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Technology transfer of neuroprosthetic devices

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Abstract—Despite long development periods for neuroprosthetic devices, the numbers in clinical use or clinical trials are rising, with an estimated 3,000 systems in use today. As they gain experience with the regulatory approval process, developers are learning to conduct research to best prepare for transfer of technology to industry. The track record of the first motor prosthesis to be approved by the United States Food and Drug Administration contains important lessons for a company planning to undergo the regulatory process. Throughout the development of a neuroprosthesis, the capabilities and preferences of the customers who will use it (physicians, surgeons, therapists, and end-users) should be sought out and used in device design. When a device has reached clinical application, particular attention is needed to maximize both the population who will use it and each individual's degree of use (optimal, partial, reluctant). Identification of person-technology mismatches can help to select training strategies and other interventions that can be applied to ensure a good rehabilitation outcome.

Key words: *FDA device regulations, FES, FNS, neuroprostheses, rehabilitation success, technology transfer.*

INTRODUCTION

In the face of long development periods for functional neuromuscular stimulation (FNS) systems, researchers in the field are encouraged by the rising number of neuroprostheses in clinical use or in clinical trials. Graham Creasey, MD, of Case Western Reserve University and MetroHealth Medical Center, conducted an informal survey of participants at the Neural Prostheses: Motor Systems IV Conference, July 1994, Mt. Sterling, Ohio, discovering that there were motor prostheses in clinical use for respiratory control and urinary control, as well as investigational clinical systems under evaluation for cardiac assist, fecal control, lower extremity control, and upper extremity control. As shown in **Figure 1,** the estimated cumulative number of implanted systems in humans up to the time of the survey was approximately 3,000. The rate of implantation of human subjects for the different applications tends to be approximately equivalent, with a slow initial period followed by more rapid uptake.

The process necessary to introduce a new motor neuroprosthesis into clinical use seems prolonged and expensive. However, when compared with that required for drug introduction, the issues are put into a better perspective. Young, in a recent review of the development of drugs for brain and spinal cord disorders, cited an average of 11.4 years development time between first discovery and Food and Drug Administration (FDA) approval (1). The cochlear prosthesis, a sensory neuroprosthesis, required 20 years from the first report of feasibility (2) to approval as the first implantable medical device for adults. The cost of drug development for brain and spinal cord disorders is typically $95 million, which includes costs incurred in testing those

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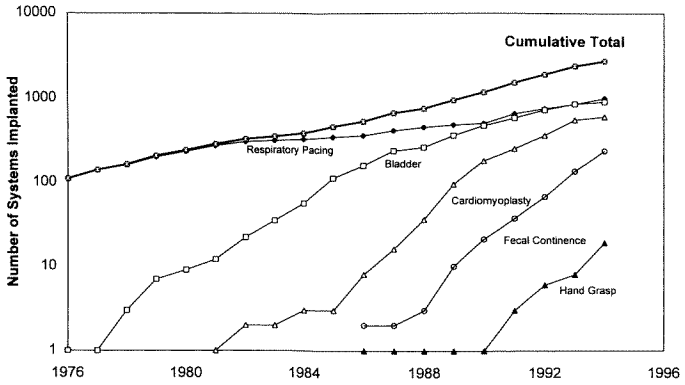

Figure 1.
Estimated number of neuroprosthetic devices in clinical use.

drugs that do not survive scientific and regulatory scrutiny (1).

Each discipline, such as electrical engineering or occupational therapy, involved in the design and feasibility testing of FNS systems is guided by its own body of knowledge and methods of experimental testing. Once a system has fulfilled the requirements of all the disciplines underlying its development, it faces a new set of challenges in the movement of technology from one setting to another: the process of technology transfer. In fact, as we will suggest, some of the requirements of technology transfer aimed toward a clinical system with commercial potential should be kept in mind even in early stages of research and development: the documentation and the protection of intellectual property, for example, are crucial considerations.

Successful technology transfer requires the research team to deliver information about their device to manufacturers, regulatory agencies, physicians, surgeons, therapists, rehabilitation engineers, and finally, but perhaps most importantly, to consumers. Manufacturers need to learn how to build systems; regulators need to be shown that systems are safe and beneficial; health care workers need to know how to fit, tune, and maintain systems and how to train their clients to use systems; and consumers need to know how FNS systems can improve their quality of life.

By recognizing the many stages of information transfer that must occur between the rehabilitation research laboratory and accepted clinical use of a device, researchers can accomplish technology transfer more efficiently. This paper will detail four aspects of that process: 1) between research and both industry and regulators, with emphasis on the researchers' role; 2) between industry and both research and customers (physicians, surgeons, and consumers), with emphasis on industry's role; 3) between industry and regulators, with emphasis on industry's role; and 4) between technology providers (both researchers and industry) and consumers, with emphasis on assessing consumer predispositions to technology use (**Figure 2**).

