The I-QOL
(Incontinence Quality of Life)

A Quality of Life Instrument Specific to Urinary Incontinence

Donald L. Patrick, PhD, MSPH, University of Washington
Mona Martin, RN, MPA, Health Research Associates, Inc.
Donald M. Bushnell, MA, Health Research Associates, Inc.

User's Manual

Revised: March 2013

Table of Contents

I-QOL User's Manual

Table of Contents
I-QOL User's Manual
(Continued)

Purpose of this Manual

The purpose of this manual is to describe the development, measurement properties, and potential applications of the Urinary Incontinence-Specific Quality-of-Life Instrument (I-QOL). In addition, the manual is intended to facilitate administration, scoring, and interpretation of I-QOL results. This manual addresses the development and both cross-sectional and longitudinal validation of the US I-QOL, the cultural adaptation and cross-sectional validation of the instrument in four European languages (French, German, Spanish, and Swedish), and the translation only methodologies for additional versions of the I-QOL. The number of I-QOL translations continues to expand -- see the Seattle Quality of Life Group website for the list of language versions currently available: http://depts.washington.edu/seaqol/IQOL.

Suggested Citation:

Patrick D, Martin M, Bushnell D, Yalcin I, Wagner T, Buesching D. Quality of life of women with urinary incontinence further development of the incontinence quality of life instrument (I-QOL). Urology 1999; 53(1): 71-6.

Several subsequent validation studies have been published and will be available on the website as shown below.

Applications of the I-QOL:

For examples of studies which have used the I-QOL in their research, go to the Seattle Quality of Life Group website: http://depts.washington.edu/seaqol/IQOL.

Address all inquiries concerning this manual to:

Donald L. Patrick, PhD, MSPH
Professor, Department of Health Services
University of Washington, Box 359455
Seattle, Washington 98195

We thank Don Buesching for his dedication to the I-QOL. We also wish to thank the clinicians and quality of life experts from the many countries that have participated in studies using the I-QOL, improving in its development.

The views expressed in this manual are the authors' own and do not necessarily represent the opinions of all the investigators participating in the project nor the views or policy of Eli Lilly and Company or Astra-Zeneca.

User Agreement

The University of Washington holds the copyright to all language versions of the I-QOL.

Users of the I-QOL are *not* authorized to make *any* changes to the instrument. Because the developers are interested in further reliability and validity documentation, I-QOL users are kindly asked to provide copies of any publications or reports resulting from its use to Dr. Donald Patrick:

Donald Patrick, PhD, MSPH
Seattle Quality of Life Group
Department of Health Services
University of Washington, Box 359455
Seattle, WA 98195
United States of America

Introduction and Significance

Significance

Urinary incontinence (UI) is characterized as the involuntary loss of urine sufficient enough to be recognized by the persons affected or others as a problem.[1] Stress incontinence was defined as the involuntary loss of urine during coughing, sneezing, or physical exertion with the participant remaining dry at night. Mixed incontinence was defined as a combination of stress and urge or the involuntary loss of urine associated with a sudden, strong desire to void (urgency).[2,3] Over recent years, clinical practice guidelines have been developed to address this prevalent condition and the ever-growing options for treatment.[1,4] Both generic outcome measures and urinary incontinence-specific instruments have been used to assess the effects of incontinence on functioning, well being, and all aspects of life.[5-13] Studies continue to confirm the significant impact that UI has on quality of life, particularly for people with moderate or severe conditions.[2,9,11,14]

Global health care initiatives now drive the rising demand for quality-of-life (QOL) measures that can be applied in different cultures. International clinical trials of treatment for urinary incontinence, including stress, urge, and mixed-type incontinence, are increasing in frequency as more and more treatments become available. Treatment options vary widely in cost, side effects, efficacy, and effectiveness.[5,6] Efficacy, or effectiveness, is often evaluated using endpoints such as a decrease in incontinence episodes or reduction in use or weight of incontinence pads. These traditional outcome measures, however, are limited in the extent to which they incorporate patients' perceptions of the effects of incontinence and its treatment. More patient-centered outcomes are increasingly used as complementary evidence of effectiveness in the evaluation of treatment alternatives,[7] including urologic treatments.[8]

Conceptual Model

Conceptual Model

Early decisions made regarding the development of the I-QOL were based on the conceptual model of health-related quality of life (HrQol) as proposed by Patrick and Erickson,[15] where impairments (diagnoses and symptoms), functional status, perceptions, and opportunities (social disadvantage) are distinguished as separate components of HrQol. In this multicomponent approach, assessment of disease and treatment outcomes may include measures of all these concepts and their relationships. Health-related quality of life, however, can sometimes be distinguished from general, perceived quality of life, although a condition such as urinary incontinence can, over time, affect aspects of life that may not be considered "health-related" by persons with the condition, such as respect or love. Perceived quality of life is defined according to a needs-based model[16] that identifies quality of life as the degree to which most or all human needs are met. This approach is similar to that developed by the World Health Organization in the cross-cultural development of a generic quality-of-life measure.[17] The WHOQOL group defined quality of life as "individuals' perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns."[18] The I-QOL was conceived to be such a quality-of-life measure specific to persons with urinary incontinence and was designed to include the most important human concerns related to the symptoms associated with UI. The multidimensional approach utilized in the I-QOL focus groups and interviews, conducted with persons with incontinence, included general questions on eliciting all areas of concern and specific probes into hypothesized areas of impact: social life, family life, job/work, intimate relationships, activities of daily life, household activities, recreation and travel, mental health, physical health, and anxiety/depression. To the maximum possible extent, the content of the measure was defined by the persons with the condition and the items written in the language of these persons.

Overview of Studies

Development of the US version of the I-QOL proceeded as follows:

Early Development

(1) *Review of the literature and existing instruments* to assess the need and scope for an incontinence-specific measure of quality of life and to investigate the content of existing items against what was important to patients
(2) *Establishment of a conceptual framework* of assessment to identify components of perceived quality of life specific to incontinence
(3) *Qualitative data collection to find content* relevant to patients with incontinence in the United States through qualitative individual and group interviews
(4) *Item Generation* including generation of a long list, deletion of items redundant in content, assessment of all items for conforming to the needs-based model, and development of a draft measure
(5) *Cognitive Debriefing Interviews* to assess relevance, clarity, and consistent interpretation of item content

Preliminary Cross-Sectional Psychometric Evaluation

(6) *Initial field test to evaluate psychometric performance* of the I-QOL
(7) *Item reduction analyses* and refinement of I-QOL
(8) *Initial publication* (Wagner, et al., 1996)

Translation and International Harmonization

(9) *Translation into 11 languages* using standardized translation criteria
(10) *International Harmonization* of these 11 languages with US version
(11) *Cultural Adaptation*

Cross-Cultural Psychometric Validation and Longitudinal Validation in the US

(12) *Evaluation of the Psychometric properties of four European versions* (German, Spanish, French, and Swedish) (Patrick, et al., 1999b)
(13) *Evaluation of the Psychometric properties* of the Revised US version
(14) *Evaluation of the Ability to detect change* of the Revised US Version (Patrick, et al., 1999a)

Further Translations Developed

(15) *US Spanish* version developed
(16) *Japanese* version developed subsequently

For the purposes of clarity in this document, the different studies will be named as follows:

INITIAL US VALIDATION STUDY *(step #6 and #7, above)*

INTERNATIONAL VALIDATION STUDY *(step #12, above)*

US VALIDATION AND ABILITY TO DETECT CHANGE STUDY *(steps #13 and #14, above)*

Early Developmental Process and Subdomains

Early Development

In October 1993, Eli Lilly and Company sponsored the development team at the University of Washington (UW), Seattle, to begin the qualitative research necessary to develop an incontinence-specific quality-of-life measure. The overall objective of the I-QOL project was to develop a condition-specific, quality-of-life measure reflecting the daily life impacts in the language of persons who experience urinary incontinence that could be used in epidemiological investigations, clinical trials, and program evaluations.

The work during this stage of the project focused on the review of literature and the existing measures that had been published at that time to evaluate quality of life in populations with urinary incontinence. Both the psychometric properties and coverage of the QOL content were evaluated for each published measure. Preliminary areas of QOL impact were identified in the literature and utilized to draft a semi-structured qualitative interview schedule for individual and focus group administration.

A sample of 20 individuals (stratified by gender, age, type, and severity of incontinence) were recruited from medical clinics in the Seattle area and invited to participate. The demographic description of this population can be found in Table 1 on the following page. A total of three focus groups and nine individual interviews were held. Quality of life research experts and urology clinicians were asked to consult on both the development of the qualitative questions and on the interpretation of the content analysis. Comparison of this qualitative work with the content of existing measures used in published UI studies demonstrated a great deal of disparity between what was being evaluated and what was actually important to patients with incontinence.[19]

TABLE 1: CHARACTERISTICS OF PARTICIPANTS IN EARLY DEVELOPMENT OF THE I-QOL (N=20)

Descriptive Variables	Category Labels	Values (N)	Percent
Age (years) Mean Age for Group = 56.3	30-40 41-50 51-60 61-70 71-80 81-90	4 4 3 6 2 1	20 20 15 30 10 5
Gender	Male Female	5 15	25 75
Ethnicity	Caucasian (non-Hispanic) African American	18 2	90 10
Marital Status	Married or living as married Widowed Separated Divorced Never married	10 1 1 5 3	50 5 5 25 15
Education Level	Some high school Completed high school Some college or vocational school College graduate Graduate or professional school	1 3 6 6 4	5 15 30 30 20

Additional descriptive information was collected from the participants in the early qualitative development work. This included self-reported type of incontinence (See items A4, A5, A6 in "About You," Appendix C),[20] the number of incontinent episodes in an average 24-hour period, the type of treatment each patient had received, and their impression of improvement of their condition following treatment. These data are shown below in Table 2.

TABLE 2: INCONTINENCE-SPECIFIC CHARACTERISTICS OF DEVELOPMENT POPULATION (N=20)

Descriptive Variables	Category Labels	Values (N)	Percent
Self-reported type of incontinence	Urge Stress Mixed	3 1 16	15 5 80
Average number of episodes in a 24-hour period	0-1 2-5 5-10 10+ Continuous leak	2 12 2 2 2	10 60 10 10 10
Type of treatment tried	None Behavioral Therapy Surgery Drug Therapy Combined Drug & Behavioral Therapy Combined Surgery & Behavioral Therapy	8 6 1 3 1 1	40 30 5 15 5 5
Impression of improvement following treatment	No Yes, partially Yes, completely	13 5 2	65 25 10

Information obtained in the early developmental work on the I-QOL showed several areas of QOL impact that caused patients significant distress. These areas tended to be highly related to limitations that incontinence caused on the daily life of patients and the negative feelings it caused them to experience about themselves. Less importance was placed on items that were closer to clinical symptoms.[19] The content in existing measures that had been used in studies up to that time were largely focused on somatic symptoms and very broad functional limitations. Neither of these areas showed significant overlap with the key content resulting from the qualitative work with incontinent participants. Therefore, the UW team considered there was room for developing a new incontinence-specific measure.

