



## REVIEW ARTICLE

# Identifying Instruments to Assess Care Quality for Individuals With Custom Ankle Foot Orthoses: A Scoping Review

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## Abstract

**Objectives:** We conducted 2 complementary scoping reviews to identify instruments that assess the experience and outcomes of custom ankle-foot orthosis (AFO) care in individuals with neurologic and traumatic conditions and to determine to what extent they might be psychometrically sound for AFO users. A stakeholder advisory committee considered to what extent the identified and psychometrically sound instruments might be feasible for use in developing quality measures for custom AFO users.

**Data Sources:** Both scoping reviews were conducted using PubMed, the Cumulative Index to Nursing and Allied Health Literature, Embase, and Cochrane Systematic Reviews. The following were used for the first scoping review only: Cochrane Central Register of Controlled Trials and the Physiotherapy Evidence Database.

**Study Selection:** The initial scoping review yielded 79 articles with 82 instruments, 16 of which were used in 4 or more studies. The second scoping review yielded 57 articles reporting psychometric properties.

**Data Extraction:** Psychometric properties for populations who use AFOs were summarized for 15 of the 16 instruments. The advisory committee eliminated 2 instruments, noted overlap between 4 instruments in terms of the constructs measured, and suggested 6 potential contemporary substitutes.

**Data Synthesis:** Most instruments assessed activity (specifically mobility) and pertained to the National Quality Forum domain of "Health-Related Quality of Life." The 10-meter walk test, 6-minute walk test, Berg Balance Scale, Timed Up and Go, and Rivermead Mobility Index were reported to have adequate reliability and validity, and were considered feasible for administration in a clinical setting.

**Conclusions:** Complementary scoping reviews demonstrated that some instruments with reasonable psychometric properties are available that are feasible to use in developing quality measures for custom AFO care. However, experience of care instruments suitable for this population were not identified but are needed for a comprehensive evaluation of care quality for AFO users.

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Orthotic services are a component of health care delivery that involve the design, fabrication, fitting, and follow-up of orthoses that provide external support of body segments and joints.<sup>1,2</sup> A recent practice analysis of certified orthotists reported that the largest proportion of their time was spent delivering ankle-foot orthoses (AFOs).<sup>3</sup> AFOs are devices that encompass the lower leg, ankle and foot to help control motion at the ankle and knee, as

well as correct or accommodate deformity and/or compensate for impairments of the ankle-foot complex.<sup>1</sup> AFOs are needed by individuals with a variety of conditions of neurologic and traumatic etiology. Although they have the capacity to improve a person's functioning,<sup>4</sup> no data are available to consumers or referring clinicians to help identify high-quality service delivery of AFOs.

To improve quality of orthotic service delivery, professional organizations responsible for accreditation of orthotic patient care facilities have developed standards that emphasize patient feedback.<sup>5</sup> Patient feedback is typically obtained through patient satisfaction surveys. However, satisfaction with a device represents only one aspect of health care quality.<sup>6</sup>

Health care quality can be defined as the "degree to which a desired health care process or outcome is achieved or the extent that a desirable structure to support health care delivery is in place."<sup>7(p121)</sup> Two frameworks for considering health care quality include those described by Donabedian<sup>8</sup> and the National Quality Forum (NQF).<sup>9</sup> The Donabedian framework describes quality across 3 domains: structure, process, and outcome. Structure measures track whether a particular mechanism or system is in place, such as whether an organization is using electronic medical records; process measures track performance of a particular action, such as fabrication of devices in a timely manner; and outcome measures consider the end results of care, such as functional ability, gait quality, falls, pain, and patient experience with devices and services. The NQF offers a framework for quality measurement focused on person- and family-centered care.<sup>9</sup> High priority topics identified by the NQF framework include interpersonal relationships, patient and family engagement, care planning and delivery, access to support, and quality of life (table 1).<sup>9</sup>

The most common framework used to classify aspects of functioning is the International Classification of Functioning, Disability and Health (ICF).<sup>10</sup> The ICF describes health-related states such as changes in body function and structure, as well as the capacity and performance levels of a person with a health condition.<sup>10</sup> It has been used to classify measurement concepts and instruments relevant to evaluation of lower-limb orthoses.<sup>11</sup>

Lower-limb orthotic concepts relevant to the ICF component of body structure and function include neuromusculoskeletal and movement-related functions (b7), pain (b280-289), and exercise tolerance (b455). Concepts relevant to the ICF component of activities and participation include mobility (d4), self-care (d5), interpersonal interactions and relationships (d7), major life areas (d8), and domestic (d6), community, social, and civic life (d9).<sup>11</sup> A candidate core set of measures and instruments based on the ICF includes goniometric assessment of joint motion, manual muscle strength testing, the Modified Ashworth Scale, the visual analog scale for assessing pain, the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) pain and physical functioning subscales, the Berg Balance Scale (BBS), the Timed Up and Go (TUG) test, the 2- and 6-minute walk tests (2MWT and 6MWT), the Nottingham Health Profile, the ACTIVLIM and Impact on Participation and Autonomy questionnaires, gas-analysis systems to assess energy cost of walking, static and dynamic posturography, and 3-dimensional gait analysis.<sup>11</sup>

However, the measurement of quality of care requires not only use of standardized instruments, but their use must be appropriate for the populations of interest and feasible to implement in routine clinical practice. Feasibility in clinical practice includes considerations regarding time, available resources, and training requirements to administer the instrument.<sup>12</sup> Furthermore, when selecting suitable instruments that can be used to develop quality measures, clinicians must consider the extent to which psychometric properties (ie, reliability, validity, sensitivity, and responsiveness) have been established for target populations.

As part of a larger project that included parallel efforts to engage stakeholders in identifying quality concepts pertinent to AFO care,<sup>13,14</sup> we needed to identify instruments that might be used to develop quality measures to assess AFO users' experience and outcomes of care. Scoping reviews are considered an ideal tool to determine the extent of a body of literature on a given topic.<sup>15,16</sup> Therefore, the objectives of 2 complementary scoping reviews were to first identify instruments that address experience and outcomes of AFO care in individuals with neurologic and traumatic conditions, and then to summarize the instruments' psychometric properties for populations that use AFOs. Both scoping reviews were required to achieve the third objective of considering to what extent the identified and psychometrically-sound instruments might be feasible for use in developing quality measures for AFO users. Collectively, the findings represent a first step in the utilization of standardized instruments that could be used to create quality measures and improve quality of care for individuals who use AFOs.

#### List of abbreviations:

<b>10MWT</b>	<b>10-meter walk test</b>
<b>2MWT</b>	<b>2-minute walk test</b>
<b>6MWT</b>	<b>6-minute walk test</b>
<b>AFO</b>	<b>ankle-foot orthosis</b>
<b>BBS</b>	<b>Berg Balance Scale</b>
<b>ICF</b>	<b>International Classification of Functioning, Disability and Health</b>
<b>MAS</b>	<b>Modified Ashworth Scale</b>
<b>MS</b>	<b>multiple sclerosis</b>
<b>NQF</b>	<b>National Quality Forum</b>
<b>OPUS CSD</b>	<b>Orthotic and Prosthetic Users' Survey Client Satisfaction with Device</b>
<b>QUEST 2.0</b>	<b>Quebec User Evaluation of Satisfaction with assistive Technology</b>
<b>RMI</b>	<b>Rivermead Mobility Index</b>
<b>SCI</b>	<b>spinal cord injury</b>
<b>SF-36</b>	<b>Medical Outcomes Study 36-Item Short-Form Health Survey</b>
<b>SMFA</b>	<b>Short Musculoskeletal Function Assessment</b>
<b>SIS</b>	<b>Stroke Impact Scale</b>
<b>TBI</b>	<b>traumatic brain injury</b>
<b>TUG</b>	<b>Timed Up and Go</b>

## Methods

To address the first 2 objectives, we conducted 2 scoping reviews similar to Parry et al,<sup>17</sup> who first identified instruments used to evaluate muscle mass, strength, and function in critically ill individuals, followed by a second search that identified articles reporting psychometric properties of the identified instruments. We accomplished the third objective through review by, and discussion with, a stakeholder advisory committee comprising 19 individuals representing orthotic and prosthetic and physical therapy professional and educational organizations (n=8), clinicians (prosthetists, orthotists, physical therapists) from varied practice settings (n=5), consumer organizations (n=3), and consumer users of AFOs (n=3). The investigators established the stakeholder advisory committee through invitations to ensure diverse representation.

**Table 1** National Quality Forum: highest priority topics and subtopics in person- and family-centered care\*

High Priority Topics	Subtopics
Interpersonal relationships	<ul style="list-style-type: none"> <li>• Dignity, respect, compassion, trust, perception of equity</li> <li>• Communication and collaboration</li> <li>• Cultural and linguistic responsiveness</li> </ul>
Patient and family engagement	<ul style="list-style-type: none"> <li>• Shared decision-making and informed choice</li> <li>• Advance care planning</li> </ul>
Care planning and delivery	<ul style="list-style-type: none"> <li>• Establishment and attainment of patient/family/caregiver objectives</li> <li>• Care concordant with person values and preferences</li> <li>• Care integration (coordination, transitions)</li> </ul>
Access to support	<ul style="list-style-type: none"> <li>• Patient and caregiver needs and support</li> <li>• Timely and easy access to care and knowledge</li> </ul>
Health Related Quality of Life	<ul style="list-style-type: none"> <li>• Physical and cognitive functioning</li> <li>• Behavioral, physical, social, emotional, and spiritual well-being</li> <li>• Symptom and symptom burden (eg, pain, fatigue, dyspnea, mood)</li> <li>• Treatment burden (on patients, families, caregivers, siblings)</li> </ul>

\* Highest priority topics and subtopics in person- and family-centered care.<sup>9(p19)</sup>

## Objective 1: identify instruments

With the assistance of a medical librarian, the following databases were searched: PubMed, the Cumulative Index to Nursing

and Allied Health Literature, Embase, Cochrane Systematic Reviews, Cochrane Central Register of Controlled Trials, and the Physiotherapy Evidence Database. The search strategy contained search terms that defined the population (neurologic and traumatic conditions), the device (AFO), and terms related to functioning and quality of care. Conditions with a neurologic etiology were identified by terms that included stroke, nervous system diseases, nerve injury, and nerve damage, whereas conditions with a traumatic etiology were identified by terms that included wounds, injuries, limb salvage, trauma, polytrauma, and fractures. Table 2 shows the search string used in PubMed; similar search strings were used in the other databases. Duplicate citations were removed after combining searches across the databases.

