Appendix Cm—The Innovative Process in the Medical Devices Field

Introduction

As a society, we value technological progress—the continual "introduction to practice of new and more useful ways of serving human purposes" (262). In the health field, technological progress is often embodied in the introduction of new medical devices. Despite its importance, there has been little systematic investigation of the process of technological change for medical devices. How and by whom do medical devices get developed? And what factors influence their development?

There are, of course, many stories about the introduction of specific new devices, such as electronic fetal monitors (410), gastric freezing (114), gastroendoscopes (448), and computed tomography (CT) scanners (348). These individual cases demonstrate the diversity of developmental pathways taken. They suggest that simple generalizations of the process are impossible. Yet, some elements of the process may be common to all medical devices and, indeed, to all new technologies.

The basic unit of technological change is innovation—a new device, product, or process introduced to practice for the first time (223,182). Innovation is also widely used to refer to the process by which technological change occurs (232). In this OTA assessment, "innovation" refers to the newly introduced technology and "innovative process" to the process by which innovations find their way into practice. This appendix explores the process of technological change in general, with emphasis on the questions of who develops innovations and under what conditions the innovative process occurs.

Innovations are valued for their capacity to increase productivity or the quality of consumption (274). Those innovations largely affecting production processes have been called process innovations, while those intended for sale are product innovations (438). New medical devices are product innovations, although they may change the process of medical care.

One important view of the innovative process is that it consists of four essential functions (274):[1]

- Invention—the act of insight by which a new and promising technical possibility is recognized and worked out (at least mentally and perhaps also physically).
- Development—the sequence of detail-oriented technical activities, including testing by trial and error, through which the original concept is modified and perfected until it is commercially viable.
- Entrepreneurship—the decision to go forward with the effort, the organization of it, and the securing of funding for it.
- Investment—the act of risking funds for the venture.

For the innovative process to succeed in producing an innovation, each of these four components is necessary, but the mix may differ widely among applications. Some innovations are the result of sudden insights, with little developmental work needed; others may require a laborious and slow development phase with high levels of investment. Nevertheless, all innovative processes contain each of these components to a greater or lesser extent.

When and Where the Innovative Process Occurs

Theories of innovation rest largely on underlying views of the innovative process as either deterministic, individualistic, or serendipitous (182). The deterministic view holds that innovations come forth when the conditions are right; the individualistic theory stresses the importance of the innovator (an individual or organization) in bringing forth and carrying through an idea; and the serendipity approach stresses the stochastic nature of the process of technological change (182).

There is, of course, some truth in each of these approaches. Variability, complexity, and uncertainty are the hallmarks of innovative processes (231). These three factors have substantial influence on the effectiveness of policies intended to affect the rate and direction of technological change (232). Innovative processes vary widely among industries and institutions and are not well characterized by simple methods. However, a brief description of how medical and surgical procedures that use medical devices come into being may highlight the characteristics of the innovative process in medicine.[2]

[1] There are several other models of the "innovative process" that focus on the chronological stages rather than on critical functions. Schumpeter defined technical change as having three steps: invention, innovation, and imitation (or diffusion) (274). A recent study of the Organization for Economic Cooperation and Development has identified four stages of innovation: **conception, reduction to practice (i.e., prototype), startup, and expansion (diffusion)** *(236).* **These alternative characterizations of the innovative process do not contradict one another; they highlight the points in the process of interest to each author.**

[2] **The description presented here is adapted from appendix D of an** OTA report entitled Strategies *for Medical Technology Assessment (351).*

Medical and surgical procedures, which often involve the use of medical devices, usually begin as user-generated (e.g., physician-generated) innovations. An innovative procedure may involve the modification of an existing procedure (usually in accompaniment with modifications of the devices being used) for application to a new use.

Innovations in procedures frequently arise in academic or academic-associated centers, where physical and professional resources are readily available; a research, innovation-seeking atmosphere is encouraged; and contacts with others in the field extend not only nationally, but also globally. Innovators in such settings know how to present the innovations in a manner that will be technically acceptable and have the prestige that gives them access to professional meetings and journals to publicize their results. Their presentations and publications not only diffuse the innovation to a wider audience, but more importantly, begin to legitimize it. Depending on the claimed innovation's nature, usually defined in terms of how the innovation will revolutionize or at least substantially influence the related area of medical or surgical practice, other academic centers will begin to pursue it.

