CHAPTER 10

Committee 6

Symptom and Quality of Life Assessment

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BACKGROUND

Symptoms of incontinence are common, particularly amongst older people, and, at any age, incontinence can have a severe impact on the quality of life of some individuals. A number of treatments for incontinence are available, most of which aim to reduce the occurrence of incontinent episodes or to limit the impact of the disorder on everyday life. In research and clinical practice it is essential that the symptoms and impact of incontinence can be properly assessed and recorded. Symptoms of incontinence and their impact on patients' quality of life can be assessed in a number of ways, but the only valid way of measuring the patient's perspective of their predicament is through the use of psychometrically robust self-completion questionnaires.

In the reports from the First and Second International Consultations on Incontinence, the impact of incontinence on quality of life and methods of measuring these factors were described, and a number of questionnaires with acceptable levels of psychometric testing were recommended for use in research and clinical practice. [1] [2] This chapter will summarise the major findings from those reviews, extend these with an up-dated systematic review of the literature, and provide new recommendations for questionnaires developed for use in clinical practice and research.

In addition, the ICIQ modular questionnaires (supported by the International Consultation) are presented in detail and their use evaluated.

LITERATURE SEARCHING STRATEGY

A number of different electronic databases were searched, limited to adults over the age of 18 years and human studies from January 2001 to June 2004, including Pub-Med, Medline, PsychInfo, the LOCATORplus database for books, serial titles and audiovisuals, the Cochrane Library for randomised controlled trials, and the NLM Gateway database. The following keywords were used separately and/or in combination: "urinary incontinence", "incontinence", "questionnaire", "epidemiology", "prostate", "prolapse", "fecal", "faecal", "bowel", "anal" and "quality of life", "sexual" and "health utilities". Questionnaires identified in previous ICI reports were also searched in PubMed and Medline. A systematic Medline search from 1966 – April 2003 using the keywords "faecal", "fecal", "anal" or "bowel" with "questionnaire", "instrument", "quality of life", or "measure" found 58 references. Of these, only six described questionnaires for use in subjects with faecal incontinence.

A. THE MEASUREMENT OF INCONTINENCE AND QUALITY OF LIFE

Symptoms of incontinence and/or its impact on quality of life can be assessed in a number of ways. Traditionally, the clinical history has been used to gain a summary view of the symptoms of incontinence experienced by patients and their impact on their lives. Increasingly, patient-completed methods of measuring incontinence are being used, including voiding diaries and questionnaires. A detailed justification for the use of questionnaires was provided in the Second Consultation chapter. [2] In summary, questionnaires provide a method for the standardised collection of data from patients relating to incontinence and lower urinary tract symptoms. It is essential to collect such data from patients as clinicians' assessments of patients' quality of life have often been show to underestimate the degree of interference perceived by patients, and to focus on issues of lesser importance to patients. [3] [4] [5] [6] Voiding diaries (also known as frequency-volume charts or urinary diaries) are widely used to assess a limited number of symptoms such as frequency, nocturia and incontinent episodes. For a full assessment of the symptoms of incontinence and their impact on quality of life, questionnaires completed by patients themselves and which have been shown to be valid and reliable are recommended (see below for details of recommended questionnaires).

I. QUESTIONNAIRES – THEORETICAL ASPECTS

Questionnaires can be used to record the presence and severity of urinary symptoms including incontinence, as well as the impact of incontinence on everyday activities and quality of life. They are tools to measure 'subjective' phenomena such as symptoms and impact on quality of life in an objective way. Questionnaire design and utilisation is not a simple process. In order to have confidence that the questionnaire is measuring what it is supposed to measure, that it does this reliably, and is appropriate for use in the patient or population group under investigation, a number of studies have to be conducted. There are increasing numbers of validated questionnaires recommended for use in incontinence. When designed and tested thoroughly, questionnaires can have levels of precision which equal or exceed clinical measures. Of particular importance is the precision and accuracy of measures - more commonly referred to as psychometric properties.

1. Psychometric properties

Empirical evidence is required to show that a questionnaire is measuring what is intended – its validity, reliability and responsiveness to change:

a) Validity

The validity of a questionnaire is simply whether it measures what is intended, and has three major aspects. *Content/face validity* is the assessment of whether the questionnaire makes sense to those being measured and to experts in the clinical area, and also whether all the important or relevant domains are included. [7] Questions should be understandable and unambiguous to the patient and clinically appropriate. *Construct validity* relates to the relationships between the questionnaire and underlying theories. This requires a number of studies to examine the ability of the questionnaire to differentiate between patient groups - for example clinic attendees compared with individuals in the community, or clinic attendees with a particular diagnosis compared with those with another. This includes 'convergent' and 'discriminant' validity - how closely a new questionnaire is related to other measures of the same construct or the absence of relationships between constructs that are postulated to be independent. *Criterion validity* describes how well the questionnaire correlates with a 'gold standard' measure that already exists, such as a clinical or other validated measure.

b) Reliability

The reliability of a questionnaire refers to its ability to measure in a reproducible fashion. [7] This includes *internal consistency* - the extent to which items within the questionnaire are related to each other, measured by item-total correlation or Cronbach's alpha coefficient; and *reproducibility* - the variability between and within observers (inter- and intrarater reliability). Particularly important for questionnaires used to examine outcome is the concept of *stability* - whether the questionnaire measures the same sorts of things in the same person over a period of time. Stability is commonly assessed by a test-retest analysis, where the questionnaire is given to the same set of respondents twice, usually with an interval of two to six weeks.

c) Responsiveness

It is important that questionnaires to assess outcome can show that they are responsive to change in appropriate ways. Where a questionnaire has a simple score, treatment effects can be assessed by examining pre- and post-treatment differences between the intervention and control group by unpaired t-tests, repeated measures analysis of variance or effect sizes. [8] [9] [10] [11] Changes may be found to be statistically significant, but this does not necessarily mean that they are of clinical significance. [12]

2. Measuring quality of life

As indicated in the previous report, the term quality of life is used widely in research, often without any clear definition. It is linked to the World Health Organisation definition of health which refers to a state of physical, emotional and social well-being, and not just the absence of disease or infirmity. [13] 'Health-related quality of life' (HRQL) has been defined as including: "those attributes valued by patients including their resultant comfort or sense of well-being; the extent to which they were able to maintain reasonable physical, emotional, and intellectual function; the degree to which they retain their ability to participate in valued activities within the family, in the workplace and in the community" (Wenger and Furberg, quoted in. [14] This definition is long, but helps to emphasise the multidimensional nature of quality of life and the importance of considering each individual's perception of their own situation in the context of non-health related aspects such as jobs, family and other life circumstances. [15] Quality of life measures are being increasingly used with a wide variety of patients and in many different studies, and their use has increased significantly since the last Consultation.

The investigation of many studies in the previous report demonstrated urinary incontinence to reduce social relationships and activities, be associated with poor self-rated health, impair emotional and psychological well being, and jeopardize sexual relationships. Incontinence causes practical inconvenience, and for many requires often elaborate planning to conceal or prepare for incontinent episodes, and may cause financial hardship. Feelings of embarrassment or negative self-perception are common.

Questionnaires to assess the impact of incontinence need to encompass symptoms and impact on everyday quality of life. In the previous Consultation, questionnaires concerned with these aspects were dealt with separately. [2] in this report, the questionnaires are considered within the broad clinical groupings of urinary incontinence and lower urinary tract symptoms, faecal incontinence and pelvic organ prolapse. Increasingly, questionnaires are attempting to cover aspects of symptoms, bothersomeness, impact on general health, specific impact of symptoms and, sometimes, impact on specific activities such as sex life. These aspects are noted and commented on below.

Individualised measures of quality of life allow patients to identify for themselves the most important aspects of their lives, which constitute their appraisal of their overall quality of life. Individualised measures have not yet been used widely in the assessment of incontinence or lower urinary tract symptoms, although it is likely that measures such as the SEIQOL[16] may be useful.

3. International implementation

Increasingly, questionnaires are required to be used in a number of different populations and settings, but psychometric properties are not necessarily transferable. There are particular problems with the interpretation of symptoms and aspects of quality of life in different population groups as these are likely to be influenced by cultural factors. [17] [18] Authors have suggested a number of steps that should be taken to ensure that questionnaires may be used by different cultural groups:[19] [20] or from the MAPI Research Trust at pduc@mapi.fr.

4. Suitability/feasibility

A further issue of importance in research and clinical practice is that the questionnaire should be suitable for its purpose and feasible to be used. There is always a tension in research between having a questionnaire that encompasses all possible aspects of the condition and the necessity to avoid respondent burden and to make the instrument simple and easy to use. Increasingly, short and long versions of questionnaires are being produced to allow detailed research as well as rapid evaluation for research and clinical practice.

5. Relationships between clinical measures/test results and scores from symptom and quality of life questionnaires

The severity of urinary symptoms is often used as a measure of the impact of lower urinary tract dys-

function in both clinical practice and clinical trials. However, symptoms alone do not adequately assess the impact of urinary incontinence on an individual's life - this requires the use of symptom and generic/condition-specific quality of life questionnaires. Measuring the magnitude of symptoms is relatively straight forward but offers little insight into their impact. For example, do fewer incontinence episodes improve quality of life or is it the volume of an incontinent episode that is of most concern to patients? Incontinent patients find that many aspects of their lives are affected by the condition, including social, psychological, occupational, domestic, physical, and sexual aspects. Although it is of value to measure the bother caused by individual symptoms, it is important to appreciate that the majority of patients present with many different symptoms. These may change as a result of time and adaptive change, or as a result of treatment.

Relationships between clinical measures/test results and scores from symptom and quality of life questionnaires were assessed. Following detailed literature searchers, all papers describing the use of incontinence symptom questionnaires and/or quality of life questionnaires AND objective measures i.e. pad testing and / or urodynamic parameters were read (n=21).

Hunskaar et al used the Sickness Impact Profile to evaluate the quality of life impact of incontinence in women with stress or urge incontinence. [21] Mean scores on the SIP were low for both groups, but the study concluded that the impact of incontinence on quality of life was both age and symptom dependent. [21] Grimby et al compared the Nottingham Health Profile scores for women divided into three groups according to pad tests, a urinary diary, a cough provocation test and clinical history: urge incontinence, stress incontinence, or both. [22] A significantly higher level of emotional impairment and social isolation was found amongst those with urge and mixed incontinence than those with stress incontinence. [22]

The relationships between the results of clinical measures/tests and scores from symptom and quality of life questionnaires are complex. Each has an important role to play in the assessment of patients with urinary incontinence.

Several studies have looked at the value of history or questionnaires in the prediction of the type of urinary incontinence as determined by urological or gynaecological assessment. Bergman and Bader evaluated 122 incontinent patients and found that a detailed urinary symptoms questionnaire had a positive predictive value of 80% for genuine stress incontinence, and only 25% for detrusor instability. [23] Versi et al, using an analysis of symptoms for the prediction of genuine stress incontinence in 252 patients found that such a system achieved a correct classification of 81% with a false positive rate of 16%. [24] Lagro Janssen et al showed that symptoms of stress incontinence in the absence of symptoms of urge incontinence had a sensitivity of 78%, specificity of 84% and a positive predictive value of 87%. [25] Kaupalla and Kujansuu tried to solve the problem of differentiating between women with detrusor instability and stress incontinence by using an urgency score composed of responses to ten structured questions. [26] They found that 81% of patients with stress incontinence had an urgency score of less than 6 compared to 26% of patients with detrusor instability. [26]

It is tempting to postulate that symptom scores and clinical measures are somehow correlated. To examine this hypothesis we reviewed papers that have used validated questionnaires and that report the correlation between questionnaires scores and various clinical tests such as frequency volume charts, pad tests and urodynamic parameters. There were 21 papers (12 published after the year 2000) that reported on correlation or agreement between questionnaire scores and objective measurement of urine loss and/or urodynamic parameters. An additional paper correlated responses to UDI and IIQ to incontinence severity questions administered in a telephone interview.

The UDI-6 (Urogenital Distress Inventory) questionnaire[27] was correlated with urodynamic parameters in 5, pad test weights in 3 and voiding-incontinence diary parameters in 1 paper. The IIQ-7 (Incontinence Impact Questionnaire) [27] was correlated with urodynamic parameters, pad test weights and voiding-incontinence diary parameters in 3, 4 and 1 paper, respectively. The I-QOL (Incontinence Quality Of Life) questionnaire [28] was correlated with urodynamic parameters in 1, pad test weights in 2 and voiding-incontinence diary parameters in 3 papers. The UISS (Urinary Incontinence Severity Score) questionnaire [29] was correlated with urodynamic parameters, pad test weights and voiding-incontinence diary parameters in 1, 2 and 1 paper, respectively. The KHQ (King's Health Questionnaire)[30] the Q-section of the SEAPI QMM [31] SGUIS (St George Urinary Incontinence Score), [32]

ICIQ-SF (International Consultation on Incontinence – Short Form), [33] the ISI (Incontinence Severity Score), [34] and various VAS (Visual Analogue Scale) scores and miscellaneous questionnaires were evaluated in single papers.

a) Questionnaire data compared with frequency volume chart and/or voiding-incontinence diary parameters

In an observational validation study conducted in a population of 162 patients, voiding-incontinence diary parameters were correlated with IIQ-7 and UDI-6 scores [27]. In this study, statistically significant correlation coefficients between the number of incontinence-episodes and IIQ-7 and UDI-6 scores were 0.33 and 0.27, respectively. Furthermore, statistically significant correlation coefficients between the treatment related *change* in number of incontinence-episodes and the *change* in IIQ-7 and UDI-6 scores were 0.43 and 0.47, respectively. In contrast to these findings Stach-Lempinen et al noted no correlation between the UISS (urinary incontinence severity score) and any parameter from the FV-chart in an observational study performed before and after treatment for urinary incontinence in 82 patients. [35]

In another observational study of 435 older adults with urinary incontinence, Dugan et al found a significant correlation between the IIQ (r=0.40) as well as the UDI score (r=0.44) and the frequency of incontinence episodes. [36] Instead of a formal voiding-incontinence diary these authors used an interview to determine the frequency of incontinence episodes.

In a placebo controlled randomised study of duloxetine in female patients with stress (n=141) and mixed incontinence (n=147), I-QOL scores worsened significantly with an increasing number of incontinence episodes [37]. I-QOL scores were also significantly different for women who reported mild incontinence from those who reported moderate or severe incontinence. A 25% or greater decrease in the number of incontinence episodes was associated with a 5-point improvement in I-QOL score compared with the group who remained the same.

In another placebo controlled double-blind randomised study of duloxetine in female patients with stress (n=141) and mixed incontinence (n=553), the I-QOL scores at baseline were significantly worse in women with symptoms of mixed incontinence as compared to those with SUI symptoms only [38].

The I-QOL score was also correlated with voiding-incontinence diary parameters in an observational study of 114 patients undergoing sacral neuromodulation implantation for urge incontinence. [39] Additionally, a significant correlation between the I-QOL and the number of incontinence episodes was noted in this patient population ($r = -0.76$; $p<0.001$).

The correlation between the number of leaks per week on the frequency-volume chart and the St George urinary incontinence score (SGUIS) was studied by Blackwell et al[32] in 207 women with urinary incontinence (stress, urge or mixed). The SGUIS correlated moderately well ($r=0.610$; $p<0.001$) with the number of leaks per week on the frequency-volume chart. In women who had been treated surgically for genuine stress urinary incontinence (about a third of the total population), the correlation between change in the number of SGUIS-points and change in the number of leaks per week was good ($r=0.74$; $p<0.001$).

Filbeck et al used a non-validated own QoL questionnaire. [40] Continent patients as well as patients who still had a certain degree of incontinence after an operation for stress urinary incontinence, had improved QoL scores. These scores were in the "satisfactory" range for both groups. The authors conclude that QoL can improve significantly in spite of sub-optimal (objective) treatment results.

In general, the correlation between voiding-incontinence diary parameters and incontinence questionnaire scores is weak. This is particularly true for the UISS, UDI-6 and IIQ-7. The correlation between change diary parameters and change in questionnaire score may be somewhat better. In spite of this, the questionnaire scores were worse if the number of incontinence episodes was higher in some studies using the I-QOL. The type of incontinence (i.e. stress versus mixed or urge incontinence) seems to influence the questionnaire score with those who have pure stress incontinence exhibiting the lower scores.

b) Questionnaire data compared with pad test results

Fraser et al showed a poor correlation between the subjective degree of incontinence measured by a visual analogue scale and leakage as measured by pad testing. [41]

In a study of 255 women with stress incontinence, Slack et al graded incontinence in three severity categories according to the 24-hr pad test weight (in grams). [42] The categories were as follows: mild (0-8 gram), moderate (8.1-30 gram) and severe (>30

gram). Median values of the total scores of the I-QOL ($p<0.001$), UISS ($p<0.001$), and a visual analogue scale (VAS) score ($p<0.001$) showed a statistically significant worsening with increasing severity.

Wyman et al, using the IIQ, showed that women with detrusor instability experienced greater psychosocial dysfunction as a result of their urinary symptoms than women with genuine stress incontinence, although no relationship was found between the questionnaire score and urinary diary or pad test results. [43]

In an observational validation study conducted in a population of 162 patients, pad test weights were correlated with IIQ-7 and UDI-6 scores. [27] In this study, statistically significant correlation coefficients between the pad test weights and IIQ-7 and UDI-6 scores were 0.27 and 0.24, respectively. No report was given on treatment-related change in pad test volume and the change in questionnaire scores.

The IIQ was also evaluated in a setting involving male patients. [44] In a prospective randomised study of the treatment of post-radical prostatectomy incontinence 21 men were assigned to a control group, 18 to a group undergoing pelvic floor muscle exercises [PFME] and 19 to a group undergoing PFME in combination with electrical stimulation [ES]. Pearson correlation coefficients between the 24-hour pad test weight and the IIQ-7 score, were 0.34 ($P<0.05$) and 0.51 ($p<0.05$), respectively at 12 weeks and 24 weeks of follow-up. The EORTC QLQ C30 score showed no relationship with urine loss.

Van Kampen et al also studied men with post-radical prostatectomy incontinence. In a prospective randomised study of the treatment of post-radical prostatectomy incontinence, the men were divided in a control group (n=52) and a group receiving PFME+ES (n=50). [45] A Spearman correlation coefficient of 0.85 ($P<0.05$) between urine loss (24-hr pad test) and VAS score of the degree of incontinence was found at 1 month post-operatively.

In a clinical trial of a urethral device in women with stress-incontinence who had not undergone a urodynamic evaluation, Harvey et al found no correlation between the result of the 1-hr pad test and IIQ-7 or UDI-6. [46] In a placebo controlled randomised study of duloxetine in stress (n=141) and mixed incontinence (n=147), I-QOL scores significantly worsened with increasing pad weight [37]. A 25% or greater decrease in pad weight was associated with a 2-point improvement in I-QOL score compared to the group without changes in pad weight.

In an observational study of pre- and post treatment parameters in 82 patients Stach-Lempinen et al found that greater leakage in the 48-hr pad test predicted poorer QOL on the UISS (urinary incontinence severity score) (beta 0.25; $p= 0.034$). [35] A visual analogue scale (VAS) score of the degree of bother from incontinence, significantly correlated with pad weight ($r=0.46$; $p<0.05$). The *change* in urine leakage after treatment best predicted the *change* in UISS (beta 0.30; $p=0.024$) and the *change* in the VAS (beta 0.48; $p=0.001$). In an observational study of 52 female patients, Nager et al found a significant correlation between pad weight and QoL as measured with the Q-section of the SEAPI QMM score ($r=0.46$; $p=0.001$). [47] However, the Stamey incontinence grade had a low correlation with pad weight ($r=0.23$; $p=0.05$).

In Norway, Kulseng-Hanssen et al have developed the "Stress and urge incontinence and Quality of Life questionnaire". [48] This questionnaire yields 3 indexes: a SI-Index, an UI-Index and a QoL-Index. In an observational study using this questionnaire in 628 women, they found a significant correlation between the 24-hr pad test weights and the SI-Index and UI-Index scores of 0.23 ($p=0.01$) and 0.30 ($p=0.01$), respectively. The result of the SI-Index score and the result of the stress test were also significantly correlated ($r=0.31$; $p=0.01$).

