

2009

4th International Consultation on Incontinence

Co-Sponsored by

INTERNATIONAL
CONSULTATION ON
UROLOGICAL DISEASES
(ICUD)

INTERNATIONAL
SOCIETY OF UROLOGY
(SIU)

*In collaboration
with*

the Major
International
Associations of
Urology,
Gynecology 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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INTRODUCTION

The 4th International Consultation on Incontinence met from July 5th – 9th 2008 in Paris and was organised by the International Consultation on Urological Diseases, in order to develop recommendations for the diagnosis evaluation and treatment of urinary incontinence, faecal incontinence, pelvic organ prolapse and bladder pain syndrome.

The recommendations 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 Chairmen of all the committees then refined the final recommendations.

These recommendations published in 2009 will be periodically re-evaluated 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 appeared in the journal *Neurourology and Urodynamics* (2002; 21:167-178 and 2006; 25: 293) or can be viewed on the ICS website: www.icsoffice.org

The following ICS definitions are relevant:

1. Lower Urinary Tract Symptoms (LUTS)

LUTS are divided into **storage** symptoms 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

- **Overactive Detrusor Function**, is characterised by involuntary detrusor contractions during the filling phase, which may be spontaneous or provoked.

The overactive detrusor 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 as an unpleasant sensation (pain, pressure, discomfort) perceived to be related to the urinary bladder, associated with lower urinary tract symptom(s) of more than 6 weeks duration, in the absence of infection or other identifiable causes.

4. Pelvic Organ Prolapse

- **Uro-genital 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. Uro-genital prolapse is measured using the POPQ 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 may be divided into:
 - **Faecal incontinence**, any involuntary loss of faecal material
 - **Flatus incontinence**, any involuntary loss of gas (flatus)

* To date, 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 initial 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 **Anal 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.

I. 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 4th International Consultation on Incontinence (ICI, 2008).

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 every patient 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 emphasized:**

a) 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. It is useful to use validated questionnaires to assess symptoms.
- 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

b) 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

c) Social History:

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

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

d) 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 carers).
- **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, and 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/confusion, and depression screening for individuals for whom the clinician has concerns about abnormal affect. Proxy respondents, such as family and carers, may be used to discuss history, goals of care, and treatment for individuals with dementia 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 patients symptoms and their severity, there are a number of components in the examination of patients with incontinence and/or pelvic organ prolapse.

a) General status:

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

b) Abdominal/flank examination: for masses, bladder distention, relevant surgical scars

c) Pelvic examination:

- Examination of the perineum and external genitalia including tissue quality and sensation.
- Vaginal (half-speculum) examination for prolapse

- Bimanual pelvic and anorectal examination for pelvic mass, pelvic muscle function, etc.
- Stress test for urinary incontinence.

d) Neurological testing (see chapter on assessment)

Neurological 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.

3. Urinalysis

In patients with urinary symptoms a **urinary tract infection** is a readily detected, and easily treatable cause of LUTS, and urine testing is highly recommended. Testing may range from dipstick testing, to urine microscopy and culture when indicated.

Conclusion

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

II. 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

In patients with **urinary symptoms** the use of a **simple frequency volume chart** or **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.

The use of the **highest quality questionnaires** (Grade 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 (Grade A) for the basic evaluation of the patient's perspective of urinary incontinence; with other Grade A questionnaires recommended for more detailed assessment. **Further development is required in the areas** of pelvic organ prolapse, bladder pain syndrome and faecal incontinence, and for specific patient groups, as only Grade B questionnaires are currently available (see Appendix).

2. Renal Function Assessment

Standard **biochemical tests for renal function** are recommended in patients with urinary incontinence and a probability of **renal impairment**.

3. Uroflowmetry

Uroflowmetry with the measurement of postvoid residual urine is recommended as a screening test for symptoms suggestive of urinary voiding dysfunction or physical signs of POP or bladder distension.

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 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.

In anorectal conditions anal US or MRI prior to anal sphincter surgery is highly recommended, when obvious anatomic defects are not evident (cloacal formations). Defaecating proctography or dynamic MRI is recommended in suspected rectal prolapse which cannot be adequately confirmed by physical examination.

6. Endoscopy

Although **routine** cystourethroscopy is not recommended, LUT endoscopy is **highly recommended**:

- When initial testing suggest other pathologies, e.g. haematuria
- When pain or discomfort features 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).

7. Urodynamic Testing

a) Urodynamic 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).

b) The aims of Urodynamic Evaluation are

- To reproduce the patient's symptoms and correlate these with urodynamic findings
- The assessment of bladder sensation
- The detection of detrusor overactivity
- The assessment of urethral competence during filling
- The determination of detrusor function during voiding
- The assessment of outlet function during voiding
- The measurement of residual urine

8. Small bowel follow-through, CT entography or capsule endoscopy.

These tests are recommended in the presence of unexplained diarrhoea or when Crohn's disease is suspected.

III. OPTIONAL DIAGNOSTIC TESTS

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. Both US and X-ray imaging can be used.

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

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

- repeated routine 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 neurophysiological 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.

Pudendal nerve latency testing is **not recommended**.

Further imaging of the central nervous system, including spine, by myelography, CT and MRI may prove useful if simple imaging, for example by spinal X-rays in patients with suspected neurological disease, proves normal.

4. Further Imaging

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

- 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 or recurrent UI (e.g. after failed SUI surgery)

6. Anorectal physiology testing

Anal manometry is useful to assess resting and squeeze anal pressures.

3. Management Recommendations

The management recommendations 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, obstetric fistula, pelvic organ prolapse, bladder pain syndrome, and faecal incontinence. The management of incontinence is presented in **algorithm form** with accompanying **notes**.

The Consultation recognised 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. Obstetric Fistulae
- V Urinary Incontinence in Frail Older Men and Women
- VI. Urinary Incontinence in Neurological Patients
- VII Bladder Pain Syndrome
- VIII. Pelvic Organ Prolapse
- IX. Faecal Incontinence in Non-Neurological Patients
- X. Faecal Incontinence in Neurological Patients

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

Although the management algorithms are designed to be used 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**".

➡ The algorithms for **initial management**

are intended for use by all **clinicians** including health care assistants, nurses, physiotherapists, generalist doctors and family doctors as well as by specialists such as urologists 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**

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 700 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 grades of recommendation to inform patient management.

It should be noted that these algorithms, dated **March 2009**, 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**. 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 the long term.

◆ 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

◆ 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 sufferer of incontinence 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 indications and the **risks of treatment**. The assumption that patients almost always wish to have treatment is flawed, and the need to consult the patient 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 is determined jointly by the treating health care providers and the patient, considering all the relevant factors listed above.

In the **initial management algorithms**, treatment is **empirically based**, whilst, the **specialized 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.

◆ Use of Continence Products

The possible role of **continence products** should be considered at each stage of patient assessment, treatment and, if treatment is not (fully) successful, subsequent management.

- **Firstly**, intermittent catheterisation or indwelling catheter drainage often have a role to play in addressing urinary retention .
- **Secondly**, assisted toileting using such devices as commodes, bedpans, and handheld urinals may help to achieve **dependent continence*** where access, mobility and / or urgency problems under-mine a patient's ability to maintain **independent continence***, be it urinary and / or faecal.
- **Finally**, containment products (to achieve **contained incontinence***) for urine and / or faeces find an essential role in enhancing the quality of life of those who:
 - Elect not to pursue treatment options
 - Are awaiting treatment
 - Are waiting for treatment to take effect
 - Are unable to be (fully) cured

Further guidance and care algorithms on which products might be suitable for a given patient are given in Committee 20.

* *Useful terms suggested by Fonda & Abrams. (Cure sometimes, help always – a “continence paradigm” for all ages and conditions. Fonda D and Abrams P, Neurology & Urodynamics 25: 290-292, 2006).*

I. CHILDREN

A. INITIAL MANAGEMENT

Children produce specific management problems for a variety of reasons: assessment requires help from their parents and carers; 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 a micturition diary and structured questionnaires.

➔ **Referrals for specialist treatment are recommended for a group of children who have complicated incontinence associated with:**

- recurrent urinary infection
- voiding symptoms or evidence of poor bladder emptying
- urinary tract anomalies,
- previous pelvic surgery
- neuropathy

➔ **Initial treatment is recommended for the remaining patients who have:**

- Nocturnal enuresis without other symptoms (mono-symptomatic enuresis).
- Daytime symptoms of frequency, urgency, urgency incontinence with or without night-time wetting

2. Treatment

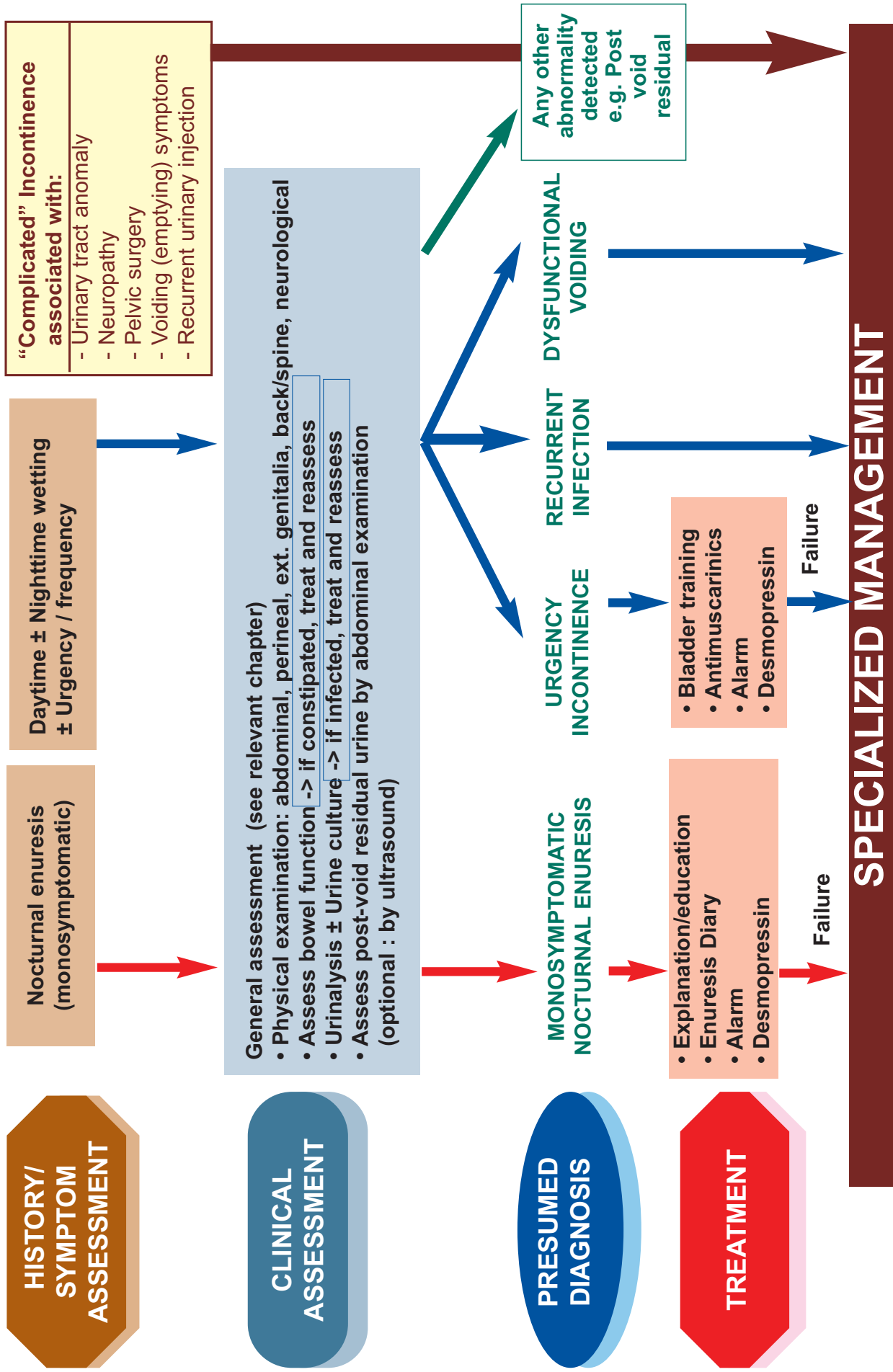
➔ Initial treatment for **mono-symptomatic nocturnal** enuresis should include:

- parental counselling and motivation
 - a choice between either alarm (Grade A) and anti-diuretic hormone analogues desmopressin (Grade A)*. It may be a parental choice if advantages and disadvantages are well explained.
- ➔ **Daytime incontinence** should be managed holistically including:
- counselling, bladder training (timed voiding), behaviour modification and bowel management when necessary (Grade B).
 - antimuscarinics may be used if there are symptoms that suggest detrusor overactivity (Grade C).

Should initial treatment be unsuccessful for either enuresis or daytime symptoms, then after a reasonable period of time (8-12 weeks), referral for a specialist's advice is highly recommended.

* A regulatory warning exists for the danger of overhydration in children on desmopressin.

Initial Management of Urinary Incontinence in Children



I. CHILDREN

B. SPECIALIZED MANAGEMENT

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

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 the **upper urinary tracts** is **highly recommended**.

Those who **fail treatment** and have neither neurogenic nor anatomical problems **should be reassessed** using micturition charts, symptom scores, urinalysis, Uroflowmetry and residual urine determination.

If there are recurrent 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**
 - If **invasive treatment** is under consideration, for example, stress incontinence surgery or bladder augmentation, when there is sphincteric incompetence, or if there is detrusor overactivity.
 - If **upper tract dilatation exists** and is thought to be due to bladder dysfunction.
- Urodynamic studies are not recommended** if the child has normal upper tract imaging and is to be treated by non invasive means.

- **Spinal Imaging** (US/Xray/MRI) may be needed if a bony abnormality or neurological condition is suspected.

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 pathophysiology** 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.