TECHNOLOGY TRANSFER BETWEEN RESEARCH AND BOTH INDUSTRY AND REGULATORS

There are several mechanisms available to researchers who wish to realize the commercialization of technology developed in the laboratory. One path is that being followed by NeuroControl Corporation, a company formed in 1993 to provide FNS products and services. The company is the sponsor of a clinical trial of the upper extremity neuroprosthesis developed at Case Western Reserve University, the Cleveland VA Medical Center, and MetroHealth Medical Center (CWRUNA) and initiated by the Cleveland FES Center, a consortium of those organizations (3). This change represents a significant effort to transfer a neuroprosthetic system and its means for deployment from research to industry, and it contains lessons for others who want to either transfer their technology to industry or go to market directly with a neuroprosthesis.

Within a research organization, technology transfer may mean research and development, prototyping, clinical feasibility tests, clinical trials at a single site, or multicenter clinical trials. This entire range of activities

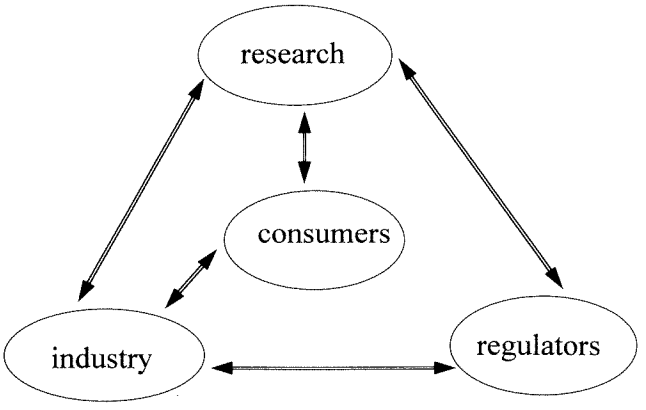

Figure 2.
Technology transfer occurs among research, industry, regulators, and consumers. The arrows represent the transfer activities that are described in this paper.

was achieved in Cleveland over the past two decades with ongoing research support, primarily from the National Institutes of Health and the Department of Veterans Affairs (VA), and with a special initiative from the VA Rehabilitation Research and Development Service for technology transfer.

Throughout this process, a research organization can determine whether it wants to transfer a particular technology to industry. Once a device is started on the path to commercialization, it must go through product development, marketing, and distribution before earning royalties. Ultimately, there may be a financial return to the basic research and development process, but this is by no means assured, and if it does happen, it will take many years.

The Researchers

What makes particular researchers and their products attractive to manufacturers? Researchers who always adhere to formal documentation practices will have adequate data to effect a transfer when the manufacturer expresses an interest in the technology. Researchers must comply with regulatory requirements during feasibility studies and clinical trials. Approval must be obtained from the local Institutional Review Board (IRB). If the IRB judges a device to have significant risk, then an Investigational Device Exemption (IDE) from the FDA is required. When researchers have taken these steps, an interested manufacturer will have less regulatory work to do. In the late 1980s, industry listed increases in product quality and functionality as more important than totally new products as desired inputs from research (4). Clearly, there are various ways for researchers to be attractive to industry.

Researchers should patent their ideas so that they are protected, therefore making it possible to have meaningful negotiations with an interested manufacturer. In the last decade, universities have made great progress in increasing the number of patents received from 22 in 1987 to 1,112 in 1992, realizing an income of $172 million. Combined US universities ranked 21st among all groups or individual companies in the number of patents received in 1993[1].

People who want to effect the transition of their technology to a commercial product need to have patience and perseverance, and they must be champions of that technology. For example, the idea of the photocopy originated in 1934 but it was not until 1959 that the first photocopier was marketed by Xerox. The successful transferer of technology must be an integrator and team builder who learns from mistakes. Both the vision of the technology and the strategic approach for implementing it must be developed and shared among the team. Additional characteristics are the acceptance of risk and ambiguity, and the ability to manage parallel processes. People who transfer technology must be action-oriented and self-directed.

Conducting Multicenter Clinical Trials

The elements of conducting a multicenter clinical study can be divided into clinical and technical areas (**Figure 3**). As a device becomes specified and proven, it undergoes changes. For example, early in the development of the CWRU/VA neuroprosthesis, each user was initially expected to use a percutaneous system, prior to being fitted with an implantable system up to a year later. While a good research approach, this was rejected by clinicians who said it would take too long and the device would not perform like a product. To go directly to implantable systems meant that engineers had to devise different designs that would support clinical trials. The target group to be educated was no longer other engineers, but rather surgeons and therapists.

