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The Emergence and Emergency of Assistive Technology Outcomes Research Methodology

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Abstract

Assistive technology (AT) outcomes in rehabilitation made major strides in the early 2000s. However, despite major advancements in the technology environment, AT devices, and rapid advances in outcomes methodology, outcomes never seemed to charge into the mainstream of AT research. This has turned into a significant field-wide problem as evidence-based funding has become a reality. This paper summarizes the history of AT outcomes to highlight continuing methodology issues and opportunities in rehabilitation to create systems and research methodologies more conducive to measurable AT outcomes and disability research than traditional randomized controlled trials. The health and medical outcomes fields have matured to include registries, acceptance of small studies as key steps in measuring outcomes, and mHealth to leverage the capabilities of mobile interventions and data collection. AT and rehabilitation engineering professionals, researchers, and policy makers must take advantage of these new methods and engage in a new level of defined research that includes these emerging techniques. Without this investment in outcomes research, the budgetary constraints of evidence-based funding will continue to leave the field in a state of marginal financial support.

Keywords: assistive technology, outcomes measurement, rehabilitation, methodology

The Emergence of Assistive Technology Outcomes Research

Research in assistive technology (AT) outcomes has a historically strong foundation, a weak current focus, and major potential to contribute to improving future AT services and the lives of people with disabilities. However, documenting AT outcomes is challenging. This is in part because AT outcomes are multifaceted as a key interest of many stakeholders, each having their own reasons for wanting to know about outcomes (DeRuyter, 1995, 1997, 1998). Basic researchers want to understand foundational factors explaining why AT works and the related causes and effects. People with disabilities and service providers want to know which AT devices work and under what real-life conditions. Manufacturers and developers want to demonstrate that their products work. Funders want to know what functional improvements are made with which devices and services and at what costs. Moreover, the concept of "outcomes" and the varied domains of outcomes are a terminology debacle. People with disabilities even have difficulty relating to the word "outcomes". People with disabilities want products that work. Outcomes are an abstract construct (Lenker, Harris, Taugher & Smith, 2013). The context describing "outcomes" emerged from conversations among service providers trying to describe what they thought third-party payers needed.

This complexity around outcomes must be organized and simplified. The consequence of any confusion around outcomes is a disservice to the field. This paper focuses on the outcomes that service providers, manufacturers, and people with disabilities must document so that funders can understand. At its core, if the field fails to deliver practical outcomes data on this level, current and future funding of AT devices and services will continue to be in jeopardy.

To better understand the current state, where the AT field fundamentally lacks evidence of AT outcomes, it is helpful to examine the history of outcomes in rehabilitation and AT, review the unique methodology challenges encountered by the field, and highlight the implications of inaction. This background will help explain what the communities of AT consumers, practitioners, educators, researchers, and industry need to do.

Historical Need for Measuring Outcomes in Rehabilitation

The need for measuring outcomes in rehabilitation has existed and been documented for many decades. Understanding the path that medical rehabilitation outcomes research took as it matured informs new directions for managing AT outcomes research. Early on, researchers and clinicians acknowledged the need and prompted publications that created new assessments for disability outcomes measurement (Granger & Gresham, 1984; Keith, 1997; Fuhrer, 1987). Many new functional assessment instruments were created during this time and standards for developing instruments were articulated (Johnston & Graves, 2008). In the 1980s, work supported by the National Institute on Disability and Rehabilitation Research (NIDRR, now the National Institute on Independent Living, Disability and Rehabilitation Research - NIDILRR) through a field-initiated project, spawned the Functional Independence Measure (FIM) as a simple 10-20 question outcome measure. The foundational questions heavily overlapped the Barthel Index (Mahoney & Barthel, 1965). The FIM development process created a consensus through a multi-disciplinary and substantial national effort with stakeholders across rehabilitation service provider sectors.

What resulted was not only the development of the FIM (Stineman et al., 1996), but also the creation of the Uniform Data System (UDS) (Fiedler & Granger, 1996; Uniform Data System, 2015) that later evolved into being embedded in several national data collection systems such as the Centers for Medicare and Medicaid Services' (CMS) Minimum Data Set 2.0 Resident Assessment Instrument User's Manual for nursing homes (CMS, 2008), and the NIDRR Burns national registry (Klein et al., 2007). Eventually, this FIM initiative provided the foundation for the current rehabilitation and disability funding system based in the CMS (Clayback et al., 2015). This system, called the Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI) (CMS, 2016), highly resembles the early work in the 1980s and is a direct descendent of the 18-question, seven- point FIM scale. The researchers in medical rehabilitation realized that aggregating data into field-wide data sets was necessary to demonstrate positive outcomes and to help direct the funding systems to support successful practice. As a relatively defined area of practice, medical rehabilitation has been able to successfully focus its methods. National outcomes data systems have resulted.

