

ORIGINAL RESEARCH

Survey of U.S. Practitioners on the Validity of the Medicare Functional Classification Level System and Utility of Clinical Outcome Measures for Aiding K-Level Assignment



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Abstract

Objective: To characterize the opinion of the prosthetic clinical care community on the Medicare Functional Classification Level (K-level) assignment process to classify the mobility and rehabilitation potential of persons with lower-limb loss, including limitations and practicalities involved with the integration of outcome measures (OMs) into the clinical practice framework for K-level assignment.

Design: Survey.

Setting: English online questionnaire with built-in logic.

Participants: Volunteer sample of prosthetics practitioners (N=236). Data were analyzed only for U.S. practitioners (n=213).

Interventions: Not applicable.

Main Outcome Measures: Subjective responses to 19 multiple choice, Likert scale, and open-ended questions.

Results: Forty-seven percent of respondents indicated that they were the sole determinant in the K-level assignment process, while 43% indicated that it was a collaborative process with other health care professionals. Sixty-nine percent of respondents reported using standardized OMs to assist in K-level assignment, and most did not agree that commonly reported barriers to implementation (eg, lack of time and training) were relevant. Sixty-seven percent of respondents did not believe the K-level system can accurately assign a level of rehabilitation potential, with 75% agreeing that incorporating OMs into clinical practice would enhance objectivity of the K-level assignment process.

Conclusions: The results suggest that most prosthetics practitioners are involved in the K-level assignment at some level, and most agreed that there are considerable limitations with this system. To address these issues, many practitioners are using OMs to assess various aspects of patient mobility and rehabilitation potential, and minimize the subjectivity of the assignment process.

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Adopted by the United States Centers for Medicare and Medicaid Services in 1995, the Medicare Functional Classification Level (MFCL) is an index for classifying the functional mobility and rehabilitation potential of individuals with lower-limb loss.^{1,2} The

MFCL system consists of 5 categories (K-levels) that are ordered by increasing functional mobility (K0–K4) and that broadly define patient mobility level (table 1). The MFCL system facilitates reimbursement from third-party payers for prosthetic devices, of which selection is limited to those component types (designated by L-codes as determined by Durable Medical Equipment Medicare Administrative Contractors) considered medically necessary for each K-level. The underlying definition of medical necessity finds its roots in clinical practice theory, which suggests that a prosthesis should support the mobility potential of the patient. The system

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Table 1 Descriptors of the MFCL and component types considered medically necessary for each K-level without additional justification

K-Level	Descriptor	Foot/Ankle	Knee
K0	This patient does not have the ability or potential to ambulate or transfer safely with or without assistance, and a prosthesis does not enhance his/her quality of life or mobility.	Not eligible for prosthesis	Not eligible for prosthesis
K1	This patient has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence—a typical limited or unlimited household ambulator.	External keel, SACH feet, or single-axis ankle/feet	Single-axis, constant friction knee
K2	This patient has the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces—a typical community ambulator.	Flexible-keel feet and multiaxial ankle/feet	Single-axis, constant friction knee
K3	This patient has the ability or potential for ambulation with variable cadence—a typical community ambulator with the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic use beyond simple locomotion.	Flex-foot and flex-walk systems, energy-storing feet, multiaxial ankle/feet, or dynamic response feet	Fluid and pneumatic control knees
K4	This patient has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels—typical of the prosthetic demands of the child, active adult, or athlete.	Any ankle foot system appropriate	Any ankle-knee system appropriate

Abbreviation: SACH, solid ankle, cushion heel.

therefore controls spending by restricting certain component eligibility to patients who will derive the full benefit from those devices.^{3,4} The prosthesis that a patient receives, the prosthesis-related health care cost, and more critically the rehabilitation outcomes the patients experience are principally dependent on the K-level assigned by their clinical rehabilitation team. Consequently, clinical care when implementing the MFCL system ultimately relies on the ability of that system to accurately and reliably classify patients.

Importantly, anecdotal evidence from within the rehabilitation community suggests that there are limitations to the usefulness and validity of the MFCL system for patient classification. K-level assignment relies heavily on subjective information and the varied experience and personal opinions of care providers. Additionally, the content validity of the K-level system has been questioned, especially since it was not established from research evidence.⁵ A large range of factors such as comorbid disease and preoperative ambulatory status affect the mobility of a lower-limb prosthesis user,⁶⁻⁸ but the K-level system only considers a limited set of variables (eg, ability to ambulate at variable cadences and traverse environmental barriers). Importantly, given the variability of those factors that influence patient mobility,⁹ the 5-level system may not provide sufficient resolution to effectively classify rehabilitation

potential. The concern with validity is also relevant to clinical research, because the K-level system is often adopted to classify subjects by functional mobility for grouping or inclusion criteria, or both.^{3,10-12}

One potential means for partially addressing limitations with the K-level assignment process and increasing its reliability and validity would be the incorporation of clinical outcome measures (OMs). Validated OMs provide clinical means to accurately and reliably assess and document patient mobility and ambulation potential, thereby reducing reliance on subjective information. To aid in standardization, validated OMs based on performance, self-report, and information from wearable device instruments¹³ are available to practitioners for assessing patient mobility.

Although there are potential benefits to using OMs for K-level assignment, the literature on this topic is minimal. Evidence from known-group analyses of a small selection of OMs including the Amputee Mobility Predictor (AMP), the mobility subscale of the Prosthesis Evaluation Questionnaire, and wearable devices (eg, mobile phone accelerometers and pedometers) has suggested that the outcomes from these measures can discriminate between K-levels, but with some associated variability and overlap across levels.^{1,12,14-19} These results and the fact that OMs are becoming more widely applied in clinical practice are promising,²⁰ but evidence suggests that OM use is still limited because of various barriers, with only 38% of prosthetic care practitioners reporting that they are regular users of OMs.²¹

Although the issues with the K-level system are discussed within the rehabilitation community, the professional opinion on

List of abbreviations:

AMP Amputee Mobility Predictor
MFCL Medicare Functional Classification Level
OM outcome measure

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