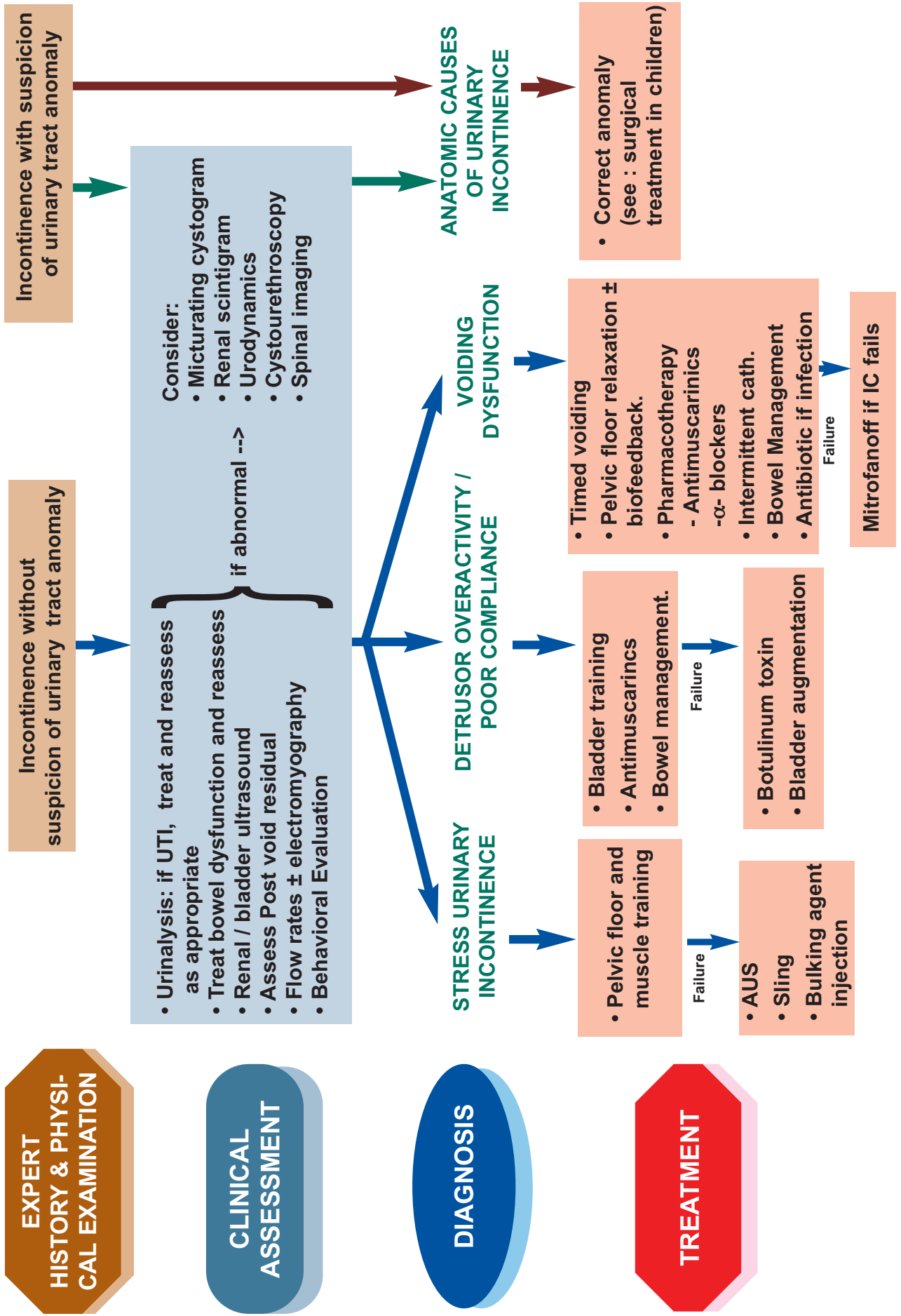
- **Initial treatment should be non-surgical.**
- **For stress urinary incontinence (SU)**: pelvic floor muscle training (Grade C)
- **For suspected detrusor overactivity (DO)**: bladder training and antimuscarinics (Grade C)
- **For voiding dysfunction**: timed voiding, biofeedback to teach pelvic floor relaxation, intermittent catheterisation (when PVR > 30% of bladder capacity). (Grade B/C)
- **For bowel dysfunction**: as appropriate

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 urodynamics is recommended to confirm the diagnosis.
- **For SUI**, sling surgery, bulking agent injection and AUS may be considered
- **For DO / poor compliance**, botulinum toxin * and bladder augmentation may be performed.
- **If the child cannot do IC** then a Mitrofanoff channel may be needed.

* *At the time of writing, botulinum toxin is being used “off label” for refractory DO and must be used with caution.*

Specialized Management of Urinary Incontinence in Children



II. MEN

A. INITIAL MANAGEMENT

1. Initial Assessment should identify :

➔ **Complicated” incontinence group**

Those with pain or with haematuria, recurrent infections, suspected or proven poor bladder emptying (for example due to bladder outlet obstruction), or incontinence following pelvic irradiation, are recommended for **specialized 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 incontinence** (most often post-prostatectomy), and
- Those with **mixed** urgency and stress incontinence (most often post-prostatectomy)

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. (Grade B)

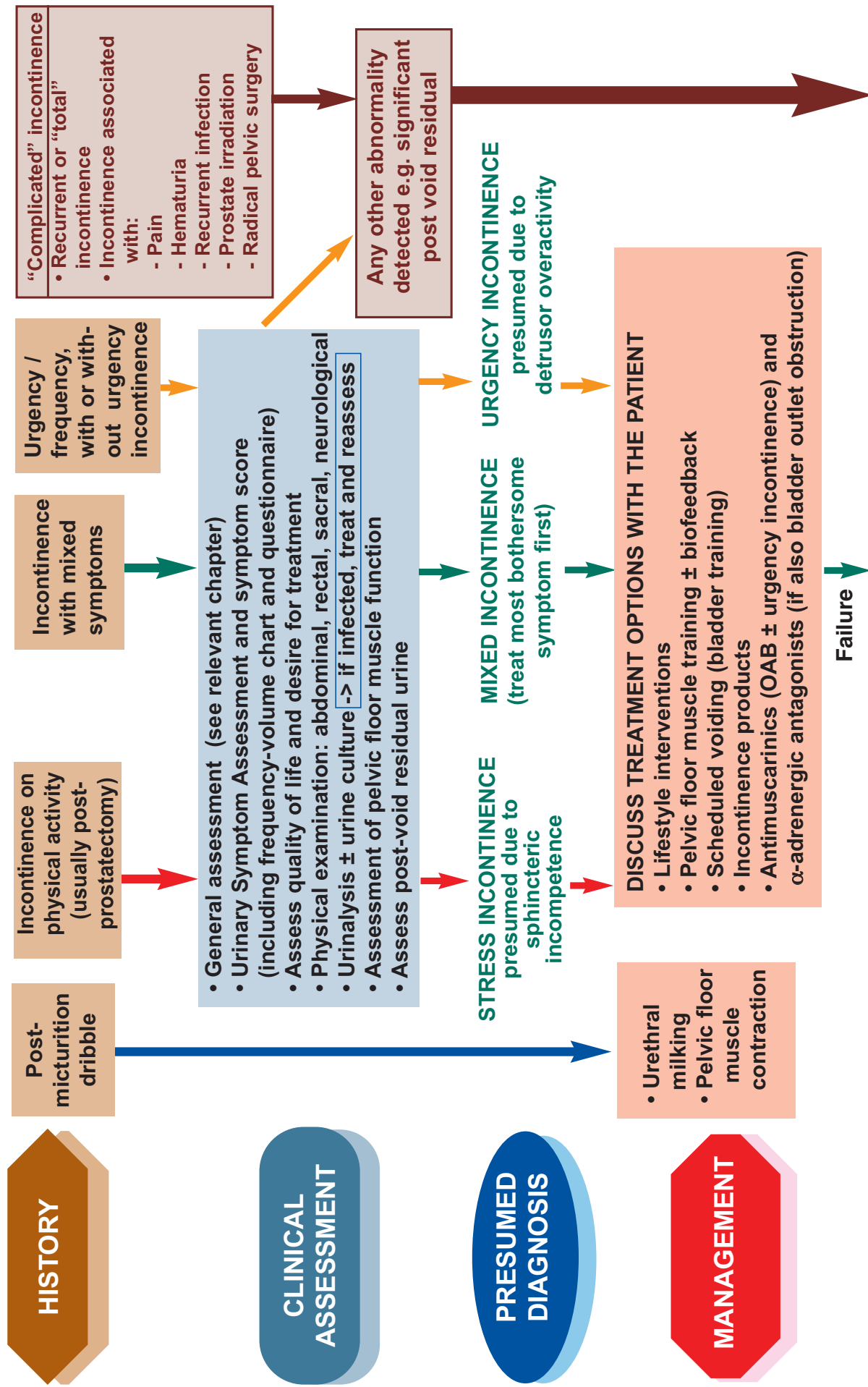
➔ For men with **stress, urgency or mixed** urgency / stress incontinence, initial treatment should include appropriate lifestyle advice, physical therapies, scheduled voiding regimes, behavioural therapies and medication. In particular:

- Lifestyle interventions (Grade D)
- Supervised pelvic floor muscle training for men with post radical prostatectomy SUI (Grade B)
- Scheduled voiding regimes for OAB (Grade C)
- Antimuscarinic drugs for OAB symptoms with or without urgency incontinence (Grade B) and 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. (Grade C)

➔ **Should initial treatment be unsuccessful** after a reasonable period of 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.

Initial Management of Urinary Incontinence in Men



II. MEN

B. SPECIALIZED 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 specialized management, are likely to require **additional testing**, cytology, cystourethroscopy and urinary tract imaging.

If these tests prove normal then those individuals can be treated for incontinence by the initial or specialized management options as appropriate.

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

2. Treatment

When basic management has failed

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 (Grade B). other options, such as a male sling, may be considered (Grade C).

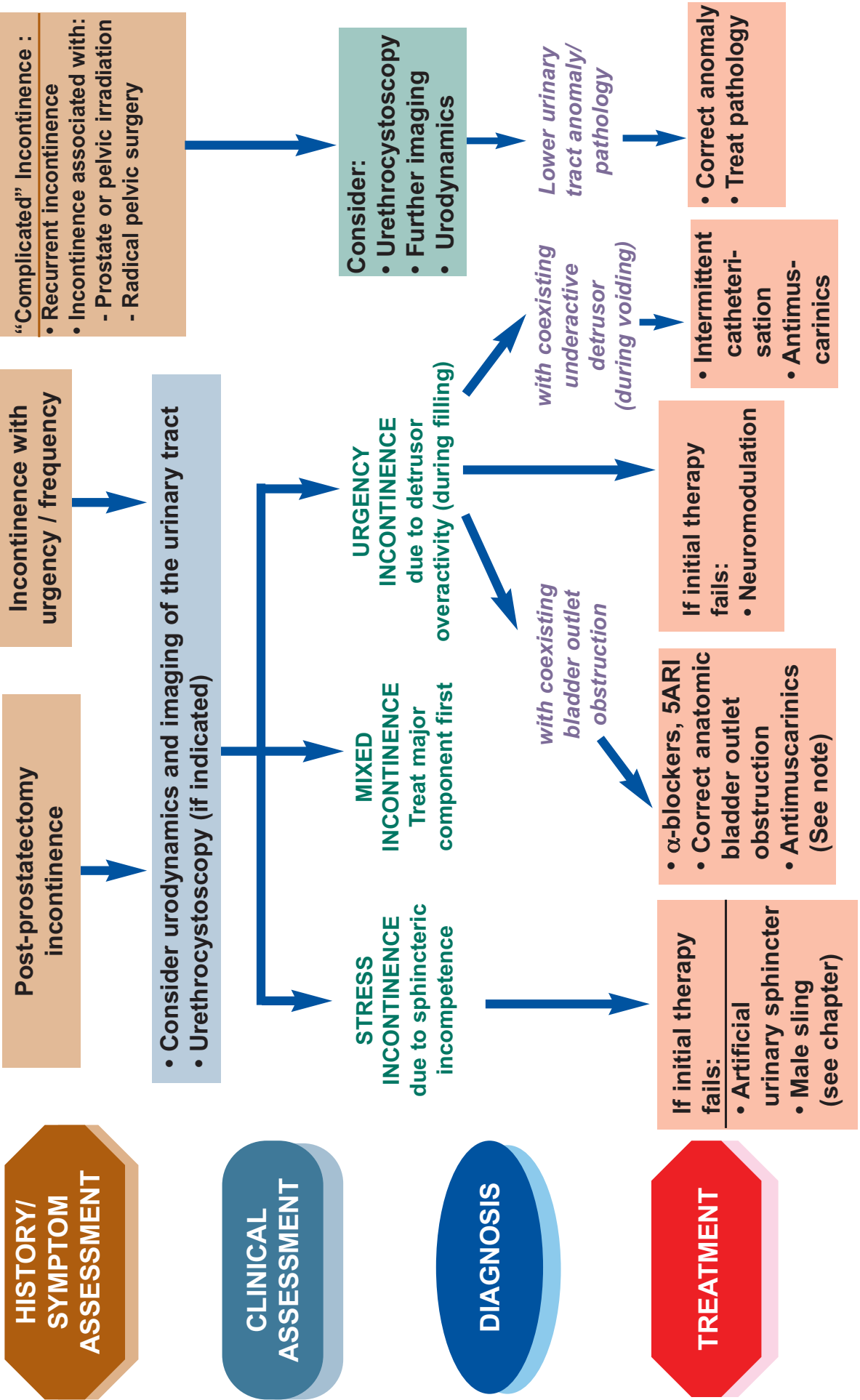
➔ **For idiopathic detrusor overactivity**, (with intractible overactive bladder symptoms) the recommended therapies are bladder augmentation (Grade C) and neuromodulation (Grade B). Botulinum toxin continues to show promise in the treatment of symptomatic detrusor overactivity unresponsive to other therapies*

➔ When incontinence has been shown to be associated with **poor bladder emptying** and **detrusor underactivity**, it is recommended that effective means are used to ensure bladder emptying, for example, intermittent catheterisation (Grade B/C).

➔ **If incontinence is associated with bladder outlet obstruction**, then consideration should be given to surgical treatment to relieve obstruction (Grade B). α -blockers and/or 5 α -reductase inhibitors would be an optional treatment (Grade C). There is increased evidence for the safety of antimuscarinics for overactive bladder symptoms in men, chiefly in combination with an α -blocker (Grade B).

*Note: At the time of writing, botulinum toxin is being used “off-label”.

Specialized Management of Urinary Incontinence in Men



III. 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, for specialist referral.

➤ 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
 - 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 uro-genital 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, physical

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

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

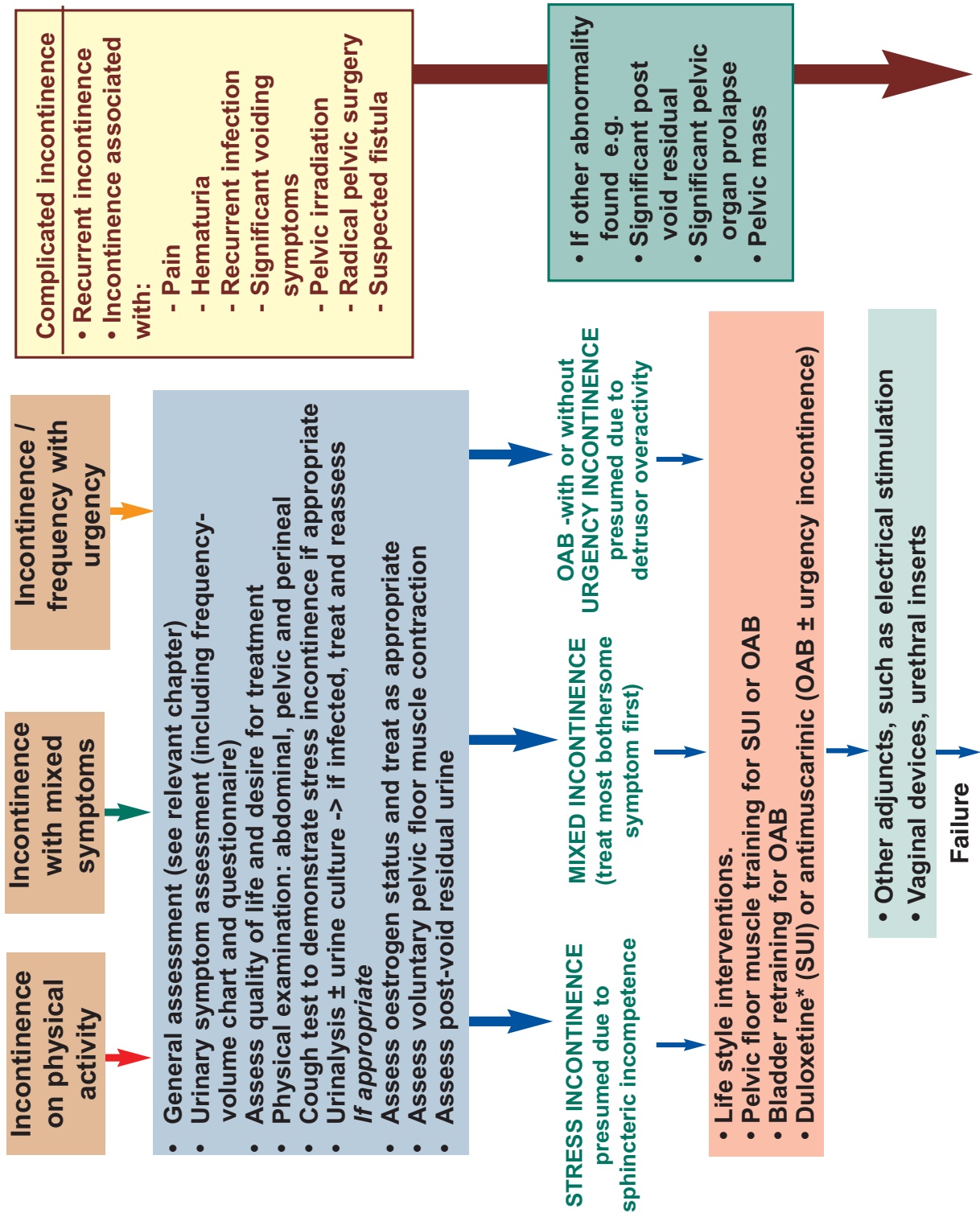
Initial treatment should be maintained for **8-12 weeks** before **reassessment** and possible specialist referral for further management if the patient has had insufficient improvement.

Clinicians are likely to wish to treat the **most bothersome symptom first** in women with symptoms of mixed incontinence. (Grade 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. It is approved for use in Europe for 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



HISTORY

CLINICAL ASSESSMENT

PRESUMED DIAGNOSIS

MANAGEMENT

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

III. WOMEN

B. SPECIALIZED MANAGEMENT

1. Assessment

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

➔ Those women who have **failed 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 desirable**. Prior to intervention **urodynamic testing** is highly recommended, when the results may change management. It is used to diagnose the type of incontinence and therefore inform the management plan. Within the urodynamic investigation urethral function testing by urethral pressure profile or leak point pressure is optional.

➔ Systematic assessment for **pelvic organ prolapse** is highly recommended and it is suggested that the POPQ method should be used in research studies. Women with co-existing pelvic organ prolapse should have their prolapse treated as appropriate

2. Treatment

➔ If **urodynamic stress incontinence is confirmed** then the treatment options that are recommended for patients with **some degree of bladder-neck and urethral mobility** include the full range of non-surgical treatments, as well as retropubic suspension procedures, (Grade A) and bladder neck/sub-urethral sling operations:(Grade A). The **correction of symptomatic** pelvic organ prolapse may be desirable at the same time.

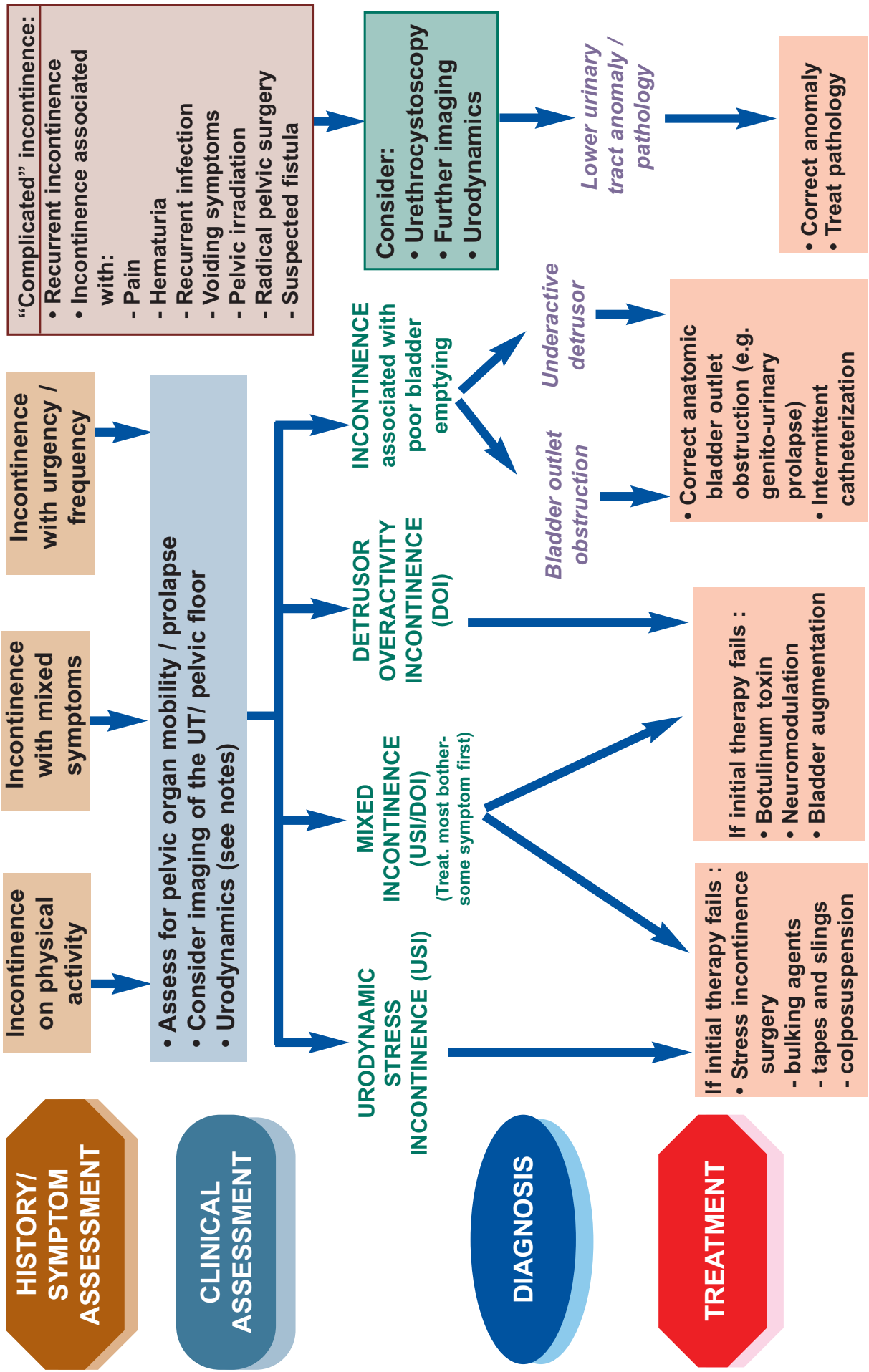
For patients with **limited bladder neck mobility**, bladder neck sling procedures, (Grade A) injectable bulking agents (Grade B) and the artificial urinary sphincter (Grade B) can be considered.

➔ **Urgency incontinence** (overactive bladder) secondary to idiopathic detrusor overactivity may be treated by neuromodulation (Grade A) or bladder augmentation (Grade C). Botulinum toxin can be used in the treatment of symptomatic detrusor overactivity unresponsive to other therapies (Grade C).*

➔ 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 cause of voiding dysfunction.

* *At the time of writing, botulinum toxin is being used “off-label” and with caution.*

Specialized Management of Urinary Incontinence in Women



IV. VESICOVAGINAL FISTULA IN THE DEVELOPING WORLD

I. INTRODUCTION

- **Obstructed labour** is the main cause of vesicovaginal fistula in the developing world. The obstructed labour complex not only induces the vesicovaginal fistula and fetal death in most cases, but can also have urological, gynaecological, neurological, gastro-intestinal, musculoskeletal, dermatological and social consequences.
- **Other aetiologies** such as sexual violence or genital mutilation are less frequent. For these causes the general principles listed here should be adapted according to the patient's need.
- **Patients with vesicovaginal fistula** should be treated as a person, and they deserve the right to adequate counseling and consent to the treatment they will eventually undergo, despite language and cultural barriers that may exist.
- **Surgeons embarking on fistula surgery** in the developing world should have appropriate training in that setting and should be willing to take on a long-term commitment.
- **Prevention of fistula is the ultimate goal.** Collaboration between fistula initiatives and maternal health initiatives must be stimulated.

II. ASSESSMENT

It is important to make a distinction between **simple fistulae**, which have a good prognosis, and **complex fistulae**, which have a less favourable outcome.

Careful **clinical examination** will allow the type of fistula to be determined, although no generally accepted **classification system** is available. **Key items** are the size and location of the fistula, the extent of the involvement of the urethra and the urethral closure mechanism, and the amount of vaginal scarring.

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 and defined.

III. TREATMENT

The treatment for vesicovaginal fistula is **surgical**. (**Grade A**)

➔ Simple fistula

A **vaginal approach** is preferred, since most simple fistula can be reached vaginally and since spinal anaesthesia carries less risk than general anaesthesia needed for an abdominal approach. A trained surgeon should be able to manage these simple fistula.

After wide dissection a tension-free single layer closure of the bladder wall and closure of the **vaginal wall** in a separate layer are advocated. A Martius flap in primary simple obstetric fistula repair is optional.

A **care program** for failed repairs and for persisting incontinence after a successful repair needs to be installed.

➔ Complex fistula

Complex fistulae should be referred to a fistula expert in a fistula centre. (**Grade B**)

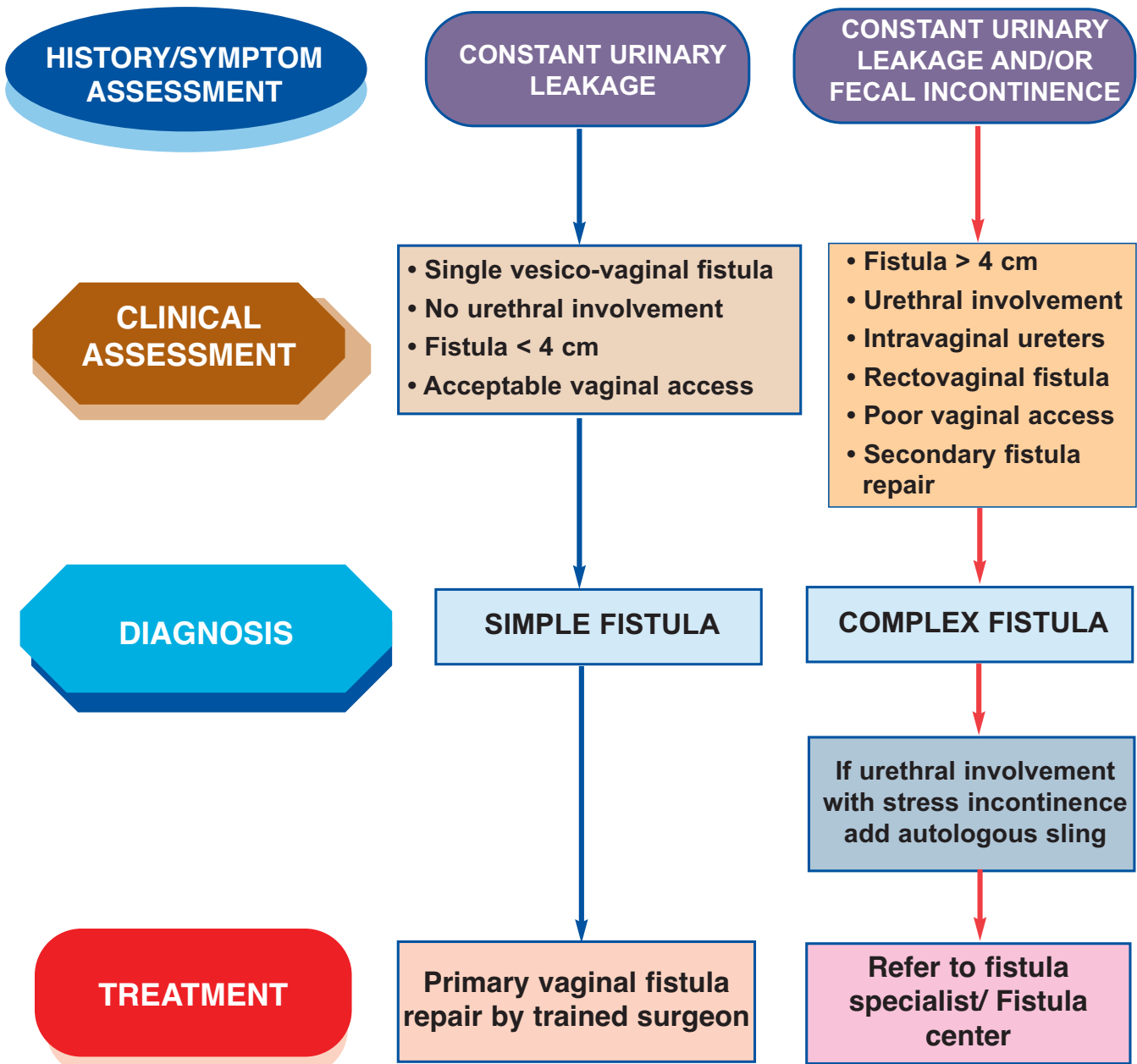
In principle, most complex fistulae can be dealt with by the vaginal approach, but an abdominal approach may be needed in some cases (e.g. concomittant reconstructive procedures). Advanced training and surgical skills are prerequisites for treating this type of fistula.

