INCONTINENCE

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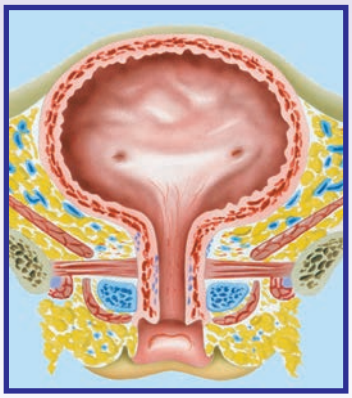

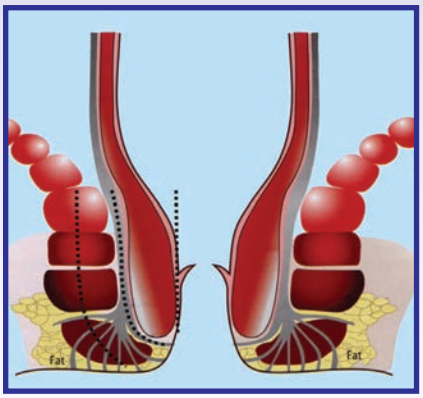

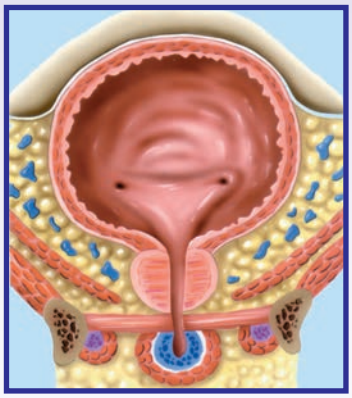

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Patient-Reported Outcome Assessment

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I. INTRODUCTION

The last update of the International Consultations on Incontinence reports broadened the scope of this review to include all patient-reported outcomes, not just health-related quality of life. This update will continue in the same vein to extend and update the prior literature reviews of PROs, for lower urinary tract symptoms (LUTS) and bowel incontinence outcome measures, and provide recommendations for questionnaire selection for use in clinical practice and research. In addition, this summary will review the purpose and content of the ICI questionnaire (ICIQ) modules. The expansion in scope of this review to include all types of patient reported outcomes (PRO) is an important step in recogniesing the inherent conceptual differences of various PROs each with different assessment goals. A PRO is "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"([1], page 2). PROs measure different aspects of disease and therapeutic impact such as: symptom frequency or symptom bother, health-related quality of life (HRQL), treatment satisfaction, or work productivity measures (**Figure 1**). An essential component of selecting a PRO for use is to ensure that the selected PRO is consistent with the objective of the study or clinical purpose. For example, if the goal is to assess treatment satisfaction, then a treatment satisfaction measure should be incorporated into the study design or as a clinical outcome. The matching of appropriate PRO selection with one's desired outcomes is critical to success when assessing PRO's and will be reviewed further in this chapter.

Ultimately, the last decade has been one of tremendous growth in the area of PROs with influences from scientific and regulatory communities. As such, the ICI will endeavour to continually update the recommendations it offers on the basis of emerging data and published evidence based on the sound and rigid recommendations of the prior reviews.

1. SELECTING PRO MEASURES FOR CLINICAL TRIALS AND CLINICAL PRACTICE

How does a researcher choose which instruments are most appropriate for a particular research study and/or clinical assessment? The following section provides general guidelines for use in conducting PRO assessments in clinical trials or other research investigations related to urinary or faecal incontinence.

As there are many available PROs, it is of utmost importance to select the PRO measure that is relevant and applicable to one's desired outcome. If an intervention is designed to reduce symptom bother, then a relevant PRO would be a symptom bother measure. Multiple PROs can be included in clinical practice or in a research study; however the designation of the PRO as a primary, co-primary, secondary,

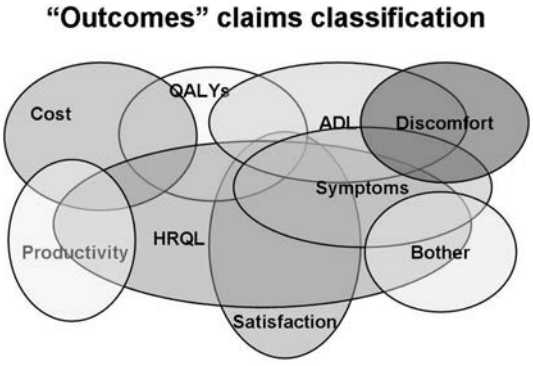

Figure 1. Patient-Reported Outcomes Assessment Areas. *Burke L, Evidence Review Branch DDMAC, FDA; DIA Workshop on Pharmacoeconomic and Quality of Life Labelling and Marketing Claims New Orleans October 3, 2000*

tertiary or exploratory endpoint must be noted. In addition, issues of staff and participant burden, time constraints, and resources should be considered in the selection of a PRO measure. Once it has been decided which outcomes are to be assessed it is important to choose a questionnaire that has been scientifically developed and validated. Principles of validation and questionnaires that have been validated are presented in this chapter.

2. SELECTING PRO MEASURES FOR RESEARCH STUDIES

a) Study Design

There are several protocol concerns that must be taken into account when using PRO measures in research studies, including the length of the study, the frequency of contact with the study participants, the timing of clinical assessments, the complexity of the study design, the number of participants enrolled, and participant and staff burden. The goal of the PRO assessment is to "fit" the PRO measures to the protocol without compromising either the study objective or design. For example, if the study design is complex with frequent participant contacts and multiple clinical measures, it may be necessary to keep the PRO measures at a minimum or to reduce the number of times the PRO is assessed (e.g. baseline and end of study rather than during all participant contacts) to minimise participant and staff burden. At the same time, however, PROs must be viewed as an important variable in the overall trial design and cannot be devalued in the data collection process. Consequently, PRO measures cannot be altered or reduced to accommodate study design as such alterations may yield less reliable measures or may seriously diminish the integrity of the overall study design and yield useless information. Having well developed research goals and questions regarding PROs will help to guide you in the selection of measures for a study. The aim is to develop a conceptually adequate, yet practical PRO battery given the study population, the specific intervention, and the study design.

The frequency with which PRO will need to be assessed in a research study will depend upon the nature of the condition or intervention being investigated and the expected effects (both positive and negative) of treatment. At a minimum, as with all measurements collected in a research study, a baseline and end of study assessment should be completed. In addition, PRO assessments should be timed to match expected changes in functioning due to either the intervention or the condition or the disease itself. Timing follow-up assessments to coincide with typical patient follow-up visits, if appropriate, may also reduce the costs involved in follow-up PRO assessments.

b) Study Population

It is critical to specify key population demographics that could influence the choice of instruments, the relevant dimensions of the PRO to be assessed, and the mode of administration. Thus, age, gender, educational level, the language(s) spoken, and cultural diversity should be carefully considered prior to selecting PRO measures. For example, a cohort of patients over the age of 70 may have more vision problems than middle-aged persons, making self-administered questionnaires potentially inadvisable. Ethnically diverse groups also require measures that have been validated across different cultures and/or languages.

In clinical trials, it is also as important to consider how the disease or condition will progress and affect the outcomes of patients in the control group as it is to understand the effects of the study treatment. For example, in patients with incontinence assigned to a placebo-control arm of a study, one might expect a symptom to worsen and thus have an effect on daily functioning. The point is to select PRO measures that are sufficiently sensitive to detect changes in both the treatment and the control group patients. Use of the same measures for both groups will ensure an unbiased and comparable assessment.

c) Intervention

There are three major factors related to the intervention that are relevant to PRO assessment, and therefore require careful consideration: 1) the positive and adverse effects of treatment; 2) the time course of the effects; and 3) the possible synergism of the treatment with existing medications and conditions. It is crucial to understand how a proposed treatment can affect patient outcomes in both positive and negative ways. For example, some drug therapies may relieve LUTS but produce side effects like dry mouth or sexual dysfunction.

In addition, the time course of an intervention's effects on PROs is also critical both in terms of the selection of measures and the timing of when PRO measures are administered to study participants. For example, in a trial comparing coronary artery bypass graft (CABG) surgery to angioplasty, an assessment of PRO one week post-intervention might lead to an interpretation that the surgical arm had worse outcomes than angioplasty for PRO since the individuals in this arm of the trial would still be suffering the effects of the surgical procedure (for instance, sore muscles and surgical site discomfort) which could overwhelm any benefits associated with CABG. However, at six months post-intervention, the benefits of CABG surgery such as, relief from angina might be more profound than the benefits received from angioplasty. Thus, when PROs are assessed could influence how one interprets the benefits (or negative effects) of the interventions.

Finally, it is important to have a clear understanding of the current medications the patient population is likely to be taking prior to randomisation to the study treatment, and how these medications might

interact with the trial intervention, (either a pharmacological or behavioural intervention), to influence patient outcomes.

3. TYPES OF PRO MEASURES

There are two types of PRO measures: generic and condition-specific. Generic measures are designed to assess outcomes in a broad range of populations (e.g., both healthy as well as ill individuals). These instruments are generally multidimensional, and assess at least the physical, social and emotional dimensions of life. An example of this type of instrument is the Medical Outcomes Study SF-36 Health Status Profile [2]. A second type of measure is condition-specific (e.g., instruments designed to assess the impact of specific diseases, conditions, age groups, or ethnic groups). Condition-specific measures can be similar to generic instruments in that they assess multiple outcome dimensions, but condition-specific measures also include items more specific to the particular condition or population being studied. Examples of condition specific instruments in urology include the Incontinence Impact Questionnaire [3], the King'sHealth Questionnaire [4], and the OAB-q [5].

In general, the growing trend has been to include condition-specific outcome measures in clinical trials due to their enhanced sensitivity to change and the need to minimise participant burden. Importantly, the type of instruments selected for inclusion in a research study will depend on the goals of the intervention and the specific research questions to be addressed. In practice, clinical trials that include PROs usually incorporate a combination of PRO measures most relevant to the study population and intervention, if applicable, being mindful of resource constraints and staff and participant burden.

Quality-adjusted Life Year (QALY)

Increasingly HRQL outcome measures are being used in the development of quality-adjusted life year (QALY) measures. A QALY is a universal health outcome measure applicable to all individuals and all diseases, which combines gains or losses in both life quantity (mortality) and life quality (morbidity) and enables comparisons across diseases and programs. QALYs are widely used for cost-utility analysis[6]. In the past decades, economic evaluation has been increasingly important for the decision maker to decide which treatment or intervention is more cost-effective, in order to allocate limited healthcare resources soundly. Economic evaluation aims to compare interventions in terms of their costs and benefits, including their patient outcome impact. Health benefits can be quantified as QALYs (pronounced "qualies"), which have become a standard measure and are now recommended in most of health economics guidelines as the method of choice [7]. The economic chapter contains additional information regarding QALYs, as do the following references: [8, 9].

4. LITERATURE SEARCH STRATEGY

For the current version of this chapter the previous literature search was updated. A number of databases were accessed, electronically, with specific search criteria, such as validation work from the period January 2006 through August, 2011. Age and gender limits were not specified. Databases used included Pub-Med/MEDLINE, and websites accessed included oab.com, proqolid.com, ncbi.nlm.nih.gov and mapi-institute.com. The following keywords were used separately and/or in combination: "urinary incontinence", "urinary symptoms", "urgency", "overactive bladder", "stress incontinence," "incontinence," "questionnaire," "epidemiology," "prostate," "prolapse(d)," "faecal," "bowel," "anal," "quality of life," "sexual," "geriatric," "paediatric," "satisfaction," "symptom bother," "goal attainment", "screener," and "generic." Questionnaires evaluated in this chapter were updated with any new information if new validation work was found. New questionnaires not in the previously updated resource tool were added to appropriate sections if they were validated and relevant with regard to the search terms specified above. Grades were evaluated for correctness, based on previous and new validation work, and modified if and when necessary to demonstrate any changes with respect to instrument validation.

II.THE MEASUREMENT OF PATIENT-REPORTED OUTCOMES (PROS) OF INCONTINENCE, OTHER LOWER URINARY TRACT SYMPTOMS, AND BOWEL PROBLEMS

Incontinence and other lower urinary tract symptoms (LUTS) as well as bowel problems and their impact on patients and their lives can be assessed in a number of ways. Traditionally, the clinical history has been used to gain a summary view of the symptoms experienced by patients and in some cases the impact on their lives. Increasingly however, patient-completed methods of measuring incontinence and LUTS are being used, including voiding diaries and questionnaires.

Patient self-completed questionnaires or patient reported outcomes (PROs) represent the most important clinical review of symptom impact and treatment benefit from a patient perspective. PROs provide a method for the standardised collection of data, or an objective assessment of subjective phenomena, from patients relating to incontinence, other LUTS, and bowel problems. Clinicians' assessments of patients' outcomes have often been shown to underestimate the degree of bother perceived by patients, and to focus on issues of lesser importance to patients [10].

1. PRO QUESTIONNAIRE DEVELOPMENT AND VALIDATION

PRO questionnaires can be used to record the presence and severity of urinary and bowel symptoms,

as well as the impact of symptoms on everyday activities and health-related quality of life (HRQL) and satisfaction with treatment, etc. To ensure that the results obtained with PROs are clinically useful, data must be gathered using valid and reliable instruments. Questionnaire design and development is not a simple process. Developing such instruments requires a multistep, structured process that incorporates cognitive psychology, psychometric theory, and patient and clinician input. The process begins by determining the intent and purpose of the PRO and culminates in studies that demonstrate the measure's validity, reliability, and responsiveness. The specific steps required for developing a PRO questionnaire are outlined in the following section and are shown in **Figure 2**.

The development of a PRO is a rigorous, scientific process to provide confidence that the PRO is measuring what it is intended to measure, that it does this reliably, and is appropriate for use in the patient or population group under investigation. The final instrument must have demonstrated validity and reliability in the intended target population. PROs need to be developed with patient and clinician input and have the psychometric, or measurement, properties of the PRO evaluated to determine that it is a valid outcome measure. To be a useful measurement tool, a PRO instrument must also be easy to administer, reliable, and valid. Only PROs that have undergone this process and have published validation data are discussed in this chapter.

Food & Drug Administration [1]. Guidance for industry - patient-reported outcome measures: Use in medical product development to support labelling claims. Silver Spring, MD: FDA; 2009.

a) Determining Questionnaire Intent and Purpose

The first task in developing a PRO measure is to determine why the instrument is needed. Given the current number of disease-specific questionnaires available in the field of incontinence and related pelvic disorders, a new PRO measure must fill a need that has not already been met by an existing instrument. Once the need for the measure is recognised, its purpose and clinical usefulness need to be considered because the purpose dictates the validation design process. For example, a symptom- and a treatment-satisfaction measure would be developed and validated differently because the outcome is different.

The development stage would focus on the outcome of interest (e.g., symptoms patients experience and the significance of each symptom, or what issues patients consider when determining how satisfied they are with treatment) with the items derived from the patient perspective and relating to the outcome

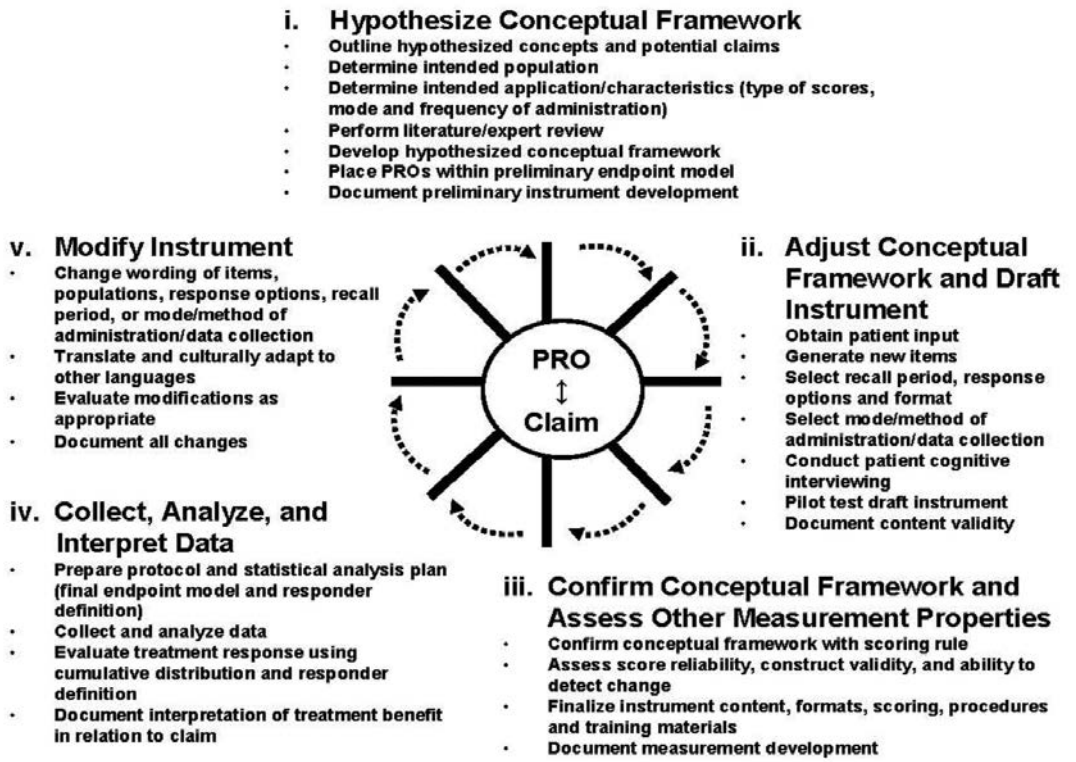

Figure 2. The development of a patient reported outcome is a multistep process

of interest. Validation efforts would include designing a study focused on the outcome of interest with the appropriate patient inclusion/exclusion criteria to enhance generalisability while maintaining internal consistency and providing opportunities to test—at a minimum—reliability and validity.

b) Developing the Items

Designing a clinically useful PRO measure involves more than just developing a series of questions. In addition to clinician input and literature review, questionnaire items must be generated from a patient perspective and include the patient voice. This is obtained through focus groups or one-on-one interviews to provide qualitative data on issues pertinent to patients and to identify the words patients use to describe their symptoms or disease impact. Focus groups and one-on-one interviews should be carefully planned to address the goals of the questionnaire being developed. For example, if a measure is intended to assess symptom bother, interview questions should pertain to the patient's symptom experience. Importantly, rather than using clinical terminology which patients may not comprehend, the words used during the focus groups or interviews should be common to patients. The results of the qualitative patient interviews lead to item generation. After items are generated, the newly drafted questionnaire should be reviewed by other patients and experts to ensure its readability and content validity.

