Chapter 3

Research and Development of Devices

Chapter 3

Research and Development of Devices

Though the Federal Government purchased medical devices as long ago as the years following the Civil War, groundwork for the current system of device-related research and development was laid in the 1940s by the National Academy of Sciences and the Armed Forces in response to the postwar needs of veterans. Much initial research on prosthetic devices was conducted by the Department of Defense (DOD) and the Veterans Administration (VA). Since 1947 the VA has spent over $3o million on prosthetics research alone. Prosthetics research, along with growing research in other areas, still continues in the VA system (109).

VA research and development are now divided among three programs or "services": Medical Research, Health Services Research and Development, and Rehabilitation Research and Development (Rehabilitation R&D). Only the last, Rehabilitation R&D, is substantially concerned with medical devices and so is the main focus of this chapter. The other two services are briefly described, since their programs do affect device evaluation and procurement specifically and technology transfer generally, as later chapters report.

MEDICAL RESEARCH

The Medical Research Service provides opportunities for clinicians and scientists to study the health problems of veterans. During fiscal year 1981 approximately 4,100 investigators participated in 5,44o medical research projects conducted at 129 VA health care facilities, including medical centers and independent outpatient clinics (118). Since many VA investigators are health care providers in VA medical centers, many of these studies emphasize the practical care of veterans and the general population (119).

Research Programs

The *Merit Review Program* is by far the largest program within the Medical Research Service, involving approximately 2,000 funded investigators. This research is investigator initiated, as opposed to centrally directed. Although the program supports basic science, it emphasizes clinical research. Approximately 85 percent of all principal investigators in the VA system are physicians who carry out their research part time, spending most of their time with veteran patients. Research interests arise from daily clinical practice, and results are applied to patient care. Each investigator pursues his or her own interests, and each competes against all the others for funding.

High Priority Research focuses on problems of particular importance to veterans, whether because of the prevalence or incidence of a condition or because it results from military service, especially from combat *(142).* Current research areas are aging, spinal cord injury and tissue regeneration, schizophrenia, alcoholism, Agent Orange, and delayed stress disorders.

The *Cooperative Studies Program* supports multi-center clinical trials within the VA system. The program is administered through the VA Central Office in Washington, DC, and has one experimental drug unit and four centers to coordinate data in different parts of the country.

As of September 1982, 19 studies were in progress, 11 were in active planning, and 12 were in final analysis (106,142). The largest number of trials have tested drug therapies, followed by trials of types of surgery, such as coronary artery bypass grafts. Although most trials have concerned treatments, many have also focused on preventive health care measures, such as control of hypertension. The mix of VA clinical trials is much like that of the National Institutes of Health (NIH), except that fewer VA trials focus on cancer treatment.

Clinical trials follow a well-defined path from inception to publication. Ideas for studies come from VA physicians and investigators around the country. They are considered by VA panels and outside advisers, and if judged worthwhile and appropriate for VA research, are planned and carried out. Each study is assigned to a coordinating center for help in designing, conducting, and analyzing the trial (106).

The Cooperative Studies Program enables researchers to obtain large enough samples with geographic diversity to permit valid generalizations—for example, about the relative values of different treatments or the etiology and natural history of a medical disorder. One Army-VA Cooperative Study revolutionized the treatment of tuberculosis, virtually emptying tuberculosis wards in the early 1950s (142).

Other Medical Research

The VA not only funds research, it is also involved in clinical trials funded by others, such as NIH and pharmaceutical companies (106). The Medical Research Service maintains a computerized data system that encompasses all VA research, including that funded by outside sources.

The VA also supports the retrospective collection and analysis of data on medical procedures and devices, which, although not intended for research can still be used in research. For example, a 1980 VA Inspector General Audit of cardiac pacemaker procurement concluded that the VA's requisition and monitoring of pacemakers should be more closely controlled (120). Senate hearings later that year raised concerns about the VA's ability to track pacemaker patients and to identify and protect those affected by recalls. These events prompted the VA to develop a pacemaker registry and prosthesis profiles for all VA pacemaker patients. The registry is now reviewed periodically for both procurement and clinical care, and information is exchanged with other interested Government agencies, such as the Food and Drug Administration, DOD, and NIH (113).

HEALTH SERVICES RESEARCH AND DEVELOPMENT

The Health Services Research and Development Service (HSR&D) develops and supports projects to evaluate alternative policies and technologies for clinical and administrative decisionmaking in VA health care. HSR&D emphasizes management tools, as in developing an information system for VA clinicians, administrators, researchers, and consumers (31,119).

Recent broad research priorities focus on care of the aged veteran, VA health care operations, the cost effectiveness of patient care technologies, rehabilitation services, and preventive health care. HSR&D supported 36 investigator-initiated research projects at 25 VA medical centers during fiscal year 1982, In a VA pilot program of preventive health care established in response to Public Law 96-22, subjects of research are schizophrenia, hypertension, psychiatric screening, and dentistry, along with the evaluation of some preventive health care services (32,119).

