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Incontinence-specific Quality of Life Measures Used in Trials of Treatments for Female Urinary Incontinence: a Systematic Review

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ABSTRACT

This systematic review examined the use of incontinence-specific QOL measures in clinical trials of female incontinence treatments, and systematically evaluated their quality using a standard checklist.

Of 61 trials included in the review, 58 (95.1%) used an incontinence-specific QOL measure. The most commonly used were IIQ (19 papers), I-QoL (12 papers) and UDI (9 papers). Eleven papers (18.0%) used measures which were not referenced or were developed specifically for the study. The eight QOL measures identified had good clinical face validity and measurement properties.

We advise researchers to evaluate carefully the needs of their specific study, and select the QOL measure that is most appropriate in terms of validity, utility and relevance, and discourage the development of new measures. Until better evidence is available on the validity and comparability of measures, we recommend that researchers consider using IIQ or I-QOL with or without UDI in trials of incontinence treatments.

Key words

Systematic review, incontinence-specific quality of life measures, outcome measurement, psychometric properties, clinical face validity

Introduction

The most recent International Continence Society (ICS) definition of urinary incontinence (UI) is '*the complaint of any involuntary leakage of urine'* [1], however this definition does not take into account the wide variability in patient response to symptoms. The previous ICS definition recognised the importance of not only UI symptoms, but also their impact on the patients and those around them: UI was defined as *'the involuntary loss of urine which is objectively demonstrable and a social or hygienic problem'* [2]. In the recommendations for the standardisation of outcome measures for research in adult women with symptoms of lower urinary tract dysfunction, the Standardisation Committee of ICS accepted that UI has an impact on women's quality of life (QOL), suggesting that reliable and sensitive QOL questionnaires should be used in evaluating therapies for UI [3]. The guidelines did not recommend the use of specific QOL measures, nor did they give specific guidance on the best way to select measures. Four helpful review articles published recently, described a range of QOL measures for use in evaluating UI treatments, but did not quantify how widely individual measures are used [4-7].

Treatments for UI for women are designed to improve symptoms and incontinence-related QOL, in circumstances when improvements might be considered a benefit, even if a cure is not possible. In clinical trials designed to evaluate treatments, it is therefore important to measure change, not only in symptoms, but also to measure the impact of treatments on QOL. Therefore in clinical trials of such treatments, the inclusion of a measure of QOL is particularly important.

We set out to examine the use of incontinence-specific QOL measures in clinical trials, by undertaking a systematic review of evaluations of incontinence treatments for women, where QOL measures had been used to assess outcome, and to review the quality of the QOL measures identified. Our intention was to make recommendations for future use of such measures in clinical evaluations.

Method

A two stage methodology was used to review the literature: first, a review of trials was undertaken to determine what outcome measures were being used. Secondly, the quality of the outcomes was evaluated using a pre-defined checklist.

Stage 1: Review of Measures used in Clinical Trials

A systematic search of English language papers were carried out in PubMed (1966 to March 2004). The search used the words 'urinary incontinence' and 'quality of life' or 'patient satisfaction' or 'patient perception' or 'health status', and was limited to 'English', 'human', 'female' and 'clinical trial'. Abstracts of all the papers were reviewed by one reviewer (SR). Review articles and editorials were excluded, as were papers that did not solely investigate women, did not use QOL as an outcome, or did not investigate a treatment for incontinence. For the purpose of the review, the definition of QOL included impact of incontinence on quality of life.

All potentially relevant papers, including those describing behavioural, drug, surgical and management trials, were obtained and reviewed. Data from the relevant papers were extracted and entered into an Excel database by SR, and details were checked by AK: disagreements were resolved by consensus, or by arbitration by DS. For the purposes of analysis, where the details of the QOL measure used were not given in the paper, but a single reference was cited, then the details from the reference were used for analysis if these were sufficiently clear. QOL measure details were described as 'unclear' if conflicting details were provided in references.

Stage 2: Review of the Quality of Measures

The review of the quality of measures used a checklist that was originally developed to evaluate QOL measures in the study of menorrhagia [8]. In addition to examining the more usual measurement properties (7 items), the evaluation also involves an examination of clinical validity (10 items). For each of the measures identified, information was determined for each of the criteria in the checklist and entered into a Word table by SR for ease of comparison. All data were checked by DS.

Results

Stage 1: Review of Measures used in Clinical Trials

The search identified 154 potentially relevant papers, published from 1991 to March 2004. Reasons for excluding papers were that: 27 papers did not solely investigate women (i.e. they included both male and female patients or children); 16 papers did not directly investigate a UI treatment (for example, papers that examined UI as an outcome of hysterectomy, spinal cord

injuries, multiple sclerosis, depression, pregnancy or cancer); 40 papers did not include QOL as an outcome measure; ten papers did not discuss a trial of a treatment for UI (including five descriptive studies, two studies investigating prevention of UI, two that validated a QOL measure, and one that described a trial design). Thus the literature search yielded 61 papers that met the pre-defined criteria for inclusion, and reported QOL as an outcome.

The 61 papers, published between 1991 and March 2004, 34 (55.7%) from North America and 13 (21.3%) from Europe, described a wide range of studies, investigating a variety of interventions and employing a number of different research methods (Table 1). Forty-six papers (75.4%) reported using an incontinence-specific QOL measures alone, 3 (4.9%) reported a generic health outcome only, and 12 (19.7%) reported using both types of measure. Ten (16.4%) of the papers used an incontinence-specific QOL measure for which there was neither a reference, nor information about the development or testing of the measure [7;9-17], and one paper used a single question extracted from a validated measure [18]. Forty-seven (77.0%) papers used one of eight previously published incontinence-specific QOL measure (Table 2), of which the most commonly used were IIQ (reported in 19 papers), I-QoL (12 papers) and UDI (9 papers). The most frequently used combinations of incontinence-specific QOL measures were IIQ with UDI (8 papers.[19-26]), and IIQ-7 with UDI-6 (5 papers [25-29]).

