Chapter 5

Medical Technology

Learning Objectives

- To understand the meaning and role of medical technology in health care delivery
- To appreciate the growing role of information technology and informatics in the delivery of health care
- To survey the factors influencing the creation, dissemination, and utilization of technology
- To discuss the government’s role in technology diffusion
- To examine the impact of technology on various aspects of domestic and global delivery of health care
- To study the various facets of technology assessment
- To discuss the current and future directions in health technology assessment
- To become familiar with provisions in the Patient Protection and Affordable Care Act of 2010 that pertain to medical technology
Introduction

Drake and colleagues (1993) labeled technology as “the boon and bane of medicine.” In one respect, medical technology has been a great blessing to modern civilization. Sophisticated diagnostic procedures have reduced complications and disability, new medical cures have increased longevity, and new drugs have helped stabilize chronic conditions. However, most new technology comes at a price that society must ultimately pay. A tremendous amount of costly research is necessary to produce most modern breakthroughs. Once technology is developed and put into use, even more costs are generated through staff training, increased need for skilled professionals, facility upgrading, and demand from both consumers and providers for the utilization of new technology. As total health care spending continues to rise, debates have emerged as to whether unrestrained development and use of new technology is worth the cost.

Chapter 3 pointed out that developments in science and technology were instrumental in drastically changing the nature of health care delivery during the postindustrial era. Since then, the ever-increasing proliferation of new technology has continued to profoundly alter many facets of health care delivery. Technology has triggered several main changes: (1) Technology has raised consumer expectations that the latest may also be the best. These expectations have led to increased demand and utilization of new technology once it becomes available. (2) Technology has changed the organization of medical services. Specialized services that previously could be offered only in hospitals are now available in outpatient settings. (3) Technology has driven the scope and content of medical training and the practice of medicine, fueling specialization in medicine. (4) Technology has influenced the way status is imputed to various medical workers. Specialization is held in higher regard than primary care and public health. (5) Technology has contributed to health care cost inflation. From the consumer’s standpoint, the cost of excessive treatment is no concern as long as a third party—either an insurance plan or the government—pays for it. (6) Technology assessment is becoming a growing activity because new drugs, devices, and procedures are not always useful or safe. Their effectiveness and potential negative consequences must be evaluated using scientific methods. (7) Technology has raised complex social and ethical concerns that defy straightforward solutions. Perplexing social and ethical controversies raised by modern innovations and promises of “miracle cures” include such questions as Who should be subjected to the experimental evaluations of technological breakthroughs to determine their safety? Who should and who should not receive high-tech interventions? To what extent should life-supporting procedures be continued? Is it moral to use human embryos in biomedical research?

The phenomenon of economic globalization has also enveloped biomedical knowledge and technology. In both developed and developing nations, physicians have access to the same scientific knowledge through medical journals and the Internet. Most drugs and medical devices available in the United States are also available in almost all parts of the world. However, depending on the extent of supply-side rationing (see Chapter 2), the timing of adoption and subsequent diffusion of new technology often differ widely from one country to another. Thus, even in developed nations, people do...
not necessarily have adequate access to the latest high-tech therapies. Conversely, in almost all parts of the world, people who possess adequate means can gain access to the latest and best in medicine regardless of the type of health care delivery system in their country.

From an economic standpoint, technology includes all inputs, both human and nonhuman, used in the production and management of medical goods and services (Warner 1982). This chapter discusses technology and related issues within this broad context. Highlights from the American Recovery and Reinvestment Act of 2009 and the Patient Protection and Affordability Act of 2010 are also incorporated.

**What Is Medical Technology?**

At a fundamental level, *medical technology* is the practical application of the scientific body of knowledge for the purpose of improving health and creating efficiencies in the delivery of health care. Medical science benefited from rapid developments in other applied sciences, such as chemistry, physics, engineering, and pharmacology. For example, advances in organic chemistry made it possible to identify and extract the active ingredients in plants to produce drugs and anesthetics, which then became available in purer forms that were better adapted to controlled dosages than their earlier botanical forms. Developments in electrical and mechanical engineering led to such medical advances as radiology, cardiology, and encephalography (Bronzino et al. 1990). Magnetic resonance imaging (MRI), a technology that had its origins in basic research on the structure of the atom, was later transformed into a major diagnostic tool (Gelijns and Rosenberg 1994). The disciplines of computer science and communication systems find their application in information technology and telemedicine (Tan 1995).

A broad concept of technology includes not just sophisticated machines and ultra-modern facilities but also pharmaceuticals and biologicals, medical and surgical procedures used in rendering medical care, organizational support systems through which care is delivered (Riley and Brehm 1989), and the use of computer-supported information systems. For example, computers used to facilitate billing and other systems used to operate and manage health services organizations are part of health care technology (Rakich et al. 1992). Table 5–1 shows some of the main categories of medical technologies.

Information Technology and Informatics

Information technology (IT) deals with the transformation of data into useful information. IT involves determining data needs, gathering appropriate data, storing and analyzing the data, and reporting the information generated in a user-friendly format. Different types of information are made available for specific uses by health care professionals, managers, payers, and patients. Today, many health care organizations have IT departments and managers to handle the continually increasing flow of information (Tan 1995). IT departments play a critical role in decisions to adopt new information technologies that improve health care delivery and organizational efficiency. These technologies include medical records systems to collect, transcribe, and store clinical data; radiology and clinical laboratory reporting systems; pharmacy...
data systems to monitor medication use and avoid errors, adverse reactions, and drug interactions; scheduling systems for patients, space (such as surgery suites), and personnel; and financial systems for billing and collections, materials management, and many other aspects of organizational management (Cohen 2004a).

In health care organizations, IT applications fall into three general categories (Austin 1992):

1. **Clinical information systems** involve the organized processing, storage, and retrieval of information to support patient care delivery. Electronic medical records, for example, provide quick and reliable information necessary to guide clinical decision making and produce timely reports on quality of care delivered. Computerized physician order entry (CPOE) enables physicians to electronically transmit orders from a patient’s bedside. The system’s design increases efficiency and reduces medical errors. However, because of high costs, only about 5% of hospitals use this technology (Jha et al. 2006).

2. **Administrative information systems** assist in carrying out financial and administrative support activities, such as payroll, patient accounting, billing, materials management, budgeting and cost control, and office automation. For medical clinics, CPOE technology can interface with the billing system to minimize rejected claims by pinpointing errors in billing codes. Administrative information systems are also increasingly used in predictive modeling.

### Table 5–1 Types of Medical Technologies

<table>
<thead>
<tr>
<th>Type</th>
<th>Examples</th>
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<tbody>
<tr>
<td>Diagnostic</td>
<td>CAT scanner, Fetal monitor, Computerized electrocardiography, Automated clinical laboratories, Magnetic resonance imaging, Ambulatory blood pressure monitor</td>
</tr>
<tr>
<td>Survival (life saving)</td>
<td>Intensive care unit (ICU), Cardiopulmonary resuscitation (CPR), Bone marrow transplant, Liver transplant, Autologous bone marrow transplant</td>
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<tr>
<td>Illness management</td>
<td>Renal dialysis, Pacemaker, PTCA (angioplasty), Stereotactic cingulotomy (psychosurgery)</td>
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<tr>
<td>Cure</td>
<td>Hip joint replacement, Organ transplant, Lithotripter</td>
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<tr>
<td>Prevention</td>
<td>Implantable automatic cardioverter defibrillator, Pediatric orthopaedic repair, Diet control for phenylketonuria, Vaccines for immunization</td>
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<tr>
<td>System management</td>
<td>Medical information systems, Telemedicine</td>
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<tr>
<td>Facilities and clinical settings</td>
<td>Hospital satellite centers, Clinical laboratories, Subacute care units, Modern home health</td>
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<tr>
<td>Organizational delivery structure</td>
<td>Managed care, Integrated delivery networks</td>
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applications that use health care claims data to identify patients who are likely to generate significant health care costs and, therefore, would benefit from newer utilization management programs, such as case management (see Chapter 9; Short et al. 2003).

3. **Decision support systems** provide information and analytical tools to support managerial decision making. Such tools are used to forecast patient volume, project staffing requirements, and schedule patients to optimize utilization of patient care and surgical facilities.

Managers, boards of directors, and medical staff increasingly depend on information systems for timely management data in several areas: financial performance, utilization of services, clinical quality, and trends in health care delivery. They use such information for cost control and productivity enhancement, strategic planning, utilization analysis and demand assessment, program planning and evaluation, simplification of external reporting, clinical research, and quality assessment and improvement (Austin 1992).

The field of **health informatics** is broadly defined as the application of information science to improve the efficiency, accuracy, and reliability of health care services. Health informatics requires the use of IT but goes beyond IT by emphasizing the improvement of health care delivery. For example, the use of IT is necessary for designing clinical decision support systems for practitioners, such as those used to improve decision making in cancer treatment. Health informatics is a wide and growing field, which includes, for example, nursing informatics, imaging informatics, consumer health informatics, public health informatics, clinical research informatics, bioinformatics, and pharmacy informatics. Applications of informatics are also found in electronic health records and telemedicine.