Historical Need for Assistive Technology Outcomes Measurement in Rehabilitation

While the AT community began paying attention to outcomes after the efforts in the general rehabilitation community, by the 1990s it was clearly acknowledged that a focus on AT outcomes measurement and research was needed (Smith, 1996). At that time, many AT outcomes researchers were predicting that if the profession did not seriously begin developing and using outcomes measures, AT funding would be in peril. As part of a field-driven response, the Rehabilitation Engineering and Assistive Technology Society of North America (RESNA) developed an active Special Interest Group on AT outcomes in the late 1990s and 2000s. Al Cook, then president of RESNA, created an ad hoc Committee on Quality Assurance that actively participated in the efforts to develop service provider credentialing in AT to facilitate competent service provision and the resulting outcomes. Key to this process was the writing and compilation of a three-volume resource on AT outcomes published by RESNA (1998). Additionally, during this project, RESNA brought together expert groups to create taxonomies of the skills and knowledge related to best practices that served as the core for the development of the Assistive Technology Professional (ATP) credentialing and targeted future specialty credentialing areas (RESNA, 1996).

In 1996, a special issue of the journal Assistive Technology was devoted to outcomes. The focus revolved around methodology. In 2004, the e-journal of Assistive Technology Outcomes and Benefits (ATOB) was launched with support of the Assistive Technology Industry Association. ATOB went dormant for two years in 2013 and 2014. While this could be due to factors specific to the journal and editorial support, it is also a historical indicator that runs parallel to the national funding of AT outcomes initiatives in the United States. NIDRR actively funded AT outcomes research projects as earmarked activities in the early 2000s for about a decade (Schwanke & Smith, 2005; Smith, Schwanke, & Rust, 2006; CATOR Project, 2004). The Satterfield (2016) paper in this issue details this further. When the funding for these activities was discontinued, the attention to developing AT outcomes systems also languished. A historical overview of the history of AT outcomes measurement is presented as a chronological chart on The Assistive Technology Outcomes Measurement System (ATOMS) Project (2015) website, and highlights the impact of legislation, leading AT outcomes research, and related activity (Smith, Rust, Lauer, & Boodey, 2004).

Interestingly, during these NIDRR focused Disability and Rehabilitation Research Projects (DRRPs), several instruments specific to AT assessment were devised or further developed. Three well known instruments are the Psychosocial Impact of Assistive Devices Scale (PIADS) (Day & Jutai, 1996), the Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST) (Demers, Weiss-Lambrou, & Ska, 2000), and the Matching Person and Technology (MPT) (The Institute for Matching Person & Technology, Inc., 2015). These instruments are heavily documented and have been actively used in research since their inception. None of these instruments have become widely used as outcomes instruments, in part due to the domains of each of their focus which are identifiable in their names. The PIADS examines an important domain of AT use, being the psychosocial perception of the device when it is used. The QUEST focuses on the user experience as determined by their satisfaction with the device. The set of instruments surrounding the MPT assessment process was designed to help identify acceptance of devices as they were being selected by the consumer and service provider to better identify devices that would be accepted by the user.

Each of these instruments elevates and assesses an essential domain of AT device use, the subjective experience of the user or prospective user. These instruments have been critical for understanding what devices and critical features of designs are considered of value to the ultimate consumer of the device. Researchers interested in understanding the successful application of AT devices have widely deployed these data collection tools and acquired substantial information about the nature of the interactions between devices and their users. This has led to a better understanding of device abandonment, improved procedures in the selection of devices so the consumer is involved, broadly informed designers that the perspectives of people with disabilities matter when developing new devices, and, importantly, documented the internal experiences that people with disabilities have encountered when they consider a device, use a new device, continue using, or discard a device. These instruments, however, did not document functional performance or health-related quality of life domains that funding agencies have seemed to adopt as essential domains for rehabilitation and health-related interventions.

Other work from these DRRPs attempted to focus more on performance outcomes. For example, researchers extended the work of School Function Assessment (SFA) into the SFA-AT that added an Assistive Technology Supplement (Silverman & Smith, 2006; Watson, Ito, Smith & Anderson, 2010) and the School Performance Profile (SPP) focused on AT outcomes of K-12, comparing AT to other interventions (Fennema-Jansen, 2004; Edyburn, Fennema-Jansen, Hariharan, & Smith, 2005; Fennema-Jansen, Edyburn, Smith, Wilson, & Binion, 2007; Watson & Smith, 2012). Plus, in the vocational rehabilitation domain, the Isolating the Impact of Intervention (I3) was created by Johnson (2006) as a self-administered survey. While the SFA-AT, SPP, and I3 all demonstrated some success in measuring AT outcomes, like the MPT, PIADS and QUEST, they were not promoted for widespread use as outcomes instruments and none were adopted widely as an ongoing outcomes data collection methodology.

Historical Intersection of Medical Rehabilitation, AT Outcomes, and Medical Records

As documenting outcomes has increasingly been accepted as an essential task for rehabilitation service provider accountability, regulations have structured what data must be collected and how to collect it. This transition of medical and health records to electronic data collection, storage, and access was intended for increasing efficiency and data sharing for those in the need to know. While outcomes documentation has not been a driver of the move toward electronic records, it has been swept along. As one can ask almost any hospital or medical service today about the headaches of “going live” with e-records, the advantages are slowly becoming evident. Any record can be easily and immediately shared with other service providers to improve coordinated care; consumers can access their own records quickly and inexpensively; and e-record services enthusiastically highlight the reduction in human errors made during service provision. None of these seem to be purposely connected to outcomes documentation. However, the advantages are substantial and are being seen across existing and new rehabilitation related outcomes databases.

