Hypothesis / aims of study
The modular International Consultation on Incontinence Questionnaire (ICIQ) is currently being developed to produce a comprehensive and universally-applicable questionnaire for the assessment of a variety of pelvic symptoms, including those of the lower urinary tract, lower bowel and vagina, in clinical practice and research. Urodynamic investigation is the only means of objectively assessing lower urinary tract function or dysfunction in individuals with urinary incontinence (1). However, it is an invasive, undignified procedure that can be uncomfortable and has a 3% risk of urinary tract infection (2). Currently, there is no standardised outcome measure to assess individuals’ satisfaction with this and other invasive procedures. Satisfaction is defined as the state of being contented or pleased (3). Under the aegis of the ICI, a new module of the ICIQ to comprehensively assess individuals’ satisfaction with urodynamic investigation, the ICIQ-Urody namics Satisfaction, has been developed and evaluated. The ICIQ-UDS-S is intended to be universal, applicable to a wide range of individuals, including adult men and women of all ages (>18 years) in both the developed and developing world. The present study was conducted to undertake the first phase of the psychometric testing of the ICIQ-UDS-S, namely to establish the content validity of the questionnaire. Such a questionnaire is essential for ongoing quality control in all urodynamic units and for the process of audit.

Study design, materials and methods
The original developmental version of the ICIQ-UDS-S contained 19 items to assess the individual's perception of:

- the accuracy and helpfulness of the information about the investigation that they received both in the postal system and immediately prior to the procedure by the investigating doctor (4 items);
- satisfaction with the information provided (2 items);
- overall satisfaction with the success of the investigation in terms of providing an explanation for their symptoms (5 items);
- the competence, professionalism and communication of the clinical staff, including the doctor and nurse (4 items);
- how well their comfort, privacy and dignity were maintained (3 items);
- overall satisfaction with the investigation - measured using a visual analogue scale from 0 (not satisfied) to 10 (very satisfied) (1 item).

Content validity refers to whether an instrument accurately reflects the content of the concept it claims to measure. This was assessed in accordance with standard methods of psychometric testing, via consideration by a consensus committee and the interviewing and observation of potential respondents to the questionnaire:

(i) Committee assessment – a committee consisting of clinicians and nurses with relevant knowledge of urodynamic investigation was invited to comment on various aspects of the questionnaire’s content, including the individual items and domains, the wording and terminology and the appearance and layout.

(ii) Individual interviews – 10 consecutive individuals (3 males, 7 females, mean age 56.2 years, range 32 to 76 years) attending a urology clinic for a urodynamic investigation of their lower urinary tract symptoms, including frequency, urgency and stress and urge incontinence, were invited to self-complete the ICIQ-UDS-S. Each individual then participated in a semi-structured face-to-face interview with the research investigator, using a standard interview schedule. Detailed written recordings were taken.

Ethical approval was granted by the Local Research Ethics Committee.
Results
A small number of changes were made to the original developmental version of the ICIQ-UDS-S as a result of the content validation:

(i) Committee assessment – following minor alterations to the visual layout of the ICIQ-UDS-S, the selected items were determined to be appropriate, comprehensive and encompassed all important domains regarding the individual’s satisfaction with the urodynamic investigation.

(ii) Individual interviews – further changes to the layout and order of items were recommended during the first interviews to facilitate accurate completion of the items and enable clearer, more directive questioning. The remaining interviews did not highlight any subsequent issues with the layout, and the questionnaire as a whole was reported to cover all pertinent items and domains. Response categories were described as sufficient and applicable while the instructions for completion and the questions themselves were reported to be clear and unambiguous. The length of the questionnaire was deemed appropriate by individuals completing it, with a mean completion time of 7 minutes (range 3 to 15 minutes).

Interpretation of results
This study confirms the content validity of the final developmental version of the ICIQ-UDS-S, demonstrating that the questionnaire accurately reflects the content of the concept it claims to measure. Users can therefore be confident that the questionnaire is measuring what it is intended to and provides a valid summary of satisfaction with the urodynamic investigation as perceived by individuals who have undergone the procedure. Interviews with a sample of individuals who represented potential respondents to the questionnaire demonstrated that it is acceptable for use in different patient groups, including men and women of all ages with varying levels of symptoms and covers all important domains that are relevant to individuals. The relatively brief average completion time and positive responses regarding the length of the questionnaire reinforce the acceptability of the ICIQ-UDS-S as a self-completion instrument.

The final developmental version of the ICIQ-UDS-S is currently undergoing further validation including randomised postal administration to individuals who have undergone urodynamic investigation. Response rates and missing data will be analysed to further assess the questionnaire’s feasibility and acceptability. Evaluation of other psychometric properties, including construct validity and reliability, will then be undertaken.

Concluding message
The ICIQ-UDS-S demonstrates adequate content validity, indicating that it is a valid instrument for assessing satisfaction with the urodynamic investigation. The ICIQ-UDS-S will supply the need for a comprehensive, universally-applicable measurement instrument to evaluate current practice, offering opportunities to improve the experience of individuals undergoing urodynamic investigation.

References

FUNDING: AstraZeneca Pharmaceuticals LP, Boehringer Ingelheim, Eli Lilly & Co, Ferring Pharmaceuticals, Novartis Pharma AG, Pfizer Ltd, Pharmacia Corporation, Yamanouchi Pharma America, Inc.