control or uniform procedure to establish the safety, efficacy, or quality of new equipment. Although the Medical Devices Act (1970) gives the Minister of Health the authority to evaluate and regulate any device or medical appliance, this law has not been effective. Only in cases where problems have arisen (as in the case of cardiac valve implants and rubber condoms) has the government introduced specific measures for quality control. But in general any newly developed medical device can be introduced without proof of safety, efficacy, or cost-effectiveness.

This does not mean that no quality control at all takes place. Some activities are usually carried out by the health care providers themselves (as the users of the medical devices) or their representative organizations, on a voluntary basis. Examples of these activities include the following:

- *Sterilization equipment:* sterilization equipment must be produced according to good manufacturing standards set by the National Control Laboratory of the National Institute for Health and Environmental Hygiene (RIVM).
- *Electrical safety standards:* all electrical devices in the Netherlands must meet minimum safety standards; however, there are no specific standards for medical applications, with the exception of cardiac pacemakers. The National Hospital Institute tries to fill this gap with recommendations for testing and performance criteria.
- *X-ray equipment:* under EC directives, the Dutch government is committed to developing standards for x-ray machines and x-ray therapy. Regulation in this field is rather complicated, involving a number of advisory boards; licensing is by the Minister for the Environment.
- *Evaluation of technical performance:* some evaluation of medical devices is undertaken by the Dutch Organization for Applied Scientific Research (TNO) at the request of the National Hospital Institute. However, only a limited budget is available, and many devices are left untested. The majority of the technical evaluations of equipment are carried out by the hospitals themselves. The University Hospitals have put together a working party that will undertake evaluations and make the results available to other hospitals.

Planning and Regulation of MedicalServices

In the 1960s and 1970s the expansion of medical technology and care resulted in a steady increase in the cost of health care. The Dutch government

saw the prolific building of new hospitals and institutions as one of the main contributors to rising costs. The Hospital Provisions Act of 1971 was introduced both to enable the government to regulate and coordinate the creation of inpatient facilities throughout the country, and as a planning instrument. It allowed the government to create a national network of hospitals and other health care institutions to ensure maximum access of the population to medical care. The provincial health authorities had responsibility for implementing this plan.

Article 18 Regulation

Article 18 of the Hospitals Act relates specifically to the planning of supra-regional, "high-tech" medical facilities. The law requires hospitals wishing to provide specific supra-regional services to seek approval from the Minister of Health (not the provincial health authorities), much like a "certificate of need" (CON) system. When the Minister decides that a specific technology or supra-regional service should be governed by Article 18, the Minister will publish a planning document *(Plunningsbesluit)* with general planning guidelines, an estimate of the need for that service, quality criteria to be met by a hospital, etc. In order to produce a planning document, the Minister asks the Health Council to report on the scientific state-of-the-art of the technology, on safety and efficacy aspects, cost-effectiveness, appropriate use, and so on.

When a hospital puts in a request for a specialized service under Article 18, the application is put before the Hospital Planning Board (College *voor Ziekcnhuisvoorzieningen)* which evaluates whether the hospital meets the criteria, what extra facilities are needed, and what the cost will be. When a service is approved the cost of the new service is met by an increase in the hospital budget. Funding of new equipment and technology by the hospital is usually through loans on the capital market. The cost of the loan (interest and depreciation) can be included in the hospital budget and is reimbursed by the health insurers, making it possible for hospitals to keep up (in a reasonable way) with technological improvements and ensure timely replacement of equipment.

When Article 18 regulation was introduced in the 1970s it was used mainly to regulate the diffusion of new expensive technology by limiting the number of facilities and the number of procedures (e.g., computed tomography (CT) scanners, cobalt radiation units, linear accelerators, and dialysis machines) and was largely an instrument for cost-containment. But gradually the central government began to use Article 18 as a real planning instrument: to ensure geographical distribution, to promote concentration of facilities, to enhance expertise and quality, and to increase the cost-effectiveness and appropriate use.

Emphasis in the Article 18 program shifted from controlling the purchase of equipment to regulating the use of specialized medical services as a whole. Today even supra-regional services that use almost no costly equipment (e.g., genetic screening and counseling and in vitro fertilization) are regulated through Article 18. Since 1984, when the global budget system in hospitals was introduced, the government no longer attempts to regulate the number of treatments or procedures. (Such regulation is part of the local negotiations over the annual budget between hospitals and insurance agencies.)

In general, Article 18 regulation has worked quite well. Most new, costly technologies that have been introduced over the past 20 years diffusion has been controlled in such a way that oversupply has been prevented and effective use has been stimulated (table 6-6). Regulation has been effective because hospitals that break the law are confronted with severe sanctions; when a hospital offers a specialized service without obtaining approval, it is considered to be an economic offense. The hospital may be fined and the new service will be closed down. Secondly, without approval, the service will not be reimbursed by insurance agencies and patients will not be referred to that institution. Also, interest and depreciation on capital loans will not be included in the budget.

TABLE 6-6: Technologies Regulated Under Article 18

Type of service	Year brought under Article 18	Current status
Radiation treatment	1979	Regulation continued
Computer tomography	1984	Regulation lifted 1988
Renal dialysis	1976	Regulation continued
Kidney transplantation	1976	Regulation continued
Nuclear medicine (diagnostic and therapeutic)	1984	Regulation lifted 1988
Genetic screening	1984	Regulation continued
Cardiac angiography	1984	Regulation lifted 1991
Interventional cardiology (PTCA, Implantation)	1984	Regulation continued
Cardiac surgery	1984	Regulation continued
Neurosurgery	1984	Lifted for "simple" interventions 1991
Neonatal intensive care (IC)	1984	Regulation continued
In vitro fertilization (IVF)	1988	Regulation continued
Heart transplantation	1991	Regulation continued
Liver transplantation	1993	Regulation continued
Lung transplantation	1991	Regulation continued
New candidates for Article 18 regulation:		
Allogeneic/autologous bone marrow transplantation	1994	—
Pancreatic transplantation	1994	—

SOURCE Ministry of Welfare, Health, and Culture, Financial Review for Health Care 1994 (The Hague SDU Publishers, 1994)

Experience with Article 18 has not been totally positive. Procedures are rather bureaucratic and time consuming. In some cases (e.g., CT scanners, cardiac bypass surgery) diffusion had already taken place before regulation was in operation. Recently the procedure has been adapted to be more flexible; it can now be applied almost overnight when the situation requires a rapid response. Also, regulation can be applied as a temporary measure (maximum of four years) to control the early stages of diffusion of a technology. Finally, when it is considered that a new technology has become established or has lost its supra-regional function, regulation under Article 18 can be lifted.

The total expenditure for specialized services under Article 18 regulation is calculated prospectively every year by the Minister of Health in his annual Review of Health Care Costs *(Financieel Overzicght Zorg).* There is only limited room for expansion of hospital budgets for these services (approximately Df125 million), so priorities must be set.

During the recent debate on health care reforms, the need for and effectiveness of strict regulation by the central government has been questioned. However, the Minister of Health has emphasized that Article 18 regulation as an instrument to control the introduction and use of new technology will be continued under any new system.

Control of Health Technology Through the Payment System

The major explicit control that the government and the insurance agencies have over the diffusion and use of technology is the health care financing system. The system for global budgeting introduced in 1984 includes allowance for investment in new equipment and technology, but to a limited extent. Approval for a specialized service under Article 18 will lead to a budget increase.

The Sick Fund benefit package includes so-called "closed" benefits and "open" benefits, such as specialist care. The benefit package covers only

treatments or procedures considered established and accepted. Since 1984 the Sick Fund Council (which develops and controls the benefit package) has used this system more and more as a tool to control the introduction and use of health care technology. Services can be excluded from the benefit package until efficacy and cost-effectiveness are demonstrated (as in the case of in vitro fertilization) or the level of reimbursement maybe lowered (as with CT scanning) when the technology becomes less complex. Some treatments are reimbursed only for specific, limited indications (e.g., autologous bone marrow transplantation only for acute leukemia). Using these methods, the Sick Fund Council has begun to effectively influence the use of health care technology, including the "appropriate" use of established technologies that are already included in the benefit package.

Influence of the Public

The public gets information on new medical technologies and their assessment mainly through the media. Television programs in the Netherlands on medical issues are frequent and very popular. However, most of these programs (often imported from the United States, United Kingdom, and Germany) take a rather uncritical view of medical technology, sometimes claiming effectiveness where this has not yet been proven. In more recent years, some series by Dutch producers developed in cooperation with the medical associations are highly informative, discussing both pros and cons, and avoiding sensationalism. One award-winning program presented the medical and ethical dilemmas in liver and bone marrow transplantation. Another highly praised series discussed the public use and abuse of DNA-based genetic information. Through these programs the media do influence the demand for some new technologies (e.g., organ transplantation, in *vitro* fertilization (IVF), cancer therapies). The same holds true for the information that some patient organizations provide to their members. The demand for lithotripsy and erythropoietin grew significantly after the Dutch Kidney Foundation informed patients of these developments at an early stage. In 1993 the Minister of Health sponsored a series of television programs on "making choices in health care," intended to involve the general public in a discussion on the limitations of health care.

HEALTH CARE TECHNOLOGY ASSESSMENT

Development of Interest

In the Netherlands one institution has traditionally had an interest in medical technology assessment: the Health Council *(Gezondheidsraad).* The Health Council, established in 1902. reports to the government on the state of science regarding issues of health care, public health, and environmental protection. The Council evaluates the efficacy, efficiency, and cost-effectiveness; and ethical, legal, and social aspects of new medical technologies including devices, drugs, diagnostic tools, surgical therapies, and also the health system as a whole. The Council does not carry out or fund medical research, but uses literature review (meta-analysis and synthesis of the international scientific literature), expert committees, and consensus meetings. Although technology assessment had always been used by the Health Council as a research tool, it had not been an explicit issue in the policies and decisionmaking process of the government or the health insurance agencies. This situation changed in the early 1980s, when both the government and the Sick Fund Council became concerned about the tremendous development of medical technology and its impact on health care and society (especially in terms of cost).

At that time the Minister of Health could control the diffusion of medical technology (to a certain extent) through the use of Article 18, but only as far as established technologies were concerned. There was no such regulatory instrument for innovative, emerging technology. At that time, new technologies automatically y became part of the social insurance benefit package and were reim-

bursed on the basis that the medical profession judged these technologies to be useful.

Around 1982 the Sick Fund Council was confronted with patients who demanded that the costs of heart and liver transplantations that had been performed abroad be reimbursed by the sick funds. The debate focused on the question of whether these procedures should be considered established or still experimental. The outcome of the debate was that these therapies were excluded from the benefit package until they had been formally evaluated. Following this decision, the Sick Fund Council took the position that the introduction of new technologies into the benefit package should be more actively controlled.

In 1983 the Council outlined its new policy in a paper, "Limits to the Expansion of the Benefit Package." In the future all major new medical technologies were to be assessed, regarding efficacy and cost-effectiveness, and were to be admitted to the package according to their priority. When the annual budget was debated in Parliament later that year, one of the topics was the impact of technological development on health care in the light of limited money. The spokesman of the Democrats '66 Party made a plea for systematic evaluation of new medical technology in order to be able to make political choices in a more rational way. By 1984 the interest of policy makers in medical technology assessment had been roused, but there was still little expertise in the country and no coherent procedure. This gap has been filled by practical experience with technology assessment.

The First Technology Assessments

The year 1985 saw the start of three medical technology assessment projects: heart transplantation, liver transplantation, and IVF. The initiative was taken by the Sick Fund Council and the Ministry of Health. Funds came from the Sick Fund Council research budget and the actual research was carried out by the Universities of Maastricht (IVF) and Rotterdam (heart and liver transplantation).

These first projects were full-scale prospective technology assessments, aimed at evaluating the medical, social, economic, and ethical aspects of the technology. The final reports were completed in 1988 and 1989. Based on these reports, the Minister of Health and the Sick Fund Council decided to cover heart transplantation and IVF, and the decision on liver transplantation was held until further research (on long-term survival) was carried out.

The lack of expertise and experience in medical technology assessment in the Netherlands led the Minister of Health to ask the Steering Committee on Future Health Scenarios *(Stuurgroep Toekomstscenario's Gezondheidszorg,* or STG) in 1984 to recommend a long-term policy on medical technology. In its 1987 report (3), the STG raised the possibility of developing an "early warning system" for future health care technology. Six areas of emerging medical technology were described in more depth, looking at their future health and policy implications. The main policy conclusion was that if the Netherlands wanted to have greater control over the development and diffusion of medical technology, it would have to create a coordinated system for identifying technologies and assessing their benefits, risks, financial costs, and social implications. Technology assessment could then be a useful tool in making the necessary choices in a political context of increasingly limited resources.

Creating a National Fund for Medical Technology Assessment

The message from the STG was well taken by both the government and the Sick Fund Council. In 1988 a revolving National Fund for Investigational Medicine *(Fends Ontwikkelingsgeneeskunde)* was created by the Minister of Health, the Minister of Science and Education, and the Sick Fund Council at the level of Df136 million. A standing committee was given the task of selecting research proposals submitted by the hospitals (in cooperation with NWO) based on scientific excellence. Projects may evaluate new or established medical

technologies, looking prospectively at efficacy, cost-effectiveness, social, ethical, and legal implications, in view of the policy decisions to be taken (admission to the benefit package, reimbursement, redefining the established indications, regulation under Article 18, etc). The Standing Committee on Investigational Medicine (Commissie *Ontwikkelingsgeneeskunde)* is made up of experts in medicine, health economics, medical ethics, health law, and health administration; and representatives of the ministries, the sick funds, and the Health Council.

Projects are funded for three years, after which a report is submitted to the standing committee. Most assessments take the form of prospective, randomized trials, with an added component for cost-effectiveness analysis. Since 1989 more than 80 research projects have been funded for a total of Dfl 150 million. In 1993 the first projects were completed and will soon lead, it is hoped, to policy decisions on those subjects.

Until 1993 the procedure of funding proposals was essentially a "bottom-up" procedure: projects for research were chosen by the hospitals themselves. In 1993 the Standing Committee initiated a "top-down" procedure alongside the existing arrangement. Research groups are invited to submit proposals for projects selected by the Committee itself so that areas in which technology assessment has been rather weak can be studied (e.g., in mental health care, clinical geriatrics, and small-ticket routine diagnostic procedures).

Looking back at the start of medical technology assessment activities in the Netherlands, they can be considered to have been reasonably successful. However, procedures are not finally established. Some important problems remain and will have to be overcome in the near future, including:

- a need for priority-setting in technology assessment;
- a need for more international dissemination of technology assessment information and cooperation with agencies abroad, to avoid duplication;
- a need for better follow-up of technology assessment studies to ensure that the results are taken up in clinical practice; and
- a need to integrate the technology assessment approach into the thinking of the medical professional at large.

New Policies for Medical Technology Assessment

Medical technology assessment has become an important health policy issue in the Netherlands in the 1990s. The government has made the assessment of new medical technologies a key component of its policy to promote the appropriate use of medical care and to deal with problems of shortage, rationing, and waiting lists. In 1989 a committee was appointed with the task of analyzing the problems of "choices in health care." This committee looked into the different aspects of making choices on the macro-, meso- and micro-level of health care and presented a strategy to admit medical technologies to the benefit package. On the one hand, "traditional" criteria such as efficacy and effectiveness were included. On the other hand, questions like "Is a specific type of care/technology essential to let a person continue a normal role in society?" and "Can people pay for this type of care out of their own pocket?" were considered. To be able to make such choices the committee has recommended that assessment of medical technologies be carried out on a wider scale. The government has stated that this approach will be included in the coming health care reforms.

In a recent report by the Health Council (21), titled *Medical Practice at the Crossroads.* the Council observed that inappropriate use of both established and new medical procedures and technologies is widespread. The report documents examples from almost all medical specialties. focusing not so much on the efficacy and effectiveness of medical technologies themselves, but rather on how doctors use the procedures.

The main conclusion of this report is that large and unexplained variations in medical practice point to the inefficient use of resources, which can no longer be ignored. The report urges the medical profession to start their own process of critical self-evaluation (or others will do it for them). The report recommends that accountability for medical practice based on systematic evaluation should become routine for doctors. This accountability can be enhanced by setting up independent quality assurance committees with the professional organizations. The change of attitude needed in the medical profession should start from the basic medical curriculum, according to the report. Finally, the report recommends that formal assessment should be the criterion for admitting new procedures to established medical practice, and also that long-accepted procedures should be re-evaluated, preferably by the medical profession itself.

This report has influenced the current discussion on evaluation of medical practice and the assessment of medical technology within the professional bodies in the Netherlands. In 1993 the Sick Funds Council initiated a long-term project to critically evaluate the entire benefit package in terms of cost-effectiveness and appropriate use. Through a Delphi-type study (using a large panel of experts) a first selection of 126 items where doubt has been expressed on cost-effectiveness or appropriate use has been made. This list will be subjected to further critical evaluation on the basis of priorities.

Organizations Involved in Medical Technology Assessment

The Central Government

The Ministries of Health and of Education and Science are involved in health care technology assessment as cofunders of the Investigateional Medicine scheme. Technology assessment is also carried out by other organizations at their request. The Ministry of Economic Affairs has a policy for promoting the development of medical technology through funding the national industry. Technology assessment (with emphasis on technical performance and good manufacturing procedures) is an important item on the agenda.

The Health Council (Gezondheidsraad)

The Council advises the government on the scientific state of the art of medicine and health care. To this end it brings together groups of experts on specific subjects at the request of the Minister of Health or the Minister of Environmental Protection. Technology assessment has traditionally been part of the activities of the Council; many reports on specific technologies have been published (e.g., transplantation; diagnostic technologies such as CT scanners, MRI scanners, and PET scanners; neonatal intensive care; genetic screening and counseling; cardiac surgery). Committees are made up of physicians, economists, social scientists, experts in management, lawyers, and ethicists. The Council has a strong focus on identifying new technologies before they come into widespread use. The Council also recommends new emphasis for the Investigational Medicine Fund.

Sick Funds Council (Ziekenfondsraad)

This Council became involved in health care technology assessment in the early 1980s. It has funded most of the early studies (heart and liver transplantation, IVF, breast cancer screening) and it plays an important role in the Investigational Medicine Fund. In 1993 the Sick Fund Council started a project to review and redefine the criteria for "appropriate use" of a wide range of established technologies.

National Council for Health Care (/Rationale Raad voor de Volksgezondheid)

The National Council comprises representatives of health care providers, insurance agencies, and consumer organizations. It advises the government and the health care community on general policy issues. Some studies have been done on medical technology in which the importance of technology assessment is stressed.

National Institute for Health and Environmental Hygiene (RiVM)

This organization carries out clinical trials of vaccines. It monitors the adverse effects of vaccines and of toxic substances, and also looks into the safety aspects of certain medical devices.

Netherlands Organization for Applied Scientific Research (TNO)

TNO studies medical devices (e.g., filters, laminar flow units), focusing on safety and technical effectiveness. It also supports studies of medical technologies and procedures (e.g., thrombolytic therapy for blood vessel recanalization, extra- and intracranial bypass operations, and mammography). TNO has progressively become involved in technology assessment in a broader sense, taking a lead role in assessing technology for home care. In 1993, TNO formally established a medical technology assessment program.

Steering Commitee on Future Health Scenarios (STG)

STG is an independent advisory group to the Dutch government, installed in 1983 to carry out scenario studies as an aid to long-term health policy. It published a study on *Anticipating and Assessing Health Care Technology* in 1987 (3), and has published scenario-studies on accidents, aging and care for the elderly, drugs, and demographic development and health. In 1993, government discontinued funding of the STG because of budget cuts. The work of the STG may continue, using other (presumably private) funds.

National Organizatjon for Quality Assurance in Hospitals (CBO)

CBO examines quality and medical effectiveness at the hospital level, and promotes quality awareness by organizing consensus conferences on specific technologies for practicing clinicians.

Council for Health Research (Raad voor Gezondheidsondetzoek; RGO)

The RGO was created in 1987 to advise the government on the coordination of biomedical research in the Netherlands. In 1988 a report was published on the importance and coordination of technology assessment in biomedical research. The Council makes suggestions for new areas of technology assessment.

Universty Institutes for Technology Assessment

Several universities in the Netherlands are developing programs in health care technology assessment. The Institute for Medical Technology Assessment of the University of Rotterdam (IMTA) is very active in the field of economic evaluation and cost-effectiveness (e.g., in the field of transplantation and bypass surgery). It provides technical support to many hospitals carrying out research for the Investigational Medicine Fund. The Institute of Health Care Economics of the University of Limburg is also involved in cost-effectiveness studies and clinical trials of vaccines and drugs. The Institute for Medical Sociology of the University of Groningen has carried out technology assessments focusing on quality of life and social and ethical aspects of technologies. Other university institutes continue to develop interest in technology assessment.

Case studies

TREATMENTS FOR CORONARY ARTERY DISEASE

Coronary Artery Bypass Grafting (CABG)

The first attempts at CABG in the Netherlands were made in the late 1960s, in the university clinics in Groningen and Amsterdam. At that time coronary artery disease (CAD) had become the leading cause of death in the Dutch population. However, government policy focused on prevention rather than surgical intervention. In 1968 the Minister of Health asked the Health Council to report on options for preventing and treating CAD. The Council appointed a large committee which reported in 1971. One recommendation was to immediately increase the capacity for open-heart surgery to 1,300 procedures per year, since CABG had become an established intervention. The government ignored this recommendation, however, and continued to focus on prevention.

In 1972 the Nieveen Committee repeated its plea to increase the surgical capacity of the heart centers, and to bring the capacity to 3,000 operations by 1980 and increase the number of centers from seven to 11. Although this proposal was discussed in Parliament, no steps were taken to implement it. One reason was that the Minister of Finance found this masterplan too expensive (the estimate being around Df125 million). He presented a counterreport estimating the need at a maximum of 1,200 operations per year, performed in five centers. The Health Council Committee reacted furiously to this, saying that the Minister of Finance had overstepped his competence and was not qualified in any way to assess the need for medical treatment.

The real problem was that open-heart surgery took place almost exclusively in the University Hospitals, which came under the budget of the Minister of Education and Science, who paid practically all the cost: research, medical education, equipment, and a large part of the health care provided. The social and private insurance agencies paid only for the hospital stay and not for the medical procedures. If open-heart surgery in these hospitals was to be increased, the financial burden for this would fall on other parts of government, including the Minister of Finance.

By 1974 the whole situation had come to a dead end. At that time, the Dutch Heart Patient Association staged a massive demonstration and even occupied the Parliament building. The Parliament, shocked by the violent actions of the patient organization, blamed the Minister of Health for the slowness of his decisionmaking. The Minister quickly reached an agreement with the insurance agencies over a reimbursement fee for CABG that would cover the cost at the University Hospitals, and announced that he would begin to increase the capacity for CABG in the University Hospitals, but not create new centers. The Heart Patient Association, not satisfied, organized an airlift in 1976. Patients on the waiting list were sent for surgery to the United States, London, and Switzerland, with the cooperation of the insurance agencies and the heart centers.

In 1976 the Minister of Health visited the United States and was alarmed at the growth in the number of CABGS. He observed that U.S. health authorities admitted that the increase might be due to an unjustified broadening of the indications for the procedure. Returning home, the Minister stated to the press that the estimate of 4,500 open-heart procedures might be too high, and that it was not necessary to increase the number of centers.

TABLE 6-7: Development of Open Heart Operations (OHO), CABG, and PTCA, 1975–1992

Data	1975	1980	1985	1990	1992
Population (millions)	13.7	14.1	14.5	14,9	15,1
Number OHO's	1,698	4,630	8,532	11,503	12,905
OHO (per million population)	124	328	588	772	854
OHO centers	9	12	13	14	15
Pop. per center (millions)	1.5	1.2	1.1	1,0	1,0
Case-load per center	189	386	656	822	860
Number CABG	663	2,926	6,789	9,202	10,325
CABG as % OHO	39	63	79	80	80
Pop, per center (millions)	1,5	1.2	1,1	1,0	1,0
Case-load per center	74	244	522	657	688
Number PTCA		36	2,556	8,205	10,521
PTCA (per million population)		3	176	550	697
PTCA centers		2	10	12	14
Pop. per center (millions)		7	1.4	1.2	1.1
Case-load per center		18	255	683	751

SOURCE M Bos, 1994, from reports of the Health Council, 1974-1993

In 1976 the permanent advisory committee on heart surgery (based at the Health Council) began work. They organized a consensus meeting, where a prominent role was played by eight "foreign experts" (mainly from the United States). The outcome of this meeting was a revised estimate of the future need for heart surgery (mainly based on U.S. data, since epidemiological data for the Netherlands were lacking). The new estimate was 5,500 to 6,500 open heart procedures per year (4,500 to 5,000 CABG, 1,000 to 1,500 operations on valves and congenital defects). The government had no option but to expand the number of heart centers. The decision was made to start two new centers in general hospitals, with a target of 1,000 procedures each per year.

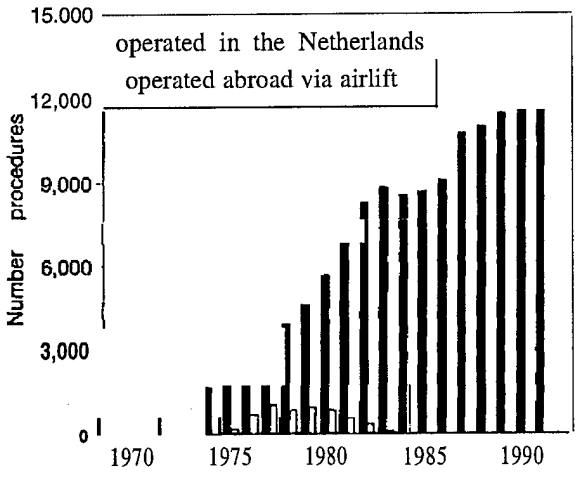
In the early 1980s the number of open-heart operations expanded rapidly because of the new centers, and the number of operations performed abroad decreased (table 6-7). In 1984 the Health Council published a new report on the long-term development of cardiac surgery. It estimated that the number of cardiac operations would grow to 12,500 in 1992. The impact of percutaneous transluminal coronary angioplasty (PTCA) was not calculated, but the Council expected a substitution effect of 15 percent on the rate of CABG.

By 1984 waiting lists began to grow again. The Minister of Health hesitated to permit further expansion of cardiac surgery because of financial constraints within the health care system. Also, there was some doubt over the appropriateness of growing referrals for CABG (in view of the fact that PTCA was also expanding rapidly). Finally, the Minister of Health gave in to the growing pressure and approved two more centers. Since 1988 the growth rate of the number of heart operations has slowed, reaching 12,900 in 1992 (figure 6-1).

Government Policies Concerning CAf3G

In the 1980s the government was keen on regulating not only the number of surgical centers, but also the volume of procedures (in particular, the number of CABG) through the use of Article 18. However, it was argued that with the introduction of the budget system this type of control was outdated. It was felt that the volume of cardiac operations should be agreed on in the negotiations between hospitals and financing agencies. In 1989 the Minister of Health stopped regulating the

FIGURE 6-1: Open-heart Procedures: Adult and Pediatric, in the Netherlands and Abroad



SOURCE M Bos, 1994, from reports of the Health Council 1970-1993

number of procedures, leaving this to the insurance agencies. Budget control was effective, but there is still a steady (but modest) increase in the number of CABGs.

Assessment of CABG

Full-scale assessment of CABG was never undertaken in the Netherlands, although it was recommended by the Health Council very early. The medical profession relied mostly on the data available from the United States and was unwilling to start a study in the Netherlands. A limited cost-effectiveness study was performed in the surgical center in Maastricht. Recently, the Dutch centers are cooperating in an international multicenter assessment study, organized by the IMTA in Rotterdam and the RAND Corp., focusing on appropriateness of use. This study is also collecting information on the effectiveness of PTCA versus CABG.

Percutaneous Transluminal Coronary Angioplasty (PTCA)

The first cardiologist to use PTCA in the Netherlands, in 1980, was Ernst (trained by Gruntzig). Others were quick to follow, and within two years all heart surgery centers were using the technique. By 1984 PTCA was considered to be established for the revascularization of (uncomplicated) single-vessel occlusions. When the Health Council reported on PTCA in its 1984 study of heart surgery, the committee (consisting of surgeons and cardiologists) was unanimous in its opinion that around 15 percent of all CABG procedures could be substituted by PTCA. However, as a growing number of cardiologists were trained in performing therapeutic interventions, they attempted more difficult coronary lesions. Also, more and more patients were treated with PTCA who were not yet candidates for CABG, but whose symptoms (anginal pain) were not successfully relieved with medicines. As a result, in the middle 1980s the number of both CABG and PTCA procedures increased rapidly, without any real coordination between cardiologists and surgeons. However, since there were long waiting lists for cardiac surgery in the Dutch heart centers at the time, the surgeons were probably relieved that the cardiologists were taking some of the workload.

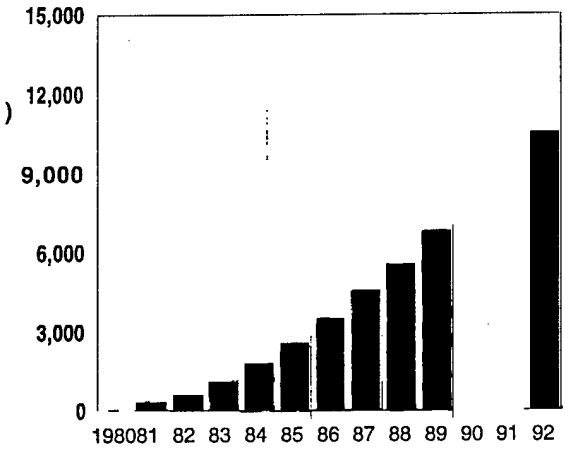
In 1987 the Minister of Health began to regulate heart surgery as well as PTCA under Article 18 of the Hospital Provisions Act. On the basis of the Health Council report (18) it was assumed that a maximum of 25 percent of all CABG could be substituted by PTCA. Following this reasoning, the growth of CABG was restricted while PTCA was allowed to expand.

The policy failed because both the surgeons and the cardiologists expanded the indications and exceeded the limits set by the Article 18 regulation. Although PTCA has replaced CABG for uncomplicated single-vessel disease, surgeons are now performing CABG in older patients (up to 85 years), and cardiologists are treating multivessel disease and patients who are not yet CABG candidates. As a result the numbers of CABG and PTCA procedures are both approaching 10,000 per year in the 1990s (see table 6-7 and figure 6-2).

Factors in the Diffusion of PTCA

The policy of the Minister of Health was to expand the number of PTCAS, to facilitate the substitu-

FIGURE 6-2: Diffusion of PTCA in the Netherlands 1980–92



SOURCE M Bos 1994 from reports of the Health Council, 1980-1992

tion of CABG by PTCA. To this end, the heart centers were given an extra budget for PTCA, while the number of CABG procedures was restricted. The health insurance agencies, which every year prospectively negotiate the number of CABG and PTCA procedures with the heart centers as part of the next year budget, also favored the expansion of PTCA. Finally. the media and the consumer organizations supported the dev 'op-ment of PTCA as a pat' .t-friendly procedure. Consequently, patient demand for PTCA has become stronger. When some hospitals tried to limit the number of PTCAS in 1990 because of a tight budget. the court ruled that patients were entitled to this procedure when there was a proper indication. The hospitals had no choice but to provide PTCA, and the insurance agencies had to pay for it.

Evaluation of PTCA has not played any part in its diffusion. In its 1984 report the Health Council recommended an evaluation of the proper indications for PTCA and the possible rate of substitution of CABG with PTCA. The Minister of Health asked the Cardiologists Association to set up the evaluation. However, such a study could not be organized during the 1980s. Because of strong competition between surgical and cardiology specialties in the field of therapeutic intervention, surgeons refused to cooperate with cardiologists to join in a prospective study. Dutch centers are currently participating in two assessment studies.

Concerns with CABG and PTCA

Both CABG and PTCA are fully accepted in the Netherlands. The rates for CABG and PTCA are the highest in Europe (but less than in the United States). However, neither procedure has been influenced by evaluation. Since there is still considerable overlap in indications for the procedures (especially for multivessel disease), evaluation is needed to ensure appropriate use. Also, patient demand and consumer pressure may have led to some inappropriate use. The Dutch health authorities have stated that they will make further expansion of the number of procedures dependent on the outcome of the ongoing assessment studies.

MEDICAL IMAGING (CT AND MRI)

Computed Tomography (CT)

The case of the CT scanner demonstrates how the international network of medical professionals functions (8). Dutch radiologists learned about CT scanning at the yearly Radiological Society of North America (RSNA) Congress in the early 1970s. Some of the leading radiologists voiced strong opinions that the Netherlands should take part in the clinical development of CT scanning from the very beginning, and they were successful. In 1975 the Minister of Education and Science (who was then responsible for the University Hospitals) gave permission for the first brain scanner to be installed in Amsterdam University Hospital, with the proviso that the scanner be used for research purposes only. Shortly afterward, a second scanner was installed in a neurological clinic in Wassenaar. Before long other hospitals requested the support of the government to buy CT scanners.

The Minister of Health then asked the Health Council to report on the state of the art of CT scanning. Specifically, the Council was asked to consider the evidence of clinical benefit of CT and the necessity of regulating the diffusion process

through article 18 regulation. The radiological community stated that this report was unnecessary because there was enough evidence already of the efficacy of CT scanners. They increased their pressure on all parties and were supported by the national industry (Philips Medical Systems). They argued that CT should not be withheld from eligible patients.

The Health Council published its first report after six months (14). The main conclusions were:

1. CT scanners should be regulated under Article 18 (because of the high cost, speed of technological developments, and special expertise needed);
2. CT scanning is of great potential value to neuroradiology (brain/CNS);
3. the value of CT scanners for other parts of the body is not yet defined; and
4. CT scanners should, for the time being, be restricted to teaching hospitals.

Although the Minister of Health had asked the hospitals not to buy CT scanners while the Health Council was preparing its report and until a decision was made about further diffusion, eight hospitals were operating scanners by 1977. In the same year the Health Council published its second report, calculating the future need for CT scanners in the Netherlands at 20 to 30 brain scanners and seven to eight whole-body scanners (one CT scanner per 300,000 to 500,000 inhabitants). The Council made a strong plea for the hospitals to join in a study of costs and effects of CT scanners, and warned that rapid improvements in CT technology caused scanners to be obsolete in just two or three years, making careful diffusion even more important. However, in the following years the Ministry of Health failed to implement a regulation for CT scanners, and no evaluation was conducted.

In 1979 the Central Board for Hospital Provisions (CvŻ) published a plan for the diffusion of CT scanners, under which each health region would have at least one scanner (this meant 27 scanners for patient care) and another 10 should be available for research and teaching. In the same year the Health Council published a third report saying that the lack of radiologists and technicians trained in CT scanning made too rapid an introduction hazardous. Nevertheless, in the next years 15 CT scanners were installed, without any planning or coordination. Some general hospitals evidently bought scanners because they anticipated future government regulation.

The Health Council published its final report in 1981, concluding that from a medical point of view there was no good reason to restrict the use of CT scanners. The need for CT scanners was set at one per 300,000 inhabitants (50 for the whole country). In the same year the Ministry of Health published a temporary decree to regulate CT scanners, to the effect that no more scanners could be installed by general hospitals until a definite plan for diffusion was published. By that time 24 general hospitals were operating CT scanners, while the seven University Hospitals had 13 scanners at their disposal.

In the next few years, only the University Hospitals (which were exempt from the regulation) were able to acquire more scanners. Finally, in 1984 (eight years after the first Health Council report), the Minister of Health promulgated a regulation, but it did not follow the Health Council's recommendations. The Ministry restricted scanner use to 130,000 scans per year until 1990 (at 4,000 scans per year per scanner this meant 33 CT scanners for the whole country, or one CT scanner per 450,000 inhabitants). In fact there were 45 CT scanners in operation at that time, producing some 160,000 scans per year; all of them were given permission to stay in operation but only until they had to be replaced. This policy had the effect that until 1987 the number of CT scanners remained at 46. This caused a lot of opposition from the radiologists, who held that introducing CT scanners in middle-size or even small peripheral hospitals added quality and could be done without extra budgetary resources (because of substitution). They were ardently supported in this by Philips Medical Systems (whose home market for CT scanners had almost collapsed). In 1989 the Minister of Health gave in and article 18 regulation for

TABLE 6-8: The Use of CT Scanners in the Netherlands

Data	1981	1984	1990	1992
Number of CT's	37	45	66	110
CT's per million population	2.6	3.1	4.5	7.3
Number of scans per year	95,000	160,000	290,000	330,000
Average number of scans per CT scanners per year	2,550	3,550	4,400	3,000
Inhabitants per CT scanners	381,000	322,000	224,000	136,000
Number of CT scans	**1989**	**1990**	**1991**	**1992**
Scans per 1,000 hospital admissions	35.7	61.0	68.1	84.8

SOURCE Health Council, *AdvisoryReport on Nuclear Magnetic Resonance* Imaging *Spectroscopy* (The Hague, 1984), National Raadvoor de Volksgezondheld (National Board of Health), *Advisory Report on MRI* (Zoetermeer, 1993)

CT scanners was abolished. Hospitals now had to negotiate with the regional insurance agencies to obtain reimbursement for CT scanning within the existing budgets. This policy has resulted in an enormous increase in the sale of scanners (see table 6-8).

Assessment of CT Scanning

In spite of the 1977 recommendation by the Health Council to start a program of evaluation and assessment of CT scanners in the Netherlands before the technology spread to the general hospitals, such a study was never performed. No initiative was taken by the Minister of Health, but there also was no real willingness on the part of radiologists, who maintained that the technology had become completely established by 1980. The only attempt to evaluate the role of CT scanners in hospital care in the Netherlands was by a young radiologist, who in his 1988 Ph.D. thesis looked into the effect of CT scanners on average inpatient stay and on the total number of radiological procedures (4). In hospitals with CT scanners at their disposal, the number of conventional radiological procedures declined, while in hospitals without CT, the number of radiological procedures increased. Therefore, CT appears to have had a partial substitution effect. However, the thesis did not determine whether the introduction of CT scanners had significantly improved the quality or reduced the cost of the diagnostic process.

Reimbursement for CT Scanning

The initial reimbursement fee (tariff) for hospital services was fixed at Df1400. However, when the number of scans began to increase rapidly and CT replaced conventional radiological procedures, the fee was lowered to Df1290. The radiologist can charge an additional fee of Df1100 (for brain CT) to Df1350 (for high-definition body CT).

Policies *Toward CT Scanners*

Government policy during the period of introduction of CT scanners in the Netherlands was focused on limiting the purchase of equipment. CT scanners were seen as a high-cost technology that added cost rather than quality. This was at a time when the health authorities were preoccupied with increasing health care costs and with instituting cost-containment measures. Article 18 regulation indeed resulted in keeping the number of CT scanners stable for several years. However, the government did not account for future increases in the use of CT scanners, and fixed the number of scans allowed at too low a level. Fierce resistance from the hospitals and the radiologists led to the regulation's abandonment.

Magnetic Resonance Imaging (MRI)

Development of MRI in the Netherlands started before most Dutch doctors had even heard of it (8,25). The Philips Co. had begun experimenting in 1973 with the MR principle in its Physics Labo-

ratory, following the first studies in 1972-73 by Lauterbur. By 1980 a prototype was ready and producing images of the human body. The Philips Co. was aware of the fact that this new technology could only be introduced into clinical practice with the help of doctors, especially radiologists. Because doctors knew nothing about the technology, and because the machines were too expensive for hospitals to acquire, Philips installed a prototype in its factory in Best. Starting in May 1981 this machine was made available without cost to radiologists from four University Hospitals, who could bring their patients there for MR examination. In this way the radiologists became familiar with the technology (and spread the word to their colleagues), and Philips was able to improve its machine through their clinical experience.

A second prototype was installed in the University Hospital in Leiden in 1982 as a test site for inpatient MR studies. In 1983 the other University Hospitals approached the Minister of Education and Science (then solely responsible for these hospitals) to get permission to invest in MR technology. He contacted the Ministry of Health in order to develop a careful policy for the introduction of MRI (the failure to regulate CT scanners was still fresh). The Health Council was asked to report on the state of the art of MRI and the Minister of Education informed the university hospitals that he would take no further steps before a detailed diffusion plan was on the table. The boards of directors of the hospitals were asked to provide the necessary coordination. However, their answer was that they were unable to come to consensus (because of competition among them over the new technology). The University Hospital in Leiden was allowed to continue its experimental MR studies (paid for by the Philips Co., which had received a subsidy for the development of national industry from the Ministry of Economic Affairs).

In January 1984 the Health Council presented its report on MRI (17). This new technology was considered to be a very promising diagnostic modality; however, the exact application in medicine was not yet defined. The Health Council proposed that three hospitals cooperate in an assessment. By mid-1984 the Minister of Education (supported by the Minister of Health) announced his policy: four University Hospitals (including the test site in Leiden) could operate MRI, under the following conditions: 1) the four hospitals would cooperate in a national assessment of MRI, and 2) the cost of MRI equipment and scans would not be borne by the Minister of Education, but would have to be covered from the health care budget. (To prevent general hospitals from acquiring MRI scanners, the Minister of Health introduced a temporary regulation under the new Hospital Budget Law.)

Early in 1985 an agreement was reached with the sick funds and private insurance companies that they would pay half the operating cost of MRI in the four selected hospitals. The other half was considered to be a research cost to be borne by the Minister of Education. (This was a breakthrough in the attitude of the insurers, since before this they considered all new technologies as "research," not payable through the health care budget. Two hospitals chose Philips scanners (for which the Ministry of Economic Affairs paid them a bonus) and one selected an American Technicare scanner; by 1987 all scanners were in operation.

At the end of December 1987 the MRI introduction period and policy was evaluated by an independent analyst at the request of the government. In addition to the evaluation, the analyst proposed that 14 MR scanners be in place in 1991 (one per million population). Following this report, a group of radiologists (supported by Philips) promoted a plan for a nationwide diffusion of MRI (in which Philips was to have a monopoly position) through a nonprofit organization run by themselves. The government quickly rejected this idea as too commercial (and in conflict with European Community free market principles).

TABLE 6-9: The Number of MR Scanners Installed Per Year and in Total, 1982/1993

Year	New MRI's per year	Cumulative number	Remarks
1982	1	1	First test-sale In Leiden
1983	0	1	
1984	0	1	Health Council report 3 MRIs
1985	2	3	4 hospitals selected, regulation
1986	2	5	Start assessment study
1987	0	5	Government policy on MRI evaluated
1988	0	5	Assessment study completed
1989	2	7	8 new MRIs approved
1990	7	14	Regulation abolished
1991	6	20	—
1992	7	27	National Board of Health report
1993	9	36a	80-90 MRI's needed in 2000

aIncluding 3 replacements—33 in operation

SOURCE National Raad voor de Volksgezondheid (National Board of Health), Advisory *Report* on *MRI* (Zoetermeer, 1993)

By 1989 the assessment in the four University Hospitals was completed. On the basis of the positive outcome, the government gave permission for six more scanners (four in university hospitals and two in national oncology centers). Extra money was provided to these hospitals to finance the scanners. However, a growing number of regional general hospitals also requested permission to operate MRI. In 1991 the Minister of Health decided to end restrictions on the diffusion of MRI, and freeing hospitals to acquire scanners provided they could cover the cost from the existing budget. The reason behind this decision was that so-called "low-budget" MR scanners (0.5 Tesla) had come on the market and were replacing (in part) conventional x-ray and CT scanners. From 1990 to 1993 another 26 scanners were installed and 14 hospitals decided to make use of a mobile MRI system (leased by a for-profit company) (see tables 6-9 and 6-10). In 1993 the future need for MRI (to the year 2000) was calculated by the National Health Care Board at 80 to 90 scanners (32).

Reimbursement for MRI

Hospitals must negotiate the reimbursement for MR scans (based on substitution within the budget) with the insurance agencies. In the beginning there was no special reimbursement fee for MRI, but radiologists and hospitals charged the same amount as for CT scanning. When the fee for CT was lowered, a separate MRI fee of Df1865 was agreed on by the insurance agencies (Df1750 for the hospital services and Dfl115 for the specialist fee).

Assessment of MRI

Because of the unfortunate experience with the introduction of CT scanning, the health authorities in the Netherlands emphasized from the start that MRI should be evaluated. Formal assessment was to be a precondition for further diffusion. The first assessment by the four University Hospitals was very limited in scope (not a true technology assessment), focused mainly on the efficacy of MRI, the established and emerging indications. and possible substitution for other diagnostic procedures. Later assessments (32) have looked into the cost-effectiveness and appropriate use of MRI.

The *Role of Philips*

The introduction of MRI in the Netherlands was influenced by the interests of Philips Medical Electronics, by far the largest medical equipment company in the Netherlands. Philips has contributed to the early introduction and diffusion of new diagnostic technologies, including digital x-ray, CT scanning, MRI. and angiography. The company has usual] y invested in test sites in major hospi -

TABLE 6-10: The Use of MRI in the Netherlands

Data	1987	1990	1993
Number of MRI in operaton	5	14	33
MRI per million population	0.3	0.9	2.2
Number of scans per year	7,000	14,000	40,000
Average number of scans per MRI per year	1,400	1,000	1,200
Inhabitants per MRI (millions)	2.8	1.1	**0.5**

SOURCE Nationale Raad voor de Volksgezondheld (National Board of Health), *Advisory Report on MRi* (Zoetermeer, 1993)

tals. Although the home market is rather small compared to worldwide sales (85 percent of imaging equipment is exported), Philips needs high-quality academic and regional hospitals in the vicinity of its research laboratories as partners in technical development. This was particularly true in the case of MRI (Philips needed to have MRI machines installed in a clinical setting for further development). Ordinarily, protection of the national industry is not practiced in the Netherlands to such an extent as in other European countries, but in the case of MRI, Philips was supported by a large grant from the Ministry of Economic Affairs. Other MRI companies have objected to the virtual monopoly of Philips in the early MRI sales in the Netherlands.

Policies Toward MRI

The Ministers of Health and of Education and Science were determined to avoid the type of situation that arose over the introduction and diffusion of CT, (34) when too strict regulation created a stalemate. With MRI, the introduction and first phase of diffusion went satisfactorily. The decisionmaking process took less time than with CT and there was constructive cooperation with the medical community. By 1990 the government as well as the radiologists considered MRI to be a standard diagnostic procedure, so strict regulation was not necessary.

Concerns About CT and MRI

In general, the use of radiological diagnostic procedures in the Netherlands is modest compared to other countries (27,35). Both the government and the hospitals have taken initiatives to limit and, where possible, push back the number of unnecessary x-ray procedures (e.g., routine pre-operative x-rays), both to save money and to diminish radiation exposure of the population (35). The introduction of new diagnostic procedures, however, presents at least two problems. If the new technology has an "add-on" effect and does not substitute for existing procedures, it will add costs to the health care sector. If it makes use of ionizing radiation, it will result in a higher exposure rate to the population, which may be a risk to health.

CT scanning contributes relatively highly to radiation exposure. The recent increase in the number of CTs in the Netherlands (which has been only partial substitution) may thus have had a negative effect. MRI on the other hand, does not use x-ray. Thus it may be advantageous to let MRI substitute for a large part of all examinations currently performed with x-ray (conventional x-ray, angiography, CT, e(c). From the quality point of view this poses no real problem, since MRI has shown to provide, in many cases, superior information. Such a policy, however, would mean that the number of conventional radiological devices (including CT) would have to be reduced. In 1992 only 25 percent of the 30,000 MR scans in the Netherlands substituted for other radiological procedures. It has been calculated that the substitution effect could be at least 50 percent. This would mean that in the coming years 50 CT installations (or 150,000 scans per year) would have to be replaced by MRI. Since most of the CT scanners in the Netherlands have been acquired in recent years, one may doubt whether hospitals and health care financiers will agree to such a policy.

Another concern with MRI is the low caseload in most hospitals (in 1993, an average of 1,200

scans). The cost of an MR scan has been calculated to be competitive with CT assuming a caseload of 2,500 to 3,000 scans per year. This should correct itself if the substitution of MRI for other radiological procedures continues to increase.

LAPAROSCOPIC SURGERY

The first laparoscopic surgical treatment introduced in the Netherlands was probably laparoscopic appendectomy, which has been performed by the surgeon de Kok since 1971. Although the new technique was successful (de Kok has performed more than 1,500), it never became popular with other Dutch surgeons. Only recently, since the successful introduction of laparoscopic cholecystectomy in 1990, has laparoscopic appendectomy become somewhat more popular.

The story is similar for laparoscopic surgery in gynecology. In 1979 Ijzermans (in Eindhoven) treated endometriosis and removed ovarian cysts through the laparoscope. For 10 years he was almost alone in this field. Colleagues began to show interest only after the publicity for laparoscopic cholecystectomy. In 1989 Ijzermans organized a symposium on the subject, and about eight hospitals are now treating endometriosis laparoscopically. Laparoscopic removal of ovarian cysts has met with little enthusiasm, however, perhaps because the procedure is technically difficult and because there seems to be consensus in the Netherlands that removal of early ovarian cysts is unnecessary.

Another development of minimally invasive surgery in urology is percutaneous nephrolithotomy (PCN), or the laparoscopic removal of kidney stones, which was introduced around 1980 (26). By 1985 all university urology departments and the majority of peripheral centers had adopted the technique. However, in 1984 shock-wave lithotripsy was introduced, and, after a difficult start, expanded rapidly. The diffusion of PCN slowed down. Today, because of the relatively low price of lithotripsy equipment and the availability of more than 10 machines in the Netherlands, most urologists prefer ESWL over PCN for treating smaller stones (up to two cm diameter). PCN is performed for larger stones. Conventional open surgery has become obsolete.

In 1990 laparoscopic cholecystectomy was introduced in Eindhoven by van Erp, who had been trained by Dubois in France. Two other surgeons soon followed. But other surgeons were not very interested in the new method, perhaps because it takes longer than conventional surgery. However, after van Erp appeared on television, patients started to demand the new procedure. By May 1991 about 60 hospitals were doing this procedure routinely, but mostly in small numbers. Reasons for the slow diffusion include the limited supply of operating laparoscope and the budgetary constraints in most hospitals. In spite of these problems the technology continues to diffuse rapidly.

Reliable evidence of efficacy and effectiveness of laparoscopic procedures was lacking at the time of its introduction in the Netherlands, and this situation has not really changed. Some controlled trials have begun (funded by the Investigational Medicine Programme run by the Sick Fund Council) to assess cholecystectomy, treatment of bladder tumors, and appendectomy.

Factors in the Diffusion Process

The introduction and development of laparoscopic techniques in the Netherlands, as elsewhere, has been very much the work of a few innovative surgeons. They saw the positive side of these techniques (less trauma to the patient, shorter hospitalization, quick rehabilitation), although they may have been technically more difficult, time-consuming, and costly in the beginning. In most cases it took several years before fellow surgeons ventured to follow their example, forced into action by public demand (informed by the lay media) for the new procedures. In general, however, the diffusion of laparoscopic surgery in the Netherlands has been slow (at least in comparison to that in the United States, Germany, and France, for example), with the exception of laparoscopic cholecystectomy and percutaneous nephrolithotomy (2).

Some other factors that have slowed down the diffusion are:

1. budgetary pressures on hospitals, which make them reluctant to undertake new, capital-intensive procedures or treatments that require extra time or personnel;
2. financial incentives for hospitals, which make shorter stays unattractive;
3. lack of reimbursement of anew procedure (seen as "experimental");
4. lack of training in minimally invasive techniques to bring skill to acceptable levels; and
5. conservatism among many surgeons.

On the other hand, there are also factors at work that facilitated the diffusion of laparoscopic surgery:

1. media reporting, raising patient demand and physician interest;
2. commercial pressure and information (equipment manufacturers);
3. convincing evidence on effectiveness for some new procedures, in some cases acquired through controlled trials in the Netherlands; and
4. the availability of appropriate training with respected physicians.

Policies Toward Laparoscopic Surgery

There has been striking lack of interest and action among policy makers at all levels with regard to laparoscopic surgery. This noninvolvement has lead to the absence of any regulation and has certainly not been an impeding factor. Interest from the insurance agencies might have been expected, since most laparoscopic procedures are claimed to be more patient-friendly and cost-saving in the end. However, no attempt has been made to facilitate the diffusion of new techniques by financial incentives or arrangements. On the contrary, most of the existing budgetary and reimbursement procedures work against their adoption

Concerns with the Technology

Policymakers have recently begun to appreciate the far-reaching implications of laparoscopic surgery. While patients may profit from procedures that cause less trauma and disability, the potential for overuse of these procedures is great because of commercial promotion by the industry and consequent patient demand, even in the absence of evidence of effectiveness. The new procedures also have important implications for physicians. The new techniques have begun to change patterns of practice where treatment is n· · provided by specialists who were traditionally diagnosticians. Also, most practicing surgeons have had no formal training in using these techniques. Finally, hospital administrators are concerned since laparoscopic surgery (minimally invasive surgery in general) is changing the organizational structure of the hospital through more outpatient treatments, day surgery, shorter hospital stays, and new equipment used outside the operating theatre. Eventually more than half of all surgical interventions may be done with minimally invasive techniques.

TREATMENTS FOR END-STAGE RENAL DISEASE (ESRD)

When Kolff developed his artificial kidney ir the Netherlands during the late 1940s he found little recognition for the innovation in his own country. Unable to get funds for further research and development he left the country in 1950 for the United States where he devoted himself to the perfection of the artificial kidney and other bioengineering projects. Soon after, dialysis for acute kidney failure became a standard treatment around the world.

In 1963 chronic intermittent hemodialysis, made possible by Scribners new shunt system, was introduced in the Netherlands in the university hospitals of Leiden, Utrecht, Amsterdam, and Nijmegen. Selection of patients was very strict, as the treatment was not covered by insurance and hospitals had to pay for it out of their own funds

TABLE 6-11: Renal Replacement Therapy (RRT) in the Netherlands (1970–92)

Number of patients	1970	1975	1980	1985	1990	1991	1992
On dialysis	400	1,050	1,468	2,386	3,042	3,203	3,318
With functioning graft	—	—	891	1,665	2,725	2,890	3,131
Total number of RRT		—	2,359	4,051	5,767	6,093	6,449
Total per million population	—	—	166	279	387	409	430
New patients on dialysis per year	—	—	523	672	965	1,041	1,088
New patients per million population	—	—	37	46	65	70	72

SOURCE M Bos 1994 from Renine Foundation Statistical Reviews

Dutch nephrologist then formed a pressure group to persuade the government and the insurance agencies that dialysis could no longer be seen as experimental. Finally, in 1967 dialysis became a reimbursed part of the social insurance benefit package. The Dutch Kidney Foundation grew in 1968 out of this pressure group of nephrologist, joined by the dialysis patients. This organization has been powerful and effective in the diffusion of renal replacement therapy, promoting dialysis and transplantation and supporting the hospitals with funds for research and patient care facilities.

The first kidney transplant in the Netherlands took place in 1966 in the University Hospital in Leiden, using an identical twin donor. The first transplants with a cadaveric organ followed in 1967, in Leiden and Amsterdam simultaneously (using two kidneys from the same donor). At Leiden University the immunologist van Rood had perfected typing and matching human tissues on the basis of human leukocyte antigens (HLA) and made the system usable for routine clinical transplantation. He later advocated matching cadaveric donor kidneys to recipients on a European scale, from which sprang (in 1967) the Eurotransplant organization, the first exchange program of its kind in the world, Today, Eurotransplant is responsible for the matching and exchange (through its central office in Leiden) of all cadaveric donor organs in the Netherlands, Belgium, Luxembourg, Germany, and Austria, resulting in more than 5,300 transplants a year (9).

