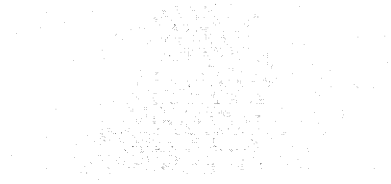
Chapter 1

Introduction and Summary



Chapter 1

Introduction and Summary

BACKGROUND AND SCOPE OF THIS STUDY

Many medical devices have been developed in recent years, and medical practice has changed accordingly, lengthening and improving the lives of American people.[1] In serving its special population, the Veterans Administration (VA) is one increasingly important provider of these sophisticated medical devices and services for diagnosis, treatment, and rehabilitation.

This technical memorandum was prepared as part of OTA's assessment of *Federal Policies and the Medical Devices Industry,* conducted at the request of the Senate Committee on Labor and Human Resources, with the endorsement of the Senate Committee on Veterans' Affairs. The memorandum responds specifically to the Senate Committee on Veterans' Affairs request for information on the VA's role in device development and procurement.

The VA health care delivery system is now the largest in the Nation, with 172 medical centers, 98 nursing homes, 16 domiciliaries, and 226 outpatient clinics,[2,3] The VA employs the full-time equivalent of almost 200,000 physicians, dentists, nurses, and administrative and support personnel. An estimated 30 million veterans are eligible for its health care services, and the VA supports a full range of these services. These same characteristics make the VA an excellent setting for evaluating medical devices and technologies (109,118).

Since the late 1940's the VA has been an important source of research and development funds, especially for rehabilitative technologies and devices. The VA evaluates new equipment for safety and technical performance. Its Office of Procurement and Supply buys many medical devices; its medical facilities acquired nearly $1.3 billion in equipment and supplies in fiscal year 1982 alone.[4] The VA is also a significant part of the market for devices such as prosthetics and wheelchairs that are designed for disabled people. In addition, other organizations, such as the Department of Defense, refer to the VA's supply catalog in making procurement decisions.

This technical memorandum emphasizes internal VA policies and procedures related to medical devices. It provides information from three different perspectives: that of the veteran as a consumer, that of the device industry as a supplier, and that of the VA itself. Topics addressed, for example, include the VA's effect on private research and development and decisionmaking more generally.

Research in the biomedical sciences, such as physiology and anatomy, provides the knowledge to develop diagnostic, preventive, and therapeutic devices. However, much of the basic research that leads to these devices is also performed in such fields as physics, chemistry, and electronics. This situation makes the creation and production of devices especially complex and difficult to analyze (7).

Nonetheless, several stages of technological development and diffusion can be identified. Ini-

[1] Medical devices encompass an enormous variety of supplies and equipment, from frequently purchased inexpensive items, such as bandages and syringes, to infrequently purchased expensive ones, such as clinical laboratory and imaging equipment. In this study the definition of a medical device is taken from the 1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act (Public Law 94-295). They define a medical device as any instrument, apparatus, or other similar or related article that is intended to prevent, diagnose, mitigate, or treat disease ***or*** to affect the structure or function of the body. Drugs, which achieve their effects through chemical action within the body, are separately defined.

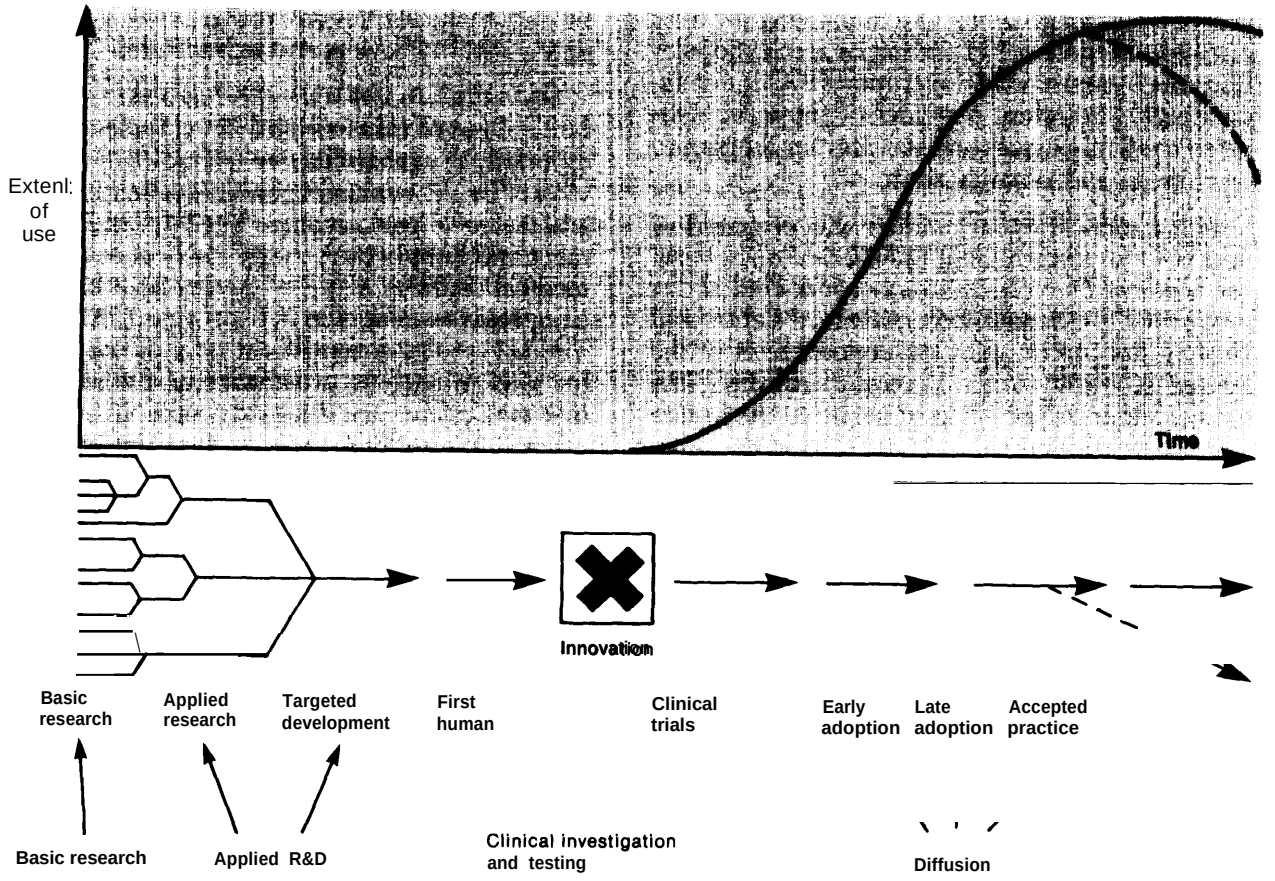
[2] Many VA medical facilities are actually self-sustaining communities, with a medical center, power plant, restaurant, fire department, garage, warehouse, movie theater, library, pharmacy, apartments, recreation areas, and business offices—with all the needs that these facilities require to operate. Medical facility purchases of equipment and supplies, therefore, also include items and services that cannot be strictly classified as medical devices (146).

[3] The Hospital Corp. of America, a private, "for-profit" hospital chain, has more facilities, but accounts for revenues only about half the size of the VA's health care delivery budget (32).

[4] Domiciliaries are homes where food, clothing, and necessary medical services are provided to ambulatory veterans.

tially, the results of basic and applied research are consulted in preparing specifications and building prototype devices (fig. 1). The next stages, refining the prototype for marketing and testing its safety, reliability, and performance, may be even more costly and lengthy than developing the prototype. Following development, facilities for manufacturing the device must be planned and constructed, and marketing efforts begun. Finally, devices are manufactured, purchased, and used.

Figure 1.—The Development and Diffusion of Medical Technologies



SOURCE: Office of Technology Assessment, Development of *Medical Technology: Opportunities for Assessment* Washington, DC US. Government Printing Office, stock No. 052-003-00217-5, August 1976), as amended.

