

Health Care Technology in the United States

by *Sean R. Tunis and Hellen Gelband*

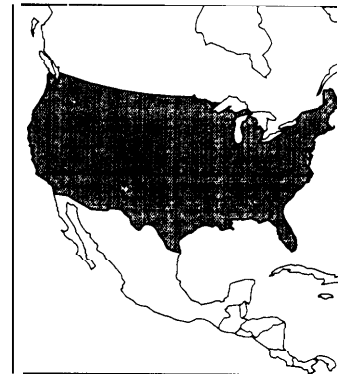
9

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 1991 (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



¹1991 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 devel-

oped 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 currently 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 (133).

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 elderly 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 older 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. Nei-

ther 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&D are 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

²State and local governments and private nonprofit foundations are the other significant supporters of health R&D. 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.

⁴About 90 percent of the NIH budget is devoted to the intramural work of NIH researchers.

⁵It is difficult to determine the precise distribution of trials supported by NIH because no comprehensive database exists on the topics addressed.

⁶A 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.

⁷A more complete description of the FDA drug approval process is available in (128).

⁸In 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 difficulty 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 II 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 III 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 be effective (66). This determination would be made on the basis of well-controlled investigations, including "clinical investigations *where appropriate*" (emphasis added) (FDCA, 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 carefully de-

financed until recently. For example, the use of laser catheters to open clogged leg arteries was approved through the 510(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 510(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 510(k) approval was sought. The number of devices approved through this route has since decreased, and review times for 510(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 be at *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 price tags 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, 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

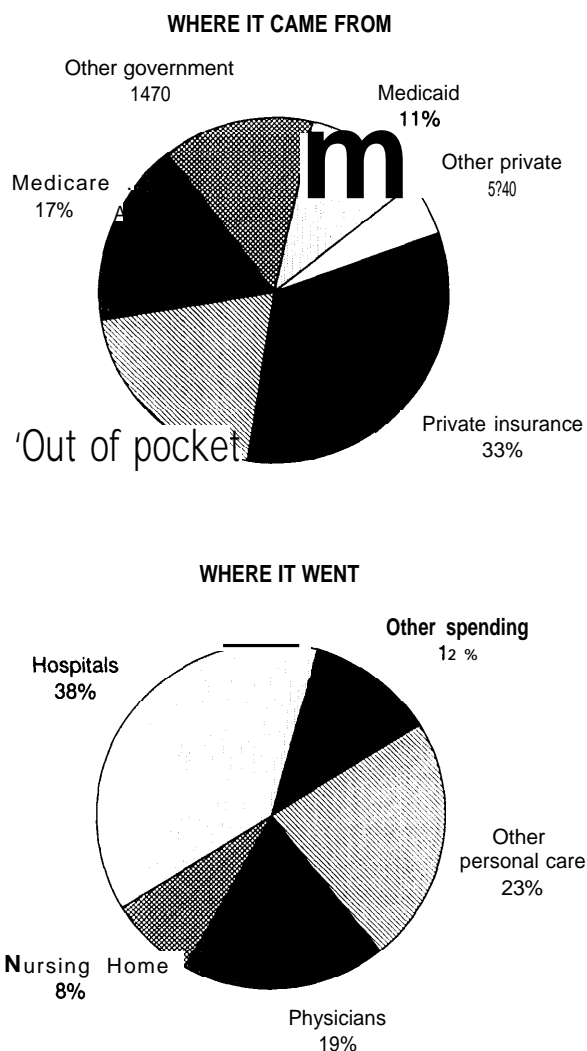
A patchwork of mechanisms has developed in the absence of structural or legal limits to growth of health care spending. Pushing against these are forces compelling greater spending, at least in part through the use of increasingly expensive medical technology. These forces exist in every country, but 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.

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

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

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 a new technology as a substitute for existing technology and bill for it using existing payment codes. Early 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)(1)(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 fully 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 pro-

grams 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.

Effectiveness of 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 (130). 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” medicine, 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).

