APPENDIXES

Appendix A

DEVELOPMENT AND DIFFUSION OF MEDICAL TECHNOLOGIES*

This appendix describes the nature of medical technologies, offers a model of their diffusion, and considers the place of efficacy and safety assessment in the diffusion process. The analysis also reveals the importance of information on efficacy and safety and demonstrates the possibility of making the assessment of safety and efficacy an integral part of the development of medical technologies.

THE NATURE OF MEDICAL TECHNOLOGIES

Medical technologies are of many different types and serve a variety of functions. Nonetheless, they can be classified into sets. Schemes of classification can help in evaluating the efficacy and safety of a particular technology and in judging new technologies on the basis of previous experience or evaluation *(223,277).*

A useful system for classifying medical technologies distinguishes these technologies according to two dimensions—medical purpose and physical nature (3.54). Each of these two dimensions can be broken down further as follows.

Medical Purpose: 1) A *diagnostic* technology helps in determining what disease processes occur in a patient; 2) A *preventive* technology protects an individual from disease; 3) A *therapeutic* or *rehabilitative* technology relieves an individual from disease and its effects (therapeutic technologies can be further divided into those few technologies that cure disease and the many technologies that give symptomatic relief, but do not alter the underlying disease process); 4) An *organizational* or *administrative* technology is used in management and administration to ensure that health care is delivered as effectively as possible; and 5) A *supportive* technology is used to provide patients, especially those in hospitals, with needed services (e.g., hospital beds and food services).

Physical Nature: 1) A *technique* is a purposive application of skills or knowledge, or both, by a health care provider to a patient; 2) A *drug* is any chemical or biological substance that may be applied to, ingested by, or injected into humans in order to prevent, treat, or diagnose disease or other medical conditions; 3) A *device* is any physical item, excluding drugs, used in medical care, and may range from a machine requiring large capital investment to a small instrument or implement; and 4) A *procedure* is a combination, often quite complex, of provider skills or abilities with drugs, devices, or both *(354).*

Drugs and devices are products; procedures, on the other hand, are utilization of a product or products according to the knowledge or skills of a medical care provider. In some cases, the drugs or devices involved are not predominant factors in a procedure. In-

*A more detailed discussion of these issues maybe found in reference (354).

stead, the technique or the provider performing the procedure are most important. A surgical procedure, for example, involves the use of scalpels, clamps, and anti-infection drugs; the key to the procedure, however, is the surgeon's actions. The case of coronary artery surgery in chapter 3 illustrates this point: mortality for such surgery ranges from 0.8 to 12 percent, a very large range in which the skill of the surgeon performing the surgery is clearly a key factor.

HOW MEDICAL TECHNOLOGIES ARE DEVELOPED AND DIFFUSED

The development, diffusion, and use of medical technologies is a process that has been described as including at least seven steps. *

1. Discovery, through research, of new knowledge, and relation of this knowledge to the existing knowledge base;
2. Translation of new knowledge, through applied research, into new technology, and development of a strategy for moving the technology into the health care system;
3. Evaluation of the safety and efficacy of new technology through such means as controlled clinical trials;
4. Development and operation of demonstration and control programs to demonstrate feasibility for widespread use;
5. Diffusion of the new technology, beginning with the trials and demonstrations and continuing through a process of increasing acceptance into medical practice;
6. Education of the professional and lay communities in use of the new technology; and
7. Skillful and balanced application of the new developments to the population.

This sequence of technology development and use is attractive because it offers a logical, linear model for understanding the development process. The model highlights the fact that it it usually possible to identify a medical innovation prior to widespread diffusion, and thus test it in advance for safety and efficacy.

