

Evidence-based Practice Center Systematic Review Protocol

Project Title: *Technical Brief – Wheeled Mobility (Wheelchair) Service Delivery*

I. Background and Objectives for the Technical Brief

Wheeled mobility or wheelchair use is at an all time high and growing in the United States. A 2005 survey of non-institutionalized individuals in the United States estimated that approximately 3.3 million people (1.4% of the population) 15 years of age and older used a wheelchair or similar device. Of those 3.3 million, approximately 1.8 million were 65 years and older, representing over 5 percent of the elderly population. Among children under 15 years of age, an estimated 83,000 used a wheelchair or similar device, representing 0.2 percent of that population.¹ An earlier survey (1994-1995 data) of non-institutionalized Americans estimated 1.6 million (0.6%) wheelchair users including 88,000 under age 18 years (0.12%) and 897,000 (2.87%) 65 years of age and older. Of the total group of wheelchair users, 1.5 million used manual wheelchairs and 155,000 used electric wheelchairs. The leading conditions associated with wheelchair use included stroke, osteoarthritis, multiple sclerosis, absence or loss of lower extremity, paraplegia, orthopedic impairment of lower extremity, heart disease, cerebral palsy, rheumatoid arthritis, and diabetes.²

At the same time that the population of mobility impaired individuals is growing, advances have been made in the area of assistive technology. Power wheelchairs are more widely available. Technological advances have greatly enhanced manual wheelchairs. Scooters or power operated vehicles (POV) are commonplace.³ These advances in wheeled mobility assistive technology offer enhanced functionality not previously achievable. The degree to which these wheeled mobility devices contribute to quality of life depends on the appropriateness of the wheeled mobility selected for the patient and their utilization of the device. Mobility devices have been shown to increase the activity and participation of individuals with mobility limitations.⁴ However, inappropriate mobility devices may result in harms to the patient.

Wheeled mobility service delivery is the process by which mobility impaired individuals and wheeled mobility devices are matched and serviced. The World Health Organization (WHO) has described key steps in wheeled mobility service delivery: a) referral and appointment, b) assessment, c) prescription (selection), d) funding and ordering, e) product preparation, f) fitting, g) user training, and h) follow-up, maintenance and repairs.⁵ To maximize the benefit of scarce resources, matching patients with mobility limitations with the most appropriate wheeled mobility device, therefore avoiding under- and over-utilization, is paramount. However, many patients, providers, and payers may not be aware of or fully understand the aspects of wheeled mobility service delivery that likely contribute to attaining the most appropriate match between patient and device.

In order to address this gap, a thorough understanding of wheelchair service delivery is necessary. This Technical Brief will identify and describe the literature and expert opinion regarding the process of wheelchair service delivery (i.e., patients, providers, payers, settings, and outcomes). It will provide background information for stakeholders interested in developing wheelchair service delivery standards of care, researchers of mobility assistive technology, and patients, providers, and payers of wheeled mobility.

II. Guiding Questions

The following questions will be addressed. The intent is to provide stakeholders with an improved understanding of the various ways in which wheeled mobility service delivery occurs in practice and the elements of the delivery process that have been studied. Consistent with Technical Brief reporting format, questions pertaining to four topics - the technology, the context, the evidence, and issues - will guide the research process.

Question 1. The Technology: What criteria (i.e., medical conditions, physical characteristics, functional and/or vocational needs, environmental factors, etc.) do *assessors* and *payers* (including Medicare, Medicaid, Veterans Affairs, and others) take into consideration when determining the appropriateness and medical necessity of a wheelchair type (i.e., manual, power scooter, power chair) and features (i.e., seating, tilt, etc.) for an individual patient?

- a. What formal criteria exist?
- b. How do the criteria differ across *assessors*?
- c. How do the criteria differ across *payers*?
- d. How do the criteria differ for patients of different ages (i.e., 21 years old and younger vs. older than 21 years)?

Question 2. The Context: Which of the following elements has been studied with regard to facilitating or hindering achievement of an appropriate patient/wheelchair match?

