

# Patient and Clinician Perspectives on Quality-of-Care Topics for Users of Custom Ankle-Foot Orthoses

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**Objective:** As in all healthcare areas, there is a need to improve quality relevant to orthotic practice, but we lack information as to what aspects of healthcare quality are meaningful to measure. Thus, the objective was to identify issues that are important to the quality-of-care for people who use custom ankle-foot orthoses as identified by ankle-foot orthosis users, orthotists, and physical therapists.

**Design:** We conducted focus groups with custom ankle-foot orthosis users, orthotists, and physical therapists. A stenographer took verbatim notes and provided transcripts. Research staff members assessed the transcripts using thematic analysis.

**Results:** Participants included 5 ankle-foot orthosis users (1 focus group), 17 orthotists (2 focus groups), and 7 physical therapists (1 focus group). They discussed domains of quality-of-care relevant for people with ankle-foot orthoses. We identified 28 thematic codes addressing 10 broad themes of quality-of-care. Six of the broad themes (organizational characteristics, patient-clinician communication, care coordination, device fit and comfort, body function, activity, and participation) mapped to the National Quality Forum's person- and family-centered care concepts. Environment of care, clinician competencies, and device characteristics and usage were important to orthotic practice but do not map to any National Quality Forum concept. Participants did not mention the National Quality Forum concept of shared decision-making.

**Conclusions:** The quality themes provide information as to what aspects of healthcare quality are meaningful to measure with respect to orthotic care, thus providing guidance on how to measure and improve ankle-foot orthosis service delivery.

**Key Words:** Foot Orthosis, Quality of Healthcare, Focus Groups, Health Services, Qualitative Study

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The National Quality Forum (NQF) plays a major leadership role in quality measurement in the United States, including prioritizing quality measure efforts and endorsing quality measures.<sup>1</sup> The NQF offers a framework for person- and family-centered care that includes interpersonal relationships, patient and family engagement, care planning and delivery, access to

## What Is Known

- Measuring and improving patient care for individuals with an ankle-foot orthosis is important.

## What Is New

- Ankle-foot orthosis (AFO) users, orthotists, and physical therapists identified the following quality-of-care themes as relevant to users of custom AFOs: environment of care, organizational characteristics, clinician competencies, patient-clinician communication, care coordination, device characteristics, device usage, device fit and comfort, body function, and activity and participation. These quality themes provide guidance as to what aspects of healthcare quality should be measured to improve AFO service delivery.

support, and quality-of-life.<sup>2</sup> This framework reinforces the notion that assessments and treatment should address medical, behavioral, and social needs and should reflect care recipients' ability or willingness to participate actively in decision-making and informed choice. Furthermore, the framework promotes goal setting and attainment and care coordination.

Quality measurement research that focuses on patient- and family-centered care for rehabilitation populations is limited. Focus groups,<sup>3</sup> surveys,<sup>4</sup> and literature reviews<sup>5</sup> involving inpatient rehabilitation samples identified relevant themes, such as interactions with staff, timely communication of accurate information, rehabilitation environment, client and informal carer engagement, and pain and functional status, which map directly to the NQF framework. Other medical rehabilitation-relevant themes identified by these studies were availability of rehabilitation services 7 days per week, and the significance of group and individual identity. A practice improvement research study discovered that prosthetic care providers value increasing patient functioning, improving activity level, enhancing quality-of-life, and maximizing patient satisfaction with services and devices.<sup>6</sup> Similar practice improvement research has not been conducted with orthotic care providers.

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The American Board for Certification in Orthotics, Prosthetics and Pedorthics' facility accreditation guidelines<sup>7</sup> include performance management standards that address fabrication time, number of follow-up visits, number of times a device needs to be remade, timeliness of response to patient concerns or complaints, ease of facility access, billing and coding procedures, and patient satisfaction. Standards require that facilities have a 30% return rate on annual patient satisfaction surveys provide evidence that patient survey data are used to track trends in care and outcomes, and providers take follow-up actions. Facilities define for themselves the criteria for actionable information and use various methods to comply with the standards; the Board does not require or recommend a standardized set of data elements or instruments for data collection. Consequently, providers within the field have limited guidance on what quality concepts to measure, how to measure quality concepts, and how their care quality compares with peers locally and nationally.

