User Manual

LURN SYMPTOM INDEX-29 (LURN SI-29)

LURN SYMPTOM INDEX 10 (LURN SI-10)

Developed by the LURN Study Group

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Contents

List of Abbreviations

AUA-SI	American Urological Association Symptom Index
BPH	Benign Prostatic Hyperplasia
CASUS	Comprehensive Assessment of Self-Reported Urinary Symptoms
GUPI	Genitourinary Pain Index
LURN	Symptoms of Lower Urinary Tract Dysfunction Research Network
LURN SI-10	LURN Symptom Index 10
LURN SI-29	LURN Symptom Index 29
LUTS	Lower Urinary Tract Symptoms
PFDI	Pelvic Floor Distress Inventory
PRO	Patient-Reported Outcome
UDI	Urinary Distress Inventory

Overview

The LURN Symptom Index-29 (LURN SI-29) and the LURN Symptom Index-10 (LURN SI-10) were developed as patient-reported outcome (PRO) measures to assess urinary symptoms in adult men and women. The LURN SI-29 and LURN SI-10 are intended for use among individuals with urinary symptoms in general, including overactive bladder, pelvic floor disorders, stress urinary incontinence, urgency incontinence, mixed incontinence, nocturia, hesitancy, and post-void dribbling. The LURN SI-29 and LURN SI-10 assess urgency, incontinence, voiding difficulty, nocturia, pain, frequency and post-micturition symptoms over the past 7 days. The measures can be administered on paper or electronically. The LURN SI-29 includes 27 questions for both men and women, and 2 questions that are sex-specific (1 for women; 1 for men). It was developed for use in clinical research and takes approximately 5 minutes to complete. The LURN SI-10, drawn from the SI-29, includes 10 items that are summed to an index total score, and a summary item on the extent of bother. It is intended for use in clinical practice and takes approximately 2 minutes to complete. Both measures are currently available in English, and have undergone translatability review[1] to facilitate their translation into additional languages.

Background

Lower urinary tract symptoms (LUTS) are common among men and women, and individuals with LUTS often experience multiple symptoms.[2,3] In both clinical practice and research, brief, precise PROs can capture aspects of the patient experience that can add to laboratory, performance-based, and clinician assessment. Although several PROs have been developed for use in LUTS (see Table 1 in Appendix A), there are some important disadvantages to existing measures. For example, several commonly used PROs were developed in a sex-specific way, focusing only on men or only on women.[4] The American Urological Association Symptom Index (AUA-SI) was originally developed for men with benign prostatic hyperplasia (BPH),[5] and the Pelvic Floor Distress Inventory (PFDI) was developed for women with pelvic floor disorders.[6] Another concern with existing measures is that many do not cover the full spectrum of LUTS. For example, the AUA-SI does not assess incontinence.[5] To address the need for a brief PRO to assess the full range of LUTS, relevant for both men and women, investigators from the Symptoms of Lower Urinary Tract Dysfunction Research Network (LURN) set out to create a PRO that could be used as a multidimensional endpoint in clinical research.[7] They also aimed to create a brief clinical practice tool for use among both women and men with LUTS.[8] These became the LURN SI-29 and LURN SI-10, respectively.

Questionnaire development

The development of the LURN SI-29 involved a multistep process to modify the Comprehensive Assessment of Self-Reported Urinary Symptoms (CASUS),[9] which had been developed by LURN investigators to help phenotype patients with LUTS.[7] The first step in the process of developing the SI-29 involved an expert consensus conference during which a panel of participants with clinical expertise in

LUTS met to review the CASUS[9] items and discuss modifications to inform selection of items from among the >90 CASUS items. Specifically, the experts reviewed the results of a factor analysis of CASUS items in order to identify the LUTS domains to consider for inclusion in the LURN SI-29. The experts then reviewed the domains identified through the factor analysis and provided input regarding which CASUS items to consider for inclusion. The expert panel reached consensus on a 29-item measure with 5 scales covering different aspects of LUTS (urgency, incontinence, voiding difficulty, nocturia, and pain) as well as an additional 9 supplemental items.

Following the development of the LURN SI-29, a similar multistep process was employed to create the LURN SI-10.[8] An expert consensus conference with a panel of participants with clinical expertise in LUTS reviewed items in the LURN SI-29, with the purpose of selecting 1-2 items from each of the LURN SI-29 subscales to create the brief clinical form (SI-10). In considering items for inclusion, the expert panel focused on items that would be indicative of the need for further clinical investigation and/or intervention. The decision-making regarding the selection of the final items was unanimous, resulting in the creation of the LURN SI-10, assessing frequency, nocturia, urgency, incontinence, bladder pain, and post-micturition symptoms with 10 items, and an unscored global rating of bother.

Psychometrics

The validation of the LURN SI-29 and LURN SI-10 is an ongoing process. Future research will continue to investigate the reliability, validity, and other psychometric properties of these measures in a variety of clinical conditions associated with LUTS.

