The International Consultation on Incontinence Modular Questionnaire: www.iciq.net

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Purpose: In 1998 the first ICI was held in Monaco, sponsored by WHO and organized by the International Continence Society and International Consultation on Urological Diseases. The Scientific Committee recognized the need to develop a universally applicable questionnaire for wide application across international populations in clinical practice and research to assess urinary incontinence, facilitating the comparison of findings from different settings and studies, in a manner similar to the International Prostate Symptom Score.

Materials and Methods: An Advisory Board was formed to steer the development of the ICIQ and a decision was made to extend the concept further, developing the ICIQ Modular Questionnaire.

Results: The first module developed was the ICIQ Short Form Questionnaire for urinary incontinence. ICIQ modules have been developed or adapted for urinary tract symptoms and they are being developed for vaginal and lower bowel symptoms. Additional sexual matters and quality of life modules will become available for each condition area. Modules to assess patient satisfaction are expected to be of particular use for assessing treatment effectiveness. The ICIQ Advisory Board recently proposed the development of the ICIQ website, which is anticipated to be crucial for informing potential users of the phase of development of all ICIQ modules.

Conclusion: The ICIQ can offer a full range of urinary tract symptom questionnaires. The website will aim to attract collaborators committed to the concept of this internationally accepted modular questionnaire who are willing to help with its development.

Key Words: bladder; urinary incontinence; quality of life; questionnaires; quality assurance, health care

In 1998 the first ICI was held in Monaco, sponsored by WHO and organized by ICS and ICUD, which is a WHO recognized, nongovernmental organization. The first consultation followed the organizational template that has been used in all ICUD consultations since 1991.

Briefly, ICUD appoints an executive committee which, in consultation with the major relevant scientific societies worldwide, develops an appropriate range of committees to cover the topic of the individual consultation. Chairs are appointed who, with the executive committee, select committee members with wide-ranging academic qualities who are representative of the worldwide scientific community and the range of specialties involved. Each committee is responsible for defining the subject matter and, in the 12 months prior to the consultation, for performing a systematic review of the relevant medical literature, which forms the content of the committee chapter. Typically at least 3 drafts are written and reviewed by the committee at preliminary meetings, which are usually held at the American Urological Association or European Association of Urology, before the final meeting at the consultation itself. The committee chair then gives a presentation at the consultation based on the final draft of this chapter. The final draft is then edited and appears in the book published from the consultation. At the end of the consultation the Scientific Committee, comprising the Executive Committee and the chairs of the individual committees, makes a series of recommendations for the investigation and treatment of patients based on the findings of the committees. These recommendations also appear in the publication.

The first ICI had 24 individual committees, including a committee on symptom and QOL assessment. The members of this committee comprised a number of experts on the subject, of whom several had worked directly on the development of symptom questionnaires and QOL measures. The committee identified a number of published questionnaires that had been developed to assess urinary incontinence and subsequently applied grades of recommendation to each based on their degree of validation of each questionnaire. The committee encouraged the use of those questionnaires, attaining the highest level of recommendation, in clinical practice and research in this field. However, it had been suggested outside of the committee that there was a need to develop a universally applicable questionnaire that could be widely applied across the population for clinical practice and research.

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At the end of the consultation the ICI Scientific Committee met and upheld support for the development of such a questionnaire that would facilitate the comparison of findings from different settings and studies in a manner similar to that of the International Prostate Symptom Score, which was derived from the American Urological Association symptom score and accepted by the ICUD consultation in 1991, and is universally used to assess benign prostatic disease. Hence, the first ICI resolved to develop the ICIQ according to the standard methods of psychometric testing outlined by the symptom and QOL assessment committee.

The ICIQ Advisory Board was formed to steer the development of the ICIQ and it met for the first time in 1999. The early progress of the project was discussed with the board and a decision was made to extend the concept further and develop the ICIQ Modular Questionnaire. The first module to be developed was the ICIQ-UI Short Form for urinary incontinence. The ICIQ-UI Short Form has now been fully validated and published.[1] Given the intent to produce an internationally applicable questionnaire, requests were made for translations of the ICIQ-UI Short Form at an early stage, for which the Advisory Board developed a protocol for the production of translations of its modules.

