Assessing the Efficacy, Effectiveness, and Cost-Effectiveness of Assistive Technology Interventions for Enhancing Mobility

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Abstract

Purpose. The aim of this paper is to highlight the contributions that complementary efficacy, effectiveness, and cost-effectiveness studies can make to assessing the outcomes of assistive technology interventions for enhancing mobility.

Method. The terms, "assistive technology outcomes research" and "assistive technology interventions," are defined. Several bases are examined for the shortage of outcomes research pertaining to mobility-related assistive technology interventions. Three presuppositions are described for the research strategy of interlocking studies being recommended. They are 1) assigning priority to evaluating both recently developed assistive technologies and ones that have long available, acknowledging the complexity of assistive technology as an intervention, and appreciating the trade-offs necessary for strengthening studies' internal and external validity. Some key study preparations are considered, including treatment theory, treatment specification, and the selection of outcome domains and measures. The essential features of efficacy, effectiveness, and cost-effectiveness studies are outlined, and their interdependence is stressed.

Results and Conclusions. To assess the outcomes of assistive technology interventions for mobility in ways that are both methodologically sound and relevant to stakeholder needs, a research strategy is required involving mutually reinforcing efficacy, effectiveness, and cost-effectiveness studies. **C**ollaborative arrangements and funding methods are discussed for fostering the needed research.

Introduction

Assistive technology (AT) outcomes research seeks to identify the changes produced by AT interventions in the lives of users and their environments [1]. Achieving that goal depends to a significant extent on conducting studies that 1) employ technically sound measures of outcomes that are relevant to stakeholders, 2) use study designs resulting in persuasive evidence that AT interventions are actually responsible for the ostensible outcomes, and 3) communicate the resulting information in ways that stakeholders can understand and use. The present focus is on the second of those requirements, i.e., generating convincing evidence that AT interventions indeed produce the outcomes attributed to them.

This paper highlights some of the limitations of available AT outcomes research, discusses some research designs for strengthening both its quality and relevance, and recommends several steps for promoting needed collaboration and funding. Apropos the ensemble of papers to which this one belongs, illustrations of AT interventions are drawn from the mobility domain. However, the principal points apply to AT interventions in many domains.

An AT intervention is described by two vital pieces of information, one pertaining to assistive technology devices (ATDs) themselves, the other to the services that result in users acquiring and using them [1]. Information about ATDs may pertain to their physical description, the functional performance they are intended to facilitate, and their particular features that enhance that performance. Information about the services surrounding their provision may concern how a candidate user is assessed (e.g. regarding the individual's functional needs), the expertise being drawn on to select a particular

ATD, the manner in which it may be customised to meet the user's requirements, the training that may be provided in its use, and the provisions being made for maintaining it in operating condition [2]. These distinctions underscore the theoretical point that the findings of an AT outcomes study may fall short of expectations because the device underperformed, the services were insufficient, or because both factors were in play [1].

Most AT interventions of relevance to mobility have not been submitted to rigorous evaluative research [3,4,5]. Much of the evidence that does exist is vulnerable to substantial methodological criticism. For example, many published studies of mobility ATDs have used outcome measures that are relatively underdeveloped from a psychometric viewpoint [6], and as discussed subsequently, most have not dealt well with methodologic issues involving treatment theory, treatment specification, and treatment fidelity.

Several reasons exist for the paucity of relevant outcomes research related to mobility. Some ATDs such as canes, crutches, and walkers, have a lengthy history of widespread usage. Little or no doubt exists that they benefit many users, notwithstanding uncertainty about the particular types of devices that enhance specific forms of mobility for users with particular impairments. Outcome studies tend to be costly, and the necessary funding is a struggle to obtain. Unlike some therapeutic or diagnostic technologies, evidence attesting to the benefits of most types of ATDs is not required by federal regulatory agencies in the USA. Many relatively new mobility devices enjoy at least limited market success without having any research-based evidence that confirms their value. The hopeful implication seems to be that sales alone are evidence of devices' importance to users. Finally, outcomes research may be unattractive to some developers

or manufacturers who fear that the findings may not support their claims for the benefits conferred on users.