Stage 2: Review of the Quality of Measures

Each of the eight incontinence-specific QOL measures is described briefly in Table 3. Each of the measures was reviewed using the evaluation checklist [8]: clinical face validity is reported in Table 4, and measurement properties in Table 5.

Clinical face validity appeared excellent for all measures (Table 4), except that none of the measures permitted supporting patient comments, or included patient ranking of important items. Six of the measures were designed to measure a variety of domains (IIQ, UDI, BFLUTS, I-QOL, KHQ and CONTILIFE), while the short forms of IIQ and UDI (IIQ-7 and UDI-6), YIPS and IQoLI each measure a single domain. Composite scores were available for all but two measures (BFLUTS and KHQ). A separate global QOL rating was available only for KHQ, differentiating this from "how much your bladder problem affects your life". All but one measure were developed from interviews with patients, and the items could therefore be regarded as relevant to patients. Relevance of the measures for clinical assessment was judged to be acceptable for all measures using the definition of inclusion of two or more of: functional items, wellbeing, global evaluation of health or QOL [8].

Measurement properties were reported for all the measures, although the type and quantity of evaluations varied considerably (Table 5). Reliability, criterion or construct validity and responsiveness were reported for all the measures, and appeared acceptable. Interpretability was difficult to examine, because the ranges of possible scores were different, and direction of scores varied: for IIQ, UDI, KHQ, BFLUTS and CONTILIFE, high scores represented most impairment or worst QOL; for I-QOL, YIPS and IQoLI high scores represented least impairment or best QOL. One author presented suggestions for IIQ cut-off points for good, moderate or poor QOL [30], and a difference of at least 5 points was found to be the minimal important difference for KHQ [31]. Acceptability to patients was difficult to determine, because few validation studies reported the number of women contacted to achieve the number of completed questionnaires.

Feasibility was generally acceptable, although only I-QOL and KHQ were available in a broad range of languages. A manual was available for only I-QOL.

UDI, IIQ, I-QOL and KHQ were subject to independent testing in addition to that carried out by the developers of the measures (UDI [30;32-38], IIQ [33;36-39], I-QOL [40], KHQ [41;42]). In general, independent authors were supportive of these measures.

Discussion

From the results of our study, we are able to report that IIQ is the most frequently used measure of incontinence-specific QOL, possibly because it was the first such measure published (in 1994).[43] I-QOL is also frequently used. UDI is often used to complement these QOL measures by evaluating the distress caused by incontinence symptoms**.** The short forms of IIQ (IIQ-7) and UDI (UDI-6) [44] are becoming more common, in order to reduce the burden of questionnaires on patients.

The clinical face validity and measurement properties of these measures are excellent. IIQ and UDI have been particularly well scrutinized by researchers not involved in the original development of the measures. Although the reports by independent researchers are generally positive about IIQ and UDI, some have been critical. The criticisms are as a result of finding poor correlation between pad test weights and IIQ and UDI scores [32;38]. We have previously commented that this could be rather as a result of problems with the pad test, than problems with

IIQ and UDI [45]. Independent evaluation of the measures is an important strength of IIQ and UDI.

Despite the availability of QOL questionnaires, new questionnaires continue to appear, for example CONTILIFE [46] and ICIQ-UI Short Form [47]. The reasons for developing additional questionnaires are not clear, but could be related to the limited range of languages available in previously developed questionnaires. CONTILIFE is available in six European languages, and ICIQ-UI Short Form in 30 languages, although validation data have yet to be published for all the ICIQ translations. ICIQ-UI Short Form is too recent a development to appear in our systematic review.

Although the majority of papers used referenced QOL measures, almost a fifth of the papers used outcomes for which there was neither a reference, nor information about the development or testing of the measure. Given the wide availability of QOL measures in a number of languages, this practice is surprising and should be discouraged.

Our study was limited to a review of a single database (PubMed). The search was designed to be systematic rather than comprehensive, and therefore has not identified all evaluations using QOL measures, nor has it identified all UI measures known to us. For example, Urge-UDI and Urge-IIQ [48], and the Symptom Severity Index and Symptom Impact Index [49] were not found, however the most commonly used measures were identified. Our search was limited to English language reports, and this may be regarded as a limitation, because we inevitably identified English questionnaires, and are unable to comment comprehensively on questionnaires in other languages. Our recommendation includes both IIQ, available in a limited range of languages,

and I-QOL which is available in a number of languages. Availability of a measure in a particular language may determine which measure is most appropriate in a particular setting.

The results of our study lead us to advise researchers to evaluate carefully the needs of their specific study, and select the measure that is most appropriate in terms of validity, utility and relevance. We can recommend the use of the checklist developed by Clarke *et al* for this purpose, because it provides a clear structure for evaluating and comparing different QOL measures [8].

The use of standardised outcome measurement for incontinence-specific QOL is to be strongly encouraged, in order that the results of trials may be combined and compared. We recently pointed out the difficulty in gathering and synthesising meaningful data on incidence and prevalence of UI, because of the variety in definitions of UI [50]: the situation is similar in relation to the measurement of outcome in trials. Without standardisation of measures of incontinence-specific QOL, we will continue to be in the situation where meta-analysis of data is impossible because of the plethora of instruments, the use of un-validated measures, and the inability to combine data from different measures.

