

116404



UNITED STATES GENERAL ACCOUNTING OFFICE

WASHINGTON, D.C. 20548

*Handwritten initials*

HUMAN RESOURCES  
DIVISION

SEPTEMBER 22, 1981

B-204389



116404

The Honorable Edward Madigan,  
George M. O'Brien, and Henry Waxman  
House of Representatives

Subject: Issues Involved in Amputees' Use of  
Artificial Limbs (HRD-81-144)

Your October 1, 1980, letter, cosigned by former Congressman Carter, asked us to study problems amputees encounter in adapting to prosthetic devices. You were especially concerned that many amputees may endure years of frustration and pain because the prosthetic industry may have fallen behind the times, medical personnel may not learn proper surgical procedures, or prosthetic practitioners may not receive adequate training.

The enclosure to this letter contains the results of our discussion with officials of several Federal and State agencies, industry groups, and hospitals, as well as practitioners and patients.

The amount or length of suffering accompanying an amputation differs by individual. Patients' reactions to amputation can be affected by the reason for the amputation, their age, and their general physical and mental health. Experts we interviewed told us that various conditions contribute to patient suffering, some of which cannot be prevented by surgery or a prosthesis. For example, surgeons told us that daily stump changes, weight-bearing pressure applied to soft tissue, and the weight of the prosthesis often cause problems.

Adequate data are not available to determine whether amputees routinely experience avoidable pain or to assess the effectiveness of efforts by health-care providers and the Federal Government to assist the amputee. Information we obtained indicates that much is being done for the amputee, but it does not show that existing medical and prosthetic knowledge is capable of eliminating all amputee pain.

(401906)

*018621*

B-204389

Copies of this report are being sent to former Congressman Carter and to officials of the agencies and organizations discussed. We will also make copies available to interested parties upon request.

*Edward A. Neusome*

*for* Gregory J. Ahart  
Director

Enclosure

ISSUES INVOLVED INAMPUTEES' USE OF ARTIFICIAL LIMBS

In an October 1, 1980, letter, Congressmen Henry Waxman, Edward Madigan, and George M. O'Brien and former Congressman Tim Lee Carter requested us to study problems amputees encounter in adapting to prosthetic devices. They were concerned that amputees may endure years of frustration and pain because the prosthetic industry may have fallen behind the times, using outmoded techniques and marketing inappropriate devices; residents in surgery may not be learning surgical procedures that would enhance the prospects of successful prosthetic adaptation; or some prosthetic practitioners may not receive adequate training.

As a result of this request and further discussions with the Congressmen's staffs, we obtained information on:

- Amputees' experiences and problems with artificial limbs (see p. 5).
- Federal and State regulation of artificial limbs (see p. 8).
- Reimbursement policies and quality assurance requirements of Federal health-care programs (see p. 9).
- Training and certification requirements for prosthetists (see p. 11).
- Standards in surgical training and information exchange on amputation techniques in the medical profession (see p. 13).
- Prosthetic research and development programs (see p. 16).

OBJECTIVES, SCOPE, AND METHODOLOGY

Our overall objective was to provide information on prosthetic-related professional services and devices provided to amputees. We did not assess the adequacy of prosthetic devices, services, or training. Rather, we focused on describing conditions and requirements affecting the selection, fabrication, and use of artificial limbs, especially lower-limb devices. We concentrated on lower-limb prostheses because they are used by more people than are upper-limb devices.

We interviewed officials and reviewed program policies, procedures, and regulations at the following Federal agencies which deal with prosthetics or amputees.

- Department of Defense: The Army, Navy, and Air Force.
- Department of Health and Human Services: The Food and Drug Administration (FDA), the Health Care Financing Administration (HCFA), and the National Institutes of Health (NIH).
- Department of Education: The National Institute of Handicapped Research (NIHR) and the Rehabilitation Services Administration (RSA).
- Veterans Administration (VA).

We also obtained information from State public health and Medicaid officials, physicians, and prosthetists in New York and Connecticut. We discussed prosthetic reimbursement programs and quality assurance requirements with executives of Aetna Life and Casualty Insurance Company in Hartford, Connecticut, and Group Health Association in Washington, D.C.

We conducted three computerized literature searches to locate professional and scientific information on artificial limbs and the experiences amputees have with them. Finding little information on these topics, we sought expert opinions through interviews with physicians, prosthetists, and physical therapists at the National Naval Medical Center in Bethesda, Maryland, and at the following non-Federal hospitals:

- Cook County Hospital, Chicago, Illinois.
- Rancho Los Amigos Hospital, Downey, California.
- Institute of Rehabilitation Medicine, New York, New York.
- Columbia Presbyterian Hospital, New York, New York.
- Hospital for Special Surgery, New York, New York.
- Albany Medical Center, Albany, New York.

