

Chapter 4

# Testing and Evaluating Devices

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Testing and evaluation encompass many activities, including requesting, funding, and conducting studies. Techniques for testing medical devices are equally various, from the informal methods of individual inventors, developers, and physicians to complex clinical trials. No technique is applicable to every medical device, and in many instances simpler methods may be more appropriate. Often, researchers use a combination of techniques (7).

Depending on the nature of a device, public agencies, nonprofit organizations, and private firms also use different criteria to evaluate it. The most common, and perhaps most important, criteria used in the early development of health-related products are safety, technical feasibility, and technical performance. Depending on the use or intended market for a device, further test criteria may be effectiveness, suitability for design-

nated goals, reliability, cost, cost effectiveness, repairability, convenience, esthetics, consumer satisfaction, patient protection, legal impacts, liability concerns, accessibility, reimbursement status, social implications, and ethical concerns (110).

Several Veterans Administration (VA) programs that evaluate innovations have evolved over the years given the many kinds of decision-making related to medical devices. The Rehabilitation R&D Service (Rehabilitation R&D) evaluates rehabilitative devices still in development. The Office of Procurement and Supply and the Prosthetic and Sensory Aids Service, along with other VA medical, surgical, and rehabilitative service offices, evaluate devices that are already commercially available but must be approved before the VA can purchase and distribute them.

## PROTOTYPE DEVICES

Rehabilitation R&D evaluates prototype devices and disseminates information, and in both cases works with the National Institute of Handicapped Research. <sup>1</sup>As noted earlier, the VA is mandated to test prosthetic, orthotic, and orthopedic appliances and sensory aids, and to disseminate information on its research for the benefit of all disabled persons (38 U.S. C. sec. 4101).

Still, rehabilitative devices often do not complete the transition from research prototypes to commercially viable products, even though Rehabilitation R&D supports dozens of ongoing device development projects. This discontinuity may be caused by several separate, but related, obstacles (which are discussed further in ch. 5). One of these obstacles is the lack of unbiased clinical evaluations of prototypes' performances and

clinical applications (154). The VA explains this problem in a 1981 internal report (144):

The problem is that, after the prototype has been developed, it is necessary to place a number of examples of the developed item into actual use, under conditions in which carefully controlled evaluations . . . can be carried out. Only after these evaluations, and any modifications which result from them, is it appropriate to manufacture such items for routine placement with veteran patients. In the case of other new health care developments (such as the development of new drugs) this evaluation phase is funded by the manufacturer's capital funds. In the development of new devices for the disabled, the developer (and/or proposed manufacturer) is frequently a very small business which cannot afford the capital outlay required to place a number of prototypes into an evaluation program . . . The Veterans Administration does not routinely purchase for its beneficiaries items

<sup>1</sup>For discussion of the National Institute of Handicapped Research, see OTA's report *Technology and Handicapped People* (109).

which have not been through testing and evaluation.

. . . . the Research and Development budget is not adequate to provide the capital for purchase of expensive prototypes to be placed in actual use by veteran patients under an evaluation protocol. Similarly, it has not been customary to use patient care funds for this purpose. The only exception has been the purchase, by [the VA Prosthetics Center] . . . of devices which are put into evaluation protocols. There is currently no feasible alternative in the VA system available for those instances where, for whatever reason, the purchase and evaluation of the device by [the VA Prosthetics Center]<sup>2</sup> . . . is inappropriate. This situation has led to a number of instances where devices have been developed with VA research and development funds which subsequently neither have been demonstrated to be ineffectual nor have been put into general use by the veteran patient.

Expensive prototypes supported by VA R&D funding, but never evaluated, include the following (144):

- a wheelchair adapted for use with the Scott Van (a specially equipped van that can be driven by a person confined to a wheelchair or gurney), with a new system of electronic controls;
- a high-performance wheelchair developed at the University of California-Berkeley on contract;
- a wheelchair control system developed at the Johns Hopkins University Physics Laboratory on contract;
- a four-bar linkage knee for above-knee prostheses developed at the University of California-Berkeley on contract; and
- a standing device for paraplegics developed by Ocean Systems Laboratory in San Diego on contract.