As a federal agency, NIDRR and its current form as NIDILRR, has advocated for outcomes research tools and studies through the programs of its core funded centers. The Rehabilitation Research and Training Centers and Model Systems each always have paid serious attention to outcomes. For decades, the Model Systems Programs in Spinal Cord Injury (SCI), Traumatic Brain Injury (TBI), and Burns have collected data depicting the nature of the population and general aspects of outcomes. NIDILRR staff publicly report when they present information about the Model Systems that extensive numbers (hundreds) of publications have been generated using the model system data.

The Veterans Administration (VA) system also has initiated key directions that may prove a foundation for outcomes research. As a self-contained health system with its own funding mechanism, the VA has created its own e-medical record system that opens the opportunity for potentially sophisticated outcomes research. However, the VA system has many challenges that restrain outcome implementation for AT devices and services. One challenge is that the VA is a standardized set of services and uses a process for approving AT devices nationwide. As a highly governed system, it has less inherent flexibility and opportunity for personalizing interventions. A second challenge noted in all VA research announcements is that the VA data have restricted access. In general, VA research is available only to VA personnel or researchers. This enables keen access to those close to the system, but is restrictive to quick research engagement by the rehabilitation and therapy research community at large.

Furthermore, across rehabilitation outcomes research, a general insidious and important disconnect has existed between rehabilitation services and AT. While AT and rehabilitation engineering have been seen as key medical rehabilitation interventions, they have been funded, trained, and treated as parallel, not integrated as part of the outcomes of overall rehabilitation interventions. Clear evidence of this perspective of segregated interventions is revealed in the functional outcome assessment instruments themselves. Rust and Smith (2005) examined 100 rehabilitation and health outcomes instruments to determine how AT was integrated into the measurement and interpretation of these tools. They found that AT usually was omitted from the instruments. Moreover, when it was included, it was often treated as a necessary, but not preferred intervention compared to the more curative rehabilitation approaches. Possibly, this perspective evolved due to the added cost of technology, that AT devices and service provision were often funded and provided outside the core rehabilitation services team, or from the constrained definition of independence that did not include assistive devices.

Large numbers of rehabilitation clientele have received and used AT devices temporarily or chronically. These range from small self-care devices, to expensive mobility equipment, to devices that support and monitor basic physiological functions such as respiratory supports, to fundamental prosthetic replacements. Rust and Smith (2003) speculated that it is not only possible, but that outcomes of rehabilitation services are commonly influenced by AT. Thus, investigations that examine rehabilitation outcomes, but neglect to document or report the contributions of AT devices and services as covariates, may draw inaccurate conclusions.

Documenting the use of AT devices and services must be integrated as foundational components of rehabilitation outcomes research and related methodologies.

The Methodological Challenge

An AT system-wide outcomes methodology is a challenge for many reasons. These include the large numbers of devices and combinations of their use, coding AT device use consistently, the provision of devices and services, the distributed application of AT across vocational rehabilitation, education, health services, and personal purchase, the special purchase and mass market availability of devices, and the fact that outcomes variables themselves cross many domains and total hundreds of factors of interest. This challenge has been said to range from daunting to impossible to solve.

Those who have disabilities or work with people disabilities know how unique each case, situation and environment is. This diversity of individual needs challenges all AT team members and stakeholders to select the most appropriate device and service. Consequently, obtaining the outcomes of such a personalized intervention is highly complex. It is critical to understand the full scope of this outcomes assessment challenge, the implications on available outcomes methodologies, and what it demands of a yet-to-be-designed future system.

Smith (1992) described the measurement of functional outcomes in occupational therapy as being particularly problematic. The paper emphasized the science of functional assessment. A key set of variables that was identified was the wide range of disability and impairment types. The enormous number of possible populations for which research outcomes of AT devices and services is needed continues to be a key challenge. In 1996, Smith pointed to the challenges specific to AT, one being the extensive numbers of AT devices and services in use, for which more than 30,000 devices were catalogued by ABLEDATA at that time, with thousands more listed today (New Editions Consulting, n.d).

ABLEDATA uses a thesaurus that structures this U.S. national database. This highlights an important component of outcomes assessment. Intervention and outcome domains must be coded for any outcome study to be generalizable and informative to other like individuals. Indeed several descriptive taxonomies related to AT interventions and outcomes have been promoted. The International Standards Organization (ISO) created a specific taxonomy to code devices. Many hundreds of device codes portray the diversity and extensiveness of the field. Very few outcomes studies, however, have been completed using these device codes (International Standards Organization, 2011). The World Health Organization's International Classification of Functioning (ICF) also has been used as a guideline for highlighting AT areas of outcomes (Bauer, Elsaesser, & Arthanat, 2011). The multidimensionality and extent these categories related to AT devices and services creates a matrix that is compatible, but highlights the size and complexity of coding structures needed for disability and AT outcomes.

Coding consistency is essential for outcomes research, particularly when data are compiled into large databases. Any coding database designs that do not exactly coincide may lose the value of the data forever. Three historical examples make an important point. First, the fundamental listing of types of impairments used by the National Health Information Survey (Disability) in the 1980s was also used by the U.S. Department of Education to code students with disabilities. While the intent for data record compatibility was clear, the two agencies elicited the survey responses differently. One requested the respondent to identify which impairment was primary. The other solicited "check all that apply." The outcome was that neither database could be used with the other for analysis of school and home health related status and outcomes (Moser, 2003).