Sandvik et al., [34] in search of a valid instrument for assessing the severity of incontinence in large epidemiological studies, found that a four-level severity index that is derived from the ISI questionnaire correlates moderately with the results of the 48-hour pad weighing test ($r=0.54$, $p<0.01$).

The correlation between the 1-hour pad weighing test and the St George urinary incontinence score (SGUIS) was studied by Blackwell et al in 207 women with urinary incontinence (stress, urge or mixed). [32] A poor correlation ($r=0.257$; $p=0.002$) was found between the SGUIS and the 1-hour pad weight. In women who had been treated surgically for genuine stress urinary incontinence (about a third of the total population), the correlation between change in the number of SGUIS-points and change in 1-hour pad weight was moderate ($r=0.53$; $p<0.001$.

The International Consultation on Incontinence – Short form (ICIQ-SF) score was compared with 24-hour pad weight results in 80 women with urodynamically proven stress urinary incontinence. [33] A moderate correlation was found (0.458, $p=0.000$).

The 24-hour pad weight correlated significantly with all 3 components of the ICIQ-SF, with the question "how much do you thinks you usually leak" showing the best but still moderate correlation (r=0.583, p=0.000). Interestingly, there was no correlation between the score and the 24-hour pad test in women with genuine stress incontinence who had already been treated surgically.

The UDI-6 and IIQ-7 are studied best. In general the correlation between questionnaire scores and pad test results is weak to moderate: the shorter the duration of the pad test, the poorer the correlation. In men with post-radical prostatectomy incontinence, the correlations appear to be slightly better. There is some evidence that visual analogue scale scores of the degree of incontinence and the I-QOL correlate somewhat better with pad test weights than UDI-6 and IIQ-7 scores.

c) Questionnaire data compared with urodynamic parameters

The predictive value of UDI-6 scores for urodynamic outcomes was analysed in a retrospective observational study of 174 female patients by Lemack and Zimmern. [49] No group of items from the UDI-6, either alone or in combination with a history of previous incontinence surgery, was able to predict patients with a coexistence of the conditions stress urinary incontinence (SUI) and detrusor instability (DI). The authors used a combination of high response (moderately or greatly bothersome problem) to question 3 which deals with leakage related to physical activity, and a history of previous anti-incontinence surgery for further evaluation. If these criteria had been used to indicate the necessity to perform urodynamic testing then this would have resulted in the identification of 91% of all critical urodynamic diagnoses. "Critical" urodynamic diagnoses as defined by the authors were: 1] SUI + DI or 2] VLPP < 60 cmH2O or 3] DI without SUI in those suspected of having SUI.

In another retrospective observational study of 128 female patients, the same authors found that a high response to question 3 of the UDI-6 was correlated to the urodynamic condition SUI (r=0.51). [50] However, the response to this question could not differentiate ISD (intrinsic sphincter deficiency) from non-ISD. A high response to question 2 of the UDI-6 which deals with leakage related to urgency, was correlated to condition detrusor instability (r=0.38).

In a placebo controlled double-blind randomised study of duloxetine in stress incontinence (n=141) and mixed incontinence (n=553), urodynamic studies were performed in a subset of 86 patients. [38] Urodynamic evidence of detrusor overactivity did not lead to an increased I-QOL score as compared to those with urodynamic stress incontinence only. The authors concluded that incontinence severity and not the presence of the urodynamic condition of detrusor overactivity, was the driver of mixed symptoms.

FitzGerald and Brubaker found that the degree of bother caused by urinary leakage with activity and the subsequent diagnosis of GSI were significantly associated in an observational study of 82 patients. [51] Of those who reported to be greatly bothered by urinary leakage with activity, 89% had GSI on urodynamics. However, the scores were not useful in detecting which patients would meet urodynamic criteria for ISD. Questions dealing with urinary frequency (46% of patients had confirmed detrusor overactivity if the patients were greatly bothered by frequency) and urge leakage (44% of the patients had confirmed detrusor overactivity if the patients were greatly bothered by urge leakage) were not predictive of detrusor overactivity on urodynamics. In this study, the UDI-6 and IIQ-7 scores could not be used as a substitute for urodynamic testing.

No correlation was noted between the UISS (urinary incontinence severity score) and any urodynamic finding in an observational pre- and post treatment study of 82 patients. [35] Interestingly, the score on a visual analogue scale (VAS) of the degree of bother from incontinence, significantly but weakly correlated with the maximal urethral closure pressure (MUCP; r=-0.29), first sensation (r=-0.26) and maximal detrusor pressure (r=0.30).

In an observational study of 75 women with stress incontinence, Theofrastous et al found no correlation between any of the studied urodynamic measures (i.e. dynamic Pressure Transmission Ratio, passive MUCP, VLPP and the scores of the UDI and IIQ scales. [52] In another observational study of 52 patients, QoL as measured with the Q-section of the SEAPI QMM score was not correlated with Q-tip angle, VLPP or MUCP. [47] FitzGerald et al noted that patients with stress incontinence who were urodynamically cured of GSI had lower UDI-6 scores than women who were not objectively cured. [53] Bidmead et al saw an objective urodynamic cure after Burch colposuspension in 92% of women undergoing a primary Burch for stress incontinence. QoL as measured by the Kings Health Questionnaire, improved in 95% of the patients. [54]

Incontinence questionnaires can not be used to select patients for urodynamic studies. The correlation between incontinence questionnaires and urodynamic parameters that are related to the diagnosis of genuine stress incontinence has been studied best. Overall, the scores on incontinence questionnaires and visual analogue scales correlate poorly with urodynamic parameters. However, patients who indicate that they are greatly bothered by urinary leakage with activity, will have GSI on urodynamics in the majority of cases. Significant bother due to urge or urge leakage is not more predictive of urodynamic detrusor overactivity than not having the symptom.

d) Conclusion

Overall there is only a weak relationship between symptomatic, QoL and objective clinical or urodynamic assessment of patients with urinary incontinence. The type, severity or number of symptoms, or the results of urodynamic or clinical investigations cannot predict the level of impairment. It is perhaps not surprising that what is demonstrated clinically is distinct and different from what is perceived by patients in their everyday lives to be troublesome: clinical measures and validated questionnaires probably measure different but related aspects of incontinence.

6. Questionnaire development and testing - a conclusion

Self-completed questionnaires are the most suitable method for assessing the patient's perspective of their incontinence and its impact on their quality of life. [55] 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 available for assessing incontinence and its impact on quality of life, and these are described below with recommendations from the Committee for their use.

B. RECOMMENDED QUESTIONNAIRES

A detailed review of recommended questionnaires was provided in the First Consultation chapter. [1] At the Second Consultation, the Committee developed standardised grades of recommendation for questionnaires which attempted to reflect the Oxford Centre for Evidence Based Medicine's Levels of Evidence. These were applied to evaluate questionnaires concerned with urinary incontinence. [2] At this Third Consultation, these grades have been revised and updated to take into account the increasing numbers of published questionnaires concerned with LUTS and incontinence, and also the broadening of the field to include pelvic organ prolapse (POP) and faecal incontinence (FI) as well as LUTS and urinary incontinence (UI). The grades are explained (**Table 1,2**) and the recommended questionnaires are described below.

I. GRADES OF RECOMMENDATION FOR QUESTIONNAIRES 2004

At the Second Consultation, the Committee devised three grades of recommendation:[2]

- 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 urinary incontinence."
- 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)."
- Questionnaires were considered to have "potential" and give 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."

The development and publication of questionnaires has proceeded apace since the Second Consultation, particularly in the area of urinary incontinence. The Committee required evidence published (or in press)

in peer-reviewed journal articles or book chapters to reach its decision about the grade of recommendation in 2001. 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.

During the review of literature published between 2001 and 2004, the Committee noted that there were a number of interesting and important developments:

- The Committee noted that the quality of evidence presented for the psychometric properties of questionnaires varied, and the Committee believed it should consider the *quality* of evidence as well as its existence in 2004
- It was noted that it was possible for evidence of validity, reliability and responsiveness to be published in one publication based on one sample population. The Committee considered that the investigation of the questionnaire's properties in other patient groups would provide more robust evidence, and this should be noted
- The development of questionnaires for urinary incontinence and LUTS had increased rapidly and the Committee felt it should focus on those including assessment of urinary incontinence
- Questionnaires in the areas of POP and FI were poorly developed to date and required encouragement and different criteria for recommendation than UI
- Several questionnaires labelled 'with potential' at the previous consultation had not had further publications, indicating limited usefulness. The Committee felt that this should be noted and reflected in the grade of recommendation.

In light of these findings, the Committee developed new grades of recommendation for questionnaires in this Third Consultation – for UI, UI/LUTS (**Table 1**) and POP and FI (**Table 2**).

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 rigour' allowed. Where the Committee had concerns about the quality of evidence, this is noted in the descriptions of the questionnaires below. Two grades of recommendation only were established, so that only questionnaires with recent data and evidence of use in the area are recommended. The Committee considered that the number of high quality questionnaires for UI 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). By the next Consultation, it is expected that Grade A^{new} questionnaires will either be promoted to Grade A because of further high quality publications or relegated to Grade B if further development does not occur.

The Committee felt that the development of questionnaires in the areas of POP and FI was at a much earlier and lower level. This necessitated a slightly different set of grades of recommendation so that researchers are encouraged to continue to work to produce questionnaires with the highest levels of evidence (see Table 2).

Table 1. Criteria for recommendation of questionnaires for UI and UI/LUTS at the Third Consultation

Grade of recommendation	Evidence required (published)
Highly recommended (**Grade A**)	Validity, reliability and responsiveness established with rigour in several data sets.
Highly recommended (**Grade A^{new}**)	Validity, reliability and responsiveness indicated with rigour in one data set.
Recommended (**Grade B**)	Validity, reliability and responsiveness indicated but not with rigour. Validity and reliability established with rigour in several data sets.

Table 2 . Criteria for recommendation of questionnaires for POP and FI at the Third Consultation

Grade of recommendation	Evidence required (published)
Highly recommended (**Grade A**)	Validity, reliability and responsiveness established with rigour.
Recommended (**Grade B**)	Validity and reliability established with rigour, or validity, reliability and responsiveness indicated.
With potential (**Grade C**)	Early development – further work required and encouraged

II. QUESTIONNAIRES TO ASSESS SYMPTOMS AND QUALITY OF LIFE IMPACT OF URINARY INCONTINENCE AND LOWER URINARY TRACT SYMPTOMS

1. New developments

At the Second Consultation, it was noted that many questionnaires for UI were developed for men or women separately, and that many included assessment of LUTS as well as UI. Many more questionnaires were published and available for evaluation at the Third Consultation, and several of the 'A', 'B' and 'C' grade questionnaires at the previous Consultation had developed to include other groups or aspects or more rigorous data. In some cases, these developments did not reach the highest level of rigour. In this chapter, only Grade A questionnaires are reported in detail, with Grade B questionnaires reported briefly; other instruments not reaching these levels of evidence are listed below.

One trend that has become more apparent since the previous Consultation 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). 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-re-test reliability, at a minimum, and sensitivity to change, in intervention studies.

For some of the more widely used instruments listed below (e.g., Incontinence Impact Questionnaire, Urogential Distress Inventory, King's Health Questionnaire), several modified 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.

Another development has been the establishment of the concept of over-active bladder (OAB) – a syndrome comprising urinary urgency, with or without urge incontinence, and usually with increased urinary frequency and nocturia. [56] This particular cluster of symptoms appears to be amenable to drug treatment. These LUTS are relatively common and are included in most of the established questionnaires and so could be evaluated by them. However, there has been a considerable drive to develop questionnaires that focus particularly on this syndrome. The first of these to reach the highest levels of evidence (OAB-q) is considered in more detail below.

2. Highly recommended (Grade A) questionnaires

Table 3 shows the highly recommended (Grade A) questionnaires for the assessment of UI alone or in the presence of LUTS, including OAB.

Table 3. Recommended questionnaires for the evaluation of UI and UI/LUTS/OAB – Grade A unless stated

Combined symptoms and quality of life impact of UI	
Men and women	ICIQ (Grade A^{new}) [33]
Women	Bristol Female LUTS-SF [57] SUIQQ (Grade A^{new}) [48]
Men	ICS*male*SF[58]
Combined symptoms and quality of life impact of OAB	
Men and women	OAB-q (Grade A^{new}) [56]
Symptoms of UI	
Women	Urogenital Distress Inventory [59] UDI-6 [27] Incontinence Severity Index [34] BFLUTS[60]
Men	[ICS*male* – LUTS primarily] [61] [DAN-PSS – LUTS primarily] [62]
Quality of life impact of UI	
Men and women	Quality of life in persons with UI (I-QOL[28] [37] SEAPI-QMM[63]
Women	King's Health Questionnaire [30] Incontinence Impact Questionnaire (IIQ) [64] IIQ-7 [27] Urinary Incontinence Severity Score (UISS) (Grade A^{new})[35] CONTILIFE (Grade A^{new}) [65]
Men	None

The following **table 4** indicates characteristics that may be important for choosing an instrument for a study or patient population:

a) ICIQ – Grade A^{new}

The ICIQ short form for incontinence has recently been subject to considerable psychometric testing. [33] A developmental version of the questionnaire was produced following systematic literature review and views of the ICI subcommittee on symptoms and quality of life. Several parallel studies were undertaken to investigate the psychometric properties of the questionnaire, including its content, construct and convergent validity; reliability; and responsiveness/sensitivity to change. The ICIQ was easily completed with low levels of missing data. It was able to discriminate between different patient groups, indicating good construct validity. Convergent validity was acceptable, with moderate to strong agreement with Grade A questionnaires. Reliability was shown by moderate to very good stability in test-retest analysis and Cronbach's alpha of 0.95. Items identified significant reductions in symptoms and quality of life impact following surgical and conservative treatment. [33] Item reduction techniques were then used to determine the final version and scoring scheme. The final version comprises three scored items (assessment of the frequency, severity and perceived impact of incontinence) and an unscored self-diagnostic item.

The questionnaire is now available for general use. It is a brief and robust questionnaire that is of use in outcomes and epidemiological research as well as routine clinical practice. It is receiving further evaluation in the UK and internationally. [2] Researchers and clinicians in the field of incontinence are encouraged to consider the further development and evaluation of the questionnaire and its scoring system for a number of uses and in a variety of different settings, populations and cultures and, in particular, to examine its applicability and potential adaptation to other patient groups.

The ICIQ has been translated into a number of languages for use in non-UK-English speaking countries (by mid 2004, completed in 27 languages including Afrikaans, Arabic, Australian-English, Brazilian-Portuguese, Bulgarian, Czech, Dutch, Estonian, French, German, Greek, Hungarian, Icelandic, Italian, Japanese, New Zealand-English, Norwegian,

Table 4 . Major characteristics of highly recommended questionnaires

Questionnaire	Men	Women	UI symptoms	UI QoL	OAB symptoms	OAB QoL
*ICIQ	✔	✔	✔	✔		
I-QOL	✔	✔		✔		
*SEAPI-QMM	✔	✔		✔		
BFLUTS-SF		✔	✔	✔	✔	
ICS*male*SF	✔		✔	✔	✔	
KHQ		✔		✔	✔	
UDI/UDI-6		✔	✔		✔	
IIQ/IIQ-7		✔		✔		
ISI		✔		✔		
*SUIQQ		✔	✔	✔		
*UISS		✔		✔		
*CONTILIFE		✔		✔		
*OAB-q	✔	✔		✔	✔	
BFLUTS		✔	✔		✔	
DAN-PSS	✔		✔		✔	
ICS*male*	✔		✔		✔	

* New

Polish, Romanian, Russian, Slovakian, South African-English, Spanish, Swedish, Turkish, Ukrainian, US-English) using standard methods.

The Japanese ICIQ has been administered to consecutive male and female patients with incontinence attending a urology clinic. The relationship between the ICIQ and the King's Health Questionnaire (Japanese version) has been investigated. In a preliminary sample of 68 patients (54 females, 14 males), agreement between ICIQ item concerned with impact on everyday life and several similar items in the KHQ (impact on life, interference with household tasks or job/daily activities) were fair (kappa 0.38, 0.24 and 0.42). Agreements between the ICIQ items on social life and sex life were fair to moderate. Agreement between the two questionnaires on the frequent use of protection was very good (kappa 0.81).

In order to further assess responsiveness, patients proceeding to treatment for incontinence according to normal clinical practice were asked to complete a second questionnaire approximately three months after treatment with surgical or medical intervention, insertion of anti-incontinence devices or conservative management. The relationship between the ICIQ and objective parameters of incontinence including the ICS pad test, abdominal leak point pressure (ALPP) and pathogenesis (including intrinsic sphincter deficiency, detrusor instability, hypermobility and so on) has been investigated in patients clinically diagnosed with stress incontinence. 500 women who consulted at an UI-specialised unit responded to the questionnaire. A urodynamic study was carried out. The mean time of administration was 3.5 (1.5) minutes. All patients answered all the items of the ICIQ-SF. According to the clinical diagnosis, patients with UI scored 11.6 (5.9) and patients without UI scored 4.5 (6.3) ($p < 0.001$). According to the urodynamic diagnosis, UI patients scored 11.1 (6.3) vs 6.2 (6.5) ($p < 0.001$). In patients with an urodynamic diagnosis of stress UI, a higher degree of severity was associated with a higher score on the ICIQ-SF. [66]

The ICIQ is a brief and robust questionnaire that can potentially be used with a wide range of people and patients. It is recommended to be included in randomised controlled trials and epidemiological studies as a brief measure which may be supplemented by other questionnaires for more detailed assessment of LUTS, UI and quality of life impact.

b) I-QOL

This questionnaire was designed to be used in clinical trials to measure the impact of incontinence on men and women. [28] Psychometric information on translated versions of the I-QOL have been reported for French, Spanish, Swedish, and German language versions. [37] In all countries, the use of three subscales, and an overall summary score was confirmed to be useful. In all countries, the internal consistency (alpha=0.87-0.93) and reproducibility coefficients (intraclass correlations=0.92-0.95) were high. I-Qol scores were found to be significantly worse in all countries as perceived severity of incontinence, use of services, and the number of incontinent episodes increased. The English version of the questionnaire has been used to show that patients with urge incontinence treated by posterior tibial nerve stimulation have fewer episodes of incontinence . [67]

c) SEAPI QMM Quality of life index – Grade A^{new}

This questionnaire was devised for the definition and standardisation of the measurement of the quality of life impact of incontinence in both sexes, with the aim of functioning in the same way as the TNM classification for cancers. [31] Stothers evaluated the psychometric properties of SEAPI QMM in 315 patients (102 men and 213 women) with incontinence and 35 without incontinence. [63] Reliability was good with a coefficient in test-retest reliability being 0.93 and with a Cronbach's alphas ranging from 0.73 to 0.83 (0.91 overall). Correlation of the index with the Nottingham Health Profile was 0.78 for women and 0.72 for men. Mean scores before and after treatment with medical and surgical management were significantly different in both genders, although sample sizes were small. The index should be used more widely to assess its usefulness.

d) BFLUTS-SF

This questionnaire was developed from the longer questionnaire covering the occurrence and bothersomeness of symptoms relating to incontinence and other lower urinary tract symptoms for women. [60] Responsiveness has been tested recently and a scored short form produced. [57] 344 women with urodynamically proven stress incontinence completed the BFLUTS questionnaire before treatment and six months later in a randomised trial comparing tension-free vaginal tape with colposuspension. Significant differences in items were seen between baseline and follow up in both treatment groups, especially for symptoms of incontinence. [57] Methods of item reduction, including factor analysis and clinical judgement were used to develop a shortened scored version of the BFLUTS questionnaire which comprises

three subscales: BFLUTS-IS (incontinence symptoms), BFLUTS-VS (voiding symptoms) and BFLUTS-FS (filling symptoms), with the addition of subscales for sexual function (BFLUTS-sex) and quality of life impact (BFLUTS-QoL). [57] Subscores were shown to be more sensitive to measuring outcome than a combined score.