Hence, it is clear that orthotic clinical care faces a critical barrier to improving patient experiences and outcomes stemming from a lack of consensus on quality measurement priorities and standardized data elements that would support developing national benchmarking data. Because custom ankle-foot orthosis (AFO) users represent one of the largest populations treated by orthotists,<sup>8</sup> it is prudent to explore these issues with a focus on quality-of-care for custom AFO users. Thus, the objective of this study was to identify issues that are important to the quality-of-care for people who use custom AFOs as identified by AFO users, orthotists, and physical therapists. We conducted focus groups to improve our understanding of (a) the relative frequency of issues that are important to the quality-of-care for custom AFO users, orthotists, and physical therapists, (b) clinical assessment instruments that might form the basis of quality measures, (c) preferred methods of data collection, and (d) recommendations for industry adoption of quality data collection. In turn, we examined the alignment of quality-of-care issues with NQF's Framework for Patient- and Family-Centered Care.<sup>9</sup>

## METHODS

### Design

We conducted cross-sectional, in-person focus groups (two with orthotists and one each with physical therapists and AFO users) to gain a thorough understanding of quality topics and concerns related to quality-of-care for custom AFO users.<sup>10,11</sup> We decided to organize focus groups because they are a participant-dominant method of learning how "real life" is experienced through the eyes of and in the words of the participants using facilitated discussion. Focus groups allow participants to build on one another's ideas and facilitate the provision of candid and thoughtful responses. Through interaction among participants, focus groups can provide a broader range of responses than data collected from participants independently.<sup>12</sup>

### Study Sample

After obtaining Northwestern University's institutional review board approval, we recruited a convenience sample of custom AFO users, orthotists, and physical therapists for participation in separate focus groups. Custom AFO users were community residents in the Chicago metropolitan area

identified by clinical and research contacts. Similarly, we recruited physical therapists from Chicago area clinics and hospitals through our professional contacts. Orthotists were members of the Midwest Chapter of the American Academy of Orthotists and Prosthetists whom we invited by e-mail to participate in advance of their annual meeting and included all who expressed interest.

Eligibility criteria for all participants included 18 yrs and older and ability to speak and understand English. Both clinician groups were required to have expertise in treating individuals with neurological conditions and familiarity with AFO use and care delivery. Custom AFO users were included to understand patients' firsthand experiences with AFOs and to offer a patient-centered view on ideal quality service and delivery. Custom AFO participants were required to have a neurological condition (eg, stroke, spinal cord injury, traumatic brain injury, multiple sclerosis, Parkinson disease) and a minimum of 5 yrs of experience wearing a custom AFO. We relied on self-report of custom AFO participants to determine eligibility.

### Data Collection

The project Advisory Committee, representing multiple stakeholders (see Acknowledgements), provided input on a focus group moderator guide developed initially by the investigators. This guide included a summary of the study's aims, a list of questions in a semistructured format to guide group discussion, and scripted prompts to encourage participants to elaborate their viewpoints.<sup>12</sup> Table 1 lists the questions that guided

**TABLE 1.** Focus group moderator questions

Defining high-quality AFO services	
What characterizes high-quality care for users of AFOs? That is, how do you know when you are receiving high-quality AFO services?	
Are there any facility characteristics that indicate high-quality services?	
Are there characteristics of how services are delivered that indicate high-quality services?	
Are there aspects of care coordination that characterize high-quality services?	
Are there characteristics of the custom AFO that indicate high-quality services?	
Items/instruments	
What kind of information is needed to measure high-quality AFO services?	
What would you need to know about the facility?	
What would you need to know about the orthotist?	
What would you need to know about the physical therapist?	
What would you need to know about the AFO?	
What would you need to know about patients' experience of care?	
Methods of data collection	
What is the most practical way to collect quality data?	
When would be the best time to collect quality data?	
How long would you be willing to spend reporting quality data?	
Industry adoption of quality measures (asked of clinician focus groups only)	
What about payers and policy makers? Do you have advice or concerns that you want to make sure they understand when moving toward quality measurement and reporting for AFO use?	
What do believe are the benefits of collecting and reporting quality data?	
What do you believe are the barriers to collecting quality data?	
What concerns do you have about using quality data?	

focus group discussions. Because we wanted a multiple perspective, thorough understanding of the custom AFO experience, ranging from what would constitute ideal quality service and delivery through to best ways to collect and measure it, we asked AFO users and clinician participants questions regarding the following three major topics: (a) features of high-quality AFO services, (b) clinical assessment instruments that measure patient experiences and outcomes and might be suitable for quality measures, and (c) practical and preferred clinical data collection methods. Questions related to the final topic, (d) Industry adoption of quality measures, were only discussed by the clinician focus groups.

Participants provided written informed consent for participation and audio recording and received a modest honorarium. Each focus group included five to eight participants and lasted 45–80 mins. To facilitate discussion, a moderator (the lead author) wrote key concepts and discussion points on large note pads, a stenographer took verbatim notes and provided a transcript of the discussion, and research staff members took field notes to supplement transcript reviews.