Other factors have also influenced the development of kidney transplantation in the Netherlands. In 1976 several private organizations (Eurotransplant, the Kidney Foundation and the Red Cross) joined forces to promote organ procurement, introducing a national donor card system. A Task Force was founded in 1980 with the goal of stimulating public support for organ donation through information and media campaigns. The number of donated organs increased significantly after the first transplant coordinator was appointed at the University Hospital in Groningen in 1979. There are now 11 regional transplant coordinators. The insurance agencies have agreed to reimburse the cost of organ removal to the donor hospitals, thus breaking down one of the important barriers that prevented hospitals from cooperating with the transplant centers.

Tables 6-11 and 6-12 show the diffusion of dialysis treatment and kidney transplantation in the Netherlands. Table 6-13 presents some basic data on the current status of ESRD patients and services.

Policy Actions Concerning Dialysis and Transplantation

During the early years of renal replacement therapy the Dutch government and the health authorities played a very modest role. Almost all actions to promote dialysis and kidney transplantation were taken by individuals and nonprofit organizations, such as the Dutch Association of Dialysis Doctors (DGN), the Dutch Kidney Foundation, Eurotransplant, and the Renal Patients Association (LVD). They not only made possible the first

TABLE 6-12: Kidney Transplants (1970–92)

Kidney transplants	1970	1975	1980	1985	1990	1991	1992
Patients on waiting list	275	480	464	977	1,343	1,412	1,434
Number of transplants	54	193	239	332	442	474	527
With cadaveric donor	50	191	236	289	406	431	445
With living donor	4	2	3	43	36	43	82
Transplants per million population	—	13.7	16.8	22.8	29,8	31.8	35.1

SOURCE M Bos, 1994 from Eurotransplant Foundation Annual Reviews

facilities for treatment, but also financed dialysis centers, facilities for home dialysis, specialist training for nephrologists, and education of the public through mass campaigns. Eurotransplant has built an extremely effective national and international network for matching donor organs with recipients. The Kidney Foundation finances almost 75 percent of all scientific research on kidney disease in Dutch institutions.

Despite a need for legislation recognized in 1968, the government has failed to get a bill on organ transplantation through Parliament (a draft was presented in 1991). In practice, a system for organ donation based on "opting-in" (explicit consent) has been adopted, whereby permission for removal of organs is given either by the deceased (carrying a donor card) or by the next-of-kin. The recent Bill on Organ Removal is also based on the opting-in principle, although the Council of Europe advocated an opting-out system based on presumed consent in 1978 and most European states have adopted this type of law.

Since renal replacement therapy is expensive, health authorities have sought to control its diffusion. Since 1979, Article 18 of the Hospital Provisions Law has required hospitals to get authorization from the Minister of Health to provide dialysis and kidney transplantation. The policy pursued by the Minister is to concentrate all transplants in a limited number of centers in order to assure a high level of quality----only eight university hospitals have been licensed so far (with an average case-load of 60 transplants per year). Dialysis facilities are present in 55 institutions (hospitals and free-standing dialysis units) with an average of 13 dialysis units and 63 patients each. In the early years the government promoted hemodialysis at home (being less costly and allowing the patient more freedom). However, since 1985 the emphasis has shifted to continuous ambulatory peritoneal dialysis (CAPD) which now accounts for 28 percent of all dialysis.

The Role of Technology Assessment

In 1972 and 1978 the Dutch Health Council published reports on dialysis and kidney transplantation that were influential in instituting regular financing for these therapies. A 1986 report looked into the cost-effectiveness of different renal treatment modalities and also presented a mathematical model to predict inflow and outflow of patients in renal replacement therapy. This report was the basis for a Planning Document published by the Minister of Health in 1987. The latest report by the Health Council, published in 1992, studied the effect of recent developments in renal therapy on the use of different treatment alternatives. A National Registry for Renal Replacement Therapy, founded in 1986, collects and analyses complete statistical data on dialysis and transplantation (33).

Concerns with the Technologies

The main concern today is with the shortage of donor organs for transplantation. The gap between the number waiting for transplants and the number of transplants is widening. Although there are enough potential cadaveric donors to fulfill the need, only a fraction are actually procured because many brain-dead patients are not recognized as

TABLE 6-13: Dialysis and Transplant Data on Jan. 1, 1993

Patients on dialysis	3,473
on hospital dialysis	2,410 (69%)
on home dialysis	104 (3%)
on CAPD	959 (28%)
Number of dialysis centers	53
Number of people per dialysis center	0.3
Number of dialysis units	680
Number of transplant centers	8
Number of people per transplant center (millions)	1.8

SOURCE Renine Foundation, *Annual* Statistical Review 1993 (Rotterdam Foundation for the Registration of Renal Replacement Therapy, 1993)

potential donors and because many families (up to 40 percent) refuse permission for removal. Pending legislation and educational campaigns may improve this situation.

Erythropoietin (EPO)

EPO was introduced to the Netherlands about 1990, following FDA licensing in the United States. The introduction was negotiated between the Association of Dialysis Doctors and the Sick Fund Council, resulting in prompt coverage by social health insurance. The cost is included in the overall dialysis fee (Df100 per dialysis treatment) and is included in the hospital budget (prospective calculation) but with the possibility of a correction afterwards. In the Netherlands, 60 to 65 percent of all dialysis patients get EPO (higher use by patients on hemodialysis than on CAPD). Use is limited to patients with nephrogenic anemia (because of chronic dialysis) and transplanted kidney patients with deteriorating kidney function.

There was no formal assessment of EPO preceding its introduction. The results of U.S. clinical trials have been accepted as conclusive. Discussions were held between the Sick Funds Council and a Dutch technology assessment center concerning the possibility of carrying out a prospective cost-effectiveness analysis, but the coverage decision was made while these discussions were still ongoing. (Nonetheless, one has been completed (28).) A clinical trial is under way to establish the optimum dosage of EPO.

NEONATAL INTENSIVE CARE

Between 1900 and 1940 infant mortality declined in the Netherlands by half because of better hygiene and nutrition, but there was little improvement in perinatal mortality during the first month of life. In the late 1940s, pediatricians became involved with obstetric care resulting in the creation of a specialized neonatal ward, situated between the obstetrics and pediatrics departments. In 1968, the University Hospital in Leiden was the first to start such an "intensive care" facility. After 1970 neonatal intensive care improved again through the introduction of controlled ventilation, making it possible to save extremely premature babies.

The development of modem, sophisticated neonatal care around 1970 led to the establishment of regional neonatal intensive care units (NICUS) in the seven University Hospitals and some pediatric hospitals. By 1978 there were 31 fully equipped intensive care beds available. However, the very success of neonatal care created its own problem: because more and more peripheral hospitals referred their premature babies to the university centers, there soon was a serious shortage of NICU facilities. In 1974 the Dutch Pediatric Association formed a committee to report on the need for NICUS and their optimal organizational structure. The Committee's recommendations (in 1975 and 1978) led to some improvement in the quality of the care and better regional referral arrangements, but could not resolve the capacity problems. The continuing shortage in the university centers led to the establishment of man y small facilities in regional hospitals, a development which was not supported by the university neonatologists who believed that it compromised the quality of care.

In 1979 when the situation had really become critical, the Minister of Health asked the Health Council to assess the scientific development of neonatal intensive care and report on the future need for facilities. In its report (16) the Health Council recommended the following:

TABLE 6-14: Development of NICUs in the Netherlands, 1978–92

	1978	1981	1987	1989	1991	1992
Approved ICU centers	7	7	8	10	10	10
Number of IC beds	31	32	47	88	98	144 a
Centers without approval	8	8	14	24	20	12
Number of IC beds	17	17	17	—	—	—

aThis number includes both intensive and high care beds, according 10 a new definition used by the Health Council

SOURCE Health Council, *Report on Neonatal Intensive Care,* publication 1982/20 (The Hague, 1982), Ministry of Health, *Planning Document* Neonatal *Intensive Care* (The Hague, 1993)

1. neonatal intensive care should be restricted to 10 fully equipped supraregional centers,
2. the future need (1 985-90) for neonatal intensive care in the Netherlands was calculated to be 140 beds and 228 high-care/medium-care beds,
3. the minimum size for a center should be 10 intensive care, 12 high-care and 10 medium-care beds, and
4. neonatal intensive care should be concentrated in these 10 centers by means of legal regulation, by applying article 18 of the Hospital Facilities Act.

In 1983 article 18 regulation came into force but the Ministry of Health did not publish a planning document until 1987 *(Planningsbesluit Neonatologie)* in which the 10 centers were actually named. Between 1986 and 1991 the Minister of Health made development of these NICUS one of his priorities, approving new facilities and increasing the budgets of the centers. During these years the capacity of the NICU centers had almost doubled (tables 6-14 and 6-15) but it was clear that the shortage was not resolved. The Minister again asked the Health Council (in 1989) to report on the future of intensive care. Their 1991 report contained a survey of NICU facilities in the Netherlands, which showed that the demand for care was growing (in part because of an increase in the multiple birth rate since the 1970s) (7). It also contained an assessment of NICU effectiveness (in improving survival and preventing handicaps). The need for NICUS was estimated to be 165 to 202 beds in the 1990 to 1995 period, to be located in the existing 10 centers. The Minister of Health acted quickly: in January 1993 a new Planning Document was published that set the future need for NICU at 168 beds. Peripheral hospitals that provide NICUS on a small scale but have not been authorized under article 18 will have to terminate this care (though some are allowed to continue until the capacity in the 10 centers is fully realized).

Factors in the Diffusion of NICUS

The development and diffusion of NICUS has been influenced to a large extent by the concern of university pediatricians and neonatologists with the quality of perinatal care. They took the initiative in the early 1970s to set up regional NICU centers and make arrangements for referral. They promoted the concentration of neonatal care in a limited number of centers.

The idea of concentration was adopted by the central health authorities, who used existing legal instruments to bring it about in the face of significant opposition from the peripheral hospitals with small NICUS (one to four beds). Between 1987 and 1993, the Minister has made the development of NICU centers one of his priorities in intramural care and pumped extra money into centers. In doing so, he was supported by the Minister of Education and Science, who shares responsibility for the university hospitals and provided financial support to build extra NICUS. The efficiency of NICU centers has increased since 1987, when a computer network was installed that enables referring hospitals to judge the availability of NICU capacity in the individual centers at any time.

TABLE 6-15: Use of NICU Facilities in the Netherlands, 1990

Number of patients treated in	
approved centers	2,372
non-approved centers	667
abroad	20
Total	3,059
Number of patients who died in ICU (%)	418 (17.61XO)
Total number of IC-days	49,168
Average stay in NICU (days)	16.1
Percent of all live-born children treated in NICUS	1.62

SOURCE Health Council, *Report on Neonatal intensive* Care, publication 1982/20 (The Hague, 1982), Ministry of Health, Planning *Document Neonatal Intensive Care* (The Hague, 1993).

The Role of Technology Assessment

Technology Assessment has played an important role in the development of NICUS. The two reports issued by the Health Council were the basis for the policy pursued by the Minister of Health (16,22). Another influential report was the POPS study (project on preterm and small-for-gestational-age infants) conducted by a group of pediatricians from Leiden University Hospital (1983 to 1987). They followed 1,338 children with a birthweight below 1,500 g for a minimum of three years. Survival, risk of perinatal mortality, quality of life, and risk of handicaps were assessed and compared with historical controls (born 1979 to 1983). The initial results show a significant increase in survival without a rise in the handicap rate (36). As yet no cost-effectiveness study of NICU. has been conducted in the Netherlands.

Extracorporeal Membrane Oxygenation (ECMO)

In 1990 ECMO was introduced in the Netherlands in the neonatal clinic of the Nijmegen University Hospital, after several years of animal experimentation (10). Although the first treatments were successful, there was doubt over ECMO long-term results (11). The Health Council, in its 1990 annual report (20) found that although immediate results were favorable (more than 80 percent survival), ECMO had significant complications, and about 10 percent of the survivors showed mental and physical disability. Experience with ECMO in older infants was also very limited. The Council voiced the opinion that ECMO should be considered as "experimental therapy" and recommended its use only in cases of neonatal respiratory failure in selected NICUS. The Council strongly recommended a prospective technology assessment.

These recommendations were followed by the Ministry of Health and the university hospitals. In 1991, four centers applied for funding of an ECMO technology assessment project from the Investigational Medicine Fund. Subsequently two centers (Rotterdam and Nijmegen) were selected. Preliminary results of their study (non randomized, with conventionally treated historical controls) have been reported. They found significant y better survival for neonates with serious respiratory distress and no difference in short-term morbidity in ECMO-treated babies at a cost of Df153,500 per baby.

In 1993, the Minister of Health restricted the use of ECMO by applying Article 18 regulation (already in force for NICUS) (29). For the duration of the technology assessment study, the use of ECMO is restricted to the two centers involved in the clinical trial. Expansion to other centers depends on the outcome of the assessment. The preliminary estimate of need from the Dutch ECMO trial is a minimum of 24 patients per year, which may increase to 45 to 50 patients per year, based on the U.S. and U.K. experiences.

SCREENING FOR BREAST CANCER

Breast cancer accounts for one quarter of all cancer deaths in Dutch women. Breast cancer incidence increased from 50 per 100,000 in 1960 to 96 per 100,000 in 1989 (although much of this increase is probably an artifact of screening). As early as 1974 some hospitals introduced screening mammography for breast cancer (in place of self-examination). organized in cooperation with regional cancer centers. Experience with this method was described in a 1974 report by the

Health Council (13). In 1977 the Minister of Health asked the Health Council to look into possibilities for a national screening program for breast cancer. The Council reported in 1981 and again in 1984, describing the experiences with breast cancer screening in Nijmegen, Utrecht, and Leiden (15). These hospitals used different age criteria (over 35 years, over 50 years) and different screening intervals (one, two, or three years). The Health Council concluded that there was insufficient epidemiological data available to decide what was the most relevant age group and time interval. Also, there was uncertainty as to the logistical and financial consequences of nationwide screening. At that time there was little experience with screening studies in general in the Netherlands. The Council recommended that a cost-effectiveness study of the possible alternatives be conducted.

In 1986 representatives of the Ministry of Health and the Cancer centers visited Sweden to study the ongoing screening program there (1). Also in 1986, the European Community convened an international working party on early detection of breast cancer to discuss issues such as the relevant age groups (consensus reached on 50 years old and over), the best screening interval (consensus reached on two years), and who should do the screening (professional radiologists or radiography technician—no consensus reached).

The Health Council published its final report in 1987 (19), recommending mammography screening for women 50 to 70 years old, at an interval of two years, by radiologists. The organization would be the responsibility of the regional cancer centers. Before screening started, education would be organized for general practitioners (GPs) and the public. An essential issue was continuous quality assurance of the screening program, to be carried out by an independent body. In 1987 the National Health Care Board (NRV) made recommendations on logistical aspects of the screening program.

The Sick Fund Council took responsibility for introducing nationwide screening in 1987. The program was to be paid for out of the Exceptional Medical Expenses Fund, a national insurance program. The Sick Fund Council asked the Institute for Medical Technology Assessment (IMTA) of the Erasmus University in Rotterdam to study the costs and effects of breast cancer screening (23). In its first report (23) IMTA calculated the cost of preventing one case of death from breast cancer by screening as Dfl 100,000; the cost per life-year saved was put at Dt19,700. It was also calculated that half the cost of the screening program could be earned back by saving on extra diagnostic and therapeutic procedures (as a result of early detection of cancer). IMTA calculated it would take seven years to introduce an effective nationwide screening program (completed in 1995).

Guidelines for mammography screening were introduced by the National Organization for Quality Assurance (CBO) in 1988 as the result of a consensus conference. Finally, the Sick Fund Council appointed a National Coordination Committee in June 1988, after which the screening program started.

Factors in the Diffusion

It was of some importance that several Dutch University Hospitals already had some experience with mammography in the early 1970s. But models for a nationwide screening program were taken from the Scandinavian countries, since there was very little experience with mass screening in the Netherlands. Although the central government was interested in starting a mass screening program, it was the social insurance programs (represented by the Sick Fund Council) that took decisive action. The cost-effectiveness study by IMTA was very influential.

Current Status of the Screening Program

In 1989 the first phase of the screening program began. The organization was carried out by the nine Basic Health Services, in cooperation with the Regional Cancer Centers. Each regional screening program will be evaluated before it starts, including logistics, costs, and assessment aspects. Furthermore, in each region a screening information system has been set up. with the rele-

vant population data. By 1993 the screening programs were operating in five regions; by the end of 1994 all regions will have begun.

IMTA published a first evaluation of the screening program for breast cancer in June 1992 (24). The following indicators of effectiveness have been developed to assess the Dutch screening program:

- a high response in the relevant age-group (more than 70 percent of women 50 to 70 years old),
- a high predictive value of a positive screening result (more than 40 percent confirmed),
- detection rate of at least 6.0 per 1,000 women screened,
- high specificity of mammography (greater than 99.1 percent),
- earlier tumor stage treatable with surgery, and
- possibilities for breast-sparing treatment.

In 1992 the first two screening regions were evaluated, with the following results:

- a response in the first round of 79 percent,
- predictive value of screening test of 57 percent,
- detection-rate of 6.6 breast cancer cases per 1,000 women screened,
- detection in early tumor stage (most tumors half the size of those found without screening), and
- most tumors were operable (38 percent had radical surgery, 51 percent had breast-sparing operation, 11 percent had lumpectomy).

In conclusion, it can be said that the first screening programs did well, when effectiveness is considered. However, these results are not yet proof of the value of mass screening.

It was also found that the screening programs had some adverse effects, that were not anticipated (5). The following problems were observed:

- an extra psychological burden on women, a relatively long period of uncertainty,
- increasing waiting time for the results of mammography, and
- an increase of diagnostic procedures and consultations with specialists.

CHAPTER SUMMARY

The Dutch health care system developed to its current form after the second World War. The main characteristics are: a mixed system of social and private insurance, almost complete coverage of health risks by insurance, and a high quality of care to which all citizens have equal access. Control and regulation of health care technology by the central government is an important feature of the system. Assessment of health care technology is becoming more important in decisionmaking.

Ways To Control Health Care Technology

In the Dutch health care system, control of health technology is effected in three major ways:

1. Before 1983 (introduction of the global hospital budget), health technology was controlled almost exclusively by the central health authority. Regulation was mostly through direct legislation, requiring approval or certification by the Minister of Health. In some cases the authority to control health care services was handed down to the regional health authority, but general guidelines for planning by the provinces were laid down by the government. In other cases (as with drugs, vaccines, and blood) control was referred entirely to an independent body.
2. The second instrument of control over health technology, which has increased in importance since 1984, is the admission of new technologies to the social insurance benefit, which is the responsibility of the Sick Fund Council. By admitting or excluding specific technologies from the benefit package, the Sick Fund Council controls the reimbursement of health services.

3. The adoption of a global budgeting system for hospitals and other health care institutions in 1983 introduced a powerful instrument of control over health care technology. Annual budgets are prospectively negotiated between health care providers and regional insurance agents, and approved by the Central Tariffs Board. Budget arrangements include the expected volume of specific health technologies. In this way caps can be put on, for example, cardiac surgery, radiation therapy, or the number of CT procedures.

The Success of the Control Mechanisms

Control of health care technology by direct legislation has been most successful in the field of drugs and biologics. The strict legal system of premarket approval by independent boards has proven to be effective, rapid, and flexible. Quality standards are very high and adverse effects are monitored closely. Least successful has been regulation of the introduction of medical devices. Although relevant legislation is on the books, there is no effective system of approval for the admission of new medical devices.

Regulation of health care technology by the central government has been most successful in the field of "high-tech" services using Article 18 legislation. Early experiences (in the 1970s), for example, with the introduction of CT and cardiac surgery, were not very successful because the procedure was too slow and bureaucratic, and often diffusion was well under way before control became effective. Later on, when the government used Article 18 regulation in a more global sense (regulating only the number of hospitals using the technology and not the number of machines and the volume of procedures), this method of planning became more effective. The main purpose of using Article 18 regulation today is to concentrate certain technologies in a limited number of centers. The relative success of Article 18 regulation (when compared to CON type regulation in other countries) is dependent mainly on two factors. First, hospitals that break the rules and provide services without approval are confronted with severe sanctions. Second, the planning document that is the basis for approving specific t ypes of services is usually very explicit as to the number of centers, quality standards, and other requirements.

Control of technology through defining the benefit package has proved to be very effective in a number of cases (e.g., IVF, bone marrow transplantation, heart and liver transplantation). The Sick Fund Council has widened its span of control and has become involved in technology assessment through this mechanism. Introduction of the hospital budget system has had an enormous effect on the introduction and use of health care technology in general: autonomous growth has been curbed to a large extent and cost containment on the macro-level became feasible.

The relative success of regulating and planning health care technology in the Dutch system relates to the fact that the three instruments described above are used in conjunction so that the effect is reinforced. For instance, the budget system may be a powerful instrument to control hospital spending, but it is not a very good instrument in itself for planning specific services. In combination with Article 18 regulation however, the budget system is very effective in controlling the diffusion of expensive health services.

Apart from these regulating mechanisms, health care technology assessment has become an increasingly successful tool to control the introduction and diffusion of health care technology. It has been demonstrated in recent years that formal assessment has made it possible to influence the diffusion and use of a number of new medical technologies. The use of prospective, randomized clinical trials and cost-effectiveness studies has been an important aspect of these endeavors. The structure for a more systematic technology assessment approach is now being developed, especially through the Investigational Medicine Fund. Both the government and the insurance agencies are taking part in this program. However, participation from the medical profession is still limited. In the coming years, policy

should be directed at involving clinicians to a greater extent by integrating technology assessment methods, information, and results into daily medical thinking and practice (by education on different levels). Also, there is a need for priority-setting in assessments and for cooperation in international efforts.

Changing Policies for Controlling Health Technology

The health care reforms that have been introduced recently in the Netherlands will have some effect on the way health services and technologies are planned and controlled. In general, the role of the central government will become less pronounced. The Minister of Health will have global control through formulating general guidelines and quality criteria (through the new Health Care Quality Act), but planning will depend on the results of negotiations between health care providers and financiers. Also, the medical professions are expected to exercise more self-regulation.

The central government will continue the planning of specific "high-tech" medical services through Article 18 but the focus will be on controlling the introduction and the first phase of diffusion. Once new technologies become generally accepted, the central government is less active in regulating them and more interested in promoting their appropriate use. Technology assessment and control of the benefit package are becoming more important instruments in this respect.

However, the Dutch health care system is going through a process of major reforms, which will affect all participants. In the new situation, possibilities and responsibilities for assessment health care technology will probably have to be redefined.

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Health Care Technology in Sweden

by Egon Jonsson and H. David Banta

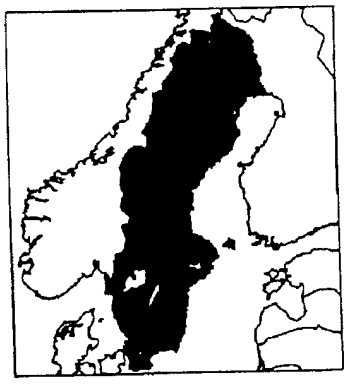
7

OVERVIEW OF SWEDEN

Sweden is the largest Scandinavian country, similar in size to California, with 8.7 million people concentrated mainly in the coastal regions and the south. Sweden is 1,500 miles long, and its northern part is above the Arctic Circle. Stockholm (the capital) is on the east coast roughly midway between north and south at the level of southern Greenland. Because of the Gulf Stream, the climate at this level of Sweden is relatively mild. The second-largest Swedish city, Goteborg, is situated further south on the west coast.

Winter snowfall in the southern part of the country is moderate, but the north has a severe winter climate dominated by snow and dark days. Northern summers have 24 hours of daylight and the famous midnight sun. Sweden's countryside is dotted with about 100,000 lakes, and forest covers about half the surface of the country. The north is dominated by a long mountain range, while southern Sweden is rather flat.

The Swedish population is relatively homogeneous; however, there are almost 1 million immigrants living in Sweden, of whom the great majority are Finns, Yugoslavs, and Greeks. Immigration accounted for 45 percent of the total population increase between 1944 and 1980. Every eighth child born in Sweden today is of foreign extraction, and foreign nationals constitute 5 percent of the workforce.



The Economy

Despite Sweden's size and geographic diversity, it is largely urban and highly industrialized. Agriculture provided employment for 80 percent of the population 100 years ago, but now accounts for only about 3 percent of the labor force. Eighty-three percent of

the population lives in urban areas, and the three largest cities have more than 30 percent of the population.

The country's economy combines capitalism and socialism. Private companies account for 80 to 90 percent of Swedish industry. In terms of employment, however, industry accounted for only 20 percent in 1990, as compared with 30 percent in 1962. Structural changes in industry in the last 20 years include decreased shipping and steel and textile manufacturing and increased engineering, chemical, and forestry products. Simultaneously, an expansion of the public sector has taken place, so that close to 40 percent of the workforce in 1992 found employment there.

A high percentage of the Swedish population (51 percent) is in the labor force (45). Eighty percent of women from ages 16 to 65 years old and 90 percent of those from 25 to 54 are gainfully employed. The female workforce, together with the aging of the population, imparts a great demand on health services (as working women are less able to be caregivers). Unemployment has been kept artificially low, but it rose to more than 4 percent in 1992 and is still increasing.

Sweden has one of the world's highest per capita incomes. The Swedish rate of gross national product (GNP) growth kept pace with that of Western European countries during the 1982 to 1990 period; however, Sweden's balance of payments has gradually worsened since 1984. Roughly 40 percent of Sweden's output is exported; 70 percent of its trade is with European countries. Recently Swedish companies have merged with both European and American firms.

Until 1991, the Swedish tax system was characterized by very high rates and a narrow tax base; in that year, a new system was introduced, under which national income tax is applied only to high incomes, and the marginal tax is reduced to a maximum of 50 percent. Local income tax is about 30 percent. Most goods and services are subject to value-added tax of 18 to 25 percent.

The high tax rate pays for extensive health and welfare benefits. All Swedes have compulsory health insurance that covers all health care, including outpatient and hospital services (except for some co-payments for physician visits), home care, long-term and nursing care, and all equipment and aids for the disabled and handicapped. It also covers most of the costs of dental care and prescribed pharmaceuticals.

Government and Political System

Sweden's internal development has occurred in an atmosphere of tranquility unknown to most Western nations. The country has been neutral since the Napoleonic Wars. Although Sweden has not fought in a war since 1812, it maintains a modern army with compulsory military service. Its tranquility manifests itself in the stability of the political system, with almost 50 years of nearly continual rule of the Social Democratic Party during the twentieth century. (Since 1991, however, a coalition of nonsocialists has been in power.) The Swedish bureaucracy is noted for its stability and effectiveness. Governance in Sweden occurs largely by social consensus.

Sweden is a constitutional monarchy in which all federal political power rests in an elected parliament, whose 349 members are elected directly for three-year terms by proportional representation. The government consists of 13 ministries. Laws are administered by about 100 central agencies and 24 county administrations. Local units of government are the 24 counties (km) and the 289 municipalities.

Responsibility for health care has rested almost completely with the county councils for the last 100 years. Recently, however, the municipalities have begun to play an increasing role. Basic education and training of doctors and other health personnel is the responsibility of the central government.

For several hundred years before the current system was developed, health care was delivered by a combination of state, parish, and church hospitals and a system with district physicians employed by the central government. County councils were established and given increasing jurisdiction over acute care hospitals in 1864; eventually, their responsibility for health care grew so that by the 1960s, it included psychiatric

care and ambulatory services. The county councils have the right to levy local taxes, most of which are income taxes that cover health care. Members of the councils are publicly elected every third year, at the same time as national and municipal elections.

HEALTH STATUS OF THE POPULATION

Swedes have one of the highest life expectancies in the world, closely following Japan and Iceland (44). Sweden also has the oldest population among OECD countries and has experienced a rapid change in its citizenry's age structure. In 1970, persons over 74 years old constituted only 5 percent of the population; that share rose to more than 7 percent by 1985 and is expected to exceed 11 percent by 2025 (21). The greatest increase is in the very elderly group, those over 85 years of age.

In many countries, health status is related to socioeconomic status. This problem is not as marked in Sweden (65); nonetheless, certain occupational categories, low-income groups, single people, immigrants, and the unemployed do have a lower health status than others(41). The fact that health status differences among different socioeconomic groups are small in S weden may well be a consequence of persistent efforts to achieve equity through a general welfare system (41).

Infant mortality in 1989 was 6 per 1,000 live births, placing Sweden in third place globally (behind Japan and Finland) (33). An increasing number of extremely premature babies are being born, many of whom survive.

The main causes of overall mortality are (as in most countries) cardiovascular diseases and cancer. Ischemic heart disease and lung cancer are leading causes of premature deaths for men. Among women, premature deaths are mainly due to breast cancer and other nonspecified tumors and ischemic heart disease. The predominant cause of death among children and teenagers is accidents.

Figure 7-1 shows the relative burden of the most important disease groups in Sweden. The parameters used for measuring disease burden are as follows:

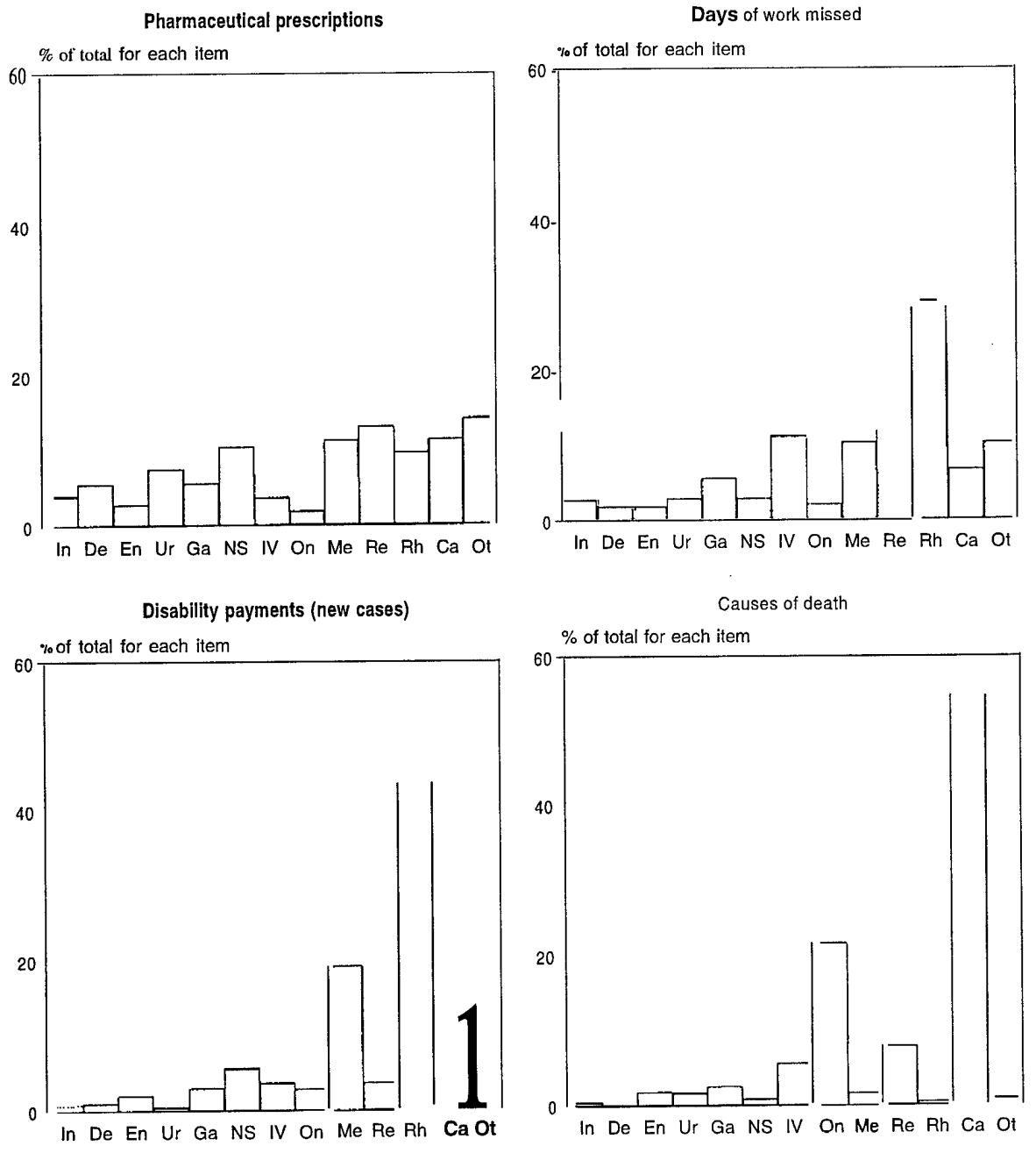
- prescriptions that indicate both drug consumption and physician contact (in or outside hospital) (1986);
- sick days (1983);
  individuals receiving (disability) pensions ("sick pensions") because of sickness per year (1986) (both sick days and new cases of sick pension indicate not only the disease burden but also the burden on professionally active age groups); and
- mortality (in 1986).

In only a few cases do d· ease burdens vary by gender. Sick pensions due to cardiovascular disease occur more than twice as frequently among men than women; the opposite is true for rheumatic diseases. Males dominate the "intoxication/violence" group by a ratio of 2 to 1.

A comparison of the two most important disease groups, rheumatologic and cardiovascular diseases, illustrates how the chosen parameters reflect different aspects of the disease burdens. A high mortality rate in a disease group (e.g., cardiovascular diseases) is connected with a heavy load on hospital care. Sick days and cases of sick pensions reflect the fact that the age group involved is professionally active and that the disease causes morbidity rather than mortality. They also denote a system with favorable conditions for eco omic compensation. During the 1980s, Sweden experienced an increase from an average of 18 days to a total average of 25 days of absence from work annually per insured person (41). Women, especially in the age group over 50 years, account for most of this increase.

During the 1980s, mortality among adults from 25 to 64 years old decreased (44). Most prominent was the decrease in mortality from accidents and from cardiovascular diseases; however, the male mortality rate in this group still is twice the female rate. In this age group, cardiovascular problems account for 45 percent of male and 25 percent of female deaths, whereas cancer accounts for 25 percent of male and 51 percent of female deaths. Alcohol-related diseases rose during the 1970s but remained constant during the 1980s. Mortality in the age group over 65 years of age also de-

FIGURE 7-1: Relative Disease Burden in Sweden, 1980s
Selected Disease Groups



In _infection
De = dermatology
En = endocrinology
Ur = urogenital
Ga = gastrointestinal
NS = neurology/sensory
IV = intoxication/violence
On = oncology
Me = mental disorders
Re = respiratory
Rh = rheumatology
Ca = cardiovascular
Ot = other

SOURCE SCB, Health in Sweden (Stockholm Statistics Sweden, 1989)

creased during the last century, mainly because of decreases in coronary heart disease and stroke.

Generally, Swedes are very concerned about their health and about illness prevention. In certain indicators of life style, Sweden (in comparison with the other Nordic countries of Denmark, Norway, Finland, and Iceland) rates lowest in smoking, low on alcohol consumption, and is in the middle on fat consumption (42).

Prevention in the Swedish context includes not only medical care but also media information and various restrictions imposed on the population. (One effect of active information campaigns is a load on the health care system, especially primary health care.) Preventive measures have been taken against such factors as poor eating habits, physical inactivity, tobacco smoking, alcohol and drug consumption, sexually transmitted diseases (including AIDS), poor work environments, and pollution. Maternal and child health care—including several programs for prevention of disease during pregnancy, childbirth, and early childhood—have been strong features of the Swedish health care system since the 1940s. Several screening programs for both children and adults have long been in use; some, such as screening for congenital diseases, dental health for children, and breast and cervical cancer screening for women, are almost compulsory.

The government established and funded several institutions years ago with the mandate to combat certain public health problems—in particular occupational diseases. In 1992 a Public Health Institute was founded and funded generously to promote healthy life styles. This new institute is establishing professorial chairs for new public health research institutions throughout the country and is also running large-scale media programs to promote healthy life styles and prevent diseases, particularly from smoking and alcohol abuse. Sweden has tried for years to limit alcohol abuse by restricting sales to special state-owned shops with limited hours. However, this measure has not prevented alcohol abuse from being a serious problem in Sweden. Rules against smoking indoors in public places (including hospitals) are becoming increasingly common.

THE SWEDISH HEALTH CARE SYSTEM

Constitutional Basis and Legislative Background

All Swedish citizens are entitled to health and medical care, regardless of where they live or their economic circumstances. Health care is considered a public sector responsibility.

The Swedish health care system is decentralized. Before the 1970s, with the exception of the creation of medical regions in 1958, few major structural changes had been made in the system since the transfer of health care administration to the county councils in 1864. In the twentieth century, Sweden concentrated on developing universal financial coverage and providing personnel for its costly, complex system of state-operated hospitals.

Private health care plays a minor role in Sweden. Although practitioners increased substantially in numbers during the last decade, most physicians (about 90 percent) are still employed in the publicly run hospitals and within the primary health services (13). Although hospitals were public and the population was largely covered for hospital care through sick funds, out-of-hospital care was often not covered until 1947. In that year the National Health Insurance Act, covering physician services, outpatient services, and drugs, was passed by the Parliament. The national health insurance program was implemented in 1954 after a period of careful planning. In 1958, Swedish counties were organized into seven medical regions, creating intercounty cooperative clusters envisioned as necessary for efficient delivery of specialized services. (Box 7-1 shows some important milestones in Swedish health care.)

In 1961 a comprehensive plan was introduced to increase medical manpower by expanding medical education. New hospital positions were created for medical school graduates. By 1970 the center of gravity of the medical profession had shifted sufficiently toward salaried service that a reform making virtually all doctors employees of the state, unthinkable in 1948, was effected with little resistance.

BOX 7-1: Important Milestones in Swedish Health Care

1862	County councils formed
1928	County councils given statutory responsibility for acute care
960	Private beds retired from public health services and county councils become formally responsible for outpatient care at hospitals
963	County councils take over district medical service
967	County councils take over mental hospitals
970	Public health services established a uniform patient fee; employed physicians receive fixed salary
975	Private physicians given opportunity to join insurance plan; reimbursement regulated
980	County councils given responsibility for vaccination programs
982/83	County councils take over two remaining state teaching hospitals
983	County councils given full statutory responsibility for planning all forms of health care
985	County councils given control over reimbursement and practice rights of private physicians
991	Opportunity for pilot projects that place primary care under municipal control
992	Municipal responsibility for health care of elderly (ADEL reform)
993	Opportunity for pilot projects to coordinate financing between social Insurance and health care

SOURCE Committee on Funding and Organization of Health Services and Medical Care, Three Models for Health Care Reform in Sweden (Stockholm Ministry of Health and Social Affairs, 1993)

Medical and social services were combined into the National Board of Health and Welfare in 1968. Even before this time, however, the central government had begun to transfer services to the counties. In 1961 responsibility for district doctors was transferred to the counties; in 1963 responsibility for mental hospitals was transferred (19). Subsequently, responsibility for university hospitals, public dental services, and services for the mentally handicapped was also given over to the counties.

The Health and Medical Services Act of 1983 finalized formal decentralization, giving the 24 county councils and three large municipalities further responsibility for the health of their inhabitants (including preventive care and rehabilitation). The money transferred from the central budget to the councils became a lump sum.

Each county has a politically elected council, but in negotiations with the central government as well as with employees' organizations, they tire organized in the Federation of County Councils (FCC). The FCC has a (politically elected) board and a well-staffed central office. During the development of the current system for health care administration the central government has been responsible for research and development as well as for the education of physicians. For historical reasons, most of the education of other health care personnel rests with local authorities, counties, or communities.

Under the Health and Medical Services Act the councils are required to promote the health of residents in their areas and to offer them equal access to good medical care and to transportation in case of disease. The councils plan the development and organization of all needed health care. The legislation provides for the protection of each patient's integrity, including the right to be informed about his or her state of health and about available investigative procedures and treatment. Special regulations cover the protection of patients' identities in

file handling and in various registers. Somatic patients are free to discontinue medical treatment. (The rules for psychiatric patients are dealt with in separate legislation.) The National Board of Health and Welfare supervises all health care personnel, and any misconduct is investigated by the National Medical Disciplinary Board.

Administration

The administration of Sweden's health care system has several levels and branches. The state is responsible for ensuring that the system develops efficiently and according to overall objectives, in the context of the goals and constraints of social welfare policy. The Ministry of Health and Social Affairs *(Socialdepartementet)* is at the first level below the government, and parliament and is concerned mainly with outlining guidelines for health care, social welfare services, and health insurance.

At the second level are a number of relatively independent administrative agencies. The National Board of Health and Welfare *(Socialstyrelsen)* is the central supervising authority for health and social services. In addition to a central office, it has about 10 county units, all with the following three well-defined tasks:

1. supervising, following up on, and evaluating developments in all areas of health and social policy;
2. acting as a center of knowledge in the realm of social policy; and
3. acting as an expert body for the government.

The Federation of County Councils plays a key role in health policy and structural and manpower issues. Other central supervising authorities (mainly for health protection) include the National Environmental Protection Board, the National Board of Occupational Safety and Health, the National Food Administration, the National Institute of Radiation Protection, the Chemical Inspection, the National Drug Institution, and the Institute of Forensic Medicine.

The Swedish Council of Technology Assessment in Health Care (SBU), funded by the central government, reviews and evaluates information on the medical, economic, and ethical impacts of new and existing health care technologies. The Swedish Planning and Rationalization Institute of the Health and Social Services (SPRI), owned in common by the central government and the county councils, works on planning and efficiency measures and special investigative tasks. It also supports research and development in health care administration. Other agencies include the National Corporation of Swedish Pharmacies *(Apoteksbolaget),* which purchases and distributes drugs; the Medical Products Agency (Lakemedelsverket), which is responsible for drug control and registration; and the National Social Insurance Board *(Riksforsakringsverket),* which is responsible for the central administration and regulation of the national health insurance system. (Table 7-1 illustrates some recent structural changes in the health care system with respect to hospital beds, bed-days, and physician visits.)

TABLE 7-1: Public and Private Health Care in Sweden: Hospital Beds, Bed-Days, and Physician Visits, 1980 and 1992

	1980	1992
Hospital beds		
Public	117,500	93,700
Private	8,400	7,800
Bed-days		
Public	35,600,000	29,000,000
Private	2,800,000	2,500,000
Physician visits		
Public	18,900,000	20,200,000
Private	2,900,000	4,600,000

SOURCE Federation of County Councils, *Statistical Yearbook for County Counccils* 1994 (Stockholm, 1994)

Financing

The national health insurance system is a state-controlled and supervised financing instrument designed to create equity in health care. Financed by the state and by employer contributions, the system is administered by regional social insurance offices *(Allmanna forsaking skassor).* Payments for medical care, dental care, and hospital

TABLE 7-2: Public Financing of Health Care in Selected OECD Countries, 1970 and 1992

	0/0 in 1970	o/o in 1992
United Kingdom	87	83
Sweden	86	88
The Netherlands	84	73
France	75	74
Germany	70	72
Canada	70	72
United States	37	44

SOURCE Organisation for Economic Cooperation and Development, OECD Health Data a Software Package for the International Comparison of Health Care Systems (Pam, France Organisation for Economic Cooperation and Development, 1993)

treatment are made directly from the social insurance office to the concerned health care administration or individual practitioner.

Patients pay fees for each contact with the health care system. The fee, set by each county council, varies from SEK50 to SEK130 ($US5 to 15) per physician visit in outpatient care up to a maximum of SEK 1,600 ($ US200) within 1 year, after which any health care service (except dental care) is free of charge during the subsequent year. This co-payment, which is the same for everyone, is kept by the county council. Consultation with private practitioners is reimbursed, and the patient pays between SEK120 and SEK200 ($US15 to 25) depending mainly on the specialty of the physician. Similarly, pharmaceuticals are reimbursed. The patient pays a maximum of SEK120 ($ US15) for the most expensive medicine and SEK 10 ($US 1.20) for every additional medicine on the same prescription.

About 88 percent of health services in Sweden is publicly financed. Over the last 20 years, only minor changes have occurred in the proportion of public financing of health care in Sweden (which also is the case in other Organisation for Economic Cooperation and Development (OECD) countries). (See table 7-2.)

Health care costs in Sweden have increased rapidly in recent decades. The annual rate of increase was limited to about 1 to 2 percent during the 1980s. Since 1990, however, the volume of health services has decreased, and the costs in real terms have decreased by about 1 to 2 percent annually. Costs are expected to decrease further in 1994 by about 3 percent (13).

In 1960 the costs of health care amounted to about 3 percent of gross domestic product (GDP), as compared with 8.5 percent in 1989 (18,34). In 1991 the total costs of health care amounted to SEK120,582 million ($US 16,750 million), corresponding to per-capita spending of almost **$US2,000. (See** table 7-3 for distribution of costs.)

The costs are financed approximately as follows: county councils, 60 percent; state subsidies, 16 percent; state funds, 12 percent; national health insurance reimbursement, 8 percent; and patients' fees, 4 percent. The general state subsidies are intended to level out differences in income between the county councils and include funds for education, research, and psychiatry (18).

Organization of the System

The health care system has several levels, the uppermost being the Federation of County Councils. The system has regional, county, and local levels, each of which is described briefly below.

Regional Level

Sweden is divided into seven medical care regions, each with a population of 11.5 million and comprising about three counties. These counties share one or more regional hospitals that are affiliated with a medical school and function as research and teaching hospitals. Among the specialized services that these institutions provide are neurology, radiation therapy, thoracic surgery, neurosurgery, pediatric surgery, and certain types of cardiac care. Some specialized services are provided on an interregional basis. (Thoracic surgery departments, for example, are located only at the four largest regional hospitals.)

County Level

Counties have an average population of 300,000, usually sharing one highly specialized central hospital with 15 to 20 specialties, and one or more district hospitals with at least four specialties

TABLE 7-3: Cost Distributions Within the Swedish Health Care System

Service	% of total
Inpatient Care	
Somatic short-term care	33
Long-term care	14
Psychiatric care	8
Total	55
Outpatient Care	
Primary care	14
Hospital outpatient care	7
Psychiatric care	2
Total	23
Drugs	10
Self-pay	12
Total	100

SOURCE LKELP 92 Report No 3, The Federation of County Councils, 1992 (In Swedish)

(e.g., internal medicine, surgery, radiology, and anesthesiology).

Local Level

At this level are the primary care districts with at least one local health care center for outpatient care and at least one nursing home for long-term care. At the health centers, care is provided by district physicians, district nurses, and midwives (if necessary as ambulatory care in the patient's home). The primary care districts also offer clinics for child and maternity care, and they operate screening and vaccination programs. Other branches of primary care include school health and industrial health services.

Because most medical care in Sweden is delivered by the hospitals, which are operated by the county councils, it is the counties that actually invest in new medical technology and decide whether to adopt a new technology. In addition, the budgetary authority of the counties constrains the services offered by the hospitals. Thus, physicians have less freedom in Sweden than they do in other Western countries to adopt services and to purchase equipment.

In theory, the four hospital tiers provide a clear hierarchy for acquisition of sophisticated new technologies. The regional hospitals come first, followed by the lower tiers. At each tier a service is provided only if there is a sufficient population base for it. (The case of computed tomography (CT) scanning, described later, will clarify how such decisions are made.) Rarely needed procedures are concentrated, and more experience with such procedures on the part of medical practitioners brings better results.

Each county's autonomy is somewhat limited by financial negotiations with the central government. Their freedom of choice also is constrained by cooperative agreements with other counties to provide specialized services on a regional basis. The objective of the regional system of medical services has been to ensure that specific types of services are delivered at the level (local, county, or regional) at which they can be provided most efficiently. In six of the regions, the university hospital, partly staffed by the medical faculty of the university, is the hospital responsible for highly specialized care in the region. The seventh region (Orebro) has no university, but its regional hospital is almost as well equipped for high technology as the university hospitals. Up to now, counties have had agreements with the regional hospitals and the other counties within the region concerning economic and administrative details of the delivery of highly specialized care.

Public Policy Concerns

In the early 1980s the Swedish economy slowed, which raised concerns about the high costs of health care. National caps have been put on county council taxes several times, constraining the rise of health care costs and also slowing medical technology diffusion.

Apart from economic pressures, the main weaknesses of health services in Sweden are considered to be (18):

- lack of integration of health and social services and health insurance (especially sickness benefits, early retirement pensions, and occupation-

al injury insurance) and, within the health sector, of primary and hospital care;
- failure of general practitioners to act as "gatekeepers" for primary care, which results in a high proportion of direct referrals to hospitals; emphasis on institutional care, which may not always be effective and efficient;
- limited choices for patients; and
- insufficient incentives for health personnel to improve the productivity and efficiency of the health sector.

Although the level of public confidence in the health care system still is high, the system is generally considered to be somewhat rigid, and the level of patient orientation is viewed as being too low. With the growing concern regarding health care priorities, the focus is increasingly on protecting the most vulnerable groups, such as the elderly.

The demand on health care services is steadily increasing not only because of the growing numbers of elderly persons, but also as a result of medico-technical advances that allow treatment of conditions that were once untreatable. These factors, together with demands for restraints on public spending, encourage reforms.

Reform Proposals and Implementation

Sweden's entire system of well-defined responsibilities for health care, with agreements on how money should flow and how patients are to be taken care of, is now under debate. To some extent this debate is due an imbalance between costs and resources, and to some extent it is due to decreased confidence in the system. Many new ideas are being tested, most of them originating in the United States or the United Kingdom. A political consensus now exists on reforming health services during the 1990s. Changes are certainly going to be introduced, probably of different types and with different goals in different counties (67). Common themes, however, are increased patient choice, reallocation of responsibilities and freer market mechanisms, competition, improved levels of service, and less bureaucracy.

A parliamentary committee was appointed in 1993 to review options for health care financing and organization. This committee was asked to consider three alternative models for the Swedish health system: 1) a continuation of the current system of financing, 2) a system in which primary health care providers become the budget allocation mechanism by buying services for their patients, and 3) a private insurance system.

The committee has responded with three models for health care reform (11). The first is based on the idea that within all county councils, there should be a separation of purchaser and provider roles, with a greater emphasis on reimbursement based on performance. The second model, described as the primary care model, involves transferring responsibility for health services from county councils to municipal councils. The assumption is that bringing services and political accountability closer to the citizens would mean that primary care would receive a higher priority. Under the new system, patients are allowed free choice of primary care center or doctor and of hospital, even across the county borders. The idea is to introduce an "internal market" with a "purchase and sale" situation in order to generate competition, based on the theory of incentives for improving productivity and efficiency (18). The third model is described as compulsory health insurance, which requires the replacement of tax financing with a system of social insurance. This would lead to a separation of insurers and providers (25).

The committee's report compares the strengths and weaknesses of these three reform models based on criteria focusing on equity and on continued public revenues as the main source of financing of health care, along with increased freedom of choice and democratic influence. Although the introduction of business concepts into health care might sound attractive in theory, reality may produce substantial challenges, such as caring for elderly people with a mix of somatic and social problems.

It is assumed that reform will entail greater needs for central follow-up and evaluation, with

an emphasis on cost-effectiveness. Any new approach will also have to include monitoring and evaluating goal achievements; comparing inputs, expenditures, and results in different places and for different activities; and observing and evaluating the content and quality of various activities. Quality assessment and quality assurance are likely to become important tasks for, say, the National Board of Health and Welfare. At present, quality assurance activities are very "soft" and hardly affect professional functioning—a situation that seems certain to change in the future.

The Role of the Public

Politically speaking, if a new technology is cost effective at the central hospital level, the county council and taxpayers both have a role in deciding whether to acquire it. This does not always lead to cost-effective decisions, however. Swedish citizens (like those of other countries) resist the closure of local hospitals and often promote new technology for reasons of local pride. Still, the close link between citizens and resource decisions helps ensure that the public feels committed to the health care system. Although Sweden has one of the highest levels of per capita expenditures on health care in the world, these amounts have been clearly promoted by popular political choice.

As patients, Swedish citizens pay little for their health care services, and price is therefore not a mechanism for limiting the demand for such services. A major constraint on demand is the fact that patients often are forced to wait for services simply because the supply is insufficient. Physical queues are often necessary for preliminary consultation. Once a referral to a specialist is made, there is another wait before a consultation. If a nonemergency procedure (e.g., a surgical procedure) is recommended, there is a further wait.

Waiting time has fallen dramatically since 1991, when the government explicitly guaranteed services in another hospital or a private hospital for patients with certain conditions who had been waiting longer than three months. Services covered by this guarantee include coronary artery disease surgery, hip joint and knee joint replacement, **cataract** surgery, gallstone surgery, hernia surgery, surgery on prolapsed uterus, treatment for incontinence, and hearing aid tests. A national fund was created to finance these procedures. As a result, there has been a rapid increase in the number of these surgical operations and there are now essentially no waiting times for them. Their increase certainly points to an expansion of indications, and concern is growing about the possibility of inappropriate procedures.

Constraints on the supply of services are successful because Swedish patients are collectivism in their orientation. The deference that Swedes display to government decisions reflects their confidence in the civil service and respect for government policies. Planners' efforts to control the dissemination of health care technology are greatly assisted by this tendency of Swedish citizens to cooperate with their government (19).

CONTROLLING HEALTH CARE TECHNOLOGY

Research Policies

Although the central government is explicitly responsible for all research, some counties (especially those connected with regional hospitals or with a stronger economy) also support research activities, particularly those aimed at improving the content and quality of health services (67). The central state budget includes resources for university-based research and education, and medical faculties have been relatively well funded. The preclinical departments have especially large and well-educated staffs, and laboratory research activities in Sweden are generally considered to be excellent. The clinical institutions are not as well supported by the state budget, partly because of the dual responsibility for operating the university hospitals, which have small academic staffs responsible for research and education of both medical students and some paramedical personnel, and large, nonacademic staffs employed by the county for patient care. For along time all academic activity was concentrated in the university hospital, with its specialized beds and large outpatient de-

partments. During the last decade all universities have created special departments of primary care (sometimes called general medicine) headed by a professor and other staff. All academics must take part in research; the unwritten rule is that such activities should constitute about 20 to 25 percent of academics' time (the rest being divided between teaching and medical service).

The main source of research support is the Medical Research Council (MRC). Most of the MRC'S research funding goes to university preclinical departments, but some also is directed to clinical departments, primary care, or social medicine. During the last decade, the MRC has appointed special committees for health services research and technology assessment. It was partly through the initiative of the MRC and its technology assessment committee that the Swedish Council on Technology Assessment in Health Care (SBU) was created (see below). Other governmental research bodies—such as the Social Research Council (SFR) and the Council of Research (FRN)—also play a role in formulating government policy toward biomedical research. In addition, clinical research is supported by several large private foundations.

Sweden invests heavily in health-related research, primarily basic biomedical research. According to a study sponsored by the U.S. National Institutes of Health in 1980, Sweden invested the highest amount of public funds per capita in biomedical research and development in the world, with the United States a close second. Sweden also has an active pharmaceutical industry with relatively heavy investments. In 1993, approximately 50 percent of health-related research was financed by government and the other 50 percent by industry.

Sweden also has explicit policies, as already noted, to encourage certain types of research that can improve Swedish health services. The development of health care technology assessment is one example. However, there is increasing concern that clinically oriented research, which is supported through clinical activities, is losing financial support under health care reforms. This problem has been noted by the Parliament, which is investigating the situation.

Medical Education and Employment Policies

The central government plans carefully to match physician training programs with current and anticipated needs. In recent years the policy has been to increase the number of Swedish physicians specializing in long-term care and psychiatry. Positions for specialists trained in the use of technology-intensive techniques has been relatively constrained. Most recently, however, the government has taken measures to further restrict admissions to medical schools and has initiated a thorough evaluation of medical education.

Once physicians are educated, the National Board of Health and Welfare can decide to a large extent where they will work, through its allocation of medical posts. Until recently, the Board determined the number of positions in different specialties throughout the system. This not only had an affected the control of health care technology but also helped ensure geographic access for the entire population. Recently, however, this policy was changed; determining the number of positions for doctors is now the responsibility of the county councils. Because the total number of phy - sicians is still decided by the central government, count y councils are limited in this respect. A similar system is applied to nurses, who represent a greater proportion of hospital personnel in Sweden than inmost countries. (Nurses are trained to a high level and perform a variety of tasks ordinarily reserved for physicians in other countries.)

