


BMJ Open Qualitative study informing the development and content validity of the HAND-Q: a modular patient-reported outcome measure for hand conditions

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ABSTRACT

Objectives The purpose of this study was to identify and understand the issues that are relevant to patients with hand conditions. The data were used to develop a patient-reported outcome measure (PROM) for adults with hand conditions (HAND-Q) and refine it with input from patients and clinician experts.

Design Semistructured qualitative interviews were used to understand what matters to patients. Cognitive debriefing was used to refine preliminary HAND-Q scales.

Setting Hand clinics in tertiary healthcare centres in Canada, Australia and USA.

Participants Eligible participants were English-speaking adults who had experienced hand surgery in the preceding 12 months and were at least 4 weeks post-hand surgery. A total of 62 in-depth interviews (females, n=34; mean age=65 years) were conducted to develop an item pool and draft the HAND-Q scales. The preliminary scales were refined through cognitive debriefing interviews with 20 participants and feedback from 25 clinician experts. All interviews were audiorecorded, transcribed verbatim and coded using a line-by-line approach.

Results Qualitative data were organised into two top-level domains of health-related quality of life and satisfaction with treatment outcomes. The scales were refined iteratively, and the field-test version included 319 unique items and 20 independently functioning scales.

Conclusions The HAND-Q is a comprehensive PROM developed using extensive patient and clinician expert input, following established guidelines for PROM development and validation. In the next phase, the psychometric properties of the HAND-Q will be established in an international field test, following which the HAND-Q will be available for use in clinical research and practice.

INTRODUCTION

Any condition or injury of the hand can significantly impact the health-related quality of life (HRQL) of an individual. While several objective and performance-based measures exist to assess the impact of hand conditions and their treatment on the range of motion, strength, dexterity, sensation and functional

Strengths and limitations of this study

- The development of HAND-Q included in-depth input from a heterogeneous, international sample of adult patients with diverse hand conditions.
- The comprehensibility, comprehensiveness and relevance of the field-test version of the HAND-Q was established using extensive feedback from patients with hand conditions and clinician experts.
- Patients with rare hand conditions (eg, congenital deformities, hand amputation or brachial plexus injuries) were not included in the development of the HAND-Q, and further validation work will be required.
- Only English-speaking patients from high-income countries were included and the scales will need to be examined for content validity and psychometrics in diverse patient populations.

impairment, the impact on an individual's HRQL is best assessed by asking patients directly. Patient-reported outcome measures (PROMs) are questionnaires that are used to assess HRQL in clinical practice and research. The data collected from PROMs can be used to understand, monitor and communicate the impact of a condition on patients and enhance shared decision making, resulting in better treatment outcomes overall.¹

A recent systematic review designed to identify all PROMs relevant to the field of hand surgery identified 24 PROMs for upper extremity conditions.² Most commonly used PROMs in hand conditions included the Disabilities of the Arm, Shoulder and Hand (DASH), the Michigan Hand Outcomes Questionnaire (MHQ) and the Patient-Rated Wrist/Hand Evaluation (PRWHE). However, these three PROMs have important limitations. The DASH, MHQ and PRWHE were developed in the 1990s using the traditional

classical test theory (CTT) approach. Importantly, qualitative interviews with patients with hand conditions were not a part of the development of the DASH, which countermands the recommendations of the Medical Outcomes Trust, the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) initiative and the US Food and Drug Administration.^{3–5} Further, increasingly modern psychometric methods that involve Rasch measurement theory (RMT) or item response theory analysis are used to develop scales that form clinical hierarchies and have interval level measurement properties. Modern approaches to scale development allow for meaningful and interpretable measurement of change in patient status, which is difficult for scales developed using the CTT approach.

To overcome the limitations of existing instruments, our team developed a PROM for hand conditions called the HAND-Q. The HAND-Q is intended to be used in clinical care, research and quality improvement initiatives in acute and chronic care of adults with hand conditions. The modular construction of the HAND-Q means that the practitioner can choose the scales of relevance for a particular application. It is anticipated that the HAND-Q will be implemented in hospital and private hand clinics that manage hand conditions surgically and non-surgically. The detailed study protocol for the development of HAND-Q is published elsewhere.⁶ This paper aims to describe the results of the first phase of the development of the HAND-Q—a qualitative study to develop and refine the HAND-Q scales—which will be tested psychometrically in a subsequent international field test study.

