



ICHOM

International Consortium for
Health Outcomes Measurement

OVERACTIVE BLADDER DATA COLLECTION REFERENCE GUIDE

Version 1.2.2

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Measuring
results
that matter

Limitation of
desired activities

Overactive Bladder



We are thrilled that you are interested in measuring outcomes for your patients with overactive bladder according to ICHOM standards. It is our hope that this Reference Guide will facilitate the process of implementing our Standard Set and ensure collection of comparable data for global benchmarking and learning.

Introducing ICHOM and the Reference Guide

ICHOM brings together patient representatives, clinician leaders, and registry leaders from all over the world to develop Standard Sets, comprehensive yet parsimonious sets of outcomes and case-mix variables we recommend all providers track.

Each Standard Set focuses on patient-centered results, and provides an internationally-agreed upon method for measuring each of these outcomes. We do this because we believe that standardized outcomes measurement will open up new possibilities to compare performance globally, allow clinicians to learn from each other, and rapidly improve the care we provide our patients.

Our Standard Sets include initial conditions and risk factors to enable meaningful case-mix adjustment globally, ensuring that comparisons of outcomes will take into account the differences in patient populations across not just providers, but also countries and regions. We also include high-level treatment variables to allow stratification of outcomes by major treatment types. A comprehensive data dictionary is included in the appendix.

Working Group Members for Overactive Bladder

The following individuals dedicated both time and expertise to develop the ICHOM Standard Set for Overactive Bladder in partnership with ICHOM, under the leadership of Drs. Adrian Wagg and Ian Milsom.

Australia Kate Moore George Szonyi	New Zealand Peter Herbison	United States Anita Anderson Jennifer Anger Caroline Foust-Wright Ann Gormley Jessica McKinney Abraham Morse Samantha Pulliam
Canada Adrian Wagg	Sweden Ian Milsom	
Netherlands John Heesakkers	United Kingdom Linda Cardozo Nikki Cotterill Philip Tooze-Hobson	

Supporting Organizations

The Overactive Bladder Standard Set is made possible only through the support of IUGA.

Thank you.



We would also like to acknowledge the following organizations for their support in sourcing consumer feedback:



Treatment Approaches Covered for Overactive Bladder

For Overactive Bladder, the following treatment approaches (or interventions) are covered by our Standard Set.

Treatment Approaches	Patient education Behavioral modification Pharmacological management Intradetrusor Botox, PTNS, SNS Surgery
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ICHOM Standard Set for Overactive Bladder

Case-Mix Variables

Patient Population	Measure	Supporting Information	Timing	Suggested Data Sources
Demographic Factors				
All patients	Year of birth	N/A	Baseline	Patient-reported
	Male or female			
Baseline Clinical Factors				
All patients	Patient height	To calculate BMI	Baseline	Patient-reported
	Patient weight			
	History of surgery to the pelvis	For example, surgery for stress urinary incontinence, pelvic organ prolapse, bowel or rectal surgery, or hysterectomy		
	Diagnosis of diabetes, irritable bowel syndrome, inflammatory bowel disease, cognitive impairment			
	Co-existing pelvic organ prolapse	N/A		
Female patients only	Co-existing stress incontinence			
	Current use of estrogens or hormone replacement therapy			
Male patients only	Diagnosis of BPH or prostatitis			
Patients reporting a history of pelvic surgery	Time since pelvic surgery	N/A		

Treatment Variables

Patient Population	Measure	Supporting Information	Timing	Suggested Data Sources
All patients	Current OAB treatments	Including behavioral modifications, pelvic floor physical therapy, oral or topical medication, Intradetrusor onabotulinumtoxinA, electrical stimulation, PTNS, SNS, and surgery	Baseline and follow-up	Patient-reported

