Standards for Assistive Technology Funding: What are the Right Criteria?

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Introduction /Background

Assistive technology developers, manufacturers, and service providers are facing new requirements to demonstrate supporting evidence about the effectiveness of Assistive Technology (AT). The level of evidence being required is comparable to standards of evidence used to support interventions in the medical arena, known as evidence-based medicine. The gold standard for this level of evidence is generally produced through conducting randomized controlled trials (RCTs), although other study designs can provide acceptable evidence depending on the clinical situation.

Unfortunately, the RCT or gold standard level of evidence is often not practical or appropriate to show the true effectiveness of assistive rehabilitation technologies for persons with disabilities. This is because the target populations for most AT devices are small, and often widely scattered making it difficult to find homogeneous groups to participate in studies. Perhaps, more importantly, RCTs require control groups who are denied an intervention, creating a potentially unethical situation. How do you provide a power wheelchair to one quadriplegic and deny it to the next for purposes of a controlled trial? Nonetheless, as a prerequisite for use by persons with disabilities as well as acquisition through third party payers, evidence of effectiveness is needed to justify funding reimbursement for new and existing Assistive Technology (AT) products. The negative impacts of misapplying these rigorous standards to determine efficiency of AT products has already been felt over the past several years, resulting in reduced access to AT by people with disabilities.

Alternative options for evidence of AT effectiveness need to be identified and accepted. Evidence currently consists of peer reviewed journal articles and case studies documenting the efficacy outcomes of AT devices. This level of evidence certainly supports the medical benefits of and need for AT, given the variability and small populations typically served by assistive technology products, as well as the small business financing that dominates assistive technology developers. However, to further demonstrate evidence of AT efficacy, innovative study designs or widely representative AT product registries could be considered for the future. Persons with disabilities and practitioners want to know

what assistive technology devices work best in any given situation. Unless addressed, the lack of documented outcomes may limit future innovation as well as limit access to existing rehabilitation and assistive technologies by those who need it most.

While RCTs remain the foci and preference of most evidence-based medicine decision-making bodies, newer applications of methodologies such as the use of registries or n =1 crossover trials are surfacing in the literature as alternative research strategies. This corroborates that innovative research methodologies are possible and shows some promise for providing the needed justification for future health related funding decision-making.

Again, while journal articles and case studies on the efficacy of AT do exist, the need for more rigorous evidence of AT outcomes is still pressing. The lack of evidence of effectiveness continues to apply to most assistive rehabilitation devices and, policy and research bodies still perceive the evidence in the field with apprehension. For example, the wheelchair industry serves as a representation of the problem. For many people with mobility limitations, a wheelchair is the primary means of mobility. Individualized wheeled mobility systems, those that are designed and manufactured to meet the specific needs of an individual, are expensive. Approximately 70% of people with long-term disabilities who need these systems are unemployed, and many do not have the discretionary income necessary to afford these systems[1]. Thus, many people who depend on wheelchairs for daily mobility in order to function do not pay for their own systems. Wheelchair purchasers rely on a third party payment system that funds wheelchairs for many people who require, but cannot afford, them.

Understanding the third-party payment system and the impact of government policy on the reimbursement of wheeled mobility devices is critical to understanding the industry. Providing individualized wheeled mobility systems to people who require them in a third-party payment system can be very difficult. Customers' seating and mobility needs must be met in a way that ensures

[1] Wheelchair Industry Profile

effective mobility, maximizes function and comfort, and maintains or improves health for the user. Manufacturers and suppliers work to meet the needs of the customer who uses the system, the medical professionals who prescribe them, and third-party payers who establish the coverage and payment policies for these devices. For a vast majority of persons with long-term mobility limitations, a government-sponsored program provides these benefits. The three major government programs that routinely cover durable medical equipment (DME) and of which wheelchairs are a part are:

- **Medicare Part B –** This federal medical insurance program is for persons older than 65 and for persons under 65 years old who have contributed to Social Security and have been unable to work for at least two years due to injury or illness and persons with chronic kidney failure.
- **Medicaid –** This state-administered medical insurance program is for people or families who are judged indigent based on household income. Eligibility requirements vary by state. However, non-income-related variables also factor in the decision to provide Medicaid. These variables include whether an individual is pregnant, disabled, blind or aged, for example.
- **Veterans Administration (VA) –** This is federal medical insurance funding DME for veterans.

Private medical insurance is also a significant source of payment for wheelchairs. Many employers offer private insurance in the form of various managed care plans as a benefit to their employees to cover the cost of medical care. Many people who are self-employed, or who do not receive employer-provided plans, purchase private insurance out of pocket. These policies may or may not include a DME coverage option. Private payment, though infrequently exercised, is always an option for people with mobility impairments who have sufficient discretionary income to pay for wheeled mobility systems.