292 | Health Care Technology and Its Assessment in Eight Countries

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

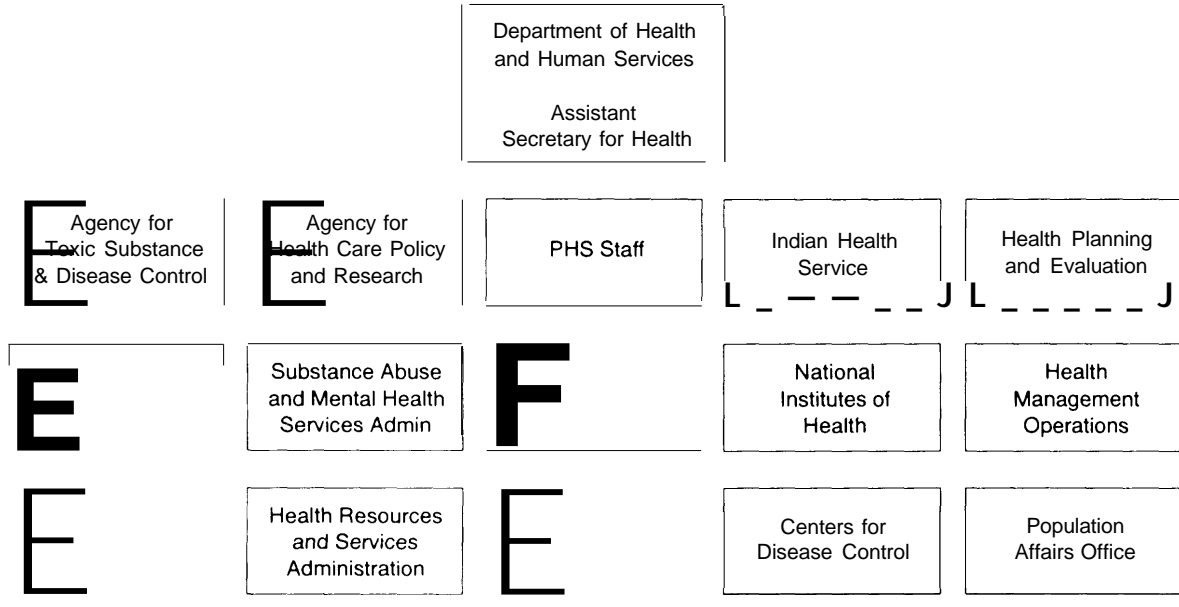
innovation. It also argued that assessments could be undertaken by existing federal entities and that the Center was therefore redundant. It seems likely that the major cause for the industry's concern was the potential for new devices to fail in the market after a negative evaluation from a central 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 tissement 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 million 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 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 methodologically 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 quality, 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.

⁹ The 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 evidence. 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 incontinence	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 Alzheimer's	In progress
Quality Determinants of Mammography	Released
Smoking Prevention and Cessation	In progress
Anxiety and Panic Disorder	In progress

SOURCE "Guidelines 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, Physician 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 tradi-

tional 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, Birmingham, AL	9/30/92	9/29/97

SOURCE U S Department of Health and Human Services, 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

¹¹Not 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 Monitoring Procure 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; <u>Combined Kidney-Pancreas Transplantation</u>	

^a“Technology Reviews are brief evaluations of health technologies prepared by the Office of Health Technology Assessment, Agency for Health Care Policy and Research (OHTA/AHCPR) of the Public Health Service. Reviews may be composed in lieu of a technology assessment because the medical or 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 Reviews)

SOURCE Office of Health Technology Assessment, Agency for Health Care Policy and Research “OHTA Assessment and Reviews, Published 1981 -,” unpublished document, Rockville, MD, February 1994 B Gordon, Office 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 (0 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 Cholecystectomy	NIDDK
1993	Impotence	NIDDK
	Early Identification of Hearing Impairment in Infants and Young Children	NIDOC
	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, NIDOC = National Institute on Deafness and Other Communication Disorders, 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, Office of Medical Applications and Research

Other Federal Evaluation and Assessment Programs

National Institutes of Health

The Office of Medical Applications of Research (OMAR) at NIH began holding 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 predefined 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 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

¹²This 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 information provided usually focuses on generating 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 are 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 use 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 probably the single largest funders of technology 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 the evidence on medical and surgical procedures suspected to be ineffective. The program was conducted in close collaboration with medical professional societies and resulted in guidelines 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 emerging 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 alternatives, 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 collabora-

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, policy-makers and the public are confronted with the downstream implications of these issues, which

¹³An 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 information 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 three-fold 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 medi-

cal 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 policies 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) (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 ex-

ceeding \$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 or close to an acute care hospital.) 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 laparoscopically (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 performed in France, about 85 percent of all cholecystectomies

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 (111)). 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 (111).

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, 111). 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 (111).

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 (11,117). 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 comorbidities 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 risk/benefit ratio similar or superior to that of the open procedure.” The analysis was also noted that the risk/benefit 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 evidence 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 laparoscopic 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 laparoscopic cholecystectomy, 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 herniorrhaphy, 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 unconditionally 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 for other 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 II hospitals are equipped to deal with some special problems, and level III hospitals are regional referral centers for the most specialized and intensive care. Although various groups have issued guidelines on level II and III units, the classification system is not applied consistently across the country. 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 II 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-birthweight babies, particularly in the lowest categories. At least 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. Very 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

320 I Health Care Technology and Its Assessment in Eight Countries

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 (93,158), 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 (151) but has fueled popular belief that breast cancer is on the increase.

The National Cancer Institute (NCI) 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 (120).

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 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.

