Committee 6

Symptom and Quality of Life Assessment

Chair

J.L. Donovan (U.K.)

Members

X. Badia (Spain),

J. Corcos (Canada),

M. Gotoh (Japan),

C. Kelleher (U.K.),

M. Naughton (USA),

C. Shaw (U.K.)

Consultant

B. Lukacs (France)

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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 report from the First International Consultation 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] This chapter will summarise the major findings from that review, extend these with an up-dated and more systematic review of the literature, and provide more specific recommendations for questionnaires developed for use in clinical practice and research.

In addition, the developmental work for the ICIQ-SF questionnaire, launched at this Second Consultation, is detailed in Appendix I, at the end of this chapter.

Literature searching strategy

A number of different electronic databases were searched, limited to adults over the age of 18 years and human studies including:

Cochrane database of randomised trials for all randomised controlled trials including the word 'incontinence' from 1998 to 2001. 48 trials were identified measuring outcome of incontinence treatments.

MEDLINE and HealthSTAR between January 1990 and October 2000, using the search strategies: "Urinary Incontinence" coupled with either "Prevalence" or "Epidemiology". Additional studies were located by examining the ascending bibliography. More than 800 studies were located.

PubMed using the keywords 'incontinence' and 'quality of life'. This yielded 415 papers in total, with 109 relating to female urinary incontinence and quality of life

MEDLINE, BIDS Embase and PsychInfo databases, with supplementary searching of references lists of articles identified. Searches were carried out using MeSH headings of Urinary Incontinence and Sexual dysfunctions as well as searches on the text words Urin* and Sex* (asterisks represent wild cards). As a check further searches were carried out combining the sexual dysfunctions MeSH headings with the Questionnaires heading.

Medline and PubMed databases from 1998 – May 2001 to update literature related to the psychosocial and quality of life impact of incontinence on daily living, and the use of generic and disease-specific questionnaires to assess incontinence, using the following key words: 'urinary incontinence,' 'quality of life,' and 'psychology' crossed in various combinations. 108 articles dealt specifically with the psychological and quality of life impact of incontinence.

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.

THE MEASUREMENT OF INCONTINENCE AND QUALITY OF LIFE

A. WHY QUESTIONNAIRES ?

Taking a thorough clinical history for patients with incontinence is an important method of assessing symptoms and degree of bothersomeness. A major concern remains, however, that it is unstandardised and probably takes a different form for each clinician and different patient encounters. The first questionnaires were an attempt to standardise the clinical history: the Boyarsky schedule for lower urinary tract symptoms, [2] and the Stamey score for incontinence [3] These instruments have not been tested for validity or reliability, are crude, and require a clinician to mediate and interpret a patient's symptoms. This has been shown to be unreliable and often not representative of the patient's perspective of their condition [4, 5, 6, 7] Clinicians' ratings of patients' quality of life in general tend to be lower than those given by patients themselves [7]. It is likely, with a socially embarrassing condition such as incontinence, that patients will find it difficult to describe their symptoms and difficulties fully to a clinician. The use of clinician-based measures of symptoms and quality of life is not recommended in research.

Voiding diaries (also known as frequency-volume charts or urinary diaries) are widely used to assess a limited number of lower urinary tract symptoms, usually frequency, nocturia and incontinent episodes. Patients are typically asked to complete these daily, recording frequency of urination day and night, incontinent episodes and sometimes also volume voided. They have been shown to exhibit reasonable test-retest reliability, particularly for incontinent episodes [8], but not to be able to differentiate patients with urodynamic diagnoses [9]. While voiding diaries can be helpful and may be accurate if completed regularly, they rely on recall of episodes which can be unreliable [10]. In the area of incontinence, they are also limited by the range of symptoms that can be accommodated - usually frequency, nocturia and incontinence episodes only.

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).

B. 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 in the public domain, many of which are listed in reference books, [11] [12] including some for questionnaires recommended for use in incontinence [1]. It is important to bear in mind the purpose for which any questionnaire was originally designed – the questions included will reflect the original aims. If the questionnaire is to be used in other contexts, further validation may be required.

If designed and tested thoroughly, questionnaires can have levels of precision which equal or exceed clinical measures. Of particular importance are the precision and accuracy of measures - more commonly referred to as psychometric properties.

I. PSYCHOMETRIC PROPERTIES

Empirical evidence is required to show that a questionnaire is measuring what is intended, measures this is a reproducible fashion, and is sensitive to changes over time or following interventions. These aspects are known as validity, reliability and responsiveness:

1. VALIDITY

The validity of a questionnaire is simply whether it measures what is intended, and has three major aspects:

a) Content/face validity

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 [13]. In particular, it is important that questions are understandable and unambiguous to the patient and that they are clini-

cally sensible. Once the questionnaire has been developed and administered, levels of missing data can be used as an indicator of misunderstood questions.

b) Construct validity

Construct validity relates to the relationships between the questionnaire and underlying theories. This is very much an ongoing procedure which requires a number of studies of the performance of a questionnaire in a range of settings and patient groups. Each one of these studies will examine some aspect of the validity of particular constructs or 'mini-theories.' [13] A common method of obtaining some indication of the construct validity of a questionnaire is to examine its ability to differentiate between patient groups - for example clinic attenders compared with individuals in the community, or clinic attenders with a particular diagnosis compared with those with another. Construct validity also includes the concepts of 'convergent' and 'discriminant' validity. Convergent validity involves seeing how closely a new questionnaire is related to other measures of the same construct. Discriminant validity relates to the absence of relationships between constructs that are postulated to be independent.

c) Criterion validity

Criterion validity describes how well the questionnaire correlates with a 'gold standard' measure that already exists. Such 'gold standards' may be clinical or other validated measures. While it is acknowledged that urodynamic studies represent the most accurate representation of leakage and a clinical diagnosis of incontinence, these factors are not the only ones that one would want to be reflected by a questionnaire. Questionnaires are primarily designed to measure patients' perspectives of their condition, and so the diagnosis of incontinence may be less important than the way in which urinary leakage is perceived by patients and the impact it has on their quality of life. For incontinence there is no clear gold standard but new questionnaires should be compared with existing measures using the methods suggested for construct validity.

2. Reliability

The reliability of a questionnaire refers to its ability to measure in a reproducible fashion [13]. This appears to be a simple concept, but involves the assessment of two main aspects:

a) Internal consistency

Internal consistency refers to the extent to which items within the questionnaire are related to each other. It can be assessed by statistical techniques such as item-total correlations or Cronbach's alpha coefficient [13]. If item-total correlations are used, each item should be correlated with the total score omitting that item, and items with a correlation of less than 0.2 should be eliminated or rewritten [13]. Cronbach's alpha coefficient should be calculated for the total score eliminating one item at a time, and any items which significantly increase or decrease the alpha should be re-evaluated. A Cronbach's alpha in excess of 0.70 is usually considered to show adequate internal consistency [14].

b) Reproducibility

This assesses the variability between and within observers (inter- and intra-rater reliability) for questionnaires administered by an interviewer, usually using analysis of variance (ANOVA) [13].

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. A questionnaire which cannot demonstrate that responses are stable over a short period of time in a pre-treatment sample will not be able to measure change following treatment. 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. For incontinence, two weeks is probably sufficient. Test-retest reliability can be assessed by the correlation between scores obtained from the two time periods. When items have more than two ratings, it is suggested that intraclass correlation coefficients are preferred [15]. These methods obscure variation from individual questions, however, and so a graphical presentation and analyses of paired differences in individual items can be helpful [16].

3. Responsiveness

There are three main aspects to the measurement of change: differentiating between those who change a lot and those who change little, the identification of factors which are associated with a good outcome, and inferring treatment effects from group differences in clinical trials [13]. Where a questionnaire results in 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 or repeated measures analysis of variance [13]. Effect sizes are also commonly used. Interpreting effect sizes can be difficult, but it is suggested that 0.3 represents a small effect, 0.6 a moderate effect and 0.8 a large effect [17, 18, 19, 20]. Outside randomised controlled trials, where there may be baseline differences between treatment groups, analyses of covariance may be more appropriate. It is important to consider the thorny question of how to interpret changes. Changes may be found to be statistically significant, but this does not necessarily mean that they are of clinical significance [21].

II. METHODS OF SCORING

Questionnaires can be scored in a variety of ways,

depending on the design of the questionnaire and its particular aim. Each method will result in different patterns of scores, and so caution in interpretation should always be exercised.

- Simple additive scores where questions have high levels of internal consistency (i.e. Cronbach's alpha in excess of 0.70, preferably in excess of 0.80. More complicated questionnaires, particularly those assessing quality of life, are often constructed as profiles. Profiles contain a number of domains, each of which has its own score. Problems with such scores include that any single score may be achieved by a wide range of component scores and may give a spurious mathematical precision to scores.
- Muliplicatory scores. Here, scores from one type of question are multiplied by scores from another and then added together to reach a total score. Small changes in the aspect multiplied can have a considerable impact on the total score.
- Weighted scores. Values are assigned to items, for example by clinicians indicating that they believe that certain symptoms are more significant or severe than others. It is often difficult to justify the weights derived, and small changes in such weights can have a significant impact on scores.
- No scores assigned. In some cases, questionnaire designers advise that total or subscale scores are not developed. Questionnaires without scores can be used for descriptive purposes, for example in indicating prevalences of particular symptoms and may be useful in identifying the impact of individual items on aspects of quality of life and outcome, but the analysis may be complex.

III. INTERNATIONAL IMPLEMENTATION

Increasingly, questionnaires are required to be used in a number of different populations and settings, but psychometric properties are not necessarily transferable between populations or settings. 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. [22] [23].Guillemin et al have suggested a number of steps that should be taken to ensure that questionnaires may be used by different cultural groups: [24] .

a. Translation of the questionnaire

b. Back translation into the original language

C. Committee review of translations

d. Pre-testing for equivalence using bilinguals or monolinguals

e. Re-examination of weighting of scores

There are other more recent recommendations for adapting quality of life instruments, for example, at http://www.euroqol.org and by Herdman et al [25] .

Researchers who seek to translate measures for use in different languages or cultures should be advised that this can be a lengthy and complicated procedure. Whenever possible, it is advisable to use existing translated measures. Details can often be obtained from the developers of specific questionnaires.

IV. 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. The majority of questionnaires so far designed in this field have a tendency to be quite long and comprehensive. There are indications, however, that shorter forms are increasingly being developed. In clinical practice (and sometimes in research), it is important for a measure to have clinical relevance, but also to be as simple and brief as possible – as, for example, with the severity index [26] and the ICIQ-SF (see below). Ultimately, the most important issue is that the most appropriate questionnaire should be used for the particular purpose intended.

V. RELATIONSHIPS BETWEEN QUESTIONNAIRES AND CLINICAL MEASURES

The relationship between urinary symptoms, the results of urodynamic investigations and quality of life impairment is complex. Each has an important role to play in the assessment of patients with urinary incontinence, and it is tempting to speculate that each would be related, in a direct and meaningful way. Quality of life assessment has become the recognised way to assess the impact of urinary symptoms on patients lives. Measuring the nature of symptoms is increasingly important if we are to accept symptom based definitions for conditions such as overactive bladder (OAB) [27] .

On the whole, few and weak relationships have been found between the presence of lower urinary tract symptoms (including incontinence) and clinical measures such as urodynamics. This has been investigated amongst men with lower urinary tract symptoms and/or bladder outlet obstruction, where urinary flow rates, residual urine volumes and pressure-flow measures

have been found to have very little relationship with lower urinary tract symptoms [28] [29] [30] [31] [32] [33]. The relationships between LUTS and uroflow variables have been shown to be poor [34].

Among women, the picture appears more complex. Although there is a move towards symptom based diagnoses and conservative treatments, research has shown that urinary symptoms alone inaccurately reflect the cause of lower urinary tract dysfunction. Jarvis et al, for example, compared the results of clinical and urodynamic diagnosis for 100 women referred for investigation of lower urinary tract disorders [35]. There was agreement in 68% of cases of genuine stress incontinence, but only 51% of cases of detrusor instability. The study found that although nearly all of the women with genuine stress incontinence complained of symptoms of stress incontinence, 46% also complained of urgency; and of the women with detrusor instability, 26% also had symptoms of stress incontinence [35].

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 [36]. 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% [37]. 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% [38]. 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 [39]. 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 [39].

Several studies have demonstrated that where stress incontinence is the only symptom reported, then genuine stress incontinence is likely to be present in over 90% of cases [40] [41]. Unfortunately, few patients present with symptoms of stress incontinence alone [42]. Individuals with diagnoses by urodynamics cannot be differentiated by questionnaires [43], [44].

Although lower urinary tract symptoms are diagnostically disappointing many patients are treated on the basis of their symptoms alone. This is particularly the case when conservative therapies are used for patients without complex pathology and when there are no contraindications to empirical treatment. Approximately 50-100 million women worldwide are thought to suffer from OAB; although many are never investigated or treated. The use of a symptom based diagnosis offers recognition that these patients have a medical condition worthy of consideration and initial treatment, without necessarily the need for complex, expensive, embarrassing and invasive urodynamic investigations.

The severity of urinary symptoms is often used as a measure of the impact of lower urinary tract dysfunction in both clinical practice and clinical trials. At its simplest severity may reflect symptom magnitude, for example the number of incontinent episodes, the number of daily voids, or the number of episodes of nocturia. Measuring the magnitude of symptoms is relatively straight forward but offers little insight into their impact.

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 [45]. Kujansuu et al, demonstrated a low correlation between the physical effort for leakage and the clinical grade of incontinence [46]. Similarly, McCormack found a poor correlation between information on urinary frequency and micturition chart findings and between the measured and subjective bladder capacities [47].

Symptoms alone do not adequately assess the impact of urinary incontinence on an individual's life - this requires the use of symptom or generic/condition-specific questionnaires, although again, relationships between these measures and clinical assessments are relatively weak [48] [49] [50] [51]. Hunskaar et al used the Sickness Impact Profile to evaluate incontinent women with stress or urge incontinence [49]. 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. [49]. 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 [52]. A significantly higher level of emotional impairment and social isolation was found amongst those with urge and mixed incontinence than those with stress incontinence [52].

