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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Lower Limb Prosthesis.

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Supplemental Evidence and Data Submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review of *Lower Limb Prosthesis,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES:

E-mail submissions: SEADS@epc-src.org.

Print submissions:

Mailing Address:

Portland VA Research Foundation

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FOR FURTHER INFORMATION CONTACT:

Ryan McKenna, Telephone: 503-220-8262 ext. 51723 or Email: SEADS@epc-src.org.

SUPPLEMENTARY INFORMATION:

The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Lower Limb Prosthesis* (LLP). AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on *Lower Limb Prosthesis*, including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: https://effectivehealthcare.ahrq.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=2451

This is to notify the public that the EPC Program would find the following information on *Lower Limb Prosthesis* helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number*.
    - *For completed studies that do not have results on ClinicalTrials.gov*, please provide a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened /eligible /enrolled /lost to follow-up /withdrawn /analyzed, effectiveness/efficacy, and safety results.
- *A list of ongoing studies that your organization has sponsored for this indication*. In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute ALL Phase II and above clinical trials sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution will be very beneficial to the EPC Program. The contents of all submissions will be made available to the public upon request. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the e-mail list at: https://www.effectivehealthcare.ahrq.gov/index.cfm/join-the-email-list1/.

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

The Key Questions

Key Question 1

What assessment techniques used to measure functional ability of adults with major lower limb amputation have been evaluated in the published literature?

I. What are the measurement properties of these techniques, including: reliability, validity, responsiveness, minimal detectable change, and minimal important difference?
II. What are the characteristics of the participants in studies evaluating measurement properties of assessment techniques?

Key Question 2

What prediction tools used to predict functional outcomes in adults with major lower limb amputation have been evaluated in the published literature?

I. What are their characteristics, including technical quality (reliability, validity, responsiveness), minimal detectable change, and minimal important difference?
II. What are the characteristics of the participants in these studies?

Key Question 3

What functional outcome measurement tools used to assess adults who use a lower limb prosthesis (LLP) have been evaluated in the published literature?

I. What are their characteristics, including technical quality (reliability, validity, responsiveness), minimal detectable change, and minimal important difference?
II. What are the characteristics of the participants in these studies?

Key Question 4

In adults who use an LLP, how do the relative effects on ambulatory, functional, and patient-centered outcomes of different prosthetic components or levels of components/prostheses vary based on study participant characteristics?

Prosthetic components include:

foot/ankle; knee; socket; liner; suspension; pylon; other.

Study participant characteristics of interest include:

K level; level of amputation; etiology of amputation; prior function (prior to new or replacement LLP); current function; expected potential function/level of activity and activities (e.g., athletics, uneven surface walking); time since amputation; initial vs. subsequent limb LLP; unilateral vs bilateral LLP; time since last assessment; age; comorbidities that may affect use of LLP (e.g., congestive heart failure, vascular dysfunction, skin ulceration/damage, visual dysfunction, peripheral neuropathy, local cancer treatment, other lower limb disease); type, setting, and description of rehabilitation, physical therapy, training; peri-amputation surgery information, including surgical details, inpatient rehabilitation details, wound status; residence setting; use of assistive devices; comfort of existing prosthesis (for patients receiving replacement LLP); psychosocial characteristics; family (etc.) support system; training and acclimation with LLP.

I. What assessment techniques that have been evaluated for measurement properties were used in these studies?

A. How do the characteristics of the participants in eligible studies that used these specific assessment techniques compare to the characteristics of the participants in the studies that evaluated the assessment techniques (as per Key Question 1II)?

B. What is the association between these pre-prescription assessment techniques and validated outcomes with the LLP in these studies?

II. What prediction tools that have been evaluated for measurement properties were used in these studies?

A. How do the characteristics of the participants in eligible studies that used these specific prediction tools compare to the characteristics of the participants in the studies that evaluated the prediction tools (as per Key Question 2II)?

B. What is the association between pre-prescription assessment techniques and validated outcomes with the LLP in these studies?