**Electronic Health Records and Systems**

**Electronic health records** (EHRs) are IT applications that enable the processing of any electronically stored information pertaining to individual patients for the purpose of delivering health care services (Murphy et al. 1999). EHRs replace the traditional paper medical records, which include a patient’s demographic information, problems and diagnoses, plan of care, progress notes, medications, vital signs, past medical history, immunizations, laboratory data, and radiology reports. Information contained in EHRs is used to coordinate care, routinely measure quality, or reduce medical errors, which paper medical records do not allow (Hillestad et al. 2005).

EHR systems make it possible to access individual records online from many separate, interoperable automated systems within an electronic network. Since the overwhelming majority of Americans receive care from more than one caregiver, interoperability makes a patient’s medical records portable and available to the different clinicians (Brailer 2005). For example, interoperability makes it possible to share EHRs among physicians, pharmacists, and hospitals. More important, however, EHR systems integrate individual records with evidence-based clinical decision support, which provides reminders and best-practice guidelines for treatment (Hillestad et al. 2005). The system can also interface with quality management and outcomes.
reporting. According to the Institute of Medicine (2003), a fully developed EHR system includes four key components: 
(1) collection and storage of health information on individual patients over time, where health information is defined as information pertaining to the health of an individual or health care provided to an individual; (2) immediate electronic access to person and population level information by authorized users; (3) provision of knowledge and decision support that enhances the quality, safety, and efficiency of patient care; and (4) support of efficient processes for health care delivery.

It is generally believed that widespread adoption of EHR systems will lead to major savings in health care costs, reduced medical errors, and improved health (Hillestad et al. 2005). However, the adoption of EHRs has been slow, particularly among physicians. In 2007, only 35% of office-based physicians reported using any EHR system although this represented an increase of 91% since 2001 (Hing and Hsiao 2010). Research suggests that among physicians, overall satisfaction with EHRs after implementation tends to be significantly lower than their preimplementation expectations (Vishwanath et al. 2010). EHR systems require a sizable investment to purchase and implement the technology, which is one major hurdle that many smaller organizations face. For example, group practices with 50 or more physicians are more likely to use EHR technology (Reed and Grossman 2004). Initial acquisition and set-up costs range between $37,000 and $64,000 per physician or nurse practitioner, and annual operating costs average $8,400 per physician or nurse practitioner; however, improved billing and decreased personnel costs do result in savings that can help recoup the investment in less than 3 years (Miller et al. 2005).

To accelerate the adoption of EHRs, some major policy initiatives were launched during the George W. Bush Administration. These initiatives culminated in the enactment of the Health Information Technology Economic and Clinical Health (HITECH) Act, which was part of the American Recovery and Reinvestment Act of 2009—the $787 billion plan to stimulate the economy—passed shortly after the Obama administration took office. This Act earmarked an estimated $19 billion in direct grants and financial incentives to promote the adoption of EHRs. Starting in 2011, Medicare and Medicaid offer financial incentives, over multiple years, of up to $40,000 to $65,000 per physician and up to $11 million per hospital for “meaningful use” of health information technology (Steinbrook 2009a). To demonstrate “meaningful use,” health care providers have to meet a range of metrics in areas such as quality, safety, efficiency, reduction of health disparities, patient engagement, care coordination, and security of health information (Halamka 2010). The law also authorized federal dollars to establish Regional Extension Centers to provide technical assistance to primary care providers, health centers, and others to achieve meaningful use. Also envisioned in the law is a Health Information Technology Research Center to conduct research and analysis and disseminate best practices for EHR use (Hogan and Kissam 2010).

In the minds of many providers and patients alike, confidentiality of patient information has been a major concern. The Health Insurance Portability and Accountability Act (HIPAA) of 1996 made it illegal to gain access to personal health information (PHI) for reasons other than health care delivery,
A number of websites also offer physician consultations, and others sell prescription medications. Patients are also forming online communities to help themselves through e-mail discussion groups and bulletin boards. Patients are interacting with their health care providers through secured specialty websites that cover disease management, personal health records, self-monitoring, and communication (Maheu et al. 2001).

**The Internet, E-Health, M-Health, and E-Therapy**

The Internet has continued to revolutionize certain aspects of health care delivery, and its use will continue to grow. Use of the Internet to obtain health care information is becoming increasingly common. In one consumer survey, 65% of respondents indicated that, before making a decision about their health, they try to find everything they can about the issue (Schur and Berk 2008). Consequently, patients are becoming active participants in their own health care. In many instances, using the right source can provide valid and up-to-date information to both consumers and practitioners. Information empowers patients, which leads to changes in the traditional patient–physician dynamics.

There appears to be a significant difference in the extent of Internet use and reliance on it for health information based on whether users are satisfied or dissatisfied with the care they receive from their physicians. Those satisfied with care tend to rely more on their physician than on the Internet, using the physician as the primary source of health information. Conversely, dissatisfied patients turn to the Internet as their primary source of information, regarding it as a more credible and more authoritative information source than their physicians. Dissatisfied patients may also be less likely to comply with treatments prescribed by their physicians (Tustin 2010).

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“E-health refers to all forms of electronic health care delivered over the Internet, ranging from informational, educational, and commercial ‘products’ to direct services offered by professionals, nonprofessionals, businesses, or consumers themselves” (Maheu et al. 2001). The proliferation of mobile phones in both developed and developing nations has led to innovative applications of mobile technology. The term mobile health, or **m-health**, has emerged to refer to “the use of wireless communication devices to support public health and clinical practice” (Kahn et al. 2010). These devices facilitate communication among researchers, clinicians, and patients. Yet, evidence for the value of m-health remains scarce, especially for the developing world (Kahn et al. 2010).

E-therapy has emerged as an alternative to face-to-face therapy for behavioral health support and counseling (Skinner and Latchford 2006). Also referred to as online therapy, e-counseling, teletherapy, or cybercounseling, **e-therapy** refers to any type of professional therapeutic interaction that makes use of the Internet to connect qualified mental health professionals and their clients (Rochlen et al. 2004). Although, at this point, e-therapy is not widely used, many Internet mental health interventions have reported early results that are promising.
Both therapist-led and self-directed online therapies indicate significant alleviation of disorder-related symptomatology (Ybarra and Eaton 2005). Nevertheless, e-therapy remains controversial. Issues and problems potentially best suited for online therapy include personal growth and fulfillment; adult children of alcoholics; anxiety disorders, including agoraphobia and social phobias; and body image and shame/guilt issues. Clients not appropriate for online therapy include those who have suicidal ideation, thought disorders, borderline personality disorder, or unmonitored medical issues (Stofle 2001).

The Internet is also used to register patients, direct them to alternative care sites, and order pharmaceuticals and other products. Using Web-based access to patient information from their homes or from hospital lounges, physicians can get a head start on their hospital rounds (Morrissey 2002). Another emerging application is virtual physician visits, which are online clinical encounters between a patient and physician. OptumHealth, a division of United Health Group, the nation’s largest insurer, plans to offer NowClinic, a service that connects patients and doctors using video chat. The program is being introduced state by state, starting with Texas, but not without resistance from state medical associations (Miller 2009).

Telemedicine and Telehealth

The terms “telemedicine” and “telehealth” are often used interchangeably. Both employ telecommunication systems for the purpose of promoting health, but there is a technical difference between the two. Telemedicine, or distance medicine, employs the use of telecommunications technology for medical diagnosis and patient care when the provider and client are separated by distance. It eliminates the requirement for face-to-face contact between the examining physician and the patient. It also enables a generalist to consult a specialist when a patient’s illness and diagnosis are complex. The term telehealth is broader in scope. It encompasses telemedicine, as traditionally known, and educational, research, and administrative uses, as well as clinical applications that involve a variety of caregivers, such as physicians, nurses, psychologists, and pharmacists (Field and Grigsby 2002).

Telemedicine can be synchronous or asynchronous. Synchronous technology allows telecommunication to occur in real time. For example, interactive videoconferencing allows two or more professionals to see and hear each other and even share documents in real time. The technology allows a specialist located at a distance to directly interview and examine a patient. Asynchronous technology employs store-and-forward technology that allows users to review the information later. It allows greater flexibility because it does not depend on the simultaneous presence of parties at the sending and receiving ends (Maheu et al. 2001). Examples of telemedicine services include teleradiology, the transmission of radiographic images and scans; telepathology, the viewing of tissue specimens via videomicroscopy; telesurgery, controlling robots from a distance to perform surgical procedures; and clinical consultation provided by a wide range of specialists.

Telemedicine and telehealth have found many actual and potential uses. The adoption of these technologies has been slow, but their use is growing. Newer applications are in the delivery of mental health services and telemonitoring patients receiving home health care. Vital signs, blood pressure, and blood
Innovation, Diffusion, and Utilization of Medical Technology

In the context of medical technology, innovation is the creation of a product, technique, or service perceived to be new by members of a society. The spread of technology into society once it is developed is referred to as technology diffusion (Luce 1993). Rapid diffusion of a technology occurs when the innovation is perceived to be of benefit that can be evaluated or measured, is compatible with the adopter’s values and needs, and is covered through third-party payment. Once technology is acquired, its use is almost ensured. Hence, the diffusion and utilization of technology are closely intertwined. The desire to have state-of-the-art technology available and to use it despite its cost or established health benefit is called the technological imperative.