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 [51]. Norton found a moderate relationship between clinical measures of urinary incontinence and the effect of incontinence on various aspects of daily life [48]. More recently, Kobelt has shown that the severity of symptoms of incontinence as expressed as frequency of voids and leakage correlates well with patient's quality of life and health status, as well as the amount they are willing to pay for a given percentage reduction in their symptoms [53].

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 a multitude of different symptoms. These may change as a result of time and adaptive change, or as a result of treatment. It is accepted that patients with stress incontinence may develop frequency in order to limit stress leakage, and that these symptoms may be more problematic than the stress urinary leakage itself. Urinary symptoms and voiding dysfunction can follow surgery for genuine stress incontinence and voiding dysfunction in addition to distressing antimuscarinic side effects can follow the drug treatment of overactive bladder. Such changes can negatively impact on the overall QoL of patients. In a recent study using the King's Health Questionnaire to assess the outcome of surgery for stress incontinence it was found that two women cured of their stress incontinence had deterioration in their QoL as a result of surgery. One woman had developed the new symptom of pain attributable to the surgical procedure and the other deterioration in her irritative bladder symptoms [54].

The importance of quantifying the multidimensional effects of urinary symptoms in an objective way is incorporated into QoL questionnaires, which address the traditional domains of QoL assessment. This embraces the concept that urinary symptoms affect different people in different ways dependent on many interrelated personal attributes, values and priorities which themselves may change in response to life circumstances and experience.

In incontinence research, perhaps more so than in other diseases or conditions, morbidity is measured by proxy endpoints that are multidimensional and not always independent, such as the number of micturitions and volume voided. The relationship of these research endpoints to the lives of patients is not well understood. 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. Loss of urinary control is associated with an increased incidence of urinary tract infections, skin infections, falls and fractures as associated co-morbidities [55].

Thus, overall, there is only a weak relationship between symptomatic, QoL and objective urodynamic assessment of patients with lower urinary tract symptoms. Filling symptoms may have the greatest impact on patients, although the type, severity or number of symptoms, or the results of urodynamic investigations cannot predict the level of impairment. Few studies have, however, used validated instruments to assess the relationships between lower urinary tract symptoms, objective investigations and impairment in quality of life. 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.

VI. 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 [56]. 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. While there are many questionnaires available for assessing incontinence and its impact on quality of life, there is not a simple robust measure that is relevant to as wide a range of patients as possible. At the first consultation, it was decided that this committee would be charged with developing a new modular questionnaire incorporating sections on all major aspects of incontinence and its impact on quality of life for use as widely as possible in research (the modular ICIQ), with the production also of a very short measure that could be added to all studies and used in clinical practice (the ICIQ-SF). The work on the modular version is currently ongoing, but considerable progress has been made in devising the short form (see below).

A detailed review of recommended questionnaires was provided in the First Consultation document [1]. In this Second Consultation chapter, the Committee developed standardised grades of recommendation for question-

naires and applied them to evaluate all questionnaires concerned with incontinence. In the sections that follow, the grades of recommendation are explained and the recommended questionnaires are described. Questionnaires which reach the recommended standard of psychometric testing but do not include questions specifically on urinary incontinence but are in areas related to incontinence are listed in Appendix II.

A. GRADES OF RECOMMENDATION FOR QUESTIONNAIRES

Table 1 below explains the basis for the Committee's recommendations. The Committee required evidence published in peer-reviewed journal articles or book chapters to reach its decision about the grade of recommendation. The Committee decided that evidence published in abstracts or posters could be used to indicate a developing questionnaire's potential, but was not sufficiently peer-reviewed to provide the basis for a stronger recommendation.

As the developmental work for the ICIQ-SF has not yet been independently published, this questionnaire currently carries Grade C status, although will reach Grade A when the material is published.

B. QUESTIONNAIRES TO ASSESS SYMPTOMS OF INCONTINENCE

Box 1 lists the questionnaires and grades of recommendation for the assessment of symptoms of incontinence.

Questionnaires to assess symptoms of incontinence, often in the presence of other lower urinary tract symptoms, originally developed separately for men and women. However, increasingly, the questionnaires reaching the highest level of recommendation are being tested for use in both men and women (for example the UDI, King's Health Questionnaire and the ICS*male*/BFLUTS questionnaires. Each of the recommended questionnaires is described below.

Box 1. Questionnaires recommended to assess symptoms of incontinence

GRADE A : HIGHLY RECOMMENDED

Urogenital Distress Inventory 57
UDI-6 50
Urge-UDI 58
King's Health Questionnaire 59
(Women only) **Incontinence Severity Index** 60
(Men only) **DAN-PSS-1** 61
(Men only) **ICS*male*.** 62
(Men only) **ICS*male*SF** 63

GRADE B: RECOMMENDED

Bristol Lower Urinary Tract Symptoms 64
Symptom Severity Index 65

GRADE C: WITH POTENTIAL

Der Inkontinenz-Fragebogen 66
Danish LUTS 67
Post-surgical questionnaire 3
Voiding patterns 68
Incontinence screening questionnaire 69
Post-radical prostatectomy questionnaire 70

Table 1 : Criteria for recommendation of questionnaires

Grade of recommendation	Evidence required
Highly recommended (**Grade A**)	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.
Recommended (**Grade B**)	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).
With potential (**Grade C**)	Published data (including abstracts) indicating that the questionnaire is **valid** or **reliable** or **responsive** to change following standard psychometric testing.

I. UROGENITAL DISTRESS INVENTORY (UDI) [GRADE A]

This questionnaire was developed in the US with women to assess the degree to which symptoms associated with incontinence are troubling [57]. It contains 19 lower urinary tract symptoms [57] It has been shown to have acceptable levels of validity, reliability and responsiveness in a community-dwelling population of women with incontinence [57] and in women over 60 years [71]. Results of a study with a Dutch version of the UDI have been published recently [71]. The UDI is being used increasingly in male patients, although data on its psychometric properties have not yet been reported as fully as they have in female patients.

1. UDI-6 (SHORT FORM) [GRADE A]

A short-form version of the UDI has been produced by regression analysis, with preliminary validation on samples of older adult males and females [50, 73]. 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 [74, 75]. A French language version of the UDI-6 has been reported in the literature [76].

2. U-UDI [GRADE A]

Lubeck, Brown, and colleagues in the U.S. have developed an Urge-Urinary Distress Inventory (U-UDI) to measure the symptoms and distress specific to urge incontinence in women [58, 77]. The UDI was modified by adding and deleting questionnaire items to measure symptoms associated with urge incontinence, based on focus group information [78], expert clinical opinion, and reviews of scientific literature. The final U-UDI contains 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 acitivity, coughing or sneezing, urine leakage not related to urgency or activity, night-time urination, and bedwetting. Participants indicate whether they have experienced these problems, and then rate the 'bothersomeness' of these symptoms on a 4 point scale from 'not at all,' 'slightly,' 'moderately,' and 'greatly.' The items in the questionnaire are averaged to form two scales: one summarising urge symptoms, and an overall score summarising the impact of mixed and urge symptoms. Higher scores indicate a higher degree of bothersomeness.

In two published studies of the U-UDI, the internal consistency reliability of the U-UDI has ranged from Cronbach alpha =.81-.84 for the urge symptoms subscale,[58], [77] and .86 for the overall score [58]. Intraclass correlation coefficients of test-retest reliability has ranged from .59 - .71 [58, 77]. Guyatt's statistics assessing responsiveness to change were reported as –0.84 for participants with a stable number of incontinent episodes, and –1.71 for participants who showed an improvement in their number of incontinent episodes [58]. The scale has demonstrated acceptable convergent and discriminant validity [77]. Further work on this scale is underway.

II. KING'S HEALTH QUESTIONNAIRE [GRADE A]

The KHQ has been shown to have good reliability and validity for both males and females [59, 79, 80, 81]. Significant correlations were found with domains of the Short Form 36 health survey questionnaire. The KHQ has been translated into different language versions by MAPI Research using the IQOLA approach established for the SF-36 translations which takes the cultural aspects of health into consideration [82]. There are eight validated cultural adaptations of the questionnaire available in 26 languages, including German, Spanish, Swedish, Greek, Italian, and Japanese.).

The questionnaire is currently only available from the authors on request via e-mail at ConJK@aol.com or by writing to Professor Linda Cardozo at 8 Devonshire Place, London W1, England. In this way the use of the questionnaire and current studies employing its usage can be monitored.

The King's Health Questionnaire has been used to assess responses to clinical changes in a recent study comparing the effects of 10 weeks of tolterodine or oxybutynin therapy on OAB symptoms in 294 patients over 50 years of age [83]. Patients completed both generic instruments (SF-36 and the Euro-QoL) and the King's Health Questionnaire. Mean scores for the King's Health Questionnaire, corrected for comorbidity, were significantly higher in younger than in older women, with higher scores indicating greater impairment. Less significant effect on quality of life in older women may be a result of adaptive changes made by women over time, or possibly that younger women have more active lifestyles and thus perceive symptoms as more bothersome. Women who received either tolterodine or oxybutynin therapy during the study showed significant improvements from baseline in all domains

other than health perceptions and interpersonal relationships. There were no significant differences in mean scores obtained from the SF-36 or Euro-QoL during the 10 weeks course of treatment; however, when measured with the King's Health Questionnaire, the quality of life improved significantly.

Responsiveness to clinical intervention has also recently been demonstrated in placebo controlled Phase 3 Tolterodine studies for women with overactive bladder [84]. 1529 patients with OAB were included in a randomized, parallel groups, double-blind, multinational study designed to compare the efficacy and safety of two dosage forms of tolterodine with placebo. This is the largest published QoL study of OAB patients.

Treatment comparisons were based on two primary dimensions, Role Limitations and Incontinence Impact selected *a priori* using an intent-to-treat population for whom KHQ translations were available. Multiple comparisons were corrected with Hochberg's procedure [82]. Criteria for a clinically meaningfulness difference was estimated without consideration for treatment group. The tolterodine SR group experienced significant and clinically meaningful improvement in Role Limitations scores compared with the placebo group ($p \leq 0.0002$) which means fewer limitations were imposed on their ability to perform household tasks, perform work, and carry out other normal daily activities. Patients in the tolterodine SR group also experienced significant improvement in Incontinence Impact scores compared with the placebo group ($p \leq 0.0001$), but the difference between the groups failed to meet the meaningful difference criteria.

Patients in the tolterodine SR group experienced statistically significant and clinically meaningful improvements in Severity (coping) Measures compared to placebo which means reductions in behaviours used to cope with OAB, such as wearing pads, monitoring fluid intake, and changing clothes, as well as worrying about an odour or experiencing embarrassment. Patients receiving tolterodine SR also experienced significant improvements in Symptom Severity, Physical Limitations, and Sleep and Energy versus the placebo group ($p \leq 0.006$) that did not exceed the meaningful difference criteria. HRQOL, measured by the KHQ, improved with tolterodine 4 mg SR treatment. Patients in the tolterodine group experienced statistically significant and clinically meaningful improvements in Role Limitations and Severity (coping) Measures and statistically significant improvements in Incontinence Impact, Physical Limitations, Sleep and Energy, and Symptom Severity compared with the placebo group.

The KHQ has also been used to assess the outcome of surgery for the treatment of genuine stress incontinence [85]. Bidmead et al have reported the results of both a subjective and objective follow up of patients with genuine stress incontinence treated by colposuspension. Colposuspension was performed in a standardised fashion and videourodynamic, symptom and quality of life assessment was performed before and between 6 to 12 months after surgery. 83 women completed the study of whom 51 underwent primary surgery and and 26 secondary. There was a broad general agreement between objective urodynamic changes demonstrating continence as a result of surgery and symptom and QoL score improvements. In addition pad usage pre and post operatively followed the general trend towards improved QoL. Interestingly two women had poorer QoL

Figure 1 : Difference in Mean KHQ Change Scores

KHQ	Tolterodine PR vs Placebo	Meaningful difference criteria
Incontinence Impact	-6.75*	-7.91
Role Limitations	-7.36*+	-6.29
Physical Limitations	-6.43*	-7.67
Social Limitations	-2.50	-4.44
Personal Relationships	-1.38	-2.12
Emotions	-2.40	-5.15
Sleep and Energy	-3.85*	-4.91
Severity (coping) Measures	-5.58*+	-4.49
General Health Perception	-0.13	-3.05
Symptom Severity	-1.46*	-1.68

* Statistically significant from placebo using Hochberg procedure with $p<0.05$.

+ Exceeded minimum criteria for meaningful difference.

scores after surgery, although the surgery had cured their stress incontinence. One woman had distressing irritative bladder symptoms and the second pain related to suture placement. On conventional testing both of these women would have been considered a successful surgical cure, although this was not upheld by QoL assessment. A total of 11 women had persistent stress incontinence on urodynamic testing after surgery. These women would normally be considered to have had failed surgery, although examination of their KHQ scores demonstrated a significant improvement in QoL for all women. Thie improvement in QoL compared favourably with the scores of women cured of their stress inbcontinence on urodynamic testing.

Studies are currently underway to develop a weighting system for the symptom subscale of the questionnaire, a QALY derived measure from the questionnaire and establish a clinical meaningfulness interpretation of KHQ scores. Three additional language translations are currently being performed.