The tenants of evidence-based practices (EBPs) have been championed in the literature of numerous health professions, among them being Occupational Therapy [7] and Physical Therapy [8], professions with which many AT providers are affiliated. According to a definition by the Institute of Medicine [9] that is derived from one by Sackett et al. [10], EBPs are based on "…the integration of best research evidence with clinical expertise and patient values". Inevitably, AT providers who are proponents of EBPs must deal with the frustration of wanting to support their clinical decisions with quality research evidence, but finding precious little of it available.

Third-party payers for health services have increasingly utilised evidence-based approaches to justify decisions about the interventions for which they will authorize payment. The processes established by Medicare, a U.S. public sector payer, are especially noteworthy for their sophistication and public accessibility [11]. Medicare, the leading third-party payer for mobility-related ATDs in the U.S.A. [12], is a federally administered hospital and medical-care insurance programme for people age 65 or older and for some people with disabilities.

The approach that Medicare took to reevaluating its guidelines for paying for mobility ATDs is particularly instructive [13]. A well-documented process was used in which the review and quality assessment of available outcomes research were central. A working group appointed by the Centers for Medicare and Medicaid Services (CMS), the federal agency responsible for administering Medicare, spearheaded the effort. Members of the group included federal employees who were clinicians (physicians, occupational

therapists, and physical therapists), researchers, and policy specialists who were familiar with mobility devices. The working group directed a survey of the research literature. The review identified only 10 studies that had assessed the benefits of mobility ATDs (principally canes, crutches, rollers, and wheelchairs) on users' performance of mobility-related activities of daily living. Just one of those studies was a randomised controlled trial. Another was a prospective cohort study, and the rest, with one exception, were based on analyses of national survey data. The working group's report acknowledges that, taken as a whole, the studies are insufficient for guiding decisions about the type of mobility ATD, e.g. a quad cane vs. a roller, that is appropriate for individuals with particular mobility limitations. Nevertheless, the group did arrive at a set of guidelines regarding the prescription of mobility ATDs and the clinical criteria for their appropriate use. The formal statement by CMS accepting the recommended guidelines acknowledges that they were based principally on the working group's collective expert judgment, rather on the available research.

Should the AT field expect that expert consensus will continue being achievable for future coverage decisions facing Medicare and other payers? It would be risky to assume so. The breadth of agreement about the value of canes, walkers, rollers, and wheelchairs is unlikely to characterize judgments about newer, innovative, often more costly technologies with which providers and users have considerably less experience. Nor is it likely that payers will continue exempting AT interventions from the evidentiary standards they apply to other interventions. To the contrary, they are likely to place greater emphasis on coverage decisions that are based on credible evidence supporting

devices' ostensive benefits, so that those decisions are as transparent and objective as possible.

Presuppositions underlying a strategy for strengthening AT outcomes research

The balance of this paper describes a research strategy grounded in mutually reinforcing efficacy, effectiveness, and cost-effectiveness studies. The strategy rests on three presuppositions that are discussed initially.

Prioritizing AT outcome investigations

The evaluative strategy being presented is resource intensive, and the AT interventions that are candidates for assessment are manifold and numerous, even within the mobility domain alone. Technologies that have only recently emerged from the research and development process vie for attention with ones that have been commonly available for a considerable time. Notwithstanding sharp limitations on available resources, the outcome studies that are supported should not be limited to devices with either one of those histories.

Outcome investigations centered on commonly available ATDs may be compelling for any number of reasons. They are especially merited when uncertainty prevails about choices among alternative device types, e.g., between powered and manual wheelchairs. Such questions increase in complexity and clinical authenticity when the particularities of specific disabling conditions are factored in. Those particularities are exemplified by the erratic course of multiple sclerosis or the uncertain amount of recovery following acute-onset conditions such as stroke. Outcomes involving users' psychological well-being or subjective quality of life may be especially problematic, as may outcomes involving individuals other than device users themselves. Uncertainty

exists, for example, about the degree to which supplying individuals with mobility ATDs for use in the home increases their independence in the sense of reducing the burden of care experienced by cohabitants. That issue is currently under study by investigators affiliated with the Consortium for Assistive Technology Outcomes Research (CATOR) [14]. Finally, a standing question exists regarding the ways in which commonly available devices fall short of meeting users' needs.