In an initial examination of the reliability of the LURN SI-29, all scales had internal consistency (Cronbach's alpha) greater than 0.7.[7] The initial examination of the validity of the LURN SI-29 demonstrated that the majority of the scales were associated with legacy PRO measures assessing LUTS (e.g., AUA-SI,[5] GUPI,[10] PFDI-20[6]) in the expected direction. The LURN SI-29 also demonstrated the ability to distinguish between patients with different symptom severity categories, as determined by the AUA-SI.[5]

In an initial examination of reliability, the LURN SI-10 had internal consistency (Cronbach's alpha) of 0.68 (0.65 for women; 0.76 for men). The examination of the dimensionality and reliability of the LURN SI-10 remains a direction for future research. In an initial examination of the validity of the LURN SI-10, higher scores on the LURN SI-10 were associated with higher patient ratings of bother and more frequent symptoms.[8] The LURN SI-10 was also associated with legacy PRO measures of LUTS (e.g., AUA-SI[5] and UDI-6[11]) in the expected direction. [8] Additionally, the LURN SI-10 demonstrated the ability to distinguish between patients with different symptom severity categories, as determined by the AUA-SI.[5]

Instructions for administration

The LURN SI-29 and LURN SI-10 are meant to be self-administered by the respondent without help from another person. Currently the LURN SI-29 and LURN SI-10 are available in paper format; however they can also be loaded into electronic administration platforms if done in such a way that adheres to the exact structure of the questions. It is recommended that administration take place in a quiet, private space. In clinical settings, respondents should be given the optimal time needed to accurately capture their perspective and to ensure data completeness. This may depend upon the clinic work flow and/or the study aims. Respondents should be instructed to read the instructions and follow them as they complete the questionnaire. They should be instructed to complete each item, without skipping, in the order in which they are presented. Respondents should also be instructed to select the response option most applicable to them for each item.

In the event that a respondent has a question about an item, it is acceptable for the questionnaire administrator to define a specific word, but not to define concepts where the respondent's subjective interpretation is the goal of the question. The administrator should not provide interpretation of concept meaning but should instruct the patient to respond based on their own interpretation of the concept. When possible, upon completion of the questionnaire, the person administering the questionnaire should review it for missing responses (in which case the respondent can be asked if they meant to leave the question blank) or instances in which more than one response is selected for a given item (in which case the respondent can be asked to select a single response option). If it is not possible to clarify when a respondent selects multiple response options for a single item, then a standard approach is to assign the more severe of the selected responses as the person's value.

When appropriate, the LURN SI-29 and LURN SI-10 can also be administered via interview. The interviewer should read the instructions and items verbatim, without any additional instruction or interpretation of the items.

The administration forms for the LURN SI-29 and LURN SI-10 can be found in Appendices B and C, respectively.

Avoiding missing data

If a person is unwilling to answer a question on the LURN SI-29 or the LURN SI-10, it is acceptable for them to leave it missing. However, sometimes people overlook questions. Thus in the clinic, it is good practice to check the LURN forms to see if any items are missing. If so, confirm with the patient that these should be left missing, or alternately if they are willing to answer. In research, if paper forms are used, check the forms for missingness before the participant is finished with their visit. The LURN symptom indices can still be scored as long as not too much data are missing (see below), but complete forms will be more informative and reduce scoring complexity.

Scoring

Each item on the LURN SI-29 and LURN SI-10 includes a set of response options, each of which have a numerical score attached to the response (see the example below).

	Never	A few nights	About half the nights	Most nights	Every night
6. In the past 7 days, how often did you leak urine during the night, including wetting a pad or the bed?	0	1	2	3	4

Scoring the LURN SI-29 and LURN SI-10 is easiest and most accurate when people answer all of the questions, so 100% completion should be encouraged.To calculate a sum score on either the LURN SI-29 or the LURN SI-10 when there are missing responses, greater than 50% of the items must have been completed by the respondent. If half or more of the items are missing, a score should not be calculated. When more than half of the relevant items have responses, scores can be prorated (see instructions below).

LURN SI-29 Scoring

The subscale and total scores for the LURN SI-29 are normalized to a scale from 0 – 100.[12] To calculate the subscale scores for Sections A – E of the LURN SI-29 *when no data are missing*:

1.	Compute the sum of all item scores for the subscale (observed score)	Box = _____ 1
2.	Compute the maximum possible score for the subscale	2 = _____
3	Box 1 / Box 2 X 100	Subscale Score = _____

For example, if a respondent's score for Section A is 12 and a maximum possible and the maximum possible score for Section A is 24, the prorated score would be 12/24 X 100, or **50**.

In the case of missing data, a prorated score can be calculated by computing the proportion of observed scores to the possible maximum score for items completed and then multiplying by 100%. To calculate the subscale scores when *< 50% of items per subscale are missing:*

1.	Verify that < 50% of items are missing (If 50% or more items are missing, a score should not be calculated)	Box
2.	Compute the sum of all completed responses from items in the subscale	= _____ 2
3.	Compute the maximum possible sum (highest possible response options) based on the items completed in the subscale	= _____ 3
4.	Box 2 / Box 3 X 100%	Prorated Score = _____

(Please note that both items in Section E must be completed in order to calculate a score.)

For example, if a respondent answers 5 of 6 questions in a Section A, with a sum of completed responses of 12, and the maximum possible sum based on the items completed of 20, the prorated score would be 12/20 X 100, or **60**.

No subscale score is computed for Section F because it consists of supplementary items rather than a single symptom domain. However, the responses to the items in Section F are included in the overall LURN SI-29 score.

To calculate the total score for the LURN SI-29, *when no data are missing*:

1.	Compute the sum of all item scores for Section A- F (observed score)	Box = _____ 1
2.	Box 1 / 105 (maximum possible score)	2 = _____
3.	Box 2 X 100 = Total score	Total Score = _____

For example, if the sum of all item scores is 90, the normalized score would be (90/105) X 100, or **85.7**.