Evaluations have to be designed to ensure that the device is performing to expectations. In our case, the targeted user group had no alternate means to open and close their hands; there was, therefore, no existing evaluation or comparison criterion. We had to design evaluation tests to determine the impact of the system on the person's deficit, including his or her impairment, functional limitation, and disability. Data had to be assessed, validated, and monitored with special attention to collaborators at other sites (**Figure 3**). The documentation of protocols and procedures, the training of clinicians from other centers, and the coordination and communication of all these elements had to be structured to feed into the collection of data.

Resource utilization became an issue when needs, such as manufacturing, went beyond the usual capabilities of a research organization. We needed to identify reliable outside contractors who could be charged with taking on special tasks of the development process.

Documentation, including software validation, is important throughout the process from research laboratory to market. With the Safe Medical Device Act of 1990 and its amendments of 1991, the concept of

[1] Personal communication, Dr. Richard Razgaitis, Batelle Institute, Columbus, OH 43201, July 20 1994.

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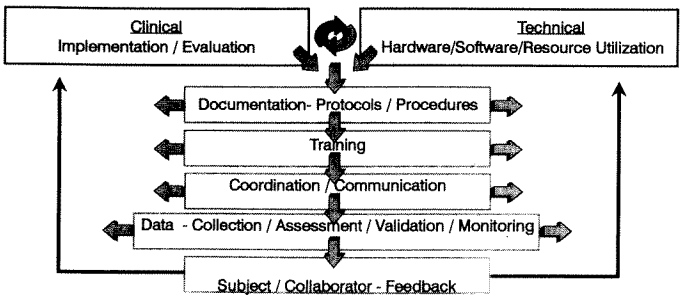

Figure 3.
Elements of conducting a clinical trial.

exemption from good manufacturing practices (GMP) is now being challenged. The FDA is moving to harmonize its regulations with the ISO 9000 directives that are being adopted in Europe. The ISO 9000 standards state that documentation must begin from the conception of the idea.

To summarize, the messages that are most relevant in technology transfer for researchers and their funding agencies are:

1. Ensure that your technology is desirable to end-users (patients) and implementors (clinicians). Understand what the customers (patients and clinicians) desire and how they presently cope without your technology (know the marketplace). Be able to answer the most fundamental of questions: what can end-users do with your technology that they could not do before? and demonstrate with data that the benefit is worth the effort needed to utilize your technology.
2. Contact medical device manufacturers early in the process, informing them of your work, inviting them to your workshops and lectures, and seeking advice regarding prototyping or clinical trial activities.
3. Adhere to formal documentation procedures, which require documentation to occur from the inception of an idea through the prototyping stage and beyond. Invest in your engineering staff's education by making it possible for them to attend formal training seminars, such as ISO-9000 quality control and quality assurance practices. Assign a person with authority to audit your own documents periodically, ensuring that they are well organized and under formal document control.
4. Protect your ideas by seeking patents, which may be the tangible basis for transferring your concepts and technology to industry in return for rights and royalties.
5. Be a champion of your technology and attract people with diverse expertise (clinicians, scientists, engineers) to be part of your team.
6. Comply with regulatory requirements. In the United States, this almost always refers to the requirements of the FDA. Seek regulatory counsel early and contact the FDA, telling them what you intend to do. Keep your clinical study focused and simple. Remember, you are required to prove that your technology is efficacious, safe, and has clinical utility.

TECHNOLOGY TRANSFER BETWEEN INDUSTRY AND BOTH RESEARCH AND CUSTOMERS (PHYSICIANS, SURGEONS, AND CONSUMERS)

Working within a company structure, one can begin to appreciate why a company may be cautious about getting involved in new therapies and devices. The high costs of development and the regulatory process cause a company to be circumspect about any candidate technology. Today in Europe, there is a multinational uniform medical device approval process that leads to commercial rights in all the countries. However, it is still necessary to negotiate with insurance companies in each country to obtain reimbursement for the therapies.

How does a manufacturer decide whether or not to take on a device technology? The devices most likely to be adopted are the ones that can be built within existing physical capabilities, that provide long-term safety and efficacy, that can be implanted by a sizable group of surgeons, and that are suited to a large group of patients.

The manufacturer wants to know about long-term safety and efficacy before making a major investment. Devices that may be easy to make on a small scale may be difficult to integrate into a large manufacturing system. If special facilities and tooling are required, manufacturing yield may be very small for the cost. A special issue with some new devices is the possible regulatory delay while new biomaterials are qualified; 2 years of biocompatibility tests are required for new materials both in Europe and the United States.

Active medical devices are used by two groups of customers: the physicians or surgeons who prescribe or

implant them and the patients who use them. Devices need to be simple and easy for the surgeon to use; this may be preferred over being the most efficient device. Implantable products need to be designed to utilize the set of skills and the learning abilities available in the surgical community if they are to receive their maximal application. Special tools may need to be developed to simplify implantation, particularly of small components. Components need to be designed to take the rigors of the surgery, including repositioning. If an engineer is required for each implant, or if complex intraoperative calibration is required, the device will be less preferable. An example of a successful device is a pacemaker that can be implanted in a simple office procedure. It can be programmed with radiofrequency at a later time; even if programmed incorrectly, it will still work.

