



# Delivering wheeled mobility and seating services

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# SOSC Topic Purpose

- Delivery of seating & mobility (SM) products and services
  - What do we know about it?
  - What do we want to know/learn about it?
  - How can it be improved?
  - How can it be studied?

# Agenda

1. Introduction (Laura)
2. Research related to SM service delivery process (Nancy)
3. Clinical decision making (Laura)
4. Use of research in delivery of health services (Elise)

# Session Objectives

1. Name prevalent activities associated with a seating and mobility evaluation
2. Describe limitations of the existing evidence for wheeled mobility service delivery
3. List common factors considered by the clinician and payer during the SM evaluation and decision making process.
4. Identify one way that AHRQ utilizes research into delivery of health services

# Background

## Seating & mobility (SM) service delivery

- Process by which individuals are matched with SM devices & provided services
- Various service delivery models used today
- Approach is not standardized
- Information collected is not standardized
- Little is known about the effectiveness of
  - Service delivery models
  - Clinical decision making
  - Coverage decision making

# Aim

*To get people the right equipment at the right time in the right setting at a reasonable cost*

# Issues

- Body of SM evidence is limited
- Stakeholders are seeking evidence for informed decisions
- Diverse stakeholder group with different interests
- Hierarchies of research methodologies do not fit well with SM



# **Seating and Mobility Service Delivery: Existing Research**

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- Key Informants

# Background

- Seating and mobility service delivery – process by which individuals are matched to wheeled mobility devices and provided service
- Appropriate match – may result in enhanced quality of life  
(Cooper 2009, Salminen 2009)
- Inappropriate match – may result in harms and/or underutilization  
(Gavin-Dreschnack 2005, Kirby 1995, Xiang 2006, Phillips 1993, Kittel 2002)

# Key Questions

- What are the existing models for seating and mobility service delivery?
- What is the existing evidence on the effectiveness of seating and mobility service delivery?
- What are the key issues related to seating and mobility service delivery?

# Methods

- Literature Search
  - MEDLINE, CINAHL, and ERIC through March, 2011 (updated for presentation to May, 2012)
  - English language, all publication types
  - Focus on relationship of seating and mobility service delivery and individual user outcomes
- Grey Literature Search
  - Topic specific databases, conference abstracts, Web sites
- Key Informant Discussions
  - Providers, payors, consumers, suppliers, & researchers
  - Structured discussion questions



# Question 1

What are the existing models for seating and mobility service delivery?



# Service Delivery Models

Source	Individual Evaluation		Equipment Selection and Delivery	Post-Delivery
	Goals	Physical, Cognitive, Functional Ability	Environment	
Paralyzed Veterans of America, 1997 Wheeled Mobility	√	√	√	
Cooper, 1998 AT	√	√	√	
Minkel, 2002 AT	√	√	√	
Schmeler & Buning, 2003 Wheeled Mobility	√	√	√	
Clinician Task Force, 2004 Wheeled Mobility	√	√	√	
Cook & Polgar, 2008 AT	√	√		
World Health Organization, 2008 Wheeled Mobility	√	√	√	
Eggers et al., 2009 Wheeled Mobility	√	√	√	
Taylor & Furumasu, 2009 Wheeled Mobility	√	√	√	
Batavia, 2010 Wheeled Mobility	√	√	√	
Arledge et al., 2011 (RESNA) Wheeled Mobility	√	√	√	

# Service Delivery Models

Source	Equipment Selection and Delivery			Post-Delivery
	Individual Evaluation	Product Selection	Trial	
Paralyzed Veterans of America, 1997 Wheeled Mobility		√		√
Cooper, 1998 AT		√		√
Minkel, 2002 AT		√	√	√
Schmeler & Buning, 2003 Wheeled Mobility		√	√	√
Clinician Task Force, 2004 Wheeled Mobility		√	√	√
Cook & Polgar, 2008 AT		√		√
World Health Organization, 2008 Wheeled Mobility		√		√
Eggers et al., 2009 Wheeled Mobility		√	√	√
Taylor & Furumasu, 2009 Wheeled Mobility		√	√	√
Batavia, 2010 Wheeled Mobility		√	√	√
Arledge et al., 2011 (RESNA) Wheeled Mobility		√	√	√



