75

Uren A[1], Cotterill N[1], Harding C[2], Hillary C[3], Chapple C[3], Klaver M[4], Bongaerts D[4], Hakimi Z[4], Abrams P[1]
1. *Bristol Urological Institute, UK,* ***2.*** *Freeman Hospital, Newcastle,* ***3.*** *Royal Hallamshire Hospital, Sheffield,* ***4.*** *Astellas Pharma B.V., Leiden, The Netherlands*

QUALITATIVE DEVELOPMENT OF A NEW PATIENT REPORTED OUTCOME MEASURE FOR UNDERACTIVE BLADDER

Hypothesis / aims of study
The patient experience of underactive bladder (UAB) was explored, for the purpose of developing a Patient Reported Outcome (PRO) measure to assess the symptoms and impact of the condition. UAB is currently proposed as the term to describe the symptom complex associated with urodynamically determined detrusor underactivity (DU), characterised by a bladder contraction of reduced strength and/or duration resulting in prolonged or incomplete emptying of the bladder. The PRO is being developed in accordance with the Food and Drug Agency PRO guidance for industry, for future use in research and clinical practice.

Study design, materials and methods
In-depth interviews were conducted with patients diagnosed with DU, followed by detailed qualitative analysis of the transcripts. Interviews continued until no new concepts were mentioned during further interviews (data saturation achieved). A draft PRO was developed in which each item corresponded to a symptom, sign or behaviour reported by patients and was worded with idiomatic language used by the patient population. Cognitive debriefing interviews were scheduled and iterative revisions of the PRO made, until no further changes were necessary.

Results
A total of 44 concept elicitation interviews with patients diagnosed with DU, with or without coexisting urological conditions were conducted in Bristol, UK. Following qualitative analysis, more than 30 lower urinary tract symptoms, signs or behaviours were identified, having a broad impact on quality of life. The first version of the PRO contained 37 items which was refined to 31 items (Table 1) based on feedback from 37 cognitive debriefing interviews, held at 3 different hospitals in the UK.

Table 1. The 31 symptom and impact items included in the PRO following cognitive debriefing.

Symptom items		**Impact items**
• Acute retention episodes • Urinary tract infections • Self-catheterisation • Hesitancy to start void • Need to concentrate to start void • Small volume of urine per void • Post-micturition dribble • Incontinence (stress and urge) • Need to immediately re-void • Sensation of incomplete emptying • Intermittency • Straining to begin void • Straining towards end of void	• Slow stream • Urgency • Nocturia and/or nocturnal voids • Daytime urinary frequency • Reduced sensation of bladder fullness • Waiting in bathroom after voiding • Length of time in bathroom • Temporarily unable to pass urine • Associated bowel symptoms • Clustering of symptoms	• Planning life around toilet visits • Social life • Impact of nocturia and/or nocturnal voids • Impact on physical activities • Fluid intake • Embarrassment • Way feel about self • Overall impact

Interpretation of results
The resultant PRO was interpreted as intended and included the items of relevance for the sample population, whilst being easy to complete.

Concluding message
Concept elicitation and cognitive debriefing interviews have been carried out in a large group of patients with DU. The result is a novel and comprehensive developmental version of the PRO for the evaluation of UAB symptoms and its impact on quality of life. Further testing will assess the psychometric properties of the PRO and refine the inclusion of items.

Disclosures
Funding: Astellas Pharma B.V., Leiden, The Netherlands **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Bristol South Research Ethics Committee. REC reference 087/99 **Helsinki:** Yes **Informed Consent:** Yes