High-tech procedures are more readily available in the United States than in most other countries, and little is done to limit the expansion of new medical technology. Compared to most European hospitals, American hospitals perform a far greater number of catheterizations, angioplasties, and bypass heart surgeries. The United States also has more high-tech equipment, such as magnetic resonance imaging (MRI) and computed tomography (CT) scanners, available to its population than most countries (Kim et al. 2001). By contrast, almost all other nations have tried to limit, mainly through central planning, the diffusion and utilization of technology to control medical costs. The British government, for instance, established the National Institute for Health and Clinical Excellence (NICE) in 1999 to decide whether the National Health Service should make select health technologies available (Milewa 2006). Thanks to central control, compared to the United States, Canada had 76% fewer MRI machines and performed 72% fewer coronary bypass procedures per 100,000 population; Great Britain also had 55% fewer MRIs and performed 82% fewer coronary bypass...
surgeries (Anderson and Hussey 2001). Only Japan and Switzerland were estimated to have more MRI machines per 100,000 population than the United States.

Even though the United States has made tremendous strides in medical innovation, corresponding innovations in the health care delivery system have lagged behind. Investments in information technology have particularly lagged behind (Institute of Medicine 2002). For example, smart cards—credit card-like devices with an embedded computer chip and memory are already in use in Europe for health care services. **Smart cards** hold personal medical information that can be accessed and updated at hospitals or physicians’ offices (Ellis 2000). Mainly due to privacy concerns, the United States is behind in using this technology.

### Cultural Beliefs and Values

Studies have shown that, when technology becomes available for a particular indication, it is used at significantly different intensities in various countries and among regions within countries (Wennberg 1988). American beliefs and values have been instrumental in determining the nature of health care delivery in the United States (discussed in Chapter 2). Based on these beliefs and values, Americans have much higher expectations of what medical technology can do to cure illness than, for instance, Canadians and Germans. In an opinion survey, a significantly higher number of Americans (35%) than Germans (21%) indicated that it was absolutely essential for them to be able to get the most advanced tests, drugs, medical procedures, and equipment (Kim et al. 2001). In another survey, 91% of Americans indicated that their ability to get the most advanced tests, drugs, medical procedures, and equipment is very important to improving the quality of health care (Schur and Berk 2008). In a national telephone random poll, 58% of Americans indicated that increased funding for medical and health research is essential for their future health and economic prosperity, and 63% expressed their willingness to pay a modest amount in additional taxes to fund medical research (Research America 2006).

The primacy of technology can also be traced to the medical model that has dominated

### Factors That Drive Innovation and Diffusion

The rate and pattern by which a technology diffuses is often governed by multiple forces (Cohen 2004b). For example, public and private financing for research and development (R&D) can promote or inhibit innovation; government regulations, such as the Food and Drug Administration (FDA) approval process, can promote or hinder the availability of new drugs and devices; marketing and promotion by the manufacturers can have an impact on the decisions of both providers and consumers about the adoption and use of technology.

Some of the main forces that have shaped the innovation, diffusion, and utilization of technology in the United States are:

- Cultural beliefs and values
- Medical specialization
- Financing and payment
- Competition
- Expenditures on research and development
- Supply-side controls
- Government policy
medical practice in the United States (see Chapter 2). American beliefs and values reinforce delivery of health care according to the medical model. Consequently, the emphasis on specialty care, rather than primary care and preventive services, raises the expectations of both physicians and patients for the use of all available technology. Similarly, cultural beliefs and values have influenced the training of health care providers, the financing of services, and the structure of medical care delivery in the United States. Each of these domains reflects the premium that US society places on high technology, and, consequently, the United States leads the world in the development of new technology.

Medical Specialization

Evidence of the technological imperative is most apparent in acute care hospitals, especially those affiliated with medical schools, because they are the main centers for specialty residency training programs in which physicians are trained to use the latest medical advances. Broad exposure to technology early in training affects not only clinical preferences but also future professional behavior and practice patterns (Cohen 2004c). Both patients and practitioners also equate high-quality care with high-intensity care. Patient demand for direct access to specialists has grown in the United States, which reflects the population’s insatiable appetite for high-technology medicine (Spann 2001). Specialty training and the inclination of specialists to use the technology they have been trained to use fuel the demand for new technology. Since medical specialization revolves around technology, an oversupply of specialists in the United States (discussed in Chapter 4) has compounded the rate of technology diffusion.

Financing and Payment

Evidence from several countries suggests that fixed provider payments, such as salaried physicians, and strong limits on payments to hospitals, such as stringent use of global budgets, curtail the incentive to use high-tech procedures. Hence, payment incentives can place limitations on how quickly and widely new treatments are diffused into medical practice (McClellan and Kessler 1999).

Traditionally, the US health care delivery system has lacked internal checks and balances to determine when high-cost services are appropriate. Financing of health care through private insurance promotes the phenomenon referred to as moral hazard and provider-induced demand (introduced in Chapter 1). Insurance insulates both patients and providers from any personal accountability for the utilization of high-cost services. As long as out-of-pocket costs are of little concern, patients expect their physicians to provide all that medical science has to offer. Knowing that insurance covers the services demanded by their patients, providers also show little hesitation to provide the services.

There is likely a two-way relationship between technology diffusion and insurance coverage. Increasingly generous insurance coverage causes increases in spending for new products. Conversely, the development of beneficial but costly new technology puts pressure on insurers to cover those costs (Danzon and Pauly 2001).

The rate of innovation is sensitive to changes in the level of reimbursement set for new interventions. Under the Medicare prospective payment system (discussed in Chapter 6), a higher level of reimbursement than the cost of the procedure itself
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stimulated rapid adoption of percutaneous transluminal coronary angioplasty (PTCA) and a high degree of innovation in PTCA catheters. By contrast, only a fraction of the cost of cochlear implants was covered. The result was not only underdiffusion but also a markedly reduced subsequent investment in research and development by the manufacturers of cochlear implants (Gelijns and Rosenberg 1994).

**Competition**

As pointed out in Chapter 1, the health care delivery system in the United States is not characterized by true market conditions in which competition is prompted by patients who shop around for the best *value*, that is, the most benefits possible for the price they are willing to pay. Providers of health care services do compete. Paradoxically, however, competition in health care often increases costs. Hospitals, as well as outpatient centers, compete to attract insured patients. Well-insured patients look for quality, and institutions create perceptions of higher quality by acquiring and advertising state-of-the-art technology. Specialists have also been responsible for stimulating competition. Many physicians, for example, have opened highly specialized hospitals, diagnostic imaging facilities stocked with next-generation scanners, and same-day surgery centers that have hotel-like facilities—these developments have fueled a de facto medical arms race. In response, hospitals are adding new service lines—such as cancer, heart, and brain centers—and are acquiring costly CT scanners and high-field MRI machines (Kher 2006). To recruit specialists, medical care centers often have to obtain new technology and offer high-tech procedures. When hospitals develop new services and invest heavily in modernization programs, other hospitals in the area are often forced to do the same. Such practices result in a tremendous amount of duplication of services and equipment.

Investment interests by physicians in various types of facilities prompted Congress to pass regulations against *self-referrals*. These laws prohibit physicians from sending patients to facilities in which the referring physician or a family member has an ownership interest. The Ethics in Patient Referrals Act of 1989 (commonly known as Stark I after Representative Pete Stark, author of the original bill) prohibited the referral of Medicare patients to laboratories in which the referring physician had an ownership interest. Provisions of this law expanded under the Omnibus Budget Reconciliation Act of 1993 (OBRA-93). Commonly referred to as Stark II, the statute covers both Medicare and Medicaid referrals. It also expanded the categories of services to include clinical laboratory services; physical therapy, occupational therapy, and speech pathology services; radiology services, including MRI, computerized axial tomography (CAT) scans, and ultrasound services; radiation therapy services and supplies; durable medical equipment and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospitalization services. There are some exceptions, however, such as in-office ancillary services (Wachler and Avery 2011).

**Expenditures on Research and Development**

Innovation is driven by expenditures in research and development. Since the early
1980s, total expenditures in biomedical sciences have exceeded those in engineering and the physical sciences (US Census Bureau 1999). It is estimated that, in 2007, both government and private sources of funding for biomedical research in the United States amounted to $101.1 billion, or approximately 4.5% of the total health care expenditures. This actually represents a slowing of expenditures, after they had doubled (on an inflation-adjusted basis) between 1994 and 2003 (Dorsey et al. 2010). In 2007, private sources accounted for 62% of the funding; the remaining came from government sources. Between 2003 and 2007, the government’s share of funding declined from 42.6 to 37.8%. Figure 5–1 illustrates the sources of funding in 2007.

The American Recovery and Reinvestment Act of 2009 allocated $10.4 billion in new funding to the National Institutes of Health (NIH). Of this amount, $8.2 billion (78.8%) is allocated to support research (Steinbrook 2009b). It is safe to assume that, compared to other countries, the United States spends the most on medical research.