As with other functions, the central government has announced that it wishes to decentralize the administration of universities and schools for higher education. It is anticipated that the local governing board of universities will decide most of its activities by itself, adhering to certain standards of quality (67). One possibility is to create local foundations to run the universities. Many would welcome such a decentralization of policymaking, but others are concerned about loss of

uality in both education and research. In any event, it seems likely that the future will see marked alterations in the administration of education and research in Sweden.

Regulation and Control of Pharmaceuticals

Sweden has a well-organized central agency for the control of pharmaceuticals, the National Pharmaceutical Board, which became an independent institution in 1990. The agency has a reputation for high scientific competence and integrity, similar to that of the U.S. Food and Drug Administration (FDA) or similar bodies in the United Kingdom or Australia. When new medicines are registered—after thorough scrutiny of efficacy and safety—their price is agreed upon by the Pharmaceutical Board and the manufacturer or distributor. The drugs are then sold through the state monopoly *(Apoteksbolaget),* mostly on the basis of physicians' prescriptions (68).

Swedish patients have enjoyed an unusually favorable subsidy with regard to prescription medicine. The patient pays only a nominal amount, slowly increasing from SEK15 to SEK120 ($ US2.50 to $US 15), for all prescriptions written at the same time by the same physician. This situation has led to patients' requesting their doctors to write many prescriptions at the same time, in order to increase the amount paid by the government. During recent years, some restrictions have been introduced both regarding the amount that can be prescribed (only a three month supply) and the type of pharmaceuticals affected (e.g., vitamins and cough medicines are no longer part of the scheme).

Anew bill is being discussed to decrease subsidies for medicines. The government has suggested both that the patient will have to pay a certain sum for each prescribed drug and that only the cheapest drug of the same kind will be subsidized. This would increase the amount that the patients must pay while decreasing government costs for drugs, now more than SEK10 billion. This bill is being resisted by both patients' organizations and the pharmaceutical industry.

There are only a few pharmaceutical enterprises in Sweden. Most medicines used are imported through subsidiaries of large international companies. The few Swedish companies are, however, quite successful and have considerable presence in the international pharmaceutical market. Part of this success is due to unusually good cooperation between university and industry research. (Highly qualified industrial researchers are appointed as adjunct professors, and this cooperation has stimulated research in both industry and the universities.)

International pharmaceutical companies frequently conduct early clinical trials in Sweden. Since the early 1980s, a clear agreement between the pharmaceutical industry and the FCC has established rules for clinical studies with new drugs. This agreement has been important for the trials' financial support as well as for patient safety and an improved image for the pharmaceutical industry.

Regulation of Medical Devices

In contrast to pharmaceuticals, medical devices have been much less regulated. Except for legislation on the control of sterilized disposable, the electrical safety of certain devices, and radiation safety, Sweden has had few legal rules to control the diffusion and use of medical devices. The main responsibility for this task has rested with health personnel. Since 1976, however, the National Board of Health and Welfare (NBHW) has had an advisory committee composed of representatives of the county councils, research institutes, and industry to monitor issues of the safety of the medical devices. All accidents and most major problems related to medical devices must be reported to this committee, which has in turn issued regulations and recommendations on safety.

In effect since 1993, new legislation has placed on industry the main responsibility "safe and appropriate" medical devices. The NBHW supervised the implementation of this legislation, which is part of a general harmonization of Sweden's rules with the policies of the European Union. The new legislation requires that produc-

ers of medical devices report malfunctioning equipment and enables the NBHW to request technical changes in the equipment or to stop the use of such devices.

Payment for Primary Health Care

In 1993 the central government introduced a radically new policy for paying for primary health care services. The new model features several characteristics of the United Kingdom's system of general practice—mainly a voluntary listing of the population with preferred providers (called "house doctors") at outpatient settings, and a per capita allocation of the primary health care budget according to each provider's population size (a minimum of 3,000 people). This model is expected to increase patients' choices of providers and to encourage competitive behavior within the publicly operated health system. A potential problem with this change is that there are essentially no incentives for cost-effective medical procedures or for the provision of preventive measures in the new model. On the contrary, the model may encourage overtreatment.

Quality Assurance

The National Board of Health and Welfare introduced a special program for quality assurance in 1991. Several organizations, including SPRI, have begun concentrating on research in this area. A committee on collaboration and coordination among national health care organizations, colleges for the medical professions, and nursing colleges has been established to promote quality-related activities. In late 1991 this council asked the medical colleges to develop specific quality indicators for each specialty, which began to be available in 1992. Their purpose is to encourage departments to monitor their own performance continuously. Indeed, quality committees are becoming common in hospitals. (All hospitals have questionnaires to assess patient satisfaction; however, quality audits are still being developed.) The effects of all these activities related to quality of care is not yet known.

HEALTH CARE TECHNOLOGY ASSESSMENT

Sweden was one of the first countries to become involved in the assessment of health care technology. A study of CT scanning was carried out in the early 1970s (see below); even before this study, the National Board of Health and Welfare asked some prominent physicians to evaluate particular technologies to determine if they were "consistent with proven scientific knowledge and good experience" (68). Over the last 15 years, formal assessments have been increasingly accepted in Sweden and are carried out in many institutions.

Swedish Council on Technology Assessment in Health Care (SBU)

Through the combined efforts of the MRC, politicians in the government and Parliament, assisted by the Board of Health and Welfare and SPRI, SBU was created in 1987. Its basic purpose was intended to update the Swedish government and the county councils with respect to scientific information on the overall value of medical technologies, especially new technologies (16). Cost containment was never the main aim, as it has been in other countries; the government did not wish to slow the introduction of new medical advancements. SBU was envisioned as an organization that would both assess important technologies and serve as a coordinating body for activities in Sweden. The idea was to give the SBU three years to see if creating a more permanent organization would be sensible. The desired outcome was the reorienting of policy and practice in constructive directions (67).

The board of the SBU was made up of representatives of important organizations in health care. It was envisaged that the board would have enough competence to select suitable fields for assessment as well as suitable methodologies. At the end of the trial period, SBU was producing high-quality reports from an international perspective and had already had important effects on clinical decisionmaking. Independent reviewers proposed that the SBU be set up as an independent authority fi-

nanced by the state. The government accepted this proposal and presented a bill to Parliament for approval; thus, the permanent Council began to function in 1992 with a budget ofSEK12 million ($US1.5 million).

The SBU depends on specialists working in the health services, mostly those outside university centers, to ensure contact with problems encountered in the daily routine of medical services (67). The SBU's studies are not merely technology assessments but also analyses of the nature of particular problems in Swedish society and evaluations of context and technology from diverse standpoints (including social and economic). Several SBU reports discuss the problems of assessment and propose methods for solving them (22,53,54,62). The SBU has also published a report recommending priorities for assessment (54).

The first SBU technology assessment concerned preoperative investigations in elective surgery (55). The study team reviewed the literature and concluded that there was little justification for routine use of preoperative x-rays, electrocardiograms, or laboratory tests. A survey of practice revealed considerable variations in the use of such tests and an economic analysis showed that the cost for complete preoperative investigations in Sweden totaled SEK726 million.

The SBU recommended that preoperative routines not be used in the absence of specific indications. An extensive "marketing" effort was used to convince surgeons and anesthesiologists of the wisdom of these recommendations. Follow-up surveys of practice were done in 1990 and 1991 to evaluate the impact of the report. The evaluation in 1990 showed a significant decrease in routine preoperative testing that continued in the 1991 measurement. The actual savings, apart from the increase in quality of care, were SEK50 million per year, or five times the SBU'S yearly budget at that time.

Another full-scale assessment concerned the problem of back pain (56). Most commonly used treatments were found, through a literature review, to be either ineffective or unproven; however, early movement and rehabilitation were found to have a positive impact on recovery. Moreover, the SBU report found that back problems were related to both physical and psychosocial working conditions. The report recommended a cautious approach to diagnosis and treatment, and more research on the efficacy of proposed treatments. It also recommended systematic approaches to changing individuals' working conditions so as to reduce the problem of back pain. Extensively publicized, this report led to a renewed discussion of the disorder throughout Sweden. Its impact is presently being assessed. Other SBU reports have dealt with stroke (59), percutaneous transluminal coronary angioplasty (58), magnetic resonance imaging (57), and early detection of diabetic retinopathy (60).

Several large projects are currently under way at the SBU. One is a thorough evaluation of the treatment of mild to moderate hypertension. Although many expert committees have made recommendations concerning this condition, the literature has never been examined to evaluate results in relation to resources needed for different types of patients. The study has already raised serious questions about the efficacy of treating mild to moderate hypertension.

Another large project concerns the rationale for radiation treatment of cancer. A Swedish working group of oncologists, economists, and experts in critical assessment is working to evaluate the voluminous literature on efficacy and cost-effectiveness. In addition, an extensive survey is being carried out to document the radiotherapy situation. Because this is a sensitive field, an international expert group has also been appointed to assist in preparing the final report. In addition, the SBU is studying the appropriateness of coronary artery bypass surgery (CABG) in Sweden, using methods developed by the RAND Corp. (10,69).

Once an SBU report is completed, it is distributed to decisionmakers, clinicians, nurses, and administrators within the health care system. The SBU has also begun publishing a newsletter that covers not only SBU studies but also national and international assessment activities. Furthermore, each year the SBU arranges at least one major conference introducing or concluding an SBU proj-

ect. It also organizes courses, seminars, and lectures by foreign experts.

During 1992 and 1993, when questions arose in Sweden concerning the benefits of psychiatric care, the SBU reviewed psychiatric procedures in Sweden and estimated the total costs for medical care for mental illness. The Parliament showed considerable interest in this area and gave the SBU additional funding to investigate mental health technology. In 1993 the SBU began to organize a large study of the use of psychotropic drugs to treat psychosis.

The growing visibility of the problems of health care evaluation, along with the SBU'S work, has given the field of technology assessment in health care a high profile in Sweden. In 1993 the Parliament discussed the possibility of setting aside 1 percent of national health expenditures for health services research, including technology assessment.

The main problem for health care technology assessment in Sweden is the large number of technologies needing assessment and rationalization. In response to an SBU survey of practitioners, administrators, politicians, and patient organizations on new and existing technologies needing assessment, 1,800 responses were received. Relatively few technologies can be scrutinized as carefully as CABG or CT scanning, and relatively few can be controlled directly by the system. Hundreds if not thousands of technologies remain unevaluated and uncontrolled.

Consensus Conferences

Consensus conferences have been organized in Sweden since 1982, following the model developed at the National Institutes of Health (NIH) in the United States (7). A conference on total hip replacement was held a few months after an NIH conference on the same subject. As of 1993, about 15 conferences had been held. Consensus conferences are organized and supported by the MRC and SPRI; the subjects they address are of importance to the county councils and are selected by a special MRC subcommittee.

Although the Swedish conferences follow the NIH format closely, they also have a different scope. In the United States conferences focus on the safety and efficacy of a technology. In Sweden this focus is retained, but the conferences also try to address questions of health care organization, cost-effectiveness, and social and ethical considerations.

An evaluation of the Swedish program of consensus conferences was undertaken in 1985 and 1986. Separate reports described how the consensus statements were reached and were received by physicians (29) and by politicians and administrators (6). More than half of the latter indicated that they had found the statements of one or more conferences to be of practical value; in some cases, the statements had a direct effect on political decisions. The physicians' evaluation studied the effects of conferences on hospital-based physicians in supervisory positions within relevant clinics. Awareness of particular consensus conferences was high. According to about 10 percent of the respondents, a consensus statement had changed clinical practice. Most physicians said that there was no change because the consensus statement reflected clinical practice prior to the conference (29). With the further development of health care technology assessment in Sweden, the MRC is reducing its support for consensus conferences. Although consensus conferences played an important role in demonstrating the need for technology assessment in health care, the MRC feels that this activity has become less important—particularly because of the establishment of SBU.

Swedish Planning and Rationalization Institute (SPRI)

SPRI has a very broad mandate to study issues of health care, including such issues as resource use, the diagnosis-related group (DRG) system, health economics, the use of computers in medical decisionmaking and administrative purposes, planning of health services, and quality of care. SPRI was involved in technology assessment very ear-

ly, particularly through studies on CT scanning (described below); and gradually developed a more comprehensive program for technology assessment. Nonetheless, technology assessment was considered insufficient, and this situation led to discussions about a new agency—which in turn resulted in the creation of the SBU. SPRI subsequently refocused its attention on quality assurance; however, it continues to undertake ad hoc studies of technology, mostly in collaboration with the Nordic Evaluation of Medical Technology (NEMT).

Nordic Evaluation of Medical Technology (NEMT)

NEMT consists of staff from four Nordic institutes: SPRI, the Danish Hospital Institute, the Finnish Hospital League, and the Norwegian Hospital Institute; there is also Icelandic representation. NEMT generally produces one report every other year. These reports are usually surveys of existing practice in the countries in a particular area of medicine and diffusion of technologies in that area. Recent reports have dealt with magnetic resonance imaging, prostate cancer, and coronary artery bypass surgery. NEMT is currently conducting a study of the diffusion, use, and effective monitoring of treatments with anticoagulants.

Center for Technology Assessment

This center, which is located at Linkoping University, was established with the financial support of the local county council in the mid-1980s. It has been particularly active in studying the cost-effectiveness of pharmaceuticals (8,30) and has also participated in primary data collection, as in a randomized study of renal lithotripsy (9). The Center has developed into an independent research institute; currently, its main areas of research are economic assessments, technology diffusion, and the use of technology by the disabled.

Case studies

TREATMENTS FOR CORONARY ARTERY DISEASE

Beginning with Lindgren's stellate ganglion resection experiments in the late 1940s (31), Sweden was at the forefront of experimental surgical techniques to relieve angina pectoris. Four fully equipped thoracic surgery clinics were established in Sweden in the 1950s. Activities were dominated initially by lung surgery for tuberculosis and carcinoma of the lung and subsequently by operations for congenital heart disease and heart valve problems.

Nonetheless, when coronary artery bypass grafting (CABG) was introduced in various Western countries, Sweden approached the new procedure with considerable caution, although experts on an advisory body of the National Board of Health and Welfare agreed that the bypass procedure was consistent with proven scientific knowledge and good practice. It was instituted on a small and experimental scale in 1973 and 1974 (66).

The central question for Swedish planners concerned how to implement the technology. Specifically, the issue became choosing the appropriate tier of the hospital hierarchy for introduction of CABG (19). CABG requires enormous ancillary support, including intensive care units, heart-lung machines, and blood gas monitoring. The sites for CABG were thus predetermined, as the location of the thoracic surgery departments had already been established.

Introduction of CABG was slow. (See table 7-4.) In 1977 only about 220 CABG operations (about 27 per million Swedes) were performed: by 1979 that number had increased to 404 (50 operations per million inhabitants). At the same time

TABLE 7-4: CABGs and PTCAs in Sweden, 1977–1992

Year	CABGs	PTCAS
1977	220	—
1979	404	—
1980	503	—
1981	727	—
1982	836	3
1983	1,236	46
1984	1,574	74
1985	1,970	165
1986	2,313	282
1987	2,774	465
1988	3,518	654
1989	3,946	858
1990	4,329	1,098
1991	4,642	1,774
1992	6,286	2,760

SOURCE T Aberg, The *Development of* Thoracic Surgery Duringi the *Last 40 Years* (Stockholm SBU (in press), 1993 in Swedish)).

the World Health Organization (WHO) had stated that the theoretical need for CABG was about 150 per million people (70). One limiting factor was the number of intensive care beds available to the thoracic surgery clinics. Another was a change in the heads of the cardiothoracic centers (all the chief surgeons retired within a period of 5 years).

When the U.S. Veterans Administration (VA) trial was published in 1977 (36) showing the clear benefits of CABG, Swedish thoracic surgeons and cardiologists attempted to treat only the most promising candidates with CABG and to treat the remainder with drugs. The Swedish level was seen as being too low, and plans were made to increase the numbers incrementally, in order to approach the WHO recommended level of 150 per million. The expansion was too slow, however, and long waiting lists developed. Private centers were established to meet some of the need; the public sector also responded, and the number of centers was gradually increased to the current number of eight.

Percutaneous transluminal coronary angioplasty (PTCA) was introduced in Sweden in 1982 and has gradually diffused into practice. However, it was adopted later and at a slower rate in Sweden than in other industrialized countries (58). At present there are about 25 PTCAS per 100,000 population in Sweden, as compared to about 70 CABGS per 100,000. The total direct costs of all CABGS is about six times that of PTCAs. Both CABG and PTCA procedures continue to increase in frequency because of their diffusion to counties where the demand still is not satisfied, expanding indications for revascularization, and the availability of resources from the Guarantee Fund, which applies to both procedures. Because surgical backup for PTCA is necessary, its diffusion has been limited to the eight centers performing CABG. There are no specific policies concerning PTCA; however, the regional structure, the limited number of surgical centers, and financial constraints have certainly slowed its diffusion. Other factors are medical concern for the high rate of restenosis, insufficient assessment of both PTCA and CABG, and cost concerns (58), along with a struggle between radiologists and cardiologists over control of PTCA (2).

Despite the slow implementation of CABG, there were no active protests from either patients or physicians until the mid- 1980s. By 1985, waiting lists were more than one year in Stockholm, Uppsala, and other sites. An evaluation sponsored by the MRC showed that patients were dying while on the waiting list (2); indeed, the mortality rate could be 10 percent per waiting year. Patients began to complain, and a 1987 report from an expert group highlighted the issue of waiting lists (15).

The Ministry of Health took the initiative of developing a "guarantee" that a patient on the waiting list for three months could go anywhere in the country as a priority case. Up to that time, patients were largely confined to their own catchment area, and counties were reluctant to send patients to another county. Waiting time is now seldom more than six weeks, and death of patients on the waiting list is rare. (The evolution of the waiting list is shown in table 7-5.)

The Ministry of Health also appointed a group of experts to develop national indications for CABG (probably setting an international precedent). An expert group appointed by the National Board of Health and Welfare reviewed the need for

TABLE 7-5: Patients with Coronary Artery Disease Awaiting Diagnostic Workup and Treatment in Sweden, 1987–1993

Year	Waiting for Diagnostic workup	Waiting for Operation
1987	2,000	750
1988	NA	1,150
1989	2,566	1,529
1990	2,903	NA
1991	1,756	1,243
1992	1,521	915
1993	1,346	827

KEY NA = not available

SOURCE T Aberg, *The Development of Thoracic Surgery During The Last* 40 Years (Stockholm SBU (in press), 1993 (in Swedish)

CABG and PTCA in 1987 (39). The group concluded that the combined need would be 6,500 procedures in 1992, at a time when the total was about 4,000. Because of these reports, additional resources were made available, leading to a rapid increase in the number of procedures, particularly PTCA. These increases are still continuing. (See table 7-4.)

Despite these reports, the costs of CABG were of little interest until the development of private sector clinics paid from public funds. The public sector then stimulated studies of the procedure's costs in public hospitals and sought ways to improve its effectiveness while reducing costs. Today, the average cost of a CABG procedure in Sweden is about SEK125,000 ($ US15,000).

In 1992 SBU published a comprehensive report on PTCA that also considered alternatives, including newer technologies. One of the main conclusions of the report was that:

> The paucity of methodologically strong comparisons, particularly the virtual absence of RCTS comparing PTCA, CABG, and medical treatment, severely limits informed clinical practice and policymaking concerning the management of coronary artery disease (58).

In 1993 SBU reviewed the appropriateness of CABG in Sweden using the RAND method (10), with support from the MRC, the county councils, and the National Board of Health and Welfare and the full cooperation of thoracic surgeons and cardiologists. Because of the failures of PTCA (primarily the problem of restenosis), there has been considerable interest in the newer technologies for opening coronary arteries, including laser technologies, stents, and rotational atherectomy. These devices all are considered experimental (58) and are used in only one of the centers for thoracic surgery.

Although Sweden's "wait-and-see" approach to new technology avoids costly mistakes, slow implementation of a new a ' beneficial technology means that many deserving candidates cannot receive the procedure. This case illustrates once more the collectivism orientation of Swedish patients and their willingness to trust their government's decisions. Despite CABG'S SLOW implementation, there were no active protests from either patients or physicians until the 1980s. Patient and provider protests and political actions are now more frequent than they were in the past.

MEDICAL IMAGING (CT AND MRI)

Computed Tomography (CT)

In general, the field of diagnostic imaging has not been the subject of specific policymaking in Sweden, with the exception of assessments f CT scanning and MRI. Hospitals have been free (within their restricted budgets) to purchase diagnostic imaging equipment as they deemed appropriate.

The CT scanner was introduced in Sweden in 1973, the same year that the United States acquired its first scanner. By May 1978, however, Sweden had 1.6 scanners per million people, whereas the United States had 4.8 per million (19). This is surprising, considering that Sweden had originated the specialty of neuroradiology and was a leader in radiology and radiotherapy. (The diffusion of CT scanning is shown in table 7-6.)

Planners in Sweden did not view the introduction of CT scanning as a simple case of adding another machine. They viewed CT as a technology that would partially replace the functions of other diagnostic modalities. which could there-

TABLE 7-6: Diffusion of CT Scanning and MRI in Sweden, 1973-1994

Year	CT scanning	MRI
1973		
1974	1	
1975	3	
1976	6	
1977	11	
1978	12	
1979	15	
1980	16	
1981	18	
1982	22	
1983	33	
1984	36	2
1985	41	2
1986	48	5
1987	56	5
1988	77	7
1989	85	9
1990	91	11
1991	97	18
1992	104	22
1993	115	34
1994	120a	42a

aEstimated,

NOTE. Figures represent the accumulated number of units installed

SOURCE Swedish Council on Technology Assessment in Health Care (SBU), *MRI--Magnettc Resonance* Imaging (English language summary). Stockholm, 1992

fore be allocated fewer resources. The problem was thus ensuring that CT scanners were not installed beyond the point of diminishing returns in terms of the diagnostic examinations they replaced. Therefore, when the first head scanner was installed by the Karolinska Hospital in Stockholm, an evaluation was immediately mounted to rationalize further purchases.

The evaluation team weighed the costs of the head scanner against those of cerebral angiography and pneumoencephalography at various levels of examination. The basic question was this: How many angiographic and pneumoencephalographic examinations would have to be replaced at a given hospital by CT scanning for the costs of the scanner to be justified economically? Only equipment, hospital, and personnel costs were included in the analysis, although other costs and benefits (including medical and psychological value of the innovation) were listed.

The cost-effective level of installation of CT scanners was determined to lie somewhere between the levels of the regional and central general hospitals (27,28). Some of the large central hospitals did almost as many brain examinations as the smallest regional hospital did; thus, the evaluation did not recommend which institutions should acquire CT scanners. Rather, it published charts that county councils could use to graph specific levels of usage of angiography and pneumoencephalography at a given hospital in order to determine whether replacement of these modalities with a CT scanner would be appropriate.

The success of the Swedish evaluation was probably due in large part to its timeliness. The county councils needed information to help their decisionmaking, and the information arrived on time and was credible. Most Swedish hospitals waited for the report and followed its recommendations. Only two scanners had been installed in Sweden at the time the report was released; by December 1978, Sweden had eight head scanners (all but one at regional hospitals) and six total body scanners (two of which were located at the largest central hospital). The county councils expected the CT scanners to pay for themselves; thus, the hospitals received only a small additional budget when they purchased a scanner.

In 1985, a consensus conference on stroke was held in Sweden (35). Based on the economic consequences of missing a diagnosis of stroke, the consensus panel suggested that all hospitals should have CT scanners. This report led to an increased diffusion of CT scanners in the late 1980s. The importance of CT scanning for this indication was further emphasized in an SBU report in 1992 (57).

Magnetic Resonance Imaging (MRI)

MRI was introduced to the world market in 1978, and the first MRI scanner was introduced in Sweden in 1984 and installed in the Academic Hospi-

tal in Uppsala (23,52). Diffusion in Sweden was slower than in some other countries. By mid- 1992 nearly 20 hospitals had installed MRI scanners. Future plans indicate that between 30 and 40 hospitals hope to have access to this technology within a few years.

The first technology assessment of MRI in Sweden was performed by SPRI in 1984 (49). Although it essentially described only the state of the art, this report immediately led to an unusual policy measure adopted by the Federation of County Councils, which stated that a moratorium should be placed on MRI until a thorough assessment of the first installed machine had been performed. This initiative did not stop some hospitals from acquiring MRI, but it certainly slowed diffusion during the following years. By 1990, however, the number of MRI units per population had caught up with the diffusion rate in most other European countries, in part as a result of the assessment of the first installment. (See table 7-6.)

In 1990 the NEMT program, representing the five Nordic countries, carried out a comprehensive evaluation of radiology in those countries. SPRI also studied the numbers and utilization of MRI in the Nordic countries in 1990 (50). These reports did not specifically affect policy or practice but focused attention once again on diagnostic imaging.

In 1992 SBU published an assessment of MRI in the context of diagnostic imaging, especially CT scanning (57). It included, in addition to a description of clinical aspects of MRI and a comparative analysis of the sensitivity and specificity of competing modalities for diagnostic imaging, a thorough literature review, studies of diffusion from an international perspective, surveys of perceived need and current examination practices, cost calculations, a cost-effectiveness analysis, and description of technical aspects of MRI. The report showed that:

- diffusion of MRI in Sweden was relatively slow,
- there was little evidence to support a speedier diffusion,
- many hospitals had plans to acquire MRI within the next few years, and
- although MRI could replace many conventional diagnostic procedures, the cost would be much higher with no clear evidence of superiority in diagnostic accuracy except in a limited number of cases and indications.

The future potential of MRI, both in research and clinical practice, was clearly acknowledged in this analysis, but the report concluded that CT scanning will remain the most important diagnostic measure for diseases of the brain for the foreseeable future. Recognizing the potential of MRI, SBU stated that its role and limintations would not be completely determined during this decade in part because of a lack of "rigorous scientific studies which compare the results of MRI examinations with other imaging techniques. Likewise, no published study verifies the cost effectiveness of MRI in relation to other techniques," (57). In addition, the report stated that the possible long-term risks of placing the body in strong magnetic fields are unknown. Although MRI can reduce the need for some other examinations, such as CT scanning, angiography, arthroscopy, and ultrasound, the report demonstrated that total net costs following the introduction of MRI would increase considerably.

This report was cautious in its attitude toward further MRI installations, pointing out the financial costs and the need to consider the existing capacity of diagnostic imaging (primarily CT) before purchasing an MRI scanner. Many hospitals are still adopting a wait-and-see attitude.

LAPAROSCOPIC SURGERY

The laparoscope has been used in Sweden since the mid- 1960s, mainly in diagnostic gynecology (20). The performance of laparoscopic cholecystectomy in France in 1987 and 1988, and the reports of Dubois and coworkers (12) were of considerable interest in Sweden. Several surgeons from Gothenberg visited France in 1990 to learn about this procedure, which they then introduced in Sweden. It spread rapidly, fueled by media re-

ports and patient demand, as in other countries. By 1991, 68 percent of surgery departments either were providing laparoscopic cholecystectomy or intended to begin (26). Other applications of laparoscopic surgery have spread more slowly.

Interest also has been increasing in laparoscopic treatment in gynecology. Beginning with sterilization via laparoscope in the early 1980s, the use of treatment laparoscopy has gradually spread. Puncture of ovarian cysts is diffusing currently. Since the late 1980s laparoscope have been used in gynecology to remove ectopic pregnancies and blocked tubes or ovaries. During the early 1990s innovative procedures spread widely through gynecology in Sweden. Although these procedures have been found to take up to 100 percent more time than traditional procedures, they are considered cost effective because of the patients' rapid return to normal functioning. Normal recuperation time in gynecology with these procedures is a few days compared to 2 to 4 weeks with traditional procedures (12).

To encourage less invasive surgery, a special fund was set up by the health insurance funds in 1991 to encourage services associated with shorter periods of sickness. Most of the 65 hospitals in Sweden that provide laparoscopic surgery received funds for acquiring the equipment, the total cost of which was SEK40 million ($US4 million).

SBU recognized the potential of less invasive surgery in 1990 and commissioned a review of the literature on all specialties of medicine and surgery. Although this review was not published, support was obtained from the European Commission to study the cost-effectiveness and the diffusion of 10 types of minimally invasive therapy (MIT) in five European countries, not including Sweden (4). Information collected on the diffusion of these procedures demonstrated that Sweden was one of the earliest innovators in this field in Europe.

Since 1990, SBU has continued to monitor developments in MIT in general and laparoscopic procedures specifically. In 1992 SBU carried out a survey of laparoscopic surgery in Sweden, focusing on five conventional surgical procedures that could be replaced partially by laparoscopic procedures. (See table 7-6.) SBU estimated that about 25,000 conventional operations could be replaced by laparoscopic technique each year, which would reduce the number of bed-days by about 32,000 and the number of days of sick leave by about 210,000; the cost savings per year thus could be about SEK200 million per year if such replacements were actually to occur (61).

The laparoscopic technique for cholecystectomy is now well established and seems to be the first option for this condition in Sweden. A recent survey showed that 70 to 75 percent of all cholecystectomies are performed by laparoscopic technique (24). Early enthusiasm for laparoscopic surgery led to the belief that within a relatively short time, about 70 percent of all conventional surgical techniques would be replaced by the laparoscopic technique. (See table 7-7.) However, applications of laparoscopic surgery in fields other than cholecystectomy (e.g., appendectomy and inguinal hernia), have been slow because of concern about complications. The general feeling in Sweden is that estimates of the efficacy of other procedures seem to have been too optimistic (24). The use of laparoscopic technique for several indications is thus viewed as appropriate only within the frame of a randomized controlled trial.

Laparoscopic surgery is not subject to other specific policy measures in Sweden. Because of budget constraints and the regionalized system, therapeutic laparoscopy is found primarily in larger hospitals, but it also has spread to smaller hospitals. The main concern with these procedures is the expansion of indications and the growing number of surgical procedures. Concern is also growing about potential future needs for reoperations because of increased risks of complications that may result when surgeons have a less complete overview of the operating field than they do with conventional operations. Several randomized controlled trials are underway in Sweden to establish whether these and other concerns are valid. In addition, a National Register of Laparoscopic Surgery established in 1993 is monitoring the volume, complications, and certain technical aspects of the procedures.

TABLE 7-7: Estimated Number of Conventional Surgical Procedures Replaceable by Laparoscopic Surgery in Sweden

	Potential replacement	
Procedure	Number of procedures	Number of bed-days
Gallstone	5,000	10,000
Gallbladder	1,000	7,000
Appendicitis	8,600	8,600
Hernia	10,000	0
Other	1,400	5,600

SOURCE Swedish Council on Technology Assessment in Health Care (SBU), "Medical Science and Practice" (Newsletter), No 1-2, 1993, (in Swedish)

TREATMENTS FOR END-STAGE RENAL DISEASE (ESRD)

Renal dialysis was introduced to Sweden in the early 1960s; by the end of 1965, six of the approximately 40 centers in Europe treating patients with ESRD were in Sweden (5). Both dialysis and transplants were performed in Sweden quite early in their development. The Swedish program has emphasized transplants; in 1980, Sweden was one of only six countries in which more ESRD patients had had transplants than were on dialysis.

Treatment of ESRD became a policy issue by 1965 because of a shortage of hemodialysis services in the Stockholm region. In 1966 an ad hoc committee investigated the issues and presented a proposal with estimates of the need for hemodialysis and the organization of renal medicine. (Transplant services were also dealt with, but more superficially.) In 1967 the National Board of Health issued national ESRD policy recommendations stating that hemodialysis should be provided at the regional level only and that transplant surgery should be concentrated in two or three regional hospitals (37). This report was followed by a 1970 policy document stating that renal medicine and hemodialysis services should be regarded as regional services (i.e., each regional hospital should provide treatment for the entire population with chronic renal failure in its region). This policy document also recommended that renal transplant be a "multiregional specialty" (i.e., four regional hospitals should serve the population of specific catchment areas made up of two or three regions) (48).

These reports led to a strong debate within the community of nephrologists in Sweden. Regional medical services committees, which had authority for planning ESRD services, did not uniformly endorse the centralization of hemodialysis services. Several hospitals already had started decentralized units and refused to close them. By 1975 most health care regions had two or more decentralized units; after that year, the Board made no efforts to stop this development (5). Transplants, however, did become a multiregional service.

The cost-effectiveness of ESRD services has always been an issue. The 1970 policy recommendations presented cost estimates and predictions; since then, although many studies have been carried out and conferences held, the government has not pursued the issue of the economic consequences of the ESRD program (5)-perhaps because ESRD was introduced during a period of economic expansion. Care for a dialysis patient in Sweden costs about 2 million SEK per year (US$250,000).

By 1970, Sweden had the highest rate of patients receiving ESRD treatment in the world, (5) and has continued to have one of the highest treatment rates. It is estimated that a 70 percent increase in the ESRD population will occur between 1990 and 1995 (from 1,500 to 2,400) because of the aging of the population (40) and improving survival rates (32).

Despite the high overall provision of ESRD treatment and high proportion of transplanted patients, several national goals have not been met. Large and persistent variations in the provision of ESRD treatment are still seen. The high reliance on hospital hemodialysis and the limited use of home dialysis are also considered unsatisfactory (5). There are currently about 400 beds for dialysis at 40 different hospitals. About 75 patients are on hemodialysis at home, and 325 are treated with peritoneal dialysis. Dialysis is also quite common in the elderly; more than 30 percent of dialysis patients were 70 years or older in 1990 (40).

Erythropoietin (EPO)

EPO was marketed in Sweden beginning in 1989. It was subject to evaluation for efficacy and safety (like any other drug), was approved for the specific indication of anemia in renal insufficiency, and was then paid for exactly like any other pharmaceutical product. Any physician may prescribe EPO, the diffusion of which has been extraordinarily rapid; the number of doses rose by 50 percent during the 1991 to 1993 period. EPO'S cost to the health services was SEK78 million in 1992 (more than $US1 million per million people). All other Scandinavian countries have lower volumes and lower average costs for EPO (although this high volume and high cost has not been an issue in Sweden to date).

A 1990 doctoral dissertation stated that people were dying because of lack of dialysis in Sweden, especially among the elderly population. Publicity on this issue led the National Board of Health and Welfare to issue a quick "alarm report" on this issue. The Board was unable to confirm that people were dying; however, it recommended that the county councils improve their planning processes for ESRD treatment, especially dialysis.

NEONATAL INTENSIVE CARE

Specialized clinics, fully equipped for neonatal intensive care, appeared in Sweden during the 1960s and gradually spread. Neonates are cared for in all of the 43 departments of pediatrics in Sweden, which include some degree of intensive care. Many high-risk pregnant women are referred to regional hospitals before delivery. Modem respiratory care, including ventilator therapy for newborns, has spread into the seven regional hospitals and to eight of the central county hospitals. There are currently 15 hospitals throughout the country with close to 100 beds for specialized neonatal intensive care for about 130,000 newborns per year. An estimated 500 to 600 babies per year are ventilated in these neonatal intensive care units (NICUS). The technology of neonatal intensive care has dramatically improved survival for the pre-term newborn; also, the technology has paved the way for increased clinical understanding of several essential physiological and pathogenic phenomena.

The organization of neonatal intensive care has developed along similar lines in most hospitals. NICUS are run by pediatric specialists, with one exception (in Gothenberg) where the clinic is under the supervision of specialists in anesthesiology. The Swedish system developed without national concern for its role and place in the overall structure of Swedish health care; nevertheless, NICUS have mainly been concentrated in the large regional and central district hospitals. They have developed with the close collaboration of obstetrics and pediatrics departments.

Improved care for very pre-term infants at extremely low birth weights has gradually become a subject for professional as well as public concern. The discussion has centered around ethical dilemmas, the limits of neonatal intensive care, the costs and benefits of this service in general, and issues of staff competence and experience and questions about the geographical distribution of the resources—particularly of new and improved medical technologies.

In the 1980s the National Board of Health and Welfare established an advisory committee of experts in perinatology to monitor developments in this field. This committee arranged a conference in 1989 at which it reviewed recent evidence on neonatal mortality and morbidity, with particular reference to prognostic factors and potential development of handicaps in premature infants. Other available epidemiological evidence in this area was also reviewed, as were legal, ethical, and economic issues (38).

Among the facts presented were the following:

- the evidence of a significant increase in survival because of NICUS is overwhelming;
- parallel to this development, with many more healthy newborns surviving, the incidence of neurological diseases (and particularly of multihandicapped individuals) among newborns could be seen as increasing;
- establishing a firm prognosis at an early stage in the neonatal period is difficult;

- cesarean sections for very pre-term deliveries bring significant increased risks for both post-operative complications and pregnancies at a later stage; and
- the relationship of costs and benefits seems reasonable in comparison with other expensive medical procedures.

The conference concluded that although it is not possible to predict prognoses in individual cases, there is a practical need to establish a limit of at least 25 weeks of pregnancy, after which (in principal) obstetric interventions should be considered. Regarding the newborn infant, a more individualized approach was recommended. The majority of the neonatologists thought it correct to take an initially open but wait-and-see attitude toward ventilator therapy in some instances; a minority thought that initially very active treatment is always justified. All agreed that it is ethically defensible to discontinue treatment of very severely injured newborns. Furthermore, a national study was recommended to investigate the incidence, mortality, short-term and long-term morbidity, and prognostic factors for neonates below 1,000 grams. (This study is in progress.) Finally, it was recommended that a national register be established for all pre-term newborns under 1,000 grams to monitor and define prognostic factors in the neonatal period.

The conference's recommendation limiting most intervention to pregnancies of at least 25 weeks has had an impact on medical practice in Sweden. This recommendation has been subsequently supported by evidence from clinical studies (17).

Extracorporeal Membrane Oxygenation (ECMO)

In 1991 a state-of-the-art conference on NICUS was organized by the Sweden Medical Research Council. The proceedings, published as a supplement to the *International Journal of Technology Assessment in Health Care (46),* pointed to many research questions, including the need for controlled studies of continuous positive airway pressure (CPAP) and ECMO. A comprehensive policy-oriented assessment of NICUS in Sweden is now underway, sponsored by the National Board of Health and Welfare. Preliminary results point to an uneven distribution of resources, overcapacity in the number of beds, and a potential relationship between volume of services and health outcomes for newborns (17). Of special concern are various aspects of quality of care, which may well be related to professional competence and experience.

Introduced in Sweden in 1991, ECMO is available in two hospitals. There is no randomized controlled trial for ECMO and its potential alternatives, such as the new generation of respirators, including the high-frequency oscillation ventilation (HFOV) system.

The demand for treatment with ECMO is generally considered to be satisfied by the existing two centers. Because there are very few cases per year with indications for care using this technology, treatment with ECMO is a marginal issue.

Neonatal intensive care has not been a visible policy issue in Sweden, nor have NICUS been assessed comprehensively. However, as noted earlier, improved care for very pre-term infants has gradually become an issue—as has its costs.

SCREENING FOR BREAST CANCER

Clinical examination, using mammography for specified indications, was introduced in Sweden in 1964. About 10 years later, it was available all over the country. Clinical trials of screening for breast cancer began as early as 1966, using physical examination and thermography as the screening methods. Mammography screening in Sweden began in one region of Sweden in 1974; by the end of the 1980s, it had covered almost the entire country.

The target population for screening varies from county to county, with some counties supporting screening beginning at age 40 and others proposing that screening begin at age 50. The total target population is 1.5 million women; probably more than 50 percent are actually screened.

The first randomized, controlled trial (RCT) of screening mammography (in women over 40) in Sweden began in 1977. The results, reported in

1985 (64), confirmed the findings in the Health Insurance Program (HIP) study in the United States of a reduction in mortality from breast cancer of 30 percent, but later analysis revealed that the benefit was restricted to women between age 50 and 70 at the start of the trial. (63). The results of this RCT were based on a small absolute number of deaths. Of the 135,000 women in the age group from 40 to 74, there were, after screening every second year, 86 deaths in the screened group as compared with an expected 118. This has raised a concern about the relationship of the costs to the benefits of mammography screening.

A second RCT in Sweden was completed in Malmo in 1988 in women aged 45 to 69. This study, however, could not confirm a statistically significant reduction in mortality from breast cancer in the screened group. After 9 years of screening 20,000 women every second year, there were 63 deaths from breast cancer in the screened group compared with 66 in the nonscreened group (3).

Two more RCTS of mammography screening are ongoing in Sweden (in Stockholm and Goteberg). As a result of the first study, the National Board of Health and Welfare recommended in 1985 that all county councils in Sweden introduce mammography screening for all women aged 40 to 74. Since then, most county councils have gradually expanded mammography screening.

Two technology assessments of screening have been carried out in Sweden. The first, performed by a parliamentary committee in 1984, examined screening programs for cancer for both effects and financial costs, finding that there was a benefit from mammography screening (47). The second assessment, performed by SPRI in 1990 (51), reviewed the incidence, prevalence, and other epidemiological data on breast cancer in the country, analyzed the results from mammography screening programs in different countries, and included cost analyses of different options for screening as well as a cost-effectiveness analysis of the first trial in Sweden (showing a cost per year of life saved of about SEK75,000 or $US10,000 in 1993 dollars, and a total cost of about SEK500 million, or about $US8 million per million people, to screen the total target population). The report concluded that ongoing monitoring of mammography screening is crucial.

There are several current concerns. First, as screening has been gradually introduced, radiologists and technicians have shifted to breast cancer screening, which has led to waiting lists and delays for other radiology services. Second, the specificity and sensitivity of mammography achieved in the RCTS are difficult to achieve in routine practice. Finally, and perhaps most significantly, various important aspects of screening for breast cancer by mammography have been neglected, such as the large number of false positive findings, the need for an effective and efficient follow up, and delays from suspicion of malignancy to final diagnosis.

CHAPTER SUMMARY

From a macroeconomic perspective, it can be said that the health sector in Sweden is consuming a considerable share of society's resources; employs a relatively high proportion (10 percent) of the workforce; maintains the health of Sweden's productive capacity; constitutes the basis for the industrial development of pharmaceuticals, medical equipment, and devices; and has the potential to grow exponentially. The health sector consumes about 8 percent of Sweden's GDP, determines a substantial portion of sick leave and early retirement, plays an important role in the export and import of medical goods, and greatly influences social policy making.

Regulation and planning have played a significant role in the Swedish health care system, but less direct controls, such as planning for personnel needs, have perhaps been more important. The regionalized system that has evolved precludes many of the problems of duplicated and underused technology that have troubled other coun-

tries. The system also encourages geographically and financially based access to services, even though limited resources do result in waiting lists and other restrictions.

Despite the generally high level of public satisfaction with the Swedish health care system, change is under way. With decentralization, the public is increasingly involved in decisionmaking. One result, already discernible, is growing pressure for choice-of physician, of institution, and of treatment procedure. Increasing patient choice must, however, be coupled with increasing responsibility. The public must have a sound basis for making reasonable choices in health care. Up to now, relatively little has been done to ensure that this is the case.

During the past decade or so, Sweden gradually developed a greater commitment to health care technology assessment. At the time of an earlier review sponsored by the U.S. Office of Technology Assessment (19), there was no organization in Sweden dedicated to such assessment. A number of such institutions now exist (including SBU at the national level) and are engaged in this vital activity. In addition, the importance of health services and clinical research is being recognized as crucial for improving the system's quality. Technology assessment is increasingly visible to policy makers, and its proposed extension to psychiatric care and social services is an indication of its growing acceptance.

The government currently is considering a proposal for a comprehensive assessment of the need to strengthen applied clinical research and possibly to earmark a percentage of the health budget for this purpose. (A figure of 1.5 percent of the total health budget has been discussed.) The pressure to do so came first from the technology assessment community, with increasing support from clinicians experiencing difficulties in financing clinical research as a result of the many ongoing experiments with a "free market" in Swedish health care. Substantial support for the proposal and for technology assessment in health care comes from a parliamentary committee that is developing guidelines for priority setting in health care and that sees the need for assessments of clinical practices.

The main achievements of Sweden's system for health care technology assessment are the development of a well-organized, respected government body for assessment and the spread of the idea of technology assessment throughout the medical profession. Sweden has been successful in institutionalizing health care technology assessment in its health services not only because such activity comports with the national character but also because technology assessment has never been viewed as threatening by Swedish health care professionals. Cost containment depends on budgets; hence, technology assessment has had a more positive slant: to ensure that beneficial and cost-effective technologies are diffused rapidly into the system.

Technology assessment in health care was introduced as an activity with two objectives: on the one hand, to speed the diffusion and use of medical technologies with proven safety, efficacy, and effectiveness to ensure broad and equitable access to the technology; and on the other hand, to monitor technologies that have not yet been scientifically assessed whose policy implications are not yet fully understood so that potentially harmful, useless, or less effective technologies can be phased out and replaced. Thus, technology assessment in Sweden has by no means aimed solely at cost savings. This is a particularly sensitive issue in Swedish health care, both for the general public and for the medical profession, which have experienced more than a decade of reductions in the volume of health services as well as seemingly endless experiments with measures to control increasing costs.

Technology assessment in health care was also introduced with strong support from the clinical scientific community. When SBU was established, the government intentionally selected individuals who represented respected research-based institutions to constitute its board and expert group (about 20 people). SBU is not seen as a separate institution that criticizes professionals; in fact, prestigious specialists carry out the SBU

studies. Swedish specialists are highly motivated to improve the quality of their care, and SBU is seen as a positive source of help. Thus, although SBU is active in advising policymakers, it is seen as a constructive addition by health care professionals.

For its part, SBU has concluded that successful assessments must meet certain requirements, including the following:

assessments must result from a strong interest among policy makers and/or clinicians;

- data on the technology in question must be available, preferably from methodologically rigorous studies, and especially from randomized trials;
- to ensure integrity, all related studies, including clinical and economic studies, must be identified and thoroughly reviewed, with the committed involvement of expert professionals;
- assessments must be scientifically and clinically credible and presented in a logical manner;
- assessments must be presented so that they are accessible to the medical profession, policymakers, and the general public;
- results must be accompanied by clearcut policy options or straightforward recommendations; and
- a strategy for strong, long-lasting marketing efforts on different fronts should accompany the results.

Perhaps the greatest single problem with health care technology assessments in Sweden is the large number of unassessed technologies—including, according to one SBU survey, about 400 new technologies. Even if more money were available, there is a limit to the number of research sites and well-trained researchers that Sweden can develop in a relatively short period of time. The only solution is international collaboration.

Swedish experts participate in a variety of international activities and are attempting to contribute to the development of permanent international structures for sharing information and coordinating activities. Increasingly, too, experts from other countries actively participate in technology assessment projects in Sweden. Although practical problems need to be overcome for such international structures and cooperative networks to be effective, this is considered a high priority in Sweden.

The experience of health care technology assessment in Sweden shows that it is possible to identify technologies needing assessment and to assess them in ways that affect their adoption and use. These lessons will surely be applied more intensively as the health care system evolves.

Finally, as SBU has come to realize, dissemination is time consuming. Assessment results need to be marketed both to professionals and to the public. The results do not necessarily affect everyday clinical practice. Although the best clinical departments are responsive to assessment results, ordinary practitioners may not follow SBU recommendations. (This problem is heightened by Sweden's size and areas of sparsely populated territory.) Better methods of dissemination are needed in conjunction with methods of quality assurance.

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Health Care Technology in the United Kingdom

8

by Jackie Spiby

OVERVIEW OF THE UNITED KINGDOM

The United Kingdom, with a total population of 48.2 million in 1992, consists of four countries: England, Wales, Scotland, and Northern Ireland. Geographically, it consists of one large island and numerous smaller islands covering 94,500 square miles. Although physically small, its position at the northwest coast of Europe has meant that it has been able to maintain independence as an island and establish close relationships with Europe and with North America. The United Kingdom is essentially an industrial and trading nation; most of its working population is engaged in manufacturing and commerce.

Government and Political Structure

The United Kingdom has a constitutional monarchy, and one sovereign body governs all four countries. The central government takes its authority from the two-tiered Parliament (the House of Commons and the House of Lords). The Prime Minister is the leader of the party with the majority of Members in the House of Commons. Government departments and ministries are headed by Secretaries of State or Ministers, a subset of whom form the Cabinet. All departments and ministries are led by individuals from the majority party in Parliament, so there is no separation of the executive and legislative branches of government. The departments and ministries also have permanent secretaries and other executives who assist these Secretaries and Ministers.

Northern Ireland has regional independence but not a federal relationship. Wales and Scotland have a degree of administrative devolution that is of limited significance, although it has led to some differences in how health services are organized.

HEALTH STATUS OF THE POPULATION

Despite an increasing emphasis on prevention, the United Kingdom continues to compare poorly in health status to most of its European neighbors. Death rates for ischemic heart disease in England and Wales are just over 300 per 100,000 male population aged 45 to 64; in contrast, West Germany has a rate of approximately 250 and France, 100. The rates of Scotland and Northern Ireland are even higher than those of England at 450 and 400, respectively. This pattern is similar for breast cancer.

The main causes of death in the United Kingdom have remained stable, with the major burden resulting from coronary heart disease (CHD) and cancer. Stroke is also a major health problem, accounting for 6 percent of health service spending. The health of newborns has been continually improving; the infant mortality rate fell from over 10 per 1,000 live births in 1982 to 6.5 in 1992. Although the progress is encouraging, infant mortality is still higher than it is in several European countries, such as Sweden and Denmark.

Smoking remains the single most important cause of preventable disease and premature death in England, but some trends are improving. Adult smoking rates are falling; in men, this is reflected in a reduction in lung cancer. The epidemic in women (who have generally taken up smoking more recently) is still rising. Rates of smoking among children are not falling quickly enough, and efforts are being made to stop children from smoking.

Sexual health has also become a focus of national and public health policy, with two primary areas of concern. First is the rising level of conceptions, especially among young teenagers. Second is the increase in AIDS cases, mostly in and around London and mainly homosexual men. However, the highest proportional rise in AIDS cases is among heterosexuals.

Britain remains low in the level of expenditure on health services. In Europe it ranks only above Greece, Portugal, Spain, and Ireland in the level of expenditure per person.

National Targets for Improving Health

A white paper entitled "The Health of the Nation," published in 1992, set forth the government's strategy for improving health (18). It established the following targets for CHD and stroke:

- to reduce death rates for both CHD and stroke in people under 65 by at least 40 percent by the year 2000 (baseline 1990),
- to reduce the death rate for CHD in people aged 65 to 74 by at least 30 percent by the year 2000 (baseline 1990), and
- to reduce the death rate for stroke in people aged 65 to 74 by at least 40 percent by the year 2000 (baseline 1990).

For cancers:

- to reduce the death rate from breast cancer in the population,
- to reduce the incidence of invasive cervical cancer by at least 20 percent by the year 2000 (baseline 1990),
- to reduce the death rate for lung cancer in people under the age of 75 by at least 30 percent for men and by at least 15 percent for women by 2010 (baseline 1990), and
- to halve the annual increase in the incidence of skin cancer by 2005.

For mental illness:

- to improve significantly the health and social functioning of mentally ill people,
- to reduce the overall suicide rate by at least 15 percent by the year 2000 (baseline 1990), and
- to reduce the suicide rate of severely mentally ill people by at least 33 percent by the year 2000 (baseline 2000).

For HIV/AIDS and sexual health:

- to reduce the incidence of gonorrhea by at least 20 percent by 1995 (baseline 1990) as an indicator of HIV/AIDS trends, and
- to reduce by at least 50 percent the rate of conceptions among the under- 16 population by the year 2000 (baseline 1989).

For accidents:

- to reduce the death rate for accidents among children under 15 by at least 33 percent by 2005 (baseline 1990),
- to reduce the death rate for accidents among young people aged 15 to 24 by at least 25 percent by 2005 (baseline 1990), and
- to reduce the death rate for accidents among people aged 65 and over by at least 33 percent by 2005 (baseline 1990).

The Patient's Charter

The Patient's Charter, published in 1991 by the Department of Health, articulates numerous rights and standards, many of which have existed since the establishment of the National Health Service (NHS) (15). The Patient's Charter provides a yardstick against which performance is based. It gives patients the right to:

- receive health care on the basis of clinical need, regardless of ability to pay;
- be registered with a general practitioner (GP);
- receive emergency medical care at any time through a GP or through the emergency ambulance service and hospital accident and emergency department;
- be referred to a consultant (acceptable to the patient), when a GP deems it is necessary and to be referred for a second opinion if the patient and GP agree that this is desirable;
- be given a clear explanation of any treatment proposed, including any risks and alternatives;
- have access to health records and know that those working for the NHS have a legal duty to keep the contents confidential;
- choose whether to take part in medical research or medical student training;
- be given detailed information on local health services, including quality standards and maximum waiting times;

TABLE 8-1: Sources of Funding for the NHS, 1991/92

Source	% of total
National Exchequer (general taxation)	83
National Insurance Fund	14
Other sources (charges, land sales, etc.)	3

SOURCE C Ham, The *NHS—A Guide for Members and Directors of Health Authorities and Trusts* (Birmingham National Association of Health Authorities and Trusts, 1993)

- be guaranteed admission for treatment by a specific date no later than two years from the day when the patient is placed on a waiting list; and
- have any complaint about NHS services investigated and receive a full, prompt, written reply from the chief executive or general manager.

One of the most important elements of the drive to improve the quality of care has been the policy of reducing waiting times for treatment. No patients wait more than two years for treatment. In 1993 a guarantee was introduced that no one should wait more than 18 months for a hip or knee replacement or a cataract operation.

THE BRITISH HEALTH CARE SYSTEM

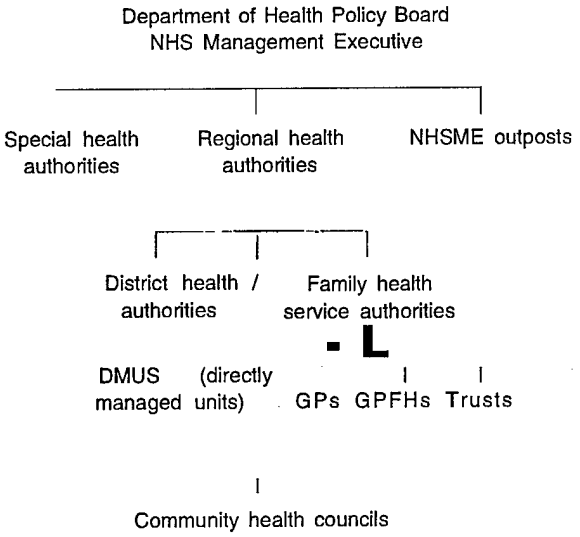
Introduced in 1948 by the Labor Party, the NHS is based on the principle that everyone is entitled to any kind of medical treatment for any condition, free of charge. The NHS is not insurance-based but is funded primarily from general revenues (see table 8-1 and figure 8-1).

There are nearly 980,000 staff employed in the delivery of health services. In the fiscal year April 1993 to March 1994, the total expenditure was set at 29.9 billion.[1]

In England the Secretary of State for Health is responsible to Parliament for the provision of health services. In Scotland, Wales, and Northern Ireland, the respective secretaries of state assume the responsibility. The relationship between the

1 Exchange rate in mid. 1994: $US 1.4410 1.00.

FIGURE 8-1: General Structure of the NHS



SOURCE J Spiby, 1994

Department of Health and the NHS has its origin in a series of acts, starting with the National Health Services Act (1946) and consolidated in the National Health Service Act (1977) and the NHS and Community Care Act (1990) (13,14).

England

In England the secretary of state is assisted by the executive at the Department of Health. The Policy Board sets the NHS'S strategic direction. Chaired by the Secretary of State, it has these members:

- health ministers,
- the Chief Executive of the NHS Management Executive,
- the Permanent Secretary of the Department of Health,
- key individuals from outside the Department, including two regional chairpersons and top business people, and
- the Chief Medical Officer and Chief Nursing Officer.