The inclusion criteria were use of an AFO (also referred to as a short leg brace), age of 18 years or older with neurologic or traumatic conditions, and use of an instrument to assess experiences or outcomes in an inpatient or outpatient setting.

The exclusion criteria were editorials, descriptive reports, protocols without data, and review articles because they were unlikely to mention relevant data elements (eg, AFO description, instrument used), animal studies, articles that assessed robotic or externally powered AFOs, knee-ankle-foot orthoses or hip-knee-ankle-foot orthoses, and instruments that required expensive or complex equipment (eg, 3-dimensional gait labs or metabolic carts), that were used solely to characterize the study population, or that were non-standardized (ie, those created on an ad-hoc basis by authors). To align with contemporary clinical practice, articles were limited to those published in English between 1990 and April 2017.

Two reviewers independently reviewed the title and abstract of each article identified from the initial search and determined whether a full text review was warranted. The reviewers compared their selection of articles and resolved discrepancies by consensus, with feedback from a third reviewer, where needed. The same 2 reviewers extracted data from the full text of included articles,

**Table 2** Sample PubMed search string for initial review of AFO studies

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(ankle-foot[tw] or foot-ankle[tw] or "ankle foot"[tw] or "foot ankle"[tw]) AND ("Orthotic Devices"[Mesh] OR "Braces"[Mesh] OR orthosis[tw]
or orthoses[tw] or orthotic[tw] OR orthotics[tw] OR brace[tw] or braces[tw])) OR short leg brace*) OR ("Foot Orthoses"[Mesh] OR AFO[tw]
OR AFOs[tw])
AND
(("Nervous System Diseases"[Mesh] OR "Stroke"[Mesh] OR "Paralysis"[Mesh] OR "neurologic condition"[tw] OR "nerve injury"[tw] OR "nerve
injuries"[tw] OR "nerve damage"[tw] OR "CVA"[tw] OR "cerebrovascular accident"[tw] OR "stroke"[tw] OR hemip*[tw] OR "paralysis"[tw]))
AND
("Wounds and Injuries"[Mesh] OR "Limb Salvage"[Mesh] or trauma[tw] or traumas[tw] or polytrauma[tw] or polytraumas[tw] or injury[tw] or
injuries[tw] or fracture[tw] or fractures[tw] or wound[tw] or wounds[tw] or "limb salvage"[tw])
AND
(((("Postural Balance"[Mesh] OR "Walking"[Mesh] OR "Gait"[Mesh] OR "Posture"[Mesh] OR "Stair Climbing"[Mesh] OR "Muscle Strength"[Mesh]
OR "Pain"[Mesh] OR "Accidental Falls"[Mesh] OR "Personal Satisfaction"[Mesh] OR "Patient Satisfaction"[Mesh] OR "Fatigue"[Mesh] OR
"Muscle Fatigue"[Mesh] OR "balance"[tw] OR "walking"[tw] OR "gait"[tw] OR "quality of life"[tw] OR "posture"[tw] OR "stairs"[tw] OR
"strength"[tw] OR "pain"[tw] OR "fall"[tw] OR "falls"[tw] OR "satisfaction"[tw] OR "fatigue"[tw] OR "stability"[tw] OR "instability"[tw] OR
"step"[tw] OR "stride"[tw] OR "Outcome Assessment (Health Care)"[Mesh] OR "Quality Assurance, Health Care"[Mesh:noexp] OR "Quality of
Health Care"[Mesh:noexp] OR "Quality Indicators, Health Care"[Mesh] OR "Quality Improvement"[Mesh:noexp] OR "Quality of Life"[Mesh]
OR "Health Care Quality, Access, and Evaluation"[Mesh] OR quality[tw] OR measure[tw] OR measures[tw] OR measurement[tw] OR outcome
[tw] OR outcomes[tw]))
NOT
(Comment[sb] OR Editorial[ptyp] OR Letter[ptyp] OR Case Reports[ptyp] or "case study"[ti])
Limited to English, 1990 to present
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confirmed one another's selections, and resolved any discrepancies by consensus. For each article, the population, type of AFO (custom-made or prefabricated), and instruments used were recorded.

The reviewers generated a list of identified instruments and assessed the frequency of their use within the included articles. Given that the intent was to identify instruments that are broadly applicable and could be routinely administered across patients, clinicians, and service providers, we presumed frequency of use to be a reasonable indicator of broad usefulness and feasibility of an instrument. Hence, instruments used 4 or more times were included and categorized by method of data collection, ICF code,<sup>10</sup> Donabedian's 3 aspects of quality,<sup>8</sup> and the NQF's person- and family-centered care domains.<sup>9</sup>

## Objective 2: psychometric properties of identified instruments

To summarize the psychometric properties of the final list of instruments identified by the first scoping review, a medical librarian searched the following databases: PubMed, Cumulative Index to Nursing and Allied Health Literature, Embase, and Cochrane Systematic Reviews. The search strategies contained terms that defined the name of the instrument and neurologic and traumatic conditions, as well as the COSMIN filter, which was developed for

finding measurement properties of assessment instruments,<sup>18</sup> and filtering for review articles. Table 3 shows the search string and COSMIN filter used in PubMed for 1 instrument. Similar search strings were used in all databases for each instrument. When a search found no review articles, the review filter was removed and the search was repeated for articles describing original reports that assessed the psychometric properties of that instrument. Duplicate citations were removed after combining searches across the databases.

The inclusion criteria for reviews and articles included English language source, reporting of instrument psychometric properties, relevance to adults with neurologic and traumatic conditions, and activities associated with AFO use (ie, gait, balance, etc). Reviews and articles were excluded if they focused on subjects younger than 18 years old, assessment of interventions, and activities that do not use AFOs (eg, wheeled mobility).

Two reviewers reviewed these articles following a methodology similar to that described for the preceding scoping review of AFO studies. For each article, reviewers recorded the article type (systematic review, review, or study); population; instrument type; and information regarding reliability, validity, sensitivity, and responsiveness. Instrument types were categorized as performance-based, defined as a measurement based on a task performed by a patient according to instructions from a health care professional; patient-reported, defined as a measurement based on

**Table 3** Sample PubMed search string for review of psychometric properties of 10MWT (shaded row indicates COSMIN Filter)<sup>18</sup>

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(("Nervous System Diseases"[Mesh] OR "Stroke"[Mesh] OR "Paralysis"[Mesh] OR "neurologic condition"[tw] OR "nerve injury"[tw] OR "nerve injuries"[tw] OR "nerve damage"[tw] OR "CVA"[tw] OR "cerebrovascular accident"[tw] OR "stroke"[tw] OR hemip*[tw] OR "paralysis"[tw]))
AND
("Wounds and Injuries"[Mesh] OR "Limb Salvage"[Mesh] or trauma[tw] or traumas[tw] or polytrauma[tw] or polytraumas[tw] or injury[tw] or injuries[tw] or fracture[tw] or fractures[tw] or wound[tw] or wounds[tw] or "limb salvage"[tw])
AND
(instrumentation[sh] OR methods[sh] OR Validation Studies[pt] OR Comparative Study[pt] OR "psychometrics"[MeSH] OR psychometr*[tiab] OR clinimetr*[tw] OR clinometr*[tw] OR "outcome assessment (health care)"[MeSH] OR outcome assessment[tiab] OR outcome measure*[tw] OR "observer variation"[MeSH] OR observer variation[tiab] OR "Health Status Indicators"[MeSH] OR "reproducibility of results"[MeSH] OR reproducib*[tiab] OR "discriminant analysis"[MeSH] OR reliab*[tiab] OR unreliab*[tiab] OR valid*[tiab] OR coefficient [tiab] OR homogeneity[tiab] OR homogeneous[tiab] OR "internal consistency"[tiab] OR (cronbach*[tiab] AND (alpha[tiab] OR alphas [tiab])) OR (item[tiab] AND (correlation*[tiab] OR selection*[tiab] OR reduction*[tiab])) OR agreement[tiab] OR precision[tiab] OR imprecision[tiab] OR "precise values"[tiab] OR test-retest[tiab] OR (test[tiab] AND retest[tiab]) OR (reliab*[tiab] AND (test[tiab] OR retest [tiab])) OR stability[tiab] OR interrater[tiab] OR inter-rater[tiab] OR intrarater[tiab] OR intra-rater[tiab] OR intertester[tiab] OR inter-tester [tiab] OR intratester[tiab] OR intra-tester[tiab] OR interobserver[tiab] OR inter-observer[tiab] OR intraobserver[tiab] OR intra-observer [tiab] OR intertechnician[tiab] OR inter-technician[tiab] OR intratechnician[tiab] OR intra-technician[tiab] OR interexaminer[tiab] OR inter-examiner[tiab] OR intraexaminer[tiab] OR intra-examiner[tiab] OR interassay[tiab] OR inter-assay[tiab] OR intraassay[tiab] OR intra-assay[tiab] OR interindividual[tiab] OR inter-individual[tiab] OR intraindividual[tiab] OR intra-individual[tiab] OR interparticipant[tiab] OR inter-participant[tiab] OR intraparticipant[tiab] OR intra-participant[tiab] OR kappa[tiab] OR kappa's[tiab] OR kappas[tiab] OR repeatab*[tiab] OR ((replicab*[tiab] OR repeated[tiab]) AND (measure[tiab] OR measures[tiab] OR findings[tiab] OR result[tiab] OR results [tiab] OR test[tiab] OR tests[tiab])) OR generaliza*[tiab] OR generalisa*[tiab] OR concordance[tiab] OR (intraclass[tiab] AND correlation*[tiab]) OR discriminative[tiab] OR "known group"[tiab] OR factor analysis[tiab] OR factor analyses[tiab] OR dimension*[tiab] OR subscale*[tiab] OR (multitrait[tiab] AND scaling[tiab] AND (analysis[tiab] OR analyses[tiab])) OR item discriminant[tiab] OR interscale correlation*[tiab] OR error[tiab] OR errors[tiab] OR "individual variability"[tiab] OR (variability[tiab] AND (analysis[tiab] OR values[tiab])) OR (uncertainty[tiab] AND (measurement[tiab] OR measuring[tiab])) OR "standard error of measurement"[tiab] OR sensitiv*[tiab] OR responsive*[tiab] OR ((minimal[tiab] OR minimally[tiab] OR clinical[tiab] OR clinically[tiab]) AND (important[tiab] OR significant[tiab] OR detectable[tiab]) AND (change[tiab] OR difference[tiab])) OR (small*[tiab] AND (real[tiab] OR detectable[tiab]) AND (change[tiab] OR difference[tiab])) OR meaningful change[tiab] OR "ceiling effect"[tiab] OR "floor effect"[tiab] OR "Item response model"[tiab] OR IRT[tiab] OR Rasch[tiab] OR "Differential item functioning"[tiab] OR DIF[tiab] OR "computer adaptive testing"[tiab] OR "item bank"[tiab] OR "cross-cultural equivalence"[tiab])
AND
"10 meter walk test"[tiab] OR "10 meter walk test"[tiab] OR "10-meter walk test"[tiab] OR "10-meter walk test"[tiab] OR 10MWT[tiab] OR "ten meter walk test"[tiab] OR "ten meter walk test"[tiab] OR "ten-meter walk test"[tiab] OR "ten-meter walk test"[tiab] OR "ten MWT"[tiab]
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self-report that comes directly from the patient or study subject; and clinician-reported, defined as being based on a report that comes from a trained health care professional after observation of a patient or subject's health condition.<sup>19</sup> To augment the information from the search, reviewers also consulted repositories such as the Rehabilitation Measures Database ([www.rehabmeasures.org](http://www.rehabmeasures.org)), StrokeEdge, MSEdge, SCIEdge, and TBIEdge (see <http://www.neuropt.org/professional-resources/neurology-section-outcome-measures-recommendations>) for additional information regarding psychometric properties and recommendations regarding instruments.