Four regional field programs have recently been established to integrate research with the information requirements of managers and clinicians. These field programs conduct research, provide technical assistance to investigators and consultation to administrators and clinicians, educate VA staff about the uses of health services research, and serve as a systemwide resource in such areas as care of the aged veteran, ambulatory care, and operational efficiency. In addition, HSR&D addresses information needs of VA Central Office managers.

REHABILITATION RESEARCH AND DEVELOPMENT

Rehabilitation R&D (formerly Rehabilitation Engineering R&D) is the most directly important VA Service in relation to medical devices. Rehabilitation R&D was the VA's response to the needs of disabled people, particularly veterans. The Service evolved from the R&D Division of the Prosthetic Service, dating back to *1946,* and was at first mainly an artificial limbs program. In 1973, as a result of increased national focus on rehabilitation research and engineering needs, Rehabilitation R&D was separated from other VA R&D and given a mandate to improve the quality of life and facilitate the independence of physically disabled veterans (109, *127).* This mission is to be accomplished through research, development, and evaluation of new devices, techniques, and concepts in rehabilitation. The Rehabilitation Act of 1973 (Public Law *93-112),* additionally requires Rehabilitation R&D to cooperate and coordinate activities with the National Institute of Handicapped Research, Legislation further requires research and development for automotive adaptive equipment (153).

Rehabilitation R&D primarily develops sophisticated, "usable" devices to help individuals. Other goals include improved rehabilitation methods (e.g., functional electrical stimulation and methods to avoid decubitis uIcers, or bedsores) and technology transfer, including increasing the availability of new devices on the open market. Rehabilitation R&D does not directly furnish or fabricate devices for veterans; rather, prototype devices are developed and adapted from commercially available items purchased from local private sources (153). Successful models may then be produced commercially.

Rehabilitation R&D organizes both intramural and extramural research and development programs, has established Rehabilitation R&D Centers and research affiliations with engineering schools, and generally attempts to ensure the dissemination and clinical use of new devices, techniques, and concepts (144).

The topics of Rehabilitation R&D range from traditional artificial limbs to robotic devices for the totally paralyzed person (153). Activities are concentrated in three areas, representing the most prevalent service-connected disabilities:

- Prosthetics *and amputation.* Rehabilitation R&D emphasizes lower limb prosthetics, including improved fitting techniques, especially for the elderly. Rehabilitation R&D is now most heavily committed to this area, which represents about *40* percent of its total budget.
- *Spinal cord injury.* Rehabilitation R&D devotes about *30* percent of its budget to improving wheelchairs by improving motor and controller efficiency, reducing noise, and developing a fail-safe braking system.
- *Sensory aids.* Special emphasis is given to aids for visually impaired people. Studies include those of new sensory aids, people's mobility and orientation needs, and new communication and vocational aids. This area represents about 30 percent of the Rehabilitation R&D budget (119,152).

Table 1 presents a summary list of Rehabilitation R&D projects in fiscal year 1983. Research priorities are identified in special meetings, which include representatives from rehabilitation research, clinicians, manufacturers, and disabled veterans' consumer groups. Workshops and seminars in fiscal year 1982 focused on hearing impairment, prosthetics, and commercializing VA technology (152). (For the views of veterans' groups on VA research, see app. B.) Rehabilitation R&D has not traditionally supported device development for cardiovascular, pulmonary, and renal disabilities because they have seldom been service connected (153). However, such devices may receive attention in the Medical Research Service and be used in VA clinical practice.

Rehabilitation R&D Centers

Three VA Centers perform and support rehabilitation research and development. The VA Prosthetics Center (VAPC) in New York City' is

'Within the VA, VAPC has also unofficially been known as the Prosthetics Evaluation, Testing, and Information Center, and the Rehabilitation Engineering Center.

Table 1.—Summary of Rehabilitation Research and Development Projects, Fiscal Year 1983

Topic	Number of projects
Prosthetics/amputation:	
Diagnostic procedures	4
Surgical procedures	9
Internal joint/prostheses	17
Gait analysis	5
Maxillofacial prostheses	1
Prosthetics and orthotics	8
Total	44
Spinal cord injury:	
Mobility (including wheelchairs and automotive adaptive equipment)	***6***
Manipulative devices (including computer-assisted devices and environmental controls)	2
Surgical procedures	5
Neuromuscular control (including functional electrical stimulation, nerve conduction studies, and neural models)	**10**
Total	***23***
Sensory aids:	
Blindness and visual impairment	***8***
Deafness and hearing treatment	***9***
Speech impairment	***5***
Total	22
Technology dissemination and use:	
Rehab R&D centers	2
Rehab R&D affiliation	2
Information dissemination	6
Total	10

SOURCE: Office of Technology Assessment, 1984,

organizationally separate from Rehabilitation R&D.[2] VAPC was established in 1956 to conduct research and development in rehabilitation engineering, to evaluate commercially available devices, to provide customized devices for difficult cases,[3] and to manufacture and distribute orthopedic footwear and prosthetic and orthotic devices. In the 1950s, VAPC was the basis of a successful VA intramural research program, developing most of the prosthetic limbs and the fitting techniques used today (127).