But medical technologies, like others, in fact emerge from a process that is far less systematic and certainly less linear than that which this model implies (345). An additional weakness of this model is that it does not acknowledge the importance of epidemiological research (39). Epidemiological methods have been used in testing efficacy and safety of medical technologies and have led to advances in the prevention and control of disease. The causes of such diseases as cholera, scurvy, and lung cancer have been identified through epidemiological research; epidemiological data have made control programs possible. For example, epidemiological data have shown that cigarette smoking is the major cause of lung cancer, and thus, as noted in the case study in chapter 3, lung cancer is almost totally preventable. Yet basic research has not discovered the mechanism by which cigarette smoking causes cancer **(39).**

Once a technology has been developed through the complex of activities referred to as "basic or fundamental research" and "applied research, " it usually must be tested on

● Modified from reference (392).

human subjects. This area of clinical investigation and testing encompasses a range of activities from first human use to large-scale clinical trials in patients. Occasionally, the first human use of a new technology is spectacularly successful, as it was in the case of the cardiac pacemaker (354). More often, however, it is not, and modifications in the technology are required. After a new technology is shown to be useful in scattered clinical experiments, organized trials may be carried out; increasingly these are controlled clinical trials. The issue of testing for efficacy and safety by the use of clinical trials is discussed in chapter 4.

After human trials have been conducted, and in some cases, before adequate trials are completed, diffusion and adoption of the technology takes place. If clinical trials of a new technology are promising, Government-supported demonstration projects may be organized to show that a technology which is efficacious under controlled clinical conditions is also useful in the community, where social, economic, and other factors may modify its impact. Usually, however, practitioners are persuaded to adopt new developments through less formal channels (79).

Extensive work in primarily nonmedical areas has shown that the diffusion of technology usually follows a sigmoid ("S" shaped) curve in which the rate of adoption accelerates as time goes on **(289).** Diffusion of some medical technologies also follows this curve. A slow initial diffusion rate often is interpreted as an indication of caution on the part of potential users, but in fact may also reflect poor communication between sellers and buyers and among buyers. Those who accept the new technology soonest are referred to as innovators. Early adopters and late adopters account for subsequent diffusions (187,289).

Not all medical technologies follow the diffusion pattern of the sigmoid curve. One major type of departure from the standard model occurs when diffusion reaches a high rate soon after the technology becomes available. This pattern has been referred to as the "desperation reaction model" *(407).* Initial rapid diffusion seems to occur in the absence of evidence of efficacy or safety because of a lack of a suitable alternative technology combined with desperation on the part of patients and of providers responsible for treatment. Later, however, the results of clinical tests and experience begin to influence physician's behavior. If the results are positive, diffusion of the new technology may continue rapidly. More ambiguous results may give rise to physician caution, possibly slowing diffusion. When later evidence is negative, use of the new technology may decline.

Whatever its initial pattern of diffusion, a technology may be partially or completely abandoned if it proves to be of little use clinically. Medicine is replete with examples of procedures fallen out of use.

Both private industry and the Federal Government invest large sums of money in the development of medical technology. The applied research leading to new pharmaceuticals occurs primarily in the drug industry itself. Likewise, most of the research and development leading to medical devices or equipment takes place among manufacturers of medical devices.

Drugs, devices, and procedures in general, especially technique-dependent procedures, pose quite different problems for the evaluation of safety and efficacy. Drugs can be assessed for chemical purity and often have effects that can be tested in the laboratory and can also be tested appropriately in animals. Medical devices, resting on a solid theoretical basis of science in electronics and physics, also may be evaluated by methods not involving human subjects. Procedures, however, involve the use of human skills. The efficacy of a procedure depends on the skill of the provider carrying out the pro-

cedure. Furthermore, drugs and devices are developed in more or less well-defined sites, while medical procedures are developed in many settings. Also, established drugs and devices are often used in an entirely new procedure. For example, the Food and Drug Administration (FDA) may certify anticoagulants as efficacious ("doing what they purport to do") in preventing the coagulation of blood. Such certification, however, does not establish whether use of anticoagulants is an efficacious procedure for the treatment of myocardial infarction or stroke.

Medical procedures, such as surgery, that depend primarily on provider skills are complex and have a correspondingly complex development. New procedures of this type are often developed and tested in hospitals, many of which are university affiliated. Support for their early use and testing often comes from Federal research funds, but considerable funding also comes from service funds, that is, payment for medical services. Chemotherapy for lung cancer (see chapter 3) is an example of an experimental procedure that is often covered by insurance programs.