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and other medical associations

3rd International Consultation on Incontinence

Recommendations of the International Scientific Committee:

Evaluation and Treatment of Urinary Incontinence, Pelvic Organ Prolapse and Faecal Incontinence

P. Abrams, K.E. Andersson, L. Brubaker, L.Cardozo, A. Cottenden, L. Denis, J. Donovan, D. Fonda, C. Fry, D. Griffiths, P. Hanno, S. Herschorn, Y. Homma, T. Hu, S.Hunskaar, P. van Kerrebroeck, S. Khoury, R. Madoff, J. Morrison, J. Mostwin, D. Newman, R. Nijman, C. Norton, C. Payne, F. Richard, A. Smith, D. Staskin, J. Thuroff, A. Tubaro, D.B. Vodusek, L. Wall, A. Wein, D. Wilson, JJ. Wyndaele, and The Members of the Committees

INTRODUCTION

The 3rd International Consultation on Incontinence met from June 26 - 29, 2004 in Monaco.

Organised by the International Continence Society (ICS), the International Consultation on Urological Diseases a non-governmental organisation the in official collaboration with the World Health Organisation, Societe International d'Urologie (SIU) in order to ***develop recommendations*** for the diagnosis evaluation and treatment of ***urinary incontinence, faecal incontinence*** and ***pelvic organ prolapse***.

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 ***2005*** will be ***periodically re-evaluated*** in the light of clinical experience and technological progress and research.

Content

1. Definitions

The consultation agreed to use the new International Continence Society definitions (ICS) for lower urinary tract dysfunction (LUTD) including incontinence. These definitions appeared in the journal Neurourology and Urodynamics (issue 2, 2002; 21:167-178) 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. A definition suitable for epidemiological studies, and
- ***Involuntary loss of urine*** that is a social or hygienic problem.

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 occuring 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 urge 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. Painful Bladder Syndrome

- ***Painful bladder syndrome*** is the complaint of suprapubic pain related to bladder filling, accompanied by other symptoms such as increased daytime and night-time frequency, in the absence of proven urinary infection or other obvious pathology.

4. Pelvic Organ Prolapse

- ***Pelvic organ 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. Prolapse support can be staged from stage 0 to stage IV.

5. Faecal Incontinence

Faecal incontinence may be divided into:-

- ***Faecal incontinence***, any involuntary loss of faecal material
- ***Flatus incontinence,*** any involuntary loss of gas (flatus)
- ***Anal incontinence***, any involuntary loss of faecal material and/or flatus.

These definitions are not currently covered by the ICS terminology but follow the above definition for urinary incontinence.

2. Evaluation of Incontinence and Pelvic Organ Prolapse

The following was utilised 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*** (including rectal prolapse) and ***Faecal Incontinence***.

I. HIGHLY RECOMMENDED TESTS DURING INITIAL EVALUATION

The ***main recommendations*** for this consultation have been abstracted from the ***extensive work*** of the 25 committees of the ***3rd International Consultation on Incontinence (ICI).***

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 faecal incontinence.

The ***initial evaluation*** should be undertaken in every patient presenting with symptoms/signs suggestive of these conditions, by a health care professional.

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. In addition to the usual general history the assessment has a number of ***important components***:

- ***Presence, severity, duration and bother of any urinary, bowel or prolapse symptoms***. It is useful to use validated questionnaires to assess symptoms systematically and their impact on quality of life.
- ***Effect of any symptoms on sexual function*** : validated questionnaires are useful in a full assessment.
- ***Previous conservative, medical and surgical treatment***, in particular as they affect the genitourinary tract and lower bowel.
- ***Environmental issues***: these may include the social, cultural and physical environment.
- ***Mental status***: each individual needs to be assessed for their ability to understand proposed management plans and to enter into discussions when there are a range of treatment options. In some groups of patients formal testing of cognitive function is essential, eg. those thought to be suffering from dementia.
- ***Physical abilities***: individuals who have compromised mobility, dexterity, or visual acuity may need to be managed differently
- ***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***.
- ***Lifestyle***: including exercise and food/fluid intake.
- ***Assess patients goals and expectations of treatment***
- ***Patient's support systems (including carers).***

2. Physical Examination

The more complicated the history, and the more extensive 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 sufferers with incontinence and/or pelvic organ prolapse (POP).

- ***Abdominal examination***.
- ***Perineal examination*** including sensation.
- ***Rectal examination***.
- ***Examination of the external genitalia***.
- ***Vaginal examination***.
- ***Stress test for urinary incontinence***.
- ***Neurological testing*** (see chapter on assessment)

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

3. Urinalysis

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

4. Tests before Further Investigation/ Treatment

a) Quatification of symptoms

In a patients with urinary symptoms the use of a simple frequency volume chart (example 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.

b) 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.

c) Imaging

Initial imaging may be by ***Ultrasound, or plain X ray.***

Imaging of the lower urinary tract/pelvis is highly recommended in those with urinary symptoms or whose initial evaluation indicates a possible co-existing lower tract or pelvic pathology.

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

- 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 where indicated
- urodynamic studies which show a raised intra-vesical pressure on bladder filling (poor 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).

d) Endoscopy

LUT endoscopy is ***highly recommended***:

- when initial testing suggest ***other pathologies***, e.g. haematuria raises the possibility of bladder tumour
- 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 fecal incontinence. Colonoscopy or air contrast barium enema is highly recommended in the presence of unexplained change in bowel habit, rectal bleeding or other alarm symptoms or signs (see basic assessment chapter).

II. RECOMMENDED FURTHER ASSESSMENT TESTS

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 QoL Assessment

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 and faecal incontinence, and for specific patient groups, only Grade B questionnaires are currently available.

2. Renal Function Assessment

Standard biochemical tests for renal function are recommended in patients with urinary incontinence ***and*** a high ***probability of renal impairment or prior to surgical interventions***.

3. Uroflowmetry

Uroflowmetry with the ***measurement of postvoid residual urine*** is recommended as a screening test for symptoms suggestive of voiding dysfunction (urinary) or suspicious physical signs.

4. Urodynamic Testing

a) Urodynamic evaluation is recommended :

- prior to most ***invasive treatments***
- after ***treatment failure*** if more information is needed in order to plan further therapy.
- as part of a ***long-term surveillance*** programme in neurogenic lower urinary tract dysfunction
- in ***"complicated incontinence".*** (For details please see relevant subcommittee reports).

b) The aims of Routine Urodynamic Evaluation are

- 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***

5. Imaging of Rectal Prolapse

Proctography or MRI is recommended in suspected rectal prolapse which cannot be adequately confirmed by physical examination.

6. Endoscