Committee 4

Initial assessment of urinary incontinence in adult male and female patients (A)
Patient-reported outcome assessment (B)

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Funding for speaker to attend:

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Committee 4: Initial Assessment and Outcome Assessment

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Committee 4: Initial Assessment and Outcome Assessment

- The recommendations presented in this report are evidence-based and utilise the ICUD-EBM grades
- A search of the available literature in English obtained from Medline and Pubmed up to August 2021 by the individual committee members employed multiple search terms related to the initial assessment of the patient with urinary incontinence and patient reported outcome assessment

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Committee 4: Purpose of Initial Assessment

The 'initial assessment' represents the components of the history, physical examination, laboratory tests, and basic office testing in order to:

- Establish a presumptive or condition specific diagnosis excluding underlying conditions
- Assess the level of bother and desire for intervention
- Prepare for the institution of empirical or disease specific primary therapy
- Prompt the recommendation of additional more complex testing or specialist assessment
- Assess the level of improvement after intervention

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Initial Assessment: Women

History and examination

- Urinary Incontinence should be identified
- The degree of bother and the desire for treatment should be assessed.
- Complicated incontinence should be identified for referral.
- The clinical assessment should seek to identify relevant predisposing and precipitating factors and other related and non-related diagnoses that may require referral for additional investigation and treatment.
- UI may be further categorized as stress UI, mixed UI, or urge UI/OAB
- Initial conservative treatment may be started without specific categorisation, however, additional pharmacological therapy should be started on this basis. In mixed UI, treatment may be directed towards either symptom, the predominant symptom, or both symptoms.

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Initial assessment of urinary incontinence: Key questions

Stress urinary incontinence: Do you sometimes leak urine when you cough or sneeze or when you exert yourself, such as when lifting a heavy object?
Urgency urinary incontinence: Do you sometimes feel an urge to void that is so sudden and strong that you sometimes don't make it to the bathroom on time?
How long have the symptoms been present?
How often do you leak urine and how much do you leak? (Do you need protections and how many during day and night?
Circumstances surrounding urine leakage e.g. sexual activity, change in position, provocation by running water or "key in the latch"?
Nocturnal symptoms or enuresis?
Association with other lower urinary tract or pelvic organ prolapse symptoms?

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Initial assessment of urinary incontinence: Key questions

Impact on personal and social life?
Amount and type of fluid intake e.g. coffee, tea, alcohol?
Episodes of urinary tract infection or haematuria?
Previous treatment attempts (successful and unsuccessful)?
Mobility problems?
Cognitive deficits?
Neurological deficits?
Problems with constipation or faecal incontinence?
Number of pregnancies and the type of delivery, with complications?
Previous prostate, pelvic or abdominal surgeries or radiation treatment?
Coexisting diseases (diabetes, heart disease, neurological impairment)?
Types of medications consumed?

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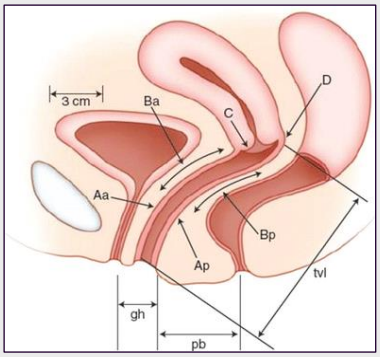
Physical Examination: Women

- Abdominal palpation
- Neurological Assessment
- Vulval and vaginal examination
- Pelvic examination
- Rectal examination

Specialised Testing

- Stress Test
- Pad Test
- Q-Tip Test

- Pelvic Floor muscle strength
- Pelvic Floor muscle contraction
- Pelvic organ prolapse



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Urgency Questionnaires

Questionnaire	Aim of tool	Items	Population sample	Reliability	Content Validity	Construct Validity	Concurrent Validity	Discriminant Validity	Responsiveness	GR
UPS (Urgency Perception Score) (6)	Grading the urgency to void and assessing the reason why individuals usually void	5	Men Women OAB + LUTS LUTS (without urgency) Healthy	Yes	Yes	Yes		Yes		B
UQ (Urgency Questionnaire) (7)	Severity of urgency and urge incontinence Impact of urgency and urge incontinence on the quality of life Discomfort of urgency with VAS scale	15 + 10 VAS	Women OAB	Yes	yes	Yes	Yes	Yes	Yes	A
USIQ-QoL (Urgency Severity and Life Impact Questionnaire-Quality of life) (8)	Impact of urgency on the quality of life	8	Women Men OAB	Yes	Yes	Yes .		Yes		B
USIQ-S (Urgency Severity and Life Impact Questionnaire: Severity Symptsoms QQQ) (8)	Severity of urgency	5	Women Men OAB	Yes	Yes	Yes		Yes		B
UU Scale (9)	Monitoring efficacy treatment	10	Women Man • OAB	Yes		Yes			Yes	A

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Urgency Scales

Scale	Aim of tool	Degrees of urgency	Population sample	Reliability Test-re test	Content validity	Construct Validity	Concurrent Validity	Discriminant Validity	Responsiveness	GR
UPS (Urgency Perception scale) (10)	Severity of urgency	3	Men Women OAB		Yes	Yes	Yes		Yes	B
IUSS (Indevus urgency Severity Scale) (11)	Severity of urgency per void The ability to complete actives	4	Men Women OAB with urge Incontinence	Yes	Yes	Yes	Yes	Yes	Yes	A
PPIUS (Patients' perception of intensity of urgency scale) (12)	Severity of urgency Urgency incontinence	4	Men Women Urgency Urge incontinence	Yes	Yes			Yes	Yes	A
USS (Urinary Sensation Scale) (13)	Severity of urgency	5	Men OAB+LUTS Women OAB		Yes	Yes	Yes	Yes	Yes	A
URS(Urgency Rating Scale)(14)	Severity of urgency	5	Men	Na	Na	Na	Na	Na		C