The early developmental stage closed with selection of items and formatting of a first draft of the measure, which was then used in cognitive debriefing interviews with an additional 7 patients. The characteristics of this group generally matched those who had been recruited for the initial qualitative work (Tables 1 and 2). The draft I-QOL was administered to these patients followed by a short cognitive debriefing interview that focused on the relevance and importance of each item to the respondent and assessed their interpretation of each item against the meaning of the item as intended by the investigators. These interviews indicated that all 28 items in the draft measure were understandable, relevant, and consistently interpreted by the respondents.

At this point in time, the decisions regarding global trials had not yet been made at Eli Lilly. Therefore, this initial 28-item measure was prepared for the next stage of development -- preliminary assessment of its cross-sectional psychometric performance in a US population.

Development of Subdomains

During the development of the I-QOL, an *a priori* designation of a subscale structure for the I-QOL items was proposed by investigators and then compared to a domain grouping exercise completed by a group of 20 patients with varying types of urinary incontinence. The designated groupings of items resulted in four hypothesized domains (avoidance or limiting behaviors, psychological impacts, social life impacts, and social embarrassment). These subdomain groupings were later evaluated in confirmatory factor analyses (See: Psychometric Properties, Results Section).

Psychometric Properties of the IQOL

Study Design

INITIAL US VALIDATION STUDY

The primary objective of this study was to test the cross-sectional psychometric properties of the 28-item I-QOL that was piloted in the early development stage and to identify any items that could potentially be dropped from the scale.[4]

A total of 68 participants were recruited from urology clinics at the University of Washington Medical Center and screened for eligibility using an algorithm based on self-report symptoms defined by Fultz and Herzog[20] in 1991. People were excluded if they were under age 18 years or if they experienced symptoms inconsistent with stress, urge, or mixed incontinence, such as neurogenic bladder disease.

Each eligible participant was screened and enrolled by telephone and then mailed a survey package containing the 28-item I-QOL. The packages also included two generic instruments for comparison data with generic health status (the SF-36) and general psychological well-being (The Psychological General Well-Being Schedule - PGWB). After the first surveys were completed and returned, the participants were sent a retest package at two weeks.

Sixty-two of these participants (91%) returned the I-QOL questionnaire. A non-respondent analysis on data collected during the initial telephone screen indicated that those failing to return the I-QOL questionnaire did not differ significantly from the enrolled population with respect to age, gender, incontinence type, or self-reported severity.

In addition to the demographic information shown in Table 3, a variety of incontinence-related variables were also collected and shown in Table 4. Tables 3 and 4 appear on the following page.

TABLE 3: CHARACTERISTICS OF PARTICIPANTS IN INITIAL US VALIDATION STUDY (N=62)

Descriptive Variables	Category Labels	Values (N)	Percent
Age (years) Mean Age for Group = 64	30-45 46-60 61-75 76 plus	8 11 31 12	12.9 17.7 50.0 19.4
Gender	Female Male	42 20	67.7 32.3
Ethnicity	Caucasian (non-Hispanic) Native American	59 2	95.2 3.2
Marital Status	Married or living as married Widowed Separated Divorced Never married	23 12 1 21 4	37.1 19.4 1.6 33.9 6.5
Education Level	Some high school Completed high school Some college or vocational school College graduate Graduate or professional school	6 18 23 8 6	9.7 29.0 37.0 12.9 9.7
Income	0-$9,999 $10,000 - $24,999 $25,000 - $49,999 $50,000 and over	16 19 16 8	25.8 30.6 25.8 12.9

Note: variables with number discrepancies are from incomplete data

TABLE 4: INCONTINENCE-RELATED CHARACTERISTICS OF PARTICIPANTS IN INITIAL US VALIDATION STUDY (N=62)

Descriptive Variables	Category Labels	Values (N)	Percent
Length of time with UI	Less than 1 year 1-4 years 5-10 years 11-25 years 26-40 years	1 31 18 6 3	4.8 50.0 29.0 9.7 4.8
Medical Appointments for UI	0 1-3 4-7 12 and over	24 25 7 4	38.7 40.3 11.3 6.5
Surgery for UI	Yes No	12 48	19.4 77.4
Self-Rated Severity	Mild Moderate Severe	20 17 24	32.3 27.4 38.7
UI type	Stress Urge Mixed	6 4 52	9.7 6.5 83.9

Note: variables with number discrepancies are from incomplete data

Cross-Cultural Translation and Adaptations

Overview

The original instrument was developed in Seattle in the United States.[4] Both translation activities and cross-sectional validation studies were conducted in France, Spain, Sweden, and Germany. Because of resource constraints, direct translations and cultural adaptations without any psychometric validation were made for British English, Afrikaans, Norwegian, Finnish, Italian, Danish, and Dutch.

The project to develop these initial I-QOL translations and additional cultural adaptations was coordinated by the University of Washington. MAPI (Lyon, France) was contracted to coordinate the activities between the European countries and to organize a central meeting for international harmonization of these 11 translations.

Translation Methods

Experienced quality-of-life researchers in each country provided the first independent forward translations. These QOL experts were asked to locate a second researcher or linguistic expert in their country who developed a second independent translation. These two experts worked together to develop a single reconciled version, which was then tested on eight incontinent women. In addition to responding to issues of relevance, clarity, and format, these women were asked to "think aloud" and describe the meaning that each item presented to them, a form of cognitive debriefing. The reconciled forward translations and the comments from patient interviews were then prepared for review at an international harmonization meeting with all QOL experts present. Each item was reviewed in sequence and assessed for both conceptual and linguistic equivalence. All suggested changes for achieving maximal equivalence were reviewed by the developers of the I-QOL to maintain content validity against the qualitative data derived from the original interviews in the US.

During the international harmonization process, it became clear that equivalence across so many different translations was difficult to achieve in terms of a consistent response scale structure. In order to solve these discrepancies, it was necessary to adopt a five-point, Likert-type scale over the original four-point scale used in the INITIAL US VALIDATION STUDY.[4] The five-point response scale was adopted for all versions and incorporated into the subsequent re-validation study in the United States.[21] In addition, various translation difficulties required phrasing changes (such as "urinary problems" instead of incontinence) in order to maintain appropriateness for participant understanding in the different countries. Finally, conceptual equivalents were accepted in many of the translations, such as "I'm afraid of…." instead of "I worry that…." due to the differences in language use across cultures.

Additional Language Adaptations

Following international harmonization of the primary translations, language adaptations were made from the French (for French Canada), the Dutch (for Belgian Flemish), the UK English (for Australia, New Zealand, South Africa), and US English version (for English Canada). Cultural differences were assessed by recruiting a primary QOL research consultant in each country who reviewed the translation and made culturally appropriate changes in the translated versions which held constant the concepts and meanings of the items, but provided more culturally appropriate idioms and language structure. These adapted translations were then reviewed with a second translation expert in each country and reconciled prior to being tested on eight women with urinary incontinence.

All final translations and adaptations were backwards translated, and the results were compared to the original US English instrument. Discrepancies were then discussed once more with the primary QOL consultant for the forward translation process and resolved with the developers of the original measure.

Additional Translations and Cultural Adaptations

In January 1999, Health Research Associates (HRA) prepared an additional language adaptation from the Iberian Spanish version of the I-QOL for use with multi-ethnic Spanish speaking populations in the USA. This adaptation followed the *same procedure as indicated above*, with the following additions:

(1) The primary and secondary translation consultants were selected to represent two separate multi-ethnic language groups (South American and Chicano);

(2) The reconciliation meeting was coordinated by two project staff from Health Research Associates: one having familiarity with the development process and intended content of the US version of the I-QOL, and one a native of Spain and fluent in Iberian Spanish with familiarity in other dialects;

(3) A panel was added between the reconciliation of the forward versions and the cognitive debriefing interviews. This was a harmonization panel in nature, and consisted of consultants representing the Mexican/Central American, Chicano, South American, and Caribbean language groups;

(4) Finally, the selection of 10 patients for cognitive debriefing interviews was done so that all ethnic groups were represented in this stage of evaluating the adaptation.

The primary focus of this process was to utilize the standard translation and adaptation criteria with the necessary additions that would allow the consultants to arrive at a version that all Spanish speaking peoples in the United States could understand, regardless of their cultural background and its influence on their language.

In January 1999, Health Research Associates also began work on an additional translation of the I-QOL, this time in Japanese. This version was completed in late April of 1999, and it was prepared utilizing the standardized criteria of the Medical Outcomes Trust. A primary and secondary translation consultant were identified - both natives to Japan and both fluent in English. A forward translation and translation report was obtained from each of them. Prior to their reconciliation meeting, Health Research Associates reviewed the report for each forward translation, returned specific questions regarding some of the choices made, and provided guidance for the interpretation of select item content. The forward reconciliation was reviewed, and HRA obtained two back translations: one from a Japanese native who is fluent in English, and the other from a US native fluent in Japanese. The review comments from the reconciled forward and the back translations were provided to the primary consultant residing in Japan, who obtained input on the translation from a prominent Japanese clinician and researcher. The results of this process were discussed in a meeting between the project coordinator at Health Research Associates and the primary translation consultant, and the Japanese version of the I-QOL went into cognitive debriefing to be finalized. Six patients will be recruited in Japan to participate in cognitive debriefing interviews, and final revisions will be made to the translation.

Summary

Four translations (German, French, Spanish, and Swedish) have been psychometrically validated by a cross-sectional design and shown to perform in parallel fashion to the original US version. The remaining translations and language adaptations have been linguistically validated but remain without further psychometric evaluation to date.

INTERNATIONAL VALIDATION STUDIES

In July 1995, Health Research Associates was awarded the contract to coordinate the international validation of the I-QOL. This study aimed to collect I-QOL data on a group of 240 women (60 in each country) with various types of incontinence in four different European countries (Germany, France, Spain, and Sweden) and to assess the cross-sectional psychometric performance of the measure in comparison to the original US version of the measure.

Participants were recruited from individual clinical practices at multiple sites in each of the four countries. All participating investigators were oriented to the study protocol and forms and monitored during the recruitment of participants and the data collection process. Participants were stratified by type of incontinence (targeting 1/3 each: stress, urge, and mixed). They had to be over 18 years of age and could not have clinical profiles inconsistent with stress or urge incontinence (i.e., post surgery for BPH or spinal cord trauma). Each participant was asked to complete the I-QOL, the PGWB, the SF-36, a short clinical information page, and several demographic items. The Demographic data on this population (by country) is shown in Table 5 below.

Additional variables related to urinary incontinence were also collected from this population. Data summaries for the length of time having incontinence, urination frequency at night, number of medical appointments related to incontinence, and whether or not participants underwent surgery for their incontinence are shown on the following page in Table 6.