REFERENCES

1. Aaron, I-I. J., *Serious and Unstable Condition: Financing America's Health Care* (Washington, DC: Brookings Institution, 1991).
2. Ackermann, S. P., Brackbill, R. M., Bewerse, B. A., et al., "Cancer Screening Behaviors Among U.S. Women: Breast Cancer, 1987-1989, and Cervical Cancer, 1988-1989," *Morbidity and Mortality Weekly Report* 41(SS-2), 17-25, Apr. 24, 1992.
3. American College of Cardiology and American Heart Association Task Force, "Guidelines for Percutaneous Transluminal Coronary Angioplasty," *Journal of the American College of Cardiology* 12(2): 529-545, 1988.
4. American College of Cardiology and American Heart Association Task Force, "Guidelines for Coronary Artery Bypass Graft Surgery," *Journal of the American College of Cardiology* 17(3):543-589, 1991.
5. American College of Cardiology and American Heart Association Task Force, "Guidelines for Percutaneous Transluminal Coronary Angioplasty," *Journal of the American College of Cardiology* 22(7): 2033-2054, 1993.
6. American College of Physicians, "Magnetic Resonance Imaging of the Brain and Spine: A Revised Statement," *Ann. Intern. Med.* 120(10):872-875.
7. American Hospital Association, *Hospital Statistics* (Chicago, IL: 1990-1991).
8. American Medical Association, *Physician Characteristics and Distribution in the U. S., 1992 edition* (Chicago, IL: 1992).
9. American Society of Transplant Surgeons, *Survey on Present Status of Reimbursement for Immunosuppressive Drugs* (Des Plaines, IL: 1990).
10. Banta, H. D., and Kemp, K. B., *The Management of Health Care Technology in Nine Countries* (New York, NY: Springer Publishing Co., 1982).
11. Barkun, J. S., Barkun, A. N., Sampalis, J. S., et al., "Randomised Controlled Trial Laparoscopic Versus Mini Cholecystectomy," *Lancet* 340:1116-1119, 1992.
12. Berstein, S.J., Kosecoff, J., Gray, D., et al., "The Appropriateness of the Use of Cardiovascular Procedures: British versus U.S. Perspectives," *International Journal of Technology Assessment in Health Care* 9(1):3-10, 1993.
13. Bice, T. W., "Health Services Planning and Regulation," *Introduction to Health Services*, S.J. Williams, and P.R. Torrens (eds.) (New York, NY: John Wiley & Sons, Inc., 1988).
14. Bice, T. W., and Urban, N., "Effects of Regulation on the Diffusion of Computed To-

- mography Scanners,” report for grant #HS03750, National Center for Health Services Research, Washington, DC, 1982.
15. Brown, L. D., “Common Sense Meets Implementation: Certificate-of-Need Regulation in the States,” *Journal of Health Politics, Policy and Law* 8:480-494, Fall 1983.
 16. Chaitman, B. R., Fisher, L. D., Bourassa, M.G. et al., “Effect of Coronary Bypass Surgery on Survival Patterns in Subsets of Patients with Left Main Coronary Artery Disease. Report of the Collaborative Study in Coronary Artery Surgery (CASS),” *Am. J. Cardiol.* 48(4):765-77.
 17. Concato, J., Horwitz, R. I., Feinstein, A. R., et al., “Problems of Comorbidity in Mortality after Prostatectomy,” *Journal of the American Medical Association* 267: 1077-1082, 1992.
 18. Darby, M., “Disagreement on Screening Mammography Left Unresolved,” *Report on Medical Guidelines and Outcomes Research* 4(5): 1-2,5, 1993.
 19. Davis, D. A., Thomson, M. A., Oxman, A. D., et al., “Evidence for the Effectiveness of CME: A Review of 50 Randomized Controlled Trials,” *Journal of the American Medical Association* 268(9): 1111-1117, 1992.
 20. De Lew, N., Greenberg, G., and Kinchen, K., “A Layman’s Guide to the U.S. Health Care System,” *Health Care Financing Review* 14(1): 151-169, fall 1992.
 21. Desmond, M., “A Review of Newborn Medicine in America: European Past and Guiding Ideology,” *American Journal of Perinatology* 8(5):308-322, 1991.
 22. DiMasi, J. A., Hansen. R. W., Grabowski, H. G., et al., “The Cost of Innovation in the Pharmaceutical Industry,” *Journal of Health Economics* 10: 107-142, 1991.
 23. “The Doctors’ Dilemma,” *Economist* 314(639):69, 1990.
 24. Dodd, G. D., “American Cancer Society Guidelines on Screening for Breast Cancer,” *Cancer* 69(7) (suppl.):1885-1887, 1992.
 25. ECRI, Health Technology Assessment Information Service, *Technology Assessment Custom Report Level 2—Home Uterine Activity Monitoring for Women at High Risk of Preterm Birth* (Plymouth Meeting, PA: ECRI, March 1993).
 26. Edwards, N., Prospective Payment Assessment Commission, personal communication, Sept. 24, 1993.
 27. Eggers, P. W., Health Care Financing Administration, U.S. Department of Health and Human Services, Baltimore, MD, personal communication, 1990, as cited in Institute of Medicine, *Kidney Failure and the Federal Government?*, R.A.Rettig and N.G. Levinsky (eds.)(Washington, DC: National Academy Press, 1991).
 28. Elliott, S. J., “Neonatal Extracorporeal Membrane Oxygenation: How Not to Assess Novel Technologies,” *Lancet* 337: 476-478, 1991.
 29. Escarce, J.J., Bloom, B. S., Hillman, A.L. et al., “Diffusion of Laparoscopic Cholecystectomy Among General Surgeons in the United States,” University of Pennsylvania School of Medicine, Philadelphia, PA, in press.
 30. Farley, P., “Who are the Uninsured?,” *Milbank Quarterly, Health and Society* 63: 476-503, 1985.
 31. Feinleib, M. F., Havlik, R. J., Gillum, R. F., et al., “Coronary Heart Disease and Related Procedures. National Hospital Discharge Survey Data,” *Circulation* 70(6) (suppl.): 113-118, 1989.
 32. Feldstein, P. Wickizer, T., and Wheeler, J., “Private Cost Containment: the Effects of Utilization Review Programs on Health Care Use and Expenditures,” *New England Journal of Medicine* 318: 1310-1314, 1988.
 33. Fendrick, A. M., Escarce, J. J., McLane, C., et al., “Hospital Adoption of Laparoscopic Cholecystectomy,” *Med Care* 32(10): 1058-63, 1994.