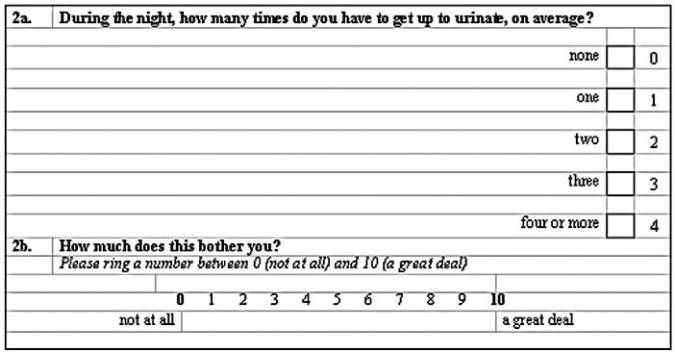
The protocol proscribes the production of the new language version by 2 native speakers of the target language (step 1), back translation into the source language (English) by a native English speaker (step 2), resolution of any differences between the original and the language version (step 3), and revalidation of the new language version. To date ICIQ-UI Short Form has been translated into 30 languages.

Therefore, the production of new questionnaires is extremely time-consuming and costly. Based on the recommendations of the symptom and QOL assessment committee at the first and second ICI consultations in 1998 and 2001 a number of existing validated questionnaires have been adopted as ICIQ modules and renamed with the permission of their authors (Appendix 2).[1–9] It is recommended that for the first 5 years after inclusion as ICIQ modules the derivation of these questionnaires should be cited in any ICIQ publications.

ICIQ modules are being developed for urinary tract, vaginal and lower bowel symptoms. Additional modules that are condition specific deal with sexual matters and QOL, and will become available for each of these subject areas. There will be additional modules to assess patient satisfaction, which will be of particular use for assessing treatment effectiveness. The modules have been developed by faculty members of the ICI committees and the ICS, which is the largest multidisciplinary body in the world, and they deal with the 3 subject areas covered by the ICIQ, namely the urinary tract, pelvic organ prolapse and lower bowel dysfunction. Experts have been involved when necessary, such as gastroenterologists in the development of the ICIQ-Bowel Symptoms module.

QUESTION FORMAT

Each module uses a common question format. Most questions use 5-point Likert scales to assess the presence or absence of a symptom and its severity, followed by a scale to assess associated bother. This format has proved successful in the development of the ICSmale,[2] Bristol Female Lower Urinary Tract Symptoms[3] and ICIQ-UI Short Form[1] with low levels of missing data, indicating not only that the questions are easy to understand, but also that the format is clear and well interpreted. Bother is now assessed by a visual analog scale of 0 to 10 (see figure).



ICIQ-FLUTS question 2a

URINARY SYMPTOM MODULES

Appendix 2 lists the fully validated urinary symptoms modules and their derivations.[1–9] All modules were awarded a grade A recommendation by the symptom and QOL assessment committee of the third ICI in 2004. The grade A recommendation represents high recommendation and it is reserved for questionnaires that have undergone rigorous psychometric testing and have published evidence regarding the validity, reliability and responsiveness of the instrument, as established in several data sets.

Two QOL questionnaires have been incorporated into the ICIQ to allow the impact of lower urinary tract symptoms on patient life to be assessed, namely the ICIQ-LUTSqol[4] and the ICIQ-UIqol.[5] However, it is recognized that other fully validated QOL questionnaires are available. Nevertheless, the ICIQ Advisory Board decided to make specific recommendations to achieve a standard questionnaire. The 2 selected questionnaires are each needed because they are complementary and cover different domains, with the ICIQ-UIqol5 focusing on incontinence and its emotional impact, in particular.