This view was reiterated recently by the ICS, and the most recent recommendations from the Third International Consultation on Incontinence will be published in June 2005 (www.continet.org). We believe that our review adds to that work by being more specific about measures for use in urogynaecology, and by highlighting the measures that are actually in current use, as opposed to the more usual reviews of the complete range of measures available [4-7].

Although a number of measures were used frequently, better evidence is needed before concluding which single questionnaire should be considered the gold standard. Until that evidence becomes available, we recommend that researchers consider using IIQ or I-QOL with or without UDI as their first choice of QOL measures in trials of incontinence treatments. Our recommendation is based on the assessment of validity, reliability, responsiveness, utility, and frequency of use of these measures. Consistent use of IIQ or I-QOL with or without UDI would in addition promote options for comparisons between trials.

Table 1 Description of papers included in the review of QOL measures

Description of research	Number of studies n=61	References
Treatment under investigation *		
Pelvic floor muscle training (exercises, vaginal cones or electrical/magnetic stimulation)	21 (34.4%)	10;11;13;19;51-60
Surgical interventions, including bulking agents	13 (21.3%)	12;15;17;18;21;27;28;61;61-66
Pharmacological agents	12 (19.7%)	14;24;29;67-75
Educational/ behavioural intervention	11 (18.0%)	9;23;76-84
Urethral or vaginal devices	8 (13.1%)	16;20;22;85-89
Specialist nurses	2 (3.2%)	25;26
Acupuncture	1 (1.6%)	90
Research design $		
Randomised and quasi-randomised trials	19 (31.1%)	9-11;15;19;21;23-26;52;58;60;64-69;71-77;79-84;88
Prospective studies (eg case series, multi centre series)	43 (70.5%)	11-14;16-18;20;22;27-29;51;53-57;59;61-63;70;78;85-87;89;90

Notes:

* Seven papers examined multiple interventions [9;23;80-84]

$ One paper reported a prospective study and an RCT [11]

Table 2 ***Incontinence-specific measures reported (among the papers which reported using such a measure, n=58)***

Incontinence-specific measures reported	No of studies using this outcome n=58	References
IIQ *		
IIQ (full version) [43]	19 (32.8%)	19-26;54;61;68;76;77;79;80;82-84;89
IIQ-7 [44]	6 (10.3%)	25-29;81
UDI		
UDI (full version) [43]	9 (15.5%)	19-26;87
UDI-6 [44]	5 (8.6%)	25-29
I-QoL [91]	12 (20.7%)	51;55-57;69-71;73;75;81;85;86
BFLUTS [92]	5 (8.6%)	53;59;60;65;67
KHQ [93]	4 (6.9%)	52;62;72;74
CONTILIFE [46]	2 (3.4%)	63;66
YIPS [79]	1 (1.7%)	79
IQoLI [94]	1 (1.7%)	90
Other (unreferenced) measure	11 (19.0%)	9-18

Note:

* One paper presented both the long and short forms of UDI and IIQ [25].

IIQ: Incontinence Impact Questionnaire
UDI: Urogenital Distress Inventory
I-QOL: Incontinence QOL instrument
BFLUTS: Bristol Female Lower Urinary Tract Symptoms questionnaire
KHQ: King's Health Questionnaire
YIPS: York Incontinence Perception Scale
IQoLI: Incontinence QOL Index

Table 3: ***Descriptions of the incontinence-specific QOL measures identified***

QOL Measure	Description of measure	For which patients?	How developed	Population in which tested
IIQ [43 44]	The current IIQ questionnaire asks about 30 activities, and the impact UI has had on these [43]. Each item is scored from 1 (not at all) to 4 (greatly). For each of 4 subscales, the mean score of items in the subscale is calculated, subtract 1, multiply by 100/3. Each subscale has a range of 0 to 100, and the total IIQ score is the sum of all 4 subscales, range 0-400 (high scores are highest impact). An alternative method of scoring simply sums the score for each item, giving a total score of 30 to 120 [30]. (A Dutch translation of IIQ found an additional subscale: embarrassment [35].) A short form was also developed, with 7 items (IIQ-7) each scored 0-3. The average of scores is taken for each patient (range 0-3), multiplied by 33 1/3 - this questionnaire produces a single score for overall impact ranging from 0 to 100, higher score is lower QOL. If more than two items are missing, then a total score should not be calculated. [44].	Women with UI specific to lower urinary tract dysfunction and genital prolapse [44].	Review of literature, previous experience with an earlier questionnaire [38;95 96], face-to-face interviews with patients, interviews with health providers. Two measures were developed, to measure symptoms associated with UI (UDI), and to measure the impact of UI (IIQ) [43]. From the longer forms of the questionnaires, short forms were developed by selecting the items that would correctly predict the long form total score: IIQ-7 and UDI-6 [44].	Originally reported in 162 community-dwelling women recruited into 3 clinical studies (average age 61 years, 96% white, 22% had high school education or less): 104 with genuine stress (GS) UI, 58 with detrusor instability (DI) ± GSUI [43;44]. IIQ has also been tested in other populations by investigators associated with the original research: a 26 item version was given to 69 women in a trial of behavioural treatment [95] and in 123 older community-dwelling women taking part in an RCT of bladder training [76]; and by investigators not associated with the original research: in 36 English and 34 French-speaking women (aged 30 to 80) attending a clinic for symptoms of stress UI [32], in 79 community-dwelling women with UI (mean age 76), 75 women attending a continence clinic (mean age 50), and 83 from a surgical waiting list (mean age 50) [33], 69 women (mean age 56) with stress UI, followed up after treatment [30], 27 women (mean age 56) seeking treatment for stress UI [34] and a Dutch translation tested in 2043 randomly selected community-dwelling women (mean age 47) and 196 patients attending a gynecology clinic (mean age 55) [35]. IIQ-7 has been tested in a telephone survey of 384 community-dwelling incontinent women aged ≥ 60 [36], and in 55 women (mean age 58) attending for surgery for genuine stress UI or POP [37]. IIQ and IIQ-7 have been tested in 150 women (mean age 55) taking part in a trial of an external urethral device [38].
UDI [43 44]	The current UDI questionnaire asks about 19 symptoms, and the degree of 'bother' caused by each [43]. Each item is scored from 1 (not at all) to 4 (greatly). For each of 3 subscales, the mean score of items in the subscale is calculated, subtract 1, multiply by 100/3. Each subscale has a range of 0 to 100, and the	Women with UI specific to lower urinary tract	Review of literature, previous experience with an earlier questionnaire [30;95 96], face-to-face interviews with patients, interviews with health care providers. Two measures were developed, to measure symptoms associated with UI (UDI),	Originally reported in 162 community-dwelling women recruited into 3 clinical studies (average age 61 years, 96% white, 22% had high school education or less): 104 with genuine stress (GS) UI, 58 with detrusor instability (DI) ± GSUI [43;44]. UDI has also been tested in other populations by investigators not associated with the original research:

	total UDI score is the sum of all 3 subscales, with possible scores ranging from 0 to 300 (high scores are highest impact). A short form was also developed, with 6 items (UDI-6) scored 0-3. The average of scores is taken for each patient (range 0-3), multiplied by 33 1/3 - this questionnaire produces a single score for overall symptom distress ranging from 0 to 100, higher score is lower QOL [44].	dysfunction and genital prolapse [44].	and to measure the impact of UI (IIQ) [43]. From the longer forms of the questionnaires, short forms were developed by selecting the items that would correctly predict the long form total score: IIQ-7 and UDI-6 [44].	in 128 women (mean age 61) attending a clinic for lower urinary tract complaints [39], in 79 community-dwelling women with UI (mean age 76), 75 women attending a continence clinic (mean age 50), and 83 from a surgical waiting list (mean age 50) [33]. UDI-6 has been tested in a telephone survey of 384 community-dwelling incontinent women aged ≥ 60 [36], and in 55 women (mean age 58) attending for surgery for genuine stress UI or POP [37]. UDI and UDI-6 have been tested in 150 women (mean age 55) taking part in a trial of an external urethral device [38].
I-QoL [91 97 98]	22 item scale, scored from 1 (extremely) to 5 (not at all). Scores for each item are summed, then transformed to 0 to 100 scale for greater interpretability: higher score is greater QOL. For each of 3 subscales, scores are also summed and transformed to a 0 to 100 scale, higher score is better QOL [91].	People with chronic UI: urge, stress & mixed.	Originally developed from interviews with 20 patients with UI, refined following interviews with a further 17 patients, the I-QOL originally consisted of 28 items, but was reduced to 22 items.	Tested in 62 patients with UI: 68% female, average age 64, 96% white, 39% had high school education or less: 60/62 returned a second questionnaire [91]. Women in a placebo-controlled RCT of duloxetine for stress (141) and mixed (147) incontinence, completed I-QOL before and during treatment in the trial: 76% 45 yrs or over, 93% white [97]. Women in France (n=62), Spain (n=65), Sweden (n=64), and Germany (n=68) were recruited for validation of translations [98]. Direct translations (without psychometric testing) were also prepared for British English, Afrikaans, Norwegian, Finnish, Italian, Danish, Dutch, and adaptations produced for Canadian French, Belgian Flemish, and Australian, New Zealand, South African and Canadian English [98]. A secondary analysis of data from 2 RCTs of duloxetine was used to validate I-QOL in 1133 female patients (mean age 51, 91% white) [40].
BFLUTS [92 99]	34 item questionnaire: 19 symptom questions' (plus asking 'how much of a problem' for each), 4 sexual function questions, 11 QOL questions, and. Each symptom item is scored 1 to 4 or 5 (high indicates worse symptoms), degree of problem scored 1 to 4 (4 is most problematic). BFLUTS-SF (scored form) has 19 items, each scored 0 to 3 or 4 as appropriate. High scores indicate most problems. 3 symptom subscales, 1 subscale for sexual function and 1 for QOL are calculated.	Women with lower urinary tract symptoms.	Developed from ICSmale (previous questionnaire for male patients), after consultation with clinicians, a health scientist, a literature review and discussion with patients. BFLUTS-SF was further developed from BFLUTS in women who were part of an RCT [99].	Tested in 85 consecutive women attending for urodynamics (mean age 51). Test-retest done 2 weeks later in 20 symptomatic women who had received no treatment. 20 women in the community also completed the questionnaire (mean age 41) [92]. BFLUTS-SF was developed and tested in 344 women with stress incontinence who were taking part in an RCT of TVT versus colposuspension [83 99].
KHQ [93]	Questionnaire with 21 QOL questions: 2 general items (general health perceptions and incontinence impact), 19 QOL questions, 4 point score for each item (with not applicable option for personal relationship items): 8	Women with UI.	Detailed urinary symptom questionnaire that asked about problems associated with UI with 1105 patients, review of the literature, discussion with clinicians and with women.	293 consecutive women referred for urodynamic investigation, test-retest with 110 women, 193 women asked to complete SF-36. Mean age 51.4yr, a variety of urodynamic diagnoses [93]. KHQ is available in a number of languages and was tested in a tolterodine clinical trial involving 1529 patients: 1284