In this whitepaper, we address the issue of the expectation of an evidence-based standard to determine AT product efficacy, and the impact of this standard on the transfer, use, and payment for assistive technologies designed for persons with disabilities. The National Institute on Disability and Rehabilitation Research (NIDRR) recently funded the Center on Knowledge Translation for Disability and Rehabilitation Research (KTDRR). The KTDRR in turn created a diverse working group whose

purpose was defined as delineating the current reimbursement issues and providing suggestions for methodological standards of evidence for assistive technology reimbursement. Each of the working group members is a representative for their respective stakeholder (AT Consumers, AT Service Providers, AT Researchers and Methodologists, AT Manufacturers/Product Developers, and AT Payors and Policy Makers) group, which are the five key groups that comprise the entire system of manufacture, prescription, application, funding, reimbursement, and efficacy research within each field of AT devices and services.

During our working group conversations, we discussed the current Medicare Coverage of Wheeled Mobility and Seating devices, Competitive Acquisition Policy (competitive bidding) and its impact, the impact of Medicare Policy on consumers and industry, and expected future of Medicaid coverage. In addition, the working group investigated the state of current reimbursement regulations for assistive technology devices, explored and interpreted recent changes to health care reimbursement policy, and documented anticipated changes in healthcare reimbursement with the upcoming implementation of the Health Care and Education Reconciliation Act of 2010. Lastly, the working group was tasked with making recommendations on how to develop a useful and workable outcomes reporting system for Assistive Technology funding. This paper summarizes the results of this effort.

Five Target Populations

This section describes the need for a comprehensive AT outcomes system from the perspective of the five target populations: AT Consumers, AT Clinicians/Practitioners/Suppliers, AT Researchers and Methodologists, AT Manufacturers and Product Developers, and AT Payors and Policy Makers.

AT Consumers

An individual with a disability has unique personal characteristics, unique environments, and specific activities to which they are applying technology devices and requiring AT services. People with disabilities (PWD) of all ages, their families, and their caregivers are increasingly in need of personal

empowerment to assist in decision-making related to assistive technology devices (ATDs) and services (ATSs), purchasing and acquisition. It has been documented that currently as much as 40% of AT, primarily lower cost technology, is purchased by the user themselves[2, 3]. As medical practice heads toward a more person centered model, individuals will be more involved in their own healthcare decision-making, including using the evidence of effectiveness to select AT devices for their own use. Data are needed to assist them with their product decisions.

AT Service Providers (Clinician/Practitioner/Supplier)

Currently, objective data to assist with AT product recommendations are sparse and scattered. When studies are published they are often group studies with normative inferential statistics whose population context may not fit the specialized needs of a client or be too general to be informative. The clinician is often left to rely solely on their personal expertise and judgment, which may or may not align with the outcome efficacy needed for funding provisions. Along with AT consumers, AT service providers (clinicians/practitioners/suppliers) who want the best outcomes for their clients, may be those in the best position to gather needed outcome based data (albeit, since practitioners can easily inject bias, reliable and valid data collection methods must be applied). Today, objective measures are not systematically available or used. The field needs adequate mechanisms to document AT outcomes for later review or sharing. AT service providers need reliable, systematic, and objective methods for quickly documenting AT related performance outcomes and making AT outcome inquiries. Contributing to the problem is that service providers lack a standardized terminology for coding AT interventions and outcomes. When combined with barriers in communication due to service specific terminology this further complicates consistent and compatible documentation. Ultimately, lack of consistent documentation results in abandonment, inappropriate provision of AT devices, and inefficient use of

[2] DeRuyter, F., Evaluating outcomes in assistive technology: Do we understand the commitment? Assistive Technology, 1995. 7(1): p. 3-8.

[3] DeRuyter, F., The importance of outcome measures for assistive technology service delivery systems. Technology and Disability, 1997. 6(1-2): p. 89-104.

resources[4, 5, 6, 7, 8]. It is imperative that AT Service Providers be a part in designing the solution to address their needs.

AT Researchers and Methodologists

It is the mandate and essential work of AT researchers to provide meaningful assistive technology outcomes (ATO) tools and databases for use by all of the aforementioned stakeholders. Three general types of research need to be done:

1) Safety and Effectiveness – for Product Development – to describe the problem a product is designed to address and how safely and effectively it addresses the problem. New products need this early evidence.
2) Outcome Measurements for Evidenced-Based Practice – for users and clinicians to have objective guidance in determining which interventions are more likely to be successful over time, and how they should be used to maximize effectiveness for an individual. For example, power tilt/recline wheelchair seating systems are prescribed to maintain skin integrity. In those tilt/recline systems, users and clinicians need to know the correct angle of tilt/recline that the user needs to obtain to produce pressure relief, how often the pressure relief tilts should be performed, and for what duration the pressure relief tilt should be maintained to achieve the desired result of the lowest incidence of skin breakdown.
3) Device Design and Targeted Population Use – not all assistive technology works for everyone the same way. While general outcomes knowledge is needed for broad policy decisions, the science of successfully applying assistive technology devices depends on a multitude of variables,