Table 5: CHARACTERISTICS OF PARTICIPANTS IN INTERNATIONAL VALIDATION STUDY (N=259)

	France n=62		Spain n=65		Sweden n=64		Germany n=68		Total n=259	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Age										
18-29	2	(3.2)	1	(1.5)	1	(1.6)	3	(4.4)	7	(2.7)
30-45	15	(24.2)	15	(23.1)	15	(23.4)	11	(16.2)	56	(21.6)
46-60	22	(35.5)	27	(41.5)	25	(39.1)	13	(19.1)	87	(33.6)
61-75	19	(30.6)	21	(32.3)	22	(34.4)	32	(47.1)	94	(36.3)
76+	4	(6.5)	1	(1.5)	1	(1.6)	9	(13.2)	15	(5.8)
Marital Status										
Living as a couple	36	(58.1)	50	(76.9)	43	(67.2)	33	(48.5)	162	(62.5)
Living alone	22	(35.5)	12	(18.5)	15	(23.4)	26	(38.2)	75	(29.0)
Other	4	(6.5)	3	(4.6)	6	(9.4)	9	(13.2)	22	(8.5)
Education Level										
Some High School	13	(21.0)	25	(38.5)	5	(7.8)	0	(0.0)	43	(16.6)
High School Graduate	26	(41.9)	11	(16.9)	7	(10.9)	36	(52.9)	90	(34.7)
Some College	12	(19.4)	12	(18.5)	10	(15.6)	21	(30.9)	46	(17.8)
College Graduate	4	(6.5)	5	(7.7)	17	(26.6)	5	(7.4)	31	(12.0)
Some Graduate School	7	(11.3)	12	(18.5)	25	(39.1)	6	(8.8)	51	(19.7)
Employment Status										
Full Time	10	(16.1)	16	(24.6)	20	(31.3)	15	(22.1)	61	(23.6)
Part Time	13	(21.0)	11	(16.9)	16	(25.0)	6	(8.8)	46	(17.8)
Unemployment	4	(6.5)	1	(1.5)	2	(3.1)	0	(0.0)	7	(2.7)
Retirement	19	(30.6)	3	(4.6)	22	(34.4)	20	(29.4)	64	(24.7)
Housewife	15	(24.2)	34	(52.3)	3	(4.7)	23	(33.8)	75	(29.0)
Student	0	(0.0)	0	(0.0)	1	(1.6)	0	(0.0)	1	(0.4)
Invalid	1	(1.6)	0	(0.0)	0	(0.0)	4	(5.9)	5	(1.9)

TABLE 6: INCONTINENCE-RELATED CHARACTERISTICS OF PARTICIPANTS IN INTERNATIONAL VALIDATION STUDY (N=259)

	France n=62		Spain n=65		Sweden n=64		Germany n=68		Total n=259	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Women in Menopause										
Yes	35	(56.5)	42	(64.6)	38	(59.4)	48	(70.6)	163	(62.9)
No	27	(43.5)	23	(35.4)	26	(40.6)	20	(29.4)	96	(37.1)
Length of Time with UI										
Less than 1 year	7	(11.3)	14	(21.5)	1	(1.6)	9	(13.2)	31	(12.0)
1 - 4 years	31	(50.0)	29	(44.6)	30	(46.9)	31	(45.6)	121	(46.7)
5 - 10 years	14	(22.6)	14	(21.5)	18	(28.1)	20	(29.4)	66	(25.5)
11 - 25 years	8	(12.9)	7	(10.8)	9	(14.1)	6	(8.8)	30	(11.6)
Over 26 years	2	(3.2)	1	(1.5)	6	(9.4)	2	(2.9)	11	(4.2)
Urination Frequency at night										
0 to 1 per night	43	(69.4)	33	(50.8)	45	(70.3)	26	(38.2)	147	(56.8)
2 per night	13	(21.0)	24	(36.9)	7	(10.9)	14	(35.3)	68	(26.3)
More than 2 per night	6	(9.7)	8	(12.3)	12	(18.8)	18	(26.5)	44	(17.0)
Medical Appts for UI (in the past year)										
0	14	(22.6)	5	(7.7)	17	(26.6)	1	(1.5)	37	(14.3)
1 - 3	36	(58.1)	40	(61.5)	30	(46.9)	30	(44.1)	136	(52.5)
4 - 7	10	(16.1)	13	(20.0)	8	(12.5)	23	(33.8)	54	(20.8)
7 - 11	1	(1.6)	7	(10.8)	4	(6.3)	8	(11.8)	20	(7.7)
12 or more	1	(1.6)	0	(0.0)	5	(7.8)	6	(8.8)	12	(4.6)
Surgery for UI										
Yes	9	(14.5)	5	(7.7)	5	(10.9)	10	(14.7)	31	(12.0)
No	53	(85.5)	60	(92.3)	57	(89.1)	58	(85.3)	228	(88.0)

US VALIDATION AND ABILITY TO DETECT CHANGE STUDY

Because international harmonization changed the instrument originally used in the cross-sectional validation study conducted in Seattle, validation of the revised measure needed to be repeated on the US version of the I-QOL. In addition, validation work was needed to include longitudinal construct validation for the assessment of ability to detect change.[22]

In 1996, Health Research Associates and Donald Patrick received support from Eli Lilly and Company to analyze select portions of data from a multi-center, double-blind, placebo-controlled, randomized clinical trial to assess the efficacy of duloxetine in the treatment of incontinence. Eligibility criteria included significant leakages and discrete incontinent episodes during the 2 to 3 weeks before randomization. Major exclusion criteria included diabetic neuropathy, congenital urologic disorders, previous central nervous system damage, bladder cancer, urinary tract infection, conditions that may have caused neurogenic bladder disease, and other major neurologic diseases. Participants were classified as having stress or mixed incontinence, primarily on the basis of the investigator's judgment of the participant's history and/or urodynamic measures at the first visit.[21]

Two hundred eighty-eight women participated in the trial. Seventy-six percent were 45 years of age or older, and 93% were Caucasian. The breakdown of age groups and ethnicity appear below in Table 7.

TABLE 7: CHARACTERISTICS OF PARTICIPANTS IN US VALIDATION & ABILITY TO DETECT CHANGE STUDY (N=288)

Descriptive Variables	N	Percent
Age		
18-29	5	1.7
30-44	64	22.2
45-60	126	43.8
61-75	82	28.5
76+	11	3.8
Ethnicity		
Caucasian non-Hispanic	267	92.7
African-American	10	3.5
Asian-American	2	0.7
Hispanic	9	3.1

In accordance with the study design, all participants were female. Approximately one-half were diagnosed with stress incontinence (n=141; 49%), and the remaining participants (n=147; 51%) reported symptoms consistent with a mix of stress and urge incontinence. Only 35 (12%) perceived their UI as being severe. As shown in Table 8 on the following page, 72% of the participants had UI between one and 10 years (24% for over 10 years); and 58% stated that they had not seen a doctor in the past year for UI. Table 9 shows the distribution of type of incontinence across self-reported severity.

TABLE 8: INCONTINENCE-RELATED CHARACTERISTICS OF PARTICIPANTS IN US VALIDATION & ABILITY TO DETECT CHANGE STUDY (N=288)

Descriptive Variables	N	Percent
Length of Time with Incontinence*		
Less than 1 year	12	4.2
1-4 years	104	36.6
5-10 years	100	35.2
11-25 years	53	18.7
26+ years	15	5.3
Medical Appointments for UI in Past Year*		
0	166	58.4
1-3	93	32.7
4-6	19	6.7
7-11	3	1.1
12+	3	1.1
Type of Incontinence		
Stress	141	49.0
Mixed	147	51.0
Self-Reported Severity*		
Mild	91	31.8
Moderate	160	55.9
Severe	35	12.2

***Note**: variables with number discrepancies are from incomplete data

TABLE 9: DISTRIBUTION OF TYPE OF INCONTINENCE BY SELF-REPORTED SEVERITY IN DATA FROM: US VALIDATION & ABILITY TO DETECT CHANGE STUDY (N=288)

	Mild	Moderate	Severe	Total
Stress Incontinence	54	76	11	141
Mixed Stress/Urge	37	84	24	145*
Total	91	160	35	286

***Note**: variables with number discrepancies are from incomplete data

In addition to pre-screening activities, the study included a 2-week placebo lead-in period, followed by random assignment to receive duloxetine, an inhibitor of serotonin and norepinephrine reuptake, or a placebo during a 6-week double-blind treatment period. Participants remained in the same treatment groups and all returned during the 1-week post-treatment period for follow-up measures. Self-administered surveys and objective and subjective clinical measures were collected at the screening (visit #1), pre-treatment (visit #2), and every two weeks during the treatment period (visits #3 through #6).[21]

Methods Used for Testing the Psychometric Performance of the I-QOL

The psychometric testing of the I-QOL was conducted using standardized procedures and instrument review criteria developed by the Scientific Advisory Committee of the Medical Outcomes Trust.[23]

Item Reduction

Using data from the INITIAL US VALIDATION STUDY, each of the 28 I-QOL items was reviewed against the following criteria:

(1) ceiling effect in which greater than 50% circled "Not at all";

(2) greater than 5% missing data;

(3) indications that an item measures a different construct demonstrated by an item-to-total correlation less than 0.40; and

(4) redundancy with another item as indicated by an inter-item correlation greater than 0.70.

In order to not adversely affect the ability of the I-QOL to discriminate between different groups of people, as well as diminish its chances of detecting important changes that result from treatment, application of the above criteria resulted in the dropping of six items.[4] The remaining 22-item I-QOL was then prepared for the translation process.

Measurement and Scaling Model

During the development of the I-QOL in the US, investigators and a group of patients with urinary incontinence independently categorized the 22 items into domains, with a high level of agreement between the two.[21] The four hypothesized subdomains (avoidance or limiting behaviors, psychological impacts, social life impacts, and social embarrassment) were restructured into three (combining psychological and social life impacts into psychosocial impacts). Using data from visit #2 of the US VALIDATION AND ABILITY TO DETECT CHANGE STUDY, principal component factor analysis with varimax rotation was performed to compare and confirm the I-QOL's domain structure against these *a priori* designations. First order factors were submitted to a higher-order factor analysis to support use of an overall summary score.[24]

Internal Consistency Reliability

Cronbach's alpha was used to assess internal consistency reliability (i.e., the association among items within domains and the overall measure).[25] A high internal consistency suggests that the scale or subscales are measuring a single construct. A minimum correlation of 0.70 is necessary for group comparisons, but it is preferable to have alpha values above 0.90 for individual comparisons.[3,25] Cronbach's alphas were computed for the I-QOL summary scores in the INITIAL US VALIDATION STUDY and for the I-QOL summary scores and subdomain scores in the INTERNATIONAL VALIDATION STUDY and the US VALIDATION AND ABILITY TO DETECT CHANGE STUDY.

Reproducibility

Reproducibility (test/retest reliability) was assessed over a two-week interval in each of the three studies (referred to above). Test/retest reliability was evaluated using the intraclass correlation coefficient.[26] This is a preferred measure of strength of association for determining stability of scores over time because it corrects for lack of independence between measurement intervals. The recommended level for group comparisons is 0.70.[27,28]

Construct Validity

Convergent and discriminant validity each involved comparing logically related measures to see if they correlated more strongly (convergent) or more weakly (discriminant) according to *a priori* expectations based on the content and theoretical relationships among constructs and their measures. If expectations were met, then construct validity would be supported for the particular population evaluated.