At some point in the innovative process, a prototype device must be developed. This activity may occur in a variety of settings including the academic center, a hospital, a medical device firm, or even a home laboratory. The development and refinement of a prototype can be a costly and time-consuming part of the innovative process.

At this point, several U.S. Government agencies may enter the picture. The National Institutes of Health (NIH) may provide support for the innovator and researchers in other health centers through randomized clinical trials, most likely conducted in some of the clinical research centers funded by NIH. A new device or modification of an existing device requires the Food and Drug Administration's (FDA) approval. Increasingly, FDA approves the use of investigational devices for limited testing at the same centers that NIH supports as clinical research centers (or at least to the health institutions in which these designated centers are located).

FDA must make a determination of safety and efficacy for market clearance of the device under review. FDA will often make its decision long before NIH reaches a decision and terminates funding for the clinical trials. FDA's decision may rest on the narrow question of the technical functioning and safety of the device. Release of the device to the general market, once premarket approval is given, also tends to speed up the diffusion of the procedure that NIH may be studying.

This result, in turn, places more pressure on the Health Care Financing Administration (HCFA) to reimburse for the procedure. Sooner or later, HCFA may receive a request for reimbursement of the new procedure and will consider information from any clinical trials for evidence of safety and efficacy, but only after the device has been approved for marketing by FDA.

Conditions Affecting the Innovative Process

Despite the variability and uncertainty of the innovative process, there are institutional and other contextual conditions that may influence the process in systematic ways. These conditions fall into four categories:

- conditions affecting the market for the innovation,
- conditions affecting the ability to appropriate the benefits of the effort to produce the innovation,
- conditions affecting the availability of resources to invest in the innovation, and
- conditions affecting the availability and organization of technical and entrepreneurial know-how.

Conditions Affecting the Market for Innovation

The market for an innovation depends on the willingness of each potential user to pay for its benefits. If a new medical device is to survive after a trial, it must be perceived as worthwhile by the people or organizations who will decide whether or not it will be used (232). Thus, the perceived need for and potential benefits of a new device determine the size of the market. Even the "user/innovator," the individuals or organizations that go about solving their own problems through technological change (446), are likely to assess the potential benefit of the innovation to themselves and to others in their decisions to devote time and resources to solving a problem.

Both the size and organization of the market can be important in determining the willingness to pay for useful innovations (268). For example, potential economies of scale in the production of medical services in certain devices may not be realized because of the small scale of medical care providers (168). If small-scale providers are not organized to share services, then the full benefits of the device cannot be realized by potential users, and the device is unlikely to succeed. Yet, if the potential cost savings are high enough, the availability of a new technology may, with some delay, actually bring about a change in the organization of the market that allows for its adoption (268).

Although it is difficult to sort out the many factors contributing to the emergence of newly integrated health care organizations, changing medical technology may be one cause.

The importance of the market in stimulating innovation is indicated by the fact that 60 to *90* percent of successful innovations across many fields have been developed in response to the perceived needs of the market or of users (437). Any factors affecting the size of the market for an innovation, such as changes in the prices of close substitutes, changes in the ability of potential users to pay, and regulatory constraints on use (263), are likely to affect the innovative process.

In medical care, the market is determined in large part by mechanisms of third-party reimbursement for care (see ch. 3 for more detail). Russell found that the rate of diffusion of some (but not all) of the medical device innovations that she studied increased with the onset of Medicare coverage *(265).* Recent work indicates that prospective payment approaches can have some retarding effects on the quantity of new medical devices adopted by hospitals (448). Thus, the payment procedures used by insurance companies and other third-party payers may have an important indirect effect on innovative activity in the medical devices industry.

Conditions Affecting the Innovator's Ability to Appropriate Benefits

The need for investment in research, development, and commercialization implies that a potential innovator must be able to expect a return that will make the investment worthwhile. s In addition to an evaluation of the potential market, the expected return will depend on the degree to which the innovators can expect to capture or appropriate these benefits in profits or perhaps even directly as users. The ability to appropriate benefits affects not only whether innovation results, but also what kind of organization or individual undertakes the innovative activity (445).

