

*LURN: Symptoms of Lower Urinary Tract Dysfunction Research Network
Protocol 2: Recall Study, v 1.0
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Symptoms of Lower Urinary Tract Dysfunction Research Network (LURN)

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Version 1.0

Steering Committee Approval Date

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1. Introduction and Overview

This protocol is part of an overall effort to create a state-of-the-art resource for measuring patient-reported health for patients with lower urinary tract dysfunction (LUTD). The primary purpose of this resource, known as the LURN PRO Battery, is to comprehensively characterize the self-reported experiences of patients with LUTD for the purpose of enhancing efforts to characterize and explain important subtypes of patients with LUTD (phenotypes). Secondary purposes of the LURN PRO Battery, for which additional development work will be required, include developing better patient-reported endpoints for clinical trials, monitoring symptoms in the course of clinical care, and screening patients into important subgroups for purposes of tailored interventions.

Incorporating methods we have used successfully in prior measure validation work,¹ we propose to conduct a diary study in which patients record their symptoms at various time points – at the end of each day, or across multiple days. We also ask them to complete self-report measures with different recall periods (i.e., 3-day, 7-day, and 30-day recall), and we determine how well each of these correspond to daily experiences recorded in more frequent assessments (i.e., end-of-day and 3-day patient bladder diaries). These data will help LURN investigators to determine the most appropriate reporting period for specific symptoms. This study can also help to identify causes of differences that exist between shorter and longer recall periods.

2. Background, Study Rationale

Dysfunctions of the lower urinary tract affect both men and women and have adverse effects on health-related quality-of-life and daily functioning, including work productivity.² There are many causes and risk factors for lower urinary tract symptoms (LUTS), such as bladder detrusor malfunction, impaired pelvic floor support, sleep disorders, obesity, and genetic predisposition. Moreover, patients with LUTD can suffer from significant comorbidities, which complicate research and treatment decisions. To improve our understanding of the complex interrelationships among these variables, high quality tools are needed to fully characterize LUTD patients and to comprehensively measure treatment outcomes.³ Self-report measurement is an important tool to characterize patients and to effectively guide treatment. Moreover, self-report can clarify relationships between phenotype and biological substrates.

There is an opportunity to improve the measurement of self-reported health for patients with LUTD. Items in a self-report measure usually make reference to a time period, e.g., “In the past 7 days...” Commonly used measures for LUTD have used a variety of time periods, from 7 days (LUTS Tool^{4,5}) to 4 weeks (AUA-SI⁶ and ICIQ-LUTS^{7,8}); other measures ask patients to report on their experiences without reference to a time period.⁹

We want to measure patients’ LUTS accurately without burdening them. Diaries (a voiding diary or bladder diary) have very short (or no) recall period; they are used primarily in clinical settings to assess voiding frequency, urgency, incontinence episodes, volume, etc. Because of the need for multiple assessments over the duration of a longitudinal study, short recall periods may place undue burden on patients and increase study costs. On the other hand, recall intervals that are long may over- or underestimate the health state when symptoms have diurnal or day-to-day fluctuation, which leads to bias. It is important to empirically determine how well patients are able to recall their experiences over a specific time period when deciding on the recall period to use for a patient-reported measure. For patient-reported measures of LUTS, however, it is not known how accurately people can remember experiences over different recall periods. The reliability and validity of a measure depends on how accurately respondents can report on their experience in the given time period, as was highlighted by

the US Food and Drug Administration (FDA) in their recent guidance on PRO measures for labeling claims.¹⁰

There is no gold standard for choice of recall period in a self-report measure. Figure 1¹¹ outlines the main considerations, which include the intended use of the instrument (in this case we are particularly interested in meeting the needs of the LURN phenotyping groups), the characteristics of the condition (we have both chronic and acute symptoms represented), and the patient's ability to correctly recall their experience (unknown). While some previous work has been published,¹²⁻¹⁵ it has not addressed the accuracy of recall for 7-day or monthly measures using the same reporting period, nor do we understand the accuracy of recall for all of the different LUTS symptoms.

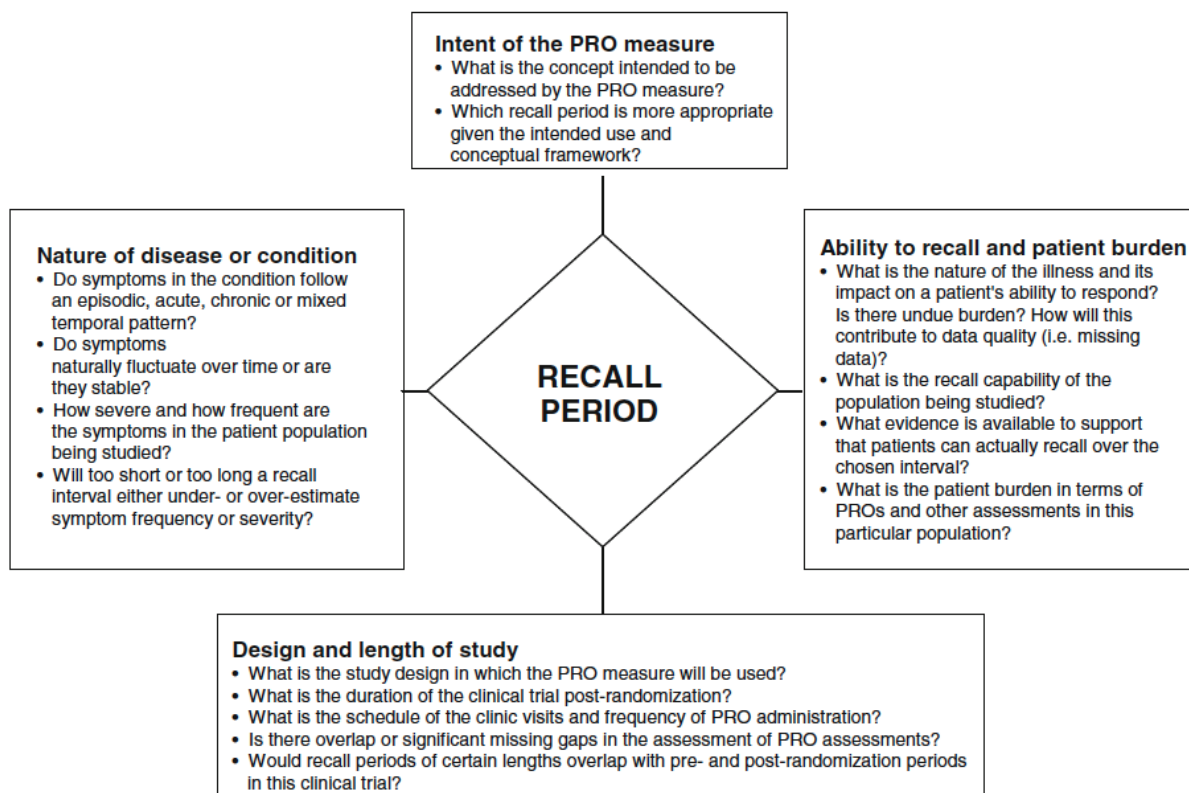


Figure 1. Considerations for selecting length of recall period. From Norquist, Girman, Fehnel et al. "Choice of recall period for patient-reported outcome (PRO) measures: criteria for consideration. *Quality of Life Research*. 2012; 21: 1013-1020.

3. Study Objectives

Specific Aim 1: To assess the correspondence between 1) average daily recall over 7 days and weekly recall of self-reported LUTS and 2) average daily recall over 30 days and monthly recall of self-reported LUTS.

Hypothesis 1.1: There will be an association between average daily recall and weekly recall of self-reported LUTS.

Hypothesis 1.2: There will be an association between average daily recall and monthly recall of self-reported LUTS.

Subaim 1A: To understand the heuristics that people may use to construct their weekly and monthly reports of LUTS (e.g., reporting peaks/valleys or most recent experience).

Subaim 1B: To describe the variation in symptoms over 30 days based on daily and weekly reports for each symptom.

Subaim 1C: To model trends in symptoms over the daily measurement periods, e.g., a decrease in symptoms may indicate increasing awareness of symptoms that lead to actions (drinking less, using the toilet more) that may reduce the symptom.

Subaim 1D: To assess the effect on weekly survey responses of having a prior week of daily surveys versus a prior week with no daily surveys.

Specific Aim 2: To assess the associations between better recall of LUTS and patient characteristics, including bother, depression, anxiety, and mood.

Hypothesis 2.1: Greater bother will be associated with lower correspondence between different recall periods, i.e., symptoms are related to over-reporting.

Specific Aim 3: To examine the association between overlapping parameters in a clinical (event-triggered) 3-day bladder diary and self-reported 3-day and weekly recall.

Hypothesis 3.1: There will be an association between overlapping parameters (i.e., frequency, leaking, urgency) in the bladder diary and 3-day and weekly recall.

4. Methods

4.1 Study Design

Participants will complete a baseline assessment; daily, weekly and monthly recall assessments of selected self-report LUTS measures, described in Appendix A; and a closing assessment. Half of the subjects (Group 1) will be randomly assigned to provide daily (24-hour) recall every day for 30 days, weekly recall at the end of each 7-day period, and monthly recall at the end of the 30-day period. The other half (Group 2) will be randomly assigned to Group 2A or Group 2B, and will complete a 3-day bladder diary in addition to daily, weekly and monthly recall assessments. Group 2A will provide the 3-day bladder diary in week 1 followed by 3-day recall and a weekly recall at the end of that week, and daily recall in week 2. Group 2B will provide one week of daily recall (week 1) followed by a 3-day bladder diary and 3-day recall at the start of week 2. Group 2 will also complete weekly recall assessments for weeks 1-4 and a monthly recall at the end of the 30-day period. An example diagram is presented in Figure 2 below.

Figure 2. Schedule of assessments in the main study

	-2T	-1T	0	Week 1							Week 2							Week 3							Week 4							29	30
Group 1	W	D	0	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D		
Group 2A	D	W	0	B	B	B					D	D	D	D	D	D	D													W	M		
Group 2B	D	D	0	D	D	D	D	D	D	D	B	B	B																	W	M		

T=Training period*

0=Baseline (includes 7-day CASUS)

D=24-hour recall

B=3-day daily bladder diary

3=3-day recall

W=7-day recall

M=30-day recall & final assessment

* Up to one week can elapse between the completion of the training period and start of the baseline assessment

4.2 Symptom Selection

While there are many symptoms of LUTD (Table 1), we assume that recall of different symptoms within each symptom cluster is likely very similar, for example, under the category of voiding, recall of weak stream is probably very similar to recall of splitting. Thus, it is not scientifically necessary to include all LUTS in the recall study. Moreover, including all LUTS in this recall study would be cost prohibitive (see 4.7 for sample size considerations). As such, we selected a subset of LUTS to study (highlighted rows in Table 1). We wanted to include at least one symptom in the Storage, Voiding, and Post-micturition clusters, and we wanted to include the most common symptoms in the Storage cluster, including frequency, urgency, and incontinence. To select symptoms from the Voiding and Post-micturition clusters, we looked at two previous large studies (Hall 2008, Coyne 2008) as well as data from our LURN qualitative interview study (Protocol 1) to estimate overlap in symptoms. For additional details see Section 4.7 and Appendix B.

Symptom Cluster	Symptom
Storage	Daytime frequency
	Nocturia
	Urgency
	Incontinence/Leakage (various types)
	Poor or absent sensation of bladder filling
	Pain/Discomfort/Pressure
Voiding	Slow/weak stream
	Splitting or spraying
	Intermittent stream/Double voiding
	Hesitancy
	Straining
	Dribbling at the end of flow
	Dysuria
	Paruresis (i.e. shy bladder, shy bladder syndrome)
Post-micturition	Feeling of incomplete emptying
	Post-micturition dribble (delayed)
	Pain/discomfort/pressure after urination
Other or Poorly Characterized	Confidence in warning signs of need to urinate soon
	Self-rating of overall bladder control
	Urgency with fear of leaking
	Abnormal bladder sensations
	Bother of symptoms

Note: highlighted symptoms are those on which the study will focus.

4.3 Recruitment

Participants will be recruited from the participating LURN sites. To avoid competition with the ongoing LURN Prospective Observational Cohort study, recruitment for the recall study will target new or return patients who are not in the Observational Cohort or who have completed their 3-month participation in

the Observational Cohort. People who previously participated in another SRM study (i.e., qualitative interviews or cognitive interviews) will be allowed to participate in this study, too.

We will contact potential participants using physician letters as well as in-person during clinic visits through the study coordinators in each participating clinic. We will recruit via flyers in the clinics and advertisements on participating sites' clinical trials websites.

Interested subjects will call or email the site study coordinator for additional information about the study, or will discuss the study with the coordinator at the end of a visit to the clinic. The coordinator will provide an explanation of the study, screen potential participants, and enroll subjects after they consent to be in the study (see Section 4.4). Patients who are determined to be ineligible for the study will be told that they do not meet the criteria.

4.4 Screening Participants

Enrollment for the recall study will be 400-500 patients with complete data to have at least 125 for each sex and targeted symptom (see Table 1) combination (see Section 4.7). Enrollment will be stopped when complete data for 125 cases within each category is obtained, and as categories are filled, enrollment will be targeted to the less common symptoms. Based on analysis of our qualitative interview sample (Appendix B), we anticipate that the majority of men and women meeting eligibility criteria will have multiple symptoms and will thus contribute data to more than one symptom category.

We will aim to enroll participants with a spectrum of severity for the involved symptoms, a range of ages, and a diversity of racial/ethnic backgrounds. In particular, we will enroll people who persistently and recently have at least one moderately severe and bothersome symptom, ascertained via the Screening Tool. The screening tool is a modified version of the LUTS Tool (Appendix C).

Eligible participants will be categorized to meet recruitment targets for storage, voiding, and post-micturition symptoms, as applicable. We will monitor the distributions of symptom severity by sex, age, and racial/ethnic background categories. If these distributions or categories do not reflect sufficient diversity, then targeted recruiting will be adopted. The total number of patients in each symptom group, as well as the number of patients with single or multiple symptoms, will be checked regularly.

Inclusion criteria:

1. age 18 or older,
2. willing and able to give informed consent,
3. able to speak, read, and understand English,
4. able to reliably complete self-reported questionnaires online at specified times (i.e., may exclude those who do not keep a regular schedule of sleeping during night hours), and
5. experienced at least moderate severity *and* bother from at least 1 of the 7 targeted symptoms in the past 2 weeks *and* in the past 3 months (Table 1)

Exclusion criteria:

1. dementia or other cognitive impairment that would interfere with study participation,
2. known pregnancy or delivery within past 6 months (women only)
3. planned change in medications to treat LUTS in the middle of the study time frame,
4. receiving active treatment for any malignancy (including maintenance medications),
5. received surgery with general or spinal/epidural anesthesia in the past 3 months or planned surgery during the study time frame

6. lower urinary tract instrumentation (e.g. self-catheterization or cystoscopy) in past 3 months or planned during the study time frame and
7. prostate biopsy in the past 3 months or planned during the study time frame

4.5 Procedures

Consent, Screening and Enrollment

Participants who qualify and agree to participate will be led through the informed consent process in person or by telephone (see Section 5). Paper-based consents will be used as needed. After consent, participants will have one week to complete the Screening Tool. After successful completion of the screening, eligible participants will have one week to start the training encounter.