Due to variation in the score ranges for the response options across sections, in the presence of < 50% of missing items in LURN SI-29, the proportion of observed scores to the possible maximum score for items completed is calculated and then multiplied by 100. To calculate the total score for the LURN SI-29 *when < 50% of items are missing*:

1.	Verify that < 50% of items are missing (If 50% or more items are missing, a score should not be calculated)	Box
2.	Compute the sum of all completed responses from items	= _____ 2
3.	Compute the maximum possible sum (highest possible response options) based on the items completed	= _____ 3
4.	Box 2 / Box 3 X100%	Prorated Score = _____

For example, if the sum of all completed item scores is 46 and the responses to items 6, 14, 21, and 22 are missing, the prorated normalized score would be (46/90) X 100, or **51**.

Erratum on old versions of LURN SI-29: In some previous versions of the LURN SI-29, Question #22 was missing a response option ("1-2 hours"). If you have this version of the questionnaire, we recommend recoding the maximum response option to "4" for "Less than 1 hour" and applying the same formulas as above. The corrected version of the questionnaires and the manual are available at https://nih-lurn.org/Resources/Questionnaires

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LURN SI-10 Scoring

Recommended scoring algorithm

To calculate the score for the LURN SI-10 *when no data are missing*:

Compute the sum of all item scores for items 1-10 = _____

(Please note that item 11 on the LURN SI-10 is not scored.)

Scoring if items are missing

Items 9 and 10 on the LURN SI-10 utilize score ranges for the response options that differ from items 1-8. Thus, in the presence of < 50% of missing items, the proportion of observed scores to the possible maximum score for items completed is calculated and then multiplied by the maximum score of items 1-10.

To calculate the prorated score for the LURN SI-10 *when < 50% of Items 1-10 are missing (i.e., when 6 or more items are present)*:

		Box
1.	Verify that < 50% of items 1-10 are missing (If 50% or more items are missing, a score should not be calculated)	Box
2.	Compute the sum of all completed items 1-10	= _____ 2
3.	Calculate the maximum possible sum (highest possible response options) based on the items completed	= _____ 3
4.	Box 2 / Box 3	= _____ 4
5.	Box 4 X 38 (Maximum total score of all items 1-10)	Prorated Score = _____

For example, if the sum of all completed items was 21 (Box 2) and the sum of the maximum possible response (Box 3) was 24, the prorated score would be (21/34) X 38, or **23.5.**

Office scoring

In the clinical setting, a quick scoring algorithm is desired. The office-scoring algorithm will yield exactly the same results as the above algorithm (see above) if no items are missing. If there are one or more missing items, the algorithm will yield slightly different results than the preceding algorithm, but only very slightly. We recommend only using the office-scoring algorithm for quick scoring in the clinical setting. Missing data should be avoided whenever possible (see above).

LURN SI-10 quick office-scoring algorithm:

The office-scoring algorithm is printed on the LURN SI-10 form. It is:

Q1-10 Sum × 10 / # questions answered (Max score is 38)

Interpretation

When interpreting scores on the LURN SI-29 and LURN SI-10, higher scores indicate greater severity of LUTS. The majority of the items assess the frequency with which symptoms occur as an index for severity. Scores on the LURN SI-29 range from 0 (least severe) to 100 (most severe) and scores on the LURN SI-10 range from 0 (least severe) to 38 (most severe). Currently there are not severity cutoffs established for the LURN SI-29 and LURN SI-10; the establishment of severity cutoffs in specific medical conditions (e.g., overactive bladder syndrome) remains a direction for future research.

Future directions

This User Manual provides an overview of the initial development and validation of two new PRO measures to assess symptoms among adult men and women affected by conditions associated with LUTS. As part of the ongoing development of these measures, several future directions are planned.

Development of web-based administration platform: Increasingly, surveys such as these are administered electronically, including use of web-based administration. The potential benefits of electronic administration are many, and this is an area of future development for the LURN SI-29 and LURN SI-10. The successful electronic administration of items during the initial validation phase provides support for future electronic administration platforms of the LURN SI-29 and LURN SI-10.

Translation into additional languages: Availability of the LURN SI-29 and LURN SI-10 in languages other than English is a high priority. During their development, these questions underwent a translatability review which provides some assurance that translations of these measures will succeed at conveying their intended meaning.

Responsiveness to change and responder definitions: An important next step in the validation process involves investigating how the scores on the LURN SI-29 and LURN SI-10 respond to meaningful change. Future work to examine responsiveness to change, and to define the amount of change that is meaningful to the patient, will enhance the interpretability of the measures in response to interventions.

Ongoing examination of reliability, validity, and other psychometric properties: The LURN team recognizes that validation is an ongoing process. Future work will examine the psychometric properties of the LURN SI-29 and LURN SI-10 in different clinical populations and settings.

Severity and change score guidelines: Future work will seek to establish severity cutoff scores and clinically important change scores on the LURN SI-29 and LURN SI-10. This will aid in the ability to categorize patients according to severity level and meaningful change, which may enhance diagnostic accuracy and the utility of these measures in clinical practice and research. It may also help differentiate patients based on distinct clinical clusters, such as irritative, obstructive, etc.

