7.

Veterans Administration Policies Regarding Medical Devices

War loves to play upon the young.

–Sophocles

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INTRODUCTION

The Veterans Administration (VA) has a prominent role in the medical devices industry from both the producer and purchaser sides of the market. Since the late 1940s, the VA has been an important source of research and development (R&D) funds, notably for rehabilitative technologies. In fiscal year 1983, the VA's total R&D budget was almost $160 million, of which over $10 million was specifically earmarked for rehabilitative R&D. Actively serving about 3 million out of 30 million veterans eligible for free health care and rehabilitative services with an annual budget of more than $8 billion, this agency is a significant power in the marketplace.

The VA presents a unique example of a health care system that includes the continuum of patients, needs, facilities, money, and personnel and the mandate to develop, deliver, evaluate, and support a full range of devices and services. Because of its size, the agency clearly has potential for influencing the medical devices industry. Yet although the VA health care system is completely funded by the Federal Government and centrally administered, decisions regarding the purchase and use of medical devices are primarily made at the clinical and VA medical center levels. Overall, the impact of the VA on the medical devices industry reflects this combination of targeted programs and policies and decentralized activities. The relationships among the parts of the VA discussed in this chapter are depicted in figure 4.

Throughout this chapter, medical devices are grouped and referred to in three classes:

- rehabilitative devices, such as prosthetics and sensory aids for disabled people;
- equipment, such as radiological and laboratory equipment; and
- supplies, such as bandages and other disposable.

The discussion begins with an overview of the VA health care system and then describes the VA's programs, activities, and policies with regard to the R&D, testing and evaluation, procurement and supply, and, finally, adoption and use of medical devices.

OVERVIEW OF THE VA HEALTH CARE SYSTEM[1]

The VA's health care system is the largest health care delivery organization in the Nation.[2] The vast majority of services are delivered to veterans in VA-owned facilities. Most acute care services are provided in 172 VA medical centers that are, for the most part, affiliated with medical schools. Begun after World War II, the affiliation program is generally credited with enhancing the quality of care at the VA hospitals. These hospitals operated over 82,000 beds in fiscal year 1981 and treated about 1.25 million patients.

The VA provides both institutional and noninstitutional long-term care services. Ninety-eight nursing homes associated with the VA medical centers provide highly skilled extended care after hospitalization. The VA plans to increase the number of nursing home beds from the 8,700 beds that were operated in 1981 to over 13,000 by 1987 to serve the rapidly expanding aged veteran pop-

[1]Unless otherwise noted, this section is adapted from a discussion in U.S. Congress, Congressional Budget Office, *Veterans Administration Health Care: Planning for 1990,* Washington, DC, February 1983 (327).

[2]The Hospital Corp. of America, a private, "for-profit" hospital chain, includes more facilities, but has revenues only about half the size of the VA's health care delivery budget *(130).*

ulation. Other institutional long-term care services are provided by the VA in community nursing homes, where services are purchased on a per diem basis, and at State veterans' homes, where the VA subsidizes care through grant programs.

The VA also operates 15 domiciliaries, usually on the VA medical centers' campuses, where service-disabled or permanently disabled veterans can live and receive necessary minimal health care. Noninstitutional care provided includes day-care programs for the elderly and various home-care programs.

The outpatient programs operated by the VA represent an alternative to hospitalization for many veterans. In 1981, more than 15.8 million outpatient medical visits were made to VA staff, and 2.1 million visits were made to private physicians and funded on a fee-for-service basis by the VA. Clinic services are varied. In addition to diagnostic, treatment, and rehabilitative clinics, the VA operates mental hygiene clinics and day treatment centers for psychiatric patients and provides dental care services for long-term care patients.

In all, the VA employs the full-time equivalent of approximately 194,000 physicians, dentists, nurses, and administrative and support personnel. The VA's Department of Medicine and Surgery, headed by the Chief Medical Director, administers the entire health care system with an annual budget in 1983 of just over $8 billion. The Department of Medicine and Surgery is administered from the VA's Central Office in Washington, DC. Specific areas of patient care and program function (e.g., rehabilitation medicine, surgery, radiology, and medical research) are the responsibility of VA organizational units called services. As shown in figure 4, these units are under the guidance of service directors in the VA's Central Office.

The VA's health care system operates under a limited and controlled budget with plans projected for 1 and 5 years ahead. Funding is 100 percent Federal. Once Congress determines the overall appropriation, the budget is fixed for the following fiscal year. However, after the appropriation level is decided, the VA health care system is characterized by highly decentralized planning and financial management policies, Twenty-eight regional areas, called medical districts, control the allocations that are prospectively budgeted by the Central Office. Each medical district is typically composed of 4 to 10 VA medical centers.

The Veteran Patient Population

Currently, there are an estimated 30 million veterans eligible for health care services. About 40 percent of the eligible population are World War II veterans now in their 50s or 60s. By 1990, practically all of these 12 million World War II veterans will be over 65 years old, and the VA is concerned about the impact of this aging population on the health care delivery system.

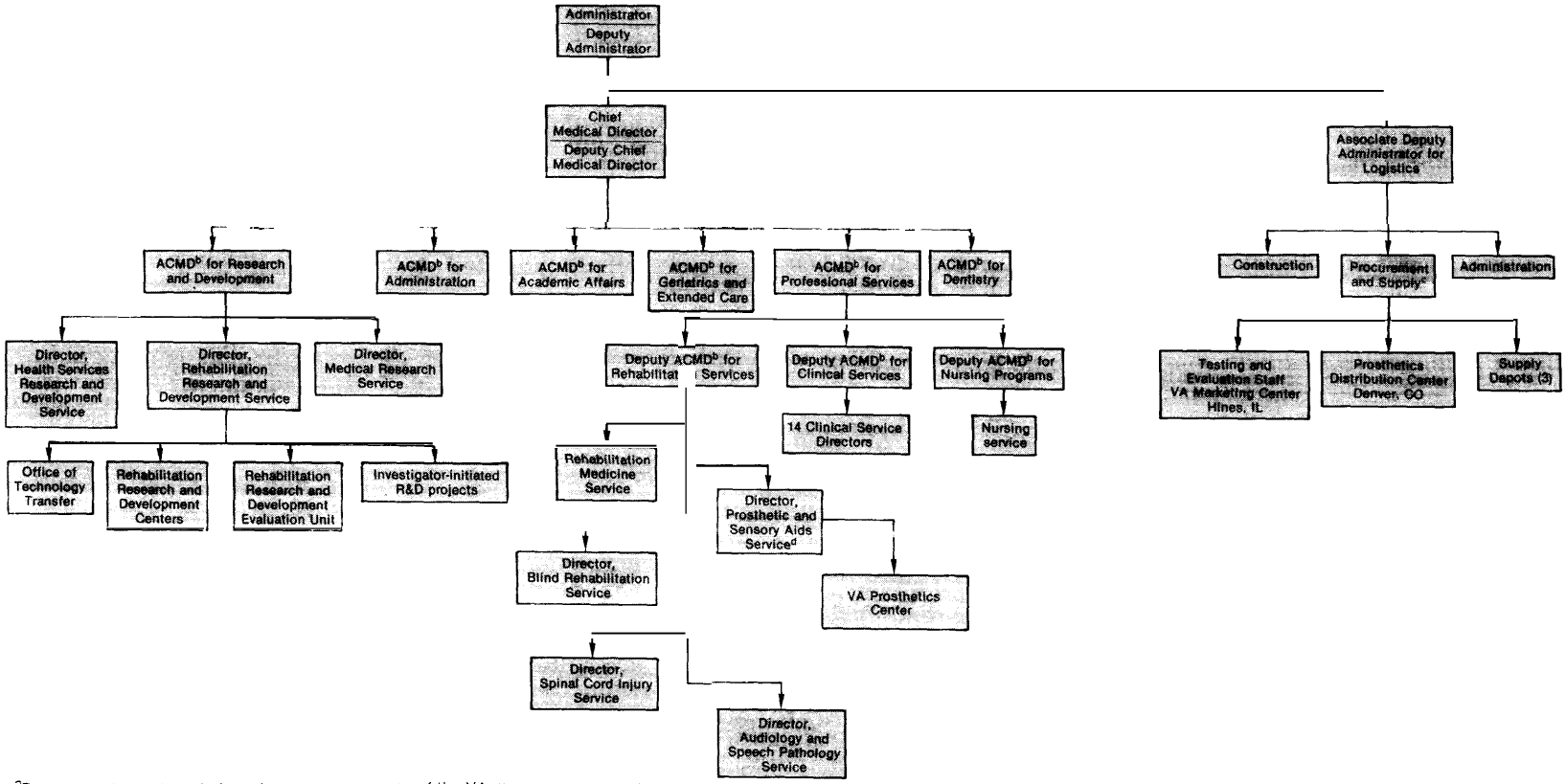
Only a small proportion of the eligible population actually uses the VA health care system, however. In 1981, about 3 million veterans, or 10 percent of those eligible, used VA services. Most veterans use community services for their health care, presumably because they have -adequate public or private health insurance or they prefer the proximity of non-VA facilities. It is estimated that only about 2 million of the World War II veterans will apply for VA health care benefits when they are over 65 years of age.