- a. Provider type (i.e., occupational therapy, physical therapy, primary care provider, physiatrist)
- b. Provider qualifications (i.e., certification, experience performing wheelchair assessments)
- c. Setting (i.e., primary care clinic, specialty clinic, school, retail store)
- d. Payer (i.e., Medicare, Medicaid, Veterans Affairs, Vocational Rehabilitation, private insurance)
- e. Components of patient assessment (i.e., diagnosis vs. functional abilities, cognitive abilities, physical abilities)
- f. Assessment, prescription, and delivery steps (i.e., access, number of visits covered by insurance, trials and simulations with wheelchair, education and/or training provided to the patient, follow-up, etc.)

Question 3. The Evidence: What studies have reported on wheeled mobility service delivery? Specifically, describe the following elements of the studies:

- a. Indication/patient inclusion criteria
- b. Study design/size
- c. Elements of service delivery (i.e., patient physical characteristics, environmental factors, needs [functional, vocational], cognitive ability, provider, payer, fitting process [trials], counseling/training/education, follow-up)

- d. Outcomes assessed (i.e., functional ability, utilization of chair, patient satisfaction, quality of life)
- e. Adverse events/harms/safety issues (i.e., pressure sores, injuries, need for repairs, need for replacement)

Question 4. Issues: What are the important issues surrounding wheeled mobility service delivery? What are the topic areas, research designs, populations, interventions, comparators, outcome measures, and settings for future research into the most effective and efficient approach to matching patients with appropriate wheeled mobility devices?

III. Methods

Answering the questions posed in this Technical Brief will require identification and utilization of a variety of information sources including key informants, the published, peer-reviewed literature, and publications in trade journals and grey literature. Key informants are critical to this project. Not only will key informants be relied upon to provide information not available in the literature, but also to provide guidance to the trade and grey literature searching.

1. Data Collection

Data collected to inform wheeled mobility service delivery includes information gleaned from discussions with key informants, comprehensively searching of the peer-reviewed literature, and targeted searching of the grey literature.

A. Discussions with Key Informants

Several key informants were identified as the topic was refined. Once disclosures were obtained from these individuals, they participated in discussions aimed at developing the guiding questions for this topic, provided leads to resources in the grey literature that informed topic background and methods, and suggested other potential key informants. For key informants willing to continue to participate in the Technical Brief report process, interviews via telephone or in-person, if logistically feasible, will be used to gather information pertaining to the guiding questions. Information requested from each key informant will vary based upon their area of expertise and/or perspective with regard to wheeled mobility service delivery (i.e., payer, provider/assessor, equipment supplier, researcher, consumer). Interview questions will be developed in advance of each key informant discussion to solicit content- and expertise-specific information in a timely manner. Potential interview questions are given in the table below.

Key Informant Group	Potential Questions
Payers	<ol style="list-style-type: none"> 1. Do you have any guidelines/checklists that you use? 2. Do you perceive any barriers in service delivery? 3. Are there ways to make the process better? 4. What impact does the provider and/or setting have on the process? 5. What research would you like to see completed?

Providers/Assessors	<ol style="list-style-type: none"> 1. What guidelines/checklists do you use (or are you aware of)? 2. Describe the delivery process (from initial contact to final delivery). 3. What are the barriers to achieving a successful match of patient and wheelchair? 4. How can the process be improved? 5. How could future research help you in your practice?
Equipment Suppliers	<ol style="list-style-type: none"> 1. How do you perceive your role in the service delivery process? 2. What prevents the ideal patient/wheelchair match? 3. Is there technology that is not getting to the patients? If so, why? 4. How does product research and development interface with the delivery process?
Researchers	<ol style="list-style-type: none"> 1. Are you aware of any research on the delivery process (or aspects of it)? 2. What are the barriers to research on the delivery process? 3. What are the key areas for future research?
Patients/Patient Advocates	<ol style="list-style-type: none"> 1. What has your experience been with different types of payers? 2. What has your experience been with different types of providers? 3. What has your experience been in different settings? 4. What barriers do patients face in the typical wheelchair delivery process? 5. What prevents patients from getting the “ideal” wheelchair for their needs?