34. Fineberg, H. V., "Technology Assessment: Motivation, Capability, and Future Directions," *Medical Care* 23(5):663-671, 1985.
35. Foote, S. B., "The Impact of Public Policy on Medical Device Innovation: A Case of Polyintervention," *Changing Economics of Medical Technology*, A.C. Gelijns and E.A. Halm (eds.) (Washington, DC: National Academy Press, 1991).
36. Freaney, M., "Did MD Make a Mistake?," *Baltimore Business Journal*, p. 1, 10-11, July 9-15, 1993.
37. Gabel, J., Fink, S., Lippert, C., et al., *Trends in Managed Health Care* (Washington, DC: Health Insurance Association of America, February 1989).
38. Garrison, Jr., L.P. and Wilensky, G. R., "Cost Containment and Incentives for Technology," *Health Affairs* 52:46-58, summer 1986.
39. Gluck, M., Branch Chief, Center for Devices and Radiological Health, Food and Drug Administration, Public Health Service, U.S. Department of Health and Human Services, Rockville, MD, personal communication, September 1993.
40. Gordon, B., Office of Health Technology Assessment, Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services, personal communication, Rockville, MD, May 1994.
41. Greco, P. J., and Eisenberg, J. M., "Changing Physicians Practices," *New England Journal of Medicine* 329(17): 1271-1274, 1993.
42. Green, G. E., Spencer, F. C., Tice, D. A., et al., "Arterial and Venous Microsurgical Bypass Grafts for Coronary Artery Disease," *Journal of Thoracic and Cardiovascular Surgery* 60(4):491-503, 1970.
43. Headrick, L. A., Speroff, T., Pelecanos, H. I., et al., "Efforts to Improve Compliance With the National Cholesterol Education Program Guidelines: Results of a Randomized Controlled Trial," *Archives of Internal Medicine* 152:2490-2496, 1992.
44. Health Insurance Association of America, "Mammography/Mastectomy," unpublished document, Washington, DC, October 1992.
45. Health Insurance Association of America, *Source Book of Health Insurance Data* (Washington, DC, 1992).
46. "Health Security Act Would Permit Local Coverage Decisions on New Technology," *Health News Daily*, p.5, March 18, 1994.
47. Hilborne, L. H., Leape, L. L., Kahan, J. P., et al., *Percutaneous Transluminal Coronary Angioplasty: A Literature Review and Ratings of Appropriateness and Necessity* (Santa Monica, CA: RAND Corp., 1991).
48. Hillborne, L. H., Leape, L. L., Berstein, S. J., et al., "The Appropriateness of Use of Percutaneous Transluminal Coronary Angioplasty in New York State," *Journal of the American Medical Association* 269(6): 761-765, 1993.
49. Hillman, B.J., "Government Health Policy and the Diffusion of New Medical Devices," *Health Services Research* 21(5): 681-711, December 1986.
50. Hillman, B. J., "Physicians' Acquisition and Use of New Technology in an Era of Economic Constraints," *Technology and Health Care in An Era of Limits*, A.C. Gelijns (cd.) (Washington, DC: National Academy Press, 1992).
51. Hillman, A. L., and Schwartz, J. S.. "The Adoption and Diffusion of CT and MRI in the United States: A Comparative Analysis," *Medical Care* 23 (11): 1283-1294, November 1985.
52. Holohan, T. V., "Laparoscopic Cholecystectomy," *Lancet* 338:801-803, 1991.
53. Holohan, T. V., Director, Office of Health Technology Assessment, Agency for Health Care Policy and Research, U.S. Department of Health and Human Services. personal communication, July 16, 1993.