e) ICSmaleSF

The scored short-form – ICS*male*SF, [58] was developed from the longer ICS*male* questionnaire to assess LUTS in men. [61] The short form has two major scored sections: ICS*male*VS (voiding subscore) containing five questions (hesitancy, straining, reduced stream, intermittency, incomplete emptying), and ICS*male*IS (incontinence subscore) containing six questions(urge, stress, unpredictable and nocturnal incontinence, urgency, postmicturition dribble). [58] The scores are obtained by simple addition. The authors indicate that questions to assess nocturia, frequency and impact on quality of life should be added to provide full data, but these questions should not be included in the score as they are separate constructs. [58]

ICS*male*SF has been used in studies focusing on prostate cancer[68] [69] and on LUTS[70] as well as minimally invasive therapies and drug treatments[71] [72] The ICS*male*SF was used to determine that high-power holmium laser vaporisation of the prostate provided a durable benefit in relieving LUTS and maintaining good urinary flow rates.

f) King's Health Questionnaire (KHQ)

The King's Health Questionnaire (KHQ) was developed at King's College Hospital in London as part of a large longitudinal study of quality of life. [73] The questionnaire consists of three parts. The first section contains two questions measuring general health and overall health related to urinary symptoms. The second section includes 19 questions divided into seven domains of quality of life: incontinence impact, role limitations, physical limitations, social limitations, personal relationships, emotions, sleep and energy, severity coping measures, general health perception, and symptom severity. The third section of the questionnaire comprises 11 questions measuring the bother or impact of urinary symptoms. There are eight validated cultural adaptations of the questionnaire available in 26 languages, including German, Spanish, Swedish, Greek, Italian, and Japanese, [74] [75] and Portuguese. [76]

The KHQ has been shown to have excellent reliability and validity for women. [77] [78] [79] Sensitivity to change has been shown successfully in observational studies and in increasing numbers of clinical trials. [77] [80] [81] [82] [83]

The development of the KHQ continues. Researchers in Japan have recently reported preliminary information on a short form version of the KHQ comprising two factors: limitations of daily life, and mental health. [84] Bug and colleagues have also presented preliminary information regarding the use of an adapted version of the KHQ for men (see below) and also women with anal incontinence in the UK (see FI section below). Studies are currently underway to develop a weighting system for the symptom subscale of the questionnaire, a QALY measure derived from the questionnaire and to establish clinical meaningful interpretations of KHQ scores.

g) Urogenital Distress Inventory (UDI) and UDI-6

This questionnaire was developed in the US with women to assess the degree to which symptoms associated with incontinence are troubling. [59] It contains 19 lower urinary tract symptoms and has been shown to have high levels of validity, reliability and responsiveness in a community-dwelling population of women with incontinence, [59] women over 60 years, [85] women in two regions of Scotland. [86] Responsiveness to changes in clinical status as or a result of treatment have been reported in a number of areas: cadaveric fascia lata sling for stress incontinence, [87] comparing abdominal and vaginal prolapse surgery, [88] and the use of a simple urethral occlusive device. [89]

A short-form version of the UDI (UDI-6 short form) has been shown to be valid and reliable in older adult males and females, [27] [36] with responsiveness data related to reconstructive pelvic surgery, [53] tension-free vaginal tape, [90] [91] and imipramine. [92] It has been suggested that the UDI-6 may provide predictive information regarding urodynamic findings in women, particularly with regard to stress urinary incontinence, bladder outlet obstruction, and detrusor overactivity. [49] [50] [93]

A study investigated the relationship between physician-assessed quality of life parameters obtained as part of a patient interview. Consecutive female patients presenting for the first visit at two academic institutions completed the UDI-6 in the waiting area and a physician completed an UDI-6 based on impressions of the patients' symptoms and responses during the clinical interview. In general, there was

poor agreement between patients' and physician's responses, with physicians underestimating the level of bothersomeness of the patients' symptoms. [94]

The UDI continues to develop. In a further analyses of the UDI in Denmark, an alternative factor structure comprising five subscales (discomfort/pain, urinary incontinence, overactive bladder, genital prolapse, and obstructive micturition) was found among a random sample of 2,042 women aged 20-70 years old, and a clinical sample of 196 women. [95] The UDI is being used increasingly in male patients (see MUDI below as data on its psychometric properties have not yet been reported as fully as they have in female patients).

h) Incontinence Impact Questionnaire (IIQ) and IIQ-7

This questionnaire was developed to assess the psychosocial impact of urinary incontinence in women and consists of 30 items (24 on the degree to which incontinence affects activities and 6 on the feelings engendered). [59] [64] [96] Scores are obtained overall or for four subscales determined by factor and cluster analyses: physical activity, travel, social relationships, and emotional health. The IIQ has been found to have acceptable levels of reliability and validity across a range of studies. [86] [97] [98] The IIQ has been assessed in a clinical trials of pelvic floor muscle training following ischaemic stroke, [99] transdermal oxybutynin and oral tolterodine versus placebo for the treatment of urge and mixed incontinence, [100] behavioural interventions in UI, and transvaginal electrical stimulation; and in observational or non-randomized treatment studies. [101] Several studies have been published in recent years further confirming the psychometric properties of the IIQ. [46] [95] The Danish team found a fifth subscale for the IIQ, embarrassment, although further work is required to confirm this. [95] A neural network approach was used to develop cut-off scores corresponding with mild, moderate, and severe levels of UI: <50 mild UI; 50-70 moderate UI; >70 severe. [102]

The IIQ has also been produced in a short form comprising 7 items, also with evidence of validity and reliability. [98] [103] Responsiveness of the IIQ has been assessed in several intervention studies, [53] [87] [91] [92] [104] [105] and modified version of the IIQ-7 has also been used in studies examining the efficacy of artificial urinary sphincters in men who had developed stress incontinence after radical prostatectomy.

The IIQ continues to develop with versions for men (MUSIQ, see below), studies examining the personal costs of incontinence in the US, [89] and the quality of life impact of pelvic floor disorders in women (PFIQ, see below). [106]

i) Incontinence Severity Index (ISI)

The ISI was developed in Norway to provide a simple severity index of female incontinence for use in epidemiological surveys, comprising two questions – how often do you experience urine leakage (four levels), and how much urine do you lose (two levels). [34] The index is calculated by multiplying the two responses together and is categorised into slight, moderate, severe and very severe. [107] The index has good levels of validity, reliability and responsiveness. [34] [108]

The index has been used in large community based epidemiological (EPINCONT) surveys in Norway during 1995-1997 and to evaluate the effect of obstetric parameters on urinary incontinence. [109] [110]

j) Stress and Urge Incontinence and Quality of life Questionnaire (SUIQQ) – Grade A^{new}

This questionnaire was developed from previously designed questionnaires and pilot studies. [48] Stress incontinence, urge incontinence and quality of life indices were constructed. Internal consistency of the indices was measured by Cronbach's alpha (<0.7) and test-retest reliability by Bland-Altman plots. Stress Incontinence Index was tested against stress test and Urge Incontinence Index and Stress Incontinence Index were tested against the 24-hour pad test (p=0.01). The Quality of Life Index was correlated with part of the King's College Hospital Quality of Life Questionnaire (0.77). 628 women completed a mean of 98.2% of all the questions. Overall, validity and reliability data were robust.

The SUIQQ was used as part of the Norwegian national database of urogynaecological surgery (30 departments). Questionnaires are completed at baseline and six months, 12 months and three years after surgery, along with other relevant clinical information. [111] Post-operative indices and all clinical outcome values except for mean voiding volume were lower than pre-operative scores, indicating that the questionnaire is sensitive to expected changes with surgery. The questionnaire provides a great deal more interesting data regarding national and local patterns of treatment, variation in outcome, levels of satisfaction etc. [111] The questionnaire is easily

completed and appears acceptable to women and clinicians in Norway. As it is completed within a national database study, it is likely to yield important and interesting results over the coming years.

k) Urinary Incontinence Severity Score (UISS) – Grade A[new]

The UISS was designed by the Finnish Gynaecological Society's urogynecologic working group in 1992, and comprises 10 items divided into 3 domains; social interactions, physical activities and sexual function, with a visual analogue scale for subjective burden of incontinence on a 100mm scale. [35] It has been widely used in clinical practice. Stach-Lempinen et al. showed that the UISS and VAS were valid, reproducible and responsive to treatment for incontinent women in one study of 82 incontinent women (Stress: 57, Urge:14, Mixed:11) and 29 controls.

The UISS has been used more in clinical practice than research and so data on its psychometric properties, while at a high level in one study, are not yet widely available.

l) CONTILIFE – Grade A[new]

The original CONTLIFE instrument was developed in France, and translated to Dutch, German, English and Danish. It contains 28 items in 6 domains: daily activities, effort activities, self-image, emotional consequences, sexuality and well being. An examination of the psychometric properties of the questionnaire in 5 languages in 505 women with stress urinary incontinence showed good construct validity in Danish and French, and acceptable in English, German and Dutch, with good levels of internal consistency and Cronbach's alphas ranging from 0.71 to 0.94. [65] Responsiveness was also assessed, with effect sizes >0.50 except for the sexuality and well-being dimensions. [65]

This measure has not been used widely and its psychometric properties have been investigated within only one study population to date.

m) Overactive Bladder Symptom and Health-related Quality of life (OAB-q) – Grade A[new]

The OAB-q was developed during the National Overactive Bladder Evaluation (NOBLE) programme in the US as the first symptom and QOL questionnaire for patients with OAB. The original questionnaire consisted of 62 items (13 symptoms and 44 HRQOL). The reduced OABq comprises 33 items (8 bladder symptoms and 25 HRQOL) including 6 domains of symptom bother, coping, concern/worry, sleep, social interaction and HRQOL total. The psychometric evaluation of the OAB-q was examined in 990 patients with OAB (25.4% men, 55.8% urge incontinence) [56] Internal consistency was high with the subscale Cronbach alphas ranging from 0.86 to 0.94. Subscale to subscale correlation ranged from 0.32 to 0.74. There was a significant difference in scores between controls and continent and incontinent OAB patients. Correlations with subscales of the SF-36 were moderate (0.16 to 0.52) and there were fair correlations with number of voids per night. [56] Responsiveness of the OAB-q to antimuscarinic treatment has recently been published. [112] Significant improvements in all OAB-q subscales were found at 4 and 12 weeks and were associated with reductions of urgency episodes, micturitions or physician perceptions of improvement.

This questionnaire has been developed and tested within one selected patient population receiving a particular drug treatment. The questionnaire needs to be used in a wider patient population to provide robust evidence that it is an effective instrument for the assessment of patients with incontinence and LUTS.

n) BFLUTS

The long form of BFLUTS [60] was developed for use with women, following the pattern established for the questionnaire developed for the ICS-'BPH' study. The questionnaire covers the occurrence and bothersomeness of symptoms relating to incontinence and other lower urinary tract symptoms. [60] It has shown good levels of validity and reliability and has been increasingly used in epidemiological and outcome studies. [113][114] [115] [116] [117] [118] Validity, reliability and responsiveness have all been tested, and a scored short form has been produced, which is now the recommended version. [57]

During the reporting period, the BFLUTS questionnaire was used to assess risk factors for urinary incontinence in both sexes [119] and in randomised trials of functional bladder capacity after transcutaneous electrical nerve stimulation and oxybutynin, [120] and TVT versus colposuspension in the treatment of stress incontinence. [121] It was also used in a retrospective observational study investigating the effectiveness of Burch colposuspension, [122] and a modified form was completed by men and women in an urban community to determine urinary symptoms and incontinence. [123]

o) DAN-PSS

This questionnaire was designed in Denmark to measure the degree to which men are bothered by urina-

ry symptoms. [124] [125] A composite score is achieved by the multiplication of the 'symptom' by the 'bother' score, with a total range of 0 to 108. [124] [125] A computer version of this questionnaire has been validated and patients seemed to appreciated more this new version than the paper version. [126] It is primarily a questionnaire for the assessment of the occurrence and bothersomeness of a wide range of LUTS in men.

p) ICSmale

The ICS*male* questionnaire contains 22 questions on 20 urinary symptoms, and, for most questions, the degree of problem that the symptom causes. [61] It has exhibited acceptable levels of validity, reliability and sensitivity to change following a range of treatments including surgery, minimally invasive therapies and drug treatments. [61] [127] [128] This long version has been largely replaced now by a scored short-form – ICS*male*SF. [58] A modified form of ICS*male* has been used to assess LUTS and incontinence in prostate cancer. [129] It also continues to be used to assess LUTS in men [70] and minimally invasive therapies and drug treatments. [71] [72] [130] [131] It is primarily a questionnaire for the assessment of the occurrence and bothersomeness of a wide range of LUTS in men.

3. Other UI/LUTS questionnaires

A number of other questionnaires have been developed to assess symptoms or quality of life impact of LUTS and UI. They do not reach the highest level of grading because they do not have the full complement of psychometric evaluation or robust data, or are less relevant for the assessment of UI than the questionnaires reported above.

a) Grade B questionnaires

1. Symptoms of UI/LUTS

• *Male Urogenital Distress inventory (MUDI) (men)*

The Male Urogenital Distress Inventory questionnaire was developed to measure the health-related quality of life for men with urinary incontinence, comprising a 27 item male version of the UDI. [132] [133] It has been shown to have acceptable preliminary levels of validity and reliability, but no responsiveness data have been published.

• *PGI-S (Patient Global Impression of Severity) and PGI-I (Patient Global Impression of Improvement)*

PGI-S and PGI-I are global indexes of severity and improvement that summarise the severity or improvement in single questions with four and seven response categories respectively. [134] Construct validity has been investigated in 1133 women with stress urinary incontinence: the PGI-S revealed significant correlation to incontinence episode (Spearman's rho:0.36, p<0.0001), pad test (rho 0.20, p<0.0001) and I-QOL (rho -0.5, p<0.0001); and the PGI-I showed significant correlation to incontinence episode (Spearman's rho:0.49, p<0.0001), pad test (rho 0.33, p<0.0001) and I-QOL (rho -0.43, p<0.0001). No assessment of reliability and responsiveness was made.

• *St George Urinary Incontinence Score (SGUIS) (women)*

Aspects of validity, reliability and responsiveness were examined for this questionnaire in one study. [32] The SGUIS correlated moderately well with the number of leaks per week (Spearman's r = 0.610, 95% confidence interval 0.516-0.689, P < 0.001), the test-retest reliability was acceptable, and the change after treatment correlated well with the improvement in the number of leaks per week (r = 0.742, 0.662-0.805, 156 samples, P < 0.001) and 1-h pad test loss (r = 0.531, 0.405-0.636, 151, P < 0.001). Further evaluation of the validity and reliability of the questionnaire is required.

2. Impact of UI/LUTS on quality of life

• *Leicester Impact Scale (LIS) (men and women)*

This questionnaire was developed to assess the impact of storage symptoms (with and without incontinence) in a community sample of men and women over 40 years old. [135] [136] This interview- administered questionnaire evaluates impact on activities and feelings in 21 items. Standard psychometric methods were used to evaluate and shorten the questionnaire, and it was compared with other questionnaires including the HADS. The two sub-scales had high internal consistency (Cronbach's alpha 0.87 and 0.91 – 0.93 overall). Test-retest and inter-rater reliability were not very high and the author's caution that the questionnaire may not be reliable for use in surveys or among older people. [136] While this questionnaire has produced evidence of validity, reliability and responsiveness, the evidence about the reliability of the measure is poor and so it is not recommended at the highest level.

• *Male Urinary Symptom Impact Questionnaire (MUSIQ) (men)*

The purpose of the MUSIQ is to determine the effect of urinary incontinence on health-related quality of

life of men, comprising a 32 item male version of the IIQ. [132] [133] Preliminary information was provided regarding the construct validity and reliability of this measure, but no information regarding the sensitivity of this measure was provided.

• *King's Health Questionnaire (KHQ) (Men)*

The KHQ has been shown to have good reliability and validity for men. [30] [77] Data relating to responsiveness was not provided.

• *Nocturia quality of life questionnaire (men)*

This was developed to assess the specific impact of nocturia in men. It was developed following focus group interviews and piloted in 107 men with nocturia in the UK. [137] The final version contains 13 items with a high alpha and intraclass correlation, high correlation with a sleep index and the energy/vitality domains of the SF-36, and the ability to distinguish between patients with different levels of nocturia. [137]

b) Other questionnaires

A number of other questionnaires in this area have been published, but it is the Committee's view that these have not produced sufficient evidence to attain or maintain a Grade B (validity, reliability and responsiveness indicated but not with rigour; or validity and reliability established with rigour in several data sets). Several have not produced publications in the reporting period or are focused on particular patient groups in single studies.

1. SYMPTOMS OF UI/LUTS

• *Symptom Severity Index (SSI) (women)*

This short questionnaire was developed in the UK to assess stress incontinence, with acceptable levels of validity and reliability, but responsiveness has not been assessed and no further validation has been published in the reporting period. [138]

• *Urge-UDI (women)*

The UDI was modified to focus on urge incontinence, comprising 9 questions assessing frequent urination, urgency to empty your bladder, difficulty holding urine, urine leakage, urine leakage related to the feeling of urgency, urine leakage related to physical activity, coughing or sneezing, urine leakage not related to urgency or activity, night-time urination, and bedwetting. [139] [140] [141] No additional studies using the U-UDI were found that have been published since 1999.

• *Urinary Incontinence and Frequency Comfort questionnaire (UIFC) and Bladder Function Questionnaire (BFQC)*

These questionnaires have been designed to assess changes in what is termed 'compromised urinary bladder syndrome' (CUBS). [97] Some aspects of validity and reliability have been examined in 47 patients, with evidence of acceptable internal consistency, test-retest reliability and correlation with urinary loss. Further work is required and responsiveness has not yet been assessed.

2. IMPACT OF UI/LUTS ON QUALITY OF LIFE

• *U-IIQ (women)*

An adapted version of the IIQ has been developed to be specific to the assessment of urge incontinence. [140] It contains 32 questions, arranged into 6 domains (travel, activities, feelings, physical activities, relationships, sexual function), two single items (night bladder control, and satisfaction with treatment), and a mean summary score composed of the 6 domain scales. In two published reports of the U-IIQ, the internal consistency reliability of the U-IIQ has ranged from 0.74-0.96 (Cronbach alpha) for the individual subscales, [140] [141] and .90 for the overall index score. [140] Intraclass correlation coefficients of test-retest reliability have ranged from 0.68-0.88. [140] [141] Guyatt's statistics assessing responsiveness to change were reported as –0.62 to –0.83 for participants with a stable number of incontinent episodes, and -1.00 to –1.61 for participants who showed an improvement in their number of incontinent episodes. [140] The scale has demonstrated acceptable convergent and discriminant validity. [141] Further work on this scale is reported to be underway, but has not been published in the reporting period.

• *Symptom Impact Index (SSI) (women)*

This questionnaire was developed in the UK to assess the impact of stress incontinence and has acceptable levels of validity and reliability, but no responsiveness data or publication in the reporting period. [142]

• *Der Inkontinenz-Fragebogen*

This questionnaire [143] was used a randomised controlled trial. [144] although no information relating to the questionnaire's validity and reliability has been produced.