If the **urethra** and/or the **urethral closure mechanism** is involved, a **sling procedure**, using an autologous sling, should be performed at the same time as the fistula correction. There is **no place for synthetic sling** material in this setting. (**Grade B**)

➔ After care

The **majority of patients** with a simple fistula will be **cured** after the repair. However, a proportion of them, and an even larger proportion of the patients after complex fistula repair, will remain incontinent. Depending on the local possibilities an **after care program** should be installed.

SURGICAL MANAGEMENT OF OBSTETRIC FISTULA



V. PELVIC ORGAN PROLAPSE

I. INTRODUCTION

Pelvic organ prolapse includes **urogenital** and **rectal** prolapse. Treatment for pelvic organ prolapse should be reserved for **symptomatic women**, except in rare, selected, cases.

1. ASSESSMENT

Symptom enquiry may reveal a variety of symptoms. Symptom severity **may not correlate** with the severity of the anatomic changes.

Physical examination should:

- define the severity of maximum anatomic support defect,
- assess pelvic muscle function and
- determine if epithelial/mucosal ulceration is present.

Post void residual should be measured; nearly all elevated post void residuals resolve with treatment of urogenital prolapse. **Imaging of the upper tract** is indicated when treatment of vaginal prolapse beyond the hymen is observation only (i.e. no pessary or surgery).

2. MANAGEMENT

- **Observation** is appropriate when medically safe and preferred by the patient (Grade C).
- **Pelvic floor muscle training may:**
 - reduce the symptoms of urogenital prolapse (Grade B), although topographic change is not expected
 - prevent or slow deterioration of anterior urogenital prolapse (Grade B)
- **Pessaries**, when successfully fitted, may improve protrusion symptoms (Grade B). Regular follow up is mandatory. **Support pessaries** that concurrently treat stress incontinence should be considered when appropriate.
- **Local oestrogens** may benefit hypoestrogenic women for the prevention and/or treatment of vaginal epithelial ulceration (Grade C).
- **Reconstructive surgery** should aim to optimise anatomy and function (see full text for grades of recommendation for specific surgical techniques). Pre and postoperative pelvic floor muscle training may promote quality of life and fewer symptoms after surgery for urogenital prolapse (Grade C).
- **Obliterative surgery** is reserved for selected women who agree to permanent vaginal closure (Grade B).

Management of Pelvic Organ Prolapse (including urogenital prolapse, and recta prolapse)

HISTORY

Bothersome pelvic organ prolapse

Complex or recurrent prolapse

CLINICAL ASSESSMENT

Symptoms Screening: assess bothersomeness, frequency and severity of urinary, ano-rectal, genital and sexual symptoms

- **Urinary:** PVR, cough stress test, urinalysis.
- **Physical Examination:** Sufficient to determine the site and severity of prolapse and detect other significant findings
 - Selective use of urodynamics when results would alter planned treatment
 - Selective use of upper tract imaging when observation is planned
- **Ano-Rectal:** Endoscopy, lower GI tract

Investigation by specialist

DIAGNOSIS

UROGENITAL PROLAPSE WITH OR WITHOUT OTHER PELVIC SYMPTOMS

- observation
- lifestyle interventions
- pelvic floor muscle training
- pessary
- reconstructive surgery
- obliterative surgery

RECTAL PROLAPSE WITH OR WITHOUT OTHER PELVIC SYMPTOMS

- observation
- lifestyle interventions
- transperineal surgery
- transabdominal surgery

MANAGEMENT

Specialist management

VI. NEUROGENIC URINARY INCONTINENCE

A. INITIAL MANAGEMENT

I. STRONG GENERAL RECOMMENDATIONS

- Patients with known neurologic disease often need evaluation to exclude neurologic bladder, not only if symptoms occur, but as a standard diagnostic approach as **neurogenic bladder** has a high prevalence in this disease (for prevalence figures see chapter)
- A **possible neurologic** 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 neurologic** patients does **not necessarily relate** to the neurologic pathology. **Other diseases** such as prostate pathology, pelvic organ prolapse, et al might have an influence. These have to be ruled out.
- **Extensive diagnostic workout** is often useful and necessary only 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 due to bad medical condition or limited life expectancy.
- There is often a need to manage **bladder** and **bowel** together

II. INITIAL ASSESSMENT

- The management of neurologic 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**.
- Therefore neurogenic incontinence patients can be divided into those having

- **peripheral lesions** (as after major pelvic surgery) including those with lesions of the cauda equina (eg.lumbar disc prolapse);
- **central lesions below the pons** (suprasacral infrapontine spinal cord lesions);
- **central lesions above the pons** (cerebro-vascular accidents, stroke, Parkinson's disease).
- **History** and **physical examination** are important in helping **distinguish** these groups.

III. INITIAL TREATMENT

- ➔ Patients with **peripheral nerve lesions** (e.g. denervation after pelvic surgery) and patients with **suprasacral infrapontine spinal cord lesions** (e.g. traumatic spinal cord lesions) should get **specialised management (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 (C) and anti-muscarinic drugs for presumed detrusor overactivity (A). Appliances (B) or catheters (C) may be necessary for non-cooperative or less mobile patients.

Initial Management of Neurogenic Urinary Incontinence

HISTORY, level of lesion

Suprapontine cerebral lesion (e.g. Parkinson's disease, stroke, multiple sclerosis)

Suprasacral infra-pontine spinal cord lesion (e.g. trauma, multiple sclerosis)

Peripheral nerve lesion (e.g. radical pelvic surgery)
Conus/cauda equina lesion (e.g. lumbar disc prolapse)

CLINICAL ASSESSMENT

- Further history
- General assessment including home assessment
- Urinary diary and symptom score
- Assessment of functional level, quality of life and desire for treatment
- Physical examination: assessment of anal sphincter, bulbocavernosus and anal reflexes, gait tone and voluntary contraction of anal sphincter, bulbocavernosus and anal reflexes, gait
- Urine analysis + culture (if infected: treat as necessary)
- Urinary tract imaging, serum creatinine : if abnormal : specialised management
- Post void residual (PVR) by abdominal examination or optional by ultrasound

This assessment will give basic information, but does not permit a precise neurological diagnosis

PRESUMED DIAGNOSIS

Stress urinary incontinence due to sphincter incompetence

Urinary incontinence due to detrusor overactivity

- Behavioural modification
 - External appliances
- Failure

With Poor bladder emptying (Significant PVR)

- Intermittent catheterisation with or without
 - Antimuscarinics
- Failure

With Negligible PVR

- Depending on cooperation and mobility :
 - Behavioural modification,
 - Antimuscarinics,
 - External appliances,
 - Indwelling catheter
- Failure

MANAGEMENT

Specialised management preferable for more "tailored" treatment

VI. NEUROGENIC URINARY INCONTINENCE

B. SPECIALIZED MANAGEMENT

I. ASSESSMENT

- Most patients with neurogenic urinary incontinence require specialized assessment : **urodynamic studies are mandatory** with videourodynamics if available
- **Upper tract imaging** is needed in most patients and more detailed renal function studies will be desirable if the upper tract is considered in danger: high LUT pressure, UUT dilatation, 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

II. TREATMENT

Also for specialized management conservative treatment is the mainstay (A). Management of neurogenic urinary incontinence has several therapeutic options. The algorithm details the recommended options for different types of neurologic dysfunction of the lower urinary tract. The dysfunction does not necessarily correspond to one type/level of neurologic lesion but **must depend** mostly on **urodynamic findings**. One should always ascertain that the used management is **urodynamically safe** (low pressure, complete emptying) It is recommended to look at **urinary** and **bowel** function **together** if both systems are affected, as symptoms and treatment of one system can influence the other and vice versa (A).

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

III. TREATMENT MODALITIES (often in combination)

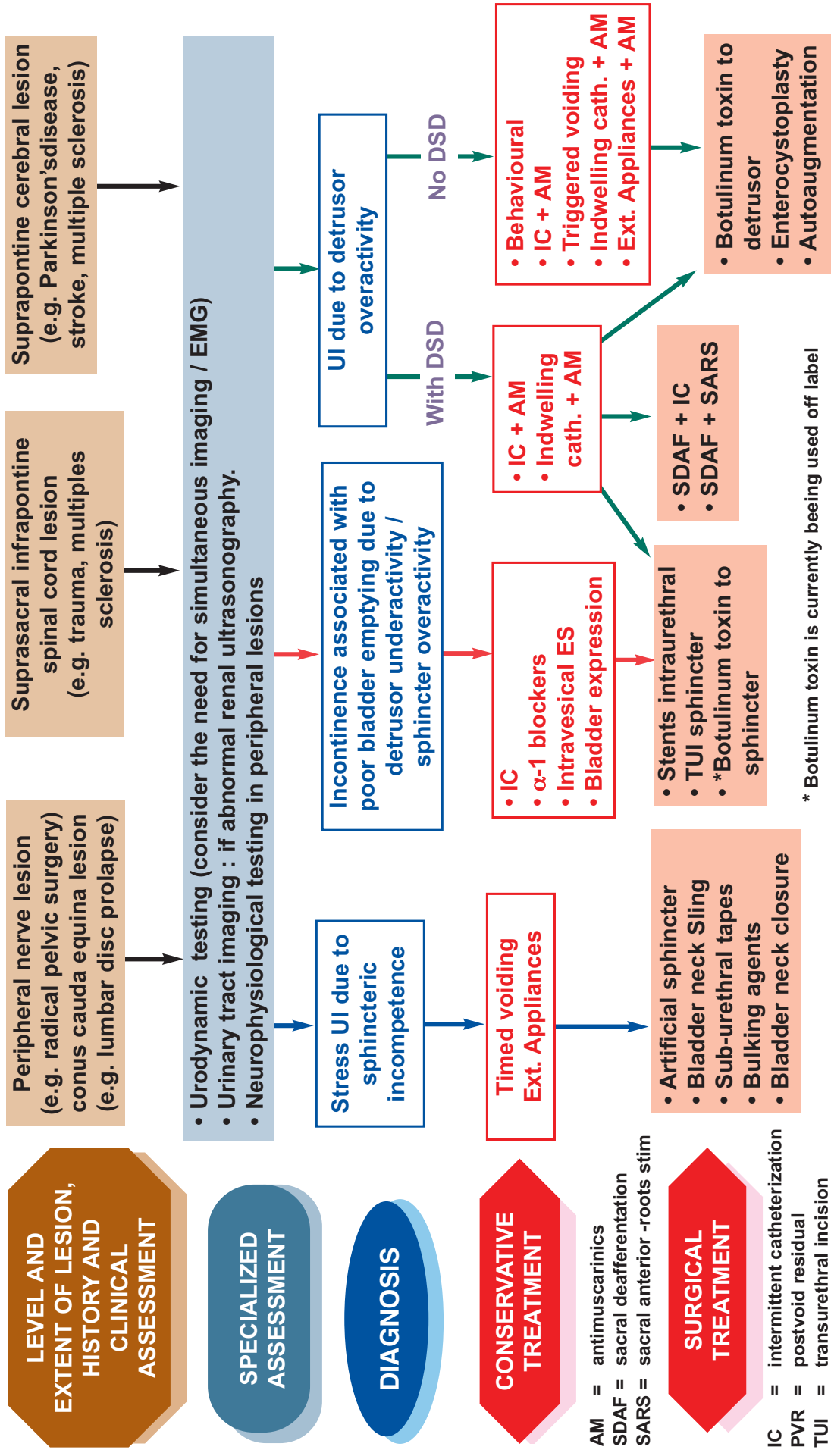
➔ Conservative

- Intermittent catheterization (A)
- Behavioural treatment(C)
- Timed voiding (C)
- Ext. Appliances (B)
- Antimuscarinics(A)
- Alpha 1 blockers (C)
- Intravesical electrical stimulation (C)
- Bladder expression (B)
- Triggered voiding (C)
- Indwelling catheter (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)
- Botulinum toxin for : sphincter(C) detrusor (A)
- Sacral deafferentation (B)
- Sacral anterior root stimulator (B)
- Enterocystoplasty (B)
- Autoaugmentation (D)

Specialized Management of Neurogenic Urinary Incontinence



AM = antimuscarinics
 SDAF = sacral deafferentation
 SARS = sacral anterior -roots stim

SURGICAL TREATMENT

- IC = intermittent catheterization
- PVR = postvoid residual
- TUI = transurethral incision
- DSD = Detrusor sphincter dyssynergia

* Botulinum toxin is currently being used off label

Stoma/diversion may be an option in selected cases

VII. URINARY INCONTINENCE IN FRAIL OLDER MEN AND WOMEN

URINARY INCONTINENCE IN FRAIL OLDER MEN AND WOMEN

Healthy older persons should receive the *similar range of treatment options* as younger persons, but **frail older persons** require a **different approach** addressing the **potential role of comorbid disease, current medications (prescribed, over-the-counter, and/or naturopathic), and functional and/or cognitive impairment in UI**. The **extent of investigation and management** should take into account the **degree of bother** to the patient and/or carer, **goals for care**, cooperation, and **overall prognosis and life expectancy**. Effective management to meet the goals of care should be possible for most frail elderly.