Any veteran with a service-connected disability is eligible for health care services. Veterans with service-connected disabilities represented about 34 percent of the applicants who sought medical care from the VA in fiscal year 1982. The remainder of the VA patients were veterans aged 65 or older (about one-fourth of patients discharged from VA hospitals in 1981), veterans who were unable to pay for their medical care, former prisoners of war, and veterans who were exposed to Agent Orange in Vietnam. Other veterans are eligible on a space-available basis.

Veterans' Service Organizations

A number of veterans' service organizations play a significant role in the overall delivery of health care by the VA (106). In terms of size of membership, the major organizations are The American Legion, the Veterans of Foreign Wars, and the Disabled American Veterans. At the national level, these groups lobby for services and

Figure 4.–Organization Chart of the Veterans Administration (VA),[a] May 1984



[a]This chart shows the relationships among the parts of the VA discussed in this chapter.
[b]ACMD—Assistant Chief Medical Director
[c]VA supply services are located in individual VA medical centers
[d]The prosthetic Technology Evaluation Committee advises the Prosthetics and Sensory Aids Service

SOURCE Office of Technology Assessment

attempt to influence legislative decisionmaking. At the local level, they are involved in a variety of activities including substantial support for community programs. Because of their high visibility in the community, local chapters of these organizations can have an important influence on VA hospital activities. Hospital administrators are sensitive to their inquiries and complaints and usually try to consult these organizations when major planning decisions are under consideration.

RESEARCH AND DEVELOPMENT

The goals and priorities of the VA's R&D program are diverse, with broad mandates to address the very complex and difficult problems of veterans. The official role of the Federal Government in the R&D of medical devices, especially prosthetic and disability-related research, dates back to the 1930s and 1940s. Since 1947, the VA has spent over $25 million on prosthetic device research alone (225).

Research indicates that the Federal Government can be particularly effective in sponsoring R&D if the Government is itself the buyer of the resulting technologies (228). The VA spent well over $1 billion on all supplies and equipment for its various medical facilities in 1983. Especially in the area of rehabilitative devices, not only is the VA the major buyer in the country, but its R&D efforts are very important because of the small and fragmented nature of the market for many rehabilitative technologies.

Table 38 shows the VA budget for R&D activities, as divided among the VA's three major R&D services: the Medical Research, the Rehabilitation Research and Development, and the Health Services Research and Development Services. Although funds committed to these R&D services by the VA in current dollars have increased over the past few years, the budgets of these services have been stable or declining if inflation is taken into account. Furthermore, total R&D as a proportion of medical care expenditures by the VA has been steadily declining for a decade. In fiscal year 1970, R&D budgets accounted for 3.4 percent of the outlay for the medical care program, compared with only 2 percent in fiscal year 1982 (433).

Veterans' service organizations have expressed concern about effective cutbacks in R&D budgets, especially in the areas of prosthetics research and research on sensory aids for blind and hearing-impaired veterans. The organizations argue that these research areas have received decidedly less funding than they merit (344).

The bulk of R&D funds goes to the Medical Research Service, which provides opportunities for clinician and nonclinician scientists to study health problems in the veteran population. The emphasis of the medical research is on clinical research, most of which is initiated by physician investigators who carry out their research part-time and spend the majority of their time treating veteran patients. Current studies involve cardiovascular, respiratory, and renal devices. A number of research projects are also conducted cooperatively, with clinical trials at multiple sites within the VA medical care system. The largest number of cooperative studies have tested drug therapies, fol-

Table 38.—Veterans Administration (VA) R&D Budget Overview, Fiscal Years 1977-83 (thousands of dollars)

	Fiscal year						
	1977	1978	1979	1980	1981	1982	1983
Medical Research Service	$101,567	$108,153	$118,016	$122,745	$129,943	$130,842	$141,052
Staffing	4,220	4,367	4,217	4,171	4,171	3,845	4,015
Rehabilitation R&D Service	4,419	5,502	7,191	8,085	8,784	7,185	10,001
Staffing	69	90	112	143	-143	128	250
Health Services R&D Service	3,604	2,996	3,004	3,153	3,083	2,828	3,786
Staffing	45	90	105	104	104	93	120
Total	$113,924	$121,198	$132,645	$138,401	$145,942	$144,921	$159,224

SOURCE: U.S. Veterans Administration, 1983.

lowed by surgical procedures, such as coronary artery bypass surgery (342).

The Health Services Research and Development Service, which was organized in 1976, develops and supports programs designed to improve clinical and administrative decisionmaking in the VA medical care system. Its only research priority area that concerns medical devices is the assessment of the cost effectiveness of patient care technologies. The third VA service, the Rehabilitation R&D Service, is substantially involved with research and medical devices, as described in the following section.

Rehabilitation Research and Development Service

The Rehabilitation R&D Service is the result of an increased focus, both at the VA and at the national level, on rehabilitation research and engineering needs. In 1973, this program was separated from other R&D efforts at the VA and given a mandate to improve the quality of life and to facilitate greater independence for physically disabled veterans.

The Rehabilitation R&D Service undertakes research, development, and evaluation of new rehabilitative devices and techniques. The main goal of the program, which is primarily oriented to sophisticated equipment, is to develop "usable" devices that assist individuals. All activities are coordinated with the National Institute of Handicapped Research at the Department of Education. The Rehabilitation R&D Service is also concerned with technology transfer, including increasing the availability of new devices on the market (352).