Additional urinary symptoms modules for specific conditions and patient groups. The ICIQ Advisory Board has approved condition specific questionnaires, namely modules for the assessment of overactive bladder symptoms (ICIQ-OAB[2,3]) and its impact on QOL (ICIQ-OABqol[6]), which have been fully validated and published, and modules for the assessment of nocturia symptoms (ICIQ-N[2,3]) and its impact on QOL (ICIQ-Nqol[7]), which have also been fully validated and published. Subgroups of the ICIQ Advisory Board are also working on urinary questionnaires for specific subsets of patients.

Children: This project is more complex than most others since different approaches are needed for young children (ages 5 to 8 years) and older children (ages 9 to 16 years). The ICIQ modules are intended for self-completion when possible, although this is likely to prove difficult in younger children. Therefore, parent completed questionnaires are being developed in addition to child completed versions that use picture based items.

Patients with Neurological Conditions: Some patients in this group may not report certain symptoms because neurological deficits may interfere with afferent nerve function and, therefore, with patient felt experiences of these symptoms. Questionnaires are being developed to assess patient views on various treatment methods, including intermittent catheterization, indwelling catheters (urethral or suprapubic) and sheath appliances in men.

VAGINAL SYMPTOMS MODULES (APPENDIX 3)

No existing questionnaires are currently available that have achieved adequate levels of validation. Modules to assess vaginal symptoms have been developed using the same question template that has proved highly successful during the development of the male and female symptom questionnaires from which the ICIQ-MLUTS and ICIQ-FLUTS modules were developed (Appendix 2).[2,3,8,9]

Validation has followed the protocol outlined by the ICI symptom and QOL assessment committee. The vaginal symptoms modules are being submitted for presentation at international meetings and in 2005 they will be submitted for publication.[10]

BOWEL SYMPTOM MODULES (APPENDIX 3)

Similarly, while there are a number of bowel questionnaires available, few have been fully validated. Developing the bowel symptom modules will be the main focus of attention in the next phase of work for the ICIQ group (2004 to 2006). The ICIQ questionnaire format will be used and the aim is to develop a full set of modules.

WWW.ICIQ.NET

The ICIQ Advisory Board recently proposed the development of the ICIQ website. The website was registered in September 2004 and is currently undergoing development. It is anticipated that the website will be useful to inform potential users of the phase of development of all ICIQ modules. The website will aim to attract collaborators committed to the concept of an internationally accepted questionnaire who are willing to help in its development. The website will list the questions contained in each module but it will not be possible to download questionnaires directly. This policy is designed to ensure that questionnaires are not altered, thereby, rendering their previous validation worthless, and ensure that translations fulfill the internationally recognized standards, as briefly described. However, modules will be available on request directly to the ICIQ office (iciq@bui.ac.uk).

Use of modules in research. Questionnaires can be used for research purposes free of charge by companies that have contributed to the development of the ICIQ and by academic organizations/groups. Commercial groups that have not contributed to the development of the ICIQ to date will be expected to pay royalties to use the modules. Any monies raised in this way will be used to fund the continuing development of the ICIQ.

Use of modules in clinical practice. Clinicians, eg nurses, physiotherapists, physicians, etc, are encouraged to use any of the available validated modules. Modules will be available free of charge but users will be asked to register on the ICIQ website and complete a brief online survey before the module is released.

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APPENDIX 1

ICIQ Advisory Board Members are Professors Paul Abrams, Ruud Bosch, Linda Cardozo, Jenny Donovan, Jens Peter Nørgaard and Andrea Tubaro, Simon Jackson, Drs. Kerry Avery, John Bolodeoku, Richard Bump, Mario de Gennaro, Jasper Huels, Iqbal Hussain, Con Kelleher, Charles Marotta, Natalia Price, Stephen Radley and Carlo Rizzi, and Lucy Abraham, Nikki Gardener, Tove Holm-Larsen, Roy Khoury, Zoë Kopp and LuAnn Sabounjian.

