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2017

6th International Consultation on Incontinence

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International Consultation on
Urological Diseases (ICUD)

International Continence
Society (ICS)

In collaboration with

major international
associations of urology,
gynaecology and
urodynamics

and other medical
associations

Recommendations of the International scientific Committee:

EVALUATION AND TREATMENT OF URINARY INCONTINENCE, PELVIC ORGAN PROLAPSE AND FAECAL INCONTINENCE

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and the members of the committees

INTRODUCTION

The 6th International Consultation on Incontinence met between September 13-15th 2016 in Tokyo and was organised by the International Consultation on Urological Diseases and the International Continence Society (ICS), in order to develop consensus statements and recommendations for the diagnosis, evaluation and treatment of urinary incontinence, faecal incontinence, pelvic organ prolapse and bladder pain syndrome.

The consensus statements are evidence based following a thorough review of the available literature and the global subjective opinion of recognised experts serving on focused committees. The individual committee reports were developed and peer reviewed by open presentation and comment. The Scientific Committee, consisting of the Chairs of all the committees then refined the final consensus statements. These consensus statements published in 2017 will be periodically reevaluated in the light of clinical experience, technological progress and research.

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1. DEFINITIONS

The consultation agreed to use the current International Continence Society definitions (ICS) for lower urinary tract dysfunction (LUTD) including incontinence, except where stated. These definitions were published in the journal *Neurourology and Urodynamics* (2002; 21:167-178 and 2006; 25: and can be viewed on the ICS website: www.ics.org

The following ICS definitions are relevant:

1. LOWER URINARY TRACT SYMPTOMS (LUTS)

LUTS are divided into storage and voiding symptoms.

Urinary incontinence is a storage symptom and defined as the complaint of any involuntary loss of urine. This definition is suitable for epidemiological studies, but when the prevalence of bothersome incontinence is sought, the previous ICS definition of an “Involuntary loss of urine that is a social or hygienic problem”, can be useful.

Urinary incontinence may be further defined according to the patient’s symptoms

- **Urgency Urinary Incontinence** is the complaint of involuntary leakage accompanied by or immediately preceded by urgency.
- **Stress Urinary Incontinence** is the complaint of involuntary leakage on effort or exertion, or on sneezing or coughing.
- **Mixed Urinary Incontinence** is the complaint of involuntary leakage associated with urgency, and also with effort, exertion, sneezing and coughing.
- **Nocturnal Enuresis** is any involuntary loss of urine occurring during sleep.
- **Post-micturition dribble** and **continuous urinary leakage** denotes other symptomatic forms of incontinence.

Overactive bladder is characterised by the storage symptoms of urgency with or without urgency incontinence, usually with frequency and nocturia.

2. URODYNAMIC DIAGNOSIS

- **Detrusor Overactivity** is a urodynamic observation characterised by involuntary detrusor contractions during the filling phase, which may be spontaneous or provoked.

Detrusor overactivity is divided into:

- **Idiopathic Detrusor Overactivity**, defined as overactivity when there is no clear cause
- **Neurogenic Detrusor Overactivity** is defined as overactivity due to a relevant neurological condition.
- **Urodynamic stress incontinence** is noted during filling cystometry, and is defined as the involuntary leakage of urine during increased abdominal pressure, in the absence of a detrusor contraction.

3. BLADDER PAIN SYNDROME

Bladder pain syndrome is defined by ESSIC as chronic pelvic pain, pressure or discomfort of greater than 6 months duration perceived to be related to the urinary bladder accompanied by at least one other urinary symptom like persistent desire to void or urinary frequency. Confusable diseases as the cause of the symptoms must be excluded.

4. PELVIC ORGAN PROLAPSE

- **Urogenital prolapse** is defined as the symptomatic descent of one or more of: the anterior vaginal wall, the posterior vaginal wall, and the apex of the vagina (cervix/uterus) or vault (cuff) after hysterectomy. Urogenital prolapse is measured using the POP-Q system.
- **Rectal prolapse** is defined as circumferential full thickness rectal protrusion beyond the anal margin.

5. ANAL INCONTINENCE

Anal incontinence defined as “any involuntary loss of faecal material and/or flatus and/or mucus” and may be divided into:

- **Faecal incontinence**, any involuntary loss of faecal material
- **Flatus incontinence**, any involuntary loss of gas (flatus)
- **Mucus incontinence**, any involuntary loss of mucus only (not faeces)

* At the time of this consultation, these definitions are not included in the current ICS terminology.

2. EVALUATION

The following phrases are used to classify diagnostic tests and studies:

- **A highly recommended test** is a test that should be done on every patient.
- **A recommended test** is a test of proven value in the evaluation of most patients and its use is strongly encouraged during evaluation.
- **An optional test** is a test of proven value in the evaluation of selected patients; its use is left to the clinical judgement of the physician
- **A not recommended test** is a test of no proven value.

This section primarily discusses the Evaluation of Urinary Incontinence with or without Pelvic Organ Prolapse (POP) and Faecal Incontinence.

The recommendations are intended to apply to children and adults, including healthy persons over the age of 65.

These conditions are highly prevalent but often not reported by patients. Therefore, the Consultation strongly recommends case finding, particularly in high risk groups.

A. HIGHLY RECOMMENDED TESTS DURING INITIAL EVALUATION

The **main recommendations** for this consultation have been abstracted from the extensive work of the 23 committees of the 6th International Consultation on Incontinence (ICI, 2016).

Each committee has written a report that reviews and evaluates the published scientific work in each field of interest in order to give Evidence Based recommendations. Each report ends with detailed recommendations and suggestions for a programme of research.

The main recommendations should be read in conjunction with the management algorithms for children, men, women, the frail older person, neurogenic patients, bladder pain, pelvic organ prolapse, and anal incontinence

The initial evaluation should be undertaken, by a clinician, in patients presenting with symptoms/ signs suggestive of these conditions.

1. HISTORY AND GENERAL ASSESSMENT

Management of a disease such as incontinence requires caregivers to assess the sufferer in a holistic manner. Many factors may influence a particular individual's symptoms, some may cause incontinence, and may influence the choice and the success of treatment. The following components of the medical history are particularly emphasised:

1.1. Review of Systems:

- Presence, severity, duration and bother of any urinary, bowel or prolapse symptoms. Identifying symptoms in the related organ systems is critical to effective treatment planning. The use of validated questionnaires to assess symptoms are recommended.
- Effect of any symptoms on sexual function: validated questionnaires including impact on quality of life are a useful part of a full assessment.
- Presence and severity of symptoms suggesting neurological disease

1.2. Past Medical History:

- Previous conservative, medical and surgical treatment, in particular, as they affect the genitourinary tract and lower bowel. The effectiveness and side effects of treatments should be noted.
- Coexisting diseases may have a profound effect on incontinence and prolapse sufferers, for example asthma patients with stress incontinence will suffer greatly during attacks. Diseases may also precipitate incontinence, particularly in frail older persons.
- Patient medication: it is always important to review every patient's medication and to make an assessment as to whether current treatment may be contributing to the patient's condition.
- Obstetric and menstrual history.
- Physical impairment: individuals who have compromised mobility, dexterity, or visual acuity may need to be managed differently

1.3. Social History:

- Environmental issues: these may include the social, cultural and physical environment.

- Lifestyle: including exercise, smoking and the amount and type of fluid and food intake.

1.4. Other Treatment Planning Issues:

- **Desire for treatment** and the extent of treatment that is acceptable
- **Patient goals** and expectations of treatment
- **Patient support** systems (including caregivers).
- **Cognitive function:** all individuals need to be assessed for their ability to fully describe their symptoms, symptom bother and quality of life impact, and their preferences and goals for care. They must be able to understand proposed management plans and to discuss, where appropriate, alternative treatment options. In some groups of patients, formal testing is essential e.g. cognitive function testing for individuals for whom the clinician has concerns regarding memory deficits and/or inattention or confusion, and depression screening for individuals for whom the clinician has concerns about abnormal affect. Proxy respondents, such as family and caregivers, may be used to discuss the patient's history, goals of care, and treatment for individuals with dementia, but only if the individual is incapable of accurate reporting or weighing treatment decisions.

2. PHYSICAL EXAMINATION

The more complicated the history and the more extensive and/or invasive the proposed therapy, the more complete the examination needs to be. Depending on the patient's symptoms and their severity, there are a number of components in the examination of patients with incontinence and/or pelvic organ prolapse.

Physical examination should be performed regardless of whether the patient is a child, a woman, a man, someone with neurological disease or a frail elderly person.

2.1. General status:

- Mental status
- Obesity (BMI)
- Physical dexterity and mobility

2.2. Abdominal/flank examination: for masses, bladder distention, relevant surgical scars

2.3. Pelvic examination:

- Examination of the perineum and external genitalia including tissue quality and sensation.
- Vaginal (half-speculum/Sims) examination for pelvic organ prolapse (POP), which should be done in the vertical position

- Bimanual pelvic and anorectal examination for pelvic mass,
- Digital rectal examination to assess pelvic floor muscle function and the function of internal and external anal sphincter as well as puborectalis muscle.
- Stress test for urinary incontinence.

2.4. Neurological testing (see chapter on assessment)

3. URINALYSIS

In patients with LUTS, the possibility of a urinary tract infection should be evaluated, with appropriate testing (ranging from dipstick to urine microscopy and culture when indicated as UTI is a readily detected, and easily treatable cause of LUTS,

Conclusion

For simple treatments, particularly non-invasive and inexpensive therapies, management may start without the need for the further investigations listed below.

B. RECOMMENDED FURTHER ASSESSMENT PRIOR TO, OR DURING, SPECIALIST ASSESSMENT

The tests below are recommended when the **appropriate indication(s) is present**. Some recommended tests become highly recommended in specific situations.

This section should also be read in conjunction with the relevant committee reports.

1. FURTHER SYMPTOM AND HEALTH-RELATED QOL ASSESSMENT

1.1. Bladder Diary

In patients with **urinary symptoms** the use of a **bladder diary** (examples in Annex 1) is highly recommended to document the frequency of micturition, the volumes of urine voided, incontinence episodes and the use of incontinence pads.

1.2. Questionnaires

The use of the **highest quality questionnaires** (GoR A, where available) is recommended for the assessment of the patient's perspective of symptoms of incontinence and their impact on quality of life.

The ICIQ is highly recommended (GoR A) for the basic evaluation of the patient's perspective of urinary incontinence, with other GoR A questionnaires recommended for more detailed assessment. **Further development is required in the areas** of pelvic organ prolapse, bladder pain syndrome, and for specific patient groups, as only GoR B questionnaires are currently available (see Assessment Chapter).

2. RENAL FUNCTION ASSESSMENT

Standard biochemical tests for renal function are recommended in patients with urinary incontinence when there is the possibility of renal impairment.

3. UROFLOWMETRY

Uroflowmetry with the measurement of post void residual urine is recommended as a screening test for symptoms suggestive of urinary voiding dysfunction or physical signs of POP or bladder distension. Uroflowmetry should be part of the initial assessment if the result is likely to influence management eg in older men with possible prostatic obstruction.

4. ESTIMATION OF POST VOID RESIDUAL URINE (PVR)

In patients with suspected voiding dysfunction, PVR should be part of the initial assessment if the result is likely to influence management, for example, in neurological patients.

5. IMAGING

Although routine imaging is not recommended, imaging of the lower urinary tract and pelvis is highly recommended in those with urinary symptoms whose initial evaluation indicates a possible co-existing lower tract or pelvic pathology. Initial imaging may be by ultrasound, or plain X-ray.

Imaging of the upper urinary tract is highly recommended in specific situations. These include:

- Haematuria,
- Neurogenic urinary incontinence e.g. myelodysplasia, spinal cord trauma,
- Incontinence associated with significant post-void residual,
- Co-existing renal disease such as pyelonephritis or reflux, or loin/kidney pain,
- Severe pelvic organ prolapse, not being treated
- Suspected extra-urethral urinary incontinence,
- Children with incontinence and UTIs, where indicated

- Urodynamic studies which show evidence of poor bladder compliance or high pressure detrusor overactivity.

6. INVESTIGATIONS IN FAECAL INCONTINENCE AND RECTAL PROLAPSE

- Endoanal US or MRI prior to anal sphincter surgery is highly recommended, even when obvious anatomic defects are not evident.
- Defaecating proctography or dynamic MRI is recommended in suspected rectal prolapse which cannot be adequately confirmed by physical examination.
- Anorectal manometry is useful to assess resting and squeeze anal pressures. The resting and squeeze pressures represent the function of the internal and external anal sphincter, respectively.

7. ENDOSCOPY

Although routine cysto-urethroscopy is not recommended, LUT endoscopy is **highly recommended**:

- When initial testing is abnormal, e.g. haematuria and suggests other pathologies,
- When pain or discomfort feature in the patient's LUTS, these may suggest an intravesical lesion
- When appropriate in the evaluation of vesicovaginal fistula and extra-urethral urinary incontinence (in childbirth fistulae, endoscopy is often unnecessary).

In anorectal conditions, proctoscopy or flexible sigmoidoscopy should routinely be performed in the evaluation of patients with faecal incontinence. Colonoscopy, air contrast barium enema or CT colography is highly recommended in the presence of unexplained change in bowel habit, rectal bleeding or other alarm symptoms or signs (see Basic Assessment chapter).

8. URODYNAMIC TESTING

8.1. Urodynamic (multi channel pressure subtracted cystometry) evaluation is recommended

- When the results may change management, such as prior to most invasive treatments for UI and POP,
- After treatment failure, if more information is needed in order to plan further therapy,

- As part of both initial and long-term surveillance programmes in some types of neurogenic lower urinary tract dysfunction,
- In “complicated incontinence” (for details please see relevant subcommittee reports).

8.2. The aims of urodynamic evaluation are often diagnostic, but may also relate to prognostic factors, direct management or assess response to prior therapy, and also:

- To reproduce the patient’s symptoms and correlate these with urodynamic findings
- To assess bladder sensation
- To detect detrusor overactivity
- To assess urethral competence during filling
- To determine detrusor function during voiding
- To assess outlet function during voiding
- To assess residual urine

9. SMALL BOWEL FOLLOW-THROUGH, CT ENTOGRAPHY OR CAPSULE ENDOSCOPY

These tests are recommended in those with faecal incontinence and the presence of unexplained diarrhoea or when Crohn’s disease is suspected.

C. FURTHER DIAGNOSTIC TESTS TO BE USED AS APPROPRIATE

1. ADDITIONAL URODYNAMIC TESTING

Video-urodynamics may be useful in the management of UI in children, in patients who fail surgery and in some neurogenic patients, to obtain additional anatomical information. Either X-ray or US imaging can be used depending on the needs of the individual patient.

If a more **detailed estimate of urethral function** is required, then the following optional tests may give useful information:

- Urethral pressure profilometry
- Abdominal leak point pressures
- Video-urodynamics
- Electromyography of pelvic floor or urethral sphincter

If initial urodynamics have failed to demonstrate the cause for the patient’s incontinence then the following tests are optional:

- Repeated routine urodynamics or video-urodynamics
- Ambulatory urodynamics

2. PAD TESTING

Pad testing is an optional test for the routine evaluation of urinary incontinence and, if carried out, a 24 hr test is suggested.

3. NEUROPHYSIOLOGICAL TESTING AND IMAGING

The information gained by clinical examination and urodynamic testing may be **enhanced by neurophysiological testing** of striated muscle and nervous pathways.

Appropriately trained personnel should perform these tests. The following neuro-physiological tests can be considered in patients with peripheral lesions prior to treatment for lower urinary tract or anorectal dysfunction.

- Concentric needle EMG
- Sacral reflex responses to electrical stimulation of penile or clitoral nerves.

Imaging of the nervous system (and neighbouring structures, including spine, the abdominal cavity and pelvis) by MRI or CT, may confirm suspected involvement of the nervous system, and the nature of the cause.

4. FURTHER IMAGING

Cysto-urethrography, US, CT and MRI may have an indication:

- Suspected pelvic floor dysfunction
- Failed surgery, such as recurrent posterior vaginal wall prolapse or failed sling surgery
- Suspected fixed urethra

5. CYSTO-URETHROSCOPY

This is an optional test in patients with complicated, persistent or recurrent UI (e.g. after failed SUI surgery)

6. ANORECTAL PHYSIOLOGY TESTING

Endocoil MRI has high accuracy for detecting anal sphincter injury but is second line after endoanal ultrasound. Patients with faecal incontinence may benefit from assessment with MRI, particularly those with

anorectal malformations and/or previous anal sphincter surgery.

Defaecography may be useful and is recommended in patients with faecal incontinence, who have failed conservative therapies, and are possible candidates for laparoscopic ventral rectopexy.

3. MANAGEMENT CONSENSUS STATEMENTS

The consensus statements are derived from the **detailed work in the committee reports** on the management of incontinence in children, men, women, the frail elderly and neurological patients, as well as those with obstetric fistula, pelvic organ prolapse, bladder pain syndrome, and faecal incontinence. The management of incontinence is presented in **algorithm form** with **accompanying notes**.

The chapters analyze the evidence and give it a level of evidence (LoE) and this generates a GoR of recommendation (GoR)

The Consultation recognises that no algorithm can be applied to every patient and each patient's management must be individualised.

There are algorithms for

- I. **Urinary Incontinence in Children**
- II. **Urinary Incontinence in Men**
- III. **Urinary Incontinence in Women**
- IV. **Fistulae**
- V. **Pelvic Organ Prolapse**
- VI. **Urinary Incontinence in Neurological Patients**
- VII. **Bladder Pain Syndrome**
- VIII. **Faecal Incontinence in Adults**
- IX. **Urinary and faecal Incontinence in frail Older Men and Women**

These algorithms are divided into two for groups I to III, VII and X. The two parts, initial **management** and **specialised management** require a little further explanation.

Although the management algorithms are designed for patients whose predominant problem is incontinence, there are many other patients in whom the algorithms may be useful such as those patients with urgency and frequency, so-called "**OAB dry**"

Management definitions

Management may be divided into

- Conservative, all methods that are non-medical and non-surgical, some of which do not target the disease process
- Medical (pharmacological) therapy

- Surgical therapy
- Conservative therapy includes
 - Lifestyle interventions e.g. weight loss
 - Bladder training
 - Pelvic floor muscle training (PFMT)
 - Containment products e.g. pads
 - Dependent continence strategies eg regular toileting

Consensus does not exist as to the use of the term "behavioural therapy" as some state that this term only includes bladder training and PFMT, whilst others consider that all conservative management contains a behavioural element, for example wearing and changing pads constitutes a change in behaviour. Hence the consultations recommendations list the elements of conservative management as relevant are intended for use by all clinicians including health care assistants/aides, nurses, physiotherapists, generalist doctors and family doctors as well as by specialists such as urologists, geriatricians and gynaecologists. The consultation has attempted to phrase the recommendations in the basic algorithms in such a way that they may be readily used by clinicians in all countries of the world, both in the developing and the developed world.

The algorithms for initial management

are intended for use by all **clinicians** including health care assistants/aides, nurses, physiotherapists, generalist doctors and family doctors as well as by specialists such as urologists, geriatricians and gynaecologists. The consultation has attempted to phrase the recommendations in the basic algorithms in such a way that they may be readily used by clinicians in all countries of the world, both in the developing and the developed world.

The specialised algorithms

The specialised algorithms are intended for use by **specialists**. The specialised algorithms, as well as the initial management algorithms are **based on evidence where possible**, and on the **expert opinion** of the 400 healthcare professionals who took part in the Consultation. In this consultation, committees ascribed levels of evidence to the published work on the

subject and devised GoRs of recommendation to inform patient management.

It should be noted that these algorithms, dated **April 2017**, represent the Consultation **consensus at that time**. Our knowledge, developing from both a research base and because of evolving expert opinion, will inevitably **change with time and relate to the unique context of individual patients seeking care**. The Consultation does not wish those using the algorithms to believe they are “carved in tablets of stone”: there will be changes both in the relatively short term and in the long term.

1. ESSENTIAL COMPONENTS OF BASIC ASSESSMENT

Each algorithm contains a core of recommendations in addition to a number of essential components of basic assessment listed in sections I to III.

- General assessment
- Symptom assessment
- Assessment of quality of life impact
- Assessment of the desire for treatment
- Physical examination
- Urinalysis

2. JOINT DECISION MAKING

The patient’s desires and goals for treatment: Treatment is a matter for discussion and joint decision making between the patient and his or her health care advisors. This process of consultation includes the specific need to assess whether or not the patient wishes to receive treatment and, if so, what treatments he or she would favour. Implicit in this statement is the assumption that the health care provider will give an **appropriate explanation of the patient’s problem** and the **alternative lines of management**, and the potential **benefits** and **risks of treatment**. The assumption that patients almost always wish to have treatment is flawed, and the need to incorporate patient values and preferences is paramount.

In each algorithm, treatments are listed in **order of simplicity**, the least invasive being listed first. This order does not imply a scale of efficacy or cost, two factors which need to be considered in choosing the sequence of therapy. The order is likewise not meant to imply a suggested sequence of therapy, which should be determined jointly by the treating health care provider and the patient, considering all the relevant factors listed above.

In the **initial management algorithms**, treatment is **empirically based**, whilst the **specialised management** algorithms usually rely on precise diagnosis from urodynamics and other testing.

The assumption is made that patients will be reassessed at an appropriate time to evaluate their progress.

3. USE OF CONTINENCE PRODUCTS

The possible role of **continence products** to prevent, contain and/or manage bladder and/or bowel leakage should be considered at each stage of patient assessment and treatment, to maintain dignity and social functioning, and/or to support self-management or care by others.

Consider **temporary** use of continence products:

- While treatment is awaited.
- **In addition** to treatment; for example using pads and/or urinals when taking anti-muscarinics or carrying out pelvic floor exercises, until sufficient improvement is achieved.

Consider **permanent** use of continence products:

- When treatment is not chosen or not suitable for the individual
- When treatment does not achieve (complete) cure
- For **intermittent use**; for example when the patient has a cough, or needs to travel without reliable toilet access
- For **continuous use** if incontinence is unpredictable and/or frequent or if complications related to incontinence (e.g. skin breakdown) are imminent or present

Consider offering a **mixture** of continence products (disposable/washable; absorbent/non-absorbent) to optimise effectiveness and to reduce costs; e.g. different products for day and night; or for staying at home and for going out/travel/specific activities.

Further guidance on management with continence products is given in Chapter 20 and at the ICI/ICS supported website:

www.continenceproductadvisor.org

At the foot of each of the treatment algorithms below, the phrase “Consider CONTINENCE PRODUCTS for temporary support during treatment”, emphasizes the importance of continence products for many sufferers of incontinence

I. URINARY INCONTINENCE IN CHILDREN

A. INITIAL MANAGEMENT

Children present specific management problems for a variety of reasons: assessment requires help from their parents and caregivers; consent to treatment may be problematic; and cooperation in both assessment and treatment may be difficult.