Supply-Side Controls

Americans resist supply-side controls. Most other countries employ supply-side rationing (discussed in Chapter 2), also referred to as central planning, to limit the diffusion of medical technology. It curtails costs, but it also restricts access to critically needed care. Canada, which restricts specialist services

Figure 5–1  Sources of Funding for Biomedical Research, 2007.

and limits expensive medical equipment to control health care spending, is a case in point. According to a 2006 study by the Fraser Institute, Canadians have to wait, on average, 8.8 weeks to see a specialist and another 9.0 weeks to obtain specialty treatment. The same study also found that median waiting times across Canada were 4.3 weeks for a CT scan, 10.3 weeks for an MRI, and 3.8 weeks for an ultrasound (Esmail and Walker 2006). Access to care in Canada has actually been deteriorating. The total average waiting time for specialty care increased from 13.1 weeks in 1999 to 17.8 weeks in 2006. Because of unreasonable waits for non-emergency services, as many as 72% of Canadians expressed that they experience worry, stress, or anxiety, and one-half reported experiencing pain while waiting for specialized services (Statistics Canada 2004). Waiting lists for health care in Canada have even resulted in deaths, for example, due to delayed heart surgery (Tuffnell and Kirby 1994; Steinbrook 2006).

**Government Policy**

Unlike most other developed countries, in the United States, direct controls over the innovation, diffusion, and utilization of technology through government policy have not been possible. Nevertheless, public policy does play a significant role in deciding which drugs and devices are made available to Americans. The US government is also one of the largest sources of funding for biomedical research. By controlling the amount of funding, public policy indirectly influences medical innovation. A more extensive discussion of the government’s role is covered in the subsequent section, “The Government’s Role in Technology Diffusion.”

**Managed Care and Technology Diffusion**

The growth of managed care has drawn considerable attention to the question of how managed care may have affected the services delivered to patients enrolled in these plans. An essential aspect of this question relates to the effects of managed care on the availability and use of medical technologies. Research literature that addresses the issue of managed care’s impact on technology adoption is relatively small and generally supports the view that managed care has contributed to slowing the adoption of high-cost technologies (Baker 2002). For example, a study based on all 3,705 MRI sites across the United States provides some preliminary evidence that high levels of market penetration by health maintenance organizations (HMOs) were associated with reduced levels of availability and use of MRI (Baker and Wheeler 1998). In another study that examined the relationship between managed care penetration and the adoption of neonatal intensive care units (hospital units that organize a range of equipment and personnel to care for newborns with low birth weight and other serious health problems), it was observed that managed care did not affect the diffusion of the most advanced high-level units. A slower adoption of midlevel units, however, was observed (Baker and Phibbs 2002). The authors of this study concluded that health outcomes for seriously ill newborns are better in higher-level units and that slower growth of midlevel units could actually be beneficial due to a greater likelihood that seriously ill newborns would receive care in higher-level units.

Earlier, it was believed that not only managed care was slowing the rate of technology diffusion but that there could also potentially
be harmful effects for patients. Extant literature, however, does not find any negative effects on patient care and outcomes because of slower rates of technology diffusion. Conversely, there was clear evidence that excessive technology use had occurred during the fee-for-service era before managed care (Brook 1989). Overuse of technology, in fact, needs to be curtailed because it not only wastes economic resources but can also result in adverse health outcomes. Limitations on the adoption and use of technology do not necessarily correlate with negative health status of a population, as evidence from other industrialized countries demonstrates. Despite the intensive use of high technology in the United States, Americans actually trail behind people in other industrialized nations on broad measures of health. The critical issue is not whether the use of technology is curtailed but whether its appropriate use is curtailed. The issue of appropriateness is discussed later in this chapter (see “The Assessment of Medical Technology”).

### Regulation of Drugs and Devices

The FDA is an agency of the US Department of Health and Human Services (DHHS) that is responsible for ensuring that drugs and medical devices are safe and effective for their intended use. It also controls access to drugs by deciding whether a certain drug will be available by prescription only or as an over-the-counter purchase. The FDA may also stipulate standards on how certain over-the-counter products may be purchased and sold. For example, under the Patriot Act signed by President Bush in March 2006, certain cold and allergy medicines containing pseudoephedrine were required to be kept behind pharmacy counters and sold in only limited quantities to consumers, who must show identification and sign a logbook. This action was taken because pseudoephedrine is used in making methamphetamine—a highly addictive drug—in home laboratories.

The FDA’s regulatory functions have evolved over time (Table 5–2). The first piece of drug legislation in the United States was the Food and Drugs Act of 1906. The purpose of the law was to prevent the manufacture, sale, or transportation of adulterated, misbranded, poisonous, or deleterious foods, drugs, medicines, and liquors (FDA 2009). It authorized the Bureau of Chemistry (predecessor of the FDA) to take action only after drugs had been marketed to consumers. It was assumed that the manufacturer would conduct safety tests before marketing the product. If innocent consumers were harmed, however, the Bureau of Chemistry could act only after such harm had been done (Bronzino et al. 1990). The drug law was strengthened by the passage of the Federal Food, Drug, and Cosmetic Act of 1938 (FD&C Act) in response to the infamous
Amendments) essentially stated that premarket notification was inadequate. The amendments put a premarket approval system in force, giving the FDA authority to review the effectiveness and safety of a new drug or device. Its consumer protection role enabled the FDA to prevent harm before it occurred. However, the drug approval process was criticized for slowing down the introduction of new drugs and, consequently, denying patients early benefit of the latest treatments. Drug manufacturers essentially “became prisoners of the agency’s [FDA’s] indecision, its preoccupation with other issues, or its lack of resources” (Merrill 1994).

Table 5–2 Summary of FDA Legislation

<table>
<thead>
<tr>
<th>Year</th>
<th>Law</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1906</td>
<td>Food and Drugs Act</td>
<td>The FDA was authorized to take action only after drugs sold to consumers caused harm.</td>
</tr>
<tr>
<td>1938</td>
<td>Food, Drug, and Cosmetic Act</td>
<td>Required premarket notification to the FDA so the agency could assess the safety of a new drug or device.</td>
</tr>
<tr>
<td>1962</td>
<td>Kefauver-Harris Amendments</td>
<td>Premarket notification was inadequate. The FDA took charge of reviewing the efficacy and safety of new drugs, which could be marketed only once approval was granted.</td>
</tr>
<tr>
<td>1976</td>
<td>Medical Devices Amendments</td>
<td>Authorized premarket review of medical devices, and classified devices into three classes.</td>
</tr>
<tr>
<td>1983</td>
<td>Orphan Drug Act</td>
<td>Drug manufacturers were given incentives to produce new drugs for rare diseases.</td>
</tr>
<tr>
<td>1990</td>
<td>Safe Medical Devices Act</td>
<td>Health care facilities must report serious or potentially serious device-related injuries, illness, or death of patients and/or employees.</td>
</tr>
<tr>
<td>1992</td>
<td>Prescription Drug User Fee Act</td>
<td>The FDA received authority to collect application fees from drug companies to provide addition resources to shorten the drug approval process.</td>
</tr>
<tr>
<td>1997</td>
<td>Food and Drug Administration Modernization Act</td>
<td>Provides for fast-track approvals for life-saving drugs when expected benefits exceed those of current therapies.</td>
</tr>
</tbody>
</table>

Elixir Sulfanilamide disaster, which caused almost 100 deaths in Tennessee due to poisoning from a toxic solvent used in the liquid preparation (Flannery 1986). According to the revised law, a new drug could not be marketed without first notifying the FDA and allowing the agency time to assess the drug’s safety (Merrill 1994).

The drug approval system was further transformed by the drug amendments of 1962, after thalidomide (a sleeping pill that was distributed in the United States as an experimental drug but had been widely marketed in Europe) was shown to cause birth defects (Flannery 1986). The 1962 amendments (Kefauver-Harris Drug Amendments) essentially stated that premarket notification was inadequate. The amendments put a premarket approval system in force, giving the FDA authority to review the effectiveness and safety of a new drug before it could be marketed. Its consumer protection role enabled the FDA to prevent harm before it occurred. However, the drug approval process was criticized for slowing down the introduction of new drugs and, consequently, denying patients early benefit of the latest treatments. Drug manufacturers essentially “became prisoners of the agency’s [FDA’s] indecision, its preoccupation with other issues, or its lack of resources” (Merrill 1994).
The Government’s Role in Technology Diffusion

The Orphan Drug Act of 1983 and subsequent amendments were passed to provide incentives for pharmaceutical firms to develop new drugs for rare diseases and conditions. Incentives, such as grant funding to defray the expenses of clinical testing and exclusive marketing rights for 7 years, were necessary because a relatively small number of people are afflicted by rare conditions, creating a relatively small market. As a result of the Orphan Drug Act, certain new drug therapies, called orphan drugs, have become available for conditions that affect fewer than 200,000 people in the United States.

In the late 1980s, pressure on the FDA from those wanting rapid access to new drugs for the treatment of the human immunodeficiency virus (HIV) infection called for a reconsideration of the drug review process (Rakich et al. 1992). For example, Saquinavir, a protease inhibitor indicated for patients with advanced HIV infection, received accelerated approval in late 1995; however, its manufacturer, Roche Laboratories, was required to, subsequently, show that the drug prolonged survival or slowed clinical progression of HIV.