Training Encounter

During this training encounter, study staff will go through the procedures for the recall assessments (chiefly, to fill out before bedtime) and will review the content of questions to make sure they will be well understood. During the training encounter, participants in Groups 2A and 2B will also receive instructions for completing the LURN bladder diary.

Participants will be instructed to start the training encounter on the next closest Monday, Tuesday, or Wednesday (in order that the training can be completed during the Monday-Friday work week. As part of the training (“burn-in” period) Group 1 participants will complete the 7-day recall assessment on day 1 and the 24-hour assessment on day 2, Group 2a participants will complete the 24-hour recall assessment on day 1 and the 7-day recall assessment on day 2, and Group 2b participants will complete the 24-hour assessment on days 1 and 2. After the burn-in assessments have been completed and checked, the coordinator will have up to one week to contact participants to ask if there were any questions or problems with the assessments and instruct them to complete the baseline survey (Appendix D) that evening (Day 0 of the study calendar) and then continue completing the assessments before bed according to the study calendar for the study duration. Study staff will inform participants in Group 2A that they should also begin their bladder diaries on the next morning. Study staff should remind participants that they will be receiving a reminder e-mail every day they have an assessment due.

Randomization

Separately within females and males, half of participants will be randomized to study Group 1, 25% to Group 2A, and 25% to Group 2B (2:1:1). The DCC will provide a schedule for randomization.

Reminders

Each day, a courtesy reminder will be sent to all participants who need to complete an assessment; this e-mail will contain the unique link to that day’s survey.

Participants in Group 2A should be contacted on week 1 day 1 and participants in Group 2B should be contacted on week 2 day 1 to make sure they have started their bladder diary. If they haven’t, they should be instructed to start the next day and the start date of the 3-day recall assessment will be adjusted accordingly. Participants will be contacted every day until they confirm start of the Bladder Diary or until they reach day 4 of the week.

Compliance

Although every effort will be made to get the participant to take all assessments via internet, study staff may choose to offer phone administration of these assessments at their discretion.

Baseline Assessment

If participants miss the baseline assessment, study staff will contact the participant once per business day for up to 7 days until the participant is reached (if the participant is not reached within 7 days, no further contact attempts will be made and the participant will be dropped). Participants who are more than 3 days late in filling out the baseline assessment may be dropped from the study at the study staff's discretion, depending on the participant's reason for the miss.

24-hour Recall Assessment

All participants should complete their end-of-day, 24-hour recall assessment before bed; during training they will be instructed to complete it as close to bedtime as possible. The daily assessment will be available from 6 pm local time until 2 am the following morning.

While the following cut-offs will not be specified to participants (to encourage complete data), for study purposes we intend to follow these guidelines: participants must complete at least 5 of 7 daily assessments per week to be considered compliant. A week is defined as the 7-day period with 7 daily assessments ending in a weekly assessment, regardless of the day of the week that that 7-day period starts on, e.g., it could run from Wednesday to Tuesday. Participants can miss up to 2 end-of-day assessments in a single week without penalty. After 2 am, those who have not completed the previous day's assessment will be counted as missing for that day. If someone misses a daily assessment a 2nd consecutive time, the study coordinator will call him/her to discuss the reason for the misses.

Once a participant misses 3 assessments in a week, study staff will contact them to let them know that they have missed too many assessments to continue being part of the study.

3- and 7-day Recall Assessment

If a participant misses a 3- or 7-day assessment, they must complete it the next day and will be sent a reminder email to do so. Participants must complete the 3- and 7-day assessments to be considered compliant.

Bladder Diary

Participants assigned to Group 2 must return a bladder diary by the end of the study month and complete the 3-day assessment by the day after it is due to be considered compliant. They can start the bladder diary on days 1-4 during the target week (week 1 for Group 2A and week 2 for Group 2B).

30-day Recall & Final Assessment

The 30-day recall & final assessment will stay open for 3 days to allow the participant as much time as possible to complete. Additionally, study staff will make every effort to contact the study participant and encourage them to complete the final assessment as soon as possible, to prevent missing data.

Participant Compensation

Participants who complete the main study will be compensated \$220 for Group 1 and \$150 for Groups 2A and 2B. Availability of prorated payments will be up to each site, as determined by their IRB policies, as well as method of payment (gift cards, checks, etc.).

4.6 Data Collection

Measures

At baseline we will collect sociodemographic information and details about health (e.g. height, weight, chronic illnesses, health status, functional limitations, see Appendix D). This baseline assessment will include the full set of CASUS items using a 7-day recall period.

Subsequent assessments will include daily, weekly (Groups 1 and 2) and 3-day (Group 2 only) modified versions of the CASUS items (see Appendices E and F) and a simplified LURN event-triggered 3-day bladder diary (Group 2 only; see Appendix G).

The 30-day recall and final assessment (Groups 1 and 2, Appendices F and H) will include the modified CASUS items using a 30-day recall period, questions about treatments and treatment changes, behavior changes (fluid intake and voiding habits), and bother, as well as measures of depression (PROMIS), anxiety (PROMIS), and mood (the Positive and Negative Affect Schedule, PANAS).

4.7 Statistical Considerations

4.7.1 Sample Size and Power Calculations

In a previous recall study with similar participant burden, we experienced 7% dropout over the study month. For this study we estimate 10% dropout over the month.

Sample size calculation for Aim 1 is based on precision of estimation (measured as length of the 95% confidence interval) for both the bias (mean difference) and the correlation coefficient between average daily and weekly (or the average daily and monthly) reports in each subject. The more frequent report in each case (daily) will be considered to represent actual symptoms more closely than longer-term recall, so any difference between the two measures will be interpreted as bias in the less frequent report. Bias and correlation will be estimated for each survey item, and may also be estimated for subscales created as summaries of several items.

Confidence intervals (CI) for both the bias and the correlation coefficient should be narrow enough to rule out substantially undesirable values, such as bias of more than half a level of a 5-point ordinal scale (assuming the true bias is ≤ 0.25 point) and correlations of less than 0.40 (assuming the true correlation is at least 0.50). Thus we calculate the sample size needed to achieve a confidence interval half-width of 0.25 or less for the bias. We calculate a lower confidence bound on the correlation coefficient that is above 0.50 if the true correlation is 0.60 or greater. For both bias and correlation, we assume a confidence coefficient of 0.95; for bias, we specify a probability of 0.90 that the confidence interval half-width is at most the value specified. We assume a common variance (σ) for daily, weekly and monthly summary values, so the average of 7 daily recall values would have variance $\sigma^2/7$, and the average of 30 daily recall values would have variance $\sigma^2/30$. We assume a value of $\sigma^2=1$ for Likert scales with range of 5. Thus, variances for (1) the weekly average of the daily values, (2) the monthly average of the daily values, and (3) the weekly or monthly value for the two recall times are $\sigma^2/7$, $\sigma^2/30$, and σ^2 , respectively. The variance (var) of the difference between the average daily and weekly measures is $\text{var}(\text{difference}_1) = \text{var}(\text{weekly}) + \text{var}(\text{ave. daily}) - 2 \cdot \rho \cdot \text{SD}(\text{weekly}) \cdot \text{SD}(\text{ave. daily})$, where ρ is the correlation between the average daily and weekly values, conservatively assumed to be 0.5, and SD =standard deviation. Assuming $\text{var}(\text{weekly})=1$ and $\text{var}(\text{ave. daily})=1/7$, then $\text{var}(\text{difference}_1)=1+(1/7)-2 \cdot 0.5 \cdot 1 \cdot \sqrt{1/7} = 0.765$, or $\text{SD}(\text{difference}_1)=\sqrt{0.765} = 0.875$. Similarly, $\text{var}(\text{difference}_2)$ for the difference between average daily and monthly values is $1+(1/30)-2 \cdot 0.5 \cdot 1 \cdot \sqrt{1/30} = 0.851$, and

SD(difference_2)= 0.922. Because these SD values for the two differences (SD_1=0.875 and SD_2=0.922) are very similar, we use the larger value in the table below with similar results in either case.

Because analyses will be performed in subpopulations, including males and females and symptom subgroups, the table below gives the confidence interval (CI) properties for a range of sample size values. Reasonably small CI half-widths (for bias) and lower confidence bounds (for correlation) are shown in boldface in Table 2.

Table 2. Confidence interval properties by sample size

	N=200	N=150	N=100	N=50	N=25
For bias:					
Half-width of CI	± 0.14	± 0.16	± 0.20	± 0.31	± 0.44
For correlation:					
Full width of CI, true $\rho=0.6^*$	0.18	0.21	0.25	0.37	0.54
Full width of CI, true $\rho=0.8^*$	0.10	0.12	0.15	0.21	0.32
Lower confidence bound**	0.52	0.51	0.48	0.43	0.33

CI=confidence interval; *CI is asymmetrical

****Conservatively assuming a true correlation of 0.60**

We conclude that a sample size between 100 and 150 will be optimal for the analysis of a particular symptom for either men or women. Subgroups smaller than 50 will yield imprecise estimates of bias and correlation¹⁶. Analysis of men and women separately for each of 7 symptoms would require at most a sample size of 1400 if 100 per subgroup were assumed. However, we expect substantial savings from patients with multiple symptoms. Two symptoms that occur frequently together in both men and women can reduce the effective number of symptoms to ~6, and require a sample size of 1200 instead of 1400. The symptom overlap observed in the LURN Qualitative Interviews from responses to the LUTS Tool (N = 76) was used to estimate the degree of overlap we expect to see in the Recall Study. Patients in this sample were recruited from two clinical populations (general and sensory), as well as the community (Appendix B). These three groups exhibited similar levels of overlap, thus all 76 were used for this investigation, even though the Recall Study will only be recruiting from clinical populations. For any two of the seven symptoms of interest, the overlap ranged between 50% and 82%, indicating considerable overlap. Furthermore, 83% of the patients reported at least five of the seven symptoms.

To estimate the level of overlap for the proposed study, we performed a simulation by drawing at random and with replacement from the sample of 76 (Appendix B). Initial exploration informed us that a sample of 200 patients would provide at least 125 patients in each symptom category (excluding females with “weak stream”, which had approximately 100 patients). These results were confirmed with ten iterations of the simulation, with very little variability occurring in the number of patients in each symptom category. This high level of overlap resulted in substantial savings in terms of sample size; thus, a target of 200 patients of each sex will fully power this study. However, during the study, the sample size for each symptom will be monitored at regular three-month intervals to ensure adequate sample size for each symptom. Although the estimated total sample size is 400 patients, we plan to recruit based on this monitoring until we have at least 125 patients of both sexes with each symptom. With targeted recruitment for the less common symptoms, as needed, we are confident that an upper limit of the sample size would be 500 patients. These sample sizes assume patients with complete data

(allowing for missing up to 2 questionnaires during any given week); replacement patients would need to be recruited for any dropouts during the sampling month

4.7.2 Statistical Analysis Plan

We will describe baseline clinical and sociodemographic characteristics and responses to the daily, 3-day, weekly and monthly recall items using frequencies and percentages. These analyses will be performed separately for each symptom and by sex. We will stratify patients by age or adjust for patient age during analyses.

Specific Aim 1: To assess the correspondence between 1) average daily recall over 7 days and average weekly recall and 2) average daily recall over 30 days and monthly recall of self-reported LUTS.

We will assess correspondence between daily reports and both weekly and monthly recall in terms of (i) bias (i.e., over- or underestimation) in weekly and monthly recall; and (ii) consistency of individual differences (i.e., correlation) between daily reports and weekly/monthly recall. The presence of bias is indicated by a mean daily report that is systematically higher or lower across participants than the recalled score. Bias affects the interpretation of the absolute level of the responses (e.g., on a 1-to-5 scale) across different measurement methods or how sensitive the score can be (e.g., if the weekly/monthly recall demonstrates a ceiling effect while the mean daily report does not). Low correlation between aggregated daily responses and weekly/monthly recall, regardless of whether there is bias, may suggest, for example, that participants who reported severe symptoms in daily scores would not necessarily report severe symptoms in weekly/monthly recall.

We will use paired t-tests to assess the statistical significance of bias. We will assess the consistency of individual differences using Pearson correlation coefficients (or point biserial coefficients for weekly/monthly recall with dichotomous responses).

Subaim 1A: To understand the heuristics that people may use to construct their weekly and monthly reports of LUTS (e.g., reporting peaks/valleys or most recent experience).

We will assess whether the weekly or monthly measures more closely reflect the most recent experience, or the worst (or best) experience, or the average experience. We will investigate this effect by comparing the correlation of weekly reports with the individual daily reports, and comparing the correlation of monthly report with individual daily reports. If the correlation between the longer-term recall and the most recent previous day or week is the highest among the 7 daily (for weekly) or 30 daily (for monthly) correlations, and if the correlations damp over time, then we will conclude that recall is short-term. The implications would be that we would need to use a shorter-term recall period. We will also compute correlations using the worst (or best) of the weekly values, and the worst (or best) of the monthly values and compare with the daily and weekly average values.

We will also assess the effect of recency on bias by calculating paired t-tests between the weekly and each of the daily reports, and between the monthly and each of the weekly reports, and looking for increasing bias with increased time between reports. The worst (or best) of the daily or weekly values will be similarly compared.

Subaim 1B: To describe the variation in each symptom over 30 days based on daily and weekly reports.

Daily variation in each symptom will be measured by the SD and range in daily symptom scores, either over a week or over a month. Plots of variation over time will be used to assess whether variation is episodic, random, or has some other pattern. In addition, variation in symptoms over

time will be assessed after adjusting for any trends over the 30-day period identified in Subaim 1C.

Subaim 1C: To model trends in symptoms over the daily measurement periods, e.g., a decrease in symptoms may indicate increasing awareness of symptoms that lead to actions (drinking less, using the toilet more) that may reduce the symptom.

We will assess the effect of research participation resulting in modified behavior leading to improved symptoms: We will test whether LUTS symptoms improve (or decline) over the daily reports each week, and also over the daily reports each month. These tests will be performed for each of the symptoms, and there may be subsets of patients (e.g., with particular symptoms, such as nocturia) for whom symptoms do improve. To test these effects, we will use a linear mixed model with random patient trajectories (slopes) over time. As an exploratory measure, we will compare boxplots of the individuals' slopes for those using adaptive behaviors vs not using, for each LUTS item. An effect would be indicated if those using adaptive behaviors tended to have slopes showing greater improvement. Such an effect would be formally tested by including use of the adaptive behavior in the mixed model, e.g., as 'any behavior' or a specific type.

Subaim 1D: To assess the effect on weekly survey responses of having a prior week of daily surveys versus a prior week with no daily surveys.

We will assess whether weekly reports following daily reporting are systematically different, either in mean or variance, from weekly reports without prior daily reporting. Each patient in Groups 2A and 2B will have weekly reports both with and without prior daily reports in the same week. These weekly reports in the same patient will be compared by paired t-test to detect systematic differences. For example, it is possible that without daily reports, the weekly report tends to exaggerate the symptoms.

We will also compare the weekly reports following daily reporting with the completely naive weekly report on Training Day -2 for Group 1. Further, we will test for any monotone trend in weekly reports as a function of the number of prior days with a daily report. In addition to the completely naive weekly report, this analysis will include data with a single daily report prior to a weekly report (from Group 2A) and two daily reports prior to a weekly report (from Group 2B) based on data collected during the Training Days (-1) and (-2) and Baseline (Day 0) .

We will also compare monthly reports following daily reports (Group 1) versus monthly reports not following daily reports at least in the previous 1-2 weeks (Groups 2A and 2B). This comparison will have less power since the comparison is between subjects instead of within subjects. Even still, we would expect to see an effect consistent with that seen in the weekly analysis.