III. What functional outcomes that have been for measurement properties were used in these studies?

A. How do the characteristics of the participants in eligible studies that used these specific functional outcomes compare to the characteristics of the participants in the studies that evaluated the outcomes (as per Key Question 3II)?

Key Question 5

How do the patients' pre-prescription expectations of ambulation align with their functional outcomes?

I. How does the level of agreement vary based on the characteristics listed in Key Question 4, including level of componentry incorporated into their LLP?

Key Question 6

What is the level of patient satisfaction with the process of accessing a LLP (including experiences with both providers and payers)?

I. How does the level of patient satisfaction vary based on the characteristics listed in Key Question 4, including level of componentry incorporated into their LLP?

Key Question 7

At 6 months, 1 year, and 5 years after receipt of a LLP, (accounting for intervening mortality, subsequent surgeries or injuries) what percentage of individuals maintain bipedal ambulation; use their prostheses only for transfers; are housebound vs. ambulating in community; have abandoned their prostheses; have major problems with prosthesis.

I. How do these percentages vary based on the following characteristics?

A. Patient residence and setting
    i. Living situation (e.g., homebound, institutionalized, community ambulation)
    ii. Setting for rehabilitation, physical therapy, or training (e.g., in-home or at facility)

B. Patient characteristics
    i. Age
    ii. Level of amputation
    iii. Number of lower limbs amputated (unilateral vs. bilateral)
    iv. Prior level of function (prior to onset of extremity disability)
    v. Current level of function
    vi. Etiology of amputation
    vii. Time since amputation
    viii. Comorbidities (e.g., diabetes, CVD, PVD)
    ix. Operative treatment
    x. Use of assistive device
    xi. Cosmesis of the prosthesis

xii. Comfort of the prosthesis
xiii. Other

C. Prosthetic componentry

II. What were the reasons for suboptimal use of the prosthetic device?

PICOTS (Population, Intervention, Comparator, Outcomes, Timing, Setting)

Pertinent to all Key Questions:

Population

I. Adults with lower limb amputation who are being evaluated for or already have an LLP
   A. Lower limb amputees who require or have a lower limb prosthesis
II. Exclude if study includes only participants with battle-related trauma
III. Exclude if study includes only congenital amputations (and not otherwise Medicare eligible)
IV. Exclude if study includes only children ≤18 years old
   A. If a study has a mixed population (related to battle trauma, congenital amputations, or pediatrics) and they report subgroup data based on these factors, include analyses of relevant populations (exclude substudy data on excluded populations). If study reports only combined data (e.g., adults and children), include overall study, but note issue related to population.

V. Exclude if study conducted in low income or low resource country

Intervention

I. Custom fabricated lower limb prosthesis
II. Specific prosthetic component, including foot/ankle, knee, socket, liner, pylon and suspension, or components with specific characteristics (e.g., shock absorbing, torque, multiaxial, computer assisted, powered, flexion, microprocessor)

III. New or existing definitive or replacement prosthetics
IV. Exclude initial or preparatory prosthetics (used temporarily prior to definitive or replacement prostheses immediately after amputation surgery)
V. Exclude studies comparing only rehabilitation, physical therapy, or training techniques or regimens
VI. Exclude evaluation of orthotics and of implanted devices

Comparators,Outcomes

I. Variable by Key Question

Study Design

I. Published, peer reviewed study
II. Any language (that can be read by research team or machine translated)
III. No publication or study date restriction
IV. Exclude case reports

Setting

I. Patients homebound, institutionalized, community ambulation, any residence
II. Clinical or laboratory setting (for evaluation of specific ambulatory function outcomes)
III. Rehabilitation setting (e.g., physical therapy clinic, in-home)
IV. Exclude exclusively post-acute (post-surgical) setting or inpatient rehabilitation (immediately post-amputation)

Key Question-Specific Criteria

Key Questions 1-3

Population

I. As per criteria pertinent to all Key Questions

II. Also allow studies of amputees, whether or not they use LLPs (Key Questions 1 & 2)

Predictors/Tools/Tests/etc. (Key Questions 1 & 2)