1. INITIAL ASSESSMENT SHOULD INVOLVE A DETAILED INVESTIGATION OF VOIDING AND BOWEL HABITS USING BLADDER/BOWEL DIARIES AND STRUCTURED AND VALIDATED QUESTIONNAIRES.

The child's social environment and general and behavioural development should also be formally assessed and recorded. Physical examination should be done to detect a palpable bladder, faecal loading and exclude anatomic and neurogenital causes. Urine analysis and culture is sufficient to exclude the presence of infection. If possible, the child should be observed voiding.

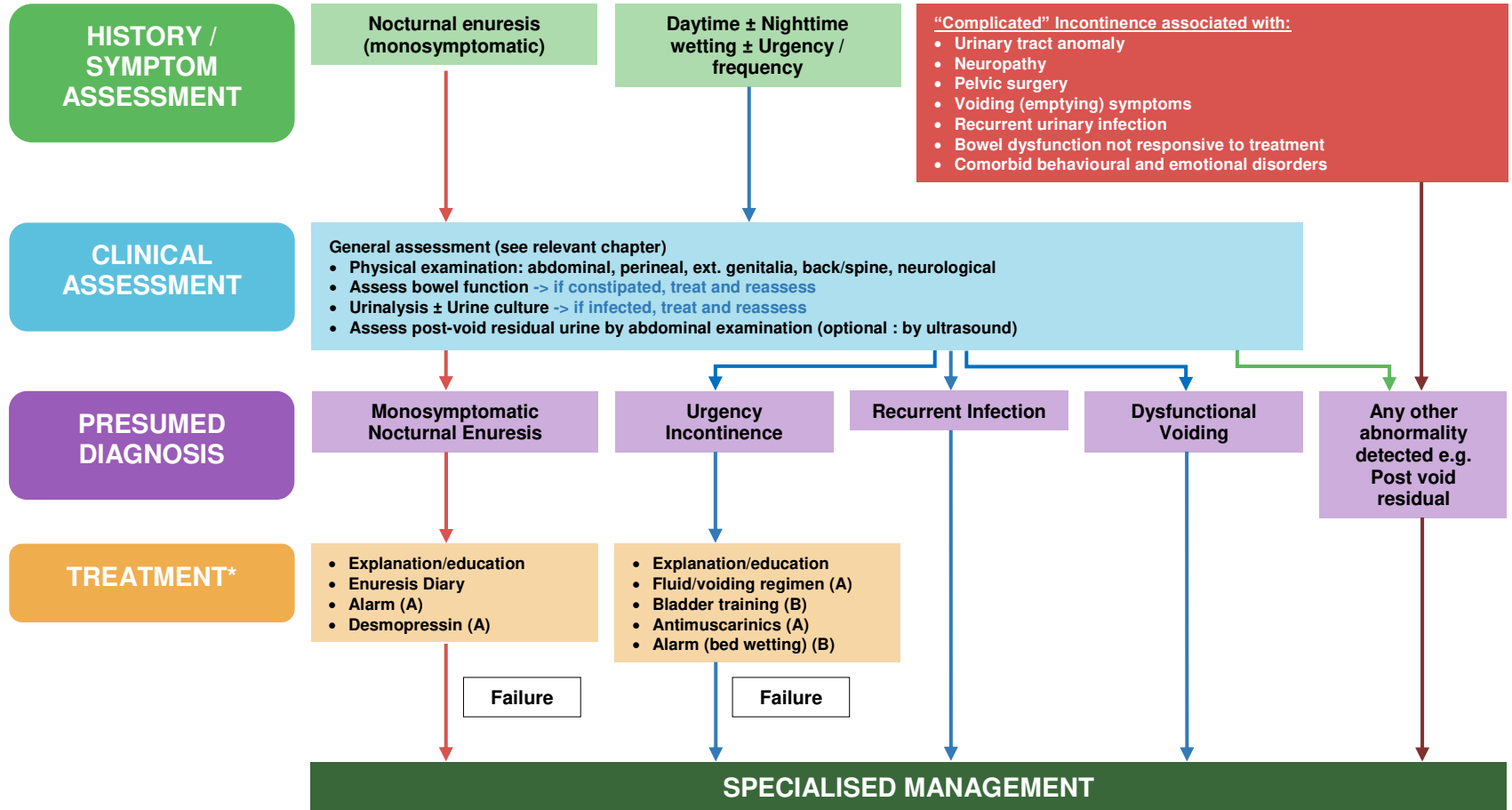
- **Referrals for specialist treatment are recommended for children who have complicated incontinence associated with:**
 - Recurrent and febrile urinary infection
 - Voiding symptoms or evidence of poor bladder emptying
 - Urinary tract anomalies
 - Previous pelvic surgery
 - Neuropathy or neuropathic origin
 - Bowel dysfunction not responsive to treatment

- Comorbid behavioural (e.g. ADHD and ODD) and emotional disorders.
- **Initial treatment is recommended for the remaining patients who have:**
 - Nocturnal enuresis without other symptoms (monosymptomatic enuresis).
 - Daytime symptoms of frequency, urgency, voiding postponement, straining, interrupted voiding, urgency incontinence with or without nighttime wetting.

2. TREATMENT

- Initial treatment for **mono-symptomatic nocturnal** enuresis should include:
 - Parental and child counselling and motivation
 - Review of bladder diary with attention to night-time polyuria
 - Age appropriate education and demystification or explanation
- A choice between either bed wetting alarm (GoR A) or anti-diuretic hormone analogues of desmopressin (GoR A). It may be a parental and child choice if advantages and disadvantages are well explained.
- Daytime incontinence should be managed holistically including:
 - Counselling, timed voiding, behaviour modification and bowel management when necessary (GoR B);
 - Antimuscarinics may be used if the child has OAB symptoms (GoR A)

INITIAL MANAGEMENT OF URINARY INCONTINENCE IN CHILDREN



* Consider CONTINENCE PRODUCTS for temporary support during treatment

I. URINARY INCONTINENCE IN CHILDREN

B. SPECIALISED MANAGEMENT

- **Two groups of children** with “**complicated**” **incontinence** should have specialist management from the outset (Fig. 2).
- Children whose incontinence is due to, or associated with, **urinary tract anomalies** and **neuropathy**.
- **Children** without urinary tract anomalies, but with **recurrent febrile infection** and, proven or suspected, **lower urinary tract dysfunction**.
- Children who **fail the basic treatment**, but who have neither neurogenic nor anatomical problems, should also receive specialist management.

Children with comorbid behavioural and emotional disorders require referral to mental health services, as compliance and treatment outcomes are lower.

Assessment and treatment should follow evidence-based practice guidelines

1. ASSESSMENT

- As part of further assessment, the measurement of **urine flow** (in children old enough), together with the **ultrasound estimate of residual urine** and appearance of the bladder wall and rectum are highly recommended. An evaluation of the **upper urinary tracts with ultrasound is also highly recommended**.

Those who do not improve **with treatment** and have neither neurogenic nor anatomical problems **should be reassessed** using bladder diaries, symptom questionnaires, urinalysis, uroflowmetry and residual urine determination.

If there are recurrent and febrile infections, upper tract imaging and possibly a VCUG should be considered. However, endoscopy is rarely indicated.

- **Urodynamics should be considered:**
- If the type and severity of lower tract dysfunction **cannot be explained by clinical findings** or in the presence of possible relevant neuropathy or urinary tract anomalies. (GoR B)

- If **invasive treatment** is under consideration, for example, stress incontinence surgery if there is sphincteric incompetence, or bladder augmentation if there is detrusor overactivity. (GoR B)
- **If upper tract dilation exists** and is thought to be due to bladder dysfunction. (GoR A)
- **Invasive urodynamic studies are generally not recommended** if the child has normal upper tract imaging and is to be treated by noninvasive means. (GoR B)
- **Spinal Imaging** (US/X-ray/MRI) may be needed if a bony abnormality or neuro-logical condition is suspected. (GoR A)

2. TREATMENT

The treatment of incontinence associated with **urinary tract anomalies** is complex and cannot easily be dealt with in an algorithm. In many children **more than one pathology** demands treatment. If there are **complex congenital abnormalities present**, the treatment is mostly surgical and it should be individualised according to the type and severity of the problem (please see Children’s Committee Report).

Care should be given by specialist children’s nurses and therapists.

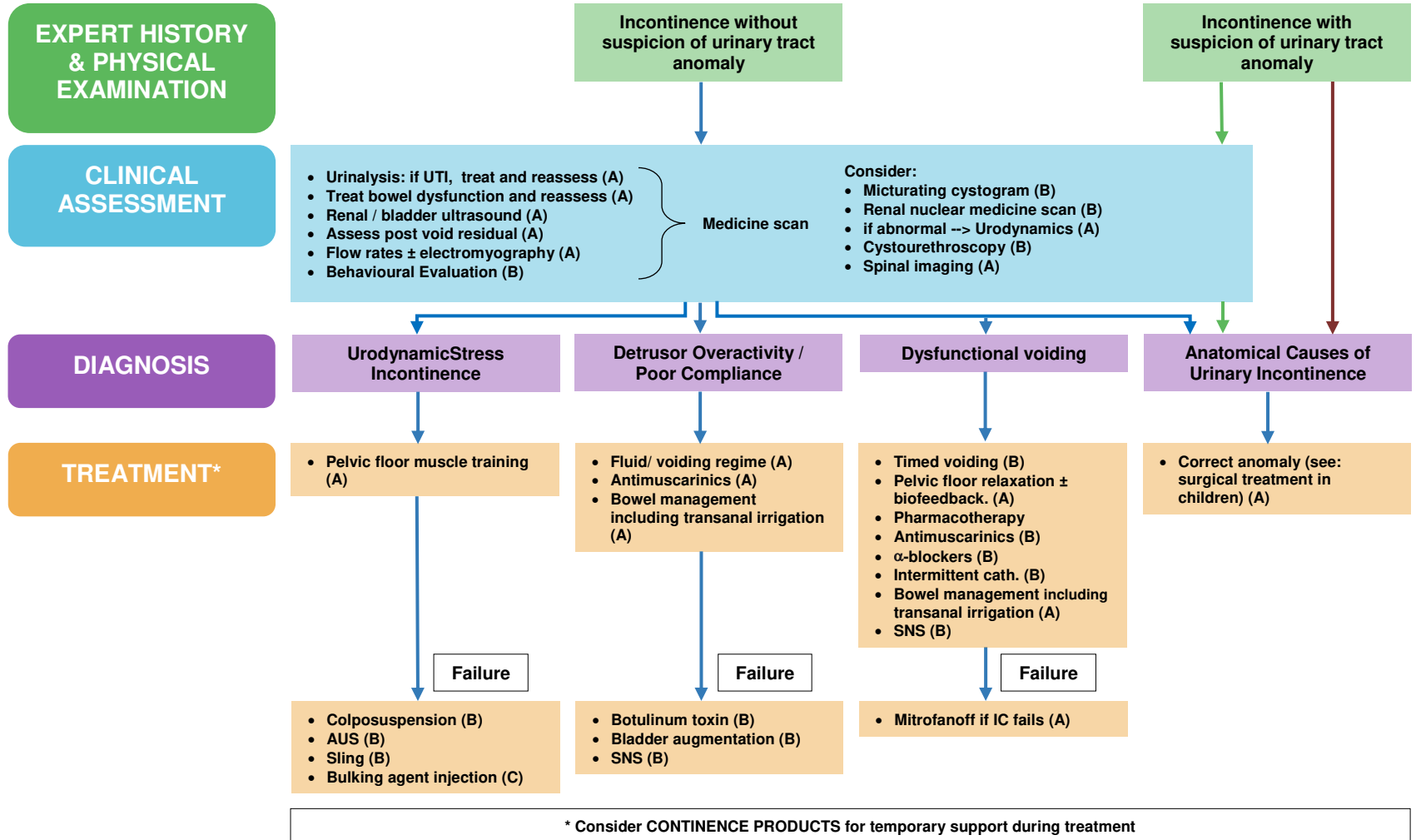
- **Initial treatment should be non-surgical.**
- **For stress urinary incontinence (SUI):** pelvic floor muscle training (GoR C).
- **For OAB symptoms:** fluid/voiding regimens and antimuscarinics (GoR A).
- **For voiding dysfunction:** timed voiding, voiding re-education, pelvic floor muscle relaxation (+/- biofeedback), alpha-blocker therapy, and intermittent catheterisation (when PVR >30% of bladder capacity) (GoR A/B).
- **For bowel dysfunction:** high fibre diet and laxatives as appropriate, and transanal irrigation in severe cases (GoR A).

The child's progress should be assessed and, if quality of life is still significantly impaired, or if the upper urinary tracts are at risk, **surgical treatment** is likely to be necessary.

- **If surgical treatment is required**, then urodynamic studies are recommended to confirm the diagnosis.
- **For USI**, colposuspension, sling surgery, bulking agent injection and AUS may be considered (GoR B).

- **For DO/poor compliance**, botulinum toxin (for DO, and off-label) and bladder augmentation may be performed (GoR B).
- **If the child cannot do IC** then a Mitrofanoff channel may be needed (GoR A).

SPECIALISED MANAGEMENT OF URINARY INCONTINENCE IN CHILDREN



II. URINARY INCONTINENCE IN MEN

A. INITIAL MANAGEMENT

1. INITIAL ASSESSEMENT SHOULD IDENTIFY:

➤ “Complicated” incontinence group

Those with pain or with haematuria, recurrent infection, suspected or proven poor bladder emptying (for example due to bladder outlet obstruction), or incontinence following pelvic irradiation or radical surgery, are recommended for **specialised management**.

Poor bladder emptying may be suspected from symptoms, physical examination or if imaging has been performed by X-ray or ultrasound after voiding.

➤ **Four other main groups** of men should be identified by initial assessment as being suitable for **initial management**.

- Those with post-micturition dribble alone,
- Those with overactive bladder (OAB) symptoms: urgency with or without urgency incontinence, together with frequency and nocturia
- Those with stress urinary incontinence (most often post-prostatectomy),
- Those with mixed urinary urgency and stress incontinence (most often post-prostatectomy)

➤ For men with **stress, urgency** or **mixed** urgency / stress incontinence, initial treatment should include appropriate lifestyle advice, pelvic floor muscle training, scheduled voiding regimens, behavioural therapies and medication. In particular:

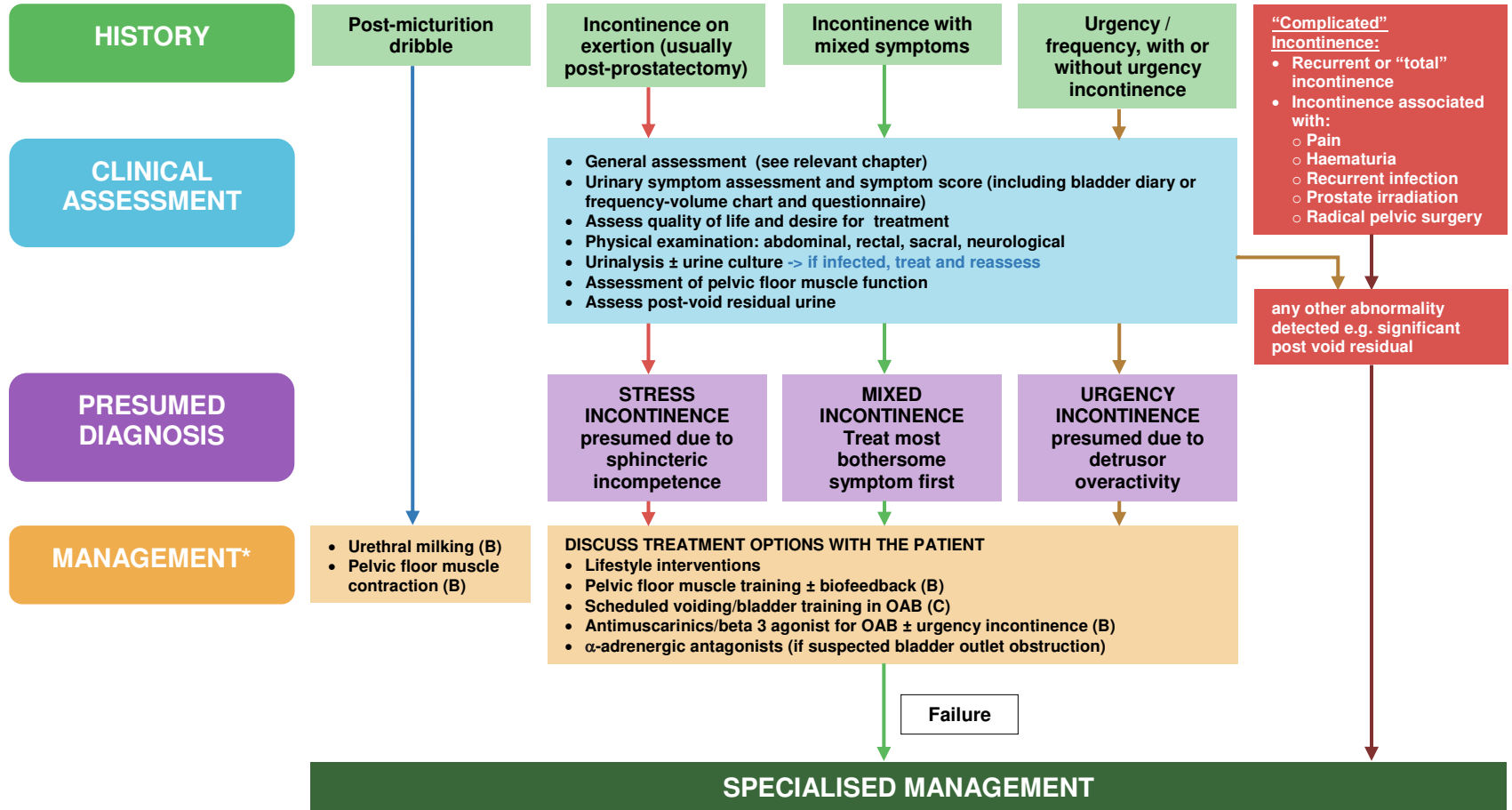
- Lifestyle interventions (eg weight loss GoR B)
 - Supervised pelvic floor muscle training for men with post radical prostatectomy SUI accelerates recovery time(GoR B)
 - Scheduled voiding regimen for OAB (GoR C)
 - Antimuscarinic/beta 3 agonist drugs for OAB symptoms with or without urgency incontinence (GoR B) if the patient has no evidence of significant post-void residual urine
 - α -adrenergic antagonists (a-blockers) can be added if it is thought that there may also be bladder outlet obstruction. (GoR C)
- **Should initial treatment be unsuccessful** after a reasonable time (for example, 8-12 weeks), **specialist advice** is highly recommended.

Clinicians are likely to wish to treat the **most bothersome symptom** first in men with symptoms of **mixed** incontinence.

2. MANAGEMENT

➤ For men with **post-micturition dribble**, this requires no assessment and can usually be treated by teaching the man how to do a strong pelvic floor muscle contraction after voiding, or manual compression of the bulbous urethra directly after micturition. (GoR B)

INITIAL MANAGEMENT OF URINARY INCONTINENCE IN MEN



* Consider CONTINENCE PRODUCTS for temporary support during treatment

II. URINARY INCONTINENCE IN MEN

B. SPECIALISED MANAGEMENT

The specialist may first **reinstitute initial management** if it is felt that previous therapy had been inadequate.

1. ASSESSMENT

- Patients with “**complicated**” **incontinence** referred directly to specialised management, are likely to require **additional testing**, such as cytology, cystourethroscopy and urinary tract imaging.

If additional testing is normal then those individuals can be treated for incontinence by the initial or specialised management options as appropriate.

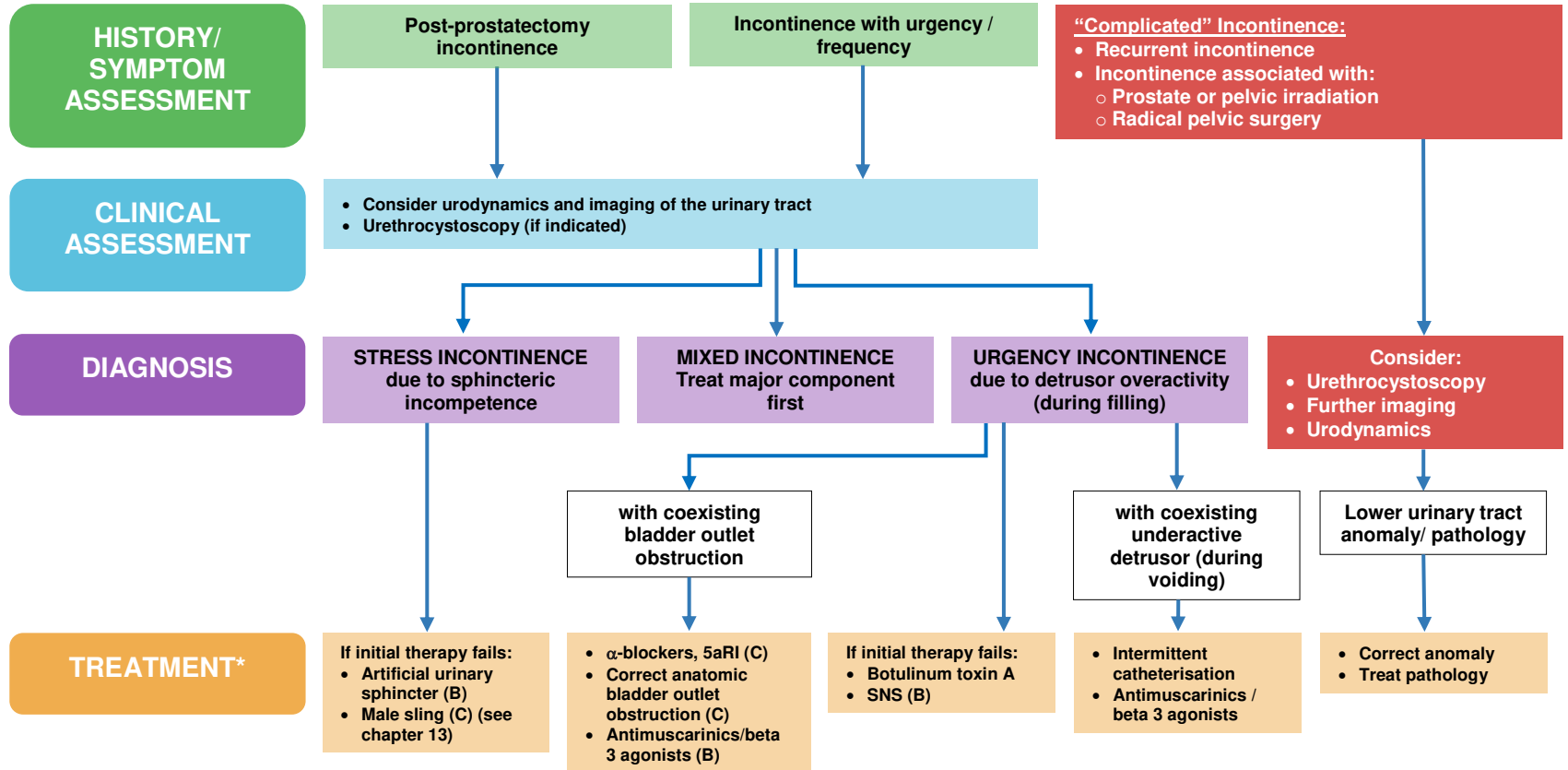
If symptoms suggestive of detrusor overactivity, or of sphincter incompetence **persist**, then **urodynamic** studies are advisable in order to arrive at a precise diagnosis, prior to invasive treatment.