54. Hoppszallern, S., "Overview of Mammography Quality Standards Act of 1992," *Hospital Technology Scanner* 11(19): 1-3, 1992.
55. Iglehart, J. K., "Health Policy Report: The New Law on Medicare's Payments to Physicians," *New England Journal of Medicine* 322: 1247-1252, 1990.
56. Iglehart, J. K., "The American Health Care System: The End Stage Renal Disease Program," *New England Journal of Medicine* 328(5):366-371, 1993.
57. Institute of Medicine, *Assessing Medical Technologies*, C. Goodman (ed.)(Washington, DC: National Academy Press, 1985).
58. Institute of Medicine, *Controlling Costs and Changing Patient Care?: The Role of Utilization Management* (Washington, DC: National Academy Press, 1989).
59. Institute of Medicine, *Kidney Failure and the Federal Government*, R.A. Rettig and N.G. Levinsky (eds.)(Washington, DC: National Academy Press, 1991).
60. Institute of Medicine, *Guidelines for Clinical Practice: From Development to Use*, M.J. Field and K.N. Lohr (eds.) (Washington, DC: National Academy Press, 1992).
61. Javitt, J. C., Tielsch, J. M., Canner, J.K. et al., "National Outcomes of Cataract Extraction: Increased Risk of Retinal Complications Associated With Nd: YAG Laser Capsulotomy," *Ophthalmology* 99:1487-1498, 1992.
62. Jencks, S. F., and Wilensky, G. R., "The Health Care Quality Improvement Initiative," *Journal of the American Medical Association* 268(7):900-917, 1992.
63. Kaitin, K. I., Manocchia, M., Seibring, M., et al., "The New Drug Approvals of 1990, 1991, and 1992: Trends in Drug Development," *Journal of Clinical Pharmacology* 34(2):120-127, Feb. 1994.
64. Kelly, J.T., and Swartwout, J. E., "Development of Practice Parameters by Physician Organizations," *Quality Review Bulletin* 2:54-57, 1990.
65. Kent, D. L., Haynor, D. R., Longstreth, W.T. Jr., et al., "The Clinical Efficacy of Magnetic Resonance Imaging in Neuroimaging," *Ann, Intern. Med.* 120(10):856-7, 1994.
66. Kessler, D. A., Pape, S. M., and Sundwall, D.N., "The Federal Regulation of Medical Devices," *New England Journal of Medicine* 317(6):357-366, 1987.
67. Kosecoff, J., Kanouse, D. E., Rogers, W. H., et al., "Effects of the National Institutes of Health Consensus Development Program on Physician Practice," *Journal of the American Medical Association* 258: 2708-2713, 1987.
68. Leape, L. L., Hilborne, L. H., Kahan, J. P., et al., *Coronary Artery Bypass Graft: A Literature Review and Ratings of Appropriateness and Necessity* (Santa Monica, CA: RAND Corp., 1991).
69. Leape, L. L., Hilborne, L. H., Park, R. E., et al., "The Appropriateness of Use of Coronary Artery Bypass Graft Surgery in New York State," *Journal of the American Medical Association* 269(6):753-760, 1993.
70. Legorreta, A. P., Silber, J. H., Castantina, G. N., et al., "Increased Cholecystectomy Rate After the Introduction of Laparoscopic Cholecystectomy," *Journal of the American Medical Association* 270(12):29-32, 1993.
71. Letsch, S. W., Lazenby, H. C., Levit, K. R., et al., "National Health Expenditures, 1991," *Health Care Financing Review* 14(2): 1-30, winter 1992.
72. Levit, K. R., Lazenby, H. C., Cowan, C. A., et al., "National Health Expenditures, 1990," *Health Care Financing Review* 13(1):29-54, fall 1991.
73. Lewin-VHI, Inc. "Estimating the Costs of Defensive Medicine," report prepared for MMI Companies, Inc., Fairfax, VA, Jan. 27, 1993.
74. Lomas, J., "Words Without Action? The Production, Dissemination, and Impact of

- Consensus Recommendations," *Annual Review of Public Health* 12:41-65, 1991.
75. Lomas, J., "Retailing Research: Increasing the Role of Evidence in Clinical Services for Childbirth," *Milbank Quarterly* 71(3): 439-475, 1993.
 76. Mahaney, F. X., "Survey Says Leading Firms Support Mammography," *Journal of the National Cancer Institute* 84(21): 1618-1619, 1992.
 77. Maine Medical Assessment Foundation, *Annual Progress Report 1992* (Augusta, ME, 1993).
 78. Marwick, C., "NCI Changes Its Stance on Mammography," *Journal of the American Medical Association* 271(2):96, 1994.
 79. Miller, A. B., Bains, C. J., To, T., et al., "Canadian National Breast Screening Study: 1. Breast Cancer Detection and Death Rates Among Women Aged 40-49 Years," *Canadian Medical Association Journal* 147: 1459-1476, 1992.
 80. Mittman, B. S., and Siu, A. L., "Changing Provider Behavior: Applying Research on Outcomes and Effectiveness in Health Care," *Improving Health Policy and Management: Nine Critical Research Issues for the 1990's*, S.M. Shorten and U.E. Reinhardt (eds.) (Ann Arbor, MI: Health Administration Press, 1992).
 81. Muri, J., Associate Director, Administration, National Perinatal Information Center, Providence, RI, personal communication, October 1993.
 82. Myers, S. A., and Gleicher, N., "A Successful Program to Lower Cesarean-Section Rates," *New England Journal of Medicine* 319(23): 1511-1516, 1988.
 83. New York State Department of Health, "Health Department Issues Advisory on Laparoscopic Surgery," press release prepared by P. Siocum, Albany, NY, June 14, 1992.
 84. Organisation for Economic Co-operation and Development, *OECD Health Systems: The Socio-Economic Environment Statistical References*, Volume II (Paris, France, 1993).
 85. Orlando, 3rd, R., "Laparoscopic Cholecystectomy. A Statewide Experience. The Connecticut Laparoscopic Cholecystectomy Registry," *Archives of Surgery* 128(5): 191-198, 1993.
 86. Pauly, M. V., Eisenberg, J. M., Radany, M. H., et al., *Paying Physicians: Options for Controlling Cost, Volume, and Intensity of Services* (Ann Arbor, MI: Health Administration Press, 1992).
 87. Perry, S. "The Brief Life of the National Center for Health Care Technology," *New England Journal of Medicine* 307(17): 1095-1100, 1982.
 88. Pharmaceutical Manufacturers Association, *PMA Annual Survey Report: Trends in U.S. Pharmaceutical Sales and R&D* (Washington, DC, 1993).
 89. Physician Payment Review Commission, *Annual Report to Congress 1992* (Washington, DC: U.S. Government Printing Office, 1992).
 90. Politzer, R. M., Harris, D. L., Gaston, M. H., et al., "Primary Care Physician Supply and the Medically Underserved," *Journal of the American Medical Association* 266(1): 104-109, 1991.
 91. Prospective Payment Assessment Commission, *End-Stage Renal Disease Payment Policy* (Washington, DC, June 1992).
 92. Prospective Payment Assessment Commission, *Report and Recommendations to The Congress* (Washington, DC, Mar. 1, 1994)
 93. Randal, J., "Mammogram," *The New Republic* 207(16): 13-14, 1992.
 94. Rettig, R. A., "Health Policy in Radiology: Technology Assessment—An Update," *Investigative Radiology* 26: 162-173, 1991.
 95. Rice, T., "Containing Health Care Costs in the United States," *Medical Care Review* 49(1):19-65, spring 1992.
 96. Roche, J. K., and Stengle, J. M., "Facilities for Open Heart Surgery in the United