Innovative ATDs emerging from the research and development process merit outcomes study as well, especially ones possessing two characteristics. First, the devices should reflect novel design concepts on which a new generation of ATDs may be based. Second, they should hold promise for enhancing users' physical functioning, psychological well-being, and device-satisfaction beyond what is being achieved with available ATDs. Studies in the mobility area might assess any number of claims, including the following ones: 1) markedly lighter wheelchairs constructed of advanced materials result in fewer secondary conditions such as shoulder-joint deterioration; 2) wheelchairs capable of climbing or descending stairs and curbs are more effective at increasing users' social participation; 3) wheelchairs with computerised navigation aids do more to increase users' independent mobility; or 4) lower-limb prostheses that are micro-processor-controlled allow users to ambulate with greater self-confidence and safety from falls. Third-party payers are likely to resist approving such technologies for funding, being skeptical that their ostensibly greater benefits for users are commensurate with their typically higher costs. Well-designed outcomes studies with generally positive findings have the potential of neutralizing those reservations, making it more likely that the technologies will become available to people who will benefit from their use.

Acknowledging the complexity of AT as an intervention

Several authors have emphasised that outcome studies must take into account the complexity of the interventions being assessed [15,16,]. Approaches that are appropriate for evaluating discrete, readily delineated interventions such as pharmacological agents have to be considerably adapted to be suitable for assessing interventions comprised of multiple, interacting components. From that standpoint, it is important to recognize the actual complexity of AT interventions. As highlighted in a previously published framework for conceptually modelling ATD outcomes [1], the active agent in such intervention is not simply the device itself and the services associated with its provision and maintenance. Companion agents, acting as mediating variables, concern devices' operating condition and the extent and manner of their usage. Devices' operating condition may vary from being "like new" to being inoperable. Extent of use may vary from none at all to use at every opportunity. Manner of use may differ on several dimensions that include whether or not human assistance is involved in the equipment's use, and the degree to which it is being used appropriately, i.e. according to the design intent associated with it. The aggregate of these factors—some related to the device and others to its usage—mediates all other outcomes of interest, e.g. the functional benefits that users enjoy, their satisfaction with the technology, and its contributions to their quality of life.

The reciprocal relationship between studies' internal and external validity

An ideally designed AT outcomes study is one that strongly supports the inferences that 1) the type of ATD and associated services being evaluated were causally responsible for the behaviour changes that constituted the outcomes; 2) the study

conditions approximated ones under which users customarily acquire their devices, thereby enhancing the findings' "real-world" applicability; and 3) the participants represented the diverse populations for which the intervention is relevant. In short, the ideal design is one assuring both the internal and external validity of the findings. The rub is that, practically speaking, those desiderata cannot be realised within the confines of a single study. As methodologists beginning with Cronbach [17] have pointed out, features that enhance a study's internal validity, e.g. restrictively delineated study populations, interventions, and outcomes, are precisely ones that attenuate its external validity. Conversely, relaxing those restrictions in order to increase a study's external validity, e.g. by conducting it under ordinary clinical conditions and by encompassing a diversity of participants, threatens its internal validity.

A strategy for establishing important outcomes of AT interventions

The tradeoffs between internal and external validity suggest that a single outcomes investigation seldom, if ever, is sufficient to provide the evaluative information that AT stakeholders need. Instead, a combination of studies is required, comprised of at least one quintessential efficacy study for which internal validity is of utmost concern, and one or more quintessential effectiveness studies for which external validity is of principal concern. The number of each kind of study depends on several considerations, including the extent to which the resulting findings confirm the value of the AT intervention and the need for evidence applicable to specific user populations or service settings.