Recently, Rehabilitation R&D has named its own evaluation unit to establish and operate a national program with the following goals (154):

. . . . conduct clinical trials (or evaluations) on new devices, techniques and concepts in rehabilitation; promote commercialization of re-

search devices evaluated by the program; and direct a technical information acquisition and dissemination program, which includes developing educational guidelines and technical manuals [for training programs].

The Rehabilitation R&D Service envisions the unit as a “facilitating and coordinating” center to improve the “organization and visibility” of the Service’s evaluations. Various VA facilities, including Rehabilitation R&D Centers, the VA Prosthetics Center (VAPC), and individual medical centers, have been involved in testing and evaluating new and emerging rehabilitative devices through Service funding (154).

There have been concerns in the past, however, about duplication in testing and evaluating specific rehabilitative devices as they proceed from development to marketing and diffusion. For example, recreational ski equipment for the disabled person (later commercially produced as Arroya sit-ski equipment) was developed and tested at the Palo Alto Rehabilitation R&D Center and tested at four independent testing and evaluation centers. Still, it could not be purchased for veterans until VAPC had tested it again (5,6,53).

The Rehabilitation R&D evaluation unit is also intended to improve prototype testing and evaluation themselves through several means:

- developing uniform evaluation protocols and reporting procedures,
- developing criteria for patient or client selection,
- designating an appropriate number and the locations of facilities involved in particular evaluations,
- preparing and disseminating evaluation results, and
- integrating requirements of the Food and Drug Administration (FDA) and other regulatory agencies.

The unit generally oversees the evaluations performed. In simple cases, staff will negotiate arrangements. When an evaluation calls for a substantial national or international effort, a workshop may be held to bring together developers and evaluation professionals to work out arrangements. It is hoped that funding for major evaluations can be negotiated among all partici-

<sup>2</sup>Recall that the VA Prosthetics Center, as noted in ch. 3, primarily evaluates commercially available devices rather than prototypes.

pants who have a stake in a device's development and ultimate commercial success (154).

It is premature to assess the Rehabilitation R&D evaluation unit. However, the program is important insofar as prototype testing and evaluation—in the clinic or in the community—can provide

information on the likelihood of commercial success and indications for use, or information on changes that might lead to success. The information can also lead to more informed decisions about new research and development for rehabilitative devices (154).

## COMMERCIALLY AVAILABLE DEVICES

Any vendor who wishes to sell new medical devices, including equipment, supplies and expendable, and rehabilitative products, may have to submit the device for a product demonstration, "bench testing," or some other type of testing, to evaluate safety and various other criteria of the VA. New rehabilitative devices have traditionally been tested and evaluated by VAPC in New York City, and new equipment and supplies by the Testing and Evaluation Staff (T&E) at the VA Marketing Center in Hines, Illinois.

### The VA Prosthetics Center<sup>3</sup>

VAPC is a unique organization within the VA by virtue of combining programs in clinical practice—in prosthetics, orthotics, and technical aids—and programs in development and evaluation for their mutual benefit. New devices can then be used promptly in the clinic, as part of an evaluation or to study their wider applicability.

VAPC has long stressed in-house evaluation of commercial devices. It has been the VA's organizational focus for nearly all bioengineering and clinical evaluations of commercially available rehabilitative devices and for some hospital equipment for nearly three decades.<sup>4</sup> During its early years, evaluations concentrated on limb prostheses in response to the overwhelming needs of World War II veterans. In more recent years,

evaluation has emphasized orthotics and the spinal-cord-injured patient. Evaluations in the 1970s emphasized bioengineering directed especially at the stroke patient, the patient with developing vascular insufficiency, and the aged person with problems of independence in daily living.

### Standards Development

Throughout the 1970s, the VA increasingly employed standards in its prosthetic and sensory aids program. Developing standards requires not only evaluating devices in drafting the standards, but also compliance testing after the standards are established. In theory, compliance testing further tests the current standard and determines whether products meet the purchaser's needs. The standards developed reflected desired qualities of prosthetic and orthotic hardware, orthopedic aids, fitted limbs and braces, and sensory aids. "Specifications" of product attributes were included to control devices' quality, safety, and performance. Such standards were perceived as benefiting both VA beneficiaries and other disabled people. Once developed, standards were implemented through the VA Office of Procurement and Supply and its contracts with manufacturers and fitters.

