

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

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

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## Introduction / Background

- AT technology developers, manufacturers, and service providers are facing new requirements to demonstrate evidence of AT effectiveness
- Level of evidence required for AT is comparable to standards used to support interventions in evidence-based medicine
- Gold standard for this level of evidence is Randomized Controlled Trials (RCTs)
  - Not practical or appropriate to show true effectiveness of AT for PWD
- Target populations for AT devices are very small, making it difficult to find homogeneous groups to participate in studies

## Introduction / Background

- RCTs require control groups who are denied an intervention
- How do you provide a power wheelchair to one quadriplegic and deny it to the next for purposes of a controlled trial?
- Evidence of effectiveness is needed to justify funding reimbursement for AT Products
- Negative impacts of misapplying standards to determine efficiency of AT products has resulted in reduced access to AT by PWD
- Alternative options for evidence of AT effectiveness need to be identified and accepted

## Introduction / Background

- To further demonstrate evidence of AT effectiveness, innovative study designs or AT product registries should be considered
- PWD and clinicians want to know what AT devices work best in any given situation
- While RCTs remain the focus, newer applications of methodologies such as registries or n=1 crossover trials are surfacing
- While journal articles and case studies on the efficacy of AT do exist, the need for more evidence is pressing

## Introduction / Background

- Third Party Payment System
  - Mfg./suppliers work to meet the needs of the consumer, the medical professionals who prescribe them, and the 3<sup>rd</sup> party payers who establish coverage and payment policies
- Medicare Part B
  - Federal medical insurance program for persons older than age 65, persons under age 65 who have contributed to Social Security and have been unable to work for at least 2 years due to injury or illness, and persons with chronic kidney failure
- Medicaid
  - State administered medical insurance program for people or families who are judged indigent based on household income.

## Introduction / Background

- Veterans Administration
  - Federal medical insurance funding for veterans – funds Durable Medical Equipment (DME)
- Private Medical Insurance
  - Offered by employers to cover costs of medical care
  - People who are self-employed or who do not receive employer provided coverage purchase private insurance out of pocket.
    - May or may not include DME coverage
- Private Payment
  - Always an option for people who have sufficient discretionary income.



## Five Target Populations

- AT Consumers/People with Disabilities (PWD)
  - Have unique personal characteristics, environments, and specific activities requiring AT devices and services
  - Need personal empowerment to assist in decision-making related to AT devices and services
  - As much as 40% of AT is purchased by the PWD themselves
  - As we head toward a more person-centered model, PWD will be more involved in their own healthcare decision making
  - Data are needed to assist users with their product decisions

## Five Target Populations

- AT Service Providers (Clinician / Practitioner / Supplier)
  - Objective data to assist with AT product recommendations are sparse and scattered
  - Published studies may not fit specialized needs of a client or are too general to be informative
  - Clinician must rely solely on their own personal expertise and judgment
    - May not align with the outcomes efficacy needed for funding

## Five Target Populations

- AT Service Providers (Clinician / Practitioner / Supplier)
  - Objective measures are not systematically available or used
  - Service providers lack standardized terminology for coding AT interventions and outcomes
  - Barriers in communication due to service-specific terminology complicates consistent and compatible documentation

# Five Target Populations

- AT Researchers and Methodologists
  - 3 General types of research need to be done:
    1. Safety and effectiveness for product development
    2. Outcome measurements for evidence-based practice
    3. Device design and targeted population use

## Five Target Populations

- AT Researchers and Methodologists
  - Provide meaningful ATO tools and databases for use
  - Ability is impacted by high variation of needs, funding for AT research, and the need to examine the “best-evidence” hierarchy
  - RCTs are gold standard for evidence in certain areas of healthcare
    - Impractical
    - Cost prohibitive
    - Inconclusive due to variation within population with same diagnosis

## Five Target Populations

- AT Researchers and Methodologists
  - Efficacy of research is an issue
  - Products are so individualized that group inferential type methodologies result in studies with little value
  - Studies could result in third-party funding agency's willingness to pay for standard AFOs