METHODS

The first phase of the HAND-Q development was completed in three steps: (1) development of the conceptual framework, (2) scale formation and (3) pilot testing to establish content validity with feedback from patients and clinician experts. The COnsolidated criteria for REporting Qualitative research (COREQ) Checklist⁷ was used to report the results.

Approach

We used the applied health services approach of interpretive description⁸ to design, conduct and analyse the results of the qualitative study. Interpretive description acknowledges pre-existing theoretical and clinical knowledge informing a study, which was appropriate in our study given that much is known already about the impact of hand conditions on individual's HRQL. This approach also aims to produce knowledge relevant to the clinical context with the provision that a patient's understanding of a concept is of the most significant importance, regardless of the clinical or theoretical explanation.⁹

Stage 1: development of the conceptual framework

Study participants and recruitment

English-speaking adults (18 years or older) who had had surgery on one or both hands in the preceding 12 months and were at least 4 weeks post-hand surgery were recruited from tertiary healthcare centres in Adelaide, Australia, and Saint John, New Brunswick, Canada. The limit of 12 months was imposed to ensure that the HRQL issues were relevant and there was minimal recall bias. Although the HAND-Q is designed to be used for all patients with hand conditions (and not just those who have surgical treatment for their condition) the experience of surgery themes to be explored in the interviews required that participants had experienced surgical management. Patients who were unable to provide informed consent due to a language barrier or cognitive impairments were excluded. The recruitment followed a purposive sampling strategy to ensure heterogeneity by targeting key demographic variables (age, gender), clinical variables (hand condition), funding (public vs private) and type of anaesthesia used for surgery (general anaesthesia/sedation or local anaesthesia). Patients were screened for eligibility by treating clinician(s) or the clinic's administrative staff and informed of the study objectives and procedures by a member within their clinical circle of care. The contact information for patients who expressed an interest in participation was shared with the study research coordinator, who then contacted the patient, explained the study in detail including the credentials of the interviewer, answered study-specific questions and obtained written informed consent for participation.

Data collection

A semistructured interview guide (online supplemental appendix 1) was developed to elicit in-depth information on the treatment and experience of living with a hand condition, specifically concerning HRQL (physical, psychological, social and sexual well-being) and satisfaction (appearance and process of care). Interview probes were used to guide the patient's description of the treatment outcomes or to elicit detailed answers. The probes were informed by the clinical expertise of the study team and the concepts identified in a systematic review on this topic.^{6 10} In-depth, qualitative interviews were conducted in-person or over the telephone by an experienced qualitative interviewer (KSi, cisfemale) with no relationship to the participants, using the interview guide.⁵ The participants were asked to describe their experiences of living with their hand condition, including any treatments. The interviews were audiorecorded and transcribed verbatim, with identifying information removed.

Data analysis and rigour

The data collection and analysis took place concurrently to explore the relevance and importance of the emerging concepts identified during the interviews. Inductive content analysis of the interview transcripts was completed using a 'line-by-line' approach in Microsoft Word, Version

2019 (Microsoft, Washington, USA). Participants' quotes about any aspect of outcome or experience of care were copied into a Microsoft Excel spreadsheet Version 2019 (Microsoft), along with demographic and clinical information. Constant comparison was used to identify common concepts of interest, and the data were categorised into conceptual top domains, subdomains, and major and minor themes.¹¹ The interviews were coded by one experienced qualitative researcher and checked by another team member. Codes were confirmed after discussion with a lead researcher (AK), who oversaw the analysis. To ensure rigour, the data analysis results were reviewed with the members of the study team throughout the study.¹² Interviews continued until saturation was achieved; that is, no new concepts were identified in subsequent interviews.¹³

Stage 2: HAND-Q scale formation

The conceptual framework and the coded data developed in stage 1 were used to create items for the identified domains. For item development, efforts were made to retain the participants' language as much as possible. To ensure that the items were clear, easy to understand, and resonated with patients, we avoided double-barrelled items, or items with technical jargon or slang. For scale development, the theoretical underpinnings of the RMT were adopted.¹⁴ The RMT approach to scale development requires that the items map out a concept of interest through a clinical hierarchy (ie, measuring from a little to a lot of a concept). Therefore, each item was designed to measure the concept of interest in varying amounts. For example, in the Physical Function scale, the items range from those that would be easy to endorse for most people with a hand problem (eg, eating with your hand(s)) to more challenging (eg, eating with cutlery) to the most difficult to endorse (eg, opening a jar).