I. HISTORY AND SYMPTOM ASSESSMENT

- **Active case finding and screening** for UI should be done in all frail older persons (Grade A). **History** should include **comorbid conditions and medications** that could cause or worsen UI. The physical should include **rectal exam for faecal loading or impaction** (Grade C), **functional assessment (mobility, transfers, manual dexterity, ability to toilet)** (Grade A), **screening test for depression** (Grade B), and **cognitive assessment** (to assist in planning management, Grade C). The mnemonic DIAPPERS (see algorithm) covers some of these comorbid factors, with two alterations: 1) **atrophic vaginitis** does not itself cause UI and **should not be treated for this purpose** (Grade B); and 2) current consensus diagnostic criteria for **urinary tract infection** (UTI) are poorly sensitive and specific in nursing home residents.
- The patient and/or carer should be asked about the **degree of bother** of UI (Grade B), **goals for UI care** (dryness, decrease in specific symptom[s], quality of life, reduction of comorbidity, lesser care burden) (Grade B), likely cooperation with management (Grade C), and the patient's **overall prognosis and remaining life expectancy** (Grade C).

- **Urinalysis** is recommended for all patients, primarily to screen for hematuria (Grade C); **treatment of otherwise asymptomatic bacteriuria/pyuria is not beneficial** (Grade D), and it may cause harm by increasing the risk of antibiotic resistance and severe adverse effects, e.g., *Clostridium difficile* colitis (Grade C).
- Utility of **clinical stress test** in this population is uncertain (Grade D).
- **Wet checks** can assess UI frequency in **long-term care residents** (Grade C).
- **Post Voiding Residual volume** (PVR) testing is impractical in many care settings, and there is no consensus for the definition of "high" PVR in any population. Yet, there is compelling clinical experience for PVR testing in **selected frail older persons** with: diabetes mellitus (especially longstanding), prior urinary retention or high PVR; recurrent UTIs; medications that impair bladder emptying (e.g., opiates); severe constipation; persistent or worsening urgency UI despite antimuscarinic treatment; or prior urodynamics showing detrusor underactivity and/or bladder outlet obstruction (Grade 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 frequency (Grade C).
- **Nocturia** Assessment of frail elders with bothersome nocturia should identify potential underlying cause(s) including nocturnal polyuria (by **bladder diary [frequency-volume chart] or wet checks**; oedema on exam) (Grade C) and primary sleep problem (e.g., sleep apnoea); low voided volumes (e.g., from high PVR).

II. CLINICAL DIAGNOSIS

The most common types of UI in frail older persons are urgency, stress, and mixed UI. Frail elderly with urgency UI also may have detrusor underactivity and high PVR (without outlet obstruction), called detrusor hyperactivity with impaired contractility (DHIC). There is no evidence that antimuscarinics are less effective or cause retention in DHIC (Grade D).

III. INITIAL MANAGEMENT

- **Initial treatment should be individualized** and influenced by **goals of care, treatment preferences**, and **estimated remaining life expectancy**, as well as the most likely **clinical diagnosis** (Grade C). In some frail elders the only possible outcome may be contained UI (managed with pads), especially for persons with minimal mobility (require assistance of ≥ 2 persons to transfer), advanced dementia (unable to state their name), and/or nocturnal UI.
- **Conservative and behavioural therapy** for UI include lifestyle changes (Grade C), bladder training for more fit alert patients (Grade B), and prompted voiding for frailer, more impaired patients (Grade A).
- **For select cognitively intact patients**, pelvic muscle exercises may be considered, but there are few studies (Grade C). Antimuscarinics may be added to conservative therapy of urgency UI (Grade A-C, depending on agent).
- **Alpha-blockers** may be cautiously considered in frail men with suspected prostatic outlet obstruction (Grade 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 hyponatremia in frail persons and should not be used (Grade A).

IV. ONGOING MANAGEMENT AND REASSESSMENT

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

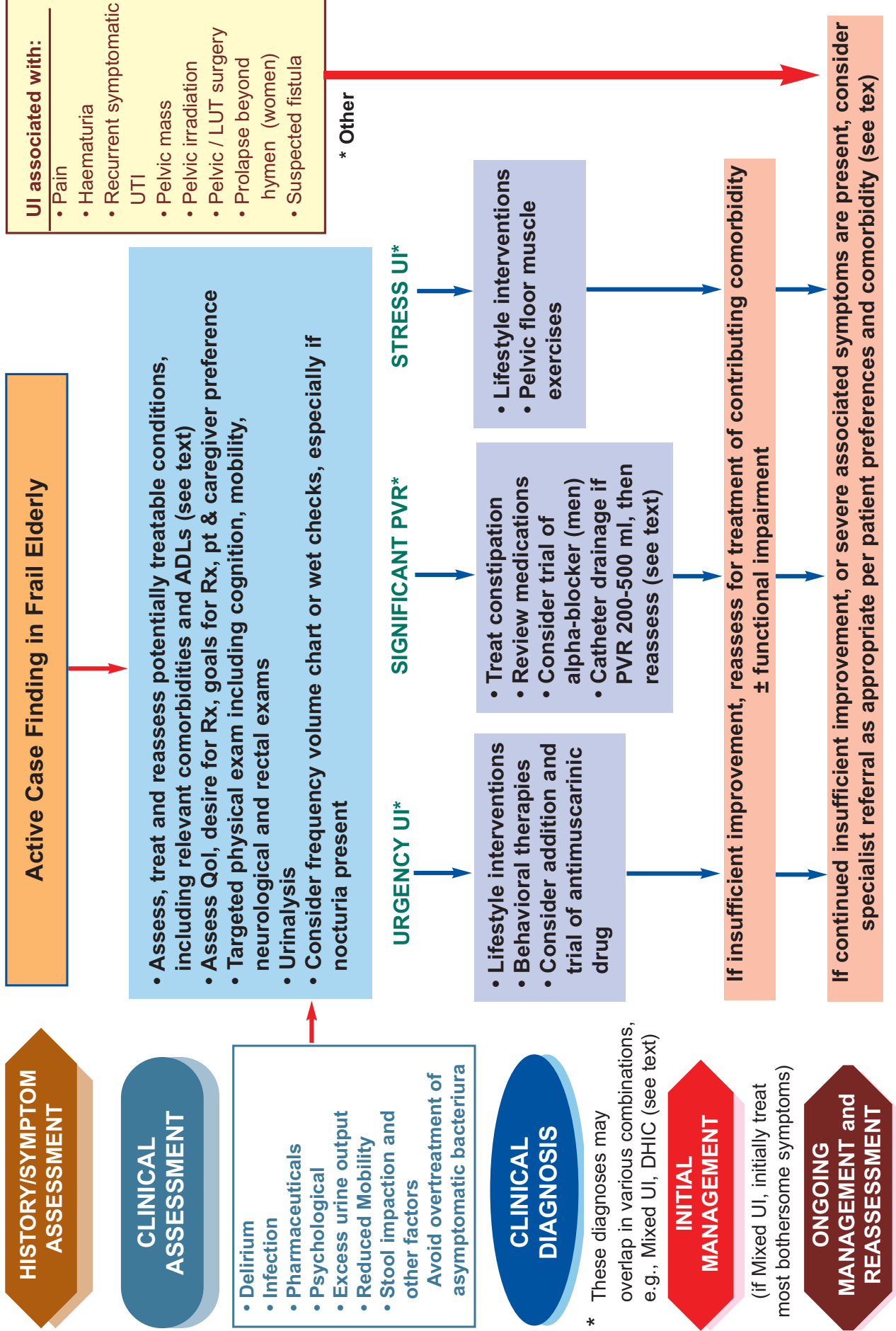
V. SPECIALIZED MANAGEMENT

If frail elderly have either **other significant factors** (e.g., pain, haematuria), **UI symptoms that cannot be classified** as urgency, stress, or mixed, or **other complicated comorbidity** which the primary clinician cannot address (e.g., dementia, functional impairment), then **specialist referral** should be considered. Referral also may be appropriate for **insufficient response to initial management**. Type of specialist will depend on local resources and the reason for referral: surgical specialists (urologists, gynecologists); geriatrician or physical therapist (functional and cognitive impairment); continence nurse specialists (homebound patients). **Referral decisions** should consider **goals of care, patient/carer desire for invasive therapy**, and **estimated remaining life expectancy**.

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

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

Management of Urinary Incontinence in Frail Older Persons



VIII. BLADDER PAIN SYNDROME

I. DEFINITION

Bladder Pain Syndrome (In the absence of a universally agreed definition, the European Society for the Study of Interstitial Cystitis –ESSIC - definition is given along with a slight modification made at a recent international meeting held by the Society for Urodynamics and Female Urology – SUFU)

- **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 “urge” to void or urinary frequency. Confusable diseases as the cause of the symptoms must be excluded.*
- **Consensus Definition from SUFU** International Conference (Asia, Europe, North America) held in Miami, Florida February 2008: *An unpleasant sensation (pain, pressure, discomfort) perceived to be related to the urinary bladder, associated with lower urinary tract symptom(s) of more than 6 weeks duration, in the absence of infection or other identifiable causes.*

II. BLADDER PAIN SYNDROME (BPS)

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), and focuses on the actual symptom complex. ***There is at this time no universally accepted nomenclature.***

2. HISTORY / INITIAL ASSESSMENT

Males or females with pain, pressure, or discomfort, that they ***perceive to be related to the bladder***, with at least ***one urinary symptom***, such as frequency not obviously related to high fluid intake, or a persistent need to void should be evaluated for possible bladder pain syndrome. The diagnosis of ***associated disorders*** including irritable bowel syndrome, chronic fatigue syndrome, and fibromyalgia in the presence of the cardinal symptoms also suggests the diagnosis. ***Abnormal gynecologic findings*** in women and well-characterized “confusable” diseases that may explain the symptoms must be ruled out, for example UTI.

➔ ***The initial assessment consists*** of a frequency-volume chart, focused physical examination, urinalysis, and urine culture. Urine cytology and cystoscopy are recommended if clinically indicated. Patients with ***urinary infection*** should be treated and reassessed. Those with recurrent urinary infection, abnormal urinary cytology, and/or hematuria are evaluated with appropriate imaging and endoscopic procedures, and only if findings are unable to explain the symptoms, are they diagnosed with BPS. (**Grade of recommendation: C**).

3. INITIAL TREATMENT

- Patient education,
 - dietary manipulation,
 - non-prescription analgesics, and
 - pelvic floor relaxation techniques
- comprise the initial treatment of BPS.

The treatment of pain needs to be addressed directly, and in some instances concurrent consultation with an anesthesia/pain center can be an appropriate early step in conjunction with ongoing treatment of the syndrome.

Treatment should be focused on the most bothersome or distressing symptoms(s).

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

- oral medication,
- intravesical treatment, or
- physical therapy

can be prescribed.

It is recommended to initiate a **single form** of therapy and observe results, adding another modality or substituting another modality as indicated by degree of response or lack of response to treatment. (Grade of recommendation: C).

4. SECONDARY ASSESSMENT

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

Findings of **detrusor overactivity** suggest a trial of antimuscarinic therapy is indicated.

The presence of a **Hunner's lesion** diagnosed at any stage in the evaluation suggests therapy with transurethral resection or fulguration of the lesion. **Distension** itself can have therapeutic benefit in 30-50% of patients, though benefits rarely persist for longer than a few months. (Grade of recommendation: C).

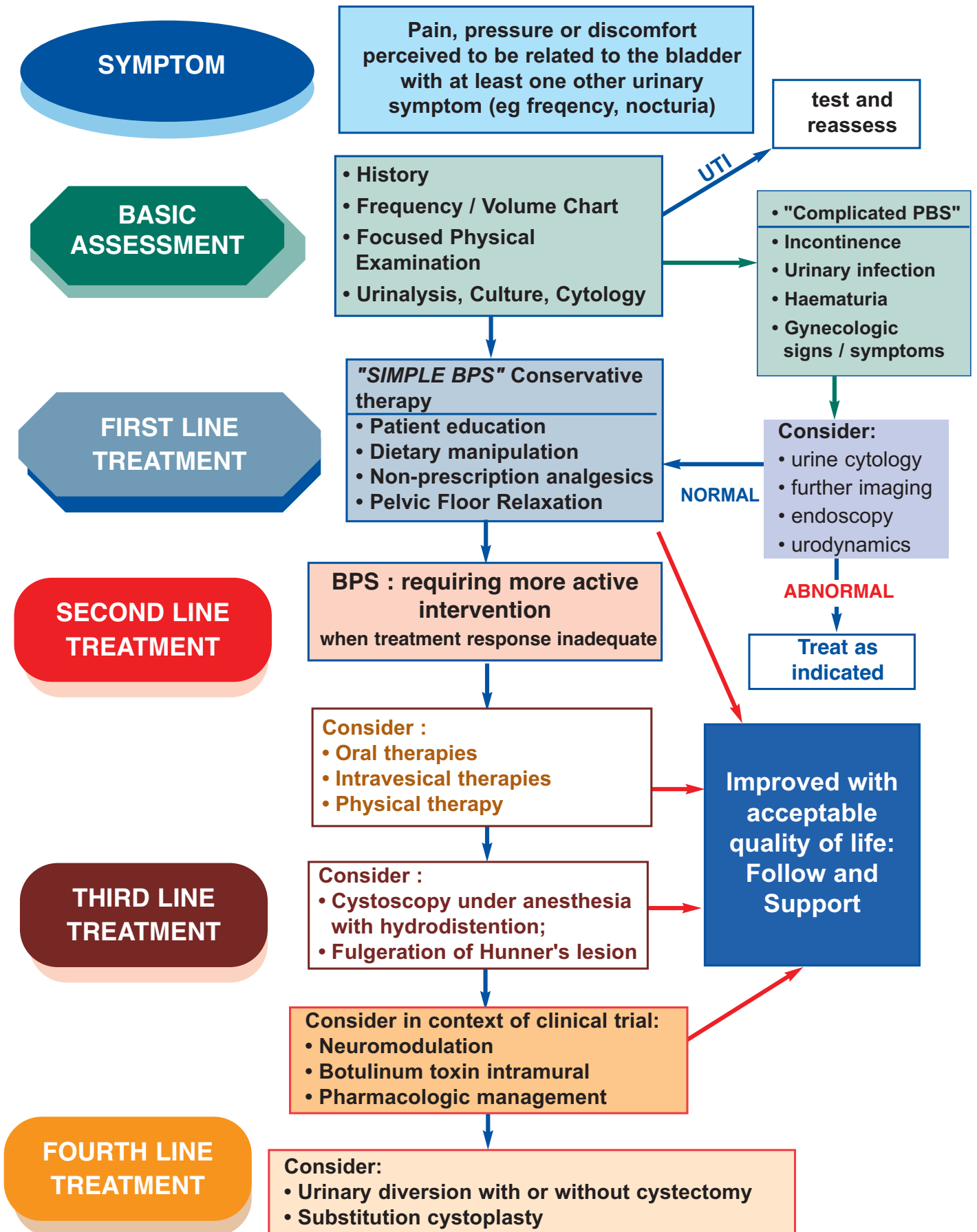
5. REFRACTORY BPS

➔ Those patients with **persistent, unacceptable symptoms** despite oral and/or intravesical therapy are candidates for **more aggressive modalities**. Many of these are best administered within the context of a **clinical trial if possible**. These may include neuromodulation, intravesical botulinum toxin, or newly described pharmacologic 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.
- **Augmentation** or **substitution cystoplasty** seems less effective and more prone to recurrence of chronic pain in small reported series. (Grade of recommendation: C).