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Summary: History and Examination

Summary of evidence	LE
History taking including symptoms and comorbidities and a focussed physical examination is an essential part of the evaluation of a woman with LUTS.	4

Recommendation	Strength rating
Take a complete medical history including symptoms and comorbidities and a focused physical examination in the evaluation of women with lower urinary tract symptoms.	Strong

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Summary: Validated Symptom Questionnaires

Summary of evidence	LE
Validated condition-specific symptom scores assist in the screening for, and categorisation of LUTS.	3
Validated symptom scores measure the severity of UI and LUTS.	3
Both condition-specific and general health status questionnaires measure current health status and change following treatment.	3
Patient questionnaires cannot replace a detailed patient consultation and should only be used as part of a complete medical history.	4

Recommendation	Strength rating
Use a validated and appropriate questionnaire as part of the standardised assessment of female lower urinary tract symptoms.	Strong

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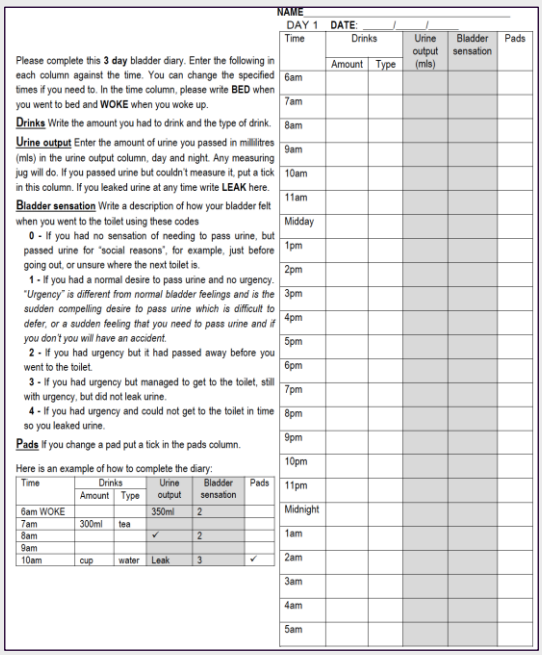

NAME

DAY 1 DATE: _____/_____/_____

Please complete this **3 day** bladder diary. Enter the following in each column against the time. You can change the specified times if you need to. In the time column, please write **BED** when you went to bed and **WOKE** when you woke up.

Drinks Write the amount you had to drink and the type of drink.

Urine output Enter the amount of urine you passed in millilitres (mls) in the urine output column, day and night. Any measuring jug will do. If you passed urine but couldn't measure it, put a tick in this column. If you leaked urine at any time write **LEAK** here.

Bladder sensation Write a description of 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 different from normal bladder feelings and is the sudden compelling desire to pass urine which is difficult to defer, or a sudden feeling that you need to pass urine and if you don't you will have an accident.*

2 - If you had urgency but it had passed away before you went to the toilet.

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.

Pads If you change a pad put a tick in the pads column.

Here is an example of how to complete the diary:

Time	Drinks		Urine output	Bladder sensation	Pads
	Amount	Type			
6am WOKE			350ml	2	
7am	300ml	tea			
8am			✓	2	
9am					
10am	cup	water	Leak	3	✓

Time	Drinks		Urine output (mls)	Bladder sensation	Pads
	Amount	Type			
6am					
7am					
8am					
9am					
10am					
11am					
Midday					
1pm					
2pm					
3pm					
4pm					
5pm					
6pm					
7pm					
8pm					
9pm					
10pm					
11pm					
Midnight					
1am					
2am					
3am					
4am					
5am					

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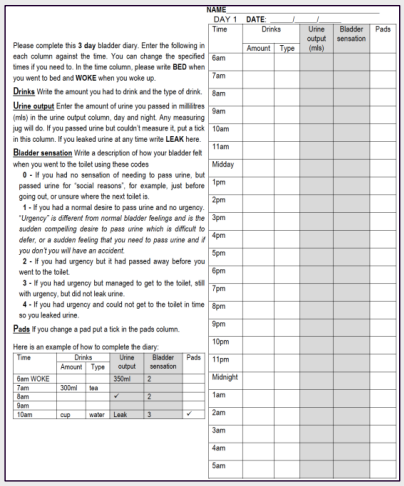
Frequency volume chart/ Bladder diary

A properly completed frequency-volume chart or bladder diary, can inform on

- Daytime urinary frequency
- Nocturnal frequency/ nocturia
- Twenty-four-hour frequency
- Twenty-four-hour urine production
- Maximum voided volume
- Average voided volume
- Median functional bladder capacity
- Polyuria (>2.8l/24h)
- Nocturnal urine volume
- Nocturnal polyuria



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8am			✓	2	
9am					
10am	cup	water	Leak	3	✓

Time	Drinks		Urine output (mls)	Bladder sensation	Pads
	Amount	Type			
6am					
7am					
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9am					
10am					
11am					
Midday					
1pm					
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4pm					
5pm					
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7pm					
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9pm					
10pm					
11pm					
Midnight					
1am					
2am					
3am					
4am					
5am					

ICIQ Bladder Diary

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Frequency volume chart / Bladder diary

Summary of evidence	LE
Bladder diaries of three to seven days duration are a reliable tool for the objective measurement of mean voided volume, day- and night-time frequency, and UI episode frequency.	2b
Bladder diaries are sensitive to change and are a reliable outcome measure.	2b

Recommendations	Strength rating
Ask patients with lower urinary tract symptoms to complete a bladder diary as part of the standardised assessment of female LUTS.	Strong
Use a bladder diary with a duration of at least three days.	Strong