The activities of the Rehabilitation R&D Service are concentrated in three areas—prosthetics, spinal cord injuries, and sensory aids, representing the most prevalent service-connected disabilities of veterans. Prosthetics research makes up about 40 percent of the Rehabilitation R&D Service budget; research relating to spinal cord injuries, with an emphasis on improving wheelchairs, makes up about 30 percent of the budget; and research on sensory aids, which include aids for visually and hearing-impaired people and for communication disorders, makes up the remaining 30 percent (426). Research priorities within these areas are identified through a combination of internal review and workshops and seminars, which include representatives from provider and research groups, manufacturers, and disabled veterans' organizations.

The Rehabilitation R&D Service supports both intramural and extramural R&D programs, although over the past few years, funding has shifted away from extramural projects and toward intramural projects such as VA-established centers and their university-affiliated programs. Two rehabilitation R&D centers, tied directly to the VA Rehabilitation R&D Service, have recently been established: one in the Palo Alto VA Medical Center in California and the other in the Hines VA Medical Center in Illinois outside of Chicago. Six more such centers are planned by 1986.

The rehabilitation R&D centers are affiliated with leading engineering schools in the same way that the VA medical centers are affiliated with medical schools. These affiliations bring faculty and students into clinical research settings to study the problems of disabled people and to investigate new procedures and devices to alleviate their problems. The rehabilitation R&D centers' primary goal is to apply advanced technology, such as microprocessors, to assist physically handicapped veterans.

In an approach similar to the rehabilitation R&D center concept, the Rehabilitation R&D Service is establishing university-affiliated research engineering programs to help support qualified engineering graduate students and faculty who undertake rehabilitation engineering projects. The thrust of the program is to interest engineering students in rehabilitation engineering and to create a flow of ideas and information between academia and the VA (69,125).

VA Prosthetics Center[3]

The VA Prosthetics Center is a VA R&D center in New York City that is within the Prosthetic

[3]Since its inception in 1956, the VA Prosthetics Center has also been known as the VA Rehabilitation Engineering Center (VAREC) and as the Prosthetic Evaluation Testing and Information Center (l' ETIC)

and Sensory Aids Service (see fig. 4). The VA Prosthetics Center was established in 1956 to conduct R&D in rehabilitation engineering, to evaluate and test commercially available rehabilitative devices, to provide direct patient care for difficult prosthetic and orthotic cases, and to manufacture orthopedic footwear and prosthetic/orthotic devices.

In its earlier years, the VA Prosthetics Center was the "flagship" of a successful VA intramural research program in prosthetics and orthotics. The majority of the prosthetic limbs and the fitting techniques used today, for example, were developed by the VA Prosthetics Center in the 1950s (431). However, a 1983 audit report by the VA's Office of Inspector General found management and operating problems at the VA Prosthetics Center, then known as the VA Rehabilitation Engineering Center (VAREC) (426). The report recommended changes in VAREC's organization, including discontinuation of the R&D program. The VA's Department of Medicine and Surgery accepted the Inspector General's recommendation, disbanded the VAREC Research and Development Service in fiscal year 1984, and changed the organization's name to the Prosthetic Evaluation Testing and Information Center (PETIC) (430).

The VA Prosthetics Center encouraged innovation in the past by demonstrating that new types of wheelchairs were technologically possible and safe, and, most importantly, that there was a substantial market for them—the VA (282). The Prosthetics Center's work with power wheelchairs in the early 1970s demonstrated that electric wheelchairs could be used safely at speeds greater than a slow walk and that they could be designed to be used on rough terrain. This situation encouraged wheelchair manufacturers to begin making chairs with those capabilities. Efforts centered around lightweight sports wheelchairs had a similar effect on manufacturers.

TESTING AND EVALUATION

Literally thousands of disability-related devices are being produced by the public, private, and nonprofit sectors. Although many are relatively simple and low-cost items, others are expensive and complex. Regardless of the devices' cost, use, or complexity, certain criteria need to be met before these products enter widespread use. Safety and effectiveness, including durability and recommended applications, are the essential criteria that need to be evaluated (412).

Currently, the responsibility for testing and evaluating medical devices is divided among several VA organizational units. *Prototype* rehabilitative devices that are still in the developmental stage are evaluated by the Rehabilitation R&D Service. Once medical devices are commercially *available,* the responsibility for evaluation is split between: 1) the Prosthetic and Sensory Aids Service, which evaluates rehabilitative devices; and 2) the Office of Procurement and Supply, which evaluates all nonrehabilitative devices, equipment, and systems purchased by the VA.

Prototype Rehabilitative Devices

Rehabilitative devices developed by the VA often do not complete the transition from research prototypes to commercially viable products. The VA's research funds have supported a number of expensive prototypes that have been neither put into general use for the veteran population nor discarded outright. Examples include a wheelchair with special electronic controls adapted for use in a vehicle, a four-bar linkage knee for use in above-knee prostheses, and a standing device for paraplegics (433).

Although there are several reasons for the failure of such prototypes to become viable products, one obstacle is the lack of unbiased evaluations of the prototypes that provide data on performance and clinical applications. The inadequacy of internal testing and evaluation for prototype rehabilitative devices has been generally recognized by the VA. Although some VA facilities, including the rehabilitation R&D centers, the VA Prosthetics Center, and individual VA medical

centers, have been involved in testing new and emerging devices through various VA services, the Rehabilitation R&D budget has not provided adequate funds to purchase expensive prototypes for clinical evaluation (433). Moreover, the VA has had a general procurement policy of not purchasing equipment unless it is commercially available and in clinical use (344).

There have also been concerns about unnecessary duplication in rehabilitative device evaluation when the Rehabilitation R&D Service has conducted testing. For example, special recreational ski equipment for disabled people, which was developed and tested at the Palo Alto Rehabilitation R&D Center and then further tested at four independent centers, could not be purchased for veterans until the equipment had gone through an essentially duplicative testing process at the VA Prosthetics Center (19,196).

In response to these criticisms, the Rehabilitation R&D Service has recently established the Rehabilitation Research and Development Evaluation Unit, a coordinating group to conduct clinical evaluations of new devices, techniques, and concepts in rehabilitation and to promote commercialization of the prototype devices that are evaluated by the program. The new unit will be responsible for developing evaluation protocols and will generally oversee and coordinate the evaluation process. However, all the organizational units within the VA that have a stake in the devices' development and ultimate commercial success will share in funding the major evaluations (435).

Although it is premature to assess the Rehabilitation R&D Evaluation Unit at this time, the unit appears to have the potential of coordinating work so that evaluations are perceived as valid by organizational units of the VA that use the results and duplication of effort is avoided.

In an attempt to further structure its technology transfer efforts, the Rehabilitation R&D Service has recently entered into an interagency agreement with the U.S. Department of Commerce to identify and develop potential markets and financing for prototype devices that were funded and developed by projects of the Rehabilitation R&D Service. The goal of the interagency program is to develop a process that leads to the commercialization of VA devices and technology.

Commercially Available Rehabilitative Devices

Once rehabilitative devices are commercially available, the responsibility for their evaluation shifts from the Rehabilitation R&D Service to the VA's primary user service, the Prosthetic and Sensory Aids Service. Throughout the 1970s, the Prosthetic and Sensory Aids Service increasingly employed performance standards in its prosthetic and sensory aids program. These standards are developed with the participation of individuals and organizations both within and outside the VA. Manufacturers, professionals, VA supply specialists, and others review the standards, which provide product specifications to control devices' quality, safety, and performance.

After a performance standard for a rehabilitative device has been established, the VA Prosthetics Center tests the device for compliance with the standard and determines whether or not products meet the VA's requirements. As noted earlier, the VA Prosthetics Center has recently become the VA's organizational focus for evaluation of commercially available rehabilitative devices.