Construct (convergent) validity was examined by comparing the I-QOL and its subscales to related measures. Pearson's correlation coefficients were computed between the I-QOL, the SF-36, and the PGWB at baseline for the INITIAL US VALIDATION STUDY and the INTERNATIONAL VALIDATION STUDY. In the US VALIDATION AND ABILITY TO DETECT CHANGE STUDY, convergent validity was assessed using the data from visit #2.

The ability of the I-QOL to discriminate among known groups was assessed by comparing tertiles of the I-QOL scores and the number of incontinent episodes per week, stress-test pad weight, number of medical appointments in the past year for incontinence, and a categorical measure of self-perceived severity (mild, moderate, and severe). We expected the overall I-QOL scores (higher scores indicating higher QOL) to be significantly lower for women with more incontinent episodes, higher pad weight, more treatment visits, and greater self-reported severity.

Longitudinal Construct Validity/Ability to detect change

Ability to detect change is the ability of an instrument to detect small but important changes.[29,30] Only the dataset from the US VALIDATION AND ABILITY TO DETECT CHANGE STUDY could be evaluated for ability to detect change. Following the recommendations of Deyo et al.,[30] ability to detect change of the I-QOL was assessed using three separate measures, including a physical measure (stress pad weight), a measure of symptoms (number of incontinent episodes), and subjective perception of change (patient global impression rating after treatment). Minimally important change in stress pad weight and number of incontinent episodes was calculated for the period of greatest expected change: between visits #3 (randomization) and #4 (first treatment follow-up). Change was defined as a 25% or greater difference (in either direction) in pad weight or number of incontinent episodes. No change was calculated to be between zero and 24% in either direction.[21] This strategy was based upon the anticipated placebo effect according to an expert panel of urologists. The patient global impression rating defined groups according to whether their urinary condition was worse (response options –2 through -7, the same (response options 0, 1, and –1), or better (response options 2 through 7).

Effect Size

The statistics to evaluate ability to detect change were effect size (mean change score divided by the standard deviation of baseline),[26] standardized response mean (mean change score divided by the standard deviation of change score),[31] and ability to detect change statistic (mean change score divided by the mean change score of the stable group).[26] Higher values for the effect size, standardized response mean, and ability to detect change statistic indicate a greater sensitivity to change.[29-31]

Burden

Respondent burden was defined as the time, energy, and other demands placed on those to whom the instrument is administered. Aspects of patient burden that have been evaluated for the I-QOL include: average administration time, general reading level, and evidences of understandability and acceptability to participants.

Alternate Forms

The I-QOL was designed to be self administered. This was the mode of administration used in all studies documented in this manual. However, there may be cases where participants are to fill out the questionnaires in a clinic setting and can be provided with an "interviewer assist" for any questions the participants may have or for where a cursory check for completeness or other special problems seem prudent. Specific directions and cautions for this approach can be found in the "Administrative Guidelines" section. Since this measure seems to work well as a self-administered survey, no interviewer-administered version has been designed.

Results

Score Distributions on HrQol Instruments

Histograms and scatterplots were utilized to examine the distribution of all data sets and to identify whether the trends were sufficiently normal to allow the use of parametric tests. No bi-modal trends were observed, but trends toward higher I-QOL scores appeared in France and Sweden, while lower overall scores were seen in Spain and a more uniform distribution in Germany. Recruitment in Spain resulted in a more severe case-mix, while the case-mix in both France and Sweden is heavier on the mild end. The results of these recruitment strata, no doubt, influenced the distributions of I-QOL scores. When adjusted for age, the distributions did not change.

I-QOL scores for each study can be seen in the following table.

TABLE 10: I-QOL MEAN SCORES AND STANDARD DEVIATIONS ACROSS ALL STUDIES

Study	I-QOL Total Score	I-QOL Avoidance & Limiting Behaviors Score	I-QOL Psychosocial Impacts Score	I-QOL Social Embarrassment Score
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
INITIAL US VALIDATION STUDY (n=59)	44.4 (26.1)			
INTERNATIONAL VALIDATION STUDY				
France (n=61)	62.6 (21.8)	59.2 (22.7)	70.3 (23.3)	54.1 (25.6)
Spain (n=65)	41.7 (20.5)	41.6 (21.8)	50.9 (25.6)	25.3 (22.0)
Sweden (n=63)	66.2 (22.8)	62.7 (22.8)	75.2 (23.5)	55.7 (27.4)
Germany (n=68)	50.7 (23.6)	44.3 (23.2)	61.7 (27.1)	41.1 (26.9)
US VALIDATION AND ABILITY TO DETECT CHANGE STUDY (n=281*)	62.3 (22.4)	57.8 (22.5)	73.2 (23.7)	49.8 (28.0)

*Could be calculated for 281 of the 288 participants in this study.

Results of Confirmatory Factor Analysis for Subdomains

The three subdomains and overall summary score identified by factor analysis from the US VALIDATION AND ABILITY TO DETECT CHANGE STUDY were then confirmed using principal components factor analysis with varimax rotation from the INTERNATIONAL VALIDATION STUDY. Separate analyses were repeated to confirm the overall summary score and subscales in each country. To test that an overall score adequately incorporated these subscales, a higher-order factor analysis, where the factor correlates of the subscales were in turn themselves factored, was done. Higher-order factor analyses were done on the aggregate data because of the small sample sizes in each individual country. Factor loadings for the original and confirmatory analyses can be found in Appendix D.

Table 11 provides an overview of the progressive development of the I-QOL subdomains. Following the investigator and participant *a priori* designation, both a forced factor analysis (into 4 domains) and an unforced factor analysis (into 3 domains) were performed. The final allocation of items into subscales appears in the far right column labeled "Final Domain".

TABLE 11: DOMAIN STRUCTURES OF THE I-QOL

#	I-QOL Item Description	Investigator a priori	Participant Selection	Forced Factor	Unforced Factor	FINAL DOMAIN
1	…not being able to get to toilet on time	SE	ALB	ALB	ALB	ALB
2	…coughing or sneezing	ALB/PS	ALB	ALB	PS	ALB
3	…careful standing up after sitting down	ALB	ALB	ALB	PS	ALB
4	…where toilets are in new places	ALB/PS	ALB/PS	ALB	ALB	ALB
5	…feel depressed	PS	PS	PS	PS	PS
6	…leave home for long periods of time	PS	PS	PS	PS	PS
7	…frustrated because UI prevents me from doing what I want	ALB/PS	PS	PS	PS	PS
8	…worry about others smelling my urine	SE	SE	SE	SE	SE
9	…UI always on my mind	PS	PS	PS	ALB	PS
10	…make frequent trips to toilet	ALB	ALB	ALB	ALB	ALB
11	…plan every detail in advance	PS	PS	ALB	ALB	ALB
12	…UI getting worse as I grow older	PS	PS	SE	SE	SE
13	…hard time getting a good night sleep	ALB	ALB	PS	ALB	ALB
14	…embarrassed or humiliated	SE	SE	SE	SE	SE
15	…UI makes me feel like I'm not a healthy person	PS	PS	PS	PS	PS
16	…UI makes me feel helpless	PS	PS	PS	PS	PS
17	…get less enjoyment out of life	PS	PS	PS	PS	PS
18	…worry about wetting myself	SE	SE	SE	SE	SE
19	…no control over my bladder	ALB/PS	ALB/PS	SE	SE	SE
20	…watch what I drink	ALB	ALB	ALB	ALB	ALB
21	…limits my choice of clothing	PS	PS	PS	PS	PS
22	…worry about having sex	SE	SE	PS	PS	PS

KEY: **ALB**=Avoidance and Limiting Behaviors, **PS**=Psychosocial, **SE**=Social Embarrassment

Internal Consistency Reliability

Overall I-QOL summary scores showed acceptable reliability statistics across all studies (see Table 12 and 13 on the following page). Focusing on the US VALIDATION AND ABILITY TO DETECT CHANGE STUDY, the overall I-QOL summary score (n=281) showed high internal consistency (*alpha* = 0.95), indicating that the 22 items could be summed to form a composite score. Each subscale also showed acceptable *alpha* values (0.87 for behaviors; 0.93 for psychosocial, and 0.91 for social embarrassment). The intraclass correlation coefficient (n=257) assessing reproducibility at two weeks was 0.91 for the total score and 0.87, 0.91, and 0.88 for the behavior, psychosocial impacts, and social embarrassment subscales respectively, demonstrating stability of the scores.

TABLE 12: INTERNAL CONSISTENCY (CRONBACH'S ALPHA) ACROSS ALL STUDIES

Study	I-QOL Total Score	I-QOL Avoidance & Limiting Behaviors Score	I-QOL Psychosocial Impacts Score	I-QOL Social Embarrassment Score
INITIAL US VALIDATION STUDY (n=62)	.95			
INTERNATIONAL VALIDATION STUDY	.94	.86	.93	.86
France (n=61)	.95	.90	.91	.86
Spain (n=65)	.92	.78	.90	.79
Sweden (n=63)	.94	.84	.92	.86
Germany (n=68)	.95	.85	.93	.86
US VALIDATION AND ABILITY TO DETECT CHANGE STUDY (n=281*)	.95	.87	.93	.91

*Could be calculated for 281 of the 288 participants in this study.

TABLE 13: REPRODUCIBILITY (INTRACLASS CORRELATION COEFFICIENT) ACROSS ALL STUDIES

Study	I-QOL Total Score	I-QOL Avoidance & Limiting Behaviors Score	I-QOL Psychosocial Impacts Score	I-QOL Social Embarrassment Score
INITIAL US VALIDATION STUDY (n=62)	.93			
INTERNATIONAL VALIDATION STUDY	.91	.88	.90	.88
France (n=61)	.93	.88	.94	.84
Spain (n=65)	.87	.76	.86	.86
Sweden (n=63)	.90	.91	.86	.85
Germany (n=68)	.89	.89	.89	.85
US VALIDATION AND ABILITY TO DETECT CHANGE STUDY (n=257*)	.91	.87	.91	.88

*Could be calculated for 257 of the 288 participants in this study.

Construct Validity: Convergent

Construct (convergent) validity was examined by comparing the I-QOL and its subscales to related measures. In the INITIAL US VALIDATION STUDY, the expectation that the scores on the I-QOL would be more highly correlated with well-being (PGWB) than functional status (SF-36) was not confirmed. However, these data indicated that the I-QOL scores were highly correlated with bodily pain. Both the US VALIDATION AND ABILITY TO DETECT CHANGE STUDY and the INTERNATIONAL VALIDATION STUDY began with expectations that previously observed patterns of correlations between the I-QOL and comparison measures would persist.

To assess convergent validity, Pearson's correlation coefficients were computed between the I-QOL, the SF-36, and the PGWB.