The NHS Management Executive (NHSME) is responsible for achieving the strategic goals set by the Policy Board It is chaired by the Chief Executive of the NHS, and its members, drawn from NHS and business, lead various directorates. Both the Secretary of State and the Chief Executive are accountable for the prudent administration of funds to the Public Accounts Committee, which oversees public expenditures of Parliament.

The Department of Health is staffed by permanent civil servants (of whom the permanent secretary is the head) and many other staff drawn from within the ranks of health care professionals, particularly doctors and nurses (about 4,500 staff in all). The Department provides:

- advice to the Secretary of State and answers to questions of Members of Parliament on all aspects of the NHS, with a particular emphasis on political considerations, and
- a range of professional advice to the Secretary of State to guide policy development with reference to national and international issues and taking into account broad political considerations.

Department of Health officials and NHSME staff have both formal and informal arrangements to ensure complementary activities. Day-to-day activity is managed by a range of agencies on their behalf (as shown in figure 8-1).

Wales, Scotland, and Northern Ireland

Responsibility for health care in these three countries rests with the Welsh Office, Scottish Office, and Northern Ireland Office, respectively. In Wales the Secretary of State is assisted by the Health and Personal Social Services Policy Board and the Executive Committee. There are nine district health authorities and eight family health services authorities that increasingly work together.

In Scotland the Secretary of State operates through the Scottish Home and Health Department and a Chief Executive. There are 15 health boards responsible for family health services as well as hospital and community services. In Northern Ireland there are four health and social services boards covering social services as well as health care.

Health Policy

The Department of Health is concerned with both health and health care. Policies for improving the quality of health care are centered on the Patient Charter, which is part of a wider governmental initiative to raise the standards of public services. The Department is also responsible for social care and seeks to improve services through policies set forth in a 1990 white paper entitled "Caring for People" (12). Local authorities are the lead agencies for community care (often used as a synonym for social care) and are expected to work closely with NHS authorities to ensure that a comprehensive range of services is available. One of the aims of policy in this area is to shift the provision of services away from residential care to supporting people in their own homes.

The three key priorities for NHS in 1994 and 1995 include:

implementing "The Health of the Nation, "
- developing the Patient's Charter at national and local levels, and
- ensuring high-quality social care.

A fourth priority is to achieve greater health care efficiency and effectiveness through sound use of resources and development of effective organizations.

The Health Care Purchaser-Provider Relationship

Since April 1991 and the introduction of the NHS and Community Care Act, there has been a philosophical and practical change in the way NHS is managed (14). Health authorities have been given specific responsibility for identifying their population's health needs and for using public money to buy services under a specific contract so as to meet those needs. Responsibility for providing services rests with hospitals, GPs, and other providers, such as community units. Providers can now obtain funds only by contracting with purchasers.

The purchaser-provider separation has accelerated changes that were already under way and has stimulated new changes, including:

- greater accountability for service provision, as the required service is more carefully specified;
- more emphasis on quality issues and on patients' rights, including the introduction of audit systems;
- more involvement of patients in specifying requirements; and
- a degree of competition between providers and the use of outside agencies to provide certain services, particularly in nonmedical areas.

The Purchasing Chain

The Regional Health Authority is a statutory body responsible for strategic planning and monitoring of the activity of purchasers as well as for allocating resources on the basis of an agreed-on formula. It also has a range of other enabling functions.

The District Health Authority (DHA) is a statutory body whose main function is to assess the health needs of the resident population and to purchase services to meet those needs. In England its key priorities for 1993/94 were as follows:

- to embrace a wider role as champions of health in the local community,
  to develop strong alliances with other agencies (e.g., social service departments, Family Health Service Authorities (FHSAs)), and
  to set an example as an employer by looking after the health of its staff.

Top priorities for action include implementing the "Health of the Nation," ensuring high-quality health and social care in partnership with local authorities, and developing the *Patient's Charter.*

FHSAs are statutory authorities that continue to plan and manage the development of services provided by GPs, family dentists. retail pharmacists, and opticians, all of whom are independent practitioners. In some places DHAs and FHSAS are forming health commissions for joint purchasing. A formal merger of the two organizations would require legislative change, which is expected in 1996.

GP Fundholders are larger GP practices—those with 7,000 or more patients. They may become purchasers for a limited range of services (11). They may purchase all investigative ser-

vices, community nursing and community psychiatric nursing, some outpatient and therapeutic services, and, most notably, a limited range of specified acute procedures (costing no more than 5,000).

DHAs and GP Fundholders place contracts with providers to deliver service, containing details on the volume and quality of service to be delivered for a price. DHAs and GP fundholders may place contracts where they choose. A contract may be with any trust, private or voluntary provider, or other directly managed units; however, these will take into consideration historic patterns of referral, access to services, and the wishes of GPs and patients. It is therefore the responsibility of purchasers to decide (within their financial allocation) what services patients will receive.

Trusts

Trusts are accountable to the Secretary of State and vary in the range of services they provide. Their performance is monitored (although not managed) by the NHSME via one of seven outposts. Most outposts span two regions and are separate from the regional function.

NHS trusts are self-governing units with their own boards of directors, and they are operationally independent of the district health authorities. They make decisions on how to deliver service to achieve the highest quality. The trusts are free to determine their own management structure, to employ their own staff, and to set their own terms and conditions of service. They are also free to acquire and sell their own assets, to retain surpluses, and to borrow money subject to annual limits.

Each trust is required to prepare an annual business plan articulating its proposals for service development and capital investment, and showing support from purchasers for the development. Each trust also prepares and publishes an annual report and accounts.

Contracts or Service Agreements

All providers now work on contract. As the trusts are completely financially independent. they can survive only if they undertake procedures for which they have a contract. (As these are not legally binding, they are officially termed "service agreements," but are commonly referred to as contracts.) If trusts undertake work for which they have no contract, they will not normally receive payment. This is of particular importance in non-emergency surgery, where the maximum number of operations is usually stipulated.

Most trusts obtain the majority of their work from the local DHA by which they were previously managed. However, there is no rule stipulating locales from which their patients should come, and DHAs are free to place contracts where they like. Certain historic patterns of patient referral are being broken down, particularly those involving referrals to inner London teaching hospitals for relatively routine conditions. Providers (if they have extra capacity) may try to persuade distant purchasers to buy their services, but cannot always generate extra business because purchasers tend to have little uncommitted money.

NHS Management Reforms Planned for 1994 to 1996

A series of changes in the NHS management in England were announced in October 1993 by the Secretary of State for Health. Subject to consultation, the new structure will be put into place by 1996; some preliminary changes were due for implementation by April 1994 (21).

Initially, mergers will reduce the number of RHAs from 14 to eight. Legislation will then be introduced to abolish the RHAs altogether, replacing them with eight corresponding regional offices of the NHS Management Executive. Another aim is to enable DHAs and FHSAs to merge, creating stronger local purchasers; this, too, requires legislation.

Provision of Funds

Public expenditures on the NHS are determined by the Public Expenditure Survey Committee, on which the NHS is represented by the Department of Health. The process begins each summer, and final figures for the next financial year are agreed on in the fall.

TABLE 8-2: NHS Expenditures on Hospital and Community Services (by Patient Group or Type of Service), 1990/91

Patient group or service type	£ million	% of total
Acute care hospital	**6,717**	**45**
Elderly	1,868	13
Other hospital	1,764	12
Mentally Ill	1,133	8
Maternity	816	6
Other community	927	6
Administration	775	5
People with learning disabilities	746	5

SOURCE C. Cam, The NHS- A Guide *for Members and Directors of Health Authorities and Trusts* (Birmigham National Association of Health Authorities and Trusts, 1993)

In 1993/94 spending on the NHS was set at 29.9 billion, or 12.25 percent of total government expenditures. Although this proportion has increased over the years, at 6 percent of the United Kingdom's gross domestic product, health care still accounts for a smaller part of the economy than it does in most developed countries. The primary source of NHS funding is general taxation.

Salaries are the biggest single budgetary item in a service with 980,000 staff members, including 500,000 nurses and midwives, 53,000 doctors and dentists, 160,000 administrative and clerical staff, and 145,000 ancillary workers (1992 figures). Workers in primary care who are self-employed, including 30,000 GPs and 15,000 dentists, are covered separately.

The NHS produces an annual report on expenditures. Table 8-2 shows the proportions of expenditures on hospital and community services by patient group in 1990/91, indicating the priority given to acute care and the importance of services for the elderly.

Distribution of Funds

Spending on health services in different parts of the country has historically been unequal. From the mid- 1970s until 1991 a formula was used to redistribute resources gradually. The main change has been the movement of resources from the southeast, particularly London, toward the north and, in each region, away from the large teaching hospitals and conurbations.

Funding is now allocated on the basis of the resident population of a health authority and not, as before, on the catchment population (i.e., patients who come to be treated in the district hospitals). This is called resident/capitation-based funding. Health authorities are allocated resources on the basis of a formula that takes into account the size and structure of the population, the pattern of illness, the number of elderly people, and certain geographical considerations. Consideration is now being given to including so-called social deprivation factors, which will give some districts more money for growth and development.

Sources of Funds for Providers

Most of the funds for activities in a provider unit come from the Exchequer through contracts with DHAs and GP fundholders (11). Most capital funds are obtained as part of the business planning process and according to agreed-on external financing limits for each trust. Although trusts can in theory borrow money on the open market, the interest rates are always higher than those available from the central government. Partnerships with private companies are encouraged for some capital projects.

Private patients provide a small but important part of the income of units. For these patients, units are free to price services as they like. They are able to offer private patients treatment and facilities in any part of the hospital but are increasingly developing separate rooms and sometimes whole buildings for them. In 1992, private patients generated 12,771 million in revenue.

Almost all hospitals have some charitable trusts, usually accumulated over many years from donations. In long-established hospitals, particularly those with a famous name, these funds can be sizable, and special trustees are usually appointed to administer them. Such funds area useful source of money for staff facilities, research, and equipment.

Public Organizations

Community health councils (CHCS) are charged with representing the local community's interest in the health service. They are an important source of public information and a channel for consultation, representation, and complaint. There is usually one CHC in each district, made up of 18 to 24 lay members, a chairperson, and a paid officer (or secretary).

The basic duty of each CHC is to review the operation of the health service in its district and make recommendations on such matters as the Council thinks fit. The CHC'S main functions are to consider complaints, visit NHS premises, serve as a forum for consultation on the planning of local health services, provide information on local services, and monitor the quality of services through surveys and other means.

Consumer interests are also represented by community health councils in Wales. They are represented by the local health councils in Scotland and by the health and social services councils in Northern Ireland.

Although not directly concerned with individual patients, two influential bodies outside the NHS carry out audits of its performance:

- The National Audit Office carries out studies, particularly ones concentrating on value for money, which are regularly used by the Public Accounts Committee when investigating the NHS'S performance.
- The Audit Commission, established in 1982, looks at local government activity. Its powers were extended in 1990 to cover the NHS, and its governing body includes ministers. The Commission appoints auditors to look at areas in which there is significant variation in performance. It attempts to spread good practice and has produced a number of influential reports.

Impact of the Reforms

One of the key changes that has resulted from the separation of purchaser and provider roles is that GPs have started to work much more closely with the DHAs. With GPs responsible for referring patients to hospitals and DHAs responsible for placing contracts, it is essential that there be a continuing dialogue between the DHAs and the physicians on which hospital and community health services should be purchased and where contracts should be placed.

As a result of this developing dialogue, service provision has shifted toward primary care. There has also been a change in the balance of power between GPs and hospital consultants, which has forced hospital doctors to pay greater attention to GPs and to be more responsive to their demands. Consultants in some districts now hold their outpatient clinics in GP offices rather than in hospitals.

Some of the most significant changes resulting from the reforms have been pioneered by GP fundholders. The first wave of fundholders included many of the best-organized GP practices, and these GPs have used their new powers to improve the services they deliver. The result has been a shift in favor of GPs and greater accountability of hospital doctors to purchasers.

The NHS trusts have also used their freedom to improve the quality of care, including steps to reduce waiting times, provide greater flexibility in clinic hours, and improve arrangements for patient appointments. Of particular importance has been the ability of trusts to run their own affairs and make decisions more quickly than in the past.

No national blueprint for reform has been set forth by the Department of Health and to a large extent implementation has been characterized by "learning by doing." In this sense the development of NHS as an organization depends on actual implementation experience and cannot be predicted in advance. This observation applies particularly to the evolution of the internal market. There was little competition in the first year of the reforms, as the main emphasis was on laying the basic building blocks of change. In 1992/93 purchasers were more active in switching to alternative providers, and such switches caused financial problems in a number of hospitals, especially in London. (The future of health services in London has been the subject of a special inquiry (45).)

It is not clear how ministers will respond to the emergence of losers in the internal market. The logic of the reforms is that competitive incentives should be used to reward providers who are efficient and to penalize those who are not. The difficulty with this approach is that the NHS'S founding principles, such as access and equity, may be undermined if people have to travel further for treatment as a result of the closure of hospitals that fail to compete successfully. Ensuring that people who have the poorest health receive the treatment they need remains a continuing challenge. For this reason the market must be managed to diminish the risk of gaps in service provision or unplanned interventions.

CONTROLLING HEALTH CARE TECHNOLOGY

There is no overriding legislation to control the purchase and use of health care technology in the United Kingdom. The regions, districts, and FHSAS are allocated budgets annually. The regions maintain some control over major capital schemes or purchases, whereas the trusts and GPs control decisions at the local level—in collaboration, at varying levels, with the DHAs and FHSAS. The Department of Health is often involved in the development o new technologies at an early stage, but its involvement is variable, as is its level of control. Pharmaceuticals are the only area in which there is a clear process for controlling introduction; otherwise, the mechanisms of control vary considerably.

In recent years the need to control the introduction of new technologies has become more widely appreciated. This is due mainly to the fact that the health care budget is already under heavy pressure from the growing elderly population, and also to an increased awareness of the need to ensure that health care technology is effective and offers justifiable additional health gains and minimal side effects.

Development of a National Policy

In 1988 the House of Lords Select Committee on Science and Technology. in its "Priorities in Medical Research," stated that coherent arrangements were lacking by which the NHS could articulate its research needs and ensure that the benefits of research were translated systematically and effectively into service. The Committee was particularly critical of the way in which public health research and operational research (i.e., research on the organization and management of health services) had been relatively neglected. It suggested a marked increase in funding for this area.

In response the government created a senior post of director of research and development to head the NHS Research and Development Division and to sit on the NHSME (16). A research and development strategy was launched in April 1991 as the first stage in creating an R&D program in the NHS. This R&D program emphasizes evaluation of the quality, effectiveness, and cost of health care methods and research into the delivery and content of health care. It also seeks to influence biomedical research not only by expecting NHS priorities to be taken into account when planning future programs but also by expecting the practical implications of major research discoveries to be anticipated early.

To ensure integration of R&D with NHS commissioning, the regions were given responsibility to commission and manage regional R&D programs and also to help ensure that 1) the results of good research are used to full effect, and 2) the regions promote a dialogue between the local research community and purchasers. During 1992 the regions developed their own R&D plans and appointed staff to oversee their programs. In the first round, the staff were mainly clinicians; therefore, some of the impact on NHS activity (as opposed to biomedical research) has been lost. However, to ensure that the strategy is close to NHS'S R&D needs, a Central Research and Development Committee (CRDC) was set up to review R&D of relevance to NHS'S work and to identify areas where further work would be of value. The committee brings together senior NhS managers, leading research workers from universities and elsewhere, lay members, and others with experience in industry. The work that it identifies as a priority will either be funded centrally or

by the regional health authorities and postgraduate hospitals.

The lack of real controls on medical technology and the role of technology assessment became apparent during the development of the R&D strategy. Early on, the Department of Health's director of R&D set up a health technology group to prepare a report on methods for assessing the effects of health technologies. Among the main points of the report are:

- the range of possible outcome measures by which health technology effects might be assessed should always be considered explicitly;
- existing evidence on the effects of health technologies should be reviewed systematically and the results disseminated in forms that a wide range of decisionmakers, including patients, can understand. If the evidence is strong, means should be used to ensure that it influences practice;
- there should be a systematic information system for disseminating the results of technology assessments;
- every effort should be made to assess the effects of new technologies before decisions are made on whether they should be used within the health service;
- multidisciplinary research centers, each focusing on a priority area, should be established to assess the effects of health technologies; and
- there should be training and a career structure for those who wish to specialize in technology assessment (17).

The report was considered by the CRDC, and in February 1993 a Standing Group on Health Technology was established. This Standing Group established six advisory panels to consider primary and community care; acute care; pharmaceuticals; diagnostic and imaging technology; population screening; and R&D methods. Following consultation with NHS and other interested bodies, each panel put together a list of its top 20 priorities, which was published in December 1993.

The Standing Group's key tasks are to:

- identify and rank technologies in need of assessment;
- identify and rank the need for R&D of technology assessment methods, especially in cases where diffusion of a technology must be controlled until more information becomes available; and
- identify emerging technologies likely to have major implications for the NHS.

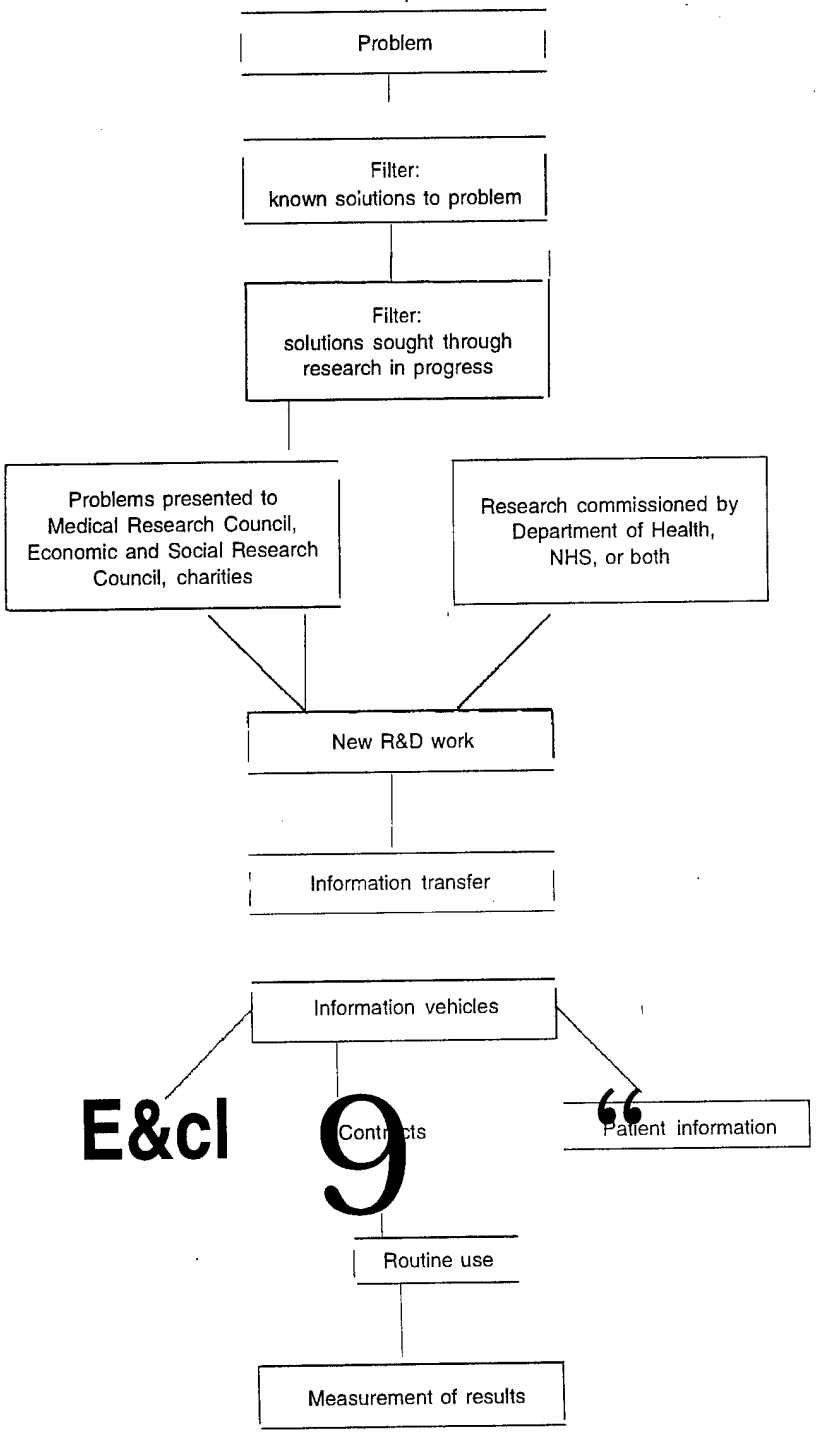
The R&D strategy, the Standing Group and associated infrastructures are major steps toward a rigorous national process. To date, however, technology assessment has been seen mainly as a source for R&D monies rather than a means of finding answers that will actually inform clinicians or managers. To address the ongoing need for practical information for short-term use, three units have been set up to handle existing research data. The Cochrane Centre was established in Oxford to undertake systematic analysis of clinical trials; a center in York will commission expert research reviews; and health care effectiveness bulletins, produced from Leeds, are already offering useful overviews of technology assessments (38). The York unit will also concentrate on the systematic transfer of this and other research information to users and will help develop skills for transferring research information to decisionmakers.

Figure 8-2 shows how a technology assessment problem is "managed" such that useful information is provided to NHS.

Regulation of Pharmaceuticals

The pharmaceutical industry, often depicted as a bastion of the free market, is in fact heavily regulated. A maze of rules has been created by separate, often isolated, government departments. The finance division pursues policies separate from those of its pharmaceutical price regulation scheme (PPRS) colleagues and often, it seems, with little liaison with officials of the Department of Trade and Industry, which pursues its own antitrust and balance of trade goals.

FIGURE 8-2: Managing a Technology Assessment Process



SOURCE M Peckham, 1994, in R Smith, "Filling the Lacuna Between Research and Practice An Interview with Michael Peckham, " Br. Med. J. *3071403-1409, 1993*

Safety and Efficacy

In the United Kingdom, voluntary regulations for pharmaceuticals emerged in the 1950s. Following the failure to prevent the teratogenic effects of thalidomide taken by pregnant women in the early 1960s, the 1968 Medicines Act created the Committee on the Safety of Medicine (CSM), which advises on the safety, quality, and efficacy of new medicines. This act also established the Committee on the Review of Medicines (CRM) to review the safety, quality, and efficacy of existing products. A licensing system was created to regulate clinical trials, marketing, the manufacture and distribution of products, and advertising and promotion.

The process of licensing a New Chemical Entity (NCE) has become long and expensive. Animal toxicity tests, if acceptable, are followed by clinical trials on human subjects. The company can then apply for a product license, without which the NCE cannot be marketed. This process may take 10 to 12 years from the time that the compound is patented.

If a new drug has potential breakthrough effects (e.g., for treating AIDS), a fast-track route can be found; however, this is rare.

Patent legislation rewards producers of innovative drugs by giving them monopoly power; without this incentive, R&D investment would probably be reduced. The legislation governing NCES has eroded patent protection and reduced the duration of monopoly power (hence profits). In addition, the licensing rules raise costs, and together these factors may well diminish drug companies' R&D investments.

Regulating Prices and Profits

Since 1957 the prices and profits of the U.K. pharmaceutical industry have been regulated by the government and the PPRS. Each year, the Department of Health assesses firms' profitability in relation to targets set to ensure that costs, profits, and prices are reasonable—that is, in the range of 17to21 percent. If a firm's **return** exceeds this figure, it may be required to repay money to the Department. If returns are less, applications can be made for a price increase. The Department also limits aggregate expenditures on sales promotion to 9 percent of total sales revenue.

PPRS is a voluntary agreement that the House of Commons Public Accounts Committee reviews irregularly and for which there is no other public review. The scheme is directly affected by cost containment mechanisms. If cost-reducing activities are successful within NHS, a firm may be allowed a price rise via PPRS.

User Charges

Prescription charges were abolished in 1965 but reintroduced in 1968 (with extensive exemptions). Since then the charge per item has risen from 13 per item in 1968 to 4.75 in 1994. This is well over five times the general price level increase; however, the revenue obtained has decreased as a result of increasing numbers of people who are exempted from payment (52 percent were exempt in 1969, 85 percent in 1991).

Generic Prescribing

Prescribing of generic alternatives to brand-name drugs becomes possible when an NCE goes out of patent. Generic prescribing is strongly encouraged, and recently several campaigns and official reports have put pressure on GPs and FHSAS to increase the level of generic prescribing. In 1979, approximately 29 percent of prescriptions were generic; this had risen to 40 percent by 1990, and a target of at least 50 percent has been set in many regions. An educational program for the general public is under way to explain why the government promotes generic prescribing.

Limited List

In 1985 the range of drugs prescribable under NHS was limited by the Department of Health. No longer prescribable were medicines for which over-the-counter alternatives were widely available. The government claimed that in the first year, 275 million was saved by this mechanism. The aim of the limited list is to force consumers of all ages to pay for some medicines and to ensure that expensive drugs are not prescribed unneces-

sarily. The limited list was extended in 1994 to include drugs such as those for hay fever and duodenal ulcers.

Prescribing Analysis and Cost Data (PACT)

PACT and similar systems used in Scotland and Northern Ireland are an attempt by the Department of Health to disseminate information on prescribing behavior to GPs to increase their awareness of costs. The feedback system began in 1988; since then, there have been some changes in prescribing patterns, although it is difficult to know whether they are due to PACT. Capacity to use the data has been increasing; all FHSAS are directly on line to the Prescription Pricing Authority, which downloads PACT data monthly.

Indicative Prescribing Budgets

The indicative prescribing scheme, introduced in 1991, aims to build on the PACT system to improve prescribing and reduce drug expenditures (10). RHAs receive an annual block allocation to cover the cost of all prescriptions dispensed within their FHSAS. Initial allocations reflected historical spending patterns but are increasingly moving toward a weighted cavitation basis. FHSAS then set indicative prescribing amounts for each GP practice based on factors such as existing costs, number and age of patients, local social and epidemiological factors, morbidity, and special circumstances. If a GP overspends the indicative budget, the FHSA medical and/or pharmaceutical adviser offers advice on how costs might be reduced. The budget is not a firm cap however, and FSHAS have no executive powers to penalize GPs. In the wake of a recent Audit Commission report, it is anticipated that the budgets soon will be cash limited.

Regulation of Medical Equipment

In comparison with pharmaceuticals, the control of medical equipment is minimal. In the Department of Health a fairly complex set of machinery supports and tracks new developments and advises scientific and supplies officers; this is not, however, the same as control. In certain extreme situations, a warning hazard note can be produced by the Department, and particular equipment is removed. The scientific and technical division of the Department is mainly responsible for producing this information. Its work covers technical quality (i.e., whether the equipment does what the manufacturer says it will do), reliability, and mechanical and electrical safety for the patient and operator. This work rarely includes analysis of cost-effectiveness or an understanding of the impact of the equipment on organizations.

The Department of Health also regulates the introduction of equipment through its role in financing high-cost technology. These so-called pump-priming funds are used to support an industry introducing equipment that is deemed necessary by the NHS. Two or three items might be purchased to help the sales take off, especially if the Department has previously supported this development through its R&D program.

In the past there was a clear procedure for the purchase of new equipment: it was purchased with funds from a regional capital budget against which districts bid for their local hospitals. Many regions devolved a portion of this budget to districts in order to purchase smaller pieces of equipment.

Eighty percent of this equipment budget is usually required for replacement purposes, and only the remainder is available for new developments. The key decisionmakers in both the district and the region are managers and clinical advisory committees. The system tends to be somewhat arbitrary and is frequently based on a "he who shouts loudest" principle rather than a systematic analysis of need.

With the introduction of the split between purchasers and providers, the relationship for capital development is purely a matter to be worked out between the provider and region or NSME outpost. The use of non-NHS monies for capital is expected to extend as the trusts become more familiar with the use of private financing mechanisms.

At present, trusts make bids to the region or outposts in their annual business plans for specific capital development. The control of large pieces of equipment and the implications of developing

new technology have become more apparent to providers as these costs are included in their full costs and called "capital charges." These charges are passed on to the purchasers; institutions with excessive building capital or equipment thus have higher costs within their contracts.

NHS Supplies Authority

In 1991 the Department of Health reversed its previous policy of devolving the purchase of medical supplies (ranging from catering to expensive scientific equipment) and established a central NHS Supplies Authority. This change resulted from a report by the National Audit Office that was critical of NHS buying. It stated that the considerable bulk buying power of the NHS was not being fully utilized because of lack of coordination and that many opportunities for more cost-effective purchasing were being missed. The main focus of the report was more cost-effective buying.

The Supplies Authority provides a central, coordinated policy for buying supplies. It has six divisions, with the national headquarters concentrating on key commodities such as food contracts, medical and surgical items, and x-ray equipment. The Authority also undertakes research into market requirements and has a small R&D program. This new development is rather at odds, however, with the establishment of trusts and the independence of providers. At present, it is expected that the trusts will be encouraged, but not required, to use the purchasing power of the Authority.

Control of Provider Locations

In the past the Department of Health and the RHAs had strong control over the placement of providers through a regional planning tier or specific, centrally promulgated regulations, concerning where GP practices could be sited. With the introduction of the internal market, it was anticipated that this regulatory planning function would be removed, and placement of providers would be subject to market forces.

It has become clear, however, that at present the government is uncomfortable with allowing trust hospitals to close merely because of market forces. The mode of control or "market management" is still under discussion. Theoretically, if purchasers do not place a sufficient number of contracts with a provider to ensure its continued existence that provider should close. In reality, while some are closing or unifying with adjacent units, no major hospital has yet closed.

In central London the government has determined that it is unhappy letting the market control the siting of providers. It has chosen to set up a central review body (the Tomlinson Review) that has clearly identified where teaching hospitals should be merged or where specific providers should close. These decisions have been much debated, and considerable lobbying has been undertaken. Some, though not all decisions have been overturned by the Secretary of State.

Regulating the Placement of Services

The role of districts in purchasing health care based on assessed needs provides a major impetus for technology assessment. For the first time, managers and public health physicians are working together to assess the literature on effectiveness of health care procedures, including cost-effectiveness.

The Department of Health has responded by commissioning a series of bulletins on the effectiveness of health service interventions for decisionmakers; the first editions were published in January 1992. These bulletins are specifically oriented toward health authorities rather than clinicians.

The need to purchase effective health care packages is also promoting interest in service evaluation, and research on local health services is increasing rapidly. At present the main effect of districts as purchasers is to reduce support for expensive technologies with little proven effectiveness. This potential conflict between teaching hospitals and their clinicians and the purchasers has not been resolved, nor have explicit mechanisms of control been established.

Districts are increasingly including GPs in this process as part of the advisory mechanism for purchasing services. This is a new role for GPs; some relish it, but others find it unacceptable either because they do not consider it is a good use of their time or because they have qualms about taking on even greater responsibility y for what they consider to be management.

The role of the DHAs in determining where resources are allocated has become increasingly explicit, as they have lost their direct management role. This explicitness, inevitable with the NHS reforms, is proving difficult politically; previously, the long waiting list dealt implicitly with excess demand. Consumer expectations have also risen, and the conflicts between resource availability and patient need and demand are making the role of the DHA purchasers increasingly difficult.

Control of Use

Within the new purchaser/provider system, use is determined through the contract between the DHAs and their providers. The level of refinement of this contract is very limited at present, and utilization is measured by numbers of consultant episodes, which means that the emphasis is on inpatient activity and events rather than on individual patients. This is obviously not adequate, and better information systems are being developed (though not quickly enough for current requirements).

On the whole, most districts are signing contracts with providers which aim to reduce the level of activity in acute hospitals, either because of limited funds or because of policies that aim to shift activity from hospitals to the community. Demand is continuing to rise, and hospitals are seeing an annual increase of 2 to 5 percent in activity. This conflict between increased patient demand and reduction of activity levels in purchaser contracts can be seen clearly in districts in the south of England, where budgets on the whole are being decreased. In some hospitals, only urgent work is done near the end of the financial year to ensure that activity is kept within the agreed contract and that budgets are not exceeded. Such restrictions are not acceptable to the government, however, and providers are being required to pace their activities throughout the year.

Utilization and Quality Control

The contracts set with providers by DHAs cover not only activity and finance but also aim to identify key quality measures. At present, the main emphasis in contracting is on activity and money. (This is due to the newness of the system rather than to a policy decision.) The level of detail and type of quality measures to be identified by the districts still are being developed. Clearly, the emphasis should be on outcome measures and expectations for the health of the population. As these are frequently difficult to identify and measure, process and structural measures probably will be used.

The Role of the Private Sector and Consumers

The private sector accounts for a small percentage of health care spending in the United Kingdom, most of which is funded through health insurance companies. There are clear rules as to which technologies are paid for under which policies; for example, cosmetic plastic surgery is not reimbursable. There is no published information on how these guidelines are determined. With increasing medical care costs, insurance companies are introducing cheaper policies that limit what can be provided.

A major part of the NHS reforms was a commitment to the role of the consumer in decision-making. The 1991 Patient's Charter sets out clearly, for the first time, the public's right to health care and to national and local charter standards, which the government intends to see achieved. This greater emphasis on the role of the consumer will no doubt increase actual patient questioning of medical practice, as well as interest in consumers' views by policy makers and others. The growing role of the consumer in technology assessment can be glimpsed in the inclusion of consumers in the planning of a few major random-

ized controlled trials (e.g., trial of chorionic villus sampling).

HEALTH CARE TECHNOLOGY ASSESSMENT

The United Kingdom has along history in some of the methods of technology assessment, such as randomized controlled trials and the development of health economics, but this has not been in a coordinated policy context. Interest in technology assessment has been slowly increasing because of pressures resulting from the costs of new technologies, increasing recognition of the potential dangers of new developments, and perceptions of more organized activity abroad. Originally, the main pressure for technology assessment came from those parts of the research community undertaking this work, including the King's Fund (a charitable health policy organization), health economists, the media, and some parts of the medical profession. More recently, however, pressure has come from NHS managers (including doctors), public health medicine, and purchasing authorities.

Raised within the context of the national R&D strategy, research dissemination and organizational issues (e.g., linkages between research and clinical practice) have become very significant. The report of the Standing Group also outlined the need for a career structure to encourage individuals in technology assessment. Problems in recruiting and retaining personnel had been a particular problem in health service research. The report argued for health technology assessment to be funded from public monies and coordinated by the national R&D strategy; to this end the funding mechanism itself was said to need clarification. The report also identified problems in organizing multicenter studies of major diseases. Finally, the report identified problems in undertaking proper randomized assessments resulting from litigation with regard to informed consent, corporate indemnity, and costs of treatment. These obstacles, stated the report, must be acknowledged more explicitly and overcome. The full impact of the Standing Group has yet to be fully felt, but it is clear that the importance and relevance of technology assessment to the NHS has been firmly established. Outside the research community, this is not yet the case.

Technology Assessment Entities

The Medical Research Council (MRC) and the Standing Medical Advisory Committees

The Medical Research Council plays a key role in British medical research activities. It has been dominated by biomedical research and has been less interested in health services research or in the wider issues related to medical technology. After the publication of the House of Lords report, the appointment of a Director of Research and Development at the Department of Health, and a new Secretary at the MRC, change has accelerated. There appears to be a more positive attitude toward health services research and applied clinical research, as evidenced by the new board structure, which includes a fourth board for health services research, public health, and epidemiology.

Relations between the MRC and the Department are governed by a concordat that acknowledges the strong role of the latter in health services research. A report is also being considered by the MRC board that proposes that the MRC take a more active role in evaluating procedures (including consideration of economic, quality-of-life, and psycho-social issues).

Questions on such developments as neural tube defect screening or heart transplants are likely to arise in discussions between the Chief Medical Officer (CMO) and the medical profession. The CMO may then seek advice from the Standing Medical Advisory Committee (SMAC). For major issues a specialist SMAC subcommittee may be set up on an ad hoc basis to study the subject. Once the subcommittee has prepared a report and its recommendations are accepted by SMAC, a Health Circular on the subject may be sent out to NHS management. Such circulars provide advice on whether, to what degree, and how a service should be provided. In the final analysis, however, decisions are made by regions and districts. In

some circumstances, such as heart transplants, some central funds may be provided, but this occurs only for quite exceptional developments.

The *Audit Commission*

The Audit Commission is an independent body that audits the public sector. It has recently developed its work in health matters and has reviewed services such as those for day surgery, AIDS prevention, and bed utilization. Because it has access to all health authorities it could potentially have a considerable impact on the use of medical technology.

King's Fund

One of the main proponents of technology assessment in Great Britain during the 1980s was the King's Fund, both behind the scenes and in the development of the U.K. Consensus Development Programme. The latter has now ceased, but as districts and RHAs authorities have come to recognize their need for assessment data, the method has been adapted to local circumstances.

Clinical Standards Advisory Group

The Clinical Standards Advisory Group (CSAG) was established in 1991 as part of the NHS Act to advise the health ministers or health care bodies on standards of clinical care, and access and availability of services to NHS patients. Most of the members are nominated by the Royal Colleges and faculties relating to medicine, nursing and dentistry, although the CSAG is funded by the Department of Health. Its initial work has covered the following:

- access to and availability of selected NHS specialist services,
- clinical standards for women in normal labor, standards of clinical care for patients admitted to hospital urgently or as emergencies. and standards of care for people with diabetes.

This body represents anew venture in developing and assessing clinical standards, and its success is still not assured-especially as it is advisory rather than mandatory. It produced a series of reports in March 1993 covering neonatal intensive care, cystic fibrosis, childhood leukemia, coronary artery bypass grafting, and angioplasty. There was no consistency in the methods or use of objective data in these reports. Their effects are difficult to assess but generally appear limited (4,5,6,7).

Medical Audit

A key part of the NHS reforms is encouraging all doctors to undertake medical audit, which includes the "systematic, critical analysis of quality of medical care and treatment, the use of resources, and the resulting outcome and quality of life for the patient." New monies have been released by the Department of Health for the development of medical audit, and in the fourth year of this initiative, a large number of clinicians are involved at some level. Much of the activity is focused on collecting data, but in some centers clinicians are now looking more critically at their work and judging it against agreed-on standards. This initiative, along with management changes that are encouraging doctors to be more involved in management issues, is forcing the professions to consider evidence on the costs and effectiveness of clinical procedures.

Case studies

TREATMENTS FOR CORONARY ARTERY DISEASE

Coronary artery bypass grafting (CABG) was developed in the United States in the late 1960s but was not introduced in the United Kingdom until the mid-1 970s, probably because of financial constraints. Percutaneous transluminal coronary angioplasty (PTCA) was introduced in the early 1980s.

Because CABG requires relatively expensive equipment, it developed at the teaching institutions where capital monies were more accessible and medical staff sought to be at the forefront of medical expertise. The most well-endowed regions tended to be those in the London area; they had the greatest number of teaching and postgraduate institutions.

By 1982 the CABG rate was 107 per million population. This overall rate disguised a 12-fold variation among regions, from 21 to 263 per million. The rate of CABG rose steadily to 212 per million in 1986 and 278 per million in 1990. The extent of inter-regional difference fell, but there remained a fivefold difference: 97 to 466 per million in 1990. The most active regions were consistently in the southeast and in areas with a concentration of teaching hospitals. This increase in surgery was accompanied by a slow increase in cardiothoracic surgeons.

The differences among regions are mirrored by variation in utilization rates among districts within regions, most marked at the earlier stages of diffusion. Not surprisingly, uptake has been higher in districts with hospitals that provide the service, or where a local cardiologist is associated with a surgical unit, and not necessarily those with the greatest need. As this variance became well documented, attempts were made to redress the balance. However, change was limited until the NHS reforms in 1990 when districts were funded according to their population size and characteristics rather than the facilities available in them. More recently, a further inequality has been reported: women have been shown to be less likely to receive surgery than men (32). Lower rates of surgery in the United Kingdom compared with the United States reflect a higher threshold for surgical intervention and greater dependence on medical treatments (based on a review of a region in the Midlands). This difference in threshold also serves to reduce demand in regions where levels of service provision are lower.

Funding Mechanisms and Changes in Control

Before the 1991 NHS reforms, CABG and PTCA were designated "regional specialities" and were funded by means of top-sliced allocations from regions. Now that districts have become responsible for purchasing these services, those districts with high levels of activity are beginning to question their spending levels and the relative efficiency of the service. Although the purchasing function is still relatively new, providers are beginning to see the impact of the reforms and to perceive the market as a form of regulation. It is unlikely that there will be a strong increase in CABG and PTCA activity unless it is achieved through an increase in efficiency. More emphasis will be put, however, on developing protocols and agreeing on criteria to establish appropriate use of these procedures. This process began with a report in a series of epidemiologically based needs assessments commissioned by the Department that stated:

. the use of CABG for disabling angina not responding to medical treatment is based on evidence derived from sound RCTS,

- the use of CABG for other indications and angioplasty for disabling angina not responding to medical treatment is based on fair evidence based on the opinions of experts and indirect evidence, and
- the use of CABG or angioplasty for other indications is based on poor evidence derived from opinions and indirect evidence (26).

Services in London

The Department of Health's "Report of an Independent Review of Specialist Services in London" (19) is part of a fundamental review of health care in London. The report suggests that the "ideal model of tertiary cardiac services consists of three equally important and interrelated parts," high quality clinical, diagnostic, treatment, and rehabilitation services; R&D to improve cardiac services and their delivery; and staff teaching to ensure current knowledge.

It was felt that none of the 14 London centers providing adult tertiary cardiac services met these criteria in all respects. There was a clear case for rationalization to create fewer, larger and stronger centers. The report proposed that nine units are required in London, with additional units elsewhere in the southeast and further afield.

The changes proposed are being hotly debated by each center and are unlikely to happen without political commitment. If they do, the likely outcome will be a more equitable distribution of services rather than any major increase in overall activity.

Department of Health Targets

In 1984 the King's Fund held its first consensus conference in London on CABG. It concluded that in the United Kingdom a realistic target for CABG should be 300 operations per million people. Despite various criticisms of the process, this target was endorsed in 1986 during a ministerial announcement at a Tory- sponsored conference by the government; it later found its way into central planning guidelines. The setting of such a clear guideline is unusual and reflects the influence of the consensus conference and the evidence published by a health economist from York University who showed that CABG is a cost-effective procedure when analyzed according to the concept of quality-adjusted life years (QUALYS) (47). Although this methodology has since been severely criticized, it still plays a strong role in priority setting. This conference also established the credibility of CABG as an effective procedure.

The Department of Health monitors the level of CABG procedures but has not enforced a limit on them. Uptake of CABG and PTCA initially reflected the willingness of teaching hospitals and regions to invest in capital and staff to support them. Suggested appropriate levels of CABG and PTCA have had only a limited impact on activity. The Department is currently reviewing whether numerical targets are the best way to improve quality and quantity. Consideration is also being given to setting up a comprehensive, randomized study to identify which patients are most appropriate for CABG, PCTA, or medical treatment.

Clinical Standards Advisory Group

A review was conducted in 1993 by a working party of CSAG which concluded that "regional utilization rates are associated with the availibilit y of consultant and nonconsultant staff in regional centres," and are also affected by varying patient expectations. In contrast, district utilization rates "are associated with the availability of a local cardiologist and the proximity of a regional center, and inversely associated with the mortality from coronary heart disease" (4).

The review expressed concern about long waiting times (particularly for CABG) resulting from lack of funds. CSAG'S report recommended that every district conform to national targets and aim to achieve a minimum level of 300 CABG procedures per million population within the next three years, with a review of the target possibly by another consensus conference. The report also proposed that a target for PTCA be set. To date, these recommendations have not been followed.

PTCA Update

By 1985, 15 hospitals had performed about 1,600 PTCA procedures, a rate of 29 per million population. At that point there was some questioning of the clinical effectiveness of the procedure, but as clinicians became more experienced, its routine use became established. The use of the procedure spread rapidly during the late 1980s so that by 1991, 53 (44 NHS and 9 private) centers had treated 9,933 patients (a rate of 174 per million population). This rapid rise has been enabled by the relatively low capital outlay required for PTCA equipment. In some regions debate has been heated as to whether angioplasty should be undertaken in hospitals without backup cardiothoracic surgery facilities because of the risk of perforated blood vessels during angioplasty. The increase in rates also reflects a 43 percent increase in the number of consultant cardiovascular physicians, from 223 in 1980 to 323 in 1990-again with a preponderance in the southeast. A greater proportion of these physicians are able to perform PTCA as younger staff trained in the new technologies become consultants. A recent report of the Royal Colleges of Physicians and Surgeons has recommended a level of 300 angioplasties per million population.

MEDICAL IMAGING (CT AND MRI)

Computed Tomography (CT)

The first clinically useful CT scanner was developed at EMI's Central Research Laboratory in Britain in the late 1960s, with funding from the Department of Health. The advantages of this brain scanner were quickly recognized; the competing technologies of cerebral angiography, pneumo-encephalography, and isotope scanning were more invasive, riskier, and more uncomfortable for the patient. Early evaluations were mainly clinically based. During the mid- 1970s, the Department of Health formulated a policy that every region should have a least one brain scanner located in a neuroradiology center. By mid-1977 there were 30 brain scanners in the United Kingdom, and others were on order (41). Here, clearly, at least in the initial phase, the Department controlled the introduction of the technology.

As the use of brain scanners increased throughout the NHS, EMI and others in the field were proceeding with the development of whole body scanners. Interestingly, the clinical evaluation of whole body scanning took a different path from that of the brain scanner. In the case of the latter, the Department maintained a high degree of control over the initial evaluation, and additional machines were not bought until the Department was satisfied (although as the clinical advantage was quickly recognized this process was not particularly delaying). With the body scanner, evaluation was much more complex because so many different organs were involved, other acceptable techniques were available for use in diagnosis, and the effect on patient management and on the final outcome was not obvious. Even more difficult was the ever-developing state of other technologies against which whole body scanners would need to be compared.

A reduction in the Department budget made it impracticable to buy enough scanners for a thorough exploration. Very early on, various philanthropists and private institutions had purchased body scanners for the NHS or for use in private hospitals, and these were not subject to the Department's control (41).

The Department decided to evaluate the scanner by bringing together all the users to discuss their studies. This mechanism proved unwieldy and was soon superseded by a committee of experts that aimed to analyze all the available data from users in Great Britain and abroad in an attempt to 1) determine the scanner's emerging place in medical care and 2) encourage research where there were gaps in evaluation. No major, randomized controlled trials were initiated, however. In retrospect, the committee's impact was limited (42).

The Role of Charitable Funds and Clinicians

The diffusion of CT scanners occurred exceptionally quickly, especially considering the initial

high cost of each machine. Although Britain was the country of origin of the technology and had the first brain scanner in action, the first commercial scanner was installed in the United States. By April 1977, 11 EMI whole body scanners were installed or on order in the United Kingdom (41), only 3 of which were bought with NHS funds. The others were donated by rich individuals, charities, or endowment funds.

Early on, fundraising events for scanners became common. The prime movers were consultant radiologists, but they rapidly involved the public, encouraging support for this "high-tech magic machine." The manufacturers also played their part in ensuring that radiologists were aware of the developments. The collaboration of interested clinicians and the public proved to be a powerful agent for diffusion.

When diffusion results from non-NHS funding without central controls, machines are sited according to resources, not clinical need or capacity. And non-NHS funding also means that ongoing maintenance of the equipment may not be funded through private donations. Today, institutions are wary of such gifts. In the 1970s, however, hospitals had yet to experience decades of reducing budgets. The first time this problem was discussed publicly was in Leeds, where the CHC questioned the Area Health Authority for accepting a body scanner from a group of businessmen. As with most other technologies, most early scanners were placed in the south of England, particularly in the London area.

Utilization

CT scanners are now available in almost all radiological departments. As they are relatively inexpensive (no more costly than other major pieces of equipment) and funding is through the hospital major capital budget, acquiring them is relatively easy. They are also considered by most managers to be an essential part of any hospital diagnostic capacity. Numerous evaluations of their use for particular conditions have been done, but in general use is widespread among all specialties with little consideration of appropriateness or cost effectiveness. One area of particular debate has been the use of brain scans for patients with stroke. The 1988 King's Fund Consensus Statement suggested that CT be used for limited indications; more widespread use would have considerable resource implications.

In 1985, a review of the use of CT in the management of cancer concluded that despite a paucity of information "reported studies [of CT in patient management in oncology] indicate that CT directly alters clinical decisions in 14-30% of patients" (24). There has been no coordinated national evaluation or technology assessment following the Department's initial control of—and involvement in the evaluation of—brain scanners.

The University of York Centre for Health Economics (one of the major health economics departments in the country) produced a user-guide for individuals and groups concerned with planning for, and management of a CT scanner in a District General Hospital in 1987 (25). It raises key questions such as, "Will CT replace existing forms of examination?" and "What impact will CT have on the demand for other related services in the hospital?" However, as it is not a standard DH document but emerges from a research organization, its impact and subsequent use has been limited.

Magnetic Resonance Imaging (MRI)

The dissemination of MRI, like CT, depended primarily on the availability of resources. The initial seven units were supported by the Department of Health and MRC. Trials were set up to evaluate MRI's clinical applications and the Department of Health/MRC Coordinating Committee on Clinical Application of NMR Imaging commissioned a cost-benefit study that also included collection of data on costs and throughput at other centers in an attempt to forecast likely implications of the adoption of MRI for the NHS. This part of the work proved to be of limited success; several units declined to be involved, which was inevitable in an environment where management research is considered to be a hindrance.

Published in January 1990 (48), the committee's report held that for the applications studied, "MRI is no more cost-effective than existing diagnostic techniques." It also stated that the perceived diagnostic and therapeutic impact of MRI does not necessarily imply a positive effect on the final outcomes for patients:

> Direct cost of MRI is much greater than that of CT. This is partly due to higher initial capital cost, but mainly due to lower throughput of patients in MRI. MRI is more cost effective if used as the first investigation of choice. However where CT is the only scanning modality there is no strong case for investing in MRI.

At the same time, a significant study was being undertaken within the West Midlands Regional Health Authority, funded by its Health Services Research Committee (43). As the service was already up and running, it was not possible to do a randomized controlled study. The report published in December 1990 determined that MRI did confer additional benefits in terms of diagnostic impact, mainly by turning a provisional diagnosis into a "diagnosis unknown." MRI also proved to be excellent at improving the accuracy of the site or location of an already diagnosed condition. In terms of value or benefit to the patient, however, the results were less obvious. This report further concluded that MRI was an additional cost to each patient and that it tended to be used as an additional means of investigation rather than to replace existing modes. When introducing such expensive services, clinical audit should be established to ensure maximum cost-effectiveness.

Neither of these reports was adopted by the Department of Health, and both were published by research units rather than by the Department or any organization with authority; thus, they have had little effect on controlling diffusion. The West Midlands work does not appear to have had any impact on policy (44). MRI adoption has been limited, mainly due to resource constraints rather than determination of need, especially as the NHS reforms have introduced capital changes that mean that the cost of expensive equipment is to be included in providers' prices to purchasers. A more recent review of clinical uses of MRI completely ignores the two earlier studies and is generally positive about MRI's success for a range of clinical conditions (1).

A report produced by the Royal College of Radiologists in 1992 identified 90 MRI units (37). This report advised that MRI be available to all teaching and district general hospitals with approximately four MRI units per million population, or 225 units in total. This considerable increase is unlikely to occur on grounds of cost rather than appropriateness.

LAPAROSCOPIC SURGERY

Because of the range of technologies encompassed in this category, the introduction of laparoscopic surgery provides different examples of the factors that help and hinder the diffusion of new technologies. The development of laparoscopic techniques in the United Kingdom is generally unstoppable; it is occurring across most medical specialties. Laparoscopic surgery has blurred the differences between surgeons, physicians, and radiologists; has supported reductions in lengths of hospital stay and requirements for hospital beds; and has made surgical treatment for many patients a short-term and relatively pain- and scar-free experience.

Early Diffusion

The early introduction of laparoscopic surgery occurred because of a few product champions that, like their first wave of followers, were sited in general hospitals, not only in teaching or academic centers. This is because most of the techniques did not require particularly expensive capital outlay, and in surgery, innovation occurs equally in nonteaching and teaching centers.

Laparoscopic cholecystectomy has diffused quickly throughout many surgical units within the last three years (box 8-1). Uptake has depended on local factors, and without any centralized planning there is wide variation in availability.

The private sector has been more easily able than the public sector to respond to the potential savings of laparoscopic surgery through shorter lengths of stay and increased patient satisfaction.

BOX 8-1: The Status of Laparoscopic Surgery in the United Kingdom, 1994

Laparoscopic treatment of endometriosis and removal of ovarian cysts

- Used and developing, evidence on cost-effectiveness and outcomes insufficient.
- Diffusion via a small number of enthusiasts.
- No central support, attractive to consumers.
- Not in position to replace conventional treatments.

Laparoscopic appendectomy

Not routine; routinely used by only one surgeon.

Laparoscopic cholecystectomy

Since 1991, actively supported by surgeons and patients.

- Extends operation time and queries as to outcomes, especially among inexperienced practitioners.
- Diffusion well en route.

Arthroscopic knee surgery

- Accepted practice but therapeutic application unevenly spread.
- No national policy, but national conferences have played key role in diffusion.
- Underfunding of orthopedics has led to shortage of equipment and facilities.
- Value of arthroscopy as diagnostic procedure accepted, but use as treatment resisted, especially by older surgeons (33).

SOURCE J Spiby, 1994

More recently, however, several private insurance companies have become concerned about the outcomes of certain procedures (e.g., laparoscopic uterine removal, laparoscopic cholecystectomy) and have banned activity until the results of longer term studies are available. Within the NHS this has not happened, as currently there are very limited mechanisms (except for peer pressure) to prevent surgeons from undertaking different techniques.

Cost Pressures and Policy

One of the main forces for the development of laparoscopic procedures has been increasing pressure on health care spending. Reduced lengths of stay in surgery has been seen as essential. There has also been considerable political impetus to reduce waiting lists, which has led NHS managers to concentrate on supporting initiatives that appear to reduce the need for costly overnight stays.

The assumption that laparoscopic surgery will achieve cost reductions is not, however, well supported by research evidence; in general, the costs and benefits have been poorly studied. Early results of studies of long-term outcomes of some laparoscopic procedures show, in some cases, that laparoscopic procedures delay rather than avert open surgery, and some have higher levels of complications. Some procedures takes two or three times longer to perform than conventional surgery (2).

The Department of Health has been noticeable for its lag in developing policy on laparoscopic surgery (33). The Department appears to have considered developments within the NHS to be well ahead of central thinking and policy.

However, concern about the lack of evidence on efficacy and cost-effectiveness have led to support for several RCTS funded through the national R&D strategy. The results of these trials may or may not be timely enough to influence the diffusion of the more popular technologies.

Continued Diffusion

Patient preference has played a strong part in the development of laparoscopic surgery, as patients are able to return to normal life so much more quickly and suffer considerably less pain (33). More recently, however, concerns have been expressed by GPs about the relentless push to discharge patients early after surgery and the lack of backup for complications. This problem will need to be addressed if laparoscopic surgery becomes the norm.

In general, the product champions and early innovators have been younger surgeons at the beginning of their careers and possess the necessary skills for laparoscopic surgery. For the next stage of innovation, older surgeons and those who are less innovative will have to develop the necessary skills. This problem has not been addressed until recently, and most hospitals have had to rely on retirement to achieve change. Some older surgeons were willing to consider the new techniques, but they have found it difficult to obtain training, and they are unlikely to acquire the skills from junior colleagues.

In November 1992 the Department's Management Executive announced that in collaboration with the Wolfson Foundation, it was funding three minimally invasive surgical procedures units. Centers in Scotland, Leeds, and London have been designated as training centers, and surgeons will start to undergo "retraining" shortly. This is a unique initiative, as the need for acquiring new skills to cope with new technologies has been frequently discussed but never positively addressed before.