The testing protocols used by the VA Prosthetics Center 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 manufacturers' claims.

Devices can undergo either special laboratory testing or "field testing" at VA medical centers. Field testing, although advantageous in that it assesses devices' "usefulness," has never been utilized extensively by the VA Prosthetics Center because of organizational difficulties. Until fiscal year 1984, no line authority existed from the VA Prosthetics Center staff or from the Prosthetic and Sensory Aids Service to the medical centers. The absence of line authority has typically resulted in loss of control over adherence to protocols and lack of reliable reporting of evaluation data (465).

The VA evaluation process for commercially available rehabilitative devices has increasingly been the target of complaints, particularly from veterans' groups. The Disabled American Veterans has characterized the evaluation system as being "fraught with inefficiencies and communication breakdowns" (439). There has also been criticism on several other fronts: that testing priorities are not adequately established; that long lags exist in the evaluation process; that the needs of veterans for devices should be better anticipated; that the devices should be evaluated for safety by the Food and Drug Administration instead of by the VA; and that the VA should test for efficacy and cost effectiveness.

The standard-setting process has also been a cause of concern for veterans' organizations and others. Critics claim that the VA specifications have often been written to the specifications of a particular manufacturer's product, putting other manufacturers at a distinct disadvantage in the VA market. If such specifications define the dimensions and materials to be used in devices, it is more difficult for emerging devices that are different in design or performance levels to enter the general marketplace (352).

Shepard and Karen, who studied the VA's effects on the wheelchair industry, concluded that the large population of users in the VA could afford an opportunity for the VA to expand its role in postmarketing surveillance of wheelchairs (252). Such surveillance could yield better data on the frequency of repairs and the advantages and disadvantages of particular models during actual use. VA standards in the past had apparently been tied to the design of a particular wheelchair (manufactured by Everest and Jennings) rather than based on performance. The need for performance-based standards in the future has been recognized, and the VA has taken steps to produce such standards. VA standards are important to the industry, as evidenced by responses to Shepard and Karen's telephone survey. One manufacturer stated that it hesitates to make anything that it cannot sell to the VA; other manufacturers stated that VA standards are considered when they make R&D decisions (282).

The VA exercises its greatest market power in the "depot" wheelchair, an inexpensive general-purpose manual wheelchair. On the one hand, the VA's large purchases of this model reduce its price to the VA. On the other hand, the VA tends to discourage ordering of chairs with more user features or better technology. If alternative models were also stocked, price advantages could still be obtained (although possibly not so good as the present ones) and more desirable features, such as lighter weight, could be offered to disabled veterans (281).

Over the past 2 to 3 years, the VA procurement process has replaced most standards and device specifications with more general purchase descriptions—commercial item descriptions (CIDs)—that are designed to accommodate the variety of privately developed and marketed devices (32). CIDs are simplified product descriptions that identify by functional or performance characteristics the available, acceptable commercial products for Government use.

Currently, the VA has standards for only four or five rehabilitative devices, though these standards are applied to a wide range of devices. For example, the standard for wheelchair lift systems covers 21 different models and 13 different manufacturers. The increased use of CIDs, however, has also been criticized. A 1982 study by the U.S. General Accounting Office concluded that the CIDs contained too little specific information, with the result that the VA was purchasing many medical items that were either unnecessary or of lower quality (332).

To address these concerns, the Prosthetic and Sensory Aids Service initiated the Prosthetic Technology Evaluation Committee in 1982. This committee has developed an evaluation and coordination process for rehabilitative devices that will soon be operational in the VA system.

The Prosthetic Technology Evaluation Committee's strengths lie in two areas. First, the committee will coordinate evaluation activities with all the concerned participants inside the VA system, as well as with other Federal agencies, independent testing labs, and veterans' organizations. Representatives from the VA's Prosthetic and Sensory Aids Service, Office of Procurement and Supply, Inspector General's Office, Rehabilitation R&D Service, Rehabilitation Medicine Service,

and from the Paralyzed Veterans of America and the Disabled American Veterans are permanent members of the Prosthetic Technology Evaluation Committee. Second, the committee will classify devices into three product levels according to potential level of risk, innovation, and cost, and the classification will determine the types of evaluations that the devices will undergo.

The Prosthetic Technology Evaluation Committee has enlisted the support of important consumer groups such as the Paralyzed Veterans of America and The American Legion, and it appears to be taking the necessary steps toward a more coherent and well-focused program of evaluation (245,288). But the committee still has some problems to resolve—such as expanding the VA Prosthetics Center's field-testing activities, making evaluations more national in scope, and establishing the committee's authority over the evaluation activities of the VA medical centers.

Commercially Available Equipment and Supplies

At any given time, at least 250 nonrehabilitative devices, ranging from hospital-based equipment to supplies and disposable, are being reviewed by the VA's Office of Procurement and Supply as a prerequisite to procurement contracts. Its Testing and Evaluation Staff, which was established in 1976 and is part of a larger marketing center and supply depot in Hines, Illinois, has primary responsibility for this aspect of the VA's device-testing activities.

The Testing and Evaluation Staff, with fewer than a half-dozen professionals, also has responsibility for a market research and analysis program. The staff identifies specific medical devices for evaluations through requests by VA medical centers, manufacturers, and the VA Central Office, as well as through in-house initiatives. Factors such as volume and interest expressed by VA health care facilities are usually more important than the cost of the products (238).

Thus, evaluations of nonrehabilitative equipment and supplies are primarily carried out on standard stock items and smaller medical equipment. Very expensive equipment, such as computed tomography (CT) scanners, is not evaluated by the Testing and Evaluation Staff; the service directors in the VA's Central Office are responsible for approving or disapproving the acquisition of such "controlled items. " These central purchase decisions are based on either test data generated by manufacturers, local medical equipment committees in individual medical centers, or, in a few instances, interdisciplinary advisory committees convened by the Central Office.

The Testing and Evaluation Staff's evaluations are usually internal "consumer research" efforts aimed at validating manufacturers' claims about their products. VA regulations prohibit explicit comparison of one product with another. Although some evaluations of classes of devices have been attempted—evaluations that begin to move toward analyses of relative efficacy or cost-effectiveness—staffing and budget constraints have restricted the number of these efforts (238).

Typically, tests on individual devices are carried out at VA medical centers around the country and take the form of user surveys. The results are synthesized into very short summaries and published quarterly by the VA Office of Procurement and Supply. The Testing and Evaluation Staff also manages a computerized information system with price and marketing data on medical devices.

The results of evaluations of nonrehabilitative equipment and supplies by the Testing and Evaluation Staff are well disseminated to users within the VA health care system. Although the Office of Procurement and Supply is sometimes reluctant to publish the test results because the particular needs of veterans may be different from the needs of the general population, such information is routinely requested by non-VA hospitals, nursing homes, and State and local governments. Manufacturers are not permitted to use the VA's evaluations in their own literature, but private publications such as *Consumer Reports, Hospital Purchasing Management,* and *Health Devices Alert* often reprint survey results (68,238,434),

The Testing and Evaluation Staff's evaluations are *advisory* in nature. Although not scientifically rigorous, these evaluations do provide an information base for purchasing by individual VA fa-

cilities. The Testing and Evaluation Staff's evaluations are, by all accounts, most often used by smaller, more rural VA facilities. The VA estimates that only about 20 percent of its medical centers strictly adhere to purchasing decisions based on the evaluations.