# Service Delivery Models

Source	Individual Evaluation	Equipment Selection and Delivery	Post-Delivery		
			Training	Followup	Outcome Assessment
Paralyzed Veterans of America, 1997 Wheeled Mobility			√		
Cooper, 1998 AT			√		√
Minkel, 2002 AT			√		√
Schmeler & Buning, 2003 Wheeled Mobility			√	√	
Clinician Task Force, 2004 Wheeled Mobility			√	√	√
Cook & Polgar, 2008 AT			√	√	√
World Health Organization, 2008 Wheeled Mobility			√	√	
Eggers et al., 2009 Wheeled Mobility			√	√	√
Taylor & Furumasu, 2009 Wheeled Mobility			√	√	
Batavia, 2010 Wheeled Mobility			√	√	
Arledge et al., 2011 (RESNA) Wheeled Mobility			√	√	√



# Service Delivery Models

- Models are based on expert opinion
- 9 of the 11 models are general models for delivery of wheelchairs or assistive technology devices
- Two models are focused on patients with complex rehabilitation needs
  - These models include all the recommended steps
    - Clinician Task Force of the Coalition to Modernize Medicare Coverage of Mobility Products (2004)
      - Presented to CMS Interagency Work Group
      - Recommend more in-depth evaluation for more complex cases (i.e., extensive seating and positioning needs)

# Service Delivery Models

- Eggers et al., 2009
  - Focus on complex needs condition (spinal cord injury)
  - Based on literature review and interviews
  - Outlined potential influences of
    - Health Care System Factors
    - Payor Factors
    - Provider Factors
    - Supplier Factors
    - Individual User Factors

on the delivery process and ultimately the match of device and client needs



# Question 2

What is the existing evidence on the effectiveness of seating and mobility service delivery?

# Evidence Map – Service Delivery

- 24 Studies – 18 from literature search, 6 from hand-search
- Study Design: 1 RCT, 1 Quasi-RCT, 1 CCT, 21 Observational
- Sample Sizes: 3 to 318
- Outcomes Assessed:
  - Satisfaction with Device (k=17)
  - Satisfaction with Service (k=11)
  - Use (k=5)
  - Mobility (k=5)
  - Goal Achievement (k=4)
  - Medical/Health Issues (k=2)
  - Abandonment (k=1)









# Knowledge Gaps

- Few randomized trials or high quality prospective studies
- Most frequently studied outcome was consumer satisfaction – 5 studies reported dissatisfaction with:
  - wait times for appointments and equipment
  - provider training
  - individual involvement in the process
  - equipment repair

# Knowledge Gaps

- Few studies looked at effect of service delivery on use, mobility, or goal achievement
- No studies have evaluated whether one service delivery approach is superior in achieving optimal match of individual and equipment
- No studies have evaluated whether certain steps in service delivery are essential



# Question 3

What are the key issues related to seating and mobility service delivery?

# Key Issues in Service Delivery

(Source: Key Informants & Gray Literature)

- **Individual User**

- experience with and knowledge of process and resources available
- access to quality providers and suppliers

- **Provider**

- type
- qualifications
- experience with individuals with similar condition
- appropriateness of medical model

# Factors in Service Delivery, continued

- **Supplier**

- experience in equipment selection, assembly, delivery, fitting
- coding system may not adequately distinguish levels of complexity or quality for equipment components and therefore innovative devices may not reach consumers

- **Payor**

- coverage policies determine equipment, features, and services that are reimbursed, documentation required, and frequency of device replacement
- type of chair is based on diagnosis rather than functional status

# Factors in Service Delivery, continued

- **System**

- different processes for different sources of equipment (clinic, storefront, Web site)
- different processes for different wheeled mobility needs (short-term, long-term, complex, progressive disease, etc.)