TREATMENTS FOR END-STAGE RENAL DISEASE (ESRD)

Despite the fact that it is a relatively uncommon condition, ESRD and its different forms of treatment were extensively (and often emotionally) discussed in the United Kingdom during the 1980s and early 1990s. This attention results from the fact that untreated patients die and treatment costs are high, particularly as patients need treatment for the rest of their lives. Patient survival for all age groups has improved consistently over the last 15 years, as have levels of service.

International Comparisons

The United Kingdom has long been regarded as a laggard in its level of treatment of ESRD, even when compared with countries with similar per capita health expenditures; however, far more patients are being treated than 10 years ago. Nonetheless, compared with Europe and the United States, relatively fewer elderly patients are accepted, reflecting the lower priority accorded to ESRD in the Britain.

Pattern of Diffusion

The United Kingdom has one of the lowest nephrologist to population ratios in developed countries (20). This is also reflected in the number of hospital centers for renal replacement therapy (RRT). Many of the existing centers were setup through a system of central planning in the 1960s (3). In the 1970s NHS established a few new centers at a time when facilities were mushrooming in other parts of Europe. British centers tend to be centralized in teaching hospitals.

Between 1980 and 1987 the number of UK RRT patients doubled from 128.6 per million population to 267.6, but the gap between the United Kingdom and other countries narrowed only slightly (see table 8-3). This low level of provision reflects the low level of spending generally on health care and the tight constraints that central control have placed on capital spending on new units and ongoing expenditures for a high-cost

TABLE 8-3: New Patients Accepted for Renal Replacement Therapy United Kingdom, Germany, France, Italy, 1980-1987 (per million population)

Year	United Kingdom	Germany (FRG)	France	Italy
1980	24.9	46.7	41.6	37,7
1983	33.4	55.8	44.3	45,5
1985	43,1	59.4	42,9	46,8
1987	50.8	84.9	58.1	48.8

SOURCE N B Mays, *Management* and *Resource Allocation m End Stage Failure Units, A Review of Current Issues* (London King's Fund, 1990)

treatment. Spending has been low despite the relatively high level of public discussion and relatively well-organized lobbies both of patients and professionals.

Selection of Patients

A result of the low level of service available is the careful selection of patients for ESRD treatment. In general, rationing is achieved by preferentially treating younger, fitter patients with dependent children. Diabetic patients are also less likely to receive treatment because of the reduced success in their outcomes. This selection appears to be due to some level of gatekeeping by GPs. In a 1984 study, GPs were more likely than hospital physicians and nephrologists to assume that treatment was not appropriate for the elderly and other higher risk patients and did not refer such patients, instead treating them conservatively (3). The reduction in referrals to treatment is also related to the low level of nephrologists, who are sited mainly in the renal units rather than in district general hospitals.

Despite increases in the numbers of patients receiving ESRD in the 1980s, a survey in 1990 concluded that there was still under-referral of patients suitable for treatment (20). The authors of the survey estimated that the incidence of ESRD is 78 per million population, and that only 55 per million were being treated.

Variations in Treatment Rates

Within the United Kingdom there is a marked variation in ESRD treatment rates between regions (see table 8-4), due primarily to the availability y of facilities. This variation can also be seen within regions where the uptake is higher by the populations living closest to the units (8). In the North West Thames region a new peripheral unit was established to provide a local service for people not close to a teaching hospital. Even then, within a few years the population closest to the unit was more likely to receive care than those further away.

Regional differences can also be seen among the different treatment modalities favored by units. East Anglia's renal replacement therapy program has long been dominated by renal transplantation at Cambridge, and continuous ambulatory percutaneous dialysis (CAPD) has been little needed. However, in the Oxford region, transplantation has grown more slowly, and home hemodialysis has played a major role, heading other methods of dialysis. These differences reflect a number of interacting factors: the preexisting pattern of dialysis provision, treatment, and selection policies of individual units and consultants; policy decisions of the RHAs; the degree of population dispersal; and the availability of different types of resources, including the domestic circumstances of patients (which affect their ability to cope with different modalities).

Cost-Effectiveness of Different Treatments

Care of ESRD is significantly more expensive per patient than many other diseases. Dialysis is expensive primarily because it is needed for a long period of time. The most cost-effective option is a successful transplant, but the costs of a graft that fails in the first year are considerable and comparable to the costs of hospital hemodialysis.

TABLE 8-4: Regional Acceptance Rates for New Renal Replacement Therapy Patients (per million population), 1984 and 1988

Region	1984	1988
'Northern	40.6	58.5
Yorkshire	34.2	44.2
Trent	40,4	49.1
East Anglia	40,5	65.0
NW. Thames	30.6	49.7
NE. Thames	30.3	61.1
S.E. Thames	47.5	76.1
SW. Thames	25.3	23.3
Wessex	27.9	44.8
Oxford	37.5	50.4
South Western	32.6	51.2
West Midlands	26.3	52.0
Mersey	31.3	34.6
North Western	31.5	83.8
Wales	34.3	66.4
Scotland	38.2	62.8
Northern Ireland	20.1	42.5
Isle of Man	33.3	40.0
United Kingdom (total)	33.8	55.0

SOURCE N B Mays *Management and Resource Allocation in End Stage Failure Units, A Review of Current Issues* (London King's Fund, 1990)

In 1990 the Department of Health estimated that the first year of hospital hemodialysis costs the NHS 16,500; home dialysis, 13,000; and CAPD, &14,000. In general the United Kingdom has a pattern of modalities that reflects a policy to invest its limited resources for ESRD (approximately 0.6 percent of the annual budget of a typical RHA) by giving greater priority to home dialysis and, recently, to CAPD than do many other countries. This was not necessarily a planned strategy was compelled by the strict control exercised in the NHS over the opening of new renal units. Heavy emphasis has also been placed on achieving a high level of transplantation, not only because it is a low-cost option but because it so dramatically achieves a better quality of life. Much work has been done to increase the harvesting of cadaver kidneys by developing increased awareness in medical staff of the need to request the use of organs, and by appointing regional nurses who are responsible for ensuring that hospitals are prepared to maximize the availability of organs.

During the 1980s, in the absence of major capital schemes for renal services in many regions, units responded in a variety of ways to increased demands. These include:

development of minimal care dialysis with shorter treatment times and more shifts;
- setting up satellite units, managed by a parent unit;
- growth of CAPD, generally considered a cheaper form of treatment, with the advantage that patients can quickly and easily be trained to treat themselves at home; and
- an increase in transplant rates, which has greatly helped reduce the required increase of dialysis programs.

CAPD has released units from the existing physical space constraints in the hospital and has allowed revenue to be converted directly into additional patient acceptances. With respect to transplants, minimal care and satellite units were often set up because of physical space constraints as well as the desire to improve geographical accessibility for distant patients. The service is primarily concentrated in regional centers; however, despite the fact that satellite units have proved to be a cost-effective means of providing dialysis, they have not developed as quickly as might have been expected.

Erythropoietin (EPO)

Erythropoietin for renal patients arrived at a time when the increase in demand and the lack of additional resources for ESRD services were posing major problems. EPO'S efficacy has been generally accepted, but what has been challenged is the level of effectiveness for the considerable cost. Health economists have led the debate, questioning the widespread use of the drug. Units limited in their resources have had to ration its use to those most at risk of anemia due to contraindications to transfusion. More recently, units have found a funding loophole and have asked GPs to prescribe

the drug, as well as other dialysis-associated drugs and consumables, from the budget for primary care drugs, which is separate from hospital budgets and at present is not cash limited. Many GPs have felt unhappy about taking clinical responsibility for a drug with which they are unfamiliar, but faced with a patient who will not receive treatment if they do not prescribe, most have reluctantly agreed to do so. However, it is expected that the funding mechanism will be changed in 1994 and such off-loading will not be possible, thereby increasing the pressure on renal units budgets.

Role of the Private Sector

The development of renal services has been assisted by the private sector since the mid- 1980s. Commercial companies moved from supplying dialysis units and, in some cases, helping units with financial information and stock management to directly providing dialysis treatment. The first private dialysis units were set up in Wales in 1985 as part of a program to increase the supply of dialysis services. Main renal units remain solely on NHS, but subsidiary care centers were contracted to the private sector. The experience has been successful, but surprisingly (considering the general changes in NHS), subsidiary care units have not developed to any major degree elsewhere.

NEONATAL INTENSIVE CARE

Services for neonatal care received their first official support in the United Kingdom in 1961, when the Joint Subcommittee and Standing Maternity and Midwifery Advisory Committee recommended the creation of a comprehensive program for the care of neonates. In the same year the Central Health Services Council argued that special care facilities would reduce neonatal mortality. Before 1961, services had developed mainly where there were enthusiasts in teaching hospitals. The development of the service was promoted by professionals, and there was little scientific evidence for their claims that neonatal mortality would be reduced or that reductions seen at that time were related to spec ial care facilities.

In 1971 the Sheldon report advocated a two-tier system of service provision, with 1) special care units in each district for low-birthweight babies and those with illnesses unique to the newborn, and 2) neonatal intensive care units (NICUs) that would provide higher level care at specialist teaching hospitals (39). As well as centralizing expert care, the latter were regarded as a prerequisite for training doctors and nurses in the special care required by the sickest neonates. There was at the time some suggestion that such centralization would increase the risk of infection or the possibility of over-aggressive treatment, but this was not investigated in any serious manner—probably because those doing research in the area were mainly proponents of the service. The consensus was that each region should have one to three NICUS: these should be sited where the high-risk obstetric service was sited and where specific expertise in neonatal intensive care existed.

Three reports of the Social Services Committee during the 1980s (5) recommended the addition of a third tier to neonatal services, such that all districts would provide short-term care backed up by subregional facilities at larger maternity units and a regional specialist perinatal center. The service by then was well established, although in most regions the actual distribution of services and level of expertise available depended on local circumstance rather than careful planning. Two explanations for this can be put forward: first, the lack of hard evidence on the service; and second (and more likely), the establishment by younger pediatricians of one or two cots in smaller hospitals in order to create a local service and provide an extra professional challenge for themselves and other staff. Several regions produced planning guidelines that they backed up with resources, but subsequent reviews found that small local services with one or two cots were being set up by clinicians despite these guidelines (29).

Policies and Diffusion

During the 1980s the main policy thrust was toward improvement in neonatal services. These services were singled out by the Royal College of

Physicians in 1988 and the National Audit Office in 1990 as an area for improvement, and the NHS'S Chief Executive made it a priority in 1990 for regions and districts to review their maternity and neonatal services with a view to further reductions in mortality (31 ,36).

In England between 1980 and 1986, the number of cots for neonatal intensive care more than doubled, and birthweight-specific perinatal and neonatal mortality fell in all categories of birthweight. There were, however, a few skeptics who had reservations about the rapid growth in neonatal services, doubting that neonatal intensive care was a determinant in the reduction in neonatal mortality. Concern was also expressed about the high cost of these services and the long-term health outcomes. By this time it was deemed unethical to undertake a randomized trial, and advocates of NICUs cited experience abroad and expert opinion rather than data. Typically, the discussion centered on the lack of services and problems in obtaining a cot for all the babies who required this level of care.

In an attempt to address these criticisms, one region, Trent, undertook a prospective study examining the short-term outcome (survival to discharge) of all infants who required admission to a baby care unit. They showed that infants of 28 weeks' gestation or less who received all their perinatal care in one of five large centers (each providing more than 600 ventilator-days per year) had significantly better survival than infants treated throughout their entire course at one of 12 smaller units (22). These differences occurred despite the elective transfer of many of the sickest infants from smaller to larger units. Differences in survival between more mature infants were not significant.

The National Perinatal Epidemiology Unit in Oxford, which has been central in developing an understanding of technology assessment and the relative valid it y of different types of clin icaltrials, raised questions regarding the interpretation of the results and implications for policy (30). It suggested that biases may have affected the results, and that the differences in mortality might have been in part the result of differences in unmeasured risk factors; moreover, a decision to transfer all babies might not reduce mortality but instead increase the mortal it y rate for admissions to the referral units **as** they take in higher risk babies. The outcome was that the case for regional NICUS was not made, but policy continued to support them.

Throughout the development of neonatal intensive care, the argument for it has been that it reduces neonatal mortality. Little or no reference has been made to its impact on morbidity. Concern has been expressed about the possibility of an increased level of severely mentally and physically handicapped children, but little epidemiological evidence has been forthcoming. Recent work indicates that increasing numbers of preterm infants survive without (major) handicaps but with more subtle long-term problems, such as learning difficulties and lower school grades. The chief implication of such information is the need to press for better obstetric care so as avoid the necessity of neonatal intensive care.

Financing NICUS and the NHS Reforms

Until the 1990 NHS reforms, the responsibility for financing and developing neonatal intensive care had belonged primarily to RHAs. The NHS reforms aimed to devolve responsibility to the districts for such services so that their relative importance would be assessed against the total needs of the population. This change created major concern among those involved in the service, who feared that centralization would be eroded (34). It was felt that the reforms might encourage the establishment of small, less well-equipped NICUS, with few if any effective constraints or controls over those providing neonatal care. This concern was reiterated in a House of Commons Health Committee report in 1992, which stated that "we are not persuaded that the establishment of contracts for regional services for perinatal and neonatal intensive care can be left to market forces and audit. "

The service became one of the first to be reviewed by the Clinical Advisory Group set up by the Secretary of State. Its report on neonatal intensive care concentrated primarily on access, as had

so many of' the previous official reports on this service. Overall. it was felt that contracting had not significantly affected the service. There was still considerable variation across the country in the service provided, and in some regions the service was under considerable pressure. However, it appeared that purchasers were intending to move an increased proportion of intensive care to local units (probably for financial rather than clinical reasons). and this might have a deleterious effect on the viability of the larger training institutions and on quality of care. The report noted that few consistent measures of quality existed and that a population-based audit of outcome in terms of mortality and disability was required.

Extracorporeal Membrane Oxygenation (ECMO)

The well-controlled introduction of ECMO to the United Kingdom is due largely to the influence of the perinatal research unit in Oxford. ECMO was introduced unevaluated in Leicester in 1991. Before any other units were installed, planning by researchers at Oxford University began for a randomized controlled trial to cover the entire United Kingdom. Recruitment started in January 1993: to date, more than 80 babies have been included, making it by far the biggest controlled trial of ECMO in the world. Results are expected in 1996.

SCREENING FOR BREAST CANCER

Interest in screening for breast cancer developed slowly in the 1970s mainly in the form of specially funded projects or adjuncts to symptomatic mammography services. During the early 1980s, a considerable lobby developed; it consisted of surgeons who specialized in breast cancer treatment and women's groups. In 1985 the health minister announced that a committee would be set up to:

- consider the information now available on breast cancer screening by mammography:
- the extent to which the literature suggests necessary changes in policy on the provision of mammographic facilities and the screening of symptomless women;
- suggest a range of policy options and assess the benefits and costs associated with them; and
- identify the service, planning, labor, financial, and other implications of implementing such options.

Forrest Report

The committee reported in November 1986 in a document known as the Forrest report (9). On the basis of evidence from randomized trials in New York and Sweden and two studies in the Netherlands, the committee concluded that "screening can reduce mortality from breast cancer, although the reduction varies with the age of the women screened." Despite the existence of a large, seven-year, multicenter, population-based trial that was being conducted and was due to report in 1988, the committee recommended the introduction of a national breast screening service for women between the ages of 50 and 64, with the expectation of reducing deaths from breast cancer by a third or more. The key screening test was to be one-view, high-quality, medio-lateral oblique-view mammography. The program was to include a personal invitation to all eligible women, arrangements to ensure that positive results were followed up, a specialist team to assess detected abnormalities, a call-and-recall system, quality control, and a designated person responsible for managing local screening services.

This report was fully implemented because the government, on announcing its acceptance of the recommendations, also agreed to finance the screening program in full. Over &50 million nationally was invested of new funds to the NHS provided by the Treasury. By 1991 there was 77 screening programs covering the 190 health authorities.

On a more practical level, the Forrest report clearly acknowledged that "the development of any national programme will require careful planning not only of the basic screening services but also to ensure the availability of the necessary as-

sessment, diagnostic and treatment services for screen-detected abnormalities."

Results of the U.K. Trials

In 1990 the Scottish arm of the U.K. Trial for the Early Detection of Breast Cancer reported a non-significant reduction in mortal it y after seven years with an initial attendance rate of 61 percent (35). The net result of the trial was to emphasize that a high level of reduction in mortality could be achieved only with high participation rate in screening (46). The service was set up with a well-structured call-and-recall system, but it became clear that although uptakes of 80 to 90 percent were possible in areas of high socioeconomic status, such rates were not achievable in inner-city areas and among those populations that traditionally do not use preventive services (28).

During this period the results of the U.K. trial led to criticism of the Forrest report. It was suggested that the expectation of a 30 percent reduction in mortality was too ambitious; that the disadvantages of screening had not been adequately measured, especially in view of the number of false positives; and that the group had been biased and should have considered selective screening to ensure proper use of resources.

The National Screening Program

Following the Forrest report, major new evidence was reviewed by Forrest and a group of experts. This evidence consisted of the U.K. trial, further evidence from Malmo (Sweden) and New York, and the Edinburgh randomized trial. This review concluded that "the original evidence that screening for breast cancer can reduce breast cancer mortality is supported by additional results from recent evidence. The expected impact after about 10 years was that roughly 1,250 deaths attributable to breast cancer would be prevented each year in the United Kingdom.

Concerns about translating trial results into national experience have focused on three main issues: population coverage, skills development, and proper introduction of the program. Adequate population coverage is clearly challenging in some parts of the country. The Forrest review acknowledged this and identified difficulties with the population denominator register used for contacting women about attending their screening. Certain sectors of the population are unlikely to attend even if contacted, however—a problem that is being addressed locally with a range of initiatives.

It was reported that the development of skills through training centers had been sufficient to train the required staff in three years. In fact, the training program had initially lagged but eventually came to play an ongoing role in supporting continuing education.

The U.K. Cancer Coordinating Committee Breast Screening Sub-Committee set up three trials looking at the interval between screening episodes, the number of views, and the effect of screening women under the age of 50. The Sub-Committee also coordinates research on acceptability and economics. This high level of central control reflects the program's unusual commitment to centralization and uniformity.

Impact of the NHS Reforms

The NHS reforms at present have not affected the screening service in any major way. At present, the funding for breast screening and the centralized style of service provision have been protected, but this will not necessarily continue to be the case.

Breast screening has been given additional impetus by virtue of its inclusion in the national health strategy. The proposed target is to reduce the death rate for breast cancer in the population invited for screening by at least 25 percent.

CHAPTER SUMMARY

The picture painted above shows a varied pattern of influences on the introduction of health care technologies in the United Kingdom and little evidence of a coherent policy for technology development until very recently.

In the past, the constant requirement to limit the availability y of care has been met primarily by general practitioners who act as gatekeepers and by the acceptance of waiting lists for nonemergency care. This system of priorities has become politically unacceptable over the last decade, however, as shown by the Department of Health's waiting list initiative. Patients have been encouraged by the Patients' Charter to demand their "rights." Consequently, without any major increase in resources, different mechanisms for the control of spending have had to be developed.

To date, limiting development by constraining resources has resulted in a haphazard control of technological development based on cost considerations rather than on effectiveness. Those who have found it easiest to obtain new resources (primarily the main teaching hospitals) have been the most successful in introducing new technologies and those who live closest to such facilities are more likely to receive care.

Looking at the way in which different technologies have developed in the United Kingdom, it is clear that the government has had little control of technological development except in the case of breast cancer screening, where specific funding was provided to fund a new national program. With other technologies, the government has tried to influence development by more indirect routes, such as identifying expected service levels or planning norms. Yet without any real method of enforcement, such means appear to have had little influence.

The most important factor in technology diffusion has been product champions: individual clinicians or members of key regional or district management teams who have found appropriate ways of obtaining resources (public, private, or charitable), and ushering in the introduction of new developments. Such champions have been found mainly in teaching institutions, where the environment is more encouraging (both in terms of availability of resources and tolerance of more maverick personalities). That this is not always true is illustrated by the development of local renal dialysis units, minimally invasive surgery, and neonatal units.

Over the past decade, awareness of the concepts of appropriateness, effectiveness, and cost-benefit analysis have moved to center stage on the agenda of purchasers and the NHS Management Executive. Ten years ago, few managers or politicians were aware of the level of inappropriate use of technology or of new developments that were about to occur—and of how to assess their usefulness. Clinicians continued to battle for resources for their particular specialities but were rarely challenged on the effectiveness of their activities.

The main challenge today is finding ways of using the NHS reforms to implement technology assessment results so as to ensure the most cost-effective use of resources. The creation and appointment of a national Director of Research and Development and the commitment of this entire structure to technology assessment is a major step forward. At present, however, there appears to be more discussion and publication of strategies than funding of useful research or use of previous work to effect change. Little new money is available, and at regional levels, R&D directors are finding it difficult to obtain realistic budgets.

Some regions have also had difficulties finding appropriately qualified candidates. Most senior clinicians with a research background who are acceptable to the medical fraternity are knowledgeable only about their own specialties; they do not have an overview of the whole of health care, nor are they experienced in working within health service management. It is hoped that these problems will be resolved and that the real power of the post-

holders will be felt. Unfortunately, this will inevitably be delayed by the structural reorganization of the regional health authorities and potential dislocation of this function.

Possibly more effective in achieving change will be the purchasing authorities. In theory, they play a powerful role in identifying what they wish to purchase and ensuring through contracts that desired patterns of health care are provided. In reality, however, difficulties arise in identifying exactly what is required and in using the contract process effectively.

In summary, although the United Kingdom did not become systematically involved in technology assessment until recently, the field has recently been much publicized and discussed. It is ironic that the randomized clinical trials and cost-effectiveness studies undertaken in British research units have had relatively little impact on health care and its management up to now. The increasing necessity for making choices, along with the increasing availability of research from health care technology assessment, makes this problem unlikely to persist.

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Health Care Technology in the United States

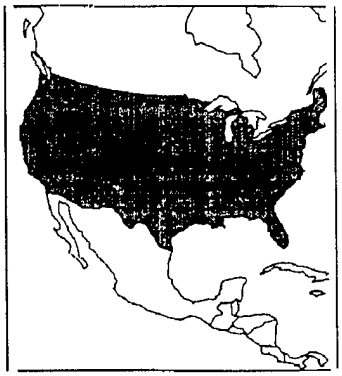
by Sean R. Tunis and Hellen Gelband

9

OVERVIEW OF THE UNITED STATES

The United States occupies over 3.5 million square miles of North America and, with just under 250 million inhabitants, is the third most populous country in the world after China and India. The population structure is younger than that of most of the European countries, with 12.5 percent of the population older than 65 in 1990 and a large, middle-aged "baby boom" population bulge. The majority of the population is Caucasian, but a large minority—20 percent in total—belong to one of four large ethnic groups: black, Hispanic, Asians, and Pacific Islander.

The United States has the largest economy in the world, driven by a free enterprise system concentrated in manufacturing and service; agriculture, mining, fishing, and tourism also make substantial contributions. The per-capita gross domestic product (GDP) in the United States is second highest among Organisation for Economic Cooperation and Development (OECD) countries (after Switzerland); at $21,399 in 19911 (84), but this hides a highly unequal distribution. Compared with most European countries, the poorest fifth of U.S. households has a smaller share of total income, and the wealthiest fifth has a higher share. Poverty rates are generally higher in the United States than in Europe; as of the mid- 1980s, 17 percent of U.S. children were living below the official poverty level (129).



The U.S. government can be described as either a constitutional democracy or a federal republic. The powers of the three branches of government are balanced: the executive comprises

'1991 data expressed as purchasing power parity, which provides a standard international measure.

the president (elected by popular vote every four years) and all the departments and other operating agencies; the legislature is composed of the Congress (the Senate, with two Senators per state, and the House of Representatives, with 435 members representing approximately equal fractions of the population) and its support staff and agencies; and the judiciary (the court system). Power not specifically assigned to the federal government by the U.S. Constitution is automatically assigned to the states, which are significant players in health care.

HEALTH STATUS OF THE POPULATION

In 1990, life expectancy at birth in the United States was 71.8 years for men and 78.8 years for women, among the lowest of the OECD countries. The 1990 infant mortality rate was 9.2 per 1,000 live births, which puts the United States in the bottom half of the distribution among all developed countries (129). These poor statistical showings have been the focus of political frustration in the face of high spending for health care.

Important causes of death and health-related trends in the United States are similar to those in other developed countries: heart disease, cancers, stroke, chronic lung disease, and pneumonia. About 20 percent of all deaths are attributable to cigarette smoking, which also is similar to other developed countries. Although overall patterns of morbidity and mortality in the United States are similar to those of other developed nations, two features stand out as different or more extreme. First, health status is correlated with socioeconomic status, which itself is correlated with race in the United States; health indicators for blacks and other minorities are uniformly and significantly worse than for whites. Second, deaths in relatively young age groups, starting in the teenage years, are dominated by violent deaths from homicide and deaths from AIDS. In the 15-to-24-year-old age group, homicide is the second leading cause of death, and black men between the ages of 15 and 44 are eight times more likely to die from violence than are white men (143). Injuries related to violence and illness related to drug use are also more prevalent in the United States than in other developed countries. These social conditions are directly and indirectly associated with both health outcomes and health care expenditures.

THE U.S. HEALTH CARE SYSTEM

The organization and delivery of health care in the United States is a good reflection of the free market system: this health care system has no fixed budget or limitations on expansion, and it now accounts for 14 percent of the U.S. gross national product-over $800 billion dollars in 1993. The delivery system is loosely structured, with hospital location determined by market forces and community preferences; physicians are free to practice in any location. The recent and rapid increase in numbers of health maintenance organizations with capitated payment arrangements (i.e., a fixed amount per person regardless of services used), a response to pressures to hold down health care costs, represents a shift in direction from the traditional laissez faire approach in the U.S. health industry.

A few states do have an effective coordinated plan to control and distribute resources, but the federal government does no central planning. The government is the major purchaser of health care for older people and, along with the states, for some poor people. By and large, however, payments for health insurance and care are private sector transactions. Access to health care is not universal, and even among those with health insurance, coverage is uneven. The level of satisfaction expressed by U.S. citizens with their health care system is lower than in other developed countries.

Expensive medical technology is a particular specialty of U.S. medicine: some major U.S. cities, for example, have more magnetic resonance imaging (MRI) scanners than do most countries in the world. (In Los Angeles there were more of these scanners (25 in 1985) along a one-mile stretch of road than there are in all of Canada (49).) The huge public and private investment in basic medical research and pharmaceutical development is often cited as an important driver of this "technological arms race." Moreover, efforts to

restrain technological developments in health care face opposition from policy makers concerned about negative impacts on medical technology industries.

Delivery System

Hospitals

The hospital system in the United States consists of 5,480 acute care hospitals, 880 specialty hospitals (psychiatric, long-term care, rehabilitation, etc.), and 340 federal hospitals (serving active military personnel, veterans, and Native Americans) for a total of 2.7 per 100,000 population (7). Fifty-nine percent of acute care hospitals are privately owned, nonprofit institutions; 14 percent are for-profit; and the rest are operated by local governments. In 1990 the average length of stay for the nation's 33 million admissions was 9.2 days. Average bed occupancy rate was 66 percent (143). Lengths of stay are shorter and admission rates lower than in other OECD countries.

Physicians

In 1990 there were 615,000 physicians practicing in the United States (2.4 per 1,000 population) (8). Rural areas are relatively underserved, with 0.9 physicians per 1,000 population (126). Primary care practitioners (practitioners of family medicine, internal medicine, and pediatrics) make up 33 percent of the active physician population; the remainder are specialists (90). Among the aims of current health care reform proposals are better geographic distribution of physicians and a more favorable balance of primary care practitioners and specialists (one goal is 55 percent for the former). Most physicians are paid on a fee-for-service basis by insurers or individuals, but an increasing number are salaried or obtain patients through insurance networks that negotiate payment rates.

Health Care Financing and Payment for Services

Health care is financed by a mixture of private insurance, government programs. and payments by individuals seeking care. Health insurance for most U.S. citizens is paid for by their employers and is considered part of their compensation for working; however, employers are not current] y required to provide health care. Public programs cover the elderly, some disabled and some of the poor, and some military veterans, but many poor Americans have no insurance—and many people have lapses in insurance coverage. Uninsured individuals may receive episodic care from public clinics, hospitals, and some private providers who will not be paid for that care. At any given time about 15 percent of the U.S. population has no health insurance (1 33).

Health Insurance

Health insurance in the United States grew out of post-Depression efforts by hospitals to establish programs that would allow patients to pay bills even when facing personal economic hardship. Organized medicine, motivated to take some action on health insurance by discussions of a national health plan in the Roosevelt administration, created various funds administered by local medical associations and authorized to pay fees for low-income families. There were *43* such plans by 1946, and this system ultimately evolved into the Blue Shield program. A Supreme Court ruling in 1948 determined that health insurance benefits could be included in collective bargaining between employers and employees, giving a powerful boost to development of employment-linked health insurance. By the early 1960s, three-fourths of U.S. citizens were covered by some health insurance; however, such insurance covered on average only 27 percent of medical bills and was entirely unavailable to many poor and elderly citizens. To address these problems, legislation proposed by President Johnson and passed in 1965 created Medicare and Medicaid, marking the first time that health insurance became compulsory for some groups. By 1967, third-party payers covered over 50 percent of medical bills, and U.S. citizens were buying increasingly comprehensive coverage through a growing private insurance industry.

In the 1990s, employers are providing insurance for 61 percent of the total U.S. population, and another 13 percent of Americans purchase their own private insurance (133). More than 1,000 private insurance companies provide a multiplicity of policies. State insurance commissions regulate health insurance quite loosely. In the past decade most large employers have moved to self-insurance, which, under federal law, immunize them from state regulation. Employer-paid health benefits are an attractive substitute for wages because they are not subject to income tax or Social Security tax. In 1990 this translated into a $56 billion federal subsidy for employment-based health insurance (156). Although most group insurance policies cover hospital care and physician services, there are few other consistencies. It is estimated that 55 million people have limits on how much their policies will pay, so they are not protected from being impoverished by serious illness (30).

Medicare

Medicare provides insurance for acute care services to people over 65, certain disabled individuals, and most of those with end-stage renal disease, totaling about 13 percent of the U.S. population (133). Hospital care is financed from a trust fund fed by a payroll tax that, at current spending levels, will be exhausted in the year 2006. Physician services are funded by a combination of premiums collected from recipients (25 percent of total outlays) and funds from the regular federal budget (75 percent of outlays). Most beneficiaries buy additional insurance—''medigap policies''—to cover expenses not covered by Medicare, including deductibles, co-payments, and uncovered services, and—perhaps most important-out-patient prescription drugs and skilled nursing care.

Medicaid

Since 1965, acute and long-term care have been provided to low-income individuals through Medicaid programs administered by each state and funded in equal parts by the state and (as long as certain minimal criteria are satisfied) the federal government. About 10 percent of the population is insured through Medicaid. Mandatory benefits are specified by the federal government by type of service, but states may decide to limit the amount of any service to recipients. Payment rates for physicians providing services to Medicaid patients are fixed by the states and are relatively low, leading many physicians not to accept these patients in their practice. Medicaid benefits must be provided to poor aged, blind, or disabled individuals, and usually to poor single mothers and their dependent children, but not to all individuals who by all measures are considered impoverished. Between 1990 and 1991, Medicaid payments by the federal and state governments increased by 34 percent (71).

Federal and Local Governments as Providers

In addition to paying through Medicare and Medicaid for services in the private sector, federal, state and local governments provide health care services directly to some groups. Through the federal government, the Department of Veterans Affairs maintains hospitals and out-patient clinics throughout the country for veterans of military service (at a cost of $14.6 billion in 1993 (157): the Civilian Health and Medical Program for the Uniformed Services (CHAMPUS) cares for active and retired military forces and their dependents ($12.8 billion); and the Indian Health Service runs facilities for Native Americans (71). State and local jurisdictions run psychiatric, municipal, and county hospitals. In 1991 the aggregate cost for these government-run programs was $81 billion (72).

Health Care Spending

Spending on health care increased from $70 billion in 1950 to $752 billion in 1991 (both in 1991 dollars) (71). Part of this rise is explained by population growth, but even looking at per-capita spending, spending grew fivefold.

At least five factors are frequently offered as having contributed to this increase.

1. The spread of *private insurance* had reduced out-of-pocket medical payments to 27 percent of the total by 1983, reducing the direct cost to the consumer and probably increasing use of services to some extent.
2. The *price of health care services* has also increased substantially, although changes in the content and quality of care make it difficult to compare prices over time.
3. *Aging of the U.S. population is* commonly cited as an important contributor to rising costs because per-capita health care spending increases dramatically with age. Currently, a large proportion of lifetime health care spending occurs in the last year or two of life, and the benefits of some of this spending are unknown and increasingly questioned. No easy approaches to prospectively identifying and eliminating unneeded care exist, and elder] y patients are likely to continue to receive high-intensity services for the foreseeable future.
4. The costs of *defensive medicine* are often cited as increasing health care spending. Premiums for malpractice insurance totaled 0.8 percent of total health care spending (about $5 billion) in the United States in 1989. It has been argued, however, that a substantial number of services (mainly diagnostic tests) are prescribed primarily or solely for the purpose of avoiding malpractice litigation and that spending attributable to defensive medicine may add up to much larger amounts (1). One high estimate reports that the US health care liability system costs nearly $45 billion per year, or about 5 percent of total of health care spending (73). Some decisions said to be motivated by malpractice may also be driven by physician uncertainty, fear of patient harm, and other reasons, and it is therefore impossible to make rigorous estimates of the true economic impact of defensive medicine (13 1).
5. Many analysts have argued that changes in the availability and use of *medical technologies* have made the largest contribution to increased health care spending. Individual new technologies may sometimes offer a less expensive alternative to more expensive lder approaches; however, total spending may still increase as a result of increased total utilization (11 1,1 18). Furthermore, many new technologies are introduced at a considerable increase in the costs of providing care. It is generally believed that a substantial fraction of increases in health care spending can be traced to greater use of increasingly sophisticated medical technologies, although it is impossible to quantify this (1).

Measures intended by the government to control health care costs over the years have largely failed. The system relies heavily on market incentives and the profit motive as driving forces in financing and organizing care—not only in the private insurance market, the hospital system, and physician services but also in the drug and medical device industries. Expansion (as in the economy as a whole) has been an implicit goal of these enterprises. Because supply-side controls have been virtually impossible to implement, demand-side cost control has been the predominant approach, most often in the form of patient cost-sharing for medical services. The failure of these measures has led to other demand-side controls. such as utilization management and preferred-provider arrangements.

Recent Reform Efforts

In 1993, the United States, at the instigation of President Bill Clinton, embarked on the most ambitious effort to reform the health care system since the enactment of Medicare and Medicaid. The issues that drove the country toward reform are the high and rising cost of the system and the failure to provide adequate health insurance to many. The quality of care, though by no means ignored in the current health care debate, receives most attention as a basis for competition between health plans rather than as a primary concern.

The President proposed a model of reform that would maintain many of the key structural features of the current system, particularly the link between employment and health insurance as well as an industry of third-party payers providing insurance. Significant changes proposed by the President would be that employers would be re-

quired to pay most of the cost of health insurance for their employees, and the government would provide coverage to the unemployed poor. To hold down the increase in health care spending, the proposal seeks to encourage health care organizations to compete for customers (individuals and companies) on the basis of price and measures of quality. Each plan would have to offer a "minimum benefits package" to be specified by the federal government. Cost control would also be implemented by limiting the annual increases in premiums that health plans would be allowed to charge.

By early July 1994, four committees of Congress had proposed alternative health plans, with the expectation that some compromise would be agreed to by the fall of 1994. Several of these included provisions in the President's plan, but softened the most controversial elements, such as control of premium increases and the requirements for employer payments. Other proposals differed more significantly, such as legislation to enact a single-payer system (similar to Canada's) or that would take incremental steps, such as malpractice reform and changes in the rules regarding insurance policies that exclude people with health problems. At some point Congress will have to decide on a fundamental question underlying health system reform: will every citizen be *guaranteed* access to health care services, or will more modest changes be made to reduce some of the major current barriers? The health care system is so large and involves so many individuals, businesses, and powerful stakeholders that the debate has been joined more broadly than with any other public policy issue in recent times. The 1994 congressional session adjourned with no action on health care reform, however.

At this point, most health care reform legislation has dealt primarily with issues of financing and has paid relatively little attention to the potential impact of reform on medical technology. Neither has much progress been made in deciding how health care services will be selected for inclusion in the standard benefits package. Few proposals would introduce new mechanisms for controlling the development and use of technology. Legislative proposals addressing technology assessment have generally proposed modest increases in funding for agencies that perform assessments and for the development of clinical practice guidelines. There is substantial debate on the potential impacts of proposed cost-containment strategies on technology development, assessment, and use, but current legislation does not attempt to address these consequences. For that reason it is likely that policy makers' interest in the management and assessment of medical technology will continue to intensify over the next decade.

HEALTH-RELATED RESEARCH AND DEVELOPMENT

Spending on basic research in health care is the necessary first stage in the development of every new technology, and the level of funding for basic research has an important impact on the rate at which new technologies are generated. The United States spends more than any other country on health research and development (R&D), although it is second to Sweden in terms of per-capita spending on biomedical R&D (103). In 1989 the health R&D budget for the federal government was $9.2 billion, and U.S. industries spent an additional $9.4 billion.[2] Total national expenditures on health-related R&Dare estimated to have risen by 50 percent (in nominal terms) between 1983 and 1992 (149).[3]

National Institutes of Health

The National Institutes of Health (NIH) receives the majority of the federal health R&D money, and most of that money (about 80 percent) goes to

[2] State and local governments and private nonprofit foundations are the other significant supporters of health R&D.

[3] Measured in constant dollars using a biomedical research price index adjuster.

universities and research institutions in competitive grants and contracts.[4] NIH is part of the Public Health Service of the U.S. Department of Health and Human Services. All areas of medicine and public health are covered to some degree by the 15 separate institutes, each of which operates with considerable autonomy.

NIH spends considerably more on basic science research ($4.1 billion in 1989) than it does for clinical trials of medical treatments in humans ($519 million in 1989). Over three-quarters of the clinical trials budget is expended by the National Cancer Institute (NCI), the National Institute for Allergy and Infectious Diseases (NIAID), and the National Heart, Lung and Blood Institute (NHLBI) (149). Most of the trials are devoted to evaluating new interventions, such as cancer treatment protocols and new treatments for complications of AIDS.[5] Little is devoted to studies of existing treatments, even though the effectiveness of many of them is unknown and questioned.

Historically, the investigational methods supported by NIH have been limited to basic science research and clinical trials. Recently NIH has begun devoting a small fraction of its funds to other methodologies, including meta-analysis and cost-effectiveness analysis and, quite recently, to data collection on cost and measures of functional status within the clinical trials it funds.

Pharmaceutical and Medical Device Industries

Drug and medical device manufacturers in the United States expend considerable resources evaluating products during the development stages and in post-marketing studies. About two-thirds of the $9.4 billion spent by industry on health-related R&D in 1989 was spent by pharmaceutical companies (88), and about one-third by device manufacturers (149).

This investment in R&D is associated with substantial successes in the development of new medical technologies. Like any competitive industry, pharmaceutical manufacturers devote considerable resources to promoting existing products. In fact, the particular forces surrounding the U.S. drug industry have prompted drug manufacturers to spend as much or more on advertising and promotion of their products (estimated in one study at 24 percent of sales (22)) as they do developing them (about 15 percent of sales (88)). In total, marketing expenses for the drug industry in 1990 were estimated at over $5 billion (23). With the combination of heavy investment in R&D, substantial promotional efforts, and a health care marketplace that has placed few restraints on pricing or utilization, the U.S. pharmaceutical industry has enjoyed healthy profits over the last two decades.[6] Some of the resulting products represent important advances in therapy, but many others provide little or no significant incremental benefit over existing products. In any case the increasing revenues of this industry are supported by public and private health care spending. To the extent that health care spending is perceived as a problem, a highly profitable drug industry exists at the price of exacerbating that problem.

CONTROLLING HEALTH CARE TECHNOLOGY

Marketing Review of Pharmaceuticals

The Food and Drug Administration (FDA) within the Department of Health and Human Services has responsibility for ensuring the safety and efficacy of drugs and biologics as well as medical devices.

[4] About 10 percent of the NIH budget is devoted to the intramural work of NIH researchers.

[5] It is difficult to determine the precise distribution of trials supported by NIH because no comprehensive database exists on the topics addressed.

[6] A recent OTA report on the pharmaceutical industry determined that the profitability of this market was greater than that of other industries with comparable investment risks (128).

Under the Federal Food, Drug, and Cosmetic Act (FDCA) as amended in 1962, drugs and biologics must be demonstrated to be safe and are held to a standard of "substantial evidence that the drug will have the effect it purports . . . consisting of adequate and well-controlled investigations, including clinical investigations" (Federal Food Drug and Cosmetic Act, Sec. 505(d)). The procedures and standards applied by FDA are widely perceived to be among the most rigorous in the world. The drug approval process, which has changed only incrementally since the 1962 amendments, involves three phases of study in humans, progressing from simple toxicity and dosing studies in small numbers of healthy volunteers to randomized clinical trials, usually involving hundreds of patients with the target clinical condition.[7]

Regulatory approvals by FDA do not consider data on the costs of therapy, nor do they consider efficacy relative to currently marketed products or nondrug alternative therapeutic strategies for a given clinical problem. FDA approval indicates simply that a product is considered safe and effective for a specified clinical indication and does not provide a basis for "controlling" the use of a product. Congress is considering legislation that would provide incentives to drug companies to conduct studies comparing the effectiveness of their products to existing therapeutic alternatives (165). However, no consideration is being given to making such comparisons a regulatory requirement.

Drug development in the United States is expensive; most estimates hold that it costs in the range of $200 million to bring a new drug to market (22,128). Part of this expense is a function of the time required to complete clinical testing (about six years on average) and to obtain FDA approval for a new drug (between two and three additional years (22,63). Because of the length of time required for drug approval and the associated expense, FDA has been under pressure from Congress and the drug industry to take steps to expedite new drug approval. In part, Congress and the pharmaceutical makers have sought to increase funding to support more FDA staff;[8] the more controversial push, however, has been toward modifying the evidence standards used for drug approval, which affect technology assessment as it relates to pharmaceuticals.

Disease-specific interest groups have added to the pressure on FDA to speed approvals, particularly for drugs to treat serious or life-threatening illness. Persistent efforts of AIDS activists resulted in two major regulatory changes in 1992 for drugs used for life-threatening illnesses, including AIDS. The first is a "parallel-track" program, in which patients outside clinical trials can have access to drugs before they are approved, while they are also being tested in randomized trials. Under the second regulatory change drugs may be approved in some cases by showing improvement in a "surrogate marker" (such as T-cell counts in AIDS) rather than actual clinical benefit to patients. This provision is limited by intent to cases in which a clinical correlation between the surrogate marker and clinical benefit is accepted; however, at least one AIDS drug has already been approved on this basis, with considerable uncertainty about whether it is actually beneficial to patients. Drugs approved through this mechanism are subject to greater post-marketing surveillance requirements and streamlined procedures for market withdrawal in the event of unexpected adverse effects, but these provisions have not yet come into play. A major countervailing pressure on reductions in the pre-approval testing of drugs is the possibility of significant undiscovered toxicities associated with use. Drug manufacturers and FDA are quickly held accountable for any adverse effects produced by these products.

[7] A more complete description of the FDA drug approval process is available in (128).

[8] In 1992, Congress passed legislation allowing FDA to collect "user fees" from drug companies submitting drug approval applications and to use these funds to hire additional reviewers (PL 102- 571).

Another approach to speeding the development and approval of drugs is the Orphan Drug Act, which was passed by Congress in 1983 to provide incentives for the development of drugs aimed at uncommon clinical problems (expected to be economically unattractive). The original law provided tax credits for research, FDA assistance with meeting regulatory requirements, and seven years of marketing exclusivity for eligible products (Orphan Drug Act, P.L. 97-414). Most policymakers consider the law successful, and by 1992 more than 60 new drugs had been approved. Several of the products approved as orphan products have in fact been extremely profitable and expensive (e.g., human growth hormone, erythropoietin), and for several years Congress has attempted to amend the act to remove the market protection for such products. The difficult of refining this law is a potent illustration of the influence of economic stakeholders on the federal legislative process.

Marketing Approval for Medical Devices

Over the past 15 years, as medical devices themselves have become more sophisticated, expensive, and potentially hazardous, they have come under greater regulatory scrutiny. Before the Medical Device Amendments to the FDCA were enacted in 1976, medical devices were subject only to basic quality control standards, and no information on safety or efficacy was required for their approval. Problems with intraocular lenses, pacemakers, and intrauterine devices first brought this regulatory vacuum to the public's attention. The 1976 amendments established a classification system for devices based on level of potential risk and applied increasing regulatory scrutiny to those devices posing greater risk (with some major exceptions for existing devices and new ones similar to existing ones) (66). Class I devices are those that present minimal risks (e.g., tongue depressors, stethoscopes, elastic bandages, enema kits) and are subject only to general controls and good manufacturing standards. Class 11 devices present modest and known risks (e.g., hearing aids, hip prostheses, electrocauterizers, urinary catheters, arterial catheters) and are approved based on performance standards established by FDA for that type of device. Class 111 devices pose the greatest potential risk (e.g., pacemakers, ventilators, heart valves, extended wear contact lenses). The manufacturers of these devices must provide FDA with evidence of their safety and effectiveness before they can be approved for marketing. MRI scanners were the first Class III devices subject to pre-market approval (107).

The standard of evidence required for device approval is legally set at a lower level than that required for new drugs. The FDA law requires "reasonable assurance" that a device will be safe and effective for a specified use, as established by "valid scientific evidence" from which experts can reasonably conclude that the device will beeffective (66). This determination would be made on the basis of well-controlled investigations, including "clinical investigations *where appropriate*" (emphasis added) (FFDCA, Sec. 513(a)(2)). In other words, controlled clinical trials may not always be required as they are for drugs. The adoption of this regulatory standard reflects the view that devices pose fewer unanticipated safety problems than drugs, that well-controlled studies are more difficult to perform for devices, that the effectiveness of medical devices is more readily predictable than that of drugs, and that an overly stringent regulatory standard poses economic barriers that would discourage the development of beneficial medical devices (35). In practice, it means that the clinical utility of medical devices must often be established in clinical trials conducted after approval, and in the absence of such studies, optimal clinical use of the devices may never be clearly defined.

The 1976 law also allowed approval of some class III devices *without* proof of safety and effectiveness if the manufacturer claimed they were "substantially equivalent" to a device marketed before 1976 (the "510(k) exemption"). This path to approval has been well worn because it is the fastest and least expensive means of obtaining approval for new devices, and the precise definition of "substantial equivalence" was not carefull y de-

fined until recently. For example, the use of laser catheters to open clogged leg arteries was approved through the 5 IO(k) process because it was judged substantially equivalent to the use of a catheter with an inflatable balloon on the tip. This laser treatment diffused rapidly in the United States until it was shown in clinical studies to be less effective than several safer alternatives. The 5 IO(k) approval meant that few clinical data were collected prior to the regulatory clearance of these devices. In 1990 Congress passed the Safe Medical Devices Act (P.L. 101-629), which imposed more stringent data requirements on devices for which 5 10(k) approval was sought. The number of devices approved through this route has since decreased, and review times for 5 IO(k) applications have increased.

Medical devices that were on the market before enactment of the 1976 amendments have been allowed to remain on the market through a"grandfather" clause in that law. However, FDA has recently begun demanding that manufacturers provide clinical data for certain devices, some of which now serve to illustrate the potential hazards of limited characterization of seemingly safe devices. Silicone breast implants, in wide use since before 1976, have been increasingly suspected of causing systemic autoimmune disease. In 1992 FDA withdrew its approval for their use, and the largest maker of these devices recently agreed to pay several billion dollars to implant patients as part of a class action suit.

Before approval, devices in the later stages of testing may be sold for use in clinical trials that will provide data for the FDA approval application, through an Investigational Devices Exemption (IDE). This allows manufacturers to recoup the cost of devices used in clinical trials (66). For most IDEs, FDA requires that the study design is adequate, that investigators are qualified, and that data are collected expeditiously; however, there is no limit on the number of units that may be installed under an IDE (107). In practice, a number of medical devices have been designated investigational while being widely used, and it is unclear whether the primary intent of these studies is to establish market share or to collect systematic data on clinical performance. For example, home uterine monitors to detect premature labor have been FDA-approved for use in women with previous preterm deliveries; however, they are being sold under IDE status for use in women considered to beat *risk* for pre-term labor. This contributes to use of these technologies in clinical practice without the benefit of studies demonstrating clinical benefit. Similarly, MRI scanners were sold under IDE status and were in widespread use prior to full regulatory or clinical assessment.

Insurance coverage for FDA-approved devices is not as automatic as it is for drugs, reflecting the lower standard of evidence required for approval and the often high pricetags of medical devices. Increasingly, Medicare has refused to pay for devices that are FDA approved even though their standards for coverage are nominally the same as FDA's for approval. For instance, breast thermography and lower-extremity pumps for venous insufficiency are FDA approved but not paid for by Medicare. Medicare has suggested that its interpretation of effectiveness applies to use in common practice rather than evidence supplied by the manufacturer. These differences also reflect the differing pressures that agencies face when making decisions regarding technology.

Like drugs, devices can be used by physicians for any clinical purpose after FDA approval has been granted for a single clinical indication. FDA laws prevent a company from labeling or promoting a product for uses beyond the one(s) for which approval was granted, but other uses are often discussed and promoted in journals and professional meetings. Unapproved use (also known as "off-label use") of both drugs and medical devices is common, and often supported by evidence, and it can be considered state-of-the art. For example, a February 1994 consensus conference held by NIH on *Helicobacter pylori* (a bacterium) and peptic ulcer disease concluded that all patients with new or recurrent ulcers should be given one of three combinations of drugs, none of which had been approved by FDA for that indication. Nonethe-

less, many off-label uses are not supported by evidence, and insurers have attempted to use that fact to deny coverage, although they have not been very successful.

There is considerable concern and debate about the effects of approval requirements on innovation in medical devices. Manufacturers argue that the approval process increases the cost of development and limits the speed with which new devices can be invented and put to use (35). Some Members of Congress, however, have been concerned that regulatory requirements for certain devices (e.g., heart valves, donor tissue, breast implants, penile prostheses) are not strict enough, and they have been urging standards with greater information requirements. Other Members hope to force FDA to streamline the management and procedures of the device approval program. Finally, a recent FDA internal report has found that many clinical trials submitted in applications for FDA approval are inadequately designed and conducted (146). Device regulation, it appears, is destined for changes over the next few years.

Technology Control Through Health Planning

The most prominent governmental attempt to control the diffusion of medical technology through a regulatory program grew from the National Health Planning and Resources Development Act of 1974. Under that federal law, each state was required to establish a mechanism for reviewing and approving hospital purchases of expensive technologies and other capital expenditures (costing more than $150,000) through a certificate-of-need (CON) program. States complied at least in part because federal funding for some state-run public health programs was contingent on their enacting CON legislation (50). The laws were intended to promote the rational introduction of new technologies, encourage equitable distribution of high-priced technology within each state, and hold down costs. Federal requirements for and funding of state health planning agencies was discontinued in 1986, but about 30 states have continued without federal support.

The original federal law left the design of CON programs to the states, setting out no specific procedures or criteria for approving projects. Not surprisingly, states took approaches ranging from automatic approval of all applications (e.g., California, Arizona, Utah) to defining strict limits on the number of devices that would be permitted in hospitals within the state (e.g., New York, New Jersey, Illinois) (109). Massachusetts instituted a strict planning program for MRI that combined CON procedures with payment rate regulation (50).

The perception is widespread that CON laws failed to control health care costs and were usually ineffective in promoting the rational introduction and use of new technology (13, 15). CON efforts to control the supply of acute care beds may have been more successful, but one such program that decreased bed supply was also associated with an increase in overall hospital costs (99). More stringent CON programs have been credited with slowing the purchase of MRI units located in hospitals but not the total number of MRI facilities (50,1 15). In New York State, regulatory policies related to cardiac surgery facilities may have reduced inappropriate procedures (see case study).

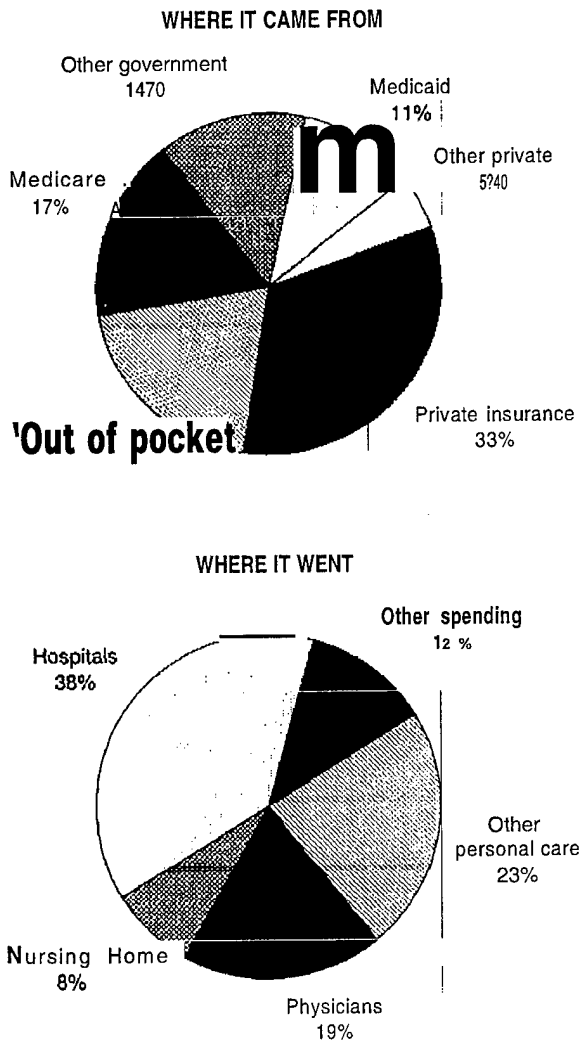
Three reasons are most commonly cited for the failure of CON programs. First, many programs were highly political and subject to manipulation by special interests rather than being guided by clinical requirements. Second, it was (and remains) difficult to quantify the "need" for specific technologies (49). Finally, because CON laws applied only to purchases of hospital equipment, technology in outpatient facilities was not affected (50). Underlying the failure of CON programs may have been the simple problem that the CON decisionmaking boards did not have powerful incentives (such as financial risk) to motivate them to deny purchases in difficult situations when faced with a variety of professional, public, and political forces encouraging approval (95).

Payment, Coverage, and Utilization Controls

A patchwork of mechanisms has developed in the absence of structural or legal limits to growth of health care spending. Pushing against these are forces compelling greater spending, at least in part through the use of increasingly expensive medical technology. These forces exist in every country, but the United States consumes substantially greater amounts of costly medical care than other developed countries. This section describes some of the policies, programs, and funding strategies designed to promote efficiency and economy in the use of medical technology.

Financing mechanisms, coverage policies, and utilization controls have assumed increasing importance in efforts to dampen rising health care costs. The common element of these approaches is limiting the use of medical services. In the 1980s most efforts to control technology were based on the perspective that increased scrutiny of medical practice and some general economic constraints would be sufficient to keep costs under control by "rationalizing" the use of care. The failure of the health care industry to respond to those too-subtle cues has led to the recognition that more information on the risks, benefits, and costs of alternative practices are needed, along with strong incentives for all parties to use this information. The federal government has direct control over payment for health care through the Medicare program and, to a lesser extent, the Medicaid program. The payment policies of these programs have influenced the greater health care market, as well.