These hospitals and the National Naval Medical Center were visited because experts we talked with recommended them as having staff who are particularly knowledgeable about programs for amputees.

We discussed the experiences and problems of amputees with representatives of the Disabled American Veterans in Washington, D.C., and the Director of the National Amputation Foundation in New York City. We also interviewed amputees at the New York VA Medical Center to obtain opinions on their experiences and problems with prosthetic services and devices. These interviews could not provide reliable statistical data on the incidence of problems, but they provided insight on the unique problems amputees may encounter.

Information on the education and training of prosthetists and on requirements for certification was obtained from the American Orthotic and Prosthetic Association (AOPA), a trade group of manufacturers and practitioners; the American Board for Certification in Orthotics and Prosthetics (ABC), the professional credentialing organization for prosthetists and orthotists; 1/ and representatives of three major training centers for prosthetists--the University of Washington, Northwestern University, and New York University. A report 2/ resulting from a 1976 conference on prosthetic education supplied much of our data on developments in prosthetic education. The Residency Review Committee of the American Board of Surgery and the Committee on Orthotics and Prosthetics of the American Academy of Orthopaedic Surgeons supplied information on surgical training.

As suggested by the requestors, we visited the Institute for the Advancement of Prosthetics in Lansing, Michigan, and we have included a brief discussion of that facility's prosthetic-care approach.

#### BACKGROUND

An artificial limb is a prosthesis that an amputee uses to replace the functions of a missing limb. Prosthetists are specialists who combine standard prosthetic components to produce an artificial limb custom fitted to a patient. Physicians, prosthetists, and physical and occupational therapists have a role in rehabilitating amputees.

#### The amputee population

In 1977, there were an estimated 358,000 major amputees--persons missing part or all of a foot, leg, hand, or arm--in the domestic civilian noninstitutional population. Seventy percent of these amputees were male, 39 percent were 65 years of age or older, 38 percent were 45 to 64, and 23 percent were 44 or younger. 3/ Physicians we interviewed estimated that 45,000 to 60,000 amputations are performed annually.

---

1/Orthotists make and fit braces and orthopedic shoes.

2/"Ponte-Vedra II, a Conference on Education, Certification and Manpower Requirements in the Orthotics-Prosthetics Profession," sponsored by the American Board for Certification in Orthotics and Prosthetics, Ponte-Vedra, Florida, February 15-19, 1976.

3/National Center for Health Statistics, Unpublished Data from the 1977 Health Interview Survey in "Digest of Data on Persons with Handicaps and Disabilities," Report No. 70-123 EPW, Congressional Research Service, Library of Congress, May 21, 1979, p. 7.

Most amputees are persons who have had part of a limb removed surgically because of such conditions as tumors or peripheral vascular disease 1/ or conditions caused by trauma. According to one study of lower-limb amputees, 2/ the causes of amputation were 48.7 percent peripheral vascular disease, 35.6 percent trauma, 8.2 percent tumor, and 7.5 percent congenital. For lower-extremity amputees in this study, below-knee amputations were about three times more common than above knee, and 15 percent of the amputees had lost part of both legs.

The number of amputees who use artificial limbs is not known. However, one study 3/ estimated that about 75 percent of the people missing a lower extremity use an artificial limb.

### Service providers

Three types of surgeons perform most amputations--general, vascular, and orthopedic surgeons (orthopedists). Several different surgical specialists may work together on amputation cases. For example, a vascular surgeon may perform an amputation and then refer the patient to an orthopedist to prepare the stump for the prosthesis. Although specific data are not available, the chairman of the New York University Medical School's Prosthetics and Orthotics Department told us that general surgeons perform most amputations. In major medical centers, however, orthopedic surgeons often perform most amputations.

The surgeon plays a critical part in an amputee's rehabilitation. The surgeon determines the level of the amputation, removes the defective limb, shapes the stump so that a prosthesis can most effectively be used, and writes the prescription for the artificial limb. Physicians on the Committee on Orthotics and Prosthetics of the American Academy of Orthopaedic Surgeons told us that a surgeon with little prosthetic experience may specify only that a limb be furnished, whereas a more experienced surgeon may specify in detail the item to be supplied. Although the surgeon's involvement

---

1/A disease affecting blood vessels at or near the toes and fingers leading to diminished blood flow to these regions of the body and leading, in some cases, to gangrene.