The response options for the HAND-Q scales were limited to four options for simplicity and per recommended guidelines.¹⁵ We deliberately did not include a neutral response option. This is because the amount of a construct measured by the neutral option is unclear and does not fit the mathematical model of RMT.

Stage 3: pilot testing of HAND-Q scales for content validity

Patient input: cognitive interview

A new sample of patients with hand conditions using the same eligibility criteria and recruitment strategy from stage 1 was recruited from Allentown, Pennsylvania, USA. Relevant drafts of the HAND-Q scales were sent to the participants before the interview. An interview guide was used, and the interviews were conducted by an experienced qualitative interviewer by telephone. The 'think aloud' technique^{16 17} was used, whereby the scales were reviewed item-by-item, and the participants were asked to comment on the clarity, ease of understanding, and relevance of the title, instructions, time frame, response options and items. Where appropriate, participants were asked to paraphrase the items in their own words

and provide examples from their treatment experience. Participants were also asked to nominate missing items (if any) and comment on the comprehensiveness of each scale.

The interviews were conducted in three consecutive rounds to allow for changes to be made to the scales in-between the rounds. The interviews were audiorecorded and transcribed verbatim, with identifying information removed. The interview transcripts were analysed descriptively by one experienced qualitative researcher and checked by another team member. Relevant participant quotes pertaining to items were copied and pasted into a Microsoft Excel spreadsheet. An item tracking matrix¹⁸ was used to document the changes made to the items between rounds of interviews. Data saturation was thought to be reached when participants did not recommend any further changes to the HAND-Q scales.

Expert opinion: online survey

We sought feedback from healthcare professionals with expertise in treating hand conditions (hereafter referred to as 'experts') to ensure buy-in and affirm that the HAND-Q scales comprehensively explored clinically important issues. A multidisciplinary team of experts was identified through the professional networks of the study investigator team and invited via email to participate in an online Research Electronic Data Capture¹⁹ survey. The experts were asked to review scales one at a time and comment on the relevance, comprehension and comprehensibility of the scale's content. Non-respondents were sent a reminder 1 week later. Expert surveys were completed after the first and second rounds of patient cognitive interviews. The feedback from experts was analysed descriptively by one experienced qualitative researcher and checked by another member of the team and used to refine the HAND-Q scales.

Patient and public involvement

The HAND-Q has been developed with patients as central focus and with patient input vital throughout the development process. An international group of patients were engaged in all stages of the development of the HAND-Q. The input of patients in stage 1 qualitative interviews was fundamental to the scale formation, with patients' words providing the content for the item development in stage 2. Feedback from patients in stage 3 helped to refine the scales. Regular team debriefs were conducted with the team members throughout the three stages.

RESULTS

Stage 1: development of the conceptual framework

The qualitative interviews took place between June and November 2017; the mean interview time was 34 min (range 12–61). A total of 62 (females, n=34, 55%) in-depth qualitative interviews with 40 participants in Australia and 22 in Canada were conducted. The mean age of the participants was 65±11 years (range 28–86). The participants'



Table 1 Demographics of participants in qualitative interviews

	Australian	Canadian	Total
Number of participants	40	22	62
Age			
Average	63	67	65
Range	38–78	27–85	27–85
Gender			
Male	18	10	28
Female	22	12	34
Hand condition			
Trigger finger	4	4	8
Osteoarthritis	8	0	8
Rheumatoid Arthritis	1	0	1
Carpal Tunnel Syndrome	8	12	20
Trauma	6	1	7
Dupuytren's Contracture	11	3	14
Other	2	2	4
Funding			
Public	17	22	39
Private	23	0	23
Anaesthesia			
Local only	7	21	28
Sedation, General Anaesthesia	33	1	34

diagnoses included carpal tunnel (n=20), Dupuytren's contracture (n=14), trigger finger (n=8), osteoarthritis or rheumatoid arthritis (n=9), trauma (n=7) and other less common conditions (n=4). Further demographic information available in [table 1](#). The completed COREQ checklist is provided in online supplemental appendix 2. Online supplemental materials also include an example of how the interview data were coded and categorised into domains and themes (online supplemental appendix 3).

The interview data were organised into top-level domains of HRQL and satisfaction with treatment outcomes. The HRQL top-level domain was categorised into the subdomains of physical well-being, psychological well-being and social well-being. The satisfaction top domain included sub-domains of satisfaction with appearance, overall outcome, process of care and anaesthesia. [Table 2](#) shows the conceptual framework of the HAND-Q with supportive data from the qualitative interviews.