B. Grey Literature Search

Targeted searching of the grey literature will be guided by investigator knowledge of relevant sources and input from key informants. It will include searching of bibliographic databases such as ProQuest Digital Dissertations and topic specific databases such as those maintained by the National Rehabilitation Information Center (NARIC) (REHABDATA, NIDRR Project Database, and the NARIC Knowledgebase). Grey literature searching may also include searches of related conference abstracts (i.e., International Seating Symposium, RESNA Annual Conference). Payment policies may be obtained by searching relevant online databases such as the Medicare Coverage database and through targeted requests for information.

Web sites of relevant not-for-profit organizations and government agencies will be searched for information and publications. Relevant Web sites may include those published by the Christopher and Dana Reeve Foundation, Paralyzed Veterans of America, the National Coalition of Assistive and Rehabilitation Technology, and others. Quality of Web site information will be evaluated to insure that any information abstracted is authoritative, up-to-date, has minimal ties to for-profit interests, utilizes references to scientific information, and provides names and credentials of Web site contributors.

Reference and text books are expected to provide background information on seating and mobility evaluation. Trade journals may be important in identifying issues related to payment policies and stakeholder perspectives. Identified trade journals (i.e., Mobility Management, New Mobility, etc.) will be searched only for the last calendar year

as the information expected to be gathered from these sources will be limited to issues currently important to the topic.

We expect the grey literature to be useful primarily in answering questions related to wheelchair service delivery technology, context, and current issues. Conference abstracts may be helpful in identifying recent and on-going research related to the wheelchair service delivery process.

C. Published Literature Search

Investigators will conduct literature searches in MEDLINE, CINAHL, REHABDATA, and ERIC from the widest time range permitted electronically. Searches will be limited to studies relevant to humans and published in English. Due to the limitations of the Medical Subject Headings (MeSH terms) for this topic and the relatively inconsistent use of terminology in this field, a search strategy with maximum recall potential was developed. In addition to the literature search, a manual search of references from reports of included studies or review articles will be conducted. A preliminary search strategy, including proposed search terms, is listed in Appendix 1.

Results from the published peer-reviewed literature will be screened for inclusion based on title and abstract, if available. Full text articles will be obtained if warranted by the title and/or abstract. All publication types will be included if they relate to the guiding questions. Preliminarily identified literature will then be screened using the following exclusion criteria:

1. Does not address wheeled mobility
2. Addresses aspect of wheeled mobility not relevant to guiding questions:
 - a. Wheeled mobility used outside of routine activities around home and community (i.e., sports chairs, standing chairs, etc.)
 - b. Very specific aspect of wheeled mobility (types of seat cushions, joysticks, etc.)
 - c. Outdated technology
 - d. Research and development on equipment not currently widely available
3. Addresses creation and/or validation of a particular outcome measure

The literature search will be updated prior to submission of the final report if input from the peer review process indicates that necessity. Additional relevant data obtained via the updated literature search will be incorporated into the final report.

2. Data Organization and Presentation

A. Information Management

For Guiding Question 1, we will obtain, via searches of the grey literature and the published peer-reviewed literature and through interviews with key informants, guidelines and checklists developed by pertinent organizations (including relevant professional societies and payer groups).

The information gathered for Question 2 will be identified through searches of the grey and published peer-reviewed literature and interviews with key informants. We will review studies and reports to identify specific elements to be extracted (e.g., provider type, provider qualifications, etc.).

For Guiding Question 3, we will identify relevant studies from the published literature and from interviews with key informants. We will extract patient characteristics, study design, sample size, the elements of the assessment process studied (i.e., patient evaluation, provider, payer, fitting process, training and education, follow-up), outcomes assessed, and adverse events from studies meeting inclusion criteria.

Interviews with key informants along with the published, grey, and trade literature (including editorials and commentaries), will be used to inform Question 4. We will also identify gaps in the existing research.

B. Data Presentation

Information gathered for Guiding Question 1 will be presented in a table within the Brief. Criteria for different payers and for different assessors will be grouped to allow for comparison across payers or assessors. Findings will be summarized in the text highlighting differences for patients of different ages and across and between payers and assessors. The sources of all guidelines and checklists will be provided in the reference list.

For Question 2, a table in the Brief will summarize the number of studies and the sample size included for each element of service delivery studied. Peer-reviewed study and grey literature findings will be presented side-by-side allowing an overall survey of the available information.