In 1992, Congress passed the Prescription Drug User Fee Act, which authorized the FDA to collect fees from biotechnical and pharmaceutical companies to review their drug applications. The additional funds provided needed resources, and, according to the General Accounting Office (GAO), the fees allowed the FDA to make new drugs available more quickly. From 1993 to 2001, the median approval time for standard new drugs dropped from 21 months to approximately 14 months. In 2004, the approval time dropped even further to 12.9 months. Although critics allege that faster reviews have allowed unsafe drugs to be brought to market, studies have found no evidence to support such claims (Agres 2005).

In 1997, Congress passed the Food and Drug Administration Modernization Act. The law provides for increased patient access to experimental drugs and medical devices. It provides for “fast-track” approvals when the potential benefits of new drugs for serious or life-threatening conditions are considered significantly greater than those for current therapies. In 1997, the FDA approved Prandin and Rezulin for Type II diabetes, Evista for the prevention of osteoporosis, and Plavix for atherosclerosis—all within 7 months (Neumann and Sandberg 1998). In addition, the law provides for an expanded database on clinical trials, which is accessible to the public. Under a separate provision, when a manufacturer plans to discontinue a drug, patients who are heavily dependent on the drug receive advance notice.

The FDA first received jurisdiction over medical devices under the FD&C Act of 1938. However, such jurisdiction was confined to the sale of products believed to be unsafe or that made misleading claims of effectiveness (Merrill 1994). In the 1970s, several deaths and miscarriages were attributed to the Dalkon Shield, which had been marketed as a safe and effective contraceptive device (Flannery 1986). In 1976, the Medical Device Amendments extended the FDA’s authority to include premarket review of medical devices divided into three classes. Devices in Class I are subject to general controls regarding misbranding, that is, fraudulent claims regarding the therapeutic effects of certain devices. Class II devices are subject to special requirements for labeling, performance standards, and postmarket surveillance. The most stringent requirements of premarket approval
regarding safety and effectiveness apply to Class III devices that support life, prevent health impairment, or present an unreasonable risk of illness or injury. For most Class III devices, premarket approval is required to ensure their safety and effectiveness. The Safe Medical Devices Act of 1990 strengthened the FDA’s hand in controlling entry of new products and in monitoring use of marketed products (Merrill 1994). Under this Act, health care facilities must report serious or potentially serious device-related injuries or illness of patients and/or employees to the manufacturer of the device and, if death is involved, to the FDA as well. In essence, the Act is intended to serve as an “early warning” system through which the FDA can obtain important information on device problems.

The Patient Protection and Affordable Care Act (ACA) of 2010 places some restrictions on the licensing of new biological products. If a product is shown to be bio-similar or interchangeable with an existing licensed biological product, referred to as a reference product, the FDA is not allowed to approve such a product until 12 years from the date on which the reference product was first approved.

Certificate of Need

The National Health Planning and Resource Development Act of 1974 designated a regional network of health systems agencies (HSAs) for the planning and allocation of health resources, including technology. States were required to enact CON laws to obtain federal funds for planning functions under this Act. These activities were intended to influence the diffusion of technology by requiring hospitals to seek state approval before acquiring major equipment or embarking on new construction or modernization projects (Iglehart 1982). In 1986, the federal government terminated funding for HSAs. Although some states have abandoned CON requirements, approximately 36 states retain some control over planning and construction of new health care facilities (National Conference of State Legislatures 2011).

Various reasons have been cited to explain why the federal government relinquished support of health planning:

- The assumption that providing quality health care did not require extensive use of technology conflicted with societal expectations that all available technology should be used (Rakich et al. 1992).

- The CON emphasis on high-cost technologies was considered misdirected because high-volume utilization of low-cost technologies could also have a significant effect on health care costs (Rakich et al. 1992).

- The CON regulations fell victim to the shift away from regulatory controls over health care providers in favor of a competitive market approach to cost containment (Haglund and Dowling 1993). In fact, the CON regulations were blamed for unfair interference with the ability of hospitals to compete based on which services they could offer.

- As technology became increasingly portable, freestanding facilities could acquire the same technology that hospitals had been prohibited from acquiring. Because these freestanding facilities were not subject to CON review (Rakich et al. 1992), the state approval process was regarded as unfair toward hospitals.
As previously noted in this chapter, the proliferation of specialty hospitals and duplication of services have, perhaps, resulted in unnecessary and costly diffusion of technology. It has been noted that virtually all of the specialty hospitals that opened since 1990 are located in states that have minimal or no CON requirements (Zimmerman 2006).

Research on Technology

The Agency for Healthcare Research and Quality (AHRQ) was established in 1989 under the Omnibus Budget Reconciliation Act of 1989 (Public Law 101–239) and was originally the Agency for Health Care Policy and Research. AHRQ, a division of the DHHS, is the lead federal agency charged with supporting research that focuses on improving the quality of health care, reducing health care cost, and improving access to essential services. For instance, the agency’s Center for Outcomes and Evidence (formerly the Center for Outcomes and Effectiveness Research) conducts and supports studies of the outcomes and effectiveness of diagnostic, therapeutic, and preventive health services and procedures. The agency’s technology assessments are available to medical practitioners, consumers, and other health care purchasers.

Funding for Research

The federal government is a major provider of financial support for biomedical research. The NIH—a division of the DHHS—both conducts and supports basic and applied biomedical research in the United States. Funding through NIH provided much of the impetus for medical schools to undertake research in the medical subspecialties, which led to the growth of specialty departments within academic medical centers (Rakich et al. 1992). These institutions have produced many specialists, which is reflected in the sustained imbalance between the number of general practitioners, compared to specialists.

The Impact of Medical Technology

Health care technology involves the practical application of scientific discoveries in many disciplines. The deployment of scientific knowledge has had far-reaching and pervasive effects, as the various categories in Table 5–1 indicate. The effects of technology often overlap, making it difficult to pinpoint technology’s impact on the delivery of health care.

Impact on Quality of Care

When advanced techniques can provide more precise medical diagnoses than before, quicker and more complete cures than previously available, or reduce risks in a cost-effective manner, the result is improved quality. Technology can provide new remedies where none existed. Technology continuously offers more effective, less invasive, and safer therapeutic and preventive remedies. Increased longevity and decreased morbidity are often the outcomes.

Numerous examples illustrate the role of technology in enhancing the quality of care. Coronary angioplasty has become a common procedure for opening blocked or narrowed coronary arteries. More than a million people receive this treatment every year in the United States. Before this treatment became available, patients suffering a heart attack were prescribed prolonged bed rest and treated with morphine and
nitroglycerin (CBO 2008). Angioplasty has reduced the need for open-heart bypass surgery. In 2005, the FDA approved the total artificial heart (TAH) for implantation in patients with end-stage heart failure. This device is a life saver for those awaiting heart transplantation. Implantable defibrillators can save lives in people who have life-threatening irregular heartbeats.

Laser technology permits surgery with less trauma; it also shortens the period for postsurgical recovery. Laser applications are widely used in most medical specialties for both medical and cosmetic procedures. For example, advanced laser procedures are available for high-precision eye surgery. In the cosmetic arena, facial resurfacing, wrinkle removal, and many other treatments are performed using lasers, which deliver a specific wavelength of light to the area to be treated.

Robot-assisted surgeries have gained significant momentum in areas such as urology. For example, in the United States, more than 70% of all radical prostatectomies are performed using the da Vinci robot (Rassweiler et al. 2010). The robotic approach allows improved dexterity and precision of the instruments.

Advanced bioimaging methods have opened new ways to see the body’s inner workings, while minimizing invasive procedures. Modern imaging technologies include MRI, positron emission tomography (PET), single-photon emission computed tomography (SPECT), computed tomography (CT), and fluorescence imaging. PET has important applications both for research and for clinical purposes in cardiology, neurology, and oncology. PET can show abnormal processes, such as those associated with cancers and metabolic dysfunction. It can spot tumors and other problems that may not be detectable with traditional MRI or CT scans. SPECT is of great value in imaging the brain. SPECT imaging could also reduce inappropriate use of invasive procedures through a more accurate diagnosis of coronary artery disease (Shaw et al. 2000). Integrated PET/CT is increasingly becoming an established imaging technique in the management of many cancers (Devaraj et al. 2007).

Molecular and cell biology has opened a new era in clinical medicine. Screening for genetic disorders, gene therapy, and powerful new drugs for cancer and heart disease promise to radically improve the quality of medical care. Genetic research might even help overcome the critical shortage of transplantable organs. Certain farm animals have been successfully cloned, which holds the promise of transplanting animal organs into humans, technically referred to as xenografting (or xenotransplantation). On a parallel track, regenerative medicine and tissue engineering hold the promise of creating other biological and bioartificial substitutes that will restore and maintain normal function in a variety of diseased and injured tissues. Products such as bioartificial kidneys, artificial implantable livers, and insulin-producing cells to replace damaged pancreatic cells are examples of what biomedical science might be able to accomplish. Treatment of disease using stem cells that can be derived from discarded human embryos (human embryonic stem cells), fetal tissue, or adult sources (bone marrow, fat, or skin) is another example of regenerative medicine.