[4] Carlson, D., et al., Highlights from the NIDRR/RESNA/University of Michigan Survey of Assistive Technology and Information Technology Use and Need by Persons with Disabilities in the United States, 2002, NIDRR/RESNA

[5] Jutai, J.W., et al., Toward a taxonomy of assistive technology device outcomes. American Journal of Physical Medicine & Rehabilitation, 2005. 84: p. 294-302.

[6] Smith, R., Accountability in assistive technology interventions-measuring outcomes. RESNA Resource Guide for Assistive Technology Outcomes: Measurement Tools, 1998. 1: p. 14-42.

[7] Smith, R.O., Measuring the outcomes of assistive technology: Challenge and innovation. Assistive Technology, 1996. 8(2): p. 294-302.

[8] Johnson, R., The impact of assistive technology on goal achievement for consumers of the division of vocational rehabilitation services, in Occupational Therapy2006, University of Wisconsin-Milwaukee: Milwaukee. p. 130.

> many of which might be unique to the individual. Understanding the specific interactions of technology, person, activity and environmental variables is necessary to match the appropriate technology to the person and situation.

The need for comprehensible usable ATO data remains essentially unmet despite strong efforts over several decades. This can be explained by several factors impacting research; high variation of needs specific to the specialized nature of AT devices and services that challenge study design; need for a mechanism to establish functional equivalence or research methodology to mitigate the need for multiple studies based on diagnosis, age, gender or other criterion; funding for AT research that aligns with the needs of policy makers and payers as well as clinical decision makers, and perhaps most critical, the need to examine the "best-evidence" hierarchy that currently guides evidence-based medicine research efforts and subsequent interpretation. It is widely accepted among policy makers that RCTs are the gold standard for evidence in certain areas of healthcare. Population size and variables, even among populations with the same diagnosis, that may influence outcomes makes RCTs with large numbers of participants impractical, unreasonable, cost prohibitive and most importantly, may not offer the necessary information to answer the questions policy makers and clinicians making technology recommendations need to have answered. Reasons for this are both theoretical and practical.

Consider the recent publication of a meta-analysis on AFOs (ankle-foot orthoses) for individuals post stroke, Archives of Physical Medicine and Rehabilitation[9]. The full text of 43 articles was reviewed and 13 trials involving 334 patients that met the inclusion criteria were included. A significant challenge in analyzing these studies occurred secondary to the varieties of AFOs. Thus, the meta-analysis needed to select one type of basic AFO for its target. The overall findings said that it appears that this particular standard AFO is beneficial, at least in the short term. The authors go on to say:

[9] Scherer, M. and R. Glueckauf, Assessing the benefits of assistive technologies for activities and participation. Rehabilitation Psychology, 2005. 50(2): p. 132-141.

> However, although clinically relevant, it is at an insufficient level to fully inform clinical practice, and many crucial questions remain unanswered. Clinicians need to know the best type of AFO to prescribe, for whom they should be prescribed, the optimal time to prescribe one, how long they should be used, the adverse effects, and the factors influencing acceptability and adherence to their use. It is particularly important that these factors are investigated in the long term, because most patients are prescribed an AFO for long-term use. These are complex questions, the answers to which probably differ according to the patients' level of, and combination of, impairments.

Efficiency of research is an issue. The expense and time supporting all of the necessary studies and meta-analyses would be substantial. Even when traditional RCTs and meta-analyses are used in the field of AT, products are so keenly individualized that group inferential type methodologies often result in studies with relatively little value. This meta-analysis about AFOs provides little information to help practitioners make better decisions about what AFOs to use in practice. Nor does it, in the long run, help other stakeholders make appropriate decisions of major impact.

That said, however, studies such as this, based on investments of hundreds of thousands of dollars, could eventually result in third party funding agency's willingness to pay for standard AFOs for the specific population. Unfortunately, the number of similarly funded and published investigations can only meet a small fraction of the evidence needs of service providers. Furthermore, the types of evidence secured by classical investigation have lengthy timelines when AT devices are emerging and requiring rapid decisions in very short time frames.