A second national database with significant AT outcomes potential was the Rehabilitation Services Administration (RSA) 911 longitudinal database of over 600,000 records per year. It listed key outcomes variables, including several levels of back-to-work outcomes. In the 1990s, however, the RSA honed its database fields for efficacy and reduced the five AT and rehabilitation engineering intervention fields to three, losing the intervention granularity for outcomes (Schwanke & Smith, 2005).

Lastly, the NIDRR/NIDILRR national databases from their model systems centers were mentioned previously. These SCI, Burns, and TBI databases are extraordinary, as they contain decades of follow-up national population data. However, they never embedded sufficient codes to delineate rehabilitation interventions, including the delineation of AT and rehabilitation engineering devices and services.

There is a lesson to be learned from this outcomes history. When databases are created, attention must be paid to the details, and they must delineate AT and rehabilitation engineering interventions. This is easier said than done. The ATOMS Project documented the importance and suggested a possible elicitation method (Whyte, 2002) for coding the implementation of specific AT interventions. Of interest, one intervening variable is that users of AT devices may fail to recognize that they are using an AT intervention. The more integrated the device is in the daily activities of an individual, the more the person views the device as a part of themselves and may miss that they are using an AT device. One can understand why a prosthesis might lose its special AT device status when used day in and day out, but large obtrusive devices like wheelchairs also can be omitted inadvertently by users (Fennema-Jansen, Whyte, & Smith, 2006).

An additional challenge for measuring AT outcomes is that AT device use does not reside in any specific service model or funding domain. The ATOMS Project posed that AT devices that a person uses often cross health, community living, vocational, and educational service domains. Thus, any service provider may be able to elicit outcomes in one of the domains, but it becomes more difficult to obtain outcomes data from multiple domains. One possible solution that, to date, has only been suggested, is to increase the role of device automation and intelligent outcomes acquisition. We can embed data collection into devices for more unobtrusive and widespread outcomes data leveraging Internet-based data collection and the cloud. However, this would require funding support or an external mandate since little to no financial incentive currently encourages such an implementation. Another option would be to increase the role of the AT device consumer (and their responsibility) in contributing to the AT outcomes system. The AT device consumer resides as the focal point across domains. Figure 1 depicts this relationship. Of course, this also would require a new model of funding as agencies support the mission and focus of their particular service sector. A new external mandate is needed to operationalize a cross sector outcomes system for AT interventions.

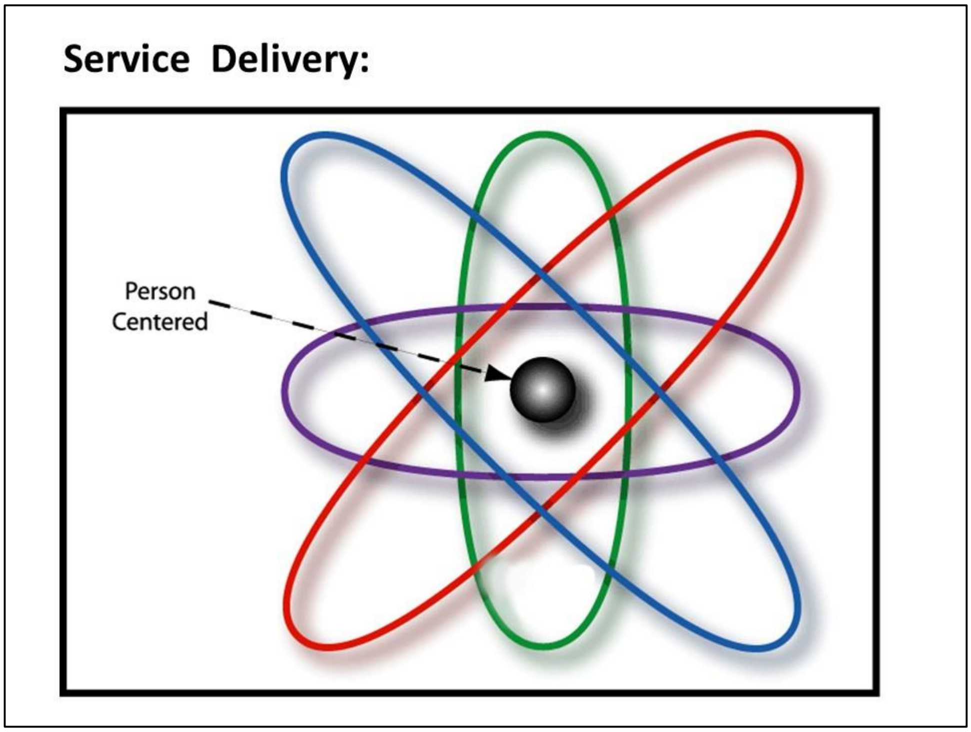

Figure 1. The ATOMS Project logo as it depicts the four service delivery models looping around the AT user in the center (Edyburn, Smith, Schwanke, & Fonner, 2002).