An alternative approach to questionnaire development is to adapt an existing measure to meet the needs of the desired questionnaire. Patients need to be involved in the questionnaire adaptation to ensure that the revised measure is pertinent to the population of interest. The adapted questionnaire must be validated on its own in the target population as the validity of the original questionnaire does not apply to an adapted measure.

For newly developed and adapted questionnaires, think-out-loud interviews or cognitive interviews should be used to ascertain the correctness and validity of the revised questionnaire. In a think-out-loud interview, patients are asked to review a question and describe what they are thinking as they cognitively process the question; the patients think out loud about what the question means to them and how they think through their response to the question. For a cognitive interview approach, patients review and respond to the questionnaire items, and then they are interviewed about what each item meant to them as they completed the questionnaire. Both approaches provide information about what patients consider when responding to each question.

c) Determining the Mode of Administration of a Questionnaire

When generating the PRO items, the mode of administration must be considered. Will the measure be completed by the patient (i.e., self-administered) or administered by an interviewer (i.e., interviewer-administered)? How the questionnaire will be completed needs to be determined before the validation stage because mode of administration can affect patient responses. For highly personal or intimate questions, a self-administered questionnaire is recommended to avoid response bias. Questionnaires that are self-administered are preferable to interviewer-administered questionnaires because the data collection burden is reduced and patients are more likely to provide unbiased information on self-administered questionnaires. Importantly, if a questionnaire has been validated for a particular mode of administration (self-administered pen and paper), this does not make the questionnaire valid for all modes of administration (e.g. electronic administration via web or hand held device). Should the mode of administration change from the original validation, processes must be undertaken to ensure no change in meaning or content have occurred with the format change. Guidelines for this type of adaptation are clearly outlined by Coons et al (2009) [11].

d) Questionnaires' Psychometric Properties

All PRO measures must demonstrate reliability, validity, and responsiveness, which are described in detail below. This can be accomplished in several ways:

(1) Perform a stand-alone cross-sectional study to validate the questionnaire in the patient population for which it was designed;

(2) Administer the untested questionnaire in a clinical study and use the baseline data to perform psychometric validation (the end-of-study data can also be used to evaluate responsiveness); or

(3) Perform a stand-alone longitudinal study with an intervention to determine the instrument's psychometric performance and responsiveness in a non-clinical trial setting.

The following psychometric properties must be tested for and demonstrated in a validated questionnaire.

Reliability refers to the ability of a measure to produce similar results when assessments are repeated (i.e., is the measure reproducible?). Reliability is critical to ensure that change detected by the measure is due to the treatment or intervention and not due to measurement error [12]. One measure of reliability is the questionnaire's internal consistency, which indicates how well individual items within the same domain (or subscale) correlate. Cronbach's alpha coefficient is used to assess internal consistency reliability, with higher alphas indicating greater correlation. Typically, Cronbach's alpha should be greater than 0.70 to indicate good internal consistency reliability [12, 13]. If the item-to-total alpha is less than 0.20, the question should be removed or rewritten.

T**est-retest reliability**, or **reproducibility**, indicates how well results can be reproduced with repeated

testing. To assess test-retest reliability, the same patient completes the questionnaire more than once, at baseline and again after a period of time during which the impact of symptoms is unlikely to change (e.g., a few days or weeks) [12, 13]. The Spearman's correlation coefficient and intraclass correlation coefficient are used to demonstrate reproducibility. For group data, a Spearman's correlation coefficient or an intraclass correlation coefficient of at least 0.70 demonstrate good test-retest reliability [12, 13].

Interrater reliability indicates how well scores correlate when a measure is administered by different interviewers or when multiple observers rate the same phenomenon [12]. Demonstration of interrater reliability is not necessary for self-administered questionnaires but is necessary for instruments based on observer ratings or using multiple interviewers. A correlation of 0.80 or higher between raters indicates good interrater reliability [12].

Validity refers to the ability of an instrument to measure what it was intended to measure [12, 13]. A measure should be validated for each specific condition or outcome for which it will be used. For example a measure designed to assess stress incontinence would not be valid for OAB unless it were specifically validated in patients with OAB symptoms.

Content validity, convergent validity, discriminant validity and **criterion validity** typically are required to validate a questionnaire [12, 13]. Content validity is a qualitative assessment of whether the questionnaire captures the range of the concept it is intended to measure [12, 13]. For example, does a measure of symptom severity capture all the symptoms that patients with a particular condition have, and if so, is the measure capturing the items in a manner meaningful to patients in language patients can understand? To obtain content validity, patients review the measure and provide feedback as to whether the questions are clear, unambiguous, and comprehensive.

Convergent validity is a quantitative assessment of whether the questionnaire measures the theoretical construct it was intended to measure [12, 13]. Convergent validity indicates whether a questionnaire has stronger relationships with similar concepts or variables. Stronger relationships should be seen with the most closely related constructs and weaker relationships seen with less-related constructs [12, 13].

Discriminant validity indicates whether the questionnaire can differentiate between known patient groups (e.g., those with mild, moderate, or severe disease) [12, 13]. Generally, measures that are highly discriminative are also highly responsive.

Criterion validity reflects the correlation between the new questionnaire and an accepted reference, or gold standard [12, 14]. One difficulty in establishing criterion validity is that a gold-standard measure might not be available [12, 14]. When criterion validity can be established with an existing measure, the correlation should be 0.40 to 0.70; correlations approaching 1.0 indicate that the new questionnaire may be too similar to the gold-standard measure and therefore redundant [12, 14].

Responsiveness indicates whether the measure can detect change (for better or worse) in a patient's condition [15]. An aspect of responsiveness is determining not only whether the measure detects change but whether the change is meaningful to the patient. This can be done by determining the minimal important difference (MID) of the measure. The MID is the smallest change in a PRO questionnaire score that would be considered meaningful or important to a patient [16]. A treatment that is statistically significantly better than another may not necessarily have made a meaningful difference to the patient; the MID indicates whether the treatment made such a difference from a patient perspective.

Unfortunately, there is no scientific test for MID as it is an iterative process that involves two methodologies to determine the MID of a questionnaire: an anchor-based approach and a distribution-based approach [17, 18]. With the anchor-based approach, the MID is determined by comparing the measure to other measures (or "anchors") that have clinical relevance [17]. With the distribution-based approach, the MID can be determined by the statistical distributions of the data [17], using analyses such as effect size, one-half standard deviation, and standard error of measurement [17-19].

Another methodology to evaluate treatment benefit is to examine the cumulative distribution function (CDF) of responses between treatment groups. The CDF provides plots to examine the treatment effect and mean improvements by treatment group to see if the mean improvement varies by patient subsets [1, 19].

e) Linguistic and Cultural Validation

Increasingly, PRO questionnaires are required to be used in a number of different populations and settings, however, questionnaires and their psychometric properties are not necessarily transferable [20, 21]. A measure that is valid and reliable for a particular language and culture may not prove to be so after translation. Linguistic and cultural adaptation of a questionnaire can occur during the development phase before validation, or it can be done after the questionnaire is validated in the language in which it was initially developed, with the latter being the more common approach. Ensuring the linguistic and cultural validity of a questionnaire is especially important for measures used in multinational clinical trials [20, 21].

The principal steps in adapting a measure for different languages and cultures are as follows:

(1) two forward translations of the original instrument into the new language;

(2) quality-control procedures that may include a backward translation (translating the instrument back into the original language) [21];

(3) adjudication of all translated versions;

(4) discussion by an expert panel to ensure clarity of the translated questionnaire; and

(5) testing the translated instrument in monolingual or bilingual patients to ensure that it measures the same concepts as the original instrument [21, 22].

However, if a backward translation of the measure does not produce a semantically equivalent instrument, then the instrument may need to be developed in the target language, rather than just translated [21].

After cultural and linguistic validation, PROs should also be psychometrically validated within the target language. Thus, reliability, validity, and responsiveness need to be assessed with each language translation to confirm the same measurement properties are present in the translated language(s) to ensure psychometric equivalence. If psychometric equivalence is not present (e.g., not achieving similar or better results in new language translation), the cultural and linguistic translations need to be re-evaluated and perhaps a new instrument may need to be developed.

The ICIQ questionnaires and many of the other questionnaires discussed in this chapter have multiple linguistically validated versions making them useful for International implementation. It is also important to note that the step after linguistic validation, demonstrating psychometric equivalence, should also be demonstrated to ensure that the PRO performs equivalently in different languages and cultures (e.g., Coyne et al. 2008 [23]).

f) Regulatory Oversight

As clinicians and scientists have begun to appreciate and accept PROs as appropriate outcome measures, regulatory authorities have issued guidance documents on current best practices in the development and implementation of PRO in clinical trial settings [1, 24, 25]. For PROs to be acceptable outcome measures for regulatory authorities, documentation of measurement properties must be present as well as evidence of inclusion of the patient perspective and understanding of the PRO and a cohesive conceptual framework that stipulates how the PRO is related to the intervention. While PROs within this document may have a "recommended" status, they may not meet all of the required regulatory guidelines and may require additional validation work either from a qualitative or quantitative perspective. It is strongly suggested that regulatory authorities be contacted early in the process of selecting a PRO for clinical trials to ensure regulatory acceptance of the PRO.

g) Questionnaire Development - A Conclusion

PROs are the most suitable method for assessing the patient's perspective of their lower urinary tract, vaginal and bowel symptoms [26]. Questionnaires may be long and detailed for use in research, but need to be short and easy to use to be relevant for clinical practice. In addition to being valid and reliable, they need to be easy to complete, and, if they are being used to measure outcome, sensitive to change. Developing a new questionnaire and testing it thoroughly takes a great deal of time and is only necessary if there is not an existing instrument available.

There are many questionnaires currently available for use and these have been reviewed and described with recommendations from the Committee for their use in the last three ICI reports.

The major purpose of the ICI has been to provide a definitive international review and consultative opinion regarding the recommended measures to assess patient reported outcomes within the area of urinary incontinence and LUTS. To this end since the First Consultation, the ICI has worked to develop a modular format for the various patient reported outcomes allowing clinicians and researchers to select internationally recommended questionnaires for the assessment of their patients in both clinical practice and clinical trials. In this fifth ICI review, the ICIQ modular questionnaires (supported by the International Consultation) are presented in detail and their use evaluated. Whilst some of the modular questionnaires are still currently under full evaluation their content and format are presented within this chapter.

III. RECOMMENDED PRO QUESTIONNAIRES

Grades of Recommendation for Questionnaires 2012

As with previous Consultations, the Committee continues to use three grades of recommendation. However, we have added a + sign to indicate when published content validity is available for an instrument:

- Questionnaires were 'highly recommended' and given a **Grade A** if the Committee found "Published data indicating that the questionnaire is valid, reliable and responsive to change following standard psychometric testing. Evidence must be published on all three aspects and questionnaires must be relevant for use with persons with incontinence. **Grade A + indicates there is additional evidence of *published* content validity."**
- Questionnaires were "recommended" and given a **Grade B** if the Committee found "Published data

indicating that the questionnaire is valid and reliable following standard psychometric testing. Evidence must be published on two of the three main aspects (usually validity and reliability). **Grade B + indicates there is additional evidence of *published* content validity."**

- Questionnaires were considered to have "potential" and given **Grade C** if the Committee found "Published data (including abstracts) indicating that the questionnaire is valid or reliable or responsive to change following standard psychometric testing. **Grade C + indicates there is additional evidence of *published* content validity."**

The Committee decided that evidence published in abstracts or posters could be used to indicate a developing questionnaire's potential, but was not sufficiently peer-reviewed to provide the basis for a stronger recommendation.

As decided in the Fourth Consultation the recommendation will be to preferably utilise questionnaires from the ICIQ modules described in detail below. Many, but not all, of these questionnaires are Grade A or A+ questionnaires by previously stipulated criteria. Within the description of the ICIQ modules below the grade assigned to each module is indicated.

Should none of the modular questionnaires be deemed appropriate for specific research or clinical purposes, ICI's recommendation is to use a Grade A+ or A questionnaire as previously recommended. When no suitable instrument exists a Grade B or C questionnaire, performing additional validation as indicated prior to use if feasible, should be used.

For UI and UI/LUTS, the Committee examined the quality of the psychometric evidence. Only where published data were scientifically sound was the label 'with rigor' allowed. Where the Committee had concerns about the quality of evidence, this is noted in the descriptions of the questionnaires below. The Committee considered that the number of high quality questionnaires means that there are now sufficient questionnaires for most purposes and it is not necessary to encourage the development of new questionnaires, except for particular patient groups (see below).

IV. INTERNATIONAL CONSULTATION ON INCONTINENCE MODULAR QUESTIONNAIRE (ICIQ): WHAT IS THE ICIQ?

The ICIQ modular questionnaire was developed to meet the need for a universally applicable standard guide for the selection of questionnaires for use in clinical practice and clinical research [27, 28]. The decision to develop standard questionnaire modules was taken by the Committee after the first ICI meeting in 1998, and resulted in the development of the ICIQ core questionnaire discussed in this section. It was recognised at that time that there were many good validated questionnaires each developed for a specific purpose and each subtly different. Although developers of the questionnaires were familiar with their content and use, the increasing number of questionnaires made appropriate selection difficult and limited the ability to compare similar clinical and research data due to different data collection methods.

An international advisory board was established to continue the development of the modular ICI questionnaire outside the limits imposed by triennial convening of the ICI Committee. Early discussions with the advisory board resulted in the decision to expand the concept to include wider urinary symptoms, bowel symptoms and vaginal symptoms. The advisory board consisted of clinicians and researchers with experience in the design and use of questionnaires representing the major societies involved in the assessment and research of lower genital tract, lower urinary tract and bowel function. The members of the advisory board of the ICI can be seen on the ICIQ website at www.iciq.net. The ICIQ modular questionnaire was then established. Researchers who have developed questionnaires that they would like to be reviewed by the advisory board for inclusion should send the questionnaires and relevant publications to www.iciq.net. The project is a series of living documents that will be continually updated.

1. AIMS AND OBJECTIVES

The ICIQ's objective is to provide international consensus on the use of patient completed questionnaires for the assessment of lower pelvic symptoms and their impact on patient's lives. Three aims underpin the ICIQ in order to achieve clarity over questionnaire use:

- To recommend high quality self-completion questionnaires according to evidence of validation as stipulated by the three prior ICI Committees;
- To promote wider use of questionnaires to standardise assessment of lower urinary tract and pelvic dysfunction and its impact on patients' lives, in order to;
- Facilitate communication in different patient settings and different patient groups both in clinical practice and wider clinical research.

The ICIQ recognised that many high quality published questionnaires already existed and, with permission from the authors, those instruments were adopted into the modular project. It was not possible to adopt all available questionnaires and where more than one option existed, the most appropriate questionnaire for the purpose was included. Where high quality questionnaires were not available, the need to develop a new questionnaire/s was acknowledged. Collaborative efforts to develop new questionnaires are welcome and encouraged.

The ICIQ's international nature requires that linguistically validated translations are available. More than 50 language versions of various modules have been validated to date, conducted according to established protocol.

Fourteen ICIQ modules/questionnaires are currently available for use, with further modules in development (discussed in detail below). Clinicians or researchers are able to select module(s) to meet the particular requirements of their study or clinical practice. In order to simplify this selection process, modules have been categorised as shown in **Table 1**. It must be stressed that although multiple questionnaires can and probably should be used they must be used in the format in which they were originally designed and the questionnaires cannot be merged together.