2/Bernice Kegel, Margaret L. Carpenter, and Ernest M. Burgess, "A Survey of Lower Limb Amputees: Prosthesis, Phantom Sensations, and Psychosocial Aspects," Bulletin of Prosthetic Research, Spring, 1977, p. 44.

3/Maurice A. LeBlanc, "Patient Population and Other Estimates of Prosthetics and Orthotics in the U.S.A." Orthotics and Prosthetics, September 1973, p. 38.

in rehabilitation varies, he or she may work closely with the prosthetist and physical therapist in the patient's rehabilitation program.

As part of an amputee-clinic team, the prosthetist may become involved before surgery in assisting the surgeon to determine the best prosthesis and the best shape of the remaining limb to accommodate it. Upon receiving the prescription, the prosthetist measures and makes impressions of the remaining limb and fabricates the device. The prosthetist may make one or more casts of the limb and may try several combinations and adjustments in the fitting process. Ideally, the prosthetist will work with physical or occupational therapists to assure that the device fits correctly, has the proper alignment, and is acceptable to the patient.

In 1980, ABC listed 1,188 individuals certified <sup>1/</sup> to practice prosthetics. The number of persons practicing prosthetics who are not certified by ABC is not known but is reputed to be small. Most prosthetists are employed by private prosthetic suppliers, but some work for hospitals and government agencies. For example, VA employs 170 prosthetists, and the military employs 15.

Physical and occupational therapists help the amputee adapt to and use a prosthesis. Generally, physical therapists work with lower-limb amputees and occupational therapists work with upper-limb amputees. Often the therapist will begin working with a patient before the amputation with exercises to prevent swelling and joint tightening.

#### AMPUTEE EXPERIENCES AND PROBLEMS WITH ARTIFICIAL LIMBS

The nature, extent, and causes of pain and other problems associated with the use of artificial limbs are critical issues among amputees and those who serve them. Physicians and prosthetists we interviewed told us that pain and frustration accompany an amputation but that factors, such as the patient's age and physical and mental health, affect the severity and duration of these difficulties: Patients who have endured a lengthy, painful illness may have fewer adjustment difficulties than a person who loses a limb in an accident. Surgeons and amputees told us that some pain is unavoidable due to such routine occurrences as daily stump changes and the effect of pressure on soft tissue and that this pain was not caused by improper or poorly fitting prostheses. Amputees also told us that they sometimes experience phantom pain, in which pain is perceived as originating in an amputated limb.

---

<sup>1/</sup>The certification process is discussed beginning on page 11.

Although we did not attempt to obtain a statistically valid sample of expert opinions, the following opinions were expressed to us:

- Surgeons on the Committee on Orthotics and Prosthetics of the American Academy of Orthopaedic Surgeons told us that all amputees will have problems with their prostheses and some amputees would never be satisfied. They said that daily changes in the stump contribute to problems, but with positive management and followup, many amputees would function satisfactorily.
- The executive director of the National Amputation Foundation's Prosthetic Center told us that amputees will experience some pain because they are putting pressure on soft tissue and areas that never before experienced pressure. He said that phantom pain and normal daily stump changes are major causes of pain and difficulties with artificial limbs.
- The chairman of the Department of Prosthetics and Orthotics at New York University emphasized three points: (1) discomfort is a normal part of wearing an artificial device, (2) stump changes continually affect the device's fit, and (3) artificial limbs can be annoyingly heavy. He believed that all professions contained a few incompetent practitioners and that, in the prosthetics profession, there undoubtedly will be some prosthetists who are careless and unknowledgeable and, in these instances, prosthetic devices contribute to patient suffering.
- The director of the Orthotic and Prosthetics Department at the Institute of Rehabilitation Medicine in New York City told us that a small proportion of the amputee population may have difficulties that could have been avoided by recent advances in surgery and prosthetics. He mentioned, as an example, that because of recent developments in prosthetic devices, amputation at the knee joint is now considered one of the best kinds of amputations. However, because some surgeons are not familiar with new devices, they may amputate above the knee. He also pointed out that some amputees may suffer from nerve problems that could have been avoided by special microsurgery, but necessary microsurgery techniques may take years to filter out to practicing surgeons.

Although we did not interview a statistically valid sample of amputees, we talked with patients at the New York VA Medical Center to learn of their individual experiences and their perspectives on pain and problems with their devices. Some of their comments are shown below:



--A 60-year-old World War II above-the-knee amputee said he originally had a lot of pain and depression, and some phantom pain persists today. He said it required quite a while to adapt to the device. He also said that many amputees suffer similar problems like rashes, stump sores, and lower back problems that may continue through their entire life.