The sequence of efficacy and effectiveness studies will depend on the history of the AT intervention in question. In one case, an ATD representing a new generation of technology may just have emerged from the development process. If so, an efficacy trial is especially appropriate in order to confirm its putative benefits under more-or-less ideal conditions. Disappointing findings may suggest the need for developing the technology further, while positive results may support plans to market it in its present form. Initial success in the marketplace in turn may stimulate the conduct of effectiveness studies to confirm that the technology continues benefiting users who receive it through ordinary service channels.

In another case, a technology may be like most others that have been vigorously marketed without any systematic evidence for their efficacy. Effectiveness studies, e.g. ones conducted by particular clinical programs to assess outcomes for their clients, may be the first ones to evaluate a technology. Generally positive findings are likely to spur further interest in it, especially on the part of clinicians and consumers who are oriented to evidence-based decision making. Largely negative findings may result in additional effectiveness studies. If the results continue to be disappointing, an efficacy study may be called for to determine if the technology can at least produce the outcomes expected of it under more or less ideal conditions. Few technologies are likely to attract that much attention, save for those that represent design concepts to which considerable importance is attached.

Preparing for efficacy and effectiveness studies

The two types of outcome studies require some of the same groundwork. The three preparatory steps discussed below are 1) formulating an intervention theory specific

to the AT intervention being evaluated, 2) developing means of documenting intervention delivery, and 3) selecting outcome domains and measures.

Formulating Intervention theory

Planning efficacy and effectiveness studies entails a large number of reasoned choices involving, for example, the populations to sample and the potential confounding factors to control. The rationale for those choices can be made explicit by formulating a "small theory", i.e. one that is specifically applicable to the intervention being investigated and to the research context in which it is being administered [18]. A fully developed small theory includes specification of: "1) the functional problems on which the intervention is intended to impact; 2) characteristics of individuals that make them candidates for the intervention; 3) critical features of the intervention that are ostensibly responsible for the intended outcomes; 4) elements and contingencies in the causal chain connecting provision of the intervention with likely outcomes; and 5) expected changes in recipients' status and in their environment that constitute those outcomes, both near- and long-term" [19]. The theory will necessarily be provisional, and it may be incomplete, e.g. regarding some of the causal pathways linking features of the AT intervention with specific outcomes. Nevertheless, a study's small theory can contribute importantly to planning it, helping to clarify the hypotheses being tested, and to devising the treatment protocol that prescribes how the intervention should be administered. The theory may also be useful in designing statistical procedures such as path analysis that depend upon notions of underlying causal relationships. Finally, the theory offers a structure within which to interpret a study's findings.

Developing means of documenting intervention delivery

An accurate picture of how interventions are actually administered throughout the course of outcome studies is needed for interpreting their results and for possibly replicating them. Study preparations must include, therefore, the design and pilot testing of means for monitoring ongoing intervention delivery. An instrument is currently being developed under CATOR auspices for identifying and quantifying salient aspects of mobility AT interventions [14]. It features a report that is completed by clinicians following each treatment session. Among the items are ones identifying the clinical objectives that were pursued, e.g. client assessment or trial usage of a device, and the presence of other individuals such as family members. All prospectively designed outcome studies share a need for aggregated descriptive information of that kind. The data can be especially useful for dealing with the challenge of maintaining treatment integrity, i.e. assuring that the intervention is being administered in a manner that conforms to the study's treatment protocol. That entails continuous scrutiny of the post-session reports for departures from the protocol, and the initiation of actions to prevent future discrepancies.

Selecting outcome domains and measures

The first step in choosing outcome measures is to designate the domains that are likely to be impacted by use of the technology. A provisional taxonomy of AT outcome domains has been developed for facilitating those decisions [20]. It encompasses the areas of effectiveness—the significance of the technology for the user's ability to function; social significance—its impacts on other people and more generally on society; and subjective well-being—how users appraise and feel about their lives and about the particular technology. The small theory associated with a study should also contribute to

selecting outcome domains, and expedient considerations may apply as well. For instance, the permissible timeframe for a study may dictate the choice of outcome domains that are expected to be influenced relatively quickly, e.g. in-home mobility, as distinguished from domains that require a longer time to exhibit change, e.g. secondary conditions such as postural deformities or musculoskeletal problems of the shoulder, elbow, or wrist.