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Copyright Statement

References

1. Acquadro C, Patrick DL, Eremenco S, et al. Emerging good practices for Translatability Assessment (TA) of Patient-Reported Outcome (PRO) measures. *Journal of patient-reported outcomes.* 2017;2(1):8.
2. Coyne KS, Sexton CC, Thompson CL, et al. The prevalence of lower urinary tract symptoms (LUTS) in the USA, the UK and Sweden: results from the Epidemiology of LUTS (EpiLUTS) study. *BJU Int.* 2009;104(3):352-360.
3. Sexton CC, Coyne KS, Kopp ZS, et al. The overlap of storage, voiding and postmicturition symptoms and implications for treatment seeking in the USA, UK and Sweden: EpiLUTS. *BJU Int.* 2009;103 Suppl 3:12-23.
4. Griffith JW. Self-report measurement of lower urinary tract symptoms: a commentary on the literature since 2011. *Current urology reports.* 2012;13(6):420-426.
5. Barry MJ, Fowler FJ, Jr., O'Leary MP, et al. The American Urological Association symptom index for benign prostatic hyperplasia. The Measurement Committee of the American Urological Association. *J. Urol.* 1992;148(5):1549-1557; discussion 1564.
6. Barber MD, Kuchibhatla MN, Pieper CF, Bump RC. Psychometric evaluation of 2 comprehensive condition-specific quality of life instruments for women with pelvic floor disorders. *Am. J. Obstet. Gynecol.* 2001;185(6):1388-1395.
7. Cella D, Smith AR, Griffith JW, et al. A new outcome measure for LUTS: Symptoms of Lower Urinary Tract Dysfunction Research Network Symptom Index-29 (LURN SI-29) questionnaire. *Neurourol. Urodyn.* 2019.
8. Cella D SA, Griffith JW, Kirkali Z, Flynn KE, Bradley CS, Jelovsek JE, Gillespie BW, Helfand BT, Talaty P, Weinfurt KP, LURN Study Group. A new brief clinical assessment of lower urinary symptoms for women and men: The LURN Symptom Index-10 (LURN SI-10). *J. Urol.* In Press.

9.   Weinfurt KP, Griffith JW, Flynn KE, et al. The Comprehensive Assessment of Self-Reported Urinary Symptoms: A New Tool for Research on Subtypes of Patients with Lower Urinary Tract Symptoms. *J. Urol.* 2019;201(6):1177-1183.

10.   Clemens JQ, Calhoun EA, Litwin MS, et al. Validation of a modified National Institutes of Health chronic prostatitis symptom index to assess genitourinary pain in both men and women. *Urology.* 2009;74(5):983-987, quiz 987.e981-983.

11.   Shumaker SA, Wyman JF, Uebersax JS, McClish D, Fantl JA. Health-related quality of life measures for women with urinary incontinence: the Incontinence Impact Questionnaire and the Urogenital Distress Inventory. Continence Program in Women (CPW) Research Group. *Qual. Life Res.* 1994;3(5):291-306.

12.   Cohen P, Cohen J, Aiken LS, West SG. The Problem of Units and the Circumstance for POMP. *Multivariate Behavioral Research.* 1999;34(3):315-346.

13.   Uebersax JS, Wyman JF, Shumaker SA, McClish DK, Fantl JA. Short forms to assess life quality and symptom distress for urinary incontinence in women: the Incontinence Impact Questionnaire and the Urogenital Distress Inventory. Continence Program for Women Research Group. *Neurourol. Urodyn.* 1995;14(2):131-139.

14.   Utomo E, Korfage IJ, Wildhagen MF, Steensma AB, Bangma CH, Blok BF. Validation of the Urogenital Distress Inventory (UDI-6) and Incontinence Impact Questionnaire (IIQ-7) in a Dutch population. *Neurourol. Urodyn.* 2015;34(1):24-31.

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

16.   Bradley CS, Rahn DD, Nygaard IE, et al. The questionnaire for urinary incontinence diagnosis (QUID): validity and responsiveness to change in women undergoing non-surgical therapies for treatment of stress predominant urinary incontinence. *Neurourol. Urodyn.* 2010;29(5):727-734.

17.   Barber MD, Walters MD, Bump RC. Short forms of two condition-specific quality-of-life questionnaires for women with pelvic floor disorders (PFDI-20 and PFIQ-7). *Am. J. Obstet. Gynecol.* 2005;193(1):103-113.

18.   Homma Y, Yoshida M, Seki N, et al. Symptom assessment tool for overactive bladder syndrome--overactive bladder symptom score. *Urology.* 2006;68(2):318-323.

19.   Avery K, Donovan J, Peters TJ, Shaw C, Gotoh M, Abrams P. ICIQ: a brief and robust measure for evaluating the symptoms and impact of urinary incontinence. *Neurourol. Urodyn.* 2004;23(4):322-330.

20.   Coyne K, Revicki D, Hunt T, et al. Psychometric validation of an overactive bladder symptom and health-related quality of life questionnaire: the OAB-q. *Qual. Life Res.* 2002;11(6):563-574.

21.   Coyne KS, Thompson CL, Lai JS, Sexton CC. An overactive bladder symptom and health-related quality of life short-form: validation of the OAB-q SF. *Neurourol. Urodyn.* 2015;34(3):255-263.

22.   Brookes ST, Donovan JL, Wright M, Jackson S, Abrams P. A scored form of the Bristol Female Lower Urinary Tract Symptoms questionnaire: data from a randomized

controlled trial of surgery for women with stress incontinence. *Am. J. Obstet. Gynecol.* 2004;191(1):73-82.