2. TREATMENT

When basic management has been unsuccessful and if the patient’s incontinence markedly disrupts his quality of life then **invasive therapies** should be considered.

- **For sphincter incompetence** the recommended option is the artificial urinary sphincter (GoR B). Other options, such as a male sling, may be considered (GoR C).
- **For refractory idiopathic detrusor overactivity**, (with intractable overactive bladder symptoms) the recommended therapies are: Botulinum toxin A (GoR B), and SNS (GoR C),
- When incontinence has been shown to be associated with **poor bladder emptying** due to **detrusor underactivity**, it is recommended that effective means are used to ensure bladder emptying, for example, intermittent catheterisation (GoR B/C).
- If incontinence is associated with bladder outlet obstruction, then consideration should be given to surgical treatment to relieve obstruction (GoR B). α -blockers and/or 5 α - reductase inhibitors would be an optional treatment (GoR C).
- There is increased evidence for the safety of antimuscarinics for overactive bladder symptoms in men, chiefly in combination with an α -blocker (GoR B).

SPECIALISED MANAGEMENT OF URINARY INCONTINENCE IN MEN



* Consider CONTINENCE PRODUCTS for temporary support during treatment

III. URINARY INCONTINENCE IN WOMEN

A. INITIAL MANAGEMENT

1. INITIAL ASSESSMENT SHOULD IDENTIFY:

➤ **“Complicated” incontinence group.**

Those with pain or haematuria, recurrent infections, suspected or proven voiding problems, significant pelvic organ prolapse or who have persistent incontinence or recurrent incontinence after pelvic irradiation, radical pelvic surgery, previous incontinence surgery, or who have a suspected fistula, should be referred to a specialist.

- **Three other main groups** of patients should be identified by initial assessment.
- Women with **stress incontinence** on physical activity
 - Women with **urgency, frequency** with or without urgency incontinence: over-active bladder (OAB)
 - Those women with **mixed** urgency and stress incontinence

Abdominal, pelvic and perineal examinations should be a routine part of physical examination. Women should be asked to perform a “stress test” (cough and strain to detect leakage likely to be due to sphincter incompetence). Any pelvic organ prolapse or urogenital atrophy should be assessed. Vaginal or rectal examination allows the assessment of voluntary pelvic floor muscle function, an important step prior to the teaching of pelvic floor muscle training.

2. TREATMENT

- For women with **stress, urgency or mixed** urinary incontinence, initial treatment should include appropriate lifestyle advice, pelvic floor muscle training,

PFMT), scheduled voiding regimes, behavioural therapies and medication. In particular:

- **Advice** on caffeine reduction for OAB (GoR B) and weight reduction (GoR A).
- Supervised pelvic floor muscle training (GoR A), supervised vaginal cones training for women with stress incontinence (GoR B).
- Supervised bladder training (GoR A) for OAB.
- **If oestrogen deficiency** and/or **UTI** is found, the patient should be treated at initial assessment and then reassessed after using vaginal oestrogens for a suitable period (GoR B).
- **Antimuscarinics/beta 3 agonist** for OAB symptoms with or without urgency incontinence (GoR A); duloxetine* may be considered for stress urinary incontinence (GoR B)

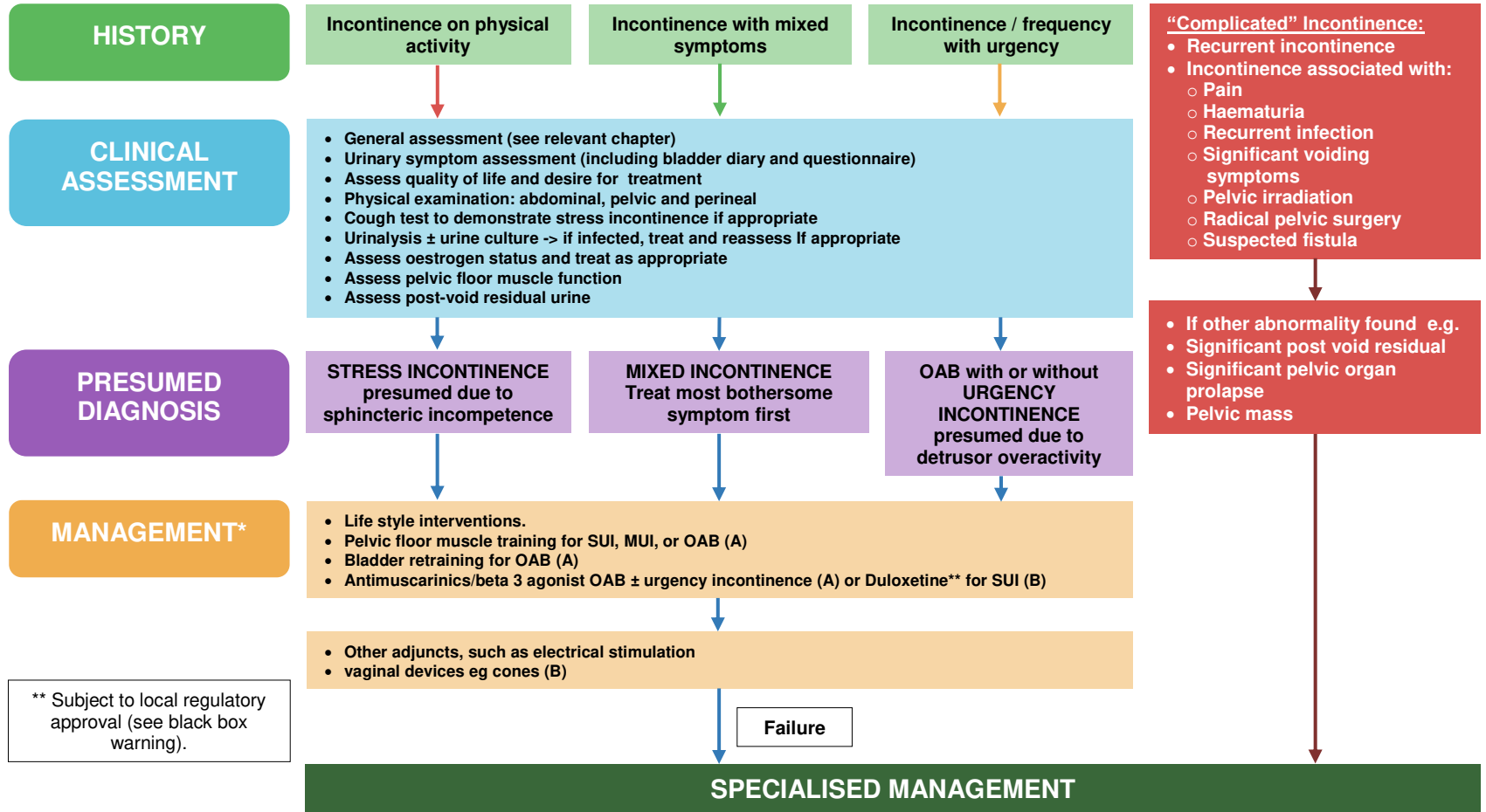
PFMT should be based on sound muscle training principles such as specificity, overload progression, correct contraction confirmed prior to training and use of “the Knack” for 12 weeks before reassessment and possible specialist referral.

Clinicians are likely to wish to treat the **most bothersome symptom first** in women with symptoms of mixed incontinence. (GoR C).

- Some women with significant pelvic organ prolapse can be treated by vaginal devices that treat both incontinence and prolapse (incontinence rings and dishes).

*Duloxetine is not approved for use in United States. In Europe it is approved for use in severe stress incontinence (see committee report on pharmacological management for information regarding efficacy, adverse events, and 'black box' warning by the Food and Drug Administration of the United States).

INITIAL MANAGEMENT OF URINARY INCONTINENCE IN WOMEN



- If other abnormality found e.g.
- Significant post void residual
- Significant pelvic organ prolapse
- Pelvic mass

** Subject to local regulatory approval (see black box warning).

* Consider CONTINENCE PRODUCTS for temporary support during treatment

III. URINARY INCONTINENCE IN WOMEN

A. SPECIALISED MANAGEMENT

1. ASSESSMENT

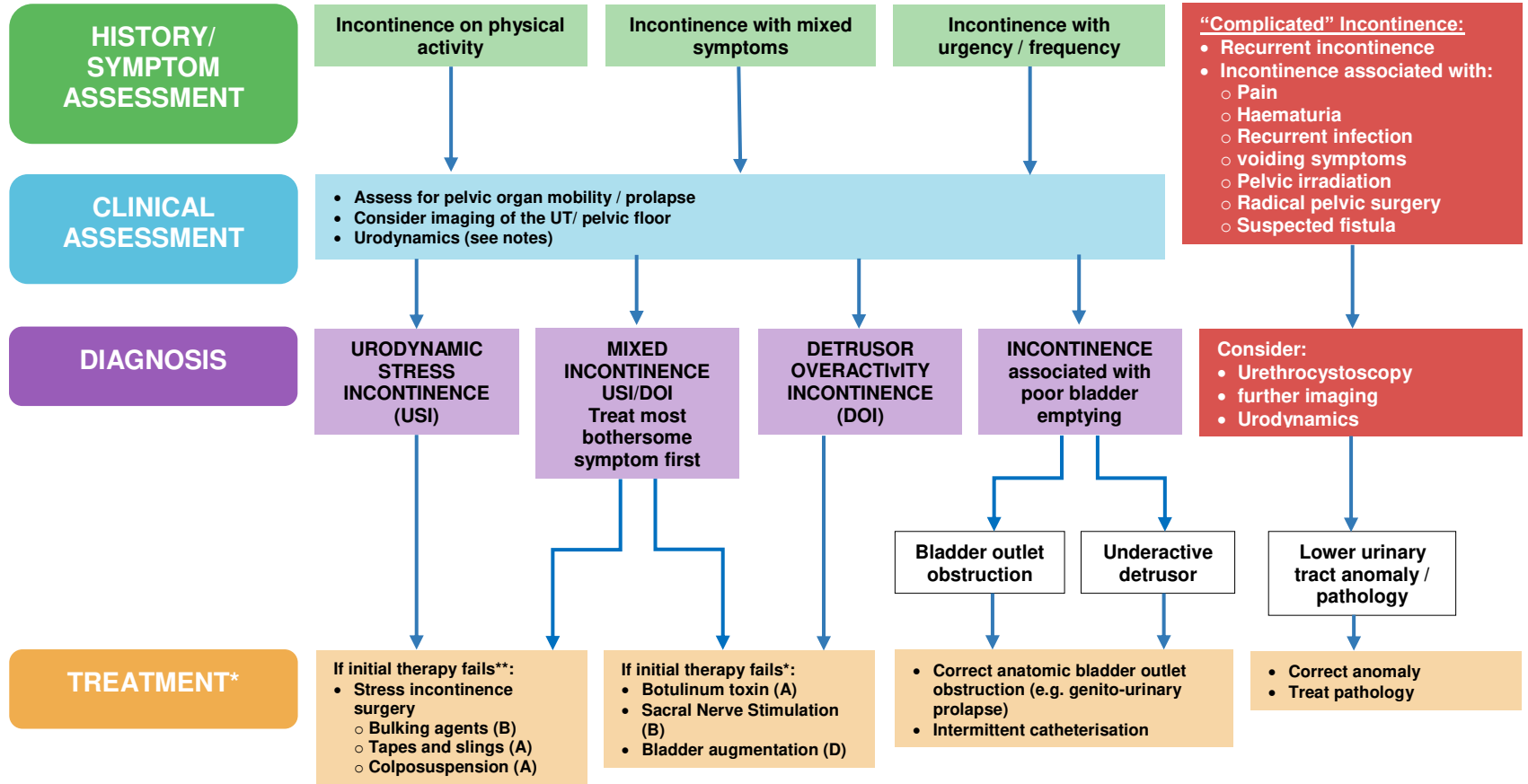
Women who have “**complicated**” **incontinence** (see initial algorithm) may need to have additional tests such as cytology, urodynamics, cystourethroscopy or urinary tract imaging. If these tests are normal then they should be treated for incontinence by the initial or specialised management options as appropriate.

- Those women with persistent symptoms despite **initial management** and whose quality of life is impaired are likely to request further treatment. If initial management has been given an adequate trial then **interventional therapy may be desired**. When the results of urodynamic testing may change management, we highly recommend testing prior to intervention in order to diagnose the incontinence type and, therefore, inform the management plan. Urethral function testing by urethral pressure profile or leak point pressure is optional.
- Systematic assessment for **pelvic organ prolapse** is highly recommended and the POP-Q method should be used in research studies. Women with co-existing pelvic organ prolapse should have their prolapse treated as appropriate.

2. TREATMENT

- **If stress incontinence is confirmed** then the treatment options that are recommended for patients include the full range of non-surgical treatments, as well as colposuspension procedures, (GoR A) and bladder neck/sub-urethral sling operations (GoR A). All of these procedures have potential risks and associated complications which should be discussed with the individual. **The correction of symptomatic pelvic organ prolapse** may be desirable at the same time. For selected patients injectable bulking agents (GoR B) and the artificial urinary sphincter (GoR C) can be considered.
- **Refractory urgency incontinence** (overactive bladder) secondary to idiopathic detrusor overactivity may be treated by botulinum toxin A (GoR A), sacral nerve stimulation (GoR B) or bladder augmentation/intestinal cystoplasty (GoR D).
- Those patients with **voiding dysfunction** leading to significant post-void residual urine (for example, >30% of total bladder capacity) may have bladder outlet obstruction or detrusor underactivity. Prolapse is a common reversible cause, of voiding dysfunction.

SPECIALISED MANAGEMENT OF URINARY INCONTINENCE IN WOMEN



** Note procedures in increasing level of invasiveness

* Consider CONTINENCE PRODUCTS for temporary support during treatment

IV. FISTULAE

In the developing world fistulae occur as a consequence of poor perinatal care. Despite vast surgical experience in some centres, published research is of low quality.

In the developed world, iatrogenic urogenital fistulae are known complications of pelvic surgery and oncological treatments such as radiotherapy, chemotherapy or a combination of both. In the oncological context, fistulae may also occur as a result of primary or recurrent malignancy. The development of fistula following radiotherapy for primary treatment should trigger a search for evidence of tumour recurrence (GoR D). The use of neoadjuvant or adjuvant therapies is likely to be associated with a greater risk of fistula development than the primary treatment alone.

The most common non-obstetric causes of fistulae involving the gastro-intestinal tract are diverticular disease, Crohn's disease, malignancy and radiotherapy.

1. INITIAL ASSESSMENT

Early detection of fistulae could be improved by examining all women after their delivery, or prevented by Caesarian section for women who suffer prolonged labour and who are at risk of developing an obstetric fistula. Associated pathologies should be actively searched for and should be taken into account in the treatment plan: all components of the 'obstructed labour injury complex' should be examined. Prevention by better health education, and by avoiding harmful practices must be encouraged.

Classification of fistulae is recommended. Although many classification systems exist, the committee recommends the use of the Goh, WHO or Tafesse classification systems (GoR B)

The formal classification of the fistula should be done under anaesthesia when the patient is on the operation table, just before surgery.

- Leakage of stool, urine, or possibly both is the hallmark sign of a fistula. The leakage is usually painless, may be intermittent if it is position dependent, or may be constant.
- CT and cystoscopy appear more consistent in the confirmation and location of possible intestino-vesical fistulae, than other investigations (GoR C)

- Level 3 evidence indicates that the routine use of cystoscopy with dye testing at gynaecological surgery has high sensitivity, specificity and negative predictive value in the detection of ureteric injury, although false positive tests do occur. (GoR C)
- Ureteric injury or fistula may be suspected in patients following pelvic surgery if a fluid leak or pelvi-calyceal dilatation occurs postoperatively. (GoR D)
- Uretero-arterial fistula may be suspected in patients presenting with haematuria with a history of relevant pelvic surgery and indwelling ureteric stent. (GoR D)
- Elevated levels of creatinine in drainage fluid following pelvic surgery are suggestive of urine leaking due to a urinary tract injury. (GoR D)

2. MANAGEMENT OF NEW AND ESTABLISHED VVF

Management of VVF depends on whether the fistula is diagnosed within a few weeks of its occurrence or whether the woman presents late with an established fistula.

Early fistulae are those which are not re-epithelialised, and ischaemic and necrotic tissue can be present at the time of examination. There is evidence that early catheter care will result in the cure of a significant minority of VVFs. (GoR C)

Established fistulae are re-epithelialised and show no oedema, ischaemic changes or inflammation. These fistulae and those that fail catheter treatment should be treated surgically by an experienced surgeon. (GoR C)

3. TREATMENT

If catheter drainage fails, then fistula repair will be necessary. There are certain principles behind fistula repair:

- Necrotic tissue must be removed prior to fistula repair.
- Fistula repair must only be undertaken by a properly trained surgeon.
- Adequate post-operative care is essential.

- Proper follow-up should be arranged.

In principle, most fistulae can be dealt with by the vaginal approach, but an abdominal approach may be needed in some cases (e.g. concomitant reconstructive procedures e.g. ureteral reimplantation or bladder augmentation). (GoR C)

A tension-free single layer closure of the bladder wall and closure of the vaginal wall in a separate layer is advocated. A Martius flap in primary fistula repair is not recommended.

When reporting on outcome after fistula repair, authors should make a clear distinction between fistula closure rates and post-operative incontinence rates and the time at which the follow-up was organised.

Prevention of post-operative stress incontinence must be added to the surgical procedure if the urethral closing mechanism is involved. This can be done by a good repair of the pubocervical fascia and refixation or by adding a sling procedure.

Attention should be given as appropriate to skin care, nutrition, rehabilitation, counselling and support prior to and following fistula repair. (GoR D)

There is no proven benefit to delayed repair of vesicovaginal fistulae; the timing of repair should be tailored to the individual patient and surgeon requirements, but can be undertaken as soon as any oedema, inflammation, tissue necrosis, and infection have resolved. (GoR B)

There are no high quality data to indicate greater cure rates for any one technique as compared to others; level 3 evidence indicates similar success rates for vaginal and abdominal, and for transvesical and transperitoneal approaches. (GoR C)

A variety of interpositional grafts can be used in either abdominal or vaginal procedures, although there is little evidence to support their use in any specific setting. (GoR C)

Conventional and robotically-assisted laparoscopic approaches have both been shown to be feasible in selected cases; the indications for, or optimal patient for these techniques is not yet clear. (GoR C)

A period of continuous bladder drainage is crucial to successful fistula repair; there are no high level data to support any particular type, route, or duration of catheterisation. Current practice suggests, 10-14 days for simple and/or post-surgical fistulae; 14-21 days for complex and/or post-radiation fistulae. (GoR D)

Whilst diversion is used more widely in radiation-associated fistulae of all types as compared to non-radiated fistulae, there is low-level evidence that repair procedures can achieve successful fistula closure and continence in appropriately selected cases. (GoR C)

Where urinary and/or faecal diversions are required, attempts should be made to avoid using irradiated tissues wherever possible, and to minimise the potential for anastomotic complications. (GoR C)

There is low-level evidence to support the use of interposition grafts when repair of radiation-associated fistulae is undertaken. (GoR C)

4. MANAGEMENT OF THE COMPLICATIONS OF VVF

The complications of vesico-vaginal fistulae are many but include:

- Persistence or recurrence of urinary incontinence
- Persistence of lower urinary tract symptoms or occurrence of new lower urinary tract symptoms, including overactive bladder
- Urinary tract infections
- Upper urinary tract symptoms, including loin pain
- Dyspareunia and sexual dysfunction
- Infertility
- Neurological symptoms
- Psychological problems and mental illness

MANAGEMENT OF VESICOVAGINAL FISTULA

HISTORY

Leakage of urine from vagina / perineum

CLINICAL ASSESSMENT

- Clinical examination
- Urethro-cystoscopy
- Imaging (X-ray/CT/MRI, US)
- Evaluate upper urinary tract

PRESUMED DIAGNOSIS

Recent VVF

Established VVF

Consider Catheter, evaluate weekly

Healed

Persistent leakage

MANAGEMENT*

Primary simple

Primary complex

Recurrence

Post-irradiation

Vaginal repair
Consider timing

Surgical repair
Consider timing
Consider interposition material

If small, consider catheter, evaluate weekly

Surgical repair
6-12 months
Consider interposition material

Surgical repair
Consider timing
Consider interposition material

Assess fistula closure & assess continence status

* Consider CONTINENCE PRODUCTS for temporary support during treatment

1. MANAGEMENT OF FISTULAE INVOLVING BOWEL

- There is limited evidence to support a non-surgical or conservative surgical approach in colo-vesical fistulae where there are minimal symptoms or evidence of limited bowel involvement. (GoR C)
- A one-stage approach to surgery for intestino-vesical fistulae is appropriate in many cases, but should be limited to those patients whose nutritional state is good, and where there is no evidence of additional intra-abdominal pathology (e.g. severe inflammation, radiation injury, advanced malignancy, intestinal obstruction) or major co-morbidity. (GoR B)
- A laparoscopic/robotic approach to one-stage management is feasible, although there is no high level evidence to allow comparison of outcomes with open surgery. (GoR D)

2. MANAGEMENT OF URETERIC FISTULAE

- Surgeons undertaking complex pelvic surgery should be competent at identifying, preserving and repairing the ureter. (GoR D)
- Ureteric stents are not required as prophylaxis against injury during routine gynaecological surgery, while their role in more extensive surgery remains to be established. (GoR B)