To further aggravate the challenge of knowing what AT interventions are used, the boundaries between AT devices and services and general information technologies are blurring. A prime recent example is the advent of the smart phone. Mobile phones have replaced the need for extensive and expensive TDD/TTY devices with texting that is mobile. Specialty blind accessibility devices have been supplanted with social networking or inexpensive or free apps. For example, today, people who are blind can use the mobile "MoneyReader" app to confidently identify currency/bills in the U.S. and across the world through smart object recognition. This challenges methodologies that measure outcomes that revolve around a pharmaceutical intervention model. Prescribed medications reside in a category of their own due to Food and Drug Administration approval that delineates open versus prescribed access to interventions. AT is not so governed.

While this confounded and complex nature of AT outcomes is clear from the previous discussion, there are still additional complexities that are important to highlight. The fact that AT devices and AT services are concurrent interventions used in parallel with most rehabilitation interventions should not be underestimated in its methodological significance. The interactions of AT device outcomes are embedded in a larger context of the environment and concurrent rehabilitation and educational interventions.

The unique needs of an individual frequently require custom application of AT devices and services that are personalized for the physical and social environments for which they are used, the functional activities they are addressing, and their interaction with a wide range of other rehabilitation interventions. The ATOMS Project found that it needed to place AT devices and AT services in the context of overall human functional performance. The IMPACT2 model portrays this structure and context where AT devices and services reside.

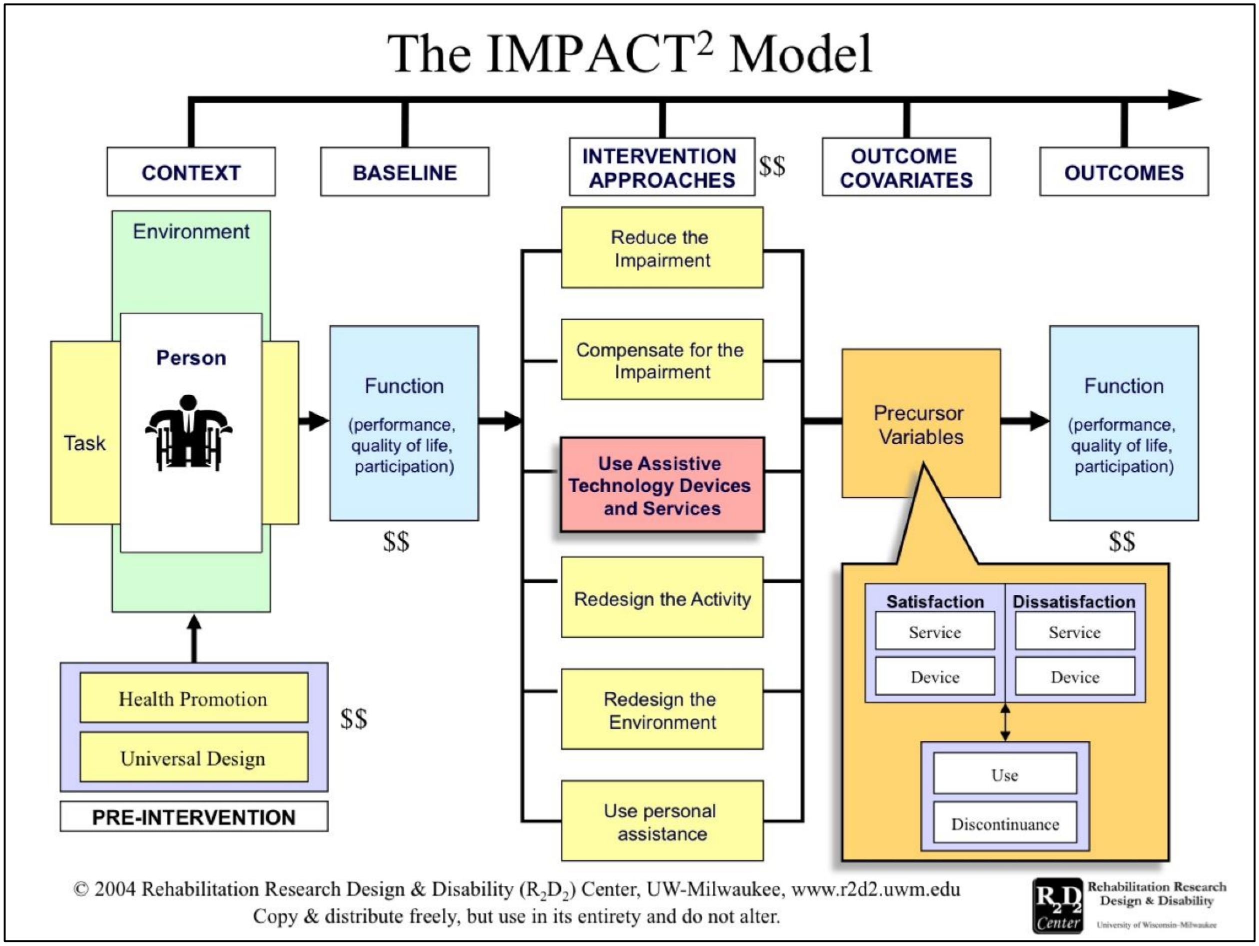

Figure 2. IMPACT² Model depicting the multiplicity of factors related to AT outcomes with particular focus on the concurrent interventions for which AT is one of six. (Smith, 2005)

The IMPACT2 model as depicted in Figure 2 also highlights the relationships between AT and universal design. Universal and accessible design must be considered as AT devices are being examined for their outcomes. For example, a wheelchair will not work well if the environment has stairs and narrow doorways. Both types of intervention must be examined together.