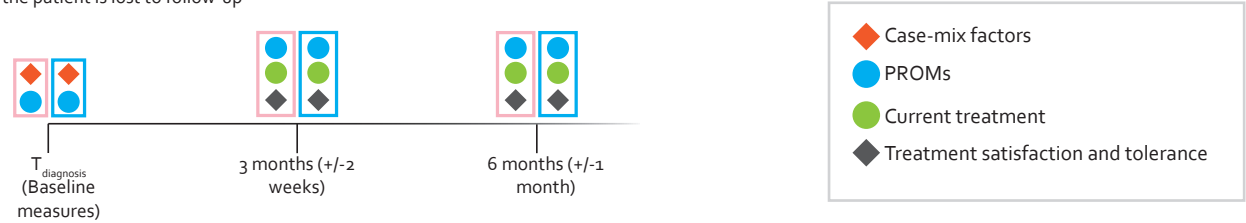
Outcomes

Patient Population	Measure	Supporting Information	Timing	Suggested Data Sources
OAB Symptom Severity and Burden				
All patients	Frequency and perceived burden of OAB symptoms	Tracked via the ICIQ-OAB	Baseline and follow-up	Patient-reported
Health-Related Quality of Life				
All patients	The effect of OAB on HRQoL domains	Assessed via the OAB-q SF (4-week recall)	Baseline and follow-up	Patient-reported
Sexual Function				
All patients	Interference with sexual functioning	Assessed via the ICIQ-FLUTSsex (women) or ICIQ-MLUTSsex (men)	Baseline and follow-up	Patient-reported
Side Effects and Burden of Treatment				
All patients	Treatment benefit and tolerance	Assessed via the TBS and a single question on treatment tolerability	Follow-up	Patient-reported
Treatment Satisfaction				
All patients	Patients satisfaction with treatment	Single item question	Follow-up	Patient-reported

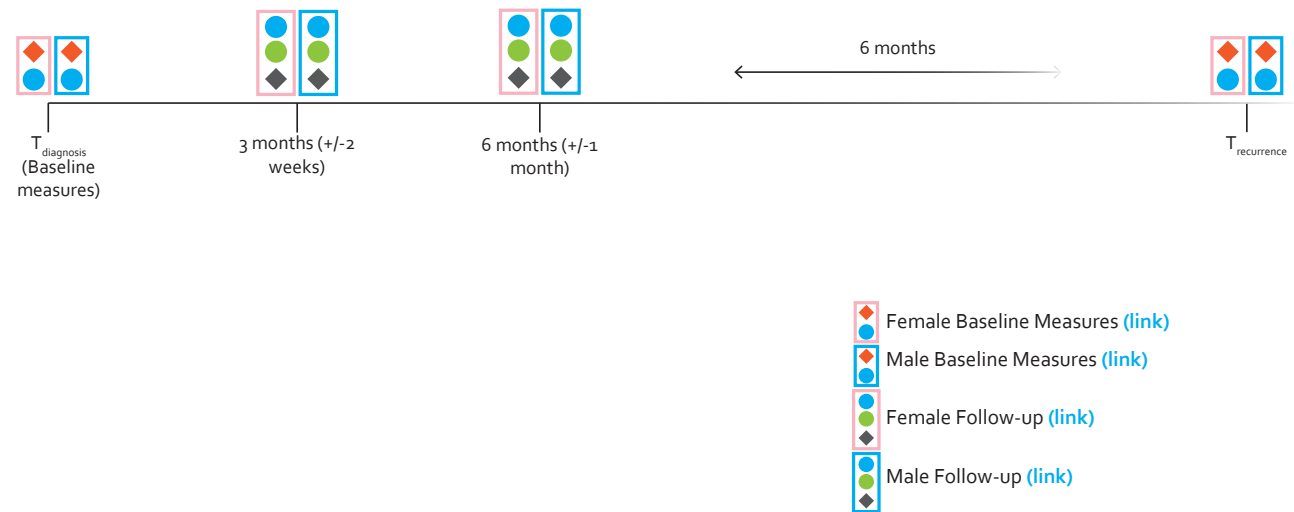
Follow-Up Timeline and Sample Questionnaires

The following timeline illustrates when Standard Set variables should be collected from patients, clinicians, and administrative sources. Links to the sample questionnaires may be found in the legend below.