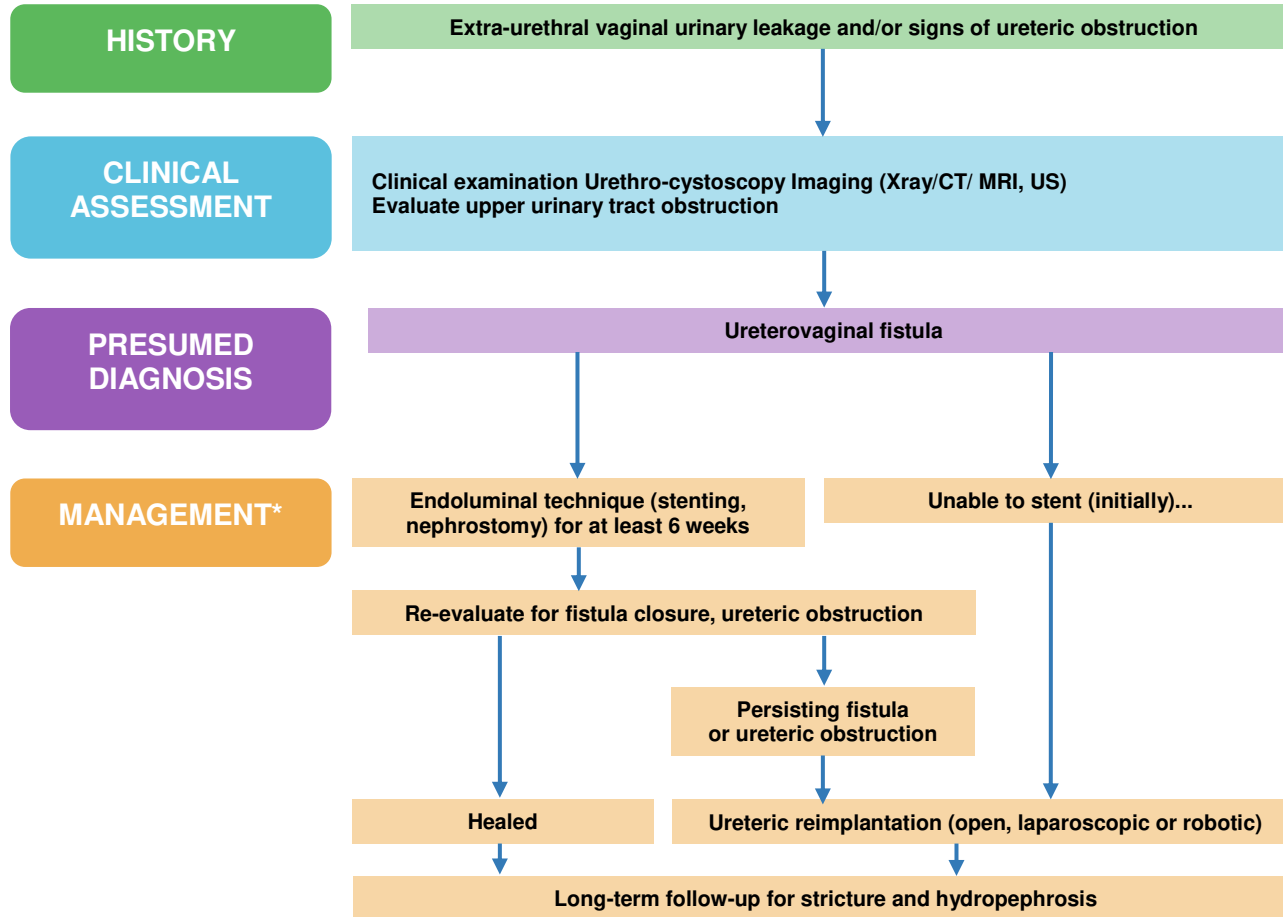
- Most upper urinary tract fistulae should be initially managed by conservative or endoluminal techniques where such expertise and facilities exist. (GoR B)
- Persistent ureterovaginal fistulae should be repaired by an abdominal approach using open, laparoscopic or robotic techniques according to availability and competence. (GoR D)
- For patients with ureteric fistulae associated with advanced pelvic cancer and poor performance status, palliation by nephrostomy tube diversion and endoluminal distal ureteric occlusion is an option. (GoR C)

3. MANAGEMENT OF URETHRO-VAGINAL FISTULAE

Recommendations

- Urethrovaginal fistulae are preferably treated by a vaginal approach. (GoR C)
- A variety of autologous tissue interposition techniques have been described, but their value remains uncertain. (GoR C)
- Urethrovaginal fistulae repair may be complicated by stress incontinence, urethral stricture and urethral shortening necessitating long-term follow-up. (GoR C)

MANAGEMENT OF IATROGENIC URETERIC FISTULAE



* Consider CONTINENCE PRODUCTS for temporary support during treatment

V. PELVIC ORGAN PROLAPSE

1. INTRODUCTION

Pelvic organ prolapse includes vaginal and rectal prolapse. Treatment of pelvic organ prolapse is generally reserved for symptomatic prolapse. Clinicians should recognise that coexistent pelvic floor symptoms are frequently present and that these symptoms may or may not be related to the prolapse. Women with prolapse require a careful and detailed initial assessment not only of the prolapse but associated bladder, bowel and sexual function.

2. ASSESSMENT

Symptom assessment preferably with a validated pelvic floor questionnaire that assesses bladder, bowel, vaginal and sexual function and bothersomeness is required. (Grade C).

Physical examination should:

- Report the most distal site of vaginal descent in relation to a fixed point such as the hymen and include an assessment of the anterior posterior and apical vagina. While standardised reporting utilising tools such as the Pelvic Organ Prolapse Quantification (POP-Q) are encouraged. The system used to measure the extent of the prolapse should be documented.
- Be undertaken in the standing position to evaluate the full extent of the prolapse.
- Determine if coexistent pelvic pathology is present on careful bimanual examination. Cytological screening of the cervix should be undertaken if required.
- The prolapse should be reduced to document the presence of occult stress urinary incontinence (see chapter for prolapse and urinary incontinence pathway).
- Assess pelvic floor muscle function (see chapter for full review).
- Determine if epithelial/ mucosal ulceration is present.
- Evaluate anal sphincter tone and or the presence of rectal prolapse in those with bowel symptoms (refer to chapter for pelvic organ prolapse and bowel symptom pathway).

When examination findings of the extent of the prolapse are not consistent with the history the examination can be repeated in a few weeks' time. (GoR C).

Post void residual should be measured; while most elevated post-void residual urines (150mls) resolve with treatment of the prolapse, a specialist consultation is required.

3. MANAGEMENT

Observation is appropriate when medically safe (GoR C).

Lifestyle interventions include weight loss, treating constipation, avoiding straining at stool and heavy lifting (GoR C).

Pelvic floor muscle training:

- Reduces associated pelvic floor symptoms (GoR A).
- May reduce the symptom of vaginal bulge (GoR C).
- Does not reduce extent of prolapse on examination based on POP-Q stage (GoR B).

Vaginal Pessary: when successfully fitted

- May reduce prolapse symptoms (GoR B)
- Need to be regularly reviewed (GoR C)
- Have high rates of discontinuation (GoR C)

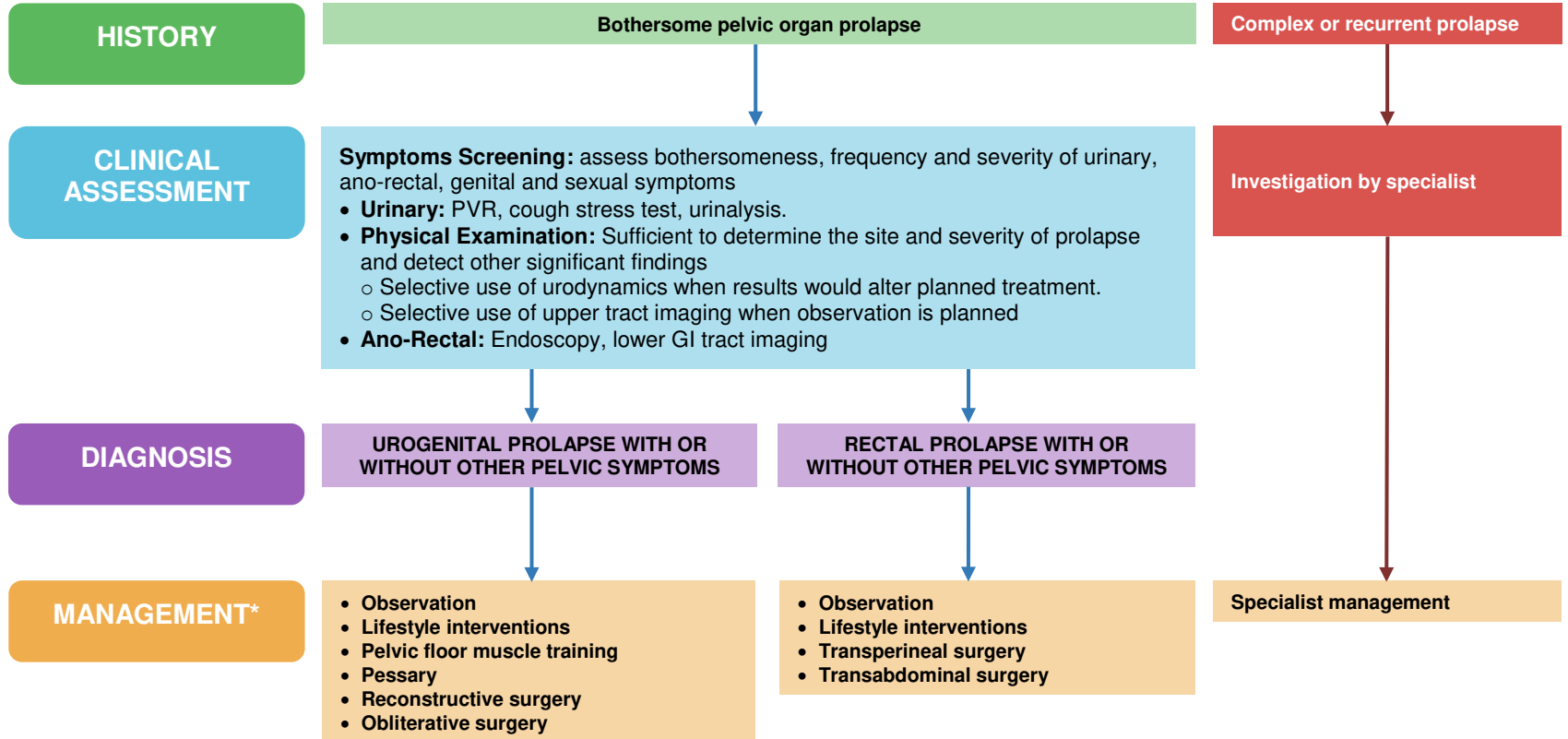
Local Oestrogens are recommended in those with hypo-oestrogenic symptoms and in those with urethral prolapse or vaginal ulceration (GoR B)

Reconstructive surgery is reserved for those with symptomatic prolapse and is aimed at correcting the vaginal topography and functional pathology. Please see text for full recommendations.

Obliterative surgery is an important and effective treatment option in those who are happy to sacrifice coital activity. (GoR C)

MANAGEMENT OF PELVIC ORGAN PROLAPSE

(INCLUDING UROGENITAL PROLAPSE AND RECTAL PROLAPSE)



* Consider CONTINENCE PRODUCTS for temporary support during treatment

PATHWAY FOR THE SURGICAL MANAGEMENT OF PELVIC ORGAN PROLAPSE

The pelvic organ prolapse (POP) surgery pathway was designed to provide an evidence based guide for both clinicians and women for the surgical management of pelvic organ prolapse. Within the pathway green lines highlight the preferred option and yellow lines indicate reasonable options.

An early option in the treatment pathway for women not wanting to preserve sexual function is obliterative surgery (colpocleisis) which is an efficacious intervention that has low morbidity (LoE 3).

The majority of women will enter the reconstructive pathway. Apical suspension procedures should be considered in all cases with 10-year re-operation rates for prolapse being significantly reduced if apical suspensions are performed concomitantly with both anterior and posterior colporrhaphy as compared to those performed without apical support.

In those undergoing anterior and posterior colporrhaphy the evidence is supportive of traditional native tissue suture plications (LoE 1). In the anterior compartment permanent mesh could be considered for recurrent cases when the patient understands the risk benefit profile for these interventions and that the data for their use is scant. Evidence is not supportive of biological grafts in the anterior compartment (LoE 2).

In the posterior compartment, fascial plication is superior to site specific native tissue repair (LoE 2) and levatorplasty should be avoided due to higher rates of dyspareunia (LoE3). Data are not supportive of biological or permanent mesh grafts. Posterior colporrhaphy is superior to transanal repair of rectocele (LoE 1) and there is no data to support ventral rectopexy with or without vaginal graft for rectocele.

With recognition of the importance of apical vaginal support in minimising the risk of subsequent recurrence, the pathway separates those with post-hysterectomy (vault) prolapse from those with uterine prolapse.

Data are supportive of sacral colpopexy as the preferred intervention for vault prolapse with superior anatomical and functional outcomes when compared to a variety of vaginal based interventions with and without transvaginal mesh (LoE1). This preference is highlighted by a green preferred option arrow in the management pathway. In recognition that not all patients are suitable for sacral colpopexy, a yellow reasonable option is included for vaginal based apical support (uterosacral or sacrospinous colpopexy). Both uterosacral and sacrospinous colpopexy are

equally effective vaginal options (LoE 1) and utilisation of transvaginal permanent mesh apical support is not supported by the data (LoE1).

When performing sacral colpopexy the laparoscopic approach is preferred with reduced peri-operative morbidity and cost when compared to both the open or robotic approach (LoE 2). The yellow reasonable option pathway exists for both open and robotic options in recognition of the longer learning curve associated with the laparoscopic approach (LoE3).

Apical support in those with uterine prolapse can be performed abdominally or vaginally and includes options for both uterine preservation (hysteropexy) and hysterectomy, with not insignificant relative contraindications for uterine preservation listed in Table 6. In post-menopausal women undergoing hysterectomy, bilateral salpingo-oophorectomy (BSO) significantly reduces the rate of ovarian cancer without increased morbidity. In those retaining ovaries at hysterectomy, bilateral salpingectomy also reduces rate of subsequent ovarian cancer.

Vaginal hysteropexy is equally effective as vaginal hysterectomy with apical suspension and is associated with reduced blood loss and operating time as compared to hysterectomy (LoE 1). Vaginal hysterectomy with apical support has a lower re-operation for prolapse than abdominal sacrohysteropexy (LoE1). Sacrohysteropexy has a higher re-operation for prolapse than sacral colpopexy with hysterectomy however sacral colpopexy with hysterectomy is not recommended due to the high rate of mesh exposure (LoE2). Supra-cervical hysterectomy at sacral colpopexy reduces the rate of mesh exposure associated with hysterectomy and sacral colpopexy however in a single retrospective study, recurrent prolapse was more common in the supracervical hysterectomy group. Although those data is not complete, vaginal based hysterectomy and hysteropexy with apical support should generally be considered as preferred options for uterine prolapse with sacral colpopexy reserved for vault prolapse.

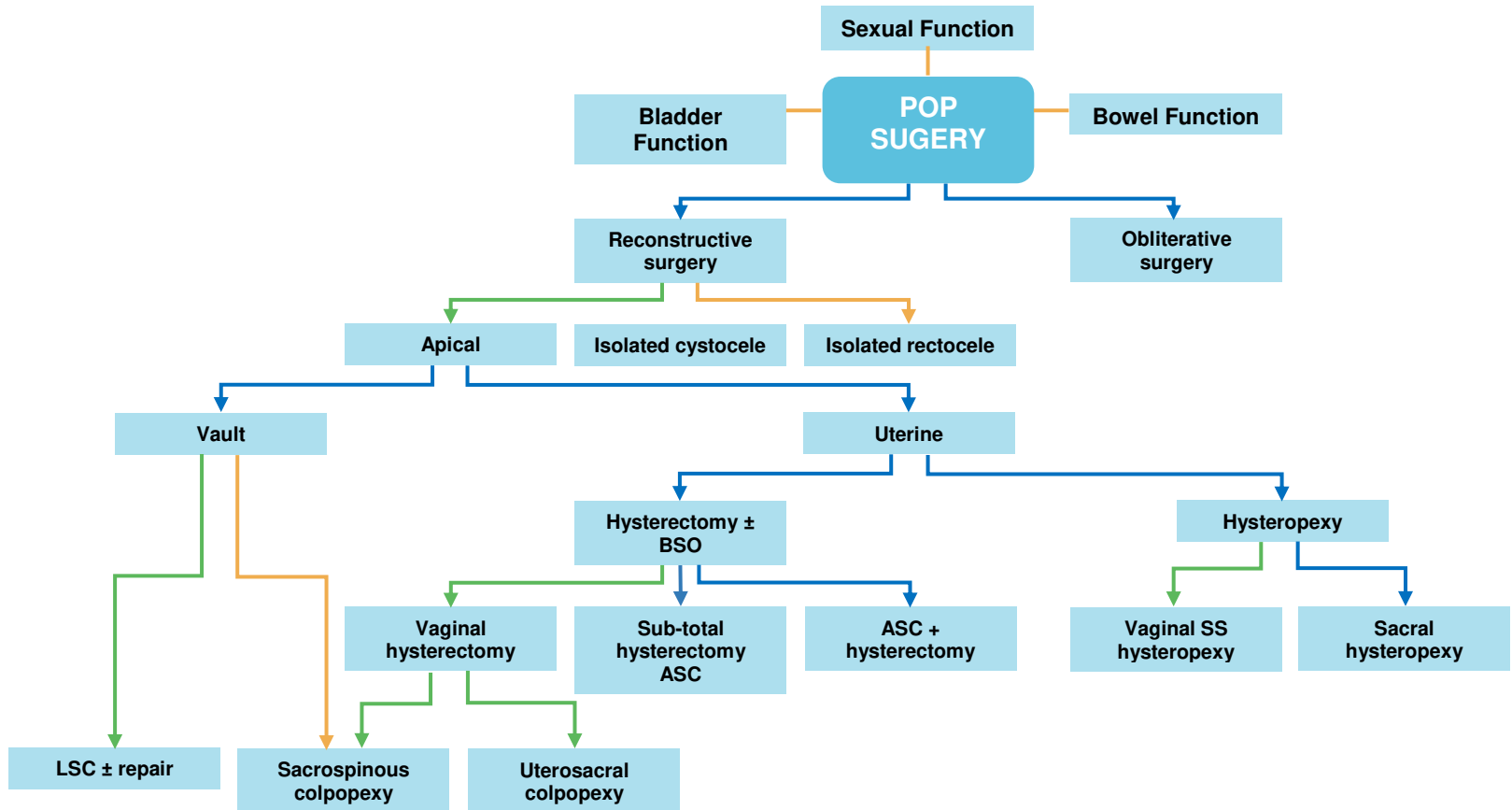
Those undergoing prolapse surgery with stress urinary incontinence (SUI) and occult SUI should generally have continence surgery performed at the time of prolapse surgery (LoE1). Those with prolapse without SUI or occult SUI should not undergo continence surgery at time of prolapse surgery (LoE1).

Based largely upon expert opinion (LoE3) those with prolapse without bowel symptoms and those with impaired defaecation with rectocele should undergo prolapse surgery as per the above pathway. Those with POP and impaired defaecation without rectocele, and those with faecal incontinence require colorectal assessment. If

rectal prolapse exists, these patients may benefit from combined colorectal and gynaecological interventions. Those with significant constipation and prolapse should be approached cautiously and may benefit from gastroenterology assessment prior to entering the POP surgery pathway.

Those undergoing POP surgery generally have improved sexual function post-operatively but a small number undergoing any POP surgery will experience painful intercourse post-operatively that may require subsequent intervention (LoE 1).

PATHWAY FOR THE SURGICAL MANAGEMENT OF PELVIC ORGAN PROLAPSE



Consider CONTINENCE PRODUCTS for temporary support during treatment

VI. URINARY INCONTINENCE IN NEUROLOGICAL PATIENTS

A. INITIAL MANAGEMENT

1. STRONG GENERAL RECOMMENDATIONS

- Patients with known neurological disease often need evaluation to exclude bladder dysfunction, not only if symptoms occur, but as a standard assessment as neurogenic bladder has a high prevalence in the particular disease (for prevalence figures see chapter)
- A possible neurological cause of “idiopathic” incontinence should always be considered. Diagnostic steps to evaluate this include basic assessments, such as history and physical examination, urodynamics and specialised tests.
- Incontinence in neurological patients does not necessarily relate to the neurologic pathology. Other diseases such as prostate pathology, pelvic organ prolapse, might have an influence. These factors should be evaluated as potential primary or contributory causes.
- Extensive diagnostic evaluation is often useful and necessary to tailor an individual treatment based on complete neurofunctional data. This may not be needed in every patient e.g. patients with suprapontine lesions or in patients where treatment will consist merely of bladder drainage when the person is frail or has limited life expectancy.
- There is often a need to manage both bladder and bowel dysfunction simultaneously

2. INITIAL ASSESSMENT

- The management of neurological urinary incontinence depends on an understanding of the likely mechanisms producing incontinence. This can in turn depend on the site and extent of the nervous system abnormality.
- Under current classifications, neurogenic incontinence patients can be divided into four groups. History and physical examination are important in helping distinguish these groups:

- peripheral lesions (as after major pelvic surgery) including those with lesions of the cauda equina (eg.lumbar disc prolapse);
- sacral spinal cord lesions involving the sacral micturition centre
- suprasacral spinal cord lesions (suprasacral infrapontine spinal cord lesions);
- central lesions of the brain or brain stem (stroke, Parkinson’s disease).
- Assessment should be made using Questionnaires, urinalysis, bladder diary, uroflowmetry with assessment of PVR, and imaging of the urinary tract (ultrasonography); all provide basic data for the initial assessment of the NLUTD.
- Invasive urodynamics should be used as part of the initial assessment in select patient populations (SCI, meningomyelocele)
- Due to increasing data on organ cross-sensitisation and the debilitating effect of faecal incontinence on QOL, a history of bowel function should be also included

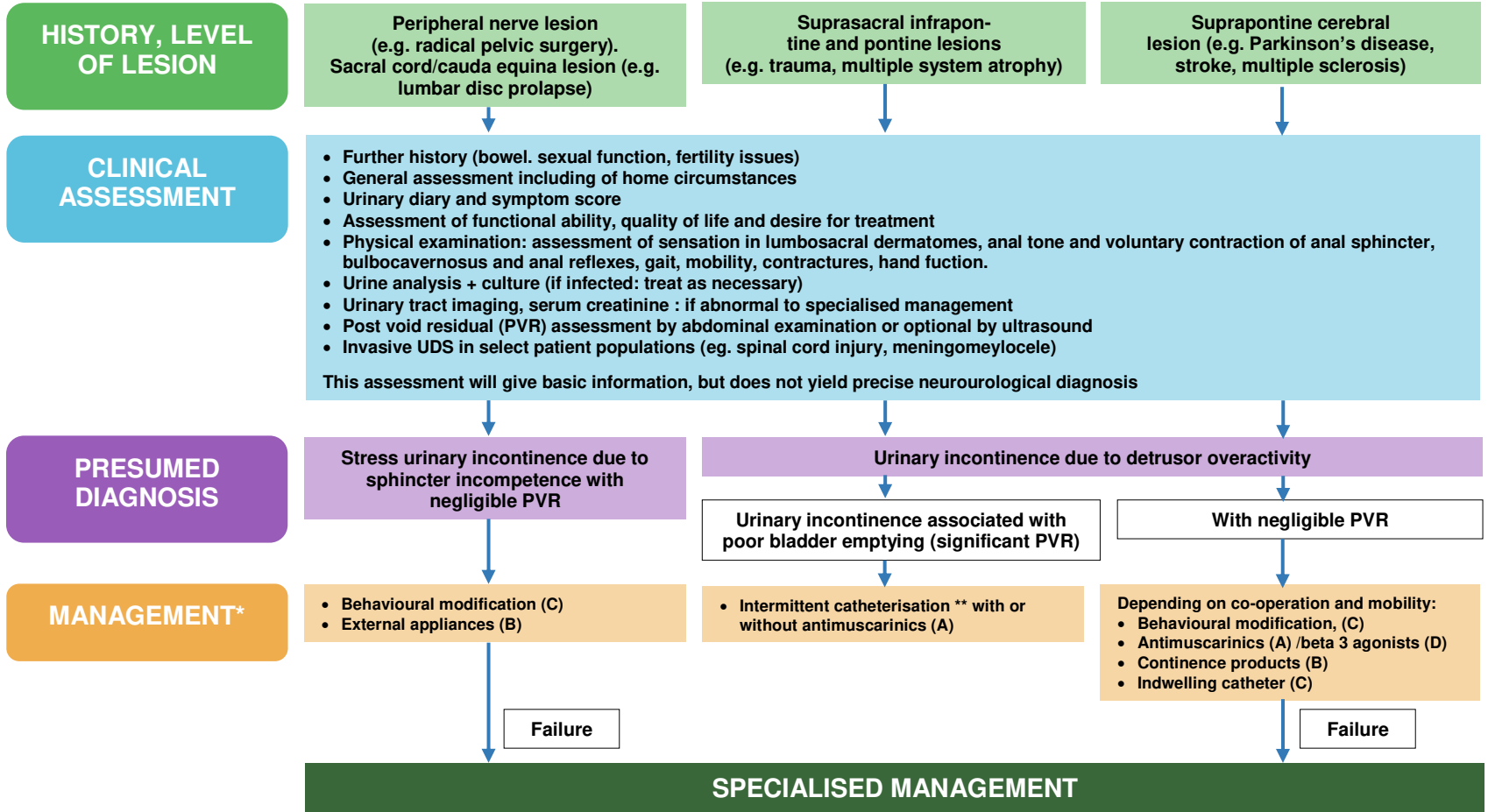
3. INITIAL TREATMENT

- Patients with peripheral nerve lesions (e.g. denervation after pelvic surgery) and patients with spinal cord lesions (e.g. traumatic spinal cord lesions) should receive specialised urological management (GoR A).
- Initial treatment for patients with incontinence due to suprapontine pathology, like stroke; need to be assessed for degree of mobility and ability to cooperate. Initial recommended treatments are behavioural therapy (GoR C) and antimuscarinic drugs for presumed detrusor overactivity (GoR A). If incontinence persists and if operative procedures are not indicated then continence products (GoR B) or catheters (GoR C) may be necessary on a long-term basis. These can also be necessary in non-cooperative or less mobile patients.