### Objective 3: suitability of instruments

To determine to what extent these instruments may be suitable to use in developing quality measures for individuals who use AFOs, the researchers and the stakeholder advisory committee considered the findings from both reviews, as summarized in tables 4 and 5. As described above, the advisory committee represented experts from various stakeholder groups. They considered which instruments may be suited for use in developing quality measures across populations who use AFOs, had documentation of adequate psychometric properties, had been recommended for use in clinical practice, and were feasible for use in inpatient or outpatient clinical settings. Additionally, we asked stakeholders to report other instruments that may serve as a contemporary substitute or if there was redundancy among instrument constructs. These steps resulted in a short list of instruments that might be considered for use when developing quality measures for persons who use AFOs (table 6).

## Results

### Objective 1: identify instruments

Searching all databases yielded 2134 articles, from which 1105 duplicates were removed (fig 1). After a review of the titles and abstracts of the remaining 1029 articles, an additional 935 articles were excluded because they did not meet the selection criteria. A full text review of the remaining 94 articles led to the exclusion of 15 articles because they did not meet the review criteria. The review was based on the remaining 79 articles that focused on adults with neurologic and traumatic conditions who use AFOs and used instruments considered feasible for use in an inpatient or outpatient clinical setting.

The majority of the 79 articles focused on individuals with neurologic conditions who use AFOs (87%), with a smaller proportion of articles focused on individuals with traumatic conditions who used AFOs (13%). Neurologic conditions were mostly stroke, with 1 or 2 articles each on multiple sclerosis (MS), post-polio syndrome, and Charcot-Marie-Tooth disease. Traumatic conditions included spinal cord injury (SCI), traumatic brain injury (TBI), fractures, and severe ankle sprains. Most studies (70%) assessed the use of a single AFO, whereas the remaining studies assessed use of 2 to 4 different types of AFOs. Approximately two-thirds of the studies (68%) evaluated custom-made or prefabricated AFOs, or both. Some studies provided descriptions of the AFOs but did not specify whether they were custom-made or prefabricated (18%), whereas others provided no description of the AFO (14%).

In summary, the first review identified 82 unique instruments. However, 80% appeared in only 1 to 3 articles and were therefore

excluded from the final list of instruments (see table 4). Twenty percent (16 instruments) were used in 4 or more studies (see table 5) and form the basis of this review, with 62% being performance-based, 19% patient-reported, and 19% clinician-reported.<sup>19</sup> Most measures evaluated aspects of the ICF activity domain (81%), with others assessing body function (19%), body structure (6%), and participation (6%) (see table 5). Activities including mobility tasks of rising from a chair, ambulating, turning, stepping agility, and stair-climbing were evaluated in terms of independence. Other activities, including walking speed and distance, balance abilities, and exertion level were measured directly. All instruments were classified as pertaining to the NQF quality domain of "Health Related Quality of Life" given that they all assessed physical functioning (see table 1). Completion of this objective allowed us to proceed with objective 2.

### Objective 2: psychometric properties of instruments

Searching all databases yielded a total of 957 articles, from which 652 duplicates were removed (fig 2). After a review of the titles and abstracts of the remaining 305 articles, 212 articles were excluded because they did not meet the selection criteria. A full text review of the remaining 93 articles led to the exclusion of 36 articles because they did not meet the selection criteria. The review was based on the remaining 57 articles that reported psychometric properties for the 16 instruments identified in the initial AFO review.

articles reported psychometric properties of the Timed Up and Down Stairs. For all other instruments, up to 10 articles were found, with a range from 1 article for the Modified Ashworth Scale (MAS)<sup>135</sup> to 10 articles for the FIM.<sup>100-102,115,136-141</sup> Included articles consisted of 37 reviews (16 of which were systematic reviews<sup>100,103-105,110-112,115,116,119,125,126,142-144</sup>), 101,102,106-108,113,117,118,122,127,135,136,138-141,146-148,160 18 original reports,<sup>87,109,120,121,123,124,129-134,145,149,151-154</sup> and 2 panel recommendations.<sup>114,150</sup> Stroke was the focus of 29 articles,<sup>87,103,104,108,109,111,112,115,116,118-121,124,126-131,134,137,143-150,153</sup> 8 articles focused on MS,<sup>106,113,114,133,141,151,152,160</sup> 6 articles focused on SCI,<sup>100-102,132,136,145</sup> 3 articles focused on TBI,<sup>139,140,154</sup> 2 articles focused on injuries (general),<sup>122,138</sup> and 1 article each for Parkinson disease,<sup>107</sup> burns,<sup>123</sup> spasticity,<sup>135</sup> cerebral palsy,<sup>110</sup> and cervical spondylotic myelopathy.<sup>117</sup> Four articles focused on individuals with a combination of neurologic conditions.<sup>105,125,142,144</sup>

Table 5 categorizes the instruments as generic or condition-specific, by ICF and NQF domains, and reports the psychometric properties, including reliability, validity, sensitivity, and responsiveness. The majority of the instruments were generic (n=12), with the remaining instruments (n=4) specific to the stroke population. With respect to NQF person- and family-centered care domains, all 16 instruments were categorized as assessing the physical functioning component of health-related quality of life. When the instruments were categorized by ICF domain, most instruments (n=11) were categorized as assessing the activity domain, specifically related to assessment of mobility (d450 walking [n=7]; d498 other specified [n=2]) and self-care (d598 other specific [n=2]). The Stroke Impact Scale (SIS) was the only instrument that assessed some aspects of participation in addition to activity. The remaining instruments (n=5) evaluated body function (specifically: b429 functions of the cardiovascular system [n=2]; b710 mobility of joints [n=1]; b7350 tone of

**Table 4** Unique instruments and frequency of use to assess AFOs (shaded rows indicate instruments used by 4 or more studies that were included in this review, n = 16)

Instrument Used to Assess AFOs (n = 82)	Frequency of Use
10MWT <sup>20-46</sup>	27
6MWT <sup>21,22,31,34-36,39,41,46-58</sup>	21
BBS <sup>20,21,34,36,40,43,46,55,59-65</sup>	15
TUG <sup>21,27,29,34,37,40,45,46,62,66-70</sup>	14
Timed Up and Down Stairs, <sup>27,41,46,67</sup> timed up stairs, <sup>29,68,70,71</sup> timed down stairs	11
Functional Ambulation Categories <sup>26,27,36,38,40,46,63,72-74</sup>	10
modified Emory Functional Ambulation Profile <sup>21,22,50,59,75-78</sup>	8
Goniometer Ankle Passive Range of Motion <sup>26,79-84</sup>	7
Fugl-Meyer Assessment <sup>34,55,61,75,79,85</sup>	6
FIM <sup>26,61,75,81,86</sup>	5
Physiological Cost Index <sup>28,53,68,70,87</sup>	5
SIS <sup>21,34,38,58,59</sup>	5
5-Meter Walk Test <sup>24,72-74</sup>	4
Borg Rating of Perceived Exertion <sup>37,51,65,87</sup>	4
MAS <sup>26,33,79,81</sup>	4
RMI <sup>20,28,36,46</sup>	4
Barthel Index <sup>36,46,88</sup>	3
Device-related serious adverse event rate <sup>21,22,59</sup>	3
Footprints (used to assess temporospatial gait variables) <sup>70,72,74</sup>	3
Four Square Step Test <sup>66,71,89</sup>	3
Functional Reach Test <sup>34,68,70</sup>	3
SF-36 <sup>20,90,91</sup>	3
Stroke Specific Quality of Life <sup>21,75,78</sup>	3
Visual analog scale - pain <sup>38,89,92</sup>	3
25-Foot Walk Test <sup>54,77</sup>	2
EuroQOL-5D <sup>90,91</sup>	2
Motricity Index <sup>26,27</sup>	2
Perry Ambulation Category <sup>48,55</sup>	2
Sickness Impact Profile <sup>79,93</sup>	2
10 step/s test (timed) <sup>83</sup>	1
100-Meter Walk Test <sup>68</sup>	1
15-Meter Walk Test <sup>71</sup>	1
20-Meter Shuttle Run <sup>89</sup>	1
20-Meter Walk Test <sup>24</sup>	1
2-Minute Walk Test <sup>20</sup>	1
40-Yard Dash <sup>71</sup>	1
5-point rating scale for self-confidence <sup>27</sup>	1
5-point rating scale for stair difficulty <sup>27</sup>	1
Activities-Specific Balance Confidence Scale <sup>94</sup>	1
Achilles tendon reflex (physical exam) <sup>79</sup>	1
Ankle clonus (physical exam) <sup>79</sup>	1
Ashburn walking and stairs test <sup>62</sup>	1
Borg Category Rating Scale for confidence <sup>41</sup>	1
Boston City Hospital loaded ankle method for measuring ankle range of motion <sup>95</sup>	1
Clinical Spasticity Index <sup>61</sup>	1
Comfort (scored on a scale of 1-5) <sup>30</sup>	1
Single leg standing balance (eyes open) (timed) <sup>96</sup>	1