	domains, with scores for each ranging between 0 and 100 (high scores = greater impairment, ie worst QOL). A six item short form has been developed in Japan, with two domains ('limitations of daily life' and 'mental health'), scored similarly to KHQ, and a total score [100].			completed questionnaires (79% female, mean age 60 yrs) in 14 countries [101]. Data from the tolterodine trial, and a further study involving 827 patients was used to determine the minimally significant difference in KHQ [31]. Further validation has been carried out for a Japanese version, in 293 overactive bladder patients with urge incontinence (67% female, mean age 62) [102], and a Portuguese version in 68 women having sling procedures for SUI [103].
CONTILIFE [46]	Questionnaire with 28 items, 5 or 6 point Likert scale for each, produce a global score, and a score for each dimension (daily activities, effort activities, self-image, emotional consequences, sexuality, well-being). Scores range from 0 to 100, higher score is lower QOL [46].	Women with stress, urge and mixed incontinence.	Developed from an unspecified urge urinary incontinence questionnaire. Interviews with 12 patients to identify additional concepts [104]. Originally developed in French, later translations into Belgian, Danish, English, German and Dutch [46].	Questionnaire tested in 104 patients with stress, urge and mixed incontinence, (mean age 50) [104]. Translations tested in 505 Belgian, Danish, English, French, German and Dutch women [46].
YIPS [79]	Questionnaire with 8 items (scored 1 to 7), additive scores 7 to 56, higher scores indicate least impact. 3 additional questions about change in incontinence and general health.	Women with UI.	Open ended questions to patients to identify the physical & psychosocial consequences of incontinence. [79;105] YIPS was developed from psychometric item analysis & selection for psychosocial content.	Questionnaire tested in women from a rural Canadian area, taking part in an incontinence trial, mean age 67, 78% had secondary education or less.
IQoLI [106 94]	Questionnaire with 25 items, scored from 0 to 3. Range of scores from 0 (poor UI specific QOL) to 75 (high UI specific QOL).	Women with urge UI.	Originally developed from interviews with 7 male and 13 female urge UI patients in Sweden: original interviews highlighted differences between male and female response to UI, so further development was for an instrument for women [94]. English translations were reviewed by 9 Canadian women, field tested with 19 UK & 16 Canadian women [106]	In Sweden, 44 women with urge UI (5 incontinence clinics) were asked to comment on suitability and difficulties completing IQoLI. Reliability and validity tested in 79 Swedish women taking part in a double-blind RCT. Reliability, internal consistency and construct validity were further tested: in the UK, 42 women with urge or mixed incontinence (mean age 53); in Canada, 25 women with urge UI (mean age 66).

Table 4: ***Face validity of the incontinence-specific QOL measures identified ****

QOL Measure	QOL definition	Reasons for developing instrument	Domains	Single composite score	Separate global rating	Distinguished overall QOL from health related QOL	Relevance of items to patients	Relevance of items to clinicians: functional, wellbeing & global items
IIQ [43 44]	The ways in which UI interferes with different aspects (activities, roles and emotional states) of women's daily lives.	To address a gap in the UI literature: lack of a UI-specific measure of health-related QOL.	Four subscales of 30-item version: physical activity (6 items), travel (6 items), social relationships (10 items), emotional health (8 items). IIQ-7 has a single domain: life impact caused by UI.	Yes: 0-400 for IIQ, 0-100 for IIQ-7 (high scores are low QOL).	No.	No - no measure of overall QOL.	Developed using interviews with patients to ensure full range of items and relevance of items.	Development of questionnaire involved interviews with health care providers. Questionnaire includes functional and wellbeing items (no global items).
UDI [43 44]	Symptoms associated with UI, and the 'bother' caused by those symptoms.	To address a gap in the UI literature: lack of a UI-specific measure of health-related QOL.	Three subscales of 19-item version: irritative symptoms (6 items), obstructive/discomfort (11 items), stress symptoms (2 items). UDI-6 has a single domain: distress caused by UI.	Yes: 0-300 for UDI, 0-100 for UDI-6 (high scores are low QOL).	No.	No - no measure of overall QOL.	Developed using interviews with patients to ensure full range of items and relevance of items.	Development of questionnaire involved interviews with health care providers. Questionnaire includes functional and wellbeing items (no global items).
I-QoL [97 91 98]	Subjective QOL associated with UI and its treatment.	For use in clinical trials covering patients with varying types and severity of UI. Also for use in patient care.	Three subscales: avoidance & limiting behaviours (8 items), psychosocial impacts (9 items), social embarrassment (5 items).	Yes: 0-100 (100 is high QOL).	No.	No - no measure of overall QOL.	Patient interviews were used to develop questions, and to further refine measure.	Questionnaire includes functional and wellbeing items (no global items).

BFLUTS [92 99]	Symptom severity and impact on daily activities and social interactions.	To develop a questionnaire sensitive to changes in FLUTS, that would characterise symptom severity, impact on QOL, and evaluate treatment outcome. Designed for clinical & research use.	BFLUTS has 3 domains: symptoms, sexual matters, & lifestyle impact [92]. BFLUTS-SF has 3 subscale scores for incontinence, voiding and filling symptoms, and a combined symptom score, plus subscales for sexual function and QOL [99].	BFLUTS: no - individual items. BFLUTS-SF has a composite score for symptoms.	No: in BFLUTS-SF, an 'overall' question asks how much urinary symptoms interferes with life [99].	No - no measure of overall QOL.	Discussions with patients were conducted when developing the BFLUTS questionnaire.	Development of questionnaire involved interviews with clinicians. Questionnaire includes functional and wellbeing items (no global items).
KHQ [93]	QOL, strategies for coping, & severity of symptoms.	A condition-specific QOL questionnaire for the assessment of women with UI.	General health perception (1 item) plus 8 QOL domains: incontinence impact (1 item), role limitations (2 items), physical limitations (2 items), social limitations (3 items), personal relationships (2 items), emotions (3 items), sleep/energy disturbance (2 items), severity measures (5 items) [107]. Japanese short form has two domains ('limitations of daily life' and 'mental health') [100].	For KHQ, no - domain scores. Japanese short form has a total score as well as the 2 domains.	Yes - 'how would you describe your health at present?'	Yes - question about general health & about 'how much your bladder problem affects your life'.	Questionnaire developed from patient questionnaires about incontinence, and discussion with women.	Development of questionnaire involved discussion with clinicians. Questionnaire includes functional and wellbeing items.
CONTILIFE [46]	The impact of UI on women's QOL [104].	To develop a subjective measure available in a number of languages, for use in pharmaceutical trials [46]	A global score (27 items) and 6 domains: daily activities, effort activities, self-image, emotional consequences, sexuality, well-being [46].	Yes: 0-100 (100 is poor QOL) [46].	No. The 'Global' measure is worded as 'taking your UI into account' [46].	No - no measure of overall QOL.	Patient interviews were used to identify measurememnt concepts [104].	Questionnaire includes functional and wellbeing items (no global items).

