

Committee 5

Initial Assessment of Urinary and Faecal Incontinence in Adult Male and Female Patients

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Committee 5 A
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Incontinence in Adult Male and Female Patients**

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Committee 5 A

Initial Assessment of Urinary and Faecal Incontinence in Adult Male and Female Patients

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INTRODUCTION

Organization of this committee report

Urinary (UI) and faecal incontinence (FI) are a concern for individuals of all ages and both sexes. This report reviews the “initial assessment” of urinary and faecal incontinence – and in addition, reviews the available outcome measures for symptom assessment and quality of life for these disorders. Therefore, the report is divided into 2 major sections: 5A-A initial assessment of urinary incontinence (UI) in adult male and female patients, 5A-B initial assessment faecal incontinence (FI) and 5B outcome measures. The initial assessments for the conditions of incontinence in paediatric, neurogenic, and geriatric patients and for patients with pelvic pain are presented in the specific Committee reports pertaining to these sub-groups and conditions.

5A- A. INITIAL ASSESSMENT OF URINARY INCONTINENCE IN ADULT MALE AND FEMALE PATIENTS

For the purpose of this report, the ‘initial assessment’ represents the components of the history, physical examination, laboratory tests, and basic office testing to:

1. Establish a presumptive or condition specific diagnosis, and exclude underlying organ-specific related or unrelated conditions that would require intervention.
2. Assess the level of bother and desire for intervention from information obtained from the patient or caregiver.

3. Institute empiric or disease specific primary therapy based on the risk and benefit of the untreated condition, the nature of the intervention and the alternative therapies.
4. Prompt the recommendation of additional more complex testing or specialist referral.

Within the initial assessment of UI, various sub-populations / subgroups are recognized because of the differences within patient groups or the interrelationship between the conditions. The subsections in this report should be utilized in conjunction with other population or condition specific Committee Reports of the Consultation and the final recommendations of the Consultation which are presented in simplified form along with treatment algorithms in the Management Recommendations. These subgroups include patients with lower urinary tract symptoms (LUTS) without incontinence and with pelvic pain. The requirements of specific sub-populations negate the ability to recommend a ‘universal’ initial evaluation. Pelvic organ prolapse in the female and prostatic obstruction in the male require uniquely different approaches to lower urinary tract dysfunction. Congenital and maturational issues in the paediatric subgroup and the effects of ageing on the lower urinary tract and medical co-morbidities in the geriatric group present unique challenges. Specific risks for combined storage and emptying abnormalities and upper urinary tract deterioration in the neurogenic bladder population demand a more involved initial evaluation.

This committee report is evidence based and utilizes the ICUD - EBM grades. A search of the available literature in English obtained from Medline© and Pubmed© up to June 2008 by the individual committee members utilized multiple search terms related to assessment (eg., ‘urinary incontinence’, ‘faecal incontinence’, ‘lower urinary tract symptoms’, ‘vaginal prolapse’, and terminology related to ‘outcome assessments’ and ‘quality of life measures’).

Purpose of the initial assessment

The initial assessment must consider the degree of bother, and the costs of further evaluation, balanced against the consequences of a failure to diagnose an underlying condition, the risk and benefits of conservative management or pharmacological therapy and the need for an accurate diagnosis before more complex intervention or empiric therapy. The burden of these conditions and the availability of resources to different patients, physicians, and health care systems require that primary intervention strategies be formulated, when available from evidence based findings and decisions emanating from the initial evaluation. As will be noted, especially in this committee report, the amount and sophistication of the literature that contributes to the levels of evidence that are available for determining the grades of recommendation in the area of "initial assessment" may often rely on expert opinion of the panel.

Of note, LUTS cannot be used to make a definitive diagnosis of a specific lower urinary tract condition or lower urinary tract disease (LUTD), as these symptoms may suggest and indicate pathologies such as urinary infection or more serious underlying conditions. Basic laboratory tests, such as testing for urinary or faecal infection or blood, and appropriate screening for malignancy should be considered before the decision is made to choose therapy for incontinence.

Concomitant pathology may affect urinary or faecal production as co-morbid contributory issues, by affecting fluid balance or renal function (dietary or alimentary function) and may need to be addressed. The physician should elicit neurological symptoms and signs that may indicate alterations in the control of the lower urinary tract / bowel function or the cognitive, motivational, physical, and environmental factors that determine the ability to perform toileting functions effectively.

I. LOWER URINARY TRACT SYMPTOMS

Symptoms are either volunteered by, or elicited from, the individual or may be described by the individual's caregiver. The International Continence Society (ICS) has classified lower urinary tract symptoms (LUTS) into storage, voiding, and post-micturition symptoms [1]. The National Institutes of Health (NIH) recommend similar (but not identical) standards of terminology in pelvic floor disorders[2]. Although an accurate urological history will not establish a definitive diagnosis it will ultimately guide investigation and treatment [1].

The following section summarises the definitions of symptoms described by the International Continence Society [1]. NIH definitions are given (*in italics and in parentheses*) where they differ from ICS terminology.

1. STORAGE SYMPTOMS

OVERACTIVE BLADDER (OAB) - Urgency with or without urgency incontinence usually with frequency and nocturia in the absence of an underlying metabolic or pathological condition.

URINARY INCONTINENCE (UI) is the complaint of any involuntary leakage of urine. In each specific circumstance, urinary incontinence should be further described by specifying relevant factors such as type, frequency, severity, precipitating factors, social impact, effect on hygiene and quality of life, the measures used to contain the leakage (wearing of protection, number and type of pads and change of underwear or outer clothes) and whether or not the individual seeks or desires help because of urinary incontinence. Urinary leakage may need to be distinguished from perspiration or vaginal discharge.

STRESS URINARY INCONTINENCE (SUI) is the complaint of involuntary leakage on effort or exertion, or on sneezing or coughing (NIH – *the patient's or caregiver's statement of involuntary loss of urine during physical exertion*).

URGENCY URINARY INCONTINENCE (UUI) is the complaint of involuntary leakage accompanied by or immediately preceded by urgency. Urge incontinence can present in different symptomatic forms; for example, as frequent small losses between micturition or as a catastrophic leak with complete bladder emptying. Information should be sought on triggering events such as cold, running water and 'latch key' incontinence.

MIXED URINARY INCONTINENCE (MUI) is the complaint of involuntary leakage associated with urgency and also with exertion, effort, sneezing or coughing.

CONTINUOUS URINARY INCONTINENCE is the complaint of continuous leakage.

OTHER TYPES OF URINARY INCONTINENCE may be situational, for example the report of incontinence during sexual intercourse. Coital incontinence may occur during arousal, on penetration, throughout intercourse, or specifically at orgasm; although urodynamic stress incontinence is the most common urodynamic finding in each of these situations, detrusor overactivity is found more often when leakage is restricted to orgasm [3].

URGENCY is the complaint of a sudden compelling desire to pass urine which is difficult to defer (NIH – *the statement that the patient feels a strong need to pass urine for fear of leakage*).

INCREASED DAYTIME FREQUENCY is the complaint of voiding too often by day (NIH - *the statement that the patient voids eight or more times in 24 hours*).

Increased daytime frequency may arise in the presence of a normal bladder capacity when there is

excessive fluid intake, or when bladder capacity is restricted secondary to detrusor overactivity, impaired bladder compliance, or increased bladder sensation.

NOCTURIA is the complaint that the individual has to wake at night one or more times to void (NIH - *the statement that the patient wakes from sleep to pass urine*). The term 'night time frequency' differs from that for nocturia, as it includes voids that occur after the individual has gone to bed, but before he/she has gone to sleep, and voids which occur in the early morning which prevent the individual from getting back to sleep as he/she wishes. These voids before and after sleep may need to be considered in research studies. If this definition were used then an adapted definition of daytime frequency is required. Nocturia may arise for similar reasons to daytime frequency, but may also occur due to an increase in fluid output due to other physiological abnormalities resulting in 'nocturnal polyuria'. (see Bladder diaries below).

NOCTURNAL ENURESIS is the complaint of loss of urine occurring during sleep. Enquiry should include previous childhood nocturnal enuresis as delayed bladder control in childhood is associated with detrusor overactivity in adulthood.

BLADDER SENSATION may be categorised as:

NORMAL: the individual is aware of bladder filling and increasing sensation towards capacity.

INCREASED: the individual feels an early and persistent desire to void.

REDUCED: the individual is aware of bladder filling but does not feel a definite desire to void.

ABSENT: the individual reports no sensation of bladder filling or desire to void.

NON-SPECIFIC: the individual reports no specific bladder sensation but may perceive bladder filling as abdominal fullness, vegetative symptoms, or spasticity. These symptoms are most frequently seen in neurological patients, particularly those with spinal cord trauma or malformation.

2. VOIDING SYMPTOMS

Voiding symptoms may occur in situations of overactive outlet, or under active detrusor[1]. The former may be secondary to outlet obstruction from urogenital prolapse, urethral stricture or following previous bladder neck surgery. Detrusor atonia or hypotonia is however much more common in the female, and may arise idiopathically, or secondarily to over distension after parturition or surgery, in peripheral neuropathy due to diabetes mellitus, and in other neurological conditions. Women with prolapse may require to digitate vaginally to initiate or complete voiding.

SLOW STREAM is the individual's perception of reduced urine flow, usually compared to previous performance or in comparison to others.

INTERMITTENT STREAM (INTERMITTENCY) is when the individual describes urine flow which stops and starts, on one or more occasions, during micturition.

HESITANCY is when an individual describes difficulty in initiating micturition resulting in a delay in the onset of voiding after the individual is ready to pass urine.

STRAINING to void describes the muscular effort used to initiate, maintain or improve the urinary stream.

TERMINAL DRIBBLE is the term used when an individual describes a prolonged final part of micturition, when the flow has slowed to a trickle.

POST-MICTURITION SYMPTOMS

Post micturition symptoms are experienced immediately after micturition.

FEELING OF INCOMPLETE EMPTYING is a self-explanatory term for a feeling experienced by the individual after passing urine.

POST MICTURITION DRIBBLE is the term used when an individual describes the involuntary loss of urine immediately after he or she has finished passing urine, usually after leaving the toilet in men, or after rising from the toilet in women.

3. MEASURING THE FREQUENCY AND SEVERITY OF LOWER URINARY TRACT SYMPTOMS

The frequency-volume chart or micturition diary records a patient's voiding pattern during normal daily activities. In some women it may be therapeutic as it provides them with insight into their bladder behaviour [4]. The ICS has described three different forms of diary, namely the micturition time chart which records the timing of voids in twenty four hours; the frequency volume chart (FVC) which also includes the volumes voided , and the bladder diary which in addition includes incontinence episodes, pad usage, fluid intake, degree of urgency and degree of incontinence.¹ However, increasing either the complexity of the diary or duration of recording is associated with poorer compliance [5]. The optimum duration of recording depends on the clinical context and the purpose of the measurement. A properly performed 1-day FVC, which includes the first morning void the following day, is a reasonable tool to gain insight into voiding habits during normal daily routine.

However, a 3-day FVC or diary is recommended for accurate assessment of lower urinary tract symptoms and for confirming a consistent clinical pattern in day-to-day practice. Although never completely diagnostic, several different diary patterns have been described which may characterise normal and abnormal states[6]. For atypical clinical scenarios, a 7-day FVC or diary should be used. Equally, a 7-day diary has been recommended for clinical research, [7] however, of note, most pharmacological studies now employ a

three day diary as a standard for improved patient compliance (see Committee Report Pharmacology for further recommendations).

The following measurements can be abstracted from frequency volume charts and bladder diaries:

DAYTIME FREQUENCY is the number of voids recorded during waking hours and includes the last void before sleep and the first void after waking and rising in the morning.

NOCTURIA is the number of voids recorded during a night's sleep; each void is preceded and followed by sleep.

NIGHT-TIME FREQUENCY is the number of voids recorded from the time the individual goes to bed with the intention of going to sleep, to the time the individual wakes with the intention of rising.

24-HOUR FREQUENCY is the total number of daytime voids and episodes of nocturia during a specified 24 hours period.

24-HOUR PRODUCTION is measured by collecting all urine for 24 hours; this is usually commenced after the first void produced after rising in the morning and is completed by including the first void on rising the following morning.

POLYURIA is defined as the measured production of more than 2.8 litres of urine in 24 hours in adults. It may be useful to look at output over shorter time frames.

NOCTURNAL URINE VOLUME is defined as the total volume of urine passed between the time the individual goes to bed with the intention of sleeping and the time of waking with the intention of rising. Therefore, it excludes the last void before going to bed but includes the first void after rising in the morning.

NOCTURNAL POLYURIA is present when an increased proportion of the 24-hour output occurs at night (normally during the 8 hours whilst the patient is in bed). The night time urine output excludes the last void before sleep but includes the first void of the morning. The normal range of nocturnal urine production differs with age and the normal ranges remain to be defined. Therefore, nocturnal polyuria is present when greater than 20% (young adults) to 33% (over 65 years) is produced at night. Hence the precise definition is dependent on age.

AVERAGE VOLUME VOIDED is the mean volume of urine passed in each void. This is calculated by dividing total voided volume by number of voids.

NORMALISED MICTURITION FREQUENCY is a more meaningful way of expressing voided volume. This is defined as the number of micturitions required to pass 1 litre of urine, and is calculated by dividing 1000

ml by average volume voided. This is a more specific measure of bladder function than micturition frequency, since it takes into account behavioural, dietary and pharmacological factors that affect urine volume.

MAXIMUM VOIDED VOLUME is the largest volume of urine voided during a single micturition and is determined either from the frequency/volume chart or bladder diary.

INCONTINENCE EPISODE FREQUENCY is the number of episodes of accidental urine leakage that occur over a specified period (e.g. 24 hours).

URGENCY is the complaint of a sudden compelling desire to pass urine, which is difficult to defer, and which leads to a fear of incontinence. The impact of this symptom may be derived from a bladder diary by recording episodes of urgency, episodes of urgency leading to incontinence and severity of urgency (e.g. using a daily visual analogue scale).

PAD USAGE is the number of pads used over a specified period (e.g. 24 hours).

Recommendations

1. Lower Urinary Tract Symptoms (LUTS) cannot be used to make a definitive diagnosis; they may also indicate pathologies other than Lower Urinary Tract Disease (LUTD). Specific to this report, LUTS may include Overactive Bladder (OAB) a syndrome which may be associated with urgency incontinence (OAB-wet) or without incontinence (OAB-dry). Likewise, bowel symptoms should prompt consideration and as appropriate, an evaluation for other similar symptom based pathology. (Level 5 - Grade D)
2. Urinary and faecal incontinence should be described by specifying relevant factors such as type, frequency, severity, precipitating factors, social impact, effect on hygiene and quality of life, the measures used to contain the leakage and whether or not the individual seeks or desires help. (Level 5 - Grade D)
3. Urinary incontinence should be categorized by symptoms into urgency incontinence, stress incontinence or mixed incontinence and conservative (non-invasive) therapies may then be started based on this classification to treat the most troublesome component, or either component of the incontinence. (Level 5 - Grade D) More sophisticated testing (eg. urodynamic studies) is not required prior to the institution of conservative therapy (see indications for urodynamics in the Committee Report on Urodynamic Studies). (Level 3 - Grade C)

4. A bladder diary is recommended in order to document and communicate the frequency of voids and incontinence episodes experienced by the patient - as well as additional metrics. Additional information as appropriate may include volume of intake, voided volume, and / or symptoms such as urgency or discomfort. Additional metrics may be added for research purposes such as degree of urgency or time from urgency to toileting. A bladder diary is recommended for a minimum of 3 days for accuracy (Level 3 - Grade C) as the ideal duration is not clear (Level 4). The committee acknowledges the difficulty with patient compliance and acknowledges some value of shorter periods for patient compliance. (Level 5 - Grade D).
5. Referral to a specialist is recommended for hematuria (visible or microscopic), urinary tract infection (persistent or recurrent), prolapse (symptomatic or below the introitus), obstruction or retention (symptoms or findings of palpable bladder, hydronephrosis 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) (Level 5 - Grade D).

Future research

1. Standardisation of the 'definition of symptoms' and the 'measurements of symptom frequency, severity and bother' are essential for patient care and research. Continued research into the appropriate scales and metrics should be accompanied by a significant attempt to establish best practice guidelines for their use and a consensus on the adoption of universal standards.
2. Recognition and resolution of the differences in common language usage and scientific utilisation of terms should continue (e.g. common use of 'urge to void' and the 'desire to void' versus the ICS terminology of "urgency"). In addition, continued research into the development of accurate measures to objectify subjective symptoms such as "urgency". This would include resolution of the differences in the ICS and NIH definitions (in addition to other regulatory agencies) is essential for communicating data with respect to patient care, research, and treatment outcomes.
3. Further development and standardisation of symptom assessment tools (questionnaires) to improve the diagnostic accuracy of lower urinary tract symptoms. (Refer to section 2 of this committee's report)

4. Further validation of the accuracy of specific components of the history and physical findings to establish an accurate diagnosis and initiate non-invasive conservative or pharmacological therapy. In addition, to further identify components that would indicate the need for more invasive testing, complex therapeutic interventions, and indications for referral.

II. URINALYSIS IN THE EVALUATION OF THE PATIENT WITH LUTS AND UI

"The urinalysis is a fundamental test that should be performed in all urological patients. Although in many instances a simple dipstick urinalysis provides the necessary information, a complete urinalysis includes both chemical and microscopic analysis" [8].

In relation to urinary incontinence, dipstick urinalysis is not a diagnostic test, but a screening test, important in order to detect haematuria, glucosuria, pyuria and bacteriuria. Haematuria can indicate important pathology such as urothelial carcinoma in situ, leading to lower urinary tract storage symptoms including incontinence [9]. Glucosuria is relevant, as a potential indicator of diabetes mellitus. This can cause symptoms via several mechanisms including polyuria secondary to osmotic diuresis, peripheral autonomic neuropathy affecting bladder innervation leading to impaired bladder emptying and chronic urinary retention and finally due to increased risk of urinary tract infection (UTI), directly related to the glucosuria and as a sequel to impaired bladder emptying.

Pyuria and bacteriuria, detected from urinary dipstick leukocyte esterase and nitrite tests respectively, are important signs of urinary tract infection. The specificity and sensitivity of these latter tests for UTI is increased when used together compared to either individual test [10,11]. Even in the absence of controlled studies, there is general expert consensus that the benefits of urinalysis clearly outweigh the costs involved, although the use of urinalysis should always be associated with prognostic significance [12]. A positive dipstick urinalysis will prompt formal urine microscopy and culture to detect UTI prior to antibiotic treatment and/or the use of additional tests such as endoscopy and urinary tract imaging. In the evaluation of urinary incontinence and lower urinary tract symptoms, the value of urinalysis can be illustrated by the finding that 60% of women with stable bladder will develop detrusor overactivity at the time of UTI.

The importance of urinalysis in the basic assessment of patients with urinary incontinence and lower urinary tract symptoms is not dependent on gender, age or aetiology. Indeed, it has been recommended in the evaluation of geriatric patients including nursing home residents who are incontinent, [13,14] in peri- and postmenopausal women, [15] and in older women

reporting urinary incontinence [16]. In the latter context, it has been suggested that significant urine samples can even be obtained from disposable diapers in elderly incontinent women [17].

A Norwegian survey of general practitioners' management of female urinary incontinence suggested that urinalysis is the most frequently performed test (73%) and is far more frequent than gynaecological examination (54%) [18]. Another survey proposed that urinalysis is one of the three-part assessment of urinary incontinence together with patient history and physical examination [19].

The clinical relevance of asymptomatic bacteriuria (without pyuria) and pyuria (without bacteriuria) in the elderly is controversial, as eradication of bacteriuria appeared to have no effect on resolution of incontinence, and many suggest that it does not deserve any treatment. [20,21].

Recommendation

1. It is considered standard to perform a urinalysis either by using a dipstick test or examining the spun sediment. (Level 5 - Grade D)
2. If a dipstick test is used, it is recommended that a "multiproperty" strip that includes fields for haematuria, glucose, leukocyte esterase and nitrite tests be chosen. (Level 5 - Grade D) Dipstick is not as accurate as urine culture, being specific for infection but not sensitive. (Level 2 - Grade C)
3. Additional tests available on urine dipstick strips, such as 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. (Level 5 - Grade D)

Future research

1. Determine the role of urinalysis as a screening test in various incontinent populations, specifically the elderly patient with acute or established incontinence in combination with asymptomatic bacteriuria. Specifically, to determine the relevance of asymptomatic bacteriuria without pyuria, and pyuria without bacteriuria, in elderly patients. (see Geriatric Committee Report).
2. Determine the prognostic significance of urinalysis results and the impact of therapy the outcome of treatment of urinary incontinence.

III. THE UTILITY OF POST-VOIDING RESIDUAL [PVR] URINE VOLUME DETERMINATION IN THE INITIAL ASSESSMENT OF INCONTINENT PATIENTS

The PVR is the volume of urine remaining in the bladder following a representative void. PVR measurement can be accomplished within a few minutes of voiding either by catheterisation or by calculation of bladder volume using a portable ultrasound scanner. Several studies have compared volumes measured with portable ultrasound scanners versus catheterisation and found portable scanners to be 85-94% accurate [22,23]. A study has imaged the bladder volume after catheterisation and found that the volume of urine remaining in the bladder after catheterisation accounted for most of the difference between the two measurements [22]. Bimanual palpation cannot reliably estimate the post-void residual urine volume [24].

Since PVR may vary, one measurement of PVR may not be sufficient [25]. PVR should probably be measured several times to increase its reliability. Griffiths et al found a significant variability in PVR measurement depending on the time of the day, with the greatest volume occurring in the morning [26]. A non-representative PVR is particularly common if the patient's bladder is not full enough to yield an urge to void.

An increased PVR alone is not necessarily a problem, but if combined with high pressures it can lead to upper tract problems. If related to UTI's, PVR may need to be treated since UTI's may not be eradicated in the presence of an infected residual. A significant PVR also decreases the functional bladder capacity and contributes to urgency/frequency, urge incontinence and nocturia. However, a Scandinavian study in nursing home residents found that an elevated PVR was not associated with bacteriuria and incontinence [27].

Review of the literature does not show an evidence-based specific maximum PVR that is considered normal, nor is there a minimal PVR that is considered abnormal. The amount of residual urine that precludes treatment by various therapies has also not been determined. The AHCPR guidelines state that, in general, a PVR less than 50 ml is considered adequate bladder emptying and over 200 ml is considered inadequate emptying (expert opinion of the panel members) [28].

“Normal values” of PVR have been determined in several groups of non-incontinent and incontinent women. Gehrich et al studied 96 women (mean age 60 ± 11 yrs) that were seen in a well-women clinic. These women had no history of incontinence, retention, symptomatic prolapse or neurologic disorders. Most (97%) had a minor (asymptomatic) degree of prolapse, 80% was post-menopausal and 30% had had a hysterectomy. The median PVR was 19 ml (range 0-145 ml; mean 24 ± 29 ml); only 5% had PVR > 100 ml. Only, age > 65 yrs was associated with higher PVR [29]. Tseng et al studied 107 women with urodynamic stress incontinence. They found a mean PVR of 62.5 ml by bladder scan and 38.5 ml by catheterization. Only 15.9% had a PVR greater than 100 ml. The PVR determined by bladder scan offered a sensitivity of 64.7% and a specificity of 94.3% in detecting PVR greater than 100 ml [30]. Haylen et al studying women with lower urinary tract dysfunction found that 81% had a PVR of less than 30 ml. Postvoid residual volumes higher than this level are significantly associated with increasing age, higher grades of prolapse, and an increased prevalence of recurrent UTIs. [31]. Fitzgerald et al studied women with urgency, frequency and urge incontinence: 10% had an elevated PVR of > 100ml. In these women with OAB, the following independent risk factors of increased PVR were found: vaginal prolapse, symptoms of voiding difficulty and absence of stress-incontinence [32]. Lukacz et al found that only 11% of women with pelvic floor disorders had an elevated PVR [33]. Wu and Baguley studied 319 consecutive patients (196 women, 123 men) in a subacute general, but predominantly geriatric, rehabilitation unit. 22 had been admitted with catheter and were excluded. Of the 297 “asymptomatic” patients, 21.5% had PVR volumes of 150 mL or more. Patients with elevated PVR (> 150 ml) were significantly more likely to have a urinary tract infection at admission and have urinary incontinence on discharge [34]. Milleman et al retrospectively reviewed 201 women (mean age 55; range 20-90) who presented with complaints of urinary frequency, urgency and /or urge incontinence. 19% had an elevated PVR of more than 100 ml (mean 211 ml; range 100-997 ml). On multivariate analysis the following independent predictors of raised PVR were identified: age > 55 yrs [OR 3.71], prior incontinence surgery [OR 4.32], a history of multiple sclerosis [OR 15.32] and pelvic organ prolapse grade 2 or greater [OR 3.61] [35].

In summary, an elevated PVR > 100 ml was found in 5% of women visiting a well-women clinic, in 10- 19% of women with OAB, in 11% of women with pelvic floor disorders and in 15.9% of women with urodynamic SUI.

Does a significant PVR have an impact on the outcome of treatment in patients with incontinence? Nager et al studied the predictive value of urodynamic measures

on stress continence outcomes after surgery for stress urinary incontinence. They found that urodynamic measures do not predict outcomes. However, since women with PVR > 150 ml were excluded in this study, one can only conclude that PVR volumes < 150 ml did not have an adverse impact on stress continence outcome [36].

POST VOIDING RESIDUAL URINE IN THE MALE PATIENT

PVR measurement is especially recommended in men with suggestive of bladder outlet obstruction (BOO). PVR can be measured within a few minutes of voiding by catheterization to confirm that the bladder is empty [37] or by ultrasonography [38]. The AHCPR guidelines state that, in general, a PVR less than 50ml is considered adequate bladder emptying and over 200ml is considered inadequate emptying. More recently, a dedicated ultrasound system has been developed for automatic measurement of PVR, thereby improving the accuracy over catheterization [39] which has been largely abandoned in clinical practice. International Consultation on BPH defined a range of 50 to 100 ml as the lower threshold to define abnormal PVR [40]. Both the AUA and the EAU guidelines suggest a threshold of 300 ml to identify patients at risk of unfavorable outcome following LUTS / BPO treatment [41,42].

There is no consensus about the relation between PVR and UTI in the male patient. Although the negative role of large residuals has been reported, the evidence is controversial. Large residual urine volume has been considered a bad prognostic factor for disease progression. However, in the standard patients, renal failure, acute retention and UTIs are uncommon in men with large, chronic residuals [43]. No factors are available to identify patients, with significant residual urine, who are at risk for progression [44].

Therefore, on the basis of these trials, untreated LUTS may place the male patient at risk for potential clinical deterioration. Thus, periodical measurements of PVR are recommended in such patients.

Recommendations

1. 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 co-morbid risk factors for retention may be assessed for bladder emptying by history and physical examination alone, depending on the potential morbidity of the failure to diagnose and the nature of the intended therapy. (Grade B).
2. A palpable bladder on physical exam is an indication for referral to a specialist (Grade D).

3. Residual urine determination by bladder scan is preferable to catheterisation due to the increased morbidity associated with instrumentation. (Grade D).
4. Due to the increased possibility of bladder outlet obstruction due to prostatic obstruction is increased in the male patient, the threshold for investigating residual urine in the male is significantly lower (Grade D).
5. A PVR should be performed in patients where decreased bladder emptying is suspected, especially if treatments that decrease bladder contractility or increase outlet resistance are being considered. (Grade D)

Summary of 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 patients (eg., male patients with bladder outlet obstruction, in neurogenic patients who demonstrate combined disorders of storage and emptying, and preoperatively in female patients being considered for incontinence surgery) should be based on an association of the condition with poor bladder emptying (Grade D), whereas in individual patients this decision may be based on symptoms or physical findings. (Grade C)

Future Research

1. Development of more specific indications for PVR testing for diagnosis and prior to instituting therapy based on history, physical examination, and disease specific findings.
2. Further development of low cost, minimally invasive, and accurate means of measurement of PVR that do not require catheterisation.
3. Continued research in subsets of patients is required to determine the need for PVR assessment and the correlation between elevated PVR and treatment outcome, generally, to determine the effect of varying levels of PVR on the outcomes of observational, conservative, pharmacological and surgical interventions, and more specifically, the female patient prior to surgeries that increase outlet resistance, the male patient with bladder outlet obstruction where medications that can potentially decrease bladder contractility are considered, and the patient with elevated residual urine where intermittent catheterization is not practical and where recurrent urinary tract infections and decreased functional bladder capacity are potential complicating factors.