Specific Aim 2: To assess the associations between better recall of LUTS and patient characteristics, including bother, depression, anxiety, and mood.

To test whether disagreement between daily reports and weekly/monthly recall is a function of patient characteristics, we will use a general linear model or a multiple logistic regression model to model weekly/monthly recall as a function of the daily summary (e.g., mean daily rating), the patient characteristic, and the interaction between the daily summary and the patient characteristic. In the model for each LUTS symptom, we will test the effect of bother for the same symptom, collected at the final (30-day) assessment. Although it is possible that bother from other symptoms may affect reporting

of a given symptom, testing both for all possible symptoms would be unwieldy. We may test symptom both for selected other symptoms, or test a composite measure of both over all symptoms.

A significant intercept in these models would imply bias in the weekly/monthly recall, and significant main effects of variables such as bother or depression may explain some or all of the bias. Interactions between patient characteristics and daily summaries will indicate non-constant bias across the severity of daily summaries; for example, an interaction between average daily urgency and bother might reflect exaggeration of urgency in weekly reports when bother is high, and under-reporting when bother is low. We will assess model fit using R-squared, and assess the cumulative proportion of explained variance due to each covariate. These results can be compared to the evaluation of concordance (correlation) calculated in Aim 1.

If joint significance tests of the patient characteristic main effects and the daily summary–pt-characteristic interaction effects yields $P < 0.05$, we will examine the daily summary–pt-characteristic interaction effects. If they are not statistically significant at $P < 0.05$, we will estimate the model again using only the main effects. If none of the main effects or interaction effects are statistically significant (despite a significant joint test of the terms), we will not interpret the model. For weekly/monthly responses for which we used general linear models, we will conduct sensitivity analyses using ordinal logistic regression.

Specific Aim 3: To examine the association between overlapping parameters in a typical clinical (event-triggered) 3-day bladder diary and self-reported 3-day and weekly recall.

For measures that are similar between bladder diaries and survey data, we will use correlation coefficients and linear regression, possibly adjusting for covariates, to assess these relationships. For comparing categorical responses in the LUTS questionnaire to continuous responses on the bladder diary (e.g., counts of urination events), kappa statistics will also be used. To the extent that the questions are identical or transformable to the same scale, we will perform the analyses described in Aim 1. We will also assess variability in the daily bladder diary responses.

For the bladder sensation responses, we will correlate the counts of experiences of urgency on the bladder diary with the LUTS scale response(s) of “never to always”. This will provide a calibration of the LUTS questionnaire responses to actual counts of sensations of urgency.

For the leak questions, which are counts from the bladder diary but answered in a “never to always” format in the LUTS questionnaire, in addition to estimating correlation coefficients, we will also investigate the mapping of response options between the two scales. This will provide a calibration of the LUTS questionnaire responses to actual counts of total leaks per day. The pad responses will be used to validate the leak data; inconsistencies between leak and pad data may be used to revise leak data to be consistent with pad reports. For example, patients who report no leakage but report pad changes will be counted as having the same number of leaks as pad changes. Additional conventions to incorporate pad information will be considered at the time of data analysis.

4.7.3 Missing Data

Every effort will be made to obtain complete data for all variables. Preliminary analyses, performed prior to the end of data collection and cleaning, will be performed using complete cases (that is, we will drop a participant from the analysis if one or more of the participant’s data points of interest are missing). Once all data have been collected, we will examine patterns of missing data and also evaluate whether the data can be assumed to be missing at random. If appropriate, we will perform multiple imputations using IVEware to address missing data before completing final analyses.

4.8 Interpretation of Results

Our goal is to recommend a single recall period (if possible) for the LURN battery that has evidence for validity (with regard to recall) and is longer than 1-day (which would be burdensome in practice). There is no empirical basis for the ideal thresholds to use when interpreting our results with regard to correlation and bias on each of the comparisons specified in the Specific Aims. Instead, we will use a process that considers both ideal correlations/bias and practicality. We expect, based on other studies¹⁷⁻¹⁹, to consider correlations higher than 0.70 as “good” higher than 0.50 as “good enough” when weighing other considerations. Likewise, we expect to consider bias less than 0.25 a level of a Likert scale as “good” and less than 0.50 a level of a Likert scale as “good enough” when weighing other considerations. If there are troubling correlations for certain items or symptoms and/or troubling bias that would suggest different recall periods for different LUTS items, then we will weigh that against the practicality of having multiple recall periods within the same battery. Any evidence of differences in recall periods by LUTS items will be useful to publish for the benefit of future researchers designing questionnaires. Although designers of a comprehensive LUTS tool would probably prefer a common recall period, studies with targeted LUTS items might benefit from a recall period tailored to the items of interest.

5. Human Subjects

5.1 Protection of Human Subjects

5.1.1 Institutional Review Board

This study and analysis will be performed under Institutional Review Board (IRB) oversight. Prior to the initiation of the study, an IRB approval for study of human subjects will be obtained separately from the IRB of each of the participating LURN clinical study centers and the data coordinating center (DCC). Revisions to the study protocol and changes in the study design will also be submitted to the individual IRBs for approval prior to implementation.

Subjects will be enrolled in the LURN Recall Study protocol with full and written informed consent, which will include collection of protected health information (PHI).

Each participating center will be responsible for obtaining such human subjects research authorization and will create an informed consent document detailing the procedures described above in the language required by their respective organizations. All key personnel at the participating centers will have successfully completed IRB-required training and certification for human subjects research. Additionally, participants will satisfy HIPAA researchers’ privacy requirements.

5.1.2 Patient Confidentiality

Special procedures for ensuring patient confidentiality will be implemented. Data transmission and the distributed data systems will have multiple layers of security as discussed in Section 7, Study Management. Each study subject will be assigned an identification number. Only this number will be used to identify subjects in any individual tabulation. The PHI that is collected will represent the minimum necessary to successfully execute the study. Most PHI entered into the database at the site level will only be visible to study personnel accessed through a triple password regimen. The PHI is encrypted at the site level. Site personnel will have the decryption key, and it will not be available to the DCC. The only PHI that will not be encrypted at the site level will be email addresses, which the DCC will

need to administer the online survey. The DCC will keep email addresses separate from all other patient-reported data; they will not be present in the analytic data set.

It is expected that only group data will be published. If individual subject data are to be published, no identifying information will be included. The study files will be maintained in a secure location. Access to computerized data will be restricted to study personnel. Password authorization will be enforced. Previous use of this security system and a secured server indicates that this technique is very successful in assuring the protection of confidential information. Authorized representatives of the Sponsor, the National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH), participating LURN clinical study centers, DCC monitoring staff, as well as the IRBs at each site, will have access to medical records and records from participants in this study. Such access is necessary to ensure the accuracy of the findings.

5.1.3 Risks to the Patient and Adequacy of Protection Against Risk

Patients enrolled in the Recall Study will experience more than the normal amount of testing that is customary for patients with LUTD. Individuals may experience psychological discomfort in answering repeated, longitudinal assessment questions related to LUTS, demographic and clinical characteristics, and health-related quality of life. With respect to potential discomfort developing during clinical assessment, we note that study personnel will be trained by the investigators to be sensitive to participant discomfort and concerns. There is a potential risk of breach of confidentiality that is inherent in all research protocols, and steps to minimize this risk are described above. Steps to minimize risk and address any psychological discomfort are addressed below.

Recruitment and Informed Consent. At each LURN site, individuals eligible for Recall Study (based on criteria described in Section 4.3) will be approached by a LURN investigator or study coordinator for release of their protected health information and contact information so that study staff may approach them to describe the study and obtain informed consent. All consent forms will be HIPAA-compliant. A copy of the signed consent forms will be kept by the study participant, and one will be kept in the research records at the site where the participant was enrolled.

Psychological discomfort during study procedures (i.e., during completion of study questionnaires). With regard to participants' psychological discomfort and overall well-being, we noted above that the study personnel will be specifically trained to be sensitive to subjects' discomfort and concerns. If a participant finds the research procedures to be upsetting, he/she will have the option to withdraw from the study at any time.

5.1.4 Unauthorized Data Release

The data sets will be stored on a secure server with restricted access (requires a unique username and password) at the DCC and every precaution will be taken to keep the information private. However, there is always the possibility of unauthorized release of data about subjects. Such disclosure would be extremely unlikely to involve a threat to life, health, or safety. It is conceivable that such disclosure could have psychological, social, or legal effects on the patient. Using the standard security procedures (described above under patient confidentiality) can effectively minimize the risk of unauthorized disclosure of data. All study personnel who have access to patient data will be educated regarding the need to protect confidentiality and the procedures to be followed to ensure such protection. All staff will also be required to sign a standard medical record confidentiality agreement. The computer system on which data are maintained uses standard password protection procedures to limit access to authorized users. After the study is completed, the database will be stored at the NIDDK Data

Repository. The database in the Repository will be de-identified to obviate further privacy and security considerations.

5.1.5 Adverse Event Monitoring and Reporting

An adverse event (AE) is any untoward medical occurrence or unfavorable and unintended sign in a research subject that occurs during or as a result of a research procedure.

For this study, each center will review the list of study procedures and identify the specific procedures that are not standard-of-care at their institution and these will be considered research procedures. Complications that are a result of research procedures will be reported and tracked as adverse events.

5.2 Benefits to the Patient

There are no direct benefits to the patients for participation in the study.

5.3 Inclusion of Women

Approximately 50% of the study participants will be women. Recruitment will be monitored to ensure adequate representation of women.

5.4 Inclusion of Minorities

Racial and ethnic minorities will be recruited into the study. We anticipate that the representation of racial and ethnic minorities will correspond to the fraction of minorities in the population presenting to the participating clinics as patients. Recruitment will be monitored to ensure that the representation of minority groups parallels the racial/ethnic composition of patients seen at LURN Clinical Sites.

5.5 Inclusion of Children

Children under the age of 18 will not be enrolled into this study as the LURN physicians do not see pediatric patients.

5.6 Data Safety and Monitoring Plan

Accepted principles of data and safety monitoring will be observed throughout the conduct of the LURN study. The NIH has appointed an independent External Expert Panel (EEP) that will provide study oversight. The EEP will review the study protocol prior to enrollment and will also review all subsequent protocol revisions. The EEP will also evaluate the occurrence of adverse events related to study participation.

LURN principal investigators will be responsible for monitoring the enrollment of subjects, submission of data to the DCC, and monitoring and reporting of adverse events related to study participation. The DCC will be responsible for monitoring for effective conduct of the protocol and accurate and timely data submission.

IRBs will be provided feedback on a regular basis.

Training of study coordinators and study monitoring activities will be conducted by the DCC to ensure patient confidentiality and privacy and to maximize the reliability, accuracy, and timeliness of study data.

The LURN clinical sites, the DCC, and relevant research center staff will conduct regular meetings to review recruitment/enrollment progress, data collection activities, and participant retention. The DCC

will produce regular reports regarding enrollment, data quality, and timeliness and share the reports with NIDDK, the Steering Committee, and the participating clinical center. Data will be routinely exported from the data collection systems, examined for accuracy and completeness, and backed up to secure storage devices. Upon completion of data collection, final processing and cleaning of data will be conducted. A technical report detailing specific project methodology, response rates, and other details will be produced.

6. Study Organization

6.1 Clinical Centers

The LURN clinical study centers participating in the Recall Study will have primary responsibility for developing the study protocol, maintaining high rates of follow-up and data collection, obtaining data of high quality, and interpreting, presenting, and publishing findings from the study.

Northwestern University
Chicago, IL

Principal Investigators: David Cella, PhD and Brian T. Helfand, MD, PhD

University of Iowa
Iowa City, IA

Principal Investigators: Karl J. Kreder, MD, MBA and Catherine S. Bradley, MD, MSCE

Duke University
Durham, NC

Principal Investigators: Kevin P. Weinfurt, PhD (Steering Committee Co-chair) and Cindy L. Amundsen, MD

University of Washington
Seattle, WA

Principal Investigator: Claire C. Yang, MD (Steering Committee Co-chair)

University of Michigan
Ann Arbor, MI

Principal Investigator: J. Quentin Clemens, MD, FACS, MSCI

Washington University in St. Louis
St. Louis, MO

Principal Investigators: Gerald L. Andriole, Jr., MD and H. Henry Lai, MD

6.2 Data Coordinating Center

The DCC contributes biostatistical expertise and shares in scientific leadership of the research group. The DCC has developed a communication infrastructure that includes meetings, teleconferences, email and bulletins, interactive Web-based encounters, and written correspondence. The DCC assists in protocol development and preparation of scientific publications. The DCC has the major responsibility of creating a database and data collection systems for the participating LURN clinical study centers, ongoing evaluation of data quality, performance monitoring of the LURN clinical study centers, and statistical analyses of the data. The DCC will also create a comprehensive Manual of Operations (MOO) that will

govern the conduct of the study. The manual will detail the protocols, protocol clarifications and amendments, summary of the regulatory requirements for the study, instructions for enrollment, data collection, data management, visit schedules, and detailed instructions on the use of the electronic data submission. The DCC is responsible for clinical monitoring of the study.

Arbor Research Collaborative for Health
Ann Arbor, MI
Principal Investigator: Robert M. Merion, MD

6.3 Steering Committee

The primary governing body of the study is the Steering Committee, consisting of each of the Principal Investigators of the LURN clinical study centers, the Principal Investigator of the DCC, and the NIDDK Project Scientist. The Steering Committee develops policies for the study pertaining to access to patient data, performance standards, and publications and presentations. It develops the study protocol and meets to discuss the progress of the study and to consider problems arising during its conduct. The Steering Committee may establish subcommittees to further develop specific components of the study protocol. Small working groups may be established to prepare manuscripts and presentations.

7. Study Management

7.1 Data Collection, Data Collection Forms, Data Entry

The DCC will utilize a web-based electronic data capture application as the data management nucleus for the LURN Recall Study, combined with a survey administration application for daily, 3-day, weekly, and monthly symptom reporting and for other self-reported measures (bother, depression, anxiety, and mood).

The 3-day bladder diaries will be completed by the participants and entered into the database by the study coordinator.

7.2 Data Management

All study data will be reported directly by participants into the survey administration application. These data will be encrypted and transferred to the DCC and stored on a secure server at Arbor Research. Access to the server and data entry system is limited and requires a unique username and password combination. The servers are backed up daily and physically stored in a locked facility.

All analysis of the data sets will utilize de-identified (coded) data sets.

7.3 Quality Control and Database Management

The first steps in ensuring protocol compliance are good protocol design and careful orientation of study personnel. Following final agreement on the protocol, and prior to study initiation at any of the LURN clinical study centers, the DCC will organize a Training and Certification session for LURN Study Coordinators/data entry personnel.

The electronic data entry system will have built-in data checks as part of study quality assurance. Protocol compliance will be assessed by monitoring the submission of data at required intervals. Data inconsistencies and discrepancy reports will be reviewed by the Clinical Monitors so that necessary queries can be generated and sent to the LURN clinical study centers for verification and resolution.

Periodic requests may be generated for the submission of random source documents to assess the quality of data acquisition and data entry at each site. In addition, the Clinical Monitor or Project Manager will visit each site at least once a year to review source documents, monitor regulatory compliance, and assess protocol adherence.

In addition to source document verification, the Clinical Monitor and Project Manager will produce reports from the database to look for inconsistencies in submitted data, particularly for repeated measures data elements, even if data do not fall outside of built-in validation routines.