23. Sandvik H, Hunskaar S, Seim A, Hermstad R, Vanvik A, Bratt H. Validation of a severity index in female urinary incontinence and its implementation in an epidemiological survey. *J. Epidemiol. Community Health.* 1993;47(6):497-499.

24. Patrick DL, Martin ML, Bushnell DM, Yalcin I, Wagner TH, Buesching DP. Quality of life of women with urinary incontinence: further development of the incontinence quality of life instrument (I-QOL). *Urology.* 1999;53(1):71-76.

25. Coyne KS, Sexton CC, Kopp Z, et al. Assessing patients' descriptions of lower urinary tract symptoms (LUTS) and perspectives on treatment outcomes: results of qualitative research. *Int. J. Clin. Pract.* 2010;64(9):1260-1278.

26. Brandt BA, Angun C, Coyne KS, Doshi S, Bavendam T, Kopp ZS. LUTS patient reported outcomes tool: linguistic validation in 10 European languages. *Neurourol. Urodyn.* 2013;32(1):75-81.

27. Coyne KS, Barsdorf AI, Thompson C, et al. Moving towards a comprehensive assessment of lower urinary tract symptoms (LUTS). *Neurourol. Urodyn.* 2012;31(4):448-454.

28. Black N, Griffiths J, Pope C. Development of a symptom severity index and a symptom impact index for stress incontinence in women. *Neurourol. Urodyn.* 1996;15(6):630-640.

29. Coyne K ML, Versi E. Urinary urgency: Can ''gotta go'' be mea- sured? . 10th Annual Meeting of the International Society for Quality of Life Research; 2003; Prague, Czech Republic.

30. Matza LS, Thompson CL, Krasnow J, Brewster-Jordan J, Zyczynski T, Coyne KS. Test-retest reliability of four questionnaires for patients with overactive bladder: the overactive bladder questionnaire (OAB-q), patient perception of bladder condition (PPBC), urgency questionnaire (UQ), and the primary OAB symptom questionnaire (POSQ). *Neurourol. Urodyn.* 2005;24(3):215-225.

31. Piault E, Evans CJ, Espindle D, Kopp Z, Brubaker L, Abrams P. Development and validation of the Overactive Bladder Satisfaction (OAB-S) Questionnaire. *Neurourol. Urodyn.* 2008;27(3):179-190.

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

33. Coyne KS, Matza LS, Kopp Z, Abrams P. The validation of the patient perception of bladder condition (PPBC): a single-item global measure for patients with overactive bladder. *Eur. Urol.* 2006;49(6):1079-1086.

34. Lowenstein L, FitzGerald MP, Kenton K, et al. Evaluation of urgency in women, with a validated Urgency, Severity and Impact Questionnaire (USIQ). *Int. Urogynecol. J. Pelvic Floor Dysfunct.* 2009;20(3):301-307.

35. Cardozo L, Coyne KS, Versi E. Validation of the urgency perception scale. *BJU Int.* 2005;95(4):591-596.

Appendix A

Table 1. Existing Measures of Lower Urinary Tract, Incontinence, and Overactive Bladder Symptoms and Impacts

Measure	Description
Comprehensive Assessment of Self-reported Urinary Symptoms (CASUS)[9]	A comprehensive pool of 93 items designed to evaluate a wide range of lower urinary tract symptoms (LUTS) experienced by men and women. CASUS was designed to provide granular and precise information about symptom experience for phenotyping. Items cover a range of LUTS symptoms and sensations (i.e., daytime frequency, nighttime frequency, sensations, urgency, effort with urination, urine flow, incontinence, incomplete emptying).
Lower Urinary Tract Dysfunction Research Network Symptom Index-29 (LURN SI-29)[7]	A 29-item patient reported outcome (PRO) tool that evaluates LUTS. The LURN SI-29 consists of five sub-scales that assess urgency, incontinence, voiding difficulty, nocturia, and pain along with nine individual questions that measure voiding, nighttime urgency, constant urgency, incomplete emptying, leakage just after voiding, splitting, spraying, change of direction of urine stream, and overall bother over the past 7 days. Items evaluate severity of symptoms with scores ranging from 0 (least severe) to 100 (most severe).
Lower Urinary Tract Dysfunction Research Network Symptom Index-10 (LURN SI-10)[8]	An 11-item short form version of the LURN SI-29 that assesses urinary frequency, nocturia, urgency, incontinence, bladder pain, post-micturition symptoms and one unscored global rating item over the past 7 days. Items evaluate severity of symptoms with scores ranging from 0 (least severe) to 38 (most severe).
Urogenital Distress Inventory (UDI)[11]	A 19-item questionnaire that assesses the experience of lower urinary tract dysfunction symptoms and the degree of bother associated with each. Participants indicate whether they experience each symptom (yes/no) for the symptoms experienced rate the degree of bother on a 4-point Likert scale (1=not at all; 4=greatly). The measure consists of three subscales: irritative symptoms (9 items), obstructive/discomfort (11 items), and stress symptoms (2 items). Mean scores are calculated for each subscale and transformed to a common scale of 0-100. The sum of all subscales yields the total UDI score, range 0-300.
Urogenital Distress Inventory (UDI-6)[13,14]	A 6-item short form that evaluates overall symptom distress of lower urinary track dysfunction across three symptom domains (i.e., irritative, stress, obstructive/discomfort). Respondents indicate whether they experience the symptom and rate the degree of bother on a 4-point Likert scale (1=not at all; 4=greatly). The instrument is scored by averaging the score of items responded to and transforming to a 0 to 100 scale, yielding a single index score representing overall symptom distress. If more than