VA standards development has required the participation of individuals and organizations both within and outside the VA. A draft standard of appropriate language can be developed from clinical experience with devices and techniques and the knowledge and experience of R&D and evaluation staff. The draft must then be evaluated by those who will work with it: manufacturers, prosthetists, orthotists, educational specialists, VA supply specialists, and others. Such reviews have also included professional asso-

<sup>3</sup>Except where noted, information in this section is based on U.S. Veterans Administration, Department of Medicine and Surgery, *Veterans Administration Prosthetic and Sensory Aids Program Since World War II* (Washington, DC: U.S. Government Printing Office, 1978).

<sup>4</sup>VAPC's work has been complemented over the years by some evaluations of contractors, developers, manufacturers, and inventors of prototype devices, largely in weighing priorities for its own R&D.

ciations such as the American Society for Testing and Materials, the International Standards Organization, and the Rehabilitation Society of North America.

Once a rehabilitative device standard has been employed, the VA—through VAPC—performs compliance testing of hardware, sampling the market and conducting laboratory tests. The VA makes known the results of such tests to its procurement personnel and to manufacturers.<sup>5</sup> When results of compliance testing have been negative, the VA has also developed engineering design recommendations.

VAPC has developed standards for lift aids, motor vehicle systems for handicapped people, wheelchairs, knee mechanisms, foot-ankle assemblies, stump socks, elastic hosiery, crutches, canes, and other related devices. When VAPC has not developed a standard for a device, the VA Office of Procurement and Supply has relied, when possible, on other appropriate standards. The research and testing of the National Bureau of Standards (NBS) have been valuable to the VA in evaluation (18,109). NBS has developed devices to measure slip resistance on walkways, conducted performance and reliability tests on hearing aids and cardiac pacemakers, developed standards for acrylic bone cements and metals, and in general has helped address technical issues related to the needs of disabled individuals.

Veterans' organizations and others have expressed concern that the VA has used specifications and standards for existing technologies to evaluate and purchase new ones. Thus, emerging devices of unusual design or performance may have trouble entering the market, especially the large VA market (109). (Small firms may have pronounced difficulties since they have fewer resources to address regulations on marketing. ) Older standards have been particularly vulnerable to such criticism, because they tend to specify product dimensions and materials.

Newer standards have emphasized, instead, functional or performance requirements, Precise

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<sup>5</sup>Manufacturers are prohibited by previous policy agreements from directly or indirectly using the results of VA evaluations for advertising (18).

materials, fabrication methods, and design features have generally not been specified. The goal has been to allow innovation while providing adequate controls for patient safety. At present, the VA has only four or five general standards for rehabilitative devices; for example, the standard for wheelchair lift systems covers 21 different models and 13 different manufacturers. Yet despite the VA's efforts, existing standards may still bar new technologies.

Shepard and Karen came to this conclusion in the case of wheelchairs (80). Historically, the VA's standards were written with a specific wheelchair, usually an Everest & Jennings model, in mind. The VA's evaluations of wheelchairs may have promoted safety, but they also functioned in the interests of the major manufacturers. As the largest purchaser of wheelchairs in this country, the VA might not only overlook new technologies, but possibly discourage innovation and product improvement.

In the last few years the VA has replaced most standards and device specifications with more general Commercial Item Descriptions (CIDS). CIDS are designed to accommodate better the variety of privately developed and marketed devices (see ch. 5 for a critical discussion of CIDS) (12).

### General Testing and Evaluation

VAPC device testing typically follows several preliminary steps (163):

- gathering background information, often from the manufacturer;
- developing an evaluation protocol that encompasses any appropriate VA standards and specifications as well as criteria to validate manufacturers' claims; and
- having the protocol approved by the R&D committees of any local VA medical centers involved in the trial.

Standardized protocols are also employed for certain general classes of devices.

Testing protocols range from simple validation assessments to complex clinical evaluations involving dozens of VA medical centers or clinics. At the least, rehabilitative devices are tested for safety, reliability, and the validity of manufac-

turers' claims. New wheelchair products, for example, are tested for strength, safety, maneuverability, and ease of use, although not necessarily for durability (18).

Devices can undergo either special laboratory testing or field testing at VA medical centers or clinics, or both. Field testing is advantageous in assessing a device's "usefulness," that is, the conditions in which a device is most appropriately prescribed and used. Field testing also decreases the probability of observer bias by relying on a larger and more random group of testers. Yet VAPC has not always used field testing because of organizational difficulties.