The culminating step, choosing one or more measures for each selected outcome domain, is likely to entail a number of compromises. Relatively few measures of individuals' functional status are designed in a manner that takes the use of AT into account [21]. Measures used in previous AT outcome studies merit consideration, but many of them were developed to meet the needs of a particular investigation, without much effort being devoted to establishing their psychometric properties [6].

A few psychometrically well-developed scales are available for assessing AT outcomes. One is the Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST) scale that assesses users' satisfaction with an ATD and the related services [22]. Another is the Psychosocial Impact of Assistive Technology Scale (PIADS) that measures users' psychological well-being [23]. Both instruments' item-rating formats have respondents express their judgments in terms of how they are affected by the equipment they are using. Two other instruments with that format are under development. The Assistive Technology Outcome Measure (ATOM), currently undergoing psychometric appraisal, is promising as a means of quantifying the outcomes of wheeled mobility AT [24]. Impacts are measured in multiple areas including usage in different environments, community participation, functional activity, assistance, comfort,

and hassles. The Assistive Technology Outcomes Profile/M is being developed by CATOR collaborators to assess mobility device outcomes in the domains of activity, participation, satisfaction, and well-being [14]. Because the instrument is based on the application of item response theory and computer adapted testing, only questions that retrieve maximum information from device users are administered, thus minimizing respondent burden.

Efficacy Studies

In the context of AT outcomes research, the goal of most efficacy studies is to determine unequivocally whether or not particular AT interventions benefit users in their daily lives. Study designers may concede that the device under investigation affords users particular performance advantages, e.g., making it less physically demanding to move from location to location. The designers' intent is to determine if those advantages translate into benefits for users and others as the device is used in the home and/or community.

Efficacy studies have three essential characteristics. First, they involve a comparative format, one in which the intervention of interest is compared with an alternative intervention or control condition. Second, they are based on designs that are especially capable of supporting the conclusion that the observed effects of an intervention are attributable to it, rather than to extraneous or uncontrolled factors. Third, efficacy studies are typically conducted under relatively restrictive conditions intended to maximize impacts of the intervention being assessed. Each of those characteristics is considered below as it may play out in AT outcomes research.

Judicious consideration is required of the comparative intervention or control condition to be used in an efficacy study. That is because the findings of interest concern the *differences* between either of their observed effects and those of the experimental intervention, and not just the effects of the experimental intervention alone. A control group in an AT outcomes study that is denied use of the experimental ATD is probably not the equivalent of an untreated control group in other areas of study. Its members are unlikely to ignore the functional problems being targeted by the experimental ATD. Many control group members can be expected to cope actively with those problems in various ways, e.g. by using personal assistants or other types of AT obtained from sources unrelated to the study. The resulting heterogeneity of coping strategies makes it difficult to characterize that kind of control condition and to interpret its outcomes.

It is feasible to set up a comparison condition involving a different AT intervention. It may entail an ATD that lacks the innovative features of the experimental one, but that otherwise addresses similar functional problems. Implementing such an arrangement can be challenging. On the one hand, a highly particularised technology may be selected, e.g. a single ATD having a particular manufacturer and model number. Consequently, the comparative findings may not generalize readily beyond it and the device being assessed. On the other hand, a comparison technology may be chosen that includes several different devices, their common denominators being the function they target and absence of the features that characterize the experimental device. That arrangement, however, may create an interpretive problem of its own, viz., differences among the devices may compete with their common denominators as bases for explaining the observed outcomes.

The preferred design for an efficacy trial involves the random assignment of participants to groups receiving the experimental and comparison interventions [25,26]. Randomization is key to being able to conclude that differences between the groups' outcomes are attributable to the dissimilarities between the interventions, and not to other factors such as preexisting disparities—recognised or not—between the groups being compared. Other means are available for promoting the equivalency of the experimental and comparison/control groups. Participants can be matched on variables that are likely to influence the outcomes, independently of the intervention. Alternatively, statistical procedures can be applied retrospectively to correct for between-group differences that relate to the outcomes. However, those maneuvers are only applicable to variables whose potential confounding effects are recognised and measured. Randomization affords the enormous advantage of guarding against a host of other variables whose confounding effects are real, but unrecognised. Possible selection bias is thus effectively controlled, assuming sufficient sample sizes.