IV. THE FEMALE PATIENT

1. GENERAL MEDICAL HISTORY

The general history should include questions relevant to precipitating and aggravating factors of urinary loss, time of onset and duration of symptoms, and degree of bother. Acute symptoms may be further defined by documenting patterns of fluid intake and output, acute infection, recent surgery or trauma. Chronic symptoms may be further defined by eliciting a history of congenital abnormalities, neurological disease, relevant surgery or general health. Information must be obtained on medications with known or possible effects on the lower urinary tract. The general history should also include assessment of menstrual, obstetric, sexual and bowel function. The reader is referred to the report of the Committee on Epidemiology for risk specific risk factors to be considered during the medical history and to the second section of this report for recommendations for disease specific questionnaires.

2. URINARY SYMPTOMS

Women with urinary incontinence may have had the condition for many years before presenting; they are often embarrassed in disclosing their condition and are likely to have undertaken significant adaptations to their lifestyle to ameliorate their symptoms [45]. In establishing the history the opportunity should be taken not only to describe symptoms, but also their progression, impact on lifestyle and possible risk factors. Multiple symptoms are commonly reported, [46] and during the history it is important to define the most troublesome symptoms and the patient's expectations from treatment.

Section 2 of this Committee Report presents a complete review and evaluation of questionnaires that are applicable for clinical and research use in evaluating patient symptoms. Structured condition specific questionnaires may be used, [47] and may be either clinician or self-administered. Questionnaires may facilitate disclosure of embarrassing symptoms, ensure that symptoms are not omitted, and standardise information thereby aiding audit and research.

3. CORRELATION OF SYMPTOMS AND SIGNS WITH SOPHISTICATED TESTING

Harvey & Versi evaluated the symptom and sign of stress incontinence in predicting the presence of urodynamic stress incontinence, using the results of a MEDLINE search for 'urinary incontinence', 'urodynamic' or 'urodynamics' [48]. Of 42 articles evaluated, 12 yielded analysable data. The isolated symptom of stress incontinence had a positive predictive value (PPV) of 56% for the diagnosis of pure urodynamic stress incontinence (USI) and 79% for USI with other abnormalities. The PPV for stress

incontinence with other symptoms was 77% for USI with or without other abnormalities. A positive cough test had a PPV of 55% for the diagnosis of pure USI and 91% for USI with other abnormalities. They concluded that in isolation, either symptom or sign were poor predictors of USI, although in combination prediction may be more promising [48].

Horbach reviewed the literature regarding the reliability of stress symptoms in predicting USI; PPV values ranged from 64% to 90% [49]. Summitt et al reported that 53% to 71% of women with detrusor overactivity (DO) gave similar histories to those with pure USI [50]. The PPV of a history of pure urge incontinence may be as low as 37%, [51] and overactive bladder symptoms (OAB) only 54%, [52] in the diagnosis of DO. It is however of interest to note that in a secondary analysis of data from a drug study in patients with predominant stress incontinence, the main determinant of concurrent urge symptoms was not the pathophysiological condition present (i.e. the presence of concurrent detrusor overactivity) but the severity of incontinence [53].

Martin et al, have reported a systematic review of methods of assessing urinary incontinence. (54) From an electronic search of MEDLINE, EMBASE and CINAHL between 1966 and 2002 they identified 6009 individual papers; only 197 were relevant, and of these 121 reached the standards required of their report. Only a limited number could be combined and synthesised, although they were able to conclude that a large proportion of women with urodynamic stress incontinence can be correctly diagnosed in primary care from clinical history alone (sensitivity 0.92; specificity 0.56). The value of validated scales and pad tests could not be determined from the available data. The urinary diary appears to be the most cost effective of tests that might be used alongside clinical history within the primary care setting (sensitivity 0.88; specificity 0.82) [54].

Holroyd-Leduc performed a systematic review concerning the most accurate way to determine the type of urinary incontinence during an office assessment was performed incorporating a review of the literature from 1966-July 2007. The authors found that "In women, simple questions modestly helped diagnose stress urinary incontinence but are more helpful in diagnosing urge urinary incontinence. They concluded that a positive bladder stress test may help diagnose stress urinary incontinence, however, a negative test is not as useful. Also, a systematic assessment combining the history, physical examination, and results of bedside tests to establish a clinical diagnosis appears to be of modest value in diagnosing stress urinary incontinence. In addition, a systematic assessment is less helpful in diagnosing urge urinary incontinence. They concluded that "the most helpful component for diagnosing urge urinary incontinence is a history of urine loss associated with

urgency. A bladder stress test may be helpful for diagnosing stress urinary incontinence [55].

The reader is referred to the report of the Committee on Sophisticated Testing - Uroynamics for specific indications for complex testing

4. OTHER SYMPTOMS OF PELVIC FLOOR DYSFUNCTION IN THE FEMALE PATIENT

a) Prolapse symptoms

The feeling of a lump ("something coming down"), low backache, heaviness, dragging sensation, or the need to digitally replace the prolapse in order to defaecate or micturate, are amongst the symptoms women may describe who have a prolapse. Prolapse symptoms may be associated with urinary storage or emptying symptoms. Outlet symptoms as diverse as genuine or occult stress incontinence or obstruction, and bladder overactivity or underactivity may have a common aetiology, exist as a cause or effect, or co-exist with lower urinary tract dysfunction.

b) Bowel symptoms

In addition to urinary complaints, women may have symptoms relating to bowel function, sexual function, and pelvic organ prolapse (POP). Jackson et al. evaluated 247 women with either UI or POP. Thirty one percent of women with UI and 7% with POP had concurrent anal incontinence (AI) [56]. In a report from Sweden, 62% of 21 consecutive women undergoing a Burch colposuspension for urodynamic stress urinary incontinence had concurrent faecal incontinence [57]. In a Norwegian study of women presenting with a complaint of urinary incontinence (UI), 38% of the women were found to have significant prolapse and 19% reported faecal incontinence [58]. All these aspects of the pelvic floor and pelvic floor function must be included to plan a comprehensive treatment strategy.

c) Symptoms associated with sexual dysfunction

Dyspareunia, vaginal dryness and coital incontinence are amongst the symptoms women may describe during or after intercourse. These various symptoms are reported by one third to two thirds of women with stress incontinence, and 68% report their sex life to be spoilt by their urinary symptoms [59]. Symptoms of sexual dysfunction should be described as fully as possible; it is helpful to define urine leakage as occurring during arousal, on penetration, during intercourse, or at orgasm (*vide supra*) [3].

5. PHYSICAL EXAMINATION

a) General examination

There are few data linking bladder, bowel, or sexual function to variations in examination findings of women seeking routine gynaecological care. Similarly data on

women with complaints of urinary incontinence do not include detailed, specific information about their pelvic examinations.

Physical examination is essential in the assessment of all women with lower urinary tract dysfunction. Height and weight should be recorded so that body mass index can be calculated (Kg/M^2); this has recently been shown to be a significant risk factor for incontinence [59].

Neurological examination should be performed, with attention to the sacral neuronal pathways. Assessment of gait, abduction and dorsiflexion of the toes (S3) and sensory innervation to the labia minora (L1-L2), sole and lateral aspect of the foot (S1), posterior aspects of the thigh (S2), and perineum (S3) and cutaneous sacral reflexes (bulbo-cavernosus and anal reflexes) may be assessed. A rectal examination will provide a subjective assessment of resting and voluntary anal tone (S2-S4). For patients with possible neurogenic lower urinary tract dysfunction, a more extensive neurological examination is needed (*vide infra*).

The agitated patient with urgency and frequency might have a behavioural cause and those who are clinically depressed have a less successful response to surgical treatment for stress urinary incontinence. A minimal state assessment will assess cognitive function, and is particularly helpful in the elderly (*vide infra*). Restriction in mobility may lead to functional incontinence and a lack of hand dexterity may preclude self-catheterisation and the use of prosthetic continence devices.

b) Abdominal examination

Scars from previous surgery should be noted. Increased abdominal striae may be found in association with other markers of abnormal collagen metabolism, and are more likely in patients with prolapse and stress incontinence [60].

An attempt should be made to palpate the kidneys, particularly where a voiding dysfunction or neurogenic bladder dysfunction are suspected. A distended bladder may be identified by abdominal palpation or by suprapubic percussion. In one study designed to look at the clinical utility of basic assessment in elderly women, palpable enlargement indicated a post-void residual volume of at least 300ml [61].

c) Perineal/genital inspection

Inspection of the vulva and perineum allows a description of the skin and, for example, the presence of any abnormal anatomical features, of atrophy or excoriation, and erythema due to incontinence and the wearing of pads.

The patient should be asked to cough and strain to demonstrate stress urinary incontinence and to

observe urethral length, position, and mobility, and reflex contraction of the external anal sphincter. Howard and associates tested vesical neck descent during cough and Valsalva manoeuvre [62]. They found incontinent women have similar vesical neck mobility with both manoeuvres, whereas continent women have less vesical neck descent with a cough than with Valsalva.

The clinical sign of urinary incontinence is defined as urine leakage seen during examination; this may be urethral or extra-urethral.

Stress urinary incontinence is the observation of involuntary leakage from the urethra, synchronous with exertion/effort, or sneezing or coughing. If stress urinary incontinence is suspected, provocative stress testing (direct visualization) can be performed by having the individual relax and then cough vigorously while the examiner observes for urine loss from the urethra. Optimally these tests should be done when the patient's bladder is full, but they should not be performed when the patient has a precipitant urge to void. The test is usually performed initially in the lithotomy position, although if no leakage is observed, it should be repeated in the standing position, since the yield is increased when the test is repeated in the upright position. Coughing may induce a detrusor contraction, hence the sign of stress incontinence may only be a reliable indication of urodynamic stress incontinence when leakage occurs synchronously with the first cough and stops at the end of that cough. It has however been shown that following an increase in intra-abdominal pressure, and the immediate fall in urethral closure pressure, there follows a 'refractory period' of several seconds during which the urethra maintains a lower pressure than at rest [63]. The extent of pressure loss, and the time to recovery are both less in stress continent than stress incontinent women [64]. If further increases in intra-abdominal pressure occur during this time, stress leakage is more likely to be demonstrated after a series of coughs than following a single cough.

Bonney's original stress test was performed to demonstrate urinary leakage during coughing [65]. Subsequent modifications of the test require support of the urethra-vesical junction during coughing in women who leak during a stress test. These modifications are not reliable in selecting a surgical procedure or in predicting cure.

Extra-urethral incontinence is defined as the observation of urine leakage through channels other than the urethra. This may result from congenital abnormality such as ectopic ureteric opening, or from urogenital fistula.

d) Urethro-vesical junction (bladder neck) mobility

Urethro-vesical junction (bladder neck) mobility should

be assessed in all women with urinary incontinence. It is generally felt that women with urodynamic incontinence fall into several categories based on assessment of urethral support and urethral function. The choice of therapy may be affected by the assessment of bladder neck mobility [66]. One method of assessing bladder neck mobility is by visual inspection. When the patient is in lithotomy position, the urethral meatus is horizontal to the floor in a woman with good bladder neck support. When she increases intra-abdominal pressure you can observe for posterior rotation of the anterior vagina and deflection of the meatus toward the ceiling, both signs of some loss of support. You may ask her to contract the pelvic muscles to determine if urethral support improves with muscle contraction, a sign pelvic floor training may be therapeutic.

The cotton swab or Q-tip test is a simple out-patient procedure to quantify bladder neck mobility [66]. A sterile, lubricated cotton or *Dacron* swab (Q-tip) is inserted into the urethra until it lies just within the urethra-vesical junction. Using a goniometer, the angle circumscribed by the distal end of the swab is measured relative to the horizontal while the woman is performing a maximum Valsalva effort. Urethro-vesical junction hypermobility is defined by a maximum strain axis exceeding +30 degrees from the horizontal.

There are no published reports about the reproducibility of the cotton swab test for measuring bladder neck hypermobility, despite its widespread clinical application in the evaluation and management of women with urinary incontinence. The validity of this test for diagnosing stress urinary incontinence was not systematically evaluated until 15 years after its introduction. At that time, investigators found that a sizable minority of women with the urodynamic diagnosis of stress incontinence did not have a positive cotton swab test result [66] (considered a straining angle $>30^\circ$) and that many women with a positive cotton swab test result did not have stress urinary incontinence on urodynamic testing. The test was not able to distinguish women with stress incontinence from continent control subjects [67,68], or women with stress incontinence from those with other urologic disorders [69]. The cotton swab test is now used primarily to assess results of incontinence surgery or to determine whether the degree of urethral hypermobility may influence treatment outcomes. Although the test is simple to perform, the insertion of the small cotton swab may be uncomfortable for some women. Investigators have explored other methods to assess hypermobility, including the POP-Q anatomic evaluation system and ultrasonography. In one study, the correlation coefficient between the cotton swab straining angle and point Aa (the urethro-vesical junction) on the POP-Q system was 0.47 [70]. However, the cotton swab test was positive in 95% of patients with stage II prolapse at point Aa and in 100%

of patients with stages III and IV prolapse at point Aa, which suggests that the test may be unnecessary in patients with stage II or greater prolapse at point Aa. A study evaluating the use of a urinary catheter to assess urethral hypermobility used the Q-tip test for comparison in women with urinary incontinence and pelvic organ prolapse. Results of the study showed reduced angles of excursion from resting to Valsalva manoeuvre using a catheter [71].

Ultrasonography can be used to measure the angle between the urethra and an axis corresponding to the pubic symphysis, the urethra, the bladder base, and the position of the internal urethral meatus. Other tests to document bladder neck mobility are used, including bead-chain cystourethrography, and videocystourethrography. The report of the Committee on Imaging of the urinary tract addresses the place of these techniques.

A comparison study was conducted to assess the interobserver reliability of the Q-tip test, the Sensor-Qtrade mark test and ultrasonographic measurement of urethral mobility in women. 90 women took part in the study; and underwent one method of the assessment by two different clinicians. The correlation coefficient of the Q-tip test, the Sensor-Qtrade mark test and the ultrasonographic measurement was 0.83, 0.92 and 0.43, respectively. The Sensor-Qtrade mark and Q-tip test showed a higher inter-observer reliability for the evaluation of urethral mobility compared to ultrasound assessment [71,72].

The Q-tip test has been used in a number of studies evaluating changes in urethrovesical junction hypermobility and efficacy of surgical treatment of stress incontinence including mid-urethral tapes, vaginal wall sling procedures and Burch colposuspension [73-80]. A study investigating factors associated with severity of stress incontinence in women found that reduced urethral mobility using the Q-tip test was associated with greater severity of urinary incontinence [81].

Correlation of Q-tip test and urethroscopic imaging of the bladder neck was assessed in stress incontinent women. After the Q-tip test, patients underwent an urethroscopy; at bladder capacity the patient was asked to strain and opening or closing of the bladder neck was noted. An abnormal Q-tip test during Valsalva ($> 30^\circ$) was observed in 80% of patients. The authors suggest that a Q-tip test could diagnose bladder neck opening with a sensitivity of 91% and a specificity of 35% [82]. The correlation between the straining Q-tip angle and anterior vaginal wall prolapse assessed using the POP-Q system has been investigated in a number of studies. Noblett et al assessed the correlation between urethral mobility and anterior wall prolapse, in order to determine whether the Q-tip test was necessary in patients with stage 0/1 prolapse graded using the POP-Q system.

Results of this study suggested that the POP-Q system was highly predictive of urethral hypermobility; the positive and negative predictive values were 82% and 94% respectively [83].

A retrospective analysis conducted by Larrieux et al also concluded that descent at point Aa is a strong predictor of urethrovesical junction mobility, however urethral length did not affect the correlation between Q-tip angle and point Aa [84]. Zyczynski et al investigated the correlation between POP-Q graded anterior vaginal wall prolapse and Q-tip test findings in urinary incontinent women. The study showed that on clinical examination, one third of the study participants with urethral hypermobility by Q-tip test had a well supported urethrovesical junction. The results of this study suggested that clinicians who determine urethral mobility by watching descent of the distal anterior vagina during Valsalva manoeuvre may underestimate the true incidence of urethral hypermobility [85]. Mattison et al and Rosencrantz et al conducted retrospective reviews of a clinical database in order to determine the correlation between POP-Q evaluation of anterior vaginal wall prolapse and the straining Q-tip angle [86]. Mattison et al found the correlation between q-tip straining angle and point Aa was 0.54 ($P < 0.001$). Rosencratz found correlation values between 0.26 and 0.78. Both studies concluded that urethral hypermobility could not be predicted from POP-Q measurement alone [87]. The Q-tip has not been shown to be predictive of Valsalva leak point pressures in women with urethral hypermobility and stress urinary incontinence [88].

e) Vaginal examination

Presently there are few scientific data documenting the parameters of a normal pelvic examination in women of various ages and with various obstetrical histories. The components of the examination have not been universally agreed upon. It seems intuitive the examination should include an assessment of the bony architecture, pelvic floor muscle tone and muscle mass, connective tissue support, the epithelial lining of the vagina, the size, location, and mobility of the uterus, the adnexal structures, and innervation of the pelvic floor structures.

It is important to establish the oestrogen status as oestrogen receptors are present within the lower urinary tract [89], and are shown to influence cell proliferation [90]. Women with oestrogen deficiency may complain of urgency and frequency and recurrent urinary tract infections may develop because of loss of urethral mucosal coaptation. In women of reproductive age symptoms may vary with the menstrual cycle [91].

The well oestrogenised vagina has a thickened epithelium, with transverse rugae in its lower two-thirds. The poorly-oestrogenised vagina has a thinned epithelium with loss of transverse rugae [92]. A number

of authors have shown that vaginal pH levels are generally 5 or less in women with no infection and other definitive signs of good oestrogen effect. The use of a pH indicator paper may help you evaluate the oestrogen status in women with no vaginal infection [93]. The appearance of vaginal secretions may suggest a vaginal infection; urine within the vagina suggests genitourinary fistula, hypospadias or ectopic ureter.

Bimanual examination is performed to determine the size of the uterus and of the ovaries. Some women have co-existent pelvic disease which may require attention in addition to the urinary incontinence. When hysterectomy or oophorectomy is indicated, there is no adverse effect on surgical success with a colposuspension procedure. Pelvic masses are rarely the cause of urinary incontinence, and rarely does hysterectomy by itself relieve incontinence.

Urethral diverticula are occasionally congenital but most are acquired. They may have either a simple or complex sacculation. Many patients with urethral diverticula are asymptomatic and need no treatment. Symptomatic patients report recurrent cystitis, frequency, dysuria, dyspareunia, urinary incontinence and voiding difficulties. On clinical examination a sub-urethral mass may be palpable; the urethra is usually tender; and, if the sacculation communicates with the urethra, it may be possible to express a purulent exudate from the urethra. Occasionally, a stone may develop within the diverticulum [94]

6. PELVIC ORGAN PROLAPSE

The anterior, superior, and posterior segments of the vagina should be examined for pelvic organ prolapse. The examiner may use a mirror to demonstrate the findings to the patient; she can then confirm that the examiner has identified the extent of prolapse that she experiences. If the patient indicates that she normally has a greater amount of prolapse that you presently see, provocative manoeuvres which normally are associated with her symptoms may be undertaken, and the examination repeated while the patient is standing.

Several systems for the description and classification of prolapse have been described. This may be quantified descriptively as slight, moderate, marked [95], or first, second and third degree, or objectively using the Baden and Walker halfway method [96], or the International Continence Society Pelvic Organ Prolapse Quantification (ICS POP-Q) [97], or modified POP-Q [98]. In the latter, utilizing the introitus as the threshold, six specific vaginal sites and the vaginal length are assessed using centimetres of measurement from the introitus. In addition, the lengths of the genital hiatus and perineal body are measured in centimetres. **Figure 1** demonstrates the summary diagram of this quantitative system.

A simplified technique for use of the POP-Q system was evaluated for inter-examiner agreement and inter-system association with the standard POP-Q exam in 48 subjects. The four areas examined are the anterior and posterior vaginal walls, the apex/cuff, and the cervix. In a patient who is post-hysterectomy, only three measurements are taken: the anterior and posterior vaginal walls and the cuff scar/apex. Kappa statistics (0.86) revealed good agreement between examiners using the simplified POP-Q system. Inter-system agreement was evaluated using Kendall's tau-b statistic (0.90) also indicating good agreement between the two classification systems [99].

The pelvic organ prolapse quantification index (POP-Q-I) has been proposed for use in the research setting, as it provides a continuous variable rather than categorical variables. The POP-Q was modified such that points Aa, Ab, C, Bp, and Ap are measured. Point D is used only for the identification of patients with cervical hyperplasia. Genital hiatus, perineal body, and total vaginal length are not assessed. The POP-Q-I has not undergone rigorous validation [100,101].

The original POP-Q system has been used extensively in research settings for the assessment of short-and long-term outcomes of pelvic floor surgeries [102 - 105] including the use of mesh [106-120], laparoscopic surgery [121-123].

robotic assisted vault suspension [124], sexual dysfunction associated with pelvic organ prolapse, [125- 128], and also in community-based prevalence studies and selected patient populations with pelvic organ prolapse [129-138].

The POP-Q has been used in the validation of the Brazilian version of the vaginal symptoms module of the ICIQ, [139] and for an interviewer-administered pelvic floor symptoms questionnaire [140].

A novel speculum has been designed to facilitate use of the POP-Q system. The top and bottom blades of the speculum are adjustable and are marked in centimeters from the tip to the base of the blade. [141] **Figure 2.**

POP-Q definitions ICS report - simplified

Pelvic organ prolapse is defined as the descent of one or more of anterior vaginal wall, posterior vaginal wall, and apex of the vagina (cervix/uterus) or vault (cuff) after hysterectomy.

Anterior vaginal wall prolapse is defined as descent of the anterior vagina so that the urethra-vesical junction (a point 3cm proximal to the external urinary meatus) or any anterior point proximal to this is less than 3cm above the plane of the hymen.

The well-supported anterior vaginal wall should not cross the longitudinal axis of the vaginal canal. Hypermobility of the urethra-vesical junction is demonstrated by having the patient perform a

maximum Valsalva effort. In women with hypermobility the increase in intra-abdominal pressure causes descent of the urethra-vesical junction (bladder neck). On vaginal examination there may be loss of the transverse crease between the lower and middle thirds of the anterior vaginal wall and descent of the anterior vaginal wall. Anterolateral protrusion into the vaginal canal may represent unilateral or bilateral detachment of the pubocervical fascia along the anterolateral vagina sulcus from its attachment to the arcus tendineus fascia pelvis (white line). Central protrusions of the anterior vaginal wall may represent defects in the pubocervical fascia below the trigone and base of the bladder. Advanced prolapse of the upper anterior vaginal wall may obstruct a well-supported bladder neck.

Prolapse of the apical segment of the vagina is defined as any descent of the vaginal cuff scar (after hysterectomy) or cervix, below a point which is 2cm less than the total vaginal length above the plane of the hymen. Descent of the cervix or of the vaginal apex following hysterectomy, below the level of the ischial spines is evidence of a defective vaginal suspension mechanism. In some women, the intravaginal portion of the cervix may become elongated and cause the cervix to extend into the lower vaginal canal, simulating prolapse; however the fundus may have good support. In other women the uterus may prolapse fully outside the hymen as uterine procidentia. Following hysterectomy the vaginal cuff may be well supported or may prolapse fully outside the hymen along with other vaginal segments.

Posterior vaginal wall prolapse is defined as any descent of the posterior vaginal wall so that a midline point on the posterior vaginal wall 3cm above the level of the hymen or any posterior point proximal to this, less than 3cm above the plane of the hymen. The well-supported posterior vaginal wall should not cross the longitudinal axis of the vaginal canal. Posterior protrusions into the vaginal canal are most commonly caused by defects in the recto-vaginal fascia allowing protrusions of the small bowel (enterocele) and/or rectum (rectocele). Normally, the anterior vaginal wall lies upon the posterior vaginal wall. Therefore, protrusions of the posterior vaginal wall can affect the function of the urethra and bladder which lie upon the anterior vaginal wall. For example, distal loss of support in the posterior segment may result in a bulge which compresses the urethra and affects voiding.

As with most new systems, clinicians and researchers have mixed opinions regarding this system. Excellent inter- and intra-observer reliability has been established, although patient position may affect reproducibility in that the degree of pelvic organ prolapse was higher when women were examined in a birthing chair at a 45° angle rather than in dorsal lithotomy. This system has been widely adopted for

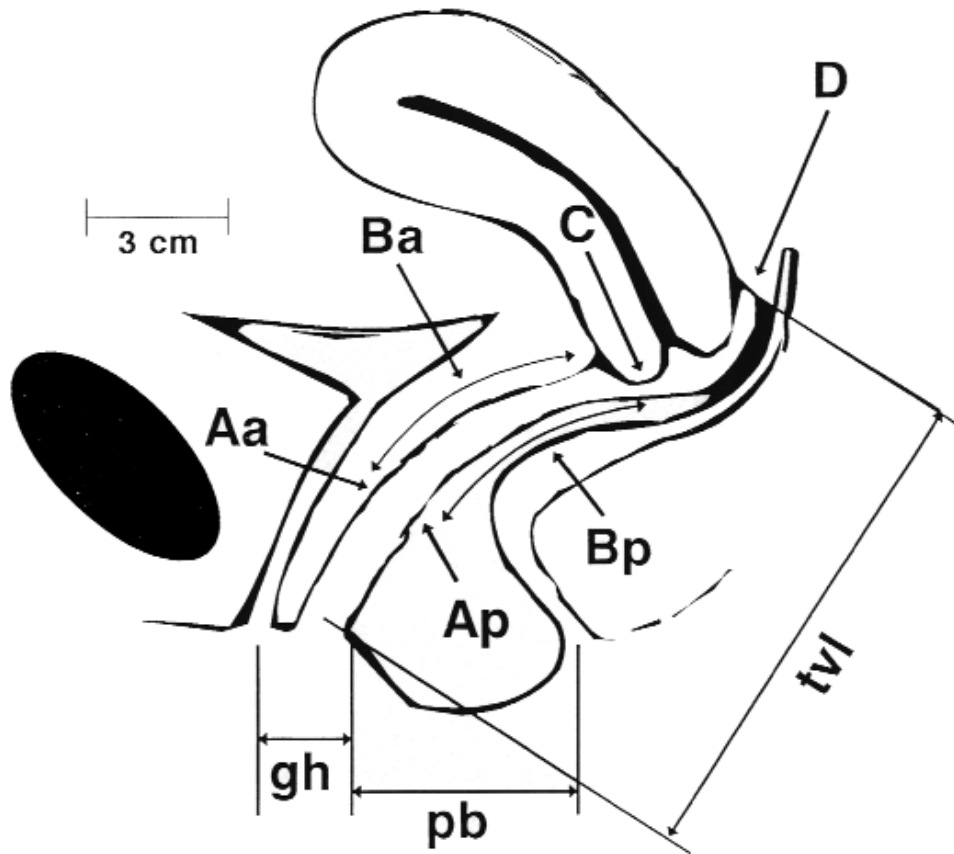


Figure 1 : ICS POP-Q. Six sites (points Aa, Ba, C, D, Bp, and Ap), genital hiatus (gh), perineal body (pb), and total vaginal length (tvl) used for pelvic organ support quantitation.