III. INCONTINENCE SEVERITY INDEX (ISI) [GRADE A]

This was developed in Norway to provide a simple severity index of female incontinence for use in epidemiological surveys [60] It comprises two questions – how often do you experience urine leakage (four levels), and how much urine do you lose (two levels). The index is calculated by multiplying the two responses together and is categorised into slight, moderate, severe and very severe [86]. The authors advocated its use routinely as a semi-objective and quantitative measure which does not include the woman's subjective perception of her leakage as being a problem or not. The index has good levels of validity, reliability and responsiveness. It was able to distinguish between women with incontinence and those without compared with pad tests, and confirmed a higher rate of prevalence in middle age [60] It has also been shown to have good test-retest reliability and to be sensitive to change following surgery [26]

IV. DAN-PSS-1 [GRADE A]

This questionnaire was designed in Denmark to measure the degree to which men are bothered by urinary symptoms [87] [88]. It has been developed and tested for use with men only. A composite score is achieved by the multiplication of the 'symptom' by the 'bother' score, with a total range of 0 to 108 [87] [88] The questionnaire has shown acceptable levels of validity and reliability, [88] and was shown to be responsive in the assessment of the outcome of TURP and drug therapies [88]

V. ICS*MALE* AND ICSMALESF QUESTIONNAIRES [GRADE A]

The ICS*male* and ICS*male*SF questionnaires have been developed for use with men only (although the BFLUTS questionnaire for women is almost identical). The ICS*male* questionnaire contains 22 questions on 20 urinary symptoms, and, for most questions, the degree of problem that the symptom causes. 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 [62] [89] [90]

Most recently, a scored short-form of the questionnaire has been produced – ICS*male*SF [63] The developmental version of the questionnaire was subjected to a range of statistical tests including factor analysis, Cronbach's alpha and regression models within a randomised trial of treatments for men with LUTS and the questionnaire was reduced to two major 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) [63]. 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, as indicated by the statistical analysis [63]

VI. BRISTOL LOWER URINARY TRACT SYMPTOMS (BFLUTS) [GRADE B]

This questionnaire was developed for use with women only in the UK, 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 [64]. It has shown good levels of validity and reliability, and responsiveness and a scoring scheme are currently under development. The questionnaire has also been used to assess incontinence in both sexes in Austria [91] and is being increasingly used in epidemiological and outcome studies [92] [93] [94] [95] [96] [97] [98].

VII. SYMPTOM SEVERITY INDEX (SSI) [GRADE B]

This short questionnaire was developed in the UK for women only to assess stress incontinence [65] It has shown acceptable levels of validity and reliability, but responsiveness has not been assessed [65]

VIII. DANISH LUTS [GRADE C]

This questionnaire was published from Denmark [67] but the layout and questions suggest that it is based on the ICS*male* and BFLUTS questionnaires [62, 64].

IX. DER INKONTINENZ-FRAGEBOGEN [GRADE C]

The aim of this questionnaire, published in German, is to differentiate between women with stress and urge incontinence (as determined by cystometry), with the intention of avoiding the need for urodynamics in all women [66].

X. POST-SURGICAL QUESTIONNAIRE [GRADE C]

A questionnaire was devised by the authors for patients to report levels of incontinence, other urinary and sexual symptoms, and satisfaction with treatment after bladder neck suspension surgery [3]

XI. VOIDING PATTERNS (DENMARK) [GRADE C]

A questionnaire was designed to assess the prevalence of incontinence and voiding patterns among women aged 29 to 79 years in Denmark but the methods of development and testing were not specified [68].

XII. INCONTINENCE SCREENING QUESTIONNAIRE (AUSTRALIA) [GRADE C]

Gunthrope and colleagues (2000) have completed preliminary validation of a screening questionnaire to assess urinary incontinence in female patients in primary care settings [69]. The resulting 5 item scale was capable of predicting almost 70% of patients who showed objective leakage of urine and misclassified fewer that 15% of these patients.

XIII. POST-RADICAL PROSTATECTOMY QUESTIONNAIRE [GRADE C]

This questionnaire was devised in the US to assess incontinence and other side-effects following radical prostatectomy for prostate cancer [70, 99]. Some preliminary testing for validity has been carried out [70, 100].

C. QUESTIONNAIRES TO ASSESS IMPACT ON QUALITY OF LIFE

The concept 'quality of life' is a complex one. A number of key domains are typically included within it, including physical, psychological and social functioning, pain overall life satisfaction, perception of health status, sometimes supplemented by others including sleep disturbance, neuropsychological functioning, sexual functioning and/or satisfaction, and participation in employment (see [1, 101] for further details). Quality of life measures can be classified into four main categories and recommended questionnaires in each category are reproduced below.

I. GENERIC MEASURES

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 tend, however to be relatively insensitive to conditions such as incontinence.

All questionnaires listed have reached the highest levels of evidence relating to psychometric testing. Those highly recommended are the most commonly used for incontinence.

Box 2. Questionnaires recommended to assess generic health status in persons with incontinence

GRADE A : HIGHLY RECOMMENDED

SF-36 [102]

EuroQol EQ-5D [103]

GRADE B: RECOMMENDED

Whilst the following questionnaires have reached the highest levels of evidence relating to psychometric testing, they have only rarely been used in incontinence:

Sickness Impact Profile [104, 105, 106]

Nottingham Health Profile [107]

Göteborg Quality of Life [108]

1. MEDICAL OUTCOMES STUDY SHORT-FORM: SF-36 [GRADE A]

The MOS Short Form - 36 (SF-36) [102] has been used

for QoL assessment of men and women. When used with men who presented with moderate to severe urinary symptoms, the SF-36 profile was worse than that of the general population [109] [110] Kutner et al. (1994) applied the SF-36 to 352 community-dwelling elderly, of whom 14% (n=47) had urge incontinence and significantly lower scores in each of the subscales [111]. The internal consistency of the scales varied from .78 to .93 [112]. Used as an interview instead of a self-administered scale, the SF-36 has shown an internal consistency of 0.80 or better [113].

Mozes and colleagues (1999) examined the relationship between urinary symptoms and various domains of the SF-36 in 960 men taking into account their co-morbid status [114]. In the entire population, severely bothersome urinary symptoms were related to scores on three SF-36 domains: social functioning, role-emotional, and mental health. In men without co-morbidity, however, urinary symptoms were substantially related to physical functioning and general health perceptions. These findings indicated that the relative weight of the impact of urinary symptoms on quality of life may change by the presence of co-morbidities or other competing factors, such as sociodemographic characteristics.

In a study examining the use of the SF-36 to assess quality of life across six chronic disorders (incontinence, prostate cancer, COPD, AIDS, fibromyalgia, hyperlipidaemia), the measure demonstrated good discriminant and construct validity [115]. The incontinent patients were similar to the COPD and AIDS patients, in having lower physical functioning, role-physical, general health, vitality, and role-emotional domain scores than the patients with other chronic conditions. However, sample sizes within each of the six groups were low (range=n12 to n=213). In pooling the data across the six studies (n-321), the internal consistency of the subscales was very acceptable (alpha=.80 - .97). Good construct validity was also reported with the pooled data, by correlating the SF-36 with the Center for Epidemiologic Studies – Depression Scale, the Hamilton Depression Rating Scale, and several functional status and other psychological scales. These results suggest similarities in the impact of quality of life on daily life across conditions, although the factors that influence the individual domain scores (e.g., age, condition severity) could vary substantially by the type of chronic condition evaluated.

Test-retest reliability has been moderate to high (r = 0.60-0.80) [116]. However, responsiveness has been reported to be poor in several studies [17] [117] [118] and specifically in benign prostatitic hyperplasia (BPH) patients [119], prostate cancer patients, [120] and women with stress urinary incontinence (SUI) [121]. In an unpublished randomised trial comparing surgery and collagen injections in the treatment of stress incontinence, poor responsiveness was found with an effect size ranging from 0.13 to 0.34 for collagen injections and 0.01 to 0.35 for surgery (Corcos, unpublished data). In addition, no significant differences were found between or within groups in a community-based UI intervention for women aged 65 years or older on measured individual domains of the SF-36 [122].

In recent years, the use of the physical (PCS) and mental (MCS) health summary scores for the SF-36 have been used to assess incontinence [123]. In a study of 37,814 women from the Women's Health Australia Project, the adjusted PCS and MCS scores were lower in young (aged 18-23), middle-aged (45-50), and older (aged 70-75) women who reported leaking urine. [124] However, the greatest differences were reported in the MCS scores in the young and middle-aged women, indicating that the quality of life impact was greater among younger versus the oldest age group of women. No information was provided in the article regarding the reliability of the measures, although the adjusted means reported were comparable to the published norms for the PCS and MSC published elsewhere [123] [125].

The SF-36 has been culturally adapted and/or translated into several languages, including German, Spanish and French. A derivative of the SF-36, the MOS Short Form, containing only 12 items, has been found to perform poorly with prostatectomy patients [126].

2. EuroQol/EQ-5D [Grade A]

The EQ-5D questionnaire, developed by the EuroQol group, consists of the EQ-5D self-classifier, the EQ VAS and the EQ SDQ (standard set of socio-demographic questions). Respondents are asked to describe their own health status using self-classifier [127] with 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. Currently there are 31 official versions of EQ-5D, of which 11 are adaptations (e.g. Spanish for Argentina). A further 19 have been completed and are awaiting official ratification by the EuroQol Group's Translation Committee.

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.

EQ-5D is a standardised instrument for use as a measure of health outcomes. EQ-5D is designed for self-completion by respondents and is ideally suited for use in postal 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 heath 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 heath surveys. EQ-5D has been a specially designed to complement other quality of life measures such as the SF-36, NHP, SIP or disease-specific measures. It is one of a handful of measures recommended by the Washington Panel on Cost-Effectivenesss. In the UK, a NHS Task Group has been set up to co-ordinate the testing of EQ-5D as an outcome measure for use by clinicians and managers (www.europol.org).

Construct validity of the EQ-5D in the assessment of urinary incontinence on quality of life was tested in 1997 [53]. 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 another 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 [110].

The EQ-5D was included in an open, prospective multicenter, clinical trial conducted on 75 women with urinary incontinence with overactive bladders in order to determine the effects of trospium chloride on quality of life [128]. The results showed an improvement in quality of life and urodynamic parameters which reflect the EQ-5D sensitivity to change in the assessment of changes in urinary incontinence.

3. Sickness Impact Profile [Grade B]

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 [49]. Overall, the impact of incontinence was highest on sleep and rest, emotional behaviour, social interaction and recreation/past-times [49]. No new reports of the use of the SIP in observational and clinical trials of UI and BPH have been reported since the last review.

4. Nottingham Health Profile [Grade B]

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. [52]. Overall, all women with incontinence were more socially isolated than those in the general population [52]. The use of the NHP to assess incontinence has been minimal in recent years.

5. Göteborg Quality Of Life Instrument (GQL) [Grade B]

This questionnaire was designed in Sweden to assess general levels of health and their impact on well-being [108]. It was constructed originally for men, but has been tested on women. In a study of community based women in Sweden, those with incontinence were found to have significantly lower scores than continent women on four of the subscales: health, sleep, fitness and work satisfaction [129].

6. Generic measures - conclusion

In general, although several of the generic measures have achieved acceptable reliability and validity in individuals with incontinence, no measures have been shown to have sufficient sensitivity to detect changes in condition severity as a result of either treatment or a worsening/improving physical condition. The generic instruments, however, may be useful in comparing across chronic conditions or to describe the general health status of incontinent adults.

II. CONDITION-SPECIFIC MEASURES – BOTHERSOMENESS

Condition-specific measures are designed to assess the impact of incontinence on quality of life. The simplest are those concerned with the particular impact of incontinent symptoms, otherwise known as 'bothersomeness.'

For details of these questionnaires, see above – these are all highly recommended or recommended symptom questionnaires.

Box 3. Questionnaires recommended to assess bothersomeness in persons with incontinence

Grade A: Highly Recommended

DAN-PSS-1 [87]

ICS*male* [62]

Grade B: Recommended

BFLUTS [64]

III. CONDITION-SPECIFIC MEASURES - IMPACT OF INCONTINENCE ON QUALITY OF LIFE

A number of condition-specific measures have been designed to assess the wider impact of incontinence on aspects of everyday quality of life. Most have been developed for either men or women, although a small number are being evaluated for use in both sexes.

Box 4. Questionnaires recommended to assess the impact of incontinence on quality of life

GRADE A: HIGHLY RECOMMENDED

(Men and women) **Quality of life in persons with urinary incontinence (I-QoL).** [130]

(Men and women) **King's Health Questionnaire** [59]

(Women only) **Incontinence Impact Questionnaire (IIQ)** [131]

(Women only) **IIQ-7.** [50]

(Women only) **Urge-IIQ**. [58]

(Men only) **Modified IIQ and IIQ-7.** [132]

GRADE B: RECOMMENDED

(Women only) **Symptom Impact Index (SII)**. [65]

(Men only) **ICS*QoL***. [110]

(Men only) **EORTC metastatic prostate cancer**. [133]

(Men only) **Changes in Urinary Function**.134

(Men only) **Prostate-targeted Health Related Quality of Life**. [120]

(Men only) **Functional Assessment of Cancer – Bladder/ General Scales.** [134] [135]

GRADE C: WITH POTENTIAL

SEAPI QMM.136

Overactive Bladder Symptom and Health-related Quality of life (OAB-q).

(Women only) York Incontinence Perceptions Scale (YIPS). [137]

(Women only) Stress Incontinence Questionnaire (SIQ). [138]

Incontinence Stress Index. [139]

BFLUTS*QoL*. [64]

Psychosocial consequences questionnaire. [140]

Philadelphia Geriatric Center Multilevel Assessment Instrument. [141]

QOL – Synthelabo. [142]

Symptom and psychological status in stress incontinence [143]

Post-radical radiotherapy questionnaire [144]

1. QUALITY OF LIFE IN PERSONS WITH URINARY INCONTINENCE (I-QOL) [GRADE A]

This questionnaire was designed to be used in clinical trials to measure the impact of incontinence on men and women [130]. The questionnaire reaches acceptable levels of validity and reliability [130]. Reports of the use of the I-Qol in a multi-centre, double-blind placebo controlled, randomised trial confirmed the use of an overall score and three subscale scores (avoidance and limiting behaviours, psychosocial impacts, and social embarrassment) [145] All scores achieved high internal consistency (alpha=0.87-0.93), and reproducibility (intraclass correlations – 0.87-0.91). Responsiveness statistics using changes in stress test pad weight, number of incontinent episodes, and patient global impression of the improvement of their condition ranged from 0.4-0.8. Minimally important changes ranged from 2%-5% in association with these measures and effect sizes [145]

Psychometric information on translated versions of the I-QOL have been reported for French, Spanish, Swedish, and German language versions [145]. In all countries, the use of three subscales, and an overall summary scores was confirmed. 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. Translated versions are reported to be available in 7 other languages, but information on the psychometric properties of these instruments has not yet been published.