Stage 2: scales formation

The conceptual framework was used to develop the first draft of the HAND-Q scales. Item generation was based on

content from participant interviews and the participants' wording was maintained as much as possible. A total of 20 scales were developed to measure the concepts identified in stage 1. The full list of scales is shown in [table 3](#).

Stage 3: pilot testing of HAND-Q scales for content validity

Cognitive interviews were conducted to review draft scales with patients. The draft scales were reviewed and discussed in detail to ensure that the scales were measuring the concepts important to patients in an easy-to-understand format. Any instructions or items that caused confusion were subsequently altered to improve the interpretability of the scales. A total of 20 cognitive interviews in three rounds were performed with patients between 1 January 2018 and 28 February 2018. Participants were in Australia (n=9), Canada (n=7) and the USA (n=4). The majority of the participants were females (n=13, 65%), and the mean age of the sample was 60±12 years (range 32–76 years). Participants were seeking or had received treatments for a range of hand conditions, including carpal tunnel (n=9), Dupuytren's contracture (n=3), trigger finger (n=3), osteoarthritis or rheumatoid arthritis (n=8), trauma (n=5) and other less common conditions (n=3). Further demographic information is available in [table 4](#).

A total of 25 experts provided input in two rounds (round 1, n=14) on the content of the HAND-Q scales. [figure 1](#) shows the composition of experts for each round. A summary of the number of items that were added, retained, revised or dropped is shown in [table 3](#).

The field-test version of the HAND-Q consists of a total of 319 unique items organised into 20 independently functioning scales (online supplemental appendix 4).

DISCUSSION

In-depth qualitative interviews were conducted with an international sample of adult patients with hand conditions to gain a comprehensive understanding of the range of treatment outcomes and experience of care-related concepts. The qualitative data were used to develop a conceptual framework, which was used to develop a draft of the HAND-Q, a comprehensive PROM for patients with hand conditions. The draft version of HAND-Q was refined through patient and expert feedback, and content validity was demonstrated.

We adopted a patient-centred approach for this study, where patients were engaged in content generation and refining of the HAND scales. Measuring what matters to patients is fundamental to understanding the burden of hand conditions and providing effective and efficient care that aligns with patients' treatment preferences and values. Due to HAND-Q's 'bottom-up' approach, we were able to identify and develop scales for concepts that are either missing or incompletely assessed in the existing hand-specific PROMs to-date.² For example, the HAND-Q has a unique scale that measures the impact of hand

Table 2 Conceptual framework of the HAND-Q with supportive participant quotes and examples

Top level domain	Subdomain	Major theme	Minor theme	Categories (where applicable) and participant words and examples			
Health-related quality of life	Physical	Symptoms	Pain	Intensity ('mild', 'severe')			
				Frequency ('all the time', 'on and off')			
				Type ('ache', 'stinging', 'burning', 'cramp') 'discomfort', 'sore')			
			Aggravating Factors (eg, during activities, at rest, when touched)				
			Sensation				
		Function	Experience	Lack of Sensation ('numb', 'dead feeling')			
				Abnormal Sensation ('buzzing', 'going to sleep', 'pins and needles')			
			Excessive Sensation ('sensitive')				
			Weakness ('weak', 'feeling tired')				
			Impact				
	Psychological	Emotional distress	Irritation				
			Being down				
			Overwhelmed				
			Self-conscious				
		Acceptance					
Social	Isolation						
	Function (incl. work)						
	Relationships						
	Accept						
Appearance	Appearance	Hand region (ie, fingers, thumb, palm, knuckles, skin, nails, scar)	Size				
			Shape				
			Colour				
			Contour				
			Similarity				
			Smoothness				
			Scenarios				
			Age				
			Skin				
			Qualitative				

