

# Development of a Patient-Reported Outcome Measure Focusing on Intermittent Catheter-Related Quality of Life

Pinder B and Lloyd AJ\*

Oxford Outcomes (an Icon plc Company), Seacourt Tower, Oxford, OX1 0JJ, UK

## Background

Intermittent catheterisation has become the gold standard treatment option for many people with urinary disorders, including spinal cord injury, multiple sclerosis, spina bifida [1,2]. It is an effective and practical method which involves the periodic insertion of the catheter into the bladder to drain urine and its immediate removal after the bladder empties. This procedure can either be performed by the self (intermittent self-catheterisation: ISC) or by health-care professionals, relatives or caregivers [3-5]. This procedure is recommended over other types of catheterisation such as indwelling catheterisation due to the numerous health benefits, including a lower risk of developing urinary tract infections, pyelonephritis, and renal inflammation [6-9]. Other advantages to intermittent catheterization include improvement in self-care and independence, ability to decide when and where to perform the procedure with a minimum amount of equipment, fewer barriers to intimacy and sexual activities, and a decrease in the risk of blockage, catheter rejection, pain, and trauma [10-14]. The benefits of innovations such as ISC are often quite broad in terms of how they affect a patients' life. For example it may mean people are less worried about their need for catheterisation and so become more likely to socialise with family and friends. These psychological and social benefits are only really possible to capture directly from the patient. These types of broader benefits in health care are best recorded through the use of patient reported outcomes (PROs). PROs are standardised survey instruments that are designed to measure outcomes from patients in clinical trials and clinical practice.

In recent years emphasis has been placed on the greater involvement of patients in the health and medical care they receive. PROs are described as "any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else" [15]. Thus, PROs are used to gain understanding of health outcomes from the patients' perspective. In the UK the NHS believe that the data from patient outcome measures can drive better health care decision making [16]. PROs are also used to accompany clinical assessments by the pharmaceutical industry for labelling claim purposes and market access [15,17,18]. The ISC-Q was developed to provide better data regarding important outcomes for people who rely on ISC [19].

## Results from the ISC-Q Development Study

### Development and validation

The ISC-Q outcome measure was developed in 2012 and the study was divided into two phases [19]. The first phase focused on the development of the ISC-Q with 20 interviews using a depth interview technique [20,21] and a review of selected literature. Based on the interview and review, 26 items of importance for individuals performing ISC were selected and categorised into four domains: 'ease of use', 'convenience', 'discreetness', and 'psychological well-being'. Ten cognitive debriefing interviews with UK and French individuals who performed ISC were conducted to ensure face and content validity of the ISC-Q. A urology expert was also consulted to provide further support for content validity of the ISC-Q. The items were accordingly revised based on these interviews.

The second phase of the study focused on the validation of the ISC-Q. The PRO measure was administered online in the UK, France, and Germany to 306 individuals diagnosed with a neurologic disorder (spinal cord injury, multiple sclerosis, and spina bifida) that used ISC as their main method of bladder management. Various psychometric assessments were performed to:

- ✓ Evaluate item performance including skew, floor or ceiling effects, item facility, item-to-domain correlation, and principal component analysis.
- ✓ Assess the conceptual framework of the ISC-Q using exploratory factor analysis to determine the structure of the ISC-Q and whether they matched the predefined ISC-Q domains.
- ✓ Measure reliability of the final ISC-Q domains/items in terms of internal consistency and test-retest reliability.
- ✓ Measure validity of the final ISC-Q domains in terms of convergent validity.

### Results of validation study

The full details for the psychometric evaluation are reported elsewhere [19] and a short summary is provided here.

**Phase I:** Revisions were made to the draft ISC-Q based on the cognitive debriefing interviews, resulting in a total of 27 items. Domain scores were transformed to a 0 to 100 scale, with a higher score representing fewer burdens associated with ISC. An aggregate score of all domain scores was also provided to calculate the ISC-Q total score.

**Phase II:** The analysis of item performance identified three problematic items, based upon skewed distribution of responses, and a negative and low item-total correlation. Two items showed low factor loadings ( $\leq 0.4$ ) when assessed on the principal component analysis. These items were removed from the measure, resulting in a total of 24 items in the final version of the ISC-Q. The exploratory factor analysis supported the domain structure of the ISC-Q. The analysis provided evidence of four distinct factors which accounted for 48.9% of the total variance. The internal consistency reliability of the ISC-Q domains ranged from 0.83 to 0.86, and the total ISC-Q score was 0.92. The test-retest reliability assessment revealed acceptable-good reproducibility; the 'discreetness' and 'psychological well-being' domains and the overall total scores performed well, but the 'ease of use' and 'convenience' domains showed slightly weaker performance. Lastly, the ISC-Q

\*Corresponding author: Lloyd AJ, Oxford Outcomes (an Icon plc Company), Seacourt Tower, Oxford, OX1 0JJ, UK, E-mail: [andrew.lloyd@oxfordoutcomes.com](mailto:andrew.lloyd@oxfordoutcomes.com)

Received July 23, 2013; Accepted September 23, 2013; Published September 26, 2013

Citation: Pinder B, Lloyd AJ (2013) Development of a Patient-Reported Outcome Measure Focusing on Intermittent Catheter-Related Quality of Life. Int J Phys Med Rehabil 1: 155. doi:10.4172/2329-9096.1000155

Copyright: © 2013 Pinder B, et al. This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.