2. KING'S HEALTH QUESTIONNAIRE [GRADE A]

[For details, see above]

3. INCONTINENCE IMPACT QUESTIONNAIRE (IIQ) [GRADE A]

This questionnaire was developed to assess the psychosocial impact of urinary incontinence in women. It has acceptable levels of validity, reliability and responsiveness [57] [131 - 137] It has been used in several clinical trials,[146] [147] [148] and observational studies [149] [150] [151] [152].

A modified version has been used in men [153]. The questionnaire has also been used in Holland [72], Denmark [154], and Australia.[146] The IIQ has also been used in a study examining the use and cost of incontinence pads in the US.[155].

a) IIQ-7 (short form) [Grade A]

The IIQ has also been produced in a short form comprising 7 items, also with evidence of acceptable validity and reliability [50], [73]. A French version of the IIQ-7 was used in a study by Blanc and colleagues (1999) of stress and mixed incontinent women [76].

b) U-IIQ [Grade A]

An adapted version of the IIQ has been developed to be specific to the assessment of urge incontinence [58], [77]. The IIQ was modified by adding and deleting questionnaire items to measure symptoms associated with urge incontinence, based on focus group information, [78] expert clinical opinion, and reviews of scientific literature. The final U-IIQ 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. The response categories were increased from a 4-point Likert scale to a 6-point Likert scale to allow for increased responsiveness to therapeutic changes [77]. For some questions, response categories of "never regularly do this" and "does not apply to me" were added to better characterize the impact of UI. Higher scores on the subscales and individual items indicate greater impact on daily life.

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, [58], [77] and .90 for the overall index score [58]. Intraclass correlation coefficients of test-retest reliability has ranged from 0.68-0.88 [58], [77]. 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 [58]. The scale has demonstrated acceptable convergent and discriminant validity [77]. Further work on this scale is reported to be underway.

c) Modified IIQ and IIQ-7 [Grade A]

A modified version of the IIQ and the IIQ-7 has been used in two studies examining the efficacy of artificial urinary sphincters in men who had developed stress incontinence after radical prostatectomy. Fleshner and Herschorn (1996) used 17 items of the IIQ to examine activities of daily living and self-perception [132]. They also changed the response choices to some of the items and added two questions from the AUA Symptoms Index. They compared 30 men receiving artificial urinary sphincters to a group of 31 men who had also undergone radical prostatectomy but who had not developed incontinence. Urinary control was similar in both groups yet several IIQ questions discriminated between groups. However, the total score was not given or analysed. The questions from the AUA Symptoms Index did not differentiate between groups (Fleshner & Herschorn, 1996) [132].

The IIQ-7 and the short form of the Urogenital Distress Inventory (UDI) were used in a study of 52 men implanted with an artificial urinary sphincter and compared to a group of 15 men with post prostatectomy incontinence. In this study, IIQ-7 scores were significantly correlated with the use of protective pads (r =.75), and the mean scores on the IIQ-7 and UDI were significantly greater after implantation of the artificial sphincter group than before [153]. Although both studies supported the validity of using the IIQ with men, it is unfortunate than none reported its reliability or responsiveness with this population.

4. Symptom Impact Index (SII) [Grade B]

This questionnaire was developed in the UK to assess the impact of stress incontinence and has acceptable levels of validity and reliability [65].

5. ICS*QoL* [Grade B]

This questionnaire is part of the ICS-'BPH' study questionnaire [89] and includes six items addressing general and specific aspects of QoL [110]. ICS*QoL* exhibits good validity but poor reliability and hence questions have to be considered independently [110].

6. EORTC metastatic prostate cancer [Grade B]

Developed in Portugal and Belgium, this questionnaire is based on other EORTC measures and aims to assess quality of life in patients with metastatic prostate cancer [133]. It has high internal consistency but test-retest reliability has not been confirmed. There is some evidence it is responsive to change following prostate cancer treatments [133].

7. Changes in Urinary Function [Grade B]

This questionnaire was tested for validity and reliability as part of a Radiation Therapy Oncology Group (RTOG) study (reported in [134].

8. Prostate-targeted Health Related Quality of Life [Grade B]

This questionnaire consists of 20 items in three domains: sexual, urinary and bowel function and exhibits adequate validity and reliability [120].

9. Functional Assessment of Cancer Therapy - (FACT-G) and Prostate form (FACT-P) [Grade B]

A group of measures has been developed under the

general umbrella of the Functional Assessment of Cancer Therapy Scales. The FACT-BL (bladder version) has been used with patients recruited to a trial of radiation therapy in prostate cancer, and includes questions concerned with micturition, fatigue and sexuality [156].

10. SEAPI QMM Incontinence Classification System [Grade C]

This system was devised for the definition and standardisation of the measurement of incontinence in both sexes, with the aim of functioning in the same way as the TNM classification for cancers.[136] Psychometric testing is reported to have been completed, but currently this is only in the form of abstracts.

11. Overactive Bladder Symptom and Health-related Quality of life (OAB-q) [Grade C]

A questionnaire is in development by Medtap International specifically to assess the impact on quality of life of an overactive bladder in men and women. The questionnaire was developed during the National Overactive Bladder Evaluation (NOBLE) programme in the US. It contains 33 items (8 on bladder symptoms including urge incontinence and accidental loss of urine and 25 related to the impact of the symptoms on three major domains of life – concern, sleep and social. A considerable amount of work has been undertaken to evaluate the psychometric properties of this questionnaire, but it is as yet unpublished except in abstract form.

12. Stress Incontinence Questionnaire (SIQ) [Grade C]

This questionnaire, developed in the US, consists of 16 items on a four-point Likert scale to assess stress incontinence [138]. Some aspects of validity and reliability have been assessed [138].

13. York Incontinence Perceptions Scale (YIPS) [Grade C]

This questionnaire aims to evaluate psychosocial aspects of urinary incontinence and its management [137]. It has shown acceptable levels of validity, but test-retest reliability and responsiveness have not been fully assessed [137].

14. Incontinence Stress Index (ISI) [Grade C]

The original aim of this questionnaire was to measure psychological stress associated with urinary incontinence in women living in institutions [157]. but it has also been assessed for women in the community [139]. Development work using principal components and factor analyses has reduced the questionnaire to 20 items, but little data is available on psychometric properties.

15. Bristol Lower Urinary Tract Symptoms*QoL* [Grade C]

This questionnaire is the same in style as the ICS*QoL* questionnaires but only preliminary data on validity and reliability have been published [64].

16. Psychosocial Consequences Questionnaire [Grade C]

This questionnaire was developed in Norway to be used in a prospective study of the treatment of incontinence in general practice [140]. This questionnaire appears to be completed by the clinician for the patient, which has been shown to be unreliable. Test-retest reliability has not been calculated, and internal consistency is low.

17. Philadelphia Geriatric Center Multilevel Assessment Instrument (MAI) [Grade C]

This questionnaire was used to assess quality of life in housebound women in the US and has published some data indicating reliability [141].

18. QOL questionnaires concerned with incontinence (Synthelabo) [Grade C]

Questionnaires have been developed by the pharmaceutical company to assess quality of life in patients with stress and urge incontinence, but only one abstract has been published indicating these are still under development [142].

19. Symptom and psychological status in stress incontinence [Grade C]

A study was conducted in the US to assess the symptom and psychological status of women with stress incontinence but no formal evaluation of psychometric properties was undertaken [143].

20. Post-radical radiotherapy questionnaire [Grade C]

This questionnaire was developed 'ad hoc' for a specific study of radical radiotherapy and shows some evidence of adequate reliability [144].

IV. DIMENSION-SPECIFIC MEASURES – SEXUAL FUNCTION/SATISFACTION

Dimension-specific measures aim to assess just one aspect of quality of life. Questionnaires have been developed to assess aspects of sexual function and satisfaction, with a small number of these also being used to examine these factors in patients with incontinence. On the whole, these questionnaires are at the early stages of development – both psychometrically and in terms of their application to the field of urinary incontinence.

Box 5. Questionnaires recommended to assess sexual function/satisfaction

GRADE A: HIGHLY RECOMMENDED

The Psychosocial Adjustment to Illness Scale (PAIS). 158

Rust and Golombok Inventory of Sexual Satisfaction. 159

GRADE B: RECOMMENDED

Brief Sexual Function Inventory. 160

BPH QOL9. 161

ICS*sex*. 162

GRADE C: WITH POTENTIAL

BFLUTS*sex*. 163

Simple sexual function questionnaire. 164

Effect of urinary incontinence on sexuality questionnaire. 165

Effects of urinary incontinence on sexual activity questionnaire. 166

Several major symptom and quality of life questionnaires have also added single questions to assess sexual aspects. For details, see Table 2, below.

1. THE PSYCHOSOCIAL ADJUSTMENT TO ILLNESS SCALE (PAIS) [GRADE A]

This questionnaire 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)* 158. It contains a sexual relationships domain consisting of 6 items. These items assess 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 Hodgkins 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 ($t=1.53$, $p<0.10$) 101.

The PAIS has been used to investigate the impact of different types of urinary incontinence on sexual function 167 in a sample of 200 patients referred for urodynamic assessment. Compared to patients with GSI, patients having DI were significantly 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 168. 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.

2. GOLOMBOK-RUST INVENTORY OF SEXUAL SATISFACTION [GRADE A]

This questionnaire was developed systematically by sex therapists at the Maudsley Hospital Sexual Dysfunction Clinic 159. It contains 56 items, 28 for men and 28 for women. There are four subscales covering anorgasmia, vaginismus, impotence and premature ejaculation, and 6 subscales giving separate male and female scores for avoidance, dissatisfaction and non-sensuality. 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. These relate to interest in sex generally.

The questionnaire was validated on a clinical sample recruited from sexual dysfunction clinics throughout the UK of 68 men and 63 women, and a control group of 29 men and 30 women randomly selected from primary care attenders. Split half reliability was 0.94 for the female scale and 0.87 for the male overall scale.

Internal consistency of subscales was, on average, 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).

This questionnaire has been used by Hunt & Moss (1996) in a small study exploring the relationship of unwanted sexual experience to detrusor instability and sexual dysfunction [169] High levels of sexual dysfunction were found in incontinent subjects compared to other clinical groups.

3. A BRIEF MALE SEXUAL FUNCTION INVENTORY FOR UROLOGY [GRADE B]

The aim of this study was to provide a brief questionnaire concerning male sexual function that could be used for clinical and research purposes in urological settings [160]. Items were identified from the literature to produce a 50 item questionnaire which was reduced down to 22 items in a series of pilot studies for the final validation study. The questionnaire was made up 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.

5. QOL9 [GRADE B]

The QOL9 is a short form of the QOL20, a questionnaire previously validated in French [161]. 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 which 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 was assessed by rates of completion of the questionnaire which was above 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 quality of 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 the initial severity of symptoms but had a mean of 0.02 and 0.55 for patients treated in each of the two studies.

6. ICS*SEX* [GRADE B]

The ICS*sex* is part of the ICS-BPH questionnaire. [162]. This instrument contains questions pertaining to symptoms, quality of life and sexual function. The symptom questionnaire was described in some detail in the previous consultation document but the sexual function domain has not been validated to the same extent. 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 [162]. The strongest associations were found between storage symptoms, particularly incontinence, and sexual dysfunction. This pattern was seen in both samples. Test-retest reliability has been assessed and responses on the sexual function questions changed by one category at most, apart from the question concerning the perception that sex life has been spoilt be urinary symptoms which changed by more than one category on retest.

7. Bristol Female Lower Urinary Tract Symptoms BFLUTS*sex* [Grade C]

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. In addition to each of these items the respondent is asked how much of a problem this is for them.

Jackson et al. (1999) reported data on the sexual function questions in a study of the effects of hormone replacement therapy on post-menopausal urinary stress incontinence [163]. Sex-life spoilt by urinary symptoms was reported by around one quarter of patients and intercourse incontinence by about 10%. There was little change in these symptoms as a result of intervention, but numbers were small and the mean age was>60years with many of the sample not being sexually active. Bo, Talseth and Vinsnes (2000) also reported sexual function data using this questionnaire in a study of pelvic floor muscle training, with significant differences occurring post treatment between experimental and control groups, although this effect disappeared when baseline levels were controlled [170]. Again, however, sample sizes were small, and so responsiveness data on this questionnaire needs further evaluation.

A very similar questionnaire was devised by Bernstein et al. (1996) with some validation carried out in a clinical sample of females in Denmark [67]. This questionnaire asks whether the respondent is sexually active, whether their sex life has suffered because of urinary symptoms, leakage during intercourse and pain during intercourse. The level of accompanying bother is ascertained for 2 of the questions: impact on sex life and pain on intercourse. Missing data was found to be high for these questions, but this may reflect a low level of sexual activity in the sample. Test-retest reliability was between 69.6% and 91.1%.

8. Simple Sexual Function Questionnaire [Grade C]

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. 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 [164]. 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 [171]. The short questionnaire was found to detect all cases of sexual dysfunction identified by in-depth interview.

9. Effect of Urinary Incontinence on Sexuality Questionnaire (EISQ) [Grade C]

This questionnaire, published in Japanese but with an English abstract, aims to evaluate the effect of incontinence on sexual function in women [165]. It exhibits good reliability and further studies are planned.

10. Effects of urinary incontinence on sexual activity [Grade C]

An eleven item questionnaire was used to assess the effects of incontinence on sexual activity in women, although no formal psychometric testing has been undertaken [166].