Pharmacological detrusor relaxation and/or antibiotics may be useful in cases of persistent bypass leakage and/or recurrent UTI (patients with continuous drainage)

In all cases, bowel management should complement management of NLUTD

INITIAL MANAGEMENT OF NEUROGENIC URINARY INCONTINENCE



* Consider CONTINENCE PRODUCTS for temporary support during treatment

** Some patients omit IC through personal choice or inability to self catheterise

***Add complimentary bowel management in all cases

VI. URINARY INCONTINENCE IN NEUROLOGICAL PATIENTS

B. SPECIALISED MANAGEMENT

1. ASSESSMENT

- Most patients with neurogenic urinary incontinence require specialised assessment: Invasive urodynamic studies should be used with videourodynamics if available when surgical interventions are planned or when the “bladder may be unsafe”.
- Upper tract imaging is needed in some patients and more detailed renal function studies will be desirable if the upper tract is considered in danger: high bladder pressure, upper urinary tract dilation, recurrent or chronic upper tract infection, (major) stones, (major) reflux.
- In patients with peripheral lesions, clinical neurophysiological testing may be helpful for better definition of the lesion

2. TREATMENT

For specialised management, conservative treatment is the mainstay (GoR A). Management of neurogenic urinary incontinence has several options. The algorithm details the recommended options for different types of neurological dysfunction of the lower urinary tract. The dysfunction does not necessarily correspond to one type/level of neurological lesion and is defined best by urodynamic studies. One should always ascertain that the management ensures a safe lower urinary tract (storage at low pressure and complete emptying)

Both urinary and bowel function should be assessed together if both systems are affected, as symptoms and treatment of one system can influence the other, and *vice versa* (GoR A).

As therapeutic approaches can differ in various neurological diseases, the most prevalent diseases are discussed separately in the chapter

3. TREATMENT MODALITIES (OFTEN IN COMBINATION)

➤ Conservative

- Intermittent catheterisation (GoR A)
- Behavioural treatment (GoR C)
- Timed voiding (GoR C)
- Continence products (GoR B)
- Antimuscarinics (GoR A)
- Alpha-1-adrenergic blockers (GoR C)
- Oral cannabinoid agonists (MS) (GoR C)
- Beta-3-agonist alone or as an add-on to AM (GoR D)
- Bladder expression (GoR B)
- Triggered voiding (GoR C)
- Indwelling catheter (GoR C)

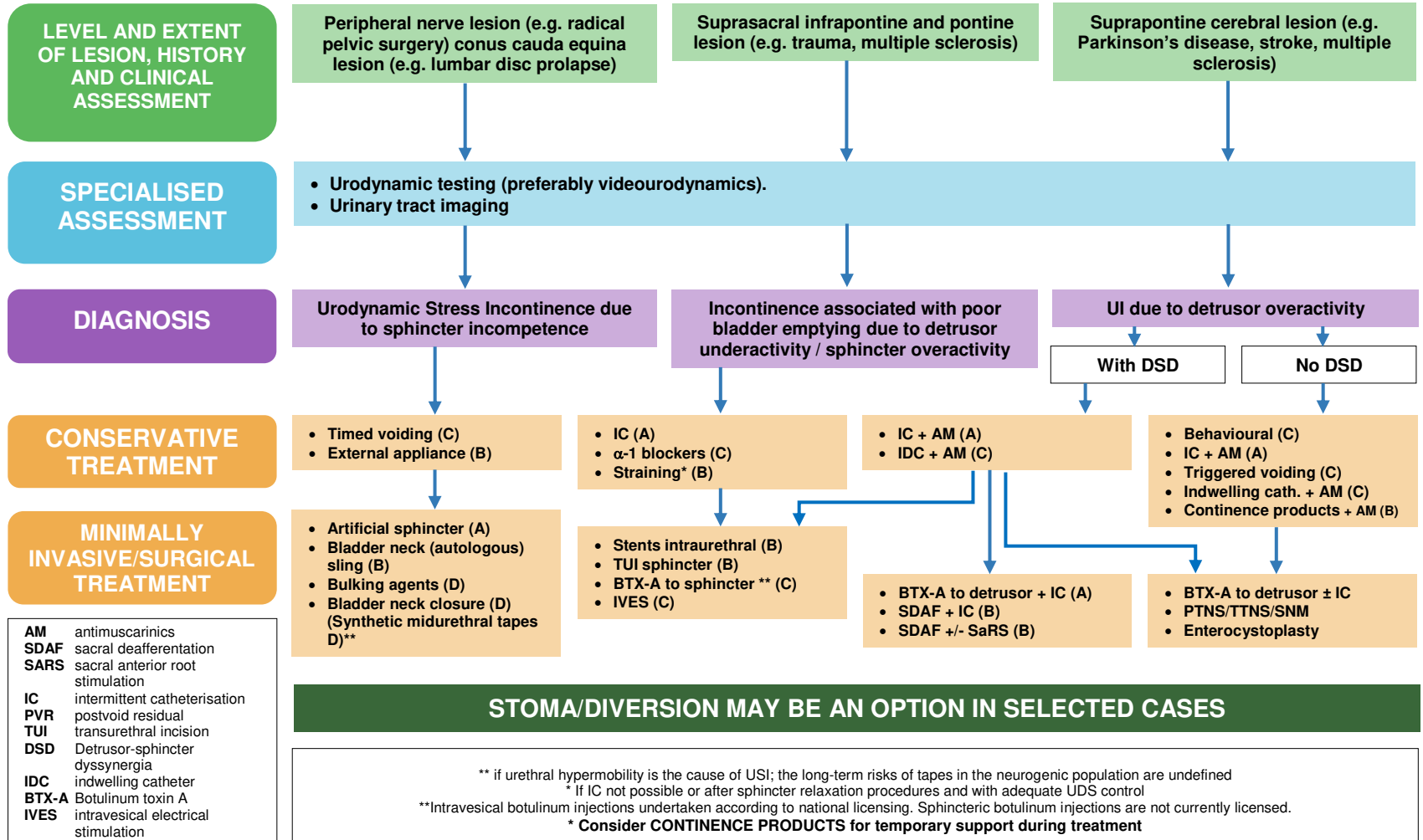
➤ Minimally invasive treatments

- Botulinum toxin for: sphincter (C) detrusor (A)
- Intravesical electrical stimulation (C)
- PTNS/TTNS (C)
- SNM (stable disease only) (C)

➤ Surgical treatment

- Artificial sphincter (A)
- Bladder neck sling (B)
- Sub-urethral tapes (D)
- Bulking agents (D)
- Bladder neck closure (D)
- Stents intraurethral (B)
- TUI sphincter (B)
- Sacral deafferentation (B)
- Sacral anterior root stimulator (B)
- Enterocystoplasty (B)

SPECIALISED MANAGEMENT OF NEUROGENIC URINARY INCONTINENCE



VII. BLADDER PAIN SYNDROME

Definition

Bladder Pain Syndrome (BPS): in the absence of a universally agreed definition, the International Society for the Study of Interstitial Cystitis – ESSIC definition is given (1).

ESSIC: Chronic pelvic pain, pressure or discomfort of greater than 6 months duration perceived to be related to the urinary bladder accompanied by at least one other urinary symptom like persistent desire to void or urinary frequency. Confusable diseases as the cause of the symptoms must be excluded.

There are no published data as to what duration of symptoms indicates that early spontaneous resolution of symptoms is unlikely. While ESSIC arbitrarily uses a 6 month duration, the American Urological Association Guideline suggests that a 6 week history is long enough to initiate diagnosis and treatment of BPS (2). Without further data, the Consultation cannot make a recommendation and believes that it is up to the discretion of the physician and patient as to the proper interval between symptom onset and evaluation and diagnosis of a chronic condition.

1. NOMENCLATURE

The scientific committee of the International Consultation voted to use the term “bladder pain syndrome” for the disorder that has been commonly referred to as interstitial cystitis (IC). The term painful bladder syndrome was dropped from the lexicon. The term IC implies an inflammation within the wall of the urinary bladder, involving gaps or spaces in the bladder tissue. This does not accurately describe the majority of patients with this syndrome. Painful Bladder Syndrome, as defined by the International Continence Society, is too restrictive for the clinical syndrome.

Properly defined, the term Bladder Pain Syndrome appears to fit in well with the taxonomy of the International Association for the Study of Pain (IASP) (see below), and focuses on the actual symptom complex rather than what appears to be long-held misconception of the underlying pathology.

Bladder Pain Syndrome (XXIII-2) (per IASP)

Bladder pain syndrome is the occurrence of persistent or recurrent pain perceived in the urinary bladder region, accompanied by at least one other symptom, such as pain worsening with bladder filling and day-time and/or night-time urinary frequency. There is no proven infection or other obvious local pathology. Bladder pain

syndrome is often associated with negative cognitive, and behavioural, sexual, or emotional consequences, as well as with symptoms suggestive of lower urinary tract and sexual dysfunction.

The Consultation believes that, based on the pathology and endoscopic finding characteristics of the Hunner lesion, the epidemiological pattern that distinguishes it from bladder pain syndrome, the clinical response to local treatment of the lesion by resection, fulguration, or steroid injection, the response to cyclosporine, and the absence of reports in the literature that non-Hunner patients go on to develop Hunner lesions (ie, the finding of a Hunner lesion does not represent a continuum in the

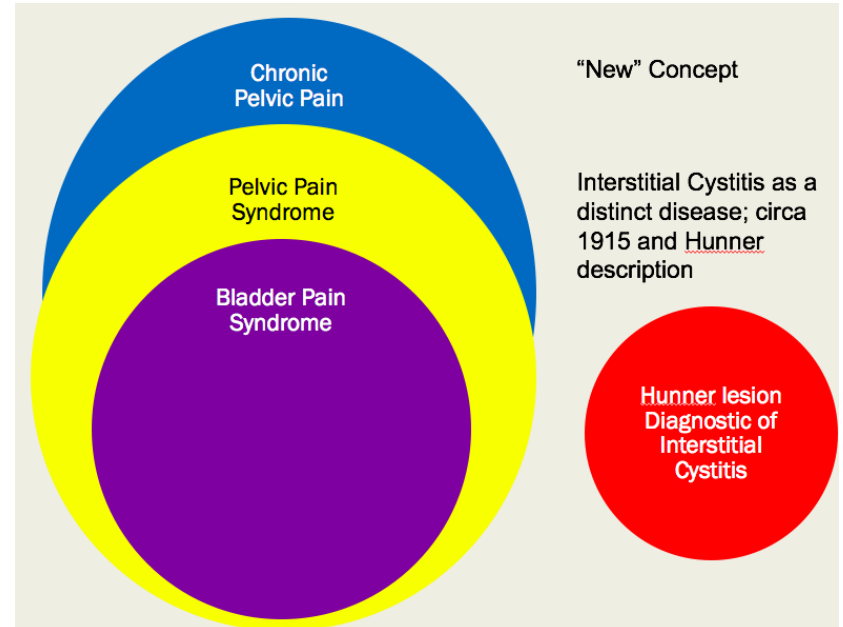


Figure 1

natural history of bladder pain syndrome), that the presence of a Hunner lesion

should be considered a distinct disease. It therefore should drop out of the bladder pain syndrome construct, much like we do not consider other painful conditions like radiation cystitis, ketamine cystitis, or urinary tract infection a part of bladder pain syndrome.

The Consultation concludes that it would be reasonable to designate the Hunner lesion in symptomatic patients with the term “interstitial cystitis”, thus indicating a true interstitial inflammation. It would be defined much as Hunner defined it 100 years ago, and harmonise the largely Asian, European, and North American concepts of interstitial cystitis. The Consultation will continue to refer to the symptom complex as “bladder pain syndrome”. Hunner lesion will be considered a distinct phenotype, but in the future may be classified as a separate disorder entirely, albeit with local symptoms that are difficult to differentiate from bladder pain syndrome in the absence of endoscopy. In other words, we may be coming full circle in the historical perspective Figure 1.

2. HISTORY / INITIAL ASSESSMENT

Males or females whose symptoms meet the requirements of the definition of bladder pain syndrome should be evaluated. The presence of commonly associated disorders including irritable bowel syndrome, chronic fatigue syndrome, and fibromyalgia in the presence of the cardinal symptoms of bladder pain syndrome also suggests the diagnosis. Abnormal gynaecological findings in women and well-characterised, confusable diseases that may explain the symptoms must be ruled out.

The initial assessment consists of a bladder diary or frequency/volume chart, focused physical examination, urinalysis, and urine culture. In the absence of confusable disorders (uncomplicated disease), a diagnosis can be made and treatment instituted. Urine cytology, cystoscopy, and urodynamic evaluation are recommended if clinically indicated and/or the diagnosis is in doubt (complicated disease). Patients with urinary infection should be treated and reassessed. Those with recurrent urinary infection, abnormal urinary cytology, and microscopic or gross haematuria are evaluated with appropriate imaging and endoscopic procedures, and only if the findings are unable to explain the symptoms, are they diagnosed with BPS. GoR C

3. INITIAL TREATMENT

- Patient education, (GoR B)

- Dietary manipulation, (GoR B)
- Nonprescription analgesics,
- Stress reduction,
- Pelvic floor relaxation techniques comprise the initial treatment of BPS. In the patient with findings suggesting pelvic floor dysfunction, pelvic floor physical therapy with myofascial trigger point release and intravaginal Thiele massage is often an effective therapeutic intervention. The treatment of pain needs to be addressed directly, and in some instances referral to an anesthesia/pain centre can be an appropriate early step in conjunction with ongoing treatment of the syndrome. (GoR A)

When conservative therapy fails or symptoms are severe and conservative management is unlikely to succeed,

- Oral medication (GoR B) or
- Intravesical treatment can be prescribed. It is recommended to initiate a single form of therapy and observe results, adding other modalities or substituting other modalities as indicated by the degree of response or lack of response to treatment. (GoR B)

4. SECONDARY ASSESSMENT

If initial oral or intravesical therapy fails, or before beginning such therapy based on clinician judgment, it is reasonable to consider further evaluation which can include urodynamics, pelvic imaging, and cystoscopy with bladder distention and possible bladder biopsy under anaesthesia.

- Findings of detrusor overactivity suggest a trial of antimuscarinic or beta-3-agonist therapy.
- The presence of a Hunner lesion suggests therapy with transurethral resection, fulguration of the lesion, or direct steroid injection into the lesion. (GoR B)
- Bladder distention itself can have therapeutic benefit in 30-50% of patients, though benefits rarely persist for longer than a few months. (GoR C)

5. REFRACTORY BPS

Those patients with persistent, unacceptable symptoms despite oral and/or intravesical therapy are candidates for more aggressive treatment modalities. Many of these are best administered within the context of a clinical trial if possible. These may include

- Sacral nerve stimulation, (GoR B)
- Intradetrusor botulinum toxin, (GoR B)
- Oral cyclosporine A (GoR C), or

- Clinical trials of newly described pharmacological management techniques. At this point, most patients will benefit from the expertise of an anaesthesia pain clinic.

The last step in treatment is usually some type of surgical intervention aimed at increasing the functional capacity of the bladder or diverting the urinary stream.

- Urinary diversion with or without cystectomy has been used as a last resort with good results in selected patients. Cystectomy and urethrectomy do not appear to add any additional efficacy to diversion alone.

Augmentation or substitution cystoplasty seems less effective and more prone to recurrence of chronic pain in small reported series (GoR C)

BLADDER PAIN SYNDROME

SYMPTOMS

Pain, pressure or discomfort perceived to be related to the bladder with at least one other urinary symptom (e.g. frequency, nocturia)

BASIC ASSESSMENT

History

- Bladder diary or frequency/volume chart
- Focused physical examination
- Urinalysis, culture

“Complicated” BPS:

- Incontinence
- Urinary infection
- Haematuria
- Gynaecologic signs/symptoms

Consider:

- Urine cytology
- Further imaging
- Endoscopy
- Urodynamics
- Laparoscopy

URINARY INFECTION

Test and reassess

1ST LINE RX

“Uncomplicated BPS”

- Conservative Therapy
- Stress reduction (B)
- Patient education (B)
- Dietary manipulation (B)
- Nonprescription analgesics
- Pelvic floor relaxation
- Pelvic floor physical therapy (A)
- Consult if associated disease

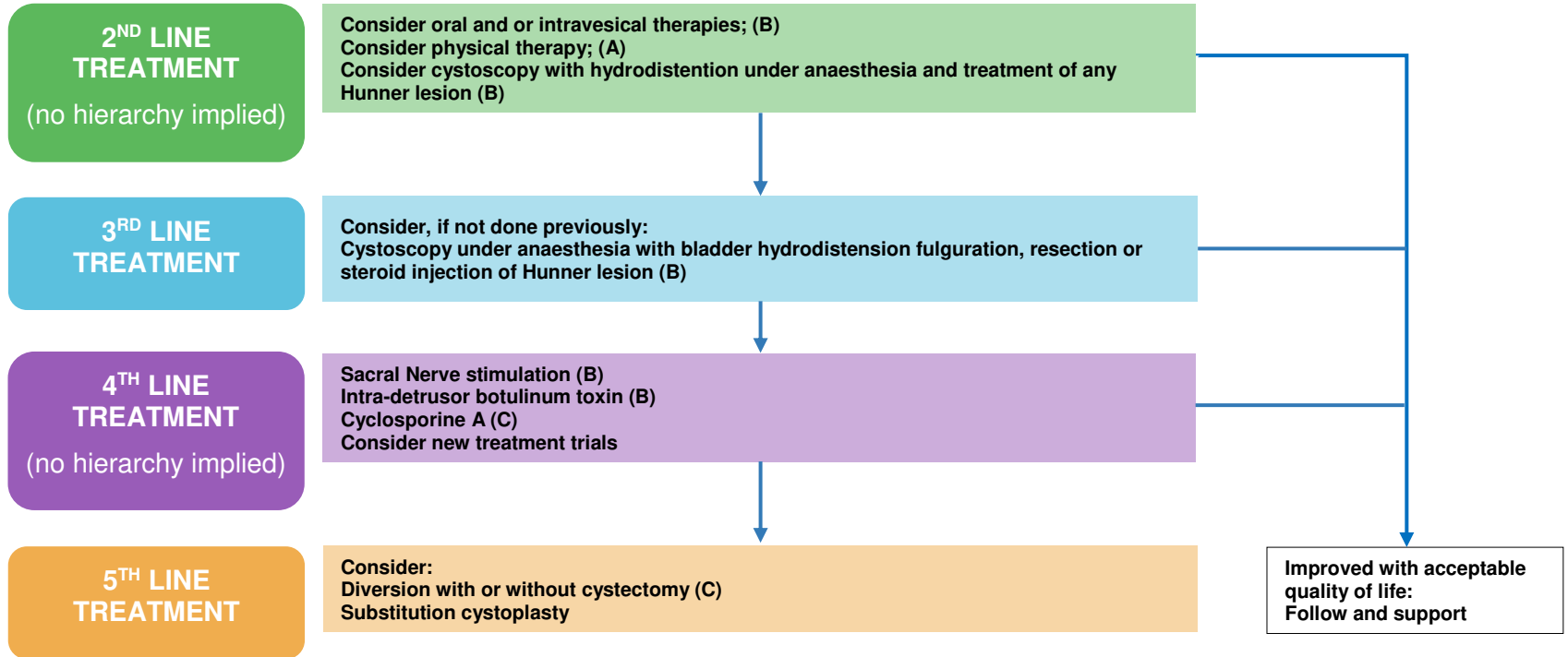
Normal

Abnormal

TREAT AS INDICATED

Consider CONTINENCE PRODUCTS for temporary support during treatment

BPS REQUIRING MORE ACTIVE INTERVENTION



**Note: The only FDA approved therapies are DMSO and pentosan polysulfate.
Consider CONTINENCE PRODUCTS for temporary support during treatment.**

- Pain management is a primary consideration at every step of the algorithm
- Patient enrollment in appropriate research trial is a reasonable option at any point
- Evidence supporting SNS, cyclosporine A, and botulinum toxin for BPS remains limited. These interventions are appropriate only for practitioners with experience in treating BPS and who are willing to provide long-term care post-intervention

VIII. FAECAL INCONTINENCE IN ADULT PATIENTS

ASSESSMENT AND MANAGEMENT

1. INITIAL CLINICAL ASSESSMENT

Adult patients with faecal incontinence present with a variety of symptom complexes. As many people are reluctant to admit to having faecal incontinence, it is important to proactively enquire about it, especially in known high risk groups (such as older community-living individuals, post partum women who might have had an obstetric injury and patients with loose stools).