For example, in a relatively few short months the entire Augmentative and Alternative Communication (AAC) field needed to make decisions about how to adopt iPads and other mobile device technologies and infuse them into AAC decision-making and interventions. Parents were bringing iPads to the clinics with newly installed and untested AAC apps asking AAC professionals to consider implementing their

use. Due to the rapid development of these interventions no evidence was available to help service providers make appropriate decisions. The only recourse for service providers in this circumstance was to use best judgment and apply sensible assessments and evaluations in their immediate intervention planning. To assist researchers, the field needs to consider rapid report research strategies, review and annotate accepted evidence hierarchies as to how they relate to assistive technologies, prompt and provide advice around the spectrum of potentially appropriate methodologies, and begin considering widespread implementation of ongoing assistive technology outcomes systems.

AT Manufacturers /Product Developers

Manufacturers and AT product developers have their own unique needs for AT outcome data[10]. Manufacturers need guidance from the Coverage and Payment community with regard to a mechanism to establish effectiveness. There needs to be transparency in the criteria used to determine coverage, based on both an agreed upon standard for demonstrating effectiveness as well as pricing and payment methodology. Exacerbating the challenge for manufacturers to acquire and cite outcomes data, is the fact that the field is extremely small with minimal R&D, testing, financing, or research infrastructure. AT manufacturers need efficient methods for collecting and managing device testing data, and obtaining outcomes data. Many research methods require substantial infrastructure. This disenfranchises the AT industry in its ability to compete, not against other companies, but in its survival within a policy structure that requires documented evidence of health related outcomes but does little to work with manufacturers and providers to define the nature of the evidence required for individualized products.

AT Payors and Policy Makers

These stakeholders rely on the best available evidence provided by researchers. Many indications are showing that evidenced-based practice (EBP) is leading towards evidence-based funding (EBF). As the quality and quantity of the evidence is so limited, resulting decisions can be disastrous. Stories are

[10] Brown-Triolo, D.L., Understanding the person behind the technology, in Assistive technology: matching device and consumer for successful rehabilitation, M.J. Scherer, Editor 2002, American Psychological Association: Washington, DC. p. 31-46.

increasingly emerging in which funding agencies have limited or substantially delayed paying for AT devices and services due to the lack of acceptable documented successful outcomes even when what is considered an acceptable outcome has not been defined or disclosed.

A recent example is Wisconsin Medicaid virtually shutting down reimbursement for AAC devices due to a lack of evidence. In this case, the minimal evidence available suggested that AT devices were predominantly abandoned and thus provided rationale to cease provision. Obviously there is a critical need to provide reputable AT outcome data to these parties. Processes that require appealing a large percentage of devices to obtain authorization for payment becomes not only inefficient but impossible to continue in the long term. A faster mechanism must be available for funding authorization for specific and unique situations. In common with other stakeholders, funding agencies seek the evidence of positive outcomes. The problem is that while successful individual patient outcomes are occurring, they are predominantly undocumented or unavailable. An effort must be undertaken to systematically record these outcomes otherwise, researchers, funders and the AT industry have virtually no way to summarize the evidence.

Current Use of Evidence-Based Medicine

Evidence-Based Practice (EBP)

From 1993 to 2000, the Journal of the American Medical Association published a series of 25 articles on evidence-based medicine that launched a paradigm shift[11]. Evidence-based medicine (EBM) developed into evidence-based practice (EBP) and launched similar concepts in education including the U.S. Department of Education special education programs promoting "What Works"[12]. Interestingly, the methodology of EBP has evolved and recognized an important concept related to disability and AT. In the fourth issue of the 25 article series, a hierarchy of the level of evidence methodologies was presented.

[11] National Institutes of Health. Big Data to Knowledge. 2013 [cited 2013 August 10, 203]; Available from: http://commonfund.nih.gov/bd2k/.

[12] Computer & Information Sciences & Engineering. Big Data Research Initiative. 2013; Available from: http://www.nsf.gov/cise/news/bigdata.jsp

Group data with inferential statistical outcomes were considered the state of the science, with RCT placed at the top of the hierarchy. Twenty-one issues later in the last issue of the series[13], the hierarchy was revised with a significant caveat. The authors of the evidence-based medicine JAMA series placed n=1 RCT at the top of the hierarchy, thereby acknowledging an extraordinary point. The authors explain and, place in context, that individuals have differences and are sometimes not represented in groups, group data or group designs. This, in no way undermines the importance of the group RCT gold standard, but clearly highlights the challenge in AT outcomes documentation due to the extraordinary variability of people with disability. However, double-blinded RCT studies using n=1 design are virtually impossible in rehabilitation and AT because individuals obviously know what the intervention is, and it can be difficult to blind the researchers to the ATD as well.

Designs using n=1, that do not require double-blinding may be an ideal method for providing experimental evidence in the AT field. As mentioned above, n=1 trials, as indicators that the intervention works for the individual, may also provide the most important clinical evidence. While n=1 is not appropriate for pharmacologic medical models[14, 15,] no methodology is better suited to a unique individual using a unique AT. Recently, protocols for conducting robust Single Case Experimental Designs (SCED) have emerged[16, 17]. Further, meta-analysis techniques for SCEDs are emerging that could allow large collections of SCEDs to gain standing as legitimate evidence for AT outcomes.

