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Transfer of Rehabilitation Research and Development Results into Clinical Practice

by Margaret Giannini, M.D.*

The Veterans Administration, Rehabilitation Research and Development Service (Rehab R&D) funds approximately 100 projects a year aimed at developing new methods or improving existing techniques for assisting disabled veterans. The program was created by a Congressional mandate, U.S.C. 38, Sec. 4101, (c)(1) and (2), which directs that the VA "carry out a program of medical research including prosthetics research. Prosthetics research should include research and testing in the field of prosthetic, orthotic and/or orthopedic appliances and sensory devices."

A review of Rehab R&D scientific and engineering accomplishments provides insight into the VA/Rehab R&D technology-transfer programs. Some of the recent and ongoing research conducted under this sponsorship includes: maxillofacial restorations—to include use of biomaterials and their clinical applications; development and evaluation of robotic aids for the severely disabled; seat cushions for the paralyzed to prevent decubitus ulcers; functional electrical stimulation (FES) systems for upper extremity control; physiological effects of FES on paralyzed muscles; walking restored in a paralyzed man using FES; a motion-guiding load-bearing external frame for the knee; possible myoelectric controlled above-knee prosthesis; oprimum prosthetic foot characteristics for the dysvascular below-knee amputee.

In addition to sponsoring such research in the past, Rehab R&D has established a program concerned with the transfer of research into clinical practice. This program consists of the following six parts:

1. Establishing clinically relevant research priorities.
2. Insuring that the significant research encompasses clinically relevant factors.
3. Dissemination of research findings to the scientific community.

*For more than thirty years, Dr. Margaret Giannini has been a pioneer in creating programs for the diagnosis, treatment, education, rights and affairs of the mentally retarded, developmentally disabled and the handicapped.

In 1950, Dr. Giannini founded and directed the Mental Retardation Institute at New York College. In 1980, she accepted a Presidential appointment as the first Director of the National Institute of Handicapped Research, a branch of the U.S. Department of Education. In April, 1981, Dr. Giannini took over the position of Director for the VA Rehabilitation Research and Development Service (Rehab R&D).

In addition to these positions, Dr. Giannini is past-president of the American Association on Mental Deficiency and past-president of the American Association of University Affiliate Progams, two of the most influential organizations concerned with the mentally and physically handicapped.

Dr. Giannini is the recipient of many awards from varying organizations in recognition of her professional and humanitarian services and achievements. She also has authored and co-authored numerous publications; presented many lectures, papers, keynote addresses; and participated in panel discussions and workshops throughout the world.

A native of New York, Dr. Giannini is married to Louis J. Salerno, M.D. and has raised four sons. Dr. Giannini is scheduled to speak at the Academy Annual Meeting in Orlando on January 26, 1984.

4. Evaluation of research results for suitability for transfer to clinical settings.
5. Support to private industry to make new devices and equipment commercially available.
6. Dissemination of new methods to clinical practitioners.

Each of these is examined at length in the remainder of this paper.

Establishing Clinically Relevant Research Priorities

In the past, the VA had only general research priorities for award of Rehab R&D funds. Oftentimes researchers focused proposals on esoteric topics which were of little or no clinical significance while major clinical issues went unaddressed. To remedy this situation, a series of workshops were held with consumers and clinical leaders to develop priorities for research on clinically significant issues.

Many of the workshops sponsored by RESNA and the VA have been published. Workshop topics have included sensory aids, functional electrical stimulation, and prosthetics/amputation. Rehab R&D also has participated in meetings of the International Standards Organization (ISO) which established specific priorities within the areas of prosthetics/amputation, spinal cord injury (including wheelchairs), and sensory aids. Rehab R&D now has a policy of soliciting and approving funding for only those proposals which fall within these priorities.

Ensuring that Research Addresses Relevant Clinical Issues

There is a vast distance between research and clinical application of methods and devices. Rehab R&D has the responsibility not only to fund research, but also to initiate and support the development of the clinical methods necessary for effective application. For example, the outstanding work done by Ernest Burgess, M.D., in Seattle, and others on immediate postoperative fitting requires new and complex clinical procedures. A necessary step in promoting clinical application of this method has been the development of a clinical procedures manual and the training of practitioners and patients.

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Dissemination of Research Findings

The new VA *Journal of Rehabilitation R&D* replaces the earlier *Bulletin of Prosthetics Research* with a number of major changes. Aimed at the entire scientific community, and charged with following the highest standards of scientific quality, the *Journal of Rehabilitation R&D* is designed to offer an interdisciplinary vehicle for publication of technical materials which can most directly reach rehabilitation professionals. In addition to the *Journal,* the first edition of a new annual publication *Rehabilitation R&D Progress Reports,* is now in press. This publication is aimed at providing a comprehensive overview of research and development now in progress both in the United States and internationally. One of the publication's functions will be to serve as a guide to sources of information within the areas of Rehab R&D priorities.

Rehab R&D, in the planning stage of developing, will work in coordination with professional organizations in the field to facilitate the translation of scientific results into technical clinical information of direct relevance to practicing clinicians.

Evaluation of Research Results

The Chief Medical Director of the VA has given approval to establish the Development and Evaluation Program (DEP) for the evaluation of research and development findings to determine their suitability for adoption into clinical practice. The program is designed to stimulate, evaluate, and acquire and disseminate information, including the development of educational guidelines and technical manuals.