History will include symptoms such as loose stools and urgency, the type and severity of bowel incontinence, systemic disorders, neurological disorders, and ano-rectal surgeries (e.g., haemorrhoidectomy), obstetric history for women, medications, diet, chronic straining, cognitive status, and effects of symptoms on quality of life.

2. INITIAL INTERVENTIONS

- Assessing the type of bowel incontinence may help identify an aetiology. Types of bowel incontinence: Anal incontinence is the involuntary loss of faeces and/or flatus and/or mucus). Faecal incontinence is the involuntary loss of faeces. Flatus incontinence is the involuntary loss of rectal gas, which may indicate rectal sensory impairment and/or anal sphincter dysfunction. Mucus incontinence is the involuntary loss of mucus only (See Figure 1).
 - Some subtypes of faecal incontinence are urgency faecal incontinence, which is the involuntary loss of faeces due to an inability to defer defaecation, once the desire is perceived, for long enough to reach a toilet. Urgency faecal incontinence is often a symptom of external anal sphincter dysfunction. The symptom of urgency does not necessarily result in urgency faecal incontinence. Functional faecal incontinence is due to limitations in mobility or toileting ability or delayed assistance. Passive faecal incontinence, incontinence without forewarning, is typically related to internal anal sphincter dysfunction or poor closure of the external sphincter due to rectal prolapse or stage III/IV haemorrhoids.

- Physical examination will include anal inspection, abdominal palpitation, a brief neurological examination, digital rectal examination and usually procto-sigmoidoscopy or colonoscopy.
- Further diagnostic testing needs to be considered if the patient has symptoms such as an unexplained change in bowel habit, weight loss, anaemia, rectal bleeding, severe or nocturnal diarrhoea, or an abdominal or pelvic mass and bowel pathology when organic conditions such as cancer, inflammatory bowel disease (IBD), a recto-vaginal fistula, full thickness rectal prolapse, or cloacal deformity are suspected. Condition specific management is indicated for these patients.
- Reversible factors (such as inadequate access to toilets and side effects of medications resulting in loose stools) should be assessed and addressed at the outset.

➤ Some initial management can often be performed in primary care. After environmental factors and local or systemic pathology have been excluded, initial interventions include:

- Discussion of options and goals of management with the patient
- Provision of patient or caregiver information and education (GoR A)
- Adjustment of diet and fluid advice, fibre intake (GoR A)
- Establishing a regular bowel habit (GoR C) or urgency training if relevant (GoR C)
- Anti-diarrhoeal medication can help if stools are loose (GoR B)
- Use of continence products including various types and sizes of absorbent pads, briefs, etc., to contain leaked faeces and prevent skin damage
- Provide advice on practical coping skills when incontinence occurs (GoR C)

3. SECONDARY INTERVENTIONS

- If initial interventions fail to improve symptoms after 8-12 weeks, consideration should be given to referral to an incontinence specialist (e.g., gastroenterologist, continence nurse, advisor physiotherapist, or colorectal surgeon) for other interventions or further assessment.
- Pelvic floor muscle training (PFMT) – contraction of pelvic floor muscles, multiple times per day to improve strength of contraction and increase awareness of anorectal muscle function. (GoR C)
- Biofeedback therapy – behavioural treatment designed to enhance the strength of sphincter contraction and improve rectal sensation using specialised equipment. Biofeedback therapy can be combined with PFMT to improve strength. (GoR B)
- Transanal Irrigation to maximise bowel emptying and minimise faecal incontinence primarily in patients with incomplete elimination, passive faecal incontinence, or faecal incontinence with defaecation difficulty. (GoR C)

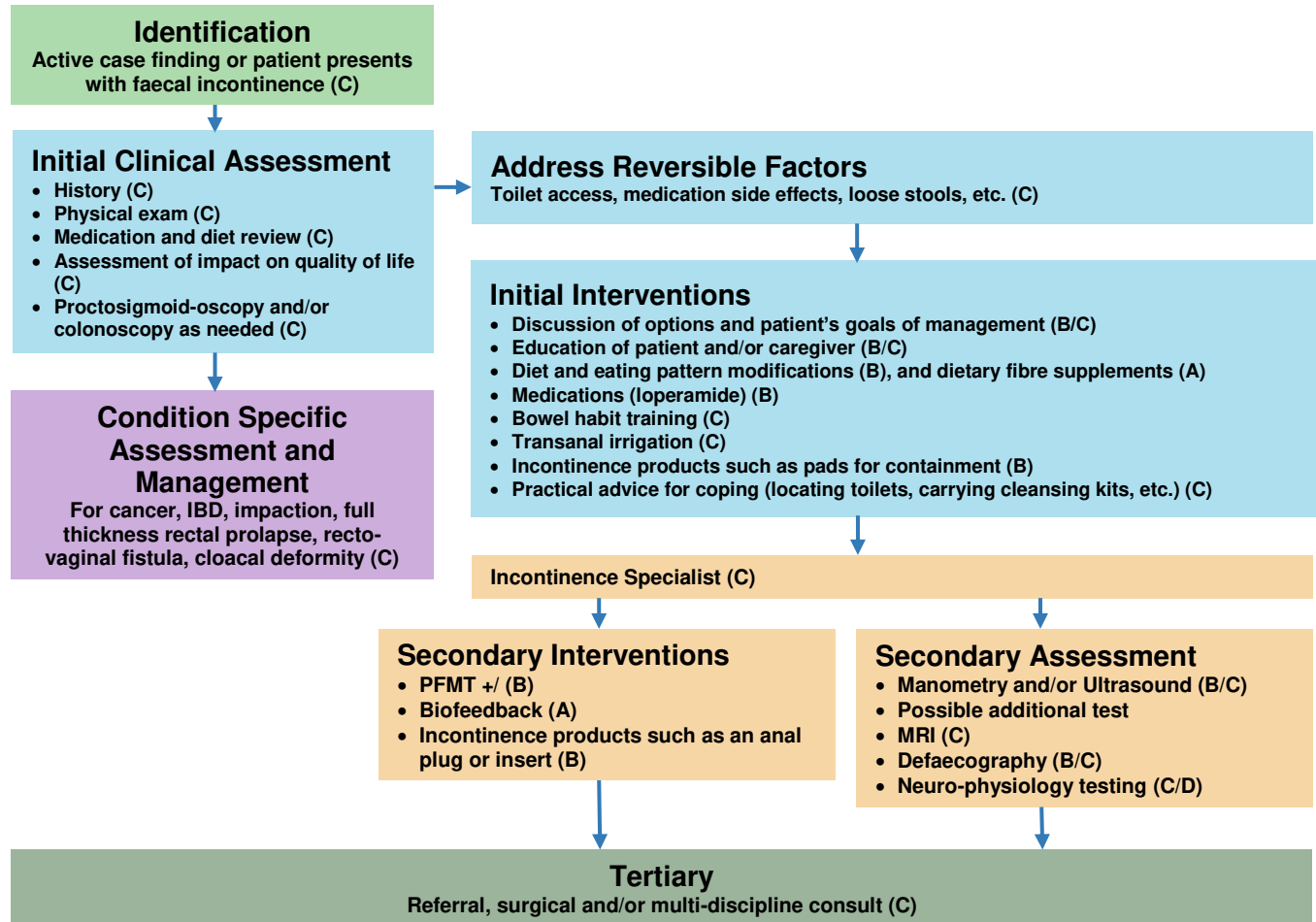
4. SECONDARY ASSESSMENT

- A variety of anorectal investigations, including manometry, anal ultrasound, and possibly MRI, defaecography, and neurophysiological testing can help to define structural or functional abnormalities of anorectal function and guide management if initial and/or secondary interventions are ineffective

5. TERTIARY REFERRAL, SURGICAL OR MULTI-DISCIPLINARY CONSULTATION

- Faecal incontinence that fails to respond to initial and secondary management requires specialised consultation by a gastroenterologist, colorectal surgeon, urogynaecologist, and/or a multi-disciplinary team

ASSESSMENT AND CONSERVATIVE MANAGEMENT OF FAECAL INCONTINENCE



* Consider CONTINENCE PRODUCTS for temporary support during treatment

VIII. FAECAL INCONTINENCE IN ADULT PATIENTS

SURGERY FOR FAECAL INCONTINENCE

1. PATIENT ASSESSMENT

- The reader is referred to the relevant chapter sections in “Dynamic Testing” and “Conservative Treatment for Faecal Incontinence.” In general, patients referred for surgical management of faecal incontinence must either have failed conservative therapy or not be candidates for conservative therapy due to severe anatomic or neurological dysfunction.
- Prior to surgical management of faecal incontinence, the integrity of the anal sphincter complex should be assessed. This assessment is best performed with endoanal ultrasound, though pelvic MRI may also be useful. Ancillary tests include anal manometry, electromyography, and defaecography.
- If the patient has persisting faecal incontinence, he or she should undergo repeat assessment, including endoanal ultrasound.

2. SPECIALISED MANAGEMENT

- The surgical approach is influenced by the presence and magnitude of an anatomical anal sphincter defect. If no defect is present, or if the sphincter defect is minimal, options include SNS and biomaterial injection therapy.
- Acute anal sphincter repair is usually required following obstetric or direct trauma. End to end or overlapping repair may be performed. When possible the internal anal sphincter should be separately repaired. (GoR C)
- Patients with rectal prolapse, rectovaginal fistula or cloacal deformity often have associated faecal incontinence. Initial therapy should be directed at correction of the anatomical abnormality. (GoR C)
- For patients with moderate sphincter defects, sphincteroplasty, SNS or biomaterial injection therapy can each be considered. For patients with large sphincter defects (>120 degrees), sphincteroplasty is likely to be the best option, though a PNE trial for SNS can be considered. (GoR C)

- Patients with sphincter defects of greater than 180° or major perineal tissue loss require individualised treatment. In some cases, initial reconstruction can be performed. Should incontinence persist, alternatives include stimulated muscle transposition (usually graciloplasty) artificial anal sphincter implantation, or SNS. (GoR C)

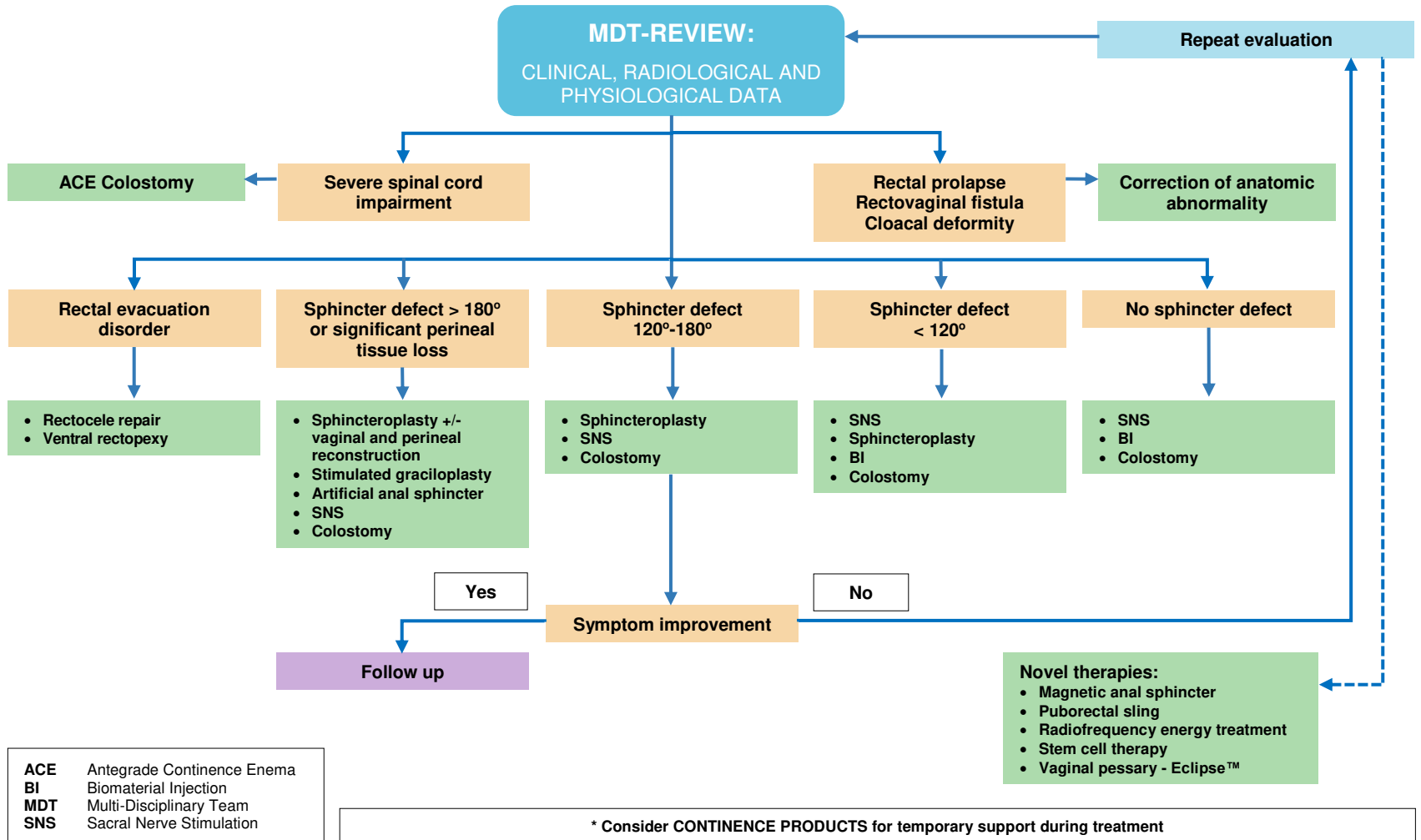
3. SALVAGE MANAGEMENT

- For patients who remain incontinent following sphincteroplasty, repeat endoanal ultrasound should be undertaken to reassess the status of the repair. If no defect is present, or if the sphincter defect is minimal, options include SNS and biomaterial injection therapy. If there is a large persisting sphincter defect, repeat sphincteroplasty can be considered. (GoR C)
- Patients who have failed SNS can be considered for biomaterial injection therapy or sphincteroplasty if a sphincter defect is present. Other alternatives include stimulated graciloplasty and implantation of an artificial anal sphincter. (GoR C)
- Patients who fail surgical therapy for faecal incontinence, or who do not wish to undergo extensive pelvic reconstruction, should consider placement of an end sigmoid colostomy. (GoR C) While this procedure does not restore continence, it does restore substantial bowel control and appears to improve social function and quality of life. Novel therapies can also be considered under protocol: PTNS, the magnetic anal sphincter, SECCATM, vaginal pessary (EclipseTM) and sling procedures. (GoR D)

4. SPECIAL SITUATIONS

- Individuals with congenital abnormalities may be amenable to surgical repair. Often this will involve both laparoscopic abdominal and perineal approached. Poor functional outcomes may be treated by an Antegrade Continence Enema (ACE) procedure or colostomy. Patients with cauda equina type neurological disorders, either congenital or acquired, should be considered for an ACE procedure or colostomy. (GoR C)

SURGICAL MANAGEMENT OF FAECAL INCONTINENCE



IX. FAECAL INCONTINENCE IN NEUROLOGICAL PATIENTS

A. INITIAL MANAGEMENT

- Patients with known neurological disease may present with symptoms related to neurological bowel dysfunction, such as; difficulty in defaecation, constipation and faecal incontinence which disturb their activities of daily living and impair quality of life. Many have permanent impairments and functional limitations and disabilities, which are due to neurological deficits and complications

- Functional assessment:

- Hand and arm use, fine hand use, mobility – maintaining body position, transfer and walking ability.

- Environmental factors assessment:

- toilet accessibility; devices for bowel care and mobility; caregiver support and attitude;

1. INITIAL ASSESSMENT

- The history should include:

- Neurological diagnosis and functional level
- Previous and present lower gastrointestinal (LGIT) function and disorders
- Severity of neurogenic bowel dysfunction
- Current bowel care and management including diet, fluid intake, medications affecting bowel functions
- Co-morbidity / complication e.g., urinary incontinence, autonomic dysreflexia, pressure ulcers, sexual dysfunction
- Patient's satisfaction, needs, restrictions and quality of life
- Environmental factors and barriers and facilitators to independent bowel management.

- Physical examination:

- Cognitive function; motor, sensory and sacral reflexes – voluntary anal sphincter contraction, deep perianal sensation, anal tone, anal and bulbo- cavernosus reflexes
- Spasticity of the lower limbs
- Abdominal palpation for faecal loading and rectal examination

2. BASIC INVESTIGATIONS

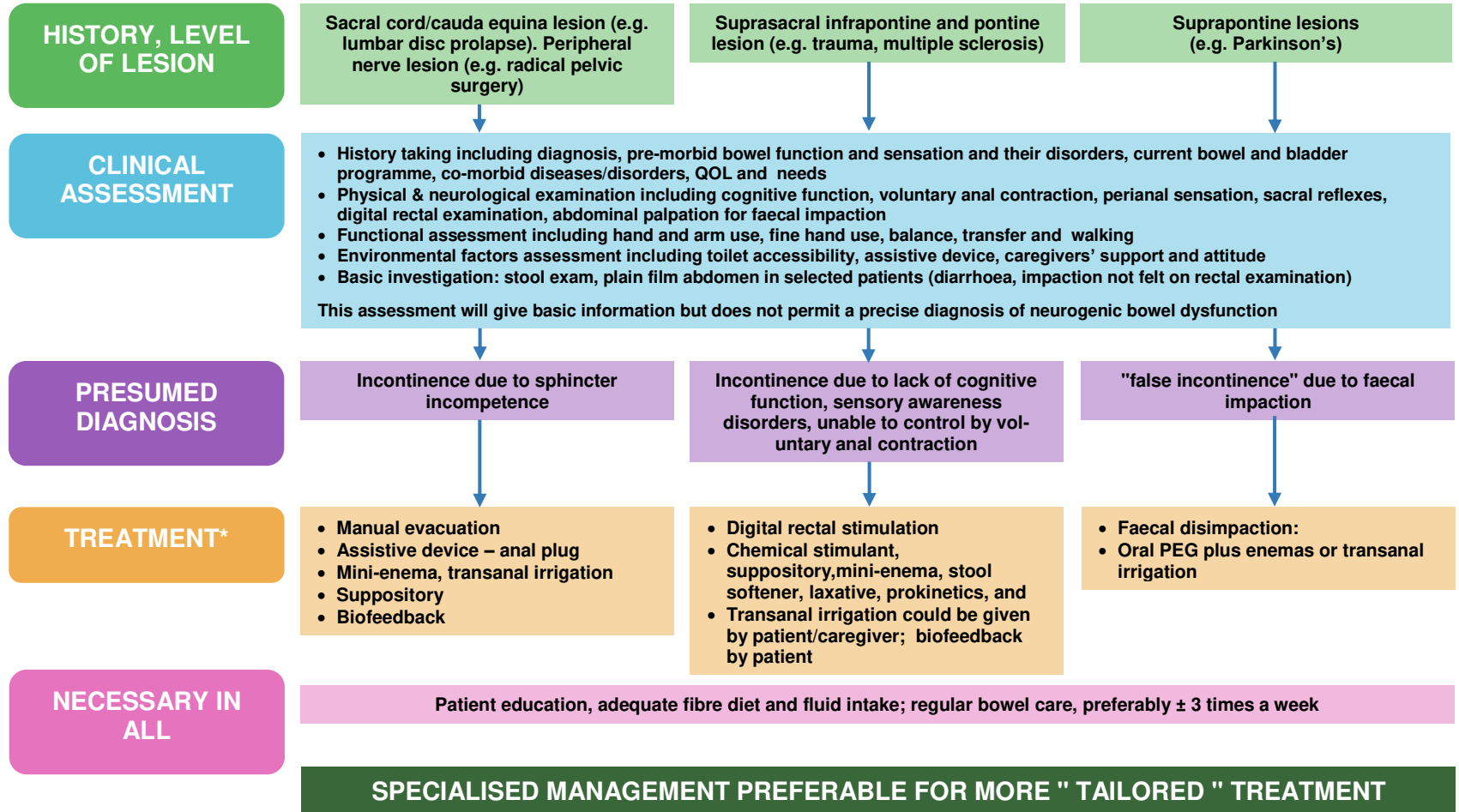
Stool examination, plain abdominal X-Ray

3. INITIAL TREATMENTS

- Patient education and goals-setting to achieve complete defaecation on a regular basis and faecal continence based on right time, right place, right trigger and right consistency
- Adequate fibre diet and fluid intake; appropriate trigger according to preservation of sacral (anorectal) reflex – digital rectal stimulation (GoR C); suppository and enema (GoR B); if no anorectal reflex, manual evacuation (GoR B); abdominal massage (GoR C) can also be helpful
- Prescribe medications – stool softener, laxative, prokinetic agents, anti-diarhoeal drugs as necessary
- Assistive techniques may be necessary for
 - Defaecation – transanal irrigation (GoR A)
 - For incontinence – anal plug (GoR C)

The algorithm does not apply to management in acute neurological patients that need regular bowel emptying.