--A 55-year-old World War II below-the-knee amputee said it initially required about 6 months to adapt to a device, but with every new device the adjustment period gets shorter. He occasionally suffers phantom pain.

--A 54-year-old World War II below-the-knee amputee said it required about 5 years to adapt to his prosthesis, but about a year following amputation he could play baseball and other sports. He told us he occasionally has pain from sores on the stump.

--A 36-year-old Vietnam Era below-the-knee amputee said it required about 6 months to adapt to one device, but only 2 weeks to adapt to another. He felt there was more physical pain than psychological problems.

The Kegel survey of lower-limb amputees (see footnote 2 on p. 4) disclosed that about two-thirds of the respondents found their prosthesis comfortable and were satisfied with it. (See tables 1 and 2.)

Table 1

Was the Prosthesis Comfortable?

	<u>Below-knee</u>		<u>Above-knee</u>		<u>Bilateral</u>		<u>Total</u>	
	<u>Number</u>	<u>Per- cent</u>	<u>Number</u>	<u>Per- cent</u>	<u>Number</u>	<u>Per- cent</u>	<u>Number</u>	<u>Per- cent</u>
Yes	58	67	13	59	9	69	80	65
No	22	25	8	36	-	-	30	24
Moderate	<u>7</u>	8	<u>1</u>	4	<u>4</u>	30	<u>12</u>	9
	<u>87</u>		<u>22</u>		<u>13</u>		<u>122</u>	

Table 2Was the Patient Satisfied With the Prosthesis?

	<u>Below-knee</u>		<u>Above-knee</u>		<u>Bilateral</u>		<u>Total</u>	
	<u>Number</u>	<u>Per- cent</u>	<u>Number</u>	<u>Per- cent</u>	<u>Number</u>	<u>Per- cent</u>	<u>Number</u>	<u>Per- cent</u>
Yes	64	75	10	38	12	67	86	66
No	20	23	16	62	6	33	42	32
Moderate	<u>3</u>	2	<u>-</u>	-	<u>-</u>	-	<u>3</u>	2
	<u>87</u>		<u>26</u>		<u>18</u>		<u>131</u>	

FEDERAL AND STATE REGULATION  
OF ARTIFICIAL LIMBS

Artificial limb quality depends on the manufacture of quality limb components and the skillful and proficient fabrication and fitting of an appropriate device to the patient. Regulatory agencies, such as FDA, focus on assuring that device components are manufactured properly; professional associations, such as surgical specialty boards and ABC, focus on assuring that medical and prosthetic service providers are proficient; and agencies conducting health-care programs, such as VA, focus on assuring that patients receive appropriate devices and services.

Food and Drug Administration

Before 1976, FDA regulation of the manufacture of most devices used outside the body was largely limited to preventing false labeling and eliminating fraudulent devices, such as copper bracelets marketed as an arthritis remedy. The 1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)) broadened FDA's authority to regulate the manufacture and quality of devices. The amendments required FDA to categorize medical devices into one of three classes according to how critical the device is to the user's health.

In draft regulations, FDA has tentatively placed artificial limb components in Class I, the least critical class, and will impose general controls on manufacturers. Requirements that component manufacturers must fulfill relate to such good manufacturing practices as having (1) an adequate manufacturing facility, (2) sufficiently trained personnel, and (3) adequate records and reports. The Deputy Director of FDA's Bureau of Medical Devices said the agency plans to issue final regulations relating to artificial limbs in late 1981.

FDA has tentatively classified some factory-assembled artificial limbs, such as knee/shank/ankle/foot assemblies, in Class II. A Class II designation requires the device to fulfill performance standards for safety and effectiveness in addition to the requirements of Class I. The Class II designation will apply to artificial limbs assembled at a factory, not those custom made in a prosthetic supply house.

### State regulation

Neither of the States we visited regulates the manufacture, fabrication, or sale of artificial limbs. A representative of the New York State Health Department told us that department officials recently decided that no need exists to develop standards and regulations for prosthetic manufacturers and suppliers because few complaints had been received. Connecticut health officials also said they received few complaints about artificial limbs.

### REIMBURSEMENT POLICIES AND QUALITY ASSURANCE REQUIREMENTS OF FEDERAL HEALTH-CARE PROGRAMS

The major Federal programs that furnish or reimburse for artificial limbs are the health-care programs of VA, Medicare, and Medicaid. VA's prosthetic program incorporates quality assurance requirements in its procurement procedures and reinforces quality by supporting education, research, and information dissemination activities. The Medicare and Medicaid programs rely chiefly on the patient's physician and prosthetist to assure that services and devices are of acceptable quality.