# Future Research

- Consider well-designed prospective studies and randomized, controlled trials
- Populations – evaluate effectiveness of process for individuals with different
  - needs (physical and/or cognitive)
  - funding sources
  - goals
  - support systems



# Future Research

- **I**nterventions/**C**omparators – Evaluate effectiveness of
  - different service delivery models
  - components of the service delivery model – for example:
    - different types of professionals with different qualifications
    - equipment trial vs. no equipment trial
    - extensive consumer training vs. minimal consumer training
  - telerehabilitation

# Future Research

- **Outcomes** - use standard, validated outcome measures to allow comparisons between studies and pooling of results
  - Outcomes of interest include:
    - functional abilities
    - comfort
    - utilization
    - adverse events
    - equipment breakdown

# Future Research

- **T**iming – evaluate effectiveness of process at different stages of wheeled mobility use  
(e.g., initial prescription vs. subsequent prescriptions)
- **S**etting – evaluate effectiveness of process in different types of clinics  
(e.g., specialty seating and mobility vs. general rehabilitation clinic)

# References – available in:

- AHRQ Technical Brief

<http://www.effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?productid=751&pageaction=displayproduct>

- Annals of Internal Medicine

<http://www.annals.org/content/156/2/141.full.pdf+html>



# Clinical Decision Making

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# Elements of clinical decision making (CDM)

- Clinical Expertise
- Evidence Based Research
- Client Evidence

# Model of Clinical Decision Making



Figure 3. Model of Professional Expertise in Clinical Decision Making.

(Rappolt, 2003; CAOT et al, 1999)

# Evaluation of Clinical Decision Making

- Body of literature



(Higgs & Jones, 2000)

- Common factors to approaches
  - Use of “clinical knowledge base” and “processing of information”



# Evaluation of CDM- Limitations

- Research evaluating the quality & effectiveness of CDM needs further development
- Qualitative research contributes to the understanding phenomena

# Evidence Based Practice (EBP)

- EBP is “about integrating individual clinical expertise and the best external evidence”.  
(Sackett, Rosenberg, Gray, Haynes & Richardson, 1996)
- Premise of EBP
  - A clinician’s application of research evidence to clinical practice will improve therapeutic outcomes  
(Sackett, Straus, Richardson, Rosenberg & Haynes, 2000)

# Evaluation of EBP

- Focus on methods to acquire the skills to access and evaluate research evidence
- “Evidence” has been synonymous with research evidence
- More recently emphasis place on integration of “client evidence” and “research evidence”

# EPB Practice Issues

1. Complexity of clinical practice
2. Shortage of credible research evidence
3. Organizational barriers to research utilization
4. Neglect of qualitative research as evidence
5. Current health policies
6. Difficulty interpreting evidence

(Eddy, 1984; Rappolt, 2003; Maher, 2004)

# Appraising Qualitative Research in EBP

- Expanded Sackett's Rules of Evidence
- Rosalind Franklin- Qualitative Research Appraisal Instrument (RF-QRA)
  - Based on Guba's Model of Trustworthiness of QR
  - 5 levels of qualitative evidence
    - Credibility (Internal Validity)
    - Transferability (External Validity)
    - Dependability (Reliability)
    - Confirmability (Objectivity)
  - Developed grades of recommendations of qualitative evidence

(Henderson and Rheault; 2004)

# Decision Makers

- Decision makers
  - Clinician
  - Policy maker
  - Payer

*How do we know if we are making good decisions?*

*How do we judge the effectiveness of our decisions?*

- Common stakeholder ideal to get the individual the most appropriate & necessary SM equipment.
- Tension exists in the perspectives of decision makers.

# Clinical Decision Making Perspectives

## Clinical Perspective

- Appropriate match between person, technology & environment (Batavia, Batavia & Friedman, 2001)
- Attain functional outcome (A&P)
- Fiscally responsible solution

## Payer Perspective

- Medically necessary
- Clinically appropriate utilization decisions
- Use objective scientific knowledge & clinical experience
- Cost effective quality solution

(Thompson, 2011)

# Clinical Evaluation

- Addresses multiple components
- Clinical judgment & complexity of an individual's needs determine the sequence, items, and depth of examination required.
- Content experts generally agree about information collected
- Audits suggest submitted *documentation* is incomplete and lacking



# Clinical Decision Making (CDM)

The quality of the evaluation documentation is often deciding factor for coverage & payment.