11. Other measures of sexual aspects

Many of the questionnaires assessing psychosocial impact of urinary symptoms contain one or possibly two questions related to sexual function. The majority of these are discussed above, either as symptom questionnaires or general quality of life questionnaires. Table 2 summarises these with particular emphasis on validation data related to the sexual activity question. Data are reported pertaining to either the subscale containing the sexual activity question or to the questionnaire as a whole when no specific information is given on the sexual activity question itself. Questionnaires containing just one question tend to focus on a general assessment of the overall impact of urinary symptoms on sexual functioning.

The Symptom Impact Index [172]. The Kings Health Questionnaire, [59] the Incontinence Impact Questionnaire [173] and the IQOL [174] are recommended by the Committee for use as condition specific quality of life questionnaires. However, when considering the sexual items it must be borne in mind that validation of the sexual items was not always carried out e.g. Symptom Impact Index or made explicit e.g. Kings Health Questionnaire. 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).

Table 2 : Questionnaires that include one or two questions pertaining to sexual function. Questionnaires validated in women only.

Questionnaire/Authors	Sample	Topics covered in relation to sexual activity	Findings
KINGS HEALTH QUESTIONNAIRE 59	293 women referred for urodynamics with any type of incontinence. (n=285 completed questionnaires, mean age 51.4 years))	Impact of bladder problem on sex life.	Subscale data Internal consistency -alpha =0.892 Test-retest- rho=0.87 No validation of subscale
SYMPTOM IMPACT INDEX 172	Women undergoing surgery for Stress Incontinence (n=442 60% were between 41 and 60 years of age)	Leakage during intercourse. Impact of bladder problem on sex life.	Content validity =missing data 2.9% Validation of questionnaire did not included the sexual items
SOCIAL ACTIVITY INDEX 175	Women with stress incontinence undergoing urodynamics (n=14, mean age 42.8 years)	Perceived ability to participate in sexual activity	Complete questionnaire data Test-retest at 1 hour - r=0.94
URGE INCONTINENCE QUALITY OF LIFE QUESTIONNAIRE 176	Women with urge incontinence recruited from 44 investigators in France (n=98)	Anxious at the thought of sex	Internal consistency - ranged from 0.69 - 0.84 across all items Validity - total score correlated with symptom severity.
Incontinence Quality of Life Index (IQOLI) 177	Women with urge and mixed incontinence taking part in a trial of emepronium carrageenate (n=75, aged 35-65 years)	Impact of bladder problems on enjoyment of sex life.	Complete questionnaire data Internal consistency = 0.9 Test-retest at 2 weeks - rho=0.92 Construct validity - correlation with generic QOL = 0.4 - 0.56 Responsiveness- significant difference pre and post treatment

V. INDIVIDUALISED MEASURES [GRADE C]

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 179 may be useful.

VI. 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. However, some specific patient groups may experience particular problems with incontinence (for example, children 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 180 181.

1. 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 182. 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 182.

2. INCONTINENCE IN PATIENTS WITH MULTIPLE SCLEROSIS [GRADE C]

A study by Catanzaro explored the effects of incontinence on patients with multiple sclerosis through the use of interviews 181.

3. INCONTINENCE IN CHILDREN

Although children can be affected by urinary incontinence, no questionnaires designed specifically for use with children could be identified. One article reported on the relationship between enuresis and self-esteem 183.

Table 3 : Questionnaires validated in both women and men.

Questionnaire/Authors	Sample	Topics covered in relation to sexual activity	Findings
INCONTINENCE IMPACT QUESTIONNAIRE (IIQ) 173	Women undergoing urodynamics who had GSI or DI (n=162, mean age 61.3 years)	Impact of leakage on ability to have sexual relations	Subscale data. Internal consistency =0.9 Construct Validity - significant correlation with generic QOL measures. Criterion validity - significant correlation with number of incontinent episodes and pad test.. Responsiveness - significant difference between pre and post treatment scores.
Wyman et al. (1987) 170	Women with GSI and DI taking part in trial of behavioural treatment. (n=69, mean age 67.8 years)	Impact of leakage on ability to have sexual relations	Test retest of complete questionnaire r=0.73 at 1 week; r=0.65 at 6 weeks
Smoger et al. (2000) 178	809 men recruited from primary care clinics. (n=261 with current incontinence)	Impact of leakage on ability to have sexual relations	Subscale data Significant correlation with frequency of incontinence
URGE IIQ Brown, Posner & Stewart (1999) 77	Volunteer sample of women with urge or mixed incontinence (with predominantly urge). (n=83, mean age 63.8 years)	Impact of leakage on ability to relax and enjoy sex having an orgasm	Data on sexual function questions: Internal consistency = 0.91, Test-retest at 2 weeks ICC = 0.71, Divergent validity - weak correlation with other IIQ domains <0.1 No correlation between sexual function questions and frequency of leakage or overall ratings of impact.
Lubeck et al. (1999) 58	Men and women with urge and mixed incontinence enrolled in a trial of oxybutynin. (n=22 male and 235 female, mean age 59.6 years))	Impact of leakage on ability to relax and enjoy sex having an orgasm	Data on sexual function questions. Content validity- 34% floor effect. Dicriminant validity - significant relationship with severity of UI. Responsiveness - Guyatt's stat=-1.07. Construct validity - i nterscale correlations were in the expected directions.
IQOL Wagner et al. (1996) 174	62 men and women with stress, urge and mixed incontinence recruited from clinics and adverts (n=42 female and 20 male, mean age 64 years))	I worry about having sex because of my incontinence	Complete questionnaire data. Internal consistency - alpha=0.95, Test-retest at 18 days - ICC=0.93 Descriminant validity - IQOL related to severity, self perceived severity and number of medical appointments.
Patrick et al. (1999) 145	Women with stress and mixed incontinence taking part in a trial of duloxetine.(n=288 76% were 45 years of age or older)	I worry about having sex because of my incontinence	Subscale data. Internal consistency - alpha=0.93 Test-retest at 2 weeks- ICC=0.91. Complete questionnaire data. IQOL correlated with SF36 and PGWB. and pad test, diary and self perceived severity Responsiveness statistic =0.4

USE OF QUESTIONNAIRES IN RESEARCH

The prevalence of incontinence and its impact on the quality of life of individuals varies, depending on the severity of the condition as well as other social and medical factors involved. A number of reviews of the prevalence and impact of incontinence have been published – see [1] and, since the last report. [74] [83] [97] [184 - 200].

Questionnaires can be used in outcomes research and epidemiological research and it is encouraging that since the publication of the previous report,[1] an increasing number of such studies are being published which include results from validated questionnaires. It remains, however, that many studies do not include validated (recommended) questionnaires and we would strongly urge researchers to include such measures in their research. In the sections below, we update our literature review on outcome assessment (randomised trials and observational studies) and epidemiological studies.

I. RANDOMISED TRIALS

The ideal study design for assessing the outcome of treatments for incontinence is the randomised controlled trial. We would contend that the assessment of a patients' symptoms and impact on quality of life using validated self-completed questionnaires should be an essential component of any study evaluating treatments. A review of 9 trials from 1980 to 1996 concerned with electrical stimulation concluded that the standard of published trials was poor and that there was a need for more trials with larger sample sizes and using sensitive, reproducible and valid outcome measures [201]. Below, we consider the studies found relating to treatments for incontinence and their use of validated questionnaires.

Few randomised trials using recommended questionnaires were identified in the first ICI report [1] Searching of Medline and the Cochrane trials databases between 1998 and mid 2001 identified 48 randomised trials of treatments for incontinence of various sorts. Of the 48 randomised trials identified, only 19 included validated questionnaires as an outcome measure (see Table 4). Eight were undertaken in Europe, 7 in the USA, and two each in Japan and Australia. Six involved bladder training or physical therapies such as pelvic floor exercises, 5 with drug therapies, three minimally invasive therapies such as magnetic stimulation, 1 compared surgical procedures, and four involved guidelines or health care organisation. Three trials included more than 200 patients but 13 fewer than 100. Six trials were considered to reach the highest level of rigour. The trials covered a wide range of types of incontinence. Four trials employed the SF-36, 3 the IIQ, 3 the BFLUTS, 2 the QoLS-N and 4 some sort of VAS.

In the other trials, the outcome measures typically used was the frequency-volume diary (11 trials): spinal cord patients, drug trial; [202] 197 women in behavioural v. drug trial; [203] sacral nerve stimulation in 76 elderly patients; [204] 105 patients with urge or mixed incontinence, drug trial; [205] 277 with overactive bladder, drug trial; [206] 105 housebound adults, behavioural trial; [207] 361, drug trial; [208] 68 with detrusor overactivity, electrical stimulation v. sham trial; [209] 67 detrusor instability, drug trial; [210] 197 women with urge incontinence, behavioural v. drug trial; [211] 130 responders, drug type trial. [212]. In 13 trials, outcome focussed on clinical measures, with an uspecified subjective assessment by patient or clinician (unlikely to be validated) [213 - 225]. In a further 5 trials, the outcome measures employed were unclear [226 - 230].

These findings suggest that while it is encouraging that the use of validated questionnaires is increasing, far too many randomised trials still do not employ them. As these trials are evaluating the impact of treatments which 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.

Table 4 : Randomised trials using validated questionnaires

Reference	Country	Inc. type	n	RCT	QoL measure	Result	Level evidence
Wyman 147	USA	Stress & DI	204	Bladder training	IIQ, UDI	Combined therapy best	1
Serels 231	US	Urge	34	Hyosya-mine v. doxazosin	Expanded AUA	Improved	2
Cammu 232	Belgium	Stress	60	Pelvic floor v. cones	VAS, diary	No difference	2
Wikander 233	Sweden	Post-stroke	34	Functional prog v. control	Katz ADL, FIM	Improved intervent. group	2
Moore 234	Australia	Post-prostatec-tomy	63	Pelvic exercise v. elect. Stim. v. standard	IIQ-7, EORTC QLQC30	Inc. symptoms improved – no difference	2
Kammerer 235	USA	Stress	35	Burch v. colporr-haphy	IIQ, own design	Lower quality of life Burch	2
Reuben 236	USA	Any	363	Geriatric assess. v. standard	SF-36	Some improv. Intervent.	1
Jackson 93	UK	Stress	67	HRT v. placebo	BFLUTS, SF-36, diary	No effect	2
Patric 145	USA	Stress&mixed	288	Drug v placebo	I-QoL	Validity testing	1
Petersen 237	Denmark	Detrusor hyper (spinal cord)	12	Casaisin v. placebo	VAS	No difference	2
Fujishiro 238	Japan	Stress	62	magnetic stim. v. sham	Own	Sig. improve-ment	2
Bo 94	Norway	Stress	59	Pelvic floor v. control	QoLS-N, BFLUTS	Sig. reduction in sex, social & phys problems	2
Weil 239	Neths	Urge	44	Neuromod-ulation	Beck, SF36	QoL & UDS improved	2
Chadha 240	Australia	Any	449	Guidelines	SF-36	No effect	1
Bo 92	Norway	Stress	59	Pelvic floor v. control	QoLS-N, BFLUTS	Sig.Improved sex and social life	2
Choe 241	USA	Stress	40	Mesh v. sling	VAS	Mesh better	2
Van Kampen 242	Belgium	Post prostat-ectomy	102	Pelvic floor v. placebo	VAS	Improved intervent.	1
Fujishiro 243	Japan	Stress	62	Magnetic stim. v. placebo	Unspec. score	Improved intervent.	2
Burgio 244	USA	Urge	197	Biofeed-back v. oxybutynin v. placebo	Hopkins Symptom Checklist (SCL-90-R)	Psychological distress reduced in biofeedback and drug arms	1

II. OBSERVATIONAL STUDIES

Searching identified 28 observational studies, 10 of which used a prospective design with controls, 2 prospective design with historical controls, and there were 16 studies without controls (see Table 5). As these studies were not randomised, they scored poorly in terms of research quality, with 10 reaching a score of 3 but the majority (16) having the lowest rating. Most studies were small – 22 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 (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.

Table 5 : Observational studies of outcome using questionnaires

Ref	Country	Incontinence type	n	Design	Treatment	QoL measure	Results	Level of evidence
Lemack [245]	USA	Stress	56	R	Surgery	Own	Sex func worse post op	5
Sung [95]	Korea	GSI	60	Pro	Biofeedback v pelvic floor	BFLUTS QoL	Biofeed better	3
Amunsden [246]	USA	Obstruction	32	R	Surgery post op	IIQ, UDI	Success	5
Winters [247]	USA	Stress	58	R	Collagen	Own	Improved	5
Fuertes [248]	Spain	Urge	67	Open trial	Drug	EuroQoL	Improved	5
Morgan [249]	USA	Stress	247	R Sling	surgery	UDI-SF	92% satisfaction	5
Sampselle [149]	USA	Stress	132	Pro	Pelvic floor & Bl. exercise	IIQ	Improv	5
Sander [250]	Denmark	Urge & mixed	408	Pro	Conservative clinic	SF36 and own	Signif improv	3
Filbeck [251]	Germany	Stress	105	R	Surgery	Backle QoL	Signif improv	3
Moore [252]	Australia	Stress, urge, mxd	57	Pro	Fem Assist	UDI	Equal response	3
Sand [253]	USA	Stress	63	Pro	Insert	SF36	Signif improv	3
Galloway [254]	USA	Stress	83	Pro	Innervation	1-QoL	No improv	3
Davila [150]	USA	Stress & mixed	53	Pro	Support prosthesis	IIQ	Signif improv	4
Blanc [76]	France	Stress & mixed	37	R	Bladder neck Suspension	IIQ7 UDI 6	Unclear	4
Weinberger [255]	USA	Stress & mixed	81	R	Non-surgical trial	Own	Benefit	3
Sander 154	Denmark	Stress	41	Pro	Vaginal device	IIQ, SF36	Signif improv, SF36 no diff	5
Hassouna [256]	USA	Stress	82	R	Surgery	SIP	Signif improv	5
Versi [151]	USA	Stress	14	Pro	External device	IIQ, UDI	Improved	5
Amarenco [257]	France	Urge	1701	Pro	Drug	Ditrovie	Effective	5
Versi [258]	USA	Stress & Urge	96	Pro	Device	IIQ, UDI	Signif improv	5
Rabin [259]	USA	Stress & mixed	38	Pro	Device	Own	50% improved	5
Sander [260]	Denmark	Stress	55	Pro	Device	IIQ, SF36	Signif improv, No diff	5
Black [172]	UK	Stress	442	Pro	Surgery	Black q'aire	75% improved	5
Shaker [106]	Canada	Urge	18	Pro	Sacral root	Beck, SF36	Improved	5
Wyman [146]	Australia	Stress & mixed	21	Pro	Prosthesis	IIQ	Improved	5
Siegel [152]	USA	Urge & mixed	68	Pro	Stim (elect)	IIQ	Improved	3
Richardson [261]	USA	Stress	21	Pro	Stim (elect)	IIQ	Improved only travel & physical	3
Berglund [242]	Sweden	Stress	45	Pro	Surgery	Interview	Decrease in impediments	3

III. EVALUATION OF THE IMPACT OF INCONTINENCE ON 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 [263]. '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 [101]) 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 [14]. One study has shown that partners of men with LUTS can suffer because of their spouse's condition, particularly in terms of being worried about cancer or the need for surgery, and also because of disturbed sleep [264]. 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 1997.