### Coding and Analysis

We used a thematic analysis approach to identify and organize focus group transcript data<sup>13</sup> using an inductive-deductive process.<sup>14–16</sup> Pairs of researchers independently read each transcript and identified text representing themes; then, the entire research team reviewed the words and coded phrases and drafted a codebook that organized and defined the themes. Pairs of researchers used the codebook to code exhaustively all transcripts using QDA MINER Lite (version 2.0.1, Provalis Research 2014–2016) and met to discuss disagreements and reach consensus. We created a summary of the themes and the frequency with each theme occurred. We counted a code the first time a given focus group member mentioned a theme, but not subsequent comments by that same individual during

which they elaborated on their response. We shared the codebook and frequency of codes with the Advisory Committee to obtain feedback.

This study conforms to all Strengthening the Reporting of Observational Studies in Epidemiology guidelines and reports the required information accordingly (see Supplemental Checklist, Supplemental Digital Content 1, <http://links.lww.com/PHM/A938>).

## RESULTS

### Sample Characteristics

Table 2 summarizes the characteristics of focus group participants for AFO users ( $n = 5$ ), orthotists ( $n = 17$ ), and physical therapists ( $n = 7$ ). The AFO users had 7–23 yrs of experience using one or more orthoses and reflected diverse racial and ethnic backgrounds. Their primary underlying medical conditions included traumatic brain injury ( $n = 2$ ), stroke ( $n = 2$ ), and cerebral palsy ( $n = 1$ ). Clinicians had considerable practice experience (a minimum of 3–42 yrs) with an average of 20 yrs for orthotists and 11 for physical therapists and were predominantly white (78%). Most orthotists were men (70%), whereas most physical therapists were women (71%).

### Defining High-Quality AFO Care Delivery

Thematic analysis identified 28 subthemes that addressed 10 broad themes of quality-of-care that are summarized in Table 3, along with definitions, recommended sources of information, and representative quotes that illustrate the themes. The broad themes were Environment of Care, Organizational Characteristics, Clinician Competencies, Patient-Clinician Communication, Care Coordination, Device Characteristics, Device Usage, Device Fit and Comfort, Body Function, and Activity and Participation.

The Environment of Care theme included subthemes of facility accessibility, layout, and ambiance. An orthotist provided an example that patients “...need to feel confident that

**TABLE 2.** Focus group participants' demographic characteristics

Demographic Characteristic	Orthotists (2 Groups) ( $n = 17$ )	Physical Therapists ( $n = 7$ )	AFO Users ( $n = 5$ )	Total ( $N = 29$ )
Age, average (range), yr	48 (29–64)	37 (29–56)	54 (26–71)	46 (26–71)
Clinical experience, average (range), yr	20 (3–42)	11 (3–33)		15 (3–42)
Experience with neurological patient care, average (range), yr	21 (3–35)	11 (3–33)		16 (3–35)
Custom AFO experience, average (range), yr			20 (7–23)	20 (7–23)
Sex				
Female	30%	71%	60%	54%
Male	70%	29%	40%	46%
Race				
White	94%	100%	40%	78%
African-American	0%	0%	60%	20%
Asian/Indian	0%	0%	0%	0%
Multiracial	0%	0%	0%	0%
Unknown	6%	0%	0%	2%
Hispanic				
Yes	0%	0%	0%	0%
No	94%	100%	100%	98%
Unknown	6%	0%	0%	2%

**TABLE 3.** Focus group themes, subthemes, definitions, sample quotes, and recommended sources for assessment (Related NQF Care Concepts indicated where applicable)