No Government-wide quality assurance program exists for Federal procurement of artificial limbs. FDA is developing an agreement with VA and the Department of Defense to provide plant inspections of medical device manufacturers under contract to those agencies.

### Veterans Administration

Except for a few temporary devices, most artificial limbs provided to veterans are obtained from commercial prosthetists under VA contract. In fiscal year 1979, VA had 405 prosthetic supply contracts with local providers and paid \$8.9 million for 8,721 permanent lower-limb devices and \$430,000 for 522 permanent upper-limb devices.

VA's contracts with prosthetic providers establish the price that VA will pay for a specific type of device. The contracts also include a quality assurance provision requiring the provider to fulfill VA quality assurance standards and specifications.

To obtain a VA contract to provide artificial limbs, the provider must employ a VA-qualified prosthetist; that is, a prosthetist who either is certified or meets equivalent VA requirements. If the contractor wants to furnish unusually complex devices, it must show that one of its VA-qualified prosthetists has special training. Furthermore, a contractor must fulfill VA's facility specifications relating to structural characteristics, such as ramps and doorways wide enough to allow wheelchair passage.

In addition to VA's quality assurance standards incorporated in its procurement contracts, VA also promotes quality in the prosthetic services and devices provided its patients by (1) providing continuing education in prosthetics to VA staff physicians and prosthetists and (2) publishing information on device evaluations and developments emanating from VA prosthetic research.

VA's continuing education program in prosthetics sends agency physicians, prosthetists, and physical and occupational therapists to university courses and courses sponsored by the American Academy of Orthotists and Prosthetists (AAOP). In fiscal year 1980, VA spent \$164,000 to send its staff to special prosthetic-related courses.

VA's New York Rehabilitation Engineering Center augments the quality assurance program by evaluating and testing new devices and informing VA staff of the results of these tests. To further assist medical and prosthetic staff, in 1980 VA began distributing to its medical centers a new compilation of product evaluations entitled the "VAREC Review."

### Medicare and Medicaid

Artificial limbs are a specific statutory benefit of the Medicare program, but Federal law gives States the option of providing them as a Medicaid benefit. Medicaid does not maintain data on artificial limb coverage of State programs, but according to an AOPA study of the Medicaid program, in 1980, 35 States and the District of Columbia included artificial limbs, 12 States did not, and 3 States had limited coverage.

Medicare reimbursement policy provides that the proportion of an artificial limb's cost covered by Medicare depends on whether the device is supplied in a hospital. For a prosthesis supplied under Medicare Part A to an inpatient beneficiary, the hospital pays the prosthetist, and the Medicare carrier reimburses the hospital for 100 percent of the prosthetist's charge. Non-hospitalized Medicare outpatient beneficiaries can obtain prosthetic devices under Part B, which pays 80 percent of the usual, customary, and reasonable cost.

Officials of HCFA's 1/ Office of Research, Statistics, and Demonstrations told us that, because Medicare carriers do not maintain readily available, detailed data on the cost of artificial limbs and limb components, the carriers essentially base payment on the charge as submitted in the beneficiaries' claim.

Medicaid prosthetic reimbursement policies vary by State. Usually, Medicaid regulations require the prosthetic provider to accept Medicaid reimbursement as payment in full for items supplied to program beneficiaries.

HCFA does not require either program to impose quality assurance requirements on providers that furnish artificial limbs to program beneficiaries. HCFA's Chief of Coverage Policy said that, although Medicare carriers could mandate that prosthetic providers have certification, he is not aware of any that have done so. Rather, he said, HCFA relies on the physician's professional judgment to ascertain that an artificial limb is adequate and of acceptable quality.

In the Medicaid program, each State has the authority to impose specific quality assurance requirements, such as a requirement for certification, on providers of artificial limbs. AOPA's director of governmental affairs told us that some States have specific quality assurance requirements for providers who furnish artificial limbs to beneficiaries of some State health-care programs other than Medicaid. For example, California requires prosthetists who supply devices to its crippled children's program to have special training in pediatric prosthetics.

#### TRAINING AND CERTIFICATION REQUIREMENTS FOR PROSTHETISTS

Although professional certification is not essential to practice, since 1948 ABC has set professional standards for prosthetists by establishing education, experience, and competency requirements which a practitioner desiring certification must fulfill. To be certified, a person must (1) fulfill ABC's formal educational requirements, (2) fulfill practical experience requirements under the supervision of a certified prosthetist, and (3) pass a certifying examination after paying required fees. The certificate is renewed annually by paying a fee.