Until fiscal year 1984, neither VAPC staff nor the VA Prosthetic and Sensory Aids Service, the primary users of rehabilitative device evaluations, had authority over researchers, in contrast to the case of VA testing and evaluation of medical equipment and supplies (see the later section of this chapter on VA Marketing Center testing and evaluation). This absence of authority typically resulted in lack of control over experimental protocols and data reporting, and often created an initial resistance to cooperating in device studies. Group evaluations, which compare similar devices, have been attempted but never fully developed (163), since they frequently involve extensive field testing.

VA evaluation of commercially available rehabilitative devices has been the target of complaints, especially from veterans' groups. The Disabled American Veterans organization has characterized the evaluation system as "fraught with inefficiencies and communication breakdowns" (160). In addition to the Disabled American Veterans' complaints, there have been other criticisms: that testing priorities are not adequately established and that there are long delays in evaluating devices; that clinical prescription criteria must be more standardized to ensure more consistent quality of care; that device needs of veterans must be better anticipated; and that devices should be evaluated by the FDA (not the VA) for safety (though by the VA for efficacy and cost effectiveness) (164).

## Prosthetics Technology Evaluation Committee

To address concerns about VA evaluations of commercially available devices, the Prosthetics and Sensory Aids Service established the Prosthetics Technology Evaluation Committee (PTEC) early in 1982. The committee—including representatives from the Prosthetic and Sensory Aids Service, the Office of Procurement and Supply, and Rehabilitation Medicine Services, the VA Inspector General's Office, and Rehabilitation R&D—has developed an evaluation and coordination process for VA products and devices, which is now almost fully operational.

PTEC will be responsible "for assessing and ranking the legitimacy and appropriateness of evaluation proposals and for assessing and approving the results of clinical evaluations" (125). The Prosthetic and Sensory Aids Service established PTEC primarily because of concern that the VA evaluation process was not sufficiently formalized. Not only were evaluation efforts hampered, but, faced with increasingly expensive devices and technologies and steady or declining budgets, the VA was using its lack of a process to deter supplying expensive prosthetic and sensory aids to veterans.<sup>b</sup>

The PTEC evaluation process probably has two main strengths: 1) classifying devices into three types to determine the testing and evaluation that devices will undergo; and 2) coordinating with other parties interested in rehabilitative devices, in the VA delivery system, other Federal agencies, independent testing labs, and veterans' groups. (The Paralyzed Veterans of America and the Disabled American Veterans, for example, both have permanent representatives on this committee. Other veterans' groups are informed of its activities and invited to participate in meetings.)

<sup>b</sup>VA policy is to provide blind veterans with all necessary services and devices to overcome their handicaps and to provide other disabled veterans with devices and technologies deemed medically necessary. As in the case of disability compensation and pensions, a major concern to users and policy makers is the cost of covering all available technologies (62, 109). This issue is discussed further in ch 6.

The PTEC process groups devices into three types, according to potential risk, innovation, and (importantly) cost. It is like the FDA classification in determining the kind and extent of evaluation by a device's type. This classification system is not yet final. It will depend significantly on a survey of the users (which will also lead to prescription guidelines).

Generally, however, devices in the lowest category of risk, newness, and cost will seldom be subjected to laboratory testing other than the manufacturers. Additional laboratory testing will concern only safety. Devices in the middle class will be laboratory tested, as needed, for compliance with existing standards, safety, and validation of manufacturers' claims. Provided the test results are positive, products will then undergo limited clinical trials to substantiate laboratory findings and to obtain users' opinions. Only devices at the highest level of classification will be subjected to extensive VA lab testing and clinical trials (22,50).

PTEC can provide information for various kinds of decisionmaking, from that of users to that of policy makers. To the extent possible, PTEC will rely on data from the FDA, independent laboratories testing, and others. The amount of testing information shared by the VA and the FDA has traditionally been negligible, however. Evaluation criteria have generally differed because of the VA's special needs and client population. The VA has also been hesitant for the FDA to use VA data because private device manufacturers might request free evaluation services from the VA (50).

### **Testing and Evaluation Staff, VA Marketing Center**

At any one time, about 250 devices, ranging from hospital-based equipment to supplies and expendable, are being reviewed by the VA Office of Procurement and Supply as a requisite for procurement contracts. The Office's Testing and Evaluation Staff (T&E), part of the VA Marketing Center and supply depot in Hines, Illinois, has primary responsibility for this aspect of VA device testing.