<b>Theme and Related NQF Care Concept (If Applicable)</b>	<b>Subtheme</b>	<b>Definition</b>	<b>Recommended Source for Assessment</b>	<b>Sample Quote</b>
Environment of Care	Accessibility of Facility	The facility is in a convenient location and accessible to patients.	Patient Report	If it is easy to drive to and get in the building, it is not a pain for them to come see you. (O)
	Facility Layout	There is adequate space and equipment that is organized in an efficient manner that enhances delivery of care.	Patient Report	They need to feel confident that you have the equipment to properly assess them and make good decisions. (O)
	Ambiance	The facility is clean, provides privacy, and is calm and inspiring.	Patient Report	It just made me think of like ambiance, pictures. (P)
Organizational Characteristics Interpersonal Relationships	Courtesy of Reception Staff	Reception staff members are courteous, polite, and empathic.	Patient Report	But that point person is critical to get that comfort level.... If you do not have that, you are in trouble right off the get go. It really can impact quality care significantly. (O)
	Ease of Scheduling	Patients are able to schedule appointments easily.	Patient Report/ Facility Records	.... I can get an appointment at 7:30 in the morning before I have to go to work, and I know that there are other orthotists who are available later in the evening, and so not having to take time off of work to schedule an appointment is really helpful. (U)
	Timeliness of Device Delivery	The facility delivers services in a streamlined and efficient manner.	Patient Report/ Facility Records	The timely production and fitting of the orthotic device... when there is a delay and it's not really explained to the patient why, it just undermines our recommendation if the patient actually needs it, and the importance of it. (P)
	Collects Meaningful/ Actionable Data	The facility collects data that are useful for care delivery and quality improvement.	Facility Records	Does the facility collect outcome measures and are they compiling them in a meaningful way? Their definition of quality is 'do I have a product there on time and did it break within 90 d.' (O)
	Clinician Competencies	Clinician Education/ Experience	Clinicians have the requisite education and experience to deliver high-quality services.	Facility Records
Comprehensive Evaluation		Clinicians conduct a comprehensive evaluation of patients' function, goals, and situations; also device fit/condition.	Facility Records	I'm starting my evaluation right there in the waiting room and see how he's walking and everything, so I can really determine right away what's going on with this patient. (O)
Clinician Certification/ Continuing Education		Clinicians maintain appropriate certification by completing continuing education.	Facility Records	I would say their continuing education or do they have a certification. And, you know, orthosis management ... advanced training. (P)
Patient-Clinician Communication Interpersonal Relationships Access to Support and Self-management	Clinician Follow-up With Patients	Clinicians schedule follow-up appointments and are available for patients' questions.	Patient Report/ Facility Records	I would say follow-up calls to just kind of check in either like every 3, 6, 12 mos the patients are actually like using the device. (P)
	Rapport	Clinicians establish rapport with patients.	Patient Report	You have to build that rapport between yourself and the family. (O)
	Setting Patient Goals	Clinicians develop goals and individualized treatment plans and communicate their expectations of patients and themselves.	Patient Report	In talking with the patient and getting their goals or expectations and then really trying to meet those expectations as best you can. (O)
	Patient Education	Clinicians provide instruction on how to use a device including donning, doffing, wearing schedule, care for the device, and maintenance procedures.	Patient Report	And I think we have to teach and I think probably we all do is teach, educate the patient on what to expect from the wearing of this device. (O)

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TABLE 3. (Continued)

Theme and Related NQF Care Concept (If Applicable)	Subtheme	Definition	Recommended Source for Assessment	Sample Quote
Care Coordination Care Planning and Delivery	Continuity of Care	The facility assures continuity of care by clinicians and coordinates care with other providers.	Patient Report/ Facility Records	So having that same therapist, and that same orthotist working with them who knows the whole patient case. (P)
	Documentation of Assessment and Services	Clinicians document assessments and services in a manner that allows other clinicians and facilities to coordinate care.	Facility Records	I think the best place for the data collection is in electronic medical records. If you develop it in such a way that you can extract it and compile it. (O)
Device Characteristics	Material Quality	The device is constructed of suitable materials that are durable and provide the intended benefits.	Patient Report	Quality of fabrication and end product. All the edges is everything correct on it, before it goes out the door. (O)
	Device Durability	The device is durable and maintains its integrity.	Patient Report	It is very durable. I mean, the one I'm wearing right now I've had for 7 yrs. So I think it's going to keep on going. (U)
	Device Adjustability	The patient is able to adjust the device as appropriate to meet his/her needs.	Patient Report	Kind of looking back at the adjustability of it, is it something that has been hinged or is it prearticulated, how have they been using it? (P)
	Device Modifiability	The device can be easily modified to enhance ideal fit and performance.	Patient Report	Probably the ease of the actual device to be remolded or recast just in case, you know, it did not fit the particular patient. (P)
	Device Weight	The device weight is acceptable to the patient.	Patient Report	Maybe there is lighter material. The one that I got probably 20 some years ago, it was quite heavy, and it would tire me out. See I live on the street, my grandmother is across the street, and I would walk over there 3 or 4 times, the second time that walk got longer and longer. (U)
Device Usage	Cosmesis	The patient evaluates the device's appearance favorably.	Patient Report	They are not willing to wear it if they think it is ugly. It can be something that they would actually wear or wouldn't wear. (O) Mine is just pretty now. I had a black one, and now I have butterflies, and I get compliments on it all of the time. It's like, okay, who knew that my AFO could actually be pretty. (U)
	Social Confidence Wearing Device	The patient feels comfortable wearing the device in social settings.	Patient Report	There is also a stigma with using bracing that people have to get over. (O)
	Ease of Donning and Doffing	The patient is able to don and doff the device easily.	Patient Report	If you are sitting there and you could slide that shoe on and off they go and they go home and they can't figure out how to put it on or you haven't educated them properly in putting it on or if you have, and they still can't physically do it, it ends up in the closet. (O)
	Adherence to Device Use	The patient follows recommendations on device use.	Patient Report/ Facility Records	I would say compliance, usually by the time I see the patient back at home...they had great care in the hospital or the nursing home, but if they have a great AFO and they are not using it properly... I would say compliance is pretty big. (P)

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TABLE 3. (Continued)