TABLE 14: CONVERGENT VALIDITY ACROSS ALL STUDIES

	Correlation with I-QOL				Correlation with I-QOL		
PGWB[1]	Initial Study	US Validation	International Validation	**MOS SF-36[2]**	Initial Study	US Validation	International Validation
Total	.62	.43	.51	RP	.67	.29	.47
HWC	.59	.28	.47	SF	.62	.34	.45
EV	.55	.42	.43	PF	.53	.42	.56
DM	.52	.33	.49	RE	.53	.24	.35
ANX	.51	.30	.45	MH	.53	.34	.47
PWB	.48	.42	.44	GH	.52	.41	.48
BEC	.45	.23	.34	VT	.43	.46	.41
				BP	.35	.19	.35

1 HWC=Health Worry Concern
EV=Energy and Vitality
DM=Depressed Mood
ANX=Tension and Anxiety
PWB=Positive Well Being
BEC=Behavioral and Emotional Control

2 RP=Role-Physical
SF=Social Functioning
PF=Physical Functioning
RE=Role-Emotional
MH=Mental Health
GH=General Health
VT=Vitality
BP=Bodily Pain

In the US VALIDATION AND ABILITY TO DETECT CHANGE STUDY, correlations between the I-QOL total scores and the subscales of the SF-36 ranged between 0.19 and 0.46. Correlations with the PGWB summary and subscale scores ranged between 0.23 and 0.45. With the exception of "bodily pain," all correlations were significant at the 0.001 level. As expected, I-QOL scores were found to be more closely related to well-being (0.42) than to either mental health (0.34) or to bodily pain (0.19). The correlations in this study, however, were lower than in the INITIAL US VALIDATION STUDY. For example, the mean score on the overall PGWB in this study was 0.44 (compared to 0.62), and the SF-36 physical function mean score was 0.46 for this study (compared to 0.53).

Correlations between I-QOL, SF-36, and PGWB scores in the INTERNATIONAL VALIDATION STUDY were higher than the US VALIDATION AND ABILITY TO DETECT CHANGE STUDY, but still lower than the INITIAL US VALIDATION STUDY. These data confirmed the expectation that the I-QOL would be more related to well-being (r = 0.44-0.62) than to more somatic scores such as bodily pain (r = 0.19-0.35). Although supportive of convergent validity, the moderate correlations between the I-QOL, the SF-36, and the PGWB also suggest that the I-QOL is measuring content or domains not reflected in the other two generic instruments.

Construct Validity: Discriminant/Known Groups

In the INITIAL US VALIDATION STUDY, the I-QOL demonstrated the ability to discriminate between levels of severity. Scores were grouped according to both clinician-designed questions for severity categories and patient self-reported severity categories. I-QOL scores were also grouped by the number of appointments reported for UI treatment in the last year.

TABLE 15: DISCRIMINANT VALIDITY OF THE I-QOL IN THE INITIAL US VALIDATION STUDY

Characteristic	*n*	*Mean I-QOL Scores (sd)*
Classification of Disease Severity **(p<0.0001)**		
Mild	15	68.5 (21.0)
Moderate	21	47.7 (22.7)
Severe	23	25.7 (16.8)
Self-perceived Severity **(p<0.0001)**		
Mild	20	70.3 (15.4)
Moderate	15	39.4 (20.5)
Severe	24	25.9 (17.8)
Appointments for Treatment in Past Year **(p<0.0001)**		
No Treatment Visits	24	59.4 (20.2)
1-2 Treatment Visits	16	45.1 (25.5)
3+ Treatment Visits	19	24.9 (20.8)

In order to confirm the negative association between quality of life and perceived severity, severity classification, and medical appointments per year, we developed a linear regression model. We assessed potential confounding by examining changes in the standardized regression coefficients (ß); and, as expected, gender, age, education, marital status, income, and time with incontinence were not important covariates. We removed these demographic variables from the model in order to assess the primary relationships of interest. Results confirmed the negative relationship between quality of life and perceived severity, severity classification, and medical appointments per year. Entered simultaneously, each variable proved to be a significant predictor of quality of life: $R2=0.66$, $F(1,55)=-3.9$, $p<0.001$; $F(1,55)=-2.0$, $p=0.05$; $F(1,55)=-3.7$, $p<0.001$, respectively.

In the INTERNATIONAL VALIDATION STUDY, I-QOL scores were grouped according to categories of disease severity and the number of appointments for UI treatment in the last year.

TABLE 16: DISCRIMINANT VALIDITY OF THE I-QOL IN THE INTERNATIONAL VALIDATION STUDY

	Mean I-QOL Scores				
	France	**Spain**	**Sweden**	**Germany**	**Total**
Self-Perceived Severity	p<0.001 [1]	p<0.001	p<0.001	p<0.001	p<0.001
Mild	78 (12.4)	56 (19.6)	84 (14.0)	73 (16.7)	74 (18.0)
Moderate	58 (14.8)	39 (19.4)	58 (18.0)	50 (20.7)	50 (20.4)
Severe	31 (14.9)	33 (16.3)	46 (13.4)	26 (17.9)	33 (16.7)
Medical Appts to Treat UI during the Last Year	p<n.s.	p<0.05	p<0.001	p<0.05	p<0.001
0	73 (19.5)	45 (19.8)	83 (14.3)	69 (23.8)	74 (19.9)
1 to 2	56 (22.8)	53 (25.1)	51 (20.2)	61 (20.8)	55 (22.3)
3 or more	62 (17.5)	36 (14.7)	65 (19.2)	47 (22.4)	50 (22.0)

[1] Univariate analysis of variance, controlling for age

In the INTERNATIONAL VALIDATION STUDY, the I-QOL was able to discriminate between different levels of self-reported severity. In addition, significant differences in I-QOL scores (p=0.05 to <0.001) were observed for Spain, Sweden, and Germany when comparing I-QOL scores by the number of incontinence-related medical visits made by patients during the past year (0, 1-2, 3 or more). I-QOL scores were also significantly different by the number of incontinent episodes reported per day, week, and month (p<0.01-p<0.001) in participants from France and Sweden who reported higher total I-QOL scores than participants in Spain and Germany.

Table 17 shows I-QOL scores according to the categories of incontinent episodes, stress pad weight, the number of incontinence-related medical visits reported during the past year, and the participants' perceived severity from the US VALIDATION AND ABILITY TO DETECT CHANGE STUDY. As expected, I-QOL scores were significantly worse with increasing episodes, stress pad weight, and number of UI-specific medical visits. I-QOL scores were also significantly different for women who reported mild incontinence compared with those who reported moderate or severe incontinence. This pattern was repeated for the subscale scores with similar results, except that no significant differences were observed for social embarrassment in relation to number of treatment visits in the last year. Overall, the total and the subscale scores were able to discriminate as expected among known groups.

TABLE 17: DISCRIMINANT VALIDITY OF THE I-QOL IN THE US VALIDATION AND ABILITY TO DETECT CHANGE STUDY

Characteristic	*n*	*I-QOL Mean (Std Dev)*			
		Total	***Avoidance & Limiting Behavior***	***Psychosocial Impacts***	***Social Embarrassment***
Number of Incontinent Episodes					
1-12	96	72.2 (17.4)	66.4 (19.0)	83.2 (17.0)	61.7 (24.8)
13-23	90	60.2 (22.2)	56.8 (21.9)	70.8 (23.7)	46.7 (27.3)
24 +	92	54.4 (23.2)	50.1 (23.7)	65.8 (26.0)	40.8 (27.8)
F stat (p value)		17.4 (p<0.001)	13.5 (p<0.001)	14.9 (p<0.001)	15.5 (p<0.001)
1-hr Stress Test Pad Weight (g)					
0 - 8.99	91	69.0 (18.6)	64.2 (18.8)	79.3 (19.2)	58.0 (24.6)
9-19.99	99	63.3 (21.2)	59.7 (21.6)	74.1 (22.7)	49.9 (28.1)
20 +	91	54.4 (24.7)	49.3 (24.4)	66.2 (27.0)	41.4 (28.9)
F stat (p value)		10.5 (p<0.001)	11.3 (p<0.001)	7.4 (p<0.01)	8.3 (p<0.001)
Appointments for Treatment in past year					
No Treatment Visits	164	66.0 (20.9)	61.4 (21.6)	77.1 (21.2)	53.3 (26.9)
1-3 Treatment Visits	89	57.4 (27.5)	52.5 (22.4)	68.1 (26.3)	45.7 (28.1)
4-6 Treatment Visits	19	56.2 (27.5)	52.3 (25.7)	67.4 (28.5)	42.1 (34.9)
7+ Treatment Visits	6	52.1 (20.9)	52.6 (25.4)	57.4 (17.6)	41.6 (25.2)
F stat (p value)		3.9 (p<0.01)	3.6 (p<0.05)	4.2 (p<0.01)	2.2 (p=n.s.)
Self-Perceived Disease Severity					
Mild	90	77.0 (13.2)	71.3 (17.2)	87.0 (11.9)	68.1 (19.2)
Moderate	156	59.2 (20.7)	55.1 (20.3)	70.7 (23.2)	45.1 (25.9)
Severe	34	37.4 (22.3)	34.2 (21.8)	47.9 (25.4)	23.7 (27.5)
F stat (p value)		59.2 (p<0.01)	47.6 (p<0.001)	47.2 (p<0.001)	48.3 (p<0.001)

In the US VALIDATION AND ABILITY TO DETECT CHANGE STUDY, the ability of the I-QOL to discriminate among known groups was assessed by comparing tertiles of the I-QOL scores and the number of incontinent episodes per week, stress test pad weight, number of medical appointments in the past year for incontinence, and a categorical measure of self-perceived severity (mild, moderate and severe). We expected the overall I-QOL scores to be significantly lower for women with more incontinent episodes, higher pad weight, more treatment visits, and greater self-reported severity. The ability for the I-QOL to discriminate between known groups was assessed by comparing mean I-QOL scores for self-perceived severity (mild, moderate, severe), use of services (0, 1-2, 3 or more visits), and the number of UI episodes (1-2 x per month; 1-3 x per week; 1 or more per day). From previous analyses[14] we expected the overall I-QOL scores to be significantly lower for women who rated their condition as severe compared to mild or moderate, with more treatment visits, and with more incontinent episodes. We also expected higher or better I-QOL scores the older the respondent under the hypothesis that these women had experienced incontinence for a longer period of time and had developed accommodations to the condition or were more likely to expect incontinence symptoms as part of the aging process.

Longitudinal Construct Validity/Ability to detect change

Ability to detect change of the I-QOL was evaluated only in the US VALIDATION AND ABILITY TO DETECT CHANGE STUDY. Effect sizes, ability to detect change statistics, and standardized response means[26,29,30] are shown in Table 18 for changes in pad weight, number of incontinent episodes, and patient global impression ratings. Minimally important changes were defined as the percent change in I-QOL score for the improved group using the measures of pad weight and number of incontinent episodes and lowest category of improvement for patient global impression ratings. I-QOL scores improved for all participants regardless of the comparative measure used. A 25% or greater decrease in stress pad weight was associated with a 2-point (2%) improvement in I-QOL score compared to the group who remained the same. A 25% or more decrease in number of incontinent episodes was associated with a 5-point (5%) improvement in I-QOL score. No participants reported their urinary condition to be worse. Participants who reported their condition as "a little better" had a 2-point (2%) improvement in I-QOL score while those who reported their condition as "very much better" improved by 13 points (13%).