	two items are skipped, a total score should not be calculated. Although the IIQ-7 does not yield separate subscale scores, item-level analyses can be conducted. The short form is useful for frequent assessments and when time is limited.
Incontinence Impact Questionnaire (IIQ)[11]	A 30-item questionnaire that evaluates the impact of urinary incontinence on a range of activities and emotions. The instrument consists of four subscales: physical activity (6 items), travel (6 items), social relationships (10 items), and emotional health (8 items). The degree to which urinary incontinence affects each activity or emotion is rated on a 4-point Likert scale (1=not at all; 4=greatly). Mean scores are calculated for each subscale and transformed to a common scale of 0-100. The sum of all subscales yields the total IIQ score, range 0-400.
Incontinence Impact Questionnaire –Short Form (IIQ-7)[13,14]	A 7-item short form that evaluates the impact of urinary incontinence on physical activity, travel, social relationships, and emotional health. The degree to which urinary incontinence affects each is rated on a 4-point scale (1=not at all; 4=greatly). The instrument is scored by averaging the score of items responded to and transforming to a 0 to 100 scale, yielding a single index score representing life impact. If more than two items are skipped, a total score should not be calculated. Although the IIQ-7 does not yield separate subscale scores, item-level analyses can be conducted. The short form is useful for frequent assessments and when time is limited.
The Questionnaire for female Urinary Incontinence Diagnosis (QUID)[15,16]	A 6-item measure designed to assess two domains of female urinary incontinence: stress (3 items) and urge (3 items). Responses are scored from 0 (none of the time) to (5 all of the time). Scores are summed for each domain and range from 0-15.
Pelvic Floor Distress Inventory (PFDI-20)[17]	A 20-item measure that evaluates quality of life impact of lower urinary tract, lower gastrointestinal tract, and pelvic organ prolapse symptoms of women with pelvic floor disorders with three scales: Urinary Distress Inventory (UDI-6 items), Pelvic Organ Prolapse Distress Inventory (POPDI-6 items), and Colorectal-Anal Distress Inventory (CRADI-8 items). All 3 scales are scored from 0 (least distress) to 100 (greatest distress) for each, and sum score of all 3 scales provides an overall summary score of the PFDI-20 (range 0 - 300).
Pelvic Floor Impact Questionnaire—short form 7 (PFIQ-7)[17]	A 7-item instrument adapted from IIQ-7 that evaluates the fecal and urinary incontinence symptoms experienced by women with pelvic floor disorders and the impact on physical activity, travel, social relationships, and emotional health over the past three months. The questionnaire consists of 3 subscales (Urinary Impact Questionnaire, UIQ-7); Colorectal-Anal Impact Questionnaire (CRAI-Q-7); and Pelvic Organ Prolapse IMpact Questionnaire (POPIQ-7). The degree to which incontinence affects each impact is rated on a 4-point Likert scale from 1 (not at all) to 4 (greatly). The 3 subscales are scored from 0 (least impact) to 100 (greatest impact) that can be summed for an overall summary score (0 to 300).

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Overactive Bladder Symptom Impact Score (OABSS)[18]	A 4-item instrument that assesses frequency of overactive bladder symptoms over the past week. Items capture daytime frequency, nighttime frequency, urgency, and urgency incontinence. Scores across the four items are summed yielding an overall OAB symptom score.
ICIQ-UI Short Form[19]	ICIQ has multiple modules for men and women. One example is this 4-item questionnaire that assesses urinary incontinence over the past 4 weeks in terms of frequency, severity, and QOL impact and an unscored perceived cause item. Responses to the first 3 items (frequency, severity, impact) are summed yielding total score ranging from 0 to 21.
Overactive Bladder Health-Related Quality of Life Questionnaire (OAB-q)[20]	A 33-item PRO measure of OAB symptom bother and HRQL impact over the past 4 weeks. The OAB-q consists of an 8-item symptom bother scale and 4 HRQL subscales: coping (8 items), concern/worry (7 items), social interaction (5 items), sleep (5 items). Responses are scored on a 6-point scale from 1 (none of the time) to 6 (all of the time). Higher scores on the symptom bother scale indicate more symptom bother and higher scores on HRQL subscale indicates better HRQL.
Overactive Bladder Health-Related Quality of Life Questionnaire Short Form (OAB-q SF)[21]	A 19-item OAB short form comprised by two scales: Symptom Bother Scale (6 items) and HRQL Scale (13 items). High symptom bother scores indicate greater symptom bother and higher scores on HRQL subscale indicate better HRQL.
American Urological Association Symptom Index (AUA-SI)[5]	A 7-item symptom index that assesses symptoms of benign prostatic hyperplasia (BPH). The AUA-SI was developed and validated by a multidisciplinary measurement committee of the American Urological Association (AUA).
Bristol Female Lower Urinary Tract Symptom (BFLUTS-SF) Questionnaire[22]	A 19-item instrument that assesses female lower urinary tract symptoms, sexual functioning, and quality of life over the past month. The BFLUTS-SF consists of three incontinence symptom subscales (incontinence symptoms: 5 items; voiding symptoms: 3 items; filling symptoms: 4 items) and subscales for sexual function (2 items) and quality of life (5 items).
Incontinence Severity Index (ISI)[23]	A 2-item severity index of female urinary incontinence that assesses the frequency and volume of urinary leakage. Scores range from 1-8, yielding an index of incontinence severity of slight (1-2), moderate (3-4), or severe (6-8) urinary incontinence.
Incontinence Quality of Life Instrument (I-QOL)[24]	A 22-item measure of the impact of urinary incontinence on quality of life. The instrument is composed of three sub-scales: avoidance and limiting behaviors (8 items), psychosocial impacts (9 items), and social embarrassment (5 items). Scores are summed across sub-scales yielding a composite incontinence quality of life score. Higher scores indicate better quality of life.
Lower Urinary Tract Symptoms (LUTS) Tool[25-27]	An 18-item measure that evaluates the frequency and bother of lower urinary tract symptoms in women and men over the past month. The development of the instrument was based on qualitative findings from 8 focus groups and linguistic validation via cognitive interviews in 10 languages. The LUTS Tool has yet to be validated in a clinical sample.