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Bladder Diary: Recommendations

- Ask patients with urinary incontinence to complete a bladder diary to evaluate co-existing storage and voiding dysfunction (GA)
- A bladder diary is recommended in order to document and communicate both objective information and to objectify observations by the patient during the diary period. Although never completely diagnostic, diary patterns may characterise normal and abnormal states. (GA)
- A 1-day frequency volume chart (FVC) which includes the first morning void on the following day is a reasonable tool to gain insight into voiding habits during normal daily routine (GC)

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Bladder Diary: Recommendations

- A 3-day FVC or diary is recommended for accurate assessment of LUTS and for confirming a consistent clinical pattern in day-to-day practice. For atypical clinical patterns or clinical research (GC)
- A 7-day diary might be recommended, although it should be realised that compliance decreases. Most pharmacological studies now employ a 3-day diary as a standard to optimize patient compliance (GC)
- The validated ICIQ bladder diary is recommended for use over a 3-d period. The inclusion of the diary in research studies is recommended and will provide ongoing evidence of validation, as well as the external validity of the diary (GA)

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Bladder Diary: Future Research

- The ideal duration of a bladder diary based on the utility of the diary for diagnosis, the selection of therapy, and improving the outcomes of therapy requires further investigation
- The utility of paper versus electronic methods of recording voiding patterns requires further research
- The ICIQ bladder diary should be culturally and linguistically validated for as many other languages as possible and be included in research studies for further validation as well as determining external validity

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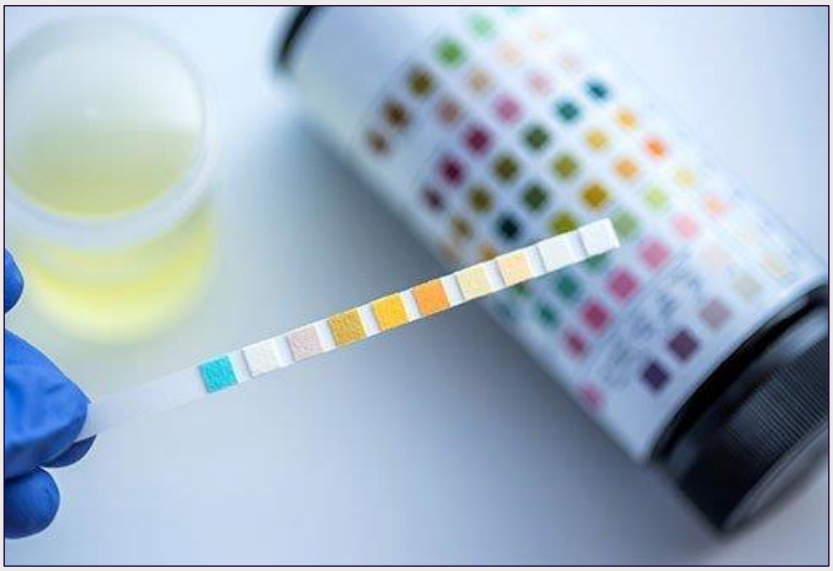

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Urinalysis: Recommendations

- Urinalysis using a dipstick test or examining spun sediment in incontinent patients is recommended (L3,GC)
- If a dipstick test is used, it is recommended that a "multi-property" strip that includes fields for haematuria, glucose, leukocyte esterase and nitrite tests be chosen (L4,GD)
- Dipstick is not as accurate as urine culture, being specific for infection but not sensitive (L2,GC)
- Additional tests available on urine dipstick strips, such a protein, bilirubin, ketones and pH, may be helpful in the broader medical management of patients
- However, they are not essential in the context of evaluation of the patient with urinary incontinence or lower urinary tract symptoms (L4,GD)

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Urinalysis: Recommendations

- Urinalysis negative for nitrite and leucocyte esterase may exclude bacteriuria in women with LUTS (L3,GC)
- Urinary incontinence may be a symptom during a UTI, and LUTS may deteriorate during a UTI (L3,GC)
- If a urinary tract infection is present with LUTS, reassess the patient after treatment (L3,GC)
- The presence of a UTI worsens existing symptoms of UI (L3,GC)
- Do not routinely treat asymptomatic bacteriuria in elderly patients to improve urinary incontinence (L2,GB)
- Elderly nursing home patients with UI do not benefit from treatment of asymptomatic bacteriuria (L2, GB)

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Urinalysis: Recommendations

Summary of evidence	LE
Urinalysis negative for nitrite and leucocyte esterase may exclude bacteriuria in women with LUTS.	3
Urinary incontinence may be a symptom during a UTI, and LUTS may deteriorate during a UTI.	3
The presence of a UTI worsens existing symptoms of UI.	3
Elderly nursing home patients with UI do not benefit from treatment of asymptomatic bacteriuria.	2

Recommendations	Strength rating
Perform urinalysis as a part of the initial assessment of a patient LUTS.	Strong
If a urinary tract infection is present with LUTS, reassess the patient after treatment.	Strong
Do not routinely treat asymptomatic bacteriuria in elderly patients to improve urinary incontinence.	Strong

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Urinalysis: Future Research

- Emerging evidence challenges the long-held paradigm that the healthy bladder is sterile and evidence indicate that the human urinary tract contains microbial communities; however, the role of these communities in urinary health remains to be elucidated
- Further research to clarify the role of urinary microbiota in maintaining urinary health and inducing LUT dysfunction will help refine treatment algorithms and prevention strategies
- Certain microbes have characteristics that protect against uropathogens by producing antibiotics, antimicrobial peptides, and/or other antimicrobial compounds that inhibit or kill other pathogenic microbes