## Five Target Populations

- AT Researchers and Methodologists
  - AT devices require rapid decisions but classical investigations have lengthy timelines
    - Result: Service providers cannot make decisions based on evidence, use best judgment
  - The field needs to:
    - Develop rapid report research strategies
    - Review accepted evidence hierarchies
    - Provide advice on potential methodologies
    - Consider widespread implementation of ongoing ATO systems

## Five Target Populations

- AT Manufacturers / Product Developers
  - Need guidance to develop mechanism to establish effectiveness
  - Transparency in criteria used to determine coverage
  - The field is extremely small with minimal R&D, testing, financing, or research infrastructure, making it difficult for manufacturers to find and cite outcomes data
  - Efficient methods for collecting and managing device testing data and obtaining outcomes data are needed
  - Substantial infrastructure involved in many research methods limits the ability of the AT industry to compete



## Five Target Populations

- AT Payors and Policy Makers
  - Rely on the best available evidence provided by researchers
  - Indication evidence-based practice is leading towards evidence-based funding
  - Resulting decisions can be disastrous because quality and quantity are so limited

## Five Target Populations

- AT Payors and Policy Makers
  - Increasingly common for funding agencies to limit or delay paying for AT devices and services
    - Due to lack of documented successful outcomes
  - Successful individual patient outcomes are occurring
    - Predominantly undocumented or unavailable
  - Outcomes must be systematically recorded
  - Researchers, funders, and the AT industry have no way to summarize the evidence

# Current Use of Evidence-Based Medicine

- Evidence-Based Practice (EBP)
  - EBM developed into EBP and launched similar concepts in education
  - Important concept related to disability and AT recognized
    - From 1993-2000, the Journal of the American Medical Association published a series of 25 articles on EBM
    - Hierarchy of the level of evidence methodologies was presented with n=1 RCT placed at the top of the hierarchy
    - Significance: recognized individuals have differences that are sometimes not represented in groups, group data, or group designs

## Current Use of Evidence-Based Medicine

- Evidence-Based Practice (EBP)
  - Highlights the challenge in ATOs documentation due to the extraordinary variability of PWD
  - Double-blinded RCT studies using  $n=1$  are impossible
    - Individuals know what the intervention is
  - Designs using  $n=1$  that do not require double-blinding may be an ideal method for providing experimental evidence in the AT field

## Current Use of Evidence-Based Medicine

- Evidence-Based Practice (EBP)
  - n=1 trial may provide the most important clinical evidence
    - Suited to a unique individual using a unique AT device
  - Protocols for conducting Single Case Experimental Designs (SCED) have recently emerged
  - Large collections of SCEDs could gain standing as legitimate evidence for ATOs

## Current Use of Evidence-Based Medicine

- Evidence-Based Funding (EBF)
  - Third-party funding agencies have embraced the concept of EBP and operationalized decision-making around EBF
  - Funding streams are being shut off due to the lack of evidence to support the success of using an AT intervention
  - EBF has impacted the funding of devices for PWD as well as the policy side of funding that authorizes certification, billing codes, and approval protocols

## Current Use of Evidence-Based Medicine

- Evidence-Based Funding (EBF)
  - Entrepreneurial R&D cycle of the AT industry negatively impacted by EBF
  - Service providers and consumers have reduced access to innovative AT products
  - Nationwide constraints in funding increase the need for accountability and documentation of outcomes

## Current Use of Evidence-Based Medicine

- Case Example: Coding Trends
  - Centers for Medicare and Medicaid Services (CMS) coding trend leads to difficulty obtaining a new HCPCS code for new AT product
    - Result: Many products cannot be reimbursed at the proper level
  - Without proper coding and reimbursement, the product is not available on the broad market that relies on third-party payment