• *Specific questionnaires*

The following questionnaires were identified that

focus on particular patient groups, often in single or small scale studies. Several of these questionnaires are well-established in other areas (e.g. cancer) but have had limited use in patients with incontinence: Danish LUTS, [145] Post-surgical questionnaire, [146] Voiding patterns, [147] Incontinence screening questionnaire, [148] Post-radical prostatectomy questionnaire, [149] ICS*QoL*, [150] EORTC metastatic prostate cancer, [151] Changes in Urinary Function, [152] Prostate-targeted Health Related Quality of Life, [153] Functional Assessment of Cancer – Bladder/General Scales, [152] [154] York Incontinence Perceptions Scale (YIPS), [96] Stress Incontinence Questionnaire (SIQ), [155] Incontinence Stress Index, [156] BFLUTS*QoL*, [60] Psychosocial consequences questionnaire, [157] Philadelphia Geriatric Centre Multilevel Assessment Instrument, [158] QOL – Synthelabo, [159] Symptom and psychological status in stress incontinence, [160] Post-radical radiotherapy questionnaire. [161]

III. QUESTIONNAIRES TO ASSESS SYMPTOMS AND QUALITY OF LIFE IMPACT OF PELVIC ORGAN PROLAPSE

Many women present with vaginal symptoms and pelvic organ prolapse (POP) is frequently implicated. A traditional clinical history is usually used in an effort to assess the symptoms experienced by the patient and a thorough clinician will try to gain insight into how these symptoms are impacting on the patient's life. However, symptoms often do not correlate with objective examination findings. Indeed the clinical assessment itself can be inconsistent, depending upon the position of the patient, whether they have been standing for a prolonged time or have just used a pessary or tampon. While there is a little research defining the association between specific symptoms and support defects, [162] [163] [164] measuring subjective outcome after treatment is problematic. Unlike urinary incontinence, where increasingly patient-completed methods such as diaries and questionnaires are being used to measure outcome, very few such instruments are yet available for POP. Clinician based history is inconsistent, disease impact may not be assessed, leading questions can be asked and patients may be unwilling to volunteer symptoms, particularly after surgical intervention, for fear of appearing ungrateful or a nuisance. Consequently, despite the highly prevalent nature of this condition we have little idea how intervention, which is frequently surgical, alters symptoms and quality of life. As for incontinence, questionnaires to assess symptoms and quality of life impact of pelvic organ prolapse would be highly desirable.

For POP, the Committee examined the quality of the psychometric evidence and only where published data were scientifically sound was the label 'with rigour' allowed. The Committee noted that this is a developing area with few questionnaires currently reaching the highest levels of evidence. Thus three grades of recommendation were established (**Table 5**).

Table 5. Criteria for recommendation of questionnaires for POP at the Third Consultation

Grade of recommendation	Evidence required (published)
Highly recommended (**Grade A**)	Validity, reliability and responsiveness established with rigour.
Recommended (**Grade B**)	Validity and reliability established with rigour, or validity, reliability and responsiveness indicated.
With potential (**Grade C**)	Early development – further work required and encouraged

Table 6 : Recommended questionnaires for the evaluation of symptoms and quality of life impact of pelvic organ prolapse

Grade A (highly recommended)
- None

Grade B (recommended)
- Pelvic Floor Distress Inventory (PFDI)[106]
- Pelvic Floor Impact Questionnaire (PFIQ)[106]

Grade C (with potential)
- P-QOL/St. Mary's Questionnaire [165]
- Pelvic Floor Dysfunction Questionnaire [166]
- e-PAQ Pelvic Floor Symptoms Questionnaire [167]
- Danish Prolapse Questionnaire [168]
- ICIQ-Vaginal Symptoms Questionnaire (not published)

1. Highly recommended questionnaires [Grade A]

No questionnaires in this area currently meet these criteria.

2. Recommended questionnaires [Grade B]

a) Pelvic Floor Distress Inventory (PFDI)

This questionnaire is an adaptation of the well-esta-

blished UDI with the aim of developing a comprehensive condition specific instrument to assess impact from pelvic organ prolapse and other aspects of colorectal-anal dysfunction, as well as LUTS. [106] The PFDI retains the 19 original items of the UDI, and adds 9 items related to lower urinary tract symptoms that are common in women with pelvic floor disorders. The three original subscales of the UDI are retained (i.e., obstructive, irritative/discomfort, and stress). Psychometric testing included internal reliability (PFDI Cronbach's alpha 0.88, PFIQ 0.98), 1 week test-retest (interclass correlation coefficient PFDI 0.87, PFIQ 0.86). Both correlated with stage of prolapse (Spearman correlation coefficient for pelvic organ prolapse distress inventory and impact questionnaire 0.32 $p<0.01$, 0.33 $p<0.01$). Responsiveness has not yet been tested.

b) PFIQ (Pelvic Floor Impact Questionnaire)

PFIQ is an adaptation of the IIQ to assess quality of life impact in women with pelvic floor disorders. It contains items included in the original IIQ and new items related to other pelvic floor disorders. PFIQ has 3 scales including 92 items: IIQ (30 items), Colorectal-anal impact Questionnaire (CRAIQ) (31 items) and Pelvic Organ Prolapse impact Questionnaire (POPIQ) (31 items). Each scale includes 4 domains of travel, social, emotional and physical activity. The psychometric properties of the PFIQ were evaluated in 100 female patients with pelvic floor dysfunction. [106] The PFIQ showed good validity; each of IIQ, CRAIQ and POPIQ revealed significant correlation with incontinence episode and number of pad use per week, faecal incontinence per week and stage of prolapse, respectively. Internal consistency was excellent (Cronbach alpha 0.98) and test-retest reproducibility was high (overall ICC 0.86 ranging from 0.69 to 0.92). A French language version has been produced. [54] Responsiveness has not yet been evaluated.

3. Questionnaires with potential [Grade C]

a) P-QOL/St Mary's Questionnaire

An evaluation of a version of this questionnaire in Italian has been published. [165] It has acceptable levels of some aspects of validity and reliability, but requires further evaluation of these aspects and responsiveness.

b) Pelvic Floor Dysfunction Questionnaire

This has eight domains: urinary incontinence, urinary irritative symptoms, voiding dysfunction, pelvic prolapse symptoms, faecal incontinence, defaecatory dysfunction, pelvic pain, sexual dysfunction. Only the correlation of symptoms with location and severity of pelvic organ prolapse has been investigated, [166] and so a full evaluation of the validity, reliability and responsiveness of the questionnaires is required.

c) e-PAQ Electronic Pelvic Floor Symptoms Questionnaire

This questionnaire aims to assess pelvic floor symptoms using an electronic format. Two posters have been presented but there are no publications to date. [167] [169] [170]

d) Danish prolapse questionnaire

This questionnaire aims to assess symptoms, bother and quality of life in women referred with pelvic organ prolapse. Some evidence of content and construct validity has been investigated, [168] but further work is required on these aspects and responsiveness.

e) ICIQ-Vaginal Symptoms

This questionnaire is being developed as part of the ICIQ modular programme (see below). Posters have been presented but no publications have yet been produced.

IV. QUESTIONNAIRES TO ASSESS SYMPTOMS AND QUALITY OF LIFE IMPACT OF FAECAL INCONTINENCE

A large number of questionnaires have been developed for clinical and research purposes that include items relating to faecal incontinence. Although there are clear relationships between faecal incontinence and other pelvic floor disorders (in particular urinary incontinence), it must be borne in mind that partly due to clinical tradition and pragmatism, these conditions have commonly been viewed separately. 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 specialities dealing with pelvic floor disorders [171] [172] The increasing multidisciplinary approach to incontinence necessitates the inclusion of such instruments in reviews of this nature, recognising the high preva-

lence of faecal incontinence, particularly in women, and the interrelationship of this condition with other pelvic floor disorders. It is also important to remember that the normal range of bowel function is wide, 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 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. [173] Anal incontinence occurs in both sexes, but is commoner in women than men. [174] Symptoms are considered crucial to diagnosis as specific symptoms are thought to reflect the underlying pathophysiology. [175] Thus, urgency (the inability to defer defecation) and urge incontinence are thought to indicate loss of voluntary control due to impaired external anal sphincter function, whereas passive incontinence is thought to indicate impairment of the smooth muscle of the internal sphincter.

For FI, the Committee examined the quality of the psychometric evidence and noted that this is a developing area with few questionnaires currently reaching the highest levels of evidence. A commonly used score for FI (Wexner), for example, does not appear to have published data related to its psychometric properties and thus while it is used widely cannot be recommended by the committee. Three grades of recommendation were developed (**Table 7**).

Table 7. Criteria for recommendation of questionnaires for FI at the Third Consultation

Grade of recommendation	Evidence required (published)
Highly recommended (**Grade A**)	Validity, reliability and responsiveness established with rigour.
Recommended (**Grade B**)	Validity and reliability established with rigour, or validity, reliability and responsiveness indicated.
With potential (**Grade C**)	Early development – further work required and encouraged

Table 8. Recommended questionnaires for the evaluation of symptoms and quality of life impact of FI

Grade A (highly recommended)
- None

Grade B (recommended)
- Faecal Incontinence Quality of Life Scale[176]
- Manchester Health Questionnaire[177]
- Birmingham Bowel and Urinary Symptoms Questionnaire
- (BBUS-Q)[178] [179]

Grade C (with potential)
- Wexner score [180]
- St Mark's score [181]
- Faecal Incontinence Survey [182]
- Elderly Bowel Symptoms Questionnaire [183]
- Postpartum Flatal and Faecal Incontinence Quality of Life Scale [184]
- Bowel Disease Questionnaire [185]
- Gastrointestinal Quality of Life Index [186]

1. Highly recommended questionnaires [Grade A]

No questionnaires are currently available at this level.

2. Recommended questionnaires [Grade B]

a) Faecal Incontinence Quality of Life Scale

The 29-item Faecal Incontinence Quality of Life Scale developed and tested by Rockwood et al measures impact of anal incontinence over four scales of quality of life; Lifestyle (10 items), Coping/behaviour (9 items), Depression/Self perception (7 items) and Embarrassment (3 items). [176] The instrument was designed to measure the effect on quality of life of treatment for individuals with faecal incontinence. A panel of colorectal surgeons and researchers generated items. Psychometric properties were tested in 118 patients with faecal incontinence 72 controls. The questionnaire showed good discriminant validity, with significant differences between patients with faecal incontinence and those with other gastrointestinal disorders. There were also significant correlations with selected subscales of the SF-36. Test-retest reliability at a mean interval of 8 days was satisfactory, with alpha values for the 4 scales of 0.8 - 0.96. Internal consistency of the 4 scales was >0.7. The instrument does not measure physical symptom severity and has not been tested in asymptomatic controls, but appears to offer a valid and reliable measure of the impact of faecal incontinence on quality of life in men and women with this condition. [176] However, in order to demonstrate discriminant validity, the researchers deemed it necessary to

modify the questionnaire for use in controls. Its use in an unscreened population is as yet unreported, and no responsiveness data have yet been produced.

b) Manchester Health Questionnaire

This questionnaire consists of items adapted from the King's Health Questionnaire. [177] It uses the same basic structure and format but items have a 5-point response scale (rather than the 4-point scale in the KHQ). It includes items in the 8 domains of quality of life as well as a symptom severity scale. Face validity was assessed by interview with 15 patients with faecal incontinence. Test-retest reliability was measured (Pearson correlation > 0.8 in all 9 domains). The questionnaire was posted to 236 women with faecal incontinence, of which 159 returned completed questionnaires. 121 performed test-retest at a mean interval of 20 days. Cronbach's alpha was > 0.7 in all domains tested, indicated adequate internal consistency. Convergent validity was assessed by comparison with responses in the SF-36, which showed significant correlations between domains of the 2 instruments. Data relating to women without faecal incontinence or unscreened women are not yet available. The questionnaire's sensitivity to change is also not yet established.

c) Birmingham Bowel and Urinary Symptoms Questionnaire (BBUS-Q)

This is a 22-item questionnaire developed to evaluate symptoms of both bowel and urinary dysfunction in women which has a published scoring manual. [178] [179] Items were generated by a panel of clinicians and scientists and following review of existing instruments in the literature. The instrument was tested in the gynaecology departments of three hospitals, a urogynaecology clinic, a functional bowel clinic and a general practice. A total of 630 women completed the questionnaire; 379 women awaiting hysterectomy, 45 women following hysterectomy 65 women referred with functional bowel and/or urinary symptoms and 141 asymptomatic controls. The content, construct and criterion validity, internal consistency, reliability and responsiveness of the questionnaire were measured. Low levels of missing data, peer and patient reports supported face and content validity. Factor analysis showed a clinically relevant four-factor structure: Constipation, Evacuatory function, Anal incontinence and Urinary symptoms with low content replication able to distinguish between patient groups, indicating good internal structure. Comparison with clinical, anorectal physiological, videoproctographic, transit time and urodynamic test results supported the instrument's criterion validity. Key domain question analysis and Cronbach's alphas showed internal consistency. Kappa values and limits of agreement demonstrated good test-retest reliability. Some responsiveness data have been produced.

The authors recommended the questionnaire for use as both a research tool and as a useful clinical measure. This questionnaire also forms a core element in an electronic pelvic floor symptoms assessment questionnaire (e-PAQ) (see above).

3. Questionnaires with potential [Grade C]

a) Wexner score

This score was developed in the early 1990s to allow an objective comparison of incontinence within groups of patients and assessment of treatment effectiveness. [180] It comprises a set of tables for the entry of relevant clinical details, with a grading system for type of incontinence ranging from 'never' to 'always'. The instruction states "the continence score is determined by adding points from the table, which takes into account the type and frequency of incontinence and the extent to which it alters the patient's life."[180] The score appears to be completed by the clinician. This score is used regularly and frequently in clinical practice. For it to achieve a higher grading from the Committee, it requires conversion to a patient-completed format and investigation of its psychometric properties.

b) St. Mark's score

This scale attempts to provide a scoring system for the assessment of the severity of FI. [181] There are five questions concerned with faecal leakage, bowel urgency, use of pads, medication and interference with activities. Small samples of patients (n=23 and n=10) completed the Wexner, Pescatori and American Medical Systems scores alongside the new scale. The new scale correlated well with the others, a diary card and 'clinical impression', and scores changed significantly in response to surgical treatment. [181] The questionnaire is promising but requires further development work.

c) Faecal incontinence survey

This questionnaire was designed for the assessment of anal incontinence, associated symptoms and risk factors in the community. [182] The questionnaire is based on previously validated instruments from the Mayo Clinic[187] [188] and includes a 13-item sub-

set of questions relating to the quantification of faecal incontinence. Initial validation and reliability testing was carried out in 94 clinic attendees. Assessment of reliability included a follow-up patient – clinician telephone interview (n=41) as well as a mailed questionnaire (n=34), combined test-retest data which produced a median kappa value of 0.59. In some areas reliability was found to be particularly low. [189]. Further work is required to establish adequate levels of validity, reliability and responsiveness.

d) Elderly Bowel Symptom Questionnaire (EBSQ)

O'Keefe et al have reported on the feasibility, reliability and validity of the Elderly Bowel Symptom Questionnaire (EBSQ) in clinic attendees in a medical outpatients department and 424 community based, independently living elderly subjects aged 65 – 93. [183] The response rate of 77% in the postal survey part of the validation was relatively high and may provide evidence of good acceptability. Test - retest reliability was also acceptable, with a median Kappa value of 0.65. Further work is required to establish adequate levels of validity, reliability and responsiveness.

e) Postpartum Flatal and Faecal Incontinence Quality of life Scale

Cockell et al conducted in-depth interviews with 10 women who suffered postpartum faecal or flatal incontinence and developed the Faecal Incontinence Quality of Life Scale. [184] This condition-specific scale has yet to undergo psychometric testing but is now being used in a clinical trial comparing different methods of repairing anal sphincter injuries following childbirth.

f) Bowel Disease Questionnaire

This is a 47-item bowel disease questionnaire for the assessment of symptoms including faecal incontinence and constipation. [185] The questionnaire was introduced into a Swedish colorectal clinic in 1992 for the initial assessment of patients prior to investigation and included items relating to symptoms as well as the patient's past medical and surgical history. A prospective study was conducted to assess validity and reliability. Subjects included 36 with faecal incontinence, 38 with constipation and 16 asymptomatic controls. Discriminant validity and overall test-retest reliability were reported as acceptable, though reliability in the faecal incontinence group was only 0.57 compared to the control group (0.95). Reliability was poor for 6 items relating to enema use, stool consistency, straining, incontinence to solid stool, pruritis and differentiation of gas from stool. Although patient numbers were small, the authors found that the instrument was sensitivity to change following intervention. The questionnaire has not been validated in English and requires further work.

g) Gastro-intestinal Quality of Life index (GIQLI)

This instrument was designed to measure quality of life in patients with gastrointestinal disease, with planned evaluation of psychometric and clinical properties in three phases of development. [186] It does not have any items specific to FI, although it covers a wide range of other bowel symptoms.

h) Other questionnaires

A number of other questionnaires are under development in this area but without formal publications: the clinical assessment of anal incontinence, [190] [191] [192] a scoring system based on linear analogue scales, [193] a survey of the bowel patterns of 789 students and hospital employees (unpublished).

V. GENERIC HEALTH MEASURES FOR INCONTINENCE

These self-administered questionnaires aim to measure the multidimensional nature of health status and are suitable for a broad range of illnesses and populations. They do not contain specific questions on incontinence, but they have been widely used to assess the quality of life of incontinent adults on the assumption that incontinence has an impact on the general well being of a given individual. They can, however, be relatively insensitive to conditions such as incontinence. During the past 5 year, the SF-36 has been the most widely used generic health-related quality of life measure in the assessment of UI. Several other instruments, such as the SIP, the NHP, and the EQ-5D, have had limited use in recent years. All of these measures have achieved acceptable reliability and validity in individuals with incontinence. The sensitivity of the measures to treatment or a worsening/improving physical condition has been variable, and could be related to the small sample sizes used in some treatment-related studies. The SF-36 appears to be less sensitive to detected changes among stroke and other neurological patients with UI, and in stress incontinent women. However, the generic instruments, particularly the SF-36, are useful in comparing across chronic conditions or in describing the general health status of incontinent adults (**Table 8b**).

Table 8b. Recommended questionnaires for the evaluation of generic health status in relation to symptoms and quality of life impact of UI, FI and POP

Grade A
SF-36/SF-12 [194]
Rand-36 [195]
EuroQoL EQ-5D [58]
Nottingham Health Profile [22]
Sickness Impact Profile [143]

1. Highly recommended questionnaires [Grade A]

a) Medical Outcomes Study Short-form: SF-36, SF-20 and SF-12

The MOS Short Form - 36 (SF-36) has been used extensively for QoL assessment of men and women across a variety of health conditions. [194] The SF-36 is a 36-item measure developed as part of the Medical Outcomes Study in the US. It contains eight separate subscales or domains: physical functioning, bodily pain, role limitations due to physical health problems, role limitations due to personal or emotional problems, general mental health, social functioning, energy/fatigue, and general health perceptions. The SF-36 has been culturally adapted and/or translated into a variety of languages, and is one of the most widely used generic health-related quality of life measures in the world. Short-form versions of the SF-36 have been developed, such as the SF-20 and the SF-12. The SF-20 was found to have good discriminant validity between a sample of 483 individuals with symptoms of an overactive bladder and 191 controls (Lieberman et al., 2001). The SF-12 containing only 12 items, however, has been found to perform poorly with prostatectomy patients. [196]

The use of the SF-36 to measure the impact of urinary symptoms in daily life has increased substantially during the past 5 years. The SF-36 has been found to have good construct validity, discriminant validity, and internal consistency in several research investigations of persons with incontinence, BPH, or urinary symptoms. [197] [198] [199] [200] Test-retest reliability has been moderate to high (r = 0.60-0.80). The SF-36 has also been found to discriminate amongst persons of different age groups. [200] Responsiveness of the SF-36 to changes in UI status and/or treatment, however, has been mixed. Sensitivity of the SF-36 has been reported to be poor in several studies, including a study of neurological patients treated with transcutaneous electrical nerve stimulation, [201] women receiving pelvic floor muscle training following ischaemic stroke, [99] stress incontinent patients receiving electrical stimulation, [202] stress incontinent women fitted with a Continence Guard, [101] and in a small randomised trial of transcutaneous electrical nerve stimulation and oxybutynin in patients with detrusor instability. [120] However, responsiveness of the SF-36 to changes in clinical or treatment status have been reported in clinical trials comparing UI following total and subtotal hysterectomy[99] and tension free vaginal tape versus colposuspension in stress incontinent women;[203] among urge incontinent patients receiving posterior tibial nerve stimulation, [67] with faecal incontinent patients receiving sacral nerve neuromodulation;[204] and in studies of radical prostatectomy versus external beam radiation for the early treatment of prostate cancer. [205]. A study by Salinas et al. (2002) reported improvements in SF-36 scores following surgical treatment for BPH, although these improvements were not associated with improved I-PSS or urine flow. [206] Thus, the responsiveness of the SF-36 appears to vary by the population studied and the particular research designs employed.

b) RAND-36

The RAND-36 Item Health Survey, retains the same items and subscales as the SF-36 but uses a slightly different scoring algorithm than the SF-36. [195] In recent years, there has been an increase in the number of published studies across a range of health conditions including UI that have used the Rand-36 to assess health-related quality of life. Downs and colleagues (2003) used the RAND-36 and the UCLA Prostate Cancer Index to assess the impact of brachytherapy monotherapy and radical prostatectomy on localised prostate cancer patients in the CaPSURE study. The measure was also used in a study assessing the long-term effects of sexual, urinary and quality of life outcomes among men treated by radical prostatectomy or transurethral resection of the prostate 2 years post-surgery. Smith and colleagues (2000) used the RAND-36 in a 6 year follow-up study of men with prostate carcinoma detected in screening studies. [207] In addition, the RAND-36 was used to assess generic quality of life in a cross-sectional study of non-institutionalised Dutch women regarding UI. [208] Women with UI were found to have lower physical functioning and vitality as compared to those without UI.

c) EuroQol EQ-5D

The EQ-5D is a standardised instrument for use as a measure of health outcomes and utilities[58] This questionnaire, developed by the EuroQol group, consists of the EQ-5D self-classifier, the EQ VAS (visual analogue scale) and the EQ SDQ (standard set of socio-demographic questions). Respondents are asked to describe their own health status using a five-dimensional health state classification system of mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each of these dimensions records three levels of severity, which are indicated by numbers. No problems are coded '1', some or moderate problems '2' and extreme problems '3'. A health state can therefore be described with a five-digit number, for instance 12113. This means 'no problems' on the dimension of mobility, 'some problems' on the dimension of self-care, 'no problems' with respect to usual activities and pain/discomfort and 'severe problems' on the dimension of anxiety/depression. The classification system defines 243 health states. In addition, the states of unconsciousness and death are included. The EQ-5D has been translated into many different language versions. The EQ VAS is a standard vertical 20-cm visual analogue scale for recording respondents' rating of their current health state on a 0-100 scale. A similar VAS is used when valuing hypothetically.