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[13] The White House. Big Data is a Big Deal. 2013; Available from: http://www.whitehouse.gov/blog/2012/03/29/big-data-big-deal.

[14] World Health Organization, International classification of functioning, disability and health : ICF2001, Geneva, Switzerland: World Health Organization.

[15] Chang, F., W.J. Coster, and C.A. Helfrich, Community participation measures for people with disabilities: A systematic review of content from an international classification of functioning, disability, and health perspective. Archives of Physical Medicine and Rehabilitation, 2013. 94: p. 771-781.

[16] Smith, R.O., et al. ATOMS Project technical report - The ICF in the context of assistive technology (AT) interventions and outcomes. 2006; Available from: http://www.r2d2.uwm.edu/atoms/archive/icf.html.

[17] Smith, R.O. and K.L. Rust, Matching assistive technology interventions to the ICF, in 11th North American Collaborating Center Conference on ICF2005, June.

Evidence-Based Funding (EBF)

Third party funding agencies have quickly embraced the concept of evidence-based practice (EBP) and operationalized decision-making around evidence-based funding (EBF). However, cases are proliferating throughout the nation depicting situations where funding streams are being virtually shut off due to the lack of the most robust level of evidence to support the success of using any given AT intervention. Interestingly, EBF has had an impact not only on the funding of devices for people with disabilities at the final stages of the provision of effective technology, but also has affected the policy side of funding that authorizes certification, billing codes, or approval protocols. This negatively impacts the entrepreneurial R&D cycle of the AT industry. On the delivery side, service providers and consumers are directly affected through the reduced access to innovative AT products built to address the needs of the target population and manufacturers, and R&D operations are affected on the product development side. As nationwide constraints in funding increase the need for accountability and documentation of outcomes related to AT device provision and services, we need to be cognizant of how the demand for the most robust standards of evidence extensively affects all stakeholders in the field.

Case Example

Coding Trends

To illustrate some of the difficulties manufacturers, clinicians and consumers are currently experiencing the following is an example of a current Centers for Medicare and Medicaid Services (CMS) coding trend highlighting the difficulty in obtaining a new HCPCS code for a new AT product. A negative impact of this trend is that many products cannot be reimbursed at the proper level, and without proper coding and reimbursement, the product is not available to the broad market that relies on 3rd party payment. An example of this is the Natural Fit Rims case study. This product is an ergonomically designed handrim for a wheelchair, designed to offer a conservative (non-surgical) treatment for the wrist pain experienced by wheelchair users who have Carpal Tunnel Syndrome (CTS) due to injuries incurred through their use of the traditional, round shaped push rim over many years. In 2005, CMS denied establishing a new code for this technology and stated, *"Testimonials and summaries of articles*

provided by the applicant do not demonstrate a significant therapeutic distinction between the category of items described by E2205 and the item in the coding request." The company, Three Rivers, was advised to use existing code E2205 - Handrim any type without projections, replacement only. From 1993 until December 2004, there were three HCPCS codes to address different handrim technology; K0059- Plastic coated, K0060- Steel and K0061- Aluminum. The aluminum handrims were the only ones that were not separately billable with the wheelchair. In 2005, CMS cross-walked these three codes to E2205, creating a code that essentially grouped all handrims without projections in the same code and eliminated any ability to bill any additional amount for these handrims.

In 2007, following the completion of a clinical trial (requested by CMS in 2005) reported in a peer reviewed journal which documented the effectiveness of the handrim in obviating CTS symptoms, the company applied for a fourth time to obtain a unique HCPCS code for the Natural Fit Rims. The CMS workgroup decision again was that the E2205 code was adequate for this technology and stated in their preliminary decision, *"Clinical information provided by the applicant does not include evidence that would support a claim of superior clinical outcome when using this device, as compared with other devices categorized at E2205."* However, this time CMS took an additional step and revised the definition of code E2205 to Handrim without projections, any type, (including ergonomic or contoured, e.g. Natural Fit) replacement only.[18] The merging of multiple codes into single codes and adding "any type" to code definitions creates an access barrier to important technologies and reduces access to unique products. This is especially true when these types of coding changes eliminate all ability to bill for an item.

It is important to understand the critical need to separately codify disparate technology that serves different clinical needs. This is necessary to facilitate development of appropriate coverage and payment policies. In addition, without a mechanism within the HCPCS code set for identifying and distinguishing technological differences that are designed to serve different clinical needs, it becomes

[18] Dieruf K, Ewer L, Boninger D.: The natural-fit handrim: factors related to improvement in symptoms and function in wheelchair users. J Spinal Cord Med, 2008, 31: 578–585.

extremely difficult to support comparative effectiveness research. It is unreasonable to expect studies to be conducted to compare every product within a code. Without clear delineation and definitions of products it becomes impossible to design studies that provide the evidence needed by medical professionals or policy makers to inform decisions.