PROCUREMENT AND SUPPLY

The VA Office of Procurement and Supply is responsible for supplying the most extensive medical program in the Federal Government. In fiscal year 1982, the VA spent nearly $1.3 billion on supplies and equipment for its various medical facilities. Totaling nearly 6,800 employees, the procurement and supply effort includes staff at the VA Marketing Center (VAMKC), the VA's Central Office, three supply depots, the Prosthetic Distribution Center, and 172 individual medical centers. Procurement staff have the twin goals of purchasing devices at the lowest possible cost and assuring the delivery of quality supplies and equipment for veterans. Efforts are divided between central procurement activities and the local supply activities of the VA medical centers.

Central Procurement by the VA Marketing Center

VAMKC in Hines, Illinois, is the focus of the VA's national purchasing activity. That VAMKC has acted as the contract negotiator and administrator for the U.S. Public Health Service, the armed services, and other Government agencies as well as for the VA has greatly enhanced its market leverage. In July 1983, VAMKC's shared procurement program with the Department of Defense, for example, was awarding annual contracts of $295 million (428). Overall, VAMKC procurement accounts for a substantial, but not dominant, proportion of national demand for medical equipment and supplies. Bradburd found that VAMKC procurement accounted for 5 to 10 percent of the national sales volume in the markets for X-ray, nuclear diagnostic, hemodialysis, and patient monitoring equipment (344).

The market power of the VA allows it to obtain favorable prices on medical supplies through its centralized procurement channels (167). Volume purchases of medical supplies and equipment are managed and distributed through three VA supply depots located in Somerville, New Jersey; Hines, Illinois; and Bell, California. The Prosthetic Distribution Center in Denver, Colorado, serves the approximately 200,000 veterans with service-connected disabilities. In fiscal year 1982, VA medical centers obtained about $198 million in supplies (about 15 percent of their total procurement needs) from the central supply depots (428).

Several other centralized procurement programs provide individual medical centers with opportunities to obtain economically priced supplies and equipment without having to solicit and award contracts. Under the Federal Supply Schedules program, the Government contracts with commercial vendors for a wide range of supplies and services at preestablished prices. VAMKC manages Federal Supply Schedules' contracts for medical drugs, chemicals, supplies, and equipment, while the General Services Administration manages the contracts for most other items, such as furniture and office supplies (335). About 34 percent of total purchases by VA medical centers, or $434 million, were made through the Federal Supply Schedules program in fiscal year 1982 (428).

Decentralized contracts are similar to the Federal Supply Schedules program, in that medical centers order from VAMKC-administered contracts. Usually these contracts, which account for only about 3 percent of total purchases by medical centers, are for specialized medical equipment that is unavailable through either the supply depot or Federal Supply Schedules programs.

The impact of VAMKC's centralized procurement policies and procedures on product prices was studied by Bradburd specifically for this OTA report (42). The study examined VA procurement of nine categories of major medical equipment. Although the market was found to be highly concentrated, the volatility of market shares and the

very rapid pace of technological change suggested that the market was also extremely competitive.

Bradburd's findings with regard to six VAMKC procedures or policies are presented below (42).

Brand Name Justification

When a VA hospital receives authorization to purchase a particular item of equipment, VAMKC forwards to the hospital a list of the suppliers on contract whose equipment meets the requirements of the purchase order, ranked by order of cost. The hospital is required to purchase from the least-cost supplier unless it can justify purchasing from a different source based on service availability or another acceptable consideration. This exception process is called a brand name justification. Because suppliers are anxious to maintain their share of the VAMKC market, the brand name justification requirement puts them under pressure not to price themselves out of the VAMKC market, and this concern almost certainly results in lower prices than would be obtained in the absence of this requirement.

Firm Fixed-Price Clause

Under the terms of a VAMKC contract, suppliers are not allowed to increase prices during the contract year. Furthermore, if they lower the price at any time during the year, the lower price holds for the balance of the contract year. The firm fixed-price clause may or may not result in lower procurement costs. During the course of the business year, there are times when suppliers offer temporary price discounts in the private market to promote their products. Normally, it would be expected that these promotions would be extended to VAMKC as well. However, because a temporary price cut must be extended for the entire contract year, suppliers are reluctant to offer such discount prices to VAMKC.

Even the requirement that prices cannot be increased during the course of a contract year has indeterminate effects on procurement costs. On the one hand, such a requirement protects those who buy through VAMKC from price increases for the contract year. On the other hand, it is possible that suppliers charge a higher price to begin with as a form of insurance against their margins' being eroded by cost increases. It is not possible to determine the direction of the total impact of the firm fixed-price clause.

Public Disclosure Requirements

By law, the public has access to the prices at which VAMKC procures medical equipment. There is both theoretical and empirical support for the view that this results in higher procurement costs for VAMKC. The reasoning is that the benefits that a firm receives from cutting its price below that of its rivals are in part a function of the "retaliation lag," the length of time before rivals learn of the price cut and cut their own prices in response. The price disclosure requirements have the effect of reducing the retaliation lag, and therefore act to discourage such price cutting in the VAMKC market.

In addition, because private buyers of medical equipment also have access to the price data, the fact that the VAMKC price may serve as the buyer's target in pricing negotiations can also inhibit price cutting in the VAMKC market. Suppliers in the market for X-ray equipment, nuclear medical equipment, patient monitoring, and hemodialysis equipment indicate that prices offered to VAMKC are higher than they would be in the absence of the contract disclosure requirement. In markets where the disclosure requirement has not affected pricing, the perceived reason is that pricing information is widely available from other sources.

No Volume Commitment

VAMKC does not make specific volume commitments to its suppliers, who contract to provide equipment at preestablished prices. In most equipment categories (other than X-ray and nuclear diagnostic equipment), the absence of a volume commitment is a major factor in supplier pricing behavior.

There are several reasons why a volume commitment appears to be very important in some industries and unimportant in others. First, the importance of a volume commitment seems to depend on whether the equipment is typically "custom made" or purchased from supplier stock. If equipment is purchased from stock and is fairly

homogeneous, a volume commitment can provide reductions in manufacturing cost that can be passed on to the buyer in lower prices.

Second, the importance of a volume commitment seems to depend on whether the equipment is expensive or inexpensive. If the equipment is inexpensive, the costs of preparing contracts and marketing the product to buyers are higher relative to the purchase price of the equipment. In this situation, the cost savings that come with a volume commitment are more significant, and the commitment allows some of these savings to be passed onto the buyer. Some suppliers indicated a willingness to lower prices by 5 to 10 percent in exchange for a volume commitment. Even for relatively expensive devices, such as ultrasound equipment, one supplier stated that a group purchase of 15 to 20 units would suffice for a larger price discount than now offered.

Most Favored Customer Clause

Under the terms of a VAMKC contract, suppliers are not allowed to sell their equipment under a similar contract to any private buyer at a price lower than that offered to VAMKC. If a lower price is offered to a private buyer, the vendor must lower the VAMKC contract price to the same level for the balance of the contract. Because VAMKC must be offered a price as low as that offered to any private buyer, the most favored customer clause helps ensure that the VAMKC's clients benefit from competition among suppliers in the private hospital market.[4]

Although the strictness with which the most favored customer clause is interpreted varies from one equipment category to another, it almost certainly has the effect of reducing VAMKC equipment procurement costs. The policy can also have a powerful impact on private buyers. In a few markets, private buyers are offered lower prices than VAMKC when they make contractual volume commitments, on the grounds that the contracts are not like the VAMKC contract. In these markets, the impact of the most favored customer policy is obviously less than it is in other markets.