EXAMPLE 1: Follow-up continues every three months until either the treatment is successful and the patient is discharged from care or the patient is lost to follow-up



EXAMPLE 2: Subsequent presentation for treatment after 6 months would be recorded as a new episode of care for the same patient



Collecting Patient-Reported Outcome Measures

Survey(s) Used	Licensing Information	Scoring Guide
ICIQ-OAB	Free for use in clinical practice, routine outcomes measurement, and clinical research but permission from the developer is required. Please visit the following webpage to obtain permission and an official copy and scoring guide or to inquire about translations: http://www.iciq.net/userpolicy.html	Please visit the following webpage to obtain an official copy and scoring guide: http://www.iciq.net/userpolicy.html
OAB-q SF (4-week recall)	Copyrighted to Pfizer. Licensing information to be determined.	Coyne KS et al (2015) An Overactive Bladder Symptom and Health-Related Quality of Life Short-Form: Validation of the OAB-q SF. <i>Neurourology and Urodynamics</i> 34: 255-263.
ICIQ-MLUTSsex and ICIQ-FLUTSsex	Free for use in clinical practice, routine outcomes measurement, and clinical research but permission from the developer is required. Please visit the following webpage to obtain permission and an official copy and scoring guide or to inquire about translations: http://www.iciq.net/userpolicy.html	Please visit the following webpage to obtain an official copy and scoring guide: http://www.iciq.net/userpolicy.html
TBS	Free for use without a license.	Please see Colman S et al (2008) Validation of the treatment benefit scale for assessing subjective outcomes in Treatment of Overactive Bladder. <i>Urology</i> 72: 803-807.

The Growing ICHOM Community

By implementing the ICHOM Standard Sets, you become part of an expanding, international community of innovative health care providers dedicated to improving value for patients. To learn more about how ICHOM can assist your organization in implementing outcome measurement, contact us at implement@ichom.org, or visit <http://www.ichom.org/measure>.

Introduction to the Data Dictionary

This data dictionary is designed to help you measure the ICHOM Overactive Bladder Standard Set as consistently as possible to the Working Group recommendation. ICHOM is actively preparing for benchmarking efforts based on this data, and all data submitted for comparisons will need to be transformed into the following data structure if not already structured as such. **We are happy to provide an Excel version of this data dictionary for technical use.**

Please timestamp all variables. Some Standard Set variables are collected at multiple timepoints, and we will ask you to submit these variables in a concatenated VARIABLEID_TIMESTAMP form for future analyses. For example, VARIABLEID_BASE (baseline); VARIABLEID_6MO (6 month follow-up); VARIABLEID_1YR (1 year follow-up), etc.

Case-Mix Variables

CASE-MIX VARIABLES

Variable ID:	N/A
Variable:	Patient ID
Definition:	Indicate the patient's medical record number
Supporting Definition:	This number will not be shared with ICHOM. In the case patient-level data is submitted to ICHOM for benchmarking or research purposes, a separate ICHOM Patient Identifier will be created and cross-linking between the ICHOM Patient Identifier and the medical record number will only be known at the treating institution
Inclusion Criteria:	All patients
Timing:	On all forms
Reporting Source:	Administrative or clinical
Type:	Numerical
Response Options:	According to institution

Demographic Factors

Variable ID:	AGE
Variable:	Year of birth
Definition:	In what year were you born?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Numerical
Response Options:	YYYY

Variable ID:	SEX
Variable:	Patient sex
Definition:	Please indicate your sex:
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Male 1 = Female

