# Prosthetic Limb Users
# **Survey of Mobility**

Researchers develop self-report instrument for measuring mobility of adults with lower-limb amputation

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## INTRODUCTION

Enhancing mobility in individuals with lower-limb amputation is a primary goal for prosthetists and other health-care providers. Many important clinical decisions, such as the selection of prosthetic components, are based on predictions and evaluations of a patient's mobility. Determination of a patient's mobility status (or potential) often is based on observations made by a managing physician or prosthetist. However, these subjective clinical assessments may limit clinicians' ability to accurately assess changes in mobility over time, compare mobility across individuals, or clearly communicate mobility outcomes to other providers.

Standardized outcome measures (like timed walk tests) can be used to measure and document patient outcomes, but they may be time-consuming to administer and may be limited to tasks or activities that can be completed in a clinic environment. Thus, there is a need for efficient and meaningful outcome measures that can be used to quantify patients' broad experiences with mobility.

Researchers at the University of Washington Center on Outcomes Research in Rehabilitation (UWCORR) have developed the Prosthetic Limb Users Survey of Mobility (PLUS-M) to meet this need. PLUS-M is a patient-reported outcome measure intended to efficiently and effectively measure prosthetic mobility in people with lower-limb amputation. PLUS-M has been rigorously developed to fulfill the needs of a variety of stakeholders, including clinicians, researchers, patients, and payers. This article reviews motivations for developing PLUS-M and provides an overview of efforts undertaken to develop and validate this instrument.

## Why Develop a Patient-Reported Measure of Mobility?

Patient-reported outcomes (PROs) are instruments intended to measure aspects of health from the patient's perspective, without interpretation from physicians or other health-care providers.[1] PROs are especially useful for measuring patients' perception of their health outside of the clinic, such as their mobility in their home and community. PROs provide information that is distinct from, and complementary to, physical performance measures (which are designed to assess a patient's ability to perform activities under direct observation of a clinician or researcher). In addition, outcome measures take valuable clinical time to administer, score, and interpret.

With these considerations in mind, the PLUS-M was envisioned to have the following characteristics:
- Quick and easy to administer
- Simple to score and interpret
- Able to be administered by paper, computer, tablet, or phone
- Suitable for use in both research and clinical care.