Other designs not involving randomization may be considered for efficacy trials. Quasi-experimental designs afford a number of possibilities [27]. In one such design, experimental and comparison/control groups are formed on other than a randomised basis. For instance, a clinic's successive clients may be assigned during alternating 3-month periods to either the experimental or comparison intervention. Other things being equal, stronger internal validity is associated with that kind of design than with ones based solely on before-after comparisons of an intervention's effects or on case studies. Still, quasi-experimental designs lack the strength of randomised designs for realizing the primary purpose of efficacy studies—assuring that observed differences between the

effects of experimental and comparison/control conditions are due to the dissimilarities between those conditions, and not to other factors.

Randomization alone does not assure a study's internal validity. Other threats may exist including persisting initial differences between the groups being compared, differential dropout rates, noncompliance with intervention protocols, and failures to maintain differences between the experimental and comparison conditions. Bias also may result from an inability to blind participants and investigators to the interventions being administered. That seems to be an unavoidable limitation of AT outcome studies, as it is for most rehabilitation-oriented outcome studies.

Because the chief concern of efficacy studies is to detect any treatment effects, researchers try to eliminate or hold constant factors that may obscure them. The conditions of administering the experimental and comparison/control conditions are ideally under tight control, and as such, may depart from usual practice conditions. For example, both the experimental and comparison interventions are likely to be manualised to assure they are administered in a standardised fashion. Especially well qualified and trained individuals are used to administer the interventions, and special efforts are made to maximize participants' adherence to the intervention regimens.

Effectiveness Studies

Outcome studies are needed having interventions that are adaptable to usual clinical services, findings that have known relevance to those services, and study samples that represent many of the populations whose members are candidates for such services. Effectiveness studies attempt to fulfill those needs by evaluating interventions under conditions that typify usual service provision [28]. Such studies are central to a

translational research strategy aimed at encouraging the use of AT interventions of demonstrated value.

Effectiveness studies embody the realities of usual clinical practice in several ways. Interventions are typically delivered by line clinicians who do not have the intensive, specialised training of their counterparts in efficacy trials. The guidelines for administering interventions do not regiment practices to the degree that occurs in efficacy studies, and greater variability is often permitted in the timing or duration of participant contacts.

Effectiveness studies frequently have the goal of documenting an intervention's benefits for populations that were excluded from a preceding efficacy study. Any number of population parameters may be explored, including ones that pertain to individuals' impairments, co-existing medical conditions, treatment histories, or living conditions.

Effectiveness studies may encompass a variety of designs and still fulfill their essential purposes. Experimental and comparison interventions may be administered to different cohorts, or they may be administered in a controlled order to the same individuals. Alternatively, changes may be documented in a single group of participants before and after the experimental intervention is administered. Effectiveness can be evaluated in follow-up studies conducted by particular service programmes, or rest on the study of community-based populations that are the subjects of survey research.

Hybridizing effectiveness and efficacy designs

Proposals have been made to mitigate the limitations of efficacy trials by building features of effectiveness studies into them [29,30]. One way of doing that is to add an

independent variable that normally is limited to effectiveness studies. For instance, a variable might be added to an efficacy study that concerns the exactness with which the intervention is delivered. The desired practices might be administered in a highly regimented manner under one condition. In another, practitioners would be steeped in the intervention's underlying principles, but its implementation would be left to their discretion. The transferability of the intervention to clinical practice presumably would be enhanced if it proved to be as effective under the latter condition as under the former one. Note, however, that this augmented study design would require a substantial increase in the number of participants. Indeed, the enlarged scale and correspondingly higher costs of hybrid studies are their foremost liabilities. That increased expenditure is difficult to justify before the efficacy of an experimental intervention has even been established.