Baseline Clinical Factors

Variable ID:	HEIGHT
Variable:	Body height
Definition:	How tall are you?
Supporting Definition:	For calculating BMI
Inclusion Criteria:	All patients
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Numerical
Response Options:	Numerical value of height in metric or imperial system
Variable ID:	HEIGHTUNIT
Variable:	Body height units
Definition:	Height units
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	1 = centimeters 2 = inches
Variable ID:	WEIGHT
Variable:	Body weight
Definition:	How much do you weigh?
Supporting Definition:	For calculating BMI
Inclusion Criteria:	All patients
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	Numerical value of weight in metric or imperial system
Variable ID:	WEIGHTUNIT
Variable:	Body weight units
Definition:	Weight units
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	1 = kilograms 2 = pounds
Variable ID:	COMORB
Variable:	Cormobidities
Definition:	Have you been told by your doctor or care provider that you have any of the following? Tick all that apply.
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Multiple answers
Response Options:	0 = None 1 = Diabetes 2 = Irritable bowel syndrome 3 = Inflammatory bowel disease (Crohn's, Ulcerative Colitis) 4 = A problem with your memory
Variable ID:	POP
Variable:	Pelvic organ prolapse
Definition:	Do you have a feeling of a lump or "something coming down" or the need to manually replace a prolapse in order to empty your bladder?

Supporting Definition:	N/A
Inclusion Criteria:	Female patients
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = No 1 = Yes
Variable ID:	OTHERINCONT
Variable:	Other incontinence
Definition:	Do you leak urine with physical activity, coughing, laughing, or sneezing or have you been told by a doctor that you have stress incontinence?
Supporting Definition:	N/A
Inclusion Criteria:	Female patients
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Multiple answers
Response Options:	0 = No 1 = Yes
Variable ID:	PROSTATE
Variable:	Enlarged prostate
Definition:	Have you been told by a doctor that you have a problem with your prostate? Tick all that apply.
Supporting Definition:	N/A
Inclusion Criteria:	Male patients
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = No 1 = Enlarged prostate or benign prostatic hyperplasia (BPH) 2 = Prostatitis
Variable ID:	HRT
Variable:	Hormone Replacement Therapy
Definition:	Are you currently taking estrogens or hormone replacement therapy by mouth, a patch or cream on the skin, or as a suppository?
Supporting Definition:	N/A
Inclusion Criteria:	Female patients
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = No 1 = Yes, by mouth 2 = Yes, by a patch, cream on the skin, or suppository
Variable ID:	HXPELVICSURGF
Variable:	History of pelvic surgery
Definition:	Have you had surgery to your pelvis? Please indicate what kind.
Supporting Definition:	N/A
Inclusion Criteria:	Female patients
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = No 1 = Yes, surgery for stress urinary incontinence 2 = Yes, prolapse surgery 3 = Yes, surgery to the rectum or bowel 4 = Yes, hysterectomy 5 = Yes, other surgery

Variable ID:	HXPELVICSURGM
Variable:	History of pelvic surgery
Definition:	Have you had surgery to your pelvis? Please indicate what kind.
Supporting Definition:	N/A
Inclusion Criteria:	Male patients
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = No 1 = Yes, surgery to the rectum or bowel 2 = Yes, prostate surgery

Variable ID:	TIMEPELVICSURG
Variable:	Timing of previous pelvic surgery
Definition:	When did you have this surgery?
Supporting Definition:	N/A
Inclusion Criteria:	To all patients with score >0 on HXPELVICSURG
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	1 = Less than 6 months ago 2 = More than 6 months ago but less than 1 year ago 3 = In the last 5 years 4 = In the last 10 years 5 = More than 10 years ago

Treatment Variables

Explanatory Variable

Variable ID: TX

Variable: Current treatment

Definition: What are you currently using to treat your OAB symptoms? Tick all that apply.

Supporting Definition: N/A

Inclusion Criteria: All patients

Timing: Baseline and follow-up

Reporting Source: Patient-reported

Type: Multiple answers

Response Options: 0 = Nothing

1 = Behavioral modifications such as changing your fluid intake, bladder training, or Kegel exercises

2 = Pelvic floor physical therapy

3 = Medication taken by mouth or from a patch or jelly on the skin

4 = Botox injections to the bladder

5 = Electrical stimulation

6 = Percutaneous tibial nerve stimulation (PTNS)

7 = Sacral nerve stimulation (SNS)