# PLUS-M Protocol
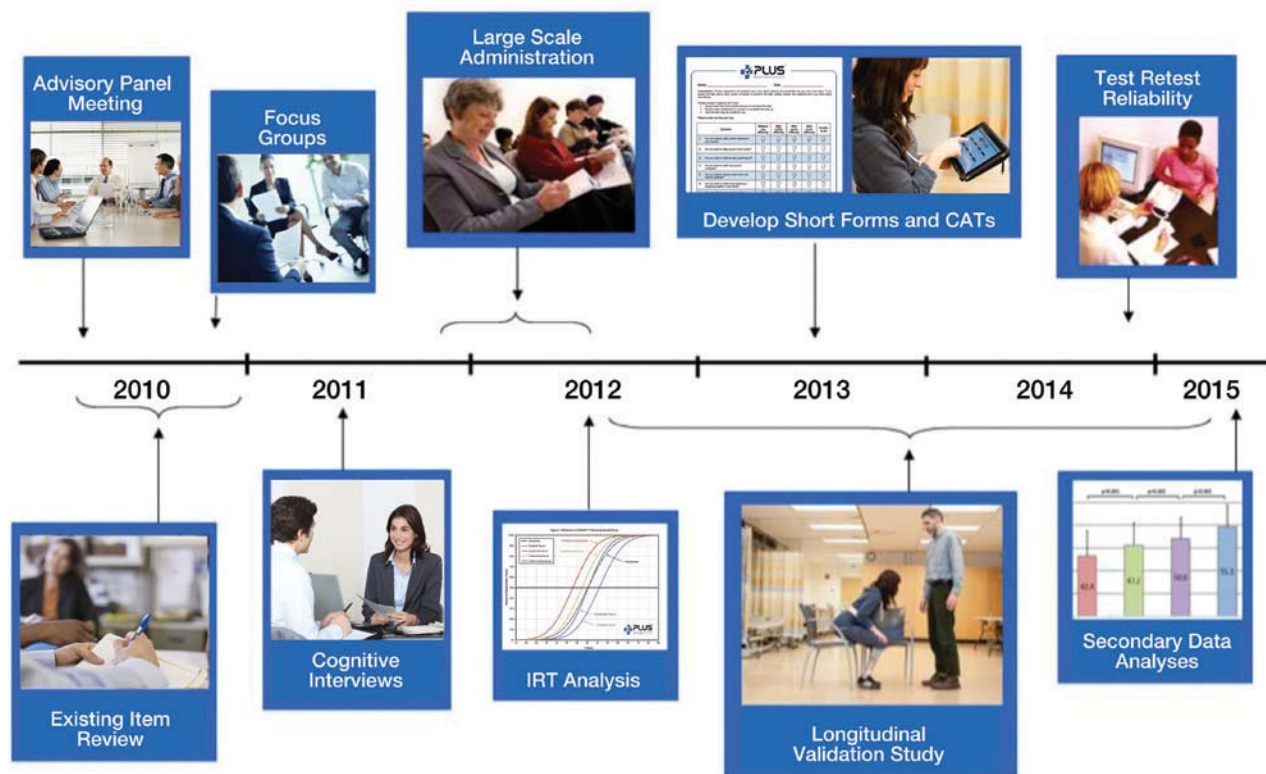


Work to create and test the PLUS-M item bank began in 2010 under a five-year research grant from the National Institutes of Health (NIH). The development efforts described in this article have been guided by existing standards for creating high-quality PROs.[2] These standards encourage use of rigorous qualitative and quantitative research techniques to produce measures that are both psychometrically sound and clinically meaningful.

## Advisory Panel

An advisory panel of key stakeholders was assembled to guide PLUS-M's development and validation efforts. Panel members included consumers, researchers, clinical providers, and representatives from prosthetic industry partners and government agencies. These stakeholders met regularly to review the project's progress and guide future research and dissemination efforts. The first step in developing the PLUS-M was to gather this group to define and discuss mobility while using a prosthesis. This group also reviewed and prioritized items for potential inclusion in the PLUS-M item bank.

## Literature Review

Development of the initial PLUS-M item bank, or a collection of survey questions, began with a thorough literature review to find questions that could be used or adapted to measure prosthetic mobility. In total, more than 1,000 questions from 45 different PROs were identified. These questions were analyzed and used to identify general mobility activities (like "walking over uneven terrain") that could be included in the new survey.

PLUS-M questions were then developed around each of the activities identified in the review. In cases where



existing questions could be included, PLUS-M developers requested permission from the original item authors to include them in the list of candidate questions. The developers also created novel questions based on unique or complex mobility activities (like "walking up steep gravel driveway"). Ultimately, more than 120 questions were developed or included from existing surveys.

## Focus Groups

Focus groups were assembled to discuss mobility from the perspective of prosthetic limb users. Four focus groups, with a total of 37 adults with lower-limb amputation (between six and 12 participants per group), were conducted across the United States to solicit perspectives of people from different geographic areas and climates. These groups consisted of individuals who had diverse perspectives on mobility with a prosthesis, including people with various amputation levels, etiologies, and prosthetic experience.

The focus group sessions were semi-structured, and allowed for informal interviews to be conducted in

an interactive, supportive group environment. These group sessions were moderated by clinicians and researchers trained in qualitative methods.

Example of a focus group discussion about a mobility challenge:

- Moderator: *"Are there things that you encounter in your environment that makes walking tough?"*
- Participant A: *"Sidewalks."*
- Participant B: *"One difficult thing is walking on sidewalks that are angled toward the street at different levels."*

Later, transcripts of the groups' conversations were qualitatively analyzed to identify common themes related to the amputees' experiences with mobility. Items identified in the existing item review were then reassessed to ensure that they addressed aspects of mobility that were identified as important to prosthetic limb users. Focus group discussions informed development of seven new items that were subsequently evaluated in cognitive interviews.

## Cognitive Interviews

Cognitive interviews are one-on-one sessions with respondents that explore the cognitive processes used when answering survey questions.[3,4] These interviews were used to elicit the perspective of prosthetic limb users in regard to the quality of items selected and written by the development team.

This qualitative process was critical in determining whether items were meaningful to patients with lower-limb amputation and if they were understood as intended. Cognitive interviews were conducted by members of the research team who had experience working with people with lower-limb amputations. A total of 156 items (130 items from existing item review and focus groups and 26 new items created through the cognitive interview process) were assessed in 36 cognitive interviews. Following the interviews, items were revised or deleted based on participant feedback.

Example of question revised through cognitive interviews:

- Initial item: *"Are you able to walk on a sideways incline (e.g., a sidewalk that slopes toward the street)?"*
- Revised item: *"Are you able to walk on a surface that slants sideways where one side is higher than the other?"*

Of the 156 items assessed, 80 were accepted as is, 22 were substantially revised, and 54 were removed. In addition, three items were split, resulting in three additional items. The remaining 105 items were then administered to more than 1,000 prosthetic limb users.

## Large-Scale Administration

Following the cognitive interviews, the remaining items were co-administered with legacy measures of mobility to more than 1,000 prosthetic limb users in an 18-month national survey. This group of prosthetic limb users will be referred to as the development sample because their responses were used to assess each of the 105 items using quantitative modern measure development methods. In addition, normative data for the PLUS-M is established from the development samples' responses.

