Identifying content gaps in health status measures for intermittent claudication using the International Classification of Functioning, Disability and Health

David S. Kauvar, MD, FACS,[a,b] *and* Candice L. Osborne, PhD, MPH, OTR,[c] *Fort Sam Houston and Dallas, Tex; and Bethesda, Md*

ABSTRACT

Objective: The Walking Impairment Questionnaire (WIQ) and Intermittent Claudication Questionnaire (ICQ) are commonly used patient-reported functional outcome measures for intermittent claudication, but their functional representation has not been characterized. The World Health Organization's International Classification of Functioning, Disability and Health (ICF) framework comprehensively describes health-related function and has been used to evaluate health status and quality of life (QOL) measures. We applied a content analysis technique commonly used in functional rehabilitation research to evaluate ICF domains represented by WIQ and ICQ to characterize their health status and functional representation.

Methods: The overall perspective of each question was assigned as health status—function, health status—disability, Environment—facilitator, Environment—barrier, or QOL. All meaningful concepts in each question were identified and linked to the most appropriate and precise ICF code from the hierarchy of component, chapter, or category using the validated technique. A 20% random sample of questions was secondarily coded with disagreements resolved by discussion.

Results: Codability was agreed upon for 87% of questions; agreement was 100% on component and chapter and 88% on category. WIQ contains 18 concepts among 14 questions (1.3 concepts per question); all questions are from the health status—disability perspective. All WIQ concepts are from the "Activities/Participation-d" ICF component, "Mobility-d4" chapter. "Walking long distances" (d4501, >1 km) is omitted. ICQ contains 37 codable concepts among 16 questions (2.3 concepts per question). Thirteen questions are from health status-disability perspective, three from QOL. Sox of the nine chapters of the "Activities/Participation-d" ICF component are represented by 20 of 37 concepts; 11 of 20 in the "Mobility-d4" chapter. The other "Activities/Participation-d" chapters and categories in ICQ are "Learning/applying knowledge" ("thinking-d163"), "General tasks/demands" ("carrying out daily routine-d230"), "Domestic life" ("shopping-d6200," "doing housework-d640"), "Major life areas" ("Maintaining a job-d8451"), and "Community life" ("socializing-d9205," "hobbies-d9204"). "Body Functions-b" ICF component is represented 11 times, covering pain, numbness, emotion, mood, and cardiovascular functions. "Body Structures-s" is represented three times as lower extremity. Neither WIQ nor ICQ specifically addresses "Walking on different surfaces," (64,502) "Walking around obstacles" (d4503), or "Moving around using equipment" (d465), which includes assistive devices. Walking on an incline is not addressed in WIQ, ICQ, or the ICF.

Conclusions: Applying this ICF-based content assessment methodology to patient-reported vascular disease outcome measures is feasible, representing a novel method of assessing such instruments. WIQ's scope is limited; it does not address functional capacity and covers only health status pertaining to walking disability. The ICQ is more inclusive, but concept density may obscure meaning. Neither instrument is functionally comprehensive and both have significant omissions that should be considered for inclusion. (J Vasc Surg 2018;67:868-75.)

Intermittent claudication (IC) is a common manifestation of peripheral artery disease that, although not a life- or limb-threatening problem, can result in significant functional impairments. Understanding IC patients' disease-related disability and resulting functional limitations is a key part of constructing treatment plans and assessing their outcomes. To this end, numerous clinical IC assessments have been used, falling into two main categories. Corridor or treadmill walking assessments such as the 6-minute walk test and tests of the functional, minimum, or initial claudication and maximal walking distances can be used to identify speed and distance limitations.[1,2] Because these tests can be difficult to perform in standard clinical situations, a number of questionnaire measures of walking

From the Vascular Surgery Service, San Antonio Military Medical Center, Fort Sam Houston[a]; the Department of Surgery, Uniformed Services University of the Health Sciences, Bethesda[b]; and the Department of Physical Medicine and Rehabilitation, University of Texas Southwestern, Dallas.[c]

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Correspondence: David S. Kauvar, MD, FACS, San Antonio Military Medical Center, 3551 Roger Brooke Dr, Fort Sam Houston, TX 78234 (e-mail: davekauvar@gmail.com).