8 = Surgery

Outcomes

OAB Symptom Severity and Burden

Variable ID:	ICIQ-OAB ₁
Variable:	Question 1 of the ICIQ-OAB
Definition:	How often do you pass urine during the day?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	1 = 1 to 6 times 2 = 7 to 8 times 3 = 9 to 10 times 4 = 11 to 12 times 5 = 13 or more times
Variable ID:	ICIQ-OAB ₂
Variable:	Question 2 of the ICIQ-OAB
Definition:	How much does this bother you?
Supporting Definition:	Please select a number between 0 (not at all) and 10 (a great deal).
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = 1 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = A great deal
Variable ID:	ICIQ-OAB ₃
Variable:	Question 3 of the ICIQ-OAB
Definition:	During the night, how many times do you have to get up to urinate, on average?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = None 1 = One 2 = Two 3 = Three 4 = Four or more
Variable ID:	ICIQ-OAB ₄
Variable:	Question 4 of the ICIQ-OAB
Definition:	How much does this bother you?
Supporting Definition:	Please select a number between 0 (not at all) and 10 (a great deal).
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Patient-reported

Type:	Single answer
Response Options:	0 = Not at all 1 = 1 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = A great deal
Variable ID:	ICIQ-OAB ₅
Variable:	Question 5 of the ICIQ-OAB
Definition:	Do you have to rush to the toilet to urinate?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Never 1 = Occasionally 2 = Sometimes 3 = Most of the time 4 = All of the time
Variable ID:	ICIQ-OAB ₆
Variable:	Question 6 of the ICIQ-OAB
Definition:	How much does this bother you?
Supporting Definition:	Please select a number between 0 (not at all) and 10 (a great deal).
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = 1 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = A great deal
Variable ID:	ICIQ-OAB ₇
Variable:	Question 7 of the ICIQ-OAB
Definition:	Does urine leak before you can get to the toilet?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = never 1 = occasionally 2 = sometimes 3 = most of the time 4 = all of the time

Health-Related Quality of Life

Variable ID: ICIQ-OAB8

Variable: Question 8 of the ICIQ-OAB

Definition: How much does this bother you?

Supporting Definition: Please select a number between 0 (not at all) and 10 (a great deal).

Inclusion Criteria: All patients

Timing: Baseline and follow-up

Reporting Source: Patient-reported

Type: Single answer

Response Options: 0 = Not at all

1 = 1

2 = 2

3 = 3

4 = 4

5 = 5

6 = 6

7 = 7

8 = 8

9 = 9

10 = A great deal

Variable ID: OAB-q SF1

Variable: Question 1 of the OAB-q SF

Definition: During the past four weeks, how often have your bladder symptoms caused you to plan "escape routes" to restrooms in public places?

Supporting Definition: N/A

Inclusion Criteria: All patients

Timing: Baseline and follow-up

Reporting Source: Patient-reported

Type: Single answer

Response Options: 0 = None of the time

1 = A little of the time

2 = Some of the time

3 = A good bit of the time

4 = Most of the time

5 = All of the time

Variable ID: OAB-q SF2

Variable: Question 2 of the OAB-q SF

Definition: During the past four weeks, how often have your bladder symptoms made you feel like there is something wrong with you?

Supporting Definition: N/A

Inclusion Criteria: All patients

Timing: Baseline and follow-up

Reporting Source: Patient-reported

Type: Single answer

Response Options: 0 = None of the time

1 = A little of the time

2 = Some of the time

3 = A good bit of the time

4 = Most of the time

5 = All of the time

Variable ID: OAB-q SF3

Variable: Question 3 of the OAB-q SF

Definition: During the past four weeks, how often have your bladder symptoms interfered

	with your ability to get a good night's rest?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = None of the time 1 = A little of the time 2 = Some of the time 3 = A good bit of the time 4 = Most of the time 5 = All of the time
Variable ID:	OAB-q SF4
Variable:	Question 4 of the OAB-q SF
Definition:	During the past four weeks, how often have your bladder symptoms made you frustrated or annoyed about the amount of time you spend in the restroom?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = None of the time 1 = A little of the time 2 = Some of the time 3 = A good bit of the time 4 = Most of the time 5 = All of the time
Variable ID:	OAB-q SF5
Variable:	Question 5 of the OAB-q SF
Definition:	During the past four weeks, how often have your bladder symptoms made you avoid activities away from restrooms (i.e., walks, running, hiking)?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = None of the time 1 = A little of the time 2 = Some of the time 3 = A good bit of the time 4 = Most of the time 5 = All of the time
Variable ID:	OAB-q SF6
Variable:	Question 6 of the OAB-q SF
Definition:	During the past four weeks, how often have your bladder symptoms awakened you during sleep?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Patient-reported
Type:	Single answer