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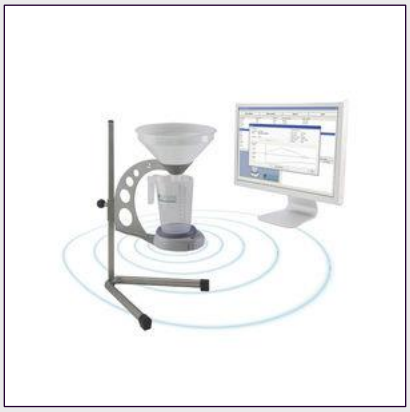

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Post Void Residual: Recommendations

- Varying degrees of decreased bladder emptying or urinary retention may be a cause of LUTS that are associated with symptoms of decreased urinary storage
- The decision to perform a PVR in disease specific sub-groups of incontinent patients should be based on an association of the condition with poor bladder emptying (GD), whereas in individual patients this decision may be based on symptoms or physical findings (GC)
- Female patients who present with storage specific symptoms, with normal sensation and no complaints of decreased bladder emptying, and no anatomical, neurological, organ-specific, or comorbid risk factors for retention may be assessed for bladder emptying by history and physical examination alone (GB)

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Post Void Residual: Recommendations

- Due to the increased possibility of bladder outlet obstruction secondary to prostatic obstruction in the male patient, the threshold for investigating residual urine in the male is significantly lower (GD)
- A PVR should be performed in incontinent patients when decreased bladder emptying is suspected, especially if treatments that decrease bladder contractility or increase outlet resistance are being considered (GD)
- Non-invasive ultrasound measurement of PVR is as accurate as measurement by catheterization and is therefore the preferred method (GA)
- A palpable bladder on physical examination is an indication for referral to a specialist (GD)

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Post Void Residual: Recommendations

Summary of evidence	LE
Lower urinary tract symptoms are associated with a higher PVR compared to asymptomatic population groups.	2

Recommendations	Strength rating
Measure post-void residual volume (PVR) in patients with LUTS during initial assessment.	Strong
Use ultrasound to measure PVR.	Strong
Monitor PVR in patients receiving treatments that may cause or worsen voiding dysfunction.	Strong
Provide Bladder Voiding Efficiency as an additional parameter when measuring PVR.	Weak

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Post Void Residual: Future Research

- Development of more specific indications for PVR testing for diagnosis and prior to instituting therapy based on history, physical examination and disease specific findings
- Further development of low cost, minimally invasive , and accurate means of measurement of PVR that do not require catheterisation

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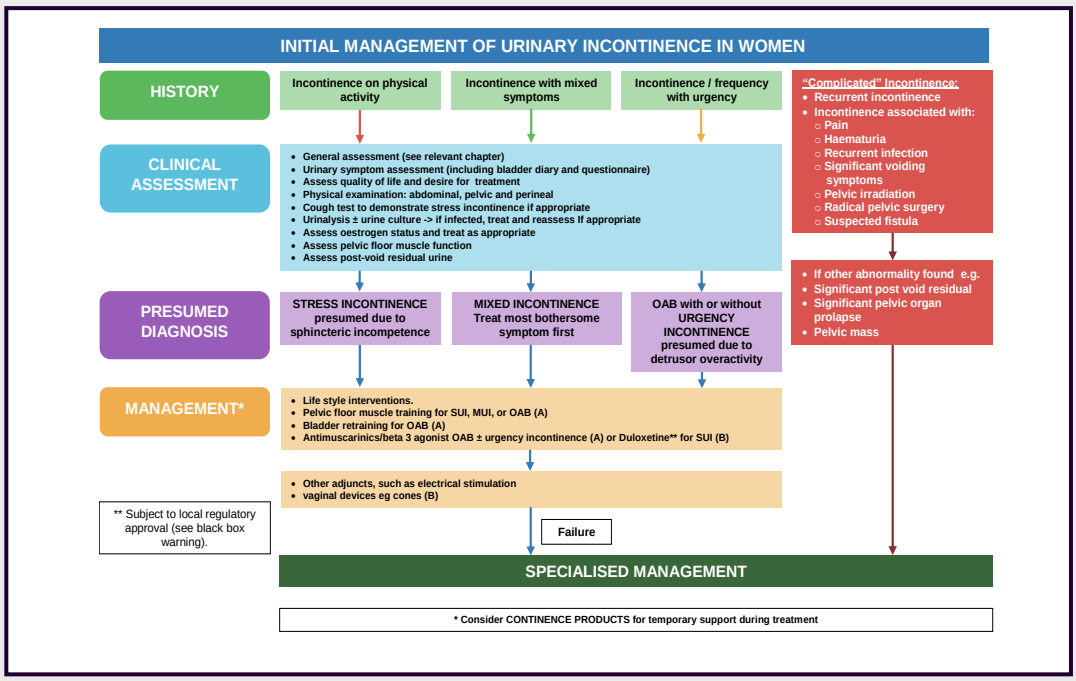

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Initial Assessment in Men: Recommendations

- A variety of symptom scores have been described to assess patients with Male-LUTS. The IPSS, ICIQ-MLUTS, and DAN-PPS have been the most tested and were found to reproducible, valid, and sensitive for initial assessment. (L2). However, the IPSS neglects of symptom of incontinence.
- Urinalysis is recommended in patients with male-LUTS. There are currently insufficient evidences to recommend routine measurement of serum creatinine and post-void residual urine in male patients with incontinence
- In addition to DRE, PSA measurement is recommended in selected male patients with OAB.