Cost-effectiveness Studies

From a cost-containment perspective, AT is vulnerable to being tarred by the same brush that has been applied to health technology generally, namely, the accusation that it is a driver of increasing healthcare costs. A meaningful response to that concern requires that knowledge about the effectiveness of AT interventions be complemented by information about their costs. That is an issue of cost-effectiveness, viz., the incremental difference in cost that is associated with an incremental difference in outcome, comparing one AT intervention with another. Here, "incremental" refers to the difference between the cost (or outcome) of the intervention and the cost (or outcome) of an alternative one.

Cost-effectiveness studies pose their own distinctive demands. Their outcomes frequently take the form of health utilities, i.e. systematically determined preferences for

particular health states [31]. Diverse outcomes can be integrated into a single score, thus facilitating comparisons among interventions. Considerable controversy exists, however, regarding the extent to which the utilities determined for one population (e.g. individuals with chronically disabling conditions) apply to other populations (e.g. individuals without such conditions) [32].

Data pertaining to costs are of little value unless they are captured comprehensively and in a state-of-the-art manner [33]. For AT interventions, the costs of devices are relevant, as are expenditures for services associated with their provision and maintenance. Included in the latter two categories are costs related to assessing candidate users, selecting, and ordering devices, adapting them to users' needs, training individuals in their use, and keeping devices in operating condition. Expertise in health economics is needed to assure that such costs are quantified appropriately in AT outcomes studies. Informed judgment is required at numerous junctures, e.g., critiquing stated prices in terms of how well they represent actual costs, suggesting appropriate methods for capturing overhead costs, and seeing to it that all of the parties who are incurring costs are represented. Among those parties are device users, their family members, AT providers, third-party payers, employers, the government, and society as a whole. Achieving consensus on a comprehensive categorization of the resources consumed by AT interventions will constitute an important first step in achieving the standardization of cost measures called for by Harris and Sprigle [34].

Cost-effectiveness studies require a groundwork of preceding studies in order to be meaningful. Apropos of being effectiveness studies, their underlying design is typically one that stresses the external generalisability of the findings, i.e. their

applicability to the world of ordinary service provision. In short, the internal validity of their findings is often not their strong suite. That underscores the importance of outcomes findings being available from companion studies in which internal validity was a principal concern.

Some Ways Forward

Two steps are discussed below for increasing the amount and quality of evaluative knowledge that users, clinicians, and payers have about AT interventions. One is concerned with strengthening opportunities for collaborative AT outcomes research, the other, with increasing research funding.

Infrastructure for facilitating collaboration

An AT outcomes investigation requires a team of principals who bring different backgrounds, capabilities, and resources to the endeavor. Skills in designing and implementing outcome studies and in analyzing the resulting data may be supplied by some individuals, while others contribute clinical expertise in providing AT services and mobilizing the cooperation of needed services settings. Projects devoted to evaluating outcomes of a new technology may also include individuals who participated in its development. Assembling and sustaining such teams can be demanding, because their members often represent distinct institutional cultures and because they may have had little or no history of working together.

Outcomes research networks, standing consortia of academic and clinical settings that collaborate in conducting efficacy, effectiveness, and cost-effectiveness studies in defined areas, are a way of fostering the required teams of researchers. The Traumatic Brain Injury Clinical Trials Network funded by the National Center for Medical

Rehabilitation Research (NCMRR) nicely exemplifies this kind of cooperative endeavor [35]. The formation of AT outcomes research networks could serve an important bridging function among AT researchers, clinicians, and developers. The networks might be distinguished by the type of AT on which they focus (e.g. for mobility or for augmentative and alternative communication), impairment groups (e.g. stroke or spinal cord injury), age groups (e.g. children or elderly individuals), or by a combination of such factors. The networks would share the aims of shortening the start-up times of AT outcomes studies, ensuring that a broad spectrum of expertise is drawn on in planning and conducting those studies, and of expediting the recruitment of participants from relevant study populations. They could pursue those aims by identifying and disseminating information about best practices for conducting AT outcome studies; publicizing training opportunities; and by maintaining two kinds of registries—a technical assistance registry profiling individuals with skills in developing study protocols and conducting data analyses, and a facilities registry profiling clinical sites that serve defined AT user populations and that are willing to consider collaboration in outcome studies. The networks might be fostered initially by an organisation such as the Rehabilitation Engineering and Assistive Technology Society of North America (RESNA) [36] or the American Congress of Rehabilitation Medicine (ACRM) [37], and subsequently encompass collaboration with European organisations such as the Association for the Advancement of Assistive Technology in Europe (AAATE) [38]. The evolved, externally funded versions of the networks might be able to support the conduct of pilot studies that are selected on a competitive basis. The successful projects might then mature into full-scale investigations funded by other means.