The EQ-5D is designed for self-completion by respondents and is ideally suited for use in mail surveys, in clinics and face to face interviews. It is cognitively simple, taking only a few minutes to complete. Instructions to respondents are included in the questionnaire. Applicable to a wide range of health conditions and treatments, it provides a simple descriptive profile and a single index value for health status, from which QALY (Quality Adjusted Life Years) can be calculated, and that can be used in the clinical and economic evaluation of health care as well as population health surveys. (for details of economic evaluation, see chapter x). EQ-5D has been a specially designed to complement other quality of life measures such as the SF-36, Nottingham Health Profile, Sickness Impact Profile or disease-specific measures.

Construct validity of the EQ-5D in the assessment of urinary incontinence on quality of life was tested in 1997. The study showed a good correlation between EQ-5D index and urinary symptoms. More evidence of the construct validity of the EQ-5D in urinary incontinence was demonstrated in a study which showed strong relationships between the EQ-5D index and general quality of life questions in ICS*QoL*, and a moderate relationship with the question associated with incontinence (p=0.0022). On the other hand, much weaker relationships were found with other specific impact questions. [150]

A recent multicentre trial used the ED-5D to assess quality of life years between baseline and six months follow-up for patients randomised to either tension-free vaginal tape versus colposuspension for primary urodynamic stress incontinence. [209] The results indicated that tension-free vaginal tape was a cost-effective alternative to colposuspension. A similar randomised controlled trial examining tension-free vaginal tape and colposuspension was reported to have used the EQ-5D, although no information was provided in the summary article regarding the performance of this measure in the study population. [203]

d) Nottingham Health Profile

The Nottingham Health Profile (NHP) has been used in Sweden to assess the quality of life of women with incontinence compared with an age-matched sample. Overall, all women with incontinence were more socially isolated than those in the general population. [22] Women with urge and mixed incontinence reported more emotional disturbances than the control group, and urge incontinent women also reported more sleep disturbance than the control group. In a study to assess late physical psychosocial sequelae in patients treated with external beam irradiation and brachytherapy for localised prostate cancer, no diminished patient QOL was found as compared to an age matched, healthy control group, using the NHP and the EORTC-QLQ-C30. [210] Persistent health problems among survivors, however, included sexual disorders, urinary incontinence, and urinary incontinence.

A study by Skeil and colleagues (2001) used the NHP and the SF-36 to evaluate the use of transcutaneous electrical nerve stimulation (TENS) in patients with urinary symptoms secondary to neurological diseases. [201] Patients reported decreases in irritative urinary symptoms, urinary frequency, incontinence and clothes changing as a result of treatment. There were, however, no significant changes in quality of life scores for either the NHP or the SF-36 suggesting a lack of sensitivity in both of these measures to these urinary changes.

The use of the NHP to assess incontinence has been minimal in the past several years, although a recent study used the NHP as a means of validating a new

incontinence-specific quality of life measure[63] and so it remains Grade A.

e) Sickness Impact Profile

The full 136-item version of the Sickness Impact Profile (SIP) was used in Norway to assess the quality of life of women with urinary incontinence. Overall, the impact of incontinence was highest on sleep and rest, emotional behaviour, social interaction and recreation/past-times. [21] Three subscales of the SIP were used in a recent cross-sectional study of 1,688 men with and without lower urogenital tract dysfunction. [137] Men with LUTS had worse emotional functioning, recreation, and social interaction scores than those without LUTS. The SIP was also found to discriminate by LUTS severity, in that scores on the three SIP subscales worsened as the severity of LUTS increased. No other reports of the use of the SIP in observational and clinical trials of UI and BPH have been reported in the past decade.

3. Other questionnaires

Other generic health status questionnaires have been used in a small number of studies to assess patients with incontinence. These instruments have not been used in many or any publications in the reporting period, however, and as they appear less relevant for incontinence are thus not highly recommended by the Committee even though they reach the highest levels of evidence.

• Göteborg Quality Of Life Instrument (GQL)

This questionnaire was designed in Sweden to assess general levels of health and their impact on well-being. [211] It was constructed originally for men, but has been tested on women. No studies using the GQL to assess quality of life in persons with urinary incontinence have been reported in recent years.

VI. QUESTIONNAIRES TO ASSESS SEXUAL FUNCTION/SATISFACTION AND INCONTINENCE

Sexual function may be regarded as a dimension or aspect of overall quality of life 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 satisfaction. A number have been specifically developed or adapted to examine sexual function in patients with pelvic floor disorders such as incontinence.

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 (**Table 9**).

1. Highly recommended questionnaires [Grade A]

a) Golombok-Rust Inventory of Sexual Satisfaction

The Golombok-Rust Inventory of Sexual Satisfaction (GRISS), is a self-report inventory which has 56 items, from them 28 are for males and 28 are for females and it takes approximately 15 minutes to complete. [212] The questionnaire was developed systematically by sex therapists at the Maudsley Hospital Sexual Dysfunction Clinic. The GRISS assesses the quality of a sexual relationship in a heterosexual couple and an individual's functioning within it. This questionnaire is designed for people who are currently in a relationship. There are 12 domain scores, 5 of which are female specific, 5 male specific and 2 non-gender specific. The 5 female specific domains are: Anorgasmia, Vaginismus, Avoidance, Nonsexuality and Dissatisfaction. The 2 non-gender specific domains are: Frequency of sexual contact and Non-communication. The ques-

Table 9. Recommended questionnaires for the evaluation of sexual function/satisfaction in patients with incontinence

Grade A	
Men and women	Golombok-Rust Inventory of Sexual Satisfaction [212]
Men tion	International Index of Erectile Func- [213]
	ICS*sex* [214]
	BPHQOL9 [215]
Grade B	
Men and women	Psychosocial Adjustment to Illness Scale [216]
Women	Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire
[217]	
	Brief Index of Sexual Function for Women [218]
Men	Brief Sexual Function Inventory [219]
Grade C (with potential)	
Men and women	Derogatis Interview for Sexual Functioning [216] Sexual Behaviour Inventory [220]
	Changes in Sexual Functioning Questionnaire [221]
	Sexual Interaction Inventory [222]
	Index of Sexual Satisfaction [223]
	Multidimensional Sexuality Questionnaire [224]
Women	McCoy Female Sexuality Questionnaire [225] BFLUTSsex [60]
	Female Sexual Function Index [226]
	Sexual Function Questionnaire [227]
	Simple Sexual Function Questionnaire [228]
Men	DAN-PSSsex [229]
	Sexual life quality questionnaire [230]

tionnaire was validated on a clinical sample recruited from sexual dysfunction clinics throughout the UK, consisting of 68 men and 63 women, and a control group of 29 men and 30 women randomly selected from primary care attendees. Split half reliability was 0.94 for the female scale and 0.87 for the male overall scale. Average internal consistency of subscales was 0.74. Both the overall female and male scores were found to discriminate well between clinical and non-clinical samples and scores on subscales successfully discriminated specific diagnostic groups. There was also a significant correlation between therapists' ratings of severity and scores on the questionnaire. Responsiveness was assessed by comparing change in the questionnaire scores with rated improvements by sex therapists. Correlations were moderate but statistically significant (0.54 for males and 0.43 for females, $p<.005$ and $p<.01$ respectively). Test-retest reliability was assessed in 41 couples receiving either marital or sex therapy. A further two subscales apply to both males and females and cover infrequency and non-communication. An additional 2 items each for males and females contribute to the overall scores but are not included in the subscales. The GRISS has been used by Hunt & Moss (1996) in a small study exploring the relationship of unwanted sexual experience to detrusor instability and sexual dysfunction. [231] High levels of sexual dysfunction were found in incontinent subjects compared to other clinical groups. The GRISS is not applicable to homosexual couples or people without a partner, but does provide an otherwise comprehensive, effective and well-used questionnaire.

b) International Index of Erectile Function (IIEF).

The international index of erectile function (IIEF) is a 15-item self-administered questionnaire. It was designed to assess erectile function and is culturally and linguistically validated in at least 10 languages for use in multinational clinical trials. [213] It was initially validated in 351 patients with erectile dysfunction (ED) and found to have a high degree of internal consistence (Crohnbach's alpha > 0.85) and sensitivity to change with treatment. The questionnaire was culturally and linguistically validated in the following languages: Danish, Dutch, English (American, Australian and British), Finnish, French, German, Italian, Norwegian, Spanish and Swedish. The final 15-item instrument addresses five different domains of sexual function: erectile function, orgasmic function, sexual desire, intercourse satisfaction and overall satisfaction. The IIEF has a high degree of internal consistence. Test-retest repeatability was high for the domains of erectile function and intercourse satisfaction and moderately high for the other domains. Discriminant validity was good for most domains (except the sexual desire domain). Construct validity was good and all five domains showed a high degree of sensitivity to change. An abridged 5-item version of the questionnaire has also been developed (IIEF-5). [232] Of the 5 items, 4 are from the erectile function domain and one addresses

sexual intercourse satisfaction. The main difference between the 5- and the 15-item version is that the former asks patients to self-assess erectile function and satisfaction over the past 6 months while the latter refers to a time frame of 4 weeks. It has been used recently in a multinational survey of male ageing. [229]

c) ICSsex

The ICS*sex* is part of the ICS-BPH questionnaire. [214] It consists of 4 items: to what extent sex life has been spoilt by urinary symptoms, ability to have erections, ability to ejaculate, and pain or discomfort on ejaculation. As with the other ICS questionnaires each item has an additional part to each item concerning the amount of bother the symptom causes i.e. how much of a problem is this for you? It has been used in both clinic and community samples to assess the relationship between urinary symptoms and sexual function, [214] and to show that urinary symptoms most frequently associated with sexual dysfunction were those related to incontinence. [233] It has also been used in a randomised trial of treatments for LUTS to investigate sexual side effects. [234] Aspects of reliability, validity and responsiveness have been tested and found to be satisfactory.

d) BPH QOL9

The QOL9 is a short form of the QOL20, a questionnaire previously validated in French for men with LUTS related to BPH. [215] The short form was developed using a large-scale cohort study of 7093 men with BPH who received alfuzosin for 3 months. The items were reduced by identifying questions that contributed most to establishing the global score and that reflected the structure of the questionnaire on principal components analysis. The final, 9-item questionnaire consists of 3 items concerning general well being, 3 items assessing BPH interferences with activities, and 3 items pertaining to patients' perceptions of their sexual life. The sexual function domain covered sexual desire, erectile function and satisfaction with sex life. The QOL9 was validated in two studies, a longitudinal study of alfuzosin, having a sample size of 4259, and a smaller cross-sectional study of men having symptomatic BPH (n=48), or no symptoms of BPH (n=42), and a group of younger men (n=23). Feasibility and acceptability of the questionnaire were assessed by completion rates that exceeded 85%. Principal components analysis confirmed the three-factor structure. Discriminant validity was measured by comparing cases and non-cases. On the sexual function domain cases scored 10.5, non-cases 15.2 and young men 26.3. The most strongly discriminating question between cases and non-cases was satisfaction with sex life. There was also a good correlation between symptom severity and the total QOL9 score. Internal consistency of the overall scale was fair with Cronbachs alpha of 0.79 for patients with BPH and 0.85 for the control groups. Test-retest reliability was good for the total score but moderate for the sexual function subscale (ICC = 0.69 - 0.88) with the reliability of the erection item having an ICC of 0.53. After treatment the effect size of the change in the sexual function domain was linked to age and initial symptoms severity but had a mean of 0.02 and 0.55 for patients treated in each of the two studies.

2. Recommended questionnaires [Grade B]

- The Psychosocial Adjustment to Illness Scale (PAIS)

The Psychosocial Adjustment to Illness Scale (PAIS) was designed to assess the psychological and social adjustment of male and female medical patients to their illness and is in an interview or self-report format (*PAIS and PAIS-SR)*. [216] It contains a sexual relationships domain consisting of 6 items assessing the quality of interpersonal sexual relationships, sexual interest, frequency of sexual activity, sexual satisfaction, sexual dysfunction and interpersonal sexual conflict. Validation was carried out on groups of patients having renal dialysis, lung cancer, cardiac problems, breast cancer, and Hodgkin's disease. Internal consistency of the sexual relationships domain ranged from 0.8 to 0.93 in these different clinical groups. Factor analysis confirmed the subscale structure. All 6 items in the sexual relationships domain had very marked loadings on this dimension, with no appreciable loadings from other items. Convergent validity was assessed by comparing the scale to the Global Adjustment To Illness Scale (r-0.46), the SCL-90R (r=0.13), Affect Balance Scale (r=0.42), and the Patients Attitudes, Information and Expectancies Scale (r=0.40). Discriminant validity was assessed by comparing patients screened positive and negative for lung cancer. There were differences in the mean scores between the two groups which approached significance ($t=1.53$, $p<0.10$). [14] The PAIS has been used to investigate the impact of different types of urinary incontinence on sexual function[235] in a sample of 200 patients referred for urodynamic assessment. Compared to patients with GSI, patients having DI were signifi-

cantly impaired on all items of the sexual relationships subscale, apart from the 'sexual satisfaction' item. Some aspects of validation were also carried out in a small study of 29 patients who had been treated successfully for penile cancer[236]. Internal consistency of the sexual relationships scales was good having Cronbach alpha of 0.83. Convergent and discriminant validity was shown in significant correlations with well-being scales but not with social scales. In addition, patients who had had the most radical treatments in terms of partial or total penectomy scored lower on the sexual relationships scale as did older patients (mean age 63 years) compared to younger patients (mean age 41 years), whereas having a mental disorder showed no correlation with sexual relationship scores.

b) Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ)

Rogers and colleagues in the United States have reported the development and validation of a measure of sexual function in women with urinary incontinence or pelvic organ prolapse. [217] The scale consists of 31 items spread across 3 domains: behavioural/emotive, physical, and partner-related. The measure has been found to have acceptable convergent and divergent validity and to be able to discriminate between women with and without urinary incontinence or pelvic organ prolapse. [217] [237] Test-retest ranged from 0.56 to 0.93, showing some variability in the moderate to high reliability ranges. [238] The internal consistency of the total measure and the behavioural/emotive, physical and partner-related domains was .85, .86, .77, and .43, respectively. [238] Sensitivity of the PISQ-31 was not assessed.

A short form version of the questionnaire PISQ-12 has also been developed by the same team of researchers. [239] All subsets regression analyses with $r > 0.92$ identified 12 items, across all three domains, that were the most highly predictive of the PISQ-31 scores. Construct validity of the PISQ-12 was examined through correlations with the long form of the questionnaire PISQ-31 (r=0.75-0.95), the Sexual History Form -12, and the IIQ-7. Correlations of the PISQ-12 with these latter measures were similar to those found for the PISQ-31. The PISQ-12 scores were lower in those patients with poorer sexual functioning and more depressive symptoms. Test-retest reliability was moderate to high. Internal consistency reliability was stated as having been done, although the values were not reported in the article. Sensitivity of the PISQ-12 was not assessed.

An initial validation of a Spanish version of the PISQ-31 was reported for 34 bilingual patients of Mexican, Central or South American, Puerto Rican and Cuban origins living in the United States. [240] Good agreement between the Spanish and English versions was achieved for 30 of the 31 items. The three-factor structure of the original measure was validated in this sample of participants.

c) The Brief Index of Sexual Function for Women (BISF-W)

The Brief Index of Sexual Function for Women (BISF-W) is a 22-item self-completed questionnaire that takes 15-20 minutes to complete. [218] It is designed to assess current levels of female sexual function and satisfaction. It was originally validated in a sample of 269 sexually active women age 20-73, and used a 3-factor scoring system (Interest/desire, Sexual activity, Sexual satisfaction) with acceptable test-retest reliability. A new quantitative scoring algorithm was developed to facilitate the use of the BISF-W in clinical trials, providing an overall composite score for sexual function and 7 domain scores; Thought/desire, Arousal, Frequency of sexual activity, Receptivity/initiation, Relationship satisfaction, Pleasure/orgasm, and Problems affecting sexual function. Norms for the composite score and for each of the seven dimension scores are available, derived from a sample of 225 healthy women (age 20-55). [241] Comparing these scores with those of 104 surgically menopausal, sexually active women who reported impaired sexual function (age 20-55), the instrument showed good discriminant validity between women with and without sexual complaints in each of the 7 sexuality domains. In a placebo-controlled study, the BISF-W was sensitive to detecting differences between treatment groups in two of the 7 sexuality domains and on the overall composite BSIF-W score.

d) Brief Sexual Function Inventory

This 22-item questionnaire concerning male sexual function was designed for clinical and research purposes in urological settings. [219] Items were generated from the literature to produce a 50-item questionnaire which was then reduced down to 22 items in a series of pilot studies prior to the final validation study. The questionnaire comprises of 5 subscales: Libido, Erectile function, Ejaculation, Assessment of significance of each domain and Overall satisfaction. Validation was carried out on a sample of 74 men with sexual dysfunction and 60 general medical patients. Mean age was 55 and 45 years respectively.

The study describes development of individual subscales down to a final questionnaire of 11 items based on measures of internal consistency and test-retest reliability. Internal consistency of the subscales ranged from 0.62 to 0.95 and ICC's from 0.79 to 0.89 for test-retest reliability. All subscales except the drive and ejaculation subscales discriminated between patients being treated for sexual dysfunction and general medical patients, but it was not expected that drive would be reduced in patients experiencing sexual dysfunction and ejaculation did not appear to be an important issue for patients.