Lastly, the field still needs to determine which variables are most important and efficient to measure in AT outcomes. Personal performance with and without the device, satisfaction of device, quality of life, health-related quality of life, and the source of the data (user, observer, or physiological) are all relevant and serve as complications for measuring AT outcomes (Lenker, Harris, Taugher, & Smith, 2013; Lenker & Paquet, 2003, 2004; Smith, 2000).

Clearly, the quick review of issues related to the valid and reliable measurement of AT outcomes is daunting. The number of potentially relevant AT outcomes variables themselves verge on countless. Substantial research is needed to continue to clarify best measures and measurement tools. Even more problematic is that feasible research methodologies for assessing AT outcomes are elusive. Traditional outcomes research methodologies are expensive and highly time demanding; for which both of these resources are scarce. The small research capacity of the AT field is dwarfed by the needs for research. Thus, new research strategies and methods must be innovatively designed, developed, tested, considered, and adopted by practitioners, researchers, funders, and policymakers.

Lack of Sufficient and Acceptable Methodologies

The RCT (Randomized Controlled Trial)

While the RCT is the gold standard for research, due to the types of factors portrayed above, the RCT is not practical for the AT field. RCTs require large and homogenous samples. RCTs require independent control and intervention groups for which to compare outcomes. Control groups typically require a placebo or alternate interventions and are double blinded so participants and data collectors are not aware of which intervention is being investigated. RCTs are staged with pilot and small rounds, prior to executing a large study. RCTs are costly to run (tens of thousands to millions of dollars each) and extremely time consuming, requiring highly specialized personnel and many hundreds of labor hours. Many dozens of methodology texts and papers guide researchers in this methodology.

Simply, there are not enough time, funding, and qualified research personnel resources to mount a sufficient set of RCT studies for AT outcomes. The large number of interventions used are prescribed individually for what comprises unique and small populations. This makes the large group RCT gold standard that depends heavily on population-based inferential statistics not only challenging, but totally impractical. Looking at the economics of outcomes research alone, even if U.S. research agencies devoted substantial funding to perform RCTs for AT, there is not enough money across all of these agencies to mount and complete the RCTs needed to document the needed effects of all of the numerous AT devices and services. Additionally, this is one area in which the AT field differs dramatically from the larger medical equipment and pharmaceutical industries. The field is primarily supported by small businesses that lack the research and development funding or research capacity to perform the necessary research in addition to their basic day-to-day business expenses.

The Onset of Evidence-Based Practice

The British Medical Journal published a paper that is a “must read” for all practitioners, researchers, developers, educators, students, and policy makers in the AT field (Smith & Pell, 2003). The paper, using a “tongue in cheek” format, reviews published evidence for the use of parachutes, and explains that according to evidence-based practice concepts, parachutes should not be used (or funded). The relevance to AT research and the industry is obvious. Funding policy is driving toward withholding funding unless there is evidence that a device or service works. Since we have a paucity of research capacity, another model must be implemented. Funding agencies need to innovate. For example, a provisional funding model for new device types might be implemented while studies are being implemented. Or, trial device use with documented baseline and follow-up outcomes could be used when sufficient evidence is not available for generic funding decisions.

The Emergency of AT Outcomes in Rehabilitation

Criticality of Now

Earlier in this paper it was noted that more than a decade ago outcomes researchers predicted that funding agencies would begin to restrict funding AT devices and services unless researchers documented evidence that assistive technologies worked. It is no longer a prediction, but a reality. Policymakers are encountering the need to use any apparent acceptable criteria to manage their limited resources in the current funding environment. Even when they acknowledge the limitations of using the lack of evidence to make decisions, at face value it seems like a rational choice when charged with allocating limited funding. In recent years, more and more anecdotal stories are emerging about funding denials. They are often embedded in “fugitive literature” such as funding denial letters. Occasionally, however, a letter or statement rises to public attention. One example is that of the medical director in a Pacific Northwest state who explained that the quantity and quality of evidence needed to adequately defend the funding of a particular seating system was that of an RCT of a sample of over 200 participants. Those who know the field understand how unrealistic to impossible it is to expect research on this level across AT devices and systems that need outcomes studies. Many AT devices are only available in small lots due to small populations of specific need. Furthermore, these small populations may be distributed across large geographical areas and served by a wide variety of independent AT services and programs. And if it is the manufacturers that need to create this evidence, such as in the pharmaceutical industry, we know that small companies in AT do not have the funds or expertise to support such large research studies.

AT also changes quickly. Indeed, measuring AT outcomes is a moving target (Smith, 1996). RCTs are ponderous and take substantial time preparing several phases of research to lead up to clinical trials. Then, rarely is an RCT run quickly. This is a conundrum. Technology can advance so quickly that an RCT has little hope of documenting its effects before it is outdated. The augmentative communication (AAC) industry serves as an example. AAC discovered that the advent of the mobile smart phone and tablets dramatically shifted the entire industry within relatively few months. Traditional research methods simply are not feasible under these rapidly changing conditions when new assistive technologies are emerging daily.