Recommendations of the KTDRR Working Group

NIDRR Funded RERC on Assistive Technology Outcomes

At this particular moment in time, with NIDRR moving from the U.S. Department of Education to the Department of Health and Human Services (HHS), NIDRR now has an opportunity to provide guidance to the AT community on the standards of AT device efficacy needed for AT reimbursement. This effort would provide HHS with the data it needs to base its ongoing and future coverage and policy decisions on. HHS is now the overarching agency which has oversight over both CMS and NIDRR. With this agency restructuring, our group recommends that NIDRR fund an RERC on Assistive Technology Outcomes to address this void. Through our discussions on data analysis of current trends and future projections, we agreed that the restructuring offers a new opportunity for intra-agency dialogue. Such dialogue would result in a research agenda and framework through which HHS coverage and payment policies are based on NIDRR driven research and outcome measurements.

One tool/methodology that the working group believes is a viable option within the field of Assistive Technology is the development of a database of assistive technology usage and outcomes. This database would impose a standardized and systematic collection of before and after information inputted by clinicians and researchers. Once the outcomes of assistive technology can be aggregated, there will be a greater likelihood of research acceptance/funding. Regarding the format of this database, we suggest using a minimal data set for the data collection, for example a 10-question format. While the minimal data set would be required, there would also be places for individuals to expand on their information. In addition, we strongly feel that there should be both pre and post assessments as part of the process. The post assessment should be recorded at least 30 days after the equipment is given to allow enough time

for the consumer to use and understand the benefits and drawbacks of the equipment. To ensure these assessments occur, outcome data should be part of the process, as seen in the state of Ohio. There, the Special Education Department offered to fund assistive technology devices for the students but only if pre and post assessments were part of the process.

Managing Repeated Measures Data

An additional consideration for use of the ATO database is data collection for research purposes. When users select this option they will be required to register their intent to conduct a research study whether it be pre/post, single case experimental design (SCED) - also known as single-subject design in this field, repeated measures, or RCT. These applications will require additional data fields to properly describe the data (e.g. phase reporting) and this required flexibility will be explored during development.

Security & Privacy

The author of said database must at a minimum, comply with the HIPAA requirements for covered information, though ideally, they should seek to provide even higher levels of security and privacy. All communication with the cloud servers should be performed using HTTPS, and, as such, will be encrypted in transit. In addition, data will be encrypted at rest (e.g. server drives and backups). Privacy controls will be designed into the database layer, such as storing personally identifying information (e.g. name, SSN, address) in separate tables or even a different database. All data access will be logged to create an audit trail, allowing effected users to be contacted in case of a security breach.

However, there are some issues surrounding the use of the database. First, in addition to CMS, there needs to be buy-in from other third party payors. It will be necessary to work with third party payors to ensure that the correct data is being collected and that it will be sufficient evidence so that reimbursement will be a possibility. A second possible challenge will be for the service providers and consumers to input the information into the database. However, we feel that through altruism and interest in contribution to the field this will not be an issue for the service providers. Perhaps most importantly, the information that will result from the collection of the data will streamline the

therapists' job, thereby providing enough payback to justify a therapist taking the time to input the data. For consumers, we feel that for a short information request they will not need an incentive because of the benefits to the field. For more detailed information, a small monetary incentive may be required. In addition, it is important that the details of the information are properly recorded to ensure similar conditions when aggregating the data.

Big Data

AT devices and services, as previously discussed, have numerous variables that affect their outcome. This wide spectrum of variables makes AT outcomes so difficult to quantify. From a scientific standpoint, covariates are enticing to work with when data are collected on the variables and large data sets are available. Given the uniqueness of people with disabilities and the AT systems they use, sufficient aggregate data sets are not only elusive but often completely impractical given today's data collection methodologies and research financing. However, as previously presented, the data collection methodologies have dramatically shifted on a paradigm level creating the potential of aggregate data sets that are large and can compile data from individuals who are geographically disparate and seemingly unique. Sophisticated databases can identify like individuals and users of AT systems with a sufficiently sophisticated data collection methodology.

This concept of big databases is not entirely new. NIH and NSF have indicated their interest in the usefulness of big databases through the launch of extensive research initiatives[19, 20]. This is in part due to the increased capacity of researchers to evaluate complex, multi-factorial, high quality data sets to examine relationships. Statisticians and methodologists have developed new quantitative analysis systems and data mining methodologies, and are in the process of continuing to improve these analyses. The supercomputing era and the need for complex variable decisions and reporting (such as weather-

[19] Lenker, J.A., et al., Classification of assistive technology services: Implications for outcomes research. Technology and Disability, 2012. 24: p. 59-70.