(continued on next column)

**Table 4** (continued)

Instrument Used to Assess AFOs (n = 82)	Frequency of Use
Equiscale Test <sup>24</sup>	1
Falls Efficacy Index – International <sup>50</sup>	1
Figure-of-8 Walking Speed <sup>28</sup>	1
Five Times Sit to Stand Test <sup>71</sup>	1
Foot and Ankle Outcome Score <sup>90</sup>	1
Goal Attainment Scaling <sup>65</sup>	1
L-Test <sup>97</sup>	1
Maximal Step Length Test <sup>69</sup>	1
Mini Balance Evaluation Systems Test <sup>45</sup>	1
Nottingham Extended Activities of Daily Living questionnaire (modified version) <sup>65</sup>	1
NASS Questionnaire <sup>20</sup>	1
Pedometer (assessed steps/d) <sup>42</sup>	1
Pedrio Test <sup>24</sup>	1
Physical Activity Scale for Individuals with Physical Disability <sup>58</sup>	1
Plantar flexor strength with Gillies Spring <sup>84</sup>	1
Postural Assessment Structural Scale <sup>26</sup>	1
Scandinavian Stroke Scale <sup>39</sup>	1
Self-selected speed over a 6m rock pit <sup>71</sup>	1
SF-12 <sup>90</sup>	1
Short Musculoskeletal Function Assessment <sup>89</sup>	1
Spasticity (physical exam) <sup>79</sup>	1
Stability (scored on a scale of 1-5) <sup>30</sup>	1
Stair Climb <sup>89</sup>	1
Star Excursion Balance Test <sup>98</sup>	1
Step Test <sup>66</sup>	1
Stroke Rehabilitation Assessment of Movement Measure <sup>62</sup>	1
Subject Perception of Functional Benefit Survey <sup>97</sup>	1
Timed Balance Test <sup>40</sup>	1
Visual analog scale (level of perceived comfort) <sup>99</sup>	1
Visual analog scale (limb pain) <sup>20</sup>	1
Visual analog scale (perceived exertion) <sup>41</sup>	1
Visual analog scale (perception of change in walking) <sup>38</sup>	1
Visual analog scale Foot and Ankle Questionnaire <sup>92</sup>	1
Veterans Rand 12 Health Survey (VR-12) <sup>89</sup>	1
World Health Organization Disability Impact Profile <sup>91</sup>	1

isolated muscles and muscle groups [n = 1]; b760 control of voluntary movement functions [n = 1]).

Overall, reliability and validity were reported more often than sensitivity and responsiveness. Although it was not surprising that stroke-specific instruments such as the modified Emory Functional Ambulation Profile and SIS were only evaluated for use in individuals with stroke, for several generic instruments such as the 5-meter walk test, MAS, and Functional Ambulation Categories, our review also found psychometric evaluation only in persons with stroke.

Among reviewed instruments, the 10-meter walk test (10MWT), 6MWT, BBS, TUG, FIM, and RMI had evidence of adequate

**Table 5** Categorization of instruments used in 4 or more studies to assess AFOs

Instrument	ICF		Psychometric Properties Reported in Literature			
	Domain	Code	Reliability	Validity	Sensitivity/ Responsiveness	Recommendation
<b>Performance-Based Instrument</b> 10MWT <sup>100-109</sup>	Activity	d450	Health Related Quality of Life: Physical functioning	Generic	NQF Person- and Family Centered Care Domain Specific	Generic/Condition-Specific
			<b>Stroke</b> • Good test-retest and interrater reliability <sup>103,105</sup> <b>MS</b> • Good test-retest and interrater reliability, <sup>105,106</sup> regardless of normal or fastest speed <sup>106</sup> <b>SCI</b> • Excellent intratester and interrater reliability (>0.9) <sup>101,102</sup>	<b>Stroke</b> • Excellent validity <sup>103</sup> • Good validity <sup>105</sup> <b>MS</b> • Good validity <sup>105</sup> <b>SCI</b> • Concurrent validity: negatively correlated with WISCI II ( $P = -0.68$ ) and 6MWT ( $P = -0.95$ ), positively correlated with TUG ( $P = 0.89$ ) <sup>102</sup> • Correlation coefficients of >0.97 <sup>101</sup>	<b>Stroke</b> • Excellent responsiveness but a poor ceiling effect <sup>103</sup> • Good sensitivity <sup>105</sup> • 10MWT performed within first week of stroke has moderate predictive values for identifying risk of falling within first year of stroke <sup>108</sup> <b>MS</b> • Good sensitivity <sup>105</sup> <b>SCI</b> • Good sensitivity <sup>105</sup> • Adequate responsiveness based on receiver operating curve analysis in mildly disabled and those with EDSS 0-6.5 <sup>106</sup> <b>SCI</b> • Adequate responsiveness <sup>100</sup> • Has a ceiling and floor effect <sup>101</sup> <b>TBI</b> • Good sensitivity <sup>105</sup> <b>PD</b> • Good sensitivity <sup>105</sup> • Gait speed accurately predicted fall risk <sup>107</sup>	<b>Stroke</b> • Met the criteria for clinical use (reasonable time to complete, cost, portability, no need for specialist equipment) <sup>105</sup> <b>MS</b> • Met the criteria for clinical use (reasonable time to complete, cost, portability, no need for specialist equipment) <sup>105</sup> <b>SCI</b> • Does not account for ambulation aids or assistance <sup>101</sup> <b>TBI</b> • Met the criteria for clinical use (reasonable time to complete, cost, portability, no need for specialist equipment) <sup>105</sup> <b>PD</b> • Easy to administer and useful for identifying changes in gait speed over time in mild to moderate PD; presence of freezing may affect outcome <sup>107</sup> • Instrument summary available on RMD: <a href="http://www.rehabmeasures.org/Lists/RehabMeasures/DispForm.aspx?ID=901">http://www.rehabmeasures.org/Lists/RehabMeasures/DispForm.aspx?ID=901</a>

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Table 5 (continued)

Instrument	ICF		Psychometric Properties Reported in Literature					
	Domain	Code	NQF Person- and Family Centered Care Domain	Generic/Condition-Specific	Reliability	Validity	Sensitivity/Responsiveness	Recommendation
6MWT <sup>59,100-107,110-114</sup>	Activity	d450	Health Related Quality of Life: Physical functioning	Generic	<p><b>Stroke</b></p> <ul style="list-style-type: none"> <li>Good test-retest reliability<sup>103,111,112</sup></li> <li>Excellent intratester reliability<sup>103</sup></li> </ul> <p><b>MS</b></p> <ul style="list-style-type: none"> <li>Excellent intratester and retest reliability with ICCs &gt;0.9<sup>113,114</sup></li> </ul>	<p><b>Stroke</b></p> <ul style="list-style-type: none"> <li>Excellent validity<sup>103</sup></li> <li>Good concurrent validity<sup>112</sup></li> <li>Moderate to strong correlations (<math>\geq 0.5</math>) with 6MWT distance, balance, motor function, walking speed, mobility, and stair capacity<sup>111</sup></li> </ul>	<p><b>Stroke</b></p> <ul style="list-style-type: none"> <li>MDC = 0.15m/s usual pace and 0.25m/s at fast pace<sup>105</sup></li> <li>MCID = 50 m<sup>103</sup></li> <li>Highly responsive to change<sup>104</sup></li> <li>Good sensitivity<sup>105</sup></li> </ul> <p><b>MS</b></p> <ul style="list-style-type: none"> <li>Discriminated between MS and healthy controls, as well as those with different levels of MS disability<sup>106,113</sup></li> <li>Walking shorter distances = significant predictor of perceived difficulties in performing ADLs<sup>106,113</sup></li> </ul>	<p><b>Stroke</b></p> <ul style="list-style-type: none"> <li>Adequate burden to administer<sup>103</sup></li> <li>Meets criteria for clinical use (reasonable time to complete, cost, portability, no need for specialist equipment)<sup>105</sup></li> </ul> <p><b>MS</b></p> <ul style="list-style-type: none"> <li>Recommended for research only<sup>59</sup></li> </ul> <p><b>TBI and PD</b></p> <ul style="list-style-type: none"> <li>Meets the criteria for clinical use (reasonable time to complete, cost, and portability, and no need for specialist equipment)<sup>105</sup></li> <li>Instrument summary available on RMD: <a href="http://www.rehabmeasures.org/">http://www.rehabmeasures.org/</a></li> </ul>

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Table 5 (continued)