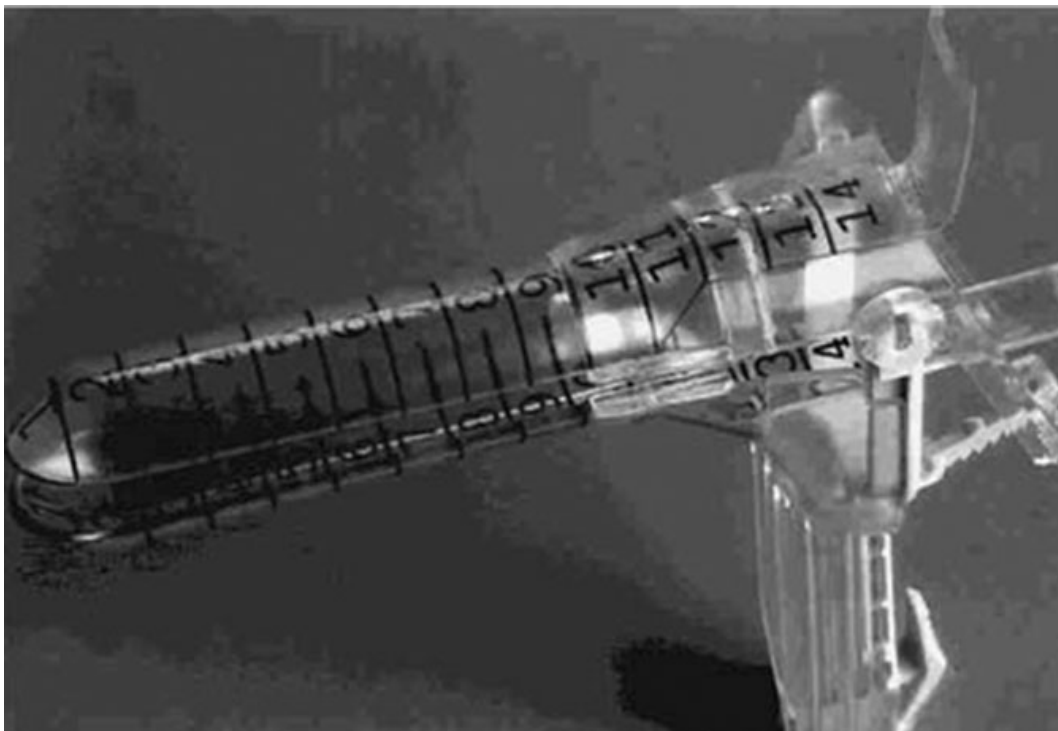


Figure 2 : Speculum with adjustable blades and scale markings designed to allow easier assessment of pelvic organ prolapse using the POP-Q system. (Diokno AC, Borodulin G. A new vaginal speculum for pelvic organ prolapse quantification (POPQ). *Int Urogynecol J Pelvic Floor Dysfunct.* 2005 Sep-

pelvic organ prolapse researchers. In addition to collecting specific centimetre measures, an ordinal stage (0-IV) can be assigned.

Absence of prolapse is categorised as stage 0 support; prolapse can be staged from stage I to stage IV. The clinical utility of such a classification might be questioned, since clearly some degree of descent is the norm especially in a parous population. In a study of 477 women attending for annual gynaecological examination, Swift et al found that the average number of positive responses to a 7-question prolapse questionnaire was 0.27 in patients with stage 0 prolapse, 0.55 for stage I, 0.77 for stage II, and 2.1 for stage III. They concluded that women with prolapse with the leading edge beyond the hymenal ring had a significantly increased likelihood of having symptoms. In a general population of Swedish women ages 20-59, the prevalence of prolapse was found to be 31%, whereas only 2% of all women had a prolapse that reached the introitus. It might seem more reasonable therefore to define prolapse not on the basis of any finding greater than stage 0, but on the basis of findings with a significant likelihood of being associated with symptoms.

Urinary incontinence and pelvic organ prolapse are separate clinical entities which often coexist. Significant protrusions of the vagina can obstruct voiding and defecation. Surgical repair of one pelvic support defect without repair of concurrent asymptomatic pelvic support defects appears to predispose to accentuation of unrepaired defects and new symptoms. Women with pelvic organ prolapse may have to reduce their prolapse in order to void. Women with pelvic organ prolapse and a large PVR should be evaluated for voiding phase dysfunction (e.g., outlet obstruction, detrusor hypotonia).

Although anatomy can be measured and assessed accurately, reproducibly and reliably, the relationship of these anatomic findings with functional abnormalities is not well understood. For example, support abnormalities in the anterior vaginal wall are common in vaginally parous women; however, stress urinary incontinence is not always associated with this anatomic alteration. Likewise, distal posterior vaginal wall support abnormalities may exist with or without defecation abnormalities. The important relationships between anatomy and function are one of the most pressing research needs in the field of physical examination for women with pelvic organ prolapse.

Other important research needs include the development of clinically relevant ordinal staging that more appropriately separates meaningful prolapse from anatomic changes following vaginal delivery. Such revised staging would allow a meaningful dialog about the appropriate surgical indications for pelvic organ prolapse and development of clinically relevant anatomic outcome measures.

7. RECTAL EXAMINATION

Digital rectal examination allows the description of observed and palpable anatomical abnormalities and is the easiest method of assessing pelvic floor muscle function in children and men. In addition, rectal examination is essential in children with urinary incontinence to rule out faecal impaction. In all women a digital rectal examination is also performed to assess sphincter tone (both resting and active) and to detect faecal impaction or a rectal mass.

8. ADDITIONAL BASIC EVALUATION

a) Pad tests

The objective of pad testing is to quantify the volume of urine lost by weighing a perineal pad before and after some type of leakage provocation. This test has also been used in an attempt to distinguish continent from incontinent women. Pad tests can be divided into short-term tests, usually performed under standardized office conditions, and long-term tests, usually performed at home for 24–48 hours. Pad tests are generally performed with a full bladder or with a fixed known volume of saline instilled bladder before beginning the series of exercises. A pad weight gain >1 g is considered positive for a 1-hour test, and a pad weight gain >4 g is positive for a 24-hour test. There is wide variation in the pad weight gain in incontinent women participating in clinical trials. Although some studies have found high test-retest correlations in pad tests [142,143], other studies have reported low inter-subject and intra-subject reliability [144,148]. Traditional pad testing may be negative in women with mild leakage; an alternative “paper towel test” was shown to be a simple and reliable measure of cough-related urine loss typical of mild stress incontinence. (149) Long-term tests are more reproducible. The correlation coefficient between total leakage during two 24-hour pad tests is good, at 0.66 [150] and 0.82 [151] and increased to 0.90 in one study in which two 48-hour periods were compared. There was no correlation between the leakage volume found in the 48-hour test and a standard 1-hour test.

b) Dye testing

When it has proved impossible to confirm a patient's complaint of urinary leakage, it may be appropriate to seek to confirm firstly that the reported discharge is in fact urinary, secondly that the leakage is extra-urethral rather than urethral, and thirdly to establish the site of leakage. Although other imaging techniques undoubtedly have a role in this regard, carefully conducted dye studies should be considered. Excessive vaginal discharge or the drainage of serum from a pelvic haematoma postoperatively may simulate a urinary fistula. If the fluid is in sufficient quantity to be collected, biochemical analysis of its urea content in comparison to that of urine and serum will confirm its origin. Phenazopyridine may be used orally (200mg

tds), or indigo carmine intravenously, to stain the urine and hence confirm the presence of a fistula. The identification of the site of a fistula is best carried out by the instillation of coloured dye (methylene blue or indigo carmine) into the bladder via catheter with the patient in the lithotomy position. The traditional 'three swab test' has its limitations and is not recommended; the examination is best carried out with direct inspection; multiple fistulae may be located in this way. It is important to be alert for leakage around the catheter, which may spill back into the vagina creating the impression of a fistula. It is also important to ensure that adequate distension of the bladder occurs as some fistulae do not leak at small volumes; conversely, some fistulae with an oblique track through the bladder wall may leak at small volumes, but not at capacity. If leakage of clear fluid continues after dye instillation a ureteric fistula is likely, and this is most easily confirmed by a 'two dye test', using Phenazopyridine to stain the renal urine, and methylene blue to stain bladder contents[152]

c) Pelvic floor muscle strength

Pelvic floor muscle function: can be qualitatively defined by the tone at rest and the strength of a voluntary or reflex contraction as strong, weak or absent or by a validated grading system (e.g. Oxford 1-5). A pelvic muscle contraction may be assessed by visual inspection, by palpation, electromyography or perineometry. Factors to be assessed include strength, duration, displacement and repeatability.

The continence mechanisms imply that integrity of the levator ani and external urethral sphincter is necessary to maintain continence [153]. It is therefore important to test the contractility of these muscles. Once the patient understands how to contract the pelvic floor muscles correctly, the evaluation is carried out during a maximum contraction [154].

STRENGTH is defined as the maximum force or tension generated by a muscle or muscle group [155]. It reflects the power, endurance and functional status of the muscle.

WEAKNESS is defined as failure to generate the expected force.

FATIGUE is defined as failure to maintain the expected force with continued or repeated contraction [156].

When considering methods/devices used to measure pelvic muscle strength, cost and availability should be recognized as important factors. Four methods of assessment are considered here: observation, digital palpation, perineometry and cotton swab (Q-tip) testing.

Observation - This qualitative measure can detect an in-drawing of the anus, lifting of the posterior vaginal wall and narrowing of the vaginal introitus (females); an in-drawing of the anus and slight lifting of the penis (males).

- **Advantages:** Suitable for both sexes and all age groups, where an internal evaluation may be inappropriate. Inexpensive. Able to detect reflex contraction with cough, and bulbo-cavernosus reflex. Observe accessory muscle activity.
- **Disadvantages:** Subjective. Cannot distinguish right and left sides independently. Generally observing activity of the superficial perineal muscles, and assuming levatores are responding in a like manner. Difficult to observe when the patient is standing.

Digital palpation - Palpation of the right and left levator ani, per vaginam. Palpation of the perineal body.

- **Advantages:** Suitable for both sexes. Inexpensive. Able to differentiate right from left. Quantitative - using modified Oxford scale or other systems [157,158]. Able to measure strength and endurance. Can detect reflex contraction with cough and patient's ability to hold contraction during a cough. Can be used when the patient is standing.
- **Disadvantages:** Subjective. Not sensitive.

Perineometer - Manometric measure of change in a vaginal/anal pressure probe. Sensitivity depends on the device.

- **Advantages:** Relatively inexpensive. Able to measure strength and endurance. Quantitative. Can be used when the patient is standing.
- **Disadvantages:** Unable to distinguish right from left. Pressure changes may be caused by increase in intra-abdominal pressure, due to co-contraction of the abdominal muscles. No 'Gold Standard' device; different results with different probe sizes and materials [159].

Cotton swab (Q-tip) test Downward, posterior movement of stem (measured on a goniometer) is dependent on the strength of the contraction of the pubo-coccygeus muscles, and mobility of the urethra [160].

- **Advantages:** Inexpensive. Can measure strength and endurance.
- **Disadvantages:** Lacks sensitivity and specificity. Invasive. Females only.

The information learned from assessment of pelvic floor muscle strength has the following practical applications:

1. The patient has good pelvic floor muscles that need skill training to help maintain continence. DeLancey and associates have described 'knack' teaching [161,162].
2. The patient has weak muscles that are capable of contracting but need strength and skill training.

An effective exercise program should increase resting tone (Type I fibres) as well as improve the ability of fast twitch (Type II) fibres to respond to increases in intra-abdominal pressure [163].

3. The patient has no perceptible contractions and needs further evaluation (EMG, MRI, neuro-physiologic testing) or passive contraction therapy i.e., functional electro stimulation.

Recommendations

1. Although the value of individual urinary symptoms and symptom complexes in predicting the underlying abnormality of lower urinary tract function is not high, a significant proportion of women with stress incontinence can be correctly diagnosed from basic evaluation only. Grade C
2. The frequency/volume chart or urinary diary is the most effective additional test for use alongside basic evaluation in primary or secondary care. Grade C
3. In assessing patients with urinary or faecal incontinence, the clinician should consider all aspects of pelvic floor dysfunction, i.e. urinary, bowel, prolapse, and sexual function. Grade D
4. Prolapse visible at the introitus or below may be associated with symptoms (Level 3) In describing patients with pelvic organ prolapse, one of the several systems available for classification and quantification of urethral hypermobility and pelvic prolapse should be employed. The ICS recommends the POP-Q. (Grade D). In addition, an assessment of pelvic floor identification and strength should be considered. Grade D

Future research

1. Correlation of symptoms and physical findings with urodynamic and colorectal investigations, and both basic and complex evaluations with treatment outcomes.
2. The development of a clinically relevant ordinal staging that meaningfully separates significant from insignificant pelvic organ prolapse.
3. Impact of surgical interventions for incontinence on pelvic organ support, and for pelvic organ prolapse on continence mechanisms.

V. THE MALE PATIENT

1. CHARACTERISTICS OF MALE INCONTINENCE?

In the male patients, lower urinary tract dysfunction, and obstruction from benign prostatic enlargement presents a multi-factorial paradigm for symptom aetiology. Lower urinary tract symptoms (LUTS) in men have a significant effect on quality of life (QOL), as compared with the unaffected general population. [163]. Several epidemiological reports demonstrated that overactive bladder (OAB) syndrome also increase with age in men [164,165]. Older age and higher grade of obstruction has been reported in men with bladder outlet obstruction and idiopathic detrusor overactivity [166].

In the NOBLE study, a different sex-specific pattern emerged for OAB with or without urge incontinence [165]. The prevalence of OAB with urge incontinence displays a steeper age-related increase among women than among men and the gender difference is statistically significant. In women, OAB with urge incontinence increased more than nine-fold from 2.0 % in those 18-24 years of age to 19.1% among those 65-74 years of age. In contrast, a substantial increase in prevalence of OAB with urge incontinence among men did not occur until 65 years of age, reaching 8.2% for ages 65-74 years and 10.2% for those 75 years and older. In men, OAB without urge incontinence increased approximately three-fold, from 8.5% below 45 years of age to 21.8% after 55 years of age, whereas OAB without urge incontinence gradually increased in women less than 44 years of age and reached a plateau in women over the age of 44 years.

'Prevalence ratios for OAB with urge incontinence and for OAB without incontinence were significantly elevated for men who self-reported with a history of prostate problems. Thus, the evaluation of men with symptoms of OAB syndrome depends on the identification and assessment of lower urinary tract obstruction that may be a cause (in part or in entirety) of the presenting symptoms.

The aetiology of obstructive symptoms may vary, from benign prostatic hyperplasia (BPH), urethral stricture, primary bladder neck dysfunction, or abnormal voiding dynamics of detrusor. Chronic prostatic pain syndromes (e.g. non-bacterial chronic prostatitis) and other pelvic floor dysfunctions can also present with

a component of symptoms compatible with OAB. In younger men, primary bladder neck dysfunction is a common cause of LUTS, with or without pelvic pain [167]. Functional abnormalities of striated sphincter relaxation may also occur in young men [168]. The complexity of the presenting symptoms and the various differential diagnoses mandate a thorough basic assessment of the lower urinary tract in men to plan optimal therapeutic intervention.

Another important issue in male patients is incontinence after surgery or intervention for BPO and prostate cancer. A survey in England of 5276 patients who had undergone TURP found that one-third of men (n=1759 men) who were continent before surgery reported some incontinence 3 months post TURP [169]. Recently many minimally invasive and surgical techniques in management of BPO have been reported. A systematic review of the literature showed Urinary incontinence is more often seen following TURP (1.4%). The rate of urinary incontinence after other techniques are as follows: HIFU: 0.0%, ILCP: 0.1%, TUMT: 0.1%, TUNA: 0.0%, TUVP: 0.9%, VLAP: 0.2%, HoLEP: 1.2% [170].

It has been reported that after permanent prostate brachytherapy, urinary incontinence was observed 0-19% [171]. After radical prostatectomy, Donnellan et al reported that 6 % of men were mildly incontinent, 6 % were moderately incontinent and 4 % were severely incontinent at 1 year after surgery [172]. Carson et al. reported that incontinence occurs in 0.5 to 1.0% of all patients undergoing prostatectomy for benign disease; high rates (5 to 30%) are associated with radical prostatectomy [173].

Although prostate-ctomy has a clinically significant beneficial effect on LUTS with significant improvements of AUA symptom index and flow rate, [174, 175] urinary leakage can have a major impact on QOL. Greater degrees of urine loss are correlated with greater bother and more significant life-style changes [172]. A Medicare survey by Fowler showed that in 1072 patients, more than half of the patients with urinary leakage considered it to be a medium or large problem [176]. In spite of these findings, many investigators have been encouraged by overall patient satisfaction with surgery and patients willingness to undergo surgery again, if faced with the same situation [176].

In the immediate postoperative period, stress and urge incontinence are common. This has been attributed to varying degree of oedema and inflammation present in the healing prostatic urethra. The majority of men achieve continence without invasive intervention following total prostatectomy. Final continence status should be measured using self-administrated disease specific instruments at 24 months after operation [176]. And no factors (age, severity of LUTS, Gleason score, bilateral nerve sparing surgery and estimated blood loss) were

identified that predicted early return of continence [172].

Post-prostatectomy incontinence may be caused by sphincter malfunction and/or bladder dysfunction. [177,178]. Urinary control in the adult male depends on integrity of both the internal and external sphincters. During TURP, the internal sphincter mechanism is virtually destroyed, and in some cases, the external sphincter is also damaged. Thus post-prostatectomy stress incontinence may result.

In a recent study of patients undergoing radical prostatectomy that specifically evaluated detrusor dysfunction [179] de novo detrusor underactivity and impaired or poor compliance, presumed to be a consequence of bladder denervation, occurred in a limited proportion of patients (28.6% and 18.4% respectively), and this bladder dysfunction resolved in the majority within 8 months. Detrusor underactivity and decreased bladder compliance are also pre-existing conditions in about 30% and 20% of patients.

The conditions relate to the presence of BOO, and they do not appear to be influenced by prostatectomy. Persistent detrusor overactivity after obstruction relief is probably related to concomitant sphincter deficiency and stress urinary incontinence, which increase afferent nerve activity of the proximal urethra and induce involuntary detrusor contractions [180].

Obstruction after prostatectomy, resulting from an anastomotic stricture or residual prostatic tissue (post TUR-P), may also play an important role in the development of post-prostatectomy incontinence. Obstructing stricture often causes increase in post-void residual urine, resulting in the urinary leakage and/or a weak urinary stream. It has been reported that the anastomotic stricture treatment rates after radical prostatectomy are 16% to 33% [181,182].

2. GENERAL MEDICAL HISTORY

The medical history should focus on the urinary tract, previous surgical and radiation therapy history, medical condition and symptoms that may cause to bladder dysfunction or polyuria, familial history of prostate diseases (BPH and cancer), and a review of sexual and bowel habits. Urinary incontinence is rare in men without a history of previous trauma or prostatic or pelvic surgery; therefore, neurogenic bladder dysfunction must be considered in men with no history of surgery or trauma. A critical assessment of current medications is recommended to exclude the effects of any pharmacological agents on lower urinary tract function.

In the evaluation of the patients with post-prostatectomy incontinence, an important aspect of the history should be a description of the type and severity of incontinence and precipitating events, Severity may be determined by the number of episodes per day, the

need for protection (e.g., pads, penile clamp, external catheter), and the impact of incontinence on activities of daily living. Bladder diaries and pad tests can quantify severity. The presence of other LUTS such as OAB and decreased force of urinary stream should be determined.

3. SYMPTOM ASSESSMENT

Diagnostic evaluation of men with LUTS depends on an initial estimation of subjective bother and objective data on bladder emptying. Because the occurrence of LUTS does not necessarily indicate concomitant prostate enlargement and/or obstruction, specific modalities should be used to ascertain the potential for the aetiologic role of these entities. A bladder diary may be useful in almost all male patients, especially in those with OAB. Bladder diary completion by the patient provides useful evidence about the normal urinary habits of the patient, including giving some estimate of bladder capacity and diurnal and nocturnal frequency, urgency and incontinence. The data obtained from frequency-volume chart provide a strong correlation to cystometric capacities and are reasonably immune to the effect of detrusor overactivity in men with LUTS [183]

A variety of symptom scores have been described to assess male patients with LUTS. In men, the American Urological Association symptom score for BPH (AUA-7) is most commonly used in North America for assessment of subjective symptoms. However, equally reproducible data can be obtained from the International Prostate Symptom Score (IPSS), the ICSmale questionnaire (now renamed the ICIQMLUTS, long and short forms, as part of the ICIQ modular questionnaire: www.iciq.net).

The IPSS has been the most widely used (in many countries and languages), but neglects the symptom of urgency incontinence, a symptom that produces significant bother. The ICIQMLUTS (ICSmale-SF) is slightly longer, but takes into account the symptom of urgency incontinence, and in fact may be divided into voiding and incontinence subscores. To date, it has not been as widely used as the IPSS, but may see more widespread use as part of the ICIQ Modular Questionnaire.

Among LUTS, urgency, nocturia, and hesitancy are most bothersome, whereas weak stream, urgency, and frequency are the most prevalent in pooled populations being evaluated for BPH [184] Post-micturition dribbling is often provoked by an obstructing disease such as BPH or urethral stricture but can also be a symptom of a urethral diverticulum. Post-void residual urine volume and careful palpation of the genitalia are recommended in these patients.

To determine the cause of post-prostatectomy incontinence, many studies have stressed the lack

of reliability of symptoms and emphasised the important role of urodynamic testing [185,186]. Nevertheless, valuable information can be gained from a careful history with regard to incontinence, especially when related to sphincter dysfunction. The symptom of stress incontinence is highly predictive of the presence of sphincter dysfunction. Chao and Mayo found that 67 of 71 men with post-prostatectomy incontinence secondary to sphincteric dysfunction complained of the symptom of stress incontinence [187]. Similarly, Ficazzola and Nitti found 95% positive predictive value and a 100 % negative predictive value for symptom of stress incontinence [177]. Urge incontinence as a predictor of bladder dysfunction does not seem to be as valuable, and the presence of bladder dysfunction cannot be determined accurately without urodynamic testing [177,187].

4. PHYSICAL EXAMINATION

A general physical examination with specific attention to the presence or absence of a distended bladder, excoriation of the genitals secondary to urinary incontinence, evidence of urethral discharge and a focused neurological examination is also highly recommended.

The assessment and treatment algorithm focuses on the abdominal examination, digital rectal examination (DRE) and neurological testing of the perineum and lower extremities. In a patient suspected of neurogenic bladder, evaluation of perineal sensation and lower extremity neuromuscular function, and anal sphincter tone, which is often decreased in neurogenic patients [188] is important. A focused neurogenic examination should also assess the patient's general mental status and ambulatory status. The examination should also include external genitalia, location of the urethral meatus, retractability of the foreskin and evidence of congenital malformation. Abdominal palpation should be performed to evaluate bladder distension, especially in elderly incontinent men, who may have overflow leakage due to obstruction. In patients suspected of urinary retention, post-void residual volume (PVR) should be measured. The patients with incontinence should be asked to cough and to perform a Valsalva manoeuvre so that the presence of stress incontinence can be ascertained.

DRE should include palpation of the prostate to assess size, symmetry and consistency of the gland and its relation to the pelvic sidewall and the rectum. The locally advanced prostatic cancer can also produce OAB-like symptoms. DRE may exclude prostatic cancer, although its specificity and sensitivity is low [189] DRE tends to underestimate the true prostatic size: if the prostate feels large by DRE, it usually also is found to be enlarged by ultrasound or other measurement technique [190, 191]. Prostate volume has been recently associated with the risk of BPH

progression [192] and response to treatment [193]. It has been reported that men with BPH with idiopathic detrusor overactivity showed a significantly higher incidence (54%) of intravesical protrusion of the prostate [194]. This finding suggests that intravesical protrusion may in some way increase afferent impulses from the prostate and alter the stability status of the bladder. Occasionally tumours of the anal canal can be diagnosed while performing DRE of the prostate.

Incontinence combined with evacuation problems in a man often requires further investigation including urodynamics. It may be helpful to ask these patients to measure the voiding time for the first voided 100 ml on several different occasions.

5. URINALYSIS AND URINE CYTOLOGY

Bladder cancer, carcinoma in situ of the bladder, urinary tract infections, urethral strictures, and bladder stones can cause OAB-like symptoms in aged men. Although haematuria or pyuria is not universally present in those conditions, urinalysis is important to rule out these diseases. Urinalysis is not a single test, complete urinalysis includes physical, chemical, and microscopic examinations. Dipstick urinalysis is certainly convenient but false-positive and false negative results may occur. It is considered an inexpensive diagnostic test able to identify patients with urinary tract infection as indicated by the presence of leucocyte esterases and nitrites. A substantial proportion of older patients with chronic OAB-like symptoms have significant bacteriuria, sometimes accompanied by pyuria. In men, recent urinary tract infections were associated with OAB without urge incontinence (prevalence ratio=2.9; 95% CI: 1.6-5.0) [165].

However, infection may exist in the absence of pyuria and, in the elderly population, pyuria may develop in the absence of urinary tract infection. Microscopic haematuria can be easily identified by dipsticking because of the presence of haemoglobin. The detection of haematuria is important because the condition is associated with a 4-5% risk of diagnosing urological disorder or malignancy within 3 years. Because of the high prevalence of urinary tract infection and the increase of LUTS in the presence of urinary tract infection, all guidelines on the management of patients with LUTS suggestive of BPO, and urinary incontinence, endorse the use of urinalysis in primary care management [195,196].

Urine cytology is also recommended in male patients with haematuria and a predominance of storage symptoms, especially with a history of smoking or other factors, to aid in the diagnosis of bladder carcinoma in situ and bladder cancer

6. MEASUREMENT OF THE SERUM CREATININE

Epidemiological studies in community dwelling men

have shown the absence of any association between BPO / BPE / BPO and chronic kidney disease [197] suggesting that screening for renal function is not justified in male patients. Recently, data from the MTOPS study showed that the risk of developing de novo renal failure in men with LUTS is low (less than 1 %) suggesting that is not necessary to monitor renal function in patients with LUTS / BPO [197].

7. MEASUREMENT OF THE SERUM PROSTATE-SPECIFIC ANTIGEN (PSA)

In most patients, a normal DRE may be sufficient to exclude locally advanced cancer as a cause of LUTS or OAB. There is no consensus as to the measurement of prostate specific antigen (PSA) in patients with LUTS. The rationale for measuring PSA is twofold: to screen for prostate cancer [198] and to measure a parameter with prognostic value for the progression of BPH and the response to treatment [192,193]. Because prostatic cancer is one of the potential causes of LUTS or OAB in men, PSA (together with DRE) is a relatively sensitive way to exclude prostatic cancer as a diagnosis [199,200].

However, it is important to understand that about 25% of men with BPH have a serum PSA greater than 4 ng/ml. Because of the overlap between serum PSA values in men with BPH and those with clinically localised prostate cancer, other parameters (PSA velocity, free/total PSA ratio, complexed PSA and PSA density) will assist diagnostic specificity [201, 202]. It has been suggested that a relationship between initial PSA level and subsequent prostate cancer detection with a stepwise increase in cancer detection rate (from <1% to 58%) in patients with <1.0 ng/ml, 1.1-2.5, 2.6-4.0, 4-1-10.0 and >10 ng/ml PSA value in over 26,000 patients enrolled in a screening programme [203]. In addition, Thompson reported data on prostate cancer prevalence from the prostate cancer prevention trial [204] confirming a stepwise increase in the risk of having a prostate cancer in patients with serum PSA from 0.5 to 4.0 ng/ml but showing the limitation of the current threshold of 4.0 ng/ml. Change of PSA threshold from 4.0 to 2.0 ng/ml has been proposed but currently no consensus exists [205]. PSA measurement is recommended in men with LUTS and a life expectancy of over 10 years in whom the diagnosis of prostate cancer would change the management of patient's symptoms.

It has been reported that the role of IPSS score in the assessment of BOO is questionable, and that the grade of obstruction is more related to prostate volume, PVR, and Qmax [44]. It has been demonstrated that moderate-to-severe LUTS in men can result in urinary retention. The incidence of retention in men with untreated LUTS in community-based trials is 6.8 per 1000 during longitudinal follow-up of 4 years [206]. If only patients with moderate-to-severe symptoms are considered, the rate of retention increases to 25 per 1000 [207]. Moreover, in considering men with weak

urine flow, symptoms, and increased age, without urodynamic evaluation, other parameters become independently predictive of the development of acute urinary retention. In a meta-analysis of predictors of retention in pooled groups of placebo patients from clinical trials of men with LUTS undergoing active interventions (4300 patients), Roehrborn et al. found prostate-specific antigen and prostate volume to be strong independent predictors of urinary retention and the need for surgery in men with LUTS followed up longitudinally in clinical trials [191,208].