However, in many cases the most favored customer clause may have the effect of increasing prices that private buyers must pay for medical equipment. Specifically, both buyers in the VA and suppliers indicated that prices were affected in the markets for X-ray, nuclear diagnostic, ultrasonic, and patient monitoring equipment, as well as for CT scanning devices.

Reluctance To Procure Mixed Systems

Despite the absence of a formal restriction, VAMKC has exhibited a reluctance to purchase medical equipment systems in which items of equipment produced by several different companies are interconnected. There are several reasons for this, the most important of which are the difficulties of assigning financial responsibility for repair-s under warranty and of determining responsibility for the actual interconnection of the equipment. Unfortunately, VAMKC's policy can have the effect of practically eliminating many smaller companies from the procurement process, and may, as a result, cause higher initial procurement costs for the VA. The reluctance to purchase mixed systems is based on actual procurement experience, but the practice merits periodic review to determine if it saves costs over time.

Procurement by VA Medical Centers

Actual purchase of medical equipment and supplies is carried out by local supply officers located in each of the VA medical centers. Although VAMKC is responsible for centrally managing and negotiating contracts for items commonly used by the medical facilities, individual VA medical centers make their own purchase decisions. To the extent that the medical centers use the centrally managed supply channels, lower product costs are available to them through the combined VA-wide quantity purchases. However, the VA hospital system is actually a loose confederation of semiautonomous institutions in terms of device procurement, thereby reducing many of the advantages available to it as a large market power.

Increasingly, the VA medical centers have purchased their supplies and equipment on the open market rather than using central supply channels.

[4] As noted above, VA suppliers may offer lower prices to private buyers if contract terms, such as volume commitments, differ.

Whereas in the early 1960s, only about 10 percent of their medical supplies were acquired through local-level open market purchases, in fiscal year 1982, 39 percent of total purchases were made on the open market (131,428). Table 39 shows the relative contribution of each of the VA's supply channels to the total purchases made by the VA medical centers. The increase in open market purchases has resulted primarily from an implicit policy within the VA system to allow individual physicians the freedom to choose their own medical equipment and supplies.

Both a 1980 General Accounting Office report (335) and the recent report by the President's Private Sector Survey on Cost Control (Grace Commission) (131) concluded that the VA was unnecessarily paying more for supplies and equipment because of the large percentage of purchases being made on the open market. Finding that the VA defeats the price advantages available to it through greater item standardization and volume purchases, the reports called for greater central purchasing through an expansion of national contracts.

Table 39.—Veterans Administration Medical Center Purchasing Source Priorities, Fiscal Year 1982

Supply channel	Veterans Administration priority ranking	Approximate annual purchases ($ in millions)	Percentage of total
Veterans Administration excess	1		NA
Veterans Administration supply depots	2	$197.9	15.30/0
Other Government excess	3	0.4	
Federal prisons and correctional institutions, blind-made and severely handicapped products	4	1.0	1
General Services Administration stock	5	34.1	2.7
Veterans Administration decentralized contracts	6	41.4	3.2
Federal Supply Service contracts	7	434,4	33.6
Open market purchases	8	498.2	38.5
Other	none	86.0	6.6

NA indicates information not available.

SOURCE: U.S. Veterans Administration, 1983.

ADOPTION AND USE

Rehabilitative Devices

Unlike coverage policies under Medicare and Medicaid (see ch. 3), the VA's policy is to make available all rehabilitative technologies and devices that are suited to the needs of millions of eligible veterans. Of course, determinations about circumstances and clinical needs still need to be made, but VA policy is to provide blind veterans with the necessary services and devices to overcome their disability and to provide disabled veterans with all technologies and devices deemed medically necessary. An issue of mounting concern to the VA users and policymakers is the cost of this policy of covering all available technologies and devices (352).

The range of rehabilitative medical devices provided by the VA health care system is enormous. There are, for example, over 300 types of sensory aids provided for blind people (39). In fiscal year 1982, about 34,000 hearing aids and over $80 million in prosthetic services were made available to eligible veterans (426). In the area of rehabilitation services, more than 80 percent of eligible veterans have non-service-connected disabilities, with a large proportion suffering from the effects of chronic diseases associated with aging.

Determinations of individual veterans' needs are made at the clinical level, within the patient-physician relationship. Usually, the health professional caring for the patient requests procure-

ment of needed medical devices through the VA Supply Service in an individual VA medical center. However, procurement of prosthetic devices is handled differently. All prostheses, from eyeglasses to motorized wheelchairs, are obtained through the prosthetic representative, a veteran with a service-connected disability hired by the VA to serve as the purchasing agent.

Clinical teams of physicians, physical/occupational therapists, prosthetists, and prosthetic representatives meet with the veteran to decide which prostheses should be prescribed. They then choose from among the possible range of devices that have been approved by the Prosthetic and Sensory Aids Service.

Photo credit: Amigo Sales, ***Inc.***

This woman is using an Amigo power wheelchair. For the provision of power, as opposed to manually operated, wheelchairs to veterans, the VA requires the approval of an individual VA medical center.

Because of the relatively high volume of devices handled by the Prosthetic and Sensory Aids Service, the other VA rehabilitative services, such as the Spinal Cord Injury Service, have come over the years to use that service as a central purchasing clearinghouse for their own supplies and devices. This situation has involved the Prosthetic and Sensory Aids Service in ordering devices such as pacemakers that have very little to do with the actual functions of the prosthetic representatives. Although this manner of handling supply procurement has helped hold down the personnel requirements of the other services, it has also placed increased fiscal and administrative burdens on the Prosthetic and Sensory Aids Service (93,439).

The budget of the Prosthetic and Sensory Aids Service has tripled in 8 years to $84 million, and it has been projected to reach $500 million annually in 4 to 5 years (93). One of the major reasons for the steep rise in costs has been the increasing purchase of the sophisticated technology that is now available for use by disabled veterans. Another reason has been the growing population of veterans whose mobility and senses are affected by the aging process (426). Probably the most important reason for the budget increases, however, is that, by law, the provision of prosthetics to veterans is unlimited, The growth in these costs has in turn taken resources from other parts of VA health care,

Influence of Social, Political, and Economic Factors

Political and social forces greatly influence the adoption and use of medical devices within the VA health care system. As mentioned earlier, for example, veterans' service organizations frequently approach their local VA hospital administrators about buying the latest technologies for their veteran constituencies. As another example, Thompson has argued that decisions about VA hospital construction depend more on access to medical school skills and resources than on other concerns,

such as promoting access of veterans to medical care (298).

The VA medical centers have tried to make their institutions hospitable places for teaching and research. In this regard, medical schools have often successfully encouraged VA hospitals to seek the latest in equipment and specialized facilities. A study by the National Academy of Sciences noted marked proliferation of special care units in VA hospitals by the end of the 1970s (224).

Health planning and utilization review agencies (see ch. 6) have no authority over VA medical centers. The National Health Planning and Resources Development Act of 1974 (Public Law 93-641) gave the VA voting membership on State health coordinating councils and on local health systems agencies, but VA medical centers submit applications for new construction or equipment to the local health planning agencies on a strictly voluntary basis. Likewise, the VA has successfully resisted efforts to place its hospitals under the authority of utilization and quality control peer review organizations, which perform utilization reviews for the Medicare and Medicaid programs. Instead, the VA moved to establish its own Health Services Review Organization to foster quality assessment and utilization review.