Many studies have examined the impact of lower urinary tract symptoms as well as incontinence. Lower urinary tract symptoms in men have been reported to have a deleterious impact on aspects of quality of life in a great number of studies [23, 110, 126, 265 - 276] Symptoms causing the most bother include those associated with filling (so called 'irritative' symptoms) such as frequency, urgency, nocturia and incontinence [268, 270, 277, 278]. Increasing levels of symptoms are sometimes associated with increasing impact on everyday life [273].

Incontinence has been found to reduce social relationships and activities [43, 49, 52, 131, 141, 279 - 284] be associated with poor self-rated health, [285] impair emotional and psychological well-being, [49, 52, 283, 284, 286, 287] and impair sexual relationships [162, 288, 289]. Some report that incontinence causes at least practical inconvenience, [60, 280, 290] and for many requires often elaborate planning to conceal or prepare for incontinent episodes, [138, 291] and may cause financial hardship [155]. Feelings of embarrassment or negative self-perception are common [282, 291, 292]. In some studies, it is suggested that urge or mixed incontinence can have a more severe impact than stress incontinence. [72, 284, 293, 294].

It is clear, however, among both men and women experiencing lower urinary tract symptoms or incontinence, that there is considerable variability in complaints of deleterious impacts. For a small proportion, these conditions seriously affect daily life including psychological and social well-being. There is a relatively large group, however, who appear to experience more limited impact or adapt to their symptoms and report only limited effects in some domains. Some are not sufficiently concerned to request treatment [295-297]. Some of this variability is likely to be related to the range of different questionnaires and measures used. More severe incontinence is seen to result in greater impact on quality of life in some studies [71]. Older women may be less affected than younger [294]. One study focused on nocturnal incontinence, showing that this symptom is more common than originally thought (present in 5.8% of women aged 19 years and older in a general practice in the UK), and that it is extremely troublesome [98].

Table 6 : Use of questionnaires to assess impact of incontinence on quality of life

No.	Country	Type of incontinence	QOL measures	Results
Simeonova [298]	Norway	stress, urge, mixed	Generic: RAND-36 disease specific:UDI and IIQ	The prevalence of urinary incontinence was 57.1%: 28.7% for stress incontinence, 5.6% for urge incontinence and 22.7% for both. Women with urge or mixed incontinence had more severe impairment of QOL as compared with only SUI.
Temml [91]	Austria	stress, urge, mixed	BFLUTS	65.7% of women and 58.3% of men stated that QOL was affected by their incontinence. A moderate or severe impairment was reported by 18.3% of women and 16.6% of men.
Simeonova [299]	Sweden	stress, urge, mixed	visual analogue scale	Women with urinary incontinence reported a poorer quality of life compared to continent women ($p<0.01$). Women with urge incontinence and women with mixed incontinence reported a poorer quality of life compared to women with stress incontinence ($p<0.05$).
O'Connor [281]	Sweden	urge, mixed	SF-36	QOL among the sample population was significantly lower in 5 of 8 dimensions compared with the general US population, and was significantly related to the severity of the symptoms in 6 of 8 dimensions.
Brown [300]	USA	urge	their own QOL questionnaire	Urge incontinence affects many QOL issues and contributes to limitation of activities, loss of control, and negative self-perception.
McClish [301]	USA	any type	IIQ	Cost and pad usage were significantly associated with number of incontinent episodes and QOL.
Kinn [302]	Sweden			QOL and pad use were evaluated in 460 women utilizing the free provision and home delivery of urinary incontinence pads by the Swedish health services. Satisfaction with the supplied pads was generally good, with absorptive and antiodor properties most appreciated.
DuBeau [303]	USA	urge	32 urge incontinence related QOL items obtained from literature, more than half of which were not described previously	Community-dwelling 25 women and 5 men more than 60 years of age with urge incontinence were included. Experts and patients viewed the impact of urge incontinence on QOL differently. Whereas experts focused more on functional impact, patients more often cited the impact of urge incontinence on their emotional well-being and on the interruption of activities.
Schlenk [115]	USA	any	SF-36	To examine HR-QOL as measured by the Medical Outcomes Study Short Form-36, across patient populations with chronic disorders and to compare QOL in these subjects with normative data on healthy persons. 6 disorders (urinary incontinence, prostate cancer, chronic obstructive pulmonary disease, AIDS, fibromyalgia and hyperlipidemia. Homebound, elderly, incontinent patients had the lowest QOL for physical functioning.

Table 6 : Use of questionnaires to assess impact of incontinence on quality of life (to be continued)

No.	Country	Type of incontinence	QOL measures	Results
Robinson 304	USA	any women over 60 ys	IIQ UDI	To determine if patient reports of urinary incontinence symptoms can predict QOL as measured by the short forms of the IIQ and UDI. The question, "Do you consider this accidental loss of urine a problem that interferes with your day-to-day activities or bothers you in other ways?" was the best predictor of the subject's responses to both QOL measures. The patients' symptoms that best correlated with both QOL measures and the report of bothersome incontinence were frequent episodes of incontinence, greater amounts of urine loss and more frequent voids.
Chiverton 287	USA	any	no specific QOL questionnaire	To explore the incidence of depression, the correlation between mastery and depression and/or self-esteem, and depression as a mediating factor in the QOL in women with urinary incontinence. There was a higher incidence of depression in women with incontinence compared with the general popu lation. Depression did not emerge as a mediator in QOL. Mastery was the only predictor with a direct effect on QOL in women with incontinence.
Grimby 305	Sweden	any	Nottingham Health Profile Questionnaire	Comparison between women (n=120) with urinary incontinence and an age-matched women (n=313). Women with incontinence obtained higher scores in the domains of emotional disturbance and social isolation than controls. Women with urge and mixed incontinence reported emotional disturbances more than control. But there was no difference within the domain of emotional disturbances between stress-incontinent women and the control group. Women with urge incontinence reported more disturbances of sleep than the control. Women with all types incontinence were socially more isolated.
Hunskaar 306	Norway	urge stress	SIP	Women with incontinence obtained higher scores in the domains of emotional disturbance and social isolation than controls. Women with urge and mixed incontinence reported emotional disturbances more than control. But there was no difference within the domain of emotional disturbances between stress-incontinent women and the control group. Women with urge incontinence reported more disturbances of sleep than the control. Women with all types incontinence were socially more isolated.

IV. IMPACT OF INCONTINENCE ON SEXUAL FUNCTION AND SATISFACTION

Studies that have assessed sexual functioning in relation to urinary symptoms have shown that it is an important concept to measure when considering condition specific quality of life [1]. The majority of studies assessing the impact of incontinence on sexual life have, however, not used validated questionnaires. Most have either included one or two questions about sexual function to existing incontinence questionnaires or have relied on unvalidated instruments.

A number of studies have assessed sexual dysfunction in relation to urinary symptoms and/or surgery for incontinence (Table 7). These have been mainly carried out on female populations and the focus of questions have concerned the presence of leakage and the phase of sexual activity during which leakage occurs. The impact of urinary symptoms on sexual activity, and satisfaction with sexual activity are also commonly assessed. Studies evaluating outcomes of surgery for stress incontinence have focused on the changes in sexual activity resulting from surgery, in terms of frequency of intercourse, frequency of desire, satisfaction, pain and dyspareunia, and frequency of leakage during intercourse. Infrequently the impact of sexual dysfunction on partners is also considered.

Results of these studies are equivocal in relation to prevalence of dysfunction, differences between aetiological groups, and impact of surgery on sexual function. This points to a need for more systematic research into the aspects of sexual dysfunction that are most pertinent to quality of life and standardisation of measurement of sexual functioning with the development of well constructed and validated instruments. These instruments must take account of all aspects of sexual activity whether involving a partner or not. Consideration also needs to be given and measures developed for the impact of incontinence on partners' quality of sex life.

As can be seen, the findings from these studies are very variable and, at least in part, these variations are probably due to differences in the questionnaires and methods used. However, some studies do indicate that incontinence can have an impact on sexual matters and so this is an area requiring further investigation. It remains that the assessment of the impact of incontinence on sexual function and satisfaction is still a developing research area.

Table 7: Studies assessing sexual function and urinary symptoms using non-validated questionnaires.

Authors	Sample	Topics covered in relation to sexual activity	Findings
Lam et al. (1992) 307	Community survey of 3114 women (n=511 with UI mean age 45.1 years)	Presence of leakage during sexual intercourse.	Leakage during intercourse = 12.2% of SI, 14% of Urge, 15.3% of mixed and 7.1% of non-specific UI.
Nygaard & Milburn (1995) 308	292 Women attending routine gynaecological examination (n=224 responded, mean age 41.4 years)	UI associated with orgasm or penetration, volume of UI, whether it was a problem and if partner found it a problem.	12.9% experienced UI during sexual activity, associated with severity of UI. 45% during orgasm, 21% during intercourse and 35% during both. Only 1 woman found it a problem, and no partners did.
Sutherst & Brown (1980) 309	289 Women attending an incontinence clinic (n=208 responded, mean age 46.1 years)	Whether urinary symptoms had interfered with marital relations and sexual life in any way.	43% of those with urinary symptoms had adversely affected sexual lives. Women with DI had greater dysfunction than GSI.
Gordon et al. (1999) 310	Women attending a urogynaecology clinic (n=100 mean age 62 years)	Detailed questionnaire administered by a psychiatrist addressing desire, arousal, orgasm, and satisfaction. Also impact of urinary symptoms on sexual function.	Women with DI had worse sexual function than those with GSI or mixed incontinence.
Vierhout & Gianotten (1993) 311	254 Women attending clinic for incontinence. (n=66 with UI during sexual activity mean age 47 years)	Assessed activities during intercourse which resulted in leakage.	Deep penetration and abdominal pressure responsible in 77%, orgasm in 74%, clitoral stimulation in 50%.

Table 7 : Studies assessing sexual function and urinary symptoms using non-validated questionnaires. (CTD)

Authors	Sample	Topics covered in relation to sexual activity	Findings
Hilton (1988) 312	400 women attending urogynaecology clinic (n=79 with UI during sexual activity, mean age around 43 years)	Assessed whether leakage was associated with arousal, penetration or orgasm.	67% experienced leakage on penetration (70% GSI,4%DI and 9% mixed) and 33% on orgasm (42% GSI, 34% DI and 5% mixed)
Haase & Skibsted (1988) 313	63 Women undergoing surgery for stress incontinence and/or genital descensus. (n=55 responded, mean age 49years)	Sexual desire, dyspareunia, frequency of coitus, and any change in sex life after surgery.	24% experienced improvement, 67% no change and 9% deterioration.
Lemack & Zimmern (2000) 245	93 Women who hadundergone surgery for incontinence (n=22 sexually active Mean age 56 - 60 years)	Frequency of intercourse, satisfaction with intercourse and comparison with pre-surgery, leakage, and dyspareunia	No change after surgery
Berglund et al. (1996) 262	Women with Stress incontinence undergoing surgery (n=45 mean age 50 years)	Semi-structured interview concerning frequency of intercourse, sexual desire and sexual dysfunction	No change in frequency of intercourse post surgery. One third had increased sexual desire, slight increase in dysfunction.
Weber, Walters & Piedmonte (2000) 314	165 women undergoing surgery for UI or prolapse (n=81 sexually active, mean age 54 years)	Frequency of intercourse, incontinence during intercourse, dyspareunia, vaginal dryness	No change in frequency and vaginal dryness. 8% pre and 19% post surgery had dyspareunia. 22% pre and 26% post surgery had intercourse UI.
Iosif (1988) 315	Women undergoing surgery for UI (n=156, mean age 40.6 years)	Change in sexual relations post surgery. Frequency of intercourse, desire, enjoyment and frequency of orgasm.	1 year after surgery frequency of intercourse had increased in 15%, desire increased in 15%, enjoyment increased in 25% and orgasm frequency increased in 10%.
Clark & Romm (1993) 166	90 Women with UI evaluated by urodynamics (n=48 with completed questionnaires, mean age 41 - 48 years)	Ways in which UI affected sexual activity, satisfaction with sex life, pain, presence of orgasm, problems during sexual activity, changes that have helped problems, advice to other sufferers, advice to health professionals.	56% reported UI with sexual activity., 66% reported any urinary symptoms during sexual activity. There was little difference in prevalence rates of UI during sexual activity between diagnostic groups.
Berglund & Fugl-Meyer (1995) 316	105 Women undergoing surgery for GSI. (n=44 eligible, mean age 50 years)	Sexual activities, sexual function/ dysfunction, sexual satisfaction, impact of UI and the effects of the surgical intervention.	No significant difference between frequency of pre and post surgery coitus. Neither the magnitude of leakage nor the duration of UI influenced sexual experiences. Continence after surgery promoted sexual desire.
Macfarlane et al. (1996) 317	Community sample of 2011 men	Frequency of sexual desire and sexual intercourse, difficulties in having an erection and ejaculation, overall satisfaction	Presence of urinary symptoms and severity associated with dissatisfaction. Symptoms that most affected sex life were hesitancy, forcing, poor stream urgency and incontinence.