One influence on the ability to appropriate benefits is the market structure of the industry, which influences the rate of imitation and therefore the market share that an innovator can expect over time. The effect of market structure is controversial. Schumpeter and Galbraith postulated that industries with a few dominant firms would be able to appropriate more of the benefits of their inventions because they face less of a threat from imitation and would therefore be more innovative than highly competitive industries *(274).*

Other researchers have concluded that high barriers to entry in an industry, particularly in relation to the capital investment required to compete, encourage research and development (R&D) by the firms in the industry (66). Fellner has suggested that the effect of monopoly power on the innovative process may differ between product and process innovations (112). Firms in industries in which a few firms hold a substantial share of the total market would have less to gain from introducing cost-reducing process innovations than would firms in highly competitive industries, and firms in more competitive fields may have to innovate to keep pace with rivals. Kamien and Schwartz observed that the greatest degree of innovation occurs in a market structure where rivalry is greater than in monopoly but less than in perfect competition (178).

Empirical evidence testing this hypothesis in U.S. industry is conflicting. Greer and Rhoades found that the rate of process innovation (as measured by productivity growth) was actually higher in concentrated industries, but Scherer points out that this association could be the result of a bias in process innovations toward large-scale operations, which are most likely to predominate in concentrated industries *(134,274).* Romeo, on the other hand, found that firms in concentrated industries adopted numerically controlled machine tools (a process innovation) more slowly than firms in more competitive industries ***(261).***

The ability to appropriate benefits from investment may also depend on the size and level of diversification of the innovating firm. Larger firms with greater diversification may be able to apply a process innovation across a variety of applications and may therefore be able to recoup investment costs more readily (230). Empirical studies relating to this hypothesis are inconclusive (274).

Despite the large number of companies in the medical devices field, especially small ones, concentration in the medical devices categories is similar to that in other manufacturing industries. There is some evidence, however, that merger activity in medical devices accelerated during the latter part of the 1970s (see ch. 2 for details).

Government policies can also affect the extent to which a developer captures the benefits of an innovation, The patent system is, of course, designed for that purpose, but its power is limited. It is easy to design around some areas of technology, such as electronic circuitry and computer software (142). Also, firms holding critical patents may refuse to license them, thus blocking further technological innovations (142). In short, the ability to appropriate benefits may carry

[3]**The innovator's best guess about the potential market may be wrong, for uncertainty and failures of human judgment are inherent in the process. Unless there is some reason to suspect a bias in the direction of error, however, the investment decision can be assumed to deal with the probability of error through its tradeoff of expected risk for return. Government policies such as regulation may increase the level of uncertainty about outcomes of the innovative effort and therefore increase the level of expected return required to justify an R&D investment (97).**

with it the ability to resist pressure to apply potential innovations.

Conditions Affecting the Availability of Resources

Several scholars have noted the increasing institutionalization of R&Din the post-war period (175,182). Although there is variation across industries and fields of technologies, organized R&D as opposed to individual efforts have become the predominant source of innovation in this country as well as others. This trend toward institutionalization stems at least partly from the complexity of technology and the increasing need for financial resources and trained manpower to bring forth innovations.

Two kinds of resources are needed for R&D: personnel and financial capital. The availability of a pool of adequately trained personnel capable of carrying on R&D should become more important to technological innovation as the technology base gains in complexity. This OTA report does not explore issues of personnel or the role of scientific and technical education as it relates to industrial innovation in general and to the medical devices industry.

Financial capital can take the form of government or philanthropic grants and contracts for R&D, funds generated internally by firms (e.g., undistributed profits), and debt or equity instruments (including venture capital arrangements). The flow of these funds depends on the expected return and risk inherent in specific R&D projects, which in turn depend on the market and the appropriability of benefits. Government policies also influence the flow of R&D funds and therefore the location of R&D activities and the ultimate innovations.

As discussed in this OTA report, Government R&D policies influence not only the kinds of projects that are initiated, but also the kinds of organizations in which R&D takes place. Taxation policy also affects the availability of different kinds of capital. Appendix G discusses the impact of taxation policy on R&D for medical devices.

Conditions Affecting the Availability of Technical and Entrepreneurial Know-How

Successful innovation requires the joining of technical and entrepreneurial expertise. Although these areas of expertise need not reside in a single individual, they must be integrated in an appropriate fashion. Are there conditions or environments that foster or inhibit the existence and productive use of these skills?