Bladder Pain Syndrome



IX. FAECAL INCONTINENCE

INITIAL MANAGEMENT

I. INITIAL ASSESSMENT

Patients present with a variety of symptom complexes. As many people are reluctant to admit to symptoms of FI, it is important to proactively enquire in known high risk groups (such as women with obstetric injuries, patients with loose stool and neurological patients).

- **Serious bowel pathology** 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.
- **History** will include bowel symptoms, systemic disorders, local anorectal procedures (e.g. haemorrhoidectomy), childbirth for women, medication, diet and effects of symptoms on lifestyle.
- **Examination** will include anal inspection, abdominal palpation, a brief neurological examination, digital rectal examination and usually anoscopy and proctoscopy.
- **Two main symptoms are distinguished: urgency faecal incontinence (FI)** which is often a symptom of external anal sphincter dysfunction or intestinal hurry; and **passive loss of stool** may indicate internal anal sphincter dysfunction. Both urgency and passive FI may be exacerbated in the presence of loose stool.

II. INITIAL MANAGEMENT

➔ Once local or systemic pathology has been excluded, **initial management includes :**

- Discussion of **options** with the patient
- Patient **information** and **education**,
- **Diet** and fluid advice, adjusting fibre intake (**Grade A**), and establishing a regular bowel habit with complete rectal evacuation and

- **Simple exercises** to strengthen and enhance awareness of the anal sphincter (**Grade C**).
- **Anti-diarrhoeal** medication can help if stools are loose (Grade B).
- **Irrigation** is helpful in a small number of patients (mainly neurological - **Grade C**).
- **Initial management can often be performed in primary care**. If this is failing to improve symptoms after **8-12 weeks**, consideration should be given to referral for **further investigations**.

III. INVESTIGATIONS

A variety of anorectal investigations, including manometry, EMG, and anal ultrasound can help to define structural or functional abnormalities of anorectal function.

IV. FURTHER MANAGEMENT

- **BIOFEEDBACK**
therapy is usually a package of measures designed to enhance the patient's awareness of anorectal function, improve sphincter function and coordination and retrain the bowel habit (Grade C).
- **PRODUCTS**
to manage severe faecal incontinence are ineffective in most cases.
- **SEVERE FAECAL INCONTINENCE**
which fails to respond to initial management requires specialised investigations and a surgical opinion.

V. SPECIAL PATIENT GROUPS

The main chapter (refer to the book) also gives algorithms for the management of complex vesico-vaginal fistulae and faecal incontinence in frail older adults. Committees 10 and 16 gives information on neurogenic FI.

Initial Management of Faecal Incontinence

Active Screening in High Risk Groups

Patient presents with FI

Basic assessment (history, examination, medication and diet review)

Take out of pathway:

- **Alarm signals:** referral for investigation
- **Impaction:** treat then evaluate
- **Surgical evaluation needed:** e.g. rectal prolapse, recent sphincter injury, recto-vaginal fistula, cloacal deformity

Address reversible risk factors
e.g. Medication; toilet access;
loose stools

- Patient and / or carer education
- Bowel habit and training
- Manage constipation
- Diet (e.g. soluble fibre for loose stool)
- Medication (e.g. loperamide for loose stool)
- PFMT / anal sphincter exercises
- Adequate containment (e.g. pads or plugs) and practical management advice (Committee 20)

If initial management fails to achieve adequate symptom relief consider:
Diagnostic testing; Biofeedback; Irrigation

Surgical evaluation or symptom management if adequate relief not obtained from conservative management, depending on symptom severity and patient preference

IX. FAECAL INCONTINENCE

SURGERY FOR FAECAL INCONTINENCE

I. INITIAL ASSESSMENT AND MANAGEMENT

The reader is referred to the relevant sections on “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, physiologic or neurologic dysfunction.

Prior to surgical management of faecal incontinence, the **morphological integrity** of the anal sphincter complex should be assessed. This assessment is best performed with **endoanal ultrasound** (EAUS), though pelvic **MRI** may also be useful. **Ancillary tests** include anal manometry, electromyography (EMG), and defecography. [GRADE OF RECOMMENDATION C]

➔ Patients with **rectal prolapse**, **rectovaginal fistulae**, and **cloacas** often have associated faecal incontinence. Initial therapy should be directed at **correction of the anatomic abnormality** (in the case of rectovaginal fistula or cloaca, this surgical repair may include overlapping sphincteroplasty.) If the patient has persisting faecal incontinence, he or she should undergo repeat assessment, including especially endoanal ultrasound.

II. SPECIALIZED MANAGEMENT

The **surgical approach** to the incontinent patient is **dictated** by the presence and magnitude of an **anatomic sphincter defect**.

➔ **If no defect is present**, the patient should undergo percutaneous nerve evaluation (PNE), which, if successful, should lead to sacral nerve stimulation (SNS). [GRADE OF RECOMMENDATION B]

➔ For **patients with sphincter defects of less than 180°**, sphincteroplasty has been conventional therapy. [GRADE OF RECOMMENDATION B] However, as long-term outcome of sphincteroplasty appears to deteriorate with time, and SNS has been proven effective in

many patients with sphincter defects, there is a trend towards SNS if initial evaluation by PNE is successful.

➔ **Patients with sphincter defects of greater than 180°** or major perineal tissue loss require individualized treatment. In some cases, initial reconstruction can be performed. Should incontinence persist, alternatives include stimulated muscle transposition, artificial anal sphincter implantation, or sacral nerve stimulation. [GRADE OF RECOMMENDATION C]

III. SALVAGE MANAGEMENT

For patients who **remain incontinent following sphincteroplasty**, repeat endoanal ultrasound should be undertaken to reassess the status of the repair. If there is a **persisting sphincter defect**, repeat sphincteroplasty can be considered. Alternatively, such patients can undergo individualized therapy, including sacral nerve stimulation. [GRADE OF RECOMMENDATION C]. For patients who remain **incontinent despite an anatomically satisfactory sphincteroplasty**, sacral nerve stimulation is recommended.

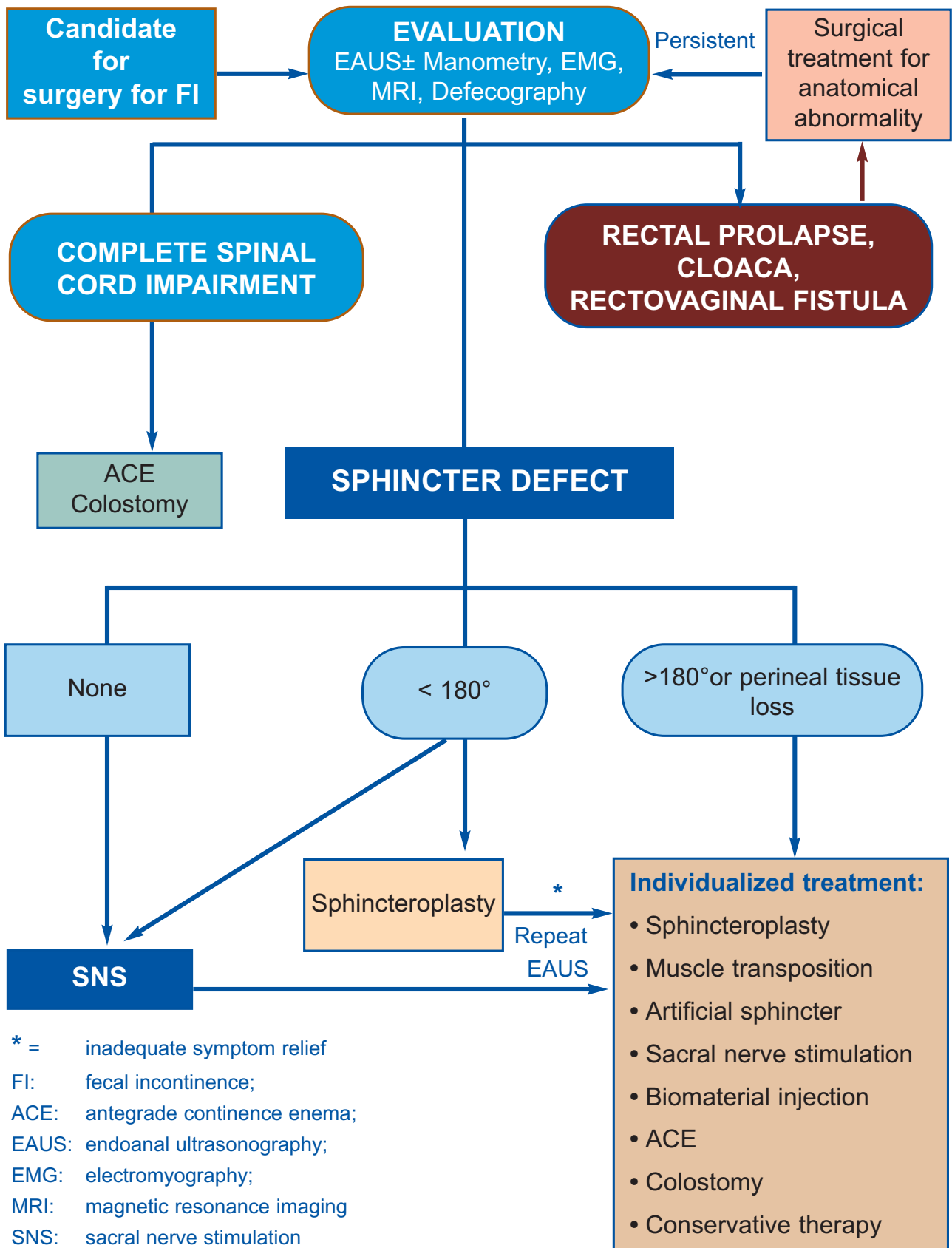
Patients who have failed sacral nerve stimulation can be considered for sphincteroplasty if a sphincter defect is present. Other alternatives include stimulated muscle transposition and implantation of an artificial anal sphincter. [GRADE OF RECOMMENDATION C]

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**. [GRADE OF RECOMMENDATION C]. While this procedure does not restore continence, it does restore substantial bowel control and appears to improve social function and quality of life.

IV. SPECIAL SITUATIONS

Individuals with **severe spinal cord dysfunction** (due, e.g., to injury or congenital abnormality) should be considered for an Antegrade Continence Enema (ACE) procedure or colostomy. [GRADE OF RECOMMENDATION C]

Surgical Management of Faecal Incontinence



X. FAECAL INCONTINENCE IN NEUROLOGICAL PATIENTS

A. INITIAL MANAGEMENT

➔ Patients with **known neurologic disease** may present with symptoms related to neurologic bowel dysfunction – difficulty in defecation, constipation and faecal incontinence which disturb their activities of daily living and quality of life. Many have permanent impairments and functional limitations and disabilities, which are due to neurological deficits and complications

I. INITIAL ASSESSMENT

➔ **History taking:** this includes

- 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 sores, sexual dysfunction
- Patient's satisfaction, needs, restrictions and quality of life
- Environmental factors and barriers and facilitators to independent bowel management.