Political and economic forces have acted to constrain the adoption and use of medical devices. The VA's overall health care budget has been stable during the past few years, and the tight budget has undoubtedly served as the most powerful rein on overadoption. In addition, the congressional appropriations committees and other oversight groups have frequently opposed the VA's autonomy in decisionmaking with regard to resource allocation. In 1978, for example, efforts by the VA to supplement 24 existing CT scanners with 13 additional scanners were criticized by the General Accounting Office, and congressional resistance eventually prompted the VA to withdraw the request (330). As another example, the Office of Management and Budget successfully pressured the VA to reduce its supply of hospital beds from roughly 121,000 in 1964 to fewer than 90,000 by 1980 (298).

Overall, the concurrent social and political pressures that develop incentives to overadopt devices in some areas, while constraining expenditures in others, have had important implications over time. The often sporadic patterns of adoption and use of devices and other technologies and patterns of care by the VA have led to a distribution of resources that may not be equitable or efficient across geographic areas or types of facilities. Thus, for example, although the VA is an international leader in such areas as cardiac care and radioisotopes, fewer than one-third of the VA medical centers had CT scanners in 1983 (150). In fact, an extensive study by the National Academy of Sciences in 1977 found ample evidence of maldistribution in terms of equipment, basic and specialized services, staffing, and number of beds (224).

Strategic Planning

There is every indication that with regard to medical device and technology acquisition, the VA is in transition. Perhaps the most significant initiative undertaken by the agency in relation to medical equipment adoption and use has been the implementation since fiscal year 1981 of Medical District Initiated Program Planning (MEDIPP). The MEDIPP process is an attempt to create a decentralized long-range "strategic planning system" in which major plan development responsibilities are assigned to the VA's 28 medical districts.

The VA has recognized that past resource-based planning and management approaches are no longer feasible in an era of stable or declining health care budgets and changing demands by its aging veteran population. Although there will be increased demand for services in the short term as the size of the elderly veteran population grows, in the long-term, demand for services will decline as this largest group of beneficiaries now entering old age dies.

Because the future certainly holds cutbacks or termination of specific services or facilities, understanding and acceptance within the VA and its constituencies are important factors in the eventual success and implementation of the MEDIPP process. A key element of the new planning process is its emphasis on involving administrative and clinical personnel at several levels within the VA Department of Medicine and Surgery (429).

The MEDIPP process consists of a cycle of events throughout the fiscal year. It begins with direction by the VA's Chief Medical Director on broad-based issues, objectives, and goals for the future. Each VA medical district then appoints a District Planning Board and staff to develop a district plan within the overall framework of systemwide goals. The district plans include a demographic analysis, a workload forecast, and a review of the local resources that are submitted by the VA health care facilities within its jurisdiction. Finally, the district administrators and councils review and approve the district plans and submit them to the VA Central Office (218, 426,432).

The first MEDIPP cycle ended in November 1982 and covers fiscal years 1985 to 1990. An internal VA study examined the relationship between technology needs and the MEDIPP plans that were submitted (45). It found that most of the medical districts were using the MEDIPP process to request the purchase of specific major medical devices and equipment, in addition to proposals for the creation, expansion, or dismantling of services. In effect, the MEDIPP process could serve as a vehicle for identifying and monitoring the need and demand for various types of major medical equipment. The study also found that VA administrators and planners ranked the issue of device acquisition (and the larger issue of medical technology) fourth in importance among 50 VA-wide issue areas.

These findings confirm and reinforce the potential utility of the MEDIPP process, not only as a planning tool, but also as an early warning and tracking system for major equipment adoption and use. As new device and equipment requests begin to surface through medical district plans, a coherent and well-focused program of evaluation could be initiated (45). Such evaluations could include broader technology assessment issues such as devices' cost effectiveness in the overall delivery of care.

Another new process that may affect medical device adoption and use is setting the budgets of VA medical centers on the basis of diagnosis related groups (DRGs) (103). Although the VA has budgeted prospectively because of the congressional appropriations process, the use of a case-mix measure such as DRGs is intended to distribute the available funds more rationally among the medical centers.

DRGs classify patients according to principal diagnosis, presence of a surgical procedure, age, presence or absence of significant comorbidities or complications, and other relevant criteria. The new Medicare prospective payment system for hospitals is also based on DRGs (see ch. 3). Both the VA budgeting system and the Medicare payment system use similar mathematical models to assign patients to DRGs and to allocate resources among DRGs.

Data sources included all VA discharge abstracts, costs across different service categories (medical, surgical, psychiatric), the current 470 DRG model,[5] and the New Jersey Reimbursement Schedule. Since the VA has no patient-based method of assigning costs, the VA used New Jersey cost data to assign relative DRG weights to the VA discharges, and these weights were used for allocation decisions (104).

The VA expects the new budget method to encourage more efficient use of resources within hospitals and to distribute the funds more rationally because hospitals will receive funds on the basis of case mix instead of historical budgets. DRGs are also to be used in VA utilization review and quality assurance programs (104). Adoption of medical devices will be more affected by MEDIPP, although DRG budgeting will probably affect use of the devices.

[5]There are 467 DRGs, plus 3 that require special treatment of the data: DRG 468 flags an operating room procedure that is unrelated to the principal diagnosis; DRG 469 represents a patient with a diagnosis that is valid as a principal diagnosis, but not acceptable as a principal diagnosis; and DRG 470 indicates invalid data.

DISCUSSION AND POLICY OPTIONS

The VA has the potential to use its extensive procurement to influence the type and price of medical devices that are developed and marketed. Although the VA appears to have obtained lower prices because of purchases from least-cost suppliers, other procedures such as more standardized purchases and volume commitments to device suppliers might result in greater price reductions. In addition, R&D evaluation, and procurement have been separate, unintegrated activities within the VA. The potential of the VA's leverage has not been realized in stimulating the development of certain types of devices. Nor have the results of the VA's own R&D and evaluation activities been systematically incorporated into the VA's procurement and adoption decisions.

In an attempt to coordinate these activities, the VA is discussing an administrative reorganization that would put the Rehabilitation R&D Service, the Prosthetic and Sensory Aids Service, and the VA Prosthetics Center in one line (39). The following sections offer options for specific improvements within the areas of R&D, testing and evaluation, procurement, and adoption and use of medical devices by the VA health care system.

Research and Development

To give increased focus to its rehabilitation research efforts, the VA in 1973 organized the Rehabilitation R&D Service. More recently, the VA has established rehabilitation R&D centers that are affiliated with engineering schools (two at present, six more planned by 1986) for broader outreach. However, when inflation is taken into account, the VA's funding commitment to R&D has been stable *or* declining. Veterans' service organizations have expressed concern about effective cutbacks in R&D budgets, especially in the areas of prosthetics research and research on sensory aids for the blind and hearing-impaired.

Option 1: Increase the VA's funding for rehabilitative research that is focused on longer term development of devices.

The appropriate placement of rehabilitation R&D of this type could be at the rehabilitation R&D centers, at the VA Prosthetics Center, or at both, depending on the goals of the Rehabilitation R&D Service. The rehabilitation R&D centers at Hines and Palo Alto are connected with their local engineering communities. The primary mission of these centers is to apply advanced technology to assist physically handicapped veterans with the goal of commercialization of the devices.