It is expected that medical records

- reflect the need for care & equipment provided
- paint a clinical picture of the individual
- provide rationale for the items requested

# Evaluation Components

## ICF Categories

- Body Functions and Structure
- Activities and Participation
- Environmental Factors

(WHO, 2001)

## Domains

- Intake & History
- Equipment Assessment
- Functional Assessment
- Systems Review
- Physical Examination
- Wheelchair Assessment
- Plan of Care

(APTA, 2003, Cohen, 2012)

# The Person-Technology Match

Purpose of SM documentation report:

- 1) Present evaluation findings,
- 2) Identify the individual's problems and potentials,
- 3) Define goals of the SM intervention,
- 4) Specify recommended technology features, &
- 5) Provide clinical rationale for each feature required.

**Connect the dots**

# Payer Decision Making

- Judgments of necessity & appropriateness
- Increasingly based on rigorous EB benefit policies
- Decision support tools and care guidelines
  - Diagnosis and procedure specific (HCPCS/CPT)
  - Based on EB reviews
  - Used for individual level decisions
  - Some proprietary products
  - Multiple federal, state, private policy makers & payers

# Why decision making is challenging

## Variations in practice patterns

- Differences in incidences of diseases/impairments
- Patient preferences
- Available resources

## Challenges

- Complex tasks
- Poorly understood
- Uncertainty
- Biases
- Errors
- Differences in opinions
- Motives
- Easy for honest people to come to different conclusions

(Eddy, 1984)

# Here are the questions

- How is clinical information translated to prescription/recommendation?
- How might the effectiveness of the evaluation and prescription process be judged/studied?
- How might the appropriateness of a recommendation be judged? Determined to be medically necessary and appropriate?
  - How are outcomes determined, measured and evaluated?
  - What outcome measures exist or are needed?

# State of Research Environment

- Practicalities of carrying out research necessary is above and beyond what any one stakeholder group is capable of supporting
- New innovative models are needed to tackle work ahead

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# **Finding Evidence for Delivering Wheeled Mobility and Seating Services**

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# Goals of Systematic Review

- Provide explicit and transparent framework for finding and appraising evidence
- Systematically identify benefits and harms of medical interventions
- Identify important gaps in knowledge on the use of medical interventions
- Identify when knowledge is sufficient
  - Several studies show that experiments continue to be repeated on questions for which evidence is sufficient

# Evaluating Effectiveness

- Patient population: Who to give the intervention to
- Protocol of use: How to give the intervention
- Timing of use: When to give the intervention
- Provider characteristics: What are the qualifications necessary to use the intervention safely and effectively
- Setting characteristics: Where to give the intervention
- Trade-offs: Benefits and harms compared to alternatives

# Study Design Issues

- Appropriate patient population
- Reference treatments
- Specific parameters of the intervention
- Appropriate outcome measures
- Statistical Issues
  - Power of studies
  - Dropouts/Intention-to-treat analysis
- Time scale of studies/follow-up
- Reporting of results

# Reporting of Results

## ■ Resources

- Diagnostic Tests (STARD statement):  
<http://www.stard-statement.org>
- Trials of Therapeutics (CONSORT statement):  
<http://www.consort-statement.org>
- Observational Studies of Therapeutics (STROBE statement):  
<http://www.strobe-statement.org>

# Determining Strength of Evidence

- Risk of Bias
- Consistency
- Directness
  - Health outcomes vs. intermediate outcomes
  - Head-to-head comparisons vs. indirect comparisons
- Precision
  - Statistical significance

[www.effectivehealthcare.ahrq.gov](http://www.effectivehealthcare.ahrq.gov)

# Independent Review of NCDs 1999-2003 (69 Technologies)

	Number	Percent
<b>Level of evidence</b>		
Good	11	16
Fair	29	42
Poor	23	33
Could not be determined	6	9
<b>Limitations of evidence<sup>a</sup></b>		
Limited number of studies	47	68
Limited number of patients	40	58
Lack of controls	36	52
Relevance of outcomes	28	41
Selection bias	27	39
Lack of randomization	22	32
Length of study	20	29
Other <sup>d</sup>	29	42

<sup>a</sup>Includes nonuniformity of care (n = 12), high dropout rate (n = 11), applicability of specific issue to Medicare population (n = 8), and lack of blinding (n = 6), among others.

Neumann PJ et al. (2005) Medicare's National Coverage Decisions, 1999-2003: Quality of Evidence and Review Times. Health Affairs Volume 24 Page 243.