A recent audit report (1982) by the VA's Office of Inspector General, however, disclosed substantial management problems at VAPC over the last several years and recommended changes in its goals and organization, including the discontinuation of its research and development program (139). The VA hopes to transfer VAPC'S Development Section to the Technology and Performance Evaluation Service. Personnel in the Research Section were offered reassignment to the Engineering Service at a nearby VA hospital (22). (Other VAPC activities and program changes are discussed later in this report.)

The other two Rehabilitation R&D Centers were established only in the last few years and are directly tied to the VA Rehabilitation R&D program. One is in the Palo Alto VA medical center in California, the other in the Hines, Illinois, VA medical center outside Chicago. Six more Centers are planned by 1986.

These Centers provide engineering support in VA medical centers where there are existing relationships between VA medical and engineering communities, and they are affiliated with leading engineering schools, just as 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 new procedures and devices in engineering. The Centers' primary goal is to apply advanced technology (e.g., microprocessors) to help physically handicapped veterans. The VA views the Centers as natural outcomes of engineering school affiliations that successfully produced new rehabilitative devices, techniques, and concepts in VA clinical settings.

Each Rehabilitation R&D Center is administered by a director and an assistant director, one a physician and the other a rehabilitative engineer, Each Center is staffed with investigators and technicians, but receives administrative support from its associated health care facility (144).

The Rehabilitation R&D program is also establishing university-affiliated engineering research

[2]Since this technical memorandum was drafted, the VA has proposed a reorganization that would put VAPC, Rehabilitation R&D, and Prosthetics and Sensory Aids Service under one director.

[3]VAPC represents a merger of the New York Regional Office and the Prosthetic Testing and Development Laboratory, then part of the Research and Development Division of the Prosthetic and Sensory Aids Service, to bring research and clinical programs together for the benefit of each. In 1969, VAPC established a program of satellite stations to help its engineers and professional personnel work more closely with patients at the site of hospitalization. Such stations have been established at VA hospitals in Brooklyn, NY, East Orange, NJ, the Bronx, NY, and Castle Point, NY.

programs to help support graduate students and faculty who undertake rehabilitation engineering projects. The program is designed not only to interest engineering students in rehabilitation, given the critical shortage of trained rehabilitation engineering professionals in this country, but also to infuse new ideas into the Rehabilitation R&D program through its frequent communication with academia (19,30,109).

Technology Transfer

Part of the VA's rehabilitation research program mandate (38 U.S. C. sec. 4101(c)(2)) is to test prosthetic, orthotic, and orthopedic appliances and sensory aids, and to disseminate VA results and information for the benefit of all disabled persons (154).

The VA has traditionally attempted to ensure the clinical use of new devices, techniques, and concepts in three major ways:

- Through VA investigators who have appointments in affiliated medical or engineering schools and who can communicate the results of VA research to students and colleagues.
- Through peer-reviewed research in the VA intramural program. Because competition for support is keen and the review considers the number and quality of publications and presentations at scientific meetings, there is pressure to disseminate information promptly to the research community, whether in the VA or outside.
- Through funded Rehabilitation R&D investigator;, two-thirds of whom are involved in patient care and have direct professional interests in physically disabled veterans. Application of recent results can thus be direct (144).

Rehabilitation R&D also supports the Office of Technology Transfer, whose main responsibility has been preparing the *Journal of Rehabilitation R&D* (formerly the *Bulletin of Prosthetics Research).* The Office also maintains the Prosthetic Reference Collection and the Prosthetics Film and Audio-Visual Lending Service for interested researchers and clinicians (144).