Instrument	ICF		Psychometric Properties Reported in Literature					
	Domain	Code	NQF Person- and Family Centered Care Domain	Generic/Condition-Specific	Reliability	Validity	Sensitivity/Responsiveness	Recommendation
BBS <sup>102-105,108,115-118</sup>	Activity	d498	Health Related Quality of Life: Physical functioning	Generic	<p>both acute and sub-acute patients with ICCs &gt;0.9<sup>101,102</sup></p> <p><b>TBI</b></p> <ul style="list-style-type: none"> <li>• Good test-retest and interrater reliability<sup>105</sup></li> </ul>	<p>be a good predictor of ability to walk independently outside<sup>107</sup></p> <ul style="list-style-type: none"> <li>• Concurrent validity with 6MWT, TUG, 10-minute walking test, and WISCI II<sup>102</sup></li> <li>• Correlated well with <b>SCI</b> other self-paced gait speed tests such as 10MWT and TUG (&gt;.88), independent of ability to walk<sup>101</sup></li> <li>• Good validity with speed, moderate validity with motor control<sup>105</sup></li> </ul>	<p>MDC is 92.16 m for subjects with EDSS 0 –6.5<sup>114</sup></p> <ul style="list-style-type: none"> <li>• Limited responsiveness to change across a range of ambulatory patients<sup>113</sup></li> <li>• Responsiveness demonstrated and an MDC of 82 m<sup>107</sup></li> <li>• Sensitivity affected by floor and ceiling effect<sup>101</sup></li> </ul>	<p>Recommended by ANPT Taskforce as a core outcome measure in their Clinical Practice Guidelines for adults with neurological conditions: <a href="http://www.neuropt.org/professional-resources/anpt-clinical-practice-guidelines/core-outcome-measures-cpg-core-measures">http://www.neuropt.org/professional-resources/anpt-clinical-practice-guidelines/core-outcome-measures-cpg-core-measures</a></p>
					<p>Excellent test-retest reliability with ICCs of 0.98<sup>103,115</sup></p> <ul style="list-style-type: none"> <li>• Excellent intrarater reliability with ICCs of 0.97<sup>115</sup></li> <li>• Excellent interrater reliability with ICCs of 0.95-0.98<sup>115</sup></li> <li>• Excellent internal consistency (Cronbach alpha = 0.92 –0.98)<sup>115</sup></li> </ul>	<p>Excellent validity<sup>103</sup></p> <ul style="list-style-type: none"> <li>• Excellent correlations with Barthel Index, Postural Assessment Scale for Stroke Patients, Functional Reach Test, balance subscales of FM, FIM, and RMI (except for weight shift and step-up items), and gait speed<sup>115</sup></li> </ul>	<p>Moderate to excellent responsiveness<sup>103,115</sup></p> <ul style="list-style-type: none"> <li>• Responsiveness varies depending on time post stroke<sup>104</sup></li> <li>• BBS score &lt;49 is predictive of falling while an inpatient<sup>108</sup></li> <li>• MDC of 6 out of 56 points<sup>105</sup></li> </ul>	<p><b>Stroke</b></p> <ul style="list-style-type: none"> <li>• Burden taking about 10-15 min to administer<sup>103</sup></li> <li>• Instrument summary available on RMD: <a href="http://www.rehabmeasures.org/Lists/RehabMeasures/PrintView.aspx?ID=888">http://www.rehabmeasures.org/Lists/RehabMeasures/PrintView.aspx?ID=888</a></li> <li>• Recommended by StrokeEdge (MDC reported as 6 points), MS Edge reported as 6 points) and SCIEdge</li> <li>• Recommended by ANPT Taskforce as a core</li> </ul> <p>(continued on next page)</p>

Table 5 (continued)

Instrument	Domain	ICF	NQF Person- and Family Centered Care Domain	Generic/Condition-Specific	Psychometric Properties Reported in Literature				
					Reliability	Validity	Sensitivity/Responsiveness		
TUG <sup>100,102,105,107,108,114,116,118,119</sup>	Activity	d450	Health Related Quality of Life: Physical functioning	Generic	<p><b>SCI</b></p> <ul style="list-style-type: none"> <li>Interrater reliability between 0.84–0.98 for single items, with ICCs of 0.95 for total score<sup>102</sup></li> </ul> <p><b>SCI</b></p> <ul style="list-style-type: none"> <li>Correlates well with FES-I and AIS motor scores (<math>r(s) = -0.93-0.93</math>; <math>P &lt; .001</math>), WISCI II, SCI-FAI, 10MWT, and TUG (<math>0.714 &lt; R_s, 0.816</math>; <math>P &lt; .01</math>); however, there is no correlation with number of falls (<math>r(s) = -.17</math>; <math>P = .28</math>)<sup>102</sup></li> </ul>	<p><b>Stroke</b></p> <ul style="list-style-type: none"> <li>Content validity with respect to speed of walking and turning<sup>116</sup></li> <li>Correlated well with plantar flexor strength of affected ankle (<math>P &lt; .01</math>), correlated positively with stair ascending (<math>r = 0.86</math>) and descending (<math>r = 0.9</math>), and correlated negatively with the Dynamic Gait Index (<math>r = -0.77</math>), fast and comfortable gait speed, and 6MWT<sup>119</sup></li> </ul> <p><b>SCI</b></p> <ul style="list-style-type: none"> <li>Adequate convergent construct validity and floor and ceiling effects<sup>100</sup></li> </ul>	<p><b>Stroke</b></p> <ul style="list-style-type: none"> <li>Low to moderate responsiveness<sup>116</sup></li> <li>Responsive to moderate and fast walking<sup>119</sup></li> <li>Score differs between fallers and non-fallers with a cutoff score of <math>&gt; 14s</math><sup>119</sup></li> <li>Predicts risk of falls during first week after stroke with a cutoff point of <math>&gt; 15s</math>, cannot predict falls in chronic phase<sup>119</sup></li> <li>Predicts ability to go outside alone safely<sup>118</sup></li> <li>Ceiling effect<sup>116,119</sup></li> </ul> <p><b>TBI</b></p> <ul style="list-style-type: none"> <li>Significant differences between pre- and post-physical and surgical</li> </ul>	<p><b>Stroke</b></p> <ul style="list-style-type: none"> <li>Met criteria for clinical use (reasonable time to complete, cost, portability, no need for specialist equipment)<sup>105</sup></li> <li>Does not account for use of a walking aid in scoring or interpretation of change in score<sup>116</sup></li> </ul> <p><b>MS</b></p> <ul style="list-style-type: none"> <li>Excellent intrarater and interrater reliability with ICCs <math>&gt; 0.95</math> in ambulatory people<sup>116,119</sup></li> <li>Excellent test-retest reliability with ICCs of 0.91 and 0.97 and MDC of 12.6 seconds<sup>114</sup></li> </ul> <p><b>SCI</b></p> <ul style="list-style-type: none"> <li>Excellent intrarater (<math>r = 0.979</math>) and interrater (<math>r = 0.973</math>) reliability<sup>102</sup></li> </ul> <p><b>PD</b></p> <ul style="list-style-type: none"> <li>Adequate test-retest and interrater reliability, with ICCs from 0.80 to 0.99<sup>107</sup></li> </ul>	<p>outcome measure in their Clinical Practice Guidelines for adults with neurological conditions: <a href="http://www.neuropt.org/professional-resources/ant-clinical-practice-guidelines/core-outcome-measures-cpg/core-measures">http://www.neuropt.org/professional-resources/ant-clinical-practice-guidelines/core-outcome-measures-cpg/core-measures</a></p>
				Condition-Specific	<p><b>Stroke</b></p> <ul style="list-style-type: none"> <li>Met criteria for clinical use (reasonable time to complete, cost, portability, no need for specialist equipment)<sup>105</sup></li> </ul>				

(continued on next page)



Table 5 (continued)

Instrument	ICF		NQF Person- and Generic/		Psychometric Properties Reported in Literature			
	Domain	Code	Family Centered Care Domain	Condition-Specific	Reliability	Validity	Sensitivity/Responsiveness	Recommendation
Goniometer Ankle PROM <sup>122-124</sup>	Body Function	b710	Health Related Quality of Life: Physical functioning	Generic	<b>Stroke</b> • Moderate to good intratester and interrater reliability for ankle dorsiflexion PROM using the goniometer for 2 raters <sup>124</sup>	• Convergent validity with 10MWT and RMI <sup>121</sup>	<b>Stroke</b> • SEM and MDC95 for each ankle dorsiflexion PROM measurement between 0.8 and 2.0 degrees, and 2.2 and 5.6 degrees, respectively <sup>124</sup>	
				<b>Ankle injuries</b> • Satisfactory reliability, especially for ankle dorsiflexion; but, measures are tester dependent given issues of goniometer alignment and variations in location and magnitude of forces applied to the foot <sup>122</sup>			<b>Burns</b> • MDC using goniometry at the ankle $\geq 5$ degrees and for all other joints was $\geq 9$ degrees <sup>123</sup>	
FMA <sup>115,125-129</sup>	Body Function	b760	Health Related Quality of Life: Physical functioning	Specific	<b>Stroke</b> • Excellent test-retest and interrater reliability <sup>126-129</sup> <b>Neurological conditions</b> • Weak to excellent interrater reliability individual items <sup>125</sup>	• Very good face and content validity for motor domain; however, scaling is weighted heavily for the upper extremity (66 points) compared with lower extremity (34 points) <sup>127</sup> • Moderate concurrent validity with BI and FIM <sup>126-128</sup>	• Responsiveness inferred based on FM reliability in stable patients and on wide range of impairments captured by 100-point motor domain (from complete paralysis to recovery or very mild motor impairment) <sup>133</sup> • Sensitive to change after intervention <sup>134</sup>	• Instrument summary available on RMD: <a href="http://www.rehabmeasures.org/Lists/RehabMeasures/DispForm.aspx?ID=908">http://www.rehabmeasures.org/Lists/RehabMeasures/DispForm.aspx?ID=908</a> • Recommended by StrokeEdge (MDC reported as 5 points for Lower Extremity Motor Score)

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Table 5 (continued)