Funded by the Robert Wood Johnson Foundation



# Update of Independent Review to 2007

Neumann PJ, Kamae MS, Palmer JA. Medicare's national coverage decisions for technologies, 1999-2007. *Health Aff (Millwood)*. 2008 Nov-Dec;27(6):1620-31.

# Example: Natural Fit Handrims Biomechanics

## NIH-Funded Research: The Effect on Wheelchair Propulsion Biomechanics

- The National Institutes of Health (NIH) funded research comparing wheelchair propulsion efficiency when using the Natural-Fit versus using a standard handrim.
- A prototype Natural-Fit Handrim was used during a two-week trial period with before and after measurements of propulsion efficiency.
- After the two-week trial use period, wheelchair users generated significantly more forward force with a lower hand gripping moment (16% reduction in effort to grip the rim) with the Natural-Fit than with a standard handrim.
  - With the Natural-Fit, hand gripping moments were reduced without any reduction in overall power output toward propelling the wheelchair. This means that less work was required to achieve the same outcome.
  - This the best indication of a healthier propulsion stroke with the Natural-Fit Handrim.

Type of handrim tested first randomly assigned to control for learning or order effects

[http://www.out-front.com/naturalfit\\_research.php](http://www.out-front.com/naturalfit_research.php)

# Natural Fit Handdrims: QOL

- In a 2004 study, 46 users completed questionnaires.
- In a 2005 study, 82 users completed questionnaires.
- Responses to questionnaires in both studies were anonymous.
- Use of the Natural-Fit in these two studies ranged from 2 weeks to over 2 years, and average duration of use was 6-9 months.

Not before-after study

The results of both questionnaires indicated that the Natural-Fit led to important reductions in pain in the hands and wrists. Since using the Natural-Fit:

- 76%-85% of respondents reported less pain in the hands.
- 71%-80% of respondents reported less pain in the wrists.
- Reports of reduced pain were more pronounced as time using the Natural-Fit increased.

•Voluntary response bias?  
•Recall bias?

The 2005 questionnaire also examined daily function. Since using the Natural-Fit:

- 67% of respondents reported that daily tasks were "less work".
- Each of eight activities of daily living were perceived, on average, as less difficult.

Statistical  
Significance?

# Minimizing Potential Sources of Bias

- The observed benefit or harm with the intervention compared to alternatives is due to the intervention itself and NOT to confounding characteristics of the patient, setting, etc.
- Understanding of all potential variables is key

“Randomization properly carried out...relieves the experimenter from the anxiety of considering and estimating the magnitude of the innumerable causes by which his data may be disturbed”

R.A. Fisher 1935

# Why Clinical Trials Often Don't Measure Effectiveness



- Difficult to capture real-world complexity in an RCT
  - Multiple simultaneous variables
  - Restrictive patient selection criteria
  - Adherence to protocol in RCT not equivalent to practices in community practice

Figure from:

<http://mobilitymgmt.com/articles/2012/05/01/bariatric-business.aspx>



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# EHRs vs. Registries

## ■ EHRs

- Focused on individuals
- Designed to collect, share and use information for the benefit of the patient

## ■ Registries

- Focused on populations
- Designed to fulfill specific purposes defined before the data are collected and analyzed

# Sources of Data/Data Needs for Studying a Medical Intervention

	Diagnostic Criteria	Description of Intervention	Clinical Outcomes	Quality of Life	Subsequent Hospitalizations, Procedures, Diagnostic Tests	Other Subsequent Adverse Events	Mortality
Registries Designed for Clinical Research	√	√	√	√	√	√	√
Hospital Quality Improvement Registries	√	√	±				±
Insurance Claims	±	±	±		√	±	±
Electronic Medical Records	√	√	√		±	±	±
National Death Index	±						√



# CMS Proposed e-Clinical Template

- Face-to-face examination to determine eligibility for wheeled mobility
- Data Elements
  - A. Chief Complaint
  - B. History of Present Illness
  - C. Past Medical History
  - D. Social History
  - E. Review of Systems (ROS)
  - F. Physical Exam
  - G. Patient Assessment
  - H. Plan
  - I. Physician or Treating Practitioner's Information

<http://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/ESMD/ElectronicClinicalTemplate.html>

# Using the e-Clinical Template for Longitudinal Study

- Linking to Medicare claims data for outcomes
  - Matching
    - Data with identifiers: informed consent, patient privacy issues
    - Probabilistic matching with de-identified data
  - Limited outcomes
    - Outcomes with associated claims such as treatments for pressure ulcers
- Quality of Life
  - New data collection linked to baseline data in the e-clinical template: informed consent, patient privacy issues

# Recruiting Patients: National Wheelchair User's Registry

Table I. Wheelchair Users Registry questionnaire items.