Devices that involve very invasive surgery, such as intraneural electrodes, or that require placement near sensitive structures, such as the spinal cord or phrenic nerves, can cause damage. Even a five-percent risk of nerve damage may be very costly for the company.

Keeping it simple for both surgeons and patients means more work for engineers, but this is necessary to achieve a successful commercial device. FNS users want devices that work and that do not require special awareness of their operation. Low maintenance is very desirable. Need for frequent calibration, with or without outside help, is a disadvantage. Users will also be concerned about the amount of specific care (e.g., of skin or connectors) required. Of course, the device's sensitivity to the environment (electromagnetic interference, magnetic fields) will affect the mobility and peace of mind of the user.

TECHNOLOGY TRANSFER BETWEEN INDUSTRY AND REGULATORS

On the way from inventor to user, a medical device must pass the rigors of governmental regulatory review to complete the process of technology transfer successfully. Simply stated, a manufacturer must convince the FDA that its device is both safe and effective in doing what it is claimed to do before being granted approval to market the device. For many companies, this requirement spells the difference between success and failure.

In the late 1950s, Crest® added fluoride to its toothpaste and was able to obtain a market share advantage over its major competitors, Colgate and Ipana. On every box of Crest was written: "Crest has been shown to be an effective decay preventive dentifrice when used in a conscientiously applied program of oral hygiene and regular professional care." Crest was the first company to successfully conduct a clinical study showing that its toothpaste was safe and effective in preventing tooth decay, even though Ipana® and Colgate® were also adding fluoride to their products. Completion of the FDA process gave Crest the right to make its claim on labelling and propelled the company to both clinical and marketing success.

Product labels contain the claim of effectiveness or benefits, as well as indications for use. An example is:

> The Parastep I System is indicated for enabling appropriately selected, skeletally mature persons with spinal cord injury (C6–T12) to stand and attain limited ambulation and/or take steps, with assistance if required, following a prescribed program of Physical Therapy performed in conjunction with rehabilitation management of spinal cord injury.

Such statements in marketing and advertising are possible only after FDA review and approval of the evidence demonstrating safety and efficacy.

Federal Law and the FDA

The Food, Drug and Cosmetic Act of 1936 (FDC Act) mandates the FDA to regulate all medical devices that are introduced into interstate commerce in the United States, Puerto Rico, and the District of Columbia. A common misunderstanding exists concerning the role the FDA plays in bringing devices to market: the FDA does not independently conduct studies of the devices submitted for its approval. Comparative analysis is not performed in an FDA laboratory to determine the quality of the devices it reviews. Rather, in its mission to protect the public, the FDA reviews evidence submitted by a manufacturer supporting a product's claim of effect or benefit. Only after review of this evidence will the FDA grant approval to market the product.

Passed in 1976, the Medical Device Amendment to the FDC Act requires that medical devices be placed in one of three categories: Class I—General Controls, Class II—Performance Standards, and Class III—Premarket Approval (**Table 1**). If there is insufficient evidence to comply with Class I requirements, a device is given a Class II rating and required to conform with the regulatory standards of premarket notification and other appropriate third party standards. American National Standards Institute (ANSI) standards for FNS

Table 1.
Medical device classification.

Class I—General Controls (applies to all medical devices)

- Register with the FDA and provide a list of devices intended for marketing.
- Conform to Good Manufacturing Procedures (GMP).
- Notify health care providers of associated risks.
- Maintain reports and records of manufacturing methods, facilities, and controls used during manufacturing, packing, storage and installation of medical devices.
- Must meet "Substantial Equivalence" test.

Class II—Special Controls (pre-market notification)

- Conform to appropriate regulatory standards when established by the FDA and/or others; American Society for Testing and Materials (ASTM), International Standards Organization (ISO), American National Standards Institute (ANSI).

Class III—Pre-market Approval

- General controls do not provide reasonable assurance of safety and effectiveness.
- Not substantially equivalent to an approved device.
- Requires premarket approval (PMA) involving bench, animal, or clinical studies to support the claims made for the device.

devices are only now being developed. ANSI standards for transcutaneous neuromuscular stimulation exist and some are being carried over into the FNS standards. If a device uses electric current, Underwriters Laboratory (UL) standards also apply.

Class III devices are those for which general controls do not provide reasonable assurance of safety and effectiveness, and those that are also not substantially equivalent to previously approved devices. For such devices, premarket approval applications (PMA) must be filed to demonstrate safety and effectiveness through valid scientific evidence. A shorter procedure, specified in section 510(K) of the FDC Act, allows a company to file a premarket notification (PMN) requesting the FDA to determine substantial equivalence to a Class III device that has already been approved. Substantial equivalence means the proposed device is similar to an already approved device in its nature, its mechanism of action, and its target diagnostic group.