Studies of intra-subject and inter-subject data variability by LURN clinical study center as well as intra-center and inter-center data variability will be used to further ascertain random or systematic data quality issues.

7.4 Data Security/Data Transfer

For the Recall Study, personnel at each study center will collect and enter data into the web-based data entry system. The following data security contingencies are in place:

- Compliance with Industry Standards Regarding Data Security (HIPAA and 21 CFR Part 11)
- Audit trails are maintained for all activity and all changes to any data element
- All servers, web servers, firewalls, etc. are configured and maintained according to industry best practice guidelines for backup, security, continuity of operations, and protection of PHI
- All data are available only to authorized users from each site after secure login with encryption, with all site activity audited at the user level
- All transmissions between the Internet and the database are encrypted using a 128-bit encryption algorithm
- There is a comprehensive security plan in place

Detailed instructions on the use of the database platform, data element definitions, and a code list will be provided in a MOO. Each study site will be provided a copy of the MOO and the entire manual will be available on the study website, and in the Help area of the database user interface.

7.5 Resource Sharing Plan

During the study, data will be shared with internal and external investigators according to the guidelines agreed upon by the Steering Committee.

Upon study completion, study data will be transferred to the NIDDK Data Repository. Minutes of meetings of the Steering Committee, Project Executive Committee, subcommittees, and the External Expert Panel will be kept on file at the DCC.

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9. Appendix A: Questionnaire Mapping

Domain	Item Code	30-, 7-, and 3-day Recall	24-hour Recall		3-day Bladder Diary		Validation	
			Item	Derived Summary	Item	Derived Summary	Analysis for Bias	Analysis for Correlation
Daytime Frequency	A1	In the past 30/7/3 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	During waking hours today, how many times did you urinate? 3 or fewer times 4-7 times 8-10 times 11 or more times	Mean of 7 or 30 responses, using 1=3 or fewer times, 2=4-7 times, 3=8-10 times, 4=11 or more times	Count of daytime urination events coded into 4-category frequency	Average over 3 days	Difference between 24-hr recall mean and X-day mean count	Pearson or Spearman
	A2	In the past 30/7/3 days... During a typical day, how much time typically passed between urinations? More than 6 hours 3-6 hours 1-2 hours Less than 1 hour	During the day today, how much time typically passed between urinations? More than 6 hours 3-6 hours 1-2 hours Less than 1 hour	Mean of 7 or 30 responses, using 1=less than 1 hour, 2=1-2 hour, 3=3-6 hours, 4=more than 6 hours	Computed daytime urination interval coded into 4-category frequency	Average over 3 days	Difference between 24-hr recall mean and X-day mean	Pearson or Spearman

Domain	Item Code	30-, 7-, and 3-day Recall	24-hour Recall		3-day Bladder Diary		Validation	
			Item	Derived Summary	Item	Derived Summary	Analysis for Bias	Analysis for Correlation
Nighttime Symptoms	B1	In the past 30/7/3 days... During a typical night, how many times did you wake up and urinate? None 1 time 2-3 times More than 3 times	Last night, how many times did you wake up and urinate? None 1 time 2-3 times More than 3 times	Mean of 7 or 30 responses, using 1=less than 1 hour, 2=1-2 hour, 3=3-6 hours, 4=more than 6 hours	Computed daytime urination interval coded into 4-category frequency	Average over 3 days	Difference between 24-hr recall mean and X-day mean	Pearson or Spearman
	B2	In the past 30/7/3 days... How often did you wake up at least once during the night because you had to urinate? Never A few nights About half the nights Most nights Every night	Last night, did you wake up because you had to urinate? No Yes (at least once)	Proportion "yes (at least once"	Count of nighttime urination events coded into 5-category frequency	Average over 3 days	Difference between proportion who answered "every night," "most nights," "about half the nights," or "a few nights" in X-day recall vs. proportion who answered "yes" in at least one 24-hr report	Point biserial
	B5	<If N-1 not none> In the past 30/7/3 days... When you woke up and urinated, how often did you leak urine on your way to the bathroom? Never A few times About half the time Most of the time Every time	<If N-1 not none> When you woke up and urinated last night, did you leak urine on your way to the bathroom? No Yes (at least once)	Proportion "yes (at least once"	Bladder sensation scale response dichotomized as (0-3) vs (4)	Average over 3 days, with response dichotomized as 0 (0-3) vs 1 (4)	Difference between proportion who answered "always," "often," "sometimes," or "rarely" in X-day recall vs. proportion who answered "yes" in at least one 24-hr report	Point biserial

Domain	Item Code	30-, 7-, and 3-day Recall	24-hour Recall		3-day Bladder Diary		Validation	
			Item	Derived Summary	Item	Derived Summary	Analysis for Bias	Analysis for Correlation
Urgency	D1	In the past 30/7/3 days... How often did you feel a sudden need to urinate? Never A few times About half the time Most times Every time	In the past 24 hours... How often did you feel a sudden need to urinate? Never A few times About half the time Most times Every time	Mean of 7 or 30 responses, using 0=Never, 1= A few times , 2= About half the time , 3= Most times , 4= Every time	Bladder sensation scale response options 2-4 during waking hours	Map response options (#s from diary to qualitative response from LURN), take mean of 3 days	Difference between 24-hr recall mean and X-day mean Bias may not be estimable for diary since mapping will be done to remove bias	Pearson or Spearman
	D2	In the past 30/7/3 days... Once you noticed the need to urinate, how difficult was it to wait more than a few minutes? Not difficult A little difficult Somewhat difficult Very difficult Unable to wait	In the past 24 hours... Once you noticed the need to urinate, how difficult was it to wait more than a few minutes? Not difficult A little difficult Somewhat difficult Very difficult Unable to wait	Mean of 7 or 30 responses, using 0=Not difficult, 1=A little difficult, 2=Somewhat difficult, 3=Very difficult, 4=Unable to wait	Bladder sensation scale response options 3-4 during waking hours	Map response options (#s from diary to qualitative response from LURN)	Difference between 24-hr recall mean and X-day mean Bias may not be estimable for diary since mapping will be done to remove bias	Pearson or Spearman
Incontinence screener	G1	In the past 30/7/3 days... Have you leaked urine or wet a pad? No Yes	In the past 24 hours... Did you leak urine or wet a pad? No Yes	Proportion "yes"	Count of leaks	Average over 3 days	Difference between proportion who answered "yes" in X-day recall vs. proportion who answered "yes" in at least one 24-hr report	phi

Domain	Item Code	30-, 7-, and 3-day Recall	24-hour Recall		3-day Bladder Diary		Validation	
			Item	Derived Summary	Item	Derived Summary	Analysis for Bias	Analysis for Correlation
Non-specific incontinence	G2	In the past 30/7/3 days... How often did you completely lose control of your bladder? Never A few times About half the time Most times Every time	In the past 24 hours... Did you completely lose control of your bladder? No Yes	Proportion "yes"	--	--	Difference between proportion who answered "every time," "most times," "about half the time," or "a few times" in X-day recall vs. proportion who answered "yes" in at least one 24-hr report	phi
	Stress incontinence	G4	In the past 30/7/3 days... How often did you leak urine or wet a pad while laughing, sneezing, or coughing? Never A few times About half the time Most times Every time	In the past 24 hours... Did you leak urine or wet a pad while laughing, sneezing, or coughing? No Yes	Mean of 7 or 30 responses, using 0=no or 1=yes	Count of leaks, stress	Map response options (#s from diary to qualitative response from LURN) [or maybe use mean of 0=none, 1=any for each day]	Difference between proportion who answered "always," "often," "sometimes," or "rarely" in X-day recall vs. proportion who answered "yes" in at least one 24-hr report
		G5	In the past 30/7/3 days... How often did you leak urine or wet a pad when doing physical activities, such as exercising or lifting a heavy object? Never A few times About half the time Most times Every time	In the past 24 hours... Did you leak urine or wet a pad when doing physical activities, such as exercising or lifting a heavy object? No Yes	Mean of 7 or 30 responses, using 0=no or 1=yes	Count of leaks, stress	Map response options (#s from diary to qualitative response from LURN) [or use mean of 0=none, 1=any for each day]	Difference between proportion who answered "always," "often," "sometimes," or "rarely" in X-day recall vs. proportion who answered "yes" in at least one 24-hr report

Domain	Item Code	30-, 7-, and 3-day Recall	24-hour Recall		3-day Bladder Diary		Validation	
			Item	Derived Summary	Item	Derived Summary	Analysis for Bias	Analysis for Correlation
	G6	In the past 30/7/3 days... How often did standing up from a chair cause you to leak urine or wet a pad? Never A few times About half the time Most times Every time	In the past 24 hours... Did standing up after sitting cause you to leak urine or wet a pad? No Yes	Mean of 7 or 30 responses, using 0=no or 1=yes	Count of leaks, stress	Map response options (#s from diary to qualitative response from LURN) [or use mean of 0=none, 1=any for each day]	Difference between proportion who answered "always," "often," "sometimes," or "rarely" in X-day recall vs. proportion who answered "yes" in at least one 24-hr report	point biserial
	G7	In the past 30/7/3 days... How often did walking at your usual speed cause you to leak urine or wet a pad? Never A few times About half the time Most times Every time	In the past 24 hours... Did walking at your usual speed cause you to leak urine or wet a pad? No Yes	Mean of 7 or 30 responses, using 0=no or 1=yes	Count of leaks, stress	Map response options (#s from diary to qualitative response from LURN) [or use mean of 0=none, 1=any for each day]	Difference between proportion who answered "always," "often," "sometimes," or "rarely" in X-day recall vs. proportion who answered "yes" in at least one 24-hr report	point biserial
Urgency incontinence	G3	In the past 30/7/3 days... How often did you leak urine or wet a pad after feeling a sudden need to urinate? Never A few times About half the time Most times Every time	In the past 24 hours... Did you leak urine or wet a pad after feeling a sudden need to urinate? No Yes	Mean of 7 or 30 responses, using 0=no or 1=yes	Count of leaks, urge	Map response options (#s from diary to qualitative response from LURN) [or use mean of 0=none, 1=any for each day]	Difference between proportion who answered "always," "often," "sometimes," or "rarely" in X-day recall vs. proportion who answered "yes" in at least one 24-hr report	point biserial

Domain	Item Code	30-, 7-, and 3-day Recall	24-hour Recall		3-day Bladder Diary		Validation	
			Item	Derived Summary	Item	Derived Summary	Analysis for Bias	Analysis for Correlation
Other/ unknown incontinence	G10	In the past 30/7/3 days... How often did you leak urine or wet a pad without any reason you could identify? Never A few times About half the time Most times Every time	In the past 24 hours... Did you leak urine or wet a pad without any reason you could identify? No Yes	Mean of 7 or 30 responses, using 0=no or 1=yes	Count of leaks, unknown	Map response options (#s from diary to qualitative response from LURN) [or use mean of 0=none, 1=any for each day]	Difference between proportion who answered "every time," "most times," "about half the time," or "a few times" in X-day recall vs. proportion who answered "yes" in at least one 24-hr report	point biserial
	G11	In the past 30/7/3 days... How often did you leak urine or wet a pad without feeling it? Never A few times About half the time Most times Every time	In the past 24 hours... Did you leak urine or wet a pad without feeling it? No Yes	Mean of 7 or 30 responses, using 0=no or 1=yes	Count of leaks, urge	Map response options (#s from diary to qualitative response from LURN) [or use mean of 0=none, 1=any for each day]	Difference between proportion who answered "always," "often," "sometimes," or "rarely" in X-day recall vs. proportion who answered "yes" in at least one 24-hr report	point biserial
Slow/weak stream	F3	In the past 30/7/3 days... How often was your urine flow slow or weak? Never A few times About half the time Most times Every time	In the past 24 hours... How often was your urine flow slow or weak? Never A few times About half the time Most times Every time	Mean of 7 or 30 responses, using 0=Never, 1= A few times, 2= About half the time, 3= Most times, 4=Every time	--	--	Difference between 24-hr recall mean and X-day mean	Pearson or Spearman

Domain	Item Code	30-, 7-, and 3-day Recall	24-hour Recall		3-day Bladder Diary		Validation	
			Item	Derived Summary	Item	Derived Summary	Analysis for Bias	Analysis for Correlation
Post micturition incomplete emptying	H2	In the past 30/7/3 days... How often did you feel that your bladder was not completely empty after urinating? Never A few times About half the time Most times Every time	In the past 24 hours... How often did you feel that your bladder was not completely empty after urinating? Never A few times About half the time Most times Every time	Mean of 7 or 30 responses, using 0=Never, 1= A few times, 2= About half the time, 3= Most times, 4=Every time	--	--	Difference between 24-hr recall mean and X-day mean	Pearson or Spearman
Post micturition dribble	H3	In the past 30/7/3 days... How often did you dribble urine just after zipping your pants or pulling up your underwear? Never A few times About half the time Most times Every time	In the past 24 hours... How often did you dribble urine just after zipping your pants or pulling up your underwear? Never A few times About half the time Most times Every time	Mean of 7 or 30 responses, using 0=Never, 1= A few times, 2= About half the time, 3= Most times, 4=Every time	--	--	Difference between 24-hr recall mean and X-day mean	Pearson or Spearman

Bladder sensation:

- 0 - If you had no sensation of needing to pass urine, but passed urine for “social reasons”, for example, just before going out, or unsure where the next toilet is.
- 1 - If you had a normal desire to pass urine and no urgency.
“Urgency” is feeling a sudden need to urinate.
- 2 - If you had urgency, but it had passed before you went to the toilet, and you did not leak urine.
- 3 - If you had urgency but managed to get to the toilet, still with urgency, but did not leak urine.
- 4 - If you had urgency and could not get to the toilet in time so you leaked urine.

10. Appendix B: Symptoms

Table B1. Total number of symptoms for participants in LURN Qualitative Interview Study based on responses to the LUTS Tool

Type of Participant		Total # of Symptoms								Total
		0	1	2	3	4	5	6	7	
Clinic	N	0	0	0	3	3	7	5	8	26
Community	N	0	0	0	1	5	10	7	7	30
Sensory	N	0	0	0	1	0	3	5	11	20
Total	N	0	0	0	5	8	20	17	26	76
	% of Sample	0.0%	0.0%	0.0%	6.6%	10.5%	26.3%	22.4%	34.2%	100.0%

Table B2. Symptom overlap in LURN Qualitative Interview Study based on responses to the LUTS Tool

% of patients who have overlapping symptoms (all patient types)

Symptom (# of positive responses)*	Daytime Frequency (59)	Nocturia (67)	Urgency (65)	Incontinence (64)	Weak Stream (47)	Incomplete Emptying (58)	Post-micturition Dribble (44)
Daytime Frequency	100.0	69.7	65.8	67.1	50.0	57.9	72.4
Nocturia		100.0	75.0	73.7	59.2	69.7	81.6
Urgency			100.0	77.6	54.0	67.1	81.6
Incontinence				100.0	50.0	61.8	80.3
Weak Stream					100.0	54.0	59.2
Incomplete Emptying						100.0	72.4
Post-micturition Dribble							100.0

*N = 76 for all comparisons except for post-micturition comparisons, where N = 50

11. Appendix C: Screening Tool

A. Participant Information

- A1 | Are you able to reliably complete self-reported questionnaires online during specified times, typically 6pm to 2am local time, for the duration of the study?
- - No
 - Yes

- A2 | What time zone will you be in for the duration of the study?
- - Atlantic (UTC-4:00; Halifax, Puerto Rico)
 - Eastern (UTC-5:00; New York, Detroit)
 - Central (UTC-6:00; Chicago, Dallas)
 - Mountain (UTC-7:00; Denver, Phoenix)
 - Pacific (UTC-8:00; Los Angeles, Seattle)
 - Alaska (UTC-9:00; Anchorage, Juneau)
 - Hawaii-Aleutian (UTC-10:00; Honolulu, Adak Island)

URINARY SYMPTOMS OVER TWO WEEKS

For each symptom below, please tell us how often you have experienced it in the past two weeks, For any symptom that you *have* experienced, then tell us how much it bothers you.