Theme and Related NQF Care Concept (If Applicable)	Subtheme	Definition	Recommended Source for Assessment	Sample Quote
Device Fit and Comfort <i>Quality of Life</i>	Pain/Discomfort	The patient experiences minimal pain or discomfort wearing the device.	Patient Report	I think number one is just comfort, if it hurts to wear, you are not going to be able to do their functional activities. (P)
	Skin Integrity	The patient experiences no skin damage from orthosis.	Patient Report	I would say skin assessment, just to make sure that they don't have skin breakdown... do they have wounds that are developing. Is it allowing them to heal properly, and... making sure that the AFO is not causing additional damage to any parts of their skin. (P)
Body Function <i>Quality of Life</i>	Gait Speed	The device allows a comfortable and desirable gait speed.	Patient Report/ Instrumented	I would say gait speed that's a good indicator for community participation. (P)
	Gait Pattern	The device enhances gait pattern.	Patient Report/ Instrumented	I take a visual of his gait to see if there is an improvement with him. You know, when we started treatment and after the treatment so we could see... if his gait is better when I'm doing. (O)
	Walking Endurance	The device maximizes walking endurance.	Patient Report/ Instrumented	The amount of the mileage you can walk. (O)
	Range of Motion	The device maximizes range of motion.	Patient Report/ Instrumented	Just to add maybe, um, range of motion as well, so that's something that we often will measure especially if there is an impairment. The orthotist will sometimes measure it. (P)
	Balance	The device enhances balance.	Patient Report/ Instrumented	I would say like increases in balance, add more balance, they can walk more safely. (O)
Activity and Participation <i>Quality of Life</i>	Other, Unspecified Function	The device provides a functional benefit.	Patient Report/ Instrumented	I think from the patient perspective, it is all about function. (O)
	Activity Level/ Independence	The device enhances the patient's activity level and independence.	Patient Report/ Instrumented	If they're not using it there's a problem with it. So activity level. (O) You don't want to go to church in gym shoes so. Sometimes you want to dress up. It's like I got a banquet coming up, and I really want to put on a nice pair of shoes. So what do I, and where do I go, that's kind of frustrating. (U)
	Quality of Life	The device enhances the patient's perceived quality-of-life.	Patient Report	Take me back to the quality-of-life I had before I needed a brace. (O)

O, orthotist; P, physical therapist; U, user.

you have the equipment to properly assess them and make good decisions.”

The Organizational Characteristics theme included subthemes of reception staff courtesy, scheduling ease, timeliness of device delivery, and collection of quality improvement data. An orthotist illustrated that quality should focus on “do I have a product there on time and did it break within 90 days.”

The Clinician Competencies theme included subthemes of education and experience, skilled comprehensive patient assessment, and certification and continuing education. An AFO user commented, “I [would want to know if they have] continuing education or do they have certification. And, you know, orthosis management, you know, advanced training.”

The Patient-Clinician Communication theme included subthemes of follow-up with patients, rapport, goal setting, and patient education. An orthotist's comment reflected the importance of education: “I think probably we all... teach,

educate the patient on what to expect from the wearing of this device.”

The Care Coordination theme included subthemes of continuity of care and documentation of assessment and services. An orthotist emphasized the importance of “having that same therapist, and that same orthotist working with them who knows the whole patient case.” An AFO user expressed a similar sentiment, “I think being able to have the same orthotist, if possible, for a significant period of time is helpful.”

The Device Characteristics theme included subthemes of material quality and device durability, adjustability, modifiability, and weight. One user said of her orthosis, “It's lighter, it's lighter, much lighter” indicating satisfaction with the weight of her device.

The Device Usage theme included subthemes of cosmesis, social confidence, ease of donning and doffing, and adherence to device use recommendations. One AFO user observed, “The

first one I had was really ugly.” When referring to her current device, she said, “It doesn’t look as sick. It doesn’t look – it doesn’t look prosthetic as the – it isn’t the nasty skin color.” Users also emphasized their desire to wear a variety of footwear with their AFO.

The Device Fit and Comfort theme included subthemes of pain and skin integrity. An orthotist stated, “Making sure that if they are going to be using an off the shelf AFO, that it’s being properly fitted, and if that didn’t work for them, then having customized fitting as well as a follow-up. So making sure that over time with use it’s not causing any further injury, any skin breakdown, and then it’s doing what it is supposed to do as far as the assist required.”

The Body Function theme included subthemes of gait speed and pattern, walking endurance, range of motion, balance, and other functions, illustrated by a therapist’s comment: “I think from the patient perspective, it is all about function.” An AFO user commented, “The design [helps] me control my foot... better, and my walk is... better.”

The Activity and Participation theme included subthemes of activity level/independence and quality-of-life. One AFO user said, “When I got my AFO it gave me real, a whole bunch of confidence in walking, period, especially in my house. When I am at home, I’m not in a wheelchair at all. But the AFO gives me – that’s where I got all of my confidence from walking at home.”