To sit for the certifying 1981 examination, in addition to obtaining specified practical experience, candidates must have fulfilled one of the following requirements:

---

1/HCFA manages the Medicare and Medicaid programs at the Federal level.

- Have a bachelor's degree in orthotics and prosthetics.
- Have any bachelor's degree and a long-term program certificate. 1/
- Have any bachelor's degree and complete three short-term courses.
- Have an associate degree and a long-term program certificate. 1/
- Have foreign certification status.
- Have a unique combination of qualifications.

ABC does not require certified prosthetists to attend continuing education courses to maintain certification. However, AAOP develops and schedules continuing education programs and, to provide an incentive for prosthetists to attend, grants yearly recognition certificates and issues awards to practitioners who attend courses for 3 consecutive years. Eighty-one continuing education courses were attended by 448 individuals in 1980, and AAOP awarded 174 individuals 3-year awards.

The formal educational background of most practicing prosthetists is not extensive; however, according to the Ponte-Vedre II report, in 1975 over 60 percent of all certified prosthetists and orthotists had been practicing over 16 years.

Leaders from health, education, and other professional fields became concerned about the educational needs of the profession and, in 1970, convened to develop a plan, shown on the following page, to upgrade the educational requirements for new entrants to the profession.

---

1/Long-term program certificates are awarded after the student completes a 6- to 12-month accredited course in prosthetics.

Table 3

1970 Plan for  
Increasing Educational Requirements  
for Certification

<u>Year</u>	<u>Minimum education</u>
1970	High school
1972	High school plus three short-term <u>a/</u> courses
1975	2 years of college plus three short-term <u>a/</u> courses
1980	Bachelor's degree in prosthetics and orthotics

a/Short-term courses require about 4 weeks each.

Because of a perceived shortage of practitioners and problems in funding prosthetic education programs, ABC deferred plans to require candidates for certification in 1980 to have a bachelor's degree in orthotics and prosthetics.

According to the director of the Rehabilitation Services Administration's Division of Manpower Programs, 1/ in 1980 there were 24 bachelor's degrees awarded in orthotics and prosthetics. Also in 1980, ABC had accredited prosthetic and orthotic programs at six schools: two offered 4-year programs leading to the bachelor's degree in orthotics and prosthetics, four offered long-term program certificates, and three of these also offered short-term courses.

Although data on nationwide expenditures for prosthetic education are not readily available, an RSA official estimated total nationwide spending for prosthetic and orthotic education at \$2.5 to \$3.0 million. In 1980, RSA provided grants totaling about \$1.3 million to these education programs.

STANDARDS IN SURGICAL TRAINING AND  
INFORMATION EXCHANGE ON AMPUTATION  
TECHNIQUES IN THE MEDICAL PROFESSION

Education and training standards for both general and orthopedic surgeons are high--5 years of postdoctoral residency training is generally required in both specialties. However, neither residency program has established specific requirements for training in amputation techniques or prosthetics. Statistical information

---

1/This division makes grants to programs that train workers in rehabilitation specialties.

on the prevalence of amputation training in surgical residency programs was not readily available. At hospitals we visited, residents in both programs are trained in these fields.

Although we could not assess the extent or effectiveness of information exchange on amputation surgery in the medical profession, we identified sources of information available to surgeons and the efforts of medical and prosthetic groups to disseminate information.

#### Standards in surgical training

Although the American Board of Surgery, which certifies specialists in general surgery, considers amputation procedures to be a desirable operative experience in residency training, such experience is not mandatory. The board's Residency Review Committee for Surgery, which evaluates residency training programs in general surgery to assure that they fulfill board requirements, lists amputation procedures as 1 of the 86 specified procedures in the resident's training record. Although a resident is not required to obtain experience in all 86 procedures, the number and quality of the procedures performed are factors which the board evaluates in granting a certificate.

The American Board of Orthopaedic Surgery, which certifies specialists in orthopedic surgery, states that education is expected in areas relating to prosthetics and rehabilitation. As in the case of general surgery, however, specific experience in performing amputations is not mandatory.

In a 1980 survey, the Committee on Orthotics and Prosthetics of the American Academy of Orthopaedic Surgeons, which develops continuing education programs in orthopedics, found that 106 of 120 orthopedic surgery residency programs offered some prosthetic training.

Discussions on the extent of training in amputations and prosthetics provided to residents in general and orthopedic surgery are summarized below:

- The director of the orthopedic residency program at the Hospital for Special Surgery in New York City told us that surgical residents were required to take formal training courses in both amputation surgery and prosthetics. He said that residents are on the hospital's amputee-clinic team along with the supervising physician, prosthetist, and physical therapist. He said that normally the resident consults with the prosthetist before surgery about the best type of stump needed and then is involved in the followup physical rehabilitation program. In a study, the hospital found that, for 1972-79, amputations accounted for 0.5 to 1.5 percent of all surgery.