- A3 | During a typical day in the **past 2 weeks**, how many times did you urinate during waking hours? | How much does this bother you?
- | | |
|--|------------------------------------|
| <input type="radio"/> -- | <input type="radio"/> -- |
| <input type="radio"/> 1-6 times a day | <input type="radio"/> Not at all |
| <input type="radio"/> 7-8 times a day | <input type="radio"/> A little bit |
| <input type="radio"/> 9-10 times a day | <input type="radio"/> Somewhat |
| <input type="radio"/> 11-12 times a day | <input type="radio"/> Quite a bit |
| <input type="radio"/> 13 or more times a day | <input type="radio"/> A great deal |

- Field UrWakeHrsBother of this question will be suppressed when field UrWakeHrs of question A3 has value "1-6 times a day"
- Field UrWakeHrsBother of question A3 will be suppressed if field UrWakeHrs of this question has a value of "1-6 times a day"

A4

During a typical night in the past 2 weeks, how many times did you wake up because you needed to urinate? If "1 time a night" or more, how much does this bother you?

- | | |
|---|------------------------------------|
| <input type="radio"/> -- | <input type="radio"/> -- |
| <input type="radio"/> None | <input type="radio"/> Not at all |
| <input type="radio"/> 1 time a night | <input type="radio"/> A little bit |
| <input type="radio"/> 2 times a night | <input type="radio"/> Somewhat |
| <input type="radio"/> 3 times a night | <input type="radio"/> Quite a bit |
| <input type="radio"/> 4 or more times a night | <input type="radio"/> A great deal |

- Field UrNightFreqBother of this question will be suppressed when field UrNightFreq of question A4 has value "None"
- Field UrNightFreqBother of question A4 will be suppressed if field UrNightFreq of this question has a value of "None"

A5

During the past 2 weeks, how often have you had a trickle or dribble at the end of your urine flow? If "rarely" or more, how much does this bother you?

- | | |
|-------------------------------------|------------------------------------|
| <input type="radio"/> -- | <input type="radio"/> -- |
| <input type="radio"/> Never | <input type="radio"/> Not at all |
| <input type="radio"/> Rarely | <input type="radio"/> A little bit |
| <input type="radio"/> Sometimes | <input type="radio"/> Somewhat |
| <input type="radio"/> Often | <input type="radio"/> Quite a bit |
| <input type="radio"/> Almost always | <input type="radio"/> A great deal |

- Field UrTrickleBother of this question will be suppressed when field UrTrickle of question A5 has value "Never"
- Field UrTrickleBother of question A5 will be suppressed if field UrTrickle of this question has a value of "Never"

A6

During the past 2 weeks, how often have you had a sudden need to rush to urinate? If "rarely" or more, how much does this bother you?

- | | |
|-------------------------------------|------------------------------------|
| <input type="radio"/> -- | <input type="radio"/> -- |
| <input type="radio"/> Never | <input type="radio"/> Not at all |
| <input type="radio"/> Rarely | <input type="radio"/> A little bit |
| <input type="radio"/> Sometimes | <input type="radio"/> Somewhat |
| <input type="radio"/> Often | <input type="radio"/> Quite a bit |
| <input type="radio"/> Almost always | <input type="radio"/> A great deal |

- Field UrSuddenBother of this question will be suppressed when field UrSudden of question A6 has value "Never"
- Field UrSuddenBother of question A6 will be suppressed if field UrSudden of this question has a value of "Never"

A7

- | | |
|--|---|
| <p>During the past 2 weeks, how often have you had a weak urine stream?</p> <p><input type="radio"/> --</p> <p><input type="radio"/> Never</p> <p><input type="radio"/> Rarely</p> <p><input type="radio"/> Sometimes</p> <p><input type="radio"/> Often</p> <p><input type="radio"/> Almost always</p> | <p>If "rarely" or more, how much does this bother you?</p> <p><input type="radio"/> --</p> <p><input type="radio"/> Not at all</p> <p><input type="radio"/> A little bit</p> <p><input type="radio"/> Somewhat</p> <p><input type="radio"/> Quite a bit</p> <p><input type="radio"/> A great deal</p> |
|--|---|

- Field UrWeakStreamBother of this question will be suppressed when field UrWeakStream of question A7 has value "Never"
- Field UrWeakStreamBother of question A7 will be suppressed if field UrWeakStream of this question has a value of "Never"

A8

- | | |
|--|---|
| <p>During the past 2 weeks, how often did you leak urine?</p> <p><input type="radio"/> --</p> <p><input type="radio"/> Never</p> <p><input type="radio"/> Rarely</p> <p><input type="radio"/> Sometimes</p> <p><input type="radio"/> Often</p> <p><input type="radio"/> Almost always</p> | <p>If "rarely" or more, how much does this bother you?</p> <p><input type="radio"/> --</p> <p><input type="radio"/> Not at all</p> <p><input type="radio"/> A little bit</p> <p><input type="radio"/> Somewhat</p> <p><input type="radio"/> Quite a bit</p> <p><input type="radio"/> A great deal</p> |
|--|---|

- Field UrLeakBother of this question will be suppressed when field UrLeak of question A8 has value "Never"
- Field UrLeakBother of question A8 will be suppressed if field UrLeak of this question has a value of "Never"

A9

- | | |
|---|---|
| <p>During the past 2 weeks, how often have you had the feeling your bladder was not empty after urinating?</p> <p><input type="radio"/> --</p> <p><input type="radio"/> Never</p> <p><input type="radio"/> Rarely</p> <p><input type="radio"/> Sometimes</p> <p><input type="radio"/> Often</p> <p><input type="radio"/> Almost always</p> | <p>If "rarely" or more, how much does this bother you?</p> <p><input type="radio"/> --</p> <p><input type="radio"/> Not at all</p> <p><input type="radio"/> A little bit</p> <p><input type="radio"/> Somewhat</p> <p><input type="radio"/> Quite a bit</p> <p><input type="radio"/> A great deal</p> |
|---|---|

- Field UrBldNotEmptyBother of this question will be suppressed when field UrBldNotEmpty of question A9 has value "Never"

URINARY SYMPTOMS OVER THREE MONTHS

For each symptom below, please tell us how often you have experienced it in the past three months, For any symptom that you *have* experienced, then tell us how much it bothers you.

A10	<p>During a typical day in the past 3 months, how many times did you urinate during waking hours?</p> <p><input type="radio"/> --</p> <p><input type="radio"/> 1-6 times a day</p> <p><input type="radio"/> 7-8 times a day</p> <p><input type="radio"/> 9-10 times a day</p> <p><input type="radio"/> 11-12 times a day</p> <p><input type="radio"/> 13 or more times a day</p>	<p>How much does this bother you?</p> <p><input type="radio"/> --</p> <p><input type="radio"/> Not at all</p> <p><input type="radio"/> A little bit</p> <p><input type="radio"/> Somewhat</p> <p><input type="radio"/> Quite a bit</p> <p><input type="radio"/> A great deal</p>
-----	---	--

- Field UrWakeHrsBother3M of this question will be suppressed when field UrWakeHrs3M of question A10 has value "1-6 times a day"
- Field UrWakeHrsBother3M of question A10 will be suppressed if field UrWakeHrs3M of this question has a value of "1-6 times a day"

A11	<p>During a typical night in the past 3 months, how many times did you wake up because you needed to urinate?</p> <p><input type="radio"/> --</p> <p><input type="radio"/> None</p> <p><input type="radio"/> 1 time a night</p> <p><input type="radio"/> 2 times a night</p> <p><input type="radio"/> 3 times a night</p> <p><input type="radio"/> 4 or more times a night</p>	<p>If "1 time a night" or more, how much does this bother you?</p> <p><input type="radio"/> --</p> <p><input type="radio"/> Not at all</p> <p><input type="radio"/> A little bit</p> <p><input type="radio"/> Somewhat</p> <p><input type="radio"/> Quite a bit</p> <p><input type="radio"/> A great deal</p>
-----	---	---

- Field UrNightFreqBother3M of this question will be suppressed when field UrNightFreq3M of question A11 has value "None"
- Field UrNightFreqBother3M of question A11 will be suppressed if field UrNightFreq3M of this question has a value of "None"

A12	
-----	--

During the **past 3 months**, how often have you had a trickle or dribble at the end of your urine flow?

If "rarely" or more, how much does this bother you?

--

Not at all

A little bit

Somewhat

Quite a bit

A great deal

Never

Rarely

Sometimes

Often

Almost always

- Field UrTrickleBother3M of this question will be suppressed when field UrTrickle3M of question A12 has value "Never"
- Field UrTrickleBother3M of question A12 will be suppressed if field UrTrickle3M of this question has a value of "Never"

A13

During the **past 3 months**, how often have you had a sudden need to rush to urinate?

If "rarely" or more, how much does this bother you?

--

Not at all

A little bit

Somewhat

Quite a bit

A great deal

Never

Rarely

Sometimes

Often

Almost always

- Field UrSuddenBother3M of this question will be suppressed when field UrSudden3M of question A13 has value "Never"
- Field UrSuddenBother3M of question A13 will be suppressed if field UrSudden3M of this question has a value of "Never"

A14

During the **past 3 months**, how often have you had a weak urine stream?

If "rarely" or more, how much does this bother you?

--

Not at all

A little bit

Somewhat

Quite a bit

A great deal

Never

Rarely

Sometimes

Often

Almost always

- Field UrWeakStreamBother3M of this question will be suppressed when field UrWeakStream3M of question A14 has value "Never"
- Field UrWeakStreamBother3M of question A14 will be suppressed if field UrWeakStream3M of this question has a value of "Never"

A15

- | | |
|---|---|
| During the past 3 months , how often did you leak urine? | If "rarely" or more, how much does this bother you? |
| <input type="radio"/> -- | <input type="radio"/> -- |
| <input type="radio"/> Never | <input type="radio"/> Not at all |
| <input type="radio"/> Rarely | <input type="radio"/> A little bit |
| <input type="radio"/> Sometimes | <input type="radio"/> Somewhat |
| <input type="radio"/> Often | <input type="radio"/> Quite a bit |
| <input type="radio"/> Almost always | <input type="radio"/> A great deal |

- Field UrLeakBother3M of this question will be suppressed when field UrLeak3M of question A15 has value "Never"
- Field UrLeakBother3M of question A15 will be suppressed if field UrLeak3M of this question has a value of "Never"

A16

- | | |
|--|---|
| During the past 3 months , how often have you had the feeling your bladder was not empty after urinating? | If "rarely" or more, how much does this bother you? |
| <input type="radio"/> -- | <input type="radio"/> -- |
| <input type="radio"/> Never | <input type="radio"/> Not at all |
| <input type="radio"/> Rarely | <input type="radio"/> A little bit |
| <input type="radio"/> Sometimes | <input type="radio"/> Somewhat |
| <input type="radio"/> Often | <input type="radio"/> Quite a bit |
| <input type="radio"/> Almost always | <input type="radio"/> A great deal |

- Field UrBldNotEmptyBother3M of this question will be suppressed when field UrBldNotEmpty3M of question A16 has value "Never"
- Field UrBldNotEmptyBother3M of question A16 will be suppressed if field UrBldNotEmpty3M of this question has a value of "Never"

A17

- Questionnaire Complete
- - Yes

B. Questionnaire Complete

B1

- Questionnaire Complete
- - Yes

B2

Complete Date

<input type="text"/>	<input type="text"/>	<input type="text"/>
Month	Day	Year

12. Appendix D: Baseline Assessment

A. Demographics

- A1
- Sex:
- - Male
 - Female

- Section CASUS, Sensation Female will be suppressed if this question has a value of "Male"
- Section CASUS, Sensation Male will be suppressed if this question has a value of "Female"

- A2
- Race (select all that apply):
- American Indian or Alaska Native
 - Asian/Asian American
 - Black or African American
 - Native Hawaiian or other Pacific Islander
 - White
 - Other
 - Unknown

- A3
- Ethnicity:
- - Hispanic or Latino
 - Not Hispanic or Latino
 - Unknown

- A4
- Marital Status:
- - Married/civil union
 - Living with a partner
 - Separated or divorced
 - Widowed
 - Single, never married
 - Unknown

- A5
- Education:
- - Less than HS diploma/GED
 - HS diploma/GED
 - Some college or tech school, no degree
 - Associate's degree
 - Bachelor's degree

- Graduate degree
- Unknown

-
- A6
- Employment:
- - Employed part-time
 - Employed full-time
 - Unemployed (looking for work)
 - Not employed (not looking for work, includes stay-at-home, retired)
 - Unknown

-
- A7
- Height:
-
- in.
 - cm
 - Not Done

-
- A8
- Weight:
-
- lbs.
 - kg
 - Not Done

B. Self-Reported Health

-
- B1
- Do you have difficulty walking?
- - You have no problems in walking about
 - You have some problems in walking about
 - You are confined to bed

-
- B2
- Do you have difficulty with self-care?
- - You have no problems with self-care
 - You have some problems with washing or dressing yourself
 - You are unable to wash or dress yourself

-
- B3
- In general, would you say your health is:
- - Excellent
 - Very good
 - Good
 - Fair
 - Poor
-

- B4
- In general, would you say your quality of life is:
- - Excellent
 - Very good
 - Good
 - Fair
 - Poor

- B5
- Are you currently, or have you been, on any treatments for your urinary tract symptoms? Select all that apply.
- (Non-traditional/non-medicinal treatments can refer to herbal supplements, exercise regimens, talk therapy, etc.)
- Medicine
 - Surgery
 - Non-traditional/ non-medicinal treatments
 - Other (specify)
 - None
 - Unknown

Have you ever been told by a doctor or a health professional that you have...