FIGURE 9-1: The Nation's Health Dollar: 1990



NOTES Other personal care includes dental, home health, and drugs Other spending includes public and private Insurance administration, research, and construction

SOURCE K R Levit, H C Lazenby, C A Cowan, et al , "National Health Expenditures, 1990," *Health Care Financing Review 13(1) 29-54,* fall 1991

Coverage and Payment Mechanisms Under Medicare

About 16 percent of all U.S. health care spending flows through the federal government's Medicare program, a larger share than any other single payer (see figure 9-1) (20). Because of its market share, Medicare payment and coverage policies strongly affect the behavior of health care organizations, clinicians, and patients. Furthermore, many private payers are influenced in coverage and payment policy by decisions made regarding the Medicare program.

In considering new technology, the Medicare program makes basic decisions on: 1) whether any

use of the technology should be covered, 2) whether coverage should be limited to particular clinical circumstances, and 3) if a technology is covered, how much should be paid for its use (109). Coverage decisions determine whether physicians will be paid for using a technology (e.g., radiologist interpretation of computed tomography (CT) scans), whether outpatient use of the technology will be covered, and whether the cost of purchasing and operating medical equipment will be reimbursed by Medicare (see below). The Medicare coverage process exerts substantial influence on the adoption and use of new medical technologies, particularly devices that are expensive to buy and operate (107).

A factor *not* considered in Medicare coverage decisions is cost-effectiveness (or cost); however, considerable interest (including a proposal from the Medicare program) in using cost as a criterion has been extant since the mid- 1980s. In reform discussions. there was a proposal to offer a drug benefit as part of the Medicare program, and some policy makers suggested creation of a panel that would have to approve addition of new, high-cost drugs before they could be covered under this new benefit. Substantial opposition by the biotechnology industry to such a committee makes its establishment virtually impossible

New technologies may be covered by the Medicare program through several different mechanisms. First, clinicians or hospitals may begin using anew technology as a substitute for existing technology and bill for it using existing payment codes. Earl y laparoscopic removal of the gallbladder was often billed for use as the traditional open gallbladder surgery. A second mechanism for payment decisions is approval by the local insurance company that is under regional contract to the federal government to administer the Medicare program (such companies are called intermediaries or regional carriers). The medical directors of these local insurers are responsible for ensuring that payments are made only for "reasonable and necessary" services. The third coverage mechanism entails a payment decision to be made at the national level by the coverage policy office in the Health Care Financing Administration (HCFA), the federal office that administers the Medicare program. HCFA uses a group of physicians in the Public Health Service who either make a group decision on coverage policy or refer it to the Office of Health Technology Assessment (OHTA) for a more comprehensive review. OHTA then makes a coverage recommendation to HCFA, which makes the final coverage decision. The role of OHTA is discussed below.

HCFA Coverage Standard

The law underlying Medicare coverage policy prohibits payment for "items or services which are not reasonable and necessary" (Social Security Act, Section 1862(a)(l)(A)). Although HCFA has never defined the terms "reasonable and necessary" in regulations, it has stated that a service should be safe and effective, appropriate, and not experimental (134). Judgments concerning safety and effectiveness are to be based on authoritative evidence or general acceptance in the medical community. Experimental is defined as investigational (anything that is provided for research purposes), or as subject to approval but not yet approved by FDA. Even absent evidence of safety and effectiveness, practices that are generally accepted in the medical community may *not* be considered investigational. Finally, "appropriate" means that a service is provided in the proper setting by qualified personnel. For uncommon, serious, or life-threatening conditions, Medicare may allow coverage for services even though effectiveness has not been demonstrated: "the standards for safety and effectiveness are less stringent when evaluating breakthrough medical or surgical procedures" (134). A lower threshold of evidence for life-saving therapies means that Medicare coverage procedures can provide an explicit avenue by which costly, unproven treatments may be paid for and diffuse widely.

Technologies that diffuse rapidly before there is appropriate evidence of effectiveness may be covered by Medicare based solely on their frequency of use. This was the case with MRI (although most uses would have been covered in any case). Services that are not subject to proof of effectiveness by FDA, such as procedures and de-

vices deemed substantially equivalent to existing products, are particularly likely to enter general practice without being supported by evidence of effectiveness and to be covered without question by Medicare.

Medicare's Prospective Payment System for Hospital Care

The development and use of technology may be influenced powerfully by the mechanisms through which hospitals and doctors are paid for the care they provide. A predetermined lump-sum payment for hospitalization by diagnosis, for example, creates substantially different pressures than a system in which services are paid for on a cost basis after they are provided. Until 1983, hospitals were paid by Medicare based on their costs, creating a reimbursement environment that allowed acquisition and use of new technologies with little consideration of cost (107). Prospective payment to hospitals through diagnosis-related groups (DRGs), begun in 1983, substantially altered the financial incentives faced by hospitals. The DRG program sets a fixed price for each hospitalization based on the primary diagnosis, patient's age, comorbidities, procedures, and complications. All hospitalizations are classified as one of 494 DRGs (in 1993) for which prices have been determined initially using historical patterns of care. DRG payment rates are updated regularly at the recommendation of the congressionally appointed Prospective Payment Assessment Commission (ProPAC), which carries out detailed analyses of medical practice.

Because DRG payment does not increase when additional services are provided, the policy created new incentives to be efficient in the hospital care of Medicare patients. In theory, prospective payment should encourage the introduction of cost-saving technologies, such as those that reduce the length of hospitalization or substitute for more expensive tests, and should provide a disincentive for technologies that increase costs, whether or not they would benefit patients. For existing technologies, DRGs would favor underuse as long as hospital stay was not prolonged and adverse events did not increase.

Two aspects of the DRG updating process have important implications for technology use. Individual DRG payments are updated on a regular schedule to account for new technologies associated with specific diagnoses; therefore, decisions made by HCFA (based on recommendations by ProPAC) concerning the likely cost and clinical effects of new technologies can send an important economic signal. Second, an adjustment factor is applied to all DRGs that is meant to allow for scientific and technical advances in health care. This adjustment is an estimate based on a review of specific emerging, quality-enhancing, cost-increasing technologies and is intended neither to inhibit nor to promote adoption of new technologies. ProPAC has recommended increased total DRG payments for 1995 of over $300 million dollars for advances in science and technology, sending a modest but positive signal to the health care technology industry (38,92).

Capital Equipment Payments Through Medicare

Until 1992, Medicare reimbursed hospitals for the cost of new medical equipment (capital costs) by allowing them to bill for depreciation, interest payments, and rental fees while paying for operating expenses through DRG payments. Capital costs have been full y covered as long as use of the technology is approved by Medicare, essentially providing a federal subsidy for acquisition of new equipment and possibly encouraging preferential spending on equipment over labor or other operating expenses (107). Beginning in 1992, Congress established a new method paying for capital costs through Medicare, to be phased in over a 10-year period, which includes a fixed capital cost payment added onto each DRG. Hospitals that spend more on capital investments no longer get increased payments from Medicare to cover these capital expenses, thereby removing a financial incentive to introduce expensive technologies unless they are cost reducing (92).

Physician Payments Under Medicare

In 1989 Congress responded to persistent increases in Medicare payments to physicians by replacing the "usual, customary, and reasonable" (UCR) method of physician payment that had been in place for the previous three decades with a resource-based relative values scale (RBRVS) that allows Congress to establish the payment rates for medical services, control the rate of increase in payment rates, and control the increase in the number of services provided. Rates under RBRVS are determined by considering physician's time and effort as well as the expenses of practice.

The new system is seen as correcting an imbalance that had grown worse over the years between payment for "procedures," which were highly paid relative to time and expense and "cognitive services" (i.e., services such as diagnosis by history and physical exam, preventive counseling, patient education, and soon) which have historically been paid poorly relative to time and expenses. Increases in payments to physicians in the mid-1980s were driven strongly by procedures such as cataract surgery, endoscopy, total knee replacement, hip replacement, hernia repair, and coronary artery bypass graft surgery, all of which were reimbursed at high rates (86). Studies during the same period showing geographic variation and high rates of inappropriate utilization of some of these services raised hopes that payment tools could be used to reduce services without compromising the quality of care. Under RBRVS, cognitive services are given relatively greater weight, whereas procedures (especially those that take little time) may be less generously reimbursed. The hoped-for effects are greater attention on the part of physicians to preventive and other primary care services; a gradual increase in income for primary care providers; an eventual increase in the supply of generalists; and a decrease in use of expensive technologies by specialists.

Another new feature of the payment system is the volume performance standard, which is designed to control increases in the total volume and intensity of services provided. Each year Congress will decide what increase in total physician expenditures will be allowed, taking into account general inflation, changes in technology, evidence of over- or undersupply of services, and distribution of services among the population. Once the expenditure target has been set, spending over the target will result in downward adjustments across the entire fee schedule (55). Such a payment mechanism is anticipated to offset any tendency for physicians to respond to reduced fees by increasing the number of services they provide. The actual impact on utilization of services is unclear: some evidence suggesting that the anticipated increase in volume of services did not occur when physician Medicare fees were reduced, but other studies document a strong behavioral response to reduced fees (11 6).

Managed Care

One of the most significant recent changes in the U.S. health care system is the growth in the number and variety of managed care plans. Health maintenance organizations (HMOS) and preferred provider organizations (PPOS) are only the best-known examples, and within these categories there are numerous variants. What all managed care plans have in common is the primary goal of reducing costs through payment policies that create financial incentives for cost-effective care and individual case management techniques. Policies include negotiation of discount rates with providers or agreements that make providers share the financial risks of the cost of care. Utilization management (UM) techniques, used to influence care at the level of the individual patient, have included preadmission certification, second-opinion programs, high-cost case management, and others described below.

The increase in managed care enrollment has been most pronounced for workers who receive health coverage through their employers. Although only a small minority of such employees belonged to such plans in the early 1980s, by 1993 more than half were enrolled in managed care. Furthermore, for the minority who remained in the indemnity insurance program, the vast majority are subject to UM programs. In 1984,5 percent

of fee-for-service insurance plans used some form of UM service, and in 1992, only 5 percent did not (37,45). Because of these trends, the differences between managed care programs and traditional indemnity insurance are decreasing. By virtue of the increasing prevalence of UM in both managed care and indemnity insurance programs, it is an increasingly important source of influence on use of medical technology.

Utilization Management

All the various forms of UM involve 1) collecting data on what was wrong with patients and how they were (or will be) treated, and 2) applying preset algorithms to identify care that may not be appropriate. With a few exceptions UM has been targeted at determining whether in-patient hospitalization is required for particular medical problems and what length of hospital stay is necessary. A small but growing number of organizations are applying more detailed algorithms to specific conditions and medical services, and some are devising methods for translating practice guidelines into review criteria.

Individual hospitals report working with up to 250 different review organizations which approve and monitor their care for different payers. UM organizations may specialize in areas such as mental health, drug utilization, or high-cost case management; some cover all areas.

Initial efforts to control utilization in the Medicare program consisted of a requirement that hospitals establish committees to review the quality and necessity of care. By avoiding a government review program, this policy satisfied the stipulation in the preamble of the legislation that created Medicare, which prohibits federal "supervision or control over the practice of medicine or the manner in which medical services are provided." As costs continued to rise and the perception grew that hospital review was ineffective, Congress passed legislation in 1972 creating professional standards review organizations (PSROs)-community-based, physician-controlled organizations that set practice standards and reviewed institutional care. The limited effectiveness of PSROS led to the establishment of statewide programs of utilization and quality-control peer review organizations (PROS), which have also not been particularly successful in controlling utilization or improving quality of care (58). In part the limited impact of Medicare review can be attributed to its focus on surveillance mechanisms to identify markedly substandard care. In 1992 HCFA announced a new approach to reviewing care that is based on analysis of patterns of care rather than case-by-case review, adopting some of the principles of continuous quality improvement for the program (62).

Physician Profiling

Physician profiling examines individual physicians' patterns of treatment—in particular, their use of specific procedures (e.g., cesarean section, hysterectomy) and compares them with defined standards or average practices. Profile information is used to encourage physicians to alter their practices if they are "inappropriate" or possibly to select physicians for a network of providers in a group practice arrangement. The use of profiling is growing rapidly, and health reform proposals may encourage its further use by emphasizing development of computerized data and patient records and by linking the use of profiles with quality-of-care measurement.

Profile information has been associated with significant changes in the use of medical technologies in some cases. A Chicago hospital was able to decrease cesarean section rates by encouraging physicians whose rates were high to modify clinical decision strategies (82). The Maine Medical Assessment Foundation (MMAF), which brings together physicians to discuss variations in the rates of use of common procedures, reported reductions in lumbar disc surgery, admission for pediatric asthma, cesarean section, and hysterectomy using physician profiling and feedback (77). Although profiling is unlikely to be the sole explanation for these results, the comparative practice information did serve in each case as a basis for applying other forces to change practice.

Simply comparing rates of practice or outcomes of care has its limits, however, as average, lowest, or highest rates may not in fact be the "correct"

rates. Increasingly, technology assessment is being used to provide an objective standard against which existing practices are compared. The increasing use of profiling represents a movement away from case-by-case review of patient care and is considered less burdensome by physicians—and easier as a result of better systems for collecting computerized clinical data.

Effectivenessof UM

The impact of UM has been largely unevaluated. Certainly, the increase in health care costs over time does not seem to have been substantially influenced by the rapid increase in use of UM, but it is impossible to know what the cost trend would have been without it. Positive effects have been reported in the few studies of UM that have been published. In one case, claims data from 200 insured groups over a four-year period showed an immediate 6 percent decrease in health care costs after implementation of preadmission and concurrent review; however, there were no additional changes noted over the study period (32). Other evidence suggests, however, that in-patient savings from UM may be offset at least partially by increasing costs of out-patient care. Few studies have addressed the significance of changes in decisionmaking associated with UM for the quality of patient care. Patient outcomes usually have not been measured, nor has the appropriateness of use of services been evaluated (58).

Systematic studies of the influence of managed care on the purchase and use of medical technologies have not been performed, debate continues on the extent to which managed care plans are able to produce savings (1 30). To the extent that such plans force providers to operate within fixed budgets, the financial incentive to provide access to more costly technologies would be reduced. Many of these plans have established committees that discuss the need for and appropriate use of new technologies; these committees have occasionally decided to limit the availability of some technologies. For example, one large HMO decided that a new FDA-approved drug for Alzheimer's disease should not be included on the plans formulary. However, when another HMO decided not to provide a bone marrow transplant for a patient with breast cancer, it was required by a jury to pay an $89 million fine. The specific effect of managed care on the management of health care technology may be unpredictable, but it is clearly exerts an important and growing influence.

HEALTH CARE TECHNOLOGY ASSESSMENT

Federal Health Technology Assessment

Several developments in the mid- 1970s are commonly associated with rising interest in health care technology assessment. Breakthrough technologies, such as renal dialysis and CT scanning, promised great potential benefits at enormous costs at a time when national health care spending already was considered at a crisis level. At the same time large gaps in information on medical technologies were increasingly recognized, and exposed the possibility that money was being spent on ineffective treatments. One prominent health economist (Victor Fuchs) captured these concepts in the notion of "flat-of-the-curve" medic ine, a reference to the shape of the cost benefit curve at increasing levels of expenditure. Among the analytically oriented, these factors contributed to a growing interest in examining the benefits and costs of medical technologies in a systematic way.

The economic and clinical importance of the failure to evaluate technology was first made concrete by several studies of CT scanning, and was highlighted by a 1978 report from OTA (121). This 1978 study provided examples of many common medical practices supported by limited published evidence and concluded that information on safety and efficacy of most technologies "may be inadequate to allow the rational and objective utilization of medical technologies." The report provided an argument for a more systematic, coordinated and active role for the federal government in conducting or promoting systematic evaluations of technologies (122).

In 1978 Congress created the National Center for Health Care Technology (NCHCT) to advise Medicare and Medicaid on coverage decisions, provide technology assessment information to health planning agencies, establish priorities for technology assessment, and help develop methods for evaluating the safety and efficacy of medical technology (34). The Center was directed to consider broadly the implications of new and existing medical technologies, including their legal, ethical and social aspects. A National Council on Health Care Technology, composed of 18 members who included scientific experts, technology industry representatives, clinicians, lawyers, ethicists, and members of the general public, was created to advise NCHCT (87). This ambitious agenda was funded at a modest $4 million per year.

During three years of operation, NCHCT published three broad assessments of high-priority technologies and made about 75 coverage recommendations to Medicare (87). Despite its apparent value and success, NCHCT was put out of business by Congress in 1981, a casualty of the political climate under which it operated. From the time of NCHCT'S establishment, the medical profession and the medical device industry opposed it (87,94). An AMA representative testified before Congress in 1981 that:

> . clinical policy analysis and judgments are better made—and are being responsibly made—within the medical profession. Assessing risks and costs, as well as benefits, has been central to the exercise of good medical judgment for decades. The advantage the individual physician has over any national center or advisory council is that he or she is dealing with individuals in need of medical care, not hypothetical cases (87).

AMA may have seen the functions of NCHCT as a move in the direction of greater federal involvement in medical decisionmaking, particularly NCHCT'S role in recommendations to enforce government-sponsored judgments on coverage.

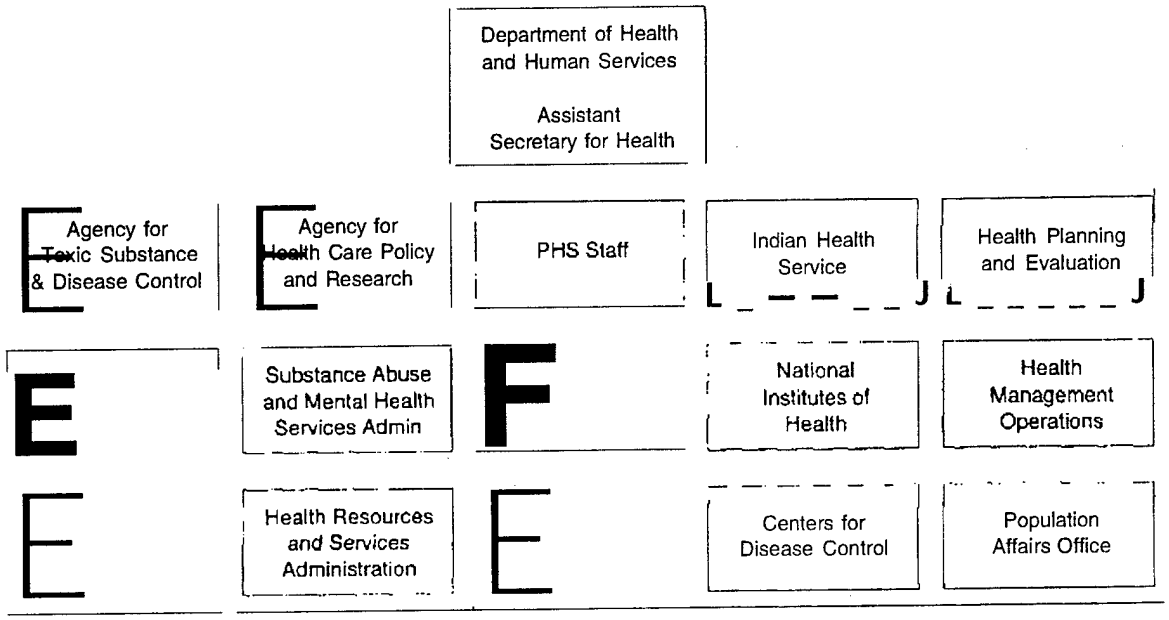
The medical device industry objected to NCHCT'S compiling a list of emerging technologies and argued that early assessments might stifle innovation. It also argued that assessments could' be undertaken by existing federal entities and that the Center was therefore redundant. It seems likely that the major cause for the industry's concern was the potential for new devices to fail in the market after a negative evaluation from a central government source. This way of thinking persists. In a March 1994 hearing on the Clinton health care reform proposal, the device industry trade association representative testified that "no single provision of health reform could work greater harm on medical innovation or patients in this country than national assessments of technologies before they could be used by local plans" (46).

In addition to opposition from AMA and the medical device manufacturers, the anti-regulatory climate of the early Reagan administration may have contributed to the Center's demise. When it was disbanded, responsibility for advising Medicare on technology issues was transferred to the Office of Health Technology Assessment (OHTA) within the National Center for Health Services Research (NCHSR), both of which are described below.

Council on Health Care Technology

After eliminating NCHCT, Congress still perceived a need for some capacity to explore the implications of medical technology (124). Responding to a 1984 congressional mandate, the Council on Health Care Technology (CHCT) was formed by the Institute of Medicine (IOM) (part of the National Academy of Sciences). CHCT was intended to be a public-private venture and received "matching" government funding only on the condition that it first obtain private funds (P.L. 98-55 1). CHCT focused primarily on conceptual and methodological issues in technology assessment, such as approaches to priority setting, attention to a wider range of outcomes in assessments, the relationship of technology tissessment to quality assurance, and considerations in assessing diagnostic technologies (94). It produced assessments of only two technologies: the end-stage renal disease program and the artificial heart. From the beginning, the Council's goals were never

FIGURE 9-2: U.S. Public Health Service



SOURCE Office of Technology Assessment 1994

clear, and its need to raise private funds hampered its operation (94). IOM did not seek further public funds for the Council after 1989, and its statutory authorization was allowed to expire. Since 1990 IOM has maintained a smaller effort under public and private funding, its Committee on Clinical Evaluation, which has reported on quality of care, technological innovation, clinical practice guidelines, and outcomes research.

Agency for Health Care Policy and Research

The Agency for Health Care Policy and Research (AHCPR), legislated into existence in 1989, is the newest entity to take on technology assessment for the federal government. It is not an entirely new agency but rather represents the takeover and expansion (in both responsibility and funding) of the National Center for Health Services Research, which had moved during the 1980s from funding traditional health services research into areas verging on technology assessment (e.g., "geographic variation" in medical technology use and measures of "appropriateness" of care). AHCPR is part of the Public Health Service, at the same administrative level as NIH (see figure 9-2). AHCPR'S new responsibilities include launching a major initiative in "medical effectiveness research," developing clinical practice guidelines, and disseminating research findings and guidelines. AHCPR also continues many existing NCHSR funding programs, including basic health services research and an intramural program that collects and analyzes data on national medical expenditures, hospital costs and utilization, and long-term care. OHTA, which continues to provide technology assessments for Medicare. is now administratively within AHCPR.

AHCPR'S 1989 budget was $99 million, with $34 million for general health services research and $38 mill ion for medical effectiveness research and for developing and disseminating practice guidelines (the $38 million goes to the ● 'MEDTEP" program). By fiscal year 1993, funding had grown to $128 million, with $73 million for MEDTEP (141), and the agency employed 277 workers.

Clinical Practice Guidelines

In the legislation creating AHCPR, Congress said that the Agency must produce clinical practice guidelines to "assist in determining how diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically" (P.L. 101 -239). In addition, guidelines are to be used to establish review criteria for assessing the quality of health care. Unstated is the hope and belief that physicians treating patients according to these guidelines will deliver only "appropriate" care and perhaps thereby lower health care costs. These are large aims.

These guidelines have no regulatory force, but intense interest from physician and payer groups suggests that the guidelines are perceived as potentially influential in coverage and other policy-related decisions. At the this early stage, guidelines have not had much impact (in line with previous efforts of the federal government to produce expert consensus on clinical problems) (67). Most successful efforts to change practice using clinical guidelines have involved intensive programs at local institutions to develop and implement the guidelines (80).

AHCPR has not developed a formal mechanism for selecting guideline topics. The selection criteria listed in AHCPR'S legislation include the adequacy of scientific evidence, prevalence of a condition, variation in practices, and total cost of related health services. The first three guidelines addressed acute pain management, urinary incontinence, and prevention of pressure ulcers. In 1992 Congress stated that the process for selecting guideline topics must become more explicit, systematic, and accountable (PL 102-410), and the Agency has contracted with IOM to assist in developing a formal method of priority setting.

The methodology for developing guidelines is evolving over time, but the essential features are an exhaustive literature review, multidisciplinary expert panel discussions, and wide external review. For the AHCPR guideline on cataracts in adults (one of the more methodological y rigorous AHCPR guidelines to date), over 8,000 articles were reviewed (of which 4 percent met criteria for adequate study design). Building on other "strength of evidence" methods (e.g., the Canadian Task Force on the Periodic Health Examination, the U.S. Preventive Services Task Force), the cataract guideline used formal rules of evidence to assess the literature. AHCPR spends in the range of $500,000 to $1 million per guideline, and each takes two to four years to complete (60). By August 1994, 12 guidelines had been issued and a similar number were in various stages of development (see table 9-1).

The guidelines issued so far have been praised for their comprehensiveness but have also provoked controversy. Aspects of the cataract guideline and one on depression were rebutted by groups that disagreed with some recommendations.[9] As AHCPR begins to develop methods for converting the guidelines into standards of qualit y, performance measures, and medical review criteria—which it is required to do by statute—the guidelines may be greeted with ever-lessening enthusiasm by the medical profession. A more recent requirement, that cost information on alternative treatments be included in the guidelines, is likely to produce further debate. Several methodological issues concerning the guidelines will be faced by AHCPR as it continues its work, including the optimal composition of guideline panels, the best strategy for organizing the actual consensus process, and the optimal format for stating recommendations.

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me cataract guidelines were protested by high-volume cataract surgeons who believed that several diagnostic tests were indicated for which the guideline panel could find no evicience. The psychiatric profession felt that the depression guideline did not encourage sufficiently early referral of patients from primary caregivers to psychiatrists.

TABLE 9-1: Agency for Health Care Policy and Research Practice Guidelines

Acute Pain	Released
Prevention of Pressure Ulcers	Released
Urinary incontinece	Released
Depression in Primary Care	Released
Cataracts	Released
Sickle Cell Disease in Infants	Released
Cancer-Related Pain	In progress
Low Back Problems	Released
Benign Prostatic Hyperplasia	Released
Treatment of Pressure Ulcers	In progress
Management of HIV Infection	Released
Otitis Media with Effusion	Released
Congestive Heart Failure	Released
Workgroup of Guideline Translation	In progress
Post Stroke Rehabilitation	In progress
Cardiac Rehabilitation	In progress
Unstable Angina	Released
Screening for Alzheilmer's	In progress
Quaility Determinants of Mammography	Released
Smoking Prevention and Cessation	In progress
Anxiety and Panic Disorder	In progress

SOURCE "Guildelines Being Developed, ' Agency for Health Care Policy and Research, Public Health Service, U S Department of Health and Human Services, Rockville, MD, unpublished document, September 1993, E McGovern, Agency for Health Care Policy and Research Public Health Service, U S Department of Health and Human Services, Rockville, MD, personal communication, Mar 4, 1994, Physcian Payment Review Commission, *Annual* Report *to Congress, 1992* (Washington, DC U S Government Printing *Office*, 1992)

Outcomes Research

In addition to clinical guidelines, AHCPR is mandated by law to investigate the "outcomes, effectiveness, and appropriateness" of health care services. Each term in this phrase has a historical meaning derived from specific bodies of research associated with particular investigators and policymakers. "Outcomes research" is distinguished by its focus on using functional status, patient preferences, and other patient-centered information in evaluating the impact of health services. "'Effectiveness research" refers to average effects of treatment (in contrast with the results of traditional clinical trials) and is associated with the use of large existing databases for analysis (98). Motivation for this initiative derived in part from the existence of a large Medicare database available for analysis and a perceived need to provide some reassurance that the recently enacted DRG program was not forcing sick Medicare patients out of hospitals (94). "Appropriateness of care" is the term of researchers who argued that identifying inappropriate care could lead to large cost savings for the health care system.

Through common and variable usage, "outcomes," "effectiveness," and "appropriateness" have lost their sharpness of meaning and often are referred to collectively as outcomes research. They do, however, share the characteristic of being attempts to find alternatives to randomized trials for determining medical effectiveness. The AHCPR legislation outlines in detail the expectation that the Agency would use existing data and previously published research as an inexpensive and rapid approach to begin filling gaps in medical knowledge. For this reason and because they are so well funded and institutionalized in AHCPR, these "new methods" raise a legitimate source of concern about the direction of technology assessment in the United States.

"Patient outcomes research teams" (PORTS) are the main mechanism by which AHCPR funds outcomes research. Each PORT is devoted to a specific clinical condition, addressing all relevant aspects to determine "what works best, for whom, and at what cost" (140). Fourteen PORTS have been funded as of 1994, each for five years at $5 to $6 million (see table 9-2), and four of those will complete five years in 1994. PORT study methods include literature reviews and meta-analyses, database studies of geographic variation and other patterns of care, targeted primary data collection, decision analyses, and dissemination activities.

A few findings from PORT studies are often cited as examples of their potential to provide important clinical information. Analysis of several hundred thousand patients undergoing cataract surgery and a followup laser procedure has shown a higher rate of retinal detachments than was ex-

TABLE 9-2: Patient Outcomes Research Team Projects (PORTs)

Grants	Project period Start date	End date
Back Pain Outcome Assessment Team U. of Washington, Seattle, WA	9/01 /89	8/31 /94
Consequences of Variation in Treatment for Acute Myocardial Infarction (AMI) Harvard Medical School, Boston, MA	9/07/89	8/31/94
Variations in Cataract Management: Patient and Economic Outcomes Johns Hopkins U., Baltimore, MD	9/07/89	9/29/94
Assessing Therapies for Benign Prostatic Hypertrophy and Localized Prostate Cancer Dartmouth College, Hanover, NH	9/07/89	8/31 /94
Assessing and Improving Outcomes: Total Knee Replacements Indiana U., Indianapolis, IN	4/01 /90	3/31/95
Variations in the Management and Outcomes of Diabetes New England Medical Center, Boston, MA	6/01 /90	9/29/95
Outcome Assessment Program in Ischemic Heart Disease Duke U., Durham, NC	7/01 /90	8/01/95
Outcome Assessment in Patients with Biliary Tract Disease U. of Pennsylvania, Philadelphia, PA	8/01/90	8/31/95
Analysis of Practices: Hip Fracture Repair and Osteoarthritis U. of Maryland, Baltimore, MD	9/01 /90	9/29/95
Assessment of the Variations and Outcomes of Pneumonia U. of Pittsburgh, Pittsburgh, PA	9/30/90	9/29/95
Contracts		
Variations in Management of Childbirth and Patient Outcomes The Rand Corporation, Santa Monica, CA	9/28/90	9/27/95
Secondary and Tertiary Prevention of Stroke Duke U. Medical Center, Durham, NC	8/01 /91	8/01/96
Schizophrenia Patient Outcomes Research Team U. of Maryland, Baltimore, MD	9/30/92	9/29/97
Low Birthweight in Minority and High-Risk Women U. of Alabama, Bumingham, AL	9/30/92	9/29/97

SOURCE U S Department of Health and Human Servercis, Public Health Service, Agency for Health Care Policy and Research, Rockville, MD, 1994

pected from existing literature, and this finding is being explored through primary data collection (61).

In the area of benign prostatic hypertrophy (BPH), studies of claims data showed that rates of complications from prostate surgery were more common than generally believed (159).10 Given these higher rates of complications and results from patient interviews showing that patients were less bothered by symptoms than objective measures of prostatic obstruction had suggested, BPH researchers concluded that patient preferences were the critical variable in choosing treatment for BPH (160). Another finding from the BPH PORT was a higher mortality rate associated with a less invasive method for removing prostate tissue as compared with open surgery, which was a clinically counterintuitive result (97). The researchers felt that unmeasured patient differences

10The studies of BPH preceded the establishment of APHCR and served as the model for what became known as PORTS within the new agency.

might account for these results (i.e., sicker patients were more likely to be referred for the less invasive procedure) and subsequent database studies confirmed that such selection bias had occurred (17). To determine the true difference in mortality between the procedures, a randomized trial was required. Proposals to conduct such a trial were rejected by both AHCPR and NIH because neither sees support of such a trial as consistent with its agenda or resources. The value of observational studies may depend on the ability of the U.S. government to support definitive trials in the areas of clinical uncertainty identified by outcomes researchers.

In 1993 PORT investigators reviewed their experience at a workshop and made suggestions for the future of the program. In general, they sought greater flexibility to determine what methods of evaluation to use, less emphasis on comprehensive meta-analysis when literature is deficient, decreased emphasis on administrative data, and efforts to develop more accurate and clinically detailed databases. The next generation of PORTS is expected to include more primary data collection, but they will continue to emphasize the use of administrative data to study clinical effectiveness.

Because the congressional members who created AHCPR were particularly concerned that the **results** become widely known and applied, a separate division of the Agency was established to disseminate products and findings and to support research on how best to transfer new knowledge, particularly from the guidelines and PORTS, into practice. The Center for Research Dissemination Liaison has distributed millions of copies of guideline documents to consumers and clinicians, although it has only begun to develop a strategy to determine whether practices have changed as a result. The Agency is supporting numerous studies on different strategies for implementing AHCPR guidelines, and results from these should be available in a few years.

Office of Health Technology *Assessment*

Since the beginning of the Medicare program in 1965, a federal office always has been designated to advise the program on whether to pay for specific medical services. Before 1978, questions were handled by the Office of Health Practice Assessment in the old Department of Health, Education, and Welfare and later by NCHCT until it ceased to function in 1981. The Office of Health Technology Assessment (OHTA) was then established in NCHSR. Today it sits under the aegis of the successor agency, AHCPR. OHTA, which makes coverage recommendations for the Department of Defense as well as Medicare, has an annual budget of $1 million per year,[11] which supports a staff of six performing about 15 assessments annually (see table 9-3).

Individual OHTA staffmembers conduct assessments of specific technologies by collecting published literature on their effectiveness, synthesizing it informally, and consulting with FDA, NIH, and other relevant federal agencies to come to a conclusion about whether the technologies are safe and effective. Evidence from randomized clinical trials is usually but not always a necessary ingredient for a positive determination (i.e., that the benefits sufficiently outweigh the risks). No randomized trials of laparoscopic cholecystectomy were available, but OHTA analysis argued that the "risk/benefit ratio of the procedure was similar or superior to that of the open procedure" and recommended that it be approved for coverage (see the case studies below) (52).

By law HCFA cannot consider cost as a criterion for covering medical services, and although OHTA may include cost information in its reports, it does no formal cost-effectiveness analyses. On occasion OHTA has recommended against coverage for procedures that are extremely costly and minimally effective. For example, in OHTA'S assessment of liver transplantation, the five-year

[11] Not in constant dollars; therefore, actual resources have decreased as a result of inflation.

TABLE 9-3: The Activities of AHCPR's Office of Health Technology Assessment (January 1991-February 1994)

	Reviews[a]
1991	Laparoscopic Cholecystectomy
1992	Home Uterine Montoring
	Procuren A Platelet-Derived Wound Healing Formula
	Cochlear Implantation in the Outpatient Setting
1993	Lymphedema Pumps Pneumatic Compression Devices
	Intradialytic Parenteral Nutrition for Hemodialysis Patients
	Small Intestine and Combined Liver-Small Intestine Transplantation
	External and Implantable Infusion Pumps
1994	Electrical Bone Growth Stimulation and Spinal Fusion
	Assessments
1991	Intermittent Positive Pressure Breathing Therapy
	Hyperthermia in Conjunction with Cancer Chemotherapy
	Cardiac Rehabilitation Programs
	Polysomnography and Sleep Disorder Reports
	Single and Double Lung Transplantation
	Measuring Cardiac Output by Electrical Bioimpedance

Upcoming Heart-Lung Transplantation, Plethysmography; Combined Kidney-Pancreas Transplantation

a"Technology Reviews are brief evaluations of health technologies prepared by the Off ice of Health Technology Assessment, Agency for Health Care Policy and Research (OHTA/AHCPR) of the Public Health Service Reveiws maybe composed in lieu of a technology assessment because the medical of scientific questions are limited and do not warrant the resources required for a full assessment the available evidence is limited and the published medical or scientific literature is Insufficient in quality or quantity for an assessment, or the time frame available precludes utilization of the full formal assessment process (OHTA statement printed at the bottom of all Technology Reveiws)

SOURCE Off Ice of Health Technology Assessment, Agency for Health Care Policy and Research "OHTA Assessmentand Reveiws, Published 1981 -,' unpublished document, Rockville, MD, February 1994 B Gordon, Off Ice of Health Technology Assessment, Agency for Health Care Policy and Research Rockville MD personal communication, May 25, 1994

survival rate for transplant patients with cancer (O to 30 percent) was better than that for patients who did not undergo transplant, but much lower than the survival rate of patients with chronic active hepatitis, alcoholic cirrhosis, and other liver diseases (around 70 percent). Medicare ultimately decided not to cover transplants for liver cancer patients but would cover for the procedure for conditions with a better prognosis (137).

The direct effect of OHTA reports is on whether services are paid for by Medicare, the single largest payer for medical services. Private insurance companies have often used OHTA assessments in developing their own coverage policies. The drug and device industry considers Medicare coverage an important factor in the potential market for its products, so OHTA may affect technology diffusion beyond the bounds of Medicare; however, the evidence to determine this is lacking. OHTA could potentially play a greater role in federal technology assessment, including expanding beyond Medicare and systematically conducting cost-effectiveness analyses in its assessments. Political discussions about this issue have taken place from time to time, and some limits to OHTA'S activities have been removed legislatively; however, opposition to expanding its role has also surfaced, particularly on the part of the medical device industry.

TABLE 9-4: NIH Consensus Conferences, 1991-1993

Year	Topic	Sponsor
1991	**Gastrointestinal Surgery for Severe Obesity**	NIDDK
	Dental Biomaterials	NIDR
	Treatment for Panic Disorder	NIMH
	Recognition and Treatment of Depression in Later Life	NIMH
	Acoustic Neuroma	NINDS
1992	Diagnosis and Treatment for Early Melanoma	NCI
	Triglycerides, HDL, and Coronary Heart Disease	NHLBI
	Methods for Voluntary Weight Loss and Control	NIH Nutritional Coordinating Committee
	Gallstones and Laparoscopic Cholescystectomy	NIDDK
	Impotence	NIDDK
1993	Early Identification of Hearing Impairment in Infants and Young Children	NIDOCD
	Morbidity and Mortality of Dialysis	NIDDK

KEY NCI = National Cancer Institute, NHLBI = National Heart, Lung, and Blood Institute, NIDDK = National Institute of Diabetes and Digestive Disorders, NIDOCD = National Institute on Deafness and Other Communication Diorders, NIDR = National Institute of Dental Research, NIMH = National Institute of Mental Health, NINDS = National Institute of Neurological Disorders and Stroke

SOURCE Office of Technology Assessment, 1994, based on Information from U S Department of Health and Human Services, Public Health Service, National Institutes of Health, Off Ice of Medical Applications and Research

Other Federal Evaluation and Assessment Programs

National Institutes of Health

The Office of Medical Applications of Research (OMAR) at HIH began ho ing consensus conferences in 1977, and conducts about a half dozen of them each year (see table 9-4). These conferences take a "science court" approach, in which experts present the state of knowledge on a topic to a "consensus panel"-a group chosen specially for each conference and consisting mainly of scientists (but not experts on the topic under review, except for the chairperson), with "consumer" representation as well. The key questions for each conference are set out in advance by a planning group that includes appropriate NIH staff and the chairperson. After a day and a half of presentations, the panel develops a consensus statement that is finalized on the second day. Following the meeting, these statements are disseminated widely through mailings and publication in medical journals.

NIH consensus conferences have not been a particularly successful means of changing clinical practice, as most physicians are unaware of the conferences or their recommendations, and studies of impact generally document no alterations in practices following release of their results (67,74). Some analysts believe that the conferences do play a role in laying the groundwork for more gradual changes in the standard of practice over time. The literature on physician behavior change suggests that there are many factors in addition to knowledge that determine practices (75). Passive dissemination of practice policy statements, even those of nationally recognized experts, has been shown to be inadequate to affect practice (19).

U.S. Preventive Services Task Force (USPSTF)

USPSTF is a committee impaneled by the Office of Disease Prevention and Health Promotion (in the Department of Health and Human Services) that produced a set of 169 recommended preventive services, collected and published as a book in 1989 (154). A new edition of the guidelines is expected in 1994, to be developed by a standing pan-

el of 10 experts working with medical specialty experts and federal agency representatives. USPSTF has adopted an explicitly evidence-based approach to developing recommendations using predefine criteria to rate the strength of evidence from relevant studies.[12] Where no studies exist, the panel will not make any recommendation. Recommendations from USPSTF play no direct role in policymaking, but they have considerable weight in decisions on coverage and benefit design because of the rigor of the assessment methods used. The recommendations do not currently consider costs, but meetings were held in 1993 to explore using a cost-effectiveness standard in future editions.

Congressional Office of Technology Assessment (OTA)

OTA was created in 1972 to advise Congress in all areas of science and technology. (It is different from the other government offices discussed, which serve the executive branch). OTA studies are initiated by requests from congressional committees and are conducted by OTA staff. Advisory panels of experts and stakeholders are appointed for each study to help focus the work and review the products.

OTA's Health Program, one of nine original programs, issued its first report in 1976. In the early years, studies of technology assessment methods were emphasized—particularly cost-effectiveness analysis and randomized clinical trials—and case studies of specific technologies were common. The program's scope of work has broadened over the years to include health policy more generally, but the initial focus on methodology remains a constant thread. Recent assessments include a study of the cost of defensive medicine, a critique of potential use of cost-effectiveness methods in benefit design, an evaluation of the Oregon Medicaid system, a review of evidence for unconventional cancer treatments, and others. Specific technology assessments include a series on the cost-effectiveness of cancer screening strategies in the Medicare population and ongoing studies of osteoporosis, prostate cancer screening, wound-healing agents, and the role of *Helicobacter pylori* in peptic ulcer disease.

Private Sector Assessments

Interest in technology assessment outside the federal government has expanded rapidly in the last decade, particularly among professional organizations, insurance companies, health maintenance organizations, and hospitals. Work is done in academic settings and, increasingly, in profit-making companies.

Medical professional organizations have become increasingly involved in evaluating devices, drugs, procedures, and practices within their own areas of medical expertise. These activities are conducted as a means of educating the members of these organizations and also to provide payers with a professional perspective on what practices are state-of-the-art. One product of this activity is practice guidelines that review existing evidence and provide care recommendations endorsed by the professional organization. In 1938 the American Academy of Pediatrics produced the first formal guideline, on pediatric immunizations. A recent count identifies more than 30 professional organizations developing guidelines, for a total of over 1,500 individual guidelines produced (64). Explanations for this activity are the perceived need for greater accountability y and interest in controlling evaluations, particularly as they are applied to payment decisions.

Evaluation programs range from the Clinical Efficacy Assessment Program (CEAP) of the American College of Physicians (ACP), which uses a formal, evidence-based approach to assessment, to AMA's Diagnostic and Therapeutic Technology Assessment (DATTA) program, which canvases physicians on particular issues. Topics are usually selected informally based on the importance of or uncertainty surrounding an

[12] This approach to guideline development was originally developed by the Canadian Task Force on the Periodic Health Examination.

Issue, although ACP is in the process of developing more explicit approaches to choosing topics. The informtition provided usually focuses on gen - erating preferred strategies on the basis of existing evidence on safety and effectiveness. Cost information is generally not considered, but some preventive service evaluations have included it; in some cases. extreme cost differentials between alternative strategies are mentioned.

It is not clear what effect the evaluations of professional societies have on clinical practices. A variety of studies show that clinicians often are not aware of them, may not agree with the ones they arc aware of, or may not follow even those they agree with (43, 119). A growing body of research on the impact of guidelines on practice suggests that compliance with guidelines is strongly associated with the intensity of the effort undertaken to implement them (19). Particularly effective approaches include the usc of respected local clinicians to deliver messages and the involvement of local providers in the guideline development process (60). The use of clinical guidelines in utilization review, provider profiling, and as a basis for administrative restrictions within hospitals and health plans increases their likely impact on the use of specific technologies (41, 132).

Other than pharmaceutical and medical device manufacturers. *private insurers* are p. .bably the single largest funders of 'echnology assessment activity in the country, spending considerably more than the federal government. In addition to Blue Cross/Blue Shield (BC/BS). other major insurers also conduct assessments to guide their coverage decisions.

BC/BS established its Medical Necessity Program (MNP) in 1976 with the purpose of reviewing thc evidence on medical and surgical procedures suspected to be ineffective. The program was conducted in close collaboration with medical professional societies and resulted in guidclincs for coverage used by BC/BS plans as well as publications distributed by medical organizations. (For example, ACP has issued books on screening and diagnostic tests based on collaborative work with MN P.) To focus on new and cmerging technologies, BC/BS established its Technology, Evaluation, and Coverage (TEC) program, which relies on a comprehensive staff literature review and an independent, expert Medical Advisory Panel. In these evaluations the Panel determines whether a given technology satisfies five predetermined criteria:

1. status of regulatory approval,
2. adequacy of scientific evidence about the effect of the technology on patients,
3. net impact on health outcomes,
4. benefits as compared with established alte··a-tives, and
5. effect obtained outside research settings.

Although the national BC/BS organization conducts these technology assessments, the results are only advisory to individual BC/BS plans, and each plan is responsible for its own coverage decisions. In the majority of cases, coverage will not be approved when the Panel determines that a technology is experimental. However, a negative assessment does not necessarily mean that coverage will not be frequently provided for a technology. For example, most technology assessments of home uterine monitoring for women at high risk of premature delivery (including that done by BC/BS) conclude that the device has not been proven effective for that indication. Despite this, 40 to 50 percent of BC/BS plans pay for this technology, and 20 state Medicaid programs also reimburse for its use (25).

The TEC evaluation of autologous bone marrow transplantation (ABMT) for advanced breast cancer provides an interesting (though atypical) case study of this process. TEC considered all available evidence on two separate occasions and determined both times that the procedure should be considered experimental. But because of the patient demand, bad publicity, and a number of legal judgments against plans refusing COVerage, BC/BS determined that the TEC decision itself was not an adequate response to the new procedure, which in small studies showed a small advantage over conventional treatment. In 1991, BC/BS managed to have a randomized trial (actually, four separate protocols) conducted in collab-

oration with the National Cancer Institute (NCI) and a number of individual Blue Cross plans. (Local Blue Cross plans paid a fixed fee for patients willing to be randomized and the remaining costs were covered by transplant centers and NCI.) Although some patients and physicians were reluctant to accept random allocation to conventional therapy, by mid-1994 the trials had accrued about half of their target sample size (100). It will likely take 3 to 5 more years before these trials provide information on the effectiveness of ABMT for breast cancer. In the meantime, and increasing number of insurers are covering the procedure, rather than risk negative publicity or costly law suits. In the Kaiser Permanence HMO network, ABMT was determined to be experimental, but Kaiser pays for the procedure anyway. The hazards of failing to pay were made apparent in late 1993 when a California HMO was required to pay $89 million to the family of a breast cancer patient for whom it denied payment for ABMT.

If clinical trials themselves are included as technology assessments, the *drug and device industry* may be the largest supporter of technology assessment in the United States (57). These manufacturers have also increasingly used technology assessment as a policy analysis tool, as they face increasingly cost-conscious buyers. They use such analyses to provide early guidance on which product areas might be most profitable to research and also to demonstrate to providers and payers that their products are efficacious or cost-effective. Serving the needs of the medical products industry is a growing private-sector technology assessment community (e.g., Battelle, Health Technology Associates, Lewin and Associates, Arthur D. Little) as well as individual consultants in academia. As the private sector conducts more technology assessments, concerns about conflict of interest and assessment validity are mounting. Several public and private groups are involved in developing standards for appropriate conduct of technology assessment, particularly cost-effectiveness analysis.

Finally, several private *nonprofit organizations* have begun evaluating and disseminating ,information on medical technology over the past few years. ECRI (originally the Emergency Care Research Institute), long involved in performance testing of medical devices, has become increasingly active in assessing the risks and benefits of the entire range of health care technology. Its major clients are payers and hospitals, which identify the assessment topics. ECRI also has been creating large databases of existing assessments and has collaborated with the National Library of Medicine to increase the completeness and accessibility of the technology evaluations in its electronic database.

A group of over 60 academic hospitals created the University Hospital Consortium in 1989. It reviews specific technologies and coordinates small primary-data collection studies among the member institutions. The information is used in technology purchasing decisions, to help hospitals guide clinical protocols, and to select drugs for their formularies. UHC also produces reports on policy issues relevant to UHC hospitals, such as an analysis of pharmaceutical company reimbursement assistance programs, and an assessment of the impact of automation on pharmacy departments.

Summary of Recent Trends in Assessment

Several important trends in the evaluation of health care technology have emerged since 1982, when a previous international comparison of medical technology management was published (10). Most obvious is the continued rise in health care spending in the United States, which has increased the motivation to develop techniques for using existing resources with greater efficiency. Methods that analyze the benefits of technology in relation to costs, such as cost-effectiveness analysis, are of particular interest. Research over the past decade also has continued to highlight the poor state of evidence in health care practice, reflected in high variability in practice styles and high levels of marginally beneficial care. Finally, advances in computer technology have allowed the routine collection of administrative and clinical information as well as the inexpensive proc-

essing of this information. resulting in the emergence of new evaluations methods.

The pressure to improve cost-effectiveness and bring these analyses to bear in decisionmaking has grown in proportion to the fraction of GNP devoted to health care. Much of the increased attention to these methods is found in the academic community and also among the drug and device manufacturers. Explicit use of cost-effectiveness criteria for allocating health care resources has been more problematic, primarily because there is no widely accepted cut-off for a level of cost-effectiveness that demands or excludes coverage. The concept of cost-effectiveness is, from a political perspective, difficult to separate from health care rationing, which is roundly rejected by most of the U.S. public. This probably explains the lack of progress of a Medicare regulation proposed in 1989 that would have allowed the use of cost-effectiveness as a criterion for coverage under Medicare. The recently approved Oregon Medicaid proposal, which generated a list of services ordered partially by consideration of cost-effectiveness. provided a forum in which the difficulty of trading off costs and benefits in public policy could be observed. s

The U.S. health care system features numerous independent mechanisms by which the application of medical technology and total spending within the system are controlled. There is, however. little effective budget setting at any level, and when cost overruns occur in one segment of the system, they often are made up by shifting of resources from other sectors. As an example, the cost of care for patients with no insurance is partially offset by inflated charges billed for services provided to patients with good coverage. Effective cost constraints on in-patient care, such as that produced by the DRG program of Medicare, is offset by increased use of out-patient services and possibly by increased billing to payers who reimburse in-patient care on a fee-for-services basis (11 6). Overall, the system continues to expand to accommodate an increasing national appetite for technology and services. In such an environment the analytical tools provided by technology assessment, designed to facilitate efficient use of resources by making optimal tradeoffs in use of services, plays a more limited role than in constrained systems.

Databases and the Focus on Effectiveness

Developments in microcomputer technology have been one factor in changing the methods used in technology assessment. Because large amounts of electronic data now can be collected and manipulated, there has been increased emphasis on using existing data, often in the form of insurance claims databases, to evaluate health care technologies (98). Data gathered from events occurring in a wide range of practice settings have become viewed as a tool for looking at effectiveness—average outcomes achieved by average doctors and patients. The usefulness of this type of data for addressing questions of effectiveness is currently being explored. To date the primary utility of such data has been in tracking patterns of care by location and population group and over time. and also for generating hypotheses that would need to be explored in controlled trials. Moreover, payers and purchasers of health care services make use of these utilization data as a means of managing the quantity and cost of health care services. Among some policy makers and researchers, such appellation have created the impression that the effectiveness of services, rather than simply their pattern of utilization, is being measured.

While methodologists deal with these issues on a seemingly arcane and theoretical level, policymakers and the public are confronted with the downstream implications of these issues. which

[13]An OTA analysis of the Oregon priority listing found that the final rank ordering did not closely reflect cost-effectiveness. Subjective judgments made by the panel and, to some extent, by participants at public meetings were the primary determinants of the position of a particular service on the list (127).

are central to discussions of comprehensive health care reform. The development and use of informa-(ion on the performance of technology promises to be an important determinant of how rationally medical technology is managed in the United States.

Case studies

TREATMENTS FOR CORONARY ARTERY DISEASE

Before the mid-1960s, a number of procedures had been tried in the United States and around the world to improve collateral circulation around diseased coronary arteries. The only procedure that offered some hope of benefit was the known as the Vineberg procedure, which involved implanting the internal mammary artery directly into the heart muscle to enhance the flow of oxygenated blood to the diseased heart. Unfortunately the amount of blood flow through the artery was small, and more than half the patients undergoing the operation died. As these procedures were being abandoned, coronary artery bypass grafting (CABG) was being developed at three centers in the United States (the Cleveland Clinic, the University of Wisconsin, and New York University). By 1969, the operative mortality for CABG was reported to be about 12 percent, and many patients were free from angina following the operation (42).

Since the early 1970s, the number of CABGS has risen rapidly, without any apparent constraints from government policy or regulation and without a body of clinical trials to guide practice. By 1971, 432 U.S. institutions had facilities for open heart surgery (96) and an estimated 24,000 bypass procedures had been performed (16). At that time, no randomized studies of the procedure had even begun, and in most other countries procedures were done only on an experimental basis. By 1979 about 100,000 CABG procedures were performed annually in the United States (16) and this number had more than tripled to an estimated 309,000 operations per year by 1992 (see table 9-5) (163).

PTCA also surged into popular use after its U.S. introduction in 1978. Until the VA published its trial of PTCA versus medical treatment for patients with stable single-vessel disease in 1992, there was no evidence from randomized trials demonstrating a benefit from the procedure. Two randomized trials comparing PTCA with CABG are expected to report in the mid- 1990s. This scarcity of evidence is particularly striking when considering that 26,000 of these procedures were already being done annually by 1983 (31). In 1992, the same year the first randomized study of PTCA versus medical therapy was available, approximately 360,000 patients PTCAS were performed (table 9-5) (163).

The expectation that PTCA would supplant CABG for certain classes of patient (particularly those with single-vessel disease) and therefore lead to a decline, or at least a leveling off, in the number of CABGS has not been realized. Both procedures have continued to diffuse and increase in number every year as the patient population considered eligible for them expands to include older, sicker patients.

Overall use of CABG and PTCA in the United States was quite high by the early 1990s, but their use was not uniform across population groups: rates of use were significantly higher in white patients and among patients with private insurance. Furthermore, CABG rates vary as much as threefold in different geographic regions. The explanation for these disparities has not been clearly

TABLE 9-5: Trends in CABG and PTCA in the United States 1979-1992

Year	CABG (thousands)	PTCA (thousands)
1979	112	—
1980	136	
1981	158	
1982	169	
1983	186	
1984	188	
1985	201	—
1986	227	60
1987	243	152
1988	253	208
1989	260	239
1990	262	260
1991	265	298
1992	209	360

SOURCE U S Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Center for Health Statistics, unpublished 1979-1992 data from the National Hospital Discharge Survey provided by E. Wood, Hospital Care Statistics Branch, Hyattsville, MD, 1994

determined, but they suggest that supply of these procedures in the United States is based at least partly on non-clinical factors.

Evaluation

In the case of CABG, clinical trials began well after diffusion of the procedure was well under way in the United States. The National Heart, Lung, and Blood Institute (NHLBI) initiated the Coronary Artery Surgery Study (CASS) in 1973, which compared CABG to medical treatment in a randomized trial and also opened a registry to gather data on CABG patients. The trial randomized fewer than 800 patients, reflecting a reluctance to enter patients into randomized trials, even when the value of the procedure was not yet clear. Many more patients were entered into the registry, which was a good source of information on complication rates, but could not be used to compare the efficacy of CABG with medical treatment. In the meantime, the Veterans Administration conducted a randomized trial of CABG versus medical treatment in about 700 people from 1972 to 1974. It is noteworthy that all three randomized trials of CABG involved a source of graft material that it now used only rarely. The new source (the internal thoracic artery) is almost certainly associated with better surgical results than the older technique, and this may have led to variable opinions among experts concerning tradeoffs of medical and surgical therapy (68).