Continued



Table 2 Continued

Top level domain	Subdomain	Major theme	Minor theme	Categories (where applicable) and participant words and examples
Experience of care	Experience of Care	Preprocedure information	Amount	'enough', 'knew what to expect', 'more needed'
			Format of delivery	'written', 'might be more visual', 'pamphlet', 'information package'
			Accessibility	'easy to understand', 'sufficient time to review'
			Nature of information	eg, details of the procedure, type of anaesthesia, what to do in case of a complication, precautions, recovery, and outcomes to be expected
		Satisfaction—hand surgeon and hand therapist	Description	professional', 'kind', 'friendly', 'attentive', 'easy to talk to', 'caring'
		Satisfaction—hand clinic	Nature of appointment	'feeling heard', 'feeling unrushed', " included in decisions'
		Satisfaction—office staff	Overall	'nice atmosphere', 'clean', 'sterile', "ease of booking appointment
			Overall	'on schedule', 'worked as a team', 'made me feel welcomed'
Anaesthesia	Anaesthesia	Experience	Worry—not working	'amount of anaesthetic not being enough', 'feeling pain'
			Worry—recovery	eg, impact on daily activities
		Postanaesthesia symptoms	Type and experience	'feeling sleepy', 'tired', 'down', 'Irritable', 'unwell', 'confused'
		Awake procedure	Administration feeling	'pain', 'tingly', 'warm'
			Sensation at the site	'pain'
			Distress	Seeing blood or surgical equipment—'worried', 'anxious'
			Environment	Operating room—'comfortable', 'clean', 'sterile'
	Ability to ask questions			
Treatment	Hand Splint or Brace	Appearance of hand	Qualitative	'people don't look at the hand', " made my hand look normal'
			Qualitative	'it looks filthy because you cannot clean it'
		Cleaning splint or brace		
		Donning and doffing		'cumbersome', 'irritating', 'uncomfortable', 'pain', 'stuck'
		Perform daily activities		e.g., being physically active, sleep, socialise, dress, and care for hand
	Financial burden		'Expensive'	
Outcome	Appraisal		'glad', 'pleased', 'satisfied', 'changed my life', 'met expectations'	

condition on someone's sexual life. Items in this scale ask about the hand problem being a distraction during sexual activity or interfering with the ability to give pleasure. Since hands are a part of the body that are difficult to hide, participants in our study described feeling embarrassed and self-conscious about their hand condition. The HAND-Q measures appearance of hands (eg, size, shape of fingers and thumbs, how the hands look when holding a glass or resting the

palms on a table) to provide a means to evaluate treatments that change how the hand looks.

Another unique strength of the HAND-Q is that the development of the scales was embedded within the principles of a modern psychometric approach (ie, RMT), resulting in independently functioning scales. The negative impact of injuries and conditions of the hand on psychological well-being has been well established in the literature.^{20–22} Existing PROMs, such

Table 3 Summary of the number of items that were added, retained, revised or dropped during the refining of the HAND-Q scales

	Response options	Recall period	Initial items	Items added	Items revised	Items dropped	Items for field-test
Health-Related Quality of Life scales							
Function	Difficulty	Past week	34	3	14	2	35
Symptoms	Severity	Past week	18	6	17	2	22
Psychological	Frequency	Past week	16	3	0	0	19
Life impact	Severity	Past week	9	2	1	0	11
Sleep	Frequency	Past week	8	1	3	1	8
Social	Agree/disagree	Past week	13	0	4	0	13
Sexual	Bothered	None	9	0	0	0	9
Work	Agree/disagree	None	9	2	3	0	11
Acceptance	Agree/disagree	None	7	0	6	0	7
Appearance scale							
Appearance	Satisfaction	Now	29	1	10	0	30
Experience of care scales							
Anaesthesia	Bothered	None	17	0	5	3	14
Post-anaesthesia symptoms	Severity	None	12	2	0	1	13
Awake procedure	Satisfaction	None	17	1	8	1	17
Information	Satisfaction	None	21	1	7	2	20
Surgeon	Agree/disagree	Recent appointments	25	1	8	1	25
Hand therapist	Agree/disagree	Recent appointments	20	1	4	2	19
Hand clinic	Agree/disagree	Recent appointments	14	0	3	1	13
Office staff	Agree/disagree	Recent appointments	13	1	2	0	14
Hand treatment scales							
Overall outcome	Agree/disagree	Most recent treatment	10	0	13	1	9
Splint	Satisfaction	Most recent splint	11	2	1	1	12
Total			312	28	109	15	319

as the DASH,²³ PRWHE²⁴ and the MHQ,²⁵ measure the impact of condition or treatment on psychological well-being with a single item rather than a scale. When the raw score for the single item on psychological well-being is added to raw item scores of unrelated constructs to produce a total score, it makes it impossible to ascertain the impact of the condition or treatment on patient's psychological well-being. Further, it makes it challenging for clinicians and researchers to interpret the total score, discouraging them from using PROMs. In contrast, the HAND-Q includes one independently functioning scale with items that measure only one construct—psychological function—resulting in more targeted measurement. The modular design allows the clinicians to choose the scales that are most relevant to their clinical practice or research question, reducing patient burden. Additionally, as the field of hand surgery evolves and new concepts of interest are identified, the modular design allows for new scales to be added to the

HAND-Q, keeping it relevant ('fit for purpose') over time.

