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SPECIAL ARTICLE

The New Evaluation Unit of the Veterans Administration's Rehabilitation Research and Development Service

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The VA Rehab R&D Evaluation Unit (153) is a part of the Rehabilitation Research and Development Service. Administratively, it has been organized in the Research Division of the Veterans Administration Medical Center, 50 Irving St., Washington, D.C. 20422. Telephone: 202/745-8517.

While the unit is part of the VAMC, it operates in many ways as an arm of the Central Office Rehab R&D Service.

Technology has much to offer the physically or sensorially impaired veteran in overcoming the handicaps that disabilities and environmental barriers may cause. But successful technology applications require both creative research and development and effective production and distribution. To discuss evaluation, it is necessary to consider its role in all phases of this complex process.

The basic function of the VA Rehab R&D Evaluation Unit is to assist the VA Rehab R&D Service in its prime role of making effective devices and techniques available to veterans — each of whom is unique in the nature of his disability and personal desires. The unit will concentrate on evaluation as one of the major elements in the research, development, production, and distribution process. Its activities and relationships are analyzed in the schematic diagram (Fig. 1) that accompanies this writing.

As the end of 1984 approached, the Veterans Administration's new Rehab R&D Evaluation Unit had already started to mobilize personnel, assets, and resources for the evaluation of nine devices and an animal aide concept. In some of the projects involving devices, prototypes were already in production in quantities required for clinical field testing. Table 1 lists the year-end lineup and status of the Evaluation Unit's work.

The role of the new VA Rehab R&D Evaluation Unit in the evaluation process is well illustrated by the case of the VA Seattle Foot. This new prosthetic foot was de-

veloped by Dr. Ernest Burgess, Director of the Prosthetic Research Study at the VA Medical Center in Seattle, Washington, with the assistance of an engineer who is familiar with contemporary advances in materials technology. The result of their collaboration is a prosthetic foot that employs a plastic keel (really a kind of leaf spring) embedded in a cosmetic foam foot. The keel deflects with the foot under load, storing the amputee's stance energy, and then returns that energy when the amputee steps off his foot, giving him a noticeable "push". The action is somewhat like that of the intact Achilles Tendon. Amputees report improved and quicker gait and increased agility in sport activities.

The VA-Seattle Foot evaluation is the farthest along of the Evaluation Unit's current projects, and the highlights of this evaluation (summarized below) provide some insight into the creativeness and complexity that are involved in orchestrating such a program on the scale necessary for even a relatively simple device.

How the VA/Seattle Foot is being moved through a nationwide evaluation program in VA Centers

1. The long-established Prosthetic Research Study (PRS) of the VA Medical Center in Seattle, Washington, obtained the collaboration of Model Instrument Works (MIW), Inc., a "small" private firm, to assist in design and fabrication of the first 50 feet. Those feet were fitted by the PRS to volunteer subjects. A preliminary in-house evaluation was made by Dr. Burgess and staff.

2. On the basis of the encouraging results of Burgess' group's evaluation, the VA Rehabilitation R&D Service initiated a contract with MIW to produce 500 of the feet for clinical evaluation.

3. The VA's Rehab R&D Evaluation Unit and the VA's Prosthetic & Sensory Aid Service (PSAS) joined in a collaborative management plan. PSAS designated the 44 Prosthetic Services (in VA Medical Centers throughout the nation) to participate. Instructions for subject selection and for ordering feet, and the protocols for evaluation, were jointly formulated and promulgated to each of the 44 centers.

4. All requests for feet, the subject data records, and completed evaluation forms are being processed by the Rehab R&D Evaluation Unit, where data are entered into a computer. Orders then are transmitted to MIW which ships the feet directly to prosthetic contractors serving the VAMC Prosthetic Clinics.

Evaluation data are then analyzed by both the Rehab R&D Evaluation Unit and the Prosthetic Research Study in Seattle.

5. Six (6) feet were sent to the U.S. Army Research & Development Center at Natick, Massachusetts. Through an interagency agreement, Natick is life-testing these feet on a special "walking machine" originally designed to simulate normal gait for testing shoes.