Recently, Laniado et al (2004) [209] have also tested the hypothesis that PSA level could be used to predict the presence or absence of BOO, evaluated by pressure flow studies. In patients with LUTS, those with a PSA more than 4 ng/ml are significantly more likely to have some degree of BOO. Conversely patients with PSA less than 2 ng/ml have a 33% risk of BOO.

Therefore, on the basis of these trials, untreated LUTS may place the male patient at risk for potential clinical deterioration. Thus, periodical measurements of PVR are recommended in such patients.

Recommendations

1. Male patients differ from female patients in the presentation of LUTS. The incidence of OAB wet is lower until the 7th decade. (Level 2)
2. Urinary stress incontinence is primarily associated with surgery of the prostate in male patients. (Level 2)
3. Disorders of bladder emptying from benign prostatic enlargement should be considered before treating male patients for OAB symptoms. (Level 2) ((Grade B).

Future research

1. 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.
2. Development of simple, non-invasive, cost-effective methods to determine the contribution of bladder storage and bladder emptying abnormalities in male patients.

5A- B. INITIAL ASSESSMENT OF FAECAL INCONTINENCE

I. FAECAL INCONTINENCE ASSESSMENT

Basic assessment of faecal incontinence focuses on determining:

1. Type of incontinence
2. Functional limitations resulting from incontinence
3. Cause(s) of incontinence

1. HISTORY

History gathering requires particular tact in dealing with this taboo symptom, but also a willingness to ask direct questions about the complaint. In taking a history, the necessary first step is to determine the nature of the incontinence being experienced by the patient. True faecal incontinence must be differentiated from conditions that cause seepage such as external haemorrhoids, fistulas, low rectal or anal tumours, and poor perineal hygiene.

Diagnostic administration of an enema may be useful in this respect; retention of the enema suggests that the patient does not have clinically significant faecal incontinence. This serves to both clarify the patient's history, but also begins to suggest the anatomical deficit causing the incontinence (see below). The key importance of the history and examination is to identify any conditions that are amenable to condition specific management – these are cited in logical sequence in the text below, and listed in the recommendation box.

a) Type of incontinence

- *Flatus incontinence* – incontinence of flatus due to inability to differentiate gas from solid or liquid
- *Passive leakage* – involuntary soiling of liquid or solid stool without patient awareness
- *Urge incontinence* – inability to defer defaecation once the urge is perceived, for long enough to find a toilet

The first two forms are primarily related to internal anal sphincter dysfunction, the latter form due to external anal sphincter dysfunction. (Grade B) [210]. Soiling after defaecation is typically related to either a defect in the internal sphincter or poor “snapping shut” of the external sphincter after voiding. (Grade C) [211]. It is also important to determine if the incontinence is for solid or only liquid stool; if for liquid stool, the possibility of a colonic cause of diarrhoea needs to be considered. (Grade B) [212].

b) Functional status

After confirming the nature of faecal incontinence, it is necessary to determine the impact of the condition on a patient's lifestyle and quality of life. This assessment offers the opportunity to both empathise with the patient and to understand the pertinent emotional and social factors in the manifestation of symptoms. The history should include:

- Need to wear tissues or pads in underwear – indication of severity. (Grade B) [213-215]
- Degree of soiling of tissues, pads or underwear. (Grade C) [213,215]
- Duration, frequency and timing of incontinence episodes – indication of severity. (Grade C) [213,216]

Ability to wear clothing of choice, eat food of choice, participate in work and social activity. (Grade C) [213,216]

Severity of faecal incontinence can be classified as:

- minor - if faecal seepage occurs less than once a month,
- moderate - if there is incontinence to solids more than once a month or liquids more than once a week, and
- severe - if there is loss of control of solids several times a week or liquids on a daily basis.

An alternative classification grades continence as follows:

Grade 1: Complete

Grade 2: Incontinence of flatus

Grade 3: Incontinence of flatus and liquid stools

Grade 4: Incontinence of flatus, liquid stools, and solid stools.

c) Aetiology

A careful, thorough history and full physical examination are essential and will identify the majority of causes of faecal incontinence. The history should include:

- Dietary history – in particular excess ingestion of sorbitol and caffeine. (Grade C) [217]
- Medical history – particularly anti-anginals, anti-hypertensives which may reduce sphincter tone, and ferrous sulphate or antacids which may provoke diarrhoea. (Grade C) [214]
- Presence of benign anal disease – haemorrhoids, fistula, anal warts. (Grade B) [218]
- History of chronic straining – suggestive of rectal mucosal prolapse, an important cause of internal anal sphincter dysfunction. (Grade B) [219]

- Obstetric history – particularly with regard to: (Grade B) [220,221]
 - number of vaginal deliveries
 - need for forceps or Ventouse
 - birth weights
 - duration of second stage(s)
 - episiotomy
- Perianal surgery history – particularly: (Grade B) [222]
- Anal fissure surgery (sphincterotomy or anal stretch)
- Fistula surgery
- Low colonic resection surgery
- History of pelvic radiation – risk of radiation proctitis (causing heightened rectal contractions) and internal anal sphincter radiation damage (Grade B) [223]
- Symptoms of other pelvic floor problems (urinary incontinence and pelvic organ prolapse), which have similar risk factors should be elicited (Grade C) [224]
- Cognitive assessment in appropriate patients (Grade C) [225]

2. EXAMINATION

Examination is focussed towards the detection of evidence of incontinence and identifying the cause of incontinence.

a) Evidence of incontinence

Physical examination should include inspection of underclothing for soiling and staining by stool, pus, or mucus.

Perianal skin should be examined for irritation and excoriation due to over-zealous hygiene. Perianal inspection should include attempts to identify the following: (Grade B) [215,226,227]

- Perianal excoriation or erythema – suggestive of chronic passive soiling
- A patulous anus or one which gapes on gentle traction of the anal verge
- A “keyhole” deformity of the anal canal – suggesting a persisting sphincter defect

b) Cause of incontinence

Inspection may reveal scars from previous episiotomies or obstetric tears. Abnormalities at the anal verge from previous surgery or a gaping anus suggestive of marked loss of function may be present. Perianal inspection should identify: (Grade C) [215, 226,227]

- Scars from previous surgery
- Perianal disease – prolapsing haemorrhoids, fistula, anal warts
- Absence of perineal body – suggestive of obstetric trauma; at its worst this may manifest as a cloacal deformity
- Inspection for sphincter asymmetry whilst patient contracts sphincter – suggestive of regional sphincter defect
- Function of the puborectalis muscle (palpable at the anorectal junction) is assessed by asking the patient to squeeze the sphincter at which time the puborectalis should push the examiner's finger anteriorly.

Digital examination should identify: (Grade C) [210,226,227].

- Rectal content – if faecal impaction is present this could explain incontinence
- Resting tone – indicative of internal anal sphincter function
- Voluntary and involuntary squeeze pressure – indicative of external anal sphincter function and potential function, respectively. The latter is elicited most commonly by asking the patient to cough while assessing sphincter tone – a cough causes a near-maximal external sphincter contraction (analogous to the guarding reflex in the bladder)
- Regional sphincter defects – detected as asymmetry
- A thickened sphincter – suggestive of chronic straining and occult rectal mucosal prolapse

If suggested by earlier findings (history of straining, thickened sphincter), the patient should be asked to sit on a commode and attempt voiding – the perineum should then be inspected for evidence of a rectal mucosal or full thickness prolapse (Grade C) [219]

Proctoscopy or rectosigmoidoscopy with a rigid instrument is a bedside test of value in excluding potentially treatable causes of faecal incontinence:

- Anal tumours or polyps
- Low rectal cancers or adenoma (Grade B) [228].
- Solitary rectal ulcer syndrome – a functional disorder of evacuation, in which repeated straining at stool and rectal self-digitation results in an ulcerated area of the anterior rectal wall (Grade) [229].

Vaginal examination using a Simms speculum may show a rectocele, cystocele and/or uterine prolapse, all of which may contribute to developing faecal incontinence (Grade C) [230].

Physiological and complimentary radiological tests are used to confirm clinical suspicions and provide objective data on the function of the anorectum. Pelvic floor dysfunction is a complex problem and multiple tests may be needed based on the initial findings and complexity of the planned intervention.

KEY RECOMMENDATIONS FAECAL INCONTINENCE

- It is essential to perform a baseline assessment comprising:
 - focussed medical history
 - a general examination
 - an anorectal examination

a cognitive assessment (when appropriate)

- The following conditions should be specifically assessed for as they may be amenable to definitive treatment:
 - rectal prolapse or third-degree haemorrhoids
 - faecal loading
 - potentially treatable causes of diarrhoea (eg inflammatory bowel disease and irritable bowel syndrome, infection, adenomas)
 - acute anal sphincter injury including obstetric and other trauma
 - acute disc prolapse/cauda equina syndrome

Future research

- Development and validation of a digital (finger) instrument to assess anal sphincter function (analogous to the instrument in existence for urological assessment of pelvic floor musculature).
- Development of a psychometrically valid and reproducible instrument to assess quality of life in faecal incontinence.

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Committee 5 B

Patient-Reported Outcome Assessment

INTRODUCTION

In the first three International Consultations on Incontinence reports, the impact of incontinence on quality of life (QoL) and methods of measuring these factors were described with questionnaire recommendations for use in research and clinical practice [1, 2]. This triennial update is a departure from previous reports in that the scope of this chapter encompasses not only quality of life, but all patient-reported outcomes (PRO); and will also include a review of screening tools, not just outcome measures. Additionally, this chapter will extend and update the prior literature reviews of PROs, broaden the review to include lower urinary tract (LUTS) and bowel incontinence outcomes measures, and provide recommendations for questionnaire selection for use in clinical practice and research. In addition, this summary will review the purpose and content of the ICI questionnaire (ICIQ) modules. Given the burgeoning literature in this area, a complete review of all studies with PROs will not be provided, but rather PRO highlights will be included.

The expansion in scope of this review to include all types of patient reported outcomes (PRO) is an important step in recognising the inherent conceptual differences of various PROs each with different assessment goals. A PRO is an objective assessment of the patient's subjective experience and can include aspects of the patient's health. 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 (**Figure 1**). 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. For example, if the goal is to assess treatment satisfaction, then a treatment satisfaction measure should be incorporated into the study design or as a clinical outcome. The matching of appropriate PRO selection with one's desired

"Outcomes" claims classification

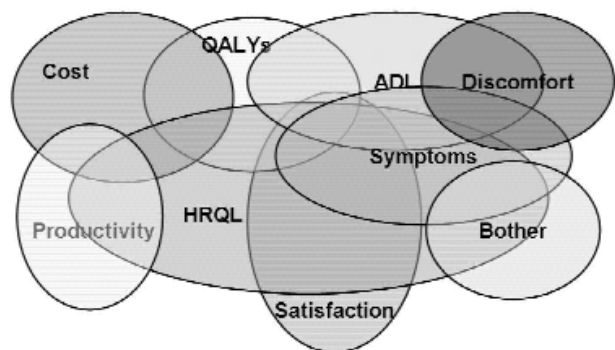


Figure 1 : Patient-Reported Outcomes Assessment Areas. Burke L, Evidence Review Branch DDMAC, FDA; DIA Workshop on pharmacoeconomic and Quality of Life Labeling and Marketing Claims New Orleans October 3, 2000

outcomes is critical to success when assessing PRO's and will be reviewed further in this chapter.

Ultimately, the last decade has been one of tremendous growth in the area of PROs with influences from scientific and regulatory communities. As such, the ICI will endeavour to continually update the recommendations it offers on the basis of emerging data and published evidence based on the sound and rigid recommendations of the previous three reviews.

LITERATURE SEARCH STRATEGY

A number of different electronic databases were searched, limited to adults over the age of 18 years and human studies from January 2004 to June 2008, including Pub-Med, Medline, PsychInfo, the LOCATORplus database for books, serial titles and audiovisuals, the Cochrane Library for randomised controlled trials, and the NLM Gateway database. The following keywords were used separately and/or

in combination: “urinary incontinence”, “urinary symptoms”, “urgency”, “overactive bladder”, “stress incontinence”, “incontinence”, “questionnaire”, “epidemiology”, “prostate”, “prolapse”, “fecal”, “faecal”, “bowel”, “anal” and “quality of life”, “sexual” and “health utilities”. Questionnaires identified in previous ICI reports were also searched in PubMed and Medline.

5B- A. THE MEASUREMENT OF PATIENT-REPORTED OUTCOMES (PROS) OF INCONTINENCE, OTHER LOWER URINARY TRACT SYMPTOMS, AND BOWEL PROBLEMS

Incontinence and other lower urinary tract symptoms (LUTS) as well as bowel problems and their impact on patients and their lives can be assessed in a number of ways. Traditionally, the clinical history has been used to gain a summary view of the symptoms experienced by patients and in some cases the impact on their lives. Increasingly however, patient-completed methods of measuring incontinence and LUTS are being used, including voiding diaries and questionnaires.

Patient self-completed questionnaires or patient reported outcomes (PROs) represent the most important clinical review of symptom impact and treatment benefit from a patient perspective. PROs provide a method for the standardised collection of data, or an objective assessment of a subjective

phenomenon, from patients relating to incontinence, other LUTS, and bowel problems. Clinicians’ assessments of patients’ outcomes have often been shown to underestimate the degree of bother perceived by patients, and to focus on issues of lesser importance to patients [3-6].

I. PRO QUESTIONNAIRE DEVELOPMENT AND VALIDATION

PRO questionnaires can be used to record the presence and severity of urinary symptoms including incontinence, as well as the impact of symptoms on everyday activities and health-related quality of life (HRQL). To ensure that the results obtained with PROs are clinically useful, data must be gathered using valid and reliable instruments. Questionnaire design and development is not a simple process. Developing such instruments requires a multistep, structured process that incorporates cognitive psychology, psychometric theory, and patient and clinician input. The process begins by determining the intent and purpose of the PRO and culminates in studies that demonstrate the measure’s validity, reliability, and responsiveness. The specific steps required for developing a PRO questionnaire are outlined in the following section and are shown diagrammatically in **Figure 2**.

The development of a PRO is a rigorous, scientific process to provide confidence that the PRO is measuring what it is intended to measure, that it does this reliably, and is appropriate for use in the patient

**Developing Guidance Issues
The PRO Development Process**

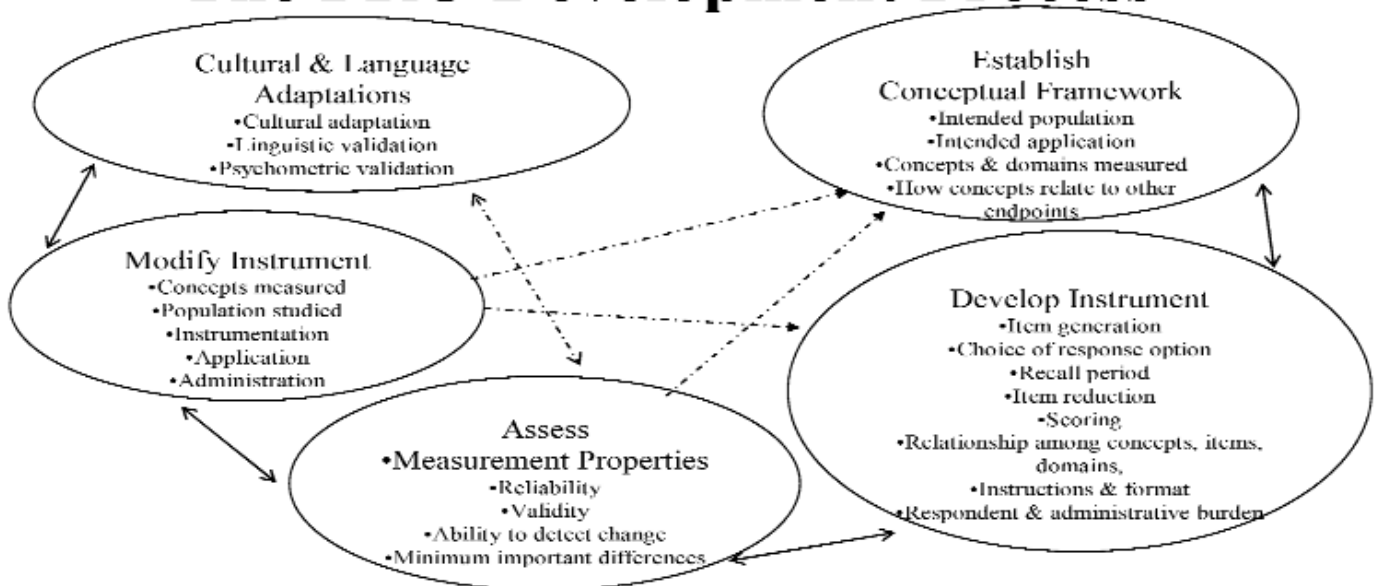


Figure 2 : The development of a patient reported outcome is a multistep process. Food & Drug Administration (3). Guidance for industry - patient-reported outcome measures: Use in medical product development to support labeling claims. Silver Spring, MD: FDA; February 2006.

or population group under investigation. The final instrument must have demonstrated validity and reliability in the intended target population. PROs need to be developed with patient and clinician input and have the psychometric, or measurement, properties of the PRO evaluated to determine that it is a valid outcome measure. To be a useful measurement tool, a PRO instrument must also be easy to administer, reliable, and valid. Only PROs that have undergone this process and have published validation data are discussed in this chapter.

1. DETERMINING QUESTIONNAIRE INTENT AND PURPOSE

The first task in developing a PRO measure is to determine why the instrument is needed. Given the current number of disease-specific questionnaires available in the field of incontinence and related pelvic disorders, a new PRO measure must fill a need that has not already been met by an existing instrument. Once the need for the measure is recognised, its purpose and clinical usefulness need to be considered because the purpose dictates the validation design process. For example, a symptom- and a treatment-satisfaction measure would be developed and validated differently because the outcome is different.

The development stage would focus on the outcome of interest (eg, symptoms patients experience and the significance of each symptom, or what issues patients consider when determining how satisfied they are with treatment) with the items derived directly relating to the outcome of interest. Validation efforts would include designing a study focused on the outcome of interest with the appropriate patient inclusion/exclusion criteria to enhance generalisability while maintaining internal consistency and providing opportunities to test—at a minimum—reliability and construct validity.

2. DEVELOPING THE ITEMS

Designing a clinically useful PRO measure involves more than just developing a series of questions. In addition to clinician input and literature review, questionnaire items should be generated from patient input. This is obtained through focus groups or one-on-one interviews to provide qualitative data on issues pertinent to patients and to identify the words patients use to describe their symptoms or disease impact. Focus groups and one-to-one interviews should be carefully planned to address the goals of the questionnaire being developed. For example, if a measure is intended to assess symptom bother, interview questions should pertain to the patient's symptom experience. Importantly, rather than using clinical terminology which patients may not comprehend, the words used during the focus groups or interviews should be common to patients. After items are generated, the newly drafted questionnaire

should be reviewed by other patients and experts to ensure its readability and content validity.

An alternative approach to questionnaire development is to adapt an existing measure to meet the needs of the desired questionnaire. Although no patient input is required at the outset when adapting an existing instrument, patients need to be involved after the questionnaire is adapted to ensure that the revised measure is pertinent to the population of interest. Also, the adapted questionnaire must be validated on its own in the target population; the validity of the original questionnaire does not apply to an adapted measure.

For newly developed and adapted questionnaires, think-out-loud interviews or cognitive debriefing interviews should be used to ascertain the correctness and validity of the revised questionnaire. In a think-out-loud interview, patients are asked to review a question and describe what they are thinking as they cognitively process the question; the patients think out loud about what the question means to them. For a cognitive debriefing approach, patients review and respond to the questionnaire items, then are interviewed about what each item meant to them as they completed the questionnaire. Both approaches provide information about what patients consider when responding to each question.

3. DETERMINING THE MODE OF ADMINISTRATION OF A QUESTIONNAIRE

Once items have been generated, the mode of administration must be considered. Will the measure be completed by the patient (ie, self-administered) or administered by an interviewer (ie, interviewer-administered)? How the questionnaire will be completed needs to be determined before the validation stage because mode of administration can affect patient responses. For highly personal or intimate questions, a self-administered questionnaire is recommended to avoid response bias. Questionnaires that are self-administered are preferable to interviewer-administered questionnaires because the data collection burden is reduced and patients are more likely to provide unbiased information on self-administered questionnaires. Importantly, if a questionnaire has been validated for a particular mode of administration, this does not make the questionnaire valid for all modes of administration. Each mode of administration should be validated separately.

4. QUESTIONNAIRES' PSYCHOMETRIC PROPERTIES

All PRO measures must demonstrate reliability, validity, and responsiveness, which are described in detail below. This can be accomplished in several ways:

1. Perform a stand-alone cross-sectional study to validate the questionnaire in the patient population for which it was designed;

2. Administer the untested questionnaire in a clinical trial and use the baseline data to perform psychometric validation (the end-of-study data can also be used to evaluate responsiveness); or
3. Perform a stand-alone longitudinal study with an intervention to determine the instrument's psychometric performance and responsiveness in a non-clinical trial setting.

The following psychometric properties must be tested for and demonstrated in a validated questionnaire.

Reliability refers to the ability of a measure to produce similar results when assessments are repeated (ie, is the measure reproducible?) [4, 5]. Reliability is critical to ensure that change detected by the measure is due to the treatment or intervention and not due to measurement error [6]. One measure of reliability is the questionnaire's **internal consistency**, which indicates how well individual items within the same domain (or subscale) correlate [7]. Cronbach's alpha coefficient is used to assess internal consistency reliability, with higher alphas indicating greater correlation [6]. Typically, Cronbach's alpha should be greater than 0.70 to indicate good internal consistency reliability [6, 7]. If the item-to-total alpha is less than 0.20, the question should be removed or rewritten [4].

Test-retest reliability, or **reproducibility**, indicates how well results can be reproduced with repeated testing. To assess test-retest reliability, the same patient completes the questionnaire more than once, at baseline and again after a period of time during which the impact of symptoms is unlikely to change (e.g., a few days or weeks) [4, 6, 7]. The Pearson correlation coefficient and intraclass correlation coefficient are used to demonstrate reproducibility. For group data, a Pearson correlation coefficient or an intraclass correlation coefficient of at least 0.70 demonstrate good test-retest reliability [6, 7].

Interrater reliability indicates how well scores correlate when a measure is administered by different interviewers or when multiple observers rate the same phenomenon [7]. Demonstration of interrater reliability is not necessary for self-administered questionnaires but is necessary for instruments based on observer ratings or using multiple interviewers. A correlation of 0.80 or higher between raters indicates good interrater reliability [7].

Validity refers to the ability of an instrument to measure what it was intended to measure [4, 6, 7]. A measure should be validated for each specific condition or outcome for which it will be used. For example a measure designed to assess stress incontinence would not be valid for OAB unless it were specifically validated in patients with OAB symptoms.

Content validity, convergent validity, discriminant

validity and criterion validity typically are required to validate a questionnaire [7]. Content, or face, validity is a qualitative assessment of whether the questionnaire captures the range of the concept it is intended to measure [6, 7]. For example, does a measure of symptom severity capture all the symptoms that patients with a particular condition have, and if so, is the measure capturing the items in a manner meaningful to patients? To obtain content validity, patients and clinical experts review the measure and judge whether the questions are clear, unambiguous, and comprehensive [4].

Convergent validity is a quantitative assessment of whether the questionnaire measures the theoretical construct it was intended to measure [4, 6]. Convergent validity indicates whether a questionnaire has stronger relationships with similar concepts or variables. Stronger relationships should be seen with the most closely related constructs and weaker relationships seen with less-related constructs [6]. **Discriminant validity** indicates whether the questionnaire can differentiate between known patient groups (eg, those with mild, moderate, or severe disease) [6]; generally, measures that are highly discriminative are also highly responsive.

Criterion validity reflects the correlation between the new questionnaire and an accepted reference, or gold standard [6, 7]. One difficulty in establishing criterion validity is that a gold-standard measure might not be available [6, 7]. When criterion validity can be established with an existing measure, the correlation should be 0.40 to 0.70; correlations approaching 1.0 indicate that the new questionnaire may be too similar to the gold-standard measure and therefore redundant [7].

Responsiveness indicates whether the measure can detect change in a patient's condition [5]. An important aspect of responsiveness is determining not only whether the measure detects change but whether the change is meaningful to the patient. This can be done by determining the **minimal important difference (MID)** of the measure. The MID is the smallest change in a PRO questionnaire score that would be considered meaningful or important to a patient [6, 8-10]. A treatment that is statistically significantly better than another may not necessarily have made a meaningful difference to the patient; the MID indicates whether the treatment made such a difference from a patient perspective [8-10].

Unfortunately, there is no scientific test for MID as it is an iterative process that involves two methodologies to determine the MID of a questionnaire: an anchor-based approach and a distribution-based approach [11, 12]. With the anchor-based approach, the MID is determined by comparing the measure to other measures (or "anchors") that have clinical relevance [12], such as a global measure of well-being or

perception of treatment benefit [10]. With the distribution-based approach, the MID is determined by the statistical distributions of the data [12], using analyses such as effect size, one-half standard deviation, and standard error of measurement [10, 13].

5. LINGUISTIC AND CULTURAL VALIDATION

Increasingly, PRO questionnaires are required to be used in a number of different populations and settings, however, questionnaires and their psychometric properties are not necessarily transferable [13, 14]. A measure that is valid and reliable for a particular language and culture may not prove so when used in a different population. Linguistic and cultural adaptation of a questionnaire can occur during the development phase before validation, or it can be done after the questionnaire is validated in the language in which it was initially developed, with the latter being the more common approach. Ensuring the linguistic and cultural validity of a questionnaire is especially important for measures used in multinational clinical trials [14].

The principal steps in adapting a measure for different languages and cultures are as follows:

1. two forward translations of the original instrument into the new language;
2. quality-control procedures that may include a backward translation (translating the instrument back into the original language) (15);
3. adjudication of all translated versions;
4. discussion by an expert panel to ensure clarity of the translated questionnaire; and
5. testing the translated instrument in monolingual or bilingual patients to ensure that it measures the same concepts as the original instrument [4, 7, 14, 15].

However, if a backward translation of the measure does not produce a semantically equivalent instrument, then the instrument may need to be developed in the target language, rather than just translated [15].

After cultural and linguistic validation, PROs should also be psychometrically validated within the target language. Thus, reliability, validity, and responsiveness need to be assessed with each language translation to confirm the same measurement properties are present in the translated language(s) to ensure psychometric equivalence. If psychometric equivalence is not present (e.g, not achieving similar or better results in new language translation), the cultural and linguistic translations need to be re-evaluated and perhaps a new instrument may need to be developed.

The ICIQ questionnaires and many of the other questionnaires discussed in this chapter have multiple linguistically validated versions making them useful for International implementation. It is also important to note that the step after linguistic validation, demonstrating psychometric equivalence, should also be demon-

strated to ensure that the PRO performs equivalently in different languages and cultures.

6. REGULATORY OVERSIGHT

As clinicians and scientists have begun to appreciate and accept PROs as appropriate outcome measures, regulatory authorities have issued guidance documents on current best practices in the development and implementation of PRO in clinical trial settings [3, 16]. For PROs to be acceptable outcome measures for regulatory authorities, documentation of measurement properties must be present as well as evidence of inclusion of the patient perspective and understanding of the PRO and a cohesive conceptual framework that stipulates how the PRO is related to the intervention. While PROs within this document may have a “recommended” status, they may not meet all of the required regulatory guidelines and may require additional validation work either from a qualitative or quantitative perspective. It is strongly suggested that regulatory authorities be contacted early in the process of selecting a PRO for clinical trials to ensure regulatory acceptance of the PRO.

7. QUESTIONNAIRE DEVELOPMENT - A CONCLUSION

Patient self-completed questionnaires are the most suitable method for assessing the patient’s perspective of their lower urinary tract, vaginal and bowel symptoms [17]. Questionnaires may be long and detailed for use in research, but need to be short and easy to use to be relevant for clinical practice. In addition to being valid and reliable, they need to be easy to complete, and, if they are being used to measure outcome, sensitive to change. Developing a new questionnaire and testing it thoroughly takes a great deal of time and is only necessary if there is not an existing instrument available.