[20] Smith, R.O., et al. ATOMS Project technical report: Models and taxonomies relating to assistive technology. ATOMS Project Technical Reports 2005 [cited 2013 August 11, 2013]; Available from: http://www.r2d2.uwm.edu/atoms/archive/technicalreports/fieldscans/tr-fs-taxonomiesmodels.html

related catastrophes) have helped move this science forward. The White House has identified the importance of big data for understanding and discovering important phenomena that affect people throughout the nation[21].

The importance of big data for understanding AT outcomes is that the complexity of variables for individuals creates small data sets for the many thousands of AT interventions. Consequently, researchers tackling an AT intervention must accumulate research groups of participants that may only consist of five, 10, 30 or 50 widely scattered individuals. This makes it not only unlikely but almost impossible for many research questions to be answered considering feasible funding levels. The concept of big data collected by individuals throughout the nation and the world using 24 /7 mobile data collection devices enables a new AT outcomes methodology that has never been possible before.

While the immediate advantages are apparent for researchers and scientists, this also becomes a boon for service providers and consumers who may desire to look up people in similar situations to see what types of interventions have been used and how successful they have been. While numerous websites and apps have recently evolved, including federally supported programs such as AbleData that solicit consumer feedback on ATDs, these systems have only been used minimally (AbleData notes are available on less than half of 1% of products with usually only one entry) and these systems have minimal data regarding user context or elicitation of common coding variables for comparison. The environment is ready for a more accessible and complete approach.

Emersion of Community Participation as an Outcome Measure

The International Classification of Functioning, Disability and Health (ICF)[22] provides an important framework for characterizing functional limitations and intervention outcomes. The model is comprised

[21] Bauer, S.M., L.-J. Elsaesser, and S. Arthanat, An assistive technology device classification based upon the World Health Organization's International Classification of Functioning, Disability and Health. Disability and Rehabilitation: Assistive Technology, 2011. 6(3): p. 243-259

[22] ISO. ISO9999:2011 Assistive products for persons with disability -- Classification and terminology. 2011; Available from: http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=50982

of three non-hierarchical levels which are influenced by mediating factors. The levels of the model are 1) body functions and structures, which considers impairments in anatomical structures and functions; 2) activities, which considers execution of a particular task in an idealized context; and 3) participation, which considers engagement in real life situations. Each of these levels can be influenced by contextual factors (personal and environmental) specific to the individual. Numerous measures are emerging that use community participation as an outcome measure for AT use[23]. The ICF classification allows for coding that can be applied to many different assessments and measures, and can be seen as a lingua franca for disability researchers wishing to compare data.

These elements of change have created an environment of possibility that can allow the field to revolutionize the way it collects, aggregates and reports AT outcome data. While the ICF provides a new framework which goes a long way to embrace the need for a Medical-Social Model to describe and ultimately measure the effectiveness of goods and services designed to meet the needs of persons with a disability; current 3rd party payor policies are restricted to meeting the needs a of person "in the home" and only covered if "medically necessary" – without description of "functional need".

Legislation

As a potential solution, we feel that federal legislation can be one of the vehicles to accomplishing this goal of providing public policy that is supportive of the framework of the ICF – supporting health, function and community participation. This legislation would include the creation of the database as explained above. In addition, we would look for our elected representatives in effect to change CMS policy. For example, this process could effectively begin with an entity such as the RESNA Government Affairs Committee (GAC) performing a comprehensive study of HCPCS coding. The HCPCS codes should be well-defined in a way that distinguishes products that have unique features, while grouping homogenous products within the same code. We are aware that there are large numbers of requests for different HCPCS codes and that evidence is needed before a new HCPCS code can be considered.

[23] ABLEDATA Website, 2004

However, if the GAC is able to more efficiently group products together, the number of these requests may decrease. From this study, legislation could be created or direction from Congress could be given to mandate the use of new more appropriate, separate HCPCS codes.

Example of Recommendations for a Specific AT Technology Sector – Complex Rehab Technology

Legislation has been introduced in Congress related to Complex Rehab Technology (CRT). CRT products and associated services include medically necessary, individually configured devices that require evaluation, configuration, fitting, adjustment or programming. These products are subject to the same issues seen with other AT devices. For purposes of this document, CRT refers to individually configured manual wheelchair systems, power wheelchair systems, seating and positioning systems, and other adaptive equipment such as standing devices and gait trainers. Significant challenges threaten access to CRT products and the supporting services that are used by individuals with disabilities and medical conditions, including coding, coverage, and payment problems. These challenges have increased over the past several years and, without meaningful change to these policies, will only become greater in the future.