We asked focus group members to recommend the preferred source of information for each of the subthemes. Table 3 summarizes the consensus recommendations. Patients were the preferred source of information for themes related to environment of care, device characteristics, and activity and participation; facility records for clinician competencies; and more than one source for other themes. Recommended were instrumented sources along with patient reports for body function themes.

Table 4 lists the frequency with which different focus group participants mentioned each quality subtheme. The rank order of themes varied considerably across stakeholder groups. Ankle-foot orthosis users most often mentioned subthemes of

**TABLE 4.** Frequency of codes related to quality themes and subthemes across participant groups

Theme	Subtheme	AFO Users	Orthotists	Physical Therapists
Environment of Care	Accessibility of Facility	1	2	2
Environment of Care	Facility Layout	3	8	8
Environment of Care	Ambiance	3	2	3
Organizational Characteristics	Courtesy of Reception Staff	4	3	2
Organizational Characteristics	Ease of Scheduling	3	1	0
Organizational Characteristics	Timeliness of Device Delivery	0	9	7
Organizational Characteristics	Collects Meaningful/Actionable Data	1	4	7
Clinician Competencies	Clinician Education/Experience	8	4	10
Clinician Competencies	Comprehensive Evaluation	0	6	3
Clinician Competencies	Clinician Certification/Continuing Education	1	1	2
Patient-Clinician Communication	Clinician Follow-up With Patients	4	4	7
Patient-Clinician Communication	Rapport	3	5	0
Patient-Clinician Communication	Setting Patient Goals	3	8	4
Patient-Clinician Communication	Patient Education	8	9	13
Care Coordination	Continuity of Care	9	9	14
Care Coordination	Documentation of Assessment and Services	0	7	4
Device Characteristics	Material Quality	2	4	11
Device Characteristics	Device Durability	5	1	4
Device Characteristics	Device Adjustability	5	0	2
Device Characteristics	Device Modifiability	0	0	3
Device Characteristics	Device Weight	3	2	2
Device Usage	Cosmesis	4	3	6
Device Usage	Social Confidence Wearing Device	0	1	0
Device Usage	Ease of Donning and Doffing	1	2	3
Device Usage	Adherence to Device Use	0	6	9
Device Fit and Comfort	Pain/Discomfort (device comfort)	7	10	6
Device Fit and Comfort	Skin Integrity	4	3	4
Body Function	Gait Speed	0	2	12
Body Function	Gait Pattern	1	7	0
Body Function	Walking Endurance	1	5	3
Body Function	Range of Motion	0	1	0
Body Function	Balance	0	7	6
Body Function	Various, Unspecified Function	0	26	19
Activity and Participation	Activity Level/Independence	3	7	1
Activity and Participation	Quality of Life	2	6	5

Note: The sample size varied across stakeholder groups. Thus, the relative frequency of themes and subthemes should be evaluated within a column, not across columns.

continuity of care, patient education, clinician education/experience, and pain/discomfort. Orthotists and physical therapists most often mentioned the subtheme of unspecified functions, whereas no AFO user mentioned this subtheme. For orthotists, the next most often mentioned subthemes were pain/discomfort, continuity of care, timeliness of device delivery, and patient education. For physical therapists, the next most often mentioned subthemes were continuity of care, patient education, and gait speed. Least often mentioned across all groups were subthemes of range of motion, social confidence wearing an AFO, device modifiability, clinician certification and continuing education, and ease of scheduling.

### Alignment of Quality Themes With NQF’s Person- and Family-Centered Care Framework

Quality-of-care themes such as Device Characteristics, Device Usage, Environment of Care, and Clinician Competencies identified by thematic analysis were unique to custom AFO use, whereas the other six aligned with NQF’s person- and family-centered care concepts quite well.<sup>1,9</sup> For example, NQF’s “Interpersonal Relationships” care concept, focusing on respect, dignity, compassion, trust, perception of equity, and cultural and linguistic responsiveness, maps well to the Organizational Characteristics theme we identified. National Quality Forum’s “Interpersonal Relationships” care concept also focuses on information sharing and communication, which is similar to our Patient-Clinician Communication theme. National Quality Forum’s “Quality of Life” care concept, relating to physical and cognitive functioning, behavioral, physical, social, emotional, and spiritual well-being, symptom and symptom burden, and treatment burden, relates well to our themes of

Device Fit and Comfort, Body Function, and Activity and Participation. National Quality Forum’s “Care Planning and Delivery” care concept contains subtopics of establishing and attaining patient, family, and care provider goals, care concordant with person values and preferences, and care integration, all of which relate closely to the Care Coordination theme we identified. National Quality Forum’s “Access to Support and Self-management” care concept, pertaining to patient and care provider needs and support, and timely and easy access to care and knowledge, relates to our themes of Patient-Clinician Communication and Organizational Characteristics. Of note, NQF’s “Patient and Family Engagement: Shared Decision-Making and Informed Choice” care concept was not discussed by focus group participants.