- B6
- High blood pressure (hypertension)
- - No
 - Yes
 - Not Sure

- B7
- Hardening of the arteries (coronary heart disease)
- - No
 - Yes
 - Not Sure

- B8
- Heart disease or heart problems
- - No
 - Yes
 - Not Sure

- B9
- Stroke or transient ischemic attack (TIA)
-

	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Not Sure
B10	Liver disease, hepatitis, or cirrhosis <input type="radio"/> -- <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Not Sure
B11	Kidney disease <input type="radio"/> -- <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Not Sure
B12	Arthritis <input type="radio"/> -- <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Not Sure
B13a	Diabetes, or high blood sugar, or sugar in your urine <input type="radio"/> -- <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Not Sure
B13b	If yes, how many years have you had diabetes? <input type="text"/> years
B14	Cancer other than non-melanoma skin cancer <input type="radio"/> -- <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Not Sure
B15	Depression <input type="radio"/> -- <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Not Sure
B16	Anxiety

-
- No
- Yes
- Not Sure

B17

Alcohol or drug problem

-
- No
- Yes
- Not Sure

B18

A sleep disorder

-
- No
- Yes
- Not Sure

B19

A spinal cord injury

-
- No
- Yes
- Not Sure

C. CASUS, Frequency Everyone

- This section suppressed if database function al.fn_GetProtocolVersion returns 1

In the past 7 days:

C1

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

C2

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

-
- C3 | During a typical day, how often did you urinate twice or more within a few minutes?
- - Never
 - A few times
 - About half the time
 - Most of the time
 - Every time

-
- C4 | During a typical night, how many times did you wake up and urinate?
- - None
 - 1 time
 - 2-3 times
 - More than 3 times

-
- C5 | How often did you wake up at least once during the night because you had to urinate?
- - Never
 - A few nights
 - About half the nights
 - Most nights
 - Every night

-
- C6 | How would you describe your typical urge to urinate when you woke up during the night?
- - No urge
 - Mild urge
 - Moderate urge
 - Strong urge

-
- C7 | How often did you leak urine during the night, including wetting a pad or the bed?
- - Never
 - A few nights
 - About half the nights
 - Most nights
 - Every night

-
- C8 | When you woke up and urinated, how often did you leak urine on your way to the bathroom?
- - Never
 - A few times

- About half the time
- Most of the time
- Every time

D. CASUS, Sensation Female

- This section suppressed if question A1 has a value of "Male"
- This section suppressed if database function al.fn_GetGender returns 1
- This section suppressed if database function al.fn_GetProtocolVersion returns 1

In the past 7 days, where did you feel sensations when you felt you needed to urinate?

- D1 Lower abdomen:
- - No
 - Yes

- D2 Bladder area:
- - No
 - Yes

- D3 Labia/vagina area:
- - No
 - Yes

- D4 Urethra:
- - No
 - Yes

- D5 Lower back:
- - No
 - Yes

- D6 Other:
- - No
 - Yes

- Question D7 will be suppressed if this question has a value of "No"

D7

If Yes to Other, where do you feel sensations:

- This question suppressed if question D6 has a value of "No"

E. CASUS, Sensation Male

- This section suppressed if question A1 has a value of "Female"
- This section suppressed if database function al.fn_GetGender returns 2
- This section suppressed if database function al.fn_GetProtocolVersion returns 1

In the past 7 days, where did you feel sensations when you felt you needed to urinate?

E1

Lower abdomen:

-
- No
- Yes

E2

Bladder area:

-
- No
- Yes

E3

Tip of the penis:

-
- No
- Yes

E4

Shaft of the penis:

-
- No
- Yes

E5

Scrotum/testicles:

-
- No
- Yes

E6 | Urethra:
 --
 No
 Yes

E7 | Lower back:
 --
 No
 Yes

E8 | Other:
 --
 No
 Yes

• Question E9 will be suppressed if this question has a value of "No"

E9 | If Yes to Other, where do you feel sensations:

• This question suppressed if question E8 has a value of "No"

F. CASUS, Sensation Everyone

• This section suppressed if database function al.fn_GetProtocolVersion returns 1

In the past 7 days, what kinds of sensations did you have when you felt you needed to urinate?

F1 | None:
 --
 No
 Yes

F2 | Bloating:
 --
 No
 Yes

F3 | Tingling:
 --
 No
 Yes

F4 | Burning:
 --
 No
 Yes

F5 | Pressure:
 --
 No
 Yes

F6 | Discomfort:
 --
 No
 Yes

F7 | Pain:
 --
 No
 Yes

F8 | Aching:
 --
 No
 Yes

F9 | Urgency:
 --
 No
 Yes

F10 | Stinging:
 --
 No
 Yes

F11 | Fullness:
 --
 No
 Yes

- F12
- Other:
- - No
 - Yes

• Question F13 will be suppressed if this question has a value of "No"

F13

If Yes to Other, what kinds of sensations do you feel:

• This question suppressed if question F12 has a value of "No"

- F14
- I have sensations, but I can't put them into words:
- - No
 - Yes

Think about the times between when you finished urinating and when you next need to urinate.

- F15
- During these times, are you aware of any feelings or sensations?
- - No
 - Yes

• Question F16 will be suppressed if this question has a value of "No"
• Question F17 will be suppressed if this question has a value of "No"
• Question F18 will be suppressed if this question has a value of "No"
• Question F19 will be suppressed if this question has a value of "No"
• Question F20 will be suppressed if this question has a value of "No"
• Question F21 will be suppressed if this question has a value of "No"
• Question F22 will be suppressed if this question has a value of "No"
• Question F23 will be suppressed if this question has a value of "No"
• Question F24 will be suppressed if this question has a value of "No"
• Question F25 will be suppressed if this question has a value of "No"
• Question F26 will be suppressed if this question has a value of "No"
• Question F27 will be suppressed if this question has a value of "No"
• Question F28 will be suppressed if this question has a value of "No"

If Yes, what kinds of feelings or sensations did you have?

F16 | Bloating:

-
- No
- Yes

• This question suppressed if question F15 has a value of "No"

F17

Tingling:

-
- No
- Yes

• This question suppressed if question F15 has a value of "No"

F18

Burning:

-
- No
- Yes

• This question suppressed if question F15 has a value of "No"

F19

Pressure:

-
- No
- Yes

• This question suppressed if question F15 has a value of "No"

F20

Discomfort:

-
- No
- Yes

• This question suppressed if question F15 has a value of "No"

F21

Pain:

-

- No
- Yes

• This question suppressed if question F15 has a value of "No"

F22

Aching:

-
- No
- Yes

• This question suppressed if question F15 has a value of "No"

F23

Urgency:

-
- No
- Yes

• This question suppressed if question F15 has a value of "No"

F24

Stinging:

-
- No
- Yes

• This question suppressed if question F15 has a value of "No"

F25

Fullness:

-
- No
- Yes

• This question suppressed if question F15 has a value of "No"

F26

Other:

-
- No
- Yes

- This question suppressed if question F15 has a value of "No"
- Question F27 will be suppressed if this question has a value of "No"

F27

If Yes to Other, what kinds of sensations do you feel:

- This question suppressed if question F15 has a value of "No"
- This question suppressed if question F26 has a value of "No"

F28

I have sensations, but I can't put them into words:

-
- No
- Yes

- This question suppressed if question F15 has a value of "No"

In the past 7 days:

F29

How often did you have pain or discomfort in your bladder while it was filling?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

- Question F30 will be suppressed if this question has a value of "Never"

F30

How much pain or discomfort did you have in your bladder while it was filling?

-
- No pain or discomfort
- Mild
- Moderate
- Severe

- This question suppressed if question F29 has a value of "Never"

-
- F31
- How often did you have pain or discomfort in your bladder when it was full?
- - Never
 - A few times
 - About half the time
 - Most of the time
 - Every time

• Question F32 will be suppressed if this question has a value of "Never"

-
- F32
- How much pain or discomfort did you have in your bladder when it was full?
- - No pain or discomfort
 - Mild
 - Moderate
 - Severe

• This question suppressed if question F31 has a value of "Never"

-
- F33
- How often did you have pain or discomfort while urinating?
- - Never
 - A few times
 - About half the time
 - Most of the time
 - Every time

• Question F34 will be suppressed if this question has a value of "Never"

-
- F34
- How much pain or discomfort did you have while urinating?
- - No pain or discomfort
 - Mild
 - Moderate
 - Severe

• This question suppressed if question F33 has a value of "Never"

F35 | How often did you have pain or discomfort right after you had finished urinating?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

• Question F36 will be suppressed if this question has a value of "Never"

F36 | How much pain or discomfort did you have right after you had finished urinating?

-
- No pain or discomfort
- Mild
- Moderate
- Severe

• This question suppressed if question F35 has a value of "Never"

In the past 7 days:

F37 | How often did you feel a sudden need to urinate?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

F38 | Once you noticed the need to urinate, how difficult was it to wait more than a few minutes?

-
- Not difficult
- A little difficult
- Somewhat difficult
- Very difficult
- Unable to wait

F39 | How often did you have a sudden need to rush to urinate for fear of leaking urine?

-
- Never
- A few times

- About half the time
- Most of the time
- Every time

F40

Did you have a constant need to urinate that did not go away?

-
- No
- Yes

G. CASUS, Effort Everyone

- This section suppressed if database function al.fn_GetProtocolVersion returns 1

EFFORT WITH URINATION

In the past 7 days:

G1

How often did you have a delay before you started to urinate?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

- Question G2 will be suppressed if this question has a value of "Never"

G2

When trying to urinate, how much of a delay was there before the urine came out?

-
- None
- A few seconds to less than a minute
- Around a minute
- More than a minute

- This question suppressed if question G1 has a value of "Never"

G3

How often did you have to push when urinating?

-
- Never
- A few times

- About half the time
- Most of the time
- Every time

- Question G4 will be suppressed if this question has a value of "Never"
- Question G5 will be suppressed if this question has a value of "Never"
- Question G6 will be suppressed if this question has a value of "Never"

G4

How hard did you have to push to begin urinating?

-
- Not at all hard
- A little bit hard
- Quite a bit hard
- Very hard

- This question suppressed if question G3 has a value of "Never"

G5

How hard did you have to push during urination?

-
- Not at all hard
- A little bit hard
- Quite a bit hard
- Very hard

- This question suppressed if question G3 has a value of "Never"

G6

How often did you push extra hard while you were urinating?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

- This question suppressed if question G3 has a value of "Never"

G7

How much did you have to concentrate to empty your bladder?

-
- Not at all

- A little bit
- Quite a bit
- Very much

-
- G8 | How often did you have to relax to empty your bladder?
- - Never
 - A few times
 - About half the time
 - Most of the time
 - Every time

URINE FLOW

In the past 7 days:

- This question suppressed if function al.fn_GetGender returns 2

-
- G9 | How often did you have splitting or spraying of your urine stream?
- - Never
 - A few times
 - About half the time
 - Most of the time
 - Every time

- This question suppressed if function al.fn_GetGender returns 2

-
- G10 | How often did you have spraying or change in direction of your urine stream?
- - Never
 - A few times
 - About half the time
 - Most of the time
 - Every time

- This question suppressed if function al.fn_GetGender returns 1

-
- G11 | Once you started urinating, how often did your urine flow stop and start again?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

G12

How often was your urine flow slow or weak?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

G13

How often did you have a trickle or dribble at the end of your urine flow?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

G14

How often did you have no sensation of urine flow while you were urinating?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

INCONTINENCE

In the past 7 days:

G15

Have you leaked urine or wet a pad?

-
- No
- Yes

- Question G will be suppressed if this question has a value of "No"
- Question G16 will be suppressed if this question has a value of "No"
- Question G17 will be suppressed if this question has a value of "No"

- Question G18 will be suppressed if this question has a value of "No"
- Question G19 will be suppressed if this question has a value of "No"
- Question G20 will be suppressed if this question has a value of "No"
- Question G21 will be suppressed if this question has a value of "No"
- Question G22 will be suppressed if this question has a value of "No"
- Question G23 will be suppressed if this question has a value of "No"
- Question G24 will be suppressed if this question has a value of "No"
- Question G25 will be suppressed if this question has a value of "No"

If Yes:

- This question suppressed if question G15 has a value of "No"

G16

How often did you completely lose control of your bladder?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

- This question suppressed if question G15 has a value of "No"

G17

How often did you leak urine or wet a pad after feeling a sudden need to urinate?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

- This question suppressed if question G15 has a value of "No"

G18

How often did you leak urine or wet a pad while laughing, sneezing, or coughing?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

• This question suppressed if question G15 has a value of "No"

G19

How often did you leak urine or wet a pad when doing physical activities, such as exercising or lifting a heavy object?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

• This question suppressed if question G15 has a value of "No"

G20

How often did getting up from a chair cause you to leak urine or wet a pad?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

• This question suppressed if question G15 has a value of "No"

G21

How often did walking at your usual speed cause you to leak urine or wet a pad?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

• This question suppressed if question G15 has a value of "No"

G22

How often did you leak urine or wet a pad without feeling an urge to urinate or not in connection with physical activity?

-
- Never
- A few times
- About half the time
- Most of the time

Every time

• This question suppressed if question G15 has a value of "No"

G23 | How often did walking down stairs or stepping off a curb cause you to leak urine or wet a pad?

- Never
 A few times
 About half the time
 Most of the time
 Every time

• This question suppressed if question G15 has a value of "No"

G24 | How often did you leak urine or wet a pad without any reason you could identify?

- Never
 A few times
 About half the time
 Most of the time
 Every time

• This question suppressed if question G15 has a value of "No"

G25 | How often did you leak urine or wet a pad without feeling it?

- Never
 A few times
 About half the time
 Most of the time
 Every time

• This question suppressed if question G15 has a value of "No"

In the past 7 days:

G26 | How often did you feel a need to urinate after you had just urinated?

-

- Never
- A few times
- About half the time
- Most of the time
- Every time

G27

How often did you feel that your bladder was not completely empty after urination?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

G28

How often did you dribble urine just after zipping your pants or pulling up your underwear?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

H. CASUS, Screening Questions

- This section suppressed if database function al.fn_GetProtocolVersion returns 1

In the past 7 days:

H1

How satisfied were you with your bladder function?

-
- Not at all satisfied
- Somewhat satisfied
- Very satisfied
- Extremely satisfied

H2

How bothered were you by urinary symptoms?

-
- Not at all bothered
- Somewhat bothered
- Very bothered
- Extremely bothered

- H3
- How often did you have urinary or bladder problems of any kind?
- - Never
 - A few times
 - About half the time
 - Most of the time
 - Every time

- H4
- How would you rate your bladder or urinary function?
- - Very poor
 - Poor
 - Good
 - Very good

I. CASUS, History Questions

- This section suppressed if database function al.fn_GetProtocolVersion returns 1

Thinking back over your whole adult life:

- I1
- Did you ever leak urine after feeling a sudden need to urinate?
- - No
 - Yes

- I2
- Did you ever have an accident where you completely emptied your bladder?
- - No
 - Yes

- I3
- Did you ever leak urine with a laugh, sneeze, or cough?
- - No
 - Yes

- I4
- Did you ever seek medical attention because you could not empty your bladder?
- - No
 - Yes

- I5 | Have you ever tried to stop urinating mid-stream?
 --
 No
 Yes

• Question I6 will be suppressed if this question has a value of "No"

- I6 | If yes, how difficult was it to stop urination mid-stream?
 --
 Not difficult
 A little difficult
 Somewhat difficult
 Very difficult
 Unable to do

• This question suppressed if question I5 has a value of "No"

- I7 | Have you ever been asked to give a mid-stream urine sample?
 --
 No
 Yes

• Question I8 will be suppressed if this question has a value of "No"

- I8 | If yes, how difficult was it to stop urination mid-stream?
 --
 Not difficult
 A little difficult
 Somewhat difficult
 Very difficult
 Unable to do

• This question suppressed if question I7 has a value of "No"

J. Questionnaire Complete

- J1 | Questionnaire Complete
 --

| Yes

J2 | Complete Date
|
| Month Day Year

13. Appendix E: 24-hour Recall

A. 24-Hour Recall

- A1 | During waking hours today, how many times did you urinate?
- - 3 or fewer times
 - 4-7 times
 - 8-10 times
 - 11 or more times

- A2 | During the day today, how much time typically passed between urinations?
- - More than 6 hours
 - 3-6 hours
 - 1-2 hours
 - Less than 1 hour

- A3 | Last night, how many times did you wake up and urinate?
- - None
 - 1 time
 - 2-3 times
 - More than 3 times

- A4 | Last night, did you wake up because you had to urinate?
- - No
 - Yes (at least once)

• Question A5 will be suppressed if this question has a value of "No"

- A5 | When you woke up and urinated last night, did you leak urine on your way to the bathroom?
- - No
 - Yes (at least once)

• This question suppressed if question A4 has a value of "No"

- A6 | In the past 24 hours...
How often did you feel a sudden need to urinate?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

A7

In the past 24 hours...