Instrument	ICF	NQF Person- and Family Centered Care Domain	Generic/Condition-Specific	Reliability	Psychometric Properties Reported in Literature					
					Validity	Sensitivity/Responsiveness	Recommendation			
PCI <sup>87,130-133</sup>	Body Function	Health Related Quality of Life: Physical functioning	Generic	<p><b>Stroke</b></p> <ul style="list-style-type: none"> <li>Extensive variability between test and retest in persons 6 months or more post-stroke<sup>87</sup></li> <li>Limited reliability compared to direct measurement of V02 (ml/kg/m)<sup>87</sup></li> </ul>	<p><b>Neurological conditions</b></p> <ul style="list-style-type: none"> <li>Weak to moderate validity with respect to BI<sup>125</sup></li> <li>Weak to moderate ability to detect change<sup>119</sup></li> </ul>	<p><b>Stroke</b></p> <ul style="list-style-type: none"> <li>Limited validity compared to direct measurement of V02 (ml/kg/m)<sup>87</sup></li> <li>Good to excellent correlation between PCI and ECW in sub-acute patients on different days (Pearson correlation = 0.919; <math>P &lt; .001</math>)<sup>130</sup></li> <li>Good to excellent correlation with oxygen cost (<math>r = 0.83</math>, <math>P &lt; .001</math>)<sup>131</sup></li> <li>ICCs of both O2 cost and PCI were high (0.94 and 0.92, respectively)<sup>132</sup></li> </ul>	<p><b>MS</b></p> <ul style="list-style-type: none"> <li>Significant correlation between PCI and EDSS with increased PCI correlated to a more severe stage of the disease<sup>133</sup></li> </ul>	<p><b>Stroke</b></p> <ul style="list-style-type: none"> <li>Good concurrent validity at comfortable walking speed<sup>112</sup></li> </ul>	<p><b>Stroke</b></p> <ul style="list-style-type: none"> <li>Good concurrent validity at comfortable walking speed<sup>112</sup></li> <li>Variable responsiveness<sup>104</sup></li> <li>MDC90 was 24.4 m<sup>111</sup></li> </ul>	<p><b>Stroke</b></p> <ul style="list-style-type: none"> <li>Recommended as an interpretable measure of outcome with relevance to community living<sup>109</sup></li> </ul>
				<p><b>Stroke</b></p> <ul style="list-style-type: none"> <li>Limited precision compared to direct measurement of V02 (ml/kg/m)<sup>87</sup></li> <li>Measurement of energy cost was a feasible for mild to moderate MS<sup>133</sup></li> <li>Not recommended by MSEdge</li> </ul>	<p><b>MS</b></p> <ul style="list-style-type: none"> <li>Sufficiently sensitive to detect differences in O2 uptake between testing sessions within subjects (<math>r = 0.86</math>) but responsiveness was lower compared to O2 cost and crutch peak force<sup>132</sup></li> </ul>	<p><b>Stroke</b></p> <ul style="list-style-type: none"> <li>Recommended as an interpretable measure of outcome with relevance to community living<sup>109</sup></li> </ul>				
5MWT <sup>104,109,111,112,134</sup>	Activity	Health Related Quality of Life: Physical functioning	Generic	<p><b>Stroke</b></p> <ul style="list-style-type: none"> <li>Good reliability at comfortable walking speed<sup>112</sup></li> </ul>	<p><b>Stroke</b></p> <ul style="list-style-type: none"> <li>Variable responsiveness<sup>104</sup></li> <li>MDC90 was 24.4 m<sup>111</sup></li> </ul>	<p><b>Stroke</b></p> <ul style="list-style-type: none"> <li>Recommended as an interpretable measure of outcome with relevance to community living<sup>109</sup></li> </ul>	<p><b>Stroke</b></p> <ul style="list-style-type: none"> <li>Recommended as an interpretable measure of outcome with relevance to community living<sup>109</sup></li> </ul>	<p><b>Stroke</b></p> <ul style="list-style-type: none"> <li>Recommended as an interpretable measure of outcome with relevance to community living<sup>109</sup></li> </ul>	<p><b>Stroke</b></p> <ul style="list-style-type: none"> <li>Recommended as an interpretable measure of outcome with relevance to community living<sup>109</sup></li> </ul>	

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Table 5 (continued)

Instrument	ICF		Psychometric Properties Reported in Literature				
	Domain	Code	NQF Person- and Family Centered Care Domain	Generic/Condition-Specific	Reliability	Sensitivity/Responsiveness	Recommendation
TUDS	Activity	d450	Health Related Quality of Life: Physical functioning	Generic		<ul style="list-style-type: none"> <li>Comfortable gait speed correlated with physical activity (<math>\rho=0.50</math>; <math>P=.043</math>) and participation (<math>\rho=0.48</math>; <math>P=.049</math>)<sup>109</sup></li> </ul>	<ul style="list-style-type: none"> <li>Recommended at comfortable pace to detect longitudinal change in walking disability in the first 5 weeks poststroke<sup>134</sup></li> </ul>
<b>Clinician-Reported Instrument</b> MAS <sup>135</sup>	Body Structure/Function	b7350	Health Related Quality of Life: Physical functioning	Generic	<p><b>Stroke</b></p> <ul style="list-style-type: none"> <li>Uncertainty surrounding the interrater reliability. MAS has lower reliability to classify movement of lower limb when compared to original Ashworth Scale. More reliable at classifying resistance to upper limb passive movement than lower limb<sup>135</sup></li> </ul> <p><b>Stroke</b></p> <ul style="list-style-type: none"> <li>Construct validity not strong since resistance to passive movement is not an exclusive measure of spasticity<sup>135</sup></li> <li>Moderate correlation with the Wartenberg's Pendulum Test<sup>135</sup></li> </ul>	<ul style="list-style-type: none"> <li>Instrument available on RMD: <a href="http://www.rehabmeasures.org/Lists/RehabMeasures/PrintView.aspx?ID=902">http://www.rehabmeasures.org/Lists/RehabMeasures/PrintView.aspx?ID=902</a></li> <li>Recommended by StrokeEdge and TBIEdge but not MSEdge and SCIEdge</li> </ul>	
FAC <sup>103,105,112,118</sup>	Activity	d498	Health Related Quality of Life: Physical functioning	Generic	<p><b>Stroke</b></p> <ul style="list-style-type: none"> <li>Good to excellent test-retest reliability<sup>103,112</sup></li> <li>Excellent interrater reliability<sup>103</sup></li> </ul> <p><b>Stroke</b></p> <ul style="list-style-type: none"> <li>Good to excellent construct validity<sup>103,105,112,118</sup></li> </ul>	<p><b>Stroke</b></p> <ul style="list-style-type: none"> <li>Moderate responsiveness<sup>103</sup></li> <li>Sensitivity of between 67% and 100% and a specificity of between 16% and 100%<sup>112</sup></li> </ul>	<p><b>Stroke</b></p> <ul style="list-style-type: none"> <li>Adequate burden, given it only takes a minute to administer<sup>103</sup></li> <li><b>MS, TBI and PD</b></li> <li>Met criteria for clinical use (reasonable time to complete, cost, portability, no need for specialist equipment)<sup>105</sup></li> </ul>

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Table 5 (continued)

Instrument	ICF	NQF Person- and Family Centered Care Domain	Generic/Condition-Specific	Psychometric Properties Reported in Literature			
				Reliability	Validity	Sensitivity/Responsiveness	
FIM <sup>100-102,115,136-141</sup>	Activity	d598	Health Related Quality of Life: Physical functioning	Generic	<p><b>Stroke</b></p> <ul style="list-style-type: none"> <li>Acceptable internal consistency<sup>137</sup></li> </ul> <p><b>MS</b></p> <ul style="list-style-type: none"> <li>Very high internal consistency of items, suggesting some items are redundant<sup>141</sup></li> </ul> <p><b>SCI</b></p> <ul style="list-style-type: none"> <li>Adequate reliability and internal consistency<sup>100</sup></li> <li>Moderate interrater reliability<sup>102</sup></li> </ul> <p><b>TBI</b></p> <ul style="list-style-type: none"> <li>Good interrater reliability and validity<sup>139,140</sup></li> <li>Moderate reliability<sup>138</sup></li> </ul> <p><b>Injury</b></p> <ul style="list-style-type: none"> <li>Moderate reliability<sup>138</sup></li> </ul>	<p><b>Stroke</b></p> <ul style="list-style-type: none"> <li>High concurrent validity with BI<sup>137</sup></li> <li>Excellent correlation with admission BBS and FIM scores; adequate to excellent correlations with BBS and FIM scores for mixed group with stroke, TBI and other impairments<sup>115</sup></li> </ul> <p><b>SCI</b></p> <ul style="list-style-type: none"> <li>Adequate construct validity<sup>100</sup></li> <li>Correlated well with the WISCI (<math>r = .88-.92</math>), BBS (<math>r = .9-.92</math>) and LEMS (<math>.85-.89</math>)<sup>101</sup></li> <li>Strong correlation between FIM and ASIA scores<sup>136</sup></li> <li>Not well validated in the SCI population<sup>102</sup></li> </ul> <p><b>TBI</b></p> <ul style="list-style-type: none"> <li>High precision<sup>140</sup></li> <li>Good validity<sup>139,140</sup></li> </ul> <p><b>Injury</b></p> <ul style="list-style-type: none"> <li>Good validity<sup>138</sup></li> </ul>	<p><b>MS</b></p> <ul style="list-style-type: none"> <li>Scores are skewed to the less disabled end of the scale, with a smaller cluster at the severely disabled end, suggesting both ceiling and floor effects<sup>141</sup></li> <li>Responsiveness of FIM sum score and many mobility items is also high<sup>141</sup></li> <li>High internal consistency and adequate discrimination<sup>136</sup></li> <li>High precision<sup>140</sup></li> <li>Ceiling effect and poor sensitivity to change in those with better walking abilities<sup>100,101</sup></li> <li>High precision<sup>140</sup></li> <li>Ceiling effect limits the usefulness in assessing change after discharge from rehabilitation<sup>139,140</sup></li> </ul> <p><b>SCI</b></p> <ul style="list-style-type: none"> <li>Limited clinical value in ASIA C and D<sup>136</sup></li> <li>Recommended as a functional outcome tool for assessment and care of acute SCI<sup>105</sup></li> <li>Instrument summary available on RMD: <a href="http://www.rehabmeasures.org/Lists/RehabMeasures/DispForm.aspx?ID=920">http://www.rehabmeasures.org/Lists/RehabMeasures/DispForm.aspx?ID=920</a></li> <li>Recommended by StrokeEdge <i>but not</i> TBIEdge</li> </ul>

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Table 5 (continued)

