

7.

# Evaluation of Technologies

Be not swept off your feet by the vividness of the impression, but say, "Impression, wait for me a little. **Let me see what you are and what you represent.** Let me try you."

—Epicetus

# Contents

	<i>Page</i>
Introduction . . . . .	75
Current Activities and Programs. . . . .	76
Discussion . . . . .	81

## LIST OF TABLES

<i>Table No.</i>	<i>Page</i>
6.DHHS Technology Coordinating Committee . . . . .	76
7. Non-DHHS Agencies Involved in Evaluation of Health Technology. . . . .	77

# Evaluation of Technologies

---

## INTRODUCTION

Evaluation covers a broad spectrum of activities. Depending on the importance and nature of a given innovation, public agencies, nonprofit organizations, and private sector firms will rely on a number of criteria to evaluate a given technology. The historically most common, and perhaps most important, criteria used in the initial stages of evaluation and development of health-related research products are safety, efficacy, technical feasibility, and technical performance. For commercial products (or potentially commercial products, even if developed with public *or* nonprofit funds), another basic criterion is potential profitability.

Other criteria will then follow. Depending on the use or intended market for the innovation, evaluation efforts might include such “tests” as: effectiveness, suitability for the goals of its use, reliability, cost, repairability, convenience, affordability, esthetics, consumer satisfaction, patient protection, legal impacts, liability concerns, accessibility, reimbursement status or potential, social implications, cost-effectiveness determinations, ethical concerns, and so on.

The periodic efforts of the National Institutes of Health (NIH), the Veterans Administration (VA), and other health-related agencies tend to rely on and support safety and efficacy more often than any of the other criteria. The Food and Drug Administration (FDA) requires drug and device manufacturers to focus on safety and efficacy criteria if they produce items that fall within FDA’s jurisdiction. If VA and the National Institute of Handicapped Research (NIHR) develop devices that fall within FDA’s guidelines, they too must submit them for clearance. The private sector manufacturers, as well as NIHR, VA in its rehabilitation research role, and the National Aeronautics and Space Administration (NASA), also rely on many of the evaluation criteria cited above to help guide their decisionmaking.

The major issue, though, remains: Are the evaluation efforts of the public and private sectors sufficient to adequately inform the many levels of decisionmaking related to technology for use by disabled people? Current analysis and informed opinion indicates to OTA that the answer is an emphatic “No. ”

If one examines the literature on the adequacy of evaluation efforts concerning safety and efficacy in the health care system in general, it is clear that there are noticeable weaknesses in the process. A recent OTA study assessed the state of evaluating the safety and efficacy of medical technologies and identified several shortcomings in the evaluation process (164):

- There is no formal or well-coordinated overall system.
- Identification of technologies to be studied remains an underdeveloped, usually agency-specific, process.
- Existing technologies are identified much less frequently for study than are new and developing technologies; thus, they are studied much less frequently.
- Medical drugs and devices are subject to a more rigorous process of assessment than medical procedures.
- Preventive technologies receive far less attention than therapeutic ones.
- Serious questions have been raised concerning the adequacy of funding for clinical trials and other types of evaluations.
- Synthesis activities are still at a modest level despite their recent expansion,
- The quality and appropriateness of medical literature, the primary source of synthesized information, has been criticized.
- Synthesis activities cannot be adequate when there is a critical lack of information regarding efficacy and safety.
- Federal agencies have not assigned a high priority to disseminating information,

In the disability technologies area, OTA found similar weaknesses. In fact, shortcomings in this area are more pronounced than in the medical technology area. The reasons for this are difficult to know with much certainty. It appears, though, that there is less of a tradition of formal and scientific evaluation in the rehabilitation area, that the diversity of disabilities makes evaluation extremely complex, that the technologies in this area are sometimes seen as less "medically necessary" and thus less in need of careful evaluation, that few funds are devoted to evaluation, and that emotionalism is very strong in this area, making evaluation a difficult undertaking.

Actual or potential improvements in many of the areas listed above for medical technology evaluation can be in part attributed to the (now ended) existence of the National Center for Health

Care Technology (NCHCT). \* For example, over half of the items on NCHCT'S list of emerging technologies that might need assessment were existing ones (this does not mean that they would have been assessed). To the extent, which might have become considerable, that NCHCT would have been involved with disability-related technologies, there was distinct potential for significant improvements in the evaluation process. However, NCHCT received no funds for fiscal year 1982 and stopped functioning in December of 1981.