Amid all the enthusiasm emerging technologies might generate, some degree of caution must prevail. Experience shows that greater proliferation of technology may not necessarily equal higher quality. Unless the
The Impact of Medical Technology

Impact on Quality of Life

Thanks to new scientific developments, thousands of people are able to live normal lives, which otherwise would not be possible. People with disabling conditions have been able to overcome their limitations in speech, hearing, vision, and movement. Long-term maintenance therapies have enabled people suffering from conditions such as diabetes and end-stage renal disease to engage in activities that they otherwise would not be able to do. Major pharmaceutical breakthroughs enable people suffering from heart disease, cancer, acquired immune deficiency syndrome (AIDS), and preterm birth to have a much longer life expectancy and improved health (Kleinke 2001).

Modern technology has also been instrumental in relieving pain and suffering, and pain management is being recognized as a new subspecialty in medicine. For example, for cancer pain management, new opioids have been developed for transdermal, nasal, and nebulized administration, which allow needleless means of controlling pain (Davis 2006). Apart from new drugs, patient-controlled analgesia allows patients to determine when and how much medication they receive, which gives patients more independence and control. HIV/AIDS was recognized as a killer disease in the early 1980s, but modern treatments, such as protease inhibitors and nonnucleoside reverse transcriptase inhibitors (known as antiretroviral agents), have suppressed the disease’s ability to proliferate and damage organs. Thanks to these treatments, HIV/AIDS has become a chronic disease, not a death sentence (Komaroff 2005). Clinical trials have been under way to evaluate the effectiveness and safety of inhaled and oral administration of insulin for patients with Type II diabetes. A substitute for injectable insulin could greatly enhance the quality of life for diabetic patients, particularly the elderly, who require assistance with insulin injections.

Impact on Health Care Costs

Technological innovations have been the single most important factor in medical cost inflation over the second half of the 20th century. They have accounted for about one-half of the total rise in real (after eliminating the effects of general inflation) health care spending during the past several decades (Institute of Medicine 2002; CBO 2008).

Technology in the health care field demonstrates a unique characteristic. In virtually all other industries, new technology has the effect of reducing labor force and production costs, and price considerations often play an important role in the adoption of new technologies. In health care, however, new technology has increased both labor and capital costs (Iglehart 1982). First, there is the cost of acquiring the new technology and equipment. Second, specially trained physicians and technicians are often needed to operate the equipment and to analyze the results, which often leads to increases in labor costs. Third, new technology may require special housing and setting requirements, resulting in facility costs (McGregor 1989).

Littell and Strongin (1996) argued that technology’s purchase price itself has a minimal effect on system-wide health care costs. The total purchase price of medical products represents only a small fraction,
Medical Technology

Instead of focusing solely on the excessive costs that new technologies may produce, increasing attention is being given to the value or worth of the advances in medical care. In a groundbreaking study, Cutler and colleagues (2006) addressed this issue by examining how medical spending has translated into additional years of life saved, based on the assumption that 50% of the improvements in life expectancy have resulted from medical care. These researchers concluded that the increases in medical spending in the 1960 to 2000 period, in terms of increased life expectancy, have rendered reasonable value for the money spent. For example, for a 45-year-old American who has a remaining life expectancy of 30 years, the value of remaining life is more than $200,000 per year (Murphy and Topel 2003). For this 45-year-old person, the average annual spending in health care for each year of life gained was $53,700 (Cutler et al. 2006).

Impact on Access

Geography is an important factor in access to technology. If a technology is not physically available to a patient population, access is limited. Geographic access can improve for many technologies by providing mobile equipment or by employing new communications technologies to allow remote access to centralized equipment and specialized personnel. For example, GPS (global positioning system) technology significantly improves emergency medical services response time to the scene of motor vehicle crashes and other emergencies (Gonzalez et al. 2009).

Mobile equipment can be transported to rural and remote sites, making it accessible to those populations. Mobile cardiac
catheterization laboratories, for example, can provide high technology in rural settings. Such services not only provide needed health care to the community, but they also protect a patient base from migrating to tertiary referral centers (Lewis 1989). Access to specialized medical care for rural and other hard-to-reach populations has transformed through innovations in telemedicine, which eliminates the requirement for face-to-face contact between the examining physician and the patient.

Impact on the Structure and Processes of Health Care Delivery

Modern technology has turned hospitals into capital-intensive institutions (Iglehart 1982). Large urban hospitals have been transformed into medical centers, where the latest diagnostic and therapeutic remedies are offered. Recent growth in alternative settings (home health and outpatient) has also been made possible primarily by technology. Financial pressures may have prompted the use of outpatient and home settings for health care delivery, but without technological innovations, extensive adaptations of modern treatments to these alternative sites may not have been possible. Lithotripsy (a noninvasive procedure for crushing kidney and bile stones by using shockwaves) and MRI have become increasingly available in outpatient settings. More patients, who would have required lengthy hospital stays, are now undergoing outpatient surgery. Extensive home health services have brought many hospital and nursing home services to the patient’s home. Monitoring devices can permit cardiac implants to transmit vital information over telephone lines; respirators maintain breathing in the home; and kidney dialyzers are commonly used at home, as is parenteral feeding—an intravenous technology used to provide full nutritional supplements to help feed patients who cannot swallow or digest food (Luce 1993).

Certain technologies adopted from other industries have improved health care delivery. For example, the bar-coding system has found several new applications in hospitals, including automation of drug dispensing, which drastically reduces medication errors. Scanning of information on nurses’ badges, patients’ wristbands, and drugs administered ensures that the right drug is given in the right dose to the right patient (Nicol and Huminski 2006). In some applications, radio frequency identification (RFID) has started to replace bar-coding technology in the areas of patient identification, equipment management, inventory control, and automatic supply and equipment billing (Roark and Miguel 2006).

Telecommunications technology used in telemedicine is also used for administrative teleconferencing and continuing medical education. For example, interactive compressed videoconferencing allows for an almost face-to-face meeting in which vendors can demonstrate new products or services and discuss their utilization, costs, and delivery schedules. Eliminating airfares, hotel expenses, and other travel-related costs can achieve significant savings. Interactive videoconferencing is also used for continuing education in the United States and abroad, with a high degree of satisfaction from participants. This technology is particularly helpful to rural health practitioners in overcoming barriers of distance to keep their knowledge and skills up to date (Klein et al. 2005). Recently, videoconferencing applications have been tried to provide language interpretation to translate physician orders and medication regimens.
for patients who have limited English proficiency (Hamblen 2006).

Managed care has been instrumental in transforming the way in which health services are delivered in the United States. Simpson (1994) observed that, without technology, managed care would not be possible because it is based on managing information and managing information requires technology. For example, information management is the backbone needed for monitoring cost effectiveness and quality and for tracking referrals to specialized services.

**Impact on Global Medical Practice**

Technology developed in the United States has significantly impacted the practice of medicine worldwide. Many nations wait for the United States to develop new technologies, which can then be introduced into their systems in a more controlled and manageable fashion. This process gives them access to high-technology medical care with less national investment. If technology development were slowed by a modest amount in the United States, it would likely have serious health consequences globally (Massaro 1990). Telemedicine has also made clinical care, distance education, and medical research possible in parts of the world traditionally unexposed to such advances (Umar 2003).

**Impact on Bioethics**

Increasingly, technological change is raising serious ethical and moral issues. For example, when in vitro fertilization is applied in medical practice and leads to the production of spare embryos, the moral question is what to do with these embryos. Gene mapping of humans, genetic cloning, stem cell research, and other areas of growing interest to scientists may hold potential benefits, but they also present serious ethical dilemmas. Life support technology raises serious ethical issues, especially in medical decisions regarding continuation or cessation of mechanical support, particularly when a patient exists in a permanent vegetative state.

**The Assessment of Medical Technology**

Technology assessment, or more specifically, health technology assessment (HTA), refers to “any process of examining and reporting properties of a medical technology used in health care, such as safety, effectiveness, feasibility, and indications for use, cost, and cost-effectiveness, as well as social, economic, and ethical consequences, whether intended or unintended” (Institute of Medicine 1985). HTA seeks to contribute to clinical decision making by providing evidence about the efficacy, safety, and cost effectiveness of medical technologies. It also informs decision makers, clinicians, patients, and the public about the ethical, legal, and social implications of medical technologies (Lehoux et al. 2009).

Technology assessment can play a critical role in distinguishing between services that are appropriate and those that are not. According to the Congressional Budget Office, roughly $700 billion each year goes to health care spending that cannot show improved health outcomes (Orszag 2008). The amount of $700 billion is 32% of total expenditures on health services and supplies ($2181 billion; Hartman et al. 2010) in 2008. Hence, HTA presents a tremendous
opportunity to reduce waste and improve health outcomes. Questions related to the adoption of new technology and decisions to control its diffusion should be governed by HTA (Garber 1994).