Instrument	Psychometric Properties Reported in Literature							
	ICF Domain	ICF Code	NOF Person- and Family Centered Care Domain	Generic/Condition-Specific	Psychometric Properties			
<b>Patient-Reported Instrument</b> RMI <sup>103-105,108,115,142-145</sup>	Activity	d450	Health Related Quality of Life: Physical functioning	Specific	<b>Reliability</b> • Excellent test-retest and interrater reliability <sup>103</sup>	<b>Validity</b> • Construct validity <sup>103</sup> • Excellent correlation with the Brunel Balance Assessment <sup>144</sup> • Poor to good validity with Standing Forward Reach Test, Standing Arm Raise Test, Sitting Arm Raise Test and Tap Test <sup>144</sup>	<b>Sensitivity/Responsiveness</b> • Good sensitivity to change <sup>138</sup>	<b>Recommendation</b>
					<b>Stroke</b> • Excellent correlation with the Brunel Balance Assessment <sup>144</sup> • Poor to good validity with Standing Forward Reach Test, Standing Arm Raise Test, Sitting Arm Raise Test and Tap Test <sup>144</sup>	<b>Stroke</b> • Highly responsive <sup>103,104</sup> • Adequate floor and ceiling effects <sup>103</sup> • May not address function at a very high level and therefore could have a ceiling effect <sup>142</sup>	<b>Stroke</b> • Met criteria for clinical use (reasonable time to complete, cost, portability, no need for specialist equipment) <sup>144</sup> • Quick test to apply (approx. 4 min), practical for use in acute setting <sup>143</sup>	
SIS <sup>146-150</sup>	Activity/Participation	d598	Health Related Quality of Life: Physical functioning	Specific	<b>Reliability</b> • Good reliability <sup>147,150</sup> • Adequate internal consistency <sup>146,148</sup>	<b>Validity</b> • Construct criteria met for domains of strength, hand function, mobility, ADL, and emotion <sup>148</sup> • Adequate construct validity of telephone, mail-administration <sup>146</sup>	<b>Sensitivity/Responsiveness</b> • No significant ceiling or floor affects and has better score discrimination among different severities of stroke than FIM and SF-36V <sup>149</sup> • Domains of strength, hand function, ADL, mobility, and	<b>Recommendation</b> • Recommended by MSEdge but not TBIEdge
					<b>Stroke</b> • Construct criteria met for domains of strength, hand function, mobility, ADL, and emotion <sup>148</sup> • Adequate construct validity of telephone, mail-administration <sup>146</sup>	<b>Stroke</b> • Represents assessment across the activity and participation domains of ICF <sup>148,150</sup> • SIS website includes a database that enables medical personnel to enter data and generate a summary report for every patient <sup>147</sup>	<b>Stroke</b> • Met criteria for clinical use (reasonable time to complete, cost, portability, no need for specialist equipment) <sup>144</sup> • Instrument summary available on RMD: <a href="http://www.rehabmeasures.org/Lists/RehabMeasures/DispForm.aspx?ID=926">http://www.rehabmeasures.org/Lists/RehabMeasures/DispForm.aspx?ID=926</a> • Recommended by MSEdge but not TBIEdge	

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Table 5 (continued)

Instrument	ICF	NQF Person- and Family Centered Care Domain		Psychometric Properties Reported in Literature			
		Code	Generic/Condition-Specific	Reliability	Validity	Sensitivity/Responsiveness	Recommendation
BRPE <sup>151-154</sup>	Body Function	b429	Health Related Quality of Life: Physical functioning	<b>MS</b>	<ul style="list-style-type: none"> <li>No systematic biases in the BRPE, suggesting reliable and agreeable measurements within subjects<sup>151</sup></li> <li>BRPE was reliable over 1 week in mild to moderate MS during submaximal cycling exercise<sup>151</sup></li> <li>High inter-individual variability<sup>152</sup></li> </ul>	<ul style="list-style-type: none"> <li>Excellent validity with working load and V02<sup>151</sup></li> <li>Weak relationships with accelerometer step counts<sup>152</sup></li> </ul>	<ul style="list-style-type: none"> <li>Relatively new with insufficient data available from clinical trials<sup>147</sup></li> <li>Instrument summary available on RMD: <a href="http://www.rehabmeasures.org/Lists/RehabMeasures/DispForm.aspx?ID=934">http://www.rehabmeasures.org/Lists/RehabMeasures/DispForm.aspx?ID=934</a></li> <li>3 of the 4 subscales had low responsiveness<sup>150</sup></li> <li>Recommended by StrokeEdge</li> </ul>
			Generic	<b>MS</b>	<ul style="list-style-type: none"> <li>Adequate convergent validity between SIS domains and NIH Stroke Scale, modified Rankin scale, BI and SF-36 domains<sup>146</sup></li> <li>Better overall responsiveness compared to SS-QoL<sup>146</sup></li> <li>3 of the 4 subscales had low responsiveness<sup>150</sup></li> <li>Recommended by StrokeEdge</li> </ul>	<ul style="list-style-type: none"> <li>participation were able to discriminate across Rankin scores<sup>148,149</sup></li> <li>Better overall responsiveness compared to SS-QoL<sup>146</sup></li> <li>3 of the 4 subscales had low responsiveness<sup>150</sup></li> <li>Recommended by StrokeEdge</li> </ul>	<ul style="list-style-type: none"> <li>Relatively new with insufficient data available from clinical trials<sup>147</sup></li> <li>Instrument summary available on RMD: <a href="http://www.rehabmeasures.org/Lists/RehabMeasures/DispForm.aspx?ID=934">http://www.rehabmeasures.org/Lists/RehabMeasures/DispForm.aspx?ID=934</a></li> <li>Recommended by StrokeEdge</li> </ul>
					<ul style="list-style-type: none"> <li>Validity of individual comparisons of exertion during exercise depends on subjects interpreting the verbal anchors with the same meaning, hence reliability may be better for within</li> </ul>		

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**Table 6** Suitability of instruments for evaluating the quality of care of AFO users

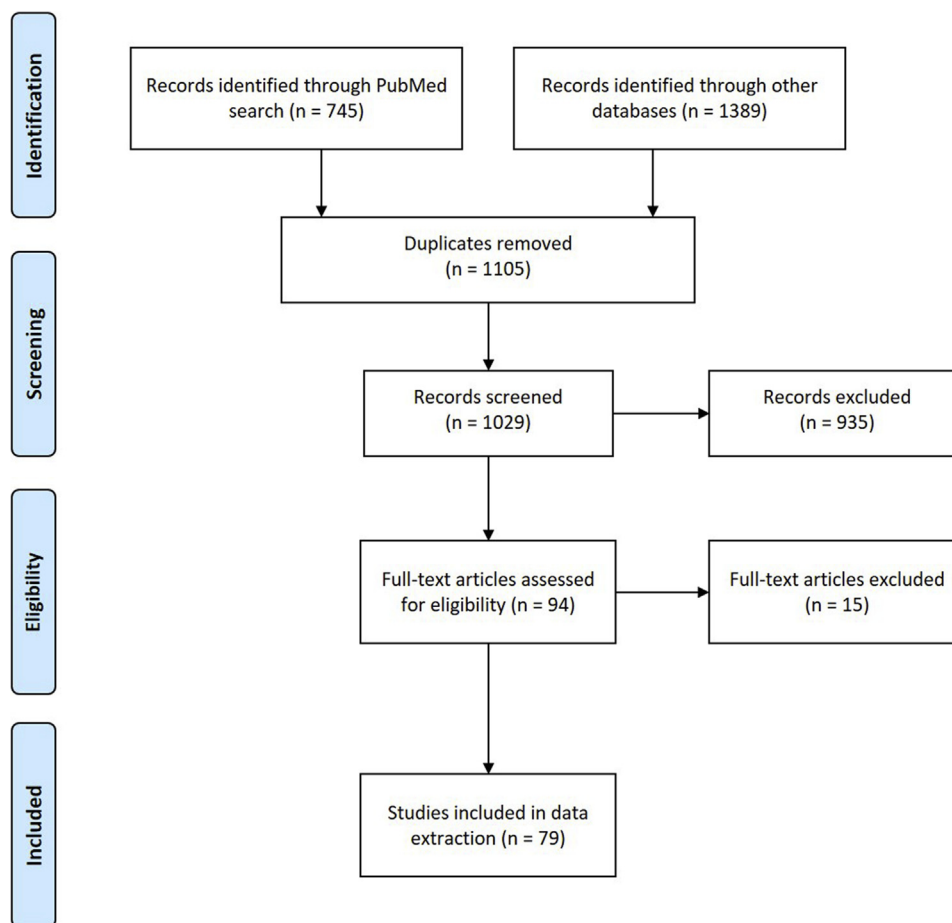
Instrument	Could Be Used to Assess Some Aspect of Quality of Care of AFO Users	Has Adequate Psychometric Properties	Is Feasible for Use in Orthotic Inpatient/ Outpatient Settings	More Contemporary Substitute Suggested	Instrument Overlaps With...	Comments
<b>Performance-based instruments</b>						
10MWT	Y	Y	Y			Can vary in administration
6MWT	Y	Y	Y	2-minute walk test <sup>155</sup>	10MWT	May take too long to administer, challenges cardiopulmonary function
BBS	Y	Y	Y			Ceiling effect in AFO users with stroke based on clinical experience
TUG	Y	Y	Y	Expanded TUG <sup>156</sup>		No psychometric data to support use in TBI patients
TUDS	Y	N	Y			No psychometric data found
mEFAP	Y	N	Y			Psychometric data available in stroke patients only
Ankle PROM	N	N	Y	SMFA <sup>157</sup> or FAAM <sup>158</sup>		
FMA	Y	N	Y			Psychometric data available in stroke patients only
PCI	Y	N	Y		BRPE	Can vary in administration
5MWT	Y	N	Y		10MWT	Psychometric data available in stroke patients only
<b>Clinician-reported instruments</b>						
FAC	Y	N	Y			Psychometric data available in stroke patients only
FIM	Y	Y	N			Training required to administer instrument
MAS	N	N	Y			Psychometric data available in stroke patients only
<b>Patient-reported instruments</b>						
RMI	Y	Y	Y	ABC Scale		
SIS	Y	N	N	EuroQOL-5D		Psychometric data available in stroke patients only
BRPE	Y	N	N		PCI	License fee required for use

Abbreviations: ABS, Activities-Specific Balance Confidence; FAAM, Foot and Ankle Mobility Measure; SMFA, Short Musculoskeletal Function Assessment.