Once you noticed the need to urinate, how difficult was it to wait more than a few minutes?

-
- Not difficult
- A little difficult
- Somewhat difficult
- Very difficult
- Unable to wait

A8

In the past 24 hours...

Did you leak urine or wet a pad?

-
- No
- Yes

- Question A9 will be suppressed if this question has a value of "No"
- Question A10 will be suppressed if this question has a value of "No"
- Question A11 will be suppressed if this question has a value of "No"
- Question A12 will be suppressed if this question has a value of "No"
- Question A13 will be suppressed if this question has a value of "No"
- Question A14 will be suppressed if this question has a value of "No"
- Question A15 will be suppressed if this question has a value of "No"
- Question A16 will be suppressed if this question has a value of "No"

A9

In the past 24 hours...

Did you completely lose control of your bladder?

-
- No
- Yes

- This question suppressed if question A8 has a value of "No"

A10

In the past 24 hours...

Did you leak urine or wet a pad while laughing, sneezing, or coughing?

-
- No
- Yes

• This question suppressed if question A8 has a value of "No"

A11

In the past 24 hours...

Did you leak urine or wet a pad when doing physical activities, such as exercising or lifting a heavy object?

-
- No
- Yes

• This question suppressed if question A8 has a value of "No"

A12

In the past 24 hours...

Did getting up from a chair cause you to leak urine or wet a pad?

-
- No
- Yes

• This question suppressed if question A8 has a value of "No"

A13

In the past 24 hours...

Did walking at your usual speed cause you to leak urine or wet a pad?

-
- No
- Yes

• This question suppressed if question A8 has a value of "No"

A14

In the past 24 hours...

Did you leak urine or wet a pad after feeling a sudden need to urinate?

-
- No
- Yes

• This question suppressed if question A8 has a value of "No"

-
- A15 | In the past 24 hours...
Did you leak urine or wet a pad without any reason you could identify?
 --
 No
 Yes

• This question suppressed if question A8 has a value of "No"

-
- A16 | In the past 24 hours...
Did you leak urine or wet a pad without feeling it?
 --
 No
 Yes

• This question suppressed if question A8 has a value of "No"

-
- A17 | In the past 24 hours...
How often was your urine flow slow or weak?
 --
 Never
 A few times
 About half the time
 Most of the time
 Every time

-
- A18 | In the past 24 hours...
How often did you feel that your bladder was not completely empty after urination?
 --
 Never
 A few times
 About half the time
 Most of the time
 Every time

-
- A19 | In the past 24 hours...
How often did you dribble urine just after zipping your pants or pulling up your underwear?
 --

- Never
- A few times
- About half the time
- Most of the time
- Every time

A20

- Questionnaire Complete
- - Yes

14. Appendix F: 3-, 7-day Recall

A. 3-Day Recall

- A1 | In the past 3 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

- A2 | In the past 3 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

- A3 | In the past 3 days...
During a typical night, how many times did you wake up and urinate?
- - None
 - 1 time
 - 2-3 times
 - More than 3 times

- A4 | In the past 3 days...
How often did you wake up at least once during the night because you had to urinate?
- - Never
 - A few nights
 - About half the nights
 - Most nights
 - Every night

• Question A5 will be suppressed if this question has a value of "Never"

- A5 | In the past 3 days...

When you woke up and urinated, how often did you leak urine on your way to the bathroom?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

- This question suppressed if question A4 has a value of "Never"

A6

In the past 3 days...

How often did you feel a sudden need to urinate?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

A7

In the past 3 days...

Once you noticed the need to urinate, how difficult was it to wait more than a few minutes?

-
- Not difficult
- A little difficult
- Somewhat difficult
- Very difficult
- Unable to wait

A8

In the past 3 days...

Have you leaked urine or wet a pad?

-
- No
- Yes

- Question A9 will be suppressed if this question has a value of "No"
- Question A10 will be suppressed if this question has a value of "No"
- Question A11 will be suppressed if this question has a value of "No"
- Question A12 will be suppressed if this question has a value of "No"
- Question A13 will be suppressed if this question has a value of "No"
- Question A14 will be suppressed if this question has a value of "No"
- Question A15 will be suppressed if this question has a value of "No"
- Question A16 will be suppressed if this question has a value of "No"

A9	<p>In the past 3 days...</p> <p>How often did you completely lose control of your bladder?</p> <p><input type="radio"/> --</p> <p><input type="radio"/> Never</p> <p><input type="radio"/> A few times</p> <p><input type="radio"/> About half the time</p> <p><input type="radio"/> Most of the time</p> <p><input type="radio"/> Every time</p>
<p>• This question suppressed if question A8 has a value of "No"</p>	

A10	<p>In the past 3 days...</p> <p>How often did you leak urine or wet a pad while laughing, sneezing, or coughing?</p> <p><input type="radio"/> --</p> <p><input type="radio"/> Never</p> <p><input type="radio"/> A few times</p> <p><input type="radio"/> About half the time</p> <p><input type="radio"/> Most of the time</p> <p><input type="radio"/> Every time</p>
<p>• This question suppressed if question A8 has a value of "No"</p>	

A11	<p>In the past 3 days...</p> <p>How often did you leak urine or wet a pad when doing physical activities, such as exercising or lifting a heavy object?</p> <p><input type="radio"/> --</p> <p><input type="radio"/> Never</p> <p><input type="radio"/> A few times</p> <p><input type="radio"/> About half the time</p> <p><input type="radio"/> Most of the time</p> <p><input type="radio"/> Every time</p>
<p>• This question suppressed if question A8 has a value of "No"</p>	

A12	<p>In the past 3 days...</p> <p>How often did getting up from a chair cause you to leak urine or wet a pad?</p> <p><input type="radio"/> --</p> <p><input type="radio"/> Never</p>
-----	--

- A few times
- About half the time
- Most of the time
- Every time

• This question suppressed if question A8 has a value of "No"

A13

In the past 3 days...

How often did walking at your usual speed cause you to leak urine or wet a pad?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

• This question suppressed if question A8 has a value of "No"

A14

In the past 3 days...

How often did you leak urine or wet a pad after feeling a sudden need to urinate?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

• This question suppressed if question A8 has a value of "No"

A15

In the past 3 days...

How often did you leak urine or wet a pad without any reason you could identify?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

• This question suppressed if question A8 has a value of "No"

-
- A16
- In the past 3 days...
- How often did you leak urine or wet a pad without feeling it?
- - Never
 - A few times
 - About half the time
 - Most of the time
 - Every time

• This question suppressed if question A8 has a value of "No"

-
- A17
- In the past 3 days...
- How often was your urine flow slow or weak?
- - Never
 - A few times
 - About half the time
 - Most of the time
 - Every time

-
- A18
- In the past 3 days...
- How often did you feel that your bladder was not completely empty after urination?
- - Never
 - A few times
 - About half the time
 - Most of the time
 - Every time

-
- A19
- In the past 3 days...
- How often did you dribble urine just after zipping your pants or pulling up your underwear?
- - Never
 - A few times
 - About half the time
 - Most of the time
 - Every time

-
- A20
- Questionnaire Complete
- - Yes
-

A. 7-Day Recall

- A1 | 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

- A2 | 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

- A3 | 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

- A4 | In the past 7 days...
How often did you wake up at least once during the night because you had to urinate?
- - Never
 - A few nights
 - About half the nights
 - Most nights
 - Every night

• Question A5 will be suppressed if this question has a value of "Never"

- A5 | In the past 7 days...

When you woke up and urinated, how often did you leak urine on your way to the bathroom?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

- This question suppressed if question A4 has a value of "Never"

A6

In the past 7 days...

How often did you feel a sudden need to urinate?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

A7

In the past 7 days...

Once you noticed the need to urinate, how difficult was it to wait more than a few minutes?

-
- Not difficult
- A little difficult
- Somewhat difficult
- Very difficult
- Unable to wait

A8

In the past 7 days...

Have you leaked urine or wet a pad?

-
- No
- Yes

- Question A9 will be suppressed if this question has a value of "No"
- Question A10 will be suppressed if this question has a value of "No"
- Question A11 will be suppressed if this question has a value of "No"
- Question A12 will be suppressed if this question has a value of "No"
- Question A13 will be suppressed if this question has a value of "No"
- Question A14 will be suppressed if this question has a value of "No"
- Question A15 will be suppressed if this question has a value of "No"
- Question A16 will be suppressed if this question has a value of "No"

A9	<p>In the past 7 days...</p> <p>How often did you completely lose control of your bladder?</p> <p><input type="radio"/> --</p> <p><input type="radio"/> Never</p> <p><input type="radio"/> A few times</p> <p><input type="radio"/> About half the time</p> <p><input type="radio"/> Most of the time</p> <p><input type="radio"/> Every time</p>
<p>• This question suppressed if question A8 has a value of "No"</p>	

A10	<p>In the past 7 days...</p> <p>How often did you leak urine or wet a pad while laughing, sneezing, or coughing?</p> <p><input type="radio"/> --</p> <p><input type="radio"/> Never</p> <p><input type="radio"/> A few times</p> <p><input type="radio"/> About half the time</p> <p><input type="radio"/> Most of the time</p> <p><input type="radio"/> Every time</p>
<p>• This question suppressed if question A8 has a value of "No"</p>	

A11	<p>In the past 7 days...</p> <p>How often did you leak urine or wet a pad when doing physical activities, such as exercising or lifting a heavy object?</p> <p><input type="radio"/> --</p> <p><input type="radio"/> Never</p> <p><input type="radio"/> A few times</p> <p><input type="radio"/> About half the time</p> <p><input type="radio"/> Most of the time</p> <p><input type="radio"/> Every time</p>
<p>• This question suppressed if question A8 has a value of "No"</p>	

A12	<p>In the past 7 days...</p> <p>How often did getting up from a chair cause you to leak urine or wet a pad?</p> <p><input type="radio"/> --</p> <p><input type="radio"/> Never</p>
-----	--

- A few times
- About half the time
- Most of the time
- Every time

• This question suppressed if question A8 has a value of "No"

A13

In the past 7 days...

How often did walking at your usual speed cause you to leak urine or wet a pad?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

• This question suppressed if question A8 has a value of "No"

A14

In the past 7 days...

How often did you leak urine or wet a pad after feeling a sudden need to urinate?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

• This question suppressed if question A8 has a value of "No"

A15

In the past 7 days...

How often did you leak urine or wet a pad without any reason you could identify?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

• This question suppressed if question A8 has a value of "No"

-
- A16
- In the past 7 days...
- How often did you leak urine or wet a pad without feeling it?
- - Never
 - A few times
 - About half the time
 - Most of the time
 - Every time

• This question suppressed if question A8 has a value of "No"

-
- A17
- In the past 7 days...
- How often was your urine flow slow or weak?
- - Never
 - A few times
 - About half the time
 - Most of the time
 - Every time

-
- A18
- In the past 7 days...
- How often did you feel that your bladder was not completely empty after urination?
- - Never
 - A few times
 - About half the time
 - Most of the time
 - Every time

-
- A19
- In the past 7 days...
- How often did you dribble urine just after zipping your pants or pulling up your underwear?
- - Never
 - A few times
 - About half the time
 - Most of the time
 - Every time

-
- A20
- Questionnaire Complete
- - Yes
-

15. Appendix G: Bladder Diary



Symptoms of Lower Urinary Tract Dysfunction Research Network (LURN) BLADDER DIARY

Diary reviewed by: _____

Table 1: Example of completed bladder diary

Please complete this bladder diary in **3 consecutive days**. In the time column, please write the time (including AM and PM) in the time column for each entry, including the words **BED** when you went to bed and **WOKE** when you woke up (you only need to record "BED" and "WOKE" once each day).

Bladder sensation: Enter the number that corresponds with how your bladder felt when you went to the toilet using these codes:

0 - If you had no sensation of needing to pass urine, but passed urine for "social reasons", for example, just before going out, or unsure where the next toilet is.

1 - If you had a normal desire to pass urine and no urgency.

"Urgency" is feeling a sudden need to urinate.

2 - If you had urgency, but it had passed before you went to the toilet, and you did not leak urine.

3 - If you had urgency but managed to get to the toilet, still with urgency, but did not leak urine.

4 - If you had urgency and could not get to the toilet in time so you leaked urine.

Time	Bladder sensation	Leak (stress, urge, or unknown/other)	Pads
7:30am WOKE	2		✓
9:00am	0		
9:45am	3		
12:15 pm		Leak, stress	
3:30pm	0		✓
5:10pm	4	Leak, urge	
7:00pm	1		
9:00pm BED	0		✓
10:30pm	2		
4:45am	2		

Leak: Any unintended loss of urine. Please indicate whether you leaked because of urgency, stress, or an unknown/other reason. "Urgency" is feeling a sudden need to urinate for fear of leaking urine. "Stress" indicates that you leaked after physical activity or movement. If you are unsure if you leaked due to stress or urgency, please write "unknown/other".

Pads: If you change a pad, put a check in the pads column.

16. Appendix H: Final Assessment and 30-day Recall

A. PANAS Questions

This scale consists of a number of words that describe different feelings and emotions. **Indicate to what extent you feel this way right now, that is, at the present moment.**

- A1
- Interested
- - Very slightly or not at all
 - A little
 - Moderately
 - Quite a bit
 - Extremely

- A2
- Distressed
- - Very slightly or not at all
 - A little
 - Moderately
 - Quite a bit
 - Extremely

- A3
- Excited
- - Very slightly or not at all
 - A little
 - Moderately
 - Quite a bit
 - Extremely

- A4
- Upset
- - Very slightly or not at all
 - A little
 - Moderately
 - Quite a bit
 - Extremely

- A5
- Strong
- - Very slightly or not at all
 - A little
 - Moderately
 - Quite a bit

	<input type="radio"/> Extremely
A6	Guilty <input type="radio"/> -- <input type="radio"/> Very slightly or not at all <input type="radio"/> A little <input type="radio"/> Moderately <input type="radio"/> Quite a bit <input type="radio"/> Extremely
A7	Scared <input type="radio"/> -- <input type="radio"/> Very slightly or not at all <input type="radio"/> A little <input type="radio"/> Moderately <input type="radio"/> Quite a bit <input type="radio"/> Extremely
A8	Hostile <input type="radio"/> -- <input type="radio"/> Very slightly or not at all <input type="radio"/> A little <input type="radio"/> Moderately <input type="radio"/> Quite a bit <input type="radio"/> Extremely
A9	Enthusiastic <input type="radio"/> -- <input type="radio"/> Very slightly or not at all <input type="radio"/> A little <input type="radio"/> Moderately <input type="radio"/> Quite a bit <input type="radio"/> Extremely
A10	Proud <input type="radio"/> -- <input type="radio"/> Very slightly or not at all <input type="radio"/> A little <input type="radio"/> Moderately <input type="radio"/> Quite a bit <input type="radio"/> Extremely
A11	Irritable <input type="radio"/> --

- Very slightly or not at all
- A little
- Moderately
- Quite a bit
- Extremely

A12

Alert

-
- Very slightly or not at all
- A little
- Moderately
- Quite a bit
- Extremely

A13

Ashamed

-
- Very slightly or not at all
- A little
- Moderately
- Quite a bit
- Extremely

A14

Inspired

-
- Very slightly or not at all
- A little
- Moderately
- Quite a bit
- Extremely

A15

Nervous

-
- Very slightly or not at all
- A little
- Moderately
- Quite a bit
- Extremely

A16

Determined

-
- Very slightly or not at all
- A little
- Moderately
- Quite a bit

Extremely

- A17
- Attentive
- - Very slightly or not at all
 - A little
 - Moderately
 - Quite a bit
 - Extremely
-

- A18
- Jittery
- - Very slightly or not at all
 - A little
 - Moderately
 - Quite a bit
 - Extremely
-

- A19
- Active
- - Very slightly or not at all
 - A little
 - Moderately
 - Quite a bit
 - Extremely
-

- A20
- Afraid
- - Very slightly or not at all
 - A little
 - Moderately
 - Quite a bit
 - Extremely
-

B. 30-Day Recall

- B1
- In the past 30 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

How much did this bother you?