APPENDIX 2

Fully validated modules, derivations and recommendation grade from third ICI

Module Name and Derivation	Assessment Area	ICI Recommendation Grade
ICIQ-MLUTS (ICS*male* Short Form[8])	Urinary symptoms (male)	A
ICIQ-FLUTS (BFLUTS Short Form[9])	Urinary symptoms (female)	A
ICIQ-UI Short Form[1]	Urinary incontinence short form	A
ICIQ-N (ICS*male*[2]/BFLUTS[3])	Nocturia	A
ICIQ-OAB (ICS*male*[2]/BFLUTS[3])	Overactive bladder	A
ICIQ-MLUTS Long Form (ICS*male*[2])	Urinary symptoms long form (male)	A
ICIQ-FLUTS Long Form (BFLUTS[3])	Urinary symptoms long form (female)	A
ICIQ-LUTSqol (KHQ[4])	Urinary symptoms QOL	A
ICIQ-UIqol (I-QOL[5])	Urinary incontinence QOL	A
ICIQ-OABqol (OABq[6])	Overactive bladder QOL	A
ICIQ-Nqol (N-QOL[7])	Nocturia QOL	Not incontinence
ICIQ-MLUTSsex (ICS*male*[2])	Sexual matters related to urinary symptoms (male)	A
ICIQ-FLUTSsex (BFLUTS[3])	Sexual matters related to urinary symptoms (female)	

APPENDIX 3

ICIQ Modules under development

Developmental Modules	Assessment Area	Purpose
ICIQ-VS	Vaginal symptoms	Assessment of vaginal symptoms
ICIQ-BS	Bowel symptoms	Assessment of bowel symptoms
ICIQ-Neuro	Neurological patients	Assessment of management of urinary tract symptoms in neurologically impaired patients
ICIQ-LUTSC	Pediatric patients	Assessment of urinary symptoms in children
ICIQ-UI LF	Urinary incontinence long form	Detailed assessment of frequency, amount and bother of urinary incontinence
ICIQ-VSqol	Vaginal symptoms QOL	Assessment of QOL specific to vaginal symptoms
ICIQ-BSqol	Bowel symptoms QOL	Assessment of QOL specific to bowel symptoms
ICIQ-LUTSCqol	Pediatric QOL	Assessment of QOL in children with bedwetting
ICIQ-VSsex	Sexual matters related to vaginal symptoms	Assessment of sexual matters specific to vaginal symptoms
ICIQ-BSsex	Sexual matters related to bowel symptoms	Assessment of sexual matters specific to bowel symptoms
ICIQ-S	Posttreatment and post-investigation satisfaction	Assessment of satisfaction following treatments or investigations

Abbreviations and Acronyms

ICI = International Consultation on Incontinence
ICIQ = ICI Questionnaire
ICS = International Continence Society
ICUD = International Consultation on Urological Diseases
QOL = quality of life

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EDITORIAL COMMENT

Accurate measurement of clinical symptoms and the associated impacts on health related QOL have gained a central place in the discipline of medical outcomes research. These authors describe the background and development of the ICI Modular Questionnaire. This work represents an important advance in the assessment of health related QOL for voiding dysfunction and associated conditions. Each module has been subjected to strict psychometric testing for reliability and validity, and to subsequent peer review. The authors note that additional modules will be developed and refined to address condition specific issues. The modular format is intriguing because researchers can choose only those sections that apply to their particular topic of interest. However, in actual practice, there could conceivably be a considerable response burden if subjects are asked to complete multiple modules for a given study. This could be particularly true if several topics are measured on multiple occasions sequentially with time. However, the attempt to create and validate a uniform set of instruments that is universally applicable is commendable. The associated website (www.ICIQ.net) will enhance widespread dissemination of the instruments and provide an easily accessible forum for the exchange of information for clinical care and research. The use of standardized survey instruments that have been validated for multilingual and multicultural use will help improve direct comparison and the international generalizability of results from different studies. Continued work in this are will further advance the field of evidence based medicine.

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