SUMMARY

Veterans and the VA Health Care Delivery System

Among congressionally mandated benefits are health care services for eligible veterans. Eligibility determination is complex but in brief, veterans with service-connected disabilities and veterans with non-service-connected disabilities who are unable to obtain or pay for needed medical care are both eligible for rehabilitative and other comprehensive medical services. Several other groups of veterans have been declared eligible for VA health care benefits without being unable to pay: those age 65 and over; Medicaid-eligible veterans;

former prisoners of war; veterans exposed to dioxin and other defoliants, such as Agent Orange, during the Vietnam War; and veterans exposed to nuclear testing or who served in Hiroshima or Nagasaki, Japan, between September 11, 1945, and July 1, 1946. Priorities must be established in providing for these groups because VA medical expenditures are limited. Veterans with service-connected disabilities are accorded top priority for medical and rehabilitative care, but approximately 80 percent of VA patients have non-service-connected disabilities.

Health benefits are administered by the VA Department of Medicine and Surgery, whose responsibilities include patient care, research, and education. Acute care for eligible veterans with medical, surgical, and psychiatric problems is provided in the VA medical centers, most of which are affiliated with medical schools. The VA pays for *some* care in non-VA hospitals, but usually only for veterans with service-connected disabilities. It provides ambulatory care in its outpatient clinics, although it also pays for some private physician visits on a fee-for-service basis. The VA has an extensive long-term care system, including nursing homes, domiciliaries, State veterans' homes, hospital-based home care, geriatric day care, hospice care, and community nursing home care.

A number of veterans' service organizations participate in the VA's delivery of health care. The largest of these organizations are The American Legion, the Veterans of Foreign Wars, and the Disabled American Veterans. Nationally, these groups attempt to influence legislation. Locally, they support community programs and often have an important influence on VA hospitals. Administrators respond to their inquiries and complaints and usually try to consult these organizations during major planning. Several veterans' service organizations have representatives on national advisory bodies to the VA and can influence national VA health care policy.

Research and Development

The Federal Government's role in the research and development of devices, especially in prosthetic and disability-related research, dates back to the 1930s and 1940s. The VA and the Department of Defense conducted much of the initial research on prosthetic devices. Since 1947 the VA has spent over $30 million on prosthetic device research alone, while its other research and development has also grown.

Research and development falls under three Services: Medical Research, Health Services Research and Development, and Rehabilitation Research and Development (Rehabilitation R&D). Rehabilitation R&D affects the medical devices industry most directly, although the Medical Research Service uses major medical equipment and also clinically evaluates and monitors such devices as cardiac pacemakers. Rehabilitation R&D concentrates on prototype devices in three general areas: prosthetics and amputation (especially lower limb), spinal cord injury (in developing wheelchairs), and sensory aids (especially for the visually impaired).

Increased funding for Rehabilitation R&D may be warranted, especially for the full development of devices, since in the past some potentially worthwhile prototypes seem to have been abandoned in early stages. This problem results in part from the VA's lack of structured programs to disseminate information on research and development. The VA is now addressing this problem of technology transfer through its Office of Technology Transfer and an agreement with the Department of Commerce to disseminate information on promising technologies. VA procurement procedures have also presented a problem for VA research: long delays in obtaining needed research equipment.

Testing and Evaluation

Once devices are commercially available, the VA may adopt them for use in its facilities or by veteran beneficiaries only after appropriate VA testing and evaluation. The Prosthetics and Sensory Aids Service evaluates rehabilitative devices, and the Office of Procurement and Supply tests and evaluates other types of medical equipment, such as X-ray equipment.

The VA has been active in standards development and has provided information on its work in this area to other public and private health care

delivery groups. Throughout the 1970s, the VA increasingly used standards in its prosthetics and sensory aids programs. Not only were devices evaluated, but they were also tested for compliance with set standards. Concern grew about using the standards developed for existing technologies to evaluate and purchase new rehabilitative devices. Newer standards, therefore, have emphasized performance requirements. This policy has attempted to allow innovation and yet to provide adequate control for patient safety and welfare; its success is not yet clear.