- States." *American Journal of Cardiology* 32:224-228, 1973.
97. Roos, N. P., Wennberg, J. E., Malenka, D. J., et al., "Mortality and Reoperation After Open and Transurethral Resection of the Prostate for Benign Prostatic Hyperplasia," *New England Journal of Medicine* 320: 1120-1124, 1989.
 98. Roper, W., Winkenwerder, W., Hackbarth, G., et al., "Effectiveness in Health Care: An Initiative to Evaluate and Improve Medical Practice," *New England Journal of Medicine* 319(18): 1197-1202, 1988.
 99. Salkever, D., and Bice, T., *Hospital Certificate of Need Controls: Impact on Investment Costs and Use* (Washington, DC: American Enterprise Institute, 1979).
 100. Scanzera, E., Blue Cross and Blue Shield Association, Chicago, IL, "The Blue Cross and Blue Shield Demonstration project on Breast Cancer Treatment," fax to Office of Technology Assessment, U.S. Congress, Washington, DC, July 27, 1993.
 101. Schwartz, J. S., Kimberly, J. R., Pauly, M.V. et al., "Adoption and Diffusion of Magnetic Resonance Imaging Under DRGs" (executive summary), prepared for the Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services, PB91-172916 (Springfield, VA: National Technical Information Service, U.S. Department of Commerce, June 1990).
 102. Schwartz, R. M., Willrich, K. K., and Gagnon, D. E., "Extracorporeal Membrane Oxygenation: Cost, Organization, and Policy Considerations," *Report of the Workshop on Diffusion of ECMO Technology*, L.L. Wright (cd.), NIH Publication No. 93-3399 (Bethesda, MD: U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Institute of Child Health and Human Development, January 1993).
 103. Shepard, D. S., and Durch, J. S., Institute for Health Research, Harvard School of Public Health, Boston, MA, "International Comparison of Resource Allocation in Health Sciences: An Analysis of Expenditures on Biomedical Research in 19 Industrialized Countries," unpublished manuscript supported by Fogarty International Center, National Institutes of Health, Public Health Service, U.S. Department of Health and Human Services, Bethesda, MD, Mar. 29, 1985.
 104. Society of American Gastrointestinal Endoscopic Surgeons, Committees on Continuing Education, Standards of Practice, and Privileging, "Framework for Post-Residency Surgical Education & Training—A SAGES Guideline," SAGES Pub No. 0017, Los Angeles, CA, January 1994.
 105. Soper, N.J., Brunt, I. M., and Korhl, K., "Laparoscopic General Surgery," *New England Journal of Medicine* 330(6):409-419, 1994.
 106. The Southern Surgeons Club, "A Prospective Analysis of 1,518 Laparoscopic Cholecystectomies," *New England Journal of Medicine* 324: 1073-1078, 1991.
 107. Steinberg, E. P., "The Impact of Regulation and Payment Innovations on Acquisition of New Imaging Technologies, Symposium on New Imaging Technologies," *Radiologic Clinics of North America* 23(3):381-389, Sept. 1985.
 108. Steinberg, E. P., and Cohen, A. B., *Nuclear Magnetic Resonance Imaging Technology: A Clinical, Industrial and Policy Analysis—Health Technology Case Study 27*, prepared for the Office of Technology Assessment, U.S. Congress, OTA-HCS-27 (Washington, DC: U.S. Government Printing Office, September 1984).
 109. Steinberg, E. P., Sisk, J. E., Locke, K. E., "The Diffusion of Magnetic Resonance Imagers in the United States and Worldwide," *International Journal of Technology Assessment in Health Care* 1(3):499-514, 1985.
 110. Steinberg, E. P., Stason, W. B., diMonda, R., et al., "Determinants of Acquisition of MR