In recent years, increasing advances have been made in the area of electronic documentation, particularly with regard to patient care. It is recognised that questionnaires requiring written completion by hand may lack versatility and therefore prevent uptake of the ICIQ, hampering

Table 1. The ICIQ Modular Structure

	CONDITION	RECOMMENDED MODULES	OPTIONAL MODULES	RECOMMENDED ADD-ON MODULES			
		Symptoms		HRQL	Generic HRGL	Sexual Matters	Post-treatment
Core modules	Urinary symptoms	Males: ICIQ-MLUTS Females: ICIQ-FLUTS	Males: ICIQ-MLUTS LF Females: ICIQ-FLUTS LF	ICIQ-LUTSqol	SF-12	Males: ICIQ-MLUTSsex Females: ICIQ-FLUTSsex	ICIQ-Satisfaction*
	Vaginal symptoms and sexual matters	ICIQ-VS		ICIQ-VSqol*	SF-12		
	Bowel symptoms and quality of life	ICIQ-B			SF-12	Males: ICIQ-Bsex* Females: ICIQ-Bsex*	
	Urinary Incontinence	ICIQ-UI Short Form	ICIQ-UI LF*	ICIQ-LUTSqol	SF-12	Males: ICIQ-MLUTSsex Females: ICIQ-FLUTSsex	
	CONDITION	B) Specific patient groups		HRQL	Generic HRQL	Sexual Matters	Post-treatment
Specific patient groups	Nocturia	ICIQ-N		ICIQ-Nqol	SF-12	Males: ICIQ-MLUTSsex Females: ICIQ-FLUTSsex	ICIQ-Satisfaction*
	Overactive Bladder	ICIQ-OAB		ICIQ-OABqol	SF-12	Males: ICIQ-MLUTSsex Females: ICIQ-FLUTSsex	
	Neurogenic	ICIQ-Spinal Cord Disease*			SF-12		
	Long-term catheter users	ICIQ-LTC*			SF-12		
	Children	ICIQ-CLUTS*		ICIQ-CLUTS qol*			

Gray: In development; black: Grade A

attempts to promote standardisation of evaluation. Evaluations of electronic ICIQ modules are currently underway. Cognitive interviewing is being conducted among the potential populations of interest to ensure the appropriateness of these formats, for example, adults with varied lower urinary tract symptoms [11]. Quantitative comparison studies of equivalence are also planned to ensure the robustness of their measurement capabilities is not compromised.

In this chapter, questionnaires forming part of the ICIQ modular format are referred to as those preferred for usage. Although many of the modules are Grade A or A+ questionnaires, others are still under various phases of development and are graded appropriately. Questionnaires that are in early stages of development and have yet to reach Grade C are described as "in development". Where an ICIQ module is not available it is recommended that a Grade A or B or C questionnaire is used.

2. ICIQ MODULES

a) Core Modules

Questionnaires to assess the core symptoms and impact on health related quality of life (HRQL) of lower pelvic dysfunction are contained in this section, in addition to impact on sexual matters. Core modules (**Table 2**) provide evaluation of:

- Lower urinary tract symptoms
- Urinary incontinence
- Vaginal symptoms
- Bowel symptoms

Each symptom module is intended for the comprehensive yet succinct measurement of symptoms and associated 'bother'. The bother item attached to each symptom enables the individual to indicate areas that cause the greatest negative impact on HRQL as perceived by them. This can be a more sensitive indicator of treatment goals than frequency of symptoms alone. The HRQL questionnaires cover specific issues that are a consequence of symptoms, such as life limitations and emotional impact.

b) Specific Patient Group Modules

Questionnaires to assess specific conditions or symptom complexes such as nocturia and overactive bladder are contained in this section along with HRQL modules for these specific symptom complexes. This category also includes specific patient groups, for example, children. These instruments contain only question items characteristic of the symptom complex or have been developed specifically for use in a diverse group making the items/questionnaire only utilisable in that population.

- Nocturia
- Overactive bladder
- Patients with spinal cord disease
- Patients using long term catheters
- Lower urinary tract symptoms in children

c) Optional Modules

This category lies within the core symptoms and includes lengthier questionnaires for more in-depth (maybe in-depth evaluation is more accurate) evaluation of lower pelvic dysfunction. Whilst these questionnaires are suitable for use in clinical practice, they have not been shortened for clinical efficiency and are therefore more widely used in research studies where exploration of broader associated symptoms may be desired.

- Lower urinary tract symptoms
- Urinary incontinence

d) Post-treatment Module

The ICIQ module for post-treatment satisfaction is in the early stages of development. Assessment of a patient's satisfaction with treatment (behavioural, surgical or medication) provides information on treatment impact on their condition and life and includes their perception of effectiveness, tolerability and convenience. It is not yet clear if satisfaction following treatment can be characterised by a set of common question items that are applicable to all lower pelvic health conditions. As with HRQL, there are generic and disease specific questionnaires that assess satisfaction. Ongoing studies will provide further evidence on which to make suggestions regarding post treatment evaluation but it is likely that this will encompass both generic and condition specific measures. Ultimately, the development of post treatment modules will also rely on advice from regulatory authorities (e.g. FDA, EMA) to ensure that measures capture a recognised multidimensionality of satisfaction.

3. GUIDANCE FOR USE OF THE ICIQ

The ICIQ recommends the use of a symptom and HRQL module that match the intended purpose of a study in order to provide a comprehensive evaluation of these two perspectives. The extent of burden placed on the respondent and the study or clinical outcomes must be considered however and ultimately guide questionnaire selection. The characteristics of each module are summarised below, although more extensive information can be found on the project website, www.iciq.net. Modules currently under development are summarised in **Table 3**.

Table 2. ICIQ Module Description

Name	Scope of assessment	Domains	Items	Grade
ICIQ-MLUTS [29] (ICS*male*SF)	Male lower urinary tract symptoms and associated bother.	• Voiding • Incontinence • Individual items evaluating frequency and nocturia	13	A
ICIQ-FLUTS [30] (BFLUTS SF)	Female lower urinary tract symptoms and associated bother.	• Filling • Voiding • Incontinence	12	A
ICIQ-VS [31]	Vaginal symptoms including prolapsed and associated bother.	• Vaginal symptoms • Sexual matters • Quality of life	14	A
ICIQ-B [32, 33]	Bowel symptoms including anal incontinence and associated bother	• Bowel pattern • Bowel control • Quality of life	21	A+
ICIQ-UI Short Form [28]	Urinary incontinence.	• Urinary incontinence frequency, overall interference • Perceived cause of incontinence	4	A
ICIQ-LUTSqol[4, 34] (King'sHealth Questionnaire))	HRQL issues associated with urinary symptoms and associated bother.	• Life restrictions • Emotional aspects • Preventive measures	22	A+
ICIQ-MLUTSsex[35] (ICS*male*)	Male sexual matters associated with urinary symptoms and associated bother.	• Erection and ejaculation issues • Overall interference	4	A
ICIQ-FLUTSsex[36] (BFLUTS)	Female sexual matters associated with urinary symptoms and related bother.	• Pain and leakage with sexual intercourse • Overall interference	4	A
ICIQ-FLUTS Long Form (BFLUTS)	Detailed assessment of female lower urinary tract symptoms and associated bother.	• Varied lower urinary tract symptoms	18	A
ICIQ-MLUTS Long Form (ICS*male*)	Detailed assessment of male lower urinary tract symptoms and associated bother.	• Varied lower urinary tract symptoms	23	A
ICIQ-N	Comprehensive assessment of symptoms of nocturia and associated bother.	• Frequency • Nocturia.	2	A
ICIQ-OAB	Comprehensive assessment of symptoms of overactive bladder and associated bother.	• Frequency • Nocturia • Urgency • Urgency incontinence	4	A
ICIQ-OABqol (OAB-q) [5]	Detailed assessment of health-related quality of life issues associated with overactive bladder.	• Coping • Concern/Worry • Sleep • Social Interaction	25	A
ICIQ-Nqol (NQOL) [37, 38]	Detailed assessment of HRQL issues associated with nocturia.	• Issues associated with sleep disturbance • Life restrictions • Preventive measures	13	A+

Table 3. ICIQ Description of modules in Development.

Name	Purpose	Current status
ICIQ-CLUTS [39]	Assessment of urinary symptoms in children.	Validitytesting published awaiting reliability and responsiveness evaluation.
ICIQ-LTCqol	Assessment of HRQL associated with long term catheter use	Validity and reliability underway but yet to be published. Requires responsiveness evaluation.
ICIQ-Bladder diary [40]	Daily diary regarding bladder pattern including frequency, volume, intake and incontinence episodes.	Validity and reliability established. Requires responsiveness evaluation.
ICIQ-Spinal cord disease	Assessment of urinary symptoms and impact on HRQL associated with specific management **devices** and related bother.	Initial qualitative development completed. Requires quantitative evaluation.
ICIQ-VSqol	Detailed assessment of HRQL issues associated with vaginalsymptoms and related bother.	Initial qualitative development completed. Quantitative evaluation underway.
ICIQ-Satisfaction	Generic assessment of post-treatment satisfaction for lower pelvic dysfunction including surgical and conservative intervention.	Initial qualitative development completed. Quantitative evaluation underway.
eICIQ	Evaluation of altered administration of ICIQ modules.	Initial qualitative evaluation completed. Quantitative evaluation of psychometric equivalence underway.

4. ICIQ QUESTIONNAIRE IMPLEMENTATION

The ICIQ modular questionnaire has attracted considerable attention from both clinicians and researchers worldwide since its structure was finalised in 2004. More than 1200 requests for use of the various modules have been documented and over 180 published studies were identified up to March 2012. The most widely applied module is the ICIQ-UI Short Form, particularly to evaluate female urinary incontinence. Reports on further validation and translations of the ICIQ and related educational projects are growing in number. This is essential in order to achieve standardised evaluation of pelvic floor dysfunction, which is a primary aim of the initiative.

The ICIQ has also been applied to clinical and general practice settings, and has been adopted in national guidelines for the management of urinary incontinence in primary care by the Scottish Intercollegiate Guidelines Network (www.sign.ac.uk/pdf/sign79.pdf) and in a primary care resource pack by the British Society of Urogynaecology.

5. CONCLUSION

The ICIQ modular questionnaire project (www.iciq.net) provides a series of standardized questionnaires for the patient reported assessment of lower pelvic dysfunction symptoms and their impact on patients lives. The ICIQ provides clarity over the selection of questionnaires by recommending only those with evidence of high quality and robust psychometric validation including validity, reliability and sensitivity to change. This assurance provides the user with confidence in the results obtained, which is important in clinical practice and research where treatment decisions or trial outcomes depend on this evidence. Increasing awareness of the ICIQ aims to promote increased use of standardised questionnaires, thereby facilitating communication between clinicians and researchers and enable more widespread comparisons between different treatments and patient groups worldwide. Collaboration with the ICIQ is encouraged among clinicians and researchers in order to conduct further evaluation and provide further translations of ICIQ modules.

V. PATIENT-REPORTED OUTCOME (PRO) QUESTIONNAIRES TO ASSESS THE IMPACT OF URINARY INCONTINENCE, OAB AND LOWER URINARY TRACT SYMPTOMS

There are a variety of PRO measures available for use in clinical practice and research that assess a range of concepts (e.g. HRQL, patient satisfaction, symptom bother, etc). This section and table series at the end of the chapter provides an overview and assessment of those measures. Importantly, clinical practitioners and researchers need to clearly determine their clinical and research objectives before selecting a PRO as it is these objectives and the target patient population that will help determine which validated PRO is appropriate to use. **Appendixed Tables 4 through 8** provide a brief overview of all current PRO measures for urinary incontinence and LUTS, their purpose, psychometric properties, translation availability, and recommended ICI grade.

Please note, as instrument development and validation is an ongoing process, the tables below contain publications through August, 2011. As additional work may have been performed on an in-

strument, it is always prudent to conduct a further literature search and/or contact the instrument developer prior to selecting an outcome measure for your clinical practice or study.

One trend that has become more apparent since the previous Consultations is the modification of more established urinary incontinence questionnaires for use in selected patient groups (e.g., pelvic organ prolapse; males; different cultural/language groups). When using a questionnaire in a patient group other than the group in which it was initially developed, cognitive interviews with the new patient population should be held to review the applicability of the questionnaire to the new patient group. Several of the main questionnaires to be discussed below have now had modified versions published in the literature. The Committee's view is that although it may be appropriate to modify established questionnaires for use with some populations, it is advisable to keep such modifications to a minimum, and to use the original versions whenever possible. Any modifications of established questionnaires may result in changes (sometimes substantial) in the psychometric performance of the instrument, and thus all modified instruments should be subjected to the same psychometric testing as that employed in developing a completely new instrument. Specifically, modified instruments should report information regarding the instrument's construct validity, reliability, and test-retest reliability, at a minimum, and sensitivity to change, in intervention studies.

For some of the more widely used instruments listed below, several modified, shortened versions have been published. Information regarding the modified versions is provided under the original source versions of the questionnaires, but the modified versions are evaluated and graded separately, based on the available information regarding their psychometric properties and performance.

1. HEALTH-RELATED QUALITY OF LIFE MEASURES

Health-related quality of life (HRQL) measures help to assess the impact of disease and treatment on those aspects of quality of life related to health. UI is a symptomatic condition that has been shown to affect many aspects of a patient's life - physical, emotional, and social relations and cause concern and burden. As such, it is important to assess HRQL in clinical research and practice. **Appendixed Table 4** at the end of the chapter provides a quick overview of the variety of HRQL measures available and their validity and characteristics to determine which measure is suitable for your objectives.

2. PATIENT SATISFACTION AND GOAL ATTAINMENT SCALING

Patient satisfaction and Goal Attainment Scaling are two important but separate types of PROs that allow for individualised assessment of disease impact and treatment. Patient satisfaction is the subjective, individual evaluation of treatment effectiveness and/or the service provided by the healthcare system. Goal attainment scaling (GAS) is a method developed to ascertain individual patient treatment goals and using those to facilitate patient-provider interaction and tailor the treatment plan based on those individual's goals [41].

Measures of patient satisfaction can include evaluation of accessibility/convenience, availability of resources, continuity of care, efficacy, finances, humaneness, information gathering and giving processes, pleasantness of surroundings and perceived quality/competence of health care personnel [42]. At its most basic level, satisfaction is a comprehensive evaluation of several dimensions of health care based on patient expectations and provider and treatment performance. As an outcomes measure, patient satisfaction allows health care providers to assess the appropriateness of treatment according to patient expectations. In chronic diseases, where patients must live with treatment, patient satisfaction may be the distinguishing outcome among treatments with comparable efficacy [43].

Two patient satisfaction methods of promise with Grade B criteria are the BSW and OAB-S [44, 45]. Generally responsiveness cannot be assessed as there is no baseline assessment of patient satisfaction with treatment as no treatment has been given. **Appendixed Table 5** at the end of the chapter presents a summary of satisfaction instruments identified in UI, OAB and other LUTS.

GAS has been used to measure clinically important change in several therapeutic areas. Although it was originally developed to assess health outcomes in mental health settings, it has recently been expanded to include evaluations in urogynecology[46-50]. GAS has been linked to several possible benefits compared with traditional outcome measures, such as improved clarity concerning treatment objectives for both the healthcare provider and the patient, active involvement of the patient in problem-solving efforts, establishment of realistic patient and healthcare provider expectations of treatment, and increased motivation of patients toward improving their health condition [41]. The end result of GAS is to clarify patients' expectations for their treatment, document goal achievement, and eventually increase patient satisfaction and improve therapeutic outcomes.

One GAS instrument for lower urinary tract symptoms has been well-developed, the Self Assessment Goal Attainment (SAGA) questionnaire. The development and pilot testing of the SAGA questionnaire has been published [46]. SAGA was developed in 3 phases: (1) a preparatory phase in which preliminary information on goal setting and attainment was gathered; (2) a goal elicitation phase that included qualitative interviews with 41 patients with OAB symptoms and/or other LUTS; and (3) cog-

nitive debriefing interviews during which the draft questionnaire was administered to 11 patients with OAB and/or other LUTS. Numerous linguistically validated translations are available at: http://www.pfizerpatientreportedoutcomes.com [51].

3. SCREENING TOOLS

In order to improve the detection of incontinence, OAB and other LUTS, several screening tools have been developed (**Appendixed Table 6**). These tools help patients self-describe symptoms and facilitate diagnosis of LUTS by the clinician. Only the B-SAQ has been designed to screen for general lower urinary tract symptoms (LUTS) rather than solely symptoms of one condition. The majority of patients with LUTS have mixed urinary symptoms, and therefore a questionnaire which can detect more than one symptom complex may be more functional as a screening tool in clinical practice than a highly specific questionnaire. The Leiscester Impact Scale (LIS), OAB-V8, OAB-SS and QUID are all Grade A, short, simple to understand and complete, and easy to interpret. However the LIS is interviewer, not patient administered. Importantly, with screeners, responsiveness is not assessed, however the sensitivity and specificity of each tool is critical.

4. ASSESSING SYMPTOM BOTHER AND OVERALL BOTHER

Measures that can be used to assess how bothered patients are by urinary symptoms are included in **Appendixed Table 7**. The Patient Perception of Bladder Condition [52] and the Urogenital Distress Inventory are the only Grade A recommend instrument.There are several Grade B and C measures which assess bother for incontinence and LUTS.