It is important for developers and inventors to recognize that demonstrating conformity to Good Manufacturing Procedures (GMP), as required in General Controls, is an extensive and complex process involving scrutiny as stringent as that of clinical trials.

The FDA is mandated by its enabling legislation to respond to all applications within 180 days. A frequent response is a request for further documentation, thus leading to an iterative process of filings. There has been considerable concern, particularly on the part of industry, regarding the slowness of FDA's device review process. In mid-1995, according to the FDA, a 510(K) approval required an average of 173 days while a PMA review took 437 days.

The final step in the review process is the panel meeting at which there is representation from experts in the field: the medical, social, academic, and related constituencies, the FDA, and consumer advocates. The public is free to comment and provide information to the FDA in support or in criticism of any application.

FDA approvals of new devices began to take longer in 1990 when the agency began a more stringent enforcement policy that left fewer resources for approval of new drugs and devices. This was in response to major problems that had occurred in both the drug and device areas, including the issues of safety of silicone breast implants and the manipulation of data in drug trials.

The Parastep Experience

In May 1989, Sigmedics, Inc., developer of the Parastep 1 system, filed a PMA claiming its device was safe and effective to achieve standing and stepping for SCI patients (**Figure 4**). The FDA determined the device to be nonequivalent to any existing devices. At that time, the only approvable indications for use of functional electrical stimulation (FES) were muscle re-education, reversal of atrophy, prevention of postsurgical thrombosis, and enhancement of blood flow through exercised muscles. As the claim of standing and stepping was not an approved indication for FES, the Parastep was classified as a Class III device, requiring the company to present scientific evidence of its safety and effectiveness for this use in people with SCI. The first PMA application, supported with data gathered at Michael Reese Hospital in Chicago by Daniel Graupe, PhD, was determined to be inadequate, as was an amendment incorporating video evidence of functional activity. The possibility of single investigator or single institution bias was the principal criticism. The FDA questioned whether success with the system could be replicated, and required that multicenter trials be conducted.

The Parastep system was then introduced in several centers that were representative of the delivery process of SCI management; ultimately 24 sites participated in the clinical trials. The system was introduced as a tool

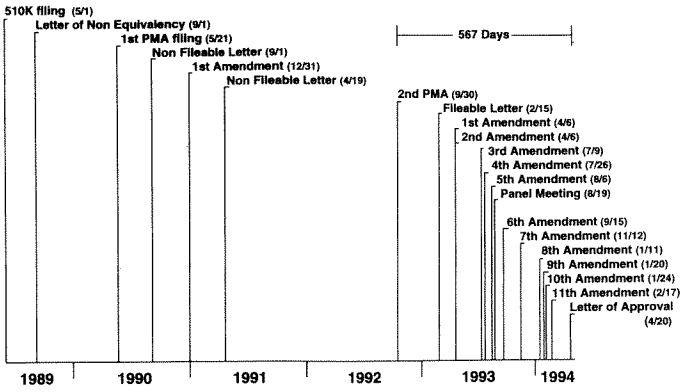

Figure 4.
Parastep approval timeline.

to assist clinicians in their ability to enhance the ambulatory potential of patients with SCI. From October 1990 through May 1992, data were collected from 67 SCI patients and the process by which they were selected and trained. These data supported the company's claim, and in April 1994, almost 5 years from the first filing, the FDA granted marketing approval for the Parastep I System. Clinical trials are continuing today, past the approval date, as part of the FDA's requirements for post-market surveillance.

Summary, Comments and Considerations

The demonstration of valid scientific evidence demands that the investigator and the manufacturer be specific in their definition of the product's success. Success must relate to the approvable indications for use of the device and the marketing claims: Who is it for? How is it to be used? What are the expected benefits? What are the risks? Safety determinations must identify the anticipated risks of device use and beyond those risks, the unexpected problems including medical complications and adverse events resulting from use. The clinical trial study must include a group of subjects large enough to provide statistically significant results according to the outcome measures chosen and the potential placebo effects.

Beyond the issues of safety and effectiveness, it is essential to demonstrate a device's clinical utility. Specifically, the FDA requires that the device must be shown to have either a diagnostic or therapeutic value. In the case of the Parastep system, therapeutic value was defined as the ability to stand and take steps, a common activity in the management of appropriate SCI subjects. It therefore follows that the practice of restoring standing and stepping to SCI subjects is consistent with the standards of therapeutic management when it is achievable. Sigmedics documented that not only is it reasonable to ask the patients to stand and take steps, but it also constitutes good and reasonable medical management, and therefore, is viewed as consistent with the existing standards of practice in rehabilitation.