- Imaging Units in an Era of Prospective Payment," *Radiology* 168(1):265-270, 1988.
111. Steiner, C. A., Bass, F. R., Talamiai, MA., et al., "Surgical Rates and Operative Mortality for Open and Laparoscopic Cholecystectomy in Maryland," *New England Journal of Medicine* 330(6):403-408, 1994.
 112. Strandjord, T. P., and Hodson, W. A., "Neonatology," *Journal of the American Medical Association* 268(3):377-378, 1992.
 113. Stuart, F. P., "Need, Supply, and Legal Issues Related to Organ Transplantation in the United States," *Transplantation Proceedings* 1:87-94, 1984.
 114. Technology Marketing Group, unpublished data on MRIs and CTS, Des Plaines, IL, 1994.
 115. Teplensky, J., "Hospital Adoption of Medical Technology: An Empirical Comparison of Prevailing Theories—Implications for Policy makers and Managers," paper presented at the annual meeting of the Association for Health Services Research, San Diego, 1991.
 116. Thorpe, K. E., "Health Care Cost Containment: Results and Lessons from the Past 20 Years," *Improving Health Policy and Management: Nine Critical Research Issues for the 1990s*, S.M. Shorten and U.E. Reinhardt (eds.)(Ann Arbor, MI: Health Administration Press, 1992).
 117. Trondsen, E., Reiertsen, O., Andersen, O. K., et al., "Laparoscopic and Open Cholecystectomy: A Prospective, Randomized Study," *European Journal of Surgery* 159:217-221, 1993.
 118. Tunis, S. R., Bass, E. B., and Steinberg, E. P., "The Use of Angioplasty, Bypass Surgery, and Amputation in the Management of Peripheral Vascular Disease," *New England Journal of Medicine* 325:556-562, 1991.
 119. Tunis, S. R., Hayward, R.S.A, Wilson, M. C., et al., "Internists' Attitudes About Clinical Practice Guidelines," *Annals of Internal Medicine* 120(11):956-963, 1994.
 120. U.S. Congress, Congressional Research Service, *CRS Report for the Congress: Breast Cancer*, prepared by J.A. Johnson, 93-15 SPR (Washington, DC: Jan. 15, 1993).
 121. U.S. Congress, Office of Technology Assessment, *Policy Implications of the Computed Tomography (CT) Scanner, OTA-H-56* (Washington, DC: U.S. Government Printing Office, August 1978).
 122. U.S. Congress, Office of Technology Assessment, *Assessing the Efficacy and Safety of Medical Technologies, OTA-H-75* (Washington, DC: U.S. Government Printing Office, September 1978).
 123. U.S. Congress, Office of Technology Assessment, *Policy Implications of the Computed Tomography (CT) Scanner: An Update, OTA-BP-H-8* (Washington, DC: U.S. Government Printing Office, January 1981).
 124. U.S. Congress, Office of Technology Assessment, *Strategies for Medical Technology Assessment, OTA-H-181* (Washington, DC: U.S. Government Printing Office, September 1982).
 125. U.S. Congress, Office of Technology Assessment, *Neonatal Intensive Care for Low Birth weight Infants: Costs and Effectiveness*, Health Technology Case Study 38, OTA-HCS-38 (Washington, DC: U.S. Government Printing Office, August 1987).
 126. U.S. Congress, Office of Technology Assessment, *Health Care in Rural America* (summary), OTA-H-435 (Washington, DC: U.S. Government Printing Office, September 1990).
 127. U.S. Congress, Office of Technology Assessment, *Evaluation of the Oregon Medicaid Proposal*, (Washington, DC: U.S. Government Printing Office, May 1992).
 128. U.S. Congress, Office of Technology Assessment, *Pharmaceutical R&D: Costs, Risks and Rewards, OTA-H-522* (Washing-

332 | Health Care Technology and Its Assessment in Eight Countries

- ton, DC: U.S. Government Printing Office, February 1993).
129. U.S. Congress, Office of Technology Assessment, *International Health Statistics: What the Numbers Mean for the United States*, OTA-BP-H-1 16 (Washington, DC: U.S. Government Printing Office, November 1993).
 130. U.S. Congress, Office of Technology Assessment, *Understanding Estimates of National Health Expenditures Under Health Reform*, OTA-H-594 (Washington, DC: U.S. Government Printing Office, May 1994).
 131. U.S. Congress, Office of Technology Assessment, *Defensive Medicine and Medical Malpractice*, OTA-H-602 (Washington, DC: U.S. Government Printing Office, July 1994).
 132. U.S. Congress, Office of Technology Assessment, *Searching for Evidence: Identifying Health Technologies That Work*, OTA-H-608 (Washington, DC: U.S. Government Printing Office, Sept. 1994).
 133. U.S. Department of Commerce, Economic and Statistics Administration, Bureau of the Census, "Current Population Survey File," tabulations prepared by the Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, Washington, DC, March 1991.
 134. U.S. Department of Health and Human Services, Health Care Financing Administration, Medicare Program, "Criteria and Procedures for Making Medical Services Coverage Decisions that Relate to Health Care Technology," proposed rules, *Federal Register* 54(18):4304-4307, Jan 30, 1989.
 135. U.S. Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research, AHCPR Health Technology Assessment Report: *Percutaneous Transluminal Angioplasty in the Treatment of Stenotic Lesions of a Single Coronary Artery*, Number 16 (Rockville, MD, 1982).
 136. U.S. Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research, AHCPR Health Technology Assessment Report: *Patient Selection Criteria for Percutaneous Transluminal Coronary Angioplasty*, Number 11 (Rockville, MD: 1985).
 137. U.S. Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research, AHCPR Health Technology Assessment Report: *U.S. Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research, AHCPR Health Technology Assessment Report: Assessment of Liver Transplantation*, Number 1 (Rockville, MD: March 1990).
 138. U.S. Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research, Office of Health Technology Assessment, Rockville, MD, "Assessments and Reviews 1981-," unpublished document, Rockville, MD, 1993.
 139. U.S. Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research, "Guidelines Being Developed," Rockville, MD, unpublished document, September 1993.
 140. U.S. Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research, "AHCPR Fact Sheet," AHCPR Pub. No. 94-0068, April 1994.
 141. U.S. Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research, "Department of Health and Human Services Fiscal Year 1994-Justification of Estimates for Appropriations Committee: Volume IX," unpublished document, Rockville, MD, 1994.
 142. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Center for Health Statistics, *Proceedings of*