5. ASSESSING THE IMPACT OF URGENCY

Several instruments have been developed specifically to assess urinary urgency, which is defined by the International Continence Society as “the complaint of a sudden compelling desire to pass urine which is difficult to defer”[53]. Urgency is the hallmark symptom of OAB [54], thus assessing the effect of treatment on this symptom and its impact on HRQL is important. With any measure designed to evaluate urgency, patients must be able to distinguish between the normal desire to urinate (urge) and the difficult-to-postpone need to urinate (urgency) [55, 56]. Wording thus becomes critical in the development of urgency assessment measures. Chapple and Wein[57] make a case for describing urgency as a “compelling desire to void in which patients fear leakage of urine” as a means of distinguishing this abnormal sensation from the normal need to void. However, some patients may have a sensation of urgency without fear of leakage, further complicating attempts to define urgency. Importantly, with some of these scales, patients have the option of indicating that they experienced UUI (an event) rather than the strongest feeling of urgency (a sensation) itself. Several instruments have been developed to assess urinary urgency these are summarised in **Appendixed Table 8**.

VI.QUESTIONNAIRES TO ASSESS SYMPTOMS AND HEALTH-RELATED QUALITY OF LIFE IMPACT OF PELVIC ORGAN PROLAPSE

Many women with lower urinary tract and bowel symptoms have pelvic organ prolapse (POP). The clinical assessment, standardized measurement, conservative and surgical treatment of POP is covered in Chapters 5A and 15. Increasingly with new surgical techniques for the treatment of POP standardised objective and subjective assessments are required. This chapter will review the standardised symptom assessment tools for POP. These tools do not allow the clinical staging or planning of prolapse treatment, nor do they assess the correction of prolapse following conservative or surgical treatments. As with many of the other sections in this chapter, it is apparent that clinical conditions affect patients differently. Ultimately, the decision to seek and offer therapy for POP and the evaluation of its success will best be measured by the patient and not necessarily by the physician assessed clinical findings. Whilst not as advanced as the assessment tools to evaluate LUTS, there has been progress in the development of POP specific assessment tools since the last triennial ICI report.

It is important to remember that where specific problems of the patient with POP require assessment (e.g., lower urinary tract symptoms, sexual function) it may be preferable to use one of the questionnaires designed specifically for that purpose.

In general questionnaires for POP tend to focus more on the symptoms related to the lower bowel and prolapse probably because of the wider availability of questionnaires to assess LUTS. The broad three categories of instruments for POP are:

1. Presence of symptoms and their severity;

2. HRQL

3. sexual function.

As prolapse is almost always multidimensional, selecting questionnaires in the modular format of the ICIQ (see above) may well be preferable for many clinical and research applications

For POP, the Committee examined the quality of the psychometric evidence and only where published data were scientifically sound was the label ‘with rigor’ allowed. The Committee noted that this is a developing area and therefore three grades of recommendation were established (**Table 9**).

VII.QUESTIONNAIRES TO ASSESS SYMPTOMS AND HRQL IMPACT OF FAECAL INCONTINENCE

A range of PROs have been developed to identify the severity of anal (AI) or faecal incontinence (FI) and its impact on HRQL. By comparison with the last triennial review, questionnaires are now being incorporated into research trials on a more regular basis recognising the importance of capturing the patient's perspective. Less is reported regarding clinical assessment. Due to the close overlap between faecal incontinence and other pelvic floor disorders (in particular urinary incontinence), some of those questionnaires used for other pelvic disorders also include items to cover faecal incontinence. For similar reasons, items relating to faecal incontinence have often been included in questionnaires addressing general gastro-intestinal and colo-rectal function, as well as condition specific instruments in such areas as irritable bowel syndrome and inflammatory bowel disease, conditions which are commonplace in colorectal practice as well as in other specialties dealing with pelvic floor disorders [66, 67].It is also important to remember that the normal range of bowel function is broad, that bowel function may be highly variable within individuals without significant pathology. Consequently instruments in this field are likely to lack a degree of sensitivity or specificity for the specific bowel disorders such as IBS, IBD evacuation disorder and constipation.

Anal/faecal incontinence and bowel evacuation are intrinsically related to pelvic floor function and it may be inappropriate to consider bowel function purely in terms of continence and constipation. Evacuatory dysfunction may result from a variety of underlying pathologies including outlet obstruction, slow transit or other mechanical, pharmacological, metabolic, endocrine and neurogenic abnormalities [68]. Anal incontinence occurs in both sexes and it is unclear whether there is any difference between genders in terms of prevalence. Studies to date suggest that in different age groups prevalence varies, with unique risk factors attributable at these stages of life [69]. Symptoms are considered crucial to diagnosis as specific symptoms are thought to reflect the underlying pathophysiology [70]. Thus, urgency (the inability to defer defaecation) and urgency faecal incontinence are thought to indicate loss of voluntary control due to impaired external anal sphincter function, whereas passive faecalincontinence is thought to indicate impairment of the smooth muscle of the internal sphincter.

Table 9: Recommended questionnaires for the evaluation of symptoms and health-related quality of life impact of pelvic organ prolapse

Grade A (recommended)
Pelvic Floor Distress Inventory (PFDI) [58]
PelvicFloor Impact Questionnaire (PFIQ) [58]
Prolapse quality of life questionnaire P-QOL [59]
Grade B
The Australian Pelvic floor Questionnaire (APFQ) [60]
Pelvic floor symptom bother questionnaire (PFBQ) [61]
PelvicOrganProlapseUrinary incontinence Sexual questionnaire (PISQ) (PISQ-12) [62]
ICIQ vaginal symptoms questionnaire (ICIQ – VS) [62]
The electronic Personal Assessment Questionnaire – Pelvic Floor (ePAQ-PF) [63]
Grade C (with potential)
Pelvic Floor Dysfunction Questionnaire [64]
Danish Prolapse Questionnaire [65]

For AI/FI, the Committee examined the scope of available measures and quality of the psychometric evidence. While this remains a developing area, the publication of the ICIQ-B questionnaire for the assessment of anal incontinence and associated impact on quality of life means that a questionnaire is now available that reaches the highest level of recommendation, including the qualitative development phase [32, 33]. Further evaluation of existing measures such as the Faecal Incontinence Quality of Life index (FIQL) has also resulted in an improved grade of recommendation [71].

The grades of recommendation are as outlined in previous sections and below. **Table 10** summarises the questionnaires reviewed and grades of recommendation accordingly.

Appendixed **Tables 11 through 13** at the end of the chapter provide details of the specific psychometric properties and development of each questionnaire.

VIII. QUESTIONNAIRES TO ASSESS SEXUAL FUNCTION/SEXUAL HEALTH AND URINARY SYMPTOMS

Sexual function may be regarded as a dimension or aspect of overall HRQL, for which a number of dimension-specific measures have been developed and validated. There is a wide choice of available instruments, the selection of which will depend on the clinical or research setting where the instrument is to be employed. Established and widely used measures that have been shown to be valid, reliable and responsive are clearly desirable, however the feasibility and appropriateness of using a particular instrument in a particular setting must also be considered. A large number of different instruments exist in this field, which aim to evaluate specific aspects of sexual function and sexual health. A number have been specifically developed or adapted to examine sexual function in patients with pelvic floor disorders such as incontinence.

Table 10: Recommended questionnaires for the evaluation of symptoms and quality of life impact of faecal incontinence

Grade A+
ICIQ-B [32, 33]
Grade A
Faecal Incontinence Quality of Life Scale [71]
Birmingham Bowel and Urinary Symptom Questionnaire [72, 73]
Questionnaire for assessment of Faecal Incontinence and Constipation [74]
Grade B
Colorectal Functional Outcome Questionnaire [75]
Manchester Health Questionnaire [76]
Bowel Control Self Assessment Questionnaire [77]
Pelvic Floor Bother Questionnaire [61]
Elderly Bowel Symptom Questionnaire [78]
Faecal Incontinence and Constipation Assessment [79]
Grade C
Faecal Incontinence Questionnaire [80]
Ungraded (require formal validation, evidence of progress published)
Postpartum Flatal and Faecal Incontinence Quality of Life Scale [81]
Bowel Function Questionnaire [82]
Surgical Outcome Tool for Faecal Incontinence [83]

Clinicians who treat sexual problems often prefer to use unstructured rather than structured interviews or questionnaires in clinical practice as an unstructured approach allows the tailoring of questions to suit the couple or the individual being assessed. Unstructured interviews enable the clinician to support patients who feel vulnerable and encourage discussion. The experienced clinician hopes to have an appreciation of the information required to make the correct diagnosis and institute appropriate treatment. In this setting, vocabulary can be modified, as can the level of assertiveness and the depth of questioning to suit the needs of the individual. This flexibility is not readily achievable with questionnaires which individuals may also find difficult to complete due their impersonal nature or because of physical or mental impairment, cultural or language differences. However, some patients find the discussion of intimate issues with clinicians very difficult and questionnaires may allow these issues to be measured in private, at ease and more effectively before subsequently exploring questionnaire responses in the clinical interview itself.

Appendixed Table 14 at the chapter's end outlines a number of sexual health measures with a Grade A or B rating based on the criteria provided above. Three measures are of particular note, obtaining an A+ rating, having demonstrated not only reliability and validity but also that content was derived with patient input and responsiveness to treatment has been shown: GRISS [84], FSFI [85], and IIEF [86]. Most of the identified measures are self-reported, easy and quick to administer and many have various language versions available. The majority have also been previously used in incontinence populations. There are various others measures that would be given a rating of C (e.g., Sexual Behaviour Inventory [87, 88], McCoy Female Sexuality Questionnaire [89]), but given the breadth of measures available with an A or B rating, researchers are encouraged to use these for assessing sexual function/sexual quality of life. Specific choice of measure will be dependent on research hypothesis. For instance, if you wanted to assess impact of OAB on sexual function e.g. arousal in women then you would want to use the FSFI rather than the SQOL-F [90] because the FSFI has a specific arousal domain whereas the SQOL-F assesses sexual quality of life.

IX. QUESTIONNAIRES FOR SPECIFIC PATIENT GROUPS

Most studies and questionnaires have been developed for use with members of the general population or urology/gynaecology patients with incontinence or POP. However, some specific patient groups may experience particular problems with incontinence (for example, children, frail elderly or those who are severely disabled), which may require independent investigation and potentially the development of more specific measures or the addition of a new subset of items on already developed instruments. The Committee advises that researchers should use existing highly recommended or recommended questionnaires if possible as this aids comparison and to reduce the increasing proliferation of questionnaires. Many of the questionnaires developed below for particular conditions (e.g. prostate cancer) pre-dated the development of highly recommended questionnaires, and highly recommended questionnaires should be used preferentially.

1. OLDER PEOPLE

Urinary incontinence symptoms play an influential role on the overall HRQL in older people (>65) and causes a significant decrease in HRQL, as severe as that of many chronic disease states. Since the elderly commonly have a number of associated comorbid conditions, it may be difficult to measure the impact of urinary incontinence with generic HRQL measures. The use of incontinence specific tools to measure patient-reported outcomes in the elderly, therefore, is of considerable importance. Validated incontinence-specific PRO questionnaires, such as IIQ, I-QOL or KHQ, are used for clinical trials or research on urinary incontinence including elderly people, but their validity has not been specifically assessed in this age group. Okamura assessed symptoms and HRQL in older people (men and women)

with lower urinary tract symptoms including incontinence, using the KHQ and IPSS. They demonstrated that symptoms and HRQL in the elderly with LUTS could be assessed by IPSS and KHQ and that urinary incontinence appeared to be more associated with a decreased HRQL in elderly women [91].

On the other hand, there are a variety of factors affecting older people, including physical, social, mental, economic or environmental conditions, which are different from those of the young. In frail elderly people with dementia or physical impairment, it may be difficult to assess the impact of urinary incontinence alone. Questionnaires specifically developed for the elderly may be of great importance in this respect. However, there is little relating to the development or validation of particular questionnaires for older people with urinary incontinence. Two questionnaires dealing with older people were found and are described below. No questionnaires dealing with patient outcomes specifically for frail older incontinent people were found.

a) The Urge Impact Scale (URIS) [Grade B]

The Urge Impact Scale (URIS) was designed and tested specifically for older persons with urgency incontinence. The URIS was developed and validated by DuBeau et al. (1999) [92] and included 32 items, reduced to 24 items (URIS-24). The URIS-24 was psychometrically assessed for validity and reliability in community-dwelling older (>65y) men and women with urgency incontinence. Cronbach's alpha was 0.84 for the URIS-32 and 0.94 for the URIS-24. In assessment of test-retest reliability, interclass coefficient (ICC) was 0.88. The URIS-24 had modest but nearly significant correlation with the number of urgency incontinence episodes (rho=-0.39, p=0.05). Factor analysis revealed 3 component structures corresponding to physiological burden, perception of personal control and self-concept. There was no analysis for responsiveness. They showed that the URIS-24 is an internally consistent, highly reproducible tool for the assessment of the QOL impact of urgency incontinence on older persons.

b) Caregivers

The Overactive Bladder Family Impact (OAB-FIM) scale was developed to assess the impact of OAB on family members of patients with OAB. This 19-item tool consists of 6 subscales [93]. Four subscales (Irritation, Activities, Travel, Concern) could be used for all family members; however 2 additional subscales (Sleep, Sex) should only be administered to spouses/significant others. The OAB-FIM was highly discriminating between OAB and control family members, with all OAB family members indicating significant impact (all $p<0.0001$). Internal consistency reliability (Cronbach's alpha >0.71) and 2-week test-retest reliability (intraclass correlation coefficients >0.73) were high for all subscales. Concurrent validity of the OAB-FIM was demonstrated through statistically significant ($p < 0.001$) Spearman correlations with the OAB-q (coefficients ranging from 0.35 to 0.58) and the PPBC (0.31 to 0.56). No differences were noted on the OAB-FIM by patient incontinence status (none, urge vs. mixed). OAB-FIM scores also discriminated by family member perceptions of OAB severity, particularly among the Irritation, Activities and Travel subscales. Correlational analyses among the OAB-FIM and relationship quality measures suggest that greater OAB symptom impact on the family member was associated with increased problems in the patient–family member relationship. The responsiveness of the OAB-FIM is yet to be assessed. This measure can be found at www.pfizerpatientreportedoutcomes.com.

2. CHILDREN

Some questionnaires have been developed specifically to address issues for children, particularly enuresis. See Chapter 9 (Children) and section on ICIQ modular questionnaire.

3. SPINAL CORD INJURED/NEUROLOGICAL IMPAIRMENT

Individuals who have a spinal cord injury or are neurologically damaged can experience particular difficulties with incontinence and the use of various devices. It would be useful to investigate whether Grade A questionnaires, developed for people without neurological damage, can be used in this group, or whether additional modules or instruments are required. This is an area where a small number of questionnaires are being developed with the Qualiveen being a notable exception (Also see section on the ICIQ questionnaire and below).

Qualiveen: Quality of Life Related to Urinary Problems in Spinal Cord Injury [Grade A]

The Qualiveen was developed to evaluate the specific impact of urinary dysfunction on the quality of life of spinal cord injury patients in France [94]. The initial items were developed following patient interviews, and were then assessed for validity and reliability in 281 spinal cord injury patients with urinary difficulties. The Qualiveen contains 30 items and has demonstrated good reliability and validity [94]. Further validation of the Qualiveen has occurred in multiple sclerosis patients [95] and it has been translated and validated into English [96], German [97], and Portuguese [98]. The Qualiveen has demonstrated responsiveness in multiple sclerosis patients and has a suggested MID of 0.5 [99].

4. PROSTATE/BLADDER CANCER

Many PRO questionnaires are available for assessment in this area: Post-radical prostatectomy questionnaire [100, 101], Cancer Rehabilitation Evaluation System - Short Form (CARES-SF) [102], Prostate Cancer Treatment Outcome Questionnaire (PCTO-Q) [103],PROSQOLI [104], Modified Southwest Oncology Group (SWOG) [105], Functional Assessment of Cancer Therapy - (FACT-G), Bladder form (FACT-B) and Prostate form (FACT-P) [106],

Functional Assessment of Cancer Therapy Vanderviet Cystectomy Index (FACT-VCI) [107], EORTC metastatic prostate cancer [103], Changes in Urinary Function [108], Prostate-targeted Health Related Quality of Life [109]. While it is beyond the scope of this chapter to review and recommend PROs in this area, the principles and guidelines discussed herein apply to selecting a PRO related to prostate and bladder cancer.

5. LOWER URINARY TRACT SYMPTOMS/BENIGN PROSTATE DISEASE

Many questionnaires have been developed to assess LUTS and benign prostate disease; however, most do not contain a full evaluation of UI. Perhaps the most widely known urology PRO is the AUA Symptom Index [110], I-PSS (International Prostate Symptom Score) [110, 111]. The IPSS has been utilitised internationally to assess symptoms of prostate disease with documented reliability, validity and responsiveness. Additional PRO measures for BPH are as follows: Patient-completed modification of the Boyarsky[112], BPH Impact Index [113], and BPH Health-related QoL survey [114].