Funding

Research projects devoted to evaluating the efficacy, effectiveness, or cost-effectiveness of AT interventions are entirely legitimate candidates for funding by both the National Institute on Disability and Rehabilitation Research (NIDRR) and by NCMRR, the federal agencies supporting the preponderance of rehabilitation-related research in the USA. The NIDRR-funded Rehabilitation Engineering Research Centers (RERC) programme is an especially appropriate host for such projects in view of its commitment to fostering research and development that advances AT in numerous areas, including mobility [39]. However, judging from abstracts describing the centres' work, outcome studies that evaluate the value of those advances do not figure prominently in their research agendas [40]. Nor has NIDRR given much visibility to such research in either its recently updated long-range plan [39] or its announcements of funding competitions for the extant RERCs. This neglect may flow from the questionable view that the centres' commitments to making AT advances have been fully discharged once prototypes of innovative devices are available and are handed off to manufacturers for commercialization.

Other especially relevant funding mechanisms are the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programmes administered by both NIDRR and NCMRR. Both agencies are required by federal law to set aside a specified portion of their annual budgets to fund those programmes. The grants support small businesses that are pursuing research or development efforts that have the potentiality of being commercialised and of benefiting the public. Collaboration between individuals affiliated with the small companies and academically affiliated

researchers is a hallmark of both programmes. Assistive technology research and development is well represented among the SBIR and STTR projects being supported currently by both NIDRR [41] and NCMRR [42]. However, those projects do not frequently incorporate either efficacy or effectiveness studies. That is unfortunate in view of the fact that SBIR and STTR applications have higher success rates than several other kinds of applications. Both agencies should do more to encourage applicants to make outcome studies an integral part of the AT development process. That would doubtlessly stimulate that research, and at the same time, help fulfill the objectives of the SBIR and STTR programmes.

Additional funding sources can contribute significantly to meeting the costs of AT outcome investigations. The manufacturers of the devices being evaluated can contribute by making them available at no cost to the research efforts. Payers for AT services might participate as well. Medicare, for example, now pays all routine costs of care for individuals enrolled in clinical trials supported by the National Institutes of Health (NIH). The possibility should be explored of extending that policy to covering services associated with AT outcome studies being funded by NCMRR or other NIH components.

Summary and Conclusions

Assistive technology devices are potentially of vital importance for maintaining the functioning, independence, and quality of life of people who are challenged by mobility-related impairments. The demand for those devices is sure to grow in view of the aging of the population and the dramatic increase in the use of AT by elderly people with disabilities [43.44]. A major industry exists to meet that demand. It supplies a wide

array of equipment options, some that have been long available and others that are based on relatively recent advances in the engineering sciences.

Users, clinicians, and payers all have a stake in having available a solid evidentiary base for guiding equipment decisions. Their need will become even greater as pressure continues mounting to contain the costs of health-related products and services, and as the rate of major advances accelerates. Discussion is needed about the investigative strategies that are best suited to obtain the necessary evidence. This paper has focussed on a strategy involving mutually reinforcing studies of the efficacy, effectiveness, and cost-effectiveness of AT interventions. Its realization will require vigorous effort by members of the field to marshal the requisite investigative resources—financial, human, and institutional. That cannot happen until more of a consensus is reached about the field's evaluative research needs and about the most promising avenues for fulfilling them. A purpose of this paper has been to energize that discussion.

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