I. Assessment techniques (that are used prior to prescription) (Key Question 1)
   A. Tests, scales, questionnaires that assess current functional or health status
   B. Include patient history and physical examination
   C. Measures of physical function and functional capacity (e.g., parallel bar ambulation without LLP)
   D. Exclude single factors (e.g., time since surgery, fasting blood glucose)
II. Predictor tools (used prior to prescription to predict functional outcomes with prosthesis) (Key Question 2)
   A. Tests, scales, questionnaires
   B. Exclude single factors (e.g., time since surgery, fasting blood glucose)

Outcomes

I. Functional, patient centered, or ambulatory outcomes per Key Question 4

Study Design

I. Any assessment of validity, reliability, reproducibility, and related characteristics
II. Exclude studies of validation of translations of non-English scales, indexes, etc.
III. Any study design
IV. No minimum sample size (except not case reports)
V. No minimum followup time

Key Question 4

Population, Intervention

I. As per criteria pertinent to all Key Questions

Comparators

II. LLPs with different components (e.g., feet/ankles, knees, sockets, pylons, liners, suspension), or that differ in other ways

Outcomes

I. Functional or patient-centered outcomes (measured or related to status in the community)
   A. Quality of life
   B. Disability measures
   C. Activities of daily living
   D. Mobility measures, including use of prostheses only for transfers
   E. Self-care
   F. Pain
   G. Fatigue post-use (e.g., end of day)
   H. Daily activity
   I. Time LLP worn per day
   J. Falls
   K. Satisfaction with LLP
   L. Exclude (simple) preference
II. Ambulatory functional outcomes
   A. Gait speed, step count, walk distance
   B. Uneven or wet surface, low lighting walking
   C. Ramps and incline traversing
   D. Step/stair climbing function
   E. Ambulatory function measured in the community setting (eg, self-report or activity monitors)
   F. Achievement of bipedal ambulation
   G. Other patient-centered ambulatory function measures
   H. Exclude biomechanical measures
III. Adverse effects of LLP
   A. Skin ulcers/infections, (injuries from) falls due to mechanical failure, etc.
   B. Other problems with prosthesis

Study Design

I. Direct comparison between any two components
II. Must include an analysis or reporting of differences in relative effect between components by a patient characteristic of interest (see text of Key Question 4) or sufficient participant-level data to make such an analysis
III. No minimum sample size (other than no case reports)
IV. No minimum followup time

Key Question 5

Population

I. As per criteria pertinent to all Key Questions

Predictor

I. Any measure of preprescription expectation of ambulation

Outcome

I. Functional, patient-centered, and ambulatory outcomes per Key Question 4 (Not adverse effects)

Study Design

I. Any study design, including qualitative studies
II. No minimum sample size (other than no case reports)
III. No minimum followup time

Key Question 6

Population

I. As per criteria pertinent to all Key Questions

Intervention

I. Accessing (or attempting to access) a LLP

Outcomes

I. Satisfaction with the process of accessing a LLP

Study Design

I. Any study design, including qualitative studies
II. No minimum sample size (other than no case reports)
III. No minimum followup time

Key Question 7

Population

I. As per criteria pertinent to all Key Questions

Intervention

I. Prescription for a LLP

Outcomes

I. Maintain bipedal ambulation
II. Use of prostheses only for transfers
III. Housebound vs. ambulating in community
IV. Abandonment of prostheses
V. Major problems with prosthesis

Study Design

I. Either longitudinal with follow up since original lower limb prosthesis prescription or cross-sectional at timepoint after amputation or prescription
II. Minimum follow up time

A. ≥6 month follow up from time of prescription, or
B. ≥1 year follow up from time of amputation, if no data reported about time since prescription

III. Minimum sample size
A. If subgroup analyses reported (based on bullet characteristics in text of Key Question 7I), N≥10 per subgroup (thus, N≥20 total) [this number may change depending on available data]
B. If no subgroup analyses reported, N≥100 total [this number may change depending on available data]

Sharon B. Arnold,
Acting Director.

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