A great deal of research has been devoted to determining whether or not the size of the firm has any relationship to its ability to develop innovations successfully. The size of the organization can be important to innovation for several reasons. First, larger firms may be more able to marshal the technical resources needed to conduct R&Don complex subjects. Second, large firms may be able to appropriate the benefits of innovations more easily than small firms. Third, large firms may have greater access to capital to finance R&D than small firms.

Against these possible advantages of large firms is one major advantage held by small firms. Small firms may be less burdened by cumbersome organizational structures that could inhibit coordination and timely decisionmaking on innovation. The interplay of these factors has suggested to some that there may be a threshold size necessary to support the R&D that results in innovation (203,179). Moreover, this threshold size is likely to vary from industry to industry. Empirical studies of the innovative process do not suggest any systematic patterns of advantage for large firms. One recent study, which examined 635 product innovations marketed during the 1970s, found that small firms accounted for approximately 40 percent of these (124). Other work has found some advantage to size but, again, only up to some threshold (200).

In a recent study, The Futures Group examined over 8,000 innovations published in trade journals in 1982 (123).[4] The number of innovations per employee was 1.43 times higher in small firms (500 employees or less) than in large firms. Innovations were categorized by Standard Industrial Classification (SIC) code. Rates of innovation in five medical device codes are presented in table C-1. With the exception of SIC 3851 (ophthalmic goods), small firms were over twice as innovative relative to levels of employment as large firms in the medical device industries.

There is also evidence from a Louis Harris survey that "the introduction of new medical devices is just as common in small as it is in large plants" *(197).* About one-half of the establishments with 500 or more employees introduced a significant new medical device in the last decade, while just under half of the firms with fewer than 500 employees reported doing so. (Indeed, more than one-half of the very small firms, 1 to 9 employees, reported such an introduction.)

[4]This study, like others that depend on a sample of published innovations, is subject to possible selection bias. The bias is most likely in the direction of overrepresentation of innovations by large firms and more significant innovations. Hence, findings showing smaller firms to be more innovative are probably strengthened by this bias.

Table C-1.—Rates of Innovation in Five SIC Code Medical Devices Categories[a]

Standard Industrial Classification (SIC) code[b]	Innovations in 1982		Industry employment in 1977[d] (thousands)		Innovations per employee small firm : large firm
	Small firm[c]	Large firm	Small firm	Large firm	
3693	10		*5.9*	*25.0*	*2.49*
3841	*36*	*30*	*11.7*	*31.5*	*3.23*
3842[e]	*33*	30	17.9	36.0	2.21
3843	2	0	7.1	9.2	NA[f]
3851	2	9	11.1	18.9	**0.38**
Total	83	86	53.7	120.6	2.17

[a] Innovations were published in 1982 trade journals.
[b] The five SIC codes areas follows: 1) SIC 3693(X-ray and electromedical equipment), 2) SIC 3841 (surgical and medical instruments), 3) SIC 3842 (surgical appliances and supplies), 4) SIC 3843 (dental equipment and supplies), and 5) SIC 3851 (ophthalmic goods). See ch. 2 for more information.
[c] Small firms have fewer than 500 employees.
[d] deployment in 1977 is used because a lag in journal publication of 4.3 years between invention and innovation was found in a detailed analysis of 375 innovating firms.
[e] This analysis excludes four innovations in SIC 3842, because the innovating companies could not be found in published directories,
[f] NA indicates information not available.

SOURCE: The Futures Group, "Characterization of Innovations Introduced on the U.S. Market in 1982," contract report prepared for the US. Small Business Administration, contract No. SBA-6050-0A-82, Glastonbury, CT, March 1984.

On balance, it appears that in the medical device field as in industry in general, small firms play an important role in spurring innovation, but the evidence is limited by the lack of consistent or validated measures of innovation and of any standardized criteria for assessing the relative importance of innovations. In addition, there maybe a great deal of variation among industries and types of technologies in the most appropriate setting for bringing forth innovations. Scherer concludes that the issue of small or large may be irrelevant when what is needed is a variety of environments capable of responding to technological opportunities wherever they arise *(274).*