3. Questionnaires with potential [Grade C]

a) The Derogatis Interview for Sexual Functioning (DISF)

The Derogatis Interview for Sexual Functioning (DISF)[216] is a 25-item semi-structured interview. It takes around 15 minutes to administer. It aims to provide a multidimensional assessment of sexual function. Like the CSFQ, DISF is used both for males and females. A self-report version is also available (DISF-SR). There are five domains that are supported by factor analysis: Sexual cognition/fantasy, Sexual arousal, Sexual behaviour/experience, Orgasm and Sexual drive/relationship. The scores can be interpreted as discrete item, domain or global summary scores, with a total score that summarises level of sexual functioning across all domains. Both the DISF and the self-report version have had normal ranges established in community samples composed of 399 participants between the age of 19 to 64. Test-retest internal consistency and inter-rater reliabilities were within the acceptable range. The CSFQ has been translated into 8 different languages, but further evaluation of other aspects of validity, reliability and responsiveness is required.

b) Sexual Behaviour Inventory (SBI)

The Sexual Behaviour Inventory (SBI)[220] measures four types of sexual behaviour both for females and males; Sexual behaviours displayed by the subject alone, by the subject to the partner, by the partner to the subject and by the subject and the partner. This instrument examines which behaviours have been experienced (experience scale), and the degree of pleasure associated with the sexual activities experienced by the subject (experimental pleasure scale) for each type of behaviour (Trudel et al., 2001). Further evaluation of other aspects of validity, reliability and responsiveness is required.

c) The Changes in Sexual Functioning Questionnaire (CSFQ)

The Changes in Sexual Functioning Questionnaire (CSFQ)[221] was designed for use in both men and women. It has 35-items for women and 36 for men. It is a structured interview designed to measure illness and medication related changes in sexual function. The CSFQ takes approximately 20 minutes to administer and provides a gender specific report (CSFQ-F & CSFQ-M). The questionnaire has five domains, Sexual desire frequency, Sexual desire interest, Sexual pleasure, Sexual arousal and Orgasm. An overall CSFQ score can also be derived. Additional questions ascertain the degree to which sexual functioning has changed over time and how extensive changes are as well as a measure of the nature and underlying cause of these changes. The interview was standardised on a sample of 122 medical students (68 males and 54 females between the age of 22-35) and 33 psychiatry residents (17 males 16 females between the age of 25-43). The questionnaire showed discriminant validity between healthy volunteers and a sample of individuals suffering from depression and in both the total CSFQ and its 5 domains. Internal consistency and test-retest reliabilities for the CSFQ were acceptable, but further evaluation of other aspects of validity, reliability and responsiveness are required.

d) Index of Sexual Satisfaction (ISS)

The Index of Sexual Satisfaction (ISS) was developed by Hudson et al in 1981[223] to measure the magnitude of problems in people with sexual dysfunction. It is a 25 item self-report inventory, which takes around 10 to 15 minutes to complete and generates five scales relating to sexual satisfaction. Evidence of divergent validity is shown by its ability to discriminate between samples with and without sex problems but further evaluation of other aspects of validity, reliability and responsiveness is required.

e) Multidimensional Sexuality Questionnaire (MSQ)

Multidimensional Sexuality Questionnaire (MSQ) [224] is a 60-item questionnaire with 12 subscales measuring various psychological tendencies and dimensions about both male and female sexuality. The subscales include; Sexual esteem, Sexual preoccupation, Internal sexual control, Sexual consciousness, Sexual motivation, Sexual anxiety, Sexual assertiveness, Sexual depression, External sexual control, Self-monitoring, Fear of sexuality, and Sexual satisfaction (Trudel et al., 2001).

f) The Sexual Interaction Inventory (SII)

The sexual Interaction Inventory (SII) is a self-completed questionnaire containing 102 items. [222] It is for both men and women and measures levels of sexual function and satisfaction in a relationship. It is not applicable to single people. Participants are asked to answer about their frequencies, desires and self and partner satisfaction for 17 sexual behaviours. Eleven scale scores are generated. Statistically significant score differences between patients and controls ($p < .05$) were found in 9 of the 11 scales. Test re-test reliability over two weeks was .53 - .90. The questionnaire takes around half an hour to complete, which may limit its clinical utility in some circumstances.

g) McCoy Female Sexuality Questionnaire (MFSQ)

The McCoy Female Sexuality Questionnaire (MFSQ) is a 25-item self-report inventory aiming to assess levels of sexual interest and response in women. [225] Initial psychometric testing involved 364 university students, though it has also been used in menopausal women where responses relating to the menopause and oestrogen levels were significantly correlated. Seven point scales are generated. It has been translated into French and Swedish. In a study employing the French translation there were significant differences between treatment and non-treatment groups as well as convergent validity with other measures. Test-retest reliability was also satisfactory.

h) BFLUTSsex.

The BFLUTS*sex* questionnaire contains 4 questions related to sexual function: pain or discomfort due to dry vagina, whether sex life has been spoilt by urinary symptoms, pain on sexual intercourse, and leakage on intercourse. [60] In addition to each of these items the respondent is asked how much of a problem this is for them. It has been used to assess sexual function after hormone replacement therapy[242] and pelvic floor muscle training. [243] This has been replaced by one item in the new BFLUTS scored short form (see above).

i) Simple Sexual Function Questionnaire

Walters, Taylor and Schoenfeld (1990) used a simple, 3 item questionnaire devised by Plouffe (1985) to assess the relationship of sexual dysfunction to urodynamic diagnosis in incontinent women. [228] The questionnaire asks if the respondent is sexually active and if so, whether there are any problems. If the respondent has problems they are asked about pain during coitus. Walters et al. (1990) added a question asking whether urinary symptoms interfered with sex. [228] Again these questions are similar to those used in the BFLUTS and the Bernstein questionnaires. Although sexual dysfunction was more prevalent in the incontinent groups there was no difference between those with GSI and those with DI. Plouffe (1985) developed this questionnaire by comparing these three items, administered by junior interns to a sample of 57 female patients in a ward environment, to longer, more in-depth interviews carried out in private. [244] The short questionnaire was found to detect all cases of sexual dysfunction identified by in-depth interview.

j) The Female Sexual Function Index (FSFI)

The Female Sexual Function Index (FSFI)[226] is a 19-item self-report questionnaire for measuring female sexual function and takes approximately fifteen minutes to administer. It provides five domains of sexual function, which have been confirmed using factor analysis they include: Desire, Lubrication, Orgasm, Arousal, Pain and Satisfaction. An overall total score is also provided. The FSFI was developed using a sample of 131 female controls (between the age of 21-68) and 128 females who met Diagnostic and Statistical Manual of Mental Disorders (DSM-IV; American Psychiatric Association, 1994) criteria for Female Arousal Disorder (FSAD). The age of the participants was matched (21-69). Norms are available for both groups (controls and FSAD) at the individual items level, the domains level, and the full-scale scores. The FSFI discriminated reliably between women with arousal disorder (FSAD) and a control group on each of the domains of sexual function as well as on the full-scale score. FSFI data were also compared with results from the Locke-Wallace Marital Adjustment test (1959), Correlations between the two were generally modest in magnitude, with the strongest observed for the satisfaction domain of the FSFI. Internal consistency and test-retest reliability of the FSFI have been established.

k) Sexual function questionnaire

The 31-item sexual function questionnaire (SFQ) was designed specifically as an outcome measure for use in clinical trials of drugs for female sexual dysfunction (FSD). [227] It was derived from semi-structured interviews with 82 women with or without FSD, initially 61 items were generated, following which 31 items were selected by a panel for face validity and clinical relevance. The questionnaire

was then used in 2 multicentre phase II clinical trials involving 781 women. Factor analysis identified 7 domains: Desire, Physical arousal-sensation, Physical arousal-lubrication, Enjoyment, Orgasm, Pain, and Partner relationship. Internal consistency in a sample of 201 women was 0.65 – 0.91. Test-retest reliability was moderate (Cohen's weighted kappa values 0.21 – 0.71, Pearson correlation coefficients 0.42 – 0.78). The instrument discriminated well between women with and without FSD as well as between those wh Multidimensional Sexuality Questionnaire (MSQ)o had improvement in FSD and those who reported no improvement ($p<0.001$).

l) DAN-PSSsex

A derived form of DAN-PSS, the DAN-PSSsex, was used in a multinational survey on the prevalence of LUTS and sexual dysfunction of men aged between 50 and 80 years old. [229]

m) Sexual life quality questionnaire (SLQQ)

This 16-item instrument was designed to evaluate sexual function and satisfaction with treatment for erectile dysfunction (ED) in men and their sexual partners[230] Its psychometric properties have been evaluated in 2 studies evaluating men being treated for ED, where it showed evidence of responsiveness and a reliable indicator of treatment preference in this context.

n) Other measures of sexual function

Many of the questionnaires assessing the psychosocial impact of LUTS and/or UI contain one or two questions related to sexual function. The majority of these are discussed above, either as symptom questionnaires or general quality of life questionnaires. Questionnaires containing just one question tend to focus on a general assessment of the overall impact of urinary symptoms on sexual functioning. The Kings Health questionnaire, [30] the Incontinence Impact Questionnaire, [245] and the I-QOL[246] are recommended by the Committee for use for UI/LUTS. However, when considering the sexual items it must be borne in mind that validation of the sexual items was not always carried out or made explicit. But the questions relating to sexual function in each of the questionnaires are very similar and judgements on validity can be made by comparing questions and psychometric data between questionnaires as well as considering the psychometric properties of the scales as a whole. If more in-depth information is required concerning sexual function, the questionnaires recommended for this aspect should be used (see above).

There are other general measures of sexual function, such as the Watts Sexual Function Questionnaire. [247] and Medical Outcomes Study (MOS) Sexual Functioning Scale. [248] There are also questionnaires that have been designed for sexual dysfunction specific to particular diseases, such as Radiumhemmets Scale of Sexual Function, [249] Sexual Adjustment Questionnaire (SAQ), [152] and Prostate-targeted Health Related Quality of Life. [153]

A small number of questionnaires have produced initial validation but without publications during the reporting period: Effect of Urinary Incontinence on Sexuality Questionnaire (EISQ), [250] and Effects of urinary incontinence on sexual activity. [251]

VII. 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 QOL in older people. Urinary incontinence causes a significant decrease in QOL, as severe as that of many chronic disease states. Since the elderly commonly have various types of comorbid conditions, it may be difficult to measure the impact of urinary incontinence with generic QOL measures. The use of incontinence specific tools to measure QOL in the elderly, therefore, is of considerable importance. The validated incontinence-specific QOL questionnaires, such as IIQ, I-QOL or KHQ, are used for clinical trials or research on urinary incontinence including elderly people. Okamura,

assessed symptoms and QOL in elderly people (men and women) with lower urinary tract symptoms including incontinence, using KHQ and IPSS. They showed that symptoms and QOL in the elderly with LUTS could be assessed by IPSS and KHQ and that urinary incontinence appeared to be more associated with QOL in elderly women. [79]

On the other hand, a variety of factors surrounding elderly people, including physical, social, mental, economic or environmental conditions, are different from those of younger generations. In fragile 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. However, there is currently little literature relating to the development or validation of particular questionnaires for older people with urinary incontinence. Two questionnaires were found and are described below.

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

The Urge Impact Scale (URIS) was designed and tested specifically for older persons with urge incontinence. The URIS was developed and validated by DuBeau et al. (1999). [252] And included 32 items, reduced to 24 items (URIS-24). The URIS-24 was psychometrically assessed for validity and reliability in community-dwelling men and women with urge incontinence, older than 60 years old. Cronbach 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 urge 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 urge incontinence on older persons.

b) Swedish questionnaire [Grade C]

A questionnaire survey was conducted among men and women aged over 75 years in Sweden. [253] The questionnaire was developed specifically for the study although many questions had been used in a previous epidemiological study. [254] The questionnaire achieved an admirable 62% response rate, but no details were published describing the psychometric properties of the questionnaire.

2. Children

Some questionnaires have been developed specifically to address issues for children, particularly enuresis. See Chapter (Children).

3. Spinal cord injured/neurologically damaged

Individuals who have 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 and where a small number of questionnaires are being developed (see below).

a) Qualiveen: quality of life related to urinary problems in spinal cord injury [Grade B]

A questionnaire has been developed to evaluate the specific impact of urinary dysfunction on the quality of life of spinal cord injury patients in France. [255] Items were selected following patient interviews, and were then assessed for validity and reliability in 281 spinal cord injury patients with urinary difficulties. The items were reduced psychometrically and the resultant questionnaire has been named Qualiveen. [255]

b) Quality of life for Spinal Cord Patients

This questionnaire is under development in New Zealand (Arnold et al) and in association with the ICIQ. Posters have been presented, but as yet there are no publications.

4. Prostate/bladder cancer

Very many questionnaires are available for assessment in this area: Post-radical prostatectomy questionnaire, [149] [256] Cancer Rehabilitation Evaluation System - Short Form (CARES-SF), [257] Prostate Cancer Treatment Outcome Questionnaire (PCTO-Q), [151] PROSQOLI, [258] Modified Southwest Oncology Group (SWOG), [259] Functional Assessment of Cancer Therapy - (FACT-G), Bladder form (FACT-B) and Prostate form (FACT-P), [260] Functional Assessment of Cancer Therapy Vanderviet Cystectomy Index (FACT-VCI), [261] EORTC metastatic prostate cancer, [151] Changes in Urinary Function, [152] Prostate-targeted Health Related Quality of Life. [153]

5. Lower urinary tract symptoms/benign prostate disease

Very many questionnaires are available for assess-

ment in this area, most of which do not contain symptoms or full evaluation of UI: AUA Symptom Index. [262] I-PSS. [262] [263] Patient-completed modification of the Boyarsky[264] schedule. [265] BPH Impact Index. [266] BPH Health-related QoL survey. [267]

One questionnaire has been designed for patients with urinary stents: USSQ. [71]

VIII. INTERNATIONAL CONSULTATION ON INCONTINENCE QUESTIONNAIRE (ICIQ)

The ICI is developing a set of modular questionnaires that, it is hoped, will become the international standard for work on pelvic problems related to lower urinary tract, vaginal and lower bowel dysfunction. There are 'core' modules, representing the major domains of UI, FI and POP, with 'optional' modules that allow more detailed evaluation of particular issues or groups, and 'add-on' modules for particular areas, such as sexual function. These modules adopt existing questionnaires wherever possible. This is still a developing area, and so is likely to change to some degree over time. The following section reports on the situation as of September 2004.

1. The modules (September 2004)

a) Core modules - symptoms

- **ICIQ-MLUTS** (urinary symptoms): this is derived from the fully-validated ICS-BPH questionnaire, the ICS*male*, without the incontinence questions. [61]
- **ICIQ-FLUTS** (urinary symptoms): this is derived from the fully-validated BFLUTS questionnaire without the incontinence symptoms. [60]
- **ICIQ-VS** (vaginal symptoms): in development
- **ICIQ-BS** (bowel/faecal symptoms): in development

b) Core modules – patient groups

- **ICIQ-UI short form** (urinary incontinence): this is the ICIQ as reported above. [33]
- **ICIQ-N** (nocturia): this includes the nocturia question from the ICIQ-LUTS module
- **ICIQ-OAB** (overactive bladder): this includes the OAB questions from the ICIQ-LUTS.
- **ICIQ-Neuro** (spinal cord injured): in development.
- **ICIQ-LUTSC** (children): in development.

c) Optional modules

- **ICIQ-MLUTS LF** (long form for urinary symptoms).
- **ICIQ-FLUTS LF** (long form for urinary symptoms).
- **ICIQ-UI LF** (long form for urinary incontinence).

d) Recommended add-on modules

- **ICIQ generic QoL**: SF-36 or SF-12. [194]
- **ICIQ I-QOL**: I-QOL. [28]
- **ICIQ KH** (King's Health) QoL: KHQ. [30]
- **ICIQ OAB QoL**: OAB-Qol. [56]
- **ICIQ N-QOL**: N-QOL. [137]
- **ICIQ-sex**: there are male and female versions of this questionnaire derived from the ICS*male* and BFLUTS questionnaires described above which are fully validated.

  Other questionnaires for various aspects of quality of life and sexual function/satisfaction related to the core conditions are in development.

2. Availability

These questionnaires are all available in English and several have either been, or are being, translated into other languages. It is planned that modules, once fully validated, will be available via the ICIQ website (www.iciq.net). For further details, contact Ms Gardener (nikki_gardener@bui.ac.uk) or Dr Avery (Kerry.Avery@bristol.ac.uk) or Professor Abrams (edu@bui.ac.uk).

C. USE OF QUESTIONNAIRES IN INCONTINENCE AND RESEARCH

Questionnaires are used in outcomes and epidemiological research and it is encouraging that since the publication of the previous report an increasing number of such studies are being published which include highly recommended validated questionnaires. It remains, however, that many studies do not include these questionnaires. It is the Committee's view that randomised controlled trials should not be undertaken without the inclusion of Grade A questionnaires. We strongly urge researchers to include such measures in all research on incontinence. In the sections below, we provide some advice about selecting measures, and update our literature review on the use of questionnaires in randomised trials and observational studies.

I. SELECTING SYMPTOM AND QUALITY OF LIFE INSTRUMENTS FOR RESEARCH PURPOSES

The previous sections have provided an overview of symptom and quality of life instruments that have achieved the highest levels of evidence regarding reliability, validity, and responsiveness. But, how does a clinical researcher choose which instruments are most appropriate for a particular research study and/or clinical assessment? The following section provides general guidelines to be used in conducting symptom and quality of life assessments in clinical trials or other research investigations related to urinary or faecal incontinence.

It is important to re-emphasise that health-related quality of life (HRQL) is a multidimensional concept referring to an individual's overall well being – physical, social, and emotional. Primary dimensions of HRQL include: physical functioning, psychological functioning, social functioning and role activities, and individuals' overall life satisfaction and perceptions of their health status. Other commonly assessed dimensions of HRQL include cognitive or neuropsychological functioning, paid or unpaid work activities, sexual functioning, sleep disturbance, pain, and the impact of symptoms on daily life. The specific dimensions relevant for a given research study will depend upon the research questions to be addressed, the type of study (e.g., intervention study; randomised trial; observational study), the disease or condition being investigated, and the study population. Attention should be paid to whether HRQL is to be a primary or secondary endpoint. In addition, issues of staff and participant burden, time constraints, and resources should be considered in the selection of HRQL measures.

1. SELECTING HRQL MEASURES FOR RESEARCH STUDIES

a) Study Design

There are several protocol concerns that must be taken into account when using health-related quality of life 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 trial design, the number of participants enrolled, and participant and staff burden. The goal of the HRQL investigation is to "fit" the HRQL measures to the protocol without compromising either the study design or the assessment. For example, if the study design is complex with frequent participant contacts and multiple clinical measures, it may be necessary to focus the HRQL assessment on a subset of critical dimensions in order to minimise participant and staff burden. At the same time, however, HRQL must be viewed as an important variable in the overall trial design. Reducing its measurement to very brief and potentially less reliable measures, or to only one or two dimensions, may seriously diminish the integrity of the overall study design and yield useless information. Having well developed research goals and questions regarding HRQL will help to guide you in the selection of measures for a study. The goal is to develop a conceptually adequate, yet practical HRQL battery given the study population, the specific intervention, and the study design.

The frequency with which HRQL will need to be assessed in a research study will depend on 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, other HRQL 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 when patients might be seen in clinic ordinari-

ly, if appropriate, may also reduce the costs involved in follow-up HRQL and symptom assessments.

b) Study Population

It is critical to specify key population demographics that could influence the choice of instruments, the relevant dimensions of HRQL to be assessed, or the mode of administration. Thus, age range, gender, educational level, the language(s) spoken, and cultural diversity should be carefully considered prior to selecting the HRQL battery of 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 important to be sensitive to how the disease will progress and affect the HRQL 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, we might expect a symptom to worsen and thus have an effect on daily functioning. The point is to select dimensions and measures of HRQL that are sufficiently sensitive to detect changes in both the treated and the control group patients. Uses of the same instruments 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 HRQL, and therefore require careful consideration: the positive and adverse effects of treatment, the time course of the effects, and the possible synergism of the treatment with existing medications and conditions. It is crucial to understand how a proposed treatment could affect the various dimensions of an individual's life quality in both positive and negative ways. For example, some drug therapies may relieve LUTS but produce symptoms like dry mouth or sexual dysfunction.

In addition, the time course of an intervention's effects on dimensions of HRQL is also critical both in terms of the selection of measures and the timing of when HRQL measures are administered to study participants. For example, in a trial comparing coronary artery bypass graft (CABG) surgery to angioplasty, an assessment of HRQL one week post-intervention might lead to an interpretation that the surgical arm was more negative than angioplasty for HRQL 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 HRQL is 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 dimensions of HRQL.