6. SUMMARY

In summary, some general points to consider in selecting PRO measures for urology studies:

- Ensure that the PRO research questions and study endpoints are clearly defined. Determine the PROs that are most critical to assess and which are most likely to be affected by a particular condition and/or its treatment.
- Make good use of prior literature searches in identifying past research in the area(s) of interest, as well as in identifying the types of PRO measures other researchers have used in past work. This information can provide valuable information on how particular outcome measures have performed in previous populations, as well as provide additional information to assist in defining research questions/issues regarding the PRO components of any given study.
- Consider the characteristics of the population in selecting measures. For example, are the study subjects to be children or older adults, well educated vs. those with limited education, or persons with low literacy? Ensure that the mode of data collection is appropriate for use with the study population. Furthermore, do not assume that an instrument validated for use with Caucasian, middle-class individuals in the U.S. will be appropriate for use in other countries, and/or those of a lower socio-economic status or of different educational backgrounds. This chapter has indicated, where possible, the extent to which specific PRO measures have been validated, and used reliably with different populations.
- Use the questionnaires recommended in this chapter whenever possible. Do not “reinvent the wheel.” Developing new PROs is a time-consuming and complicated process. If a new scale needs to be developed, ensure that the guidelines proposed by the FDA and EMEA on developing PROs are followed and that the appropriate expertise in questionnaire development and psychometrics is available to your research team in order to guide the questionnaire development process.
- Know the strengths and weaknesses of different types of PRO measures. In general, generic measures are useful in providing information on multiple patient outcome dimensions that can be compared across different populations. They may lack sensitivity, however, in addressing concerns of specific patient populations (e.g., OAB, UI, faecal incontinence). Condition-specific instruments, in contrast, do address areas of function more specific to the condition, and tend to be more responsive to changes in clinic status, due to their increased specificity in addressing the conditions of their patient populations. Weaknesses of condition-specific instruments, however, are that they are often not appropriate for use with multiple populations, and cannot be used to make direct comparisons across different patient groups.
- Know how to score your selected PRO measures and how to interpret the scores. Specifically, ensure that the scoring method of a measure provides you with the information you need to answer your research question?
- Finally, train and certify your staff to administer PRO measures using either patient interview and/or self-administration techniques, depending on the method to be used in the study. The administration process needs to be standardised and completely similarly across all participants.

X. RECOMMENDATIONS FOR RESEARCH

1.The selection of a PRO questionnaire must reflect study purpose and objectives

2. Grade A recommended questionnaires should be used in all clinical trials evaluating treatments

3. The inclusion of the ICIQ modules is preferred in all studies to standardise outcome assessment

4. Continued PRO development, refinement, and use should accurately and adequately report on the methods, samples, statistical analyses and psychometric properties of questionnaires in scientific journals (i.e. validity, reliability and responsiveness), so the quality of each study can be assessed

Researchers are encouraged to use existing questionnaires and refine for specific populations when needed (e.g. frail elderly, children)

5.Researchers are encouraged to collaborative with the ICIQ project on the development and refinement of modules and translations.

Table 4: Health-related Quality of Life measures for Lower Urinary Tract Symptoms

PRO Name/ICIQ Grade	Purpose/Description of Tool	Population Sample	Reliability		Validity				Responsiveness (Treatment Duration)	Instrument Access & Translation(s)
			Internal Consistency	Test-retest	Content (Item Generation)	Criterion	Concurrent	Discriminant		
BFLUTS (Bristol Female Lower Urinary Tract Symptoms Questionnaire). Currently the ICIQ-FLUTS (ICIQ-Female Lower Urinary Tract Symptoms); Grade A [30]	34-question tool used to assess female LUTS, particularly urinary incontinence, measure impact on quality of life and evaluate treatment outcome	Women, inconti-nence	√	√	√		√		None	www.iciq.net
Contilife® (Quality of Life Assessment Questionnaire Concerning Urinary Inconti-nence); Grade B [115]	28-intem tool used to assess the impact of urinary incontinence on HRQL. Originally developed in French and designed for women with UI (urge, stress and mixed UI)	Women, SUI	√	√ (ICC = 0.96)			√		√	www.proqolid.org
DAN-PSS-1(Danish Prostatic Symptom Score); Grade A [116]	15-item tool used to evaluate males with LUTS suggestive of uncomplicated BPH	Men, BPH	√	√	√		√			www.proqolid.org
EPIQ (Epidemiology of Prolapse and Incontinence Questionnaire); Grade B [117]	49-item tool developed and validated in English and Spanish to assess the presence or absence of AI, OAB, SUI, and pelvic organ prolapse in female population	women, PFD	√	√	√	√	√	√		contact developer
ICIQ-UI Short Form (International Consultation on Incontinence Questionnaire - Urinary Inconti-nence Short Form (ICIQ-UI Short Form); Grade A[28]	4-item tool used to assess the symptoms and impact of urinary incontinence in clinical practice and research	men and women, Urinary symptoms	√	√	√		√	√	√ (8 weeks)	www.proqolid.org

Table 4: Health-related Quality of Life measures for Lower Urinary Tract Symptoms (continued)

PRO Name/ICIQ Grade	Purpose/Description of Tool	Population Sample	Reliability		Validity				Responsiveness (Treatment Duration)	Instrument Access & Translation(s)
			Internal Consistency	Test-retest	Content (Item Generation)	Criterion	Concurrent	Discriminant		
ICSmale (ICIQ-MLUTS) (International Continence Society - Male); Grade A [35]	23-item tool used to provide a thorough evaluation of the occurrence and bothersomeness of lower urinary tract symptoms and their impact on the lives of men with benign prostatic disease	men with LUTS and possible BPH	√	√	√		√		√	www.proqolid.org
ICSQoL (International Continence Society-Benign Prostatic Hyperplasia study quality-of-life); Grade A [118]	8-item tool used to assess impact of lower urinary tract symptoms on the lives of men with LUTS	men with LUTS and possible BPH	√	√	√		√			www.proqolid.org
IIQ (Incontinence Impact Questionnaire); Grade A [119]	30-item tool developed to describe the severity of incontinence in a population. It was validated in a group of women aged 45 and over attending two continence clinics for SUI primarily. Used to assess the impact of urinary incontinence on HRQL.	Women, UI		√	√		√		√ (12Weeks)	contact developer
IIQ-7 (Incontinence Impact Questionnaire - short form); Grade A [120]	7-item tool used to assess the impact of urinary incontinence on HRQL	*validation study on men after radical prostatectomy who had UI	√ (Cronbach's Alpha = 0.93)	√ (Spearman's Rho = 0.99; ICC = 0.75)	√	√	√	√		contact developer

Table 4: Health-related Quality of Life measures for Lower Urinary Tract Symptoms (continued)

PRO Name/ICIQ Grade	Purpose/Description of Tool	Population Sample	Reliability		Validity				Responsiveness (Treatment Duration)	Instrument Access & Translation(s)
			Internal Consistency	Test-retest	Content (Item Generation)	Criterion	Concurrent	Discriminant		
IOQ (Incontinence Outcome Questionnaire); Grade B [121]	27 question tool developed for assessing quality of life after surgery for stress urinary incontinence	Women SUI	√ (Cronbach's Alpha = 0.83)		√	√			√	contact developer
I-QOL (ICIQ-Uqol) (Urinary Incontinence-Specific Quality of Life Instrument); Grade A [122, 123]	22-item tool used to assess quality of life of women with UI	women, UI	√	√	√			√	√	www.proqolid.org
ISI (Incontinence Severity Index); Grade C [124]	2-item severity measure recommended by the World Health Organization for studying the epidemiology of incontinence and other LUTS; Developed in an epidemiologic study of 28,000 women in Norway.	Women, SUI				√	√			contact developer
ISQ (Incontinence Stress Index: ISQ-P [Patient]; ISQ-SOPS [Staff Observation of Patient Stress]; ISQ-SR [Staff Reaction to UI]); Grade C [125]	40-item tool (20-items in short form) used to assess psychological stress associated with urinary incontinence	Women	√	√						www.proqolid.org
ISS (Incontinence Symptom Severity Index); Grade A [126]	8-item instrument used for the self-assessment of severity of female urinary storage and voiding symptoms, rather than symptom bother or effects of on quality of life	Females		√ (ICC = 0.62 - 0.91)			√		√ (Duration not specified)	contact developer

Table 4: Health-related Quality of Life measures for Lower Urinary Tract Symptoms (continued)

PRO Name/ICIQ Grade	Purpose/Description of Tool	Population Sample	Reliability		Validity				Responsiveness (Treatment Duration)	Instrument Access & Translation(s)
			Internal Consistency	Test-retest	Content (Item Generation)	Criterion	Concurrent	Discriminant		
KHQ (ICIQ-LUTSqol) (King's Health Questionnaire); Grade A+ [4, 34]	21-item tool used to assess the symptoms impact of LUTS including urinary incontinence on HRQL. Developed in a clinical perspective to evaluate incontinence in women.	UI, OAB, men and women	√ (all domains except severity measure (Cronbach's Alpha = 0.60) demonstrated excellent IC)	√	√	√	√	√	√ (12Weeks)	www.proqolid.org
LIS (The Leicester Impact Scale); Grade A [127]	21-item tool used as a quality of life measure for males and females with urinary storage symptoms of urgency, frequency, nocturia and incontinence.	men and women, LUTS	√	√	√		√		√	contact developer
MUDI (Male UrogenitalDistress Inventory); Grade B+ [128, 129]	27-item tool used to address the dimension of physical health, focusing on bother from multiple symptoms associated with UI in men. Created by eliminating four gender specific items from UDI and IIQ.	Men with LUTS following a radical prostatectomy for prostate cancer	√		√		√			www.proqolid.org
MUSIQ (Male Urinary Symptom Impact Questionnaire); Grade B+ [128, 129]	32-item tool used to capture mental/psychological health, social health, and global perceptions of function and well-being in men with urinary incontinence. Created by eliminating four gender specific items from UDI and IIQ.	Men, UI	√		√		√			www.proqolid.org

Table 4: Health-related Quality of Life measures for Lower Urinary Tract Symptoms (continued)

PRO Name/ICIQ Grade	Purpose/Description of Tool	Population Sample	Reliability		Validity				Responsiveness (Treatment Duration)	Instrument Access & Translation(s)
			Internal Consistency	Test-retest	Content (Item Generation)	Criterion	Concurrent	Discriminant		
N-Qol(Nocturia Quality of Life Questionnaire); Grade A+[37, 130]	13-item tool used to assess the impact of nocturia on the quality of life of patients	men and women	√	√	√		√	√	√	www.pfizerpatientreportedoutcomes.com
OAB – q SF (OAB-q Short Form); Grade A [5]	19-item tool (shortened version of the OAB-q) used to evaluate both continent and incontinent symptoms of OAB and their impact on HRQL	OAB, men and women	√	√	√		√	√	√ (12 Weeks)	www.pfizerpatientreportedoutcomes.com
OAB-q (ICIQ-OABqol) (OveractiveBladder Questionnaire); Grade A [5, 38]	33-item tool used to evaluate both continent and incontinent symptoms of OAB and their impact on HRQL. Developed from focus groups of men and women, clinician opinion, and a thorough literature review	Continent and incontinent OAB	√	√ (ICC = 0.93 for 4-week recall period)	√	√	√	√	√ (12 Weeks)	www.pfizerpatientreportedoutcomes.com
PFDI (Pelvic Floor Distress Inventory); Grade A [58]	46-item tool used to assess presence of symptoms and HRQL in women with POP; 3 Scales (Urinary-28; Colorectal-17 Prolapse-16)	Females with symptomatic POP, UI	√ (Cronbach's Alpha = 0.88)	√ (ICC = 0.87)	√			√	√	contact developer
PFDI-20 (Pelvic Floor Distress Inventory Short Form); Grade A [58]	20-item short form of the PFDI (Urinary-6; Colorectal-8; Prolapse-6)	Females with symptomatic POP, UI		√ (ICC = 0.93)	√			√	√	www.mapi-institute.com
PFIQ (PelvicFloor Impact Questionnaire); Grade A [58]	93-item functional status tool used to assess presence of symptoms and HRQL in women with POP; 3 Scales (Urinary-31, Colorectal-31, Prolapse-31)	Females with symptomatic POP, UI	√ (Cronbach's Alpha = 0.98)	√ (ICC = 0.86)	√			√	√	contact developer

Table 4: Health-related Quality of Life measures for Lower Urinary Tract Symptoms (continued)

PRO Name/ICIQ Grade	Purpose/Description of Tool	Population Sample	Reliability		Validity				Responsiveness (Treatment Duration)	Instrument Access & Translation(s)
			Internal Consistency	Test-retest	Content (Item Generation)	Criterion	Concurrent	Discriminant		
PFIQ-7 (Pelvic Floor Impact Questionnaire Short Form); Grade A [58]	21-item short form of the PFIQ used to assess presence of symptoms and QOL in women with POP; 3 Scales (Urinary-7, Colorectal-7, Prolapse-7)	Females with sympto-matic POP, UI		√ (ICC = 0.77)	√			√	√	www.mapi-institute.com
PRAFAB (Protection, Amount, Frequency, Adjustment, Body image); Grade A [131]	5 item questionnaire widely used in the Netherlands by physiotherapists and researchers used to evaluate treatment effects for UI in women	women with UI	√	√	√		√	√	√	contact developer
UIHI (Urinary Incontinence Handicap Inventory); Grade C [132]	17-item tool used to identify difficulties patients may be experiencing because of their incontinence	Elderly women, UI due to detrusor instability	√ (Cronbach's Alpha = 0.87)	√				√		www.proqolid.org
UISS (Urinary Incontinence Severity Score); Grade A [133]	10-item tool to assess symptom severity and impact of urinary incontinence	Women, UI		√	√	√	√		√	contact developer
Urolife (BPHQoL9) (Benign Prostatic Hypertrophy Health-Related Quality of Life Questionnaire); Grade A [134]	9-item tool used to assess the impact of BPH and its treatment on the quality of life of patients	Men, BPH	√	√	√		√		√	www.proqolid.org
YIPS (York Incontinence Perceptions Scale); Grade B [135]	8-item tool used to measure the psychosocial aspects of urinary incontinence and its management	Women, UI	√	√	√		√		√	www.proqolid.org

Table 5: Patient Satisfaction Measures for Lower Urinary Tract Symptoms

PRO Name/ICIQ Grade	Purpose/Description of Tool	Population Sample	Reliability		Validity				Responsiveness (Treatment Duration)	Instrument Access & Translation(s)
			Internal Consistency	Test-retest	Content (Item Generation)	Criterion	Concurrent	Discriminant		
BSW (Benefit, Satisfaction with treatment, and Willingness); Grade B [45]	3 single-item tool used to capture patients' perceived benefit, satisfaction with treatment, and the willingness to continue treatment	men and women, OAB					√	√	√	www.pfizerpatientreportedoutcomes.com
EPI (Estimated Percent Improvement); Grade C [136]	Single-item tool used to gain a patient's improvement in a percent scale	Women, UI,SUI, MUI						√	√ (2-4 Weeks)	contact developer
GPI (Global Perception of Improvement); Grade C [136]	Single-item tool used to assess patient's improvement	Women, UI,SUI, MUI						√		contact developer
OAB-S (Overactive Bladder Satisfaction measure); Grade B [44]	51-items to assess following domains: expectations, control impact on daily living, medication tolerability, satisfaction and 5 overall assessments	men and women, OAB	√	√	√		√	√		contact developer
OAB-SAT-q OAB Satisfaction questionnaire; Grade B [137]	10-item tool used to assess patients' satisfaction with overactive bladder treatment including medication or non-pharmaceutical options such as physical therapy or biofeedback. The pre-medication module is designed assess the patient's expectations with medication and impact on OAB on patient's day to day life	Men and women, OAB	√	√	√		√	√		contact developer
PSQ (Patient Satisfaction Questionnaire); Grade C [136]	Single-item tool used to measure how satisfied a subject was with a program	Women, UI, SUI, MUI						√		contact developer
TBS (Treatment Benefit Scale); Grade B [138]	Single-item tool used to assess the patient-reported benefits of treatment of OAB	Men and Women OAB					√	√	√	contact developer
SAGA (Self-Assessment Goal Achievement Questionnaire); GAS; Grade C [46]	9-item tool on Goal Attainment related to lower urinary tract symptoms and the establishment of patients' goals concerning their treatment for lower urinary tract symptoms (LUTS),	Men and Women aged ≥18 years with OAB	Not Assessed	Not Assessed	√	√ (low to moderate)	√			www.pfizerpatientreportedoutcomes.com

Table 6: Screening Tools for Lower Urinary Track Symptoms

PRO Name/ICIQ Grade	Purpose/Description of Tool	Population Sample	Reliability		Validity				Responsiveness (Treatment Duration)	Instrument Access & Translation(s)
			Internal Consistency	Test-retest	Content (Item Generation)	Criterion	Concurrent	Discriminant		
3IQ (Three Incontinence Questions Questionnaire); Grade C [139]	3-item tool used to classify urge and stress incontinence	Women, UI						√	N/A	None Found
B-SAQ (Bladder Self-Assessment Questionnaire) or Bladder Control Self-Assessment Questionnaire (BCSQ); Grade A [140]	8-item screening tool used for the presence of bothersome LUTS in Women	Women	√	√		√	√	√	N/A	www.mapi-institute.com
CLSS (Core Lower Urinary Tract Symptom Score) Questionnaire; Grade C [141]	10-item tool used in the overall assessment of lower urinary tract symptoms	Men & Women		√						contact developer
ISQ (Incontinence Screening Questionnaire); Grade B [142]	5-item tool developed to screen for incontinence in women	Women, UI		√				√	N/A	contact developer
MESA (Medical, Epidemiological, and Social Aspects of Aging Questionnaire); Grade C [143]	15-item screening tool used for urinary incontinence in female pelvic medicine and reconstructive surgery patients	Women, UI		√					N/A	www.ncbi.nlm.nih.gov
OAB-SS (Overactive Bladder Symptom Score); Grade A [144]	7-item tool used to measure overall symptom severity due to the four index symptoms of OAB	Men and women, LUTS with or without OAB	√	√	√			√	√	contact developer