The Testing and Evaluation Staff of the VA Marketing Center in Hines, Illinois, tests and evaluates medical devices and systems purchased by the VA. The staff is part of the Office of Procurement and Supply, not part of the Department of Medicine and Surgery (fig. 2). Medical devices are selected for evaluation through requests by VA medical centers, manufacturers, or the VA Central Office, as well as through the Testing and Evaluation Staff itself. Factors affecting selection include potential volume and interest on the part of the VA. Tests are usually consumer research tests, although sometimes other types of tests are conducted in cooperation with the Medical Research Service, the Department of Defense, or outside private testing laboratories. Evaluations are advisory and do not obligate VA medical centers to purchase particular products.

Both methodological and organizational problems have been identified in VA testing and evaluation. The VA's several testing and evaluation units may duplicate efforts. In addition, the units lack control in carrying out experimental protocols. New organizational plans may ameliorate these problems if they are implemented. Comparative evaluations could be good additional sources of information for procurement decisionmaking.

Marketing, Procuring, and Supplying Devices

The Marketing Research and Analysis Program at the VA Marketing Center is a procurement resource that gathers and analyzes information on the range and quality of commercially available products and their compatibility with VA needs. The size of the VA market allows it to buy medical supplies economically through centralized procurement. VA centralized procurement for its medical centers and for other Government agencies encompasses several programs. There is evidence that centralized VA procurement of some medical devices, such as catheters, needles, syringes, surgical blades, and pacemakers, has enabled the VA to obtain lower prices than other public and private organizations. VA policies on procurement have also affected the prices of several types of major medical equipment (as shown by the study presented in app. C).

Under the terms of the most favored customer clause in VA procurement contracts, suppliers are not allowed to sell their products under similar contracts to any private buyer at a price lower than that offered the VA. This policy has reduced VA procurement costs, although it may also have increased costs to private buyers.

