

## WHY MEANINGFUL OUTCOME STUDIES ARE IMPERATIVE

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### INTRODUCTION

Probably every rehabilitation professional began his or her involvement in the field with an attempt to do something which clearly appeared to be "a good thing" for a specific client or group of clients. Probably most of us have stayed in the field because of a desire to continue to do "good things". This is to be commended; at one time it was sufficient to ensure our continued employment and the acceptance of our output by government or other funding agencies.

But we cannot afford the level of health care to which we have become accustomed, and as the level of service entitlement is reduced the criteria for approval of any device or service becomes more stringent. Rehabilitation devices, systems and techniques no longer will be approved simply because we recommend them and the clients demand them; because they are "good things".

In North America, on both sides of the 49th parallel, the latest fashion is "Managed Health Care". Stripped of the rhetoric from which consultants are lining their pockets, managed health care simply means that we are losing the right to determine what we shall do with someone else's money. Both government and private sector health care insurance plans are limiting available benefits to a degree considered impossible a few years ago. Regretably, preventive and rehabilitation measures seem to be targeted for particularly drastic reduction. To ensure that any service or device will survive on the list of remaining entitlements, two requirements must be met. First, it must be proven to be cost effective, in the sense that removing it from the list will increase cost to the funding agency. Second, the evidence of this cost effectiveness must be placed before the funding agency effectively.

But we don't have such evidence. For some time now, "Outcome Studies" have been on the wish lists of health care research funding agencies, but the response from the research community has been unenthusiastic. Now, valid and convincing outcome studies are of critical importance to all of us who wish to continue to work in rehabilitation.

### EVALUATING EVALUATION

Of course, most of us have been involved in some form of outcome study. In rehabilitation engineering, the most common form of outcome study is a "clinical evaluation" which is really a

determination of the validity of an engineering model or technique, having no direct relevance to the issue of service entitlement. Often, when clinical value of a device or system is the issue, evaluations have been designed to demonstrate that a device or system did have clinical value, rather than to determine whether this was the case.

Tests have involved relatively small numbers of clients, and have been conducted by the personnel who were responsible for the original development. Frequently they were carried out fairly, with some effort to be objective, but overall the quality was fuzzy at best. Competence in statistical analysis often was not evident, the evaluation not designed so as to permit statistical testing, and as a consequence the significance of the results often in doubt. To a critic, responsible for reducing health care expenditures, such evaluations are not impressive. To even the most supportive advocate of rehabilitation engineering, they provide pathetically weak ammunition with which to debate the merit of the device or system.

There are more problems. The advancement of technology refuses to stop while we perform evaluations, so if these extend over even a few months it is likely that the technology being evaluated will be obsolete before the evaluation is completed. If a series of clients is involved, it is quite common for the devices used by those toward the end of the series to differ significantly from those used for the first clients. Moreover, the alternative treatments also are evolving during the study, so a statement by a client endorsing a new device as superior to a previous alternative may not be at all helpful in relation to the alternatives available at the end of the study.

Finally, and perhaps most critically, we simply do not have appropriate measures with which to evaluate most rehabilitation technology. For example, the most common criterion for evaluating artificial limbs is the willingness of the client to wear the device. Not, it should be noted, willingness to use the device, although there are attempts to use that criterion as well. Usually one depends on anecdotal evidence, although sometimes electronic counters are included to log wearing or use patterns.

Only very rarely, as in the outstanding study by Malone et al. [1], does an evaluation provide data which would be compelling to a third party payer, such as the effect of treatment choice upon the time between amputation and return to employment. When we get really sophisticated, we prefer to measure the number of marbles moved from one box to another in a given time, or some similar "objective" parameter [2]. Our few attempts to devise more meaningful functional tests have not been very successful nor have the resulting tests [3] been adopted widely.

Given this situation, should we be surprised if health care funding agencies conclude that the long term benefit of our latest device has not been demonstrated, or that its merit relative to a less expensive alternative remains unproven?

## **A NEW STRATEGY**

The purpose of this paper is to convince you that a new evaluation strategy is needed urgently, if rehabilitation engineering is to continue or enhance its contribution to rehabilitation. The details of appropriate evaluation techniques are not clear, but minimal requirements can be formulated with some confidence. I believe that some of these minimal requirements are as follows.

**Within a single study, the technology and all other aspects of treatment, including alternatives used in a comparative study, must be held constant.** This will require development and validation of new short term evaluation techniques, by no means an easy task.

**The claimed benefit must be defined clearly in quantitative terms:** for example "this new hearing aid will permit the user to understand conversational level speech in a general background noise level of 30 dB". How to quantify such benefits as comfort and cosmesis is a significant challenge which we must address.

**Any claimed benefit must be substantiated in all aspects.** For example, the claim that "this technology will permit a paraplegic engineer to perform all normal job functions effectively from home, thereby avoiding the expenditure of \$400.00 per month on specialized transportation" would require that reliable data be gathered on representative transportation costs for disabled persons, in addition to evidence of effective work from home.

**The evaluator(s) must not be part of the development team.** Selection criteria should include professional competence both in the relevant technology and in the relevant clinical specialty. It is not acceptable to claim, as an excuse for self evaluation, that only the developer can apply the device or system competently. Indeed, such a claim indicates immediately that the device will be of clinical value to only a very limited clientele.

**The statistical validity of the evaluation protocol must be verified.** The most difficult issues often will be to determine what constitutes an adequate number of subjects for the study, and how to obtain that number of persons

with similar disabilities. Some of the "small n" experimental design techniques developed recently may be helpful, and the services of a professional statistician will be invaluable.

**When a questionnaire is employed, great care must be used to ensure that the response is not biased, for example by feelings of gratitude on the part of clients.** Such a study in Sweden, to evaluate early fittings of myoelectric prostheses in order to determine whether funding of the development program should be continued, yielded the majority opinion that the present product was unsatisfactory and that much more development was needed [4]. At about the same time a similar study in England, to determine whether such fittings should be an entitlement under the National Health Service, yielded the opposite opinion - that the product was satisfactory and should be made an entitlement immediately [5]..... Why was no one surprised?

Finally, it is not in our interest to await the development of more appropriate evaluation strategies by someone else. We need the results now, and we should take some initiative to see that these needs are met. If we are successful, perhaps we can address the really important question of identifying and measuring features which are reliable predictors of success in specific interventions.

### CONCLUSION

Development of techniques for evaluating rehabilitation technology is not one of the tasks with which most rehabilitation researchers feel comfortable, nor is it among the favourite tasks of clinical staff on their rare moments of freedom from the immediate demands of their clients. However, because of the urgent need for authoritative outcome data it is essential that we work aggressively to develop and apply more effective evaluation methods. We neglect this task at our peril.

### REFERENCES

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