➔ **Physical examination:**

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

➔ **Functional assessment:**

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

➔ **Environmental factors assessment:**

- toilet accessibility; assistive devices for bowel care and mobility; carer's support and attitude;

II. BASIC INVESTIGATIONS:

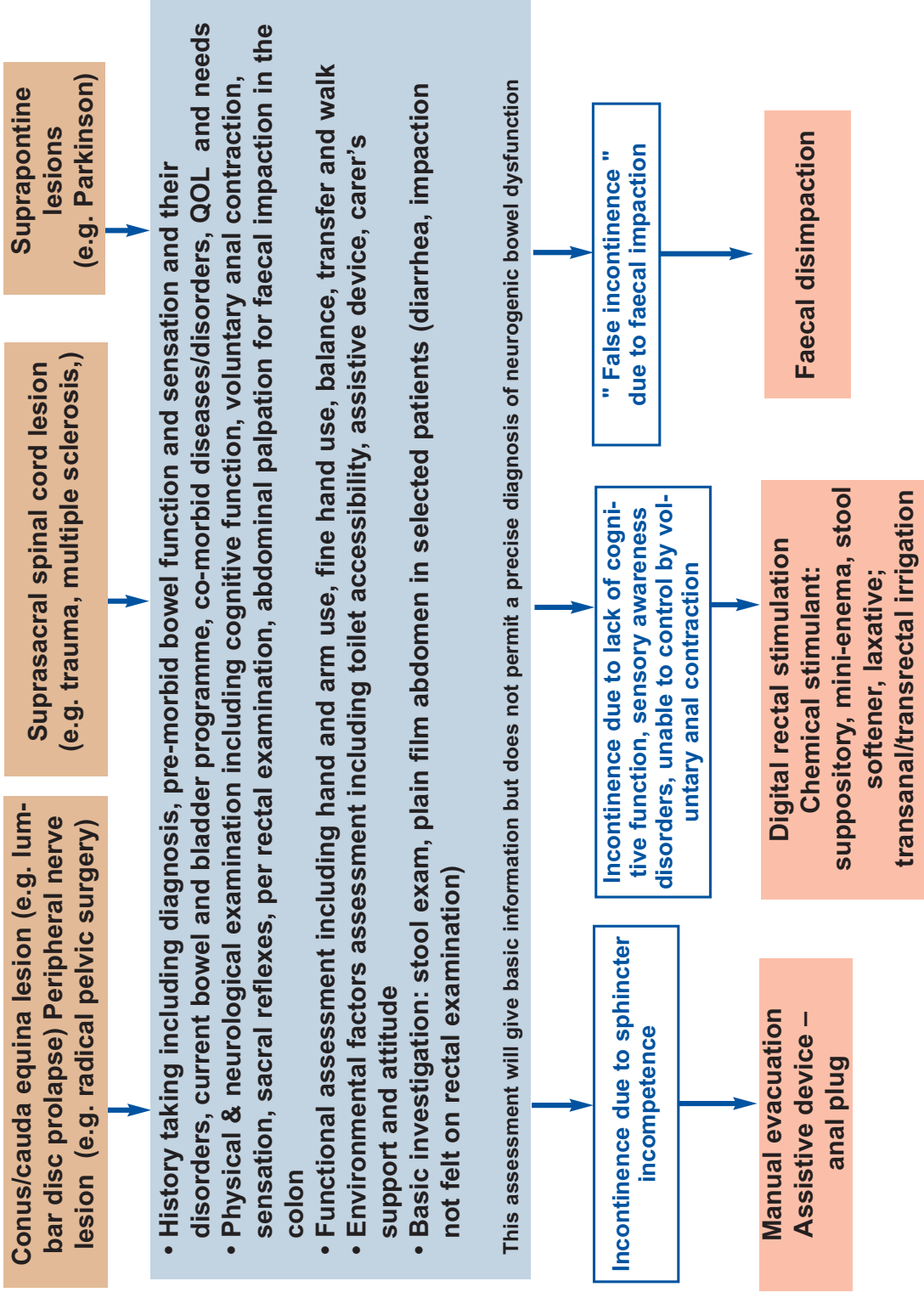
Stool exam, plain abdomen XRay

III. INITIAL TREATMENTS

- **Patient education and goals-setting** - complete defecation 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; suppository and enema; if no anorectal reflex, manual evacuation; abdominal massage can also be helpful
- **Prescribe medications** – stool softener, laxative, prokinetic agents, anti-diarrhea drugs as necessary
- Assistive techniques may be necessary for
 - defecation – irrigation
 - for incontinence – anal plug.

The diagram does not apply to management in acute neurologic patients that need regular bowel emptying.

Initial Management of Neurogenic Faecal Incontinence



X. FAECAL INCONTINENCE IN NEUROLOGICAL PATIENTS

B. SPECIALISED MANAGEMENT

I. ASSESSMENT

- **Some patients** with neurogenic faecal incontinence will need **specialized 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 neurologic 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 neurologic pathology is not sufficiently demonstrated so far.

II. TREATMENTS

➔ **Also for specialized management, conservative treatment for neurogenic faecal incontinence is the mainstay**

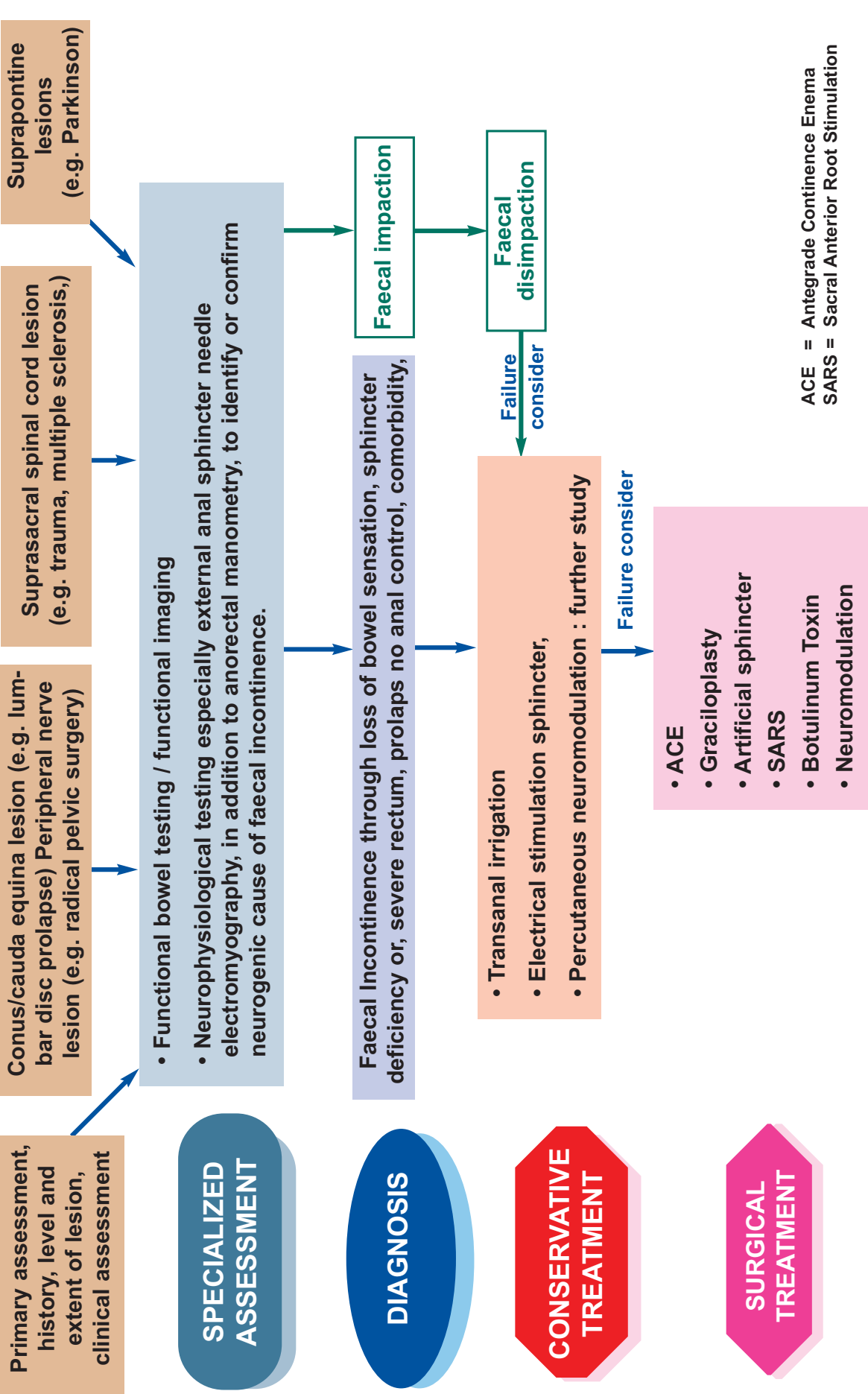
➔ **Management of neurogenic incontinence** does not include very extensive treatment modalities and many conservative are still empirical.

- Transanal irrigation (C)
- Electrical stimulation sphincter, (C)
- Percutaneous neuromodulation : further research is required
- ➔ Surgical management of neurogenic faecal incontinence has different options which need a very strict patient selection
- Antegrade Contenance Enema ACE (C)
- Graciloplasty (C)
- Artificial sphincter (C)
- Sacral Anterior Root Stimulation SARS (C)
- Botulinum Toxin (C)
- Neuromodulation (C)

➔ It is recommended to look at urinary and bowel function together if both systems are affected, as symptoms and treatment of one system can influence the other and vice versa (A).

➔ As therapeutical approach can differ in different neurological diseases, the most prevalent diseases are discussed seperately in the chapter.

Specialised Management of Neurogenic Faecal Incontinence



Stoma/diversion may be an option in selected cases

4. Recommendations for Continence Promotion, Education and Primary Prevention

Continence promotion, education and primary prevention involves informing and educating the public and health care professionals that urinary incontinence and faecal incontinence are not inevitable, but are treatable or at least manageable. In addition, other bladder disorders such as bladder pain syndrome and pelvic organ prolapse can be treated successfully. Progress has been made in the promotion of continence awareness through advocacy programs, organization of the delivery of care, and public access to information on a worldwide basis. These have also been advocated in the education of professionals and primary prevention of mainly urinary incontinence. However, not much has changed in help-seeking behaviour for these disorders. This chapter updates previous International Consultation on Incontinence (ICI) chapters on three areas: continence promotion, education and primary prevention and the following are the recommendations in these individual areas.

CONTINENCE AWARENESS AND PROMOTION

- Continence awareness should be included in any national advocacy program that is working towards an effective health literacy system, as it is consistent with and requires the involvement of many levels of educational, health-care, and community service providers. **(Grade D)**
- Continence awareness should be part of the main stream and on-going health education and advocacy programs with emphasis on eliminating stigma, promoting disclosure and help-seeking behaviour and improving quality of life. **(Grade D)**
- There is a need for research to provide higher level of evidence on the effectiveness of continence promotion programs to increase awareness, be it for primary prevention, treatment or management. **(Grade D)**
- There is a need for research on the most effective means to educate the public and professional groups on continence issues. **(Grade D)**

CONTINENCE ADVOCACY

- Government support and co-operation are needed to develop services, and responsibility for this should be identified at a high level in each Health Ministry. Incontinence should be identified as a separate issue on the health care agenda. There is a need for funding as a discrete item and for funding, not to be linked to any one patient group (e.g. elderly or disabled), and should be mandatory. **(Grade D)**

- No single model for continence services can be recommended. Because of the magnitude of UI prevalence, detection and basic assessment will need to be performed by primary care providers. Specialist consultation should generally be reserved for those patients where appropriate conservative treatments have failed, or for specified indications. **(Grade D)**
- There is a need for research on patient-focused outcomes, should include evaluation of the outcomes for all sufferers who present for care, use validated audit tools/outcome measures and longitudinal studies of the outcomes of services provided. **(Grade D)**
- There is a need for cost-effectiveness studies of current services. **(Grade D)**

PROFESSIONAL EDUCATION

- There remains a need for rigorously evaluated continence education programmes which adhere to defined minimum standards for continence specialists and, generalists, utilizing web-based and distance learning techniques alongside audit and feedback, train-the trainer models and leadership models as well as traditional methods. **(Grade D)**
- There is a need for research on the most effective means to educate professional groups on continence issues. **(Grade D)**

PRIMARY PREVENTION

- Primary prevention studies efforts should be aimed at interventions to promote a healthy body weight to assist in the prevention of incontinence **(Grade A)**.
- Primary prevention studies should not be limited to individual interventions, but also test the impact of population-based public health strategies **(Grade C)**
- PFMT should be a standard component of prenatal and postpartum care and to instruct women who experience incontinence prior to pregnancy PFMT **(Grade C)**
- Randomised controlled trials (RCTs) should be conducted to test the preventative effect of PFMT for men post-prostatectomy surgery **(Grade B)**
- Further investigation is warranted to assess the efficacy of PFMT and BT for primary prevention of UI in well older adults **(Grade B)**

5. Recommendations for Further Basic Science Research

1. Integrate data from reductionist experiments to formulate 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. Generate and improve experimental approaches to investigate the pathophysiology of the LUT and LGIT by:
 - The development of fully characterised animals models
 - Use of human tissue from well-characterised patient groups
3. Encourage greater emphasis on basic research into our understanding of tissues receiving relatively little attention: ie the lower gastrointestinal tract; the bladder neck and urethra.
4. Generate a more disciplinary approach to investigate the function of the lower urinary tract through collaborations between biological, physical and mathematical sciences.
5. Increase interaction between higher education institutions (HEIs), industry and medical centres to encourage translational approaches to research.
6. Bring about a greater emphasis on the importance of research to medical trainees through:
 - establishing research training as a core component of medical training
 - increased access to support funds, especially scholarships and personal awards
 - organisation of focussed multidisciplinary research meetings, either stand-alone or as part of larger conferences
 - greater interaction between medical centres and HEIs
7. Increase emphasis on research into lower urinary tract and gastro-intestinal tract 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 Further Research in Epidemiology

1. Longitudinal study designs are needed to estimate the incidence of urinary incontinence (UI), anal incontinence (AI) and pelvic organ prolapse (POP) and to describe the natural course of these conditions and to investigate risk factors and possible protective factors. In addition similar studies regarding other lower urinary tract symptoms (LUTS) should be initiated.
2. There is still little knowledge regarding prevalence, incidence, and other epidemiological data in developing countries. 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 the 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 and 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 disorders since most of these studies have been unable to control for heritability in relation to the complex interaction of environmental factors.
6. The ethiology 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 monzygotic 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.

7. Recommendations for Clinical Research Methodology

PART I: GENERAL RECOMMENDATIONS

I. RECOMMENDATIONS ON STUDY CONDUCT AND STATISTICAL METHODS

- Randomized controlled trials (RCTs) eliminate most of the biases that can corrupt research and provide the strongest level of evidence to direct clinical care. The primacy of RCTs in incontinence research should be fully acknowledged by researchers, reviewers, and editors.
- Careful attention to the planning and design of all research is of the utmost importance. This should begin with a structured literature review which should be described in the manuscript. High quality, systematic reviews on many topics in incontinence have been published by the Cochrane Incontinence Group (www.otago.ac.nz/cure) and provide a valuable starting point.
- The design, conduct, analysis and presentation of RCTs must be fully in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines. Statistical expertise is required at the start of the design of a RCT and thereafter on an ongoing basis.
- Equivalence trials are underutilized. Failing to find a difference between two treatments is not the same as proving equivalence if the correct design is not used.
- Inclusion and exclusion criteria inherently reflect a conflict between detecting a specific treatment effect and generalizability of the results. It is recommended that the study population in RCTs comprise a sample that is representative of the overall population. All patients who have the disorder in question, who could benefit from the treatment under investigation, and who are evaluable should be eligible. Exclusion criteria should be limited and related to clearly defined, supportable hypotheses.