Information extracted from the published literature for Question 3 will be displayed in a summary table in the text of the report. The table will reflect the number of studies reporting each of the elements. An evidence table with individual study characteristics will be presented in an Appendix.

Question 4 will be addressed in the Brief text. Important issues identified through literature searches and key informant interviews will be listed. Future research needs related to wheeled mobility service delivery will be presented the context of an analytic framework. Specifically, we will identify what is known and the need for additional research about the role of assessment criteria, payers, providers, and settings in the wheeled mobility service delivery process including how those factors impact intermediate outcomes (i.e., the matching of the patient and the wheelchair), final outcomes (i.e., functional and physiologic outcomes, patient satisfaction, use), and harms (i.e., development of pressure sores, deconditioning, weight gain). All sources will be provided in the reference list.

IV. References

1. Brault M, Steinmetz E. Americans with disabilities: 2005. Current Population Reports. Washington, DC: US Census Bureau, 2008. Available at <http://www.census.gov/prod/2008pubs/p70-117.pdf>. Accessed April 5, 2010.
2. Kaye H, Kang T, LaPlante M, editors. Wheelchair use in the United States. Disability Statistics Abstract Number 23, San Francisco: UCSF Disability Statistics Center, 2002.
3. Bauer SB, Mary Ellen, editor. The industry profile on wheeled mobility. Buffalo: Rehabilitation Engineering Research Center on Technology Transfer; 2009.
4. Salminen A, Brandt Å, Samuelsson K, Töytäri O, Malmivaara A. Mobility devices to promote activity and participation: a systematic review. *Journal of rehabilitation medicine*. 2009;41(9):697.
5. Borg J, Khasnabis C. Guidelines on the provision of manual wheelchairs in less-resourced settings. Geneva: World Health Organization. 2008.

V. Definition of Terms

1. Terminology

Manual Wheelchair – self-propelled; push hand rims are used to propel the rear drive wheels; may be designed to be propelled by the user’s legs

- a. standard – not usually tailored to an individual; simple sling seat; very limited adjustability
- b. standard hemi – lower seat height (17 to 18 inches); for individuals of shorter stature or to enable user to place feet on ground for propulsion
- c. growth – designed to meet needs of children as they change and grow
- d. lightweight/ultralight – frames made of lighter materials (e.g., aluminum, titanium, or chrome); easier to propel and transport
- e. heavy duty – for individuals who weigh more than 250 pounds or who have severe spasticity
- f. extra heavy duty – for individuals who weigh more than 300 pounds
- g. reclining – backrest reclines independently of the rest of the seating system
- h. tilt-in-space – wheelchair frame can tilt greater than or equal to 45 degrees from horizontal while maintaining the same back to seat angle

Manual Wheelchair Push-Assist – bridge between manual and power wheelchair; may be battery operated device attached to rear wheels or manually shiftable gears (similar to a bicycle); also referred to as PAPA – push rim activated power assist wheelchair

Mobility Assistive Equipment (MAE) – manual wheelchairs, power wheelchairs, scooters; also includes canes and walkers

Power Mobility Device (PMD) – power wheelchair or power operated vehicle (POV)

- Power Wheelchair – Battery powered motor that propels wheels; includes front-, center-, or rear-wheel drive options; joystick control is most common; includes power seating system
- tilt frame – tilts user backward in seated position to change pressure points and help prevent pressure ulcers; also to improve seating balance
 - reclining – reclining backrest opens hip angle; for pressure relief, resting, or self-catheterization
 - elevating – lifts user while remaining in a seated position; can improve reach and enhance ability to socially interact on a more eye-to-eye level
 - standing – lifts user from seated to standing position; pressure relief and improved reach

Power Operated Vehicle (POV) or “Scooter” – powered three-wheeled carts with seats; require good upper body strength and arm function and ability to support oneself in upright seated position for extended periods

2. Abbreviations

CMS – Centers for Medicare & Medicaid Services

MAE – mobility assistive equipment

NARIC – National Rehabilitation Information Center

PAPAW – push rim activated power assist wheelchair

PMD – power mobility device

POV – power operated vehicle

RESNA – Rehabilitation Engineering and Assistive Technology Society of North America

WHO – World Health Organization

VI. Summary of Protocol Amendments

In the event of protocol amendments, the date of each amendment will be accompanied by a description of the change and the rationale.