Response Options:	0 = None of the time 1 = A little of the time 2 = Some of the time 3 = A good bit of the time 4 = Most of the time 5 = All of the time
Variable ID:	OAB-q SF7
Variable:	Question 7 of the OAB-q SF
Definition:	During the past four weeks, how often have your bladder symptoms caused you to decrease your physical activities (exercising, sports, etc.)
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = None of the time 1 = A little of the time 2 = Some of the time 3 = A good bit of the time 4 = Most of the time 5 = All of the time
Variable ID:	OAB-q SF8
Variable:	Question 8 of the OAB-q SF
Definition:	During the past four weeks, how often have your bladder symptoms caused you to have problems with your partner or spouse?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = None of the time 1 = A little of the time 2 = Some of the time 3 = A good bit of the time 4 = Most of the time 5 = All of the time
Variable ID:	OAB-q SF9
Variable:	Question 9 of the OAB-q SF
Definition:	During the past four weeks, how often have your bladder symptoms made you uncomfortable while traveling with others because of needing to stop for a restroom?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = None of the time 1 = A little of the time 2 = Some of the time 3 = A good bit of the time 4 = Most of the time 5 = All of the time
Variable ID:	OAB-q SF10
Variable:	Question 10 of the OAB-q SF
Definition:	During the past four weeks, how often have your bladder symptoms affected your relationships with family and friends?

Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = None of the time 1 = A little of the time 2 = Some of the time 3 = A good bit of the time 4 = Most of the time 5 = All of the time
Variable ID:	OAB-q SF11
Variable:	Question 11 of the OAB-q SF
Definition:	During the past four weeks, how often have your bladder symptoms interfered with getting the amount of sleep you needed?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = None of the time 1 = A little of the time 2 = Some of the time 3 = A good bit of the time 4 = Most of the time 5 = All of the time
Variable ID:	OAB-q SF12
Variable:	Question 12 of the OAB-q SF
Definition:	During the past four weeks, how often have your bladder symptoms caused you embarrassment?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = None of the time 1 = A little of the time 2 = Some of the time 3 = A good bit of the time 4 = Most of the time 5 = All of the time
Variable ID:	OAB-q SF13
Variable:	Question 13 of the OAB-q SF
Definition:	During the past four weeks, how often have your bladder symptoms caused you to locate the closest restroom as soon as you arrive at a place you have never been?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = None of the time 1 = A little of the time 2 = Some of the time 3 = A good bit of the time 4 = Most of the time 5 = All of the time

Sexual Function

Variable ID:	ICIQ-FLUTSsex1
Variable:	Question 1 of the ICIQ-FLUTSsex
Definition:	Do you have pain or discomfort because of a dry vagina?
Supporting Definition:	N/A
Inclusion Criteria:	Female patients
Timing:	Baseline and follow-up
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	1 = Not at all 2 = A little 3 = Somewhat 4 = A lot
Variable ID:	ICIQ-FLUTSsex2
Variable:	Question 2 of the ICIQ-FLUTSsex
Definition:	How much does this bother you?
Supporting Definition:	Please select a number between 0 (not at all) and 10 (a great deal).
Inclusion Criteria:	Female patients
Timing:	Baseline and follow-up
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = 1 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = A great deal
Variable ID:	ICIQ-FLUTSsex3
Variable:	Question 3 of the ICIQ-FLUTSsex
Definition:	To what extent do you feel that your sex life has been spoilt by your urinary symptoms?
Supporting Definition:	N/A
Inclusion Criteria:	Female patients
Timing:	Baseline and follow-up
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	1 = Not at all 2 = A little 3 = Somewhat 4 = A lot
Variable ID:	ICIQ-FLUTSsex4
Variable:	Question 4 of the ICIQ-FLUTSsex
Definition:	How much of a problem is this for you?
Supporting Definition:	Please select a number between 0 (not a problem) and 10 (a serious problem).
Inclusion Criteria:	Female patients
Timing:	Baseline and follow-up
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = 0 1 = 1 2 = 2 3 = 3