The educational guidelines will be coordinated between the Continuing Education Resources Service and the Prosthetics and Sensory Aids Service (PSAS). Thus, both the people who will prescribe and/or use these new devices, techniques, or concepts, will be trained. Rehab R&D will not actually provide the training, but it will provide the data and/or research scientists as instructors for the training program. This Rehab R&D program is currently limited to devices specifically developed in VA or other federally funded R&D projects.

Rigorous evaluation will provide objective and comprehensive information to the key decision makers related to clinical adoption. Information will be provided to funding agencies—including the VA—which must formally approve reimbursement of the devices or use of procedures in clinical practice; to industry so they can decide whether to add the devices to their commercial lines; and to clinicians who must decide on how to apply the new methods or devices. VA responsibility for evaluation will be shared cooperatively between Rehab R&D on new research, and by the VA's Prosthetics and Sensory Aids Service on devices which are already commercially available, but have not been previously evaluated.

Support to Private Industry to Make New Devices Commercially Available

No matter how good research and engineering results are, they are of no value unless they become available to clinicians. Many useful devices which have resulted from research are not commercially available. To overcome this

gap, discussions have been held with industrial leaders who have offered advice on the nature of the rehabilitation market, which is just one impediment. Based upon the input of these industrial leaders, commercial availability is being attacked on two fronts.

First, an interagency agreement with the Department of Commerce has been developed to assist small minority business firms in tooling-up for offering new products as a part of their commercial lines. Specifically, the interagency agreement provides for the study of marketing and development methods to fully utilize the research and development of new devices for the disabled. The purpose of this interagency agreement is to utilize existing programs in the Minority Business Development Agency (MBDA) and stimulate marketing for devices that result from VA-sponsored R&D.

The National Commission of Technology Transfer, of the Department of Commerce, is in the process of offering funding in order to:

- plan for an international conference on making prosthetic and orthotic devices and sensory aids readily available to the handicapped population;
- identify and develop potential markets and financing for such devices;
- examine the use of microcomputers and other high technology areas;
- examine the impediments to obtaining funding for high-technology products; and,
- develop a process that leads to the commercialization of technology researched and developed by the VA, with emphasis on providing access to these markets for minority entrepreneurs.

Arrangements have been made to encourage private industry to adopt the results of individual reseach products which are judged to have particular merit. As a result of these efforts, the Johns Hopkins Manipulator will soon be commercially available. Other negotiations are continuing. To facilitate this process, VA Rehab R&D has assisted in the creation of a National Commission for Technology Transfer, which is concerned with making research results commercially available to handicapped people.

New Directions

Future plans by VA Rehab R&D to assist in the transfer of technology from research to clinical practice are as follows:

- Continued publication of the *Journal of Rehabilitation R&D* and the *R&D Progress Reports;*
- Publication and distribution of papers on subjects potentially relevant to future clinical practice (e.g. training manual for use of robotic systems for the severely disabled);
- Design and implementation of a formal research program, based at the Office of Technology Transfer, to evaluate and improve the transfer of technology, including:
  1. The collection of clinical practice data from VA facilities to give a chronological picture of the gap between state-of-the-art devices and actual clinical practice;
  2. A series of consumer surveys to determine their needs and to uncover problems or frustrations with existing rehabilitation procedures and equipment; and,
  3. A series of surveys among clinical practitioners to collect data on clinical needs, problems and priorities.
- A periodical and/or a technical communication in existing periodicals for clinicians, designed in cooperation with PSAS, the Academy, AOPA, AAOS, Paralyzed Veterans of America, Disabled American Veterans, National Institute of Handicapped Research, and other organizations to further enrich the transfer of new research findings to clinicians in a format tailored to their practical needs. In the long run, a computerized reference system may be developed;
- Seminars on selected topics between recognized clinical leaders and senior researchers who have achieved scientific breakthroughs relevant to clinical practice; and,
- Access to national and international scientific and clinical literature.

These thrusts are ambitious and will take time, but they convey the depth of Rehab R&D commitment to technology transfer.

Prosthetic-Orthotic Research—A New Thrust is Needed: A Clinician's Perspective

Charles H. Epps, Jr., M.D.*

Since the prime supporter of research, the federal government, has sharply reduced some areas of funding, the efforts of many established investigators and programs have been curtailed. Hardest hit has been the young aspiring investigator without a track record, who has found it virtually impossible to acquire funding for initial research efforts. Basic research as well as clinical research has suffered. Prosthetic and orthotic research programs which have never had abundant or even adequate funding also have been adversely affected.

In the area of upper extremity prosthetics, much research remains to be done. For the patient who wears a prosthesis, cosmesis is still a major concern. Cosmetic acceptability must be improved and sensory feedback must be developed; sockets must be made more comfortable and suspension must be improved. Myoelectric control systems and other methods of external power must be made more functional, more compact, and more economical.

In the lower extremity, newer materials and techniques must be developed to make prostheses lighter in weight, especially for the geriatric wearer. Although there seems to be less enthusiasm today for skeletal attachment of prostheses, the concept remains a challenge. The mechanical integrity and durability of knee devices can be improved along with fitting and alignment techniques.

Because of basic lack of knowledge about the effects of forces on bone, ligaments and tendons, the need for orthotic research is even greater than in prosthetics. More

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