FDA's analysis of a device compares clinical benefits not with costs but only with the risks involved in use (e.g., in the case of the Parastep system, fractures, burns, and other medical complications). While the FDA does not evaluate the cost/benefit ratio of a device or its impact on quality of life, these are central issues for the consumer. Investigators conducting clinical trials should collect data on these factors, because they will be valuable in marketing and reimbursement discussions.

Consultants are invaluable for negotiating the regulatory, technical, and legal complexities of the FDA approval process. They can help a company negotiate the specialized languages of the technical, clinical, corporate, bureaucratic, and consumer worlds.

The FDA mandates continued monitoring of safety and effectiveness by means of post-market surveillance. For the Parastep system, the company was required to continue monitoring the long-term effects of its use on bone and muscle and also to monitor user compliance and device performance for a period of 5 years.

Finally, while this FDA experience is not the ideal model, it serves as an important case study for others to review before seeking FDA approval for other devices. From May 1990 through May 1994, Sigmedics, Inc. spent $3.4 million on the regulatory process, most of which was administrative expense (**Figure 5**). The total includes $600,000 set aside to support post-market surveillance. With foresight and planning, the total regulatory expense can be significantly reduced.

TECHNOLOGY TRANSFER BETWEEN TECHNOLOGY PROVIDERS (BOTH RESEARCHERS AND INDUSTRY) AND CONSUMERS

Assessing Predispositions of Consumers to Technology Use

Quality of life should be the paramount concern.
Quality of technology does not equal quality of life.

To best utilize FNS technology, we need to identify the largest population who can benefit from it.

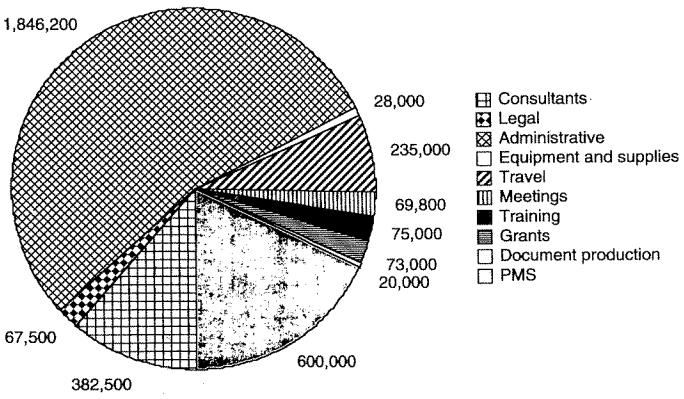

Figure 5.
Parastep expenses for regulatory process.

To accomplish this, both consumers and technology providers should ask: how can we help people to be more independent, self-confident, and have a higher quality of life? Obviously, these two groups see issues differently. For example, consumers define rehabilitation success as relative or individualized. ("As long as I have freedom to do what I want when I want, I am a rehabilitation success. I may be unemployed or stay in bed 16 hours a day, if I choose that lifestyle.") On the other hand, providers define rehabilitation success in terms of independence and restored function. ("We want to get the person back into the community in an integrated way.") Consumers focus on the interactive nature of rehabilitation success. Providers primarily focus on individual deficits: minimizing, curing, or eliminating them. Consumers say rehabilitation success depends on the opportunities available to a person. Providers tend to think it is the attitude of the consumer that will determine if that person achieves success. These significant differences should move providers to use a systematic approach in assessing potential FNS system users.

Among consumers, we can learn a lot from comparing the attitudes of technology users and nonusers with the role technology has played in their achievement of quality of life. Past research has indicated that when users are satisfied (i.e., have a high quality of life), they attribute that to themselves (5). The technology was only a means to help them attain a higher quality of life. On the other hand, those non-users who feel they do not have a satisfactory quality of life often blame that situation on problems or deficits of the device. Users tend to focus on opportunities, and non-users on limitations. Users view quality of life as being positively integrated with society, family, community, and activities. Non-users tend to believe that integration is not really possible for them, that they will always somehow be stigmatized or left out of mainstream society.

All people involved in developing FNS systems have a vested interest in the systems being used. Research shows that technology use leads to higher self-esteem, less depression, less dependency on others, increased socialization, higher activity levels, better health and strength, and reduced health care costs (6).

The potential of technology to enhance the functioning of individuals with disabilities is well recognized, yet there is a sizable abandonment of technology. In the deployment of the Parastep system, only 80 percent of those determined to be medically eligible completed the training, and 33 percent of those who had acquired the system abandoned it within 1 year. Other studies show abandonment rates from 8 to 75 percent; on average, about one-third of all devices provided to consumers are abandoned (7). We have no information about the numbers of people, such as dissatisfied ventilator users, who must continue to use devices with which they are unhappy because they cannot abandon them without consequences more severe than the inadequacy of the devices.