Although no core set of instruments for assessment of lower-limb orthoses has yet been identified, measurement concepts considered relevant in the evaluation of lower-limb orthoses and instruments have been suggested.<sup>11</sup> Consistent with instruments identified in our review, Brehm et al<sup>11</sup> suggested goniometric assessment of joint motion, MAS, visual analog scale for assessing pain, SF-36 pain and physical functioning subscales, BBS, TUG, and 6MWT for assessing suggested ICF domains. Brehm et al<sup>11</sup> also suggested manual muscle strength testing, the ACTIVLIM questionnaire,<sup>161</sup> 2-minute walk test,<sup>155</sup> Nottingham Health Profile,<sup>162</sup> and Impact on Participation and Autonomy questionnaire,<sup>163</sup> which were not identified by our review. Furthermore, Brehm et al<sup>11</sup> suggested a number of tests requiring instrumentation such as gas-analysis systems to assess energy cost of walking, static and dynamic posturography, and 3-dimensional

gait analysis, which we excluded from our review as not being feasible for use in clinical settings. Our review findings were consistent with several measurement concepts identified by Brehm et al,<sup>11</sup> suggesting that many of the instruments identified across both studies are appropriate for assessing at least some aspects of the quality of AFO care.

When working with individual patients, it is important that a clinician consider and select outcome instruments that match the unique goals of care for that individual patient.<sup>12</sup> However, the intent of this work was to identify instruments that can be used to develop quality measures for use across patients, clinicians, and service providers. As such, the focus was on identifying instruments that are broadly suitable in the population of interest receiving AFO care. Risk adjustment would be needed to compare aggregate scores across patients and providers. Risk-adjusted data



**Fig 1** PRISMA flow chart<sup>159</sup> for review of AFO studies.

from the 5 instruments we identified (ie, the 10MWT, 6MWT, BBS, TUG, and RMI) may be useful to evaluate care quality for individuals who use AFOs in terms of assessing “the degree to which a desired health care outcome is achieved.”<sup>7(p121)</sup> However, these 5 instruments assess exclusively the activity domain of functioning and, although they are mostly generic and therefore relatively broadly applicable across individuals with various neurologic and traumatic conditions, they are predominantly performance-based and may be burdensome to implement in a busy clinical setting, especially if used concurrently in a single evaluation period. Patient-reported instruments may be used to supplement or replace performance-based instruments to provide an expeditious, comprehensive evaluation of care quality that is meaningful to individuals who use AFOs. However, additional work is needed to identify and validate patient-reported instruments that evaluate patient experiences with AFO care.

Identifying suitable instruments of patient experience with care is particularly important for assessing quality of AFO care considering the emphasis placed on patient satisfaction by accreditors of orthotic facilities and that it has been argued that satisfaction with care is related to quality of care and compliance with device use.<sup>164</sup> Instruments addressing patient perception of and satisfaction with care were identified by the scoping review among the lesser used instruments (eg, EuroQOL-5D, SF-36, 12-Item Short Form Health Survey, Subject Perception of Functional

Benefit Survey, Veterans Rand 12 Health Survey, and World Health Organization Disability Impact Profile) and were not among the recommended instruments. Bettoni et al<sup>164</sup> published a review specific to questionnaires that assess patient satisfaction with orthoses and reported that, among instruments that measure satisfaction with lower-limb orthoses, the Quebec User Evaluation of Satisfaction with assistive Technology (QUEST 2.0)<sup>165</sup> and Orthotic and Prosthetic Users’ Survey Client Satisfaction with Device (OPUS CSD)<sup>166</sup> have undergone the most robust development. However, the OPUS CSD appears to capture more orthosis-related features than the QUEST 2.0. The orthosis-related features most frequently assessed by satisfaction instruments were aesthetics, ease in donning and doffing, duration of orthosis use, and comfort, whereas the orthosis-related features least frequently assessed were dimensions, orthosis cleaning, limb appearance, and cost.<sup>164</sup> Although we did not identify these instruments in our scoping review, the review by Bettoni et al<sup>164</sup> suggested that they assess orthotic features that could be used to evaluate the quality of AFO care. Therefore, the QUEST 2.0, OPUS CSD, EuroQOL-5D, SF-36, 12-Item Short Form Health Survey, Subject Perception of Functional Benefit Survey, Veterans Rand 12 Health Survey, and World Health Organization Disability Impact Profile could be given additional consideration when augmenting the instruments we recommended based on our scoping review.

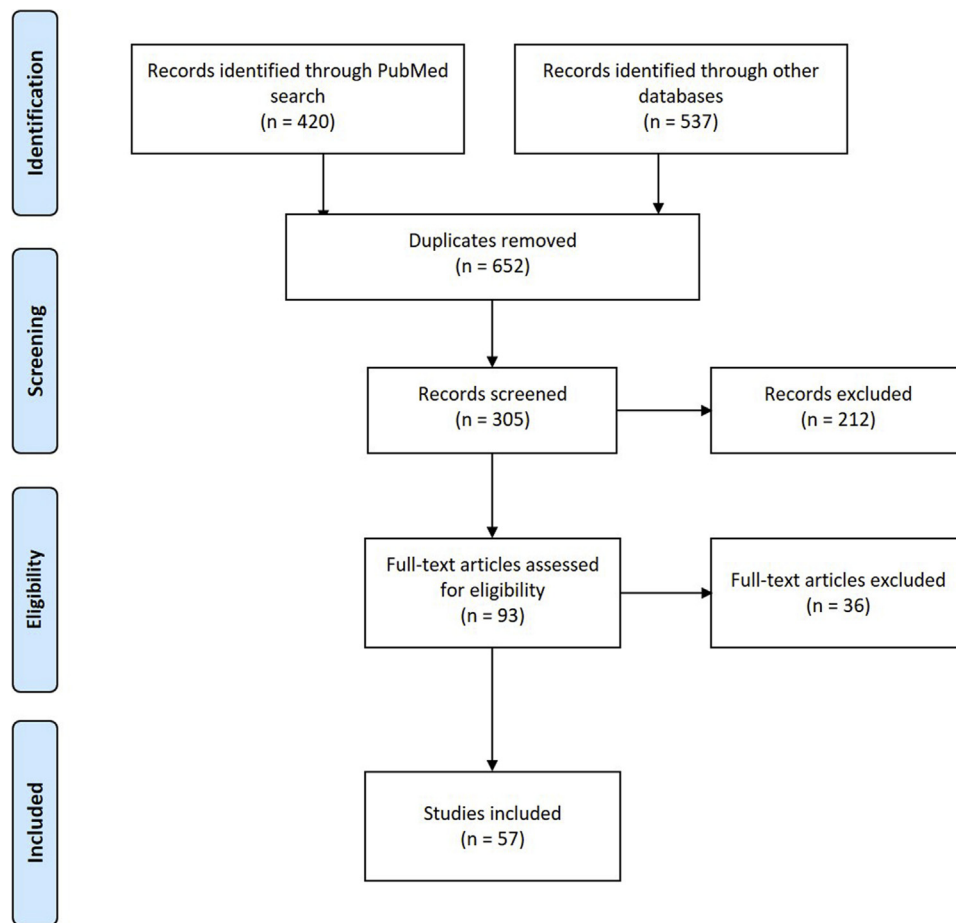


Fig 2 PRISMA flow chart<sup>159</sup> for review of psychometric properties of instruments.

## Study limitations

After completing the corresponding reviews, investigators and a stakeholder advisory committee addressed the overarching goal of evaluating the extent to which the psychometrically sound instruments might be suitable for use in developing quality measures for AFO users. We acknowledge that the criteria we used (ie, instrument is easy to access, does not require expensive or complex equipment or training to administer, requires a reasonably short time to administer, and is simple to score) are relative. Although some clinicians may consider an instrument such as the 6MWT feasible, others with limited space and time to administer instruments may not. Additionally, these reviews of AFO studies found more articles on individuals with neurologic conditions than traumatic conditions, an emphasis that may reflect the choice of search terms or may reflect that AFOs are more commonly provided by certified orthotists to persons with neurologic conditions than trauma and therefore are more commonly the focus of research studies. Generally, the types of neurologic conditions included in this review are consistent with those reported by others.<sup>164</sup> However, this review may not have adequately captured newer instruments, given that there is a lag in newer instruments appearing in the literature, especially with published psychometric data, with none or few studies having used them to assess AFO users. Inclusion of useful instruments may have been limited in that we retained instruments that were

used and reported in 4 or more articles, under the presumption that frequency of use is a reasonable indicator of broad usefulness and feasibility. Among the more contemporary instruments suggested for consideration by the advisory committee, the EuroQOL-5D was used in 2 studies<sup>90,91</sup> and the SMFA in 1 study.<sup>89</sup>

Hence, based on the findings of our review and information from previous reviews, the following instruments may be useful when developing quality measures for AFO care for persons with neurologic and traumatic conditions: 10MWT, 6MWT, BBS, TUG, RMI, QUEST 2.0, OPUS CSD, EuroQOL-5D, and SMFA. These instruments assess all the measurement concepts identified as important for lower-limb orthoses<sup>11</sup> and include instruments that assess both outcome and patient experiences or satisfaction with device. Additional evaluation of these instruments is required to assess how well they perform in clinical practice. Risk adjustment would be needed to compare aggregate scores across providers, which could lead to improved care for persons who use AFOs.

## Conclusions

Two complementary scoping reviews demonstrated that several instruments with reasonable psychometric properties are feasible to use in developing quality measures for custom AFO care.

Experience of care instruments suitable for this population were not identified but are needed for a comprehensive evaluation of care quality for AFO users.

## Keywords

Braces; Health care; Outcome assessment; Quality of health care; Rehabilitation

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