This AAC experience also revealed that no part of the AT industry can be complacent. At one time, practitioners in augmentative communication thought that the evidence-based funding decision-making was focused on seating and mobility, and they were exempt. They discovered that augmentative communication was also on the target list without evidence. Such situations can even necessitate big solutions like an “act of Congress”. The AAC challenge resulted in the Steve Gleason Act (2015). One could speculate that no AT device or service has been given a waiver in this new environment. Evidence-based funding provides a seemingly logical mechanism for managing limited funds.

The Mandate and Opportunity for Innovation in Assistive Technology Outcomes

Hope does exist for the future of AT outcomes research in rehabilitation. AT agencies that fund rehabilitation research are aware of the methodological issues and challenges. They have articulated the need to advance methodologies in this area. Plus, many outcomes research methods are beginning to be recognized in various (but disparate) research communities, demonstrating the potential of future outcomes research approaches. Some of the more open thinking about new methods is deliberate, and some are more serendipitous.

An indicator that the field has accepted the need, at least among researchers, is the draft of the Medical Rehabilitation Research Priorities in the National Institutes of Health, which was released for public comment in the fall of 2015. It included the call for future research to tackle the methodological challenges created by the limitations of group RCT methods so that the future includes the development of new robust, yet practical, outcomes research methodologies.

As is also well known to the research community, the RCT and the Cochrane-based systematic reviews have been promoted as the pinnacle of the outcomes research methods. What is lesser known is that esteemed health and medical evidence-based practice methodologists have also acknowledged that the N=1 is a legitimate and powerful outcomes assessment methodology. A prime example of this was published in the Journal of the American Medical Association (JAMA) Evidence-Based Medicine (EBM) series of 25 papers (Guyatt, Rennie, Meade, & Cook, 2015). The authors espoused the importance of sound methods and created an evidence hierarchy (Levine et al., 1994/2015). Over the period of this series, the RCT method was articulated, elevated and then superseded by the strength of systematic review. In the final issue of this EBM series (Guyatt et al., 2000/2015), however, the EBM author team updated their strength of evidence hierarchy. At the top, they placed the N=1 RCT, depicting the importance of individual differences in response to interventions. While this was largely philosophical and not practical for policy decisions (just because an intervention works for one person does not mean it should become policy), the overt placement of the single subject design at the top acknowledges the importance of personalized intervention. This depiction of the individual being the critical focus of research is fully consistent with the person-centered and highly individualized nature of AT service assessment, device selection, and implementation. We only need to more broadly convince traditional RCT researchers and agencies to instill this philosophy into their policy decision-making.

The Single Subject Design (SSD) methods are also being legitimized as an early Phase I clinical trials method for pilot and exploratory discoveries (Johnston & Smith, 2010). The phases of research are being better articulated in the medical field and have promoted some acceptance of the necessity of demonstrating the promise of an intervention using personalized small population methods (U.S. National Library of Medicine, 2008). While these are medical and health oriented, they are representative of many of the research perspectives in the rehabilitation research community. Kratochwill and colleagues have continued to update, articulate, and promote SSD methodologies in the psychology and education literature (Kratochwill & Levin, 2014; Kratochwill, Levin, Horner, & Swoboda, 2014; Kratochwill, Hitchcock, Horner, Levin, Odom, Rindskopf, & Shadish, 2010; 2012). These recent works are enabling an increased acceptance and appreciation of SSD methods in education. Hopefully, we will see a transfer of these to medical, health, and rehabilitation venues soon.

Some of this update revolves around the maturation of SSD methods to include systematic reviews. Statistical and procedural frameworks are developing. In one way of thinking, SSDs are quite random. They represent various populations, timeframes, service provider training, and settings, and most have used some personalization of the interventions. But a constant can be the AT device as the key intervention. So if SSD studies can be aggregated formally, they become a strong meta-analytical method. Of course, to aggregate like studies, the documentation must include more extensive demographic profiling of AT users and a much higher degree of detail describing the interventions than is typical today. Plus, we have little to no standardization in how we document SSD studies for AT outcomes. Important steps need to be completed to mature the aggregation of SSD AT outcomes studies.

So, one can ask how mature SSD meta-analysis methodology has become. This is a young area, but the literature is growing. Currently, no single method has been established for the meta-analysis of N=1 design studies, despite their importance to clinical practice (Gabler, Duan, Vohra, & Kravitz, 2011; Guyatt, Keller, Jaeschke, Rosenbloom, Adachi, & Newhouse, 1990). As far back as the 1970s (Gentile, Roden, & Kelein, 1972), researchers debated the proper use of statistical analysis for single case design studies (Kratochwill & Levin, 2014). A recent volume (2014, volume 52) of the Journal of School Psychology was dedicated to the issue of analysis and meta-analysis statistical methodologies for single-case research studies (Shadish, 2014). Methods include using standard mean differences (d-statistic) (Shadish, Hedges, & Pustejovsky, 2014), generalized additive models (GAMs) (Shadish, Zuur, & Sullivan, 2014), and Bayesian methods (Rindskopf, 2014; Swaminathan, Rogers, & Horner, 2014). Other authors have suggested hierarchical linear modeling (Gage & Lewis, 2012), multilevel meta-analysis of effect sizes (Moeyaert, Ferron, Beretvas, & Van den Noortgate, 2014; Ugille, Moeyaert, Beretvas, Ferron, & Van den Noortgate, 2012), and percent non-overlapping data (PND) methods (Heyvaert, Saenen, Maes, & Onghena, 2015).