The T&E was established in February 1976 by administrative fiat, based on a VA-initiated study, the "McKinsey report." The study suggested that the VA might perform several functions (57):

- be a valuable source of information on medical devices for other health care providers,
- centralize and expand existing information and evaluation activities,
- support the FDA in ensuring the safety and efficacy of medical devices, and
- stimulate the development of new or improved products for identified needs.

As the McKinsey report was released, the FDA also entered a memorandum of understanding with the VA to exchange medical device "experience." This agreement would eventually require a VA clearinghouse for medical device recalls from the FDA and hazard reports from VA medical centers. Meanwhile, the McKinsey report's recommendation to stimulate innovation was implemented with the help of NBS, which initiated the Experimental Technology Incentives Program (ETIP). The VA agreed to participate in market research to promote public or private partnerships and industry incentives to develop medical devices. ETIP, first placed in the VA Central Office, remained dormant for a year. With the establishment of T&E, however, ETIP was transferred to the VA Marketing Center with a grant of \$450,000. As a result of all these events, T&E has had responsibility for medical device evaluations, liaison with FDA on recall and hazard alerts, and ETIP (134). The ETIP-VA agreement ended in 1981, but T&E has continued its market research.

Testing and evaluating VA-purchased medical devices is T&E's central focus. Such medical devices are selected for evaluation through requests by VA medical centers, manufacturers, the VA Central Office, and "in-house" initiatives. Choices depend more on volume considerations and the interest of VA health care facilities than, for example, cost factors (67).

Once a device is selected for testing and evaluation, prospective clinical trials may be carried out under the auspices of the Medical Research Service (18) or cooperatively with the Department of Defense through an agreement with Fort Sam

Houston in Texas. Most often, however, testing and evaluation consist of internal consumer research to validate manufacturers' claims with tests carried out at VA medical centers and facilities around the country. T&E also has working agreements with nearly a dozen private testing laboratories, for needed laboratory tests, including the Emergency Care Research Institute, Utah Biomedical Laboratories, Stanford Research Institute, and Underwriters Laboratories. Information is also shared with some of these laboratories (134).

T&E develops the base protocols, which may be amended by appropriate medical services within the VA. Testing sites are also cooperatively selected, with local VA supply and procurement officers administering hospital tests (67). As the appropriate VA manual specifies (156), evaluations typically take the form of user surveys on many product features, including compliance with manufacturers' claims and industry standards, safety, design, ease of use, durability, cost, and the products' advantages and disadvantages compared to similar products.

Testing may last from 2 weeks to a full year, but averages 30 to 60 days. Information is then compiled in a brief description of the product (often derived from manufacturers' literature) and of survey findings. The Office of Procurement and Supply publishes evaluation results quarterly and distributes them to VA medical centers, medical and regional office centers, clinics, and supply depots and distribution centers, and to procurement officers at the VA Marketing Center. Results of the evaluations cannot be used by manufacturers, but they are routinely requested by private hospitals, nursing homes, and State and local governments, and are reprinted by private publications such as *Consumer Reports*, *Hospital Purchasing Management*, and *Health Devices Alert* (18,67,147).

Importantly, evaluations are *advisory*. Theoretically they are incorporated in national procurement contract requirements, but purchases are not based solely on the evaluations. Purchasing decisions still rest with individual hospitals, which, on average, purchase from national contracts only about 60 percent of the time. Furthermore, evaluations stress advantages and dis-

advantages based on a manufacturer's standard or claim. There are no evaluations of features for which manufacturers make no claims. VA regulations also prohibit explicitly comparing one product with another. There have been efforts to do group evaluations of some classes of devices. Group evaluations would better control for testing bias and could generate more meaningful information. Staffing and budgetary restraints, however, have restricted T&E to very few group evaluations (67).