V. INCONTINENCE IN SPECIFIC PATIENT GROUPS

Most studies and questionnaires have been developed for use with members of the general population or urology/gynaecology patients with incontinence. Some specific patient groups may experience particular problems with incontinence, however, 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 – for example for the severely disabled, [180] those with multiple sclerosis [181] or spinal cord injury.

VI. INTERNATIONAL PERSPECTIVES

The numbers of studies using validated questionnaires to assess incontinence has risen rapidly since the First ICI. [1]. The most commonly used questionnaires are the condition-specific IIQ/UDI and the generic SF-36, probably because the majority of studies originate from the USA. Increasing research into the symptom and quality of life burden of urinary incontinence is being conducted around the world.

Since 1960, searches of MEDLINE yielded the following results concerning articles about incontinence and quality of life: 0 from 1960 to 1970; 5 from 1971 to 1980; 27 from 1981 to 1990; and 209 from 1991 to 2001. The findings were similar for urinary incontinence symptoms: 5 from 1960 to 1970; 12 from 1971 to 1980; 16 from 1981 to 1990; and 47 from 1991 to 2001.

The pattern is repeated in individual countries. For example, in Japan, the study of QoL assessment in urinary incontinence was scanty before the first meeting of International Consultation on Incontinence in 1999. However, thereafter there has been a gradual increase in the assessment of quality of life with the publication of Japanese versions of IIQ, IQOL and KHQ in which linguistic validation was completed [318]. The further validation of questionnaires for reliability, validity and responsiveness is on-going using data from almost 200 patients.

APPENDIX I : DEVELOPING THE ICIQ AND ICIQ-SF

A. ICIQ

The aim of this new questionnaire is to provide a set of modules to cover all the major aspects of the assessment of incontinence and its impact on quality of life in detail. The questionnaire is currently in development and comprises eight sections: symptoms of incontinence, bothersomeness of symptoms, use of pads/protection, impact on aspects of everyday life including social and occupational factors, interference with sex life, emotional impact, follow-up after treatment, and diagnosis. The questionnaire is very long and comprehensive in this developmental phase. The content validity of the items has been established and work on construct validity and reliability is currently being undertaken.

B. ICIQ-SF

The aim of this version is to produce a brief and robust measure to evaluate the frequency, severity and impact on quality of life of incontinence among all groups: men and women, young and old, in the developed and developing world. The questionnaire was devised under the auspices of the ICI and work was initiated after the first consultation in 1999. It was launched at the Second ICI.

The developmental version comprised six major question areas covering: frequency of leakage and its bothersomeness, protection use and type, perceived quantity of leakage usually and at worst, interference with everyday life, interference with social life, and interference with sex life. There were additional questions concerned with age, sex, overall quality of life and perceived cause of leakage that were included primarily for validation purposes. The items are detailed below (figure 2).

The questionnaire has been undergoing psychometric testing and full results of this will be published in due course. As the details have not been published, the questionnaire has the official Committee rating of Grade C – however, it is fully expected to reach Grade A as soon as the material is published.

Figure 2 : Items in the developmental version of the ICIQ-SF

1a. How often do you leak urine (never, about once a week or less often, 2 or 3 times a week, about once a day, several times a day, all the time).

1b. How much of a problem is this for you (0 not a problem to 10 a serious problem - VAS)

2a. Sometimes people try to protect themselves against urine loss by wearing pads, using cloth, tissue paper or other protection. In the past four weeks, have you used any protection (never, some of the time, most of the time, all of the time).

2b. If you did use protection in the past four weeks, what kind of protection did you use (tissue/toilet paper/cloth, minipads/pantliners, sanitary/incontinence/other pads, something else – please describe)

3a. We would like to know how much urine you think leaks. How much urine do you usually leak whether you wear protection or not (none, a small amount, a moderate amount, a large amount).

3b. How much was the worst leakage over the past four weeks (none, a small amount, a moderate amount, a large amount)

4. Overall, how much does leaking urine interfere with your everyday life (0 not at all to 10 a great deal - VAS)

5. How much do you feel that your social life has been spoilt by urinary leakage during the past four weeks (0 not at all to 10 a great deal - VAS)

6. How much do you feel that your sex life has been spoilt by urinary leakage during the past four weeks (0 not at all to 10 a great deal - VAS)

7. In general, how would you rate the overall quality of your life during the past four weeks (0 worst quality of life to 10 best quality of life - VAS)

I. VALIDITY

1. Content validity

This was assessed following a detailed literature review, by taking soundings from the ICI committees, observation of and interviews with patients and levels of missing data. In-depth interviews with a researcher were conducted with 63 consecutive patients (46 females, 17 males) aged 18 or over, with incontinence

or other lower urinary tract symptoms, attending urology clinics in the UK. Patients were observed self-completing the questionnaire and then interviewed to establish their ease of understanding, interpretation and completion of the questionnaire items.

Review by clinical and social science experts indicated that the ICIQ-SF covered all important domains and symptoms. The developmental version of the ICIQ-SF was completed in full by 87% of patients. Most items demonstrated very low levels of missing data on self-completion (the majority <2%, and only one item in excess of 4%).

2. Construct validity

Construct validity was assessed by comparing levels of incontinence as measured by the questionnaire in patients attending urology clinics and individuals in the community, with different ages and sexes. 246 males and females, registered with two UK community general practices, and 215 consecutive male and female urology clinic attenders with incontinence or other LUTS, self-completed the ICIQ-SF. As there is no clear 'gold standard' measure, further aspects of construct validity relate to the relationships between items in the ICIQ-SF and other more established questionnaires such as the ICS*male*SF and the BFLUTS questionnaires. These relationships were investigated in 118 females and 27 males attending urology clinics. Responses to comparable items were compared by crude percentage agreements and the weighted Kappa statistic.

As anticipated, the prevalence of incontinence was lower in the community (45%) than the clinic sample, with a general increase in prevalence with increasing age ($P<0.05$). Women in the community also reported more incontinence (59%) than men (25%) ($P<0.001$). In addition, there was an expected association between sex and type of incontinence in the clinic and the community sample ($P<0.001$ for both). As anticipated, stress incontinence was the most predominant type in community women, in contrast to men who reported more urge incontinence.

Agreement between responses to ICIQ-SF and BFLUTS items measuring the amount and frequency of incontinence were 'moderate' (85%) and 'good' (93%), with weighted kappa values of 0.42 and 0.77 respectively.

II. RELIABILITY

1. Test-retest reliability

A test-retest analysis was carried out among clinic patients who were sent a second ICIQ-SF to complete within two weeks of their first questionnaire. The data were interpreted by analyses of paired differences between test and retest responses to individual items. Agreement between responses to each item was further analysed using the weighted Kappa statistic. Data were available for 144 clinic patients (121 females, 23 males) completing both questionnaires. The reliability of a sample of 4 of these items is presented below in Figure 3.

Items assessing 'frequency of protection use' and 'amount of leakage' demonstrated excellent test-retest reliability, with a maximum difference of one response category between test and retest (out of 4-10). 'Frequency of leakage' demonstrated good test-retest reliability, with only one patient moving more than two categories. Test-retest reliability was good for the 'problem' associated with frequency of incontinence and impact on 'everyday life', 'social life' and 'sex life', with only 2-5% of patients moving more than one category. 'Overall quality of life' and 'worst leakage' were less reliable. However, whilst other items measure aspects related to incontinence alone (a condition whose status is unlikely to change significantly during the time points), the quality of life item measures other aspects of the patient's life, which cannot be assumed to remain static in the same manner. These findings were also reflected in the kappa statistics with crude agreements between test and retest responses ranging from 85-96%, and weighted Kappa values of 0.57-0.90, indicating 'good' to 'very good' agreement except 'overall quality of life' and 'worst leakage', which demonstrated 'moderate' agreement.

2. Internal consistency

Cronbach's alpha coefficient was calculated to assess the correlation between items in142 females and 104 males registered with two UK community general practices and 182 females and 41 males attending urology clinics in the UK. The alpha for the nine major items (excluding the descriptive item 2b) was 0.950, indicating a very high level of internal consistency, but also suggesting that there was considerable redundancy in the developmental version (see devising the final version below).

III. RESPONSIVENESS TO CHANGE

206 patients involved in the intervention arm of a community-based trial (MRC Incontinence Community Nurse Practitioner trial) comparing a nurse-practitioner with standard GP care completed the ICIQ-SF. All patients in this observational study were in the nurse-practitioner arm and received advice from the nurse about fluid intake, pelvic floor awareness, bladder education and other conservative therapies over a period of eight weeks (details from Dr C Shaw, committee member). Figure 4 shows the proportions of patients reporting 'any level of symptom' before and after treatment for seven items in the questionnaire. Table 8 shows the

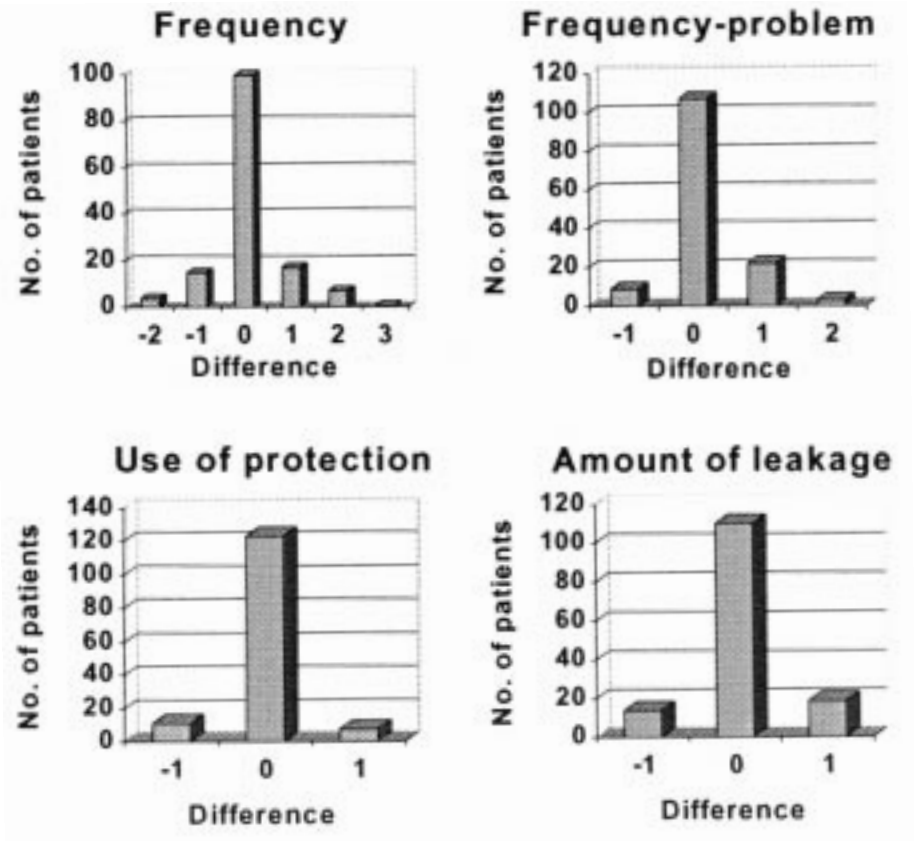

Figure 3 : Reliability of four of the developmental ICIQ-SF items

Table 8 : Change in patients reporting 'any level of symptom' (%) before and after treatment

Symptom/item	Percentage change
Frequency of leakage	-11
Frequency of leakage - problem	-15
Use of protection	-2
Usual amount of leakage	-12
Worst leakage	-7
Impact on everyday life	-12
Impact on social life	-9
Impact on sex life	-2

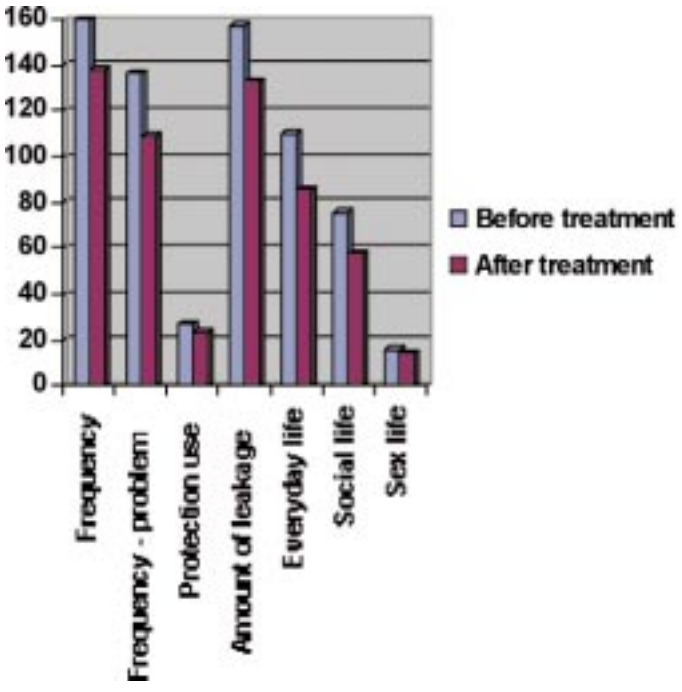

Figure 4 : Number of patients reporting 'Any level of symptom' before and after treatment

percentage change in 'any level of symptom' between baseline and follow-up. Most items were highly statistically significantly better at follow-up than baseline, i.e. 'frequency of leakage' and its associated 'problem', 'amount of leakage', 'worst leakage', impact on 'everyday life' and 'social life' (*P<0.0001*), and one item significantly better; 'impact on sex life' (*P<0.01*). There was also a decrease in the percentage of patients reporting each different type of incontinence. Following treatment, change in 'overall quality of life' and 'use of protection' did not reach statistical significance.