There are many questionnaires currently available for use and these have been reviewed and described with recommendations from the Committee for their use in the last three ICI reports.

The major purpose of the ICI has been to provide a definitive international review and consultative opinion regarding the recommended measures to assess patient reported outcomes within the area of urinary incontinence and LUTS. To this end since the First Consultation, the ICI has worked to develop a modular format for the various patient reported outcomes including health related quality of life (HRQL) allowing clinicians and researchers to select internationally recommended questionnaires for the assessment of their patients in both clinical practice and clinical trials. In this the fourth ICI review, the ICIQ modular questionnaires (supported by the International Consultation) are presented in detail and their use evaluated. Whilst some of the modular questionnaires are still currently under full evaluation their content and format are presented within this chapter.

5B - B. RECOMMENDED PRO QUESTIONNAIRES

A detailed review of recommended questionnaires was provided in the First Consultation chapter [18]. At the Second Consultation, the Committee developed standardised grades of recommendation for questionnaires which attempted to reflect the Oxford Centre for Evidence Based Medicine's Levels of Evidence. These were applied to evaluate questionnaires concerned with urinary incontinence [19]. At the Third Consultation, these grades were revised and updated to take into account the increasing numbers of published questionnaires concerned with LUTS and incontinence, and also broadening of the field to include pelvic organ prolapse (POP) and faecal incontinence (FI) as well as LUTS and urinary incontinence (UI).

GRADES OF RECOMMENDATION FOR QUESTIONNAIRES 2008

At the Second and Third Consultations, the Committee devised three grades of recommendation [19] (**Table 1**).

- Questionnaires were 'highly recommended' and given a **Grade A** if the Committee found "Published data indicating that the questionnaire is valid, reliable and responsive to change following standard psychometric testing. Evidence must be published on all three aspects and questionnaires must be relevant for use with persons with incontinence."
- Questionnaires were "recommended" and given a **Grade B** if the Committee found "Published data indicating that the questionnaire is valid and reliable following standard psychometric testing. Evidence must be published on two of the three main aspects (usually validity and reliability)."
- Questionnaires were considered to have "potential" and given **Grade C** if the Committee found "Published data (including abstracts) indicating

that the questionnaire is valid or reliable or responsive to change following standard psychometric testing."

The Committee decided that evidence published in abstracts or posters could be used to indicate a developing questionnaire's potential, but was not sufficiently peer-reviewed to provide the basis for a stronger recommendation.

This current Fourth Consultation represents a departure from the recommendation scheme of the last review. In this fourth review questionnaires will still be graded A, B, or C as outlined above. However the recommendation will be to preferably utilise questionnaires from the ICIQ modules described in detail below. Many, but not all, of these questionnaires are Grade A questionnaires by previously stipulated criteria. Within the description of the ICIQ modules below the grade assigned to each module is indicated.

Should none of the modular questionnaires be deemed appropriate for specific research or clinical purposes, ICI's recommendation is to use a Grade A questionnaire as previously recommended and where no suitable instrument exists a Grade B or C questionnaire.

For UI and UI/LUTS, the Committee examined the quality of the psychometric evidence. Only where published data were scientifically sound was the label 'with rigour' allowed. Where the Committee had concerns about the quality of evidence, this is noted in the descriptions of the questionnaires below. The Committee considered that the number of high quality questionnaires means that there are now sufficient questionnaires for most purposes and it is not necessary to encourage the development of new questionnaires, except for particular patient groups (see below). As for the last Consultation, it is expected that by the next Consultation, Grade A new questionnaires will either be promoted to Grade A because of further high quality publications or relegated to Grade B if further development does not occur.

The Committee felt that the development of questionnaires in the areas of pelvic organ prolapse (POP) and faecal incontinence (FI) was at a much earlier level. This necessitated a slightly different set of grades of recommendation so that researchers are

Table 1. Criteria for recommendation of questionnaires for UI and UI/LUTS at the Fourth Consultation 2008

Grade of recommendation	Evidence required (published)
Recommended (Grade A)	Validity, reliability and responsiveness established with rigour in several data sets
Recommended (Grade A^{new})	Validity, reliability and responsiveness indicated with rigour in one data set
(Grade B)	Validity, reliability and responsiveness indicated but not with rigour. Validity and reliability established with rigour in several data sets. To be used if suitable questionnaires not available in ICIQ modular format or Grade A or Grade A new

encouraged to continue to work to produce questionnaires with the highest levels of evidence (see Table 2).

Table 2. Criteria for recommendation of questionnaires for POP and FI at the Fourth Consultation 2008

Grade of recommendation	Evidence required (published)
Recommended (Grade A)	Validity, reliability and responsiveness established with rigour.
(Grade B)	Validity and reliability established with rigour, or validity, reliability and responsiveness indicated.
With potential (Grade C)	Early development – further work required and encouraged

5B - C. INTERNATIONAL CONSULTATION ON INCONTINENCE MODULAR QUESTIONNAIRE (ICIQ): WHAT IS THE ICIQ?

The ICIQ modular questionnaire was developed to meet the need for a universally applicable standard guide for the selection of questionnaires for use in clinical practice and clinical research [18, 19]. The decision to develop standard questionnaire modules was taken by the Committee after the first ICI meeting in 1998, and resulted in the development of the ICIQ core questionnaire discussed in this section. It was recognised at that time that there were many good validated questionnaires each developed for a specific purpose and each subtly different. Although developers of the questionnaires were familiar with their content and use, the increasing number of questionnaires made appropriate selection difficult and limited the ability to compare similar clinical and research data due to different data collection methods.

An international advisory board was established to continue the development of the modular ICI questionnaire outside the limits imposed by triennial convening of the ICI Committee. Early discussions with the advisory board resulted in the decision to expand the concept to include wider urinary symptoms, bowel symptoms and vaginal symptoms. The advisory board consisted of clinicians and researchers with experience in the design and use of questionnaires representing the major societies involved in the assessment and research of lower genital tract, lower

urinary tract and bowel function. The members of the advisory board of the ICI can be seen on the ICIQ website at www.iciq.net. The ICIQ modular questionnaire was then established.

I. AIMS AND OBJECTIVES

The ICIQ's objective is to provide international consensus on the use of patient completed questionnaires for the assessment of lower pelvic symptoms and their impact on patient's lives. Three aims underpin the ICIQ in order to achieve clarity over questionnaire use:

- To recommend high quality self-completion questionnaires according to evidence of validation as stipulated by the three prior ICI Committees;
- To promote wider use of questionnaires to standardise assessment of lower urinary tract and pelvic dysfunction and its impact on patients's lives, in order to;
- Facilitate communication in different patient settings and different patient groups both in clinical practice and wider clinical research.

The ICIQ recognised that many high quality published questionnaires already existed and, with permission from the authors, those instruments were adopted into the modular project. It was not possible to adopt all available questionnaires and where more than one option existed the most appropriate questionnaire for the purpose was included. Where high quality questionnaires were not available, the need to develop a new questionnaire/s was acknowledged. Collaborative efforts to develop new questionnaires are welcome and encouraged.

The ICIQ's international nature requires that linguistically validated translations are available. More than 50 language versions of various modules have been validated to date, conducted according to established protocol.

Thirteen ICIQ modules/questionnaires are currently available for use, with further modules in development (discussed in detail below). Clinicians or researchers are able to select module(s) to meet the particular requirements of their study or clinical practice. In order to simplify this selection process, modules have been categorised as shown in Table 3. It must be stressed that although multiple questionnaires can and probably should be used they must be used in the format in which they were originally designed and the questionnaires cannot be merged together.

In this chapter questionnaires forming part of the ICIQ modular format are referred to as those preferred for usage. Although many of the modules are Grade A questionnaires, others are still under various phases of development and are graded appropriately.

Table 3. The ICIQ Modular Structure

CONDITION	RECOMMENDED MODULES		OPTIONAL MODULES	RECOMMENDED ADD-ON MODULES			
	Core Modules (symptom assessment)			HRQL	Generic HRQL	Sexual Matters	Post-Treatment
Urinary symptoms	Males: ICIQ-MLUTS Females: ICIQ-FLUTS	Males: ICIQ-MLUTS LF Females: ICIQ-FLUTS LF	ICIQ-LUTSqol	SF-12	Males: ICIQ-MLUTSsex Females: ICIQ-FLUTSsex	ICIQ-Satisfaction*	
Vaginal symptoms and sexual matters	ICIQ-VS		ICIQ-VSqol*	SF-12			
Bowel symptoms and quality of life	ICIQ-B			SF-12	Males: ICIQ-Bsex* Females: ICIQ-Bsex*		
Urinary Incontinence	ICIQ-UI Short Form	ICIQ-UI LF*	ICIQ-LUTSqol	SF-12	Males: ICIQ-MLUTSsex Females: ICIQ-FLUTSsex		
CONDITION	B) Specific patient groups		HRQL	Generic HRQL	Sexual Matters		
Nocturia	ICIQ-N		ICIQ-Nqol	SF-12	Males: ICIQ-MLUTSsex Females: ICIQ-FLUTSsex		
Overactive Bladder	ICIQ-OAB		ICIQ-OABqol	SF-12	Males: ICIQ-MLUTSsex Females: ICIQ-FLUTSsex		
Neurogenic	ICIQ-Spinal Cord Disease*			SF-12			
Long-term catheter users	ICIQ-LTC*			SF-12			
Children	ICIQ-CLUTS*		ICIQ-CLUTSqol*				

Gray: In development; black: Grade A or A (New)

Questionnaires that are in early stages of development and have yet to reach Grade C are described as “in development”. Where an ICIQ module is not available it is recommended that a Grade A or B or C questionnaire is used.

II. ICIQ SYMPTOM AND BOTHER MODULES

1. CORE MODULES

Questionnaires to assess the core symptoms of lower pelvic dysfunction:

- Lower urinary tract symptoms (male and female specific versions).
- Urinary incontinence (male and female applicable version).
- Vaginal symptoms (female version only).
- Bowel symptoms including incontinence (male and female applicable version).

Each module is intended for the comprehensive yet succinct measurement of symptoms and associated ‘bother’. The bother item attached to each symptom enables the individual to indicate areas that cause the greatest negative impact on HRQL as perceived by them. This can be a more sensitive indicator of treatment goals than frequency of symptoms alone.

2. SPECIFIC PATIENT GROUPS

Questionnaires to assess specific conditions or symptom complexes such as nocturia and overactive bladder are contained in this section. This category also includes specific patient groups, for example, children. These instruments contain only question items characteristic of the symptom complex or have been developed specifically for use in a diverse group making the items/questionnaire only utilisable in that population.

- Nocturia (male and female applicable version).
- Overactive bladder (male and female applicable version).
- Patients with spinal cord disease.
- Patients using long term catheters.
- Lower urinary tract symptoms in children.

Bother items are again included for all except the children’s questionnaire.

III. ICIQ HEALTH-RELATED QUALITY OF LIFE AND SEXUAL FUNCTION MODULES

1. CORE MODULES

These questionnaires incorporate modules for

assessment of health-related quality of life (HRQL) and sexual matters and are recommended to be completed alongside symptom evaluations. The core symptom modules described above contain both items indicating impact on quality of life directly related to symptoms. The HRQL questionnaires recommended here cover specific issues that are a consequence of symptoms, such as limitations on activities and impact on relationships.

- HRQL associated with lower urinary tract symptoms (male and female applicable version).
- HRQL associated with vaginal symptoms (female version only).
- HRQL associated with bowel symptoms (male and female applicable version).
- Sexual matters associated with lower urinary tract symptoms (male and female specific versions).
- Sexual matters associated with vaginal symptoms are included in the symptom questionnaire as the issues were considered too intrinsically linked to separate for evaluation.

Bother sub-items are again included to provide more detailed information about impact on quality of life than frequency of impact alone. The assessment of symptoms in combination with quality of life enables a more thorough and detailed evaluation of the patient’s experience [20,21]. Given the nature of lower pelvic dysfunction, sexual matters can also be affected and questionnaires are available to evaluate this where appropriate.

2. SPECIFIC PATIENT GROUPS

In the same manner as the symptom modules, HRQL modules are available for specific symptom complexes:

- HRQL associated with nocturia (male and female applicable version).
- HRQL associated with overactive bladder (male and female applicable version).

IV. OPTIONAL MODULES

This category includes lengthier questionnaires for more exploratory evaluation of the core symptoms of lower pelvic dysfunction. Whilst these questionnaires are suitable for use in clinical practice, they have not been shortened for clinical efficiency and are therefore more widely used in research studies where exploration of broader associated symptoms may be desired.

- Lower urinary tract symptoms (male and female specific versions).
- Urinary incontinence (male and female applicable version).

V. POST-TREATMENT MODULE

The ICIQ module for post-treatment satisfaction is in the early stages of development. Assessment of a patient's satisfaction with treatment (behavioural, surgical or medication) provides information on treatment impact on their condition and life and includes their perception of effectiveness, tolerability and convenience. It is not yet clear if satisfaction following treatment can be characterised by a set of common question items that are applicable to all disorders of the lower urinary tract and pelvic floor. As with HRQL, there are generic and disease specific questionnaires that assess satisfaction. Ongoing studies will provide further evidence on which to make suggestions regarding post treatment evaluation but it is likely that this will encompass both generic and condition specific measures. Ultimately, the development of post treatment modules will also rely on advice from regulatory authorities (eg FDA) to ensure that measures capture a recognised multidimensionality of satisfaction.

VI. GUIDANCE FOR USE OF THE ICIQ

The ICIQ recommends the use of a 'core', 'symptom-specific', or 'add-on' modules that match the intended purpose of a study. Whilst this may necessitate the use of a module from each section, there is no requirement to do so. The characteristics of each module is summarised below, although more extensive information can be found on the project website, www.iciq.net.

VII. ICIQ MODULES

Tables 4, 5 a,b,c

VIII. ICIQ QUESTIONNAIRE IMPLEMENTATION

The ICIQ modular questionnaire has attracted considerable attention from both clinicians and researchers worldwide since its structure was finalised in 2004. More than 500 requests for use of the various modules have been documented and over 40 published studies were identified up to April 2008, with the majority originating from Europe, particularly the UK.

The most widely applied module is the ICIQ-UI Short Form, particularly to evaluate female urinary

incontinence, though a handful of studies evaluating severity of incontinence in men resulting from prostatectomy for cancer or treatment for bladder outlet obstruction related to benign prostatic enlargement have been reported [31, 32]. Most studies relate to epidemiological research, including prevalence surveys of urinary incontinence or lower urinary tract symptoms [33, 34]; and outcomes research, including prospective and randomised clinical trials of treatments including surgery [35], drug therapies [36] and conservative treatments [37]. For example, a recent placebo-controlled randomised trial found that duloxetine significantly reduced ICIQ scores in women with mixed urinary incontinence[36].

Reports on further validation and translations of the ICIQ and related educational projects have also been published. A recent study conducted by Franco, Lee and Fynes [38], for example, compared various validated subjective measures of urinary incontinence severity to the one hour pad test in women and reported that only the ICIQ correlated significantly with this clinical variable, thereby recommending its use in routine clinical practice as an alternative to pad tests. Encouraging relationships between the ICIQ and other urodynamic parameters have also been reported [39].

The ICIQ has also been applied to hospital and general practice settings, and has been adopted in national guidelines for the management of urinary incontinence in primary care by the Scottish Intercollegiate Guidelines Network (www.sign.ac.uk/pdf/sign79.pdf) and in a primary care resource pack by the British Society of Urogynaecology.

IX. CONCLUSION

The ICIQ modular questionnaire project (www.iciq.net) provides a series of standardised questionnaires for the patient reported assessment of lower pelvic dysfunction symptoms and their impact on patients lives. The ICIQ provides clarity over the selection of questionnaires by recommending only those with evidence of high quality and robust psychometric validation including validity, reliability and sensitivity to change. This assurance provides the user with confidence in the results obtained, which is important in clinical practice and research where treatment decisions or trial outcomes depend on this evidence. Increasing awareness of the ICIQ aims to promote increased use of standardised questionnaires, thereby facilitating communication between clinicians and researchers and enable more widespread comparisons between different treatments and patient groups worldwide.

Table 4. ICIQ Module Description

Name/Grade	Purpose	Availability	Domains	Items	Available Translations
ICIQ-FLUTS (BFLUTS-SF [22]) Grade A	Comprehensive assessment of female lower urinary tract symptoms and associated bother.	Available for use. Published evidence of validity, reliability and responsiveness[22].	Filling. Voiding. Incontinence.	12	19
ICIQ-FLUTS Long Form (BFLUTS [23]) Grade A	Detailed assessment of female lower urinary tract symptoms and associated bother.	Available for use. Published evidence of validity, reliability and responsiveness [22,23].	Varied lower urinary tract symptoms.	18	7
ICIQ-FLUTSsex (BFLUTS[23]) Grade A	Assessment of female sexual matters associated with urinary symptoms and related bother.	Available for use. Published evidence of validity, reliability and responsiveness[23].	Pain and leakage with sexual intercourse. Overall interference.	4	18
ICIQ-LUTSqol (King's Health Questionnaire [24]) Grade A	Detailed assessment of HRQL issues associated with urinary symptoms and related bother in both men and women.	Available for use. Published evidence of validity, reliability and responsiveness [24].	Life restrictions. Emotional aspects. Preventive measures.	22	45
ICIQ-MLUTS (ICSmaleSF[25]) Grade A	Comprehensive assessment of male lower urinary tract symptoms and associated bother.	Available for use. Published evidence of validity, reliability and responsiveness .	Voiding. Incontinence. Individual items evaluating frequency and nocturia.	13	26
ICIQ-MLUTS Long Form (ICSmale [26,27]) Grade A	Detailed assessment of male lower urinary tract symptoms and associated bother.	Available for use. Published evidence of validity, reliability and responsiveness [26,27].	Varied lower urinary tract symptoms.	23	29
ICIQ-MLUTSsex (ICSmale[27]) Grade A	Assessment of male sexual matters associated with urinary symptoms and related bother.	Available for use. Published evidence of validity, reliability and responsiveness [26,27].	Erection and ejaculation issues. Overall interference.	4	24
ICIQ-Nqol (N-CoL[28]) Grade A	Detailed assessment of HRQL issues associated with nocturia .	Available for use. Published evidence of validity, reliability and responsiveness [28].	Issues associated with sleep disturbance. Life restrictions. Preventive measures.	13	27

Table 4. ICIQ Module Description (continued)

Name/Grade	Purpose	Availability	Domains	Items	Available Translations
ICIQ-N (ICSmaleSF/ BFLUTS-SF [22, 25]) Grade B	Comprehensive assessment of symptoms of nocturia and associated bother.	Available for use. Evidence of validity, reliability and responsiveness [22,25,27].	Frequency. Nocturia.	2	30
ICIQ-OAB (ICSmaleSF/ BFLUTS-SF [22,25]) Grade A	Comprehensive assessment of symptoms of overactive bladder and associated bother.	Available for use. Evidence of validity, reliability and responsiveness [22,25,27]. Responsiveness not demonstrated in OAB patients	Frequency. Nocturia. Urgency. Urgency incontinence.	4	22
ICIQ-OABqol (OAB-q [29]) Grade A	Detailed assessment of health-related quality of life issues associated with overactive bladder .	Available for use. Published evidence of validity, reliability and responsiveness [29].	Coping, Concern/Worry Sleep Social Interaction	25	50+
ICIQ-UJ Short Form [18] (ICIQ) Grade A	Comprehensive assessment of male/female urinary incontinence .	Available for use. Published evidence of validity, reliability and sensitivity to change ¹ .	Urinary incontinence including items on frequency and amount of leakage and overall interference. A self-diagnostic item invites respondents to indicate the perceived cause of incontinence.	4	32
ICIQ-VS [30] Grade A	Comprehensive assessment of vaginal symptoms and associated bother.	Available for use. Published evidence of validity, reliability and responsiveness [30].	Vaginal symptoms. Sexual matters. Quality of life.	14	2

Table 5a. ICIQ Description of Modules in Development

Name / Grade	Purpose	Current Status	Development Methodology	Domains	Items
ICIQ-B Grade C	Comprehensive assessment of male/female bowel symptoms , predominantly incontinence, and associated bother.	Newly developed; testing completed; awaiting publication	Items generated by clinical experts and patients with anal incontinence [12]. Extensive content validity testing with potential respondents and clinical experts. Psychometric testing performed; awaiting publication	Bowel pattern. Bowel control. Quality of life.	21
ICIQ-CLUTS Grade C	Assessment of urinary symptoms in children .	Criterion validity testing is currently ongoing in the UK, Italy and Germany by way of comparisons with clinical flow tests to evaluate the ability of the questionnaire to reflect clinical findings.	The draft instrument has been prepared through qualitative interviews with children and their parents/caregivers in combination with clinical experts in the field to establish the clinical areas of importance and the pertinent issues for those with the symptoms.	Domains to be determined; Questions on urinary symptom, bedwetting and incontinence	
ICIQ-LTC Grade C	Assessment of urinary symptoms and impact on quality of life associated with long term catheterisation and related bother.	Content validity testing and full psychometric validation are underway.	This draft questionnaire has been prepared in collaboration with clinical experts in this area and patients who manage their urinary symptoms through long term catheterisation.	Domains to be determined; Questions to be assessed: leakage, blockage, bladder stones, infections; coping strategies; social functioning; attitudes; and body image.	

Table 5b. ICIQ Description of Modules in Development

Name/Grade	Purpose	Current Status	Development Methodology	Domains	Items
ICIQ-Spinal cord disease In development	Assessment of urinary symptoms and impact on quality of life associated with specific management devices and related bother.	Content validity testing and full psychometric validation are due to commence.	This draft questionnaire has been prepared in collaboration with clinical experts in this area and patients who manage their urinary symptoms with varying devices. Patients with spinal cord disease of varying causes participated in qualitative interviews to explore the effects and impact on quality of life associated with the devices used to manage their bladder symptoms.	Questions regarding the following will be asked: Bladder and bowel function, issues associated with specific management devices, sexual matters, and lifestyle interference.	
ICIQ-UI Long Form	Detailed assessment of perceived causes of urinary incontinence .	Content validity testing has been completed preparing the developmental ICIQ-UI Long Form for full psychometric validation. Interviews with potential respondents have confirmed that the questionnaire is applicable and appropriate for a detailed assessment of urinary incontinence symptoms. Validation is underway.	This draft questionnaire has been prepared in collaboration with clinical experts in this area and patients with symptoms of urinary incontinence. Patients with urinary incontinence participated in qualitative interviews to explore the cause of their symptoms and the issues of importance related to this.	For each perceived cause of incontinence, e.g. physical activity, urgency related, nocturnal leakage, the degree of bother and amount of leakage are evaluated.	

Table 5c: ICIQ Description of Modules in Development

Name/Grade	Purpose	Current Status	Development Methodology	Domains	Items
ICIQ-VScol (In development)	Detailed assessment of HRQL issues associated with vaginal symptoms and related bother.	Content validity testing has been completed preparing the developmental ICIQ-VScol. Interviews with potential respondents have confirmed that the questionnaire is applicable and appropriate for assessment of the effects of vaginal symptoms, capturing all aspects of relevance. Psychometric validation is underway.	This draft questionnaire has been prepared in collaboration with clinical experts in this area and women with vaginal symptoms. Patients with vaginal symptoms of varying cause participated in qualitative interviews to explore the effects and impact on quality of life associated with their symptoms.	Domains to be determined. Questions regarding the following will be asked: life restrictions and emotional aspects.	

5B - D. PATIENT REPORTED OUTCOME (PRO) QUESTIONNAIRES TO ASSESS THE IMPACT OF URINARY INCONTINENCE, OAB AND LOWER URINARY TRACT SYMPTOMS

There are a variety of PRO measures available for use in clinical practice and research that assess a range of concepts (e.g. HRQL, patient satisfaction, symptom bother, etc). This section and table series provides an overview and assessment of those measures. Importantly, clinical practitioners and researchers need to clearly determine their clinical and research objectives before selecting a PRO as it is these objectives and the target patient population that will help determine which validated PRO is appropriate to use. **Tables 6** to 10 provide a brief overview of all current PRO measures for urinary incontinence and LUTS, their purpose, psychometric properties, translation availability, and recommended ICI grade.

Certainly an area which has rapidly grown with PRO measures is that of urinary incontinence and LUTS and HRQL assessments (**Table 6**). The literature supporting HRQL assessments was reviewed and a Grade A to C recommendation assigned. Please note, as instrument development and validation is an ongoing process, the tables below contain publications prior to July 2008. As additional work may have been performed on an instrument, it is always prudent to conduct a further literature search and/or contact the instrument developer prior to selecting an outcome measure for your clinical practice or study.

One trend that has become more apparent since the previous Consultations is the modification of more established urinary incontinence questionnaires for use in selected patient groups (e.g., pelvic organ prolapse; males; different cultural/language groups). When using a questionnaire in a patient group other than the group in which it was initially developed, cognitive debriefings with the new patient population should be held to review the applicability of the questionnaire to the new patient group. Several of the main questionnaires to be discussed below have now had modified versions published in the literature. The Committee's view is that although it may be appropriate to modify established questionnaires for use with some populations, it is advisable to keep such modifications to a minimum, and to use the original versions whenever possible. Any modifications of established questionnaires may result in changes (sometimes substantial) in the psychometric performance of the instrument, and thus all modified instruments should be subjected to the same psychometric testing as

that employed in developing a completely new instrument. Specifically, modified instruments should report information regarding the instrument's construct validity, reliability, and test-retest reliability, at a minimum, and sensitivity to change, in intervention studies.

For some of the more widely used instruments listed below, several modified, shortened versions have been published. Information regarding the modified versions is provided under the original source versions of the questionnaires, but the modified versions are evaluated and graded separately, based on the available information regarding their psychometric properties and performance.

I. HEALTH-RELATED QUALITY OF LIFE MEASURES

1. BFLUTS AND BFLUTS-SF

The long form of BFLUTS [23, 26] was developed for use with women, following the pattern established for the questionnaire developed for the ICS-'BPH' study. The questionnaire covers the occurrence and bothersomeness of symptoms relating to incontinence and other lower urinary tract symptoms [23, 26]. It has shown good levels of validity and reliability and has been increasingly used in epidemiological and outcome studies [40-45]. Validity, reliability and responsiveness have been demonstrated, and a scored short form has been produced, which is now the recommended version [22].

2. DAN-PSS

This questionnaire was designed in Denmark to measure the degree to which men are bothered by urinary symptoms [46, 47]. A composite score is achieved by the multiplication of the 'symptom' by the 'bother' score, with a total range of 0 to 108 [46, 47]. A computer version of this questionnaire has been validated and patients seemed to appreciate more this new version than the paper version [48]. It is primarily a questionnaire for the assessment of the occurrence and bothersomeness of a wide range of LUTS in men.