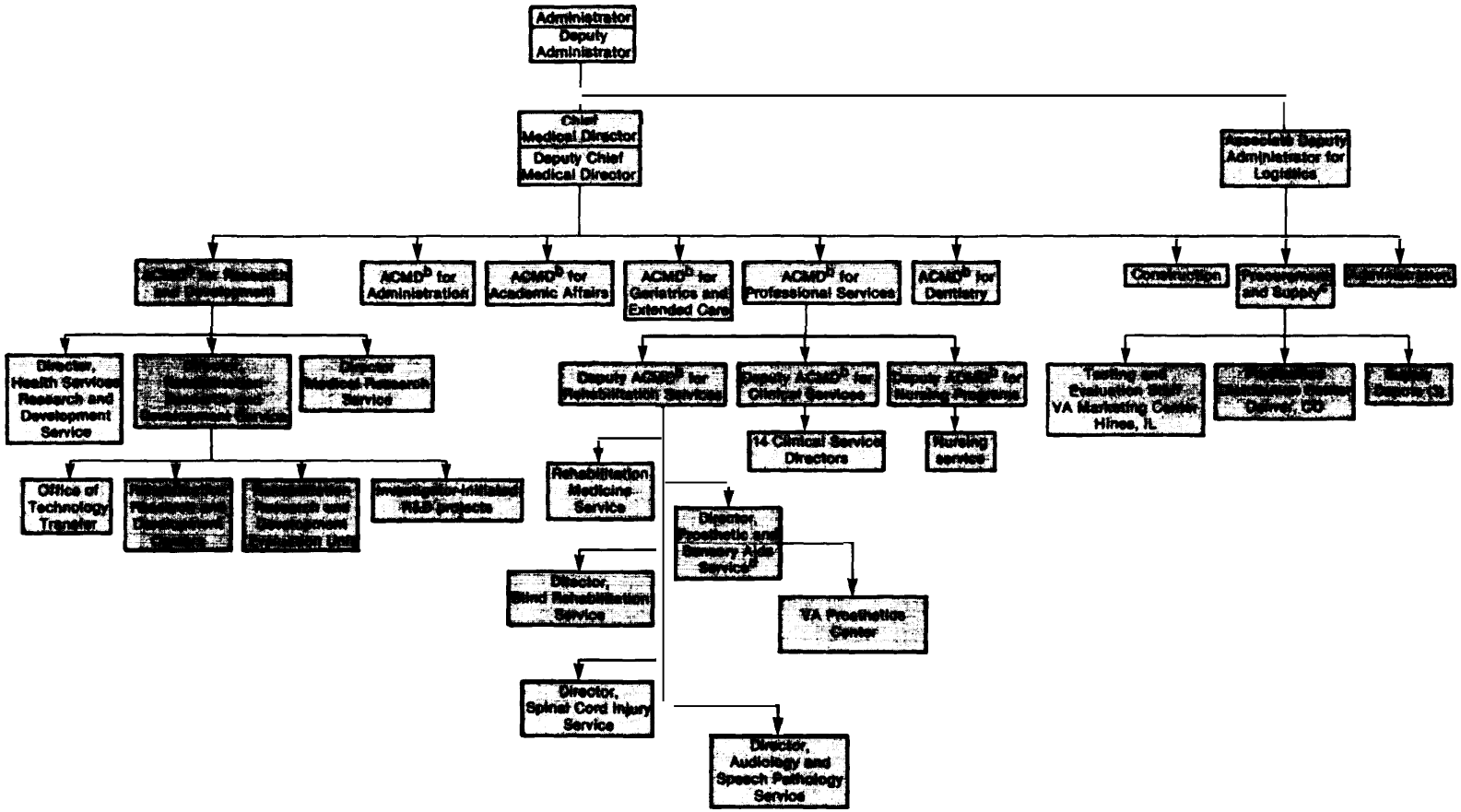
Because of the VA's brand name justification requirement, VA hospitals must justify purchasing equipment from other than the least-cost supplier on the VA list (e.g., based on service availability). Suppliers are anxious to maintain their share of the VA market, and it is likely that they lower prices to be competitive given this requirement.

VA contracts with suppliers state that prices may not be increased during the contract year, and if they decrease prices, the lower price holds for the remainder of the year. This firm fixed price clause protects the VA from price increases during a year, but suppliers may charge a higher initial price than they would in the absence of the clause.

By law, the public has access to information on VA Marketing Center procurement prices for medical equipment. This public disclosure requirement may result in higher procurement costs for two reasons. It reduces the so-called retaliation lag (the time before rival companies learn of price cuts and reduce their own prices in response). Also, the publicly known VA price may become private buyers' target price.

The VA Marketing Center does not make volume commitments, which may result in raising VA prices for many kinds of equipment. This re-

Figure 2.–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
'The prosthetic Technology Evaluation Committee advises the prosthetics and Sensory Aids Service

SOURCE. Off Ice *of* Technology Assessment.

suit depends in some measure on whether the equipment is expensive or inexpensive because of the relative transaction costs of contracts, where significant savings may be realized. An unofficial VA policy is to avoid procuring mixed equipment systems (components from several manufacturers combined in systems), to reduce warranty problems. This policy may increase procurement costs, but it may decrease repair costs.

The VA Marketing Center has also encountered problems in attempting to ensure product quality, largely because of its increasing use of simplified purchase descriptions in place of more detailed product specifications and standards, which are being phased out in response to a 1980 Federal policy directive. Product quality is likely to improve when the VA better integrates all its information-gathering activities (research, development, testing, evaluation, marketing, etc.) into purchasing contract decisions.