YIPS [79]	Psychosocial impact of UI.	To advance understanding of the role of psychosocial components in the management of incontinence. Based on cognitive social learning theory of control & well-being.	Single domain: psychosocial aspects.	Yes: scores 7-56 (56 is high QOL).	No, but asks – 'has your health status changed over past 6 months?'	No - domain of psycho-social impact, & single health status question, no measure of overall QOL.	Content areas identified from interviews with patients with UI.	Questionnaire includes wellbeing items and change in health status over past 6 months.
IQoLI [106 94]	Extent to which individuals' lives have been affected by urge UI: the emotional, social & physical impacts on QOL.	To measure QOL associated with clinically important change, that would be sensitive enough to detect small differences between therapies for urge UI.	Single domain: urge UI-related QOL.	Yes: range 0-75 (75 is high QOL).	No.	No - no measure of overall QOL.	Developed from interviews with patients, plus further interviews with patients to evaluate face validity.	Questionnaire includes functional and wellbeing items (no global items).

Note:

* This table does not include two items from the Clark *et al* checklist (inclusion of supporting patient comments, and rating of importance of items), because none of the measures include relevant items.

Table 5: ***Measurement properties of the incontinence-specific QOL measures reported in the original development work, or in other validation studies***

QOL Measure	Reliability	Criterion or construct validity	Responsiveness	Interpretability	Acceptability	Feasibility	Standardisation
IIQ [43 44]	Test-retest was good at 1 (r=0.73, p=0.0001) and 6 weeks (r=0.65, p=0.001) [95]. Internal consistency for subscales: physical activity (CA=0.87), travel (CA=0.87), social relationships (CA=0.90), emotional health (CA=0.90) [43]. For English and French versions, test-retest reliability was moderate (ICC ≥ 0.73), and each IIQ subscale demonstrated good internal consistency (CA 0.81 to 0.91) [32]. Internal consistency tested in another study and found to be good for IIQ (CA=0.95), and for IIQ-7 (CA=0.84) [38]. There was a clinically trivial but statistically significant difference in IIQ scores 5 days apart (thought to be a research effect), 28/30 items performed well on test-retest [33].	Women with detrusor instability (± sphincteric incompetence) had higher IIQ scores than those with sphincteric incompetence alone, modest correlations were found between IIQ score and # incontinence episodes/week and fluid loss [95]. IIQ measure correlated significantly with psychological and health status measures (correlations ranged from 0.37-0.52, only one of the 16 correlations was not statistically significant). Moderate correlation suggests IIQ measures something beyond health status. Total IIQ correlated significantly with incontinence episodes over past 7 days and leakage on pad test [43]. IIQ-7 total score correlated 0.97 with long form total [44]. Women with more episodes of urine loss, and more severe urine loss, had higher IIQ-7 scores [36]. Moderate correlations were found with IIQ and number of pads/day and severity ratings, but not with a 5 min pad test [32]. Another study found poor correlation between pad test weight and IIQ and IIQ-7 scores [38]. Higher IIQ scores were associated with greater severity of UI, and IIQ showed expected associations with measures of anxiety and health status [33]. Individual items were useful for discriminating between mild or moderate incontinence,	There were statistically significant changes in IIQ total score and subscales over the 3 months of the trials [43]. Comparisons of pre- and post-treatment IIQ-7 scores detected improvement in clinical status ($p<0.001$) [44]. A further study found that all subscales and composite IIQ score were significantly improved following bladder training with effects maintained 6 months later [76]. Patients who were subjectively incontinent and who underwent incontinence surgery, had reduced IIQ-7 scores after surgery [37]. Another study found IIQ and IIQ-7 scores were responsive to change [38]. There was a highly significant decrease in total IIQ score between baseline and post-intervention assessments [33]. The standard IIQ summed score underestimated magnitude of change in incontinence severity as a result of treatment [34].	Not clear - single score of 0 to 400 [43], or 30 to 120 [30] for IIQ, 0 to 100 for IIQ-7 [44] with high scores indicating worst QOL. Cut-off scores have been suggested for the total IIQ score: <50/120 represents good QOL, 50 to 70/120 is moderate QOL, >70/120 indicates poor QOL [30].	Of the IIQ, 90% answered all items, 8% missed 1 item, 1% missed 2 items, 1% missed 4 items. For the IIQ-7, only 1 subject missed a single response [44].	Scores are formed from the raw item scores, transforming fairly simply to scale scores [43 44], or else simply summing socres [30]. IIQ is also available, and has been validated, in Canadian French [32].	No manual or normal data. Data are available from a number of other investigators in publications.