The VA Prosthetics Center combines the development of commercially available prosthetics and sensory aids with clinical activities through an integrated management. Its engineers and professional personnel work closely with patients in several VA medical centers, customizing prosthetics and generally applying the expertise of the research engineers to present problems. In addition, within a fixed budget, any decision to channel more funds to long-term rehabilitative research would require a determination that such research was more worthwhile than other uses of these funds.

Testing and Evaluation

The responsibility for testing and evaluating medical devices is divided among several VA organizational units.The Rehabilitation R&D Service evaluates rehabilitative prototype devices that are still in the developmental stage. Once the medical devices are commercially available, the responsibility for evaluation is split between the Prosthetic and Sensory Aids Service for rehabilitative devices and the Office of Procurement and Supply for all nonrehabilitative devices, equipment, and systems purchased by the VA. The Disabled American Veterans organization has called the evaluation system fraught with inefficiencies and communication breakdowns. Efforts of the various organizational units have sometimes overlapped and unnecessarily duplicated each other.

The absence of internal planning and coordination for its evaluation activities has generally been recognized by the VA. Recently, the Rehabilitation R&D Service created the Rehabilitation R&D Evaluation Unit to coordinate and improve testing of prototype rehabilitative devices, and the Prosthetic and Sensory Aids Service formed the

Prosthetic Technology Evaluation Committee to develop a formal evaluation and coordination process for commercially available rehabilitative products. The Office of Procurement and Supply established the Testing and Evaluation Staff in 1976 to provide evaluations of nonrehabilitative medical devices, equipment, and supplies. The evaluations are incorporated into national procurement contract requirements, but are advisory only. Purchasing decisions still rest with individual hospitals.

These improvements in evaluation processes may result in more appropriate adoption and use of medical technologies by the VA. They may also result in better adoption and use of medical technologies by other Government agencies and by the private sector through the dissemination of evaluation findings. Although it is premature to assess these newly created committees and programs, options for specific improvements are presented below.

Option 2: Encourage the expansion of field testing of rehabilitative devices by the VA Prosthetics Center.

The VA Prosthetics Center is charged with performing "compliance testing" on all commercially available rehabilitative devices for the Prosthetic and Sensory Aids Service. Devices can undergo either special laboratory testing or field testing at VA medical centers, or both.

Field testing is advantageous in that it allows an evaluation to more accurately assess a device's usefulness to the veteran population. Because of organizational difficulties, however, the VA Prosthetics Center has never used field testing to its fullest possible extent.

Until fiscal year 1984, there was no line authority from the VA Prosthetics Center or from the Prosthetic and Sensory Aids Service to the VA medical centers, where the field evaluations are performed. Absence of line authority had resulted in a loss of control by the testing units over adherence to protocols and reporting of evaluation data and often created initial resistance to cooperation in device studies.

The new Prosthetic Technology Evaluation Committee, which includes representatives from all the concerned organizational units within the VA, is mandated to classify devices into groups which will determine the types of evaluations that the devices will undergo. This committee will need to establish some internal control over the VA medical facilities to assure adherence to evaluation protocols and the collection of accurate data during expanded field studies.

Option 3: Require the VA to conduct more comparative evaluations before purchasing commercially available devices.

Evaluations of devices by the Testing and Evaluation Staff of the VA's Office of Procurement and Supply are usually internal "consumer research" efforts that take the form of user surveys. Although not scientifically rigorous, they do provide an information base for purchasing by individual VA medical centers. The VA estimates that only about 20 percent of its medical centers strictly adhere to purchasing decisions based on these evaluations. However, results of the evaluations are also routinely requested by private hospitals, nursing homes, and State and local governments.

Evaluative information would be improved if more comparative evaluations that identified the positive and negative consequences of purchase and use of particular products were undertaken. Product quality features—such as safety, durability, and performance—could be more closely matched with cost considerations. More valid results would also result from evaluating larger samples.

Although the VA currently prohibits explicit comparison of one product with another, the Testing and Evaluation Staff has attempted some group evaluations of classes of devices. The primary obstacle to expanding these efforts has been staffing and budgetary constraints. These constraints might have to be eased in order to provide better evaluative information for VA purchasing decisions.

Procurement

Available evidence indicates that the VA's centralized procurement programs, through various contract and distribution mechanisms, have for the most part created favorable prices for medi-

cal equipment and supplies for the VA medical centers, Some policies, like the most favored customer clause, almost certainly reduce the VA's equipment procurement costs, but at the same time have the effect of increasing the prices that private buyers must pay for medical equipment. At least one policy, the VA's refusal to provide volume commitments to contractors, probably results in the VA's not getting the lowest prices possible for some medical devices. Other policies are more ambiguous with respect to their impact on procurement costs.

A greater problem for the VA is the extent to which the VA medical centers fail to use centralized procurement channels. VA medical facilities now purchase about 39 percent of their supplies and equipment on the open market, up from 10 percent in the early 1960s. This individual purchasing reduces the advantages available to the VA as a large institutional buyer.

Option 4: Encourage the VA to increase the proportion of its procurement of equipment and supplies by centralized contracts to realize lower costs from the VA's leverage in the marketplace.

Combining quantity purchases of equipment and supplies on a national basis through centralized procurement could result in lower product costs through price discounts, Centralizing more device purchases could increase the VA's buying power and could lead to even greater price discounts.

There are problems, however, in getting physicians to support more centralized procurement. As part of the effort to retain physicians on staff, it has been the practice of the VA since the 1960s to allow physicians to choose their own brands of medical equipment and supplies. The difficulty of achieving physician / user acceptance of one specific type of medical equipment is a substantial obstacle to increasing centralized procurement.

Use of consensus groups might be one mechanism to help physicians reach agreement, or perhaps hospital administrators could be given greater authority. The extent of disagreement among physicians regarding the desirability of particular brands or models of medical equipment varies depending on the type of equipment, the number of manufacturers, and other less tangible factors.

Adoption and Use

Because of incentives to overadopt in some areas and concurrent financial constraints in others, the VA has experienced sporadic patterns of adoption and use of devices and other technologies that have led to a distribution of resources that may not be equitable or efficient across geographic areas or types of facilities. For example, some types of major medical equipment, such as CT scanners, may have been underadopted by the VA because of political pressures to contain costs. On the other hand, by statute, the provision of rehabilitative devices to veterans is unlimited. As a result, resources have been drained away from other parts of the VA's health care budget as costs for rehabilitative devices have expanded.

Option 5: Encourage development of comprehensive evaluations of major medical equipment as part of the VA> strategic planning process.

The VA lacks systematic methods for distributing major new medical equipment among its medical centers and within its districts. The new MEDIPP (Medical District Initiated Program Planning) process is an attempt to create a decentralized long-range strategic planning process in which plan development responsibilities are assigned to the VA's 28 medical districts. The MEDIPP process could serve as a vehicle for identifying and monitoring the need and demand for various types of major medical equipment. A coherent, focused evaluation program could then be initiated to guide the adoption and use of new medical equipment within the VA.

In June 1983, the VA's Chief Medical Director formed a High-Technology Assessment Group to determine future VA policy on the acquisition of major new technologies. Comprehensive technology assessments have not as yet been used extensively in the VA health care system. The VA continues to face the constraints of stable or declining health care budgets, and the use of analytical methods to evaluate the health and economic effects of technologies could assist in developing in-

formation for allocating health care resources more effectively and equitably than in the past. The process of conducting such evaluations would raise relevant issues and the results might provide useful information. But decisions about device adoption and use would still require judgments about factors such as equity and ethics that are difficult to incorporate into an analysis.