Registries are also serving as a new formal outcomes tracking methodology and a robust vehicle for policy decision-making in health care. The Agency for Healthcare Research and Quality (Healthcare 411, 2012) has been publishing extensive descriptors and guidelines for developing, handling, and using registries for effective decision-making. A two-volume, 600-plus page third edition of *Registries for Evaluating Patient Outcomes: A User's Guide* was published in 2014 (Gliklich, Dreyer, & Leavy, 2014). These articulate how massive databases with a priori data can drive appropriate decision-making on clinical and policy levels. Major findings have been revealed from the use of medical registries that have changed the course of technology and clinical interventions (Bates & Bitton, 2010), e.g., hip replacements (Paxton, Inacio, Khatod, Yue, & Namba, 2010) and endarterectomies (Menyhei et al., 2011).

Another example of innovation in research methods that relate to AT Outcomes is the potential of data collection using social media. Research in rehabilitation can leverage community science based on social networking and crowd sourcing. The advent of the smart phone allows AT users to contribute directly to AT outcomes documentation passively and automatically via tracking apps or actively by responding to questions that an app asks. This outcomes data revolution was enabled when "the cloud", the cellular systems, phone providers, and user/societal acceptance of allowing the sharing of helpful personal data began to converge. Today, the many transducers in mobile devices have opened new possibilities to document community mobility (GPS), degree of activity (accelerometers), location of indoor activity (Bluetooth), environments (microphone, camera), motion (camera), and personal perspectives (surveys).

Most of the uses of the mobile and cloud joint networking have yet to be implemented and much of it is not yet conceptualized. These new possibilities may be the methods of choice in the future for AT outcomes where unobtrusive, registry capable, physiological, and deliberate response data become integrated into daily AT practices. In the NIH, an initiative called mHealth has been launched. The NIH has seen the potential of mobile health applications and generated much excitement around their emerging capabilities (Okuboyejo & Eyesan, 2014).

These new rehabilitation AT outcomes opportunities run parallel to new Electronic Health Records (EHR) that are expanding rapidly and building mobile platforms at a rapid rate. EPIC and Cerna health record software apps and Apple Health apps that integrate with health researchers and providers are quickly infiltrating modern society. Recent years have been active with product announcements in the popular press, such as the new array of fitness watches that link to the cloud and research data bases that can be monitored by personal physicians. AT outcomes, however, remains a minor player as an intervention for people with disabilities and, therefore, has not been invited to participate to any degree with these mega EHR operations.

Lastly, major advances in AT outcomes may be seen internationally, especially in the systems and models emerging from Australia or the Scandinavian nations. Australia, for example, has recently embarked on a continent-wide system called the National Disability Insurance Scheme (NDIS). This national funding entity could mandate an AT outcomes methodology that precedes any widespread rollout in more distributed and unstructured systems in the United States or Europe. It will be important to watch international colleagues as they implement AT outcomes systems (NDIS, n.d.).

Target Audience and Relevance: The Challenge to Funding Agencies, Practitioners, and Researchers, and Prospects for the Future

There is potential for a revolution of AT outcomes research on the horizon. However, whether this occurs depends on all AT stakeholders and how well they organize and coordinate. Currently, the field is sufficiently fragmented, hampering substantial progress that will only occur if separate AT communities collaborate on direction and seek common funding to influence the policies of research and service funding agencies. A core vision and the development of systemic initiatives to measure and document AT outcomes across the field are needed.

To enable this, all AT stakeholders have a role. The AT industry needs to help fund outcomes events, collaborate across organizations, and be ready to promote and facilitate standard outcomes data collection processes. Higher education professional training programs need to instruct and create a new generation of researchers comfortable with these new outcomes methodologies. Practitioners need to continue to develop an understanding of what evidence-based funding is, and ready themselves to engage in continual data collection efforts as part of day-to-day operations. People with disabilities must press researchers and policymakers to create, demonstrate, and implement methods that convey the outcomes of devices and services. Grant and journal research reviewers need to expand their understanding of practical and rigorous outcomes methodologies, so RCTs are not considered as the only acceptable approach. Funders and policymakers must support next generation outcomes data and methodologies and adopt new methods of decision-making that include mechanisms for funding devices and services for people with disabilities that change individual lives, but may not have the support of group RCTs with inferential statistical results.

Importantly, this charge cannot be aimed solely at one stakeholder such as policy makers. Each of our respective roles in the field of AT is responsible and has action to take. Practitioners, industry partners, researchers, instructors, and people with disabilities all must personally decide how they can contribute to a new AT outcomes tracking system to elevate it from a wish to a movement. With the right support, maybe planning and creating an AT outcomes tracking system can begin immediately. Perhaps testing and implementing such a system within the decade should be optimistically considered.

Declarations

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