The initial development sample consisted of adults with unilateral transtibial or transfemoral amputation as the result of traumatic or dysvascular causes. The responses from the PLUS-M and existing measures of mobility were used to establish evidence of reliability and validity. Psychometric analyses of the remaining 105 survey questions informed further removal of items, resulting in the inclusion of the 44 survey questions in the final PLUS-M item bank.

## Current and Future Directions

Longitudinal Testing: Currently, more than 200 patients with lower-limb amputation are involved in a national, longitudinal validation study to investigate the psychometric properties (reliability, validity, sensitivity, and responsiveness) of the PLUS-M outcome measure. Patients are assessed during five time points over a one-year period. Thirty-nine clinics and 79 prosthetists are administering the PLUS-M, other existing PROs, and two performance measures (AMP and TUG) to patients before and after delivery of a new prosthesis or replacement socket. Similar outcome data will be compared to evaluate PLUS-M's validity or its effectiveness in measuring mobility.

The fitting of a new prosthesis or replacement socket event was selected, as this is a point when a change in mobility may be observed. Prosthetists and patients are asked to rate the change in mobility after delivery of the new socket. This perception of change in mobility will be correlated with the change in the PLUS-M score to identify the degree of responsiveness. In other words, how many points must the PLUS-M score change to be considered clinically relevant?

Secondary Analyses: Development and validation of PLUS-M has included collection of data from more than 1,300 prosthetic limb users. This represents one of the largest prospective studies of health outcomes in persons with lower-limb amputation to-date.

To maximize the usefulness of this data, PLUS-M developers asked each study participant to complete multiple standardized outcome measures, including those designed to measure outcomes such as pain, fatigue, and concerns with cognitive function. This rich data set is now being studied by the PLUS-M developers to provide additional insight to clinicians and researchers regarding the health and quality of life of people with lower-limb amputation.

Future Research: Although originally developed for people with unilateral lower-limb amputation, efforts are underway to expand application of PLUS-M to other limb loss populations. PLUS-M is currently undergoing testing among bilateral, lower-limb prosthetic users. Developers are assessing performance of PLUS-M with these participants and plan to release a bilateral version of the PLUS-M instrument later this year.

PLUS-M researchers also have

received funding from the Orthotics and Prosthetics Research and Education Foundation to compare paper and computerized versions of PLUS-M (and other PROs). This research will allow the developers to determine if PLUS-M can be administered equally well using both paper and computer forms. Results of this research are expected to facilitate integration of PLUS-M into practice management software and electronic medical record systems.

Lastly, developers are pursuing funding to translate PLUS-M into Spanish. These efforts collectively aim to improve PLUS-M's clinical usability and convenience.

**Conclusion**

PLUS-M is a new patient-report outcome measure of prosthetic mobility that has been developed for clinicians and researchers using contemporary instrument development standards. PLUS-M instruments and user's guides are freely available from the PLUS-M website, *www.plus-m.org*. The short forms are easy to use, take little clinical time to administer and score, and are easy to interpret.

Our ongoing development efforts are intended to enhance the clinical usefulness of this measure and may provide additional insight to clinicians and researchers about outcomes affecting the health and quality of life in people with lower-limb amputation. It is our hope that the routine use of PLUS-M will provide clinicians and researchers with the means to accurately assess mobility, aid clinical decision-making, justify prosthetic care decisions, and document the effectiveness of provided services. **CP**

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# PLUS-M: Getting Started

## What does the PLUS-M measure?
PLUS-M instruments measure prosthesis users' mobility, defined as the ability to move intentionally and independently from one place to another. Individual PLUS-M questions assess respondents' perceived ability to carry out specific activities that require use of both lower limbs. PLUS-M questions cover movements that range from basic ambulation, like walking a short distance indoors, to complex activities, like hiking for long distances over uneven ground. PLUS-M response options reflect the degree of difficulty with which respondents report they can carry out these activities.

## Who can take the PLUS-M?
The PLUS-M is optimized for adult, English-speaking, unilateral, lower-limb prosthesis users who have acquired amputations. Work is underway to assess PLUS-M for use in people with bilateral amputation. Additionally, future efforts will involve translations into languages other than English.

## Can I use the PLUS-M in my clinic?
Yes, PLUS-M short forms are free for non-commercial use. Examples of non-commercial use include administration of paper surveys in clinical practices for the purposes of monitoring patients or administration in research for the purposes of assessing study participants.

## How do I administer the PLUS-M?
PLUS-M is a self-report measure, which means that the patient answers the survey items directly. The PLUS-M instrument can be administered electronically, on paper, or verbally.

## How do I interpret my patient's PLUS-M score?
The PLUS-M score is a T-score. T-scores tell you how much your patient's mobility deviates from the average mobility score of prosthetic limb users. The average mobility score for prosthetic limb users falls around the average T-score of 50, the mean mobility score of the development sample. In addition, T-scores may be compared to those reported by subgroups defined by level of amputation, etiology of amputation, gender, and age.

For more information, visit *www.plus-m.org*.

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