Table 6: Screening Tools for Lower Urinary Track Symptoms (continued)

PRO Name/ICIQ Grade	Purpose/Description of Tool	Population Sample	Reliability		Validity				Responsiveness (Treatment Duration)	Instrument Access & Translation(s)
			Internal Consistency	Test-retest	Content (Item Generation)	Criterion	Concurrent	Discriminant		
OAB-V8 (OAB Awareness Tool); Grade A [145]	8-item screening tool for use in a primary care setting to identify patients who may have OAB	Men and women, OAB	√		√	√	√	√	N/A	www.pfizerpatientreportedoutcomes.com
OAB - V3 (OAB short form) A [146]	3-Item awareness tool & shortened version of the OAB-q/OAB-V8	Men and women, OAB, UUI	√		√	√	√	√	n/a	www.pfizerpatientreportedoutcomes.com
PUF patient symptom scale (Pelvic Pain, Urgency, and Frequency); Grade C [147]	8-item tool used to evaluate of patients with suspected IC/PBS	Women and women, IC/PBS						√	√	www.ncbi.nlm.nih.gov
QUID (Questionnaire for Urinary Incontinence Diagnosis); Grade A [148]	6-item tool used to diagnose stress and/or urge types of urinary incontinence	Women with UI and SUI	√	√	√	√		√	√	contact developer
USP (Urinary Symptom Profile); Grade B [149]	13-item tool used to assess urinary symptoms in male and female with stress, urge, frequency or urinary obstructive symptoms for use in clinical practice to complement clinical measures and diagnosis	Men and women stress UI, urge UI, frequency, low stream, combined symptoms	√	√	√		√	√	N/A	www.mapi-institute.com

Table 7: Symptom Bother Measures for Lower Urinary Tract Symptoms

PRO Name/ICIQ Grade	Purpose/Description of Tool	Population Sample	Reliability		Validity				Responsiveness (Treatment Duration)	Instrument Access & Translation(s)
			Internal Consistency	Test-retest	Content (Item Generation)	Criterion	Concurrent	Discriminant		
I-PSS (International Prostate Symptom Score); Grade B [110]	8-item tool used to capture the severity of urinary symptoms related to benign prostatic hyperplasia. Originally developed from the American Urological Association Symptom Index.	Men	√	√			√	√	√	www.proqolid.org
LUSQ (Leicester UrinarySymptom Questionnaire); Grade A [150]	10-item tool used to measure the presence and severity of storage abnormality symptoms of incontinence, urgency, frequency and nocturia	Men and women	√	√	√	√	√		√ (12Weeks)	contact developer
PGI-I and PGI-S (Patient Global Impression of Severity and of Improvement); Grade A [151, 152]	Two single-item global indices used to measure symptom bother related to urinary incontinence	Women with SUI	√	√			√	√	√ (12Weeks)	contact developer
PMSES (Broome Pelvic Muscle Exercise Self-Efficacy Scale); Grade C [153]	23-item tool used to measure self-efficacy for the performance of pelvic muscle exercises in females and males	Men and women					√	√		contact developer
POSQ (Primary OAB Symptom Questionnaire); Grade C [154]	5-item tool used to assess which symptom of OAB is the most bothersome to patients	OAB, men and women		√	√					contact developer
PPBC (Patient Perception of Bladder Condition); Grade A [52]	Single-item tool used to assess patients' subjective impression of their current urinary problems. Developed as a global assessment of bladder condition	Men and women		√			√		√	www.pfizerpatientreportedoutcomes.com

Table 7: Symptom Bother Measures for Lower Urinary Tract Symptoms (continued)

PRO Name/ICIQ Grade	Purpose/Description of Tool	Population Sample	Reliability		Validity				Responsiveness (Treatment Duration)	Instrument Access & Translation(s)
			Internal Consistency	Test-retest	Content (Item Generation)	Criterion	Concurrent	Discriminant		
PFBQ (Pelvic Floor Bother Questionnaire); Grade B [61]	9-item global instrument used to assess female patients over the age of 18 years with symptoms of urinary incontinence, urinary urgency, and frequency, urge incontinence, faecal incontinence, obstructed defecation, dyspareunia and pelvic organ prolapse	Women, Urinary Incontinence, UUI, SUI	√	√	√	√		√		contact developer
SPI (Symptom Problem Index); Grade B [113]	7-item tool used to measure how troublesome the patients find their urinary symptoms	Male, BPH	√	√	√					www.proqolid.org
SSI and SII (Symptom Severity Index and Symptom Impact Index for stress incontinence in women); Grade B [155]	3-item tool used to measure stress incontinence severity and impact or bothersome of symptoms. This questionnaire was developed and administered to women undergoing stress incontinence surgery	Women, SUI		√	√		√			www.proqolid.org
UI-4 (Urinary Incontinence -4 Questionnaire); Grade C [156]	4-item tool used to assess how patients are bothered by urinary incontinence	Women, UI					√			www.ncbi.nlm.nih.gov
UDI (UrogenitalDistress Inventory); Grade A [119]	19-item tool used to asses symptom bother related to urinary incontinence. UDI is a complement to the IIQ	Women, UI, SUI	√	√	√		√	√		contact developer
UDI-6 (UrogenitalDistress Inventory -6); Grade A [157]	6-item tool used to assess LUTS, including incontinence, in women.	Women	√	√	√	√	√	√	√	contact developer

Table 8: Urinary Urgency Measures for Lower Urinary Tract Symptoms

PRO Name/ICIQ Grade	Purpose/Description of Tool	Population Sample	Reliability		Validity				Responsiveness (Treatment Duration)	Instrument Access & Translation(s)
			Internal Consistency	Test-retest	Content (Item Generation)	Criterion	Concurrent	Discriminant		
IUSS (Indevus Urgency Severity); Grade A [158]	Single-item tool used to quantify the level of urgency associated with each toilet void as measured during standard voiding diaries.	OAB with urgency inconti-nence, men and women		√		√	√	√	√ (12 Weeks)	contact developer
PPIUS (Patients' Perception of Intensity of Urgency Scale); Grade B [159]	Single-item tool used to assess female patient perception of urgency intensity in those women with UUI	Women, UUI		√					√	contact developer
SUIQ (Stress/Urge Incontinence Questionnaire); Grade B [160]	2-item tool used to differenti-ate between symptoms of stress and urge urinary incontinence	Women, UI		√			√			contact developer
U-IIQ (Urge Incontinence Impact Question-naire); Grade A [161]	32-item tool used to assess the interference of urine leakage and bladder problems Developed for use in patients with all types of incontinence.	MUI, UUI	√	√			√	√	√ (12Weeks)	contact developer
UPS (Urgency Perception Score); Grade B [162]	5-item OAB tool used for grading the urge to void and assessing the reason why individuals usually void	Men and women	√	√			√	√		contact developer
UPS (Urgency Perception Scale); Grade B [163]	Single-item tool used to assess the severity of urgency – whether or not urgency, the sudden and compelling desire to urinate should have a severity measure is debated.	OAB, men and women			√		√	√	√	contact developer

Table 8: Urinary Urgency Measures for Lower Urinary Tract Symptoms (continued)

PRO Name/ICIQ Grade	Purpose/Description of Tool	Population Sample	Reliability		Validity				Responsiveness (Treatment Duration)	Instrument Access & Translation(s)
			Internal Consistency	Test-retest	Content (Item Generation)	Criterion	Concurrent	Discriminant		
UQ (Urgency Questionnaire); Grade B [154]	15-Likert Scale Item & 4-VAS tool used o assess the severity and impact of urinary urgency symptoms on HRQL. VAS scale is used to measure the impact of urinary urgency on overall HRQL, the severity, the intensity, and the discomfort of urgency.	Women, OAB	√	√	√		√	√	√ (10 Days)	contact developer
URIS-24 (Urge Impact Scale); Grade B [92]	24-item tool used to assess of the impact of the most common form of UI in older persons	Older persons, UI	√	√	√		√			contact developer
USIQ-QOL (Urgency Severity & Intensity Questionnaire: Symptom Severity); Grade B [164]	To measure severity impact from urinary urgency	Females, POP, UI	√			√		√		contact developer
USIQ-S (Urgency Severity & Intensity Questionnaire: Quality of Life); Grade B [164]	To measure quality of life impact from urinary urgency	Females, POP, UI	√ (Cronbach's Alpha = 0.85)			√		√		contact developer
USS (Urinary Sensation Scale); Grade B [165, 166]	5-point scale used to assess the impact of urgency with patients with OAB derivation from EMA's recommended 5-point scale	Urologists or urogy-necologists, Survey respondents with OAB symptoms	√ (Cronbach's Alpha = 0.85)		√		√	√	√	contact developer
UU Scale (10-item Scale to Measure Urinary Urgency); Grade A [167]	10-item tool use to measure urinary urgency	Men and women		√			√		√	contact developer
U-UDI (Urge-Urogenital distress inventory); Grade A [161]	9-item tool used to assess the extent to which the patient is bothered by the symptoms of urge urinary incontinence or mixed urinary incontinence with a primary urge component.	Men and women		√	√		√		√	www.mapi-institute.com

Table 11: Summary of PRO Measures for Faecal incontinence and other bowel symptoms

PRO Name/ICIQ Grade	Purpose/Description of Tool	Population Sample	Reliability		Validity				Responsive-ness (Treatment Duration)	Psycho-metric Validation inOther Languages	Available Languages
			Internal Consistency	Test-retest	Content (Item Generation)	Criterion	Concurrent	Discri-minant			
Questionnaire for assessment of FI and constipation [74] **Grade A**	47-item general question-naire for constipation and anal incontinence, also including abdominal and urinary symptoms and medical history	Men and women		√		√			√	√	Contact www.iciq.net
Bowel function questionnaire [83] **Ungraded**	28-item bowel specific questionnaire including 10 anal incontinence-specific items	Men and women									
Faecal Inconti-nence Question-naire [80] **Grade C**	63-item general questionnaire for bowel habits including faecal incontinence, also urinary symptoms and medical history	Men and women		√							
BBUSQ (Birmingham Bowel and Urinary Symptom Question-naire [72, 73] **Grade A**	22-item questionnaire for bowel and urinary symptoms including 4 faecal incontinence-specific items	women	√	√		√			√		
FICA (Faecal incontinence and constipation assessment) [79] **Grade B**	98-item general questionnaire for constipation and faecal incontinence, also including abdominal and urinary symptoms and medical history	women		√		√					
PFBQ (Pelvic floor bother question-naire) [61] **Grade B**	9-item symptom and bother questionnaire for pelvic floor disorders	women	√	√		√	√				

Table 12: Summary of PRO Measures for Faecal incontinence and HRQL associated specifically

PRO Name/ICIQ Grade	Purpose/Description of Tool	Population Sample	Reliability		Validity				Responsive-ness (Treatment Duration)	Psycho-metric Validation inOther Languages	Available Languages
			Internal Consistency	Test-retest	Content (Item Generation)	Criterion	Concurrent	Discri-minant			
ICIQ-B [32, 33] **Grade A+**	19-item anal incontinence symptoms and HRQL questionnaire	Men and women	√	√	√	√	√		√	√	Contact www.iciq.net
FIQL (Faecal Incontinence Quality of life Index) [71] **Grade A**	29-item faecal incontinence HRQL questionnaire	Men and women	√	√			√		√	√	Contact author
MHQ (Manchester Health Question-naire) [76] **Grade B**	31-item anal incontinence HRQL questionnaire	Women	√	√			√				
Bowel control self-assessment questionnaire [77] **Grade B**	5-item faecal incontinence symptom and HRQL questionnaire	Men and women	√	√		√	√				

Table 13: Summary of PRO Measures for Faecal incontinence in specific patient groups

PRO Name/ICIQ Grade	Purpose/Description of Tool	Population Sample	Reliability		Validity				Responsive-ness (Treatment Duration)	Psycho-metric Validation inOther Languages	Available Languages
			Internal Consistency	Test-retest	Content (Item Generation)	Criterion	Concurrent	Discri-minant			
Postpartum flatal and faecal inconti-nence quality of life scale [81] **Ungraded**	68-item anal incontinence HRQL questionnaire (adaptation of FIQL for postpartum females)	Women			√						
Surgical outcome tool for faecal incontinence[83] **Ungraded**	10-item anal incontinence symptoms and HRQL questionnaire for evaluation of incontinence surgery	Women									
COREFO (Colorec-tal functionalout-come question-naire) [75] **Grade B**	27-item anal incontinence symptom and HRQL questionnaire for evaluation of colorectal surgery	Men and women	√	√	√		√				
EBSQ (Elderly Bowel Symptom Questionnaire) [78] **Grade B**	56-item general questionnaire for gastrointestinal function including faecal incontinence, also including and medical history and HRQL	Men and women		√		√					

Table 14. Sexual Health and Quality of Life Measures

PRO Name/ICIQ Grade	Purpose/Description of Tool	Population Sample	Reliability		Validity				Responsiveness (Treatment Duration)	Instrument Access & Translation(s)
			Internal Consistency	Test-retest	Content (Item Generation)	Criterion	Concurrent	Discriminant		
FSFI (Female Sexual Function Index); Grade B [85]	19-item tool used to assess the effects of incontinence on multiple dimensions of sexual function in sexually active, adult women	Women, OAB; SUI, MUI	√ (Cronbach's Alpha >/= 0.82)	√ (r = 0.79 - 0.86)				√		contact developer
ICIQ-VS (International Consultation on Incontinence Questionnaire -Vaginal Symp-toms); Grade B [31]	14-item tool used to assess effects of vaginal symptoms and associated sexual matter on sexual quality of life for sexually active females	Women	√ (Cronbach's Alpha = 0.81-0.88)	√	√			√ (all items except 'leakage during intercourse')		contact developer
PISQ (PelvicOrganProlapse/Urinary Incontinence Sexual Question-naire); Grade B [62]	31-item tool to assess sexual function after surgery in women with Pelvic Floor Dysfunction	Females with Pelvic Floor Dysfunc-tion	√ (Cronbach's Alpha = 0.85)	√ (k = 0.56 - 0.93)		√		√		contact developer
SFQ (SexualFunction Questionnaire); Grade C [168]	Generic Instrument used to assess the impact of OAB on sexual health/function in the male & female population	men& women with OAB								www.pfizerpatientreportedoutcomes.com
SQoL-F (Sexual Quality of Life–Female); Grade B [90]	To assess the impact of female sexual dysfunction on quality of life	women	√	√			√	√		www.pfizerpatientreportedoutcomes.com

REFERENCES

1. Food and Drug Administration (FDA): Guidance for Industry on Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims. Federal Register, 2009. 74(235): p. 65132-65133.

2. Ware JE, Jr., Kosinski M, Bayliss MS, et al.: Comparison of methods for the scoring and statistical analysis of SF-36 health profile and summary measures: summary of results from the Medical Outcomes Study. Med Care, 1995. 33(4 Suppl): p. AS264-79.

3. Wyman JF, Harkins SW, Choi SC, Taylor JR, Fantl JA: Psychosocial impact of urinary incontinence in women. Obstet Gynecol, 1987. 70(3 Pt 1): p. 378-81.

4. Kelleher CJ, Cardozo LD, Khullar V, Salvatore S: A new questionnaire to assess the quality of life of urinary incontinent women. Br J Obstet Gynaecol, 1997. 104(12): p. 1374-9.

5. Coyne K, Revicki D, Hunt T, et al.: Psychometric validation of an overactive bladder symptom and health-related quality of life questionnaire: the OAB-q. Qual Life Res, 2002. 11(6): p. 563-74.

6. Berger M, et al.: Health care cost, quality and outcomes, in ISPOR Book of Terms. 2003. p. 195-97.

7. Ingolf G, Joanna C, Jackie B: Quality-Adjusted Life-Year Lack Quality in Pediatric Care: A Critical Reiew of Published Cost-Utility Studies in Child Health. Pediatrics, 2005. 115(5): p. e600.

8. Karen B, Magnus J: Incorporating quality of life changes into economic evaluations of health care: an overview. Health Policy, 1996. 36: p. 155-66.

9. Rasanen P, Roine E, Sintonen H, et al.: Use of quality-adjusted life years for the estimation of effectiveness of health care: A systematic literature review. Int J Technol Assess Health Care, 2006. 22(2): p. 235-41.

10. Rodriguez LV, Blander DS, Dorey F, Raz S, Zimmern P: Discrepancy in patient and physician perception of patient's quality of life related to urinary symptoms. Urology, 2003. 62(1): p. 49-53.