INITIAL MANAGEMENT OF NEUROGENIC FAECAL INCONTINENCE



* Consider CONTINENCE PRODUCTS for temporary support during treatment

IX. FAECAL INCONTINENCE IN NEUROLOGICAL PATIENTS

B. SPECIALISED MANAGEMENT

1. ASSESSMENT

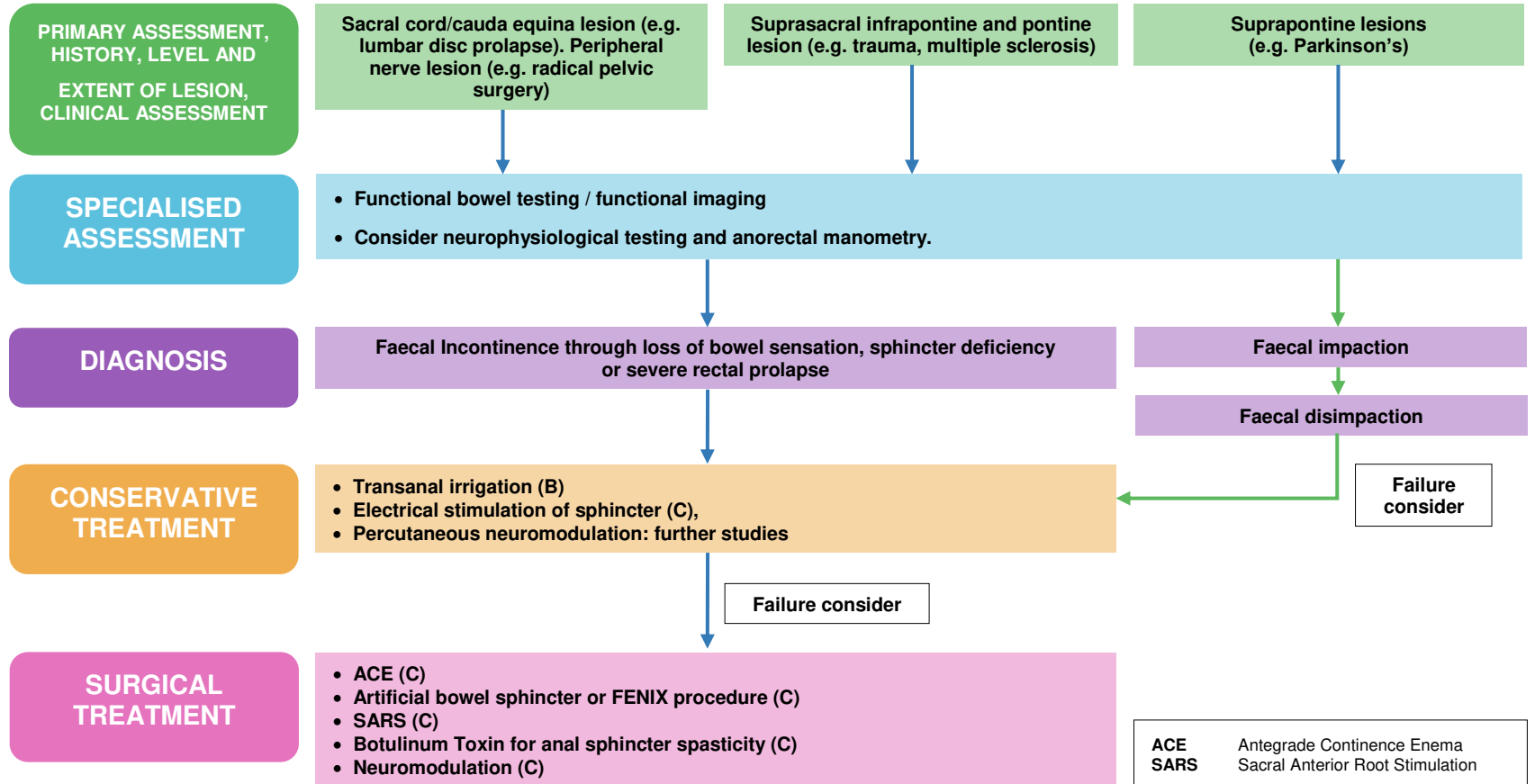
- Some patients with neurogenic faecal incontinence will need specialised assessment, especially if initial management is unsuccessful to look for comorbidity and certainly before performing invasive treatment
- Do not assume that all symptoms are due to neuropathy, e.g. women with neurological pathology might have had childbirth injury to the sphincter
- Special investigations: manometry, endoanal ultrasound, (dynamic) MRI, (needle) EMG. These specific bowel functional tests and electro-diagnostic tests must be considered optional, as their value in neurological pathology is not sufficiently demonstrated so far.

2. TREATMENTS

- Conservative treatment for neurological faecal incontinence is also the mainstay for specialised management, (GoR C).
- Management of neurological incontinence does not include very extensive treatment modalities and many conservative interventions are still empirical.
- Transanal irrigation (GoR B).

- Electrical stimulation sphincter, (GoR C).
- Percutaneous neuromodulation and sacral nerve stimulation : further research is required (GoR D).
- Surgical management of neurogenic faecal incontinence has different options which need a very strict patient selection
- Antegrade Continence Enema ACE (GoR C).
- Artificial bowel sphincter or FENIX procedure (GoR C).
- Sacral Anterior Root Stimulation SARS (GoR C).
- Botulinum Toxin (GoR C).
- Neuromodulation (GoR C).
- It is recommended that urinary and bowel function are assessed simultaneously if both systems are affected, as symptoms and treatment of one system can influence the other and vice versa (GoR A).
- As the therapeutic approach can differ in different neurological diseases, the most prevalent diseases are discussed separately in the chapter.

SPECIALISED MANAGEMENT OF NEUROGENIC FAECAL INCONTINENCE



STOMA/DIVERSION MAY BE AN OPTION IN SELECTED CASES

* Consider CONTINENCE PRODUCTS for temporary support during treatment

X. URINARY AND FAECAL INCONTINENCE IN FRAIL OLDER MEN AND WOMEN

- There is no reason to suspect why interventions which have proven efficacy in the community dwelling elderly should not also be effective in frail older people. Clinicians should, however, take due regard of the practicality, potential benefits and dangers of employing any single intervention in this population.
- Frail older people do require a different approach addressing the potential role of co-morbid disease, current medications (prescribed, over the counter and/or naturopathic), and functional and cognitive impairment in urinary and faecal incontinence.
- The extent of the investigation and management should take into account the degree of bother to the older person and/or caregiver, the goals for care, the degree that the older person is able to undertake any intervention and the overall prognosis and life expectancy.
- Effective management to meet the goals of care should be possible for most frail older people.

1. HISTORY AND SYMPTOM ASSESSMENT

- Active case finding for urinary and faecal incontinence should be done in all frail older people (GoR A).
- History should include comorbid conditions and medications that could cause or worsen incontinence.
- Physical examination should include a rectal examination for faecal loading or impaction (GoR C), functional assessment (mobility, transfers, manual dexterity, dressing and undressing ability, ability to toilet) (GoR A), a screening test for depression (GoR B), and cognitive assessment (to assist in planning and management, (GoR C)).
- The mnemonic DIPPERS (see urinary and faecal incontinence algorithms) covers some of these comorbid conditions. Note that urogenital atrophy does not, in itself, cause urinary incontinence and should not be treated for this purpose (GoR B).
- The patient and / or caregiver should be asked about the degree of bother of urinary incontinence and/or faecal incontinence (GoR B); goals for urinary and faecal incontinence care (dryness, decrease in specific symptoms, quality of

life, reduction of comorbidity, lesser care burden) (GoR B); and likely cooperation with management (GoR C).

- Evaluation for bowel “alarm” symptoms (rectal bleeding, positive blood screening from stool studies, obstructive symptoms, recent onset of constipation, weight loss, and a change in stool calibre) will need more extensive evaluation (GoR A)
- Urinalysis is recommended for all patients, primarily to screen for haematuria (GoR C).
- Treatment of otherwise asymptomatic bacteriuria/pyuria is not beneficial (GoR C), and it may cause harm by increasing the risk of antibiotic resistance and severe adverse effects. e.g., *Clostridium difficile* colitis (GoR C).
- Stool studies may not be needed in all patients with faecal incontinence. Patients with diarrhoea, especially those with more acute onset diarrhoea, may need to be tested for infectious causes of their diarrhoea. Other stool studies could involve testing for malabsorption syndromes.
- The utility of the Clinical Stress test in this population is uncertain (GoR D).
- Wet checks can assess urinary incontinence frequency in long-term care residents (GoR C).
- A post voiding residual volume (PVR) test is impractical in many care settings and there is no consensus for the definition of what constitutes a “high” PVR in any population. A PVR measurement is not recommended in the routine initial assessment of frail older people with urinary incontinence.
- However, there is compelling clinical experiential evidence for PVR testing in selected frail older people with: diabetes mellitus (especially long standing); prior urinary retention or high PVR; recurrent UTIs; medications that impair bladder emptying (e.g., opiates); severe constipation; persistent or worsening urgency urinary incontinence despite antimuscarinic/beta-3-agonist treatment; or prior urodynamics showing detrusor underactivity and/or bladder outlet obstruction (GoR C). Treatment of contributing comorbidity may reduce PVR. Trial with catheter may be considered for PVR > 200-500 ml if the PVR is felt to contribute to UI or urinary frequency (GoR C).

- Nocturia Assessment of frail elders with bothersome nocturia should identify potential underlying causes including nocturnal polyuria (by bladder diary/frequency-volume chart or wet checks; oedema on examination) (GoR C), primary sleep problems (e.g., sleep apnoea); and low voided volumes (e.g., from high PVR).
- Stool impaction/loading. If suspected on digital rectal examination, an abdominal x-ray may be necessary to further evaluate the degree and location of impaction/loading in frail older adults.

2. CLINICAL DIAGNOSIS

The most common types of Urinary Incontinence in frail older people are urgency, stress, and mixed urinary incontinence. Frail older people with urgency urinary incontinence also may have detrusor underactivity during voiding with a high PVR but without outlet obstruction. There is no evidence that antimuscarinics are less effective or cause retention in this situation (GoR D).

The most common types of faecal incontinence in frail older people are related to urgency and passive leakage. Passive leakage can refer to leakage, seepage and staining following bowel movements that are not associated with faecal urgency and may also occur with faecal impaction. Because constipation and impaction often contribute to faecal incontinence in older adults, these are considered separately in the algorithm.

3. INITIAL MANAGEMENT

- Initial treatment should be individualised and influenced by goals of care, treatment preferences and estimated remaining life expectancy, as well as the most likely clinical diagnosis (GoR C). In some frail older persons the only possible outcome may be containment; management with continence products, especially for people with minimal mobility (require assistance of > 2 people to transfer), advanced dementia (unable to state their name), and/or nocturnal urinary and faecal incontinence.
- Conservative and behavioural therapy for UI includes lifestyle changes (GoR C), bladder training for more fit alert persons (GoR B), and prompted voiding for frailer, more impaired older people (GoR A).
- For the select cognitively intact older person with UI or FI, pelvic floor muscle therapy can be considered, but there are few studies (GoR C). Antimuscarinics

may be added to conservative therapy of urgency UI (GoR A-C, depending on agent).

- For the select cognitively intact older with FI, biofeedback may be considered, but few studies exist among frail older adults.
- Alpha-blockers may be cautiously considered in frail men with suspected prostatic obstruction (GoR C). All drugs should be started at the lowest dose and titrated with regular review until either care goals are met or adverse effects are intolerable.
- DDAVP (vasopressin) has a high risk of severe hyponatraemia in frail older persons and should not be used outside specialist centres or without very careful monitoring and long term followup (GoR A).
- Improving stool consistency can be done with dietary fibre and supplementary fibre in older adults (GoR C). In older adults with diarrhoea, loperamide may be considered at low doses to improve stool consistency. However, close monitoring for constipation and impaction is needed.

4. ONGOING MANAGEMENT AND REASSESSMENT

Optimal urinary and faecal incontinence management is usually possible with the above approaches. If initial management fails to achieve the desired goals, the next steps are reassessment and treatment of contributing comorbidity and/or functional impairment.

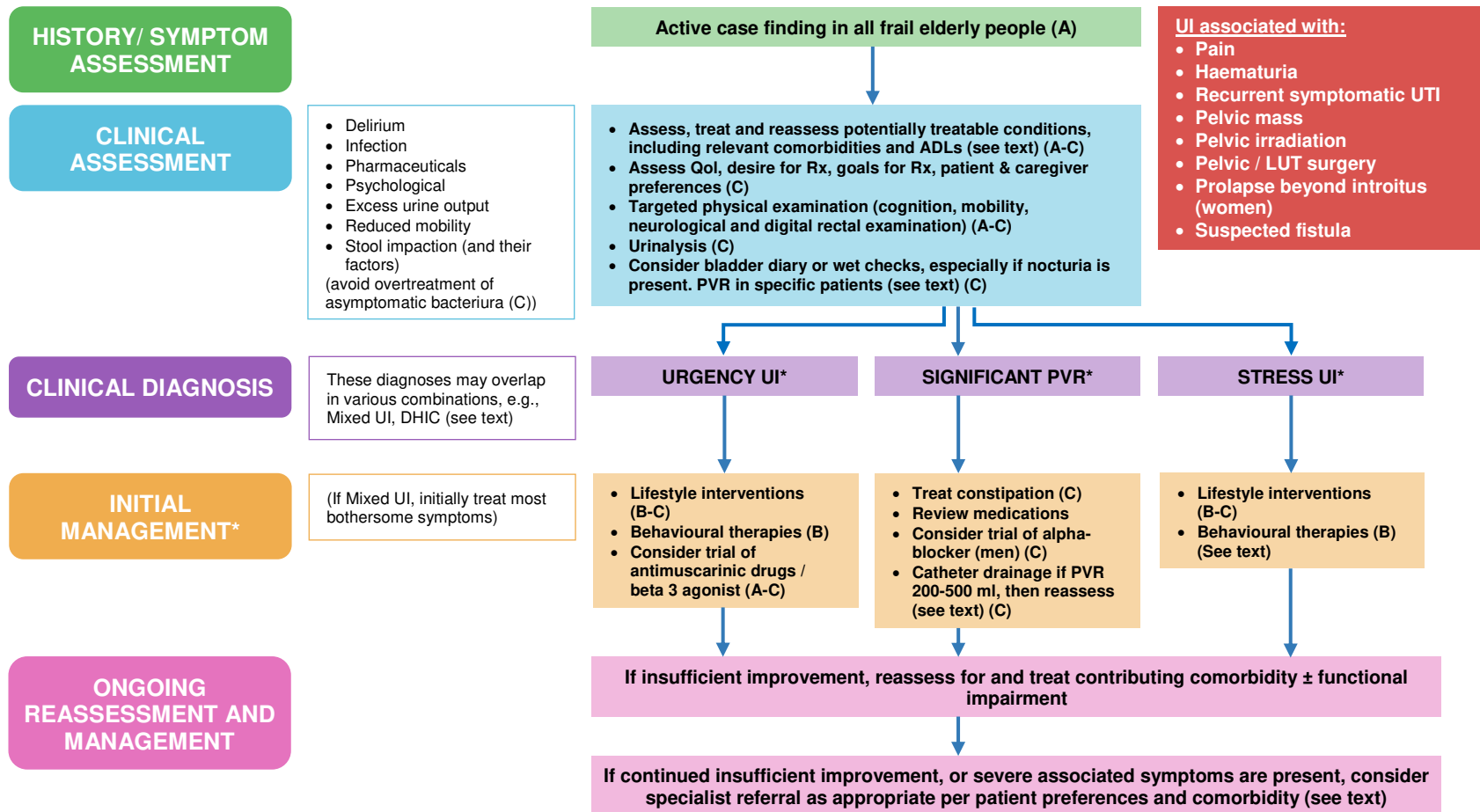
5. SPECIALISED MANAGEMENT

If frail older people have either other significant factors (e.g., pain, haematuria, bowel “alarm” symptoms), UI or FI symptoms that cannot be classified as urgency, stress, or mixed or overflow or other complicated comorbidity which the primary clinician cannot address (e.g. dementia, functional impairment), then specialist referral should be considered. Referral may also be appropriate when there is been insufficient response to initial management. The type of specialist will depend on local resources and the reason for referral: surgical specialists (urologists, gynecologists, colorectal surgeons), gastroenterologists, geriatricians or physical therapist (functional and cognitive impairment); or continence nurse specialists (homebound patients). Referral decisions should consider goals of care, patient/caregiver desire for invasive therapy and estimated remaining life expectancy.

Age *per se* is not a contraindication to UI or FI surgery (GoR C), but before surgery is considered, all patients should have:

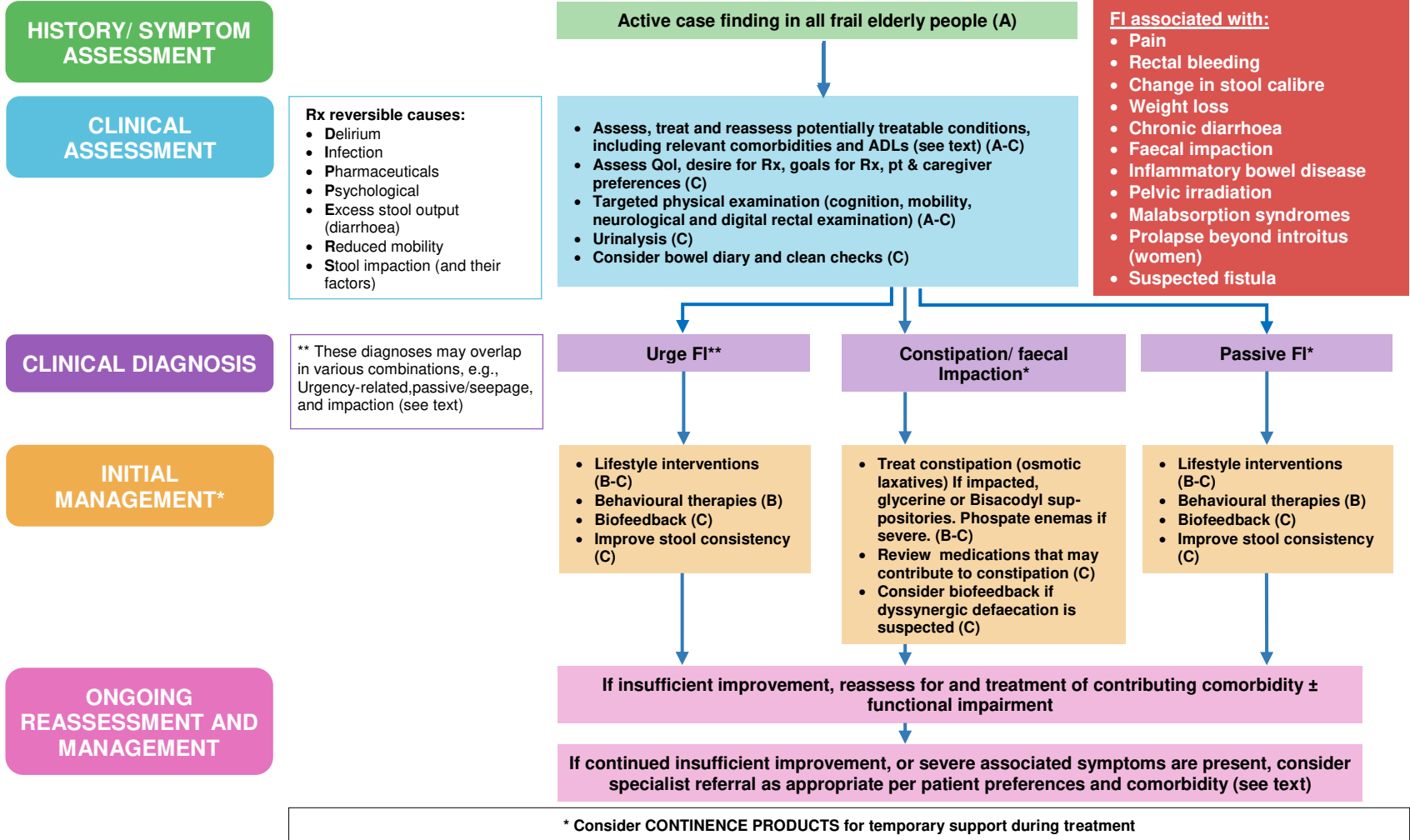
- Evaluation and treatment for any comorbidity, medications, and cognitive or functional impairments contributing to UI that could compromise surgical outcome (e.g., dementia that precludes patient ability to use artificial sphincter) (GoR C).
- Adequate trial of conservative therapy, including pharmacological therapies where relevant (GoR C).
- Discussion (including the caregiver) to ensure that the anticipated surgical outcome is consistent with goals of care in the context of the patient's remaining life expectancy (GoR C).
- Urodynamic testing or anorectal manometry, because clinical diagnosis may be inaccurate (GoR B).
- Preoperative assessment and perioperative care to establish risk of, and to minimise the risk of common geriatric post-operative complications such as delirium and infection (GoR A), dehydration and falls (GoR C).

MANAGEMENT OF URINARY INCONTINENCE IN FRAIL OLDER MEN & WOMEN



* Consider CONTINENCE PRODUCTS for temporary support during treatment

MANAGEMENT OF FAECAL INCONTINENCE IN FRAIL OLDER MEN & WOMEN



4. RECOMMENDATIONS FOR FURTHER RESEARCH IN EPIDEMIOLOGY

1. Longitudinal study designs are needed to: (i) estimate the incidence and remission rates of urinary incontinence (UI) anal incontinence (AI) and pelvic organ prolapse (POP) and to (ii) describe the natural course of these conditions and (iii) to investigate risk factors and possible protective factors. In addition, similar studies regarding other lower urinary tract symptoms (LUTS) should be initiated.
2. Although there is now more information regarding prevalence, incidence, and other epidemiological data in developing countries, further information is still needed. It is recommended that fundamental research regarding prevalence, incidence and other epidemiological data in developing countries should be encouraged, and tailored to the cultural, economic and social environment of the population under study.
3. Some potential risk and protective factors deserve more attention. For example, the role of pregnancy and childbirth in the development of UI, AI and POP must be studied in a fashion that links population-based methods to clinical assessment of pregnancy, delivery and birth trauma and follows women over many years. Such a design is necessary because the effect of pregnancy and childbirth may become clear only years later when the woman is older and because the woman will not then be able to report the exact nature of the tear, episiotomy, etc.
4. There should be more emphasis on the associations between UI, AI and POP and specific diseases like stroke, diabetes, and psychiatric diseases.
5. The variation of disease occurrence in groups of different racial origin yet similar environmental exposures, lend support to the presumed genetic influence on the causation of UI, AI and POP. This again provides circumstantial evidence for a genetic contribution to pelvic floor muscle disorders since most of these studies have been unable to control for heritability in relation to the complex interaction of environmental factors.

The aetiology of UI, AI and POP is widely recognised to be multifactorial, yet the complex interaction between genetic predisposition and environmental influences is poorly understood. Genetic components require further investigation. Twin studies provide a possible means of studying the relative importance of genetic predisposition and environmental factors. By comparing monozygotic female twins with identical genotype, and dizygotic female twins who, on average, share 50 percent of their segregating genes, the relative proportions of phenotypic variance resulting from genetic and environmental factors can be estimated. A genetic influence is suggested if monozygotic twins are more concordant for the disease than dizygotic twins whereas evidence for environmental effects comes from monozygotic twins who are discordant for the disease.