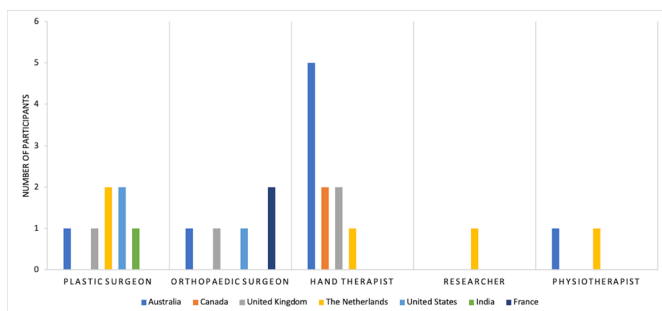
Our study is not without limitations. The study sample is not representative of the full breadth of hand conditions seen in the clinical practice. While the common conditions such as carpal tunnel syndrome, Dupuytren's contracture and trigger finger were included, rarer hand conditions such as congenital anomalies or brachial plexus injury were not. Non-surgical patients were excluded from the study; however, this was strategic as postoperative patients are able to describe their preoperative (ie, non-surgical) and postoperative experience with the hand condition and its HRQL impact. Further qualitative work would be required to examine the content validity and other psychometric properties of the HAND-Q scales in the clinical populations not included in this study. Further, we only included English-speaking participants from three developed countries with similar economic and cultural environments. To ensure that the HAND-Q

Table 4 Demographics of participants in cognitive interviews

	Australian	Canadian	American	Total
No of participants	9	7	4	20
Age				
Average	61	64	56	60
Range	47–76	55–76	32–76	32–76
Sex				
Male	3	2	2	7
Female	6	5	2	13
Hand condition				
Trigger finger	1	1	2	3
Osteoarthritis	4	2	3	7
Rheumatoid Arthritis	1	0	0	1
Carpal Tunnel Syndrome	2	5	7	9
Trauma	2	2	3	5
Dupuytren's Contracture	2	1	1	3
Other	1	1	2	3

scales are relevant globally, the scales have been translated and culturally adapted to a number of languages in preparation for an international field-test study. RMT analysis could be used in future research to examine differential item functioning by language to determine if the HAND-Q works the same across country.

The next phase of HAND-Q development is an international field test involving sites in Australia, Canada, Finland, France and the USA. The data from the field test will be analysed using RMT analysis, and the psychometric properties of reliability and validity will be examined. Once the scales are finalised, they will be made available at no charge for not-for-profit clinical and research use through www.qportfolio.org.

**Figure 1** Composition of expert panel in the rounds of refining of the scale.

CONCLUSION

The HAND-Q is a comprehensive PROM that was developed with extensive patient and clinical expert input. The content validity of the HAND-Q was demonstrated, and the scales were found to be relevant, comprehensive and comprehensible. The measurement properties of reliability and validity will be examined with an international field test study that includes adult patients with diverse hand conditions. Once the HAND-Q is finalised, we anticipate that it will be implemented in clinical practice, research and quality improvement initiatives to examine the clinical effectiveness of hand-related interventions, improve patient–clinician interactions, inform patient education, ultimately enhancing patient-centred care.

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Contributors KSi, NRD, AK and ALP conceptualised the study; AK, ALP and SJC developed the methodology used for the development of the HAND-Q; KSi conducted the interviews; KSi, KSA and AK analysed the data, AK led the development and refinement of the scales with assistance from all listed coauthors; GB, PG and DL helped with recruitment and provided content expertise, KSi and MK wrote the manuscript, which was approved for submission by all listed coauthors. KSi is the guarantor.

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Competing interests KSi, NRD, ALP and AK are codevelopers of the HAND-Q and receive a share of any license revenue on the inventor sharing policies of the institutions that they are associated with. AK is an owner of EVENTUM Research, which provides consulting services to the pharmaceutical industry.

Patient consent for publication Consent obtained directly from patient(s)

Ethics approval This study involves human participants and was approved by Southern Adelaide Clinical Human Research Ethics Committee (Australia, Reference HREC/17/SAC/5) Horizon Health Network Research Ethics Board (Canada, Reference 2017-2499) Office of Research and Innovation, Lehigh Valley Health Network, Allentown, Pennsylvania (USA, Reference STUDY00000046).

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