Symptom Severity Index (SSI) and Symptom Impact Index (SII)[28]	SSI: A 5-item index that evaluates the severity of stress incontinence in women. Questions cover frequency and amount of leakage over the past year, number of pads/sanitary towels used a week, checklist of incontinence stressors, and frequency of urine leakage over the past week. SII: A 4-item measure that assesses the impact of stress incontinence on women. Questions cover frequency of not engaging in activities, frequency of not engaging in social activities, checklist of impacts from bladder problems (holidays, family life, social life, hobbies), and impact on sex life.
Urgency Questionnaire (UQ)[29]	An instrument that assesses patient-reported severity and impact of urinary urgency symptoms via 15 Likert-scale items and four visual analog scales.
Primary OAB Symptom Questionnaire (POSQ)[30]	A 5-item questionnaire that assesses patient rated bother associated with four OAB symptoms (urinary urgency, urinary frequency, nocturia, urge incontinence) during the past 2 weeks; the fifth item asks patients to indicate which of the four symptoms is the most bothersome.
Overactive Bladder Satisfaction Questionnaire (OAB-S)[31]	A 51-item patient-reported instrument that evaluates patient satisfaction with OAB treatment (e.g., medication, physical therapy, biofeedback). The OAB-S consists of 5 scales: OAB Control Expectations (10 items); Impact on Daily Living with OAB (10 items); OAB Control (10 items); OAB Medication Tolerability (6 items); and Satisfaction with Control (10 items), and 5 additional single-item overall assessments: patient's fulfillment of OAB medication expectations, interruption of day-to-day life due to OAB, overall satisfaction with OAB medication; willingness to continue OAB medication, and improvement in day-to-day life due to OAB medication.
Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12)[32]	A short form (version of the PISQ-31) that evaluates pelvic organ prolapse and urinary incontinence symptoms and impact on sexual intercourse over the past 6 months. Responses are captured using a 5-point Likert scale from 'always' to 'never'.
Patient Perception of Bladder Condition[33]	A single-item global measure of overactive bladder condition. Participants are asked to select one of 6 response options that reflects their current bladder condition in terms of the perceived severity of problems caused by the bladder condition.
Urgency, Severity and Impact Questionnaire (USIQ)[34]	A 13-item measure of urgency symptoms independent of urge incontinence. The instrument consists of two subscales that evaluate urgency symptom severity (USIQ-S; 5 items) and the impact of urgency on quality of life (USIQ-QOL; 8 items).
Urgency Perception Scale (UPS)[35]	A single-item measure of urgency for individuals with OAB that evaluates how long one is typically able to hold their urine when experiencing urgency.

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Appendix B

LURN SYMPTOM INDEX-29 (LURN SI-29)

Instruction: **This questionnaire asks you about different urinary symptoms. Please read each question carefully, and then circle the response that best describes your symptoms.**

Section A

	Never	A few times	About half the time	Most of the time	Every time
1. In the past 7 days, how often did you completely lose control of your bladder?	0	1	2	3	4
2. In the past 7 days, how often did you leak urine or wet a pad after feeling a sudden need to urinate?	0	1	2	3	4
3. In the past 7 days, how often did you leak urine or wet a pad while laughing, sneezing, or coughing?	0	1	2	3	4
4. In the past 7 days, how often did you leak urine or wet a pad when doing physical activities, such as exercising or lifting a heavy object?	0	1	2	3	4
5. In the past 7 days, how often did walking at your usual speed cause you to leak urine or wet a pad?	0	1	2	3	4

	Never	A few nights	About half the nights	Most nights	Every night
6. In the past 7 days, how often did you leak urine during the night, including wetting a pad or the bed?	0	1	2	3	4

Section B

	Never	A few times	About half the time	Most of the time	Every time
7. In the past 7 days, how often did you have pain or discomfort in your bladder while it was filling?	0	1	2	3	4
8. In the past 7 days, how often did you have pain or discomfort in your bladder when it was full?	0	1	2	3	4
9. In the past 7 days, how often did you have pain or discomfort while urinating?	0	1	2	3	4
10. In the past 7 days, how often did you have pain or discomfort right after you had finished urinating?	0	1	2	3	4