---

\*NCHCT was established by statute in 1978 in response to the feeling of Congress that not enough careful and scientific evaluation of medical technologies was being done to assure its appropriate use. Further, there was no focus for coordinating the numerous related activities taking place,

## CURRENT ACTIVITIES AND PROGRAMS

Oddly enough, there is no shortage of agencies, organizations, and academics interested in the various issues surrounding the evaluation of technologies. If, for example, one examines the list of Department of Health and Human Services (DHHS) representatives to the Department's Technology Coordinating Committee, it is, if not surprising, then disappointing that such a disparity between interest and information exists. Table 6 shows those representatives. A similar breadth of potential involvement in evaluation is shown by the list in table 7 of non-DHHS agencies that are involved, to some degree, in health-related technology issues.

The level of Federal effort—money being spent on evaluation efforts—is impossible to fully determine. It is fairly accurate to say that no one really knows how much is being spent, either Government-wide or at specific agencies. The reason for this is easy enough to understand—it is difficult to define what activities, projects, or programs should or should not be counted when tallying up what the various agencies or programs consider "evaluation" activities. At best, agencies can provide rough estimates of these activities and spending levels. OTA has estimated that about

**Table 6.—DHHS Technology Coordinating Committee**

---

<i>Representatives of</i>
Alcohol, Drug Abuse, and Mental Health Administration
Centers for Disease Control
Food and Drug Administration
Health Care Financing Administration
Health Resources Administration
Health Services Administration
National Center for Health Statistics
National Center for Health Services Research
National Institutes of Health
<i>Liaison representatives:</i>
Office of Health Research, Statistics and Technology
Office of Science and Technology Policy, The White House
Office of Technology Assessment, U.S. Congress
Veterans Administration
National Institute of Handicapped Research
Department of Education
Office of Civilian Health and Medical Program of the
Uniformed Services

---

SOURCE Office of Technology Assessment

\$200 million a year is spent on evaluation of health technologies in general. The amount spent on disability-related health technologies is probably only a minor fraction of this amount. The exact amount of this fraction is not known. However, as a point of comparison, the percentage of total Federal health care research and development

**Table 7.— Non-DHHS Agencies Involved in Evaluation of Health Technology**

Department of Agriculture
Department of Commerce
Department of Defense
Department of Education
National Aeronautics and Space Administration
National Academy of Sciences
National Bureau of Standards
National Science Foundation
Office of Management and Budget
Veterans Administration
White House Office of Science and Technology Policy
U.S. Congress—committees and support agencies
Senate Finance Committee
House Ways and Means Committee
Senate Labor and Human Resources Committee
House Energy and Commerce Committee
Senate and House Veterans' Affairs Committees
Senate Special Committee on Aging
Housing Select Committee on Aging
Senate and House Budget Committees
Senate and House Appropriations Committees
House Science and Technology Committee
Senate Commerce, Science, and Transportation Committee
Office of Technology Assessment
Congressional Research Service (Library of Congress)
Congressional Budget Office
General Accounting Office

C) Office of Technology Assessment

(R&D) represented by evaluation of technologies is roughly 5 percent—and that is in an area with a stronger tradition of evaluation of technologies than the disability-related area.

Three additional areas of Federal evaluation activities should be mentioned here: 1) the requirement of the Medical Devices Amendments with respect to FDA's mandate (Public Law 94-295), 2) the relatively new directives to the National Bureau of Standards (NBS) (H.R. 96-949), and 3) the consensus development conferences of NIH.

In the fall of 1977, NIH began a program of consensus development designed to improve knowledge on the safety and efficacy of medical technologies and to transmit any information gained to the practicing physician and the public. Each conference, involving scientists, practicing physicians, consumers, and others, is set up to generate conclusions and recommendations concerning specific medical technologies. The conferences are run by the various Institutes of NIH; the Office for Medical Applications of Research of NIH is the coordinating and assisting office.

Several of the topics that have been covered or are scheduled to be covered are directly relevant to the disability area—e.g., continuous ambulatory peritoneal dialysis, prevention of osteoporosis in aging, and artificial hips.

In May of 1980, the Science and Technology Committee of the U.S. House of Representatives directed NBS to “undertake a general review of its activities in the disability area, and to develop a focused plan detailing potential opportunities within NBS and for interagency cooperative projects . . . ” (23). The Bureau has, in the past, conducted evaluative projects that have had relevance to disabled people. It has developed and evaluated devices to measure slip resistance on walkways for building accessibility, conducted performance and reliability tests on hearing aids and cardiac pacemakers, developed the implant standards for acrylic bone cements and metals and, in general, has helped address technical issues related to the needs of disabled individuals. Its product performance testing and materials research experience and capabilities make it a valuable asset to the area of evaluation.