2. TYPES OF HRQL INSTRUMENTS

As was stated earlier in this chapter, measures of HRQL can be classified as one of three types. *Generic instruments* are designed to assess HRQL 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 SF-36 Item Health Status Profile (described above). A second type of instrument is *condition or population-specific* measures (e.g., instruments designed to assess the HRQL impact of specific diseases, conditions, age groups, or ethnic groups). These instruments may be similar to generic instruments in that they generally assess multiple dimensions of HRQL, but they also include items more specific to the particular condition or population being studied. Examples of frequently used condition specific instruments in the UI area include the Incontinence Impact Questionnaire, and the King's Health Questionnaire (described above). Lastly, a third type of HRQL instrument is *dimension-specific measures*, which assess a single dimension or aspect of quality of life, such as sexual functioning or depressive symptoms.

It is becoming less common in studies across a wide range of chronic and acute conditions to find research investigations in which only one dimension of quality of life is assessed (e.g., social functioning), or where only one summary question is used to evaluate life quality (e.g., "How would you rate the overall quality of your life in the past month?"). Although such assessments still occur, the trend has been

toward the use of multidimensional generic or condition-specific instruments supplemented with dimension-specific instruments as needed. For example, in a study assessing the outcome of a medical therapy in reducing stress incontinent episodes in middle-aged adult women, a team of researchers may use the Incontinence Impact Questionnaire to assess the impact of the medication on the individual's overall quality of life, but may also want to assess the impact of treatment of the patients' sexual functioning. Investigators may also want to know whether the individual's emotional functioning has improved as a result of the medication (e.g., feeling less emotionally distressed or depressed). In general, 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 HRQL as outcomes usually incorporate a combination of HRQL instruments most relevant to the study population and intervention, if applicable, being mindful of resource constraints and staff and participant burden.

In general, in our review of the research studies and clinical trials to be described in the next section, we found that most investigators use a combination of QOL instruments to assess the impact of incontinence on patients' quality of life. Only in rare instance was a single questionnaire used. In some studies, objective measures of UI were combined with self-report instruments, although as was stated above, there is oftentimes poor correlation between objective measures and quality of life assessments. Self-report symptom and quality of life instruments measure patients' perceptions of the impact of symptoms on their daily life. There can be wide variability in what some patients consider to be bothersome. Some symptoms that are close to intolerable in some individuals, are to others, much more bearable with little resultant impact on their daily life. This range in individual patients' appraisal of their symptoms accounts, in part, for the poor correspondence between objective and subjective measures of UI.

3. Summary

In summary, some general points to consider in selecting HRQL instruments for incontinence studies:

- Make sure that the HRQL research questions and study endpoints are clearly defined. Determine which dimensions of HRQL are most critical to assess and which are most likely to be affected by a particular condition and/or its treatment. HRQL measures cannot be measured effectively until these specifics have been identified.
- Make good use of library literature searches in identifying past research in the area(s) of interest, as well as in identifying the types of HRQL measures other researchers have used in past work. This information can provide valuable information on how particular scales have performed in previous populations, as well as provide additional information to assist in defining research questions/issues regarding the HRQL 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? Make sure the forms are appropriate for use with the population to be assessed. 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 socioeconomic status or of different educational backgrounds. This chapter has indicated, where possible, the extent to which specific HRQL instruments 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 scales is time consuming and complicated to complete. If you must develop a new scale, ensure that expertise in psychometrics is available to your research team in order to guide the scale construction process.
- Know the strengths and weaknesses of different types of HRQL measures. In general, generic measures are useful in providing information on multiple dimensions of HRQL that can be compared across different populations. The 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 specific HRQL measures are scored. Specifically, will the scoring method of a measure provide you with the information you need to answer your research question(s)? Is there flexibility in scoring methods? Total scores in multidimensional quality of life instruments are useful in comparing overall quality of life across various patient populations. They also simplify data analyses in that multiple HRQL dimensions do not need to be analysed. Summary measures or total scores, however, do not provide you with information about which specific components of HRQL are most affected by particular conditions and/or their therapies. Dimension-specific scores are more useful in targeting specific areas of quality of life for improvements in life quality. HRQL instruments that provide options in how they can be scored (i.e., summary scores/total scores as well as individual dimension scores) may provide you with greater flexibility in answering research questions effectively.
- Pilot testing of HRQL instruments with participants/patients similar to those who will be assessed in a research investigation is always advisable. Adjustments can then be made in the protocol, if necessary, prior to the initiation of the study.
- Finally, train and certify your staff to administer quality of life instruments 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.

II. RANDOMISED TRIALS

The ideal study design for assessing the outcome of treatments for incontinence is the randomised controlled trial, and the assessment of a patient's symptoms and their impact on quality of life using validated self-completed questionnaires should be an essential component of any study evaluating treatments. Few randomised trials using recommended questionnaires were identified in the first ICI report. [1] In the second ICI report, we reviewed randomised trials carried out between 1998 and mid 2001 and found 48 trials, 19 of which used validated questionnaires as an outcome measure, but only 6 of which reached the highest level of recommendation. [2] Below, we review the randomised trials found relating to treatments for incontinence and their use of validated questionnaires between 2001 and mid 2004.

Searching of Medline and the Cochrane trials databases between 2001 and mid 2004 identified 109 randomised trials of treatments for urinary incontinence and five of anal incontinence of various sorts (see Table 10). One further trial looked at both urinary and anal incontinence. Of those assessing urinary incontinence, only 42 (38%) included recommended validated questionnaires as an outcome measure. Of these, 16 were undertaken in Europe, 13 in the North America, three in Australia, two each in New Zealand and Canada, and one each in Japan and China. One study did not state country and the remaining three were multinational. Thirteen involved bladder training, lifestyle counselling or physical therapies such as pelvic floor exercises, 17 involved drug therapies, four minimally invasive therapies such as magnetic stimulation or vaginal cones, five compared surgical procedures, two compared nerve stimulation with drug therapies and one compared oestrogen therapy, behavioural intervention and surgery. Eighteen trials included more than 200 patients (two of which included more than 1000) but 13 fewer than 100. Only 34 (32%) trials were considered to reach the highest level of rigour ('1' in the table), in that they described the methods of randomisation, blinding, power and statistical techniques clearly and appropriately. Many trials did not describe methods sufficiently well enough to determine quality. Those marked '2' in the table had clear flaws, suggesting their findings should be interpreted with caution. For trials marked 'NS' in the table, a clear grading of quality was not possible on the information provided. The trials covered a wide range of types of incontinence.

In total, 52 (48%) trials used validated and recommended questionnaires. 22 (65%) of the highest quality trials employed recommended questionnaires. Sixteen trials employed the IIQ, 12 the KHQ, 11 the I-QOL, nine the SF-36, six the UDI, five some sort of VAS, two each the BFLUTS and EuroQol/EQ-5D and one the SSI. Twenty-four trials also employed a frequency-volume diary.

Of those that did not employ recommended validated questionnaires, the outcome measure typically used was the frequency-volume diary (36 trials). Fourteen employed an unspecified questionnaire, thirteen a subjective rating scale, nine some sort of VAS, four the Stamey Continence Grading Score, two each the Social Activity Index (SAI) and SEAPI QMM, one each the Hopkins Symptoms Checklist, Contilife

QoL questionnaire, Urinary Incontinence Questionnaire, Leicester Urinary Symptoms Questionnaire, PRAFAB score, Beck Depression Inventory, Postoperative Incontinence Questionnaire, Der Inkontinenz-Fragebogen. One trial used the authors' own questionnaire and in one trial the type of outcome measure used was not clear.

Of the six trials assessing anal incontinence, two were undertaken in Australia and one each in New Zealand, the UK, the USA and Singapore. Three trials involved conservative management, biofeedback or other physical therapies such as sphincter or pelvic floor exercises, two compared surgical procedures and one involved drug therapies. Three trials included more than 100 patients but three had fewer than 50. 31 trials were considered to reach the highest level of rigour. One trial each employed a stool diary, the Cleveland Clinic Continence Score. One trial employed the St. Mark's and Pescatori faecal incontinence scores, the Direct Questioning of Objectives questionnaire and a VAS. Three trials employed an unspecified questionnaire, although one each of these also employed the Hospital Anxiety and Depression Scale (HADS) and a VAS.

These findings suggest that while it is encouraging that the use of validated questionnaires is increasing, and is associated with the employment of higher quality RCT methods, too many randomised trials still do not employ them. As these trials are evaluating the impact of treatments that aim to affect symptoms or quality of life of people with incontinence, the use of such measures should be mandatory. Without the use of valid self-completion questionnaires, the evidence from such trials should not be relied upon.

III. OBSERVATIONAL STUDIES

In the previous ICI report, 28 observational studies were identified, 10 prospective with contemporary controls, two prospective with historical controls, and 16 without controls. The majority (16) had the lowest research quality rating. The questionnaires used reflected the pattern for trials between 1998 and 2001, with the majority including the IIQ (11 studies), six the UDI, five the SF-36, and one study each employing the BFLUTS, EuroQol, I-QOL, SIP, SII, and Beck Depression Inventory. One study used patient interviews, and four assessed incontinence using their own unvalidated measure.

Searching over the period 2001 to mid 2004 for use of those questionnaires recommended by committee in their last report identified 52 observational studies, 9 of which used a retrospective design (see **Table 11**). The majority of studies did not include controls. As these studies were not randomised, they scored poorly in terms of research quality. Most studies were small – 26 relied upon less than 100 patients. The studies spanned the various treatments – surgery, drugs, devices and conservative/physical therapies, and included the range of types of incontinence. The questionnaires used reflected the pattern for trials, with the majority including the IIQ (16 studies), 13 the UDI, 13 the SF-36 or SF-12, 7 the KHQ, 7 the I-QOL, and one study each employing the BFLUTS, SEAPI-QMM, UISS or NHP. Six studies did not use a recommended questionnaire but developed one specifically for the study.

Table 10. Randomised trials for urinary incontinence using validated questionnaires

Reference	Country	Inc. type	n	RCT	QoL measure	Result	Level evidence
Adamiak [268]	Poland	Stress	103	TVT with local anaesthesia v. TVT with spinal anaesthesia	Three-degree subjective scale: complete cure, improvement or failure	No difference	2
Aksac [269]	Turkey	Stress	50	Pelvic floor muscle exercises (PFM) via digital palpation v. PFM via biofeedback v. control	SAI, VAS	Both treatment groups significantly improved, though biofeedback revealed better PFM strength results	2
Alewijnse [270]	Netherlands	Stress, mixed & urge	129	Pelvic floor muscle exercise (PFME) therapy with one of three health education program versions v. PFME alone (control)	PRAFAB, I-QOL, IIQ-7, diary	No difference	2
Anders [271]	UK	Stress	60	Contigen v. macroplastique	KHQ	No difference	2
Andersen [272]	USA	Stress	52	Durasphere v. contigen	Stamey Continence Grading	Durasphere best	2
Appell [273]	USA	OAB (urge)	854	Tolterodine v. placebo (open label extension)	6-point rating scale, diary	Significantly improved tolterodine group	1
Appell [274]	USA	OAB (urge)	378	Tolterodine v. oxybutynin	Diary	Both significantly improved, but oxybutynin significantly more effective	2
Appell [275]	USA	Non-urge	50	Oxybutynin v. placebo	Diary	Significantly improved intervention group	2
Arunkalaivanan [276]	UK	Stress	142	Porcine dermal sling v. TVT	Own ‘urinary symptoms questionnaire’	No difference	2
Arvonen [277]	Sweden	Stress	37	Pelvic floor muscle training with vaginal balls v. pelvic floor muscle training alone	Subjective improvement scale	Vaginal ball group best	2
Barber [278]	USA	Any urinary	343	Estrogen v. behavioural v. surgical therapy	UDI, IIQ, sexual function questionnaire	No overall improvement in sexual function	2

Table 10. Randomised trials for urinary incontinence using validated questionnaires

Reference	Country	Inc. type	n	RCT	QoL measure	Result	Level evidence
Berghmans [279]	Germany	Urge	83	Lower urinary tract exercises (LUTE) v. office- and home-based functional electrostimulation (FES) v. office-based FES plus LUTE v. no treatment	I-QOL	Significantly improved FES and FES plus LUTE groups	2
Bidmead [280]	UK	Stress	170	Pelvic floor muscle exercises (PFME) v. PFME plus electrical stimulator v. PFME plus dummy stimulator	Standardised symptom and quality of life questionnaire	No difference	2
Bliss [281]	USA	Anal	39	Psyllium v. gum arabic v. placebo	Stool diary	Significantly improved intervention group	2
Borrie et al[282]	USA	Any urinary	421	Behavioural and lifestyle counselling v. control	IIQ, YIPS, diary	Significantly improved intervention group	1
Bryant [283]	Australia	Any urinary	95	Caffeine reduction education v. existing caffeine intake (control)	Diary	Non-significant trend for improvement in intervention group	2
Bump et al[38]	USA	Mixed and stress	553	Duloxetine v. placebo	I-QOL, PGI-S, diary	Significant improvement intervention group	NS
Burgio et al[284]	USA	Urge	222	Biofeedback-assisted behavioural training v. behavioural training without biofeedback	IIQ, SCL-90-R, SF-36, diary	No difference	NS
Burgio [285]	USA	Urge	197	Biofeedback v. oxybutynin v. placebo	Hopkins Symptom Checklist (psychological distress)	Biofeedback best	NS
But [286]	Slovenia	Any urinary	55	Functional magnetic stimulation v. placebo	Diary	Greater improvement intervention group	2
Cardozo [287]	UK	Urge	110	Oestradiol v. placebo	Diary, unspecified questionnaire	No improvement incontinence symptoms	NS
Ceresoli [288]	Italy	Post-prostatectomy	70	Daily transcutaneous electrical nerve stimulation (DTENS) plus pelvic floor muscle training (PFMT) v. PFMT alone	VAS of improvement	Combined therapy best	NS

Table 10. Randomised trials for urinary incontinence using validated questionnaires

Reference	Country	Inc. type	n	RCT	QoL measure	Result	Level evidence
Chapple [289]	UK and Europe	OAB	225	Solifenacin v. tolterodine v. placebo	Contilife QoL questionnaire, diary	Significantly improved intervention group	NS
Chapple [290]	UK	Urge	225	YM905 (4 doses) v. tolterodine v. placebo	Diary	No significant improvement incontinence symptoms over placebo	NS
Cheon [291]	Hong Kong	Stress	90	Laparoscopic v. open colposuspension	VAS, unspecified questionnaire	No difference	NS
Corcos J, et al.[292]	Canada	Stress	133	collagen injection vs surgery (Burch, sling or transvaginal bladder neck susupension)	SF-36, IIQ	no statistical difference in 7 out of 8 domains on SF-36 nor on the IIQ	1
Davila [293]	USA	Urge	76	Transdermal v. oral oxybutynin	VAS of efficacy, diary	No difference	1
Demain [294]		Stress, urge, mixed	44	Group educational physiotherapy sessions v. individual physiotherapy	IIQ, SSI, VAS, diary	Significant improvement intervention group. Group better for self-rated symptoms (no significant difference)	2
Diokno [295]	USA	OAB	790	Oxybutynin v. tolterodine	Diary	No difference	1
Dmochowski et al [100]	USA	Urge & mixed	361	Tolterodine v. oxybutynin v. placebo	IIQ, UDI, diary	Both treatment groups significantly improved, comparably effective	1
Dmochowski et al [296]	USA	Stress	683	Duloxetine v. placebo	I-QOL, PGI-I, PGI-S, BDI-II, diary	Significantly improved duloxetine group	1
Dmochowski et al[297]	USA	Urge & mixed	520	Oxybutynin v. placebo	IIQ, diary	Significantly improved oxybutynin group	1
Dmochowski et al[297]	USA	OAB (urge)	361	Tolterodine v. oxybutynin v. placebo	IIQ, diary	Significant improvement intervention groups, no difference	1
Dmochowski [298]	USA	Stress	40	Coaptite implant v. bovine collagen	Stamey Score	Significant improvement intervention groups	NS

Table 10. Randomised trials for urinary incontinence using validated questionnaires

Reference	Country	Inc. type	n	RCT	QoL measure	Result	Level evidence
Dmochowski [299]	USA	Stress	210	Uryx urethral bulking agent v. Contigen collagen implant	Stamey Score	No difference	NS
Dougherty [300]	USA	Any urinary	178	Behavioural management v. control	IIQ, severity rating on ladder scale, diary	Significantly improved intervention group	NS
El-Toukhy [301]	UK	Stress	87	Laparoscopic mesh colposuspension v. open Burch colposuspension	Unspecified patient questionnaire, diary	Burch colposuspension best	2
Everaert [302]	Belgium	OAB (urge)	22	2-stage sacral nerve stimulation implant v. 1-stage implant	VAS, diary	No difference	2
Floratos [303]	Greece	Post-prostatectomy	42	Biofeedback v. verbal feedback for pelvic muscle exercises	Unspecified questionnaire	No difference	NS
Freeman [304]	UK	OAB/urge	772	Tolterodine v. placebo	Three-point urgency perception scale, diary	Improved tolterodine group	1
Fujishiro et al [305]	Japan	Urge	37	Magnetic stimulation v. placebo	Unspecified quality of life questionnaire, diary	Significantly improved intervention group	NS
Garely [306]	USA	OAB (urge)	1200	1) Tolterodine 2mg v. tolterodine 4mg and 2) Oxybutynin 5mg v. oxybutynin 10mg	Validated 6-point scale	Validity testing	NS
Garely [307]	USA	Urge	1015	Tolterodine v. placebo	Patient perception evaluations, diary	Significantly improved intervention group	NS
Gilling [308]	New Zealand	Stress	70	Magnetic pelvic floor stimulation v. sham	I-QOL, KHQ, diary	No difference	NS
Goode et al [309]	USA	Stress	200	Behavioural training v. behavioural training plus pelvic floor electrical stimulation (PFES) v. control	IIQ, diary	Significantly improved all groups, no difference	NS
Goode [310]	USA	Urge & mixed	197	Biofeedback-assisted behavioural therapy v. oxybutynin v. placebo	Diary	Significantly improved intervention groups, behavioural therapy best	NS
Grady [311]	USA	Postmenopausal	1525	HRT v. placebo	Unspecified questionnaire	Significantly worsened intervention group	1
Han [312]	Singapore	Stress	50	Burch colposuspension v. TVT	Unspecified	No difference	NS

Table 10. Randomised trials for urinary incontinence using validated questionnaires

Reference	Country	Inc. type	n	RCT	QoL measure	Result	Level evidence
Hay-Smith [313]	New Zealand	Stress	128	Pelvic floor muscle training (PFMT) via motor relearning v. PFMT via strengthening and motor relearning	KHQ, six-point Likert scale (symptoms)	No difference in symptoms	NS
Ho [314]	Singapore	Anal	35	Straight anal anastomosis v. colonic J-pouch anal anastomosis	Bowel function questionnaire	No difference	NS
Homma et al [315]	Japan	OAB (urge)	608	Tolterodine v. oxybutynin v. placebo	KHQ, diary	Tolterodine and oxybutynin have similar efficacy but tolterodine is better tolerated	1
Ishiko [144]	Japan	Postmenopausal stress	66	HRT plus pelvic floor muscle exercise (PFME) v. PFME alone	Der-Inkontinenz-Fragebogen	Combination therapy best	2
Jeyaseelan [316]	UK	Stress	16	Electrical pelvic floor muscle stimulation v. standard pelvic floor exercises v. both combined	IIQ, UDI, diary	Preliminary data indicate combined best	2
Kelleher [317]	UK (Europe, USA, Australia/New Zealand, Russian Federation/Ukraine)	Urge	1015	Tolterodine v. placebo	KHQ, SF-36	Significantly improved tolterodine group	1
Khullar [318]	UK	Mixed	854	Tolterodine v. placebo	KHQ, diary	Significantly improved intervention group	1
Kim [319]	Korea	Stress	48	Continence Efficacy Intervention Program (CEIP) v. control	Unspecified questionnaire, improvement score	CEIP best	2
Kuo [320]	China	Stress	50	Pubovaginal sling using rectus fascia v. mesh	Diary	No difference	2
Landis [321]	USA	OAB (urge)	986	Tolterodine v. placebo	Diary	Significantly improved tolterodine group, greater improvements in those with more severe symptoms	1

