PCR14

Development and validation of two new patient-reported outcome measures for recurrent urinary tract infection: The Recurrent UTI Symptom Scale (RUTISS) and the Recurrent UTI Impact Questionnaire (RUTIIQ)

Abigail F. Newlands[1,2] | Melissa Kramer[2,3] | Lindsey Roberts[4] | Kayleigh Maxwell[5] | Jessica L. Price[3] | David Churchman[6] | Katherine A. FInlay[1,2]

Background

Recurrent urinary tract infection (rUTI) is characterised by at least two UTIs in six months or at least three in a year. Globally, it affects over 100 million people each year and is consistently associated with significant psychosocial burden, chronic pain, and reduced quality of life (QoL).[1,2] Fragmented treatment pathways and diagnostic challenges contribute to fear and frustration among patients: there is an urgent need to address the patient perspective.[3] To date, no validated patient-reported outcome measures (PROMs) of the unique rUTI patient experience exist.

This study aimed to develop and validate the Recurrent UTI Symptom Scale (RUTISS) and the Recurrent UTI Impact Questionnaire (RUTIIQ).

Methods

A five-stage mixed-methods design was employed in accordance with PROM development recommendations by the FDA and the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) initiative (see Figure 1).[4]

A high level of heterogeneous patient involvement was prioritised throughout the study, applying maximum variation sampling, to ensure the PROMs are patient-centred.

RUTISS RUTIIQ

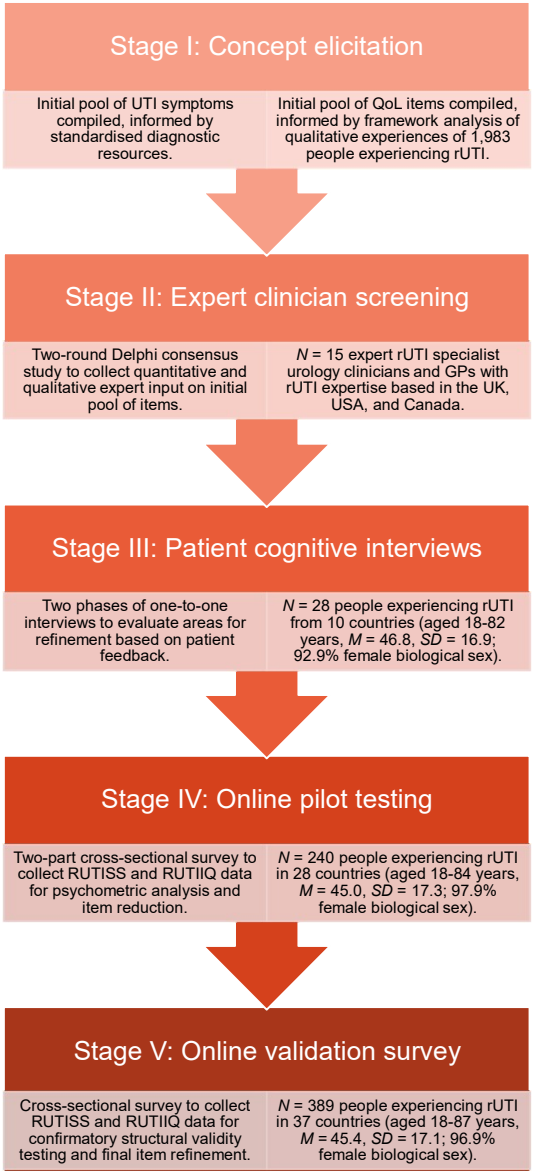

Figure 1. PROM development methodology utilised to develop the RUTISS and the RUTIIQ.

Results

Iterative refinements were made during Stages I–III in close consultation with expert clinicians and people experiencing rUTI. Both PROMs indicated strong psychometric properties (see Table 1), and both require a minimum reading age of US 6th grade.

	RUTISS	RUTIIQ
RMSEA	.041	.054
CFI	.995	.992
SRMSR	.047	.052
Content validity (I-CVI)	.75 – 1.00	.75 – 1.00
Internal consistency (Cronbach's α)	.82 – .90	.80 – .93
Construct validity (Spearman's ρ)	.77 – .82	.38 – .76
Test-retest reliability (ICC)	.73 – .82	.66 – .91

Table 1. Psychometric properties of the RUTISS and the RUTIIQ. Ranges indicate the minimum and maximum values for individual domains. RMSEA = root mean square error of approximation. CFI = comparative fit index. SRMSR = standardized root mean squared residual. I-CVI = content validity index for items. ICC = intraclass correlation coefficient.

RUTISS: 15-item questionnaire assessing patient-reported UTI symptom frequency, global change in symptoms, and severity of four symptom domains: *urinary symptoms*, *urinary presentation*, *UTI pain and discomfort*, and *bodily sensations*.

RUTIIQ: 18-item questionnaire assessing rUTI-related impact to five QoL domains: *personal wellbeing*, *social wellbeing*, *work and activity interference*, *patient satisfaction*, and *sexual wellbeing*.

Clinical implications

The first and only PROMs validated for use with people living with rUTI, the RUTISS and the RUTIIQ offer the unique opportunity to enhance rUTI management, patient-centred care, and rUTI research through standardised observation of patient outcomes and prioritisation of the patient perspective.

Next steps include evaluation of the sensitivity of the RUTISS and the RUTIIQ in response to antibiotic treatment, and determination of the minimal clinically important difference (MCID).

References

1. Zeng Z, et al. (2022). Global, regional, and national burden of urinary tract infections from 1990 to 2019: An analysis of the global burden of disease study 2019. *World J Urol, 40*(3), 755-63.
2. Wagenlehner F, et al. (2018). Social and economic burden of recurrent urinary tract infections and quality of life: A patient web-based study (GESPRIT). *Expert Rev Pharmacoecon Outcomes Res, 18*(1), 107-17.
3. Scott VCS, et al. (2021). Fear and frustration among women with recurrent urinary tract infections: Findings from patient focus groups. *J Urol*, 206, 1-7.
4. Mokkink LB, et al. (2018). COSMIN Risk of Bias checklist for systematic reviews of patient-reported outcome measures. *Qual Life Res, 27*(5), 1171-9.

Acknowledgements

- Live UTI Free, an international patient advocacy and research organisation (www.liveutifree.com/)

Affiliations

1. School of Psychology and Clinical Language Sciences, University of Reading, UK.
2. Patient-Centred Research and Data Insights Ltd., UK.
3. Live UTI Free Ltd., Ireland.
4. School of Psychology, University of Buckingham, UK.
5. Department of Psychology, University of Stirling, UK.
6. InSpired Health Outcomes, UK.

Contact information

- For licensing enquiries, visit: https://www.inspiredoutcomes.co.uk/
- For rUTI research enquiries, contact Abigail Newlands: a.f.newlands@pgr.reading.ac.uk