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performance have been developed and are advocated for use by the Society for Vascular Surgery, which recommends use of a "Quality of life assessment by validated scoring system" in the reporting of endovascular treatment of IC.[3] Results of these patient-reported outcomes measures (PROMs) have been correlated with actual physical walking performance. The evaluation of these assessments and measures has focused primarily on their ability to define the physical disability produced by IC. There have been no attempts to evaluate their ability to identify functional limitations encountered by a patient with IC in their daily life as a result of their physical disability.

The International Classification of Functioning, Disability and Health (ICF) is a system developed and endorsed by the World Health Organization with the goal of providing a "unified and standard language and framework for the description of health and health-related states."[4] The ICF is complementary to the *International Classification of Diseases, Tenth Revision* (ICD-10), and its health- and environment-related domains can be used to comprehensively describe those aspects of life affected by the diseases and conditions classified in the ICD-10, such as IC. One of the widest applications of the ICF since its first publication in 2002 has been in the evaluation of the comprehensiveness of health status and quality of life (QOL) measures for various diseases and conditions.

The objective of the research reported here was to use a standardized, validated outcome measure linking system to evaluate the ICF domains represented by the most commonly used IC health status PROMs. By linking these PROMs with the ICF, we aimed to characterize the health status and functional aspects represented and overlooked by these assessments and provide building blocks for the creation of more comprehensive IC outcome measures.

METHODS

This study was deemed exempt from institutional review board review by the human subjects research protection office at Dwight D. Eisenhower Army Medical Center.

A search of the MEDLINE database was performed to identify PROMs that had been studied in the setting of IC health status and disability. Search terms included "intermittent claudication," "peripheral artery disease," "disability," "function," "walking," "impairment," "assessment," "instrument," and "questionnaire." Abstracts were then reviewed to determine which, if any, IC PROM was studied. If an IC PROM was studied, the full text of the questionnaire was reviewed. To have been considered for inclusion in this study, a PROM was required to have patients with IC as its population of interest, to be available in English, to be validated in IC patients, and to be used not solely for the diagnosis, but for assessing the severity of IC-related disability.

ARTICLE HIGHLIGHTS

- **Type of Research:** Content analysis of questionnaires
- **Take Home Message:** Out of two questionnaires measuring patient reported functional outcome for intermittent claudication, the Walking Impairment Questionnaire (WIQ) does not address functional capacity, whereas the Intermittent Claudication Questionnaire (ICQ) is more inclusive but overly dense.
- **Recommendation:** This study suggests that neither the WIQ nor the ICQ are functionally comprehensive to assess outcome for intermittent claudication and both have significant omissions that require inclusion.

Assessments meeting these criteria were then linked to the ICF using the standardized linking technique and rules devised and validated by Cieza et al.[5,6] In this technique, each question (requiring a response from the subject) is referred to as an "item" and is considered and linked independently. If a number of items refer to a single prefix question, then the prefix is linked a single time along with each item. Before linking the items in a clinical assessment, the primary aim of the assessment is identified; in this case, the evaluation of walking disability. The ICF linking process proceeds from the perspective of this primary aim. Any necessary specific rules for coding are also developed before coding to reduce the ambiguities inherent to the process as it pertains to linking a particular assessment or assessments.

The ICF is organized hierarchically, with a topmost level of four components, each containing a number of chapters: Body Functions (b, 8 chapters), Body Structures (s, 8 chapters), Activities and Participation (d, 9 chapters), and Environmental Factors (e, 5 chapters). Each chapter contains a varying number of categories, with up to three category levels possible (Fig 1).

The linking process first involves identifying the meaningful concepts in each prefix or item (including any concepts present in the provided response options). For example, in the item "During the past 2 weeks, how often have you had to stop walking and rest because of pains in your leg," there are three meaningful concepts, namely, walking, rest, and pains in your leg. Time factors (such as the past 2 weeks) are not linked. Once all of the meaningful concepts in an assessment's prefixes and items have been identified, each concept is linked to the most appropriate ICF component, chapter, and category at the lowest possible level. Some concepts are not codable because they are not defined clearly enough (too general), or because they are not found within the ICF. Additionally, health conditions (specific diagnoses) are not coded because they can be coded using the ICD-10.