- the International Collaborative Effort on Perinatal and Infant Mortality, Volume I*, DHHS Pub.No(PHS)84-1252 (Hyattsville, MD: U.S. Department of Health and Human Services, March 1990).
143. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Center for Health Statistics, *Health, United States, 1990* (Washington, DC: U.S. Government Printing Office, 1991).
 144. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Center for Health Statistics, *International Health Data Reference Guide*, DHHS Pub. No. (PHS) 92-1007 (Hyattsville, MD: U.S. Department of Health and Human Services, 1991).
 145. 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.
 146. U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Committee for Clinical Review, Final Report of the Committee for Clinical Review (Temple Report), Rockville, MD, unpublished report, 1993.
 147. U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, "Magnetic Resonance Imaging," *NIH Consensus Statement* 6(14): 1-31, 1987.
 148. U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, "Gallstones and Laparoscopic Cholecystectomy," *NIH Consensus Statement* 10(3): 1-26, 1992.
 149. U.S. Department of Health and Human Services. Public Health Service. National Institutes of Health, *NIH Data Book 1992*, NIH Pub. No. 92-1261 (Bethesda, MD: September 1992).
 150. U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, "Morbidity and Mortality of Dialysis," *NIH Consensus Statement* 1 1(2): 1-33, 1993.
 151. U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Cancer Institute, *Cancer Statistics Review: 1973-1989*, NIH Pub. No. 92-2789 (Rockville, MD: 1992).
 152. U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Institute of Child Health and Human Development, *Report of the Workshop on Diffusion of ECMO Technology*, NIH Pub. No. 93-3399 (Bethesda, MD: January 1993).
 153. U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, U. S. Renal Data System, *1990 Annual Data Report* (Bethesda, MD: 1990).
 154. U.S. Department of Health and Human Services, Public Health Service, Office of the Assistant Secretary for Health, Office of Disease Prevention and Health Promotion, Preventive Services Task Force, *Guide to Clinical Preventive Services* (Baltimore, MD: William & Wilkins, 1989).
 155. U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, Office of Medical Applications of Research, Consensus Development Conference, "Past Conferences," unpublished document, Rockville, MD, undated.
 156. U.S. Department of Treasury, *Financing Health and Long-Term Care. Report to the President and Congress* (Washington, DC: U.S. Government Printing Office, May 7, 1991).

157. U.S. Department of Veterans Affairs, *Annual Report of the Secretary of Veterans Affairs, Fiscal Year 1993*, Report Stock No. P91934 (Washington, DC: March 1994).
158. U.S. General Accounting Office, *Screening Mammography: Higher Medicare Payments Could Increase Costs Without Increasing Use*, GAO/HRD-93-50 (Washington, DC: U.S. Government Printing Office, April 1993).
159. Wennberg, J. E., "What is Outcomes Research?" *Medical Innovation at the Crossroads, Vol. I: Modern Methods of Clinical Investigation*, A.C. Gelijns (ed.) (Washington, DC: National Academy Press, 1990).
160. Wennberg, J. E., Mulley, A. G., Hanley, D., et al., "An Assessment of Prostatectomy for Benign Urinary Tract Obstruction: Geographic Variations and the Evaluation of Medical Outcomes," *Journal of the American Medical Association* 259(20):3027-3030, 1988.
61. White, J. V., "Laparoscopic Cholecystectomy: The Evolution of General Surgery," *Annals of Internal Medicine* 115(8):651-653, 1991.
62. White, J. V., Director of Surgical Research, Temple University, personal communication, June 10, 1994.
163. Wood, E., National Center for Health Statistics, Centers for Disease Control and Prevention, Public Health Service, U.S. Department of Health and Human Services, unpublished data from the National Hospital Discharge Survey, Hyattsville, MD, July 8, 1994.
164. Woolf, S. H., "United States Prevention Services Task Force Recommendations on Breast Cancer Screening," *Cancer* 69: 1913-1918, 1992.
165. "Wyden Technology Assessment Measure Should be Incorporated into Chairman's Mark," *Health News Daily*, p.3, April 11, 1994.