In a separate study, 14 consecutive patients undergoing surgery for incontinence according to normal clinical practice completed the ICIQ-SF four weeks before surgery and then approximately 12 weeks after the procedure. This work is currently ongoing, and numbers are too small for meaningful analyses of individual symptoms, but considerable improvements in all the symptoms indicated in the table above were found – with percentage changes ranging from –36 to –50. With sufficient numbers, it is likely that these changes would be found to be highly statistically (and clinically) significant for individual symptoms (as for scores, see below).

IV. INTERNATIONAL ASPECTS

There are various countries actively participating in the development of the ICIQ. Researchers at the Bristol Urological Institute, UK, acts as coordinators.

The ICIQ-SF has been translated into a number of languages for use in non-English speaking countries (by mid 2001, completed in Dutch, Japanese, Spanish and Swedish languages, and in progress for Arabic, Chinese, German, Italian, Korean, Norwegian and Portuguese) using standard methods:

Initial translation – words and sentences are literally translated and then adapted to the cultural context and lifestyle related to the language in question. This is preferably done by a bilingual native speaker(s) of the language in question who is fluent in both languages, preferably knowledgeable about the content area and aware of the intent of the questionnaire and each item.

Back translation – the final language questionnaire is translated back into the source language (English), preferably by a bilingual native speaker of the source language who was not involved with the translation stage and who is *not* knowledgeable of the content area. Items that have lost or altered their meaning are re-translated.

a) Committee review **-** the translations and back-translations are then reviewed to identify discrepancies in the meaning of confusing or ambiguous items/text in the questionnaire.

b) Pre-testing for equivalence **–** administering the questionnaire to a small sample of patients enables a researcher to probe the patient about their understanding and completion of each item, in order to confirm the face validity and acceptability of the questionnaire and to identify any discrepancies or errors in the translation.

c) Revalidation **–** following adaptation, the questionnaire may need revalidating because the psychometric properties of the scale may not have remained constant as a result of the adaptation process.

1. Adaptation to English-speaking populations

For predominantly English-speaking countries, such as the United States, formal translation and back-translation are not required but it is necessary to adapt the questionnaire to the cultural context. A US study group, consisting of experts and clinicians in the field of urology, was formed to adapt the ICIQ-SF to an American-English speaking population. The UK version of the ICIQ-SF was reviewed and initial minor changes were made. This adapted version is now being pre-tested on a sample of patients in the USA.

2. Japanese ICIQ-SF

The Japanese ICIQ-SF has been administered to consecutive male and female patients with incontinence attending a urology clinics. The relationship between the ICIQ-SF and the King's Health Questionnaire (Japanese version) is being 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 assess responsiveness, patients proceeding to treatment for incontinence according to normal clinical practice were then asked to complete a second questionnaire approximately three months after treatment. Treatment included surgical or medical (drug) intervention, insertion of anti-incontinence devices and conservative management. The relationship between the ICIQ-SF 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) is being investigated in patients clinically diagnosed with stress incontinence.

V. DEVISING THE FINAL VERSION AND A SCORING SCHEME

As indicated above, the developmental version of the ICIQ-SF contained a considerable amount of redundancy. All available baseline data were used – 469 completed questionnaires – to devise the final version and scoring scheme.

The very high Cronbach's alpha statistic of 0.950 (see above) was mirrored by an initial factor analysis which showed one major factor in the developmental version with most items having loadings in excess of 0.73. The only exception was overall quality of life with a loading of 0.55. It is evident that the overall quality of life item measures aspects independent of incontinence both intuitively and as it exhibits the lowest consistency. As it also had the lowest level of test-retest reliability, the first decision made was to drop the overall quality of life item (7) from the final version.

Examination of the cross-tabulation of the frequency and problem items (Q1a, 1b) and the correlation coefficient (0.83) showed that the problem item mostly reflected the symptom frequency – that is, the degree of bothersomeness was related to the severity of the frequency. Thus the 'bother' subquestion was dropped. Similarly, the usual and worst leakage questions (3a, 3b) were also strongly related and highly correlated (0.89) and as the worst leakage had poorer test-retest reliability and higher levels of missing data, it was dropped. The questions concerned with 'impact on social life (5) and impact on daily life (4) were also very highly correlated (0.92), and since 'social life' might prove difficult to translate to other cultures, this item was also dropped.

At this stage, five items remained: 1a (frequency of leakage), 2a (use of protection), 3a (perceived quantity of leakage), 4 (impact on everyday life) and 6 (impact on sex life). The alpha for these 5 items was 0.916.

The questions concerned with protection (2a) and impact on sex life (6) were less responsive to change than the other items. In addition, the sex life item was relevant to a limited number of patients. On this basis, it was decided that the final version of the questionnaire could be reduced to three items (see Fig 5 below), and with the Cronbach's alpha being 0.917, these items could be combined into a single score.

Clinicians have also indicated that a patient's assessment of the cause of their incontinence would be useful, and so a set of questions to explore these issues is included in the final version of the questionnaire. These 'self-diagnostic' items (Fig 6) are not, however, included in the score – they are for descriptive purposes only.

VI. THE PRELIMINARY PERFORMANCE OF THE SCORES

As can be seen, the scores are not identical for each of the items and researchers are encouraged to investigate, for example by sensitivity analyses, the impact of varying the implicit weightings given to each item. The currently recommended score is shown above and ranges from 0 to 21. Table 9 shows descriptive statistics for the score using the preliminary data. Age groups were also significantly different ($p<0.01$).

A number of analyses have been undertaken to investigate the validity and reliability of the score. The correlation between test and retest scores was very high: 0.88 ($p<0.0001$), indicating excellent reliability. The correlation between ICIQ-SF and ICS*male*SF scores was also encouraging: 0.37 ($p=0.065$) for the voiding sub-score and 0.75 ($p<0.0001$) for the incontinence sub-score. There was also a reasonable correlation between the ICIQ-SF score and the ICI pad test in a Japanese study (MG, committee member): 0.40 ($p=0.014$). In the CNP study, there were highly statistically significant improvements in the scores between baseline and follow up: baseline mean 5.81, follow-up mean 3.88 ($p<0.0001$). There were similar findings in the surgical study: baseline mean 16.0, follow-up mean 5.62 ($p=0.0005$).

These preliminary findings suggest that the ICIQ-SF score is valid, reliable and responsive to change – but researchers are encouraged to further explore these aspects. Researchers wishing to contribute to the psychometric testing of the ICIQ-SF are encouraged to contact Jenny Donovan (jenny.Donovan@bris.ac.uk) or Kerry Avery (kerry_martin@bui.ac.uk).

Table 9 : Descriptive statistics for the ICIQ-SF score

	n	Mean	Sd	min	max	P value
All	458	7.18	6.64	0	21	
Community	245	2.36	3.26	0	16	<0.0001
Clinic	213	12.71	5.03	0	21	
Women	309	8.19	6.42	0	21	<0.0001
Men	143	4.94	6.65	0	21	

Figure 5 : Items in the final scored version of the ICIQ-SF

1. How often do you leak urine?

Never=0

About once a week or less often=1

Two or three times a week=2

About once a day=3

Several times a day=4

All the time=5

2. We would like to know how much urine you think leaks. How much urine do you usually leak whether you wear protection or not?

None=0

A small amount=2

A moderate amount=4

A large amount=6

3. Overall, how much does leaking urine interfere with your everyday life?

0 _____10

(0 = not at all) (10 = a great deal)

Figure 6 : 'Self-diagnostic' items in the final version of the ICIQ-SF (not scored)

4. When does urine leak? (please tick all that apply to you)

Never – urine does not leak

Leaks before you can get to the toilet

Leaks when you cough or sneeze

Leaks when you are asleep

Leaks when you are physically active/exercising

Leaks when you have finished urinating and are dressed

Leaks for no obvious reaso

Leaks all the time

APPENDIX II :
VALIDATED QUESTIONNAIRES IN RELATED AREAS

A number of questionnaires reaching acceptable levels of validity and reliability have been developed for the study of related conditions such as benign prostatic disease, prostate cancer or general levels of sexual function, but which do not include incontinence *per se*. Such questionnaires may be useful in conjunction with incontinence-specific measures. Details of these questionnaires were reviewed previously [1].

For men, the following questionnaires have been tested at least to the level of the basic standard of recommended incontinence questionnaires (Committee Grade A or B):

I. ASSESSMENT OF LOWER URINARY TRACT SYMPTOMS (MEN)

AUA Symptom Index. [272]

I-PSS. [272], [319]

Patient-completed modification of the Boyarsky [2] schedule. [320]

II. ASSESSMENT OF QUALITY OF LIFE IN BENIGN PROSTATE DISEASE

BPH Health Related Quality of Life Survey. [275] [321], [322]

BPH Health Related Quality of Life (BPH-HRQOL). [323] [324] [325]

BPH Impact Index. [326]

BPH Health-related QoL survey. [321]

Mayo Health-related Quality of Life. [119] [321] [327]

III. ASSESSMENT OF QUALITY OF LIFE – PROSTATE CANCER

Cancer Rehabilitation Evaluation System - Short Form (CARES-SF) [328]

Prostate Cancer Treatment Outcome Questionnaire (PCTO-Q). [133]

PROSQOLI. [329]

IV. ASSESSMENT OF SEXUAL FUNCTION (WOMEN AND MEN)

Watts Sexual Function Questionnaire. [330]

Medical Outcomes Study (MOS) Sexual Functioning Scale. [336]

Assessment of sexual function (men)

Radiumhemmets Scale of Sexual Function. [288], [331], [332], [333], [334]

International Index of Erectile Function (IIEF). [335]

Sexual Adjustment Questionnaire (SAQ). [134]

Prostate-targeted Health Related Quality of Life. [120]

RECOMMENDATIONS – QUESTIONNAIRES

The following questions are highly recommended (Grade A) or recommended (Grade B) for use in assessing symptoms of incontinence or their impact on quality of life:

SYMPTOMS OF INCONTINENCE

GRADE A: HIGHLY RECOMMENDED

Urogenital Distress Inventory. 57

UDI-6. 50

Urge-UDI. 58

King's Health Questionnaire. 59

(Women only) **Incontinence Severity Index.** 60

(Men only) **DAN-PSS-1.** 61

(Men only) **ICS*male*.** 62

(Men only) **ICS*male*SF** 63

GRADE B: RECOMMENDED

Bristol Lower Urinary Tract Symptoms.64

Symptom Severity Index. 65

BOTHERSOMENESS

GRADE A: HIGHLY RECOMMENDED

DAN-PSS-1. 87

ICS*male*. 62

GRADE B: RECOMMENDED

BFLUTS. 64

GENERIC HEALTH STATUS

GRADE A: HIGHLY RECOMMENDED

SF-36. 102

EuroQol EQ-5D. 103

IMPACT OF INCONTINENCE ON QUALITY OF LIFE

GRADE A: HIGHLY RECOMMENDED

(Men and women) **Quality of life in persons with urinary incontinence (I-QoL).** 130

(Men and women) **King's Health Questionnaire.** 59

(Women only) **Incontinence Impact Questionnaire (IIQ).** 131

(Women only) **IIQ-7.** 50

(Women only) **Urge-IIQ.** 58

(Men only) **Modified IIQ and IIQ-7.** 132

GRADE B: RECOMMENDED

(Women only) **Symptom Impact Index (SII).** 65

(Men only) **ICS*QoL*.** 110

(Men only) **EORTC metastatic prostate cancer.** 133

(Men only) **Changes in Urinary Function.** 134

(Men only) **Prostate-targeted Health Related Quality of Life.** 120

(Men only) **Functional Assessment of Cancer – Bladder/General Scales.** 134 135

SEXUAL FUNCTION/SATISFACTION

GRADE A: HIGHLY RECOMMENDED

The Psychosocial Adjustment to Illness Scale (PAIS). 158

Rust and Golombok Inventory of Sexual Satisfaction. 159

GRADE B: RECOMMENDED

Brief Sexual Function Inventory. 160

BPH QOL9. 161

ICS*sex*. 162

RECOMMENDATIONS

RECOMMENDATIONS FOR CLINICAL PRATICE

The following recommendations were unanimous:

1. Clinicians are encouraged to include in patient evaluations, the highly recommended and recommended patient self-administered questionnaires in the appropriate language, for the assessment of urinary incontinence and its impact on patients' lives.

2. Further and detailed evaluation of the usefulness of the ICIQ-SF in clinical practice is encouraged.

RECOMMENDATIONS FOR RESEARCH

The following recommendations were unanimous:

1. Researchers are strongly encouraged to use the highly recommended questionnaires in randomised controlled trials evaluating treatments which aim to relieve symptoms or reduce impact on quality of life. Evidence from randomised trials not including such measures should not be relied upon.

2. Researchers are recommended to publish further psychometric and clinical testing of recommended and potential questionnaires to ensure their validity, reliability and responsiveness in a wide range of contexts and cultures.

3. To facilitate comparison of results across studies, researchers are strongly encouraged to include the ICIQ-SF in studies evaluating symptoms and/or impact of incontinence on quality of life, and to publish the results to allow the further evaluation of the ICIQ-SF.

4. Researchers are encouraged to conduct research into the development of questionnaires or modules of the ICIQ for specific patient groups for whom general questionnaires may not be appropriate (e.g. children, those with neurological problems, frail elderly, patients with carers).

5. Researchers are encouraged to conduct research to explore other issues of importance to patients with incontinence (e.g. the impact on sexual function and satisfaction, psychological status, economic impact) and develop modules for the ICIQ or separate questionnaires as appropriate.

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