T&E primarily evaluates standard stock items and smaller medical equipment. Decisions to purchase expensive devices, for example computed tomography (CT) scanners, involve not only supply and procurement staff; they require the approval of special medical equipment committees in individual medical centers and that of Service Directors in the Central Office.<sup>7</sup> Although there are a few exceptions, Service Directors have traditionally relied only on data generated by the manufacturer or on VA "acceptance testing," which prospectively establishes "performance requirements" (e. g., for reliability, dosages, or performance times), with local interdisciplinary VA teams assessing devices against the criteria. The Medical Research Service has worked jointly with other Services in some evaluations. For example, the Radiology Service made purchasing decisions about CT scanning with the help of an advisory committee including the directors of medicine, surgery, neurosurgery, and neurology. Two research projects—one comparing the costs of in-house scanners and those of contracting for scans and another evaluating VA hospitals' sharing of CT scanners—also figured in these decisions.

Recently, manufacturers have begun to offer the VA expensive equipment outright in exchange for exclusive long-term contracts for disposable the hardware requires or in exchange for experimental data. The VA now lacks a policy on accepting *or* using such equipment (18).

In fiscal year 1983 T&E began post-marketing surveillance by surveying all VA purchasers and

<sup>7</sup>Expensive medical and dental equipment, generally items above \$30,000 and others specified in VA regulations (157), are called "controlled items." Controlled items are further discussed in ch. 6.



users of products previously evaluated. The survey's goal is to determine performance, quality, and other product characteristics after more prolonged use. Two dozen items are to be reviewed each year. Summaries of responses will be published quarterly along with new product evaluations (67,133).

T&E is also concerned with "product assurance," resolving medical device and product complaints and providing staff support for developing specifications, standards, and inspection criteria for equipment and supplies bought centrally and managed by the VA depot system (which is described in ch. 5). For example, T&E has developed standards for hospital beds and eyeglass frames, the last jointly with ETIP.

To the extent possible, T&E and, in turn, procurement components of the VA have relied on existing standards and device evaluations, such as those of the FDA's National Center for Devices and Radiological Health in the area of radiation leakage (18). The VA also wants to rely on FDA standards and testing if the provisions of the 1976 Medical Device Amendments on performance standards are implemented (13). If a device has been on the market for some time, the VA will often use any evaluations conducted by NBS and the Department of Defense (18).

The current Administration is also moving toward voluntary standards as an official policy in all areas. Office of Management and Budget Circular A-119, currently in effect, describes the use of voluntary standards for procurement. T&E has worked with several voluntary standards groups in the past, including the American Society of Testing and Materials and the National Sanitation Foundation. As an alternative to using standards, the VA has increasingly used CIDS, which are adopted as standards are, but allow a broader mix of devices to be purchased. So far CIDS have had a much greater impact than standards in the purchase of medical devices (67), as discussed in the following chapter.

The VA requires its medical centers to use depot-stocked items when possible. To ensure user satisfaction, the VA has a formal system for registering complaints with the VA's Marketing Cen-

ter, which must promptly resolve these complaints.

A 1982 General Accounting Office (GAO) report called for this system to be improved (101). Medical centers, it found, were not satisfied with depot-stocked items and often bought alternative products from other sources without filing a complaint. As a result, inferior stock was often not brought to the Marketing Center's attention. When complaints were filed, the Marketing Center often did not take appropriate action, further discouraging medical centers from reporting complaints.

The medical centers use the VA's Quality Improvement Report to file complaints about depot-stocked items. During fiscal year 1980, for example, 478 Quality Improvement Reports were filed on medical supply and equipment items. However, until fiscal year 1982, the marketing and procurement officers ("commodity managers") at the Marketing Center were also responsible for responding to Quality Improvement Reports. GAO felt that the commodity managers perhaps could not evaluate reported problems objectively. With regard to frequently registered items, GAO found that the Marketing Center: 1) did not address the medical centers' stated problems, 2) did not provide the medical centers with clear resolutions, or 3) provided the medical centers with false assurances.

In response to the GAO report, the VA transferred responsibility for the quality complaint system to the Marketing Center's T&E staff beginning in fiscal year 1982 to improve the system's objectivity and responsiveness. Transfer to T&E of the quality complaint system had the additional benefits of coordinating evaluations and encouraging better information exchange with the FDA on medical device problems and experience. All Quality Improvement Reports received by T&E are screened to determine the potential for hazard alerts or product recalls because of risk to the lives or safety of patients and employees. T&E forwards information on hazard alerts to the FDA's National Center for Devices and Radiological Health and other divisions of the Marketing Center, which in turn notify all VA medical facilities.