TABLE 18: ABILITY TO DETECT CHANGE OF THE I-QOL BY STRESS PAD WEIGHT, NUMBER OF INCONTINENT EPISODES, AND CHANGES IN PATIENT'S GLOBAL PERCEPTION OF CONDITION

Change in Stress Test Pad Weight	N	Baseline I-QOL Mean (sd)	Endpoint I-QOL Mean (sd)	Change Score Mean (sd)
Worse (=25% ↑)	48	60 (23.8)	67 (26.0)	7 (10.8)
Same (0-24% ↑↓)	38	64 (21.7)	71 (21.7)	7 (10.7)
Better (=25+% ↓)	184	65 (21.1)	74 (20.9)	9 (13.2)
Total Group	270	64 (21.8)	73 (22.0)	9 (12.4)
Effect Size = 0.4	Standardized Response Mean (SRM) = 0.7		Ability to detect change Statistic = 0.8	
Change in No. of Episodes				
More (=25% ↑)	13	73 (9.5)	74 (19.7)	1 (12.5)
Same (0-24% ↑↓)	61	58 (24.4)	63 (26.1)	5 (11.2)
Fewer (=25+% ↓)	195	65 (21.1)	76 (19.8)	10 (12.4)
Total Group	269	64 (21.8)	73 (22.0)	9 (12.4)
Effect Size = 0.4	Standardized Response Mean (SRM) = 0.7		Ability to detect change Statistic = 0.8	
Patient Global Perception of Change *				
Very much better	24	64 (19.1)	81 (18.6)	17 (12.0)
Much better	29	67 (19.0)	77 (16.8)	10 (9.5)
A little better	36	66 (22.8)	72 (22.6)	6 (9.5)
Same	26	61 (25.0)	65 (27.4)	4 (7.7)
Total Group	115	65 (21.5)	74 (22.2)	9 (10.7)
Effect Size = 0.4	Standardized Response Mean (SRM) = 0.8		Ability to detect change Statistic = 1.2	

Effect Size *(mean change in score / sd of mean baseline score)*
Standardized Response Mean (SRM) = *(mean change in score / sd of mean change score)*
Ability to detect change Statistic *(mean change in score / sd of mean change score for stable group)*

***** *(added late in study, thus total N=115)*

Interpretation and Discussion

Interpretation of Effect Size

All participants reported improvement in I-QOL scores regardless of the three measures of change used in this study: reduction in stress pad weight, reduced number of incontinent episodes, and global rating improvement. This improvement in I-QOL scores most likely reflects the effect of treatment and placebo as well as the effect of participation and expectations of improvement in a clinical trial. Statistics summarizing ability to detect change varied from 0.4-0.8 and were associated with a 2-13% change in the I-QOL. Use of three independent measures of change, ranging from objective to subjective, supports the I-QOL's capacity to detect change. The results also provide the means for estimating sample sizes for subsequent clinical trials of behavioral or pharmacologic interventions and for interpreting observed effect sizes in terms of a frequently used clinical measure (pad weight), number of reported incontinent episodes, and global ratings of change.

Patient Burden

During the developmental and validation work, the I-QOL was documented to take an average of 5 minutes to self administer. Participants required an average 5th grade reading level to understand the items. Evidence that the items were understandable and not overly sensitive is demonstrated in the very low rates of missing data and in the relatively high response rate across all three studies. As a self-administered questionnaire, and with use of this manual, administrative burden is low.

Discussion

Using data from a large, randomized clinical trial assessing treatment for urinary incontinence in women, we have demonstrated that the I-QOL shows good internal consistency, reproducibility, and validity as reported previously using cross-sectional data. The I-QOL is capable of discriminating between different levels of perceived severity, use of medical services, and frequency of incontinent episodes as well as different levels of stress test pad weight, a commonly used clinical outcome measure.

Development of the I-QOL in the item elicitation stage included males with incontinence. Subsequently, a small pilot study that included men was conducted and similar psychometric analyses were performed as were done for women. Evidence of cross-sectional validity in men was similar to that for women; but, because of the small sample sizes, we have not included this information in the manual. Similarly, the I-QOL is now being tested more thoroughly in patients with urge-only, with or without incontinent episodes. If you are interested in applications in male, urge-only, or other populations with urinary syndromes, please contact the authors of this manual for information on the most current applications of the I-QOL.

Correlations of the I-QOL with comparison measures were lower in the US VALIDATION AND ABILITY TO DETECT CHANGE STUDY than in the previous two studies, possibly due to differences in study populations that included men, persons who reported more severe incontinence, and persons with a diagnosis of urge incontinence.

The I-QOL was constructed using a needs-based model[16] to elicit subjective evaluations of UI-related effects and concerns in the language of the participants. Thus, it complements generic quality of life, functional status, and clinical measures. Since clinical measures do not reflect an individual's perspective on his or her urinary condition, the inclusion of QOL measures in clinical trials is important to give meaning to outcomes more distal to physical findings. The results from the US VALIDATION AND ABILITY TO DETECT CHANGE STUDY demonstrate the relevance of quality of life to the assessed clinical condition. The performance of the I-QOL in this clinical trial suggests that it can be an important addition to the compendium of outcome measures used to assess urinary incontinence and its treatment.

Administration Guidelines

Self-Administration Guidelines

The I-QOL is contained in Appendix B. It was designed for self administration. The 22-item version takes approximately 5 minutes to complete. No specific training is required to complete this instrument since the instructions are self-explanatory. No difficulties have been reported among the various respondent groups who have assisted with the preliminary testing and who have participated in the clinical trials that included this measure. The consistently small amounts of missing data (less than 5%) attest to the acceptability of this measure to patients.

Additional factors that should be considered when administering the I-QOL include:

- Participants should be instructed to complete the I-QOL in a quiet place away from the influence of others.

- Educational level should be considered before self-completion. This can be done by asking persons what grade level they have completed or by administering a short reading comprehension test. Persons with low literacy or diverse language skills should always be provided interviewer assistance.

- Supervisors who provide the questionnaires to the participants should be trained to not introduce bias. For example, they should encourage respondents to provide one answer (response choice) for each question according to how they, the participants, think and feel. Great care should be taken to avoid messages (verbal or otherwise) that might persuade participants to answer questions according to any bias (the supervisors', their family's, or society's).

The "About You" addition to the I-QOL is designed to provide both general and incontinence-specific demographic information. This section can be found in Appendix C, and it takes approximately 1.5 minutes to complete. This section has been simultaneously translated and adapted with the I-QOL, using the same methodology. The above comments and suggestions on self administration can also be applied to the "About You" section.

Scoring the I-QOL

Scoring Instructions for the I-QOL

The I-QOL produces quality-of-life profiles for people suffering from urinary incontinence. The survey consists of 22 incontinent-specific quality of life items all having the following five-point ordinal response scale making it easier for the respondents to understand:

1	EXTREMELY
2	QUITE A BIT
3	MODERATELY
4	A LITTLE
5	NOT AT ALL

The 22 items of the I-QOL and its subscales:

1. I worry about not being able to get to the toilet on time.	ALB	12. I worry about my incontinence getting worse as I grow older.	SE
2. I worry about coughing or sneezing because of my incontinence.	ALB	13. I have a hard time getting a good night of sleep because of my incontinence.	ALB
3. I have to be careful standing up after I've been sitting down because of my incontinence.	ALB	14. I worry about being embarrassed or humiliated because of my incontinence.	SE
4. I worry about where toilets are in new places.	ALB	15. My incontinence makes me feel like I'm not a healthy person.	PS
5. I feel depressed because of my incontinence.	PS	16. My incontinence makes me feel helpless.	PS
6. Because of my incontinence, I don't feel free to leave my home for long periods of time.	PS	17. I get less enjoyment out of life because of my incontinence.	PS
7. I feel frustrated because my incontinence prevents me from doing what I want.	PS	18. I worry about wetting myself.	SE
8. I worry about others smelling urine on me.	SE	19. I feel like I have no control over my bladder.	SE
9. Incontinence is always on my mind.	PS	20. I have to watch what or how much I drink because of my incontinence.	ALB
10. It's important for me to make frequent trips to the toilet.	ALB	21. My incontinence limits my choice of clothing.	PS
11. Because of my incontinence, it's important to plan every detail in advance.	ALB	22. I worry about having sex because of my incontinence.	PS

Subscales	I-QOL Items
Total (IQOL).....	All Items
Avoidance and Limiting Behavior (ALB).....	1, 2, 3, 4, 10, 11, 13, and 20
Psychosocial Impacts (PS)	5, 6, 7, 9, 15, 16, 17, 21, and 22
Social Embarrassment (SE).....	8, 12, 14, 18 and 19

The I-QOL and its subscale scores are computed by adding each item's response, subtracting the lowest possible score and dividing that sum by the possible raw score range.
The scores are then transformed to have a range from 0 (maximum problem) to 100 (no problem at all). The formula used to compute the transformed score follows:

$$\text{Scale Score} = \frac{\text{the sum of the items - lowest possible score}}{\text{possible raw score range}} * 100$$

Example: *If the five social embarrassment items had responses of 3,4,3,4,3, then the score would be calculated as follows:*

$$\text{Social Embarrasment Score} = \frac{17 - 5}{20} * 100 = 60$$

where the sum of the items is 3+4+3+4+3=17, the lowest possible score is 1+1+1+1+1=5, and the possible raw score range equals 20 [(5+5+5+5+5) – (1+1+1+1+1) or 25 – 5]

Missing Data: If no more than three (of the 22) items are omitted, a mean substitution may be computed for these items. However, it is recommended that I-QOL scores be set to missing if more than three items are left unanswered.

Scoring Exercise and Test Dataset for the I-QOL

The following file included is:

- **iqol.sps** ..... SPSS syntax code containing the algorithms for obtaining total and subscale scores. A hard copy of this code can be found in Appendix A

The purpose of this scoring exercise is to help I-QOL users to evaluate results in the process of calculating scores for the instrument. The test dataset, which is called "iqol.dat", contains data from 100 administrations of the I-QOL. SPSS syntax can be used to both import the raw data into SPSS format (**iqol_dl.sps**) and compute I-QOL scores (**iqol.sps**).

The following table presents statistics for the transformed scores for the I-QOL. After scoring the test dataset, the mean, standard deviation, and minimum and maximum observed values should agree with those found here.