Efficacy and safety are the basic starting points in evaluating the overall utility of medical technology. Cost effectiveness and cost benefit go a step further in evaluating the safety and efficacy in relation to the cost of using technology. Efficacy and safety are evaluated through clinical trials. A clinical trial is a carefully designed research study in which human subjects participate under controlled observations. Clinical trials are carried out over three or four phases, starting with a small number of subjects to evaluate the safety, dosage range, and side effects of new treatments. Subsequent studies using larger groups of people are carried out to confirm effectiveness and further evaluate safety. Compliance with rigid standards is required under HIPAA to protect the rights of study participants and to ensure that the experimentation protocols are ethical. Every institution that conducts or supports biomedical or behavioral research involving human subjects must establish an Institutional Review Board (IRB), which initially approves and periodically reviews the research.

**Efficacy**

Determination of efficacy is based on the premise that, if a technology is not efficacious, it should not be used. Without the information on efficacy, it is almost impossible to know a technology’s usefulness.

In a broad sense, efficacy is defined simply as health benefit derived from the use of technology. Some authors see a technical distinction between efficacy and effectiveness (see Wan 1995). Although such a distinction may be important in the actual process of assessment, in a general sense, efficacy is synonymous with effectiveness. If a product or service actually produces some health benefit, it can be considered efficacious or effective. Decisions about efficacy require that one ask the right questions. For example, is the current diagnosis satisfactory? What is the likelihood that a different procedure would result in a better diagnosis? If the problem is more accurately diagnosed, what is the likelihood of a better cure? The question of benefit is not as simple as it first seems because health outcomes have traditionally been measured in terms of mortality and morbidity. However, improvement in one’s quality of life is an important outcome. Reliable measures of improvement in quality of life, however, are difficult to obtain. They are not nearly as objective as mortality rates and are subject to bias (Fuchs 2004). Moreover, the same technology employed by different caregivers can sometimes yield different results, although such variations can be minimized by education and training.

**Safety**

Safety considerations are designed to protect patients against unnecessary harm from technology. As a primary benchmark, benefits must outweigh any negative consequences; however, negative consequences cannot always be foreseen. Hence, clinical trials involving patients who may stand to gain the most from a technology are employed to obtain a reasonable consensus on safety. Subsequently, outcomes from the wider use of the technology are closely monitored to identify any problems related to safety.
Cost Effectiveness

An evaluation of efficacy and safety alone is not sufficient. Cost efficiency (or cost effectiveness) is a step beyond the determination of efficacy. Whereas efficacy is concerned only with the benefit derived from the technology, cost effectiveness evaluates the additional (marginal) benefits derived in relation to the additional (marginal) costs incurred. Thus, cost efficiency weighs benefits against costs. A new technology may be clinically effective, that is, it may provide some benefit, but it is not cost effective if the benefit is small and the cost is high.

As shown in Figure 5–2, at the start of medical treatment, each unit of technology utilization is likely to provide benefits in excess of its costs. At some point (Point A in Figure 5–2), an additional unit of technology utilization would result in parity between benefits and costs. This is where the slopes of the benefit and cost lines are equal, as illustrated by the parallel lines. From an economic standpoint, this is the optimum point of health resource inputs. From this point on, it is highly unlikely that additional technological interventions would result in benefits equal to or in excess of the additional costs. As costs continue to increase, the health benefit curve becomes flatter. At Point B (Figure 5–2), the marginal benefits from additional care approach zero, which is referred to as the flat of the curve.

A considerable amount of the care delivered in the United States is at the flat of the curve, referring to a level of intensity of care that provides no incremental health benefit (Fuchs 2004). Hence, high-intensity care is often wasteful. In general, differences in intensity of care play, at most, a minor role in explaining cross-section differences in health outcomes, which are primarily determined by nonmedical factors: the physical and psychosocial environments.
The Assessment of Medical Technology

result in undesired side effects, iatrogenic illnesses, medical complications, injuries, or death, all of which carry a cost that is often difficult to measure. Hence, the effectiveness of medical interventions should be evaluated not only in terms of costs but also in terms of risks. Thus, Figure 5–2 can also be used to determine the optimum point at which the benefits equal the risks. Beyond that point, the risks from additional technological interventions are likely to exceed the benefits. An example is overutilization of imaging procedures, such as CT scans, which carry potentially harmful radiation exposure. When used for the wrong reason, such as whole body CT scans for asymptomatic patients, they contribute to unnecessary costs and potential harm (Roberts and Keene 2008).

Cost Benefit

In contrast to cost-effectiveness analysis, cost-benefit analysis incorporates the elements of both costs and benefits, especially when the costs and benefits are not expressed in terms of dollars (Wan 1995). In this case, costs may or may not be calculated in monetary terms. If costs cannot be monetarily measured, they may be evaluated in terms of resource inputs, such as staff time, number of service units, space requirements, and degree of specialization needed (specialist versus generalist, physician versus allied health professional). Benefits, evaluated in terms of health outcomes, include elements such as efficacy of treatment, prognosis or expected outcomes, number of cases of a certain disease averted, years of life saved, increase in life expectancy, hospitalization and sick days avoided, early return to work, patient satisfaction, and quality of life. Benefits are then evaluated in relation to dollar costs or resource inputs.

Risk is another type of nonmonetary cost. Most medical procedures are not totally safe. They may have the potential for significant benefits, but they are also accompanied by certain risks. Sometimes, these risks are small; at other times, the risks can be significant. The process of medical care can result in undesired side effects, iatrogenic illnesses, medical complications, injuries, or death, all of which carry a cost that is often difficult to measure. Hence, the effectiveness of medical interventions should be evaluated not only in terms of costs but also in terms of risks. Thus, Figure 5–2 can also be used to determine the optimum point at which the benefits equal the risks. Beyond that point, the risks from additional technological interventions are likely to exceed the benefits. An example is overutilization of imaging procedures, such as CT scans, which carry potentially harmful radiation exposure. When used for the wrong reason, such as whole body CT scans for asymptomatic patients, they contribute to unnecessary costs and potential harm (Roberts and Keene 2008).

Cost (and risk) and benefit evaluations are not precise or objective determinations. Such assessments are based on professional judgments and expert opinions. However, standardization of clinical guidelines based on clinical evidence or expert medical consensus is a step toward making this process more objective.

Cost Benefit

In contrast to cost-effectiveness analysis, cost-benefit analysis evaluates benefits in relation to costs, when both are expressed in dollar terms (Seidel et al. 1995; Wan 1995). Hence, cost-benefit analysis is subject to a more rigorous quantitative analysis compared to cost-effectiveness analysis. Cost-benefit analysis is based on four main assumptions: (1) The problem or health condition can be identified or diagnosed. (2) The problem can be controlled or eradicated using an appropriate intervention. (3) The benefit or outcome can be assigned
a dollar value. (4) The cost of intervention can be determined in dollars.

The same principles that apply to cost effectiveness are also used for assessing cost benefit. If the estimated benefits exceed costs, the additional spending on medical care is worth the extra costs. The *quality-adjusted life year* (QALY) is commonly used as a measure of health benefit. Analyses that include the use of QALYs are referred to as *cost-utility analyses* (Neumann and Weinstein 2010). QALY is defined as the value of one year of high-quality life. Cutler and McClellan (2001) assigned a value of $100,000 per QALY and demonstrated that, at least in the case of four selected conditions, namely, heart attacks, low-birth-weight infants, depression, and cataracts, the estimated benefit of technological change was much greater than the cost. For breast cancer treatment, the costs and benefits were found to be equal in magnitude. The value of $100,000 per QALY is debatable. Others have proposed $200,000 per year of life (Murphy and Topel 2003).

**Current and Future Directions in Health Technology Assessment**

**Private Sector Initiatives**

In the United States, HTA is conducted predominantly in the private sector, unlike nations such as Sweden, the Netherlands, and Canada, which have centralized technology assessment agencies (Neumann and Sandberg 1998). In the public sector, the Department of Veterans Affairs and the Department of Defense mainly conduct the clinical trials and other evaluations of technology. Hence, much of the talent needed to assess medical technology is also located, organized, and financed in the private sector. Pharmaceutical firms, for example, have developed pharmacoeconomics departments concerned with internal analysis of the cost effectiveness of new products (Rettig 1994). Before new drugs are introduced, their economic evaluation has become almost as important as the clinical trials used to determine their safety and efficacy. Private agencies, among them the Blue Cross and Blue Shield Association, Kaiser Permanente, the AMA, and other professional societies, have undertaken technology assessment.

**Need for Coordinated Effort**

At present, efforts in HTA remain fragmented and poorly funded, with little or no coordination between public or private sector groups to deliberately address the assessment and diffusion of technologies. Also, information garnered from HTA studies is not efficiently shared among medical organizations, health care systems, and policy makers. The response has been a demand for broad regional and national HTA programs that would study the effects of health care technology more systematically and involve providers, policy makers, patient advocacy groups, and government representatives (Bozic et al. 2004). Provisions under the Medicare Prescription Drug Improvement and Modernization Act of 2003 provide for increased funding for the AHRQ to support clinical effectiveness and cost-effectiveness research on new medical technology (Wechsler 2004).