4 = 4
 5 = 5
 6 = 6
 7 = 7
 8 = 8
 9 = 9
 10 = 10
 11 = 11

Variable ID:	ICIQ-FLUTSsex5
Variable:	Question 5 of the ICIQ-FLUTSsex
Definition:	Do you have pain when you have sexual intercourse?
Supporting Definition:	N/A
Inclusion Criteria:	Female patients
Timing:	Baseline and follow-up
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	1 = Not at all 2 = A little 3 = Somewhat 4 = A lot 5 = I don't have sexual intercourse
Variable ID:	ICIQ-FLUTSsex6
Variable:	Question 6 of the ICIQ-FLUTSsex
Definition:	How much does this bother you?
Supporting Definition:	Please select a number between 0 (not at all) and 10 (a great deal).
Inclusion Criteria:	Female patients
Timing:	Baseline and follow-up
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = 1 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = A great deal
Variable ID:	ICIQ-FLUTSsex7
Variable:	Question 7 of the ICIQ-FLUTSsex
Definition:	Do you leak urine when you have sexual intercourse?
Supporting Definition:	N/A
Inclusion Criteria:	Female patients
Timing:	Baseline and follow-up
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	1 = Not at all 2 = A little 3 = Somewhat 4 = A lot 5 = I don't have sexual intercourse
Variable ID:	ICIQ-FLUTSsex8
Variable:	Question 8 of the ICIQ-FLUTSsex
Definition:	How much does this bother you?
Supporting Definition:	Please select a number between 0 (not at all) and 10 (a great deal).

Inclusion Criteria:	Female patients
Timing:	Baseline and follow-up
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not at all 1 = 1 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = A great deal
Variable ID:	ICIQ-MLUTSsex1
Variable:	Question 1 of the ICIQ-MLUTSsex
Definition:	Do you get erections? (Tick one box)
Supporting Definition:	N/A
Inclusion Criteria:	Male patients
Timing:	Baseline and follow-up
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	1 = Yes, with normal rigidity 2 = Yes, with reduced rigidity 3 = Yes, with severely reduced rigidity 4 = No, erection not possible
Variable ID:	ICIQ-MLUTSsex2
Variable:	Question 2 of the ICIQ-MLUTSsex
Definition:	How much of a problem is this for you?
Supporting Definition:	Please select a number between 0 (not a problem) and 10 (a serious problem).
Inclusion Criteria:	Male patients
Timing:	Baseline and follow-up
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not a problem 1 = 1 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = A serious problem
Variable ID:	ICIQ-MLUTSsex3
Variable:	Question 3 of the ICIQ-MLUTSsex
Definition:	Do you have an ejaculation of semen?
Supporting Definition:	N/A
Inclusion Criteria:	Male patients
Timing:	Baseline and follow-up
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	1 = Yes, with normal quantity 2 = Yes, with reduced quantity 3 = Yes, with severely reduced quantity