TABLE 19: DESCRIPTIVE STATISTICS

	N	Minimum	Maximum	Mean	Std. Deviation
I-QOL Total Score (22-items)	97	7.95	96.59	54.09	22.97
I-QOL Avoidance & limiting Behaviors Score (8 items)	100	9.38	96.88	50.03	23.81
I-QOL Psychosocial Impacts Score (9 items)	97	11.11	100.00	64.86	25.67
I-QOL Social Embarrassment Score (5 items)	100	0.00	95.00	40.20	27.69
Valid N (listwise)	97				

Recommendations for Use

The I-QOL is a disease-specific instrument designed to measure the impacts of urinary incontinence on quality-of-life. Even though ability to detect change has only been evaluated on a stress and mixed population, this measure was developed for use with both male and female patients having urge, stress, and mixed urinary incontinence. The I-QOL consists of 22 items (see Appendix B), all of which are rated on a response scale with five categories: (1 = '*extremely'* to 5 = '*not at all'*). All items are summed to calculate a total I-QOL score, ranging from 22 to 110, with a high score indicating a better quality of life. To facilitate interpretations of scores, the summed total score is transformed to a 0-100 scale ranging from 0 (poor quality of life) to 100 (maximum quality of life). (See Scoring Section in this manual for specific instructions.)

These features of the I-QOL make it an appropriate tool for assessing the affects of treatment, treatment decision-making among providers and patients, and for conducting cross-cultural comparisons. The I-QOL is ideal for multinational clinical trials because it has a low patient burden and has multiple language adaptations. Published effect size and validity statistics are available for the US version,[4,21] and cross-sectional validity statistics are available for four European versions.[32,33]

Because clinical measures do not reflect a person's perspective on his or her urinary condition, the inclusion of quality of life measures in clinical trials is important to give meaning to outcomes more distal to physical findings. Instruments such as the I-QOL, however, do not permit comparisons across different diseases because they are designed to detect minimally important effects of the condition rather than provide broad comparison. For this purpose, investigators are advised to use generic measures.[21]

List of Tables

References

1. Urinary Incontinence Guideline Panel: Urinary incontinence in adults: clinical practice guidelines. Rockville, MD: Agency for Health Care Policy and Research, U.S. Department of Health and Human Services, 1992.
2. Burgio KL, Matthews KA, and Engel BT. Prevalence, incidence and correlates of urinary incontinence in healthy, middle-aged women. J Urol. 146:1255-1259, 1991.
3. Harrison GL, Memel DS. Urinary incontinence in women: Its prevalence and its management in a health promotion clinic. Br J Gen Pract. 44(381):149-512, 1994.
4. Wagner TH, Patrick DL, Bavendam TG, Martin ML, and Buesching DP: Quality of life in persons with urinary incontinence: Development of a new measure. Urology. 47 (1):67-72, 1996.
5. Lenderking WR, Nackley JF, Anderson RB, and Testa MA. A review of the quality-of-life aspects of urinary urge incontinence. Pharmacoeconomics. 9(1): 11-23, 1996.
6. Naughton MJ, Wyman JF. Quality of life in geriatric patients with lower urinary tract dysfunction. Am J Med Sci. 314(4):221-227, 1977.
7. Guyatt GH, Feeny DH, and Patrick DL. Measuring health-related quality of life. Ann Intern Med. 118:622-9, 1993.
8. Consensus Statement from the First International Conference for the Prevention of Incontinence. Yokohama, Japan, September, 1997.
9. Shumaker SA, Wyman JF, Uebersax JS, McClish D, and Fantl JA. Health-related quality of life measures for women with urinary incontinence: the incontinence impact questionnaire and the urogenital distress inventory. Qual Life Res. 3:291-306, 1994.
10. Jackson S, Donovan J, Brookes S, Eckford S, Swithinbank L, and Abrams P. The Bristol Female Lower Urinary Tract Symptoms questionnaire development and psychometric testing. Br J Urol. 77:805-812, 1996.
11. Black N, Griffiths J, and Pope C. Development of a symptom severity index and a symptom impact index for stress incontinence in women. Neurol and Urodyn. 15:630-640, 1996.
12. Yu LC. Incontinence stress index. Measuring psychological impact. J Gerontol Nurs. 13:18-25, 1987.
13. Cella D. *Functional Assessment of Incontinence Therapy*, version 2. Chicago, Rush Division of Psychosocial Oncology, 1994.
14. Bo K, Maehlum S, Oseid S, et al. Prevalence of stress urinary incontinence among physically active and sedentary female students. Scand J Sports Sci. 11:113-116, 1989.
15. Patrick DL, Erickson P. Health Status and Quality of Life in Health Care Evaluation and Resource Allocation. New York: Oxford University Press, 1993.
16. McKenna SP. A new theoretical approach to the measurement of quality of life. Drug Inf J. 28:13-18, 1994.
17. The WHOQOL Group. The development of the World Health Organization quality-of-life assessment instrument (the WHOQOL). In J Orley & W Kuyken (Eds.), *Quality-of-Life Assessment : International Perspectives*. Berlin, Germany: Springer-Verlag, 1994.

18. Patrick DL, Wild DJ, Johnson ES, Wagner TH and Martin M. Cross-cultural validation of quality-of-life measures. In J Orley & W Kuyken (Eds.), *Quality-of-Life Assessment: International Perspectives*. Berlin, Germany: Springer-Verlag, 1994.

19. Step I & II Report: Health-Related Quality of Life in Persons with Urinary Incontinence. Cost and Outcomes Assessment Team, University of Washington, Seattle, Washington, 1994.

20. Futz NH, Herzog AR. Measuring urinary incontinence in surveys. Gerontologist. 11:708-713, 1991.

21. Patrick DL, Martin ML, Bushnell DM, Yalcin I, Wagner TH, and Buesching DP. Quality of life of women with urinary incontinence: Further development of the incontinence quality of life instrument (I-QOL). Urology. 53:71-76, 1999.

22. Further Development of the I-QOL: Final Report on SAAB Data Analysis. Health Research Associates, Seattle, Washington, 1998.

23. MOT Scientific Advisory Committee Instrument Review Criteria. MOT Bulletin II: I-V. Boston, MA: MOT Committee. 1995.

24. Katz JN, Larson MG, Phillips CB, et al. Comparative measurement sensitivity of short and longer health status instruments. Med Care. 30:917-925, 1992.

25. Patrick DL, Martin ML, Bushnell DM, Marquis P, Andrejasich CM, and Buesching DP. Cultural adaptation of a quality of life measure for urinary incontinence. Eur Urol., in press, 1999.

26. Nunnally JC. *Psychometric Theory*, vol. 2. New York:Basic Books, 1994, pp 532-533.

27. Cronbach LF. Coefficient alpha and the internal structure of tests. Psychometricka. 16:297-334, 1951.

28. Deyo RA, Diehr P, and Patrick DL. Reproducibility and ability to detect change of health status measures. Control Clin Trials. 12:142s-158s, 1991.

29. Scientific Advisory Committee Instrument Review Criteria. Medical Outcomes Trust (MOT), Boston, Massachusetts, March 1997.

30. Aday LA. *Designing and Conducting Health Surveys: A Comprehensive Guide*. San Francisco, Jossey-Bass, 1991, pp 41-50.

31. Guyatt G, Walter S, and Norman G. Measuring change over time: Assessing the usefulness of evaluative instruments. J Chronic Dis. 40:171-178, 1987.

32. European Validation Studies of the I-QOL: Final Report. Health Research Associates, Seattle, Washington, 1996.

33. Deyo RA, and Centor RM. Assessing the ability to detect change of functional scales to clinical change: An analogy to diagnostic test performance. J Chronic Dis. 39:897-906,1986.

Appendix A

SPSS Scoring Syntax for Disk Labeled:
I-QOL SPSS Scoring Disk

SPSS Scoring Syntax:
I-QOL SPSS

Filename: a:\iqol_dl.sps

```
* SYNTAX FILE USED TO READ I-QOL TEST DATA INTO SPSS
* THIS WILL READ A FILE FROM THE A:\ DRIVE
* Filename="iqol_dl.sps"
* Written in SPSS for Windows v.7.0
* Last edited: 1/18/96 Original version: 9/19/94 *
* Health Research Associates, Inc., Seattle, Washington, USA

SET
   BLANKS=SYSMIS
  UNDEFINED=WARN.
DATA LIST
  FILE='A:\iqol.dat' FIXED RECORDS=1 TABLE /1
  id 1-6 iqol01 7-7 iqol02 8-8 iqol03 9-9 iqol04 10-10
  iqol05 11-11 iqol06 12-12 iqol07 13-13 iqol08 14-14
  iqol09 15-15 iqol10 16-16 iqol11 17-17 iqol12 18-18
  iqol13 19-19 iqol14 20-20 iqol15 21-21 iqol16 22-22
  iqol17 23-23 iqol18 24-24 iqol19 25-25 iqol20 26-26
  iqol21 27-27 iqol22 28-28 .
EXECUTE.
```