- The associate dean for Graduate and Continuing Medical Education at Columbia Presbyterian Hospital in New York City told us that general and orthopedic surgery residents do not have formal courses in amputation surgery or prosthetics. However, he said that residents generally perform 10 to 15 amputations per year as part of their training and, throughout their residency training, would perform 25 to 30 amputations, including minor amputations of toes and fingers.
- The vice chairman of the Department of Surgery at the Albany Medical Center said that exposure to amputations is not essential, but surgical residents would normally get such exposure by either assisting or observing operations. He cited as examples one resident who had performed 19 amputations and another who had performed 16 in the past 2 years.
- The chief of orthopaedics at the National Naval Medical Center in Bethesda, Maryland, told us that the center's surgical residency program emphasized training in amputation techniques, rehabilitation, and prosthetics. He said orthopedic residents are sent to Northwestern University's prosthetic program for 2 weeks during the first year of residency. The center also has a monthly amputation conference in which surgeons and residents meet with the physical therapist, prosthetist, and patient to evaluate the patient's progress and resolve problems.

#### Information exchange on amputation techniques and prosthetics

Professional medical associations, hospitals, and government agencies sponsor continuing education courses and professional seminars and encourage the dissemination of information on surgical techniques and prosthetics by publishing and distributing journals and newsletters. Neither the American Board of Surgery nor the American Board of Orthopaedic Surgery requires specialists to attend continuing medical education courses to maintain specialty certification. Twenty-five State medical licensing agencies require some continuing medical education to maintain licensure, but this education need not be in topics associated with amputations or prosthetics.

Federal agencies sponsor several activities to promote information exchange and the dissemination of ideas on surgical techniques and prosthetics:

- VA's Rehabilitative Engineering Research and Development Service plans three to four workshops annually to which 50 to 60 surgeons, prosthetists, and rehabilitation engineers are invited to review prosthetic developments and promote innovative applications of technology.

- As a result of a symposium held in late 1979, VA plans to hold seminars for staff surgeons on amputation techniques and recent developments in prosthetics at VA medical centers in late 1981.
- In 1980, VA and NIHR jointly sponsored a conference at the Seattle VA Medical Center on amputee management.
- In fiscal year 1981, NIHR provided a \$400,000 grant to the National Rehabilitation Information Center to operate a computerized information system containing data on all commercially available prosthetic devices along with evaluative user comments and the results of clinical studies.

VA's Office of Technology Transfer, established to promote and disseminate information on rehabilitative engineering, including prosthetic research, publishes a semiannual "Bulletin of Prosthetics Research." The "Bulletin" which contains articles on domestic and foreign research, is distributed to all 172 VA medical centers.

Although amputation surgery and artificial limbs are topics of specific interest mainly to a few specialists, computer searches of the literature revealed a number of journals and reports on these subjects. Prominent among these are:

- "Annals of Surgery," Published monthly by the American Surgical Association.
- "The Journal of Bone and Joint Surgery," Published eight times yearly by J. B. Lippincott. Co.
- "Clinical Orthopaedics and Related Research," published eight times yearly by J. B. Lippincott, Co.
- "Prosthetics and Orthotics Clinic," published quarterly by AAOP.
- "Orthotics and Prosthetics," the journal of AOPA, a quarterly publication.

#### PROSTHETIC RESEARCH AND DEVELOPMENT PROGRAMS

We could not assess whether the prosthetic industry has fallen behind the times or whether it markets obsolete or inappropriate devices. Prosthetists and surgeons told us that, although some device materials or components were superior to others, none were marketed that should never be used. For example, some patients prefer devices or materials commonly associated with the past because the patients have grown accustomed to them and resist change.

Surgeons on the Committee on Orthotics and Prosthetics of the American Academy of Orthopaedic Surgeons told us that prostheses have been gradually improved since World War II. For example, about 80 types of knee-joints and new endoskeletal artificial legs, which look similar to real legs, are now available. Surgeons told us that, in the past 15 years, much of the improvement in artificial limbs has been in refinements to established techniques and devices; for example, replacing wood with plastic laminates.

Federal organizations involved in research and development of artificial limbs are VA, NIHR, and NIH. The table below provides an overview of funding for prosthetic-related research by these agencies.