		but few distinguish between women with severe incontinence [34].					
UDI [43 44]	Internal consistency for subscales: irritative symptoms (CA=0.70), obstructive/discomfort (CA=0.77), stress symptoms (CA=0.48) [43]. Internal consistency tested in another study and found to be reasonable for UDI (CA=0.76), poor for UDI-6 (CA=0.52) [38]. There was a clinically trivial but statistically significant difference in UDI scores 5 days apart (thought to be a research effect), 18/19 items performed well on test-retest [33].	UDI measure correlated significantly for 9/16 comparisons with psychological and health status measures, with correlations ranging from 0.09-0.40. Moderate correlation suggests UDI measures something beyond health status. Total UDI correlated significantly with incontinence episodes over past 7 days and leakage on pad test [43]. UDI-6 total score correlated 0.93 with long form total [44]. Women with more episodes of urine loss, and more severe urine loss, had higher UDI-6 scores [36]. Responses to questions from UDI-6 predicted whether stress UI, bladder outlet obstruction, and detrusor overactivity were found on urodynamic testing [39]. Another study found poor correlation between pad test weight and UDI and UDI-6 scores [38]. Higher UDI scores were associated with greater severity of UI [33].	There were statistically significant improvements in UDI total score and subscales over the 3 months of the trials [43]. Comparisons of pre- and post-treatment UDI-6 scores detected improvement in clinical status ($p<0.001$) [44]. Patients who underwent incontinence surgery, and who were subjectively incontinent, had reduced UDI-6 scores [37]. Another study found UDI and UDI-6 scores were responsive to change [38]. There was a highly significant decrease in total UDI score between baseline and post-intervention assessments [33].	Not clear - single score of 0 to 300 for UDI, 0 to 100 for UDI-6 with high scores indicating worst QOL [43 44].	Of the UDI, 98% answered all items, 2% missed 1 item. For the UDI-6, all responses were complete [44].	Scores are formed from the raw item scores, transforming fairly simply to scale scores [43 44].	No manual or normal data. Data are available from a number of other investigators in publications.
I-QoL [97 91 98]	Internal consistency, overall CA=0.95, subscale CA= 0.87 to 0.93. Test-retest, overall r=0.93 after 18 days, ICC for subscales, 0.87 to 91 at 2 weeks. Similar results were found in France, Spain, Sweden, Germany. [91 97 98].	Discriminant validity: severity of incontinence ($p<0.0001$), number of medical appointments over past year ($p<0.001$), significantly predicted I-QoL scores. Convergent validity for I-QoL with PGWB ranged from correlations of 0.45 (behavioural & emotional control) to 0.62 (total PGWB), & with SF-36 ranged from 0.35 (bodily pain) to 0.67 (role, physical) [91]. Correlations were much lower in another study, eg correlation with total PGWB was 0.43 (vs 0.62), SF-36 physical function was 0.42 (vs 0.53) [97]. I-QOL scores were higher (better QOL) for patients with perceived less severity (Spearman r=-0.50 ($p<0.0001$), and for those with greatest improvement in urinary tract condition	I-QoL was capable of discriminating between different levels of perceived severity (women who reported being 'very much better' had 13% improvement in score), frequency of incontinence episodes (25% decrease in episodes was associated with a 2% drop in I-QoL) and pad test weights (25% decrease in pad weight was associated with a 2% drop in I-QoL) [91 97].	Not clear - single score of 0 to 100 with 100 indicating best QoL [97].	>90% response reported, and of those, 97% completed a second questionnaire [91].	Scores of items are summed, and transformed to 0-100 score (for total score and subscales). Translations available in 11 languages (plus 6 variants) [98].	Manual available from Medical Outcomes Trust (www.outcomes-trust.org). No normal data, but data are available in publications.

		(Spearman r=-0.43, p<0.0001) [40].					
BFLUTS [92 99]	BFLUTS - Internal consistency: for symptoms CA = 0.78, for the problem questions, CA = 0.85. Test-retest reliability, questionnaire repeated after 2 weeks: 78% of questions on symptoms & problems were answered identically on both occasions & 97% within one category [92]. BFLUTS-SF – Internal consistency for 3 symptom factors, sex and QOL subscales, CA= 0.66 to 0.75 [99].	Women in the community reported lower levels of symptoms and less 'bother', compared to clinic attendees. 87% of estimated daytime micturitions were within 1 category of the frequency/volume chart, 82% of estimates of nocturnal micturitions were identical to chart. Questionnaire items designed to assess degree of UI correlated reasonably with pad test results (eg quantity of urine lost Spearman r=0.30 (p<0.05), number of leakage episodes 0.67 (p<0.001)) [92].	Not reported for BFLUTS. For BFLUTS-SF, 13/18 items improved between baseline and follow-up after stress UI surgery. Incontinence scores improved by 9 units, QOL improved by 6 units [99].	BFLUTS - single items, clear answers to each [92]. BFLUTS-SF subscales are the sum of items that make up each subscale (ranging from 0 to 6 and 0 to 20 for different subscales): the meaning and comparability of subscales is not clear [99]	BFLUTS - 85 respondents: number of women originally approached is not reported. Number of missing items was 2% (0 to 8%) [92]. BFLUTS-SF – 322/344 (93%) women in RCT completed the questionnaire at baseline, 286/344 (83%) at 6 months follow-up. All items had less than 5% missing data [99].	Questionnaire took 10 to 15 mins to complete. Items are analysed individually [92]. Has been used in a Korean translation [53;59]	No manual or normal data are available.
KHQ [93]	Internal consistency: CA >0.72 for all domains. Test-retest Spearman r>0.80 for all domains (mean time between 9.2days) [93]. Pooled analysis (in a 14 country trial of treatments for overactive bladder) found CA ≥ 0.70 for all domains [101]. (Canadian responses on the physical	Highly significant correlation (p<0.01) between common domain scores for SF-36 and KHQ. Modest correlation (Spearman r=0.23) for general health and incontinence impact. Incontinence impact scores were higher for women with detrusor instability than those with genuine stress UI, and significantly lower for women with normal urodynamics (p<0.05) [93]. KHQ domains correlated significantly with mean incontinence episodes/week	KHQ demonstrated change from baseline to end of treatment period that increased with increase perception of improvement in bladder condition. Correlation analyses supported the responsiveness, measured by change from baseline [93]. Floor and ceiling effects were observed in some domains: patients at the 'best' level could not report an	Not clear – all domains scored from 0 to 100, with 100 indicating greatest impairment [93]. Minimal important differences were calculated using the	97% correctly completed questionnaires received, completion time 10 mins [93]. Missing values <5% except for personal	Scoring information is available [107]. KHQ has been used in 17 different countries in a variety of languages [101-103].	No manual or normal data are available.