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Initial Assessment in Men: Future Research

- To improve the understanding of the underlying pathophysiology and contributory clinical factors involved in the development and treatment of detrusor overactivity in the male patient, especially in differentiating the condition from female patients
- Development of simple, non-invasive, cost-effective methods to determine the contribution of bladder storage and bladder emptying abnormalities in male patients

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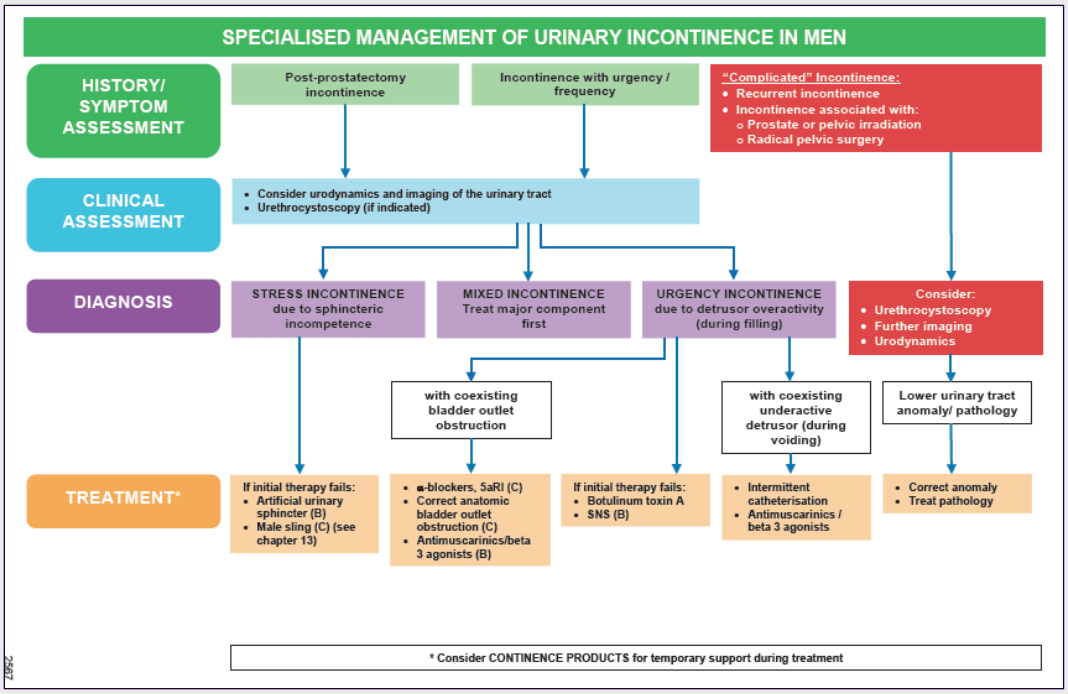

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Initial Assessment: General Recommendations

- LUTS cannot be used to make a definitive diagnosis (L4,GD)
- Urinary incontinence should be described by specifying relevant factors (L4,GD)
- Urinary incontinence should be categorised into UUI, SUI or MUI
- Conservative therapies may then be started based on this classification (L4,GD)
- More sophisticated testing is not required prior to conservative therapy (L3,GC)

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Initial Assessment: General Recommendations

- Both objective (bladder diary) and subjective (PROs) are recommended at baseline and after therapy (L3,GD)
- Evaluation of co-morbid conditions which affect fluid intake and output should be undertaken (L4,GD)
- Referral is recommended for haematuria, UTI, POP, obstruction or retention, hydro nephrosis or obstructive renal insufficiency), suspected neurological disease, mass (urethral, bladder or pelvic - benign or malignant), fistula (urinary or bowel), faecal incontinence, a history of prior pelvic surgery or radiation (incontinence, oncologic) (L4,GD)

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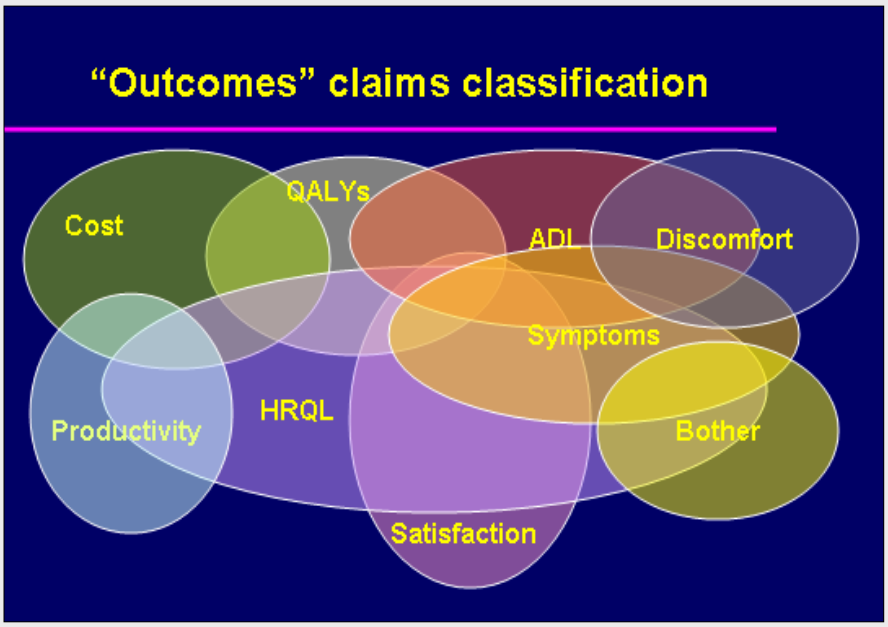

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Patient Reported Outcome: Definition

”Any report of the status of a patient´s health condition that comes directly from the patient, without interpretation of the patient´s response by a clinician or anyone else”

FDA: Guidance for Industry on PROM 2009

”Any outcome directly evaluated by the patient and based on patient´s perception of a disease and its treatments”