# Current Use of Evidence-Based Medicine

- Case Example: Coding Trends
  - Natural Fit Rims case study
    - Handrim for wheelchair that offers treatment for wrist pain that accompanies Carpal Tunnel Syndrome
    - CMS denied establishing a new code for this technology
      - Placed it in a code that grouped all handrims without projections in the same code
      - Eliminated ability to bill any additional amount for these handrims

# Current Use of Evidence-Based Medicine

- Case Example: Coding Trends
  - Natural Fit Rims case study
    - Company applied for a fourth time to obtain a unique HCPCS code for the Natural Fit Rims
    - CMS denied the request, stating the existing code was adequate



## Current Use of Evidence-Based Medicine

- Case Example: Coding Trends
  - Merging multiple codes into single codes and adding “any type” to definitions
    - Creates access barrier to important technologies and unique products
    - May eliminate all ability to bill for an item
  - Separately coding disparate technology is necessary to develop appropriate coverage and payment policies

## Current Use of Evidence-Based Medicine

- Case Example: Coding Trends
  - Difficult to support comparative effectiveness research because HCPCS codes do not identify and distinguish technological differences that are designed to serve different clinical needs
  - Impossible to design studies that provide evidence needed by medical professionals or policy makers to make informed decisions

# Recommendations of the KTDRR Working Group

- NIDRR Funded RERC on AT Outcomes
  - NIDRR moving from the US Department of Education to the Department of Health and Human Services (HHS)
  - Provide guidance to the AT community on the standards of AT device efficacy needed for AT reimbursement
    - Fund an RERC on ATOs to address void and create intra-agency dialogue
  - Intra-agency dialogue would result in HHS coverage and payment policies based on NIDRR-driven research and outcome measurements

# Recommendations of the KTDRR Working Group

- NIDRR Funded RERC on AT Outcomes
  - Develop a database of assistive technology usage and outcomes
    - Use minimal data set for data collection
    - Pre- and post- assessments should be part of process
  - Database would impose a standardized and systematic collection of before and after information inputted by clinicians and researchers
  - Once outcomes of AT are aggregated, there will be a greater likelihood of research acceptance and funding

# Recommendations of the KTDRR Working Group

- Manage Repeated Measures Data
  - Use ATO database for data collection for research purposes
  - Users will be required to register their intent to conduct a research study
  - Additional data fields may be provided to properly describe the data

# Recommendations of the KTDRR Working Group

- Security & Privacy
  - Author of database must comply with the HIPAA requirements for covered information
    - Should seek to provide even higher levels of security and privacy
  - Communication with cloud servers performed using HTTPS
  - Data will be encrypted in transit and at rest
  - All data access will be logged to create an audit trail
    - Allows effected users to be contacted in case of security breach



# Recommendations of the KTDRR Working Group

- Security & Privacy
  - Database needs to provide correct data and sufficient evidence so that reimbursement through CMS and third-party payers is possible
  - Database will offer enough benefits to the consumers and the service providers to remove the burden of completing information requests and inputting them into the database

# Recommendations of the KTDRR Working Group

- Big Data
  - Databases can identify like individuals and users of AT systems with a sufficient data collection methodology
  - Complexity of variables for individuals creates small data sets for many thousands of AT interventions
  - Consequently, researchers tackling an AT intervention must accumulate research groups that may consist of five, ten, 30, or 50 widely scattered participants.
  - This makes it almost impossible for many research questions to be answered considering feasible funding levels

# Recommendations of the KTDRR Working Group

- Big Data
  - The concept of big data collected by individuals using 24/7 mobile data collection devices enable a new ATO methodology that has never been possible before
  - Will allow service providers and consumers to look up people in similar situations to see what types of interventions have been used and how successful they have been
    - Systems that solicit customer feedback on ATDs do exist, but are used minimally and offer minimal data regarding user context

# Recommendations of the KTDRR Working Group

- Emersion of Community Participation as an Outcome Measure
  - The International Classification of Functioning, Disability, and Health (ICF) provides an important framework for characterizing functional limitations and intervention outcomes
  - Model consists of 3 non-hierarchical levels influenced by mediating factors
    1. Body functions and structures
    2. Activities
    3. Participation