-
- Not at all
- A little bit
- Somewhat
- Quite a bit
- A great deal

In the past 30 days...

During a typical day, how much time typically passed between urinations?

B2

-
- More than 6 hours
- 5-6 hours
- 3-4 hours
- 1-2 hours
- Less than 1 hour

How much did this bother you?

-
- Not at all
- A little bit
- Somewhat
- Quite a bit
- A great deal

In the past 30 days...

During a typical night, how many times did you wake up and urinate?

B3

-
- None
- 1 time
- 2-3 times
- More than 3 times

How much did this bother you?

-
- Not at all
- A little bit
- Somewhat
- Quite a bit
- A great deal

- Field QUrinateNightBother of this question will be suppressed when field QUrinateNight of question B3 has value "None"
 - Field QUrinateNightBother of question B3 will be suppressed if field QUrinateNight of this question has a value of "None"

B4

In the past 30 days...

How often did you wake up at least once during the night because you had to urinate?

--
 Never
 A few nights
 About half the nights
 Most nights
 Every night

How much did this bother you?

--
 Not at all
 A little bit
 Somewhat
 Quite a bit
 A great deal

- Field QNightOnceBother of this question will be suppressed when field QNightOnce of question B4 has value "Never"
- Question B5 will be suppressed if field QNightOnce of this question has a value of "Never"
- Field QNightOnceBother of question B4 will be suppressed if field QNightOnce of this question has a value of "Never"

B5

In the past 30 days...

When you woke up and urinated, how often did you leak urine on your way to the bathroom?

--
 Never
 A few times
 About half the time
 Most of the time
 Every time

How much did this bother you?

--
 Not at all
 A little bit
 Somewhat
 Quite a bit
 A great deal

- This question suppressed if field QNightOnce of question B4 has a value of "Never"
- Field QLeakWayBother of this question will be suppressed when field QLeakWay of question B5 has value "Never"
- Field QLeakWayBother of question B5 will be suppressed if field QLeakWay of this question has a value of "Never"

B6

In the past 30 days...

How often did you feel a sudden need to urinate?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

How much did this bother you?

-
- Not at all
- A little bit
- Somewhat
- Quite a bit
- A great deal

- Field SSuddenOftenBother of this question will be suppressed when field SSuddenOften of question B6 has value "Never"
- Field SSuddenOftenBother of question B6 will be suppressed if field SSuddenOften of this question has a value of "Never"

In the past 30 days...

Once you noticed the need to urinate, how difficult was it to wait more than a few minutes?

-
- Not difficult
- A little difficult
- Somewhat difficult
- Very difficult
- Unable to wait

How much did this bother you?

-
- Not at all
- A little bit
- Somewhat
- Quite a bit
- A great deal

B7

- Field SHardWaitBother of this question will be suppressed when field SHardWait of question B7 has value "Not difficult"
- Field SHardWaitBother of question B7 will be suppressed if field SHardWait of this question has a value of "Not difficult"

In the past 30 days...

Have you leaked urine or wet a pad?

-
- No
- Yes

B8

- Question B9 will be suppressed if this question has a value of "No"
- Question B10 will be suppressed if this question has a value of "No"
- Question B11 will be suppressed if this question has a value of "No"
- Question B12 will be suppressed if this question has a value of "No"
- Question B13 will be suppressed if this question has a value of "No"
- Question B14 will be suppressed if this question has a value of "No"
- Question B15 will be suppressed if this question has a value of "No"
- Question B16 will be suppressed if this question has a value of "No"

In the past 30 days...

How often did you completely lose control of your bladder?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

B9

How much did this bother you?

-
- Not at all
- A little bit
- Somewhat
- Quite a bit
- A great deal

- This question suppressed if question B8 has a value of "No"
- Field S LoseControlBother of this question will be suppressed when field S LoseControl of question B9 has value "Never"
- Field S LoseControlBother of question B9 will be suppressed if field S LoseControl of this question has a value of "Never"

In the past 30 days...

How often did you leak urine or wet a pad while laughing, sneezing, or coughing?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

B10

How much did this bother you?

-
- Not at all
- A little bit
- Somewhat
- Quite a bit
- A great deal

- This question suppressed if question B8 has a value of "No"
- Field SLeakLaughBother of this question will be suppressed when field SLeakLaugh of question B10 has value "Never"
- Field SLeakLaughBother of question B10 will be suppressed if field SLeakLaugh of this question has a value of "Never"

In the past 30 days...

How often did you leak urine or wet a pad when doing physical activities, such as exercising or lifting a heavy object?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

B11

How much did this bother you?

-
- Not at all
- A little bit
- Somewhat
- Quite a bit
- A great deal

- This question suppressed if question B8 has a value of "No"
- Field SLeakExerciseBother of this question will be suppressed when field SLeakExercise of question B11 has value "Never"
- Field SLeakExerciseBother of question B11 will be suppressed if field SLeakExercise of this question has a value of "Never"

In the past 30 days...

How often did getting up from a chair cause you to leak urine or wet a pad?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

B12

How much did this bother you?

-
- Not at all
- A little bit
- Somewhat
- Quite a bit
- A great deal

- This question suppressed if question B8 has a value of "No"

- Field SLeakUpChairBother of this question will be suppressed when field SLeakUpChair of question B12 has value "Never"
- Field SLeakUpChairBother of question B12 will be suppressed if field SLeakUpChair of this question has a value of "Never"

In the past 30 days...

How often did walking at your usual speed cause you to leak urine or wet a pad?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

B13

How much did this bother you?

-
- Not at all
- A little bit
- Somewhat
- Quite a bit
- A great deal

- This question suppressed if question B8 has a value of "No"
- Field SLeakWalkBother of this question will be suppressed when field SLeakWalk of question B13 has value "Never"
- Field SLeakWalkBother of question B13 will be suppressed if field SLeakWalk of this question has a value of "Never"

In the past 30 days...

How often did you leak urine or wet a pad after feeling a sudden need to urinate?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

B14

How much did this bother you?

-
- Not at all
- A little bit
- Somewhat
- Quite a bit
- A great deal

- This question suppressed if question B8 has a value of "No"
- Field SLeakAfterSuddenBother of this question will be suppressed when field SLeakAfterSudden of question B14 has value "Never"

- Field SLeakAfterSuddenBother of question B14 will be suppressed if field SLeakAfterSudden of this question has a value of "Never"

In the past 30 days...

How often did you leak urine or wet a pad without any reason you could identify?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

B15

How much did this bother you?

-
- Not at all
- A little bit
- Somewhat
- Quite a bit
- A great deal

- This question suppressed if question B8 has a value of "No"
- Field SLeakNoReasonBother of this question will be suppressed when field SLeakNoReason of question B15 has value "Never"
- Field SLeakNoReasonBother of question B15 will be suppressed if field SLeakNoReason of this question has a value of "Never"

In the past 30 days...

How often did you leak urine or wet a pad without feeling it?

-
- Never
- A few times
- About half the time
- Most of the time
- Every time

B16

How much did this bother you?

-
- Not at all
- A little bit
- Somewhat
- Quite a bit
- A great deal

- This question suppressed if question B8 has a value of "No"
- Field SLeakNoFeelBother of this question will be suppressed when field SLeakNoFeel of question B16 has value "Never"
- Field SLeakNoFeelBother of question B16 will be suppressed if field SLeakNoFeel of this question has a value of "Never"

B17	<p>In the past 30 days...</p> <p>How often was your urine flow slow or weak?</p> <p><input type="radio"/> --</p> <p><input type="radio"/> Never</p> <p><input type="radio"/> A few times</p> <p><input type="radio"/> About half the time</p> <p><input type="radio"/> Most of the time</p> <p><input type="radio"/> Every time</p>	<p>How much did this bother you?</p> <p><input type="radio"/> --</p> <p><input type="radio"/> Not at all</p> <p><input type="radio"/> A little bit</p> <p><input type="radio"/> Somewhat</p> <p><input type="radio"/> Quite a bit</p> <p><input type="radio"/> A great deal</p>
-----	---	---

- Field SFlowSlowBother of this question will be suppressed when field SFlowSlow of question B17 has value "Never"
- Field SFlowSlowBother of question B17 will be suppressed if field SFlowSlow of this question has a value of "Never"

B18	<p>In the past 30 days...</p> <p>How often did you feel that your bladder was not completely empty after urination?</p> <p><input type="radio"/> --</p> <p><input type="radio"/> Never</p> <p><input type="radio"/> A few times</p> <p><input type="radio"/> About half the time</p> <p><input type="radio"/> Most of the time</p> <p><input type="radio"/> Every time</p>	<p>How much did this bother you?</p> <p><input type="radio"/> --</p> <p><input type="radio"/> Not at all</p> <p><input type="radio"/> A little bit</p> <p><input type="radio"/> Somewhat</p> <p><input type="radio"/> Quite a bit</p> <p><input type="radio"/> A great deal</p>
-----	--	---

- Field SNotEmptyAfterBother of this question will be suppressed when field SNotEmptyAfter of question B18 has value "Never"
- Field SNotEmptyAfterBother of question B18 will be suppressed if field SNotEmptyAfter of this question has a value of "Never"

B19	<p>In the past 30 days...</p> <p>How often did you dribble urine just after zipping your pants or pulling up your underwear?</p> <p><input type="radio"/> --</p>
-----	--

- Never
 A few times
 About half the time
 Most of the time
 Every time
- How much did this bother you?
- Not at all
 A little bit
 Somewhat
 Quite a bit
 A great deal

- Field SDribbleZipPantsBother of this question will be suppressed when field SDribbleZipPants of question B19 has value "Never"
- Field SDribbleZipPantsBother of question B19 will be suppressed if field SDribbleZipPants of this question has a value of "Never"

- B20
- How well do you think you've remembered your symptoms over the last 30 days?
- Not at all
 A little bit
 Somewhat
 Quite a bit
 Very much

C. Self-Reported Health

- C1a
- Since beginning the study, do you think your bladder symptoms changed at all?
- No
 Yes
 Not Sure

- Question C1b will be suppressed if this question has a value of "No"

- C1b
- If yes, explain:

- This question suppressed if question C1a has a value of "No"

- C2a
- Since beginning the study, have you received any surgical treatments for your urinary tract symptoms?

("Surgical treatments" include any inpatient or outpatient operations or surgical procedures, including Botox treatments.)

-
- No
- Yes
- Not Sure

• Question C2b will be suppressed if this question has a value of "No"

C2b

Do you think that it had an impact on your urinary tract symptoms?

-
- No
- Yes
- Not Sure

• This question suppressed if question C2a has a value of "No"

C3a

Since beginning the study, have you stopped, started, or changed any medicinal treatments for your urinary tract symptoms?

("Medicinal treatments" refers to prescription or over the counter drugs. "Changed" refers to changes in frequency, duration, dosage, etc.)

Select all that apply:

- No
- Yes, started something new
- Yes, stopped an existing
- Yes, changed an existing
- Not Sure

• Question C3b will be suppressed if this question has a value of "No"

C3b

Do you think that it had an impact on your urinary tract symptoms?

-
- No
- Yes
- Not Sure

• This question suppressed if question C3a has a value of "No"

C4a | Since beginning the study, have you started, stopped, or changed any non-traditional or non-medical treatments for your urinary tract symptoms? ("changed" refers to changes in frequency, duration, dosage, etc.)

Non-traditional/non-medical treatments could include: nutraceutical or herbal remedies; exercise regimens other than prescribed physical therapy; talk therapy or behavioral modification; intermittent catheterization; etc.

Select all that apply:

- No
- Yes, started something new
- Yes, stopped an existing
- Yes, changed an existing
- Not Sure

• Question C4b will be suppressed if this question has a value of "No"

C4b | Do you think that it had an impact on your urinary tract symptoms?

-
- No
- Yes
- Not Sure

• This question suppressed if question C4a has a value of "No"

C5a | Since beginning the study, did you make any changes to the amount of fluids you drank?

-
- No changes
- You drank less
- You drank more
- Not Sure

• Question C5b will be suppressed if this question has a value of "No changes"

C5b | Do you think that it had an impact on your urinary tract symptoms?

-
- No
- Yes
- Not Sure

- This question suppressed if question C5a has a value of "No changes"

C6a

Since beginning the study, did you change the kinds of beverages you drink?

-
- No
- Yes
- Not Sure

- Question C6b will be suppressed if this question has a value of "No"

C6b

Do you think that it had an impact on your urinary tract symptoms?

-
- No
- Yes
- Not Sure

- This question suppressed if question C6a has a value of "No"

C7a

Since beginning the study, have you been given any new medical diagnoses?

-
- No
- Yes
- Not Sure

- Question C7b will be suppressed if this question has a value of "No"

C7b

If yes or not sure, explain:

- This question suppressed if question C7a has a value of "No"

C8

Since beginning the study, did you change how often you go to the bathroom to urinate?

-
- You urinated more often.
- You urinated less often.
- Your frequency of urination did not change.
- Not sure.

C9 | Please provide any comments that you would like to share with the research team about participating in the study.

C10 | Do you have difficulty walking?

-
- You have no problems in walking about
- You have some problems in walking about
- You are confined to bed

C11 | Do you have difficulty with self-care?

-
- You have no problems with self-care
- You have some problems with washing or dressing yourself
- You are unable to wash or dress yourself

C12 | In general, would you say your health is:

-
- Excellent
- Very good
- Good
- Fair
- Poor

C13 | In general, would you say your quality of life is:

-
- Excellent
- Very good
- Good
- Fair
- Poor

D. Self-Reported Mood

IN THE PAST 7 DAYS...

D1 | I felt worthless.

-
- Never
- Rarely
- Sometimes
- Often
- Always

- D2
- I felt helpless.
- - Never
 - Rarely
 - Sometimes
 - Often
 - Always
-

- D3
- I felt depressed.
- - Never
 - Rarely
 - Sometimes
 - Often
 - Always
-

- D4
- I felt hopeless.
- - Never
 - Rarely
 - Sometimes
 - Often
 - Always
-

- D5
- I felt fearful.
- - Never
 - Rarely
 - Sometimes
 - Often
 - Always
-

- D6
- I found it hard to focus on anything other than my anxiety.
- - Never
 - Rarely
 - Sometimes
 - Often
 - Always
-

- D7
- My worries overwhelmed me.
- - Never
 - Rarely

- Sometimes
 - Often
 - Always
-

- D8
- I felt uneasy.
- - Never
 - Rarely
 - Sometimes
 - Often
 - Always
-

- D9
- Questionnaire Complete
- - Yes
-