Table 4

Federal Prosthetic-Related Research Funding

VA (FY 1980)	\$3,400,000
NIHR (FY 1981)	2,000,000
NIH (1981-1983)	874,000

In fiscal year 1980, VA's Rehabilitative Engineering Research and Development Service spent \$2 million to fund 36 prosthetic-related research and development projects by VA medical centers, universities, and other organizations. In addition, VA funds rehabilitative engineering research and development centers at Hines, Illinois, and Palo Alto, California, devoted to improving prosthetic-related services and developing new devices. VA also funds a major rehabilitative engineering center in New York City that for fiscal year 1980 spent about \$1.4 million to perform research and development of prosthetic and orthotic devices, including artificial limbs.

In fiscal year 1981, NIHR will spend about \$8.2 million (\$2.0 million for limb-prosthesis research) to fund 15 domestic and 3 overseas rehabilitative engineering centers. These centers conduct research into applying technology to many kinds of handicapped conditions, including amputations. According to a report by the rehabilitative engineering center at the University of Virginia, these centers are major sources of prosthetic research, development, and professional training.

NIH-funded prosthetics-related research projects are generally oriented toward fundamental explorations of the functioning of limbs and joints. Examples of NIH prosthetics-related research projects include one at Harvard University analyzing walking and gait and one at the Mayo Foundation analyzing how the elbow functions.

The director of the Orthotics and Prosthetics Department at the Institute of Rehabilitation Medicine in New York City told us

that prosthetic component manufacturers are often reluctant to produce new items that have been developed in research because the market is small. To encourage manufacturers to produce new devices that the agency has tested, VA often contracts with manufacturers to produce a few of the devices. The director of VA's Office of Technology Transfer told us that manufacturers rely largely on Government and universities for research and advances in prosthetics.

NIHR's director of the Office of Technology told us that considerable foreign prosthetic research is done, particularly in Germany, Sweden, Yugoslavia, and Japan. NIHR provides about \$150,000 annually to a rehabilitative engineering center in Yugoslavia to assist in artificial limb research. The director said that NIHR works with the International Society for Prosthetics and Orthotics, the International Committee on Technical Aids, and foreign governments to coordinate international research and prevent duplication. He said that AOPA's journal entitled "Orthotics and Prosthetics" and the "International Prosthetist," published by the International Society for Prosthetics and Orthotics, reach researchers in foreign countries and serve to disseminate information on technological innovations.

#### INSTITUTE FOR THE ADVANCEMENT OF PROSTHETICS

The Institute for the Advancement of Prosthetics in Lansing, Michigan, is a private prosthetic facility that uses a unique approach. The Institute's director believes that the facility's approach merits adoption by others. Although surgeons and prosthetists we interviewed questioned the value and necessity of the Institute's prosthetics regimen, any valid and reliable assessment of the Institute's approach to prosthetics would require an extensive study considerably beyond the scope of our work.

Differences between the Institute's approach to providing an artificial limb and that generally used by other prosthetic facilities involve test sockets, patient participation in selecting prosthetic components, and time spent with patients. The Institute's director told us that many transparent test sockets are made and are tested in both walking and standing uses. The director, who is a prosthetist, emphasized that he does not believe one test socket is adequate, but he knew of no other prosthetist who used this approach. The usefulness of a transparent socket is that the prosthetist can see where pressure is exerted most acutely on stump tissue.

However, other prosthetists and surgeons we talked with believed that routine use of multiple transparent test sockets was unnecessary. The director of the New York VA Rehabilitation Engineering Center told us that usually there should be no need for a large number of test sockets, but he believed that the patient could benefit psychologically from extensive personalized attention.

The Institute allows patients to select various component parts and try out various combinations of components in the limb assembly. Other prosthetists we talked with did not specifically encourage patients to try various combinations of components; instead, the prosthetist personally selected components.

The Institute's director told us that patients spend considerably more time and have more appointments at the Institute than is customary. Often patients spend 2 weeks and make up to 17 visits to the Institute during the initial fitting. He said that it is more common for patients to make about four visits to the prosthetist for an initial fitting. According to prosthetists at Rancho Los Amigos Hospital, numerous fittings should be the exception rather than the rule, and numerous appointments over several weeks should seldom be necessary.

The director told us that, to some extent, the Institute provides a different product mix than is common. For example, 95 percent of the Institute's patients get multiaxial feet rather than a simpler foot which is usually provided at other facilities.

According to a report published by the Institute, it treats about 150 patients annually and has a waiting list of 3,000 people. The report states that the Institute's prices are two to three times higher than is common. For example, the report states that the average cost to produce a below-knee prosthesis at the Institute is over \$5,000, whereas below-knee prostheses commonly retail for from \$1,000 to \$2,000.