When we look at what separates users from non-users, we need to distinguish optimal use, partial use, and reluctant use. Reluctant use occurs often when a technology is imposed on a person, for example, by parents on a child (8). Partial use occurs when the consumer prefers to use the device only in certain settings; perhaps he or she wants to be more independent in public situations but is happy to have assistance at home. Non-use may be abandonment or total avoidance. Optimal use occurs when a device is used as prescribed or recommended and results in achievement of goals. In adults, particularly older ones, there is a strong gender effect. Many women of middle age or above in this society have not been socialized or taught to be comfortable or competent with technology.

In working for the optimal use of a device, providers should take into account the characteristics of the environment in which the system will be used, the characteristics of the individual (temperament, expectations, life experiences), and the characteristics of the technology itself (**Table 2**). It is important for the relevant environments to support the use of a system by the individual consumer. The characteristics of the environment, such as power sources,

Table 2.
Influences on use of assistive technology.

Millieu	Personality	Technology
Use		
Support from family, peers, or employer	Proud to use device	Goal achieved with little or no pain, fatigue, discomfort, or stress
Realistic expectations of family or employer	Motivated	Compatible with, or enhances the use of other technologies
Setting/environment fully supports and rewards use	Cooperative	Is safe, reliable, easy to use and maintain
Pressure for use from family, peers, or employer	Optimistic	Has the desired transportability
	Good coping skills	Best option currently available
	Patient Self-disciplined	
	Generally positive life experiences	
	Has the skills to use the device	
	Perceives discrepancy between desired and current situation	
	Willing to challenge self	
Nonuse		
Lack of support from family, peers, or employer	Fear of losing own abilities or becoming dependent	Perceived lack of goal achievement or too much strain or discomfort in use
Unrealistic expectations of others	Embarrassed to use device	Requires a lot of setup
Setting/environment disallows, prevents, discourages, or makes use awkward	Depressed	Perceived or determined to be incompatible with the use of other technologies
Requires assistance that is not available	Unmotivated	Too expensive
Medical status inhibits or limits use of device	Uncooperative, resistant, hostile, or angry	Long delay for delivery
	Intimidated by technology	Other options to device use are available
	Overwhelmed by changes required with device use	Has been outgrown
	Does not have skills for use	Is inefficient
	Training not available	Repairs or service not timely or affordable
	Poor socialization and coping skills	

This is an abbreviated version of a table from *Living in the State of Stuck: How Technology Impacts the Lives of People with Disabilities*. This version is reprinted from: *Guidelines for the Use of Assistive Technology: Evaluation, Referral, Prescription* (American Medical Association, 1994, p. 23).

assistance in donning a device, or help in emergency situations, need to be reliable. Family members, employers, and friends need to have realistic expectations and provide adequate support. Reluctant use may result from pressure by persons with unrealistic expectations. Partial use may be due to lack of assistance, fear of embarrassment in some situations, or lack of motivation. When a person tries a system and it does not meet expectations, a cascade of negative changes can occur: embarrassment, depression, low self-esteem, anger or hostility, withdrawal, resistance. Cosmesis (or esthetics) is crucial to the way in which a person will initially react to a technology and ultimately to whether he or she accepts it.

People are non-users by virtue of either technology avoidance or abandonment of a once-used technology. Reasons for avoidance include lack of support from family, peers, or employer and reasons cited above for

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partial use. Abandonment may be caused by the device being inconvenient to others or by physical factors such as weight and ease of use (9–11).

It is important to see partial, and even reluctant use as not necessarily representing failure. For example, more energy may be conserved by having a family member assist with or perform certain tasks. Sometimes, a simple change can make the system have more value and appeal to the person. Methods for accomplishing such changes are: work with the consumer, focus on choice, preserve the human element, build in human override options, and conduct a technology "overload" assessment. When you involve consumers in the process of matching them with an FNS system, you are "ego investing" that consumer in that system. Sample questions that you can ask the consumer to facilitate this process are listed in **Table 3,** but the most important thing is to listen to the consumer.

In addition to such questions for learning about the consumer's attitudes and likely acceptance of the FES system, there is an Assistive Technology Device Predisposition Assessment (ATD PA). This is a consumer-oriented self-report checklist with items of varied format, including 5-point Likert scales. There are subscales to separately assess the characteristics of the assistive device, the temperament of the individual, the environment in which the technology will be used, and the influence of disability on the technology use and quality of life of the individual. A companion form completed by professionals allows for the comparison of consumer and professional perspectives. Both forms of the ATD PA are single two-sided sheets and require about 15 minutes to complete.