As is increasingly common in the United States, various public and private entities have issued guidelines and recommendations for the use of CABG and PTCA. Unlike the case for some other technologies, the guidance of these groups is remarkably consistent in their assessments of whether the technology is appropriate in a given clinical situation. In many cases, the groups are in agreement that not enough evidence exists to provide clear guidelines (see chapter 1 for a summary of indications). The relatively small information base may be, in part, responsible for the level of agreement.

The NIH consensus program has not been active in recent assessments of CABG and PTCA. A consensus conference was held on CABG in 1980, but not since then, and PTCA has never been the subject of an NIH consensus conference. OHTA has never reviewed CABG, but they have done two assessments of PTCA. In 1982, they concluded that there was inadequate information to determine long term safety and clinical effectiveness (135). Upon re-evaluation in 1985, data from an NHLBI patient registry was used as a basis for concluding that PTCA was a "reasonable alternative" to CABG in selected patients with single-vessel disease (136). The report notes, however, that "in the absence of trials identifying the differences in outcome between PTCA and CABG, or between PTCA and medical therapy, physicians must base their therapeutic decisions on current reported results and sound clinical judgment." Approval of Medicare coverage despite this inadequate evidence basis ensured that rapid dissemination would occur prior to any further guidance from these needed trials.

The American College of Cardiology (ACC), in collaboration with the American Heart Association, has issued guidelines for both CABG (4) and PTCA (5), which have been updated over the years, most recently in 1994. AHCPR issued guidelines for Diagnosing and Managing Unstable Angina in 1994, including indications for PTCA and CABG. A private sector assessment effort that has had remarkable visibility, if not measurable impact, is the RAND rating of "appropriateness and necessity," which has been applied to both CABG (68) and PTCA (47). In this process, an extensive literature on each technology was reviewed and the efficacy of the technology under scrutiny in each of a wide range of very specific indications was assessed using a form of Delphi technique (i.e., expert opinion) (see below for more detail).

Using the RAND method, each possible indication for revascularization was rated on a scale from 1 (inappropriate) to 9 (clearly necessary). For the 230 indications considered for CABG, 144 (63 percent) were considered necessary (a median score of 7 to 9 without disagreement among the raters); 84(37 percent) were considered uncertain (either a median rating of 4 to 6 or of 7 to 9 with disagreement); and 2 (1 percent) were considered unnecessary. For PTCA, 158 indications were rated, with 36 (23 percent) rated as necessary, 120 (76 percent) rated as uncertain, and 2 (1 percent) not necessary.

The RAND researchers used their indications ratings to evaluate the actual use of CABG (69) and PTCA (48) in New York State. For CABG, they sampled about 1,300 procedures in 1990 and sorted them into categories based on the indications ratings. A small fraction (about 2 percent) were considered "inappropriate," about 90 percent were considered "appropriate" (most were "appropriate and crucial"), and about 7 percent were considered "uncertain." The results for about 1,300 PTCAS in 1990 were: 4 percent "inappropriate," 35 percent "crucial," 23 percent "appropriate," and 38 percent "uncertain."

While it might be comforting to see such a low rate of clearly inappropriate use of these procedures, the number of procedures for which experts believe the benefits are uncertain is sobering. That 38 percent of PTCAS were of uncertain value reflects directly the lack of information from randomized trials testing the efficacy of the procedure, and the cost of poor evaluation early on in the diffusion of a technology. It is also worth noting that these appropriateness categories vary when generated by different expert panels. Using RAND methodologies, a panel of British physicians rated twice as many procedures "inappropriate" as did a U.S. panel rating the same clinical cases (12).

Costs and Payment

PTCA is clearly less expensive than CABG on a per-procedure basis, largely because hospital stays are less than half as long for PTCA (4 or 5 days versus 12 or 13 days for CABG). Total costs (in 1989 dollars) were $10,000 to $13,000 for the initial hospitalization for PTCA and $20,000 to $32,000 for CABG (68). But because of the high failure rate of PTCA and the need for subsequent angioplasty or CABG, the costs of adequately treating patients with an initial PTCA or CABG look somewhat different. RAND reports that, using data from the Framingham Heart Study and expert judgment, they estimated five-year costs at about $33,000 for PTCA and $40,000 for CABG patients. Potential cost savings in the treatment of coronary artery disease by the use of PTCA in place of CABG have not been realized because of the combination of relatively high long-term costs for PTCA (relative to the cost of the initial procedure) and the expansion of the eligible patient population.

In the prospective payment system, PTCA was treated as a cost-increasing quality improving technology, and was factored into the adjustments made to hospital DRG payments. One of the effects of Medicare paying hospitals on a per-admission basis is the phenomenon of "unbundling services," meaning that visits and tests related to a procedure may be performed on an outpatient (or separate admission) basis, so that those charges can be billed separately rather than taken out of the DRG payment. Recently, Medicare has experim-

ented with paying providers a lump sum for all services related to a CABG, including preoperative visits, hospitalization, and post-operative follow-up (the package is called an "episode-of-care"). This may further encourage physicians to use resources efficiently, though no data are yet available to suggest that this impact has actually occurred.

Regulatory Policies

Neither CABG nor PTCA faced significant federal regulatory barriers to diffusion. There have not as yet been credentialing requirements for performing these procedures (although various committees and associations have developed guidelines for institutions to use in developing their own credentialing and quality of care monitoring policies for PTCA) (3). The various devices involved in CABG and PTCA all have counterparts from before 1976 to which current equipment have been considered substantially equivalent, so their approval was grandfathered in accordance with the current regulation of medical devices. Thus, even balloon catheters used in PTCA were approved through the 5 IO(k) process (see main chapter), and only limited clinical data were required to support their approval.

State regulatory polices have in some cases influenced utilization of interventions for coronary disease. The National Health Planning and Resources Development Act of 1974 established a regulatory role for states over hospital acquisition of cardiac surgery units through certificate of need (CON) programs. Some states, such as California, had very permissive CON programs, while others established rigorous limits within their states, and in some cases, such as New York, combined the CON program with payment rate regulation. In addition to a direct impact on cardiac surgery units, CON regulation also influenced the diffusion of PTCA, since facilities must be capable of providing an emergency bypass during angioplasty.

In support of their cardiac surgery CON program, New York maintains a cardiac surgery advisory board to advise on how many cardiac surgical facilities are needed and on the minimum numbers of surgeries that should be done each year to keep a center running. In part due to this limited number of surgery centers, the per-capita supply of cardiac surgeons in New York is about one-half the national average. The board also has advised on the appropriate clinical circumstances for cardiac surgery, and in 1990 funded the RAND Corp. to produce "appropriateness" guidelines to help establish new standards. As described above, these studies of cardiac surgery in New York found rates of inappropriate use to be considerably lower than they have found elsewhere (69). It is impossible to determine which element of New York's approach is most responsible for what appears to be more rational use of cardiac surgery, and therefore difficult to know whether these results are achievable in other states. During the 1980s, the Health Commissioner of New York enjoyed the strong support of the Governor, and therefore was able to enforce regulatory policy with unusual latitude. Such political strength may be a prerequisite for effective health care regulation.

MEDICAL IMAGING (CT AND MRI)

Computed Tomography (CT)

The first CT scanner in the United States was installed at the Mayo Clinic in 1973. By 1975,20 companies were developing or had developed CT scanners; by 1977,921 units were in operation. Of these, 60 percent were head scanners and 40 percent were body scanners. Every state had at least one operational scanner installed or approved by the end of 1977(121). Early adoption was primarily by non-profit community hospitals affiliated with a medical school. By 1980 the number of units was estimated at 1,471 (6.5 per million population) (123), and in 1992 the reported number of operational CT scanners was 6,060 (24.3 per million) (1 14). For purposes of comparison. there were 216 CT units operating in Canada in 1993 (see Canada chapter).

Evaluation

Early diffusion was not guided by established evidence of safety and efficacy. By 1975 about a dozen clinical studies of CT scanning of the head had been published, and over 100 units had already been installed. Even though the evidence for many applications of CT was quite limited, the relative advantage of CT scanning over existing technology was considered apparent by many clinicians, especially given the risks associated with alternative diagnostic procedures (e.g., pneumoencephalography, cerebral arteriography). Studies completed by 1977, primarily based on accumulated clinical experience as opposed to clinical trials, did confirm a high accuracy rate in detection of abnormalities and limited apparent safety problems (122). More information was available for head CT studies than for body scans.

Although CT did detect abnormalities, little information was available on the extent to which therapy was influenced or patient outcomes affected. Criteria for selecting patients likely to benefit from the test were not available. In some institutions, up to 90 percent of scans performed were negative.

Diffusion Factors

Approval by the FDA was not required for CT scanners, as they were introduced prior to the 1976 Medical Device Amendments. No evidence of safety or efficacy was required by this agency prior to marketing. During early adoption of CT, most states had not yet acted on federal laws directing them to establish certificate-of-need (CON) programs (49). Later, as these programs did come into existence, the more stringent programs did appear to slow the rate of diffusion of CT scanners. In states with stringent programs, which included CON programs combined with setting of reimbursement rates for the procedure, the rate of diffusion was halved compared to that of states with no functional program (14).

Professional standards review organizations (PSROS) were associated with a modest increase in the likelihood of adoption of CT, a phenomenon (observed with other technologies) that may be due to the fact that PSRO physicians respond to the same incentives as those using the devices. Also, PSRO panels had little objective information on efficacy upon which to base an assessment of need for the technology. Health planning laws did not require PSROS to consider the extent to which existing equipment was being used at capacity (121).

At the time of the introduction and early diffusion of CT, hospitals were still reimbursing based on costs (prior to the prospective payment system). This mechanism of payment resulted in high profitability of CT scanners.

Magnetic Resonance Imaging (MRI)

The diffusion of MRI has unique elements as well as features common to a number of important technologies. Some of the distinctive features of MRI are the high cost of acquiring and operating the technology; dramatic changes in regulation, financing, and tax policy that coincided with its introduction; and its technical complexity. Added to this is the concrete appeal of the new technology, which presented images of the brain and internal organs that, for the first time, offered a level of detail of internal anatomy that resembled actual photographs of living tissue rather than black, white, and gray shadows.

Development and Early Diffusion

MRI was introduced in 1978, with the first two scanners installed in Great Britain in that year (109). The first U.S. scanner was installed in a private office in Cleveland, Ohio, in 1980. By the end of 1984, between 108 to 150 MRI scanners had been installed in the United States (109). Large hospitals and academic medical centers were the major early adopters of MRI (101).

Because no federal or state government agency keeps track of the total number of MRI units in the United States, the best available data have been collected through surveys of individual manufacturers and facilities. One survey reports that the number of scanners rose to 1,230 (5.04 units per million population) by 1988; however, methodologic limitations of the study suggest that this esti-

mate is conservative (115). Estimates for the number of MRI units in operation in the United States in 1992 are between 2,800 and 3,000 (36,1 14). This translates to about 11.5 per million population nationwide.

Distribution of U.S. scanners is very uneven. Maryland, which does keep track of operational units, has 52 MRI scanners, 11 of which are in Baltimore (16 per million) (36). It has been reported that there are 25 operational MRI scanners within a single mile in Los Angeles, California.

A number of comparisons have been made between the diffusion of CT scanners in the United States in the mid- 1970s and the diffusion of MRI in the early 1980s. The pattern of early MRI diffusion was clearly slower than that for CT, but many differences between the two situations have been noted; any or all might explain the variance in diffusion. Among these differences are the relative advantage each technology represented over previous technologies, the adoption of prospective hospital payment by Medicare, the beginning of device approval by the FDA, active health planning programs in some states, and increasing cost-consciousness and competition for patients in health care generally (49, 109).

Evaluation

A consensus conference conducted by the National Institutes of Health in October 1987 qualified its list of clinical indications for MRI by noting that "judgments about the role of MRI relative to other imaging modalities are based on less rigorously designed studies than are desirable" (147). (The conferees, half of whom were radiologists, went on to characterize MRI as a "superb method of studying brain tumors" and "particularly valuable as a technique for imaging the heart and great vessels"; they also listed numerous other promising clinical applications (147).)

These assessments of the quality of studies supporting the use of MRI were reaffirmed in a systematic review published in 1994, that noted that less than 30 studies out of more than 5,000 citations on the use of MRI in neuroimaging were prospective comparisons of diagnostic accuracy or therapeutic choice (65). In a position statement on uses of MRI, the evidence for 13 out of 17 clinical applications was rated as "weak" by the American College of Physicians (6). Weak evidence was defined as the absence of any studies on therapeutic impact or patient outcomes.

Diffusion Factors

MRI was the first device to be evaluated as a class III device by the FDA under the 1976 Medical Device Amendments. Under the new law, it was necessary to supply evidence of safety and efficacy in order to obtain FDA approval and permission to market this product. Despite these new requirements, it does not appear that the FDA represented a barrier to acquisition of the new device (49). Under the exemption allowing device manufacturers to charge for investigational devices, 43 scanners were placed in service in the United States by 1983 (21 from a single manufacturer) (108). Technical refinements of these early prototype systems were still under way at that time. Five manufacturers had obtained full pre-market approvals by 1985 (109).

Providers considering acquisition of MRI viewed FDA approval as inevitable; therefore, lack of FDA approval was not considered a disincentive to acquisition (50). The safety of the device was not seriously questioned, and it was obvious that the device produced cross-sectional images with excellent resolution. so MRI clearly could provide diagnostic information. Neither FDA nor physicians planning to use the device required rigorous studies that demonstrated improved clinical outcomes, cost-effectiveness, or superiority of MRI compared to diagnostic alternatives.

In 1983 OHTA was asked to review MRI technology and provide recommendations to HCFA on coverage policy. It has been suggested that the delay by HCFA in making any coverage decision nullified its ability to exert any influence on diffusion, as public and professional pressure for access grew. At that time only a few studies with small numbers of patients reported on experience with MRI, and a review of this literature by Blue Cross/Blue Shield determined that the benefits of MRI were unproven. By the end of 1985,

however, public and professional pressure had led to coverage by dozens of private carriers, including many local BC/BS **plans.**

In November 1985 HCFA decided, based on the OHTA analysis, to reimburse for MRI scanning, with professional fees based on those in place for CT. Recommended clinical indications were broad enough to encompass most potential uses of the technology and were not seen as a deterrent to any proposed clinical application. HCFA approval meant not only that MRI would be paid for on an out-patient basis but also that part of the capital costs for hospital MRI scanners would be paid for and that MRI costs would be factored into a recalibration of HCFA'S prospective payments to hospitals payments when they were updated. Finally, the approval placed a strong pressure on private payers to provide coverage for MRI.

Although many MRI scanners were obtained before HCFA or other third-party payers had decided to cover the new technology, many hospitals and physicians deemed it inevitable that payment would be allowed. Insurers were rarely able to deny coverage for a major new technology when use of the device was spreading and both professional entities and the public were promoting its use.

The prospective payment system of the Medicare program has recently begun a transition to incorporate capital costs for hospitals into DRG payments. This mechanism, which no longer allows hospitals to simply pass along capital costs to the Medicare program. will force hospitals to weigh more carefully the value of purchases such as MRI against other possible uses of capital funds (1 lo).

Regulatory and Financing Issues in MRI Diffusion

CON laws were passed in each state in response to enactment of the National Health Planning and Resources Development Act of 1974. This national legislation made funding for a number of public health programs contingent upon a state's having enacted CON legislation. The federal law required state review of capital expenditures exceeding $150,000, but the procedures and criteria for approval of projects were left to state discretion. Also, federal support for health planning was discontinued beginning in 1981, and states varied considerably in the degree to which planning activities were continued (49). As a result, the extent to which CON requirements posed a barrier to technology acquisition depended heavily on what type of planning existed in each state. This may account for some of the difference of opinion as to whether CON programs influenced the rate of diffusion of MRI.

Several studies of the relationship between CON and MRI acquisition support the notion that state CON laws, when they were rigorously applied and particularly when they were coordinated with rate-setting activities, did reduce the number of MRI scanners in hospitals. For example, Massachusetts used CON rulings and rate setting to set the initial number of MRI scanners in the state at eight. Several other states frequently delayed or denied requests for MRI installation (51). In contrast, California adopted minimally intrusive CON procedures resulting in 25 MRI scanners planned or operating in Los Angeles by 1985 (50).

Some states felt unable to conduct rational CON procedures because of an inability to objectively define a "needed" level of MRI capacity. Planning required establishment of some rational criteria on which to base approval or denial of capital requests. Because of limited data on the clinical performance of MRI, objective evidence was inadequate as a basis for guiding these planning committee deliberations, substantially reducing the effectiveness of CON review.

Because most planning laws did not apply to out-patient facilities, states with effective CON programs may not have been able to control the total number of new MRI scanners. The CON regulations were one of the factors that may have encouraged out-patient location of MRI facilities (109).

State planning continues to be an important influence on MRI diffusion. Maryland discontinued its planning in 1985 and now has a higher per-capita supply of MRI (as well as CT) devices and a high concentration of units around Baltimore. Vir-

ginia discontinued its planning in 1989 and, in three years, saw the number of scanners in the state rise from 28 to 58 (36).

Diffusion of MRI was strongly influenced by the policies that provided financial incentives for entrepreneurial interests. Unlike other expensive medical technology, MRI units were frequently purchased by nonmedical investors and institutional joint ventures and located off hospital grounds. Also atypically, mobile MRI units were fairly common. These patterns of investment and siting have been linked with the high financial risk associated with MRI investments because of the high cost and complex technical issues as well as the unpredictability of regulatory influences (101). MRI magnets often required special building features that necessitated new construction (which opened the opportunity to consider non-hospital siting). (Because MRI cannot be used on critically ill patients, it is not necessary to site units near be close to an acute care hospital s.) Out-patient use of MRI was also encouraged by the fact that state planning programs applied only to hospitals, so no state approval was required. Finally, the prospective payment system does not provide a cost-based reimbursement for MRI scans performed on hospitalized patients, but the full fee could still be charged for out-patient scans.

Decision to acquire MRI made by hospitals and investors were complex and influenced by the uncertainties of the newly installed prospective payment system, elimination of many state health planning programs, rapid modification and obsolescence of MRI technology, and high demand from physicians and patients. Because of limited information on the potential clinical applications of the technology, it was difficult to predict the volume of scans that would be likely. Academic medical centers acquired the devices, even though it was unclear how the DRG system would handle the capital costs or imaging fees, because they felt that acquisition was necessary to fulfill their research and teaching mission and to maintain their prestige.

Diffusion may also have been stimulated in the mid- 1980s by competition, as some hospitals may have viewed MRI as a technology that would symbolize the sophisticated care available and thus attract patients for other services (11 O). Furthermore, many physicians prefer to practice in state-of-the-art facilities, and for hospitals, patient volume depends on recruitment of physicians. Finally, MRI almost certainly was the object of competition among medical specialists (e.g., radiologists, neurologists, orthopedists) to become leading providers of the service, stimulating additional purchase independent of actual clinical demand for the service (50).

It is evident that hospitals, physician-entrepreneurs, and medical device manufacturers have approached MRI and CT as commodities with high-profit potential, and decisionmaking on the acquisition and use of these procedures has been highly influenced by this approach. In this context clinical evaluation, appropriate patient selection, and matching supply to legitimate demand might be viewed as secondary forces. As the U.S. health care system becomes more dominated by issues of cost containment and managed care, there will be less profit potential in these and similar technologies, and the role of clinical evaluation may become relatively more important.

LAPAROSCOPIC SURGERY

Laparoscopic cholecystectomy was introduced to an enthusiastic U.S. audience at a professional surgical society meeting in late 1989. Following this introduction, the adoption of laparoscopic cholecystectomy was extraordinarily swift. Within 18 months of its introduction, about half of the general surgeons practicing in the United States (about 15,000 surgeons) had learned to remove the gallbladder laparascopically (161). By 1992 an estimated 80 percent had begun using the procedure (29). A survey in Pennsylvania revealed that laparoscopic cholecystectomy was being performed in virtually all responding hospitals by 1992. In these hospitals the fraction of cholecystectomies performed laparoscopically increased from 6.1 percent in 1990 to 71.6 percent in 1992 (33). It has been estimated that in 1993. five years after the first known procedure was per-formed in France, about 85 percent of all cholecstectomies

in the United States were performed laparoscopically (105).

The adoption of laparoscopic cholecystectomy appears to have been associated with an increase of about 30 percent in the rate at which cholecystectomies are being performed. The total number of cholecystectomies (open plus laparoscopic) increased by 34.3 percent between 1990 and 1992 in Pennsylvania (33). Similar findings were noted in a large population in a Pennsylvania health maintenance organization that saw its total cholecystectomy rate rise from 1.35 per 1,000 enrollees in 1988 to 2.15 enrollees per 1,000 in 1992; rates of the procedure had remained stable from 1985 to 1989 (70). A cholecystectomy patient registry from Connecticut and hospital discharge data from Maryland demonstrate similar trends in the use of total cholecystectomy procedures since the introduction of the laparoscopic technique (a 29 percent increase in the rate of procedures in Connecticut (85); a 28 percent increase in the rate in procedures in Maryland (11 l)). The rate appears to have reached a plateau in 1992, suggesting that the increase in use represents a change in selection criteria for the procedure (11 1).

An estimated 20 million people in the United States have gallstones, and of these, about 600,000 underwent cholecystectomy in 1991. (It is the second most common surgical procedure in the United States, after cesarean section) (148). Assuming that 75 percent of these procedures were performed laparoscopically (a middle estimate), about 450,000 laparoscopic cholecystectomies would have been undertaken in 1991.

No study has yet been performed in the United States to determine which new patient group accounts for the increase in cholecystectomy rates. There is evidence that patients undergoing the laparoscopic procedure are younger, have fewer comorbid conditions, and are less likely to have acute cholecystitis than patients having open procedures (70, 11 1). These data are compatible with the hypothesis that gallbladders are now being removed from less symptomatic patients than was the case before the laparoscopic procedure became available.

The apparent increase in the total volume of cholecystectomy procedures performed may have offset some of the potential benefits of the less invasive new procedure. With this increased volume, one large HMO saw the total costs associated with cholecystectomy increase 11.4 percent between 1988 and 1992 despite a 25.1 percent drop in the average per-procedure cost (70). Furthermore, another study showed that the mortality rate for cholecystectomy remained stable between 1990 and 1993, possibly because the lower death rate associated with the laparoscopic procedure was offset by the increased number of patients put at risk by undergoing a cholecystectomy (1 11).

Evaluation and Assessment

The adoption of laparoscopic cholecystectomy outpaced efforts to conduct randomized trials comparing the new technology to open cholecystectomy. This led some observers to argue that such trials are now unrealistic. European trials gathered patients slowly because of patient and physician reluctance to forego the new technique. The completed, small random controlled trials that have compared the laparoscopic procedure to open cholecystectomy have documented a shorter hospital stay and more rapid return to usual activities (11,1 17). Similar findings have been provided by nonrandomized studies involving several thousand patients (106). These studies also have found that laparoscopic cholecystectomy is associated with reduced in-patient duration; fewer co-morbidities from prolonged immobilization (e.g., pulmonary embolism, pneumonia, stroke); decreased post-operative pain; and a shorter period of restricted activity.

All studies have also noted an increased rates of bile duct and major vessel injuries associated with laparoscopic cholecystectomy. The rate of these complications has been observed to be inversely correlated with the number of laparoscopic procedures previously performed by the operator (148).

OHTA reviewed laparoscopic cholecystectomy to assist Medicare in determining coverage in

1991 (52). The OHTA report collated all available reported cases of laparoscopic cholecystectomy to determine complication rates, which compared favorably to complication rates reported for open cholecystectomy. Noting that no randomized study comparing open to laparoscopic cholecystectomy had yet been published, the OHTA analysis concluded that "there are sufficient published data to permit the conclusion that laparoscopic cholecystectomy can be accomplished with a risld benefit ratio similar or superior to that of the open procedure." The analysis was also noted that the risldbenefit ratio would be affected by the training and experience of surgeons; reports were cited regarding an inverse relationship between complication rate and experience (52). OHTA declined to do a full assessment, arguing that because the effectiveness of surgical removal of the gallbladder in individuals with cholecystitis and cholelithiasis was well established, accomplishing this with different instruments through a smaller incision was clearly effective therapy as well (53). The Medicare program followed the OHTA recommendation and began payment for the procedure in 1992.

Because data from clinical trials are limited, the safety and effectiveness of laparoscopic cholecystectomy for particular clinical situations is limited. There is some evidenc that suggests that common bile duct injuries and length of hospital stay increase with laparoscopic cholecystectomy for acute cholecystitis (52), raising questions about the most appropriate choice of therapy in this situation. Additional clinical data from prospective trials comparing open and laparoscopic cholecystectomy for patients with acute cholecystitis might help clarify this issue; however, none are under way.

Diffusion Factors

The rapid adoption of laparoscopic cholecystectomy might be explained by the absence of any significant restraining forces and by various potent forces that promoted adoption of the new procedure. There were no major hurdles to adoption, as no major capital investment was required and no significant regulatory barriers were encountered.

Patient demand, fueled by substantial media attention on this new technology, was a major force in promoting rapid adoption. Because of the apparent reduced discomfort and disability associated with the procedure, patient preference for the new technique was very strong. Device manufacturers played an important role in using the media to further stimulate patient interest and demand. Payers saw the potential for reduced cost from shorter hospital stays, and hospitals saw the potential for higher profits for the cholecystectomy DRG (until adjustments were made for the new procedure). In addition, this new state-of-the-art technique was attractive to surgeons, and this was reinforced by the belief that failure to learn the procedure might result in substantial losses in patient volume.

A prominent feature in the diffusion of iilaparoscopic cholecystectomy was the critical role of the medical device industry in promoting adoption of the technology. The video demonstration introducing the procedure in 1989 was produced and shown by the major manufacturer of laparoscopic equipment. This company and others continued aggressive promotion to surgeons as well as to the public through the lay press (162). A substantial percentage of surgeons who learned the procedure early in the dissemination process were trained at workshops conducted by the manufacturers, some of which involved two days or less of instruction and practical experience using pigs. There are reports of surgeons who performed unsupervised cholecystectomy following this type of training.

In a national survey, common reasons cited by surgeons for adopting the new procedure included a desire to keep up with the state of the art, preference of patients for the procedure, the likelihood of improved patient outcomes, and a desire to maintain their referral bases. Among the minority of surgeons who did not adopt the procedure. the chief reason was concerns about its safety. interestingly, the physician characteristic most strong-

ly predictive of likelihood of adoption was receipt of payment by fee for service, although this may reflect the nature of the patient population rather than the influence of economic incentives (29).

Coverage determination by insurers did not appear to be a factor in diffusion of laparoscopiccholecystectomy, as open surgery was already covered and many providers simply used the same procedure codes for each procedure. A unique procedure code was established in 1991, allowing better data collection concerning the procedure but with no importance in terms of reimbursement.

Beginning in October 1993, Medicare established a separate DRG category for laparoscopic cholecystectomy that pays about 25 percent less than the DRG for the open procedure. The adjustment was made to account for the lower costs associated with the new procedure, primarily associated with decreased length of stay (27). This removes a financial bonus to hospitals.

Other Laparoscopic Procedures

Laparoscopic approaches to removal of the appendix, exploration of the common bile duct, repair of inguinal hernias, resection of the colon, and surgical removal of the uterus are all increasingly common in the United States. In addition to these, many other diagnostic and therapeutic uses are under development. None of these clinical indications have generated as much enthusiasm as gallbladder removal. Small studies suggest that laparoscopic appendectomy offers little benefit over the open procedure, in part because the existing operation is technically simple and involves a small incision. In the case of herniomhaphy, the laparoscopic procedure is used increasingly despite the possibility that it is less effective (early series showed recurrence rates of over 15 percent following the laparoscopic approach), less safe (laparoscopic hernia procedure requires general anesthesia instead of a local anesthetic), and more expensive than the traditional hernia repair (105).

Regulatory Policies

Because laparoscopic devices had been in use prior to the 1976 amendments, the equipment used in laparoscopic cholecystectomy was eligible for FDA approval based on an abbreviated application. Achieving the designation of "substantial equivalence" as defined in section 5 IO(k) of the amendments, there was no requirement for additional data to obtain approval. No clinical data were necessary to obtain FDA clearance for the laparoscopic equipment used in cholecystectomy.

Most state health departments did not become involved in regulating laparoscopic cholecystectomy. In New York, the health department of Health became concerned with laparoscopic cholecystectomy as a result of data suggesting increased complications from the procedure. particularly bile duct injuries and major blood vessel punctures. Several of the major injuries were found to be associated with procedures performed by surgeons less experienced in the technique who had had training only at a weekend seminar. After having identified 192 complicated laparoscopic cholecystectomies between August 1990 and June 1992, the state's health department issued an advisory memorandum to all state hospitals recommending specific credentialing criteria and quality assurance protocols (83). Although the procedures outlined were not mandatory, the health department continues to monitor developments in this area and has the authority to issue regulations requiring more specific actions on the part of hospitals. The state is considering developing a state registry for laparoscopic procedures to further monitor laparoscopic cholecystectomy and some of the newer laparoscopic applications.

In its consensus statement NIH recommended the development of strict guidelines for training laparoscopic surgeons, determining levels of competence, and monitoring clinical results. Professional societies have come forward to issue

their own recommended guidelines on training and credentialing (104).

TREATMENTS FOR END-STAGE RENAL DISEASE (ESRD)

Permanent kidney failure is the only medical condition that entitles nearly all Americans uncategorically to treatment paid for by the federal government under the Medicare program. A favorable political climate, strong congressional sponsors, and the drama of a patient being dialyzed during a congressional hearing are among the factors that led Congress in 1972 to create this entitlement to dialysis and kidney transplantation. The tremendous growth of the program, both in patients treated (from the initial 10,000 treated in 1973 to more than 150,000 in 1989) and in costs, which now approach $5 billion per year, have made the ESRD program a continual focus for policymakers and payers. More than any other publicly funded medical program, this one has been subject to changing reimbursement policies that have influenced physicians' and patients' treatment choices.

Because of its unique characteristics, the ESRD program also has been fertile ground for study. The IOM was asked by Congress in 1987 to study the program thoroughly; it published the 1991 book *Kidney Failure and the Federal Government (59)*. This book chronicles the ESRD program from its inception and recommends a range of actions to improve it. In 1990 Congress required ProPAC to report on Medicare payment policies for the ESRD program, which it did in 1992 (91).

Relative to other diseases, enormous amounts of data are collected on ESRD. HCFA maintains an ESRD program management and medical information system: the U.S. Renal Data System is run by the National Institute of Diabetes and Digestive and Kidney Disorders (NIH); and the United Network for Organ Sharing database includes data on kidney transplants.

The ESRD patient population has grown not only in numbers since the inception of Medicare's program, but has changed in character. People entering the program today are older and sicker than their counterparts of the 1970s. The U.S. incidence of treated ESRD is 180 per million population, and rising at almost 8 percent per year.

Dialysis and Transplantation

Outpatient hemodialysis is the dominant treatment under the Medicare ESRD program, with 82 percent of beneficiaries using it in 1989. Continuous ambulatory peritoneal dialysis (CAPD) is used by 14 percent, home hemodialysis by 2 percent, and continuous cycling peritoneal dialysis by 2 percent. Improvements in the process of hemodialysis have been made over the years, but they have been incremental.

The dialysis setting has shifted from the dominant hospital-based, not-for-profit setting of the 1970s and early 1980s to largely for-profit independent dialysis centers. In 1980 there were 1,004 Medicare-certified dialysis centers: by 1988, there were 1,740. In 1980,342 of the centers were for-profit, and in 1988, 912 were for-profit, accounting for 70 percent of dialysis stations.

Recently, concern has focused on the quality of dialysis treatment, spurred by a rise in the mortality rate among dialysis patients (56) and a generally high rate in international comparison. Some suspicion that shorter dialysis times and, possibly. reuse of dialysis filters (which is more common in the United States than in other countries) may be responsible has led to further investigations. The Renal Physicians Association is preparing clinical guidelines recommending a minimal and an optimal dose of dialysis (56). These issues were also addressed at a 1993 NIH Consensus Development Conference (150).

Kidney transplantation would be the preferred treatment for perhaps half to three-quarters of all new ESRD enrollees (113), but the supply of kidneys falls far short of the demand. About 20 percent of current ESRD beneficiaries have had transplants. Technological advances in transplantation technique and particularly in immunosuppressive therapy have improved the results of transplants and broadened the patient population now considered eligible. Although advanced age is no longer considered a medical contraindication

to transplantation, in practice few people over 65 are transplanted; however, diabetic patients, once considered poor risks, are no longer excluded.

The number of transplants leveled off in the mid- 1980s at just under 9,000 per year, where it remains (up from about 3,200 in 1974). Transplant centers also increased from 151 units in 1980 to 219 in 1989. Early increases in transplant numbers were due almost exclusively to cadaver-donated kidneys. With 40,000 new patients per year entering the Medicare ESRD program, the shortfall is obvious. At the end of 1989, more than 16,000 people were on waiting lists for kidneys. (Shortages of kidneys and other organs became a point of national debate and prompted passage of the National Organ Transplant Act of 1984. This law created national norms for the donation and equitable allocation of organs and mandated an infrastructure to carry out its aims.)

Payment Policy for ESRD Under Medicare

Government payment for ESRD services has been a subject of recurrent interest to Congress, the executive branch, and the provider community. Since the program's inception, payment has followed somewhat different rules than those forother Medicare services, although the basic split between payment to facilities and to physicians has been retained.

Dialysis centers are paid for each dialysis session. From 1973 to 1983, reimbursement was based on the same "reasonable-charge" basis as other services; however, unlike other services, a payment ceiling was set at $138 (with some exceptions), which was what nearly all centers collected. After congressional hearings on the program from 1976 to 1978, part of the 1978 Social Security Act Amendments required that a prospective payment system for outpatient dialysis be devised on a "cost-related or other economical and equitable basis." The rules finally proposed to do this were rejected by the Reagan administration in 1981. In 1981 legislation, a similar provision required development of a single composite reimbursement rate for outpatient dialysis; a final rule by HCFA established this in 1983, with different rates for hospital-based and independent centers but with all dialysis sessions otherwise treated the same. The base rates were $131 for hospitals and $127 for independent facilities, which were adjusted only for geographic differences in wage rates; this constituted a decrease in nominal payment over the previous ceiling. In 1986 HCFA proposed reducing the base rate by $6, but Congress limited the reduction to $2. The base rate is not subject to regular adjustments (unlike payments under the DRG system used for other services under Medicare), although annual changes in wage indexes are applied.

Physicians are paid separately from facilities for services to ESRD patients. Originally their fees were included in the per-session payment to dialysis facilities, but the medical community rejected this and assisted HCFA in developing an "alternative reimbursement method," a monthly cavitation payment for each ESRD dialysis patient that physicians could opt for, starting in 1974. In 1983 a cavitation payment system for outpatient services was made mandatory at a monthly rate based on prevailing charge rates (average payment was $184.60, which varied by geographic region); the rate was reduced by $10 in 1986. Under this system the nephrologist was expected to serve as the primary care physician, providing some general internist services as well as specific dialysis-related services. The lowered payment, however, provides a disincentive for the nephrologist to offer all the services he or she might otherwise provide. ESRD physician services have been exempted from the general physician payment reform under Medicare, which in 1991 implemented a resource-based relative value scale as the basis for payment.

Peculiarities of the Medicare kidney transplant benefit affect the epidemiology of transplantation and even the success of transplants. Medicare pays all costs associated directly with kidney transplantation-organ procurement and hospital and physician fees—as well as for immunosuppressive drugs for one year. All Medicare ESRD entitlements terminate three years after

transplant. For people under 65, health insurance may become a significant problem. Once Medicare coverage is lost, the transplant is considered a preexisting condition by private insurers, so even with coverage, kidney-related problems might be excluded. In fact, nearly half the transplant recipients reaching the three-year limit have established eligibility for disability payments under the Social Security system, including eligibility for Medicare, even though many probably could return to work. The system seems to act as a disincentive, making the modest disability payment more attractive than attempting a return to work, with uncertainty about meeting medical bills (27). It also appears to discourage some people from seeking transplants, so they remain on dialysis. Although the total number of transplants is limited by the supply of kidneys, which people receive them probably is affected by financial concerns.

The one-year limit on reimbursement for immunosuppressive drugs also causes hardship for transplant recipients. According to a 1990 survey by the American Society of Transplant Surgeons (9), almost half of its members said patients had difficulty affording these drugs, and the drug cost was responsible for most cases of noncompliance.

From the perspective of the Medicare program, a successful transplant is cheaper than continued dialysis even for individuals who continue to qualify for Medicare coverage. The average dialysis patient has costs of $32,000 per year; the first-year costs for a successful transplant are $56,000, but in later years the average cost to Medicare is $6,400. Overall, Medicare estimates a break-even point at three years; after that, costs to Medicare are lower (27). This equation might change, however, when all costs (not just those covered by Medicare) are considered.

Expenditures for ESRD

From its humble beginnings at $229 million in 1974, Medicare spending on ESRD beneficiaries grew to over $4 billion in 1989 (this includes all Medicare-covered care for the eligible population, not just kidney-related services). Growth in the patient population accounts for more than a proportionate share of the rise, which follows from the falling inflation-adjusted reimbursement rate per dialysis session.

Medicare pays the biggest share of ESRD costs, but not all. In 1988, when Medicare's share was $3 billion, total ESRD costs were estimated at $5.4 billion (153). The rest comes from monthly premiums paid by beneficiaries, other insurers (including Medicaid), and patients' out-of-pocket payments.

Erythropoietin

EPO, one of the first drugs produced through biotechnology, was approved by FDA in 1989 to treat anemias caused by chronic renal failure (CRF), ESRD, and HIV. Amgen, the manufacturer, was given exclusive rights to market EPO for seven years through provisions of the Orphan Drug Act.

HCFA developed an interim policy to pay for EPO for Medicare CRF and ESRD patients. It assumed, based on Amgen's recommendations, an average dose of 5,000 units administered three times per week and single use of vials (2,000-, 4,000-, and 10,000-unit vials were available). It estimated that about 20,000 (19 percent) ESRD patients would be treated with EPO in the first year. Reimbursement was set at $40 per treatment for up to 10,000 units and $70 for more than 10,000 units, using a "per-bottle" approach. The total cost of EPO was estimated at $125 million, of which Medicare would pay 80 percent ($100 million).

In fact, 50,000 ESRD patients (43 percent) were treated with EPO that first year. They were treated with an average dose of 2,700 units, however, and somewhat less than half of those treated were achieving the desired results as measured by hematocrit levels. In addition, the vials were commonly being used more than once. Medicare's total EPO costs were $265 million, averaging $5,300 per treated individual for EPO alone.

It did not take long for HCFA to revise the way payments were calculated for EPO. Beginning in January 1991, reimbursement was set at $11 per 1,000 units, reducing any incentive to use lower

dosages and recognizing that multiple doses were being drawn from a single vial. The average dose did in fact increase to 3,450 units by December, and the number of ESRD patients treated rose to 74,600-more than half of the entire Medicare ESRD population. Contrary to HCFA'S anticipation of a lower bill for EPO, Medicare expenditures for 1991 rose to $396 million. The average cost per beneficiary for the year remained at $5,300. **According to HCFA,** blood transfusions decreased significantly among EPO-treated ESRD patients, but were not replaced entirely by the new treatment, as some patients do not respond to EPO. ProPAC concluded in its review that providers "appear to have responded to financial incentives" in their use of EPO.

Medicare's ESRD program might be viewed as a continuing experiment in how government policies can affect medical care. Its management has been driven by the desire to create a fair reimbursement system that neither induces excessive spending by the government nor compromises the quality of service to ESRD beneficiaries. Congress has been particularly active in influencing ESRD management, sometimes in concert and other times in conflict with HCFA.

NEONATAL INTENSIVE CARE

During the twentieth century the infant mortality rate has taken on importance as a "yardstick" for gauging a nation's health. In the broadest international sense the gulf in infant mortality rates between developing and developed countries is an obvious and meaningful proxy for disparities in the general level of economic development. Among the developed countries—where really large improvements in infant mortality no longer can be achieved by environmental measures, such as improving sanitation and water supply—the differentials are much smaller and. at least to some extent, attributable to reporting differences (129); nonetheless, the imperative to lower infant mortality rates remains strong.

Nowhere is it stronger than in the United States, which ranks poorly among the developed countries. Aggressive neonatal intensive care is the most visible response to high infant mortality in the United States. In 1990 the United States ranked 24th in infant mortality out of 38 selected developed countries, with a rate of 9.2 per 1,000 live births. A larger absolute differential exists within the United States between blacks and whites: in the 1987-89 period the U.S. black infant mortality rate was 18.6 per 1,000 live births and the rate for U.S. whites was 8.8 (142). A major contributor to the high rate for blacks is a very high proportion of low- birthweight babies. The factors contributing to low birthweight are understood only poorly, but there are definite correlations of rates (within other countries as well as the United States) with low socioeconomic status, suggesting that the combined effects of poor nutrition, poor medical care, and a generally poor environment all are important.

Supply of Neonatal Intensive Care Units (NICUS)

Perinatal medicine and its associated technologies began to evolve in the 1960s; with that development, hospitals began installing special units for sophisticated, intensive care of newborns. In the 1970s, the number of NICUS began to grow. By 1976 the Committee on Perinatal Health—a joint effort of the American Medical Association, the American College of Obstetricians and Gynecologists, the American Academy of Family Physicians, and the American Academy of Pediatrics—had outlined a three-tiered system of regionalized maternal and perinatal health services. Level I hospitals provide care for normal newborns with no special services, level 11 hospitals are equipped to deal with some special problems, and level 111 hospitals are regional referral centers for the most specialized and intensive care. Although various groups have issued guidelines on level II and 111 units, the classification system is not applied consistently across the coun - try. The regional structure still exists, but there are now so many NICUS that the referral system has become less important.

OTA reported that there were 534 NICUS in the United States in 1983, including both level 11 and

level 111 units. The Perinatal Information Center estimates that in 1993, there were 700 level II units and between 700 and 750 level 111 units (81).

Patient Population

About 6.5 percent of babies born in the United States weigh less than 2.500 g (classified as low birthweight). About 1 percent of babies are born weighing less than 1,500 g, (very low birthweight). The birthweight distribution has continued with a trend of increasing proportions of low-birthweigh' babies, particularly in the lowe:t categories. At ieast part of this change appears to be artifactual, as smaller and smaller babies are saved at birth and kept alive for at least some period of time in NICUS. In fact, this probably accounts to some extent for the poor performance of the United States in international comparisons of infant mortality (129).

Most babies admitted to NICUS are low-birthweight. Virtually all babies weighing less than 1,500 g require intensive care, and NICU admissions mirror the changing birthweight distribution.

Extremely low birthweight babies (less than 1,000 g) constituted about 5 percent of admissions in the 1970s, and by the late 1980s, they represented more than 10 percent. The smaller the baby, the longer the NICU stay. Ve.y -low-birthweight infants who survive until discharge can expect to stay 70 to 90 days in an NICU.

Effectiveness of NICUS

Nearly all of the decline in the U.S. infant mortality rate since 1960 is due to improved birthweight-specific survival during the first month of life. Although all of the improvement cannot be credited to NICUS. they undoubtedly have played a large role, generally believed larger than any other single factor. Decreases in mortality in the 1,500 to 2,500 g weight class had the greatest impact on overall mortality rates (125). Even in the smaller weight classes, the improvement has been significant: in 1985 a baby between 1,000 and 1,500 g had a 90 percent chance of surviving; 20 years earlier, it was 50 percent.

More and more low-birthweight infants are surviving, to be sure, but they do not all become healthy children. Although the evidence suggests no change in the birthweight-specific rate of handicap and disability among survivors, the great number of survivors means that the absolute number of children with problems increases. This is the basis of one debate about the aggressiveness of NICUS and the imperative to save smaller and smaller babies. Should we be expending enormous resources to save babies with a strong predilection for handicap? In 1987 OTA reported that about 40 percent of babies born weighing less than 800 grams have a moderate or severe handicap.

NICU Technologies

Premature infants most often need help breathing, and technology for ventilator support is the mainstay of the NICU. In the early 1970s, introduction into the NICU of continuous positive airway pressure (CPAP) was a quantum improvement over earlier technology for saving babies weighing less than 1,500 g; before that, only about 10 percent could be ventilated successfully (21). Improvements in ventilation have been incremental since that time, and have recently focused not merely on survival but on reducing the chronic lung damage (e.g., bronchopulmonary dysplasia or BPD) caused by ventilation. In the late 1980s, great enthusiasm began to develop for high-frequency, low-volume ventilators, based on a belief that they would reduce the rate of BPD in comparison to conventional ventilators. This enthusiasm, however, has not been confirmed by definitive evidence that they actually are better (11 2). Yet that lack of evidence may not have played as large a role in slowing the dissemination of high-frequency ventilators as has an FDA decision not to "grandfather" approval (under the 510(k) provisions of the FDCA) of ventilators at more than 150 breaths per minute (39).

The technology of the 1990s is surfactant for babies with hyaline membrane disease (HMD). It is distinguished by being not only a breakthrough but also the best-evaluated technology to enter the NICU. There still are many questions about the

most effective regimens and about the particular formulations but the evidence for benefits from HMD is clear and convincing. The evidence from randomized trials owes in large part to the fact that surfactant is a drug that required FDA approval before it could be marketed.

ECMO

ECMO entered the NICU in the early 1980s on a wave of enthusiasm but little evidence of efficacy. By 1986, 18 centers were active and had treated 715 newborns. By the end of 1989, more than 64 centers had treated a total of 3,595 babies. In the peak year (1992) 1,452 patients were registered (an ECMO registry keeps information on all ECMO patients reported).

The equally remarkable and sharp decline in ECMO use has come about in little more than a year as a result of the practical application of a basic science discovery: nitric oxide (NO) is a selective pulmonary vasodilator. In the first quarter of 1994, only 33 patients were entered into the ECMO registry (this may be explained partially by a time lag in reporting, but for the most part, it appears to reflect a real trend). What appears to be happening now is the systematic investigation of NO in many of the conditions for which ECMO has only recently been the treatment of choice. If the clinical trials under way are successful, they will provide a much better information base from which to determine the best uses of ECMO as well as NO in conjunction with some new ventilation techniques. A factor driving the systematic evaluation of NO is that it is not currently approved for any medical use, so it can be used (legally, at least) only under investigational protocols. This is really a postscript to the main ECMO story, however.

As recently as 1989, a survey of obstetrical hospitals suggested that more ECMO units were planned (102). This suggested a clear push toward expanding ECMO use from term to preterm infants, potentially a much bigger patient population. The most visible government activity with regard to ECMO was spurred by concern over the "apparent increasing use of this technology, especially in new patient populations, as well as concerns about long-term outcome." The result was a forum in 1990 sponsored by NIH, FDA, and AHCPR, with a report issued in 1993 (152).

ECMO was adopted on the basis of what proponents believed to be good evidence of its lifesaving abilities: they held that most of the infants treated with ECMO (of whom 90 percent or more may survive) would die if treated conventionally. A very definite "other side" believed that the evidence on which the proponents based their belief (from two small clinical trials) was faulty, and that the indications supported by evidence were, in fact, much narrower (28). The main criticism of the trials is that infants receiving "conventional" treatment were actually receiving substandard care. With careful management of newborns, the incidence of the conditions leading to the need for intervention is greatly reduced, and improved "conventional" treatment for infants in distress leads to results as positive as those for ECMO without the need for dramatic invasive technology"

There are no explicit controls on the acquisition and use of ECMO. Unlike some other new technologies, the cost of operating an ECMO unit is not so great as to pose a barrier to many hospitals. Using three different approaches, a recent study estimated the annual cost per case of an ECMO unit at between $6,000 and $16,000 (the higher figure is based on charges and is probably higher than the actual cost) (102). The total cost for ECMO averages about 4 percent of NICU operating costs, based on a sample of five hospitals. In comparing the cost of treatment with ECMO to the cost of conventional care, this analysis runs counter to earlier analyses showing that ECMO costs less.

In summary, ECMO, a highly invasive technology, diffused rapidly in the United States as a result of a highly enthusiastic group of supporters, the appeal of "high technology," modest cost, and a belief (if not necessarily well supported) that the technology could save babies, most of whom would die otherwise. A 1990 government-sponsored forum concluded that alternative means of preventing and treating (which appear to be successful in some centers) respiratory conditions in newborns have not been investigated adequately.

In the meantime, ECMO has been largely overtaken by the introduction of NO.

SCREENING FOR BREAST CANCER

Breast cancer screening is one of the few clinical preventive services for adults that the federal government has encouraged women to use, and it is one of only a handful of preventive technologies that the Medicare program will pay for. The policy issue that has captured the most attention in the United States as well as in other countries is the age at which screening mammography should start. The appropriate level of payment for the service under Medicare both to compensate appropriately for the service and to create incentives for increasing the number of women screened has been debated, and the quality of mammography services has been the focus of recent legislation. Under the Breast and Cervical Cancer Mortality Prevention Act of 1990, the Centers for Disease Control began providing money to states for comprehensive breast and cervical cancer screening, followup, and treatment programs for poor and minority women.

Most women who have a screening mammogram are referred by a physician rather than seeking it on their own. Most of the 12,000 mammography machines in the United States (more than triple the number in 1986) are in hospitals, breast screening and treatment clinics, and radiology offices (93,1 58), and payment for most mammograms is on a fee-for-service basis. Mobile mammography clinics are often at "health fairs," and a number of businesses (about one-third of the 500 largest U.S. companies in recent years) report bringing mobile mammography equipment to their workplaces (76).

Although some well-publicized cases of the disease raised awareness about breast cancer screening in the early 1970s, it was in 1980 that rates of screening really began to rise. In 1978 about 15 percent of women surveyed reported having had a mammogram. In a 1987 survey, 38 percent of women over 40 reported at least one mammogram. Screening prevalence decreased with age: the highest rate was 42 percent in women aged 40 to 54, and the lowest, 25 percent, was in women 75 years and older. Evidence that screening rates continue to increase comes from standardized surveys in about 30 states. From 1987 to 1989, the median percentage (of states surveyed) of women age 40 and over having had a mammogram rose from 49 percent to 63 percent. and in both those years, 80 to 90 percent of the women who had been screened reported a mammogram within the past two years (2). As in the previous surveys, older women were less likely to be screened. The most common reason given by women for not being screened, among all age and race groups, was that their physician had not recommended it.

Breast cancer screening has had a dramatic effect on the epidemiology of breast cancer. Mortality from breast cancer has remained more or less stable for the past 20 years, at a rate high relative to other developed countries (in the period 1985-89 it was 22.6 per 100,000, using a standard world population). It is the most frequently diagnosed cancer among women and, until recently (when it was overtaken by lung cancer), the most common cause of cancer death in women. In contrast with mortality trends, the measured breast cancer incidence rate rose by 36 percent between 1973 and 1987 (mainly from increased rates of localized and in situ cancers) and has leveled off since then. The increase in incidence is thought to be due almost entirely to cancers detected at screening (15 1) but has fueled popular belief that breast cancer is on the increase.

The National Cancer Institute (NC]) and FDA estimated that in 1990 there were more than enough mammography machines in use to handle all screening and diagnostic needs even if women followed NCI screening guidelines. The supply was estimated at 27 percent greater than need, spread relatively evenly across metropolitan areas (although in some rural areas capacity maybe insufficient). One implication is that many facilities are operating below capacity. The General Accounting Office (a congressional agency) estimated that in 1989 only 11 percent of facilities

performed more than 100 examinations per week (158).

Insurance Coverage for Mammography

Private health insurers and public programs vary in their mammography coverage. The original statutory language of the Medicare program excludes coverage for preventive services, but it has been amended to provide coverage for specific services, including mammography. A mammography benefit was first introduced as part of the ill-fated Medicare Catastrophic Coverage Act of 1988, which was repealed before it took effect. Mammography coverage was then inserted in the Omnibus Budget Reconciliation Act of 1990, taking effect in 1991 (120). The law allows payment for mammography every other year for women over 65. There has been constant pressure from activist groups and within Congress to improve coverage, resulting in the introduction of several bills during the 1991/92 session. It is likely that such activity, which is part of a broader movement toward greater attention to women's health, will continue (1 20).

In 1992 all but seven states had mandated some type of coverage for mammography by private insurers under the regulations of their state insurance commissions. A minimum schedule for screening was specified in 32 states, most of them identical:

1) baseline mammogram between 35 and 39 years of age,
2) biennial screening between 40 and 49 years of age, and
3) annual screening for women over 50.

The rules also contain various provisions that apply to payment levels and other particulars of coverage (45).

Mammography Quality Standards Act Of 1992

Each facility must have a quality assurance and quality control program, and its personnel must be licensed to perform radiological procedures. Each facility will be inspected at least annually by the Department of Health and Human Services or a state agency, and an accreditation body will review clinical images from each facility not less than every three years. If problems are found, the following sanctions are available: directed plans of correction, state on-site monitoring, civil money penalties, and suspension and revocation of the certificate.

Specific Screening Recommendations

A consensus development conference on breast cancer screening was sponsored by NCI in 1977, four years after publication of results from the landmark Health Insurance Plan (HIP) of New York study and subsequent launching of the Breast Cancer Detection Demonstration Project (BCDDP) by the American Cancer Society (ACS) and the NCI. NCI'S recommendation was for annual mammography for women over age 50, screening between age 40 and 49 only for women whose mother or sister had breast cancer, and screening for younger women based only on their personal history. Periodic breast physical examinations were recommended for all women older than 20. ACS concurred with the NCI recommendations until it modified them in 1980 to include a baseline mammogram between ages 35 and 40 and a recommendation that women under 50 consult their physicians about the advisability of a mammogram (24).

In 1983 BCDDP results were published indicating that about one-third of all breast cancers were detected in women between 35 and 49 old and most of the cases had been found with mammography and not breast physical examination. The ACS "concluded that a favorable benefit:risk ratio could be anticipated in women 40 years of age and older" and adopted a recommendation that all women over age 40 have a mammogram every one or two years (24).

In 1988 the American College of Radiology (ACR) convened a meeting to develop uniform recommendations for breast cancer screening. It accepted the ACS 1983 recommendations minus the recommendation for a baseline study. The following groups signed on to the ACR guidelines:

the American Academy of Family Physicians, the American Association of Women Radiologists, the American Cancer Society, the American Medical Association, the American Osteopathic College of Radiology, the American Society for Therapeutic Radiology and Oncology, the American Society of Clinical Oncology, the American Society of Internal Medicine, the American College of Pathologists, NCI, and the National Medical Association (24).

The dissenters were the American College of Physicians and the U.S. Preventive Services Task Force (USPSTF), both of which objected to recommending mammography for women under 50.

As technologies, both mammography and clinical breast examination met USPSTF criteria for accuracy and effectiveness of early detection; their recommendation for "average risk" women was for mammography every one to two years beginning at age 50 and ending at age 75. Baseline mammograms are not recommended. Clinical breast examination was recommended annually starting at age 40. Both physical breast examination and mammography should begin earlier for high-risk women. The task force was neutral on the question of breast self-examination, finding insufficient evidence to recommend a particular regimen (164).

Unlike ACS, USPSTF examined the effects and consequences of preventive services in a societal context and not exclusively from the individual point of view. It concluded that the potential benefit to women under 50, should one exist, is certainly smaller than the benefits to older women. Among the adverse effects of screening younger women are psychological morbidity, morbidity associated with biopsies, radiation exposure, and the "social effect of diverting health care resources away from more effective interventions." The latter concern was especially salient given USPSTF'S estimation that current resources are insufficient to screen all women over 50.

The debate over screening women under 50 was reinvigorated by publication in November 1992 of the first findings from the Canadian National Breast Cancer Study, a randomized study of 50,000 women. Mammography did not improve the mortality experience of women age 40 to 50 during the first seven years of followup of this study (79). This all but forced a reexamination of the various recommendations; NCI sponsored a meeting in February 1993 for this purpose. Part of the response has been to level severe criticism at some of the study's methods (18).