6. The Rehab R&D Evaluation Unit is responsible for the preparation of the final report.

That six-point overview illustrates the way an effective evaluation process may be accomplished within the VA system, using a relatively small unit to act as a center of management and coordination to synergize substantial resources already in place throughout the system. The result is that a significant number of veterans are provided with an improved device, a new device is brought into production and distribution by a private firm, and extensive objective and subjective evaluation data are produced, analyzed, and published ■

From monitoring research-in-progress to helping manufacturers get into production, the VA's new Evaluation Unit will help with the critical decisions.

Because the evaluation process as it is understood in the VA's new Evaluation Unit is a dynamic process, it can best be described with the aid of a flow chart. The following description is divided into paragraphs labeled [A] through [H], each of which focuses on a similarly labeled point in Figure 1 which is, in essence, a flow chart.

[A] The VA Rehab R&D Service, assisted by a Scientific Merit Review Board, determines each year its major priority areas for R&D funding. As of this writing, there are three: (i) Sensory Aids for blind and visually impaired and deaf and hearing impaired veterans; (ii) Orthotic and Prosthetic devices for physically impaired veterans; and (iii) Functional Electrical Stimulation systems that promise to someday make paralyzed veterans mobile on their own legs.

The Rehab R&D Evaluation Unit assists the Rehab R&D Service in its selection of R&D projects that are most likely to produce results.

[B] Monitoring programs and projects is a vital function of the Rehab R&D Service. The technical and administrative staff of the Evaluation Unit assists the staff of the Service as a natural part of its responsibility to be aware, in detail, of the technical activity in projects as it prepares for evaluation of developed devices that result from those projects.

[C] Internal Test and Evaluation is a critical part of the development process. Any new device must be tested for function, reliability, and safety before it may be used. If used by or on a human being, the study and human-subject forms will require approval by an Institutional Review Board and may require FDA clearance for experimental study. The inescapable fact is that not until the device is first tried on a subject (in a clinical or home environment) will the specifications for the device become really clear and the defects become apparent. For one or both of these reasons, the first prototype will be returned to the research and development group for redesign and improvement — and it is seldom that only one cycle in this loop is enough. Rather, the process becomes a continuous one, with

new and improved models being worked on and evaluated and each, in turn, contributing its share to the flow of data.

The Rehab R&D Evaluation Unit intends to stay close to these internal evaluations — assisting in the design of protocols, facilitating FDA clearances, and helping to decide when performance is sufficient to consider moving the device to private industry.

[D] "D" represents the first critical "decision switch." It is often difficult for a developer to accept the freezing of his design for production at a time when he is still working on various improved versions. But at some point, a decision that a device has attained a level of development sufficient for design of a production model must be made. The decision will usually be a joint one, involving the developer, the Rehab R&D Service, and a potential manufacturer. The Unit will serve as a facilitator and advisor to the Service in making this decision.

[E] Production Design and Tooling is principally the responsibility of a manufacturer, but very close liaison with the developer and the Service is important and usually desired by the firm. In some cases, it will be appropriate and desirable for the Service to provide financial incentive, usually in the form of an initial purchase order of units for evaluation. When the potential market is uncertain, as it often is, this may be the only way a company responsible to its stockholders can launch such a project. Other forms of support, especially for small businesses, may be facilitated from other federal agencies. In the case of use by the VA, waivers of liability may be provided. (The high cost of liability protection often deters a small firm.) The Evaluation Unit will assist the Rehab R&D Service in this process.