## Recommendations of the KTDRR Working Group

- Emergence of Community Participation as an Outcome Measure
  - Each level can be influenced by contextual factors specific to the individual
  - Numerous measures are emerging that use community participation as an outcome measure for AT use
  - ICF classification allows for coding that can be applied to many different assessments and measures, and can be used by disability researchers wishing to compare data

# Recommendations of the KTDRR Working Group

- Emersion of Community Participation as an Outcome Measure
  - Current third-party payer policies are restricted to meeting the needs of a person “in the home” and only cover if “medically necessary”
  - ICF provides a new framework that embraces the need for a medical-social model to describe and measure the effectiveness of goods and services designed to meet the needs of PWDs

# Recommendations of the KTDRR Working Group

- Legislation

- Federal legislation can be one vehicle used to accomplish the goal of providing public policy that follows the framework of ICF
- This legislation would include the creation of the database
- Elected representatives would be expected to change CMS policy
  - RESNA Government Affairs Committee performs comprehensive study on HCPCS coding
  - HCPCS codes should be well-defined in a way that distinguishes products that have unique features, while grouping homogenous products

## Example: Recommendations for 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
- Significant challenges threaten access to CRT products and supporting services
  - Coding, coverage, and payment problems



## Example: Recommendations for Specific AT Technology Sector - Complex Rehab Technology

- This group of individually configurable products does not have a distinct category, but instead is classified within the broad category of Durable Medical Equipment (DME)
- Targeted changes and improvements are proposed by a broad group of CRT stakeholders

## Example: Recommendations for Specific AT Technology Sector - Complex Rehab Technology

Changes are embodied in “The Ensuring Access To Quality  
Complex Rehabilitation Technology Act of 2013”

- Develop clearer and more consistent coverage policies that appropriately address the unique needs of PWDs
- Obtain formal recognition of the product-related services and costs involved to allow for appropriate funding
- Provide future payment stability to ensure continued access to medically necessary CRT products.
- Encourage product innovation and technological solutions
- Produce improved coverage and payment system that can serve as a model for Medicaid and other payers to follow

## Example: Recommendations for Specific AT Technology Sector - Complex Rehab Technology

### Proposed Changes Relating to Products and Coding

1. Existing HCPCS codes, when 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

## Example: Recommendations for Specific AT Technology Sector - Complex Rehab Technology

### 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

## Example: Recommendations for Specific AT Technology Sector - Complex Rehab Technology

### Proposed Changes Relating to Supplier Quality Standards

1. The CRT Company must employ at least one qualified rehab technology professional per location and this individual will be required to show additional evidence of competency in the provision of seating and mobility
2. The CRT Company must have the capability of repairing what they sell and provide such written information to the consumer

## Conclusion

Due to the lack of sufficient research needed for reimbursement our working group recommends:

- 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:
  - Determination of safety and effectiveness,
  - Determination of best clinical practice guidelines,
  - Appropriateness and practicality of data collection methods for the field to collect evidence.
  - Potential utilization and promotion of a national AT outcome database.

## Conclusion

Due to the lack of sufficient research needed for reimbursement our working group recommends:

- 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 policies 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

## Conclusion

Due to the lack of sufficient research needed for reimbursement our working group recommends:

- 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



## Wrapping Up

*Thank you for participating!*

- **Download the paper:**

[http://www.ktdrr.org/ktlibrary/articles\\_pubs/Standards\\_for\\_Assistive\\_Technology\\_Funding.pdf](http://www.ktdrr.org/ktlibrary/articles_pubs/Standards_for_Assistive_Technology_Funding.pdf)

- **We invite your feedback on today's session**

- *Please fill out the brief evaluation form:*

- <http://www.surveygizmo.com/s3/1825245/ATStandards>

- CONTACT US: [joann.starks@sedl.org](mailto:joann.starks@sedl.org)

## Disclaimer

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