However, the degree to which NBS will be able to be involved in disability-related research and testing is yet to be determined. The major problems are time and money. NBS performs almost 40 percent of its work at the request of other Federal agencies; the work is done on a reimbursable basis when it is determined to be of mutual benefit and meets one of two conditions (23):

The Other Agency needs measurements, standards or data for application that are so specific and programmatically focused that they would not ordinarily be carried out under the general NBS measurement mandate; or the Other Agency has a technical problem that could be most efficiently and effectively solved by using a unique Bureau expertise.

The Committee on Science and Technology encouraged NBS to continue and strengthen its activities in providing measurement technology and performance standards as they relate to devices and facilities unique to disabled and elderly people. However, in a climate where rehabilitation agencies are already operating with decreased, and perhaps further decreasing, budgets, it is difficult

to see how or whether these agencies will be able to "purchase" evaluation efforts from NBS or accept the research criteria established by NBS for taking on non-NBS research projects. Perhaps, NBS will be of most appropriate use as a reference laboratory for information related to general measurements, methods, standards, and data in specialized technical and materials areas.

In 1976, Congress enacted the Medical Device Amendments to the food and drug legislation. The degree to which FDA exercises regulatory control over the development, manufacturing, and marketing process will depend on a device's potential risk and classification. Wenchel provides a good review of the three classifications and what they will entail (221):

*Class I: General Controls*

*Use:* Where controls other than standards and premarket approval are sufficient.

*Scope:* Applies to all devices except those specifically exempt. Prohibits adulterated or misbranded devices. Requires registration of establishment and listings of devices. Retains authority to ban certain devices. Provides for the notification of risk, repair, replacement or refund. Has requirements for good manufacturing practices including record keeping and inspections.

*Examples:* Dental floss, blood mixing device, tongue depressor.

*Class II: Performance Standards*

*use:* Where general controls are insufficient but sufficient information exists or could be developed to establish a performance standard.

*Scope:* Includes all provisions of general controls. Requires adherence to a performance standard, when available, which may **also cover** construction, components, and properties.

*Examples:* Electrocardiograph, vascular catheter, administration kit.

*Class III: Premarket Approval*

*Use:* Where general controls or performance standards may not provide reasonable assurance of safety and effectiveness for a device that is life sustaining, life supporting, implanted, or presents a potential unreasonable risk of illness or injury or where a performance standard cannot be developed.

*Scope:* Requires all substantially new or different devices to obtain premarket approval.

*Examples:* Implantable pacemaker, infant radiant warmer.

FDA is developing for each of these categories criteria and standards that new devices will have to meet to receive approval. The importance of FDA's involvement in this area is the stimulation of evaluation activities in the areas and technologies affected. It is felt among many manufacturers that FDA's involvement will also place burdensome administrative loads on the manufacturers and will hamper innovation. According to critics, the impact on the small single- or few-product firm will be the greatest. This may be especially serious for the disability-related R&D sector, because so many of the innovators and manufacturers are in this category. In terms of industry-wide impacts, the effect of FDA's processes for premarket approval and investigational device exemptions is not known (221). Also, a factor that may possibly be more of an issue in the disability-related technology area is cost. FDA's regulations may increase the cost of technologies that go through the premarket approval process. These costs might persuade a manufacturer not to develop a technology or they may be passed on to the consumer. Disabled consumers, because of low disposable income in general, are extremely sensitive to and affected by price. However, if these increased prices help to purchase safer, more effective, and more reliable technology, then a good argument can be made in support of FDA's efforts. The debate concerning this question will continue.

The evaluation issues in the disability field mimic the problems identified for the general health care system. Adequate evaluation data are rarely available for technologies for disabled people. A study cited by NIHR found that of 300 people surveyed, over 90 percent cited a need for more buying information and advice about both special and regular goods and services that they rely on (52). Evaluation information concerning product dependability and durability, ease of use, availability of maintenance and repair services, as well as safety and efficacy information, is sorely needed by the consumer. In most cases, however, it is found lacking. Such information would prove invaluable to the users, counselors, physicians, research community, manufacturers, third-party payers, and all those who advise on the use of existing technologies or innovations.