	limitation domain showed low levels of internal consistency, CA=0.21 [101].) The Japanese version demonstrated good reliability (CA >0.63) except for personal relationships for males (CA=0.47), and severity domain for females (CA=0.59) [102]. For the Japanese short form, internal consistency was acceptable for domains and total score in women (CA > 0.69) [100]. The Portuguese version demonstrated better internal consistency after women had surgical procedures (CA=0.75 to 0.95 after, versus 0.41 to 0.90 before) [103].	(except personal relationship domain and general health perception), mean micturitions/24 hrs (except personal relationship domain) and patient-reported measures (eg perception of bladder condition) [101]. The Japanese version was considered to have good discriminant, convergent and construct validity [102]. Objective parameters (eg pad test) were strongly correlated with post-treatment Portuguese KHQ scores [103].	improvement & those at the 'worst' level could not report a decline [101]. The Japanese version was sensitive to change in patients' perception of bladder condition [102]. Responsiveness of the Portuguese KHQ (measured using standardized effect size and standardized response mean) demonstrated a large effect size for each domain [103].	results from two multinational studies: a difference of at least 5 points was found to be meaningful to patients and clinically meaningful [31].	relationships (6.7%) and sex life (7.7%) [101]. Not applicable and missing values meant that up to 81% (Belgium) had missing domain scores [101]. For the Japanese version, there were <5% missing responses, except for sex life (5.8%) [102].		
CONTILIFE [46]	Internal reliability, CA > 0.76 , good test-retest reproducibility (ICC 0.87 to 94) [104]. Internal consistency was satisfactory overall (CA = 0.71 to 0.94), but lower for the French, Dutch and German groups for 'effort activities' (CA = 0.56 to 0.69) [46]. Convergent validity was good for each item with its own dimension was good (except for being 'away from your home' as an item among the 'daily activities' dimension) [46].	Clinical validity was demonstrated by significant impairment in QOL in patients reporting urinary leaks, greater urge- and stress-related urinary handicap, p<0.0005 [104]. Similar results were found in the international trial, p<0.0007 [46].	In women who were considered 'improved' during a trial of a new drug, mean changes in QOL were highly significantly negative (ie QOL improved); for minimally improved women, mean changes were significantly improved [46].	Not clear - single score of 0-100 global score and for each domain (100 is poor QOL) [46].	Mean number of data items missing per questionnaire varied from 1.17% items/questionnaire (Netherlands) to 3.36% (Belgium). Sexual intercourse was the item with the highest number of missing data (up to 20% of	Access to scoring method and translations are only available through Mapi Research Trust (http://www.mapi-research.fr/).	No normal data are available.

					questionnaires) [46]		
YIPS [79]	Internal consistency: CA = 0.78. Reproducibility not reported [79].	Significant correlation with IIQ, higher YIPS scores for women with fewer incontinence episodes. Able to distinguish between intervention and control groups [79].	No differences between groups at baseline, but YIPS scores were higher for treatment group than control group [79].	Not clear - single score of 7 to 56 with 56 indicating least impairment [79].	101 women completed YIPS – number approached unknown [79].	Simple questionnaire, 8 items with scores summed, plus 3 change in status questions [79].	No manual or normal data.
IQoLI [106] [94]	Internal consistency: CA = 0.90 (Sweden) [94], 0.87 (UK) , 0.91 (Canada) [106]. Test-retest: Spearman correlation coefficient 0.92 (Sweden) [94], 0.86 (UK), 0.88 (Canada), demonstrating a low level of random measurement error [106].	Construct validity: women who reported more discomfort (due to urge UI) had lower IQoLI scores (UK $p<0.04$, Canada $p<0.01$), women who reported worse perceived health (due to urge UI) had lower IQoLI scores (UK $p<0.01$, Canada $p<0.005$) [106]. IQoLI was more sensitive to change than generic health status measures (GWBI (Canada, Sweden), SF-36 (Canada)) [106].	Questionnaire given at baseline and 3 months after the intervention: there was a statistically significant improvement for women in the treatment group ($p<0.001$), but not for the control group [94].	Not clear - single score of 0 to 75 with high score indicating better QOL [94].	0.7% of items were missing [106].	Questionnaire took 8 to 40 mins to complete (with interview). Scores of items are summed to produce score. Available in English and Canadian English [106].	No manual or normal data.

Notes:
CA = Crohnbach's α – a measure of internal consistency - desirable values > 0.70
ICC = Intraclass correlation – used to assess consistency between measurements of the same variable – ICC would be 1 if all subjects gave identical answers each time
Spearman's rank correlation – a measure of the strength of correlation between two variables within the same measurement

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