Table 10. Randomised trials for urinary incontinence using validated questionnaires

Reference	Country	Inc. type	n	RCT	QoL measure	Result	Level evidence
Laycock [322]	UK, Australia, New Zealand, Ireland	Stress	101	Vaginal cones v. biofeedback v. placebo	KHQ, VAS, diary	Significantly improved intervention groups: no difference	1
Lee [323]	Korea	OAB	228	Tolterodine v. oxybutynin	Diary, binomial scale for perception of treatment benefit	Tolterodine equally or more effective than oxybutynin, with significantly better tolerability	1
Lee [324]	Canada	Stress	68	Periurethral fat injection v. placebo	Urinary Incontinence Questionnaire	No effect	1
Leung [325]	Hong Kong	OAB (urge)	106	Tolterodine v. oxybutynin	VAS, diary	Tolterodine significantly better	1
Lightner [326]	USA	Stress	355	Durasphere bulking agent v. bovine collagen	Stamey continence grade	No difference	NS
Maher [327]	Australia	Stress	45	Pubovaginal sling v. transurethral macroplastique	UDI, IIQ, SF-36	Pubovaginal sling best	NS
Malone-Lee [328]	UK	OAB (urge)	308	Tolterodine v. placebo	KHQ, diary	Significantly improved intervention group	1
Malone-Lee [329]	UK	OAB (urge)	378	Tolterodine v. oxybutynin	6-point rating scale, diary	No difference but tolterodine is better tolerated	1
Manca [330]	UK	Stress	344	TVT v. open Burch colposuspension	EQ-5D (QALYs)	TVT less costly and more cost-effective	1
Mattiasson [331]	Sweden	OAB (urge)	505	Tolterodine plus simplified bladder training (BT) with tolterodine alone	Diary, 6-point rating scale	No difference	1
Millard RJ, et al.[332]	Australia	stress	458	Duloxetine vs placebo	I-QOL	Sig improvement in duloxetine group $p<0.007$	1
Miller [333]	UK	Urge	110	Oxybutynin v. placebo	Diary	Improved intervention group	NS
Moore et al [334]	Australia	Stress and/or urge	145	Nurse continence advisors v. urogynecologists conservative management	UDI, IIQ, diary	No difference	NS
Morkved [335]	Norway	Stress	103	Pelvic floor muscle training with biofeedback v. pelvic floor muscle training with biofeedback	5-point scale, Leakage Index, SAI	No difference	2

Table 10. Randomised trials for urinary incontinence using validated questionnaires

Reference	Country	Inc. type	n	RCT	QoL measure	Result	Level evidence
Naglie et al [336]	Canada	Urge	86	Nimodipine v. placebo	Modified IIQ, I-PSS	No effect	NS
Nehra [337]	USA	Post-prostatectomy	33	Extracorporeal Magnetic Innervation (ExMI) pelvic floor therapy v. sham	Unspecified validated quality of life survey and questionnaire, diary	Improved intervention group	NS
Norton et al [338]	USA	Stress	553	Duloxetine v. placebo	PGI-I, I-QOL, diary	Significantly improved intervention group	1
Norton [339]	UK	Anal	171	Hospital biofeedback v. hospital plus home biofeedback v. standard care v. standard care plus sphincter exercises	Symptom questionnaire, continence score, patient's rating of change, SF-36, disease specific QoL, HADS	No difference	NS
Osman [340]	Egypt	Stress	75	Anticholinergic treatment v. Burch/pubovaginal sling	SEAPI QMM	Surgery best	NS
Pages [341]	Germany	Stress	40	Biofeedback v. physical therapy	Standardised questionnaire, diary	Biofeedback best for subjective outcome	2
Palomba [342]	Italy	Stress	20	Estriol treatment before Burch colposuspension v. control	VAS	Significantly subjectively improved intervention group, though not objectively improved	2
Parekh [343]	USA	Post-prostatectomy	38	Biofeedback-enhanced pelvic floor exercise v. control	Postoperative Incontinence Questionnaire	Greater improvement intervention group	2
Park [344]	Korea	OAB (urge)	9	Bladder training v. tolterodine v. both combined	Subjective urgency score, subjective perception of bladder condition, diary	Combined therapy best	2
Pleil [345]	UK	OAB (urge)	1022	Tolterodine v. placebo	KHQ, SF-36, rating of bladder condition	Significantly improved intervention group KHQ. No difference SF-36.	1
Robinson [346]	UK	Stress, urge & mixed	60	Comparison of four sequences of desmopressin and placebo	KHQ, diary	No improvement in QoL	NS
Robinson [347]	Canada	Stress	24	NEAT v. Reliance Insert (urethral devices)	SF-36, leakage assessment questionnaire	Both significantly improved, equally effective	2
Rufford et al [82]	UK	Urge syndrome/ urge incontinence	40	Estrogen (estradiol) implant v. placebo	KHQ, urinary symptom questionnaire, VAS of symptom severity, diary	Urge incontinence significantly subjectively improved estradiol group, though not objectively improved	1

Table 10. Randomised trials for urinary incontinence using validated questionnaires

Reference	Country	Inc. type	n	RCT	QoL measure	Result	Level evidence
Sand [348]	USA	OAB (urge, mixed)	382	Oxybutynin v. tolterodine	Diary	Significantly improved both groups	NS
Shaw [349]	UK	Any urinary	930	Continence Nurse Practitioner (CNP) v. standard care	Leicester Urinary Symptom Questionnaire	Psychometric testing	NS
Smith [350]	USA	OAB (urge)	265	YM905 (four doses) v. placebo	Diary	Significantly improved intervention groups. Incontinence symptoms significantly decreased with YM905 10mg.	NS
Solomon [351]	Australia	Anal	120	Biofeedback with anal manometry v. biofeedback with transanal ultrasound v. pelvic floor exercises with feedback from digital examination	St. Mark's and Pescatori faecal incontinence scores, VAS, Direct Questioning of Objectives QoL measure	No difference	1
Soomro et al [120]	UK	Detrusor instability	43	Transcutaneous electrical nerve stimulation v. oxybutynin	BFLUTS, SF-36, diary	No difference on symptom-specific QoL – both significantly improved, though only oxybutynin group objectively improved	2
Sprujit [352]	Netherlands	Post-menopausal	35	Intravaginal electrical stimulation v. Kegel exercises	PRAFAB score, diary	No significant improvement	NS
Stöhrer [353]	Germany	DOA	131	Propiverine v. oxybutynin	Diary	No difference	NS
Subak [354]	USA	Any urinary	152	Behavioural therapy v. control	Diary	Improvement intervention group	1
Sussman [355]	USA	OAB (urge)	1289	Tolterodine 2 mg v. tolterodine 4 mg and Oxybutynin 5 mg v. oxybutynin 10 mg.	Perception of bladder condition measure	Tolterodine 4mg best	NS
Svihra [356]	Slovakia	OAB (urge)	28	Neuromodulation v. oxybutynin v. control	Behavioural Urge Score (BUS), IPSS, I-QOL	Significantly improved intervention groups	NS
Swift [357]	USA	OAB (urge)	1235	Tolterodine extended-release v. tolterodine twice daily v. placebo	Diary	Tolterodine-extended-release best	1

Table 10. Randomised trials for urinary incontinence using validated questionnaires

Reference	Country	Inc. type	n	RCT	QoL measure	Result	Level evidence
Takahashi [358]	Japan	Urge	48	Magnetic stimulation v. placebo	Diary, unspecified QoL score	Significantly improved intervention group	NS
Theofrastous [359]	USA	Stress, detrusor instability & mixed	134	Pelvic floor muscle training v. bladder training	Diary	No difference	NS
Thyssen [360]	Denmark, Australia, USA	Stress	94	Conveen Continence Guard (CCG) v. Contrelle Continence Tampon (CCT)	Unspecified questionnaire	CCT best	NS
Tibaek S, et al.[99]	Denmark	any	339	PFMT vs control	IIQ	no differrence	1
Tjandra [361]	Australia	Anal	23	Direct end-to-end repair v. overlapping sphincter repair	CCCS	No difference	NS
Tsai [362]	Taiwan (China)	Any urinary	98	Verbal pelvic floor muscle training (PFMT) v. biofeedback-assisted PFMT	Diary	Biofeedback-assisted PFMT best	NS
Valpas [363]	Finland	Stress	128	TVT v. laparoscopic colposuspension	KHQ, Urinary Incontinence Severity Score (UISS), Urge Score (US), VAS	No difference	1
van Kerrebroeck [364]	USA	Any urinary	89	Sacral nerve stimulation therapy v. standard care	Beck Depression Inventory (BDI)	Significantly improved intervention group	NS
van Kerrebroeck [365]	Europe and Canada	Stress	494	Duloxetine v. placebo	I-QOL, diary	Symptoms significantly objectively and subjectively improved duloxetine group	1
Viseshsindh [366]	Thailand	Stress	26	Pubovaginal sling v. vaginal wall sling	SEAPI-QMM	No difference	NS
Ward [367]	UK	Stress	344	TVT v. colposuspension	BFLUTS, EQ-5D, SF-36, diary	No difference	1
Wille [368]	Germany	Post-prostatectomy	139	Pelvic muscle exercises (PMEs) v. PMEs plus electrical stimulation (ES) v. PMEs plus ES plus biofeedback (BFB)	Unspecified questionnaire	No significant difference	2
Wilson [369]	New Zealand	Postnatal urinary and anal	747	Conservative management v. standard care	Unspecified questionnaire, VAS	No difference	NS
Wong [370]	China	Stress	38	Pelvic floor muscle exercises (PFME) with biofeedback v. PFME alone	IIQ-7, UDI-6, diary	Both groups significantly improved - no differences between groups with exception of subjective measures	NS

Table 10. Randomised trials for urinary incontinence using validated questionnaires

Reference	Country	Inc. type	n	RCT	QoL measure	Result	Level evidence
Yoon [371]	Korea	Any urinary	50	Bladder training v. pelvic muscle exercises v. control	Diary	Improved pelvic muscle exercises group only	NS
Zinner [372]	USA	Stress	683	Duloxetine v. placebo	PGI-I, I-QOL, 22-item validated condition-specific questionnaire, diary	Significantly improved intervention group	NS
Zinner [373]	USA	OAB (urge)	1015	Tolterodine v. placebo	Six-point rating scale of severity, three-point rating scale of urgency, three-point rating scale of global evaluation of treatment	Significantly improved intervention group	1
Zullo [374]	Italy	Stress	60	Laparoscopic retropubic urethropexy using sutures v. Laparoscopic retropubic urethropexy using mesh	VAS	Suture group best objectively, though not subjectively	NS

Table 11. Observational studies for urinary and faecal incontinence

Ref	Country	Incontinence type	n	Design	Treatment	QoL measure	Results	Level of evidence
Almeida [375]	Brazil	Urinary	91	Pro	Perineal magnetic stimulation	I-QOL, diary	Significant improvement	2
Amundsen CL, et al.[376]	USA	urge	25	Pro	Sacral neuromodulation	IIQ	significant improvement of QOL	2
Avery JC, et al.[377]	Australia	Stress, urge	3,010	Pro		SF-36	Significant impairment across all dimensions	2
Barber MD et al [106]	USA	Incontinence	100	Pro	Questionnaire development	PFDI and PFIQ	N/a	2
Bent [378]	USA	ISD	32	Pro	Collagen bulking	UDI-6, IIQ-7, diary	Significant improvement	2
Bidmead [379]	UK	Stress	83	Pro	Burch colposuspension	KHQ	Improvement	2
Bump RC, et al.[38]	USA	urge	171	Pro		I-QOL	More impairment for mixed incontinence	2
Cappellano F, et al. [39]	Italy	urge	113 (82 women)	Pro	Sacral neuromodulation	own	Significant improvement in QOL	2
Chiaffarino F, et al.[380]	Italy	stress, urge, mixed	1062	Pro		SF-12	QOL significantly impaired with UI or OAB	2
Van der Vaart et al [95]	Netherlands	stress, urge, mixed	1393	Cross sectional		UDI, IIQ	Urge incontinence and OAB reduced QOL; stress incontinence not	2
Diokno A, et al. [381]	USA	Urge, OAB	1067 (904 women)	Pro	Oxybutynin (extended release)	IIQ, Sleep Impact Questionnaire	Significant improvements in all QOL measures,	2
Dolan LM, et al. [382]	UK	any	492	Pro		KHQ	Impact on QoL antenatally (54.3%) and postnatally (71.1%)	2
Drahoradova et al [383]	Prague	Stress	64	Pro	Surgery	I-QOL	Significant improvement	2
Fitzgerald et al [53]	USA	Stress	55	Retro (validation study)	Surgery	UDI-6, IIQ-7	Improvement	3

Table 11. Observational studies for urinary and faecal incontinence

Ref	Country	Incontinence type	n	Design	Treatment	QoL measure	Results	Level of evidence
Gonzalez-Argente FX, et al [384]	USA	stress, urge, mixed	240	Pro	Surgery for FI or prolapse	IIQ	IIQ scores higher than controls	2
Hagen et al [86]	UK	Stress, urge, mixed	158	Pro (validation study)	Physiotherapy and behavioural therapy and surgery	UDI, IIQ, HADS, SF-36, diary	Improvement	2
Hagglund D, et al.[385]	Sweden	stress, urge	787	Pro		SF-36	Significantly lower scores on all domains	2
Ho-Yin PL, et al.[200]	China	stress, urge	170	Pro		SF-36	No difference	2
Kenefick [386]	UK	Anal	15	Pro	Nerve stimulation	SF-36, diary	Improvement	2
Kinchen KS, et al.[387]	USA	stress, urge, mixed	1970	Pro		I-QOL	Duration of symptoms, lower score on I-QOL affected healthcare use.	2
Kulseng-Hanssen [388]	Norway	Stress	111	Retro	Burch colposuspension	BFLUTS	Leakage of varying frequency, amount and bother	3
Kulseng-Hanssen S [111]	Norway	stress, mixed	883	Retro	Surgery (TVT, Burch)	own	QOL significantly improved	3
Lalos O, et al. [389]	Sweden	stress	45	Retro	Surgery (retropubic urethrocystopexy, pupbccocygeal repair)	own	No impediment in social activities	3
Liberman JN, et al.[390]	USA	urge, OAB	483	Pro		SF-36	Those with OAB had significantly lower scores	2
Lin SY, , et al.[391]	Taiwan	not specified	106			IIQ	High incontinence impact and symptom distress more likely to seek treatment	2
Matzel [392]	Germany	Anal	37	Pro	Sacral nerve stimulation	SF-36, diary	Significant improvement	2
Melville JL, et al.[393]	USA	not specified	153	Pro		SF-12, I-QOL	High correlation between patient report and physician assessment	2
Melville JL, et al.[394]	USA	stress, urge , mixed	218	Pro		I-QOL, UDI-6	Depression and panic disorder common in UI	2

Table 11. Observational studies for urinary and faecal incontinence

Ref	Country	Incontinence type	n	Design	Treatment	QoL measure	Results	Level of evidence
Mukherjee K, et al.[395]	UK	stress	242	Pro	Surgery (TVT sling)	KHQ	highly significant improvement in QOL (p<0.001)	2
Nager CW, , et al.[47]	UK	stress, mixed	52	Pro		SEAPI QMM	Moderate correlation with pad test	2
O'Connor [396]	USA	Stress	5	Retro	AUS	UDI, IIQ	Significant improvement	3
Pang et al[91]	China	Stress	45	Retro	TVT	UDI-6, IIQ-7, GHQ-12, CSQ	Significant improvement	3
Plachta et al[81]	Poland	Stress	160	Retro	TVT v. IVS	KHQ	TVT most beneficial	3
Rezapour M, et al. [397]	Sweden	stress	49	Pro	Surgery (TVT sling)	own	quality of life improvement in more than 90%	2
Richter HE, et al. [398]	USA	stress	57	Retro	Surgery (pubovaginal sling procedure)	telephone interview	88% indicated improved QOL	3
Richter et al[87]	USA	Stress	102	Pro	Sling procedure	UDI-6, IIQ-7, patient satisfaction questionnaire	Beneficial effect	2
Ripetti [399]	Italy	Anal, urinary	21	Pro	Nerve modulation	SF-36	Significant improvement	2
Robinson JP et al[133]	USA	Incontinence	153	Pro	Questionnaire development	MUDI and MUSIQ	N/a	2
Rodriguez L, et al.[94]	USA	stress, urge, mixed	79	Pro		UDI-6	Physicians underestimated the patient's bother 25% to 37%	2
Simons et al [89]	Australia	Stress, urge, mixed	57	Pro	Urethral device	UDI, IIQ	Significant improvement	2
Skeil [400]	UK	Urinary	34	Pro	Nerve stimulation	SF-36, NHP, diary	Improvement	2
Stach-Lempinen B, et al.[401]	FInland	stress, urge, mixed	82	Pro		UISS	Major depression correlated with reduced qol	2
Stewart WF, et al.[199]	USA	urge, OAB	864	Pro		SF-36, CES-D, MOS sleep scores	Poor sleep	2
Tamanini et al[402]	Brazil	Stress (ISD urodynamically diagnosed)	21	Pro	Macroplastique (Uroplasty)	KHQ	improved in all domains	2
Vandoninck et al[67]	Netherlands	Urge	35	Pro	Nerve stimulation	SF-36, I-QOL	Significant improvement	2

Table 11. Observational studies for urinary and faecal incontinence

Ref	Country	Incontinence type	n	Design	Treatment	QoL measure	Results	Level of evidence
Vassallo et al [90]	USA	Urinary incontinence	162	Pro	TVT	UDI-6, IIQ-7	Significant improvement	2
Vinker S, et al.[403]	Israel	unspecified	148	Pro		own		3
Walsh [404]	USA	Stress	31	Pro	Pubovaginal sling	UDI, IIQ	Significant improvement	2
Wang & Chen [80]	Taiwan	Dysfunctional voiding	79	Retro	TVT	KHQ	Improvement	3
Woodman et al [92]	USA	Urge-predominant	25	Pro	Imipramine	UDI-6, IIQ-7	Significant improvement	2
Yip SK, et al.[78]	China	stress, urge	65	Pro		KHQ	SUI or detrusor overactivity had poorer QOL ($p<0.05$), poorer marital relationship	2
Yu HJ, et al.[98]	Taiwan	stress, urge, mixed	205	Pro		IIQ-7	Women with mixed incontinence had higher IIQ-7 score	2

D. RECOMMENDATIONS FOR CLINICAL PRACTICE

The following recommendations were unanimous:

1. It should be acknowledged that patients are the experts in the experience of their symptoms and quality of life impact, and so clinicians are encouraged to use questionnaires to assess patients' views of their incontinence and its impact on their lives. Clinicians are encouraged to choose a questionnaire from the list of recommended instruments bearing in mind relevance and practicality for the patient group and clinical setting
2. Clinicians are encouraged to audit the impact of using questionnaires on clinical practice and collaborate with researchers investigating the impact of questionnaires on clinical practice, including cost estimates

F. RECOMMENDATIONS FOR RESEARCH

The following recommendations were unanimous:

1. Grade A highly recommended questionnaires should be used in all randomised controlled trials evaluating treatments for incontinence
2. The inclusion of the ICIQ is strongly recommended in all studies to facilitate comparisons
3. Researchers are encouraged to conduct further research in the following areas:
   a) Apply existing Grade A questionnaires to the widest range of patient groups
   b) Complete additional work on Grade A^{new}, Grade B and questionnaires with potential, with particular attention to work on the sensitivity of the questionnaire to clinical change
   c) Develop new questionnaires for specific groups only (e.g. older people, children)
   d) Report accurately and adequately 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
   e) Assess the impact on clinical practice of using questionnaires (preferably in a randomised controlled trial), including estimates of the cost, staff and participant burden and ease of implementation

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