The purpose of the ATD PA is to identify likely source(s) of person/technology mismatches, so that training strategies and other inverventions can be applied to ensure a good rehabilitation outcome. One concern regarding the measures is how well they adequately assess the myriad influences on technology use (content and criterion-related validity). Because the measures are composed of items requiring subjective judgments, another concern is the effect of "scorer variance" (inter-rater reliability). The ATD PA has content validity since it was created from the experiences of users and non-users of technologies. Also, ongoing discussions with consumers and professionals in the field and continuous literature reviews tend to support the items included. Other data support the criterion-related validity and inter-rater reliability of the measures (12,13).

Table 3.
Questions for consumers to answer when facilitating their match with an FNS system.

Characteristics of the psychosocial arena/milieu

- Where will I use the prosthesis? At home, work, community, all of these?
- Will my environment(s) support the prosthesis?
- Will I have the training and support I need to use the prosthesis?
- Could the environment disrupt performance, i.e., electronic interference?
- How may the prosthesis affect other people in my environment?

Characteristics of the person's temperament, abilities, and preferences

- Are my capabilities stable or changing?
- How do I currently manage my daily activities?
- How will the prosthesis fit in my routines?
- Can I change my activities so that I can do them without a prosthesis?
- Is it important to me to do things as independently as possible?
- Am I comfortable using technology?
- Do I have the necessary capabilities to use the prosthesis?
- Will this prosthesis contribute significantly to my quality of life?

Characteristics of the prosthesis

- Does the prosthesis reflect my lifestyle, age, personality, values?
- Have I considered all the options available?
- How well does the prosthesis work?
- How much will it cost to buy and maintain?
- Will it be easy to use and maintain?
- How long is it likely to last?
- Will I be able to try it before I buy it?
- How does the prosthesis fit with other equipment or technologies that I use?

The ATD PA, or a similar instrument that involves the consumer in the matching process, can expose the consumer's concerns and predispose him or her to work with you. The purpose of using such an instrument is *not* to preselect people for device prescription, but to identify areas that may present barriers to optimal use. This process is designed to reduce abandonment and make as many people as possible optimal users of the technologies.

Whatever instrument is used in such a process should have face validity, meaning the items should make sense in the context of the technology and the target consumer group. Special attention should be given to avoiding any questions that might be offensive to an individual. Some older standardized tests are 20 or

30 years out of date with regard to some lifestyle issues, and have been known to offend some consumers.

Similar techniques can serve researchers in the development process of a device as well as serving clinicians when equipping a particular individual with a device. Strategies for maximizing successful use of a system include: integrate the perceptions of clinicians, researchers, technicians, and consumers; have more counseling, training, and other interventions when you suspect a potential barrier to use of the technology exists; do more prototyping or testing of new devices with end users. Users who have accepted the device can serve as consultants or role models for those individuals who need help in seeing how things can work in real-life situations.

When you have a good product, it will be used. When it is good and it is used, there will be a market for it.

REFERENCES

1. Young, W. Bench-to-bedside lag time: a major problem for SCI. Paraplegia News 1995:4:64–8.
2. Djourno A, Eyries C. Prothese auditive par excitation electrique a distance du nerf sensorial a I'aide d'un bobinage inclus a demeure. Presse Med 1957:35:14–7.
3. Keith MW, Peckham PH, Thrope GB, Buckeft JR, Stroh KC, Menger V. Functional neuromuscular stimulation neuroprostheses for the tetraplegic hand. Clin Orthop 1988:233:25–33.
4. Driving technology to commercialization: A strategic approach. Seminar organized by Taratec Corporation and Batelle Institute, Chicago, IL, Dec 5–6, 1989.
5. Scherer M. Assistive device utilization and quality of life in adults with spinal cord injuries or cerebral palsy two years later. J Appl Rehabil Couns 1990:21(4):36–44.
6. Scherer M. Living in the state of stuck: how technology impacts the lives of people with disabilities. Cambridge, MA: Brookline Books, 1993.
7. Scherer MJ, Galvin JC. Matching people with technology. Rehabil Manage 1994:7(2):128–30.
8. Scherer MJ. Challenges for the psychologist when technology joins the family. Fam Psychol 1994:10(4):26–8.
9. Cushman LA, Scherer MJ. Measuring the relationship of equipment use and functional status at follow-up (Abstract). Arch Phys Med Rehabil 1994:75(6):724.
10. Scherer MJ. Matching people with technology: Why it often goes wrong. Adv Dir Rehabil 1994:3(6):25–7.
11. Scherer MJ, Cushman LA. Measuring outcomes of assistive technology use through mixed methods (Abstract). Arch Phys Med Rehabil 1994:75(6):726.
12. Scherer M. The assistive technology device predisposition assessment: how does it measure up as a measure? (Abstract). Arch Phys Med Rehabil 1993:74(6):665.
13. Cushman LA, Scherer MJ. Psychological assessment in medical rehabilitation. Washington, DC: APA Books, 1995.