Another function of T&E is developing and managing a computerized information storage and retrieval system for consumers. Another outgrowth of the VA-ETIP program, this system facilitates the flow of information among the purchasing divisions of the Marketing Center, VA medical centers, and other Government agencies;

provides product, price, and vendor histories useful in awarding VA procurement contracts; and contains marketing data useful and available to private manufacturers. Since larger companies often have in-house marketing capabilities the information has been most useful to smaller and emerging companies.

## DISCUSSION

This chapter has focused on the VA's diverse evaluation activities. Generally, VA evaluations are conducted during the later phases of R&D. Late in the R&D process is generally when information must be collected for reimbursement, financing, and drug and device regulation (i.e., for decisions affecting use). This is a good time for evaluations insofar as information and experience may be available and the device has not yet been widely diffused. Evaluations can then affect the VA's adoption of devices (109).

The separation of Rehabilitation R&D from other VA research in 1973 was partly to give more focus to VA rehabilitation research (109). In turn, this focus helped stimulate the VA to devote more attention to evaluation, as in establishing the Rehabilitation R&D evaluation unit.

At the same time, one veterans' group has criticized the divided responsibility for evaluation. Commercially available devices, especially rehabilitative ones, often need refinements before the VA can approve them for its use. According to the Disabled American Veterans, in these cases it may not be clear who is responsible for evaluation—Rehabilitation R&D, Prosthetic and Sensory Aids Service, or the VA Office of Procurement and Supply (160).

Coordinating evaluations has been addressed by forming PTEC. In calling for the involvement of all relevant VA services and in inviting consumer groups to participate, the VA appears to be taking a step toward more systematic evaluation of rehabilitative devices. PTEC has the support of such groups as the Paralyzed Veterans of America and The American Legion (71,82).

Thousands of rehabilitative devices issue from the public, private, and nonprofit sectors. Many are relatively simple and inexpensive, and others are costly and complex. Regardless of a device's cost, complexity, or proposed use, it should meet certain criteria before being widely used, notably those covering safety, effectiveness, durability, and recommended applications (112). Baseline assessments combine laboratory testing and clinical evaluations. Some devices warrant much broader assessments. Costs should be explicitly considered in some cases. In others, evaluating the devices in the user's environments may be essential (109).

Both the Rehabilitation R&D evaluation unit and PTEC would seem to embrace these testing needs. Both programs are new, however, and there are problems yet to be resolved. PTEC, for example, needs to expand its field testing activities and to make its testing more national in scope. PTEC'S authority over VA medical facilities should be established internally. The Rehabilitation R&D evaluation unit could encourage more testing and evaluation at Rehabilitation R&D Centers and ensure that its results are valid and credible to PTEC, to avoid duplication of efforts. Even with these problems, the evaluation unit and PTEC appear to have great potential.

In evaluating medical equipment, supplies, and expendable, T&E represents a modest but productive effort, given its small staff. Although not rigorous, its evaluations can provide information for purchasing by VA facilities. T&E evaluations are apparently most often used by smaller, more rural VA facilities. The VA estimates that only

about 20 percent of its medical centers make purchasing decisions based on T&E evaluations. At the same time, supply and procurement officers at all VA hospitals use the evaluations as an information resource, including in doing business with vendors.

Although T&E evaluation generally does not study such features as cost effectiveness, it could do so through more group evaluations with modest increases in budget and staff. Its publications of results and standard setting can have significant influence because of the VA's market power. For example, the VA's requirement that fibrillating catheter devices for the heart meet National Fire Protection Association Standards led to complete industry compliance in manufacturing these devices, despite the absence of industry consensus (46). VA publication of testing results on hearing aids spurred innovation and competition among manufacturers (41). (The VA Office of Procurement and Supply has occasionally been

reluctant to publish its test results, however, because the demographic characteristics of the veteran population are not always those of all consumers (18). )

It is noteworthy that large private buyers such as for-profit hospital chains have developed organizational components similar to T&E. At the recommendation of a private third-party payer, the Hospital Corp. of America recently announced the formation of "product standardization" committees to evaluate products' "safety-worthiness," failures, and performance, and to manage product recalls—all tasks of T&E (69). Special evaluation groups may be valuable to large medical systems.

T&E's weakness may lie in not integrating evaluation information and its market research into the overall VA marketing, procurement, and supply system. This issue is considered more fully in the next chapter.