For example, the Stanford Rehabilitation Engineering Center received a grant for a clinical evaluation project on potentially useful controls and interfaces for new aids and systems developed at the center and elsewhere (187). The project team decided to develop an evaluation model, using a retrospective study of a mobility device—wheelchairs with communication or interface components—to aid them in their future evaluation efforts. As part of this process, several evaluative criteria were selected: 1) technical performance, 2) client's life style, 3) physical environment, 4) interaction with family, friends and fellow workers, and 5) effect on client's self-image. The study team proceeded to examine the literature on the benefits identified for each of these descriptors in order to establish the data base on which to build the remainder of the study. This measurement was difficult to derive from the literature (187):

A review of the literature indicated that clinical evaluation of rehabilitation equipment is either not being carried out, or does not appear in print. A search of the NARIC [National Rehabilitation Information Center] database resulted in just ten items. Only three were related to evaluation. The keyword "wheelchair-evaluation" is, in fact, not even in their dictionary. Other written material on wheelchair evaluation refers primarily to technical and engineering specifications. The available data on English devices is not generally applicable to the American market . . .

References were found indicating the need for evaluative material. Cost and time factors, especially describing device life span and use factors, were also not available. Nor was any information found concerning the psychosocial aspects of using or assessing assistive devices.

This is one study being done on a specific area of technology application. What is surprising is the absence of information, or at least readily accessible information, regarding the major factors required for the investigators' study in an area—wheelchairs—that has received so much attention by so many organizations over the last several years.

There are a number of other specific areas/technologies that have also been identified as being ready for evaluation (65):

- Mobility aids
  - Wheelchairs—Many models and makes are available; other than at the VA Prosthetics Center, little testing has been done in comparative evaluation or in determining prescription criteria.
  - Hand controls—Clinical studies are needed to augment VA investigations.
  - Vehicles (cars, vans, etc. )—Data are needed on the suitability of various models and makes. Clinical studies are needed to augment VA investigations of van lifts and controls.
  - Driver simulators—Studies are needed to determine their effectiveness for instructing various disability groups,
- Sensory aids
  - Sonar cane (Mowat Development, Ltd. )
  - Hearing aids having moderate bandwidth compression
  - Mowat sensor (Mowat Development, Ltd.)
  - Nottingham obstacle detector
  - ELINFA portable braille recorder
  - Kurzweil reading machine
  - Upton eyeglass aids
- Prosthetics
  - Adjustable above-knee sockets (Rancho Los Amigos)
  - Polypropylene below-knee prostheses (Moss)
  - Above-elbow osteotomy (Marquart)
- Locomotion and clinical gait
  - Gait analyser (Rancho Los Amigos)
  - Limb load monitor (Moss)
- Tissue mechanics
  - Seat cushions (many commercial models)
  - Seating systems (Rogers—Rancho Los Amigos)
  - Mattress systems (several commercial models)
  - Pressure measuring pad (Texas Institute for Rehabilitation and Research)
  - Rigid-sole rocker shoe (Carville)
  - Laser-doppler blood flow meter (University of Washington)
  - Low pressure support beds and *turning* beds (several commercial models)
- Activities of daily living
  - Environmental aids and controls (Prentke

Romich, VA, Fidelity)

- Page turners (several commercial models)
- Functional electrical stimulation
  - Therapeutic devices and techniques (including biofeedback systems) for lower and upper extremity management and stroke
  - Pain control devices
  - Bladder evacuation and incontinence control systems
  - Cerebella stimulation (these devices are used extensively in some centers).

In addition to the above areas, the following area is in need of evaluation:

- Communication aids
  - Non-vocal communications devices
  - Writing systems for severely disabled individuals.

There are literally thousands of disability-related devices coming out of the public, private, and nonprofit sectors. Many are relatively simple and low cost items. Others are expensive, complex devices. Regardless of the technology's cost, use, or complexity, certain criteria should be applied and tested before a technology enters widespread use. The most essential are safety, effectiveness, durability, and recommended applications (65). These baseline assessments are combinations of laboratory testing and clinical evaluations. Many would argue that "life-use" testing should be an integral part of this process when a technology is past the initial research stages. Life-use testing is simply the evaluation of technology in the environment in which it will have to exist as used by a consumer. There is also an increasingly active movement toward greater "consumer" involvement in all phases of disability-related R&D, including evaluation. The major problem is that defining who the "consumer" is is not as easy as it would appear. Nonetheless, the concept is sound and has great potential.