EMA Regulatory guidance for HRQL 2005

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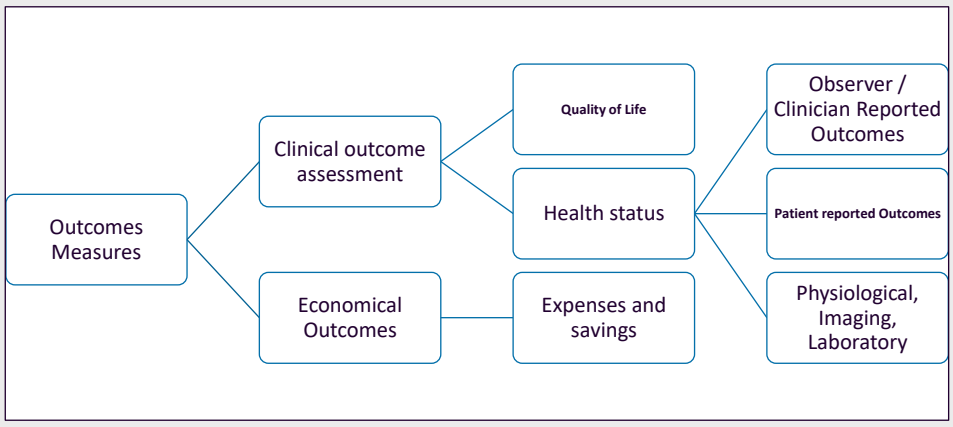
Assessment: Types of Outcome Measures



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Patient Reported Outcome Measures

- A PRO is "any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else".
- PROs measure different aspects of disease and therapeutic impact such as: symptom frequency or symptom bother, health-related quality of life (HRQL), treatment satisfaction, or work productivity measures .
- An essential component of selecting a PRO for use is to ensure that the selected PRO is consistent with the objective of the study or clinical purpose.

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Ideal properties of PRO instrument

- To be specific to the concept being measured
- To be based on end-point model
- To have conceptual equivalence
- To be based on the conceptual framework
- To contain optimum number of items
- To have easy and specific measurement properties
- To have proper evidence for the conceptual framework
- To maintain the confidentiality of the patient
- To be reproducible

Adapted from Prasanna R 2011

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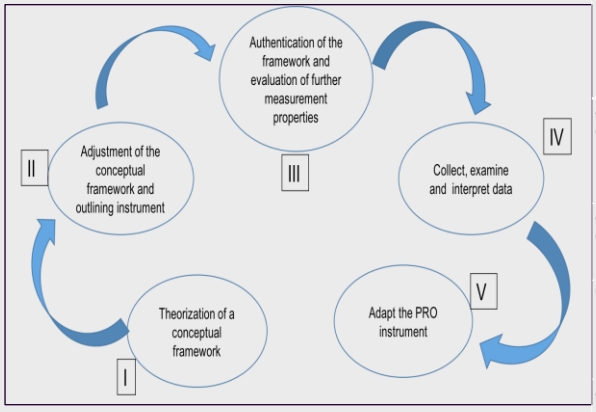
Five-step development of PRO instrument



Theorization of a conceptual framework	Outline hypothesized concepts and potential claims Determine intended population Determine intended application/characteristics (type of scores, mode and frequency of ad ministration) Perform literature expert review Develop hypothesized conceptual framework Place PROs within preliminary endpoint model Document preliminary instrument development
Adjustment of the conceptual framework and outlining instrument	Obtain patient input Generate new Items Select recall period, response options and format Select mode/method of administration/data collection Conduct patient cognitive interviewing Pilot test draft instrument Document content validity
Authentication of the framework and evaluation of further measurement properties	Confirm conceptual framework with scoring rule Assess score reliability, construct validity, and ability to detect change Finalize instrument content, formats, scoring, procedures and training materials Document measurement development
Collect, examine and interpret data	Prepare protocol and statistical analysis plan (final endpoint model and responder model) Collect and analyze data Evaluate treatment response using cumulative distribution and responder definition Document interpretation of treatment benefit in relation to claim
Adapt the PRO instrument	Change wording of items, populations, response options, recall period, or mode/method of administration/data collection Translate and culturally adopt to other languages Evaluate modifications as appropriate Document all changes

US Department of Health and Human Services, FDA Guidance for Industry 2016

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Questionnaire development

Reliability

- Is the instrument Reproducible?
- Internal consistency

Validity

Does the instrument measure what was intended?
Content validity
Construct Validity
Discriminant Validity
Criterion Validity

Responsiveness

Sensitivity to treatment outcome?

Linguistic and cultural validation

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Assessment: Use of Electronic PROMs

Benefits of ePRO	Drawbacks of ePRO
• Reduce missing data by requiring an answer before advancing • Can include complex skip patterns • Easily captured in the electronic medical record reducing data entry error by medical professionals • Real time ePRO reduce recall-bias (avoid retrospective data entry by the patient) • Automatic scoring • Increased patient compliance • No out of range data • More accurate in recording sensitive topics such as sexual function, drug use, or adverse events • Multiple formats available (personal computer, tablet, smartphone) • Convenience for massive interviews (web based questionnaires)	• An electronic device is needed • Difficulties of some patients in interacting with computers (computer anxiety or computer illiteracy) • Space limitations requiring splitting of questions (questions and responses must be short) • Referring back to response of a previous question is more difficult (flow and navigation must be easy for patients) • Should be completed in less than 30 minutes • Inability of the patient to add information about symptoms or concerns not included in the tool

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PROMs: Grades of recommendation

Grade A+

Published data of validity, reliability and responsiveness with published content validity.