Cella D, Smith AR, Griffith JW, et al. A new outcome measure for LUTS: Symptoms of Lower Urinary Tract Dysfunction Research Network Symptom Index-29 (LURN SI-29) questionnaire. *Neurourology and Urodynamics.* 2019;1-9. https://doi.org/10.1002/nau.24067

Section C

	Never	A few times	About half the time	Most of the time	Every time
11. In the past 7 days, how often did you have to push when urinating?	0	1	2	3	4
12. In the past 7 days, how often did you have a delay before you started to urinate?	0	1	2	3	4
13. In the past 7 days, once you started urinating, how often did your urine flow stop and start again?	0	1	2	3	4
14. In the past 7 days, how often was your urine flow slow or weak?	0	1	2	3	4
15. In the past 7 days, how often did you have a trickle or dribble at the end of your urine flow?	0	1	2	3	4

Section D

	Never	A few times	About half the time	Most of the time	Every time
16. In the past 7 days, how often did you feel a sudden need to urinate?	0	1	2	3	4
17. In the past 7 days, how often did you have a sudden need to rush to urinate for fear of leaking urine?	0	1	2	3	4

	Not difficult	A little difficult	Somewhat difficult	Very difficult	Unable to wait
18. In the past 7 days, once you noticed the need to urinate, how difficult was it to wait more than a few minutes?	0	1	2	3	4

Section E

	None	1 time	2-3 times	More than 3 times	
19. In the past 7 days, during a typical night, how many times did you wake up and urinate?					
Circle number here --->	0	1	2	3	

	Never	A few nights	About half the nights	Most nights	Every night
20. In the past 7 days, how often did you wake up at least once during the night because you had to urinate?	0	1	2	3	4

Cella D, Smith AR, Griffith JW, et al. A new outcome measure for LUTS: Symptoms of Lower Urinary Tract Dysfunction Research Network Symptom Index-29 (LURN SI-29) questionnaire. *Neurourology and Urodynamics.* 2019;1-9. https://doi.org/10.1002/nau.24067

Section F

21. In the past 7 days, during waking hours, how many times did you typically urinate?	3 or fewer times a day	4-7 times a day	8-10 times a day	11 or more times a day
Circle number here --->	0	1	2	3

22. In the past 7 days, during a typical day, how much time typically passed between urinations?	More than 6 hours	5-6 hours	3-4 hours	1-2 hours	Less than 1 hour
Circle number here --->	0	1	2	3	4

23. In the past 7 days, how would you describe your typical urge to urinate when you woke up during the night?	No urge	Mild urge	Moderate urge	Strong urge
Circle number here --->	0	1	2	3

24. In the past 7 days, did you have a constant need to urinate that did not go away?	Yes	No
Circle number here --->	1	0

	Never	A few times	About half the time	Most of the time	Every time
25. In the past 7 days, how often did you feel that your bladder was not completely empty after urination?	0	1	2	3	4
26. In the past 7 days, how often did you dribble urine just after zipping your pants or pulling up your underwear?	0	1	2	3	4
FOR WOMEN ONLY: 27a. In the past 7 days, how often did you have spraying or change in direction of your urine stream?	0	1	2	3	4
FOR MEN ONLY: 27b. In the past 7 days, how often did you have splitting or spraying of your urine stream?	0	1	2	3	4

28. In the past 7 days, how bothered were you by urinary symptoms?	Not at all bothered	Somewhat bothered	Very bothered	Extremely bothered
Circle number here --->	0	1	2	3

Appendix C

LURN SYMPTOM INDEX-10 (LURN SI-10)

Instruction: This questionnaire asks you about different urinary symptoms. Please read each question carefully, and then <u>circle the response that best describes your symptoms</u>.

	Never	A few times	About half the time	Most of the time	Every time
1. In the past 7 days, how often did you feel a sudden need to urinate?	0	1	2	3	4
2. In the past 7 days, how often did you leak urine or wet a pad after feeling a sudden need to urinate?	0	1	2	3	4
3. In the past 7 days, how often did you leak urine or wet a pad while laughing, sneezing, or coughing?	0	1	2	3	4
4. In the past 7 days, how often did you leak urine or wet a pad when doing physical activities, such as exercising or lifting a heavy object?	0	1	2	3	4
5. In the past 7 days, how often did you have pain or discomfort in your bladder while it was filling?	0	1	2	3	4
6. In the past 7 days, how often did you have a delay before you started to urinate?	0	1	2	3	4
7. In the past 7 days, how often was your urine flow slow or weak?	0	1	2	3	4
8. In the past 7 days, how often did you dribble urine just after zipping your pants or pulling up your underwear?	0	1	2	3	4
Circle number here --->	0	1	2	3	
9. In the past 7 days, during waking hours, how many times did you typically urinate?	(3 or fewer times a day)	(4-7 times a day)	(8-10 times a day)	(11 or more times a day)	
Circle number here --->	0	1	2	3	
10. In the past 7 days, during a typical night, how many times did you wake up and urinate?	(none)	(1 time)	(2-3 times)	(More than 3 times)	

	Not at all bothered	Somewhat bothered	Very bothered	Extremely bothered
In the past 7 days, how bothered were you by urinary symptoms?				

Office Use: (note: last question is an unscored global rating)

Office Scoring: Questions 1-10: Sum of all responses x 10 / number of questions answered

_____ x 10 / _____ = _____

Q 1-10 Sum   # questions answered   LURN SI-10 score (Max Score is 38)

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