DISCUSSION

The goals and priorities of VA R&D are diverse, given its extremely broad mandates to address veterans' complex and difficult problems. VA R&D is especially important for rehabilitative devices, because the markets for many are small and fragmented. In the past, unless the stages of research, development, and transfer have each been publicly funded, market incentives have often been insufficient to ensure the availability of rehabilitative devices from private firms *(109).*

Table 2 summarizes the VA R&D budget. Although the commitment to R&D in current dollars has increased over the past few years (and substantially increased for Rehabilitation R&D in fiscal year 1983), the budget is stable or declin-

able 2.—Veterans Administration R&D Budget Overview (thousands of dollars)

	Fiscal year						
	1977	1978	1979	1980	1981	1982	1983
Medical research program	$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 program	**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 program	3,604	2,996	3,004	3,153	3,083	2,828	3,786
Staffing	45	90	105	104	104	93	120

SOURCES" U S. Veterans Administration, Off Ice of Budget and Finance, *Congressional Budget Submission* (Washington, DC, 1983); R. Nolan, US Veterans Administration, Office of Budget and Finance, Washington, DC, personal communication, September 1983.

ing when inflation is taken into account. Furthermore, as a proportion of medical care expenditures, funds for R&D have steadily declined for over a decade: In fiscal year 1970, R&D accounted for 3.4 percent of the total medical care costs, in 1982, only 2 percent (144).

Veterans' service organizations have expressed great concern about the effects of relative cutbacks in R&D budgets, especially those for prosthetics and sensory aids.

VAPC has encouraged innovation in the past by demonstrating that new types of wheelchairs were technologically possible, safe, and most importantly, that they had a significant market—the VA (80). The Center's work with power wheelchairs in the early 1970s showed they could be safely used at speeds greater than a slow walk and on rough terrain, which encouraged manufacturers to begin making such chairs. VAPC work on lightweight sports wheelchairs had similar effects. VAPC now focuses on commercially available devices rather than prototypes, which may change the VA's role in device innovation and development.

Especially given dwindling R&D moneys, the VA peer review and advisory council systems become even more important. The Medical Research Service has a well-developed merit review system, and both HSR&D and Rehabilitation R&D have restructured and improved their systems within the last few years. The Rehabilitation R&D process, modeled on that of the Medical Research Service, relies on in-house professionals, Rehabilitation R&D directors, and a multidisciplinary panel of non-VA experts to set research priorities and review proposals and results (109). Recently, Rehabilitation R&D has also taken steps to increase consumer involvement in planning R&D, placing representatives from veterans' service organizations on its merit review board.

Rehabilitation R&D, the primary focus of VA R&D on medical devices, deserves attention in at least two other areas. The first concerns Rehabilitation R&D Centers. Funding has shifted over the last few years to these Centers and their university-affiliated programs and away from extramural support. A 1981 VA evaluation of the two existing Centers concluded that they were developing toward a "stable and productive" existence, but noted some achievements were lagging (144). Delays were experienced in selecting Center directors, in completing basic construction and renovation, and in procuring essential computers and office supplies. Procurement problems have persisted, at least at the Palo Alto Center, which buys rough!y $400,000 in devices annually (not including office supplies), because the Center must buy through the Palo Alto VA medical center procurement and supply service.

VA medical centers have relatively constant needs for medical equipment and supplies, but research centers, because of the nature of research, can exhibit highly erratic purchasing patterns. Research can also require highly sophisticated technology not normally purchased for medical care. Thus, the centralized contracting procedures used for medical center procurement may be inadequate for Rehabilitation R&D. Special contractual procedures can delay projects for a long time. The Palo Alto Center has reported equipment procurement lags of up to 18 months (53), longer than the duration of some Center projects.

The situation at the Palo Alto Center has been exacerbated by special VA procurement policies for microprocessor equipment. Much of the Center's work involves innovative uses of electronic and microprocessor technology. However, until recently all VA purchases of such equipment have been controlled by the VA's Central Office of Automated Data Processing. Even relatively unsophisticated circuit board devices costing $100 have needed approval not only of the local supply process but also of the Central Office.

Because of medical centers' increasing needs for automation, in May *1983* authority was delegated to the centers to procure all automated data-processing equipment, software, and services with a purchase value of $10,000 or less or a lease cost of $300 or less per month (53,122). Rehabilitation R&D has additionally designated smoother, more expeditious contracting procedures as one of its "special initiatives" beginning in fiscal year 1983 (152).

The second issue of interest regarding Rehabilitation R&D is that of technology transfer. For several years the VA had recognized deficiencies

in the use of results from VA-sponsored R&D on rehabilitative devices. Generally, it seems that considerable information on new devices, techniques, and concepts had been disseminated, but there were no structured efforts to transfer technology **(109). No** system routinely promoted the greater use of successful prototype devices, which were known mainly through their experimental use in VA clinical settings (144).

Rehabilitation R&D has established an interagency agreement with the Department of Commerce to identify and develop potential markets and financing for prototype devices funded and developed through Rehabilitation R&D. The program's goal is to develop a better process toward commercializing VA technologies. In addition, the VA intends to improve its in-house testing and evaluation of prototype devices.

Although still in planning, Rehabilitation R&D's new initiatives in technology transfer are a significant step for the VA with regard to medical devices. Later chapters further examine the programs mentioned here, as well as the VA's role in technology transfer.