Grade A

As above without published content validity

Grade B

Published data on 2 of the three main criteria > B+ if published content validity

Grade C

Published data on one of the three main criteria > C+ if content validity

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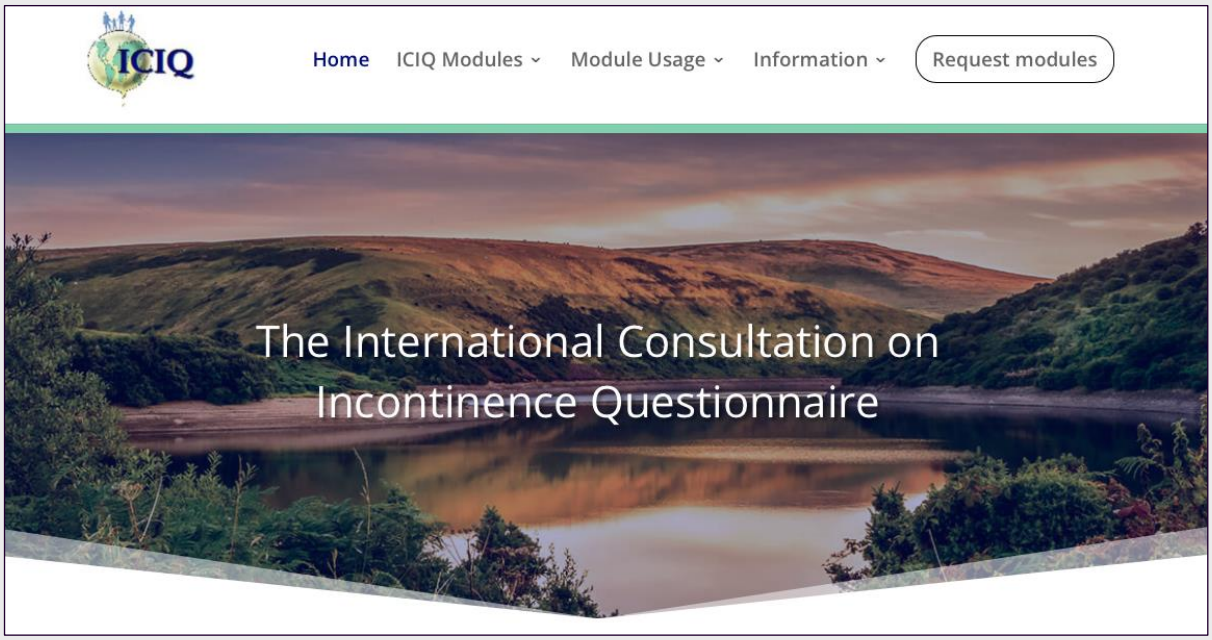

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International Consultation on incontinence modular questionnaire (ICIQ) What is the ICIQ?

- To provide international consensus on the use of patient completed questionnaires for assessment of lower pelvic symptoms & impact on patient's lives
- To recommend high quality self-completion questionnaires according to evidence of validation as stipulated by the prior ICI Committees
- To promote wider use of questionnaires to standardise assessment of LUT & pelvic dysfunction and its impact of patient´s lives, in order to
- Facilitate communication in different patient settings and different patient groups both in clinical practice and wider clinical research

- Sixteen ICIQ modules/questionnaires currently available, 50 language versions
- Should be used in the format they where designed as this may
- Electronic versions demonstrated excellent equivalence

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Condition	Core questionnaires				Post Treatment
	Symptoms	Optional	HRQoL	Sexual Matters	
Urinary Symptoms	Males: ICIQ-MLUTS(Donovan et al., 2000) Females: ICIQ-FLUTS(Brookes et al., 2004)	Males: ICIQ-MLUTS Long Form Females: ICIQ-FLUTS Long Form	ICIQ-LUTSqol(Kelleher et al., 1997)	Males: ICIQ-MLUTSsex Female: ICIQ-FLUTSsex	
Vaginal Symptoms	ICIQ-VS(Price et al., 2006)		ICIQ-VS	ICIQ-VS	
Bowel Symptoms	ICIQ-B(Cotterill et al., 2008, 2011)		ICIQ-B	ICIQ-B	
Urinary Incontinence	ICIQ-UI Short Form(Avery et al., 2004)		ICIQ-LUTSqol ICIQ-UI SF	Males: ICIQ-MLUTSsex Females: ICIQ-FLUTSsex	
Prospective bladder events	ICIQ-Bladder diary(Bright et al., 2014)				
Condition	**Specific patient groups**				
	Symptoms		**HRQoL**	**Sexual Matters**	ICIQ-Satisfaction(Uren et al., 2020b)
Nocturia	ICIQ-N		ICIQ-Nqol(Abraham et al., 2004)	Males: ICIQ-MLUTSsex Females: ICIQ-FLUTSsex	
Overactive Bladder	ICIQ-OAB		ICIQ-OABqol(Coyne et al., 2002)	Males: ICIQ-MLUTSsex Females: ICIQ-FLUTSsex	
Underactive Bladder	ICIQ-UAB*(Uren et al., 2017b, 2019)				
Long Term Catheter			ICIQ-LTCqol(Cotterill et al., 2015)		
Children	ICIQ-CLUTS(De Gennaro et al., 2010)				
Absorbent Pads			ICIQ-PadPROM(Yearwood Martin et al., 2018)		
Inflammatory Bowel Disease	ICIQ-IBD				
Cognitively Impaired Adults	ICIQ-Cog*(Volz-Sidiropoulou et al., 2018)				

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Recommended questionnaires for the evaluation of symptoms and HRQoL impact of LUTS

Grade A (recommended)

Danish Prostate Symptoms Score (DAN PSS)

ICIQ-UI Short Form

ICIQ - FLUTS

ICIQ – MLUTS

IIQ

IIQ-7

Urinary Incontinence Specific Quality of Life (IQoL)