**Need for Standardization**

Future efforts in HTA will require greater transparency of methods employed and standardization, which would allow comparison
of efficacy and cost-effectiveness results across studies. In 1996, the Panel on Cost-Effectiveness in Health and Medicine—a panel of physicians, health economists, ethicists, and other health policy experts commissioned by the US Public Health Service—recommended the use of QALYs as a standard measure of health benefits from various interventions. The use of QALYs provides a common measure of health effects across studies (Siegel et al. 1997). As a standard measure, QALYs enable comparisons of varied interventions across diverse diseases and conditions. However, the Patient Protection and Affordable Care Act of 2010 prohibits the use of cost-per-QALY thresholds by the Patient-Centered Outcomes Research Institute created under the Act (Neumann and Weinstein 2010).

**Balance Between Clinical Efficacy and Economic Worth**

American consumers often want all available medical resources utilized regardless of how little health benefit is received in relation to costs. Physicians often find themselves in a precarious situation when they are required to withhold treatment because of its known cost inefficiency. Payers are blamed as uncaring profit mongers when they intervene in the delivery of medical care based on costs. Even US policy makers are not at ease with bringing cost effectiveness into the equation of health care delivery. Consequently, cost effectiveness has not taken central stage in the United States, and its application is not openly discussed in health care decision making. In contrast, European countries, Canada, and Australia use cost effectiveness openly and explicitly in their centralized health planning decisions (Neumann and Sullivan 2006).

Current research has highlighted the value or worth of medical care spending in terms of gains in life expectancy in the United States (see Cutler et al. 2006). Although such findings may suggest current levels of expenditures for health care are acceptable, rising health care costs in the United States and excessive spending, according to international comparisons, are of growing concern to most Americans. Policy makers are likely to respond to any public outcry over health care expenditures. Hence, cost-effectiveness analysis is likely to play a larger role in the approval process for drugs and devices, and regulatory initiatives to contain future costs are likely to demand greater emphases on the economic worth of individual technologies.

**Clinical Practice Guidelines**

*Clinical practice guidelines* (or medical practice guidelines) are systematically developed protocols to assist practitioners in delivering appropriate health care for specific clinical circumstances (Field and Lohr 1990). The goal is to assist practitioners in adopting a “best practice” approach in delivering care to a given patient population with a given condition (Ramsey 2002). Practice guidelines result from an evaluation of medical procedures, regarding their effectiveness, appropriateness, and safety and the integration of these assessments into clinical practice. Such evidence-based guidelines provide a mechanism for standardizing the practice of medicine and improving the quality of care. The benchmark practice patterns become norms governing what is and is not appropriate in clinical practice. However, cost-effectiveness information is not commonly incorporated in the development of clinical practice guidelines.
associations, and the medical device and pharmaceutical industries frequently argue in favor of increasing resource inputs in delivering health care (Wild 2005). They often claim that quality would deteriorate and/or harm would ensue unless new innovations are funded. Since these same groups have also assumed major roles in HTA, the probability of circulating biased results is high. Biases might also arise in studies funded by sources that have a financial stake in the results. Such concerns have stimulated interest in developing standards for assessments, perhaps under the aegis of a governmental body.

Within social, ethical, and legal constraints, public and private insurers face the problem of deciding whether to cover novel treatments. Recent challenges include, for example, decisions about new reproductive techniques, such as intracytoplasmic sperm injection in vitro fertilization (ICSI IVF), new molecular genetic predictive tests for hereditary breast cancer, and new drugs such as sildenafil (Viagra) for erectile dysfunction (Giacomini 2005). The question arises as to whether society should even bear the cost of infertility treatments, genetic tests, and lifestyle remedies that do not affect people’s health and longevity. Therapies classified as experimental are, generally, not covered by insurance. When new treatments promise previously unattainable health benefits, decisions about assessment of such treatments are often surrounded by controversy. Critical to the debate, but defying easy answers, are questions regarding the adequacy of studies used to determine whether a certain treatment should be considered experimental, ethical questions regarding the needs of patients who could possibly benefit from the treatment, and financial questions concerning

**Ethical Issues**

With the rapid pace of innovation, concerns in HTA transcend the traditional questions about safety, effectiveness, and economic value. New technologies also raise social, ethical, and legal concerns. These issues raise complex questions but provide few answers. Yet, in an era of resource constraints, HTA will have to take into account social, ethical, economic, and legal concerns.

Health care budgets are under constraint not only in the United States but in other developed countries as well. How to provide the latest and best in health care within limited resource parameters has become a major concern for all developed countries. Insurers, pharmaceutical companies, medical device manufacturers, MCOs, and physician advocacy institutions often act and advocate out of their own self-interests. For example, physicians’ representatives, such as medical
Summary

Medical technology is the practical application of scientific knowledge produced by biomedical research and the adaptation of scientific advances from other fields to the delivery of health care. The application of information technology and informatics is becoming indispensable in efficient delivery of care and in the effective management of modern health care organizations. With the growth of Internet applications, e-health is becoming a growing field in health care delivery. Telemedicine and telehealth are used in both synchronous and asynchronous applications to deliver medical care, when the provider and client are separated by distance.

Medical technology has greatly enhanced the capabilities of the delivery system to provide more effective and less invasive treatments. The problem is that the development and diffusion of technology are closely intertwined with its use. The United States is foremost in the world in developing new technology, but the uncontrolled use of technology has prompted deep concerns about rising costs.

Several factors have influenced the growth of technology: beliefs and values in the American culture, medical specialization, financing, competition, and expenditures in research and development. Most other developed countries apply supply-side controls to limit technology diffusion and its use. It curtails cost, but it also restricts access to care. Such direct controls over the innovation, diffusion, and utilization of technology through government policy have not been possible in the United States. However, health policy does play a role through the FDA’s drug and device approval process and government funding for biomedical research.

Technology has had a tremendous impact on the delivery of health care. It has positively influenced the quality of care, enhanced the quality of life, and improved access in remote areas. Many large institutional providers and MCOs cannot function efficiently without computer-based information systems. Because much of the technology developed in the United States is either purchased or reproduced by other countries, technology development in the United States also has a profound effect on the practice of medicine globally. Advances
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in genetics and many other areas have the potential to provide unprecedented benefits, but they also raise critical ethical issues.

Given the costs and risks associated with the use of technology, its assessment has become an area of growing interest. Current thought in technology assessment calls for a balance between benefits (efficacy) and costs/risks. Additional interventions, beyond the point where costs and/or risks begin to exceed the benefits, are considered inappropriate, but the assessment of cost effectiveness is not an exact science. Evidence-based clinical practice guidelines are paving the way toward standardizing medical practice. However, there is a disconnect between practice guidelines and economic analysis. As escalating health care expenditures reach a critical point, appropriateness of medical treatments may have to be based on their incremental health value at a given cost.

Use of technology is not without controversy. Critical moral dilemmas arise from the use of experimental therapies, delays in the assessment and approval process, life-sustaining treatments, and waste of resources when interventions are not cost effective.

Terminology

administrative information systems
asynchronous technology
clinical information systems
clinical practice guidelines
clinical trial
cost-benefit analysis
cost-effectiveness analysis
cost efficiency
cost-utility analysis
decision support systems
efficacy
e-health
electronic health records
e-therapy
flat of the curve
health informatics
health technology
assessment
information technology
medical technology
m-health
orphan drugs
quality-adjusted life year (QALY)
self-referrals
smart cards
synchronous technology
technological imperative
technology diffusion
telehealth
telemedicine
value
virtual physician visits
xenografting

Test Your Understanding

1. Medical technology encompasses more than just sophisticated equipment. Discuss.
2. What role does an information systems (IS) department play in a modern health care organization?
3. Provide brief descriptions of clinical information systems, administrative information systems, and decision support systems in health care delivery.
4. Distinguish between information technology (IT) and health informatics.

Review Questions
5. According to the Institute of Medicine, what are the four main components of a fully developed electronic health records (EHR) system?

6. Why have EHR systems not been widely adopted in the United States?

7. What are the main provisions of HIPAA with regard to the protection of personal medical information?

8. What is telemedicine? How do the synchronous and asynchronous forms of telemedicine differ in their applications?

9. Which factors have been responsible for the low diffusion and low use of telemedicine?

10. Generally speaking, why is medical technology more readily available in the United States than in other countries?

11. How does competition lead to greater levels of technology diffusion? How does technological diffusion, in turn, lead to greater competition?

12. Summarize the government’s role in technology diffusion.

13. What was the effect of Kefauver-Harris Drug Amendments of 1962? Why was the law criticized?

14. Provide a brief overview of how technology influences the quality of medical care and quality of life.

15. Discuss the relationship between technological innovation and health care expenditures.

16. What impact has technology had on access to medical care?

17. Discuss the roles of efficacy, safety, and cost effectiveness in the context of technology assessment.

18. Why is it important to achieve a balance between clinical efficacy and economic worth (cost effectiveness) of medical treatments?

19. What purpose do clinical practice guidelines serve in health care delivery? What main shortcoming exists in the practice guidelines currently in use?

20. What are some of the ethical issues surrounding the development and use of medical technology?

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