Characteristic	Variables	Description
Contact information	Address/etc	-
	How recruited	Place of recruitment: expo, internet, etc
	Preference of contact	Options included email, telephone, mail
Demographics	Date of birth	Age was calculated
	Gender	Male/female
	Veteran status	Veteran/non-veteran
	Ethnicity	African American/White/Asian/Hispanic
Disability	Disability type	Checklist provided
	Date of disability or medical diagnosis	Years of disability were calculated
	Date wheelchair use began	Years of wheelchair use were calculated
Wheelchair use	Primary wheelchair used (type, make, model)	Manual/power/scooter
	Back-up wheelchair used (type, make, model)	Make and Model categorized into one of nine groups (see Table II)

Fitzgerald SG et al. The Development of a Nationwide Registry of Wheelchair Users. *Disability and Rehabilitation: Assistive Technology*, November 2007; 2(6): 358 – 365

# Example: Validating Outcomes

- Reach Measurements
  - Functional Reach: subjects instructed to reach as far forward as possible
  - Reach Area: subjects instructed to reach in a random order as far as possible without losing balance in 4 directions
  - Bilateral Reach: subjects instructed to depress switches positioned in front of each arm; targets progressively moved outward.
- Measurements taken with and without compensation, such as use of contralateral upper extremity for support

Sprigle S et al. Development of Valid and Reliable Measures of Postural Stability J spinal Cord Med. 2007; 30:40-49

# Example: Validating Outcomes continued

- Activities of Daily Living
  - Typing on a keyboard
  - Operating kitchen appliances
  - Turning faucet on and off
  - Operate an elevator
  - Etc.

Sprigle S et al. Development of Valid and Reliable Measures of Postural Stability J spinal Cord Med. 2007; 30:40-49

# Example: Validating Outcomes continued

	FR-Comp	FR-Uncomp	RA-Comp	RA-Uncomp	BR-Comp	BR-Uncomp
%ADL	0.663 $P = 0.001$	0.348 $P = 0.133$	0.647 $P = 0.002$	0.305 $P = 0.192$	0.503 $P = 0.024$	0.540 $P = 0.014$

Sprigle S et al. Development of Valid and Reliable Measures of Postural Stability J spinal Cord Med. 2007; 30:40-49

# Example: Validating Outcomes

## 2

- Assistive Technology Outcomes Measures
  - PIADS: Psychosocial Impact of Assistive Devices Scale
  - OTFACT: Occupational Therapy Functional Assessment Compilation Tool (OTFACT)
  - ATOM: Assistive Technology Outcome Measure
- Methods
  - Repeated measures of three outcome tools before and after a service delivery intervention at 1 month and 12 months

Harris and Sprigle 2008: Outcomes measurement of a wheelchair intervention. *Assistive Technology* 3(4):171-180.

# Example: Validating Outcomes

## 2

- The three outcome measures were not all significantly correlated with each other
- The three outcome measures were not all significantly correlated with themselves at the pre/post 1 month/post 12 month time periods
- The Activities of Performance (AOP) subscale of the OTFACT *decreased* over time
  - Reflects a change in overall health status (such as illness exacerbation) over time
  - Demonstrated need to separate functional improvement due to assistive device in the context of possible overall functional decline

Harris and Sprigle 2008: Outcomes measurement of a wheelchair intervention. *Assistive Technology* 3(4):171-180



# Challenges

- Harmonization of definitions for patient characteristics, interventions and outcomes
- Development of patient reported outcomes to measure improvement in functional status from the intervention in a possible context of overall physical decline over time
- Validation of the psychometric properties of the patient reported outcomes
- Development of large comprehensive databases for mining relationship between multiple complex variables and outcomes to generate hypotheses for FOCUSED experimental studies that can be done quickly and efficiently
- Sharing the cost and benefits of resources such as registries of wheelchair users, interventions and outcomes
  - Public/private partnerships?

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