Incontinence Symptom Severity Index (ISS)

ICIQ – LUTS QoL (Kings Health Questionnaire)

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Recommended questionnaires for the evaluation of symptoms and HRQoL impact of LUTS

Grade A (recommended)

Leicester Impact Scale (LIS)
Lower Urinary Tract Symptom Score (LUTSS)
ICIQ – NQoL
OABq – SF
ICIQ – OABQoL
PFDI, PFDI-20
PFIQ, PFIQ-7
Protection, Amount, Frequency, Adjustment, Body Image (PRAFAB)
Incontinence Severity Score (ISS)
Urolife (BPHQoL 9)

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LUTS: Patient Satisfaction measures

Grade B

Benefit, Satisfaction with Treatment and Willingness (BSW)
OAB Staisfaction Measure (OAB-S)
OAB Satisfaction Questionnaire (QAB SAT-q)
Treatment Benefit Scale (TBS)

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LUTS: Screening Tools

Grade A

Bladder Self Assessment Questionnaire (B-SAQ)

OAB-SS

OAB V8, OAB V3

Questionnaire for Urinary incontinence Diagnosis (QUID)

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LUTS: Symptom Bother Questionnaires

Grade A

Leicester Urinary Symptom Questionnaire (LUSQ)

Patient Global Impression of Improvement (PGI-I)

Patient Global Impression of Severity (PGI-S)

Patient Perception of Bladder Condition (PPBC)

Urogenital Distress Inventory (UDI)

Urogenital Distress Inventory - 6 (UDI-6)

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Recommended questionnaires for the evaluation of symptoms and HRQoL impact of POP

Grade A (recommended)

Pelvic Floor Distress Inventory (PFDI)

Pelvic Floor Impact Questionnaire (PFIQ)

Prolapse Quality of Life Questionnaire (P-QoL)

Pelvic Organ Prolapse Urinary Incontinence Sexual Questionnaire (PISQ),(PISQ 12)

Pelvic Organ Prolapse Urinary Incontinence Sexual Questionnaire –IUGA Revised (PISQ-IR)

ICIQ vaginal symptoms questionnaire (ICIQ-VS)

Pelvic Organ Proplase Symptom Score (POP SS)

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Recommended questionnaires for the evaluation of symptoms and HRQoL impact of POP

Grade B

The Austrian Pelvic Floor Questionnaire (AFPQ)

Pelvic Floor Symptom Bother Questionnaire (PFBQ)

Electronic Personal Assessment Questionnaire-Pelvic Floor (ePAQ-PF)

Grade C (with potential)

Pelvic Floor Dysfunction Questionnaire

Danish Prolapse Questionnaire

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Recommended questionnaires for the evaluation of symptoms and HRQoL impact of faecal incontinence

Grade A+
ICIQ-B

Grade A
Faecal Incontinence Quality of Life Scale
Birmingham Bowel and Urinary Symptom Questionnaire,
Questionnaire for assessment of Faecal Incontinence and Constipation

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Recommended questionnaires for the evaluation of symptoms and HRQoL impact of faecal incontinence

Grade B
Colorectal Functional Outcome Questionnaire
Manchester Health Questionnaire
Bowel Control Self Assessment Questionnaire
Pelvic Floor Bother Questionnaire
Elderly Bowel Symptom Questionnaire
Faecal Incontinence and Constipation Assessment

Grade C
Faecal Incontinence Questionnaire

Ungraded
Postpartum Flatal and Faecal Incontinence Quality of Life Scale
Bowel Function Questionnaire
Surgical Outcome Tool for Faecal Incontinence

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Recommended questionnaires for the evaluation of Sexual Function

Grade A

- Female Sexual Function Index (FSFI)
- Female Sexual Distress Scale (FSDS)
- International Consultation on Incontinence Questionnaire-Vaginal Symptoms (ICIQ-VS)
- Derogatis Sexual Functioning Inventory (DISFI)
- The Menopausal Sexual Interest Questionnaire (MSIQ)
- International index of erectile function (IIEF) to assess men with erectile dysfunction

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Recommended questionnaires for the evaluation of Sexual Function

Grade B

- Daily Log of Sexual Activities (DLSA)
- Female sexual distress scale-revised (FSDSr)
- Index of Sexual Functioning for women (BISF-W)
- Change in Sexual Functioning Questionnaire (CSFQ)
- Sexual Interest and Desire Inventory Female (SIDI-F)
- Pelvic Organ Prolapse Urinary Incontinence Sexual Question (PISQ-12)
- Sexual Quality of Life–Female (SQoL-F)
- Sexual Satisfaction Scale for Women (SSS-W)
- Sexual Function Questionnaire (SFQ)
- Male Sexual Health Questionnaire (MSHQ)

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Recommended questionnaires for the evaluation of Sexual Function

Grade C

- Women's Sexual Interest Diagnostic Interview--Short Form (WSID-SF)
- Pelvic Organ Prolapse/Incontinence Sexual Questionnaire, IUGA-Revised(PISQ-IR)
- Sexual Health Outcomes in Women Questionnaire (SHOW-Q)

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PROMs: Recommendations for research

- Grade A + questionnaires strongly recommended for use in RCTs evaluating treatments
- Inclusion of ICIQ strongly recommended in all studies where possible
- Consideration of regulatory requirements to be considered
- Researchers encouraged to conduct further research
  - Developing new questionnaires for specific groups only
  - Impact on clinical practice of using questionnaires
  - Clinicians are encouraged to use recommended PRO questionnaires as part of their clinical practice

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Committee 4: Initial Assessment and Outcome Assessment

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Committee 4

Initial assessment of urinary incontinence in adult male and female patients (A) Patient-reported outcome assessment (B)

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