A primary factor responsible for these challenges is that this group of individually configurable products does not have a distinct category, but instead is classified by Medicare within the broad category of Durable Medical Equipment (DME). To improve and protect access to CRT products and services, targeted changes and improvements are proposed by a broad based group of CRT stakeholders that includes consumers, clinicians, providers, and manufacturers.

These changes have been embodied in Congressional legislation entitled "The Ensuring Access To Quality Complex Rehabilitation Technology Act of 2013" (S-948 and HR-942). The legislation will develop clearer and more consistent coverage policies that appropriately address the unique needs of individuals with complex disabilities, obtain formal recognition of the product-related services and costs

involved to allow for appropriate funding, and provide future payment stability to ensure continued access to medically necessary CRT products.

This legislation will also foster an environment that encourages product innovation and technological solutions, and produces an improved coverage and payment system that can serve as a model for Medicaid and other payers to follow. Proposed changes are as follows:

Proposed Changes Relating to Products and Coding –

1) Existing HCPCS codes, as appropriate, will be classified as CRT codes and will only be available through accredited CRT companies.
2) New codes will be created where existing codes contain both CRT products and non-CRT products in order to segregate CRT products from other DME.
3) New codes will be created for "uncoded" CRT products that are routinely provided but currently do not have an assigned code.

Proposed Changes Relating to Coverage and Documentation-

1) Coverage criteria for CRT will be based on a determination of the beneficiary's functional abilities and limitations, rather than specific diagnoses or other highly prescriptive and limiting criteria.
2) A pathway will be established to require that beneficiaries who are seeking wheeled mobility and have certain diagnoses and/or clinical presentations go through a CRT Evaluation to ensure they receive the most appropriate equipment.

Proposed Changes Relating to Supplier Quality Standards-

1) The CRT Company (CRTC) must employ at least one qualified rehab technology professional (RTP) per location and this individual will be required to show additional evidence (in addition to the Assistive Technology Professional credential) of competency in the provision of seating and mobility. A reasonable transition period will be provided to allow individuals to secure this new

qualification.

2) The CRTC must have the capability of repairing what they sell and provide such written information to the consumer.

The support of consumers with disabilities, their advocacy groups, physicians, physical therapists, occupational therapists, and others will be critical in communicating the issues and needed resolutions to Congress and the Centers for Medicare and Medicaid Services (CMS). It will only be through these combined efforts that the ultimate goal of improving and protecting access to CRT products and services for individuals with significant disabilities and medical conditions will be achieved.

Conclusion

In conclusion, our AT working group discussed the current situation as well as issues surrounding the reimbursement of assistive technology for each of the five major stakeholder groups. Because of the lack of sufficient research needed for reimbursement, we feel that:

a) An intra-agency HHS conference with agencies who determine coverage and payment policy (CMS) and who can provide research data (NIDRR) is needed to consider and define the hierarchy of evidence needed for:
    i) The determination of safety and effectiveness,
    ii) The determination of best clinical practice guidelines,
    iii) The appropriateness and practicality of data collection methods for the field to collect evidence.
    iv) The potential utilization and promotion of a national AT outcome database.

b) Legislative action is needed to define the types of assistive technology that are designed to meet the long term needs for person with a disability separate from the polices governing broad Durable Medical Equipment to allow improved recognition and policies. Legislative action is also needed to shift the AT reimbursement model's emphasis from a purely medical model to a model that considers the social and functional context of the AT user, using the ICF.

c) Research funding agencies need to support projects that address the scientific and practical challenges of obtaining and reporting sufficient evidence to make appropriate coverage, coding and payment policies for a small field that has a historical life-changing impact on people with disabilities.

This paper has provided the necessary background information and suggestions for conceptual models that can be used to implement these proposed changes.

Participation

The KTDRR created a working group comprised of: Don Clayback, Executive Director of the National Coalition for Assistive and Rehab Technology (NCART) (AT Industry Representative); Rita Stanley, Vice President of Government Relations for Sunrise Medical (AT Industry Representative); Jean Minkel, Senior Vice President of Rehab Services for Independence Care System (AT Service Provider); Margaret Piper, Senior Investigator for Kaiser Permanente Center for Health Research (General Evidence Assessment and Policy Representative); Roger Smith, Professor of Occupational Sciences & Technology and Director of the Rehabilitation Research Design & Disability Center at the University of Wisconsin-Milwaukee (AT Researcher); Todd Vaarwerk, Director of Advocacy and Public Policy at Western New York Independent Living (AT Consumer Representative) and led by Jim Leahy, Co-PI and Technical Assistance Director of the Center on Knowledge Translation for Technology Transfer (KT4TT). Each of these individuals was a representative for their respective stakeholder group, which are the five key groups that are involved in the development, provision, and funding of AT devices and services.

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