Local supply officers are charged with procurement for the VA medical centers. The open market may be used to purchase items not available from centrally managed sources, needed for an emergency, or available at lower prices than through the central Federal Supply Schedule program managed by the VA. In the early 1960s, open market procurement (i.e., purchases made directly by individual VA medical centers) accounted for about 10 percent of purchases; the figure is now about 39 percent. More open market purchasing permits hospital staff to select manufacturers and models that they prefer and, perhaps, to receive orders more quickly. Nevertheless, such individual purchases prevent the VA from using its potential buying power to gain lower prices through volume purchases.

Adopting, Using, and Financing Devices

All VA activities relating to medical devices have the goal of the adoption and use of good-quality, low-cost medical technologies. Because of social and political incentives to overadopt some medical devices and because of financial constraints on others, the VA has sporadically adopted devices and other technologies, and its distribution of resources may not be equitable or efficient across geographic areas and facilities. More comparative analyses of medical devices and equipment are needed to ensure better results in this regard.

The issue of financing medical devices has increased in importance as the population of veterans ages and more of them need the assistance such devices provide. The high costs of providing unlimited prostheses to veterans, as law requires, and the use of high technology in health care draw funds from the rest of the VA health care activities.

Decisions about adopting and using new medical devices would ideally be based on information about veterans' needs and the safety, efficacy, and costs of the devices and their alternatives. However, not all needed data are always available, and current VA decisionmaking does not necessarily consider all the available data. The VA lacks formal processes to decide which VA medical centers should adopt new, expensive devices and to allocate funds among the medical centers for such purchases.

Because of limited resources, in fiscal year 1981 the VA adopted a system of strategic planning, Medical District Initiated Program Planning. As new device and equipment requests are made through medical district plans, the evaluation of technologies could be focused and the adoption of new technologies could be based on more accurate information.

Conclusions

The VA's current system of medical device-related research, development, evaluation, procurement, and use has a number of significant weaknesses. Better analytical methods for evaluating and procuring the most appropriate devices at least cost could be applied at various points in technology development and use.

VA research and development, evaluation, and procurement have often been poorly integrated. The VA's potential market leverage in procuring devices, for example, has not been realized in stimulating the development of certain devices. Nor have the results of the VA's own research, development, and evaluation been systematically

incorporated in the VA's procurement and adoption decisions.

The VA recently initiated several new programs and committees that may greatly improve the VA's development and use of medical devices. The Rehabilitation R&D Service's new Evaluation Unit, which will coordinate and improve the testing of prototype rehabilitative devices, and the Prosthetic Technology Evaluation Committee, which will develop a formal evaluation and coordination process for commercially available products, are two notable efforts. These improvements in evaluation processes may result in more appropriate adoption and use of medical devices and other technologies by the VA, and indirectly, by other Government agencies and the private sector.

A last important sign of the VA's new directions is the recent formation of a High Technology Assessment Group to determine future VA policy on acquiring major new technologies. The High Technology Assessment Group could help develop information for allocating health care resources more efficiently and equitably than in the past.

ORGANIZATION OF THIS TECHNICAL MEMORANDUM

This memorandum groups medical devices into three general classes: *rehabilitative devices* (orthotic and prosthetic devices, such as artificial limbs), equipment (radiological and laboratory devices), and *supplies* (bandages, disposable, etc.). It should be noted, however, that the diversity of medical devices defies easy classification. Medical devices include products used for different medical purposes (preventive, diagnostic, therapeutic, and rehabilitative) and by different branches of medical care (e.g., dentistry, ophthalmology, orthopedics, and neurology).

Chapter 2 provides the context for discussing present VA policies on medical devices and describes briefly the history and characteristics of the VA health care delivery system. Chapters 3 through 6 address the VA's involvement in research and development; testing and evaluation; marketing, procurement, and supply; and financing, adopting, and using devices.

Appendix A acknowledges the valuable assistance of the Health Program Advisory Committee and other individuals for their information, advice, and review of drafts. Appendix B reviews veterans' service organizations and their perspectives on the VA health care delivery system. Appendix C examines VA procurement of eight types of medical equipment and the effects of VA purchasing policies on private manufacturers and buyers of such medicaI equipment.

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