5. RECOMMENDATIONS FOR FURTHER BASIC SCIENCE RESEARCH

The following proposals for research come from the Committees' work in reviewing the current literature on Basic Science:

1. Integrate data from reductionist experiments to inform the formulation of better systems-based approaches in the investigation of the pathology of the lower urinary tract (LUT), the genital tract (GT) and the lower gastro-intestinal tract (LGIT).
2. Encourage greater emphasis on basic research to characterise tissues receiving relatively little attention: ie the lower gastrointestinal tract; the bladder neck and urethra; the ureter, pelvic floor musculature.
3. Generate research programmes for fetal and neonatal research in LUT and LGIT function.
4. Use genome-wide bioinformatic and population health surveys to generate testable hypotheses regarding the physiological and pathophysiological functions of the LUT, GT and LGIT.
5. Generate improved experimental approaches to investigate the pathophysiology of the LUT and LGIT by:
 - The development of animal models that accurately describe human pathological conditions, including the greater use of large-animal models
 - The better use of reverse translational approaches for linking animal models to the human disease.
 - The use of human tissue from well-characterised patient groups.
 - The development of emerging areas such as: tissue engineering; proteomics and metabolomics
 - Increased collaborations between biological, physical and mathematical sciences.
6. Develop centres of excellence or consortia of excellence in LUT, GT and GIT research
 - Integrate expertise from university departments, academic medical units and industry
 - Encourage translational approaches to research.
 - Develop inter-institutional research-training programmes to allow new researchers the opportunity to better interact and exchange ideas.
7. Bring about a greater emphasis on the importance of research to medical trainees and science graduates through:
 - Establishing research training as a core component of postgraduate clinical development
 - Increased access to support funds, especially scholarships and personal awards
 - Organisation of focused multidisciplinary research meetings, either stand-alone or as dedicated sessions during national and international conferences
 - Greater interaction between medical centres and Higher Education Institutions (HEIs).
 - Allowing researchers-in-training better access to international meetings through reduced registration charges and improved travel grants.
 - Inclusion in clinical meetings of point-counterpoint session(s) with both basic science and clinical viewpoints.
 - Development of research forums for exchange of ideas between active researchers and industry.
 - Lobbying research-funding organisations about the medical and social importance of LUT and LGIT disorders.
8. Increase emphasis on research into LUT and LGIT in HEIs through:
 - Greater representation on grant-funding agencies
 - Encouragement of submission to high impact factor journals and recognition of research published in specialty journals
 - More integrated teaching and training opportunities

6. RECOMMENDATIONS FOR PRIMARY PREVENTION, CONTINENCE PROMOTION, MODELS OF CARE AND EDUCATION

Primary prevention, continence promotion and advocacy, models of care and education involves informing and educating the public and health care professionals that UI and FI are not inevitable, but are treatable or at least manageable. Other bladder disorders such as BPS/IC and POP can also be treated successfully. The committee found information about recent practice and research initiatives in all of these areas but evidence-based research only on primary prevention of UI. Continence promotion and advocacy, and professional and non-professional education, require prioritisation by public health professionals, educationalists, clinicians and researchers to reduce the burden that UI, FI, BPS/IC and POP places on society, healthcare systems, caregivers, and above all, affected adults. As to models of care, the evidence supports nurse-led community services as leading to higher health-related QoL and in some instances, higher cure rates. The multidisciplinary referral settings are also reporting favourable outcomes.

1. PRIMARY PREVENTION

- Pelvic floor muscle exercises can prevent UI in pregnant and postpartum women. (Level of Evidence: 1)
- Education designed for community-dwelling older women can prevent UI. (Level of Evidence: 1)
- No recent RCTs or case-control studies were located for prevention of FI. (Level of Evidence: 4)
- Pelvic floor muscle exercises should be provided for pregnant women. (GoR A)
- Education of older women to prevent UI should be provided. (GoR A)
- Continence promotion is required to address broad gaps in knowledge about incontinence (GoR C)
- Strategies to promote awareness about incontinence and its treatment can be strengthened by the use of evidence based theories and methods from the field of health promotion, including the social determinants of health (GoR D)
- The Internet represents an important source of information about incontinence, however the quality of information is variable (GoR C)
- For help-seeking behaviour, no RCTs or case-control studies were located (Level of Evidence 4)
- Continence promotion programmes need to accommodate varying levels of health literacy and access to health information in different populations (Level of Evidence: 4)
- Public health campaigns about incontinence and other pelvic floor disorders need to use terminology targeted to consumers' understandings (Level of Evidence: 4)
- Satisfaction surveys about continence care could yield relevant and detailed information by using open-ended, rather than closed-ended questions (Level of Evidence: 1)
- Evidence for the use of leaflets or brochures in raising awareness about UI and different treatment options is inconclusive (Level of Evidence: 1).
- Evidence for the impact of continence advocacy worldwide was based on opinion (Level of Evidence: 1)
- Recommendation for help-seeking behaviour: No recommendation was possible based on the level of evidence provided by the available research.
- Worldwide Advocacy (GoR D)

2. MODELS OF CARE

- Effectiveness of service delivery models. (Level of Evidence: 4)
- A care delivery model should be based on the principles as described in the Optimum Continence Service Specification. (GoR C)
- Increased emphasis is needed on non-physician models of care. (GoR C)
- Despite the proliferation of guidelines, there is increasing evidence that practicing clinicians and nurses are not consistently following them. Implementation models should be developed on how to translate guidelines into practice. (GoR C)
- Effectiveness of guidelines in clinical practice has not been determined. (Levels of evidence: 3 to 4).
- There is a continued need for evaluation research to explore impact of guidelines on clinical care both at individual and population levels. This evaluation strategy needs to include impact on a wide range of outcomes, including incidence and prevalence of disease, treatment outcomes, prevention efforts, costs, and health care policy. (GoR: C)
- Effectiveness of public education efforts through various channels including education, public media and mass communications (Levels of Evidence 3-4)

3. EDUCATION

- Professional education of UI, FI, BPS/IC, and POP is not evident as determined by materials reviewed. (Levels of Evidence: 3-4)
- There is a need for additional focused research on methods to enhance patient and public about pelvic disorders, both at an individual and broader public level. (GoR C)
- The role of technology in public education for continence promotion should be examined in more depth. (GoR C)

7. RECOMMENDATIONS FOR TRANSLATIONAL AND CLINICAL RESEARCH

A. RECOMMENDATIONS ON STUDY CONDUCT AND STATISTICAL METHODS

The role of quality RCTs as providing the strongest level of evidence in incontinence research should be fully acknowledged by researchers, journal reviewers, and editors. (GoR A)

Careful attention to the planning and design of all research, especially RCTs, is of the utmost importance. (GoR A)

Appropriate expertise in biostatistics and clinical trial design should be employed at the design phase of a RCT and thereafter on an ongoing basis. For Phase 4, phase 5, and implementation trials, health economists should be included in trial design to support questions of value (cost-effectiveness). (GoR A)

The design, conduct, analysis and presentation of RCTs must be fully in accordance with the CONSORT Statement. (GoR A)

The design, conduct, analysis and presentation of observational studies should follow STROBE guidelines. (GoR A)

The design, conduct, analysis and presentation of meta-analyses should follow QUORUM guidelines. (GoR A)

Reporting studies of diagnostic tests, including urodynamics, should follow the STARD statement guidelines. (GoR A)

B. RECOMMENDATIONS ON RESEARCH CONDUCT

1. RECOMMENDATIONS FOR CONSERVATIVE TREATMENT TRIALS

Use correct terminology to describe the intervention. (GoR A)

Report details of ability to perform correct contraction, dose-response issues and adherence. (GoR A)

Use recommended outcome measures with high responsiveness, reliability and validity. (GoR A)

Compare new methods with the best available intervention. (GoR A)

Use power calculation in planning of the study. Avoid large sample sizes and weak (ineffective dosages) interventions. (GoR A)

For long-term follow-up studies report cross-over, co-interventions, recurrent and competing events, adherence in the follow-up period and loss to follow-up. (GoR A)

2. RECOMMENDATIONS FOR SURGICAL AND DEVICE TRIALS

- The safety and serious side effects of new operations must be completely defined with adequate follow-up so that risks can be weighed against efficacy. At a minimum, this requires more use of large scale, independent, prospective, multicentre cohort studies when RCTs are not practical. (GoR A)
- Safety and serious side effects of incontinence devices must be completely defined with adequate follow-up, especially for use of implantable devices and biological materials, so that risks can be weighed against efficacy. (GoR A)
- Valid informed research consent is required in all trials of surgical interventions, which is separate from the consent for surgery. (GoR A)
- We recommend ongoing research into the usefulness of pre- and post-operative predictive testing (such as urodynamics, ultrasound, MRI, etc) in surgical trials. (GoR A)
- Reports of successful treatment should be limited to subjects with a minimum (not mean) of one-year follow-up and should include a patient perspective measure. Specific assumptions about subjects lost to follow-up should be stated. (GoR A)

- Randomisation for surgical trials should occur at the time of surgery to minimise drop-outs and switch of procedure (GoR A)
- Long-term follow-up of RCT cohorts in an observational cohort is recommended (GoR A)

3. RECOMMENDATIONS ON COST ANALYSIS IN INCONTINENCE

- Cost analysis should be incorporated into clinical studies whenever possible (137). (GoR A)
- Cost analysis should describe the perspective of the analysis and analyses using the societal perspective and the payer perspective are useful. (GoR A)

C. RECOMMENDATIONS FOR SPECIFIC PATIENT GROUPS

1. MEN AND WOMEN WITH LUTS

1.1. Men with LUTS

- Measurement of prostate size should be performed before and after treatment (at the same time as continence outcome measures where possible) whenever prostate size is considered to be a variable, or to change during the intervention and follow up. (GoR A)
- Maximum free flow rate and measurement of post-void residual urine should be recorded pre-treatment and the effect of therapy on these parameters should be documented simultaneously with assessment of the primary outcome variables. (GoR A)
- Participants should be stratified by prostate size at randomisation when size is considered to be a potentially important determinant of treatment outcome. (GoR C)

1.2. Women with LUTS

- Specific information about menopausal status, hysterectomy, parity/obstetric history, and hormonal status should be included in baseline clinical trial data and controlled for in specified analyses in the research protocol. (GoR A)
- High quality, symptom and bother scores (e.g., ICIQ-FLUTS, ICIQ-SF, ICIQ-QoL(KHQ), PISQ, ICIQ-FLUTSsex) validated in women should be employed when assessing outcomes. (GoR A)
- Standardised assessment of pelvic organ prolapse should be performed before treatment and at the time of other outcome assessments in all

research where prolapse and continence outcomes are being assessed. (GoR A)

- Criteria for cure/improvement/failure from incontinence treatment should be defined in the protocol based on patient perception as well as objective and semi-objective instruments such as validated questionnaires, diaries and pad tests. (GoR A)
- Assessment of the impact of treatment on sexual function should be performed with other outcome assessment when appropriate. (GoR B)

2. CHILDREN

- Long-term follow-up is of critical importance in the paediatric population in order to ascertain the effect of a treatment on normal growth and development. (GoR A)
- Research is needed to develop standardised outcome measures including validated, age-specific symptom and disease-specific quality of life outcome measures. (GoR B)

3. NEUROGENIC POPULATIONS

- Detailed urodynamic studies are recommended for classification of neurogenic lower urinary tract disorders in research studies because the nature of the lower tract dysfunction cannot be accurately predicted from clinical data. Videourodynamic studies are preferred but are not mandatory. (GoR C)
- An area of high priority for research is the development of a classification system to define neurogenic disorders. Relevant features could include the underlying diagnosis, the symptoms, a precise documentation of the neuromuscular lesion by clinical neurophysiologic testing, and the nature of the urodynamic abnormality. (GoR C)

4. POPULATIONS AFFECTED BY BLADDER PAIN SYNDROME (INCLUDING INTERSTITIAL CYSTITIS)

- Broader entry criteria should be used to reflect the full spectrum of the BPS/IC patient population. (GoR B)
- The primary endpoint of BPS/IC trials should be patient driven and the Global Response Assessment is recommended. A wide spectrum of secondary endpoints will be useful in defining the effect of treatments. (GoR B)

5. POPULATIONS AFFECTED BY PELVIC ORGAN PROLAPSE

- A validated standardised assessment of prolapse (eg POP-Q) should be used for baseline and outcome assessments. (GoR A)
- Complete reporting of outcomes including a validated assessment of anatomy, functional status, and complications is essential. (GoR A)
- Complications/adverse events (especially for mesh) must be explicitly and completely reported in any research. (GoR A)
- Long term outcomes (> 2 years) of intervention studies are needed. (GoR A)

D. RECOMMENDATIONS FOR ETHICS IN RESEARCH

The GoR for this section is A.

Continuity in clinical direction from design through authorship is mandatory. Investigators should be involved in the planning stage and a publications committee should be named at the beginning of the clinical trial. The Uniform Requirements for Manuscripts

Submitted to Biomedical Journals, from the International Committee of Medical Journal Editors should be followed. Authorship requires:

- Substantial contributions to conception and design or acquisition of data or analysis and interpretation of data,
 - Drafting the article or revising it critically for important intellectual content,
 - Final approval of the version to be published
- Authors should provide a description of what each contributed and editors should publish that information.
- Authors should have access to all raw data from clinical trials, not simply selected tables

Clinical trial results should be published regardless of outcome. The sponsor should have the right to review manuscripts for a limited period of time prior to publication but the manuscript is the intellectual property of its authors, not the sponsor.

- All authors should be able to accept responsibility for the published work and all potential conflicts of interest should be fully disclosed

8. INTERNATIONAL CONSULTATION ON INCONTINENCE MODULAR QUESTIONNAIRE (ICIQ): QUESTIONNAIRES AND BLADDER DIARY

A. INTERNATIONAL CONSULTATION ON INCONTINENCE MODULAR QUESTIONNAIRE (ICIQ)

The scientific committee which met at the end of the 1st ICI in 1998 supported the idea that a universally applicable questionnaire should be developed, that could be widely applied both in clinical practice and research and should reflect the patients' perspective of their situation.

The hope was expressed that such a questionnaire would be used in different settings and studies and would allow cross-comparisons, for example, between a drug and an operation used for the same condition, in the same way that the IPSS (International Prostate Symptoms Score) has been used.

An ICIQ Advisory Board was formed to steer the development of the ICIQ and met for the first time in 1999. The project's early progress was discussed with the Board and a decision made to extend the concept further and to develop the ICIQ Modular Questionnaire to include assessment of urinary, bowel and vaginal symptoms(1). The first module to be developed was the ICIQ Short Form Questionnaire for urinary incontinence: the ICIQ-UI Short Form (2) (Fig 1). The ICIQ-UI Short Form is now widely used globally and since 2004 its use or further development has been reported in almost 100 publications.

Given the intention to produce an internationally applicable questionnaire, requests were made for translations of the ICIQ-UI Short Form at an early stage, for which the Advisory Board developed a protocol for the production of translations of its modules. The ICIQ modules have been translated into over 40 languages to date across the various modules.

Since the fifth consultation a further two modules have been published and are available for use: the ICIQ Bladder Diary (3,4) and ICIQ-LTCqol(5). The bladder diary is the first fully validated bladder diary, which notably incorporated patient and clinician input during its development. The ICIQ-LTCqol questionnaire provides an assessment of symptoms, impact and bother associated with indwelling catheter use. This brings the total number of available modules to sixteen.

With increasing demand for electronic versions of questionnaires, a study has been conducted by the ICIQ group to evaluate the equivalence of the ICIQ's psychometric properties in alternative formats (6). With equivalence demonstrated, app development for the eICIQ is underway.

www.ICIQ.net provides details of the validation status of the modules under development for urinary symptoms, bowel symptoms and vaginal symptoms and provides information regarding the content of existing modules. Information regarding production of translations and the ICIQ development protocol is also available for those interested in potential collaborations to continue development of the project.

Initial number

ICIQ-UI Short Form

DAY MONTH YEAR

CONFIDENTIAL**Today's date**

Many people leak urine some of the time. We are trying to find out how many people leak urine, and how much this bothers them. We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the PAST FOUR WEEKS.

1 Please write in your date of birth:

DAY MONTH YEAR

2 Are you (tick one):Female Male **3 How often do you leak urine? (Tick one box)**

- never 0
about once a week or less often 1
two or three times a week 2
about once a day 3
several times a day 4
all the time 5

4 We would like to know how much urine you think leaks.

How much urine do you usually leak (whether you wear protection or not)?
(Tick one box)

- none 0
a small amount 2
a moderate amount 4
a large amount 6

5 Overall, how much does leaking urine interfere with your everyday life?

Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
not at all a great deal

ICIQ score: sum scores 3+4+5 **6 When does urine leak? (Please tick all that apply to you)**

- never – urine does not leak
leaks before you can get to the toilet
leaks when you cough or sneeze
leaks when you are asleep
leaks when you are physically active/exercising
leaks when you have finished urinating and are dressed
leaks for no obvious reason
leaks all the time

Thank you very much for answering these questions.

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Figure 1: ICIQ-UI Short Form

Table 1: Fully validated ICIQ modules and derivation

| MODULES AVAILABLE FOR USE | |
|---|---|
| ICIQ-MLUTS(7) (ICS _{male} Short Form) | Urinary symptoms (male) |
| ICIQ-FLUTS(8) (BFLUTS Short Form) | Urinary symptoms (female) |
| ICIQ-VS(9) | Vaginal symptoms and quality of life |
| ICIQ-B(10,11) | Bowel symptoms and quality of life |
| ICIQ-UI Short Form(2) | Urinary incontinence short form |
| ICIQ Bladder diary(3,4) | Bladder events and fluid intake |
| ICIQ-N(12,13) (ICS _{male} /BFLUTS) | Nocturia symptoms |
| ICIQ-OAB(12,13) (ICS _{male} /BFLUTS) | Overactive bladder symptoms |
| ICIQ-MLUTS Long Form(12) (ICS _{male}) | Urinary symptoms long form (male) |
| ICIQ-FLUTS Long Form(13) (BFLUTS) | Urinary symptoms long form (female) |
| ICIQ-LUTSqol(14) (KHQ) | Urinary symptoms quality of life |
| ICIQ-Nqol(15) (N-QoL) | Nocturia quality of life |
| ICIQ-OABqol(16) (OABq) | Overactive bladder quality of life |
| ICIQ-LTCqol(5) | Long term catheter symptoms and quality of life |
| ICIQ-MLUTSsex(12) (ICS _{male}) | Sexual matters related to urinary symptoms (male) |
| ICIQ-FLUTSsex(13) (BFLUTS) | Sexual matters related to urinary symptoms (female) |

B. ANNEX 1 BLADDER CHARTS AND DIARIES

The ICS defines three types of Bladder Charts and Diaries which can be used to collect data:

MICTURITION TIME CHART

- times of voiding and
- incontinence episodes

FREQUENCY VOLUME CHART

- times of voiding with voided volumes measured,
- incontinence episodes and number of changes of incontinence pads or clothing

BLADDER DIARIES

- the information above, but also
- assessments of urgency,
- degree of leakage (slight, moderate or large) and descriptions of factors leading to symptoms such as stress leakage, eg. running to catch a bus. It is important to assess the individual's fluid intake, remembering that fluid intake includes fluids drunk plus the water content of foods eaten. It is often necessary to explain to a patient with LUTS that it may be important to change the timing of a meal and the type of food eaten, particularly in the evenings, in order to avoid troublesome nocturia.

The recent development and publication of the ICIQ Bladder Diary provides the first fully validated bladder diary that incorporated patient, clinician and statistical

input during its development (3,4). This rigorous development methodology has ensured the provision of a psychometrically robust tool that reflects the key issues from a patient's and clinical perspective to enable the gathering of required information to treat patients with LUTS (Fig 1). The diary is intended to be a standalone tool that provides instructions and an example to guide completion. The diary is intended for completion over three days and fits onto two sides of A4 to optimise administration and completion. Data collected are:

- Fluid intake
- Urine output
- Leakage episodes
- Time of sleep and waking
- Pads used
- Optional bladder sensation scale

The bladder sensation scale is intended to be an interchangeable variable that can be replaced with a more pertinent measure for an intended use, for example, a pain scale. It is advised that any scale used in this manner should be validated.

INSTRUCTIONS FOR USING THE BLADDER DIARY

This diary helps you and us to understand why you get trouble with your bladder. The diary is a very important part of the tests we do, so that we can try to improve you symptoms. On the chart you need to record:

9. When you get out of bed in the morning, show this on the diary by writing 'GOT OUT OF BED'.
10. During the day please enter at the correct time the drinks you have during the day, eg. 8.00am – two cups of coffee (total 400 ml).
11. The time you pass your urine, eg. 7.30am. Do this every time you pass urine throughout the day and night.
12. Each time you pass urine, collect the urine in a measuring jug and record the amount (in mls or fluid ozs) next to the time you passed the urine, eg. 1.30pm/320ml.
13. Each time you pass your urine, please write down how urgent was the need to pass urine:
 - 'O' means it was not urgent.
 - + means I had to go within 10 minutes.
 - ++ means I had to stop what I was doing and go to the toilet.
14. If you leak urine, show this by writing an 'W' on the diary at the time you leaked.
15. If you have a leak, please add 'P' if you have to change a pad and 'C' if you have to change your underclothes or even outer clothes. So if you leak and need to change a pad, please write 'WP' at the time you leaked.
16. If you have a leakage please write in the column called 'Comments' whether you leaked a small amount or a large amount and what you were doing when you leaked, eg. 'leaked small amount when I sneezed three times'.
17. Each time you change a pad or change clothes, please write in the 'Comments' column.
18. When you go to bed at the end of the day show it on the diary - write 'Went to Bed'.

ICIQ-BLADDER DIARY (12/13)

YOUR NAME: _____

DAY 1 DATE: ____/____/____

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

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

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

Bladder sensation Write a description of how your bladder felt when you went to the toilet using these codes

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

1 - If you had a normal desire to pass urine and no urgency. "*Urgency*" is different from normal bladder feelings and is the sudden compelling desire to pass urine which is difficult to defer, or a sudden feeling that you need to pass urine and if you don't you will have an accident.

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

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

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

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

Here is an example of how to complete the diary:

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

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

Figure 2: ICIQ-Bladder Diary (page 1)

ICIQ-BLADDER DIARY (12/13)

YOUR NAME: _____

DAY 2 DATE: ____/____/____

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

DAY 3 DATE: ____/____/____

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

Bladder sensation codes

- 0** - No sensation of needing to pass urine, but passed urine for "social reasons"
- 1** - Normal desire to pass urine and no urgency
- 2** - Urgency but it had passed away before you went to the toilet
- 3** - Urgency but managed to get to the toilet, still with urgency, but did not leak urine
- 4** - Urgency and could not get to the toilet in time so you leaked urine

Figure 3: ICIQ-Bladder Diary (page 2)

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