3. ICSMALE AND ICSMALE SF

The ICSmale questionnaire contains 22 questions on 20 urinary symptoms, and, for most questions, the degree of problem that the symptom causes [26]. It has exhibited acceptable levels of validity, reliability and sensitivity to change following a range of treatments including surgery, minimally invasive therapies and drug treatments [26, 27, 49]. This long version has been largely replaced now by a scored short-form – ICSmaleSF [25]. A modified form of ICSmale has been used to assess LUTS and incontinence in prostate cancer [50]. It also continues

Table 6. Summary of Urinary Incontinence, OAB and LUTS PRO Measures – HRQL

PRO Name / Grade	Purpose of Tool	Population Sample	Reliability		Validity				Responsive-ness (Treatment Duration)	Psychometric Validation in Other Languages	Available Languages
			Internal Consistency	Test-retest	Content	Criterion	Concurrent	Discriminant			
BFLUTS (Bristol Female Lower Urinary Tract Symptoms Questionnaire). Currently the ICIQ-Female FLUTS (ICIQ-Female Lower Urinary Tract Symptoms) [23] Grade A	To assess female LUTS, particularly urinary incontinence, measure impact on quality of life and evaluate treatment outcome	Women, incontinence	✓	✓	✓	✓	✓	✓			BFLUTS Translated in 10 Languages. http://www.icq.net/ICIQ_FLUTS.html
ContiLife® (Quality of Life Assessment Questionnaire Concerning Urinary Incontinence)[102] Grade B	To assess the impact of urinary incontinence on quality of life. Originally developed in French and designed for women with UI (urge, stress and mixed UI)	Women, SUI	✓				✓	✓			ContiLife Translated in 11 Languages. http://proqid.org/instruments/quality_of_life_assessment_questionnaire_concerning_urinary_incontinence_contilife_r
DAN-PSS-1 (Danish Prostatic Symptom Score)[46] Grade A	To evaluate males with LUTS suggestive of uncomplicated BPH	Men, BPH	✓		✓						DAN-PSS-1 translated in 9 languages http://proqid.org/instruments/danish_prostatic_symptom_score_dan_pss_1
EPIQ (Epidemiology of Prolapse and Incontinence Questionnaire)[103] Grade B	Developed and validated in English and Spanish to assess the presence or absence of AI, OAB, SUI, and pelvic organ prolapse in female population	Women, PFD	✓	✓	✓	✓	✓	✓			Translated in English and Spanish
IBS (Incontinence Bothersome Scale)[104] Grade C	One item questionnaire to assess the quality of life in women with urinary incontinence.	Women, UI									None Found
ICIQ-UI Short Form (International Consultation on Incontinence Questionnaire - Urinary Incontinence Short Form (ICIQ-UI Short Form))[18,25] Grade A	To assess the symptoms and impact of urinary incontinence in clinical practice and research	Men and Women, Urinary Symptoms	✓	✓	✓			✓ (8 weeks)	✓		ICIQ-UI SF Translated in 38 Languages http://proqid.org/instruments/international_consultation_on_incontinence_questionnaire_urinary_incontinence_short_form_icq_ui_short_form

Table 6. Summary of Urinary Incontinence, OAB and LUTS PRO Measures – HRQL (continued)

RO Name / Grade	Purpose of Tool	Population Sample	Reliability		Validity				Responsive-ness (Treatment Duration)	Psychometric Validation in Other Languages	Available Languages
			Internal Consistency	Test-retest	Content	Criterion	Concurrent	Discriminant			
ICSmale (ICIQ-MILUTS) (International Continence Society - Male)[18,25,26] Grade A	To provide a thorough evaluation of the occurrence and bothersomeness of lower urinary tract symptoms and their impact on the lives of men with benign prostatic disease	Men with LUTS and possible BPH	✓	✓	✓		✓		✓	icsmale Translated in 11 Languages. http://proqolid.org/instrument/s/icsmale_icsmale	
ICSQoL (International Continence Society-Benign Prostatic Hyperplasia study quality-of-life)[105] Grade A	To assess impact of lower urinary tract symptoms on the lives of men with LUTS	Men with LUTS and possible BPH	✓	✓	✓		✓		✓	ICSQoL Translated in 11 Languages http://proqolid.org/instruments/international_continence_society_benign_prostatic_hyperplasia_study_quality_of_life_icsqol_1	
IIQ (Incontinence Impact Questionnaire)[64] Grade A	Developed to describe the severity of incontinence in a population. Used to assess the impact of urinary incontinence on HRQL. Primarily been evaluated in patients with stress incontinence.	Women, UI, SUI		✓	✓				✓ (12 Weeks)	Available in English and Turkish	
IIQ-7 (Incontinence Impact Questionnaire - short form)[101] Grade A	Used to assess the impact of urinary incontinence on HRQL	*validation study on men after radical prostatectomy who had UI			✓					Available in English and Turkish	
IOQ (Incontinence Outcome Questionnaire)[106] Grade C	Developed for assessing HRQL after surgery for stress urinary incontinence	Women SUI			✓				✓	None Found	
I-QOL (ICIQ-Ujql) (Urinary Incontinence-Specific Quality of Life Instrument)[75,107] Grade A	To assess quality of life of women with urinary incontinence	Men, UI	✓	✓						I-QOL Translated in 35 Languages http://proqolid.org/instruments/urinary_incontinence_specific_quality_of_life_instrument_i_qol	

Table 6. Summary of Urinary Incontinence, OAB and LUTS PRO Measures – HRQL (continued)

RO Name / Grade	Purpose of Tool	Population Sample	Reliability		Validity				Psychometric Validation in Other Languages	Available Languages
			Internal Consistency	Test-retest	Content	Criterion	Concurrent	Discriminant		
KHQ (ICIQ-LUTSqol) (King's Health Questionnaire) [24, 108] Grade A	To assess the impact of lower urinary tract symptoms including urinary incontinence on health related quality of life. Developed in a clinical perspective to evaluate incontinence in women.	Men and Women, OAB	✓	✓	✓	✓	✓	✓	✓	KHQ Translated in 45 Languages. http://proqolid.org/instruments/king_s_health_questionnaire_khq
LIS (Leicester Impact Scale) [90]	A condition specific quality of life measure for males and females with urinary storage symptoms of urgency, frequency, nocturia and incontinence. Was originally developed for women with incontinence only.	men and women, LUTS	✓	✓	✓		✓			None Found
MUDI (Male Urogenital Distress Inventory)[109, 110] Grade C	To address the dimension of physical health, focusing on bother from multiple symptoms associated with urinary incontinence in men. Created by eliminating four gender specific items from UDI and IIQ.	Men with LUTS following a radical prostatectomy for prostate cancer	✓		✓		✓			None Found
MUSIQ (Male Urinary Symptom Impact Questionnaire)[109, 110] Grade C	To capture mental/psychological health, social health, and global perceptions of function and well-being in men with urinary incontinence. Created by eliminating four gender specific items from UDI and IIQ.	Men, UI	✓		✓		✓			None Found
N-QoL (ICIQ-Nqol (Nocturia Quality of Life Questionnaire))[28] Grade A	To assess the impact of nocturia on the quality of life of patients	Men and Women	✓	✓			✓			N-QoL Translated in 17 Languages www.prolutssh.com
OAB-q SF (OAB-q Short Form)[29] Grade A	A shortened version of the OAB-q to evaluate both continent and incontinent symptoms of OAB and their impact on HRQL	Men and Women OAB	✓	✓			✓		✓	OAB-q SF Translated in 40 Languages www.prolutssh.com

Table 6. Summary of Urinary Incontinence, OAB and LUTS PRO Measures – HRQL (continued)

PRO Name / Grade	Purpose of Tool	Population Sample	Reliability		Validity				Responsive-ness (Treatment Duration)	Psychometric Validation in Other Languages	Available Languages
			Internal Consistency	Test-retest	Content	Criterion	Concurrent	Discriminant			
OAB-q (ICIQ-OABq) (Overactive Bladder Questionnaire) [29] Grade A	To evaluate both continent and incontinent symptoms of OAB and their impact on HRQL. Developed from focus groups of men and women, clinician opinion, and a thorough literature review	Continent and incontinent OAB	✓		✓	✓	✓	✓	✓ (12 Weeks)		OAB-q Translated in 41 Languages www.prolutssh.com
PRAFAB (Protection, Amount, Frequency, Body Adjustment, Body image) [11-113] Grade A	5 item questionnaire widely used in the Netherlands by physiotherapists and researchers used to evaluate treatment effects for UI in women	Women, UI	✓	✓	✓				✓		English, Arabic and Dutch
IHI (Urinary Incontinence Handicap Inventory) [114] Grade C	To identify difficulties patients may be experiencing because of their incontinence	Elderly women, UI due to detrusor instability									None Found
UISS (Urinary Incontinence Severity Score) [115] Grade A	Designed by the Finnish Gynecological Society's urogynecologic working group to assess symptom severity and impact of urinary incontinence on everyday life	Women, UI		✓	✓	✓		✓	✓		None Found
UQ (Urgency Questionnaire) [116,117] Grade B	To assess the severity and impact of urinary urgency symptoms on health-related quality of life. VAS scale is used to measure the impact of urinary urgency on overall quality of life, the severity of urgency, the intensity of urgency, and the discomfort experienced in conjunction with urgency.	Women, OAB	✓		✓			✓	✓ (10 Days)		None Found UROLIFETM/BPHQoL9 Translated in 11 Languages http://proqolid.org/instruments/benign_prostatic_hypertrophy_health_related_quality_of_life_questionnaire_urolife_sup_tm_sup_bphqoL9
Urolife (BPHQoL9) (Benign Prostatic Hypertrophy Health-Related Quality of Life Questionnaire) [118] Grade A	To assess the impact of BPH and its treatment on the quality of life of patients	Men, BPH	✓	✓	✓			✓	✓		None found
YIPS (York Incontinence perceptions scale) [58] Grade C	To measure the psychosocial aspects of urinary incontinence	Women UI	✓	✓	✓			✓			None found

to be used to assess LUTS in men [51] and minimally invasive therapies and drug treatments [52-55]. It is primarily a questionnaire for the assessment of the occurrence and bothersomeness of a wide range of LUTS in men.

The scored short-form – ICSmaleSF, [25] was developed from the longer ICSmale questionnaire to assess LUTS in men. The short form has two major scored sections: ICSmaleVS (voiding subscore) containing five questions (hesitancy, straining, reduced stream, intermittency, incomplete emptying), and ICSmaleIS (incontinence subscore) containing six questions (urge, stress, unpredictable and nocturnal incontinence, urgency, postmicturition dribble). The scores are obtained by simple addition. The authors indicate that questions to assess nocturia, frequency and impact on quality of life should be added to provide full data, but these questions should not be included in the score as they are separate constructs [25]. The ICSmaleSF has been used in studies focusing on prostate cancer [56, 57] and on LUTS [51] as well as minimally invasive therapies and drug treatments [52, 53].

4. INCONTINENCE IMPACT QUESTIONNAIRE (IIQ) AND IIQ-7

This questionnaire was developed to assess the psychosocial impact of urinary incontinence in women and consists of 30 items (24 on the degree to which incontinence affects activities and 6 on the feelings engendered) [58-60]. Scores are obtained overall or for four subscales determined by factor and cluster analyses: physical activity, travel, social relationships, and emotional health. The IIQ has been found to have acceptable levels of reliability and validity across a range of studies [61-67]. The IIQ has also been produced in a short form comprising 7 items, also with evidence of validity and reliability [67, 68]. Responsiveness of the IIQ has been assessed in several intervention studies [69-74].

5. I-QOL

This questionnaire was designed to be used in clinical trials to measure the impact of incontinence on men and women [75]. Psychometric information on translated versions of the I-QOL have been reported for French, Spanish, Swedish, German, Korean and Thai language versions [76-78]. Other cultural and linguistic adaptations are available but have not been validated. In all countries, the use of three subscales, and an overall summary score was confirmed to be useful.

6. KING'S HEALTH QUESTIONNAIRE (KHQ)

The King's Health Questionnaire (KHQ) consists of three parts. The first section contains two questions measuring general health and overall health related to urinary symptoms. The second section includes

19 questions divided into seven domains of quality of life: incontinence impact, role limitations, physical limitations, social limitations, personal relationships, emotions, sleep and energy, severity coping measures, general health perception, and symptom severity. The third section of the questionnaire comprises 11 questions measuring the bother or impact of urinary symptoms. The KHQ has demonstrated reliability and validity in men and women [24] [79-81] is available in 37 languages [82-84]. Sensitivity to change has been shown successfully in clinical trials where it has been used to assess the HRQL improvement following treatment for patients with OAB, USI and mixed incontinence symptoms [79, 85-88]. A minimally important difference has been derived to establish clinically meaningful interpretations of the KHQ scores and a QALY measure has been derived from KHQ scoring [89].

7. LEICESTER IMPACT SCALE (LIS)

The LIS is a condition-specific HRQL measure for men and women assessing the symptoms of urgency, frequency, nocturia, and incontinence. It is an interviewer-administered tool so it is not a true PRO as interviewer administration can introduce potential bias into the patient responses. The LIS does have utility in the clinical and research settings [90].

8. OVERACTIVE BLADDER SYMPTOM AND HEALTH-RELATED QUALITY OF LIFE (OAB-Q) AND OAB-Q SF

The OAB-q is a 33-item questionnaire developed to assess the Symptom Bother (8 items) and HRQL impact of OAB (25 items; 4 domains: Coping, Concern/Worry, Sleep, and Social Interaction.). It has demonstrated reliability, validity, responsiveness in multiple clinical studies of men and women. A minimally important difference has been derived [91, 92] to establish clinically meaningful interpretations of the OAB-q scores and a QALY measure has been derived from OAB-q scoring [93]. The 19-item short-form (OAB-q SF) is a six-item symptom bother scale and 13-item HRQL scale that is a single score which has also demonstrated reliability, validity, and responsiveness to change [94].

The OAB-q was the basis for the OAB-V8 Awareness Tool to screen for symptoms of OAB [95] and has been used in a Parkinson disease patient population [96].

9. UROGENITAL DISTRESS INVENTORY (UDI) AND UDI-6

This questionnaire was developed in the US with women to assess the degree to which symptoms associated with incontinence are troubling [59]. It contains 19 lower urinary tract symptoms and has been shown to have high levels of validity, reliability and responsiveness in a community-dwelling popu-

lation of women with incontinence, (59) women over 60 years, [97] women in two regions of Scotland [64]. Responsiveness to changes in clinical status as a result of treatment have been reported in a number of areas: cadaveric fascia lata sling for stress incontinence, [72] comparing abdominal and vaginal prolapse surgery, [98] and the use of a simple urethral occlusive device [99].

A short-form version of the UDI (UDI-6 short form) has been shown to be valid and reliable in older adult males and females, [100, 101] with demonstrated responsiveness to reconstructive pelvic surgery, [69] tension-free vaginal tape, [71, 73] and imipramine [74]

II. OTHER UI/LUTS QUESTIONNAIRES

A number of other questionnaires noted in Table 6 have been developed to assess symptoms or health-related quality of life impact of LUTS and/or UI, however they do not reach the highest level of grading because they do not have the full complement of psychometric evaluation or robust data, or are less relevant for the assessment of UI than the questionnaires reported above. Each is referenced in the table should further information be needed.

III. PATIENT SATISFACTION

Patient satisfaction is the subjective, individual evaluation of treatment effectiveness and/or the service provided by the healthcare system. Measures of satisfaction can include evaluation of accessibility/convenience, availability of resources, continuity of care, efficacy, finances, humaneness, information gathering and giving processes, pleasantness of surroundings and perceived quality/competence of health care personnel [119]. At its most basic level, satisfaction is a comprehensive evaluation of several dimensions of health care based on patient expectations and provider and treatment performance. As an outcomes measure, patient satisfaction allows health care providers to assess the appropriateness of treatment according to patient expectations. In chronic diseases, where patients must live with treatment, patient satisfaction may be the distinguishing outcome among treatments with comparable efficacy [120].

Two patient satisfaction methods of promise with Grade B criteria are the BSW and OAB-S. Generally responsiveness cannot be assessed as there is no baseline assessment of patient satisfaction with treatment as no treatment has been given. **Table 7** below presents a summary of satisfaction instruments identified in UI, OAB and other LUTS.

1. BENEFIT, SATISFACTION, AND WILLINGNESS (BSW) QUESTIONNAIRE

This 3-item questionnaire is designed to assess

treatment benefit, patient satisfaction with treatment, and patient willingness to continue treatment. The BSW questionnaire was validated using data from three 12-week placebo-controlled trials of tolterodine in patients with OAB [121]. In this validation study, correlations were seen between patient-reported treatment satisfaction and improvements in the OAB-q, the KHQ, and micturition variables.

2. THE OVERACTIVE BLADDER TREATMENT SATISFACTION QUESTIONNAIRE (OAB-S)

The OAB-S is a 5 domain questionnaire which evaluates control expectations, impact on daily living with OAB, OAB control, fulfillment of OAB medication tolerability and satisfaction with control. Internal reliability coefficients were good (Cronbach's alpha 0.76-0.96), and test retest reliability has been established (reliability coefficients 0.72-0.87) [122, 123]. Cultural and linguistic differences were considered early in the development process, and the OAB-S is available in over sixteen languages [124].

IV. SCREENING TOOLS

In order to improve the detection of incontinence, OAB and other LUTS, several screening tools have been developed (**Table 8**). These tools help patients self-describe symptoms and facilitate diagnosis of LUTS by the clinician. Only the B-SAQ has been designed to screen for general lower urinary tract symptoms (LUTS) rather than solely symptoms of one condition. The majority of patients with LUTS have mixed urinary symptoms, and therefore a questionnaire which can detect more than one symptom complex may be more functional as a screening tool in clinical practice than a highly specific questionnaire. The Leicester Impact Scale (LIS), OAB-V8, OAB-SS and QUID are all Grade A, short, simple to understand and complete, and easy to interpret, however the LIS is interviewer, not patient administered. Importantly, with screeners, responsiveness is not assessed, however the sensitivity and specificity of each tool is critical.

1. LEICESTER URINARY SYMPTOM QUESTIONNAIRE (LUSQ)

The LUSQ is a 10-item, interviewer-administered questionnaire developed to assess storage LUTS. As an interviewer-administered tool, it is not a true PRO but is mentioned here as it may be useful in clinical practice and research when it is necessary or preferred to use interviewer administrative tools. The LUSQ assesses the presence and severity of incontinence, urgency, frequency and nocturia, and the tool can be used for both male and female patients [127].

2. OAB-V8/OAB AWARENESS TOOL

The OAB-V8/OAB Awareness tool has been adapted

Table 7. Summary of Urinary Incontinence, OAB and LUTS PRO Measures – Patient Satisfaction

PRO Name	Purpose of Tool	Population Sample	Reliability		Validity				Psychometric Validation in Other Languages	Available Languages
			Internal Consistency	Test-retest	Content	Criterion	Concurrent	Discriminant		
BSW (Benefit, Satisfaction with treatment, and Willingness)[121] Grade B	To capture patients' perceived benefit, satisfaction with treatment, and the willingness to continue treatment	Men and Women, OAB					✓	✓		www.prolutssh.com
EPI (Estimated Percent Improvement)[125] Grade C	One item questionnaire to gain a patient's improvement in a percent scale	Women, UI, SUI, MUI						✓ (2-4 Weeks)		None Found
GPI (Global Perception of Improvement)[125] Grade C	One item questionnaire to assess patient's improvement	Women, UI, SUI, MUI						✓		None Found
OAB-S (Overactive Bladder Satisfaction Questionnaire)[122, 123] Grade B	To assess patients' satisfaction with OAB treatment including/or not medication. The pre-medication module is designed to assess the patient's expectations with treatment and impact of OAB on patient's day to day life	Men and Women, OAB	✓	✓	✓		✓			None Found/though mentioned in literature
PSQ (Patient Satisfaction Question)[125] Grade C	One item questionnaire used to measure how satisfied a subject was with a program	Women, UI, SUI, MUI						✓		None Found
TBS (Treatment Benefit Scale)[126]	A single-item scale used to assess the patient-reported benefits of treatment of OAB	Men and Women, OAB		✓			✓			TBS is available in other languages

Table 8. Summary of Urinary Incontinence, OAB and LUTS PRO Measures – Screeners

PRO Name / Grade	Purpose of Tool	Population Sample	Reliability		Validity					Validation in Other Languages	Available Languages
			Internal Consistency	Test-retest	Content	Criterion	Concurrent	Discriminant	Sensitivity/specificity		
B-SAQ (Bladder Self-Assessment Questionnaire) or Bladder Control Self-Assessment Questionnaire (BCSQ) [129] Grade A	A screening tool for the presence of bothersome LUTS in Women	Women	✓	✓	✓	✓	✓	✓	✓		B-SAQ Translated in 14 Available http://www.mapi-research.fr/i_03_list_urol.htm
ISQ (Incontinence Screening Questionnaire) [130] Grade C	5 item questionnaire developed to screen for incontinence in women	Women, UI		✓						✓	None Found
LUSQ (The Leicester Urinary Symptom Questionnaire) [127] Grade A	A condition-specific screener of storage LUTS(urgency, frequency, nocturia and incontinence). Was originally developed for women with incontinence only.	Men and Women, LUTS	✓	✓	✓			✓			None Found
MESA (Medical, Epidemiological, and Social Aspects of Aging Questionnaire) [131] Grade C	A 15 item screening tool for urinary incontinence in female pelvic medicine and reconstructive surgery patients	Women, UI		✓						✓	Translated in English and Spanish http://www.ncbi.nlm.nih.gov/pubmed/17576498?ordinalpos=2&tool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_RVDocSum
OAB-SS (Overactive Bladder Symptom Score) [132] Grade A	A 7 item questionnaire validated to measure overall symptom severity due to the four index symptoms of OAB	Men and Women, LUTS with or without OAB	✓		✓				✓		None Found
OAB-V8 (OAB Awareness Tool) [95] Grade A	An 8-item screening tool for use in a primary care setting to identify patients who may have OAB	Men and Women, OAB							✓		OAB-V8 is Translated in 32 Languages http://www.oabq.com/translations.html
PUF patient symptom scale (Pelvic Pain, Urgency, and Frequency) [133] Grade C	To evaluate of patients with suspected IC/PBS	Women and Women, IC/PBS								✓	PUF available in English and Spanish http://www.ncbi.nlm.nih.gov/pubmed/15833505?ordinalpos=3&tool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_RVDocSum

Table 8. Summary of Urinary Incontinence and LUTS PRO Measures – Screeners (continued)

PRO Name / Grade	Purpose of Tool	Population Sample	Reliability		Validity				Validation in Other Languages	Sensitivity/ specificity	Available Languages
			Internal Consistency	Test-retest	Content	Criterion	Concurrent	Discriminant			
QUID (Questionnaire for Urinary Incontinence Diagnosis)[128] Grade A	6 item questionnaire used to diagnose stress and/or urge types of urinary incontinence	Women, UI and SUI	✓	✓	✓				✓	None Found	
3IQ (Three Incontinence Questions Questionnaire) [134] Grade C	A three item questionnaire used to classify urge and stress incontinence	Women, UI	Psychometric evaluation not reported						✓		
UI (Urinary Incontinence Score) [135] Grade C	Developed in German used to assess UI	Women, UI							✓	Available in German	
USP (Urinary Symptom Profile) [139] Grade B	To assess urinary symptoms in male and female with stress, urge, frequency or urinary obstructive symptoms for use in clinical practice to complement clinical measures and diagnosis	Men and Women stress UI, urge UI, low stream, combined symptoms	✓	✓					✓	None Found	
I-PSS (International Prostate Symptom Score) [137] Grade B	8- item questionnaire used to capture the severity of urinary symptoms related to benign prostatic hyperplasia. Originally developed from the American Urological Association Symptom Index.	Men	✓	✓					✓	I-PSS translated into 40 languages http://proqolid.org/instruments/international_prostate_symptom_score_i_pss	

from the OAB-q questionnaire; which is a 33 item questionnaire which assess symptom bother and HRQL impact of OAB [29]. The OAB-V8 is an 8-item questionnaire, which evaluates the symptoms of overactive bladder; namely urinary frequency, nocturia, urgency and urge incontinence. Responses are graded on a 6 point Likert scale. Patients with an overall score of eight or more are directed to seek medical advice. This questionnaire is validated for use by men and women [98].

3. OAB-SS

The OAB-SS is a validated A 7-item questionnaire validated to measure overall symptom severity due to the four index symptoms of OAB. It quantifies all symptoms of OAB in men and women. The OAB-SS includes a detailed evaluation of the urgency symptom. Responses are graded on a 5 point Likert scale.

4. QUESTIONNAIRE FOR URINARY INCONTINENCE DIAGNOSIS(QUID)

The QUID is a 6-item patient administered questionnaire developed to identify and differentiate stress vs urge incontinence. There are 3 items each related to stress and urge incontinence. Scoring is 0 (not at all) to 5 (all the time) for each response. The tool was developed for use with females [128].

V. ASSESSING SYMPTOM BOTHER AND OVERALL BOTHER

Measures that can be used to assess how bothered patients are by urinary symptoms are included in **Table 9**. The Patient Perception of Bladder Condition [138] and the Urogenital Distress Inventory are the only Grade A recommend instrument. There are several Grade B and C measures which assess bother for incontinence and LUTS.

1. PATIENT PERCEPTION OF BLADDER CONDITION (PPBC)

The PPBC is a single item questionnaire designed to rapidly assess patients' perception of their bladder condition [138].

The questionnaire asks patients to choose one of 6 statements that best describes their present bladder condition. The scale was validated during two large 12-week clinical studies evaluating the efficacy and tolerability of Tolterodine in patients with OAB. Patients taking part in the studies completed the PPBC, OAB-q, KHQ and bladder diaries. Baseline and week 12 data was used for statistical analysis. PPBC scores were well correlated with OAB-q questionnaire scores and bladder diary variables. Correlations of the KHQ and PPBC were significant for all KHQ domains with the exception of the general health perception domain. The scale was found to be responsive to change in

OAB symptoms and to have discriminant validity as reflected in the OAB-q, KHQ score and bladder diary changes. The PPBC has also shown to have good test retest reliability [117]. This scale has been widely used in studies evaluating the use of drug therapy in patients with OAB [139-141].

2. UROGENITAL DISTRESS INVENTORY (UDI-6)

The UDI-6 is a six item questionnaire which assesses the presence and bother of 6 lower urinary tract symptoms [101]. The UDI-6 assesses types of incontinence, frequency, difficulty emptying bladder and pain/discomfort in the lower abdomen/genitalia. The response options are 0-3. The instrument has demonstrated validity, reliability and responsiveness [142].

VI. ASSESSING THE IMPACT OF URGENCY

Several instruments have been developed specifically to assess urinary urgency, which is defined by the International Continence Society as "the complaint of a sudden compelling desire to pass urine which is difficult to defer" [147]. Urgency is the principle symptom of OAB [148], and, as such, assessing the effect of treatment on this symptom and its impact on HRQL is important. With any measure designed to evaluate urgency, patients must be able to distinguish between the normal desire to urinate (urge) and the difficult-to-postpone need to urinate (urgency) [149, 150]. Wording thus becomes critical in the development of urgency assessment measures. Chapple and Wein [151] make a case for describing urgency as a "compelling desire to void in which patients fear leakage of urine" as a means of distinguishing this abnormal sensation from the normal need to void. However, some patients may have a sensation of urgency without fear of leakage, further complicating attempts to define urgency. Importantly, with some of these scales, patients have the option of indicating that they experienced UUI (an event) rather than the strongest feeling of urgency (a sensation) itself. In such cases, patients who have severe urgency, but not UUI, do not have an option for endorsing the highest (worst) value, because they are not incontinent. Urgency severity scales that include a UUI response option thus may be less useful than those that do not because such scales are trying to measure 2 things at once, both urgency and UUI.

Several instruments have been developed to assess urinary urgency these are summarized in **Table 10**. Given no urgency measures have a Grade A rating, a brief summary of each urgency measure is presented below.