### Clinical Assessment Instruments

We also asked participants about the types of instruments that would be useful in quantifying quality concepts and summarize their responses here. Custom AFO users identified no specific instruments, whereas clinician participants mentioned few patient-reported instruments. Both clinician groups mentioned gait speed and endurance tests, such as the 10-meter and 6-min walk tests,<sup>17</sup> and tests of balance, such as the Berg Balance Scale.<sup>18</sup> Also mentioned as valuable by physical therapists was the FIM Instrument.<sup>19</sup> Instruments suggested by clinicians diverged from the quality themes that AFO users identified, particularly quality-of-life, a component of our Participation theme.

### Methods of Data Collection for Quality Measures

Table 5 summarizes focus group feedback on methods of quality data collection. Clinicians who used electronic medical

**TABLE 5.** Summary of focus group discussions regarding data collection and industry adoption of quality measures

Topic	Orthotists	Physical Therapists	Custom AFO Users
<b>Clinical Data Collection Methods</b>	<ul style="list-style-type: none"> <li>Data collection is a valuable, yet often forgotten topic when it comes to quality-of-care.</li> <li>Orthotists believed that data collection methods should reflect the environment or setting in which they work.</li> <li>They document patient performance by measuring distance walked and the terrain.</li> </ul>	<ul style="list-style-type: none"> <li>The physical therapists emphasized that collecting data electronically and through patient reports are good methods.</li> <li>Electronic data storage enhances accessibility and is easily updated.</li> <li>They recommend evaluating outcomes with the 10-meter walk test, FIM Instrument, and Functional Need Assessment.</li> <li>Documenting patients’ skin integrity for wounds and abrasions.</li> </ul>	<ul style="list-style-type: none"> <li>Users indicated that the best method for clinicians to collect quality data is through face-to-face discussions.</li> <li>They suggested questions such as “how does it feel driving?” “Do you have any complaints?”</li> <li>They indicated that answers allow patients concerns to be addressed.</li> </ul>
<b>Industry Adoption of Quality Data</b>	<ul style="list-style-type: none"> <li>Professional organizations influence adoption of quality measures.</li> <li>Professional organizations can provide education on how to properly perform tests to collect data, creating a public resource for clinicians who are not familiar with a particular measure and create a national database in which clinics and orthotists could upload standardized assessment data.</li> </ul>	<ul style="list-style-type: none"> <li>Quality measures are not discussed widely in the field.</li> <li>National and international conferences should focus on this topic.</li> <li>Professional organizations can increase the awareness of quality measures.</li> <li>Assuring that items/instruments are reliable and valid will help industry-wide adoption of quality measures.</li> <li>Organizations mandating therapist use of outcome measures will enhance patient care.</li> </ul>	<ul style="list-style-type: none"> <li>Not asked.</li> </ul>



records valued them as a means of storing data for subsequent extraction and aggregation for quality measure reporting. Clinicians also perceived that electronic medical records facilitated communication regarding patient care with other clinicians with whom they shared the same records. They valued electronic data collection and use of patient reports, as well as data accessibility and ease of updating patient records.

Clinicians reported collecting data from both standardized assessments and nonstandardized clinical examination. They reported routine assessment of patients' skin integrity when working with custom AFO users. Custom AFO users valued face-to-face data collection. Patient engagement through questions such as "How does it feel driving?" and "Do you have any complaints?" allowed AFO users to provide specific feedback.

### Industry Adoption of Quality Data Collection

Table 5 summarizes focus group feedback on industry adoption of quality data collection. Clinicians noted that professional associations have considerable influence in adoption and implementation of standardized assessment instruments. They suggested that professional associations could provide education on selection of standardized assessments that could be used for quality measurement and create a national database to which facilities could contribute patient-level data for analysis and calculation of quality measure data for comparative purposes. Clinicians noted that quality measures and standardized assessments are not discussed often in professional forums and that presentations at national conferences would be a good mechanism to increase awareness of quality measurement for orthotic practice. They emphasized the importance of adopting widespread and valid standardized instruments to advance the field.

## DISCUSSION

The aim of this study was to identify issues that are important to the quality-of-care for people who use custom AFOs. We used focus groups to identify and summarize the relative frequency of issues mentioned by AFO users, orthotists, and physical therapists, explore which clinical assessment instruments might be used for quality measurement, identify preferred methods of data collection, and obtain recommendations for industry adoption of quality data collection. Finally, we describe alignment of the identified issues with NQF's Framework for Patient- and Family-Centered Care. Although the perspectives of AFO users, orthotists, and physical therapists largely overlapped, some were unique. Although orthotists and physical therapists most often mentioned ideas related to the theme of Body Functions, AFO users hardly commented on this theme. Clinicians discussed Body Functions from an activity perspective, emphasizing participation. Ankle-foot orthosis users tended to focus on continuity of care, patient education, device pain/discomfort, and their experience of the clinician. The relative emphasis of each group reflects their different perspectives and priorities. For patients, the lived experience of seeking services and using a device is that of an insider<sup>20</sup> who knows their personal experience well. Clinicians, who as outsiders to the condition, have a broader experience observing and assisting many patients, but have no or limited experience in obtaining and wearing an AFO.

Orthotists' responsibility for fabricating and delivering an AFO is distinct from physical therapists' role of providing services to enhance function, perhaps accounting for their different perspectives. The quality themes identified here and their relative importance to various stakeholders can help clinicians anticipate and place in perspective quality measure development that affects patient outcomes.

Overall, the quality-of-care themes we identified map well to the NQF person- and family-centered care framework for development of quality measures with a few exceptions. Omission of device characteristics from the NQF framework is perhaps not surprising given the unique focus of orthotic care and the broader perspective of NQF. Perhaps more surprising is that focus group participants did not mention any themes or subthemes that would relate to the NQF care concept of Patient and Family Engagement in Shared Decision-Making. The closest concept might be the theme of Patient-Clinician Communication, which included goal setting, assuming that patients and clinicians share in decision-making, which was not clear from the discussions. However, even if it did, it would not encompass fully the concept of shared decision-making and informed choice regarding AFO design and related therapy.

The quality themes we identified are amenable to the development of quality measures. Some themes are more suitable for assessment using clinician-reported instruments, whereas patient report would be optimal for other themes. Given the overwhelming preference for patient reports as a source of quality measures, next steps include the development of patient surveys to collect this information and identification of clinician-reported instruments. Specifically, clinician reports are best suited to describe gait characteristics, whereas patient reports are best suited for quality-of-life, reflecting patients' insights on their health and function.<sup>21</sup> Facility records are suitable for structure and process characteristics, such as clinician certification and device delivery milestones. These findings are consonant with the conclusions of Van Der Wees et al.<sup>22</sup> that use of patient experiences and outcomes as a quality measure information source requires a shared vision among stakeholders regarding how this information will be used and trust among stakeholders.

Readers should note several study limitations. Findings are based on four focus groups of participants based in the Chicago-land area and may not be representative of all custom AFO users, orthotists, and physical therapists nationwide. In addition, although we made efforts to recruit clinicians from a variety of settings, these results may not be representative of all settings in which AFOs are used. We organized only one physical therapist and one custom AFO user focus group because of resource limitations, increasing the risk of selection bias. Although we recognize that methods such as member checking may strengthen the trustworthiness of findings,<sup>23</sup> we chose not to incorporate them into the methodology because it has the potential of altering interpretations of the original data set. For example, member-checking can result in confusion rather than confirmation because participants may change their mind about an issue; their experiences that occurred since the focus group may alter their beliefs; and among the multiple members in focus groups, there may be different views of the same data upon review.<sup>23</sup> Although all were

experienced AFO users and reflect diverse etiologies, they do not reflect a full range of lived experience. For example, we did not include children or caregivers of children. Future studies should include orthosis users with diverse age, race, ethnicity, etiology, and socioeconomic backgrounds. Furthermore, because we conducted a greater number of clinician focus groups, our findings focus more heavily on providers' perspectives, specifically those of orthotists due to the uneven distribution of individuals in the clinician groups.

Future research should seek to describe patient perspectives in detail, determine which clinician-reported and patient-reported instruments might operationalize the quality themes we identified and come to constitute a preferred set of instruments for quality measurement, and evaluate the feasibility, costs, and benefits of collecting data that reflect the quality-of-care themes identified by focus group participants. Availability of quality data with benchmarks would allow orthotists to compare their patients' progress with those of other providers. However, because insurers pay orthotists in the United States for providing devices, not for time spent with patients, it is crucial to identify data collection instruments that can be administered in a low-cost, efficient manner.

## CONCLUSIONS

Narrative text from custom AFO users, orthotists, and physical therapists led us to identify 10 quality-of-care themes and 28 subthemes related to care of people who use custom AFOs. The themes map well to the NQF person- and family-centered care framework for development of quality measures with the exception of patient and family engagement in shared decision-making, which focus group participants did not mention, and device characteristics, which are not part of the NQF framework. Although the perspectives of the stakeholders largely overlapped, orthotist and physical therapist responses focused on themes of Body Functions, but the responses of AFO users did not. These quality themes provide information as to what aspects of healthcare quality are meaningful to measure with respect to orthotic care, thus providing guidance on how to measure and improve AFO service delivery as part of future policy, research, and clinical care.

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