NOTE: The following protocol elements are standard procedures for all protocols.

VIII. Review of Key Questions

For Comparative Effectiveness reviews (CERs) the key questions were posted for public comment and finalized after review of the comments. For other systematic reviews, key questions submitted by partners are reviewed and refined as needed by the EPC and the Technical Expert Panel (TEP) to assure that the questions are specific and explicit about what information is being reviewed.

IX. Technical Expert Panel (TEP)

A TEP panel is selected to provide broad expertise and perspectives specific to the topic under development. Divergent and conflicted opinions are common and perceived as health scientific discourse that results in a thoughtful, relevant systematic review. Therefore study questions, design and/or methodological approaches do not necessarily represent the views of individual technical and content experts. The TEP provides information to the EPC to identify literature search strategies, review the draft report and recommend approaches to specific issues as requested by the EPC. The TEP does not do analysis of any kind nor contribute to the writing of the report.

X. Peer Review

Approximately five experts in the field will be asked to peer review the draft report and provide comments. The peer reviewer may represent stakeholder groups such as professional or advocacy organizations with knowledge of the topic. On some specific reports such as reports requested by the Office of Medical Applications of Research, National Institutes of Health there may be other rules that apply regarding participation in the peer review process. Peer review comments on the preliminary draft of the report are considered by the EPC in preparation of the final draft of the report. The synthesis of the scientific literature presented in the final report does not necessarily represent the views of individual reviewers. The dispositions of the peer review comments are documented and will, for CERs and Technical briefs, be published three months after the publication of the Evidence report.

It is our policy not to release the names of the Peer reviewers or TEP panel members until the report is published so that they can maintain their objectivity during the review process.

Appendix 1: Search Strategy

Concept Analysis

Two concepts relate to all key questions addressed in this Technical Brief. Therefore one search strategy will be used in multiple bibliographic databases. The concepts include wheeled mobility and patient assessment. Table A2.1 explains the concept analysis and terminology that will be used in searching Ovid MEDLINE. MeSH terms (or other terms relevant to the specific bibliographic database as determined by database thesaurus) and text words (with truncation used as necessary) relating to each concept will be aggregated. Concepts will be combined together to compile a set of literature inclusive of both concepts for screening. Limitations imposed on the Ovid MEDLINE (and other databases if available) search will include human studies published in English. The search process will be an iterative process with updating to restrict or expand the search as new terms are identified and the search process and resulting sets of literature are analyzed.

Table A2.1: Identification of Search Terms for Relevant Concepts: Wheeled Mobility and Service Delivery

	Concept	
	Wheeled Mobility	Service Delivery
Search terms [MeSH] and text words	Wheelchair [MeSH] Mobility limitation [MeSH] Wheelchair\$.tw "Wheeled mobility device".tw "Power chair".tw Powerchair.tw "Power mobility device" .tw Scooter.tw	"Service Delivery" Assess\$ Evaluat\$ Prescri\$ Provi\$ Acqui\$ Purchas\$ Match\$ Procure\$ Fit\$ Refer\$ Select\$



Medline Search Strategy

Database: Ovid MEDLINE(R) <1950 to May Week 2 2010>

Search Strategy:

- 1 *Wheelchairs/
- 2 wheelchair\$.tw.
- 3 scooter\$.tw.
- 4 "power mobility device\$".tw.
- 5 "wheel chair\$".tw.
- 6 "wheeled mobility".tw.
- 7 powerchair\$.tw.
- 8 "power chair\$".tw.
- 9 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8
- 10 assess\$.tw.
- 11 evalu\$.tw.
- 12 select\$.tw.
- 13 prescri\$.tw.
- 14 match\$.tw.
- 15 "service delivery".tw.
- 16 provi\$.tw.
- 17 acquir\$.tw.
- 18 procur\$.tw.
- 19 fit\$.tw.
- 20 purchas\$.tw.
- 21 refer\$.tw.
- 22 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21
- 23 9 and 22
- 24 limit 23 to (english language and humans)
- 25 limit 24 to (addresses or biography or case reports or dictionary or directory or in vitro or legal cases or news or newspaper article or portraits)
- 26 24 not 25