Urgency Perception Scale was designed for use in clinical trials to evaluate patient-perceived urgency

Table 9. Summary of Urinary Incontinence, OAB and LUTS PRO Measures – Symptom Bother

PRO Name / Grade	Purpose of Tool	Population Sample	Reliability		Validity				Psychometric Validation in Other Languages	Responsive-ness (Treatment Duration)	Available Languages
			Internal Consistency	Test-retest	Content	Criterion	Concurrent	Discriminant			
PGI-H and PGI-S (Patient Global Impression of Severity and of Improvement) [143] Grade C	Two single-question global indexes to measure symptom bother related to urinary incontinence	Women, SUJ				✓				✓ (12 Weeks)	None Found
POSQ (Primary OAB Symptom Questionnaire) [117] Grade C	To assess which symptom of OAB is the most bothersome to patients	Men and Women, OAB		✓							None Found
PPBC (Patient Perception of Bladder Condition)[138] Grade A	To assess patients' subjective impression of their current urinary problems. Developed for patients with urinary problems as a global assessment of bladder condition and is recommended as a global outcome measure for urinary incontinence by the European Medicine Evaluation Association	Men and Women		✓						✓	PPBC is translated in 22 Languages www.prolutssh.com
SPI (Symptom Problem Index)[144] Grade B	To measure how troublesome the patients find their urinary symptoms	Male, BPH	✓	✓	✓					✓	SPI is translated in 19 languages http://proqolid.org/instruments/symptom_problem_index_spi
SSI and SII (Symptom Severity Index and Symptom Impact Index for stress incontinence in women)[145] Grade C	To measure stress incontinence severity and impact or bothersome of symptoms. This questionnaire was developed and administered to women undergoing stress incontinence surgery	Women, SUJ		✓		✓				✓	SSI and SII translated in 5 languages http://proqolid.org/instruments/symptom_severity_index_and_symptom_impact_index_for_stress_incontinence_in_women_ssi_and_sii
UI-4 (Urinary Incontinence -4 Questionnaire) [146] Grade C	To assess how patients are bothered by urinary incontinence	Women, UI									Available only in Spanish http://www.ncbi.nlm.nih.gov/pubmed/10486097ordinalpos=3&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_RVDocSum

Table 9. Summary of Urinary Incontinence, OAB and LUTS PRO Measures – Symptom Bothers (continued)

PRO Name / Grade	Purpose of Tool	Population Sample	Reliability		Validity				Psychometric Validation in Other Languages	Available Languages
			Internal Consistency	Test-retest	Content	Criterion	Concurrent	Discriminant		
UDI (Urogenital Distress Inventory) [64] Grade B	To assess symptom bother related to urinary incontinence. UDI is meant to complement the IIQ, was developed at the same time as the IIQ.	Women, UI, SUJ	✓	✓	✓	✓	✓	✓	✓	Available in 3 languages (English, Italian and Arabic)
UDI-6 (Urogenital Distress Inventory -6) [142] Grade A	To assess LUTS bother, including incontinence, in women.	Women		✓	✓	✓	✓	✓	✓	Available in 3 languages (English, Turkish and Arabic)

[152]. This instrument consists of a single question asking patients to describe their typical experience when they feel the need to urinate. The 3 possible responses are “I am usually not able to hold urine,” “I am usually able to hold urine until I reach the toilet if I go immediately,” and “I am usually able to finish what I am doing before going to the toilet.” [152]. This scale was validated in a clinical trial evaluating the efficacy of tolterodine in treating OAB symptoms; [152] however, its limited responsiveness may preclude its usefulness in clinical practice [153].

Indevus Urgency Severity Scale asks patients to rate their level of urgency on a 4-point scale, from 0 (no urgency) to 4 (extreme urgency discomfort that abruptly stops all activity/tasks) [154]. The scale has been validated in a clinical trial of trospium in patients with OAB, [154] but Chapple et al [153] question whether this scale actually measures urgency or just the normal urge to void.

Urinary Sensation Scale is a 5-point scale ranging from 1 (no urgency; can continue activities until it is convenient to use the bathroom) to 5 (urge incontinence; extreme urgency discomfort, cannot hold urine and have a wetting accident before arriving at the bathroom) [155]. The content validity of this scale was established through a physician survey and patient interviews [155].

Urgency Rating Scale, recommended by the European Medicines Evaluation Agency, consists of a 5-point rating scale to be rated with every void, ranging from 1 (no urgency; I felt no need to empty my bladder but did so for other reasons) to 5 (urge incontinence; I leaked before arriving at the toilet) [16]. This scale was used in a tolterodine clinical trial, in which responses on this scale were used to calculate sum urgency, a measure that accounts for changes in both urgency and frequency [156].

VII. QUESTIONNAIRES TO ASSESS SYMPTOMS AND HEALTH RELATED QUALITY OF LIFE IMPACT OF PELVIC ORGAN PROLAPSE

Many women present with vaginal symptoms and pelvic organ prolapse (POP) is frequently implicated. A traditional clinical history is usually used in an effort to assess the symptoms experienced by the patient and a thorough clinician will try to gain insight into how these symptoms are impacting on the patient’s life. A detailed description of the clinical techniques of pelvic floor assessment are described in another chapter in this book. However, symptoms do not always correlate with objective examination findings. Indeed the clinical assessment itself can be inconsistent, depending upon the position of the patient, whether they have been standing for a

Table 10. Summary of Urinary Incontinence, OAB and LUTS PRO Measures – Urgency

PRO Name/Grade	Purpose of Tool	Population Sample	Reliability		Validity				Psychometric Validation in Other Languages	Responsive-ness (Treatment Duration)	Available Languages
			Internal Consistency	Test-retest	Content	Criterion	Concurrent	Discriminant			
IUSS (Indevus Urgency Severity) [157] Grade A	Used to quantify the level of urgency associated with each toilet void as measured during standard voiding diaries.	OAB with urgency incontinence, men and women		✓	✓	✓	✓	✓		✓ (12 Weeks)	None Found
SUIQ (Stress/Urgency Incontinence Questionnaire) [158] Grade C	Two item questionnaire used to differentiate between symptoms of stress and urge urinary incontinence	Women, UI		✓		✓					None Found
UDI (Urogenital Distress Inventory)[64] Grade B	To assess symptom bother related to urinary incontinence. UDI is meant to complement the IIQ, was developed at the same time as the IIQ.	Women, UI, SUI	✓	✓	✓				✓		Available in 3 languages (English, Italian and Arabic)
UPS (Urgency Perception Scale)[159] Grade C	self-report 5 item OAB questionnaire used for grading the urge to void and assessing the reason why individuals usually void	Men and Women		✓	✓				✓		None Found
UPS (Urgency Perception Scale) [152] Grade B	To assess the severity of urgency – whether or not urgency, the sudden and compelling desire to urinate should have a severity measure is debated. The UPS was designed for use in clinical trials to evaluate patient perceived urgency	OAB (double-blind), men and women			✓				✓		None Found
URIS-24 (Urge Impact Scale) [160] Grade C	To assess of the impact of the most common form of UI in older persons	Older persons, UI	✓	✓	✓						None Found
URS (Urgency Rating Scale) [161] Grade C	5-point scale to be used concurrently with voiding diaries to measure the level of urgency associated with each micturition. Advocated by the EMEA CPMP										Psychometric evaluation not reported

Table 10. Summary of Urinary Incontinence, OAB and LUTS PRO Measures – Urgency (continued)

PRO Name	Purpose of Tool	Population Sample	Reliability		Content	Validity				Psychometric Validation in Other Languages	Available Languages
			Internal Consistency	Test-retest		Criterion	Concurrent	Discriminant	Responsiveness (Treatment Duration)		
USS (Urinary Sensation Scale) [162] Grade C	To assess the impact of urgency with patients with OAB	Urologists or urogynecologists. Survey respondents with OAB symptoms		N/A	✓	N/A	N/A				None Found
UU Scale (10-Item Scale to Measure Urinary Urgency) [163] Grade B	10 item questionnaire use to measure urinary urgency	Men and Women		✓			✓			NONE	None Found

prolonged time or have just used a pessary or tampon. While there is a little research defining the association between specific symptoms and support defects [164-166], measuring subjective outcome after treatment is problematic. Unlike lower urinary tract dysfunction, where increasingly patient-completed methods such as diaries and questionnaires are being used to measure outcome, there are fewer such instruments available for POP. Clinician based history is inconsistent, disease impact may not be assessed, leading questions can be asked and patients may be unwilling to volunteer symptoms, particularly after surgical intervention, for fear of appearing ungrateful or a nuisance. Consequently, despite the highly prevalent nature of this condition we have little idea how intervention, which is frequently surgical, alters symptoms and HRQL. As for incontinence, questionnaires to assess symptoms and HRQL impact of pelvic organ prolapse would be highly desirable.

For POP, the Committee examined the quality of the psychometric evidence and only where published data were scientifically sound was the label 'with rigour' allowed. The Committee noted that this is a developing area with few questionnaires currently reaching the highest levels of evidence. Thus three grades of recommendation were established (Table 11).

Table 11. Criteria for recommendation of questionnaires for POP at the Fourth Consultation

Grade of recommendation	Evidence required (published)
Recommended (Grade A)	Validity, reliability and responsiveness established with rigour.
(Grade B)	Validity and reliability established with rigour, or validity, reliability and responsiveness indicated.
With potential (Grade C)	Early development – further work required and encouraged

1. GRADE A

a) Pelvic Floor Distress Inventory (PFDI) and PFIQ (Pelvic Floor Impact Questionnaire)

This questionnaire is an adaptation of the well-established UDI with the aim of developing a comprehensive condition specific instrument to assess impact from pelvic organ prolapse and other aspects of colorectal-anal dysfunction, as well as LUTS [167].

The PFDI retains the 19 original items of the UDI, and adds 9 items related to lower urinary tract symptoms that are common in women with pelvic floor disorders. The three original subscales of the UDI are retained (i.e., obstructive, irritative/discomfort, and stress). Psychometric testing included internal reliability (PFDI Cronbach's alpha 0.88, PFIQ 0.98), 1 week test-retest (interclass correlation coefficient PFDI 0.87, PFIQ 0.86).

Both correlated with stage of prolapse (Spearman correlation coefficient for pelvic organ prolapse distress inventory and impact questionnaire 0.32 $p < 0.01$, 0.33 $p < 0.01$). Responsiveness has not yet been tested.

PFIQ is an adaptation of the IIQ to assess quality of life impact in women with pelvic floor disorders. It contains items included in the original IIQ and new items related to other pelvic floor disorders. PFIQ has 3 scales including 92 items: IIQ (30 items), Colorectal-anal impact Questionnaire (CRAIQ) (31 items) and Pelvic Organ Prolapse impact Questionnaire (POPIQ) (31 items).

Each scale includes 4 domains of travel, social, emotional and physical activity. The psychometric properties of the PFIQ were evaluated in 100 female patients with pelvic floor dysfunction [167].

The PFIQ showed good validity; each of IIQ, CRAIQ and POPIQ revealed significant correlation with incontinence episode and number of pad use per week, faecal incontinence per week and stage of prolapse, respectively. Internal consistency was excellent (Cronbach alpha 0.98) and test-retest reproducibility was high (overall ICC 0.86 ranging from 0.69 to 0.92). A French language version has been produced [168]. Responsiveness has not yet been evaluated.

Responsiveness of the PFDI and PFIQ was tested in women with pelvic organ prolapse undergoing surgical and conservative management with vaginal pessaries. Women undergoing surgical treatment for prolapse reported significantly greater improvement in all subscales of the PFDI and PFIQ than those patients treated with pessaries.

The PFDI was found to be more responsive to change than the PFIQ [169]. French and Spanish versions of both the PFIQ and PFDI have been produced [170, 171]. Long forms of the PFDI and PFIQ have also been validated for telephone administration [172].

Short forms of the PFDI and PFIQ questionnaires have been developed. Reliability, validity and responsiveness were tested in a population of patients before and 3-6 months after pelvic floor surgery. The short form of the PFIQ and PFDI correlated well with the long form versions of the questionnaires ($r = 0.88-0.94$) [173] (Table 12).

Table 12. Recommended questionnaires for the evaluation of symptoms and quality of life impact of pelvic organ prolapse

Grade A New (recommended)
Pelvic Floor Distress Inventory (PFDI) [167]
Pelvic Floor Impact Questionnaire (PFIQ) [167]
Grade B
The electronic Personal Assessment Questionnaire – Pelvic Floor (ePAQ-PF) [174]
Grade C (with potential)
P-QOL/St. Mary's Questionnaire [175]
Pelvic Floor Dysfunction Questionnaire [176]
Danish Prolapse Questionnaire [164]

2. GRADE B

• e-PAQ Electronic Pelvic Floor Symptoms Questionnaire

The electronic Personal Assessment Questionnaire – Pelvic Floor (ePAQ-PF) is an interactive computerised system that comprehensively measures pelvic floor symptoms and their impact on HRQL in women. It comprises a maximum of 124 items in 4 dimensions (Urinary, Bowel, Vaginal & Sexual) and includes 19 scored domains:

The original 14 domain version underwent psychometric testing in primary and secondary care, where it was found to be valid, reliable and acceptable (Radley et al 2006) [177]. Since this initial validation study, a further 5 domains have been added including: Irritable Bowel, Dyspareunia, Vaginal Capacity, Urinary Voiding and General Sex Life [178]. Each domain is scored on a scale of zero (best possible health) to 100 (worst possible health) and the symptom domains also each provide a 4-point scale. Recent tests of data quality on this version of ePAQ-PF supported the 19 domain structure of the instrument and its reliability and validity (Jones et al, 2008) [179]. The responsiveness of the instrument has also been demonstrated [177].

3. GRADE C

Several other questionnaires of Grade C level or below have been developed in the area of POP. If the validation of these instruments progress they may be useful for researchers. These include:

- P-QOL/St Mary's Questionnaire [175] [180] -Pelvic Floor Dysfunction Questionnaire [176]
- -Danish prolapse questionnaire [164]
- Pelvic symptom inventory and quality of life questionnaire [181,182]

- Pelvic floor questionnaire [183]
- Sheffield prolapse symptom questionnaire [178]
- ICIQ-Vaginal Symptoms (In development). [30], [184].

VIII. QUESTIONNAIRES TO ASSESS SYMPTOMS AND HRQL IMPACT OF FAECAL INCONTINENCE

A range of questionnaires have been developed to identify the severity of faecal incontinence (FI) and its influence on HRQL. Despite the large number, only a few are in regular use in research practice, and few services routinely use them in clinical assessment. Due to the close overlap between faecal incontinence and other pelvic floor disorders (in particular urinary incontinence), some of those questionnaires used for other pelvic disorders also include items to cover faecal incontinence. For similar reasons, items relating to faecal incontinence have often been included in questionnaires addressing general gastro-intestinal and colo-rectal function, as well as condition specific instruments in such areas as irritable bowel syndrome and inflammatory bowel disease, conditions which are commonplace in colorectal practice as well as in other specialties dealing with pelvic floor disorders [185, 186]. It is also important to remember that the normal range of bowel function is broad, that bowel function may be highly variable within individuals without significant pathology. Consequently instruments in this field are likely to lack a degree of sensitivity or specificity for the specific bowel disorders such as IBS, IBD evacuation disorder and constipation.

Anal incontinence and bowel evacuation are intrinsically related to pelvic floor function and it may be inappropriate to consider bowel function purely in terms of continence and constipation. Evacuatory dysfunction may result from a variety of underlying pathologies including outlet obstruction, slow transit or other mechanical, pharmacological, metabolic, endocrine and neurogenic abnormalities [187]. Anal incontinence occurs in both sexes, but is more common in women than men [188]. Symptoms are considered crucial to diagnosis as specific symptoms are thought to reflect the underlying pathophysiology [189]. Thus, urgency (the inability to defer defecation) and urgency incontinence are thought to indicate loss of voluntary control due to impaired external anal sphincter function, whereas passive incontinence is thought to indicate impairment of the smooth muscle of the internal sphincter.

For FI, the Committee examined the quality of the psychometric evidence and noted that this is a

developing area with questionnaires currently reaching the highest level of evidence. A FI outcomes measure is currently in development by the ICIQ (Table 3). A commonly used score for FI (Wexner), for example, does not appear to have published data related to its psychometric properties and thus while it is used widely cannot be recommended by the committee. The grades of recommendation are as outlined in previous sections (Tables 13,14).

Table 13. Criteria for recommendation of questionnaires for faecal incontinence

Grade of recommendation	Evidence required (published)
(Grade A)	Validity, reliability and responsiveness established with rigour.
(Grade B)	Validity and reliability established with rigour, or validity, reliability and responsiveness indicated.
With potential (Grade C)	Early development – further work required and encouraged

Table 14. Recommended questionnaires for the evaluation of symptoms and quality of life impact of faecal incontinence

Grade A
None
Grade B
Faecal Incontinence Quality of Life Scale [190]
Manchester Health Questionnaire [191]
Birmingham Bowel and Urinary Symptoms Questionnaire (BBUS-Q) [192, 193]
Grade C (with potential)
Wexner score [194]
St Mark's score [195]
Faecal Incontinence Survey [196]
Elderly Bowel Symptoms Questionnaire [197]
Postpartum Flatal and Faecal Incontinence Quality of Life Scale [198]
Bowel Disease Questionnaire [199]
Gastrointestinal Quality of Life Index [200]

1. GRADE A

No questionnaires are currently available at this level.

2. GRADE B

a) *Faecal Incontinence Quality of Life Scale*

The 29-item Faecal Incontinence Quality of Life Scale developed and tested by Rockwood et al measures impact of anal incontinence over four scales of HRQL; Lifestyle (10 items), Coping/behaviour (9 items), Depression/Self perception (7 items) and Embarrassment (3 items) [190]. The instrument was designed to measure the effect on quality of life of treatment for individuals with faecal incontinence. A panel of colorectal surgeons and researchers generated the items. Psychometric properties were tested in 118 patients with faecal incontinence and 72 controls.

The question-naire showed good discriminant validity, with significant differences between patients with faecal incontinence and those with other gastrointestinal disorders. There were also significant correlations with selected subscales of the SF-36. Test-retest reliability at a mean interval of 8 days was satisfactory, with correlations for the 4 scales of 0.8 - 0.96. Internal consistency of the 4 scales was >0.7. The instrument does not measure physical symptom severity and has not been tested in asymptomatic controls, but appears to offer a valid and reliable measure of the impact of faecal incontinence on quality of life in men and women with this condition [190]. However, in order to demonstrate discriminant validity, the researchers deemed it necessary to modify the questionnaire for use in controls. Its use in an unscreened population is as yet unreported, and no responsiveness data have yet been produced.

b) *Manchester Health Questionnaire*

This questionnaire consists of items adapted from the King's Health Questionnaire [191]. It uses the same basic structure and format but items have a 5-point response scale (rather than the 4-point scale in the KHQ). It includes items in the 8 domains of HRQL as well as a symptom severity scale. Face validity was assessed by interview with 15 patients with faecal incontinence. Test-retest reliability was measured (Pearson correlation > 0.8 in all 9 domains).

The questionnaire was posted to 236 women with faecal incontinence, of which 159 returned completed questionnaires. 121 performed test-retest at a mean interval of 20 days. Cronbach's alpha was > 0.7 in all domains tested, indicated adequate internal consistency.

Convergent validity was assessed by comparison with responses in the SF-36, which showed significant correlations between domains of the 2 instruments. Data relating to women without faecal incontinence or unscreened women are not yet available. The

questionnaire's sensitivity to change is also not yet established.

c) *Birmingham Bowel and Urinary Symptoms Questionnaire (BBUS-Q)*

This is a 22-item questionnaire developed to evaluate symptoms of both bowel and urinary dysfunction in women which has a published scoring manual [192, 193]. Items were generated by a panel of clinicians and scientists and following review of existing instruments in the literature. The instrument was tested in the gynaecology departments of three hospitals, a urogynaecology clinic, a functional bowel clinic and a general practice. A total of 630 women completed the questionnaire; 379 women awaiting hysterectomy, 45 women following hysterectomy 65 women referred with functional bowel and/or urinary symptoms and 141 asymptomatic controls.

The content, construct and criterion validity, internal consistency, reliability and responsiveness of the questionnaire were measured. Low levels of missing data, peer and patient reports supported face and content validity.

Factor analysis showed a clinically relevant four-factor structure: Constipation, Evacuatory function, Anal incontinence and Urinary symptoms with low content replication able to distinguish between patient groups, indicating good internal structure. Comparison with clinical, anorectal physiological, videoproctographic, transit time and urodynamic test results supported the instrument's criterion validity. Key domain question analysis and Cronbach's alphas showed internal consistency. Kappa values and limits of agreement demonstrated good test-retest reliability. Some responsiveness data have been produced.

The authors recommended the questionnaire for use as both a research tool and as a useful clinical measure. This questionnaire also forms a core element in an electronic pelvic floor symptoms assessment questionnaire (e-PAQ) (see above).

3. QUESTIONNAIRES WITH POTENTIAL [GRADE C]

There are several questionnaires on faecal incontinence which have not yet reached Grade C status. They may undergo further development and be of use in future research:

- Wexner score [194]
- St. Mark's score [195]
- Faecal incontinence survey [184,185,190,196, 201, 202]
- Elderly Bowel Symptom Questionnaire (EBSQ) [197].
- Postpartum Flatal and Faecal Incontinence Quality of life Scale [198].
- Bowel Disease Questionnaire [199]
- Gastro-intestinal Quality of Life index (GIQLI) [200]

IX. QUESTIONNAIRES TO ASSESS SEXUAL FUNCTION/SEXUAL HEALTH AND URINARY SYMPTOMS

Sexual function may be regarded as a dimension or aspect of overall HRQL, for which a number of dimension-specific measures have been developed and validated. There is a wide choice of available instruments, the selection of which will depend on the clinical or research setting where the instrument is to be employed. Established and widely used measures that have been shown to be valid, reliable and responsive are clearly desirable, however the feasibility and appropriateness of using a particular instrument in a particular setting must also be considered. A large number of different instruments exist in this field, which aim to evaluate specific aspects of sexual function and sexual health. A number have been specifically developed or adapted to examine sexual function in patients with pelvic floor disorders such as incontinence.

Clinicians who treat sexual problems often prefer to use unstructured rather than structured interviews or questionnaires in clinical practice as an unstructured approach allows the tailoring of questions to suit the couple or the individual being assessed. Unstructured interviews enable the clinician to support patients who feel vulnerable and encourage discussion. The experienced clinician hopes to have an appreciation of the information required to make the correct diagnosis and institute appropriate treatment. In this setting, vocabulary can be modified, as can the level of assertiveness and the depth of questioning to suit the needs of the individual. This flexibility is not readily achievable with questionnaires which individuals may also find difficult to complete due their impersonal nature or because of physical or mental impairment, cultural or language differences. However, some patients find the discussion of intimate issues with clinicians very difficult and questionnaires may allow these issues to be measured in private, at ease and more effectively before subsequently exploring questionnaire responses in the clinical interview itself (Table 15).

1. RECOMMENDED QUESTIONNAIRES [GRADE A]

a) *Golombok-Rust Inventory of Sexual Satisfaction*

The Golombok-Rust Inventory of Sexual Satisfaction (GRISS), is a self-report inventory which has 56 items, from them 28 are for males and 28 are for females and it takes approximately 15 minutes to complete [203]. The questionnaire was developed systematically by sex therapists at the Maudsley Hospital Sexual Dysfunction Clinic. The GRISS assesses the quality

Table 15. Recommended questionnaires for the evaluation of sexual function and health in patients with urinary symptoms

Grade A	
Men and women	Golombok-Rust Inventory of Sexual Satisfaction [203]
Men	*ICIQ-MLUTS _{sex} (ICS _{male} [27]) See section on ICIQ International Index of Erectile Function [204] ICS _{sex} [205] BPHQOL9 [118]
Women	*ICIQ-FLUTS _{sex} (BFLUTS [23]) See section on ICIQ *Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ)
Grade B	
Men and women	Psychosocial Adjustment to Illness Scale [206]
Women	Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire [207] Brief Index of Sexual Function for Women [208] The Female Sexual Function Index (FSFI) [209] SQOL-F [210]
Men	Brief Sexual Function Inventory [211]
Grade C (with potential)	
Men and women	Derogatis Interview for Sexual Functioning [206] Sexual Behaviour Inventory [212] Changes in Sexual Functioning Questionnaire [213] Sexual Interaction Inventory [214] Index of Sexual Satisfaction [215] Multidimensional Sexuality Questionnaire [216]
Women	McCoy Female Sexuality Questionnaire [217, 225] BFLUTS _{sex} [23] Female Sexual Function Index [209] Sexual Function Questionnaire [218] Simple Sexual Function Questionnaire [219]
Men	DAN-PSS _{sex} [220] Sexual life quality questionnaire [221]

* Grade A new

of a sexual relationship in a heterosexual couple and an individual's functioning within it. This questionnaire is designed for people who are currently in a relationship. There are 12 domain scores, 5 of which are female specific, 5 male specific and 2 non-gender specific. The 5 female specific domains are: Anorgasmia, Vaginismus, Avoidance, Nonsexuality and Dissatisfaction. The 2 non-gender specific domains are: Frequency of sexual contact and Non-communication. The questionnaire was validated on a clinical sample recruited from sexual dysfunction clinics throughout the UK, consisting of 68 men and 63 women, and a control group of 29 men and 30 women randomly selected from primary care attendees. Split half reliability was 0.94 for the female scale and 0.87 for the male overall scale. Average internal consistency of subscales was 0.74.

Both the overall female and male scores were found to discriminate well between clinical and non-clinical samples and scores on subscales successfully discriminated specific diagnostic groups. There was also a significant correlation between therapists' ratings of severity and scores on the questionnaire. Responsiveness was assessed by comparing change in the questionnaire scores with rated improvements by sex therapists. Correlations were moderate but statistically significant (0.54 for males and 0.43 for females, $p < .005$ and $p < .01$ respectively). Test-retest reliability was assessed in 41 couples receiving either marital or sex therapy. A further two subscales apply to both males and females and cover infrequency and non-communication. An additional 2 items each for males and females contribute to the overall scores but are not included in the subscales. The GRISS has been used by Hunt & Moss (1996) in a small study exploring the relationship of unwanted sexual experience to detrusor instability and sexual dysfunction [222]. High levels of sexual dysfunction were found in incontinent subjects compared to other clinical groups. The GRISS is not applicable to homosexual couples or people without a partner, but does provide an otherwise comprehensive, effective and well-used questionnaire.

b) ICIQ-MLUTSsex (ICSsex)

This forms one of the modules of the ICIQ modular questionnaire (see above) [205]. It consists of 4 items: to what extent sex life has been spoilt by urinary symptoms, ability to have erections, ability to ejaculate, and pain or discomfort on ejaculation. As with the other ICS questionnaires each item has an additional part to each item concerning the amount of both the symptom causes i.e. how much of a problem is this for you? It has been used in both clinic and community samples to assess the relationship between urinary symptoms and sexual function, [205] and to show that urinary symptoms most frequently associated with sexual dysfunction were those related to incontinence [223]. It has also been used in a

randomised trial of treatments for LUTS to investigate sexual side effects [224]. Aspects of reliability, validity and responsiveness have been tested and found to be satisfactory.

c) International Index of Erectile Function (IIEF)

The international index of erectile function (IIEF) is a 15-item self-administered questionnaire. It was designed to assess erectile function and is culturally and linguistically validated in at least 10 languages for use in multinational clinical trials.²¹³ It was initially validated in 351 patients with erectile dysfunction (ED) and found to have a high degree of internal consistency (Cronbach's $\alpha > 0.85$) and sensitivity to change with treatment. The questionnaire was culturally and linguistically validated in the following languages: Danish, Dutch, English (American, Australian and British), Finnish, French, German, Italian, Norwegian, Spanish and Swedish. The final 15-item instrument addresses five different domains of sexual function: erectile function, orgasmic function, sexual desire, intercourse satisfaction and overall satisfaction. The IIEF has a high degree of internal consistency. Test-retest repeatability was high for the domains of erectile function and intercourse satisfaction and moderately high for the other domains. Discriminant validity was good for most domains (except the sexual desire domain). Construct validity was good and all five domains showed a high degree of sensitivity to change. An abridged 5-item version of the questionnaire has also been developed (IIEF-5) [225]. Of the 5 items, 4 are from the erectile function domain and one addresses sexual intercourse satisfaction. The main difference between the 5- and the 15-item version is that the former asks patients to self-assess erectile function and satisfaction over the past 6 months while the latter refers to a time frame of 4 weeks. It has been used recently in a multinational survey of male ageing [220].

d) BPH QOL9

The QOL9 is a short form of the QOL20, a questionnaire previously validated in French for men with LUTS related to BPH [118]. The short form was developed using a large-scale cohort study of 7093 men with BPH who received alfuzosin for 3 months. The items were reduced by identifying questions that contributed most to establishing the global score and that reflected the structure of the questionnaire on principal components analysis. The final, 9-item questionnaire consists of 3 items concerning general well being, 3 items assessing BPH interferences with activities, and 3 items pertaining to patients' perceptions of their sexual life. The sexual function domain covered sexual desire, erectile function and satisfaction with sex life. The QOL9 was validated in two studies, a longitudinal study of alfuzosin, having a sample size of 4259, and a smaller cross-sectional study of men having symptomatic BPH ($n=48$), or no

symptoms of BPH (n=42), and a group of younger men (n=23). Feasibility and acceptability of the questionnaire were assessed by completion rates that exceeded 85%. Principal components analysis confirmed the three-factor structure. Discriminant validity was measured by comparing cases and non-cases. On the sexual function domain cases scored 10.5, non-cases 15.2 and young men 26.3. The most strongly discriminating question between cases and non-cases was satisfaction with sex life. There was also a good correlation between symptom severity and the total QOL9 score. Internal consistency of the overall scale was fair with Cronbachs alpha of 0.79 for patients with BPH and 0.85 for the control groups. Test-retest reliability was good for the total score but moderate for the sexual function subscale (ICC = 0.69 - 0.88) with the reliability of the erection item having an ICC of 0.53. After treatment the effect size of the change in the sexual function domain was linked to age and initial symptoms severity but had a mean of 0.02 and 0.55 for patients treated in each of the two studies.

e) ICIQ-FLUTSsex (BFLUTSsex)

This forms one of the modules of the ICIQ modular questionnaire (see above) The questionnaire contains 4 questions related to sexual function: pain or discomfort due to dry vagina, whether sex life has been spoilt by urinary symptoms, pain on sexual intercourse, and leakage on intercourse [23]. In addition to each of these items the respondent is asked how much of a problem this is for them. It has been used to assess sexual function after hormone replacement therapy [226] and pelvic floor muscle training [40]. There are 18 linguistic translations available and there is published evidence of validity, reliability and sensitivity to change..

f) Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ)

Rogers and colleagues in the United States have reported the development and validation of a measure of sexual function in women with urinary incontinence or pelvic organ prolapse [207]. The scale consists of 31 items spread across 3 domains: behavioural/emotive, physical, and partner-related. The measure has been found to have acceptable convergent and divergent validity and to be able to discriminate between women with and without urinary incontinence or pelvic organ prolapse [207, 227]. Test-retest ranged from 0.56 to 0.93, showing some variability in the moderate to high reliability ranges [228]. The internal consistency of the total measure and the behavioural/emotive, physical and partner-related domains was .85, .86, .77, and .43, respectively [228]. Sensitivity of the PISQ-31 has now been assessed in several studies.