The disabled population, Federal agencies, researchers, and corporations are acutely aware of the problems and barriers involved in these evaluation issues. An important part of both NIHR's legislative mandate and the VA's program of Rehabilitation Engineering Research and Development (RER&D) is evaluation and information

dissemination. Part of the RER&D program's purpose is to work with NIHR in the areas of evaluation, information dissemination, and research coordination. VA's legislative mandate requires that its prosthetic research include testing of prosthetic, orthotic, and orthopedic appliances and sensory aids (title 38 U. S. C., sec. 4101). It also requires VA to disseminate the results and information of this program to the benefit of all disabled persons. The separation of the RER&D program from the general VA research efforts had, in part, the motive of giving focus to the rehabilitation research efforts of VA. This focus has, in turn, helped stimulate VA to devote more attention to evaluation and information dissemination activities. It should be mentioned here that NASA's technology transfer efforts have also added to the evaluation and dissemination capabilities of the rehabilitation field. Other agencies such as the Office of Special Education and Rehabilitation Services Administration (RSA) also are substantially involved with information dissemination efforts.

The major Federal effort in this area is at NIHR. The reason for this is clear. It is the lead agency in this field, by law. A sizable portion of the federally supported R&D is funneled through NIHR to the various research centers. NIHR, via these centers, is in an advantageous position to decide or direct, in conjunction with the centers, the level of resources to devote to evaluation efforts. Evaluation is, or can be, so much a part of the ongoing R&D that some form and level of evaluation effort is, or should be, always present. NIHR's 5-year plan states that the areas of clinical and laboratory evaluation of devices and systems is part of the proposed future expansion of its research support efforts (52). In essence, this is an explicit reaffirmation that formal evaluation efforts are a necessary and important aspect of research. Plans, though, are not reality. Therefore, the actual implementation of evaluation plans should be examined closely over the next few years in order to evaluate their extent, quality, and impact.

NIHR does not limit its evaluation efforts to those devices that are produced in its research centers. Innovations from federally funded organizations, private industry, and from abroad are in-



eluded in its testing and evaluation efforts. The testing done in the laboratories usually focuses on characteristics such as strength, durability, reliability, technical performance, and specifications compliance. Later, in clinical testing, items such as suitability, acceptability, and durability for specific consumer applications are evaluated. NIHR has also developed an evaluation plan that it intends to apply to the testing of: 1) special classes of products and services for disabled people, and 2) general classes of products with reference to their suitability for use by disabled people. Its evaluation program will do the following (52):

- select types of products and services to be tested and compared, based on surveys of disabled consumers;
- obtain samples of products to be tested;
- carry out small-scale pilot tests for each group of products to be tested;
- determine product-use patterns;
- formulate test protocols;
- carry out full-scale physical and use tests;
- analyze test results and draw conclusions; and
- prepare and disseminate the findings.

The following three examples of NIHR and research center efforts illustrate the combination of

issues and problems that are being addressed. The New York University Medical Rehabilitation Research and Training Center has ongoing projects concerned with orthotics-prosthetics, neuromuscular diseases, behavioral science, cardiopulmonary issues, and bioengineering problems. This center also is affiliated with the Spinal Cord Injury Center. The West Virginia University Vocational Rehabilitation Research and Training Center is involved in research on program evaluation, improved service models, programmatic barriers to vocational rehabilitation, affirmative action, and consumer involvement, and also maintains the Institute of Rehabilitation Issues. The University of California at San Francisco Research and Training Center in Deafness and Mental Health conducts research in areas concerning work adjustment as a function of self-image and mental health, improving clinical training for personnel working with deaf people, and evaluation of therapeutic interventions for deaf people (55).

These three centers' activities are limited, yet illustrative, examples of the diversity of research and evaluation activities that are being pursued by the Federal Government in the field of disability-related research. Other examples can be found in NIHR documents (e. g., 54).

## DISCUSSION

This chapter on evaluation has been placed between those on R&D and on diffusion. That physical placement should not be taken to mean that evaluation should occur only at that point in the lifecycle of technologies. On the contrary, *evaluation is—or should be—an ongoing and integral part of the entire lifecycle*. In public policy, however, it is most visible at the late R&D stage. That is the stage where the drug and device regulation is most intense, and that is when information has to be collected for reimbursement and financing (i.e., decisions affecting use). The late R&D stage is, on the average, a good compromise point in that enough information and experience may be available for evaluation, and the technology has not yet been widely diffused; at the late

R&D stage, therefore, it may be possible to affect the technology's future diffusion on the basis of evaluation.