ISC-Q	Responsiveness			MID			
	Mean change in scores (SD)	SRM	Effect size	1/3 SD	1/2 SD	SEM	MID Range
Ease of use	0.23 (0.89)*	0.26	0.36	0.21	0.32	0.24	0.21-0.32
Discreetness	1.20 (1.19)**	1.00	1.14	0.35	0.52	0.43	0.35-0.52
Psychological wellbeing	0.06 (0.90)	0.07	0.05	0.37	0.55	0.45	0.37-0.55
Convenience	1.12 (1.04)**	1.08	1.09	0.34	0.51	0.40	0.34-0.51
Total score	16.28 (16.87)**	0.97	0.93	5.82	8.73	4.94	4.94-8.73

SRM=standardized response ; \*p<0.05 (from paired t-test); \*\*p<0.01 (from paired t-test)

**Table 1:** Responsiveness and minimum important difference (MID) estimates of the ISC-Q.

had some evidence of convergent validity against other measures of outcomes related continence care and hand dexterity.

## Results from a Clinical Trial Which Employed the ISC-Q

Since its development the instrument has been included as the primary outcome measure in a study comparing outcomes in people using different catheter devices. An open-label, randomized, multicentre, crossover study was conducted in France, Sweden, Denmark, Germany, and Norway. This study was designed to assess the benefit of a novel intermittent catheter compared with the participant's current device using the ISC-Q. A total of 125 intermittent catheter users were randomized to receive their current device or the new device, and after a 6 week period participants were switched over. Responsiveness and sensitivity of the ISC-Q were also assessed. Good responsiveness to the new intermittent catheter were indicated by the 'discreetness' and 'convenience' domains and also the total ISC-Q score. Moderate levels of responsiveness were shown by the 'ease of use' domain, whereas the 'psychological well-being' domain was not found to be sensitive in this study (Table 1).

## Conclusion

The ISC-Q has proven to be a valid and reliable outcome measure. However, as with all new instruments, it is acknowledged that the validation of the ISC-Q is an iterative process. Nonetheless, use of this PRO measure in clinical studies could help guide both health care providers and intermittent-catheter users in selecting appropriate catheters. The ISC-Q may also be useful in understanding the benefit of intermittent catheter devices and thus lead to more finely tailored and individualized health care interventions. The development of the measure continues on from the original work published in 2012 [19]. Here we present new information regarding the sensitivity of the measure. In addition the measure is being translated and adapted for use in a study in Japan and results from this will be reported in due course.

## Acknowledgements

This study was funded by Coloplast. Some of the work reported here has been reported previously and this paper represents an update on previous work.

## References

- Lemke JR, Kasprovicz K, Worrall PS (2005) Intermittent catheterization for patients with a neurogenic bladder: sterile versus clean: using evidence-based practice at the staff nurse level. *J Nurs Care Qual* 20: 302-306.
- Pilloni S, Krhut J, Mair D, Madersbacher H, Kessler TM (2005) Intermittent catheterisation in older people: a valuable alternative to an indwelling catheter? *Age Ageing* 34: 57-60.
- Bardsley A, Kaighin B (2008) Instruction of male patients in the technique of ISC. *Continence Essentials* 1: 94-98.
- Pomfret I, Winder A (2007) The management of intermittent catheterization: assessing patient benefit. *Br J NeurosciNurs* 3: 266-271.
- Barton R (2000) Intermittent self-catheterisation. *Nurs Stand* 15: 47-52.
- Blaine C, Pellowe C, Hodgkinson S (2012) Improving infection prevention practice in primary and community care. *J Hosp Infect* 82: 274-276.
- Turi MH, Hanif S, Fasih Q, Shaikh MA (2006) Proportion of complications in patients practicing clean intermittent self-catheterization (CISC) vs indwelling catheter. *J Pak Med Assoc* 56: 401-404.
- Warren JW, Muncie HL Jr, Hebel JR, Hall-Craggs M (1994) Long-term urethral catheterization increases risk of chronic pyelonephritis and renal inflammation. *J Am Geriatr Soc* 42: 1286-1290.
- Niele-Weise BS, van den Broek PJ (2005) Urinary catheter policies for short-term bladder drainage in adults. *Cochrane Database Syst Rev* 3: CD004203.
- Newman DK, Wein AJ (2009) *Managing and Treating Urinary Incontinence*. (2ndedn), Health Professions Press, Baltimore.
- Getliffe K, Dolman M (2003) *Promoting Continence: A Clinical and Research Resource*. BaillièreTindall, London.
- McConville A (2002) Patients' experiences of clean intermittent catheterisation. *Nurs Times* 98: 55-56.
- Rew M, Woodward S (2001) Troubleshooting common problems associated with long-term catheters. *Br J Nurs* 10: 764-774.
- Doherty W (1998) The Aquacath hydrophilic coated single-use urinary catheter. *Br J Nurs* 7: 1332-1336.
- FDA (2009) *Guidance for industry. Patient-reported outcome measures: Use in medical product development to support labelling claims*.
- Department of Health (2008) *High quality care for all. NHS next stage review*.
- Devlin NJ, Appleby J (2010) *Putting health outcomes at the heart of NHS decision making*. King Fund, London.
- Black N, Jenkinson C (2009) Measuring patients' experiences and outcomes. *BMJ* 339: b2495.
- Pinder B, Lloyd AJ, Elwick H, Denys P, Marley J, et al. (2012) Development and psychometric validation of the intermittent self-catheterization questionnaire. *Clin Ther* 34: 2302-2313.
- Mason J (2006) *Qualitative Researching*. (2ndedn), Sage Publications, London.
- Gordon RL (1956) Dimensions of the depth interview. *Am J Soc* 62: 158-164.

**Citation:** Pinder B, Lloyd AJ (2013) Development of a Patient-Reported Outcome Measure Focusing on Intermittent Catheter-Related Quality of Life. *Int J Phys Med Rehabil* 1: 155. doi:10.4172/2329-9096.1000155