[F] External Test and Evaluation is perhaps the principal function of the new Evaluation Unit. It will develop the evaluation protocols and arrange for clinical and/or home trials. These may range from a relatively simple test and evaluation at one laboratory to multicenter

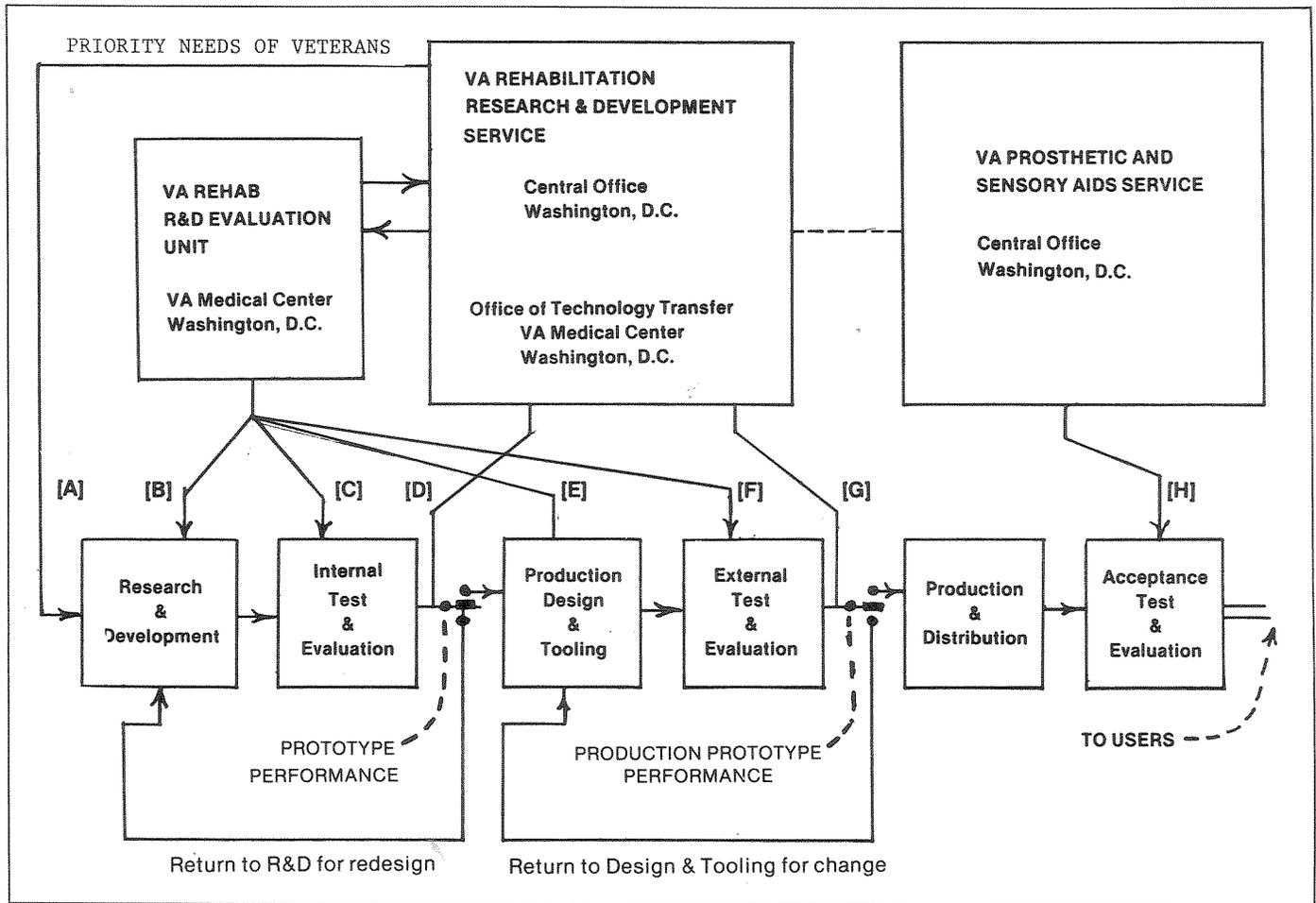


FIGURE 1

The Rehab R&D Evaluation Unit is itself represented by the box at the upper left. The six smaller boxes in the second tier represent stages in bringing research results to fruition as a clinically valuable (and available) device or method. Evaluation Unit functioning at critical points labeled [A], [B], etc., is described in the accompanying text opposite and below.

evaluations in locations throughout the nation or even worldwide. Most such activities will occur within the Veterans Administration Medical Center system, but when unique resources are required and can be identified outside the system, they will be employed. Effective evaluations are vital to a manufacturer anticipating full-scale production, since only in this way can a company be sure its product will meet a real need. In addition, the indications for the prescription and use of the device will be defined, and information will be developed for training practitioners and third-party payers in its application. Assistance with FDA premarket clearances may also be provided, as well as waivers of liability for use in the VA system, as mentioned earlier.