Many of the shortcomings of evaluation in the area of technology for disabled people are similar to those in many areas of policy. Evaluation of the direct benefits, risks, and costs of technologies in general suffers from a variety of methodological, funding, and organizational problems. The weaknesses of assessment of the efficacy and safety of health-related technologies were mentioned earlier. Comparable statements could be made in the areas of, for example, *education and transportation*. Evaluation of cost-effectiveness and cost-benefit analyses (CEAs and CBAs

especially fraught with methodological shortcomings. In an area where nonquantifiable measures play such an important role, extreme caution should be used in interpreting the results of these types of analysis. An approach based on using CEA to structure problems and force the explicit consideration of assumptions, however, could be very relevant to evaluation of appropriate use of technologies. This idea is covered more fully in chapter 11 in its discussion of techniques for resource allocation.

One type of evaluation that perhaps could be used effectively in the disability area is technology assessment, or comprehensive technology assessment, as it is sometimes called. It is a form of policy analysis designed to provide information on the range of effects of a technology —e. g., social, ethical, legal, political, economic, technical, and psychological effects. Technology assessment uses various methods of analysis and draws on a wide range of disciplines. Importantly, it takes into account: 1) unintended and unanticipated impacts of technological applications; 2) second and higher order impacts (i.e., indirect effects or effects caused by other effects); and 3) the full range of parties at interest and the distribution of costs, benefits, and other effects among them.

Technology assessment is little used in health care and not much more prevalent in other areas of technology. Very few assessments have been conducted in the area of technology for disabled people. Texas Tech University's study of rehabilitation technologies is the prime example (76).

The nature of policy issues in this area, however, indicates that there is great potential for using technology assessment in the disability area. *Some analytical method is needed to address, in a comprehensive manner, the intricate blend of ethical, economic, personal, sociological, technical, and legal factors involved in the application of technology for disabled people.* Work would be needed to develop appropriate methods of analysis for disability-related technologies, but such efforts might pay high dividends. Because this type of analysis looks at broad issues of the effects of technology, it could assist in developing information for allocating resources, an es-

pecially important source of problems in the disability-related area.

Not every technological application needs to be submitted to such analysis, but some warrant the effort. Systemwide telephone compatibility with hearing aids, mass transportation system accessibility, sheltered workshops, "mainstreaming" in education, and artificial organs (e. g., the artificial heart) are illustrative candidates.

There are several classes of users of evaluation information. As one moves further away from the technology-specific level of decisionmaking and closer to the broader social and political decision-making levels, needs for evaluation information change. For example, many levels of evaluation were and are part of the decision to provide accessible public transportation in urban areas. Political, moral, economic, and legal criteria were used to decide if, when, why, and how disabled people should have access to the public transportation system. Once these decisions were made, the process of designing, developing, and applying solutions to the policy goal was undertaken. At the policy level, the evaluation criteria were much different than the criteria at the technical solution level. At the one end, criteria such as social equity, distributive justice, ethical considerations, work force economics, political constituencies, and other decisionmaking criteria were directly or indirectly applied. At the other end, tests such as performance specification for "kneeling buses," transportation scheduling, city or State budgets, demographic considerations, cost-effectiveness calculations, number of people serviced, subway retrofitting costs, etc., became the evaluative framework in which the decisionmakers functioned.

The previous example illustrates the top-down approach to evaluation. A bottom-up example might be a communication device that is developed, tested, and found to be of use to a disabled individual. If its use increases and if wider testing proves the device to be a success, attempts are made to enlist private manufacturers or investors to put the device into full-scale distribution. At each step along the development process, the evaluation criteria change to satisfy the information needs of decisionmakers at different levels.

Safety, efficacy, convenience, usefulness, and durability issues exist at one end, and production costs, market size, patent rights, liability concerns, reimbursement, ability-to-pay criteria, and social goals operate at the other.

Some of the issues relating to evaluation are tied to the Government-private sector partnership in bringing innovations to the marketplace. Many evaluation efforts are in the exclusive domain of the private sector, yet are related to and depend-

ent upon the performance of the various Government agencies working in the area of disability-related research. The impression OTA has gained of this process is that it is not adequately designed to support fully useful efforts at evaluation and testing. *A coherent, adequately funded, and well-focused program of evaluation is necessary at all levels of technology diffusion and adoption. Such a program does not currently exist in the disability-related technology sector.*