	4 = No ejaculation
Variable ID:	ICIQ-MLUTSsex4
Variable:	Question 4 of the ICIQ-MLUTSsex
Definition:	How much of a problem is this for you?
Supporting Definition:	Please select a number between 0 (not a problem) and 10 (a serious problem).
Inclusion Criteria:	Male patients
Timing:	Baseline and follow-up
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not a problem
	1 = 1
	2 = 2
	3 = 3
	4 = 4
	5 = 5
	6 = 6
	7 = 7
	8 = 8
	9 = 9
	10 = A serious problem
Variable ID:	ICIQ-MLUTSsex5
Variable:	Question 5 of the ICIQ-MLUTSsex
Definition:	Do you have pain or discomfort during ejaculation?
Supporting Definition:	N/A
Inclusion Criteria:	Male patients
Timing:	Baseline and follow-up
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	1 = Yes, slight pain/discomfort
	2 = Yes, moderate pain/discomfort
	3 = Yes, severe pain/discomfort
Variable ID:	ICIQ-MLUTSsex6
Variable:	Question 6 of the ICIQ-MLUTSsex
Definition:	How much of a problem is this for you?
Supporting Definition:	Please select a number between 0 (not a problem) and 10 (a serious problem).
Inclusion Criteria:	Male patients
Timing:	Baseline and follow-up
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Not a problem
	1 = 1
	2 = 2
	3 = 3
	4 = 4
	5 = 5
	6 = 6
	7 = 7
	8 = 8
	9 = 9
	10 = A serious problem
Variable ID:	ICIQ-MLUTSsex7
Variable:	Question 7 of the ICIQ-MLUTSsex
Definition:	To what extent do you feel that your sex life has been spoilt by your urinary symptoms?
Supporting Definition:	N/A
Inclusion Criteria:	Male patients
Timing:	Baseline and follow-up

Reporting Source: Patient-reported
Type: Single answer
Response Options: 1 = Not at all
 2 = A little
 3 = Somewhat
 4 = A lot

Variable ID: ICIQ-MLUTSsex8
Variable: Question 8 of the ICIQ-MLUTSsex
Definition: How much of a problem is this for you?
Supporting Definition: Please select a number between 0 (not a problem) and 10 (a serious problem).
Inclusion Criteria: Male patients
Timing: Baseline and follow-up
Reporting Source: Patient-reported
Type: Single answer
Response Options: 0 = Not a problem
 1 = 1
 2 = 2
 3 = 3
 4 = 4
 5 = 5
 6 = 6
 7 = 7
 8 = 8
 9 = 9
 10 = A serious problem

Variable ID: ICIQ-MLUTSsexg
Variable: Question 9 of the ICIQ-MLUTSsex
Definition: If you have no sex life, how long ago did this stop?
Supporting Definition: Please indicate years and months
Inclusion Criteria: Male patients
Timing: Baseline and follow-up
Reporting Source: Patient-reported
Type: Free text
Response Options: N/A

Side Effects and Burden of Treatment

Variable ID: TBS
Variable: Treatment benefit scale
Definition: My condition (urinary problems, incontinence) has...
Supporting Definition: N/A
Inclusion Criteria: All patients
Timing: Follow-up
Reporting Source: Patient-reported
Type: Single answer
Response Options: 1 = Greatly improved
 2 = Improved
 3 = Not changed
 4 = Worsened during treatment

Variable ID: Txtolerance
Variable: Treatment tolerance
Definition: The tolerability of my treatment for OAB is...
Supporting Definition: N/A
Inclusion Criteria: All patients
Timing: Follow-up
Reporting Source: Patient-reported
Type: Single answer

Response Options: 1 = Inadequate
 2 = Moderate
 3 = Good
 4 = Excellent

Treatment Satisfaction

Variable ID: Sat
Variable: Satisfaction with treatment
Definition: My overall satisfaction is...
Supporting Definition: N/A
Inclusion Criteria: All patients
Timing: Follow-up
Reporting Source: Patient-reported
Type: Single answer
Response Options: 1 = Extremely satisfied
 2 = Very satisfied

ICHOM Contact Information

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Reference Guide Revisions

Reference Guide Version	Location within Reference Guide	Content Change
1.1	Outcomes table and Outcome Measures summary	Added "(4-week recall)" to OAB-q SF
1.1	Data Dictionary	Added stem of questionnaire to each question
1.2.0	Treatment Options	Added "ligament surgery"
1.2.1	Treatment Options	Revised "ligament surgery" to "surgery"
1.2.2	Contact Information	Removed inactive email address: ichomteam@ichom.org