A short form version of the questionnaire PISQ-12

has also been developed by the same team of researchers [229]. All subsets regression analyses with $r > 0.92$ identified 12 items, across all three domains, that were the most highly predictive of the PISQ-31 scores. Construct validity of the PISQ-12 was examined through correlations with the long form of the questionnaire PISQ-31 ($r=0.75-0.95$), the Sexual History Form -12, and the IIQ-7. Correlations of the PISQ-12 with these latter measures were similar to those found for the PISQ-31.

The PISQ-12 scores were lower in those patients with poorer sexual functioning and more depressive symptoms. Test-retest reliability was moderate to high. Internal consistency reliability was stated as having been done, although the values were not reported in the article. Sensitivity of the PISQ-12 was not assessed.

An initial validation of a Spanish version of the PISQ-31 was reported for 34 bilingual patients of Mexican, Central or South American, Puerto Rican and Cuban origins living in the United States [230]. Good agreement between the Spanish and English versions was achieved for 30 of the 31 items. The three-factor structure of the original measure was validated in this sample of participants [227, 231-239].

2. RECOMMENDED QUESTIONNAIRES [GRADE B]

a) The Female Sexual Function Index (FSFI)

The Female Sexual Function Index (FSFI) [209] is a 19-item self-report questionnaire for measuring female sexual function and takes approximately fifteen minutes to complete. It provides five domains of sexual function, which have been confirmed using factor analysis they include: Desire, Lubrication, Orgasm, Arousal, Pain and Satisfaction. An overall total score is also provided. The FSFI was developed using a sample of 131 female controls (between the age of 21-68) and 128 females who met Diagnostic and Statistical Manual of Mental Disorders (DSM-IV; American Psychiatric Association, 1994) criteria for Female Arousal Disorder (FSAD). The age of the participants was matched [21-69]. Norms are available for both groups (controls and FSAD) at the individual items level, the domains level, and the full-scale scores.

The FSFI discriminated reliably between women with arousal disorder (FSAD) and a control group on each of the domains of sexual function as well as on the full-scale score. FSFI data were also compared with results from the Locke-Wallace Marital Adjustment test (1959), Correlations between the two were generally modest in magnitude, with the strongest observed for the satisfaction domain of the FSFI. Internal consistency and test-retest reliability of the FSFI have been established. Test retest reliability of the scale was assessed in women with multiple

sclerosis with associated urinary and sexual symptoms [240].

Further cross validation studies were carried out to develop cut-off scores for potential classification of female sexual dysfunction [241, 242].

The FSFI was used in a study to investigate the prevalence of sexual dysfunction in women with chronic pelvic pain and with the [243] Female sexual distress score (FSDS) to investigate sexual outcomes in women with LUTS who were successfully treated with sacral neuromodulation. A 60% increase in the FSFI overall score or 50% increase in FSDS score was regarded as significant improvement [244]. The FSFI has been used in a study of pelvic floor muscle training for women with pelvic floor disorders and a study of sexual function in women with symptomatic pelvic organ prolapse who were treated with pessaries [233, 245].

The Italian version of the FSFI has been used as a screening tool for sexual dysfunction in healthy women attending annual gynaecological health checks [246]. The impact of LUTS and urinary incontinence on female sexual dysfunction was investigated over a 3 year period in women undergoing urodynamic studies using the FSFI [247]. The Malay translation has also been validated [248].

b) The Psychosocial Adjustment to Illness Scale (PAIS)

The Psychosocial Adjustment to Illness Scale (PAIS) was designed to assess the psychological and social adjustment of male and female medical patients to their illness and is in an interview or self-report format (PAIS and PAIS-SR) [206]. It contains a sexual relationships domain consisting of 6 items assessing the quality of interpersonal sexual relationships, sexual interest, frequency of sexual activity, sexual satisfaction, sexual dysfunction and interpersonal sexual conflict. Validation was carried out on groups of patients having renal dialysis, lung cancer, cardiac problems, breast cancer, and Hodgkin's disease. Internal consistency of the sexual relationships domain ranged from 0.8 to 0.93 in these different clinical groups. Factor analysis confirmed the subscale structure. All 6 items in the sexual relationships domain had very marked loadings on this dimension, with no appreciable loadings from other items. Convergent validity was assessed by comparing the scale to the Global Adjustment To Illness Scale ($r=0.46$), the SCL-90R ($r=0.13$), Affect Balance Scale ($r=0.42$), and the Patients Attitudes, Information and Expectancies Scale ($r=0.40$). Discriminant validity was assessed by comparing patients screened positive and negative for lung cancer. There were differences in the mean scores between the two groups which approached significance ($t=1.53$, $p<0.10$) [206]. 14 The PAIS has been used to investigate the impact of different types

of urinary incontinence on sexual function [249] in a sample of 200 patients referred for urodynamic assessment. Compared to patients with Urodynamic stress incontinence USI, patients having detrusor overactivity DO were significantly impaired on all items of the sexual relationships subscale, apart from the 'sexual satisfaction' item. Some aspects of validation were also carried out in a small study of 29 patients who had been treated successfully for penile cancer [250]. Internal consistency of the sexual relationships scales was good having Cronbach alpha of 0.83. Convergent and discriminant validity was shown in significant correlations with well-being scales but not with social scales. In addition, patients who had had the most radical treatments in terms of partial or total penectomy scored lower on the sexual relationships scale as did older patients (mean age 63 years) compared to younger patients (mean age 41 years), whereas having a mental disorder showed no correlation with sexual relationship scores.

c) The Brief Index of Sexual Function for Women (BISF-W)

The Brief Index of Sexual Function for Women (BISF-W) is a 22-item self-completed questionnaire that takes 15-20 minutes to complete [208]. It is designed to assess current levels of female sexual function and satisfaction. It was originally validated in a sample of 269 sexually active women age 20-73, and used a 3-factor scoring system (Interest/desire, Sexual activity, Sexual satisfaction) with acceptable test-retest reliability. A new quantitative scoring algorithm was developed to facilitate the use of the BISF-W in clinical trials, providing an overall composite score for sexual function and 7 domain scores; Thought/desire, Arousal, Frequency of sexual activity, Receptivity/initiation, Relationship satisfaction, Pleasure/orgasm, and Problems affecting sexual function. Norms for the composite score and for each of the seven dimension scores are available, derived from a sample of 225 healthy women (age 20-55) [251]. Comparing these scores with those of 104 surgically menopausal, sexually active women who reported impaired sexual function (age 20-55), the instrument showed good discriminant validity between women with and without sexual complaints in each of the 7 sexuality domains. In a placebo-controlled study, the BISF-W was sensitive to detecting differences between treatment groups in two of the 7 sexuality domains and on the overall composite BSIF-W score.

d) Brief Sexual Function Inventory

This 22-item questionnaire concerning male sexual function was designed for clinical and research purposes in urological settings [211]. Items were generated from the literature to produce a 50-item questionnaire which was then reduced down to 22 items in a series of pilot studies prior to the final validation study. The questionnaire comprises of 5

subscales: Libido, Erectile function, Ejaculation, Assessment of significance of each domain and Overall satisfaction. Validation was carried out on a sample of 74 men with sexual dysfunction and 60 general medical patients. Mean age was 55 and 45 years respectively. The study describes development of individual subscales down to a final questionnaire of 11 items based on measures of internal consistency and test-retest reliability. Internal consistency of the subscales ranged from 0.62 to 0.95 and ICC's from 0.79 to 0.89 for test-retest reliability.

All subscales except the drive and ejaculation subscales discriminated between patients being treated for sexual dysfunction and general medical patients, but it was not expected that drive would be reduced in patients experiencing sexual dysfunction and ejaculation did not appear to be an important issue for patients.

e) Sexual quality of life-female questionnaire (SQOL-F)

This questionnaire was developed to assess the impact of sexual dysfunction on womens' quality of life. Responsiveness to change has not been established [210]. The content validity of the SQOL-F, sexual function questionnaire (SFQ) and PISQ were further assessed in a postal study of women with OAB and urinary incontinence in the United States, and the SQOL-F was rated most relevant and understandable among this group of women [252].

3. QUESTIONNAIRES WITH POTENTIAL [GRADE C]

Several questionnaires that have potential and are currently under development or in need of further development. With further validations these instrument could provide additional resources to research:

- The Derogatis Interview for Sexual Functioning (DISF) [206]
- Sexual Behaviour Inventory (SBI) [212, 223]
- The Changes in Sexual Functioning Questionnaire (CSFQ) [213]
- Index of Sexual Satisfaction (ISS) [215]
- Multidimensional Sexuality Questionnaire (MSQ) [216, 223].
- The Sexual Interaction Inventory (SII) [214]
- McCoy Female Sexuality Questionnaire (MFSQ) [217]
- Simple Sexual Function Questionnaire [219, 219, 253]
- Sexual function questionnaire [218]
- DAN-PSSsex [220]
- Sexual life quality questionnaire (SLQQ) [221]

a) Other measures of sexual function

Many of the questionnaires assessing the psychosocial impact of LUTS and/or UI contain one or two questions related to sexual function. The majority of these are discussed above, either as symptom questionnaires or general quality of life questionnaires. Questionnaires containing just one question tend to focus on a general assessment of the overall impact of urinary symptoms on sexual functioning. The Kings Health questionnaire, [24] the Incontinence Impact Questionnaire [59] and the I-QOL [75] are recommended by the Committee for use for UI/LUTS. However, when considering the sexual items it must be borne in mind that validation of the sexual items was not always carried out or made explicit. But the questions relating to sexual function in each of the questionnaires are very similar and judgements on validity can be made by comparing questions and psychometric data between questionnaires as well as considering the psychometric properties of the scales as a whole. If more in-depth information is required concerning sexual function, the questionnaires recommended for this aspect should be used (see above).

There are other general measures of sexual function, such as the Watts Sexual Function Questionnaire. [254] and Medical Outcomes Study (MOS) Sexual Functioning Scale [255]. There are also questionnaires that have been designed for sexual dysfunction specific to particular diseases, such as Radiumhemmetts Scale of Sexual Function, [256] Sexual Adjustment Questionnaire (SAQ), [257] and Prostate-targeted Health Related Quality of Life [258].

A small number of questionnaires have produced initial validation but without publications during the reporting period: Effect of Urinary Incontinence on Sexuality Questionnaire (EISQ), [259] and Effects of urinary incontinence on sexual activity [260].

X. QUESTIONNAIRES FOR SPECIFIC PATIENT GROUPS

Most studies and questionnaires have been developed for use with members of the general population or urology/gynaecology patients with incontinence or POP. However, some specific patient groups may experience particular problems with incontinence (for example, children, frail elderly or those who are severely disabled), which may require independent investigation and potentially the development of more specific measures or the addition of a new subset of items on already developed instruments. The Committee advises that researchers should use existing highly recommended or recommended questionnaires if possible as this aids comparison and to reduce the increasing proliferation of questionnaires. Many of the questionnaires developed

below for particular conditions (e.g. prostate cancer) pre-dated the development of highly recommended questionnaires, and highly recommended questionnaires should be used preferentially.

a) Older people

Urinary incontinence symptoms play an influential role on the overall HRQL in older people (>65) and causes a significant decrease in HRQL, as severe as that of many chronic disease states. Since the elderly commonly have a number of associated comorbid conditions, it may be difficult to measure the impact of urinary incontinence with generic HRQL measures. The use of incontinence specific tools to measure patient-reported outcomes in the elderly, therefore, is of considerable importance.

Validated incontinence-specific PRO questionnaires, such as IIQ, I-QOL or KHQ, are used for clinical trials or research on urinary incontinence including elderly people, but their validity has not been specifically assessed in this age group. Okamura, assessed symptoms and HRQL in older people (men and women) with lower urinary tract symptoms including incontinence, using the KHQ and IPSS. They demonstrated that symptoms and HRQL in the elderly with LUTS could be assessed by IPSS and KHQ and that urinary incontinence appeared to be more associated with a decreased HRQL in elderly women [80].

On the other hand, there are a variety of factors affecting older people, including physical, social, mental, economic or environmental conditions, which are different from those of the young. In frail elderly people with dementia or physical impairment, it may be difficult to assess the impact of urinary incontinence alone. Questionnaires specifically developed for the elderly may be of great importance in this respect. However, there is little relating to the development or validation of particular questionnaires for older people with urinary incontinence. Two questionnaires dealing with older people were found and are described below. No questionnaires dealing with patient outcomes specifically for frail older incontinent people were found.

1. THE URGE IMPACT SCALE (URIS) [GRADE B]

The Urge Impact Scale (URIS) was designed and tested specifically for older persons with urgency incontinence. The URIS was developed and validated by DuBeau et al. (1999) [261] and included 32 items, reduced to 24 items (URIS-24). The URIS-24 was psychometrically assessed for validity and reliability in community-dwelling older (>65y) men and women with urge incontinence,. Cronbach alpha was 0.84 for the URIS-32 and 0.94 for the URIS-24. In assessment of test-retest reliability, interclass coefficient (ICC) was 0.88. The URIS-24 had modest but nearly significant correlation with the number of

urgency incontinence episodes ($\rho=-0.39$, $p=0.05$). Factor analysis revealed 3 component structures corresponding to physiological burden, perception of personal control and self-concept. There was no analysis for responsiveness. They showed that the URIS-24 is an internally consistent, highly reproducible tool for the assessment of the QOL impact of urgency incontinence on older persons.

2. SWEDISH QUESTIONNAIRE [GRADE C]

A questionnaire survey was conducted among men and women aged over 75 years in Sweden [262]. The questionnaire was developed specifically for the study although many questions had been used in a previous epidemiological survey [263]. The questionnaire achieved an admirable 62% response rate, but no details were published describing the psychometric properties of the questionnaire or the method of its construction.

There still remains a gap in the assessment of PROs for frail older adults by other than subjective means. Many of the commonly used measures have been used for older people as part of pharmaceutical company studies but it is not known whether these are relevant to the needs of the frail elderly or that they respond in a similar fashion when used in younger populations.

b) Children

Some questionnaires have been developed specifically to address issues for children, particularly enuresis. See Chapter (Children) and section on ICIQ modular questionnaire.

c) Spinal cord injured/neurologically damaged

Individuals who have a spinal cord injury or are neurologically damaged can experience particular difficulties with incontinence and the use of various devices. It would be useful to investigate whether Grade A questionnaires, developed for people without neurological damage, can be used in this group, or whether additional modules or instruments are required. This is an area where a small number of questionnaires are being developed with the Qualiveen being a notable exception (Also see section on the ICIQ questionnaire and below).

QUALIVEEN: QUALITY OF LIFE RELATED TO URINARY PROBLEMS IN SPINAL CORD INJURY [GRADE A]

The Qualiveen was developed to evaluate the specific impact of urinary dysfunction on the quality of life of spinal cord injury patients in France [264]. The initial items were developed following patient interviews, and were then assessed for validity and reliability in 281 spinal cord injury patients with urinary difficulties. The Qualiveen contains 30 items and has demonstrated good reliability and validity [264]. Further validation of the Qualiveen has occurred in multiple

sclerosis patients [265] and it has been translated and validated into English [266], German [267], and Portuguese [268]. The Qualiveen has demonstrated responsiveness in multiple sclerosis patients and has a suggested MID of 0.5 [269].

d) Prostate/bladder cancer

Many PRO questionnaires are available for assessment in this area: Post-radical prostatectomy questionnaire, [270, 271] Cancer Rehabilitation Evaluation System - Short Form (CARES-SF), [272] Prostate Cancer Treatment Outcome Questionnaire (PCTO-Q), [273] PROSQOLI, [274] Modified Southwest Oncology Group (SWOG), [275] Functional Assessment of Cancer Therapy - (FACT-G), Bladder form (FACT-B) and Prostate form (FACT-P), [276] Functional Assessment of Cancer Therapy Vanderviet Cystectomy Index (FACT-VCI), [277] EORTC metastatic prostate cancer, [273] Changes in Urinary Function, [257] Prostate-targeted Health Related Quality of Life [258]. While it is beyond the scope of this chapter to review and recommend PROs in this area, the principles and guidelines discussed herein apply to selecting a PRO related to prostate and bladder cancer.

e) Lower urinary tract symptoms/benign prostate disease

Many questionnaires have been developed to assess LUTS and benign prostate disease, however most do not contain a full evaluation of UI. Perhaps the most widely known urology PRO is the AUA Symptom Index, [137] I-PSS (International Prostate Symptom Score) [137, 278]. The IPSS has been utilized internationally to assess symptoms of prostate disease with documented reliability, validity and responsiveness. Additional PRO measures for BPH are as follows: Patient-completed modification of the Boyarsky [279] BPH Impact Index, [144] and BPH Health-related QoL survey [280].

XI. SELECTING PRO MEASURES FOR CLINICAL TRIALS AND CLINICAL PRACTICE

The previous sections have provided an overview of PRO measures with evidence of reliability, validity, and responsiveness. But, how does a researcher choose which instruments are most appropriate for a particular research study and/or clinical assessment? The following section provides general guidelines for use in conducting PRO assessments in clinical trials or other research investigations related to urinary or faecal incontinence.

As there are many available PROs, it is of utmost importance to select the PRO measure that is relevant and applicable to one's desired outcome. If an

intervention is designed to reduce symptom bother, then a relevant PRO would be a symptom bother measure. Multiple PROs can be included in a research study, however the designation of the PRO as a primary or secondary endpoint must be . In addition, issues of staff and participant burden, time constraints, and resources should be considered in the selection of a PRO measure.

1. SELECTING PRO MEASURES FOR RESEARCH STUDIES

a) Study Design

There are several protocol concerns that must be taken into account when using PRO measures in research studies, including the length of the study, the frequency of contact with the study participants, the timing of clinical assessments, the complexity of the trial design, the number of participants enrolled, and participant and staff burden. The goal of the PRO investigation is to "fit" the PRO measures to the protocol without compromising either the study objective or design. For example, if the study design is complex with frequent participant contacts and multiple clinical measures, it may be necessary to keep the PRO measures at a minimum or to reduce the number of times the PRO is assessed (e.g. baseline and end of study rather than during all participant contacts) to minimise participant and staff burden.

At the same time, however, PROs must be viewed as an important variable in the overall trial design and cannot be devalued in the data collection process. Consequently, PRO measures cannot be altered or reduced to accommodate study design as such alterations may yield potentially less reliable measures or may seriously diminish the integrity of the overall study design and yield useless information. Having well developed research goals and questions regarding PROs will help to guide you in the selection of measures for a study. The goal is to develop a conceptually adequate, yet practical PRO battery given the study population, the specific intervention, and the study design.

The frequency with which PRO will need to be assessed in a research study will depend upon the nature of the condition or intervention being investigated and the expected effects (both positive and negative) of treatment. At a minimum, as with all measurements collected in a research study, a baseline and end of study assessment should be completed. In addition, other PRO assessments should be timed to match expected changes in functioning due to either the intervention or the condition or the disease itself. Timing follow-up assessments to coincide with typical patient follow-up visits, if appropriate, may also reduce the costs involved in follow-up PRO and symptom assessments.

b) Study Population

It is crucial to specify key population demographics that could influence the choice of instruments, the relevant dimensions of PRO to be assessed, and the mode of administration. Thus, age range, gender, educational level, the language(s) spoken, and cultural diversity should be carefully considered prior to selecting PRO measures. For example, a cohort of patients over the age of 70 may have more vision problems than middle-aged persons, making self-administered questionnaires potentially inadvisable. Ethnically diverse groups also require measures that have been validated across different cultures and/or languages.

In clinical trials, it is also as important to consider how the disease or condition will progress and affect the outcomes of patients in the control group as it is to understand the effects of the study treatment. For example, in patients with incontinence assigned to a placebo-control arm of a study, one might expect a symptom to worsen and thus have an effect on daily functioning. The point is to select PRO measures that are sufficiently sensitive to detect changes in both the treated and the control group patients. Use of the same measures for both groups will ensure an unbiased and comparable assessment.

c) Intervention

There are three major factors related to the intervention that are relevant to PRO assessment, and therefore require careful consideration: 1) the positive and adverse effects of treatment; 2) the time course of the effects; and 3) the possible synergism of the treatment with existing medications and conditions. It is crucial to understand how a proposed treatment can affect patient outcomes in both positive and negative ways. For example, some drug therapies may relieve LUTS but produce side effects like dry mouth or sexual dysfunction.

In addition, the time course of an intervention's effects on PROs is also critical both in terms of the selection of measures and the timing of when PRO measures are administered to study participants. For example, in a trial comparing coronary artery bypass graft (CABG) surgery to angioplasty, an assessment of PRO one week post-intervention might lead to an interpretation that the surgical arm was more negative than angioplasty for PRO since the individuals in this arm of the trial would still be suffering the effects of the surgical procedure (for instance, sore muscles and surgical site discomfort) which could overwhelm any benefits associated with CABG. However, at six months post-intervention, the benefits of CABG surgery such as, relief from angina, might be more profound than the benefits received from angioplasty. Thus, when PRO is assessed could influence how one interprets the benefits (or negative effects) of the interventions.

Finally, it is important to have a clear understanding of the current medications the patient population is likely to be taking prior to randomisation to the study treatment, and how these medications might interact with the trial intervention, (either a pharmacological or behavioural intervention), to influence patient outcomes.

XII. TYPES OF PRO MEASURES

There are two types of PRO measures: generic and condition-specific. Generic measures are designed to assess outcomes in a broad range of populations (e.g., both healthy as well as ill individuals). These instruments are generally multidimensional, and assess at least the physical, social and emotional dimensions of life. An example of this type of instrument is the Medical Outcomes Study SF-36 Health Status Profile. [281]. A second type of measure is condition-specific (e.g., instruments designed to assess the impact of specific diseases, conditions, age groups, or ethnic groups). Condition-specific measures can be similar to generic instruments in that they assess multiple outcome dimensions, but condition-specific measures also include items more specific to the particular condition or population being studied. Examples of frequently used condition specific instruments include the Incontinence Impact Questionnaire, the King's Health Questionnaire, and the OAB-q (described above).

In general, the growing trend has been to include condition-specific outcome measures in clinical trials due to their enhanced sensitivity to change and the need to minimise participant burden. Importantly, the type of instruments selected for inclusion in a research study will depend on the goals of the intervention and the specific research questions to be addressed. In practice, clinical trials that include PROs usually incorporate a combination of PRO measures most relevant to the study population and intervention, if applicable, being mindful of resource constraints and staff and participant burden.

1. QUALITY-ADJUSTED LIFE YEAR (QALY)

Increasingly HRQL outcome measures are being used in the development of quality-adjusted life year (QALY) measures. A QALY is a universal health outcome measure applicable to all individuals and all diseases, which combines gains or losses in both life quantity (mortality) and life quality (morbidity) and enables comparisons across diseases and programs. QALYs are widely used for cost-utility analysis [282]. In the past decades, economic evaluation has been increasingly important for the decision maker to decide which treatment or intervention is more cost-effective, in order to allocate limited healthcare resources soundly. Economic evaluation aims to compare interventions in terms of their costs and benefits,

including their patient outcome impact. Health benefits can be quantified as QALYs (pronounced “qualies”), which has become a standard measure and is now recommended in most of health economics guidelines as the method of choice [283]. The economic chapter contains additional information regarding QALYs, as do the following references: [284, 285].

2. SUMMARY

In summary, some general points to consider in selecting PRO measures for lower urinary tract and pelvic floor disorder studies:

- Ensure that the PRO research questions and study endpoints are clearly defined. Determine the PROs that are most crucial to assess and which are most likely to be affected by a particular condition and/or its treatment.
- Make good use of prior literature searches in identifying past research in the area(s) of interest, as well as in identifying the types of PRO measures other researchers have used in past work. This information can provide valuable information on how particular outcome measures have performed in previous populations, as well as provide additional information to assist in defining research questions/issues regarding the PRO components of any given study.
- Consider the characteristics of the population in selecting measures. For example, are the study subjects to be children or older adults, well educated vs. those with limited education, or persons with low literacy? Ensure that the mode of data collection is appropriate for use with the study population. Furthermore, do not assume that an instrument validated for use with Caucasian, middle-class individuals in the U.S. will be appropriate for use in other countries, and/or those of a lower socio-economic status or of different educational backgrounds. This chapter has indicated, where possible, the extent to which specific PRO measures have been validated, and used reliably with different populations.
- Use the questionnaires recommended in this chapter whenever possible. Do not “reinvent the wheel.” Developing new PROs is a time-consuming and complicated process. If a new scale needs to be developed, ensure that the guidelines proposed by the FDA and EMEA on developing PROs are followed and that the appropriate expertise in questionnaire development and psychometrics is available to your research team in order to guide the questionnaire development process.
- Know the strengths and weaknesses of different types of PRO measures. In general, generic measures are useful in providing information on multiple patient outcome dimensions that can be compared across different populations. They may

lack sensitivity, however, in addressing concerns of specific patient populations (e.g., OAB, UI, faecal incontinence). Condition-specific instruments, in contrast, do address areas of function more specific to the condition, and tend to be more responsive to changes in clinic status, due to their increased specificity in addressing the conditions of their patient populations. Weaknesses of condition-specific instruments, however, are that they are often not appropriate for use with multiple populations, and cannot be used to make direct comparisons across different patient groups.

- Know how to score your selected PRO measures and how to interpret the scores. Specifically, ensure that the scoring method of a measure provides you with the information you need to answer your research question?
- Pilot testing of PRO measures with participants/patients similar to those in the target patient population who will be assessed in a research investigation is always advisable. Adjustments can then be made in the protocol, if necessary, prior to the initiation of the study.
- Finally, train and certify your staff to administer PRO measures using either patient interview and/or self-administration techniques, depending on the method to be used in the study. The administration process needs to be standardised and completely similarly across all participants.

5B - F. RECOMMENDATIONS FOR RESEARCH

The following recommendations were unanimous:

1. The selection of a PRO questionnaire must reflect study purpose and objectives
2. Grade A recommended questionnaires should be used in all clinical trials evaluating treatments
3. The inclusion of the ICIQ modules is preferred in all studies to standardise outcome assessment
4. Continued PRO development, refinement, and use should accurately and adequately report on the methods, samples, statistical analyses and psychometric properties of questionnaires in scientific journals (i.e. validity, reliability and responsiveness), so the quality of each study can be assessed. Researchers are encouraged to use existing questionnaires and refine for specific populations when needed (e.g. frail elderly, children)
5. Researchers are encouraged to collaborate with the ICIQ project on the development and refinement of modules and translations.

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