ACS decided not to change its guidelines based on the Canadian data but to wait for more data. In December 1993 NCI announced its new position: routine screening every one to two years for women over 50 is worthwhile, but for younger women, the evidence has not shown a net benefit. By this action NCI repudiated the advice it had received weeks before from its own National Cancer Advisory Board not to change its position (78).

As with renal dialysis, payment policies have been generous enough to encourage the proliferation of mammography units. It appears, however. that incentives to increase the screened population do not reward reaching the segment of population most likely to benefit: older women. In fact, because fees for non-Medicare patients can be considerably higher than the Medicare limited payment, the incentive may be reversed (93).

CHAPTER SUMMARY

In the United States, substantial investment in health care R&D in the public and private sector has ensured a steady flow of technological innovations. These advances, many of which provide at least some benefit to some population of patients, are introduced into an environment in which explicit fiscal limits are unusual. In the absence of macro-level policies that limit the adoption of new technologies, varied of mechanisms have emerged that seek to distinguish effective technologies from those that are ineffective. None of these mechanisms has been shown to be particularly effective in limiting the dissemination of technologies, regardless of their clinical value.

Whether or not the health care system in the United States undergoes a legislative restructuring, continue escalation in health care costs will sustain the current trend toward increased provision of care in managed care environments, many of which make use of annual payments per individual. In this setting payers and purchasers do face pressures to implement policies limiting access to technologies. These are the circumstances that encourage and sustain technology assessment in medical decision making. Any broad federal or state policy that places limits on the rate of increase in premiums charged by insurers or health plans will intensify the need for accurate analyses of the cost, risks, and benefits of medical technologies.

Over the past decade, technology assessment has burgeoned in the United States. Changes are occurring not only in how much is done but in who is doing it. In many countries, technology assessment has remained largely a governmental activity; in the United States, however, the private sector has continually ratcheted up its use and support of technology assessment methods. Insurers, drug and device manufacturers, hospitals, and professional societies have developed their own capabilities and have also fueled the growth of contract technology assessment organizations and university-based research groups. Meanwhile, the federal government has expanded its support of technology assessment, recently and most visibly in the new Agency for Health Care Policy and Research.

The government's interest in technology assessment has paralleled the growth in U.S. health care spending, and private sector interests too are inextricably linked to health care costs in one way or another. A drug manufacturer wants to show, through cost-effectiveness analysis; that its expensive new product actually will save money; the insurer may want to restrict access to an expensive technology until sufficient evidence exists to justify its use on the grounds of effectiveness—but the longer it can be held off, the better; the government wants to control overall spending, particularly by eliminating unnecessary and ineffective care. In this atmosphere technology assessment is not a neutral activity. Given the pressures and incentives, and particularly the financial consequences that depend on the use of technology assessment results, special agendas may be perceived everywhere even where they may not exist.

Taking as the broad aim of technology assessment the more rational use of health care services, it is difficult to know how successful overall efforts have been. Specific examples of when technology assessment has had a definite effect on medical practice seem to be the exception rather than the norm. Furthermore, many examples can be cited in which technology assessment results have been clear, yet payment decisions are made that do not reflect those results (usually in the direction of paying for unproven technologies). It may be that Americans do not share a single set of values about health care and how it should be used; hence, even with better information about the utility and cost-effectiveness of interventions, for instance, decisions are not obvious. And with so many players in the field, assessments from different sectors may favor different decisions. There also may be a suspicion that the main purpose of technology assessment is to save money by denying services, or that the individual is being sacrificed for some "public good" that **is not** necessarily subscribed to by the general population. Obviously, this goes beyond technology assessment itself, but it may help to understand how

assessment is viewed in the context of U.S. culture.

The biggest development in technology assessment methods over the last decade is the growth of "outcomes research" using data collected for other purposes (largely administrative, but some medical) to answer various questions, including whether interventions are effective. This may be seen as the latest attempt to obviate the need for randomized clinical trials to evaluate technologies. In the United States, randomized trials seem always to have been undervalued and their utility dismissed too easily. Innovations in clinical trials have largely taken place elsewhere, and although some proponents in the United States continue to press their case, the use of clinical trials currently is disappointing. There seems to be a growing recognition that administrative data may not yield the answers we need about technologies, but it is not clear that a similar amount of energy will be directed toward clinical trials, should the use of administrative data be abandoned.

In short, while technology assessment is thriving in the United States, and while it has clearly raised the level of debate about medical technology, understanding how it has actually affected the use of technology overall appears virtually impossible.

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Lessons from the Eight Countries

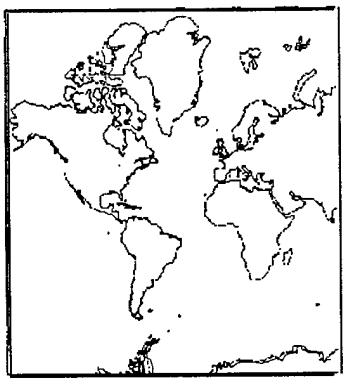
by Renaldo Battista, H. David Banta, Egon Jonsson, Matthew Hedge, Hellen Gelband

10

The preceding chapters have described the policies and mechanisms used to manage health care technology in eight industrialized countries: Australia, Canada, France, Germany, the Netherlands, Sweden, the United Kingdom, and the United States. These countries share a similar level of industrial development and confront similar challenges in meeting increasing demands for health care from aging populations (table 10-1). All currently are rethinking and restructuring their systems for health care delivery, and technology has come in for particular scrutiny in these efforts.

HEALTH SYSTEMS OF THE EIGHT COUNTRIES

Although the health systems of the eight countries have many similarities, they also differ considerably from each other. The ratio of physicians to population ranges from 1.4 to 3.1 per 1,000, and the average number of physician visits per person per year ranges from 2.8 to 11.5. The number of hospital beds ranges from 4.7 to 12.4 per 1,000 population, and the annual number of hospital days per person ranges from 1.2 to 3.7 (tables 10-2 and 10-3). The health care sector in each of these countries employs from 4.6 to 9.9 percent of the workforce (table 10-4).



The eight health care systems and their regulatory frameworks can be conceptualized in terms of the links they establish between four key constituencies: payers for health services, practitioners and providers, patients, and tax-paying citizens (table 10-5). These links (which differ in each system) establish a framework for managing health care systems, and in turn, for managing health care technology.

TABLE 10-1: Elderly Populations in Eight Countries, 1991

Country	Over 65 (%)	Over 75 (%)	Over 80 (Ye)
Australia	11.4	4,5	2.3
Canada	11,6	4.7	2.4
France	14.1	7.0	3.8
Germany	15.4	7.2	3.8
Netherlands	12,9	5.3	3.0
Sweden	17.7	8.1	4.4
United Kingdom	15.8	7.0	3.7
United States	12,7	5.2	2.9
OECD average	13.4		

SOURCE Organasation for Economic Cooperation and Development, OECD Health Data a Software Package for the Intemational Comparison of Health Care Systems (Paris, France Organisationo for Economic Cooperation and Development, 1993).

Perhaps the most striking difference among the health care systems surveyed here concerns financing and the links between payers and patients. In the United States "payers" is most definitely plural; there are more than 1,500 for-profit and not-for-profit insurers as well as substantial government expenditures on care for the elderly, the indigent, and military veterans. At the other extreme, in Canada and Sweden, there is essentially only one payer or at least one payment scale.

Several European nations have systems of linked multiple payers in which both employment-based insurance plans and government-managed plans coordinate coverage and payments. These arrangements rely on significant collaboration among the various payers such that they are able to exert something similar to the market power of a single payer.

In all health care systems, patients receiving care often incur out-of-pocket expenses, particularly for prescription pharmaceuticals and assistive devices. In the United States these expenses may include the costs of acute care for people without insurance. In the United Kingdom a parallel "private" health system, together with privately provided insurance, exists as an alternative to the universal National Health Service for those willing to pay. In France co-payments are made by most citizens, and ambulatory medical care expenses are reimbursed to the patient and not paid directly to practitioners.

Nevertheless, with the exception of the 30 to 40 million uninsured people in the United States, virtually every citizen of these eight countries is freed from contemplation of the costs of care at the point of delivery. Thus, people go to physicians or other health care providers, providers recommend treatments or investigations, and neither patient nor provider is much concerned with (or, in some cases, even aware of) the cost implications of these decisions.

Divorcing payment for services from their provision, which in some countries has advanced important social equity goals, also has facilitated the diffusion of health care technologies. This facilitation, along with concomitant efforts to regulate technology adoption and use, point to the dominant theme of this volume: namely, that *technology management* within a health care system is a function of the structure of that system *and* its surrounding cultural milieu. In France the health care system exists as an extension of the state bureaucratic apparatus. In Germany corporate influence is as strong in the health care system as it is in other aspects of German society. In the United Kingdom the health care system has changed from a benevolent government service to a pastiche of market-driven components. Despite these differences, the management of technology in all of these countries requires consideration of two distinct but related processes: adoption and utilization.

TECHNOLOGY ADOPTION

Health care technologies are goods. Markets exist for these goods, and suppliers in these markets seek competitive advantages to increase market share and profitability. The proprietary nature of much medical technology, together with the high costs of innovation, have created world markets for many technologies—particularly pharmaceuticals and imaging and surgical instrumentation.

Despite patent protection and multinational conglomeration in production, demand for tech-

TABLE 10-2: Number of Physicians, Hospital Beds, and Health Personnel Per Bed in Eight Countries, 1990

Country	Physicians (per 1,000 population)	Beds (per 1,000 population)	Health care personnel per bed
Australia		9.8[a]	3,9a
Canada	2,2	6.6a	2.4[b]
France	2,7	9.4	1,1
Germany	3.1	10.4	1.3a
Netherlands	2.5	11,5	2.1
Sweden	2 9	12,4	1.9a
United Kingdom	1 4	6.4	2.6[c]
United States	2,3	4,7	3,4
OECD average	2,4	9.0	2.0

[a]1989
[b]1988
[c]1987

SOURCE Organisatrion for Economic Cooperation and Development, OECD Health Data a Software Package for the International Comparison of Health Care Systems (Paris, France Organsation for Economic Cooperation and Development, 1993)

nological advances has been sufficient to sustain a very rapid pace of introduction of new products. Furthermore, rapid communication and the globalization of markets has meant that the range of technologies available in a given country is likely to be similar to that in another country, at least within the developed world. The six technologies considered in this volume are available in all eight countries, although the accessibility of each technology differs-quite markedly in some cases.

In this situation incentives for adoption include the benefits accruing to patients (decreased mortality or morbidity, increased quality-of-life), to providers (market advantage to a given physician or facility, more efficient provision of services), and to societies (economic development and economic nationalism focused on goods perceived to be high-tech). The relative importance of these incentives depends on the technology. Although the diffusion of computed tomography (CT) and magnetic resonance imaging (MRI) has been shaped by economic development issues in France and the Netherlands, the spread of laparoscopic cholecystectomy has been driven largely by patient and practitioner preferences.

Attempts to regulate technology are made at national or regional levels, or both. These include relatively ineffective certificate-of-need programs in Australia and the United States; the moderately effective Article 18 mechanism in the Netherlands; more effective systems of designated national centers for particular technologies in Australia; global budgets in Canada, Sweden, and the United Kingdom; and French "health maps" for planning. In countries with some form of central or system-level budgeting and expenditure management, incentives for adoption can be managed within a policy framework designed to optimize spending on technologies. In the Canadian and Swedish health care systems, particular attention is paid to siting of resource-intensive technologies, and the absence of alternative sources of capital funding acts tore inforce regulatory powers wielded at a systemwide level.

In such countries increasing energy is being invested in evaluation and assessment as part of the management process. Government-funded health systems in Canada and Europe are increasingly attempting to investigate the return on their expenditures in terms of improved health outcomes and, in some cases, in cost savings. In this climate various technology assessment schemes have evolved to marshal information relevant to spending decisions. To date, the greatest success in technology

TABLE 10-3: Numbers of Physicians Visits, Bed-days, and Average Length of Hospital Stay in Eight Countries

Country	Visits/person/year	Bed-days/person/year	Average length of stay
Australia	8.8	2.9	12,9
Canada	6.9	2.0	13.9
France	7,2	2.9	12.3
Germany	11.5	3.3	16.5
Netherlands	5.5	3.7	34.1
Sweden	2.8	3.5	18,0
United Kingdom	5.7	2.0	14,5
United States	5.5	1.2	9.1
OECD average	6.2	2.7	15,7

SOURCE Organastion for Economic Cooperation and Development, OECD Health Data a Software Package for the International Comparison of Health Care Systems (Paris, France Organisation for Economic Cooperation and Development, 1993)

management in countries with single-payer or linked multiple-payer financing has involved the shaping of policy decisions on the adoption and diffusion of resource-intensive technologies. Less costly technologies and those requiring minimal infrastructure investment have generally diffused unimpeded by macro-level management. With some exceptions, the power of financing has only begun to be used to manage technology.

In the United States, in contrast, such macro-level management is generally lacking or ineffective. Attention has been paid much more to the operational level of administration and clinical practice, through attempts to control utilization.

TECHNOLOGY UTILIZATION

Rates of procedures, the means used to deliver a specific service (such as neonatal intensive care units), and the mechanisms for regulating use vary widely. The evidence supports the theoretical expectation that fee-for-service reimbursement of providers creates incentives for technology use. For example, in France, MRI equipment diffused more rapidly in private hospitals than in public ones, apparently buoyed by opportunities for fee-for-service reimbursement in the private sector. Similar experience in several countries has fostered attempts to shift the basis of reimbursement from fee-for-service remuneration of practitioners and facilities to various forms of cavitation, global budgets, and salaries for practitioners.

Additional incentives for use emerge from the opportunity for accelerated capital cost recovery by owners of private establishments offering technological services, particularly medical imaging and laboratory services. Investment returns and subsequent incentives for use have been further enhanced by the incoherence of pricing for services such as medical imaging, particularly in the United States. Health systems in which technology use is subsumed within the budget of health facilities should theoretically encourage efficiency and specialization in service delivery as technology holders seek to reduce their average costs. In an entrepreneurial fee-for-service setting the constant rate of payment by insurers for each imaging study or laboratory test makes doing as many as possible more and more economically rewarding, as the marginal cost of each use diminishes.

Further incentives for technology use arise from the interplay of public expectations and health care systems. Among patients and practitioners, notions of rationalizing or optimizing resource use have only recently become admissible—and even then only minimally in most settings. The historical conception of practitioner responsibility as requiring an unbounded

TABLE 10-4: Percentage of Workforce Employed in Health Care Sector in Eight Countries (recent years)

Country	Percent
Australia	NA
Canada	NA
France	NA
Germany (1989)	5.6
Netherlands (1990)	6.3
Sweden (1990)	9.9
United Kingdom (1990)	4,6
United States (1989)	6.3

NA - not available

SOURCE Organisation for Economic Cooperation and Development OECD Health Data a Software Package for the International Comparison of Health Care Systems (Paris, France Organisation for Economic Cooperation and Development 1993)

commitment of resources to each and every patient has hampered the management of technology use and, with the rise of nonpractitioner health administrators, has signaled a shift in the practitioner's role from that of a steward of health care resources to that of an employee of a health care system or enterprise.

This is particularly marked in the United States, where many physicians are either employees of managed care enterprises or treated as subcontractors to such enterprises. Contract terms are increasingly set by the enterprise-a fundamental change from historical patterns of fee-for-service reimbursement at local prevailing rates. In the United Kingdom the rise of a private system may be seen as a response to perceived failures in managing health care as a public responsibility and a nonmarket service.

In the United States insurers have invested heavily in systems to review technology utilization. In the absence of a framework for national or regional management of the system, attention has shifted to the operational level, that of administration and clinical practice. Technology assessment in the United States is often taken to mean the various guidelines and procedures put in place to regulate the use of technology by providers. Many of these guidelines focus on reimbursement, such as insurers' declining to cover experimental therapies (i.e., those with little or equivocal evidence of efficacy).

Although guidelines are an important element of technology assessment in any health care system, the United States has not been able to support the effects of these efforts with national or regional policymaking. In this environment incentives for the use of certain technologies seem likely to overwhelm the mechanisms for use management, leading to overuse in some cases and underuse in other cases. In the long run, effective technology management requires attention to both system and practice levels.

PUBLIC REACTIONS AND PRESSURES

The public has played a vital role in the adoption and diffusion of' new technologies. In all of the eight countries surveyed here, the public may complain about the costs of health care, but when individuals are sick, they are unlikely to inquire as to whether the technology used in their care is being used optimally. In addition to the trust vested in practitioners, the level of knowledge required to evaluate technology use often lies beyond even the practitioners who use the technology regularly. That laypersons rely on their health care practitioners for guidance in such matters is not surprising.

Concern arises because the practitioner-patient relationship, in addition to being heavily weighted in favor of the practitioner knowledge, creates an opportunity for the practitioner not only to recommend the amount of a good (i.e.. medical care) to be supplied but often also to set the price at which it will be supplied. All of this occurs with little role for payers for these services.

Still, the public also plays an important role as a social arbiter, modulating forces favoring technology use. This takes several forms. but in all countries surveyed here, health care services and their provision and financing have been major domestic policy issues. The pressure for change comes both from policy makers and directly from the public. The public has expressed some dissatisfaction with its health care system in all the coun-

TABLE 10-5: Health Care Systems in Eight Countries

	Canada	Un ed S a es
Health care system	Public financing by federal & provincial governments, provincial administration, universal access & portability, legal prohibition of parallel private-sector activity	Multiple payers (1 ,500 insurers); Medicaid/care public financing, corporate roles and interests, administratively cumbersome and increasing reform pressure
Regulation a) drugs	FDA model, provincial formularies for publicly funded programs, price regulation through Patent Medicines Review Board	FDA; large domestic industry; applicants support costs of regulatory requirements in exchange for faster processing
b) equipment	Device registration, suggestions for enhanced system exist; siting restrictions established by payers (provincial governments)	Law establishes classes 1, 11, and III with exemptions for devices "substantially equivalent;" certificate-of-need programs in some States
c) physicians	Provincially-based self regulation, incentives for nonurban practice, some licensing restrictions; generally fee-for-service practice	Entrepreneurial, fee-for-service practice with increasing amount of "managed care;" concern over imbalance in number of specialists v. generalists
Research & development	Small industrial role, generally arms of multinational firms, government spending low compared to other OECD nations; provincial sources exist for health services research	Large industry with extensive R&D; also, high level of government funding (NIH, AHCPR)
Technology assessment	CCOHTA, provincial bodies in BC and Quebec, attention to TA in Saskatchewan and Alberta	Diverse groups but little coordination; OTA, OHTA, AHCPR, professional organizations, industry. state-level activities
	France	**Sweden**
Health care system	Mix of employer-managed sick funds & social security financing, individuals reimbursed for 80'%. of costs (remainder privately insured); system of public and private hospitals	County-level administration of local and shared regional facilities; publicly-managed insurance with annual deductible; current climate of reform to increase choice and decrease bureaucracy via internal markets
Regulation a) drugs	FDA model; cost-efficiency aspects considered by Commission de la Transparence; Agence du Medicament issues approval for marketing after examining evidence of safety and effectiveness	FDA model, state monopoly on sales with patient paying small co-payment
b) equipment	Process of needs definition and govemment authorization for siting and operation	Little regulation; current move to establish device system like that for drugs and harmonize with EC policies
c) physicians	Fee-for-service, public and private MDs, current plans to limit medical student enrollment	Physician resource plans exist, MD freedom to adopt new technology is relatively controlled
Research & development	INSERM plays prominent role	MRC; also, industrial policy to groom national champions in the drug Industry
Technology dassessment	CEDIT, ANDEM, consensus conferences, CREME mandated by law but evidence of impact not yet available	SPRI, SBU (good track record, particularly with big-ticket items), consensus conferences with social orientation

TABLE 10-5 (cont'd.): Health Care Systems in Eight Countries

	The Netherlands	Germany
Health care system	Multiple payers, sick funds, global budgeting, changes to Internal markets	1,120 employer-based sick funds, office/hospital separation with remuneration to physician associations
Regulation a) drugs	FDA model, national formulary linked to payment for drugs	FDA model; 140,000 drugs available but most not evaluated as approval applies only to new drugs
b) equipment	Minimal regulation, Article 18 for siting of big-ticket technologies	No apparent restrictions or regulation, powerful export-oriented device Industry
c) physicians	General Incomes policy; payment by capitation and fee-for-service	Regional association with bargaining power; fee-for-service remuneration
Research & development	Investigational fund, TNO, industrial development	Significant Industrial role, government support
Technology assessment	Many actors, coordination mechanisms weak; includes Health Council, CBo	Some QA activities
	Australia	**United Kingdom**
Health care system	Multiple payers with mix of private and public insurers, shared state-federal jurisdiction	NHS funds health care through regional and district health authorites, recent purchaser-provider reforms, private-sector insurance and practice also exist
Regulation a) drugs	FDA model	FDA model
b) equipment	Little regulation, some attempt at certificate-of-need program, national centers for highly specialized services	Minimal regulation; some technical commentary prepared by Department of Health in some cases
c) physicians	Fee-for-service although "national" fee schedule appears to cover most physicians	Cavitation payments to GPs, fund-holding GPs purchase care form trusts and other health services
Research & development	MRC, little Industry role	Noted role of MRC in clinical trials and substantial UK-based pharmaceutical industry in R&D
Technology assessment	NHTAP, AHTAP, AIH & NCHPE all involved in technology assessment; impact strongest in gate-keeper roles, influence growing, Increased role for public possible	Growing interest particularly with need for outcomes information as part of NHS reforms, bodies whose work may contribute to TA Medical Research Council, Audit Commission, Kings Fund, Cochrane Collaboration

SOURCE R Battista & M Hedge 1994

tries analyzed in this report. Satisfaction is at its lowest in the United States, where in the early 1990s, 29 percent of those polled felt that the health care system needed to be rebuilt completely and 60 percent felt that fundamental changes were needed. At the other extreme, the Canadian population seems the most content with its current system; 56 percent of those polled saying that only minor changes were needed (5) (see table 10-6).

TABLE 10-6: Public Views of Health Care Systems in Eight Countries, 1990

	Percentage of respondents		
Country	Minor changes needed	Fundamental changes needed	Completely rebuild system
Australia	34	43	17
Canada	56	38	5
France	41	42	10
Germany (West)	41	35	13
Netherlands	47	46	5
Sweden	32	58	6
United Kingdom	27	52	17
United States	10	60	29

SOURCE R Blendon, R Leitman, 1 Morrison, K Donelan, "Satisfaction with Health Systems in Ten Nations," *Health Affare,* pp 185-192, summer 1990

Important differences exist in public roles among the countries surveyed here. In publicly financed systems, the citizen as taxpayer is unlikely to accommodate the limitless demands of the citizen as patient. The Netherlands and several Canadian provinces have established public commissions on health care in whose deliberations financing has figured prominently. In France changes in health care financing in 1990 created a contributory tax whose existence has provided the French parliament with an inroad to the national discourse on health costs and services.

In linked multiple-payer systems, governments often play a similar role, acting as the facilitators of collaborative price-setting while also acting as payers for services delivered to some segments of the population. The quasi-governmental role of sick funds and other population-based insurance arrangements may shield governments in these systems from the extent of criticism and scrutiny that those in Canada and the United Kingdom have received over their provision of health care services.

In the United States public attitudes have created a climate for health care reform. Concern has focused less on high overall expenditures or the quality of health care available than on inadequate financial protection against the costs of illness. The 1992 presidential election brought with it the promise of significant change. It remains too early to evaluate the successor even feasibility of such massive reform; however, that the public is calling for change is recognized by virtually all participants in the debate.

There is an additional avenue through which the public affects technology use in health care systems: mass media. Technology advocates, payers, and practitioners and facilities all use media outlets with a view to shaping social discourse on health care. For example, media coverage of "waiting lists" for access to specific technologies has been a powerful factor in accelerating decisionmaking with regard to CABG in Canada, the Netherlands, and Sweden. In both France and the Netherlands, mass media coverage of laparoscopic surgical techniques is credited with increasing patient demand for these technologies.

Technologies (particularly pharmaceuticals) are advertised to patients and providers. Several countries have guidelines for advertising, but not one prohibits it. Particularly in the United States, facilities and practitioners attempt to increase business by advertising the availability of specific technologies.

All of these facets of public participation combine in ways that appear to resist generalization even within a single country. Whatever form it takes and through whatever channels, public participation is an important factor affecting health care management in all eight countries.

HEALTH CARE TECHNOLOGY ASSESSMENT

Some form of technology evaluation or assessment is occurring in each of the countries in this report. The specific details and impacts of those efforts are, however, highly variable.

Health care technology assessment is a relatively new field in the United States as well as elsewhere. Its beginnings may be traced to the establishment of a health program in the Congressional Office of Technology Assessment (OTA) in 1975. The first report to describe assessments of specific technologies was published by the U.S. National Research Council in 1975 (9). Subsequent OTA reports described methods of technology assessment and illustrated how they might be applied to a variety of technologies (12, 13,14,15).

The United States does not have a dedicated national (executive branch) agency for health care technology assessment, although various entities carry out and encourage assessment activities. Without a national focus, activities have grownup in many, probably hundreds, of different public and private organizations. In some other countries, however, both national and regional programs have been established. The first was the Australian National Health Technology Advisory Panel (NHTAP), established in 1982. Countries that have established or designated national programs to become involved in health care technology include Sweden (1987), France (1990), the United Kingdom (1990), and Canada (1990). Regional or provincial programs also have been established, as in Quebec (1988).

Although programs have been established in a number of countries, investments in technology assessment are small compared to investments in health care and health-related research. The Institute of Medicine (7) estimated that U.S.1.3 billion-O.3 percent of the money spent on health care—was related to health care technology assessment in the United States in 1984, which included U.S.$1. 1 billion for clinical trials, mostly of pharmaceuticals. Spending direct to technology assessment was less than $50 million, about 0.5 percent of health R&D funds.

Health care technology assessment has developed primarily to aid policymaking in the countries described. In some countries fixed and prospective budgets have led to limitations on rises in health care expenditures that have begun to force choices between competing alternatives. One of the main emphases of the programs in such countries as the United Kingdom. France, and Sweden is to aid such choices.

It is important not to overstate the influence of technology assessment, however. Only a small minority of existing technologies have been formally assessed. The emphasis of most agencies until the present has been on newer, capital-intensive technologies that are more often the subject of explicit policymaking. There is, however, increasing attention to the established, "small-ticket" technologies that probably contribute much more to health care budgets and may also include many ineffective tools and practices.

Furthermore, adoption and use of health care technology is influenced by many factors, including the perception and experience of health and disease, cultural responses to technology, the nature of the medical profession, industrial information and promotion, and financial and regulatory systems. Policies can strongly affect some technologies, but many others are not affected directly by such policies. Physicians and hospitals retain considerable autonomy despite formal national or regional policies. Most decisions concerning diffusion are made in the purchasing departments of hospitals and in the clinics and practices of physicians.

Several key themes deserve attention. First, *technology assessment's potential is realized only with effective links to technology management.* Health care systems with a limited policy structure for technology management, such as those of Germany and the United States, do little in the way of implementing technology assessment findings, (despite much activity in the United States). In contrast, systems with centralized public management and collectivized financing tend to have greater demonstrable links between technology assessment and technology manage-

ment, particularly at the national or regional policy level.

Second, *the level at which technology assessment activities occur in a health care system will dictate their scope and impact.* In the single-payer systems of Canada, Sweden, and the U.K. National Health Service, the "client" for technology assessment information is easily identifiable and reasonably receptive to such information. In the multiple-payer system of the United States, insurers have embarked on forms of technology assessment with a view to regulating the practice of those who provide care to their insured clients. Although these activities are not focused on the adoption or financing of technology, they have a significant impact on technology use by providers. No health care system has yet established a technology assessment program spanning these two domains.

Finally, there is much about the use of health care technologies that is unknown or uncertain. In this environment, identifying lacunae in knowledge, whether about effectiveness or economics, should be an important part of technology assessment activities. Following that, collaboration is a logical response, for the information generated about health care technologies stands to benefit patients, providers, and payers in many countries.

THE CASE STUDIES

The authors of the eight chapters in this volume each examined six areas or technologies to explore policies in health care and their results (table 10-7). The six technologies are:

1. treatment of coronary artery disease;
2. medical imaging;
3. laparoscopic surgery;
4. treatment of end-stage renal disease (including the use of EPO);
5. neonatal intensive care (including the use of ECMO); and
6. screening for breast cancer.

All the technologies examined here share the combination of at least some accepted effectiveness and relatively high cost. In some circumstances societies have had to decide how much of these services they are willing to purchase and to whom limited supplies will be offered. Each country has also had to struggle to find information to answer questions on benefits and costs. The cases shed light not only on policy mechanisms but also on the development and use of technology assessment in these decisions. Our best judgment of the relative impact of technology assessment in each country on the adoption and diffusion of the technologies examined is shown in Figure 10-1.

Treatments for Coronary Artery Disease

Coronary artery bypass grafting (CABG) was introduced in the early 1970s and diffused rapidly in the United States (which now has the highest CABG rate) but less rapidly in other countries (3) (table 10-8). The use of CABG in patients who are unlikely to benefit (and, conversely, patients who are likely to benefit by not having it) may be substantial. PTCA was introduced as an alternative to CABG in the late 1970s and was touted as a cheaper and less-invasive alternative to CABG. It also diffused rapidly, but the promise of substitution for CABG has been largely unfulfilled (table 10-9): in no country has PTCA diffusion been accompanied by slowing rates of CABG.

Policies on these procedures have generally been weak or nonexistent. Although randomized clinical trials of CABG were organized fairly early in its diffusion (especially in the United States), the results of these trials have not been used systematically in making policy or influencing clinical practice. In the United States diffusion has not been slowed by any discernible factor.

In Europe and Canada decisionmaking seems to have been guided primarily by a desire to limit resources for such care, linked to skepticism about the procedure's effectiveness early in its diffusion. Early diffusion was limited in a number of European countries because of limitations in the number of procedures that could be done and the slow pace of increasing capacity. In Sweden only four hospitals were equipped with the facilities necessary to perform the procedure; facilities were also limited in other countries, including the United Kingdom, the Netherlands, France, and Germany.

FIGURE 10-1: Relative Impact of Technology Assessment on Technology Adoption and Diffusion (Case Study Technologies)

Impact of TA	CABG/PTCA	CT/MRI	LC	ESRD	NICU	Breast cancer I
Highest	Sweden	Sweden	Sweden	Sweden	Canada	U.K
				Canada		Sweden
	Canada	U.K.	Australia		Netherlands	Canada
		Canada	Netherlands			Netherlands
	U.K		France		UK.	
	France	Netherlands	U K	France	France	
	Netherlands	France	Canada	Netherlands	Sweden	U.S.
	Australia	Australia	US.	Australia		Australia
			Germany	U.K.		France
	U.S	U.S		US.	US.	
Lowest	Germany	Germany		Germany	Germany	Germany

KEY Breast cancer = screening programs for breast cancer, CABG = coronary artery bypass grafting, CT/MRI - computerized tomography and magnetic resonance imaging, ESRD = treatments for end-stage renal disease, LC = laparoscopic cholecystectomy techniques, NICU = neonatal intensive care units & EMCO, PTCA = percutaneous transluminal coronary angioplasty
NOTE Joined cells suggest that there is little to distinguish the countries in the list

SOURCE R Battista and M Hedge, 1994

No assessments other than informal evaluations or expert judgments guided decisions on how many facilities to have, how many surgeons to train, or how many operations to perform.

Early in its life cycle the public did not demand the procedure (3). With time, however, public and political pressures developed. In Sweden and Canada the existence of waiting lists for CABG created political pressure to accelerate diffusion. In the Netherlands the government tried to maintain a restrictive policy but eventually had to expand greatly the available facilities in light of public pressure (including the patients' association occupying the Parliament building). PTCA also seems to have diffused without a great deal of policy attention: it was only after the mid- 1980s that public agencies began to publish assessments of these technologies. The assessments had little impact.

Newer treatments are now emerging, such as those using lasers. Despite the large investments that would be required for such technologies, little evaluation or information on diffusion is available. In light of the massive burden of coronary artery disease in all the countries surveyed here, conditions appear ripe for rapid diffusion of new technologies aimed at treating this disease. If the experience with CABG and PTCA is repeated, this diffusion may well proceed largely unchecked by research findings or assessment activity.

Medical Imaging

Evaluation of medical imaging is difficult. Traditionally, diagnostic technologies such as CT scanners have been assessed on the basis of their technical capability and their diagnostic accuracy. Beginning in the 1970s, however, more and more authors recognized that the result sought from diagnosis was improved patient health. Studies were mounted to examine the impact of information from imaging on therapeutic decisions, but only rarely on the effects on health outcome. The state-of-the-art of studying diagnostic technologies continues to lag behind the recognition that health outcome should be the standard for its eval -

TABLE 10-7: The Case Studies in the Eight Countries

	Canada	United States
CABG & PTCA	In Quebec, CETS work led to decision to put catheterization labs only where surgery existed; some planning attempts but few data (e.g., 1,000 procedures/500,000 people/yr); permitsfor service establishment; no PTCA evaluation	Wide diffusion, wide geographic variation and expansion of indications to include treatment of elderly persons
CT/MRI	CT. policy limited reaction very political decisionmaking MRI: tight economic times, increasing evaluation culture and links to information have slowed diffusion	CT: many machines, some experience with certificate-of-need programs MRI: like CT, for both, self-referral may act to increase diffusion
Laparoscopic Cholecystectomy	Rapid diffusion via public pressure, commonly surgeons, no specific regulation	Rapid diffusion, public pressure and professional repositioning for general surgeons
End-stage Renal Disease	Patient-level approach, rapid move to home dialysis, transplants limited by organ availability	Universally accessible; incentives for dialysis as payment for drugs post-transplant limited to three years, more than half of all patients treated with EPO
NICU	Regionalized care; ECMO in Quebec has TA using outcome data explicitly for future policy on ECMO	Rapid diffusion, championed by users
Breast Cancer Screening	Politically charged, major Canadian research (NBSS); screening is neither high-technology nor a TA-resisting practice, so TA's role focuses on choices for efficient program delivery	Range of recommendations; insured services in 32 states; apparent tension among guideline developers (ACS, NCI)
	France	**Sweden**
CABG & PTCA	Ministry of Health authorization required, rapid increase in PTCA, no identifiable role for TA	Moderate diffusion pace but increasing public concern in mid-80s over waiting lists prompted national evaluation and calls for increased CABG & PTCA, "watt-and-see" slows diffusion and affords an opportunity for TA involvement
CT/MRI	Both require government authorization and have diffused rapidly carrying France from a position of few machines to many per population, when compared to other European countries	CT slowish diffusion, planned evaluation was actually used in managing diffusion MRI much the same as CT experience with big impact for NEMT report
Laparoscopic Cholecystectomy	Started in France, no authorization required	Financial incentives for less invasive, stay-shortening technologies have encouraged diffusion
End-stage Renal Disease	Ministry of Health authorization required, health needs are defined but apparently not linked to actual practice	Regionalized services, high prevalence of ESRD and of transplanted patients
NICU	No TA role, ECMO seems low priority in light of AREC, a made-m-France technology	Regionalized despite lack of official pressure/policies to do so, 2 ECMO centers exist and are felt to satisfy demand
Breast Cancer Screening	Insurance programs pay for mammography for women 50-69 years of age, CNAMTS is now funding pilot screening projects	Introduced in 1964, now virtually national coverage of screening program with county-to-county variation in eligibility; >50% of eligibles are believed to be screened

	The Netherlands	Germany
'CABG & PTCA	Highest rates in Europe, despite inclusion under Article 18, initail Intention to use Information in policymaking never actually happened	Rapid diffusion, planning for catheterization lab needs at state level, CABG guidelines developed by surgeons for QA
CT/MRI	CT little impact of TA, covered by Article 18 from 1984-1989 MRI better timing, more impact of TA, still rapid diffusion	CT diffused rapidly, funded initially by federal Ministry of Research & Technology, certificate-of-need attempts ineffective but documentation requirements produced temporary slowing of growth MRI slower than CT, possibly limited by financing changes limiting resources from government for establishment and from sick funds for reimbursement
Laparoscoplc Cholecystectomy	Fairly rapid diffusion, little assessment	Originated in Germany and France, no particular regulatory or licensing requirements but consumer demand and competition with nonsurgeons drive rapid diffusion
End-stage Renal Disease	Health Council role in decisionmaking for payment, transplantation limited by organ supply use of predictive modeling for forecasting	Low transplant rate, possibly due to absence of law governing organ donation and retrieval 'non-profit" non-hospital dialysis has grown in Importance
NICU	Small units now consolidating	Regionalized care established by obstetricians, ECMO diffusion slow but due to no particular factor
Breast Cancer Screening	Early hospital-based screening led to 1987 recommendation to establish biennial screening for women aged 50-70, Sick Funds Council funds program administered through regional cancer centers, CBO developed guidelines for screening	Eligibility for screening reported to be women > 20 years of age, mammography Included as part of broad cancer screening programs, paid for by sick funds, currently project in place to generate data for recommendation on mammography's place in screening programs

	Australia	United Kingdom
CABG & PTCA	No evaluation of CABG, 1991 rate of 669/mIllion people, NHTAP assessment of PTCA recommended developing guidelines, waiting lists exist but average wait is < 1 month	'Regional specialty until 1991 reforms, 1986 target of 300 CABG/milion people established but not reinforced
CT/MRI	CT >1/100,000 population, CT diffused rapidly and current concern is Inappropriate use, MRI evaluated early in diffusion & NHTAP recommend a centralized planning of MRI services	Brain and body CT scanners evaluated by Department of Health (DH) and Introduction regulated by DH, MRI evaluated in DH/MRC project, diffusion slowed by NHS requiring providers to pass capital costs on to purchasers through charges for services
Laparoscopic Cholecystectomy	Assessments undertaken but diffusion still rapid, laparoscopic cholecystectomy's Introduction associated with **26%** increase in rates of gallbladder surgery, other laparoscopic techniques have diffused less rapidly	Lack of central policy combined with private sector adoption, relatively rapid diffusion
End-stage Renal Disease	AHTAC guidelines developed for transplantation minimum number (30/yr) and orgaization of dialysis services, rate of growth of home dialysis slower than rate of growth of persons with ESRD	ESRD therapies centralized in bigger centers, emphasis on home dialysis and CAPD, Increasing role for private sector contractors to provide dialysis in Wales not yet seen elsewhere
NICU	Regionalized care, 2 centers provide ECMO, growing concern about costs of care (institutional and social) for very -low- birthweight infants	Regionalized care, growing concern about long-term morbidity among NICU-treated children
Breast Cancer Screening	Small-scale Screening begun during 1980s led to national program targeted at women 50 & over, NHTAP & AHMAC heavily involved in process leading to national program	National screening program in place current concerns include ensuring adequate coverage of population and maintaing skills of program workers

SOURCE R Battista & M Hedge, 1994

TABLE 10-8: CABG Procedures in Eight Countries, 1985-1991
Number/(rate per million population)

Country	1985		1988		1990		1991	
Australia	7,100	(470)	9,566	(579)	10,775	(630)	12,649	(731)
Canada	9,690	(380)	11,400	(425)			18,360	(680)
France	5,900	(1 10)	13,200	(240)	21,450	(390)	22,250	(410)
Germany (all)					26,137	(335)		
West Germany	12,600	(190)	22,000	(360)			30,500	(500)
East Germany	3,800	(62)						
Netherlands	6,800	(478)	8,280	(563)	9,470	(635)		
Sweden	1,970	(236)	3,518	(416)	4,329	(51 1)	5,693	(670)
United Kingdom	10,840	(195)			16,233	(282)	22,882	(405)
United States	201,000	(855)	253,000	(1 ,017)	262,000	(1 ,056)	265,000	(1,055)

SOURCE *Biomedical Business International* Newsletter 14(2):10, 1991, European Society of Cardiology, "European Survey on Open Heart Surgery 1990, "Annals of the European Academy of Sciences and Arts, vOl 2, Salzburg, Austria, 1991: U S Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Center for Health Statistics, unpublished 1979-1992 data from the National Hospital Discharge Survey provided by E Wood, Hospital Care Statistics Branch, Hyattsvlle, MD, 1994

uation. This means that comparing different methods of diagnosis, including those within the field of diagnostic imaging, has not often been done vigorously.

Diffusion of CT scanners was quite rapid in relation to other technologies that have been studied (1) (table 10- 10). In the United States this occurred despite certificate-of-need programs. Several factors promoted this rapid diffusion, including high profitability and enthusiastic physician acceptance. Beginning in 1978, MRI devices diffused into U.S. health care. Health planning also was unable to regulate diffusion of MRI scanners for reasons that included weaknesses of the planning program and difficulties in obtaining objective information on MRI's value.

CT and MRI scanners entail similarly high infrastructure costs. In all countries but the United States their diffusion has been shaped by the willingness of the public purse to fund them.

The diffusion of CT scanners illustrates clearly the effects of public policies. In France, for example, diffusion of CT scanners was delayed until the French industry produced scanners. When French-made scanners were available, the policy was to encourage their purchase.

Several countries, including Australia, the Netherlands, France, and Canada, developed guidelines for the number of CT scanners per population, restricting the numbers or rates. In general, formal assessment played little role in the development of such guidelines, which subsequently were revised rather rapidly (followed by the equally rapid diffusion of CT scanners). Whether this is a failure of regulation or indicative of responsive public policy is difficult to say.

One country in which an early assessment clearly had an influence on diffusion was Sweden, where an assessment gave guidance to hospitals as to whether it might be economically advantageous for them to purchase a CT scanner. Initial diffusion was slower than in other countries despite well-developed expertise in neurology. The Canadian province of Quebec also was able to slow diffusion of CT scanners, but the resulting lack of access to CT scanning led to pressures to relax the controls.

A number of countries used the case of the CT scanner to learn what might be done in linking assessment and decisionmaking. When MRI was introduced, it was assessed earlier and more sys-

TABLE 10-9: PTCA Procedures in Eight Countries, 1985-1991
Number/(rate per million population)

Country	1985		1989		1990		1991	
Australia	1,244	(79)	4,219	(251)	4,904	(288)	5,726	(330)
Canada			10,730	(405)	12,230	(453)	12,420	(460)
France	3,480	(60)	18,000	(324)	22,863	(460)	23,125	(410)
Germany					35,881	(490)		
West Germany	4,490	(77)	18,800	(308)	30,956	(505)	34,328	(560)
East Germany					4,925	(294)		
Netherlands	2,556	(185)	6,828	(458)	8,205	(550)	8.899	(593)
Sweden	165	(20)	858	(103)	1,098	(129)	1,834	(215)
United Kingdom	1,640	(29)	7,148	(126)	8,460	(148)	9,775	(170)
United States	90,000	(380)	239,000	(1,018)	260,000	(1,048)	298,000	(1,187)

SOURCE European Society of Cardiology, "European Survey on Open Heart Surgery 1990," Annals of the European Academy of Sciences and Arts, vol 2, Salzburg, Austria, 1991, The Swedish Council on Technology Assessment in Health Care, Goodman, C, The Role of PTCA in Coronary Revascularization Evidence, Assessment, and Policy, Sept, 1992, U S Department of Health and Human Services, public Health Service, National Heart, Lung, and Blood Institute, The Bypass Angioplasty Revascularization Investigation (BARI) A Brief Description Bethesda, MD, 1990, U S Department of Health and Human Services, Public Health Service, National Institutes of Health, *NIH Dataf300k* 1993 (NIH Publication No 93-1261) (Bethesda, MD, 1993)

thematically. In addition its slower diffusion was in part due to worldwide economic problems. Whether assessment was an important cause of its slower diffusion would be difficult to say, but certainly plans for MRI diffusion were more effective (table 10-11). In the Netherlands, for example, assessments were organized with the underlying idea of affecting policy through phased changes. In Sweden a report done by SPRI influenced MRI diffusion.

Laparoscopic Surgery

All eight health care systems surveyed in this volume have been rapid adopters of laparoscopic surgical techniques. In all except Sweden, this has occurred in the absence of any particular policy incentives. In Sweden explicit policy incentives for adoption of stay-reducing technologies have acted in concert with forces present in other countries. In all countries public interest and pressures have stimulated diffusion of laparoscopic cholecystectomy, but other laparoscopic procedures have not diffused so rapidly.

The speed of diffusion has made it impossible to perform good evaluations. Policy mechanisms did not control the diffusion in the United States, where payment was readily available for conventional cholecystectomy (although the Medicare program did establish a lower payment than that for conventional cholecystectomy). Industry strongly promoted the innovation. In Canada, too, policy mechanisms did not control laparoscopic cholecystectomy. In Europe, although laparoscopic cholecystectomy diffused relatively rapidly, diffusion of other laparoscopic procedures seems to have been constrained by limited budgets and lack of fees for these procedures (2).

At the level of the hospital, laparoscopic equipment is relatively low-tech, requiring little change in infrastructure or service arrangements. New technologies substituting for existing ones with minimal capital outlay diffuse with a stealth and speed not seen with imaging or any of the other technologies surveyed in this volume, all of which require substantial infrastructure investments.

TABLE 10-10: CT Scanners in Eight Countries, 1986-1992
Number/(rate per million population)

Coun ry	986		988		990		992	
Australia	165	(10,6)	185	(10.9)	235	(137)	292	(17.1)
Canada					190	(7.0)	200	(7.5)
France	264	(4.8)	350	(6.2)	409	(7,2)		
West Germany	423	(7,0)	595	(97)	750	(122)		
East Germany							31	(1 .8)
Netherlands	45	(3.2)	83	(5.7)	109	(73)		
Sweden	45	(5.4)	75	(9 o)	90	(10.5)	102	(12.0)
United Kingdom	149	(2,7)	204	(3.6)	250	(4.3)		
United States	3,000	(12.7)	4,991	(20.4)	6,715	(26.8)		

SOURCE M Bos, 1994

All health systems share an interest in reducing hospital length of stay, but any advantage arising from laparoscopic surgery in this regard may be squandered if the bed-days freed are simply filled with persons undergoing other elective surgeries.

The rapid growth in laparosopic cholecystectomy use in several countries is consistent with a growth greater than the rate of natural increase of the open procedure it replaces. Expanding the number of persons deemed candidates for operation (particularly for an often-elective procedure such as cholecystectomy), in the absence of guidelines defining indications, may well increase overall expenditures on surgery.

Little assessment of any of the laparoscopic procedures has been done (2). As this case shows, despite the growth in technology assessment activities, such activities still may be unsuccessful in identifying technological innovations early enough to influence their diffusion. Without clear measures of benefit of expansions in surgery, evaluating the overall impact of these and other minimally invasive, stay-reducing technologies will be an ongoing challenge for all health care systems.

Treatments for End-Stage Renal Disease (ESRD)

Treatment of ESRD is different from other areas of health care technology because its efficacy and appropriate use is not at issue; patients with ESRD will die without treatment. All eight countries in this report furnish essentially full financial coverage of the cost of treatment for all or most of the people with the disease.

Because of the high cost of treatment (particularly renal dialysis) questions concerning this procedure have generally centered on how to provide it more efficiently. All countries have made some attempt to limit the number of services provided, but then have met irresistible pressures to expand the provision of treatment to all who can benefit from it.

ESRD treatment is a field in which a great deal of assessment has been performed, with a major focus on the high aggregate costs of conventional dialysis. This has led nearly all countries to advocate alternatives, including renal transplant, peritoneal dialysis, and home dialysis. If successful, a transplant eliminates the need for continuing dialysis; however, the number of transplants is limited by the availability of kidneys. Home dialysis, emphasized by some countries (such as Canada and the United Kingdom), is a method of providing more services at lower average costs.

In the United States outpatient hemodialysis is the dominant treatment under the Medicare ESRD program. which covers nearly all Americans with ESRD. Home dialysis is used by only 2 percent of program enrollees. The American system of treat-

TABLE 10-11: MRI Scanners in Eight Countries, 1986-1992
Number/(rate per million population)

Country	1986		1988		1990		1991		1992	
Australia	3	(0.2)	7	(0.4)	11	(0.6)	20	(1,2)	25	(1 .5)
Canada	5	(0.2)	9	(0.3)	20	(0.7)	22	(0.8)	28	(10)
France	29	(0.5)	36	(0.6)	70	(1.2)	95	(1 .7)	107	(19)
West Germany	41	(0.6)	91	(1.5)	143	(2.3)	200	(3.2)		
East Germany									1	(.05)
Netherlands	2	(0.1)	5	(0.3)	14	(0.9)	20	(1.3)	27	(1 .8)
Sweden	2	(0.2)	6	(0.7)	12	(1 .5)	17	(2.2)	22	(2.6)
United Kingdom	14	(0.2)	25	(0.4)	55	(0.9)	65	(1.1)	80	(1 .4)
United States	110	(0.4)	1,600	(6.6)	2,076	(8.4)	2,560	(10.1)	2,940	(11.3)

SOURCE M BOS, 1994

ment is dominated by profit-making dialysis centers, and incentives to move toward less expensive forms of dialysis are lacking. Policy changes within the ESRD program are almost continuous and are intended to avoid introducing incentives for overuse.

EPO was introduced in 1989. This drug reduces morbidity and improves the quality of life for some people on dialysis, but at a substantial cost. Because services for ESRD are managed at the system level in all eight countries, responses to EPO may provide some insight into how health care systems are managing the transition from the sole goal of prolonging life to a more complex improvement in quality of life with minimal morbidity. In Canada and France initial limitations in access to EPO led to public demonstrations, particularly by nephrologists caring for persons on dialysis, and to subsequent expansion of access. In other countries, despite its high cost, EPO has been incorporated into ESRD programs without assessment or serious public discussion. The percentage of ESRD patients receiving EPO in 1990 ranged from 60 percent in the United States and Sweden to about 20 percent in the United Kingdom (8).

Neonatal Intensive Care

Neonatal intensive care services are provided in all eight countries through organized systems of care, although the levels of services are not directly comparable. The United States is striking for its high level of such services combined with a high infant mortality rate compared with other industrialized countries.

Few figures are available concerning the diffusion of neonatal intensive care. One reason for this is the difficulty of defining such care. Techniques of intensive care are now widely used in newborn health care. The components of neonatal care vary both from center to center within a country and from country to country. As an example, extracorporeal membrane oxygenation (ECMO) is hardly used in France but is used in many centers in the United States.

ECMO diffused rapidly in the United States without consensus on effectiveness. By the end of 1989, more than 64 neonatal intensive care units had treated a total of 3,595 babies. Its rapid diffusion is probably related to the chance it may offer to save the life of a newborn, together with its revenue-generating potential in the United States and some other countries.

Assessment has generally played little role in developments in neonatal intensive care. One exception is Canada, which has a regionalized system for neonatal intensive care. An assessment of ECMO has been organized using outcome data to help decide future policy. In the Netherlands and the United Kingdom prospective randomized

studieso of ECMO are intended to guide future policy decisions.

Screening for Breast Cancer

Breast cancer screening is available in all eight countries, but there are vast differences among screening activities. Preventive measures are often not covered automatically by insurance, especially when they require special investments. In the case of screening for breast cancer special mammography equipment is required as well as specially trained staff. Special centers for this purpose maybe established. These factors may explain its slow diffusion. The differences from country to country, however, suggest that political circumstances may beat least as important for implementation as evidence of efficacy.

In the United States mammography screening has been recommended since 1977, based on a large randomized clinical trial done in New York City. Gradually, state laws have mandated insurance coverage for mammography screening, and the Medicare program has covered it since 1991. The capacity for screening in the United States is more than adequate to screen the entire target population, but the actual percentage of women over the age of 50 who have been screened falls far short of the goal of universal screening.

A number of assessments of mammography have been done in the countries covered in this report (including randomized trials in Canada, the United Kingdom, and Sweden, and formal cost-effectiveness analyses organized in Sweden, the Netherlands, and the United States). These assessments appear to have affected policy. All assessments have encouraged a public sector program for breast cancer screening. Single-payer control provides a political target for advocates of mammography and appears to have contributed to the development of coordinated programs in Canada, the Netherlands, and Sweden.

The absence of coordination among program advocates and payers remains an issue in all countries. As a result, screening programs have tended not to be focused on risk categories (e.g., age, family history) for which the greatest benefit has been demonstrated. The relative success of programs in Canada, Sweden, and the Netherlands demonstrate the difficulty of providing, managing, and evaluating preventive services in the absence of some form of central policy and coordinating mechanism for such preventive services.

CONCLUSIONS

In contrast to the situation in 1980, all of the countries examined in this report now have stated policy goals of assessing the benefits of health care technologies. Formal programs for health care technology assessment vary but are operational in all the countries studied. Although still small, these programs are beginning to change the nature of health care policymaking.

Countries with national systems of health care have attempted to develop policies to manage new and existing technologies in concert with global or prospective budgeting. One element of these policies is technology assessment and its linkage to policy decisions. Technology assessment's impact varies, but it is becoming an important factor in decisions about technology acquisition. Table 10-12 presents our best judgment of the overall impact of technology assessment on policymaking in the eight countries studied.

The United States has not developed a policy structure that makes the management of health care technology possible at the national level. Efforts in the United States are aimed at directly affecting medical practice (with varying success). The national and regional issues have not been addressed effectively.

One lesson emerging from this report is that although national and regional policymaking is essential to control health care expenditures, such policies are not sufficient for managing technology. To ensure the efficacy and cost-effectiveness of technology adoption and use, actions at the operational level of clinical medicine also seem to be necessary. Such actions are only beginning in most of the countries studied, other than the United States.

Health system reforms appear to be accelerating around the globe. All countries face increasing

TABLE 10-12: Overall Impact of Technology Assessment on Policymaking in Eight Countries

Significaton impact	Sweden
Moderate impact	Canada The Netherlands
Modest impact	Australia U.K.
Minimal impact	Us. France
No impact (Nascent Technology Assessment)	Germany

SOURCE R Battista and M Hedge, 1994

demands from an aging population for increasing costly services (even if the percentage of GNP spent on health care does not rise greatly). In addition, all are grappling with inappropriate use of technology, and consumer dissatisfaction (16). Some countries, such as Sweden, are making changes to enhance consumer choice of physicians and hospitals. Others, such as the United Kingdom, are making profound organizational changes to affect incentives in their health care systems. Some countries are planning further changes in financing mechanisms to control specialists' incomes and to change incentives in specialist payments. Quality of care is of growing concern: several countries are actively attempting to limit payments for "unnecessary" care, and the public and policy makers are beginning to question the benefits of certain clinical procedures.

These trends point to a future for technology assessment and, perhaps, to better management of health care technology. There is a growing recognition of the need for more timely and accurate information on the benefits, risks, and costs of health care technologies. To the extent that they deal with specific technologies, all policies, whether regulatory or financial, can be developed intelligently only if there is good access to such information. Physicians, institutions, and patients also need information to make their decisions. The informational needs are enormous and remain largely unmet.

Although the effects of technology assessment have so far been relatively limited in some countries, others can point to real successes. The most striking differences between the situation in 1980 and today in 1994 include:

- the substantial increase in governmental support for health care technology assessment,
- the marked increase in the number of institutions and people involved in technology assessment, and
- the strengthening of the international network in this field.

A final word about internationalism in this field: the 1980 OTA report ended with a recognition of the importance of an international perspective in health care technology assessment. The current report also demonstrates the common problems and similar solutions that countries are finding. In 1994 we can describe actual progress that has been made in this area, beginning with the establishment of the International Society for Technology Assessment in Health Care (ISTAHC) in 1985, which has furnished a forum for individuals from many countries to share concerns, results of analysis, and possible problem-solving approaches. In 1993 the International Network of Agencies for Health Technology Assessment (INAHTA), initially involving about 13 public agencies in 10 countries, was formed for the purpose of exchanging information, avoiding duplication, and perhaps actually working together on assessment. In 1994 the EUR-ASSESS program, intended to coordinate technology assessment activities among the members of the European Union, was funded by the European Commission. These networks are still relatively young, but their very formation indicates that the need for an international perspective has been recognized.

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