[G] The second "decision switch" determines whether to return the production prototype to redesign, or to terminate the project, or to proceed with full-scale production and distribution. While this must be a decision of the manufacturer, the Rehab R&D Service and the Rehab R&D Evaluation Unit will provide assistance.

[H] When the manufacturer decides to produce and market the device, he will look to the VA and the civilian sector for sales. In the case of the VA, his commercial product will come under the cognizance of the VA Prosthetics and Sensory Aids Service, which has the responsibility to evaluate the product before declaring it safe and cost-effective for purchase and use in the VA system.

The Rehab R&D Evaluation Unit is young and its staff members are few—but the need for it is great. It plans to grow gradually, taking on more and larger tasks until it attains the capability to serve the needs of the entire VA system. But, the needs of the nation's veterans are not unique and at present there is no coordinated evaluation capability throughout the country. It is hoped that the form and productivity of the new Evaluation Unit will serve as a model for a truly national system that can help developers and manufacturers to better serve all handicapped persons. ■

Continued on next page

VA Circular 10-84-162 tells how you can request an evaluation for a prototype arising from your VA-sponsored rehabilitation research.

CIRCULAR 10-84-162

Veterans Administration
Department of Medicine and Surgery
Washington, D.C. 20420 September 24, 1984

TO: Regional Directors; Directors, VA Medical Center Activities, Domiciliary, Outpatient Clinics, and Regional Offices with Outpatient Clinics (151)

SUBJ: Evaluation of new prototype devices and techniques arising from the VA Rehabilitation Research and Development (Rehab R&D) Program

1. A Rehab R&D Evaluation Unit has been established at the VAMC, Washington, D.C. to coordinate the evaluation of new prototypes and techniques that arise from the VA Rehab R&D program and to facilitate the transfer of such promising devices and techniques into commercial production and clinical use. Effective evaluation is an important activity. In order to efficiently plan for the skilled personnel and resources required for evaluation activities, it is essential to establish that a prototype device or technique is indeed ready for evaluation and potential commercialization. This circular sets up a process for reviewing the readiness of a device for evaluation.

2. Before a new device or technique can be considered for evaluation, a "Request for Evaluation (RFE)" in original and 5 copies should be submitted to:

VA Rehab R&D Evaluation Unit (153)
Veterans Administration Medical Center
50 Irving Street, N.W.
Washington, D.C. 20422

3. When preparing a Request for Evaluation (RFE) use the format of Attachment A and answer as many of the questions as possible. All requests will be signed by the Principal Investigator and the Medical Center Director or designee.

4. Questions regarding this procedure may be directed to Dr. James B. Reswick, Director, Rehab R&D Evaluation Unit, (FTS) 921-8517, (COMM) 202-745-8517.

ARTHUR J. LEWIS, M.D.
Acting Deputy Chief Medical Director

THIS CIRCULAR EXPIRES ON SEPTEMBER 23, 1985

ATTACHMENT A

Circular 10-84-162
September 24, 1984

VA REHABILITATION R&D SERVICE FORMAT FOR REQUESTING EVALUATION OF A PROTOTYPE DEVICE OR TECHNIQUE

Instructions: The questions that follow are all-inclusive. Information to answer some of them may not be available or may be incomplete. Please answer as fully as possible and where information is lacking, give a brief explanation. The word "device" is used throughout this outline since most requests for evaluation will concern a physical device. However, a new technique (e.g., a new method for fabricating a conventional prosthetic socket) is equally valid for consideration. In such cases, questions should be interpreted appropriately, with the understanding that some may not apply.