Filename: a:\iqol.sps

```
* SYNTAX FILE USED TO SCORE THE URINARY INCONTINENCE-SPECIFIC
* QUALITY OF LIFE INSTRUMENT
* Filename="iqol.sps"
* Written in SPSS for Windows v.7.0
* Last edited: 1/18/96 Original version: 9/19/94 *
* Health Research Associates, Inc., Seattle, Washington, USA

* This file creates the following variables:
*     iqol     = total I-QOL score (22 items)
*     iqol_alb = Avoidance and Limiting Behaviors score (8 items)
*     iqol_ps  = Psychosocial Impacts score (9 items)
*     iqol_se  = Social Embarrassment score (5 items)
*     iqolmiss = number of missing I-QOL items per person
*
* Labeling all items

VARIABLE LABEL
  ID     'IDENTIFICATION'
  IQOL01 'WORRY ABOUT NOT GETTING TO TOILET ON TIME'
  IQOL02 'WORRY ABOUT COUGHING'
  IQOL03 'CAREFUL STANDING AFTER SITTING'
  IQOL04 'WORRY WHERE TOILETS ARE IN NEW PLACES'
  IQOL05 'FEEL DEPRESSED'
  IQOL06 'I DONT FEEL FREE TO LEAVE HOME'
  IQOL07 'FEEL FRUSTRATED'
  IQOL08 'WORRY OTHERS SMELL URINE ON ME'
  IQOL09 'UI ALWAYS ON MY MIND'
  IQOL10 'IMPORTANT TO MAKE FREQUENT TRIPS TO TOILET'
```

```
  IQOL11 'IMPORTANT TO PLAN AHEAD'
  IQOL12 'WORRY ABOUT UI GETTING WORSE'
  IQOL13 'HARD GETTING GOOD NIGHTS SLEEP'
  IQOL14 'BEING EMBARRASED'
  IQOL15 'FEEL IM NOT HEALTHY'
  IQOL16 'FEEL HELPLESS'
  IQOL17 'GET LESS ENJOYMENT OUT OF LIFE'
  IQOL18 'WORRY ABOUT WETTING MYSELF'
  IQOL19 'FEEL NO CONTROL OVER BLADDER'
  IQOL20 'WATCH WHAT/HOW MUCH I DRINK'
  IQOL21 'UI LIMITS CHOICE OF CLOTHING'
  IQOL22 'WORRY ABOUT HAVING SEX' .

* Labeling the values of each item

VALUE LABELS
  iqol01 TO iqol22
     1 'Extremely'
     2 'Quite a bit'
     3 'Moderately'
     4 'A little'
     5 'Not at all' .

* Cleaning values and recoding to missing

RECODE
  iqol01 TO iqol22
  (LOWEST THRU 0 = 9)  (6 THRU HIGHEST=9)  (SYSMIS=9).

MISSING VALUES
  iqol01 TO iqol22  (9) .

* Calculating the number of missing I-QOL items per person.  This would
* be used in computing mean substitutions for missing items.

COUNT
  iqolmiss = iqol01 iqol02 iqol03 iqol04 iqol05 iqol06 iqol07 iqol08
             iqol09 iqol10 iqol11 iqol12 iqol13 iqol14 iqol15 iqol16
             iqol17 iqol18 iqol19 iqol20 iqol21 iqol22  (9) .
EXECUTE .

* Computing and transforming the total I-QOL score

COMPUTE iqol = (((iqol01+iqol02+iqol03+iqol04+iqol05+iqol06+iqol07+
                 iqol08+iqol09+iqol10+iqol11+iqol12+iqol13+iqol14+
                 iqol15+iqol16+iqol17+iqol18+iqol19+iqol20+iqol21+
                 iqol22)-22)/(88))*100.

* Computing and transforming the Avoidance & Limiting Behaviors subscale

COMPUTE iqol_alb=(((iqol01+iqol02+iqol03+iqol04+iqol10+iqol11+iqol13+
                 iqol20)-8)/(32))*100.

* Computing and transforming the Psychosocial Impacts subscale

COMPUTE iqol_ps=(((iqol05+iqol06+iqol07+iqol09+iqol15+iqol16+iqol17+
                 iqol21+iqol22)-9)/(36))*100.

* Computing and transforming the Social Embarrassment subscale

COMPUTE iqol_se=(((iqol08+iqol12+iqol14+iqol18+iqol19)-5)/(20))*100.
```

```
EXECUTE .

VARIABLE LABELS
    iqolmiss 'Number of missing I-QOL items per person'
    iqol     'I-QOL Total Score (22-items)'
    iqol_alb 'I-QOL Avoidance & limiting Behaviors Score (8 items)'
    iqol_ps  'I-QOL Psychosocial Impacts Score (9 items)'
    iqol_se  'I-QOL Social Embarrassment Score (5 items)' .
EXECUTE .
```

Appendix B

I-QOL Questionnaire (U.S. English)

Items arranged according to subscales

Avoidance and Limiting Behavior

1. I worry about not being able to get to the toilet on time.
2. I worry about coughing or sneezing because of my urinary problems or incontinence.
3. I have to be careful standing up after I've been sitting down because of my urinary problems or incontinence.
4. I worry about where toilets are in new places.
10. It's important for me to make frequent trips to the toilet.
11. Because of my urinary problems or incontinence, it's important to plan every detail in advance.
13. I have a hard time getting a good night of sleep because of my urinary problems or incontinence.
20. I have to watch what or how much I drink because of my urinary problems or incontinence.

Psychosocial Impacts

5. I feel depressed because of my urinary problems or incontinence.
6. Because of my urinary problems or incontinence, I don't feel free to leave my home for long periods of time.
7. I feel frustrated because my urinary problems or incontinence prevents me from doing what I want.
9. My urinary problems or incontinence is always on my mind.
15. My urinary problems or incontinence makes me feel like I'm not a healthy person.
16. My urinary problems or incontinence makes me feel helpless.
17. I get less enjoyment out of life because of my urinary problems or incontinence.
21. My urinary problems or incontinence limits my choice of clothing.
22. I worry about having sex because of my urinary problems or incontinence.

Social Embarrassment

8. I worry about others smelling urine on me.
12. I worry about my urinary problems or incontinence getting worse as I grow older.
14. I worry about being embarrassed or humiliated because of my urinary problems or incontinence.
18. I worry about wetting myself.
19. I feel like I have no control over my bladder.

PLEASE WRITE IN TODAY'S DATE: ___ _____ ____
Day Month Year

PARTICIPANT ID:

PLEASE READ THIS CAREFULLY

ON THE FOLLOWING PAGES YOU WILL FIND SOME STATEMENTS THAT HAVE BEEN MADE BY PEOPLE WHO HAVE URINARY INCONTINENCE (LEAKING URINE WHEN YOU DON'T WANT TO).

PLEASE CHOOSE THE RESPONSE THAT APPLIES BEST TO YOU RIGHT NOW AND CIRCLE THE NUMBER OF YOUR ANSWER.

IF YOU ARE UNSURE ABOUT HOW TO ANSWER A QUESTION, PLEASE GIVE THE BEST ANSWER YOU CAN. **THERE ARE NO RIGHT OR WRONG ANSWERS.**

YOUR ANSWERS WILL BE KEPT STRICTLY CONFIDENTIAL.

IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT

Your Feelings

(Please circle the number of your answer)

1. I worry about not being able to get to the toilet on time

   1 EXTREMELY
   2 QUITE A BIT
   3 MODERATELY
   4 A LITTLE
   5 NOT AT ALL

2. I worry about coughing or sneezing because of my urinary problems or incontinence.

   1 EXTREMELY
   2 QUITE A BIT
   3 MODERATELY
   4 A LITTLE
   5 NOT AT ALL

3. I have to be careful standing up after I've been sitting down because of my urinary problems or incontinence.

   1 EXTREMELY
   2 QUITE A BIT
   3 MODERATELY
   4 A LITTLE
   5 NOT AT ALL

4. I worry about where toilets are in new places.

   1 EXTREMELY
   2 QUITE A BIT
   3 MODERATELY
   4 A LITTLE
   5 NOT AT ALL

5. I feel depressed because of my urinary problems or incontinence.

   1 EXTREMELY
   2 QUITE A BIT
   3 MODERATELY
   4 A LITTLE
   5 NOT AT ALL

(Please circle the number of your answer)

6. Because of my urinary problems or incontinence, I don't feel free to leave my home for long periods of time.

   1 EXTREMELY
   2 QUITE A BIT
   3 MODERATELY
   4 A LITTLE
   5 NOT AT ALL

7. I feel frustrated because my urinary problems or incontinence prevents me from doing what I want.

   1 EXTREMELY
   2 QUITE A BIT
   3 MODERATELY
   4 A LITTLE
   5 NOT AT ALL

8. I worry about others smelling urine on me.

   1 EXTREMELY
   2 QUITE A BIT
   3 MODERATELY
   4 A LITTLE
   5 NOT AT ALL

9. My urinary problems or incontinence is always on my mind.

   1 EXTREMELY
   2 QUITE A BIT
   3 MODERATELY
   4 A LITTLE
   5 NOT AT ALL

10. It's important for me to make frequent trips to the toilet.

    1 EXTREMELY
    2 QUITE A BIT
    3 MODERATELY
    4 A LITTLE
    5 NOT AT ALL

(Please circle the number of your answer)

11. Because of my urinary problems or incontinence, it's important to plan every detail in advance.

    1 EXTREMELY
    2 QUITE A BIT
    3 MODERATELY
    4 A LITTLE
    5 NOT AT ALL

12. I worry about my urinary problems or incontinence getting worse as I grow older.

    1 EXTREMELY
    2 QUITE A BIT
    3 MODERATELY
    4 A LITTLE
    5 NOT AT ALL

13. I have a hard time getting a good night of sleep because of my urinary problems or incontinence.

    1 EXTREMELY
    2 QUITE A BIT
    3 MODERATELY
    4 A LITTLE
    5 NOT AT ALL

14. I worry about being embarrassed or humiliated because of my urinary problems or incontinence.

    1 EXTREMELY
    2 QUITE A BIT
    3 MODERATELY
    4 A LITTLE
    5 NOT AT ALL

15. My urinary problems or incontinence makes me feel like I'm not a healthy person.

    1 EXTREMELY
    2 QUITE A BIT
    3 MODERATELY
    4 A LITTLE
    5 NOT AT ALL

(Please circle the number of your answer)

16. My urinary problems or incontinence makes me feel helpless.

1 EXTREMELY
2 QUITE A BIT
3 MODERATELY
4 A LITTLE
5 NOT AT ALL

17. I get less enjoyment out of life because of my urinary problems or incontinence.

1 EXTREMELY
2 QUITE A BIT
3 MODERATELY
4 A LITTLE
5 NOT AT ALL

18. I worry about wetting myself.

1 EXTREMELY
2 QUITE A BIT
3 MODERATELY
4 A LITTLE
5 NOT AT ALL

19. I feel like I have no control over my bladder.

1 EXTREMELY
2 QUITE A BIT
3 MODERATELY
4 A LITTLE
5 NOT AT ALL

20. I have to watch what or how much I drink because of my urinary problems or incontinence.

1 EXTREMELY
2 QUITE A BIT
3 MODERATELY
4 A LITTLE
5 NOT AT ALL

(Please circle the number of your answer)

21. My urinary problems or incontinence limit my choice of clothing.

    1 EXTREMELY
    2 QUITE A BIT
    3 MODERATELY
    4 A LITTLE
    5 NOT AT ALL

22. I worry about having sex because of my urinary problems or incontinence.

    1 EXTREMELY
    2 QUITE A BIT
    3 MODERATELY
    4 A LITTLE
    5 NOT AT ALL

Appendix C

Demographic Questionnaire “About You” (U.S. English)

About You

A-1 How long have you had urinary problems or incontinence? *(Please write the number below)*

_____ _____
YEARS MONTHS

A-2 How many medical appointments have you made in the past year to treat your urinary problems or incontinence? *(Please write the number on the line provided)*

_____ NUMBER OF APPOINTMENTS IN THE LAST YEAR

A-3 How would you describe the severity of your urinary problems or incontinence? *(Please circle the number of your answer)*

1 MILD

2 MODERATE

3 SEVERE

A-4 Do you lose urine when you cough, sneeze, run, walk, jump or when you do some other specific activity?

0 NO

1 YES

A-5 Do you lose control of your bladder before you can get to the bathroom?

0 NO

1 YES

A-6 Do you lose urine at times not associated with any specific activity or the need to go to the bathroom?

0 NO

1 YES

A-7 In the last month, how many times did you lose urine, even a small amount, when you didn't want to? *(Please write the number on the line provided)*

_____ NUMBER OF TIMES IN THE LAST MONTH

A-8 In the last month, how many times did you lose urine, even a small amount, when you didn't want to?

0 NOT AT ALL IN THE LAST MONTH

1 1 TO 2 TIMES IN THE LAST MONTH

2 4 TIMES (ABOUT ONCE A WEEK)

3 2 TO 3 TIMES PER WEEK

4 ABOUT 1 TIME A DAY

5 ONE OR TWO TIMES A DAY

6 THREE OR FOUR TIMES A DAY

7 FIVE OR MORE TIMES A DAY