11. Coons SJ, Gwaltney CJ, Hays RD, et al.: Recommendations on evidence needed to support measurement equivalence between electronic and paper-based patient-reported outcome (PRO) measures: ISPOR ePRO Good Research Practices Task Force report. Value Health, 2009. 12(4): p. 419-29.

12. Streiner DL NG: Health Measurement Scales. 1989: Oxford: OUP.

13. Revicki DA, Osoba D, Fairclough D, et al.: Recommendations on health-related quality of life research to support labeling and promotional claims in the United States. Qual Life Res, 2000. 9(8): p. 887-900.

14. Kerlinger F, Lee H: Foundations of Behavioral Research. 4th ed. 1999: Wadsworth Publishing.

15. Murawski MM, Miederhoff PA: On the generalizability of statistical expressions of health related quality of life instrument responsiveness: a data synthesis. Qual Life Res, 1998. 7(1): p. 11-22.

16. Jaeschke R, Singer J, Guyatt GH: Measurement of health status. Ascertaining the minimal clinically important difference. Control Clin Trials, 1989. 10(4): p. 407-15.

17. Guyatt GH, Juniper EF, Walter SD, Griffith LE, Goldstein RS: Interpreting treatment effects in randomised trials. Bmj, 1998. 316(7132): p. 690-3.

18. Kazis LE, Anderson JJ, Meenan RF: Effect sizes for interpreting changes in health status. Med Care, 1989. 27(3 Suppl): p. S178-89.

19. Wyrwich KW, Norquist JM, Lenderking WR, Acaster S: Methods for interpreting change over time in patient-reported outcome measures. Qual Life Res, 2012.

20. Acquadro C, Conway K, Hareendran A, Aaronson N: Literature review of methods to translate health-related quality of life questionnaires for use in multinational clinical trials. Value Health, 2008. 11(3): p. 509-21.

21. Herdman M, Fox-Rushby J, Badia X: A model of equivalence in the cultural adaptation of HRQoL instruments: the universalist approach. Qual Life Res, 1998. 7(4): p. 323-35.

22. Wild D, Grove A, Martin M, et al.: Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes (PRO) Measures: report of the ISPOR Task Force for Translation and Cultural Adaptation. Value Health, 2005. 8(2): p. 94-104.

23. Coyne KS, Margolis MK, Thompson C, Kopp Z: Psychometric equivalence of the OAB-q in Danish, German, Polish, Swedish, and Turkish. Value Health, 2008. 11(7): p. 1096-101.

24. European Agency for the Evaluation of Medicinal Products CfPMP: Note for guidance on the clinical investigation of medicinal productsfor the treatment of urinary incontinence. . December 2002, London.

25. European Medicines Agency: Reflection paper on the regulatory guidance for the use of health-related quality of life (HRQL) measures in the evaluation of medicinal products, Committee for Medicinal Products for Human Use (CHMP), Editor. 2005, EMEA: London.

26. Aaronson NK: Quality of life assessment in clinical trials: methodologic issues. Control Clin Trials, 1989. 10(4 Suppl): p. 195S-208S.

27. Abrams P, Avery K, Gardener N, Donovan J: The International Consultation on Incontinence Modular Questionnaire: www.iciq.net. J Urol, 2006. 175(3 Pt 1): p. 1063-6; discussion 1066.

28. Avery K, Donovan J, Peters TJ, et al.: ICIQ: a brief and robust measure for evaluating the symptoms and impact of urinary incontinence. Neurourol Urodyn, 2004. 23(4): p. 322-30.

29. Donovan JL, Peters TJ, Abrams P, et al.: Scoring the short form ICSmaleSF questionnaire. International Continence Society. J Urol, 2000. 164(6): p. 1948-55.

30. Brookes ST, Donovan JL, Wright M, Jackson S, Abrams P: A scored form of the Bristol Female Lower Urinary Tract Symptoms questionnaire: data from a randomized controlled trial of surgery for women with stress incontinence. Am J Obstet Gynecol, 2004. 191(1): p. 73-82.

31. Price N, Jackson SR, Avery K, Brookes ST, Abrams P: Development and psychometric evaluation of the ICIQ Vaginal Symptoms Questionnaire: the ICIQ-VS. Bjog, 2006. 113(6): p. 700-12.

32. Cotterill N, Norton C, Avery KN, Abrams P, Donovan JL: A patient-centered approach to developing a comprehensive symptom and quality of life assessment of anal incontinence. Dis Colon Rectum, 2008. 51(1): p. 82-7.

33. Cotterill N, Norton C, Avery KN, Abrams P, Donovan JL: Psychometric evaluation of a new patient-completed questionnaire for evaluating anal incontinence symptoms and impact on quality of life: the ICIQ-B. Dis Colon Rectum, 2011. 54(10): p. 1235-50.

34. Margolis MK, Vats V, Coyne KS, Kelleher C: Establishing the content validity of the King's Health Questionnaire in men and women with overactive bladder in the US. Patient, 2011. 4(3): p. 177-87.

35. Donovan JL, Brookes ST, de la Rosette JJ, et al.: The responsiveness of the ICSmale questionnaire to outcome: evidence from the ICS-'BPH' study. BJU Int, 1999. 83(3): p. 243-8.

36. Jackson S, Donovan J, Brookes S, et al.: The Bristol Female Lower Urinary Tract Symptoms questionnaire: development and psychometric testing. Br J Urol, 1996. 77(6): p. 805-12.

37. Abraham L, Hareendran A, Mills IW, et al.: Development and validation of a quality-of-life measure for men with nocturia. Urology, 2004. 63(3): p. 481-6.

38. Coyne KS, Gelhorn H, Thompson C, Kopp ZS, Guan Z: The psychometric validation of a 1-week recall period for the OAB-q. Int Urogynecol J, 2011. 22(12): p. 1555-63.

39. De Gennaro M, Niero M, Capitanucci ML, et al.: Validity of the international consultation on incontinence questionnaire-pediatric lower urinary tract symptoms: a screening questionnaire for children. J Urol, 2010. 184(4 Suppl): p. 1662-7.

40. Bright E, Cotterill N, Drake M, Abrams P: Developing a validated urinary diary: Phase 1. Neurourol Urodyn, 2012. 31(5): p. 625-33.

41. Kiresuk T, Sherman R: Goal attainment scaling: a general method of evaluating comprehensive community mental health programs. Community Ment Health J, 1968. 4: p. 443-453.

42. Krowinski W, Steiber S: Measuring patient satisfacion. 2nd ed. 1996: American Hospital Publishing.

43. Weaver M, Patrick DL, Markson LE, et al.: Issues in the measurement of satisfaction with treatment. Am J Manag Care, 1997. 3(4): p. 579-94.

44. Piault E, Evans CJ, Espindle D, et al.: Development and validation of the Overactive Bladder Satisfaction (OAB-S) Questionnaire. Neurourol Urodyn, 2008. 27(3): p. 179-90.

45. Pleil AM, Coyne KS, Reese PR, et al.: The validation of patient-rated global assessments of treatment benefit, satisfaction, and willingness to continue--the BSW. Value Health, 2005. 8 Suppl 1: p. S25-34.

46. Brubaker L, Khullar V, Piault E, et al.: Goal attainment scaling in patients with lower urinary tract symptoms: development and pilot testing of the Self-Assessment Goal Achievement (SAGA) questionnaire. Int Urogynecol J, 2011. 22(8): p. 937-46.

47. Fianu-Jonasson A, Brubaker L, Kelleher C, et al.: Understanding Swedish patients' expectations for treatment of their urinary symptoms. in Nordic Urogynecological Association. 2009. Reykjavik, Iceland.

48. Hullfish KL, Bovbjerg VE, Gibson J, Steers WD: Patient-centered goals for pelvic floor dysfunction surgery: what is success, and is it achieved? Am J Obstet Gynecol, 2002. 187(1): p. 88-92.

49. Mahajan ST, Elkadry EA, Kenton KS, Shott S, Brubaker L: Patient-centered surgical outcomes: the impact of goal achievement and urge incontinence on patient satisfaction one year after surgery. Am J Obstet Gynecol, 2006. 194(3): p. 722-8.

50. Payne C, Allee T: Goal achievement provides new insights into interstitial cystitis/painful bladder syndrome symptoms and outcomes. Neurourol Urodyn, 2009. 28(1): p. 13-7.

51. Piault E, Doshi S, Brandt BA, et al.: Linguistic validation of translation of the Self-Assessment Goal Achievement (SAGA) questionnaire from English. Health Qual Life Outcomes, 2012. 10: p. 40.

52. Coyne KS, Matza LS, Kopp Z, Abrams P: The validation of the patient perception of bladder condition (PPBC): a single-item global measure for patients with overactive bladder. Eur Urol, 2006. 49(6): p. 1079-86.

53. Abrams P, Cardozo L, Fall M, et al.: The standardisation of terminology in lower urinary tract function: report from the standardisation sub-committee of the International Continence Society. Urology, 2003. 61(1): p. 37-49.

54. Brubaker L: Urgency: the cornerstone symptom of overactive bladder. Urology, 2004. 64(6 Suppl 1): p. 12-6.

55. Staskin DR: The urge to define urgency: a review of three approaches. Curr Urol Rep, 2004. 5(6): p. 413-5.

56. Brubaker L: Urinary urgency and frequency: what should a clinician do? Obstet Gynecol, 2005. 105(3): p. 661-7.

57. Chapple CR, Wein AJ: The urgency of the problem and the problem of urgency in the overactive bladder. BJU Int, 2005. 95(3): p. 274-5.

58. Barber MD, Kuchibhatla MN, Pieper CF, Bump RC: Psychometric evaluation of 2 comprehensive condition-specific quality of life instruments for women with pelvic floor disorders. Am J Obstet Gynecol, 2001. 185(6): p. 1388-95.

59. Digesu GA, Santamato S, Khullar V, et al.: Validation of an Italian version of the prolapse quality of life questionnaire. Eur J Obstet Gynecol Reprod Biol, 2003. 106(2): p. 184-92.

60. Baessler K, O'Neill SM, Maher CF, Battistutta D: A validated self-administered female pelvic floor questionnaire. Int Urogynecol J, 2010. 21(2): p. 163-72.

61. Peterson TV, Karp DR, Aguilar VC, Davila GW: Validation of a global pelvic floor symptom bother questionnaire. Int Urogynecol J, 2010. 21(9): p. 1129-35.

62. Rogers RG, Coates KW, Kammerer-Doak D, Khalsa S, Qualls C: A short form of the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12). Int Urogynecol J Pelvic Floor Dysfunct, 2003. 14(3): p. 164-8; discussion 168.

63. Radley SCJ, G. L. Kubwalo, B. E. Stevens, V. Leathard, A. Tanguy, E: Feasibility and acceptability of electronic interviewing in urogynaecology. International Urogynecology Journal, 2003. 14(SUPP/1): p. 239

64. Ellerkmann RM, Cundiff GW, Melick CF, et al.: Correlation of symptoms with location and severity of pelvic organ prolapse. Am J Obstet Gynecol, 2001. 185(6): p. 1332-7; discussion 1337-8.

65. Mouritsen L, Larsen JP: Symptoms, bother and POPQ in women referred with pelvic organ prolapse. Int Urogynecol J Pelvic Floor Dysfunct, 2003. 14(2): p. 122-7.

66. Mann CH, Radley SC, Begum G, et al.: Constipation, faecal incontinence and urinary symptoms in women awaiting hysterectomy. J Obstet Gynaecol, 2000. 20(5): p. 530-2.

67. Radley S, Keighley MR, Radley SC, Mann CH: Bowel dysfunction following hysterectomy. Br J Obstet Gynaecol, 1999. 106(11): p. 1120-5.

68. Jorge JM WS: Etiology and management of fecal incontinence. Dis Colon Rectum. , 1993. 36(1): p. 77-97.

69. Norton C, Whitehead WE, Bliss D, Harari D, Lang J: Conservative and pharmacological management of faecal incontinence in adults. in Incontinence: Proceedings of the Fourth International Consultation on Incontinence. 2008. Paris, France: Health Publication Ltd.

70. Engel AF, Kamm MA, Bartram CI, Nicholls RJ: Relationship of symptoms in faecal incontinence to specific sphincter abnormalities. Int J Colorectal Dis, 1995. 10(3): p. 152-5.

71. Rockwood TH, Church JM, Fleshman JW, et al.: Fecal Incontinence Quality of Life Scale: quality of life instrument for patients with fecal incontinence. Dis Colon Rectum, 2000. 43(1): p. 9-16; discussion 16-7.

72. Hiller L, Bradshaw HD, Radley SC, Radley S: A scoring system for the assessment of bowel and lower urinary tract symptoms in women. Bjog, 2002. 109(4): p. 424-30.

73. Hiller L, Radley S, Mann CH, et al.: Development and validation of a questionnaire for the assessment of bowel and lower urinary tract symptoms in women. Bjog, 2002. 109(4): p. 413-23.

74. Osterberg A, Graf W, Karlbom U, Pahlman L: Evaluation of a questionnaire in the assessment of patients with faecal incontinence and constipation. Scand J Gastroenterol, 1996. 31(6): p. 575-80.

75. Bakx R, Sprangers MA, Oort FJ, et al.: Development and validation of a colorectal functional outcome questionnaire. Int J Colorectal Dis, 2005. 20(2): p. 126-36.

76. Bug GJ, Kiff ES, Hosker G: A new condition-specific health-related quality of life questionnaire for the assessment of women with anal incontinence. Bjog, 2001. 108(10): p. 1057-67.

77. Krysa J, Lyons M, Williams AB: A simple quality of life questionnaire for patients with faecal incontinence. Int J Colorectal Dis, 2009. 24(10): p. 1213-7.

78. O'Keefe EA, Talley NJ, Tangalos EG, Zinsmeister AR: A bowel symptom questionnaire for the elderly. J Gerontol, 1992. 47(4): p. M116-21.

79. Bharucha AE, Locke GR, 3rd, Seide BM, Zinsmeister AR: A new questionnaire for constipation and faecal incontinence. Aliment Pharmacol Ther, 2004. 20(3): p. 355-64.

80. Reilly WT, Talley NJ, Pemberton JH, Zinsmeister AR: Validation of a questionnaire to assess fecal incontinence and associated risk factors: Fecal Incontinence Questionnaire. Dis Colon Rectum, 2000. 43(2): p. 146-53; discussion 153-4.

81. Cockell SJ, Oates-Johnson T, Gilmour DT, Vallis TM, Turnbull GK: Postpartum flatal and Fecal Incontinence Quality-of-Life Scale: a disease- and population-specific measure. Qual Health Res, 2003. 13(8): p. 1132-44.

82. Hallbook O, Sjodahl R: Surgical approaches to obtaining optimal bowel function. Semin Surg Oncol, 2000. 18(3): p. 249-58.

83. Hull TL, Floruta C, Piedmonte M: Preliminary results of an outcome tool used for evaluation of surgical treatment for fecal incontinence. Dis Colon Rectum, 2001. 44(6): p. 799-805.

84. Rust J, Golombok S: The Golombok-Rust Inventory of Sexual Satisfaction (GRISS). Br J Clin Psychol, 1985. 24 (Pt 1): p. 63-4.

85. Rosen R, Brown C, Heiman J, et al.: The Female Sexual Function Index (FSFI): a multidimensional self-report instrument for the assessment of female sexual function. J Sex Marital Ther, 2000. 26(2): p. 191-208.

86. Clayton AH, McGarvey EL, Clavet GJ: The Changes in Sexual Functioning Questionnaire (CSFQ): development, reliability, and validity. Psychopharmacol Bull, 1997. 33(4): p. 731-45.

87. Trudel G, Ravart M, Matte B: The use of the multiaxial diagnostic system for sexual dysfunctions in the assessment of hypoactive sexual desire. J Sex Marital Ther, 1993. 19(2): p. 123-30.

88. Tubaro A, Polito M, Giambroni L, et al.: Sexual function in patients with LUTS suggestive of BPH. Eur Urol, 2001. 40 Suppl 1: p. 19-22.

89. McCoy N: The McCoy Female Sexuality Questionnaire Quality of Life Research, 2000. 9(Supplement 6): p. 739-745.

90. Symonds T, Boolell M, Quirk F: Development of a questionnaire on sexual quality of life in women. J Sex Marital Ther, 2005. 31(5): p. 385-97.

91. Okamura K, Usami T, Nagahama K, Maruyama S, Mizuta E: "Quality of life" assessment of urination in elderly Japanese men and women with some medical problems using International Prostate Symptom Score and King's Health Questionnaire. Eur Urol, 2002. 41(4): p. 411-9.

92. DuBeau CE, Levy B, Mangione CM, Resnick NM: The impact of urge urinary incontinence on quality of life: importance of patients' perspective and explanatory style. J Am Geriatr Soc, 1998. 46(6): p. 683-92.

93. Coyne KS, Matza LS, Brewster-Jordan J, Thompson C, Bavendam T: The psychometric validation of the OAB family impact measure (OAB-FIM). Neurourol Urodyn, 2010. 29(3): p. 359-69.

94. Costa P, Perrouin-Verbe B, Colvez A, et al.: Quality of life in spinal cord injury patients with urinary difficulties. Development and validation of qualiveen. Eur Urol, 2001. 39(1): p. 107-13.