Request for Evaluation (RFE) — Outline/Questions

A. Identification:

1. Name and address of VA Facility
2. Name of Principal Investigator
3. Name of Device or Technique

B. Need:

1. What is the device? What does it do? How? For whom is it indicated? (Be specific in terms of personal impairment and the nature of the functional loss that the device will mitigate.)
2. What other devices are commercially available to meet the stated need? What are their shortcomings? In what ways is your device better?
3. What other devices are now in development to meet the stated need? What are their shortcomings? In what ways is your device better?

C. Potential Markets:

NOTE: The questions below should be answered in the context of the previous answers to "B. Need." Market potential should be judged in terms of relative improvement over existing devices.

1. How many persons with disabilities are likely to actually use the device? (Distinguish between the impairment description and the

specific functional loss that the devices will mitigate. For example, while there may be four million stroke victims in the Nation, relatively few are candidates for an implanted dropfoot electronic stimulator.)

2. Will the device be cost-effective, i.e., is the potential benefit worth the cost? Are prac-

tioners likely to prescribe the device and will third party payers agree to payment?

D. Federal, State, and Local Clearances:

1. In what FDA class does the device fall?
2. What steps have been taken to obtain a

TABLE 1
New Evaluation Unit lists 10 prototypes already in various stages of evaluation*

| Device | Developer | Number of units | Status* |
|---|--|-----------------|--|
| 1. VA Seattle Foot | VA Medical Center, Seattle | 500 | More than 300 subjects at 44 Centers in study |
| 2. AFB Superfold Cane | American Foundation for the Blind, New York | 50 | 4 VA Centers for the Blind are participating |
| 3. Robotic arm | Johns Hopkins University Applied Physics Laboratory, Maryland | 25 | Production prototypes are being built by P&P Industries, Maryland |
| 4. Exercise table | Allied Industries, Florida | 9 | One set of 9 tables is under evaluation at the VA Medical Center, Washington, D.C. |
| 5. Bathroom fixtures | VA Medical Center, Atlanta | — | Preliminary evaluation is under way at VA Medical Center, Atlanta |
| 6. Simian aides | Albert Einstein Medical Center, New York | 5 | Preliminary evaluation by principal investigator is under way |
| 7. Velocity wheelchair control system | Johns Hopkins University Applied Physics Laboratory, Maryland | — | Under consideration for evaluation |
| 8. Ultrasound wheelchair control system | Rehabilitation Engineering Center, VA Medical Center Palo Alto, California | — | Under consideration for evaluation |
| 9. Software for the treatment of Aphasic adults in the Apple II Microcomputer | VA Medical Center Columbia, Missouri | 3 | About to begin evaluation at 3 VA Centers |
| 10. Special Friend portable speech prosthesis | Shea Products | 3 | About to begin evaluation at 3 VA Centers |

* As of the end of 1984

classification decision and exemption for investigational use?

3. Has an Institutional Review Board (or equivalent) approved the device for use on human (or animal) subjects? Has it approved any human consent forms? Please forward copies.

E. Evaluation by Developer:

1. To what extent has the device been evaluated to date (in animals, or humans)? What were the results?
2. To what extent has the device been tested (mechanical function, strength and life; electrical function and reliability; safety from all aspects)? What were the results?
3. How much maintenance is required?
4. How much training of practitioners and patients is required?

F. Relations with Potential Manufacturer:

1. Is a manufacturer presently involved? What is the nature of the relationship?
2. How many prototypes have been made? Is the prototype ready for production tooling?
3. Has a patent been applied for? By whom? What licensing arrangements exist or have been discussed and among what parties? Has the VA been notified of all actions in accordance with PL 96-517 — Dec. 12, 1980?
4. Should an initial production run be required for evaluation by the Rehab R&D Evaluation Unit, what are the cost and delivery details?

G. Signatures:

1. Principal Investigator
2. Medical Center Director or designee

H. When and Where to submit RFE:

1. An RFE may be submitted at any time a device is deemed ready for evaluation.
2. An original RFE and 5 copies should be addressed to:

VA Rehab R&D Evaluation Unit (153)
Veterans Administration Medical Center
50 Irving Street, N.W.
Washington, D.C. 20422

Tel: (FTS) 921-8517; (COMM) 202-745-8517