II. RECOMMENDATIONS ON OBSERVATIONS DURING INCONTINENCE RESEARCH

- One or more high quality, validated symptom instruments should be chosen at the outset of a clinical trial representing the viewpoint of the patient, accurately defining baseline symptoms as well as any other areas in which the treatment may produce an effect. The objective severity and subjective impact or bother should be reflected.
- Whenever relevant, observations of anatomic support and pelvic muscle/voluntary sphincter function should be recorded using standardized, reproducible measurements.
- All observations should be repeated after intervention and throughout follow-up and their relationships with primary clinical outcome measures investigated. Most research follow-up has been inadequate in the past. Given the nature of the disorder, short term follow-up in incontinence trials should begin with all participants having reached one year.

III. RECOMMENDATIONS ON TESTS USED IN URINARY INCONTINENCE RESEARCH:

- Clinical trials of incontinence and LUTS should include a validated frequency volume chart or bladder diary as an essential baseline and outcome measure. Pad tests are a desirable adjunctive measure and should be considered in clinical trials when practical.
- Urodynamic studies have not been proven to have adequate sensitivity, specificity or predictive value to justify routine use of testing as entry criteria or outcome measures in clinical trials. Most large scale clinical studies should enroll subjects by carefully defined symptom driven criteria when the treatment will be given based on an empiric diagnosis.
- High quality, hypothesis driven research into the utility of using urodynamic studies to define patient populations or risk groups within clinical trials is greatly needed.

- In all trials employing urodynamics, standardized protocols (based on ICS recommendations) are defined at the outset. In multicenter trials, urodynamic tests should be interpreted by a central reader to minimize bias unless inter- and intrarater reliability has already been established by standardized procedures within the trial.

PART II : CONSIDERATIONS FOR SPECIFIC PATIENT GROUPS

I. RECOMMENDATIONS FOR RESEARCH IN MEN

- High quality, gender specific quality of life and bother scores should be employed when assessing outcome in male incontinence research.
- Uroflow 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. The value of invasive pressure-flow urodynamics in stratifying patients deserves further investigation.
- Measurement of prostate size (or at least PSA, as a surrogate) should be performed before and after treatment (synchronous with other outcome measures) whenever prostate size is expected to change due to the treatment. Patients should be stratified by prostate size at randomization when size is considered to be a potentially important determinant of treatment outcome.

II. RECOMMENDATIONS FOR RESEARCH IN WOMEN

- Specific information about the menopause, hysterectomy, and hormonal status, parity and obstetric history should be included in baseline clinical trial data
- Strict criteria for cure / improve / fail should be defined based on patient perception as well as objective and semi-objective instruments such as validated questionnaires, diaries and pad tests.

III. RECOMMENDATIONS FOR RESEARCH IN FRAIL OLDER AND DISABLED PEOPLE

- “Clinically significant” outcome measures and relationships of outcome to socioeconomic costs are critically important to establishing the utility of treating urinary incontinence in the frail elderly.

- Entry into RCTs should be defined by performance status rather than an arbitrary age limit.
- Establishing the safety of incontinence treatment is even more important in the frail elderly than in other populations

IV. RECOMMENDATIONS FOR RESEARCH IN CHILDREN

- We support the NIH statement ([http:// grants.nih.gov/ grants/guide/notice-files/ not98-024.html](http://grants.nih.gov/grants/guide/notice-files/not98-024.html)) calling for increased clinical research in children. All investigators that work with children should be aware of the details of the document.
- Long-term follow-up is of critical importance in the pediatric population with a primary focus of establishing safety of chronic treatments.

V. RECOMMENDATIONS FOR RESEARCH IN NEUROGENIC PATIENTS

- Detailed urodynamic studies are required for classification of neurogenic lower urinary tract disorders in clinical trials because the nature of the lower tract dysfunction cannot be accurately predicted from clinical data.
- Change in detrusor leak point pressure should be reported as an outcome as appropriate, and can be considered a primary outcome for spina bifida patients.
- An area of high priority for research is the development of a classification system to define neurogenic disturbances. Relevant features would include the underlying diagnosis, the symptoms, and the nature of the urodynamic abnormality.

VI. RECOMMENDATIONS FOR RESEARCH IN FAECAL INCONTINENCE

- Data should be collected on fecal incontinence whenever practical as part of research in urinary incontinence.
- Well designed and adequately powered studies are needed to define best practice in investigation and for all treatment modalities currently available
- Further consideration should be given to new approaches and adoption of technologies/ interventions that are of established value in treating urinary incontinence

VII. RECOMMENDATIONS FOR RESEARCH IN BLADDER PAIN SYNDROME

- The patient population for BPS trials must be carefully defined. When appropriate, relaxed entry criteria should be used to reflect the full spectrum of the BPS patient population
- The primary endpoint of BPS trials should be patient driven and the Global Response Assessment is recommended. A rich spectrum of secondary endpoints will be useful in defining the effect of treatments
- Investigation of antiproliferative factor as an entry criteria for clinical research is desirable.

VIII. RECOMMENDATIONS FOR RESEARCH IN PELVIC ORGAN PROLAPSE

- There should be a focus on patient reported outcomes with the goal of determining “clinically significant” prolapse. The implications of stage 2 prolapse in terms of natural history and treatment outcome are key issues.

IX. RECOMMENDATIONS FOR RESEARCH IN NOCTURIA

- Research is needed to define the epidemiology of nocturia and how the symptom relates to normal aging
- Clinical research in treatment of nocturia should begin with classification of patients by voiding diary categories, 24 hour polyuria, nocturnal polyuria, and apparent bladder storage disorders. If desired, patients with low bladder capacity can be further divided into those with sleep disturbances and those with primary lower urinary tract dysfunction.

PART III : CONSIDERATIONS FOR SPECIFIC TYPES OF RESEARCH

I. RECOMMENDATIONS FOR BEHAVIORAL AND PHYSIOTHERAPY RESEARCH

- Treatment protocols must be detailed to the degree that the work can easily be reproduced
- The highest practical level of blinding should be used.
- More work is needed to separate the specific and non-specific effects of treatment

II. RECOMMENDATIONS FOR SURGICAL AND DEVICE RESEARCH

- Safety and serious side effects of new devices must be adequately defined with adequate follow-up, especially for use of implantable devices and biologic materials, so that risks can be weighed against efficacy. All new devices and procedures require independent, large scale, prospective, multicenter case series when RCTs are not feasible.
- Valid informed research consent is required in all trials of surgical interventions, which is separate from the consent to surgery.
- 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 patients lost to follow-up should be stated; last observation carried forward is generally not the appropriate method of handling this data.

III. RECOMMENDATIONS FOR PHARMACOTHERAPY TRIALS

- In urinary incontinence safe, effective non-invasive therapy is available for the vast majority of patients. Most trials should offer “standard therapy” rather than a pure placebo where efficacy is established.
- Effective drug therapy is available for most forms of incontinence. Comparator arms are recommended for most trials.

IV. RECOMMENDATIONS FOR ETHICS IN RESEARCH

- 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.

ICIQ-UI on Urinary Incontinence Questionnaire (short form)

Initial number

CONFIDENTIAL

DAY MONTH YEAR

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.

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.

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. The first module to be developed was the ICIQ Short Form Questionnaire for urinary incontinence: the ICIQ-UI Short Form. The ICIQ-UI Short Form has now been fully validated and published [2].

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-UI Short Form has been translated into 30 languages to date. Two further, newly developed and fully validated, modules have been finalised since the third consultation and are now being incorporated into clinical practice and research, and translated accordingly for international use. The ICIQ-VS [7] provides evaluation of vaginal symptoms and the ICIQ-B [3] can be used to assess bowel symptoms including incontinence. Both questionnaires also provide assessment of the impact of these symptoms on quality of life (**Table 1**).

Where high quality questionnaires already existed within the published literature, permission was sought to include these within the ICIQ in order to recommend them for use. Eleven high quality modules have been adopted into the ICIQ which are direct (unchanged) derivations of published questionnaires (Table 1).

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.

Table 1. Fully validated ICIQ modules and derivation

MODULES AVAILABLE FOR USE	
ICIQ – MLUTS (ICSmale Short Form [4])	Urinary symptoms (male)
ICIQ – FLUTS (BFLUTS Short Form [5])	Urinary symptoms (male)
ICIQ-VS [2]	Vaginal symptoms
ICIQ-B [3]	Bowel symptoms
ICIQ - UI Short Form [1]	Urinary incontinence short form
ICIQ – N (ICSmale [6]/ BFLUTS [7])	Nocturia
ICIQ – OAB (ICSmale [6]/ BFLUTS [7])	Overactive bladder
ICIQ – MLUTS Long Form (ICSmale [6])	Urinary symptoms long form (male)
ICIQ – FLUTS Long Form (BFLUTS [7])	Urinary symptoms long form (female)
ICIQ – LUTSqol (KHQ [8])	Urinary symptoms quality of life
ICIQ – Nqol (N-QOL [9])	Nocturia quality of life
ICIQ – OABqol (OABq [10])	Overactive bladder quality of life
ICIQ – MLUTSsex (ICSmale [6])	Sexual matters related to urinary symptoms (male)
ICIQ – FLUTSsex (BFLUTS [7])	Sexual matters related to urinary symptoms (female)

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Annex 1 : Bladder Charts and Diaries

Three types of Bladder Charts and Diaries 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 micturition time and frequency volumes charts can be collected on a single sheet of paper (Fig. 1). In each chart/diary, the time the individual got out of bed in the morning and the time they went to bed at night should be clearly indicated.

Each chart/diary must be accompanied by clear instructions for the individual who will complete the chart/diary: the language used must be simple as in the suggestions given for patient instructions. There are a variety of designs of charts and diaries and examples of a detailed bladder diary are given. The number of days will vary from a single day up to one week.

INSTRUCTIONS FOR COMPLETING THE MICTURITION TIME CHART

This chart 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 your symptoms. On the chart you need to record:-

1. When you get out of bed in the morning, show this on the diary by writing 'GOT OUT OF BED'.
2. The time, eg. 7.30am, when you pass your urine. Do this every time you pass urine throughout the day and also at night if you have to get up to pass urine.
3. If you leak urine, show this by writing a 'W' (wet) on the diary at the time you leaked
4. When you go to bed at the end of the day show it on the diary - write 'WENT TO BED'.

INSTRUCTIONS FOR USING THE FREQUENCY VOLUME CHART

This chart 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 your symptoms. On the chart you need to record:-

1. When you get out of bed in the morning, show this on the chart by writing 'Got out of bed'.

2. The time, eg. 7.30am when you pass your urine. Do this every time you pass urine throughout the day and also at night if you have to get up to pass urine.
3. 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 - 320 mls.
4. If you leak urine, show this by writing 'W' (wet) on the diary at the time.
5. 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.
6. At the end of each day please write in the column on the right the number of pads you have used, or the number of times you have changed clothes.

When you go to bed at the end of the day show it on the diary - write 'Went to Bed'

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 your symptoms. On the chart you need to record:-

1. When you get out of bed in the morning, show this on the diary by writing 'GOT OUT OF BED'.
2. 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).
3. The time you pass your urine, eg. 7.30am. Do this every time you pass urine throughout the day and night.
4. 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.
5. 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.
6. If you leak urine, show this by writing an 'W' on the diary at the time you leaked.
7. 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.
8. 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'.
9. Each time you change a pad or change clothes, please write in the 'Comments' column.
10. When you go to bed at the end of the day show it on the diary - write 'Went to Bed'.

Frequency - Volume chart - Standard Version - 7 days

Name: Pierre Smith

Date	7:00 am	Mid-day	Midnight	6:00am	Pads used
16th APRIL	UP 150 200 50 7.30 7.30 9.30	WC 1100 3.00 6.00 9.30	150 BED 11.45 12	2.30 5.30 270 250	1
17th	UP 260 210 230 7.30 10.00 1.00	150 220 250 50 3.30 7.30 9.30 11	BED 11	275 200 1.30 4.00	0
18th	UP 300 150 200 7.00 9.00 11.15	275 100 150 175 125 2.15 4.15 6.30 8.00 10.30	BED 11	400 4.30	0
19th	UP 250 300 310 7.30 10.30 2.15	75 200 50 250 3.00 5.50 9.00 10.15 10.30	BED 10.30	260 220 200 12.00 2.30 5.00	0
20th	UP 150 250 275 7.30 10.30 2.00	175 200 250 100 4.30 7.15 9.45 11.00	100 BED 0.45	350 5.00	0
21st	UP 200 100 8 9.00	175 75 200 220 300 WC 11.00 11.45 2.30 5.30 7.30 10.20	BED 11	350 300 3.30 6.00	1
22nd	UP 150 220 150 7.30 9.30 11.00	290 300 110 2.15 5.00 7.00	WC 9.30 11 (200)	150 BED 4.30	1

No. of drinks per day: 7

BLADDER DIARY Detailed version - one day

Name: Maria Schmidt Date: 18th April 1998

Urine passed Time/Amount	Urgency?	Leakage?	Comments?	Drinks - time, type and amount
6:00 am				
7.15	0	-		800-2
7.30	+	-		Cups coffee 400mls.
11.30	++	W	Wet pants	11.00 can coke
12:00 noon				
12.30	+	-		12.30 1 glass water - 250mls
3.00	0	-		3.30
3.45	-	W	sneezed 3 times	Cup tea - 200ml
5.30	0	-		
6:00 pm				
7.45	-	-		6.30 glass water - 250mls.
9.30	-	-		8.00 glass wine - 100 mls
10.30	-	-		10.00 mug cocoa - 250 ml
12:00 midnight				
3.30	-	-		