95. Bonniaud V, Bryant D, Parratte B, Gallien P, Guyatt G: Qualiveen: a urinary disorder-specific instrument for use in clinical trials in multiple sclerosis. Arch Phys Med Rehabil, 2006. 87(12): p. 1661-3.

96. Bonniaud V, Jackowski D, Parratte B, et al.: Quality of life in multiple sclerosis patients with urinary disorders: discriminative validation of the English version of Qualiveen. Qual Life Res, 2005. 14(2): p. 425-31.

97. Pannek J, Mark R, Stohrer M, Schurch B: [Quality of life in German-speaking patients with spinal cord injuries and bladder dysfunctions. Validation of the German version of the Qualiveen questionnaire]. Urologe A, 2007. 46(10): p. 1416-21.

98. D'Ancona CA, Tamanini JT, Botega N, et al.: (2008 June 5 [Epub ahead of print]) Quality of life of neurogenic patients: translation and validation of the Portuguese version of Qualiveen. Int Urol Nephrol.

99. Bonniaud V, Bryant D, Parratte B, Guyatt G: Qualiveen, a urinary-disorder specific instrument: 0.5 corresponds to the minimal important difference. J Clin Epidemiol, 2008. 61(5): p. 505-10.

100. Fowler FJ, Jr., Barry MJ, Lu-Yao G, et al.: Patient-reported complications and follow-up treatment after radical prostatectomy. The National Medicare Experience: 1988-1990 (updated June 1993). Urology, 1993. 42(6): p. 622-9.

101. Fowler FJ, Jr., Barry MJ, Lu-Yao G, et al.: Effect of radical prostatectomy for prostate cancer on patient quality of life: results from a Medicare survey. Urology, 1995. 45(6): p. 1007-13; discussion 1013-5.

102. Schag CA, Ganz PA, Heinrich RL: CAncer Rehabilitation Evaluation System--short form (CARES-SF). A cancer specific rehabilitation and quality of life instrument. Cancer, 1991. 68(6): p. 1406-13.

103. da Silva F RE, Costa T, Denis L: Quality of life in patients wtih prostatic cancer. Cancer, 1993. 71(3): p. 113-1142.

104. Stockler MR, Osoba D, Goodwin P, Corey P, Tannock IF: Responsiveness to change in health-related quality of life in a randomized clinical trial: a comparison of the Prostate Cancer Specific Quality of Life Instrument (PROSQOLI) with analogous scales from the EORTC QLQ-C30 and a trial specific module. European Organization for Research and Treatment of Cancer. J Clin Epidemiol, 1998. 51(2): p. 137-45.

105. Clark JA, Inui TS, Silliman RA, et al.: Patients' perceptions of quality of life after treatment for early prostate cancer. J Clin Oncol, 2003. 21(20): p. 3777-84.

106. Cella D: Manual of the Functional Assessment of Chronic Illness Therapy (FACIT) Measurement System. Version 4 ed. 1997, Evanston IL: Center on Outcomes, Research and Education (CORE), Evanston Northwestern Healthcare and Northwestern University.

107. Cookson MS, Dutta SC, Chang SS, et al.: Health related quality of life in patients treated with radical cystectomy and urinary diversion for urothelial carcinoma of the bladder: development and validation of a new disease specific questionnaire. J Urol, 2003. 170(5): p. 1926-30.

108. Watkins-Bruner D, Scott C, Lawton C, et al.: RTOG's first quality of life study--RTOG 90-20: a phase II trial

of external beam radiation with etanidazole for locally advanced prostate cancer. Int J Radiat Oncol Biol Phys, 1995. 33(4): p. 901-6.

109. Litwin MS, Hays RD, Fink A, et al.: Quality-of-life outcomes in men treated for localized prostate cancer. Jama, 1995. 273(2): p. 129-35.

110. Barry MJ, Fowler FJ, Jr., O'Leary MP, et al.: The American Urological Association symptom index for benign prostatic hyperplasia. The Measurement Committee of the American Urological Association. J Urol, 1992. 148(5): p. 1549-57; discussion 1564.

111. Cockett AT, Aso Y, Chatelain C, et al. : The international consultation on benign prostatic hyperplasia (BPH). 1991, Paris.

112. Boyarsky S, Jones G, Paulson DF, Prout GR, Jr.: A new look at bladder neck obstruction by the food and drug administration regulators: guide lines for investigation of benign prostatic hypertrophy. Trans Am Assoc Genitourin Surg, 1976. 68: p. 29-32.

113. Barry MJ, Fowler FJ, Jr., O'Leary MP, et al.: Measuring disease-specific health status in men with benign prostatic hyperplasia. Measurement Committee of The American Urological Association. Med Care, 1995. 33(4 Suppl): p. AS145-55.

114. Epstein RS, Deverka PA, Chute CG, et al.: Urinary symptom and quality of life questions indicative of obstructive benign prostatic hyperplasia. Results of a pilot study. Urology, 1991. 38(1 Suppl): p. 20-6.

115. Amarenco G, Arnould B, Carita P, et al.: European psychometric validation of the CONTILIFE: a Quality of Life questionnaire for urinary incontinence. Eur Urol, 2003. 43(4): p. 391-404.

116. Hansen BJ, Flyger H, Brasso K, et al.: Validation of the self-administered Danish Prostatic Symptom Score (DAN-PSS-1) system for use in benign prostatic hyperplasia. Br J Urol, 1995. 76(4): p. 451-8.

117. Lukacz ES, Lawrence JM, Buckwalter JG, et al.: Epidemiology of prolapse and incontinence questionnaire: validation of a new epidemiologic survey. Int Urogynecol J Pelvic Floor Dysfunct, 2005. 16(4): p. 272-84.

118. Donovan JL, Kay HE, Peters TJ, et al.: Using the ICSOoL to measure the impact of lower urinary tract symptoms on quality of life: evidence from the ICS-'BPH' Study. International Continence Society--Benign Prostatic Hyperplasia. Br J Urol, 1997. 80(5): p. 712-21.

119. Hagen S, Hanley J, Capewell A: Test-retest reliability, validity, and sensitivity to change of the urogenital distress inventory and the incontinence impact questionnaire. Neurourol Urodyn, 2002. 21(6): p. 534-9.

120. Uebersax JS, Wyman JF, Shumaker SA, McClish DK, Fantl JA: Short forms to assess life quality and symptom distress for urinary incontinence in women: the Incontinence Impact Questionnaire and the Urogenital Distress Inventory. Continence Program for Women Research Group. Neurourol Urodyn, 1995. 14(2): p. 131-9.

121. Bjelic-Radisic V, Dorfer M, Tamussino K, et al.: The Incontinence Outcome Questionnaire: an instrument for assessing patient-reported outcomes after surgery for stress urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct, 2007. 18(10): p. 1139-49.

122. Bushnell DM, Martin ML, Summers KH, et al.: Quality of life of women with urinary incontinence: cross-cultural performance of 15 language versions of the I-QOL. Qual Life Res, 2005. 14(8): p. 1901-13.

123. Wagner TH, Patrick DL, Bavendam TG, Martin ML, Buesching DP: Quality of life of persons with urinary incontinence: development of a new measure. Urology, 1996. 47(1): p. 67-71; discussion 71-2.

124. Murphy M, Culligan PJ, Arce CM, et al.: Construct validity of the incontinence severity index. Neurourol Urodyn, 2006. 25(5): p. 418-23.

125. Yu LC, Kaltreider DL: Stressed nurses dealing with incontinent patients. J Gerontol Nurs, 1987. 13(1): p. 27-30.

126. Twiss C, Triaca V, Anger J, et al.: Validating the incontinence symptom severity index: a self-assessment instrument for voiding symptom severity in women. J Urol, 2009. 182(5): p. 2384-91.

127. Shaw C, Matthews RJ, Perry SI, et al.: Validity and reliability of a questionnaire to measure the impact of lower urinary tract symptoms on quality of life: the Leicester Impact Scale. Neurourol Urodyn, 2004. 23(3): p. 229-36.

128. Robinson JP, Avi-Itzhak T, McCorkle R: Psychometric properties of the Male Urogenital Distress Inventory (MUDI) and Male Urinary Symptom Impact Questionnaire (MUSIQ) in patients following radical prostatectomy. Urol Nurs, 2007. 27(6): p. 512-8.

129. Robinson JP, Shea JA: Development and testing of a measure of health-related quality of life for men with urinary incontinence. J Am Geriatr Soc, 2002. 50(5): p. 935-45.

130. Mock LL, Parmelee PA, Kutner N, Scott J, Johnson TM, 2nd: Content validation of symptom-specific nocturia quality-of-life instrument developed in men: issues expressed by women, as well as men. Urology, 2008. 72(4): p. 736-42.

131. Hendriks EJ, Bernards AT, Berghmans BC, de Bie RA: The psychometric properties of the PRAFAB-questionnaire: a brief assessment questionnaire to evaluate severity of urinary incontinence in women. Neurourol Urodyn, 2007. 26(7): p. 998-1007.

132. Rai GS, Kiniors M, Wientjes H: Urinary incontinence handicap inventory. Arch Gerontol Geriatr, 1994. 19(1): p. 7-10.

133. Stach-Lempinen B, Kujansuu E, Laippala P, Metsanoja R: Visual analogue scale, urinary incontinence severity score and 15 D--psychometric testing of three different health-related quality-of-life instruments for urinary incontinent women. Scand J Urol Nephrol, 2001. 35(6): p. 476-83.

134. Lukacs B, Comet D, Grange JC, Thibault P: Construction and validation of a short-form benign prostatic hypertrophy health-related quality-of-life questionnaire. BPH Group in General Practice. Br J Urol, 1997. 80(5): p. 722-30.

135. Lee PS, Reid DW, Saltmarche A, Linton L: Measuring the psychosocial impact of urinary incontinence: the York Incontinence Perceptions Scale (YIPS). J Am Geriatr Soc, 1995. 43(11): p. 1275-8.

136. Burgio KL, Goode PS, Richter HE, Locher JL, Roth DL: Global ratings of patient satisfaction and perceptions of improvement with treatment for urinary incontinence: validation of three global patient ratings. Neurourol Urodyn, 2006. 25(5): p. 411-7.

137. Margolis MK, Fox KM, Cerulli A, et al.: Psychometric validation of the overactive bladder satisfaction with treatment questionnaire (OAB-SAT-q). Neurourol Urodyn, 2009. 28(5): p. 416-22.

138. Colman S, Chapple C, Nitti V, et al.: Validation of treatment benefit scale for assessing subjective outcomes in treatment of overactive bladder. Urology, 2008. 72(4): p. 803-7.

139. Brown JS, Bradley CS, Subak LL, et al.: The sensitivity and specificity of a simple test to distinguish between urge and stress urinary incontinence. Ann Intern Med, 2006. 144(10): p. 715-23.

140. Basra R, Artibani W, Cardozo L, et al.: Design and validation of a new screening instrument for lower urinary tract dysfunction: the bladder control self-assessment questionnaire (B-SAQ). Eur Urol, 2007. 52(1): p. 230-7.

141. Homma Y, Yoshida M, Yamanishi T, Gotoh M: Core Lower Urinary Tract Symptom score (CLSS) questionnaire: a reliable tool in the overall assessment of lower urinary tract symptoms. Int J Urol, 2008. 15(9): p. 816-20.

142. Gunthorpe W, Brown W, Redman S: The development and evaluation of an incontinence screening questionnaire for female primary care. Neurourol Urodyn, 2000. 19(5): p. 595-607.

143. Diokno AC, Brock BM, Brown MB, Herzog AR: Prevalence of urinary incontinence and other urological symptoms in the noninstitutionalized elderly. J Urol, 1986. 136(5): p. 1022-5.

144. Blaivas JG, Panagopoulos G, Weiss JP, Somaroo C: Validation of the overactive bladder symptom score. J Urol, 2007. 178(2): p. 543-7; discussion 547.

145. Coyne KS, Zyczynski T, Margolis MK, Elinoff V, Roberts RG: Validation of an overactive bladder awareness tool for use in primary care settings. Adv Ther, 2005. 22(4): p. 381-94.

146. Coyne KS, Margolis MK, Bavendam T, Roberts R, Elinoff V: Validation of a 3-item OAB awareness tool. Int J Clin Pract, 2011. 65(2): p. 219-24.

147. Parsons CL, Dell J, Stanford EJ, et al.: Increased prevalence of interstitial cystitis: previously unrecognized urologic and gynecologic cases identified using a new symptom questionnaire and intravesical potassium sensitivity. Urology, 2002. 60(4): p. 573-8.

148. Bradley CS, Rovner ES, Morgan MA, et al.: A new questionnaire for urinary incontinence diagnosis in women: development and testing. Am J Obstet Gynecol, 2005. 192(1): p. 66-73.

149. Haab F, Richard F, Amarenco G, et al.: Comprehensive evaluation of bladder and urethral dysfunction symptoms: development and psychometric validation of the Urinary Symptom Profile (USP) questionnaire. Urology, 2008. 71(4): p. 646-56.

150. Shaw C, Matthews RJ, Perry SI, et al.: Validity and reliability of an interviewer-administered questionnaire to measure the severity of lower urinary tract symptoms of storage abnormality: the Leicester Urinary Symptom Questionnaire. BJU Int, 2002. 90(3): p. 205-15.

151. Srikrishna S, Robinson D, Cardozo L: Validation of the Patient Global Impression of Improvement (PGI-I) for urogenital prolapse. Int Urogynecol J, 2010. 21(5): p. 523-8.

152. Yalcin I, Bump RC: Validation of two global impression questionnaires for incontinence. Am J Obstet Gynecol, 2003. 189(1): p. 98-101.

153. Broome BA: Psychometric analysis of the Broome Pelvic Muscle Self-Efficacy Scale in African-American women with incontinence. Urol Nurs, 2001. 21(4): p. 289-97.

154. Matza LS, Thompson CL, Krasnow J, et al.: Test-retest reliability of four questionnaires for patients with overactive bladder: the overactive bladder questionnaire (OAB-q), patient perception of bladder condition (PPBC), urgency questionnaire (UQ), and the primary OAB symptom questionnaire (POSQ). Neurourol Urodyn, 2005. 24(3): p. 215-25.

155. Black N, Griffiths J, Pope C: Development of a symptom severity index and a symptom impact index for stress incontinence in women. Neurourol Urodyn, 1996. 15(6): p. 630-40.

156. Badia Llach X CDD, Perales Cabañas L, Pena Outeriño JM, Martínez-Agulló E, Conejero Sugrañés J, Arañó Beltrán P, Marqués Queimadelos A, Roset Gamisans M, Perulero Escobar N: [The development and preliminary validation of the IU-4 questionnaire for the clinical classification of urinary incontinence]. Actas Urol Esp., 1999. 23(7): p. 565-72.

157. Lemack GE, Zimmern PE: Predictability of urodynamic findings based on the Urogenital Distress Inventory-6 questionnaire. Urology, 1999. 54(3): p. 461-6.

158. Nixon A, Colman S, Sabounjian L, et al.: A validated patient reported measure of urinary urgency severity in overactive bladder for use in clinical trials. J Urol, 2005. 174(2): p. 604-7.

159. Cartwright R, Panayi D, Cardozo L, Khullar V: Reliability and normal ranges for the Patient's Perception of Intensity of Urgency Scale in asymptomatic women. BJU Int, 2010. 105(6): p. 832-6.

160. Bent AE, Gousse AE, Hendrix SL, et al.: Validation of a two-item quantitative questionnaire for the triage of women with urinary incontinence. Obstet Gynecol, 2005. 106(4): p. 767-73.

161. Lubeck DP, Prebil LA, Peeples P, Brown JS: A health related quality of life measure for use in patients with urge urinary incontinence: a validation study. Qual Life Res, 1999. 8(4): p. 337-44.

162. Blaivas JG, Panagopoulos G, Weiss JP, Somaroo C, Chaikin DC: The urgency perception score: validation and test-retest. J Urol, 2007. 177(1): p. 199-202.

163. Cardozo L, Coyne KS, Versi E: Validation of the urgency perception scale. BJU Int, 2005. 95(4): p. 591-6.

164. Lowenstein L, FitzGerald MP, Kenton K, et al.: Evaluation of urgency in women, with a validated Urgency, Severity and Impact Questionnaire (USIQ). Int Urogynecol J Pelvic Floor Dysfunct, 2009. 20(3): p. 301-7.

165. Coyne KS, Harding G, Jumadilova Z, Weiss JP: Defining urinary urgency: patient descriptions of "gotta go". Neurourol Urodyn, 2012. 31(4): p. 455-9.

166. Coyne KS, Margolis MK, Hsieh R, Vats V, Chapple CR: Validation of the urinary sensation scale (USS). Neurourol Urodyn, 2011. 30(3): p. 360-5.

167. Al-Buheissi S, Khasriya R, Maraj BH, Malone-Lee J: A simple validated scale to measure urgency. J Urol, 2008. 179(3): p. 1000-5; discussion 1005.

168. Quirk FH, Heiman JR, Rosen RC, et al.: Development of a sexual function questionnaire for clinical trials of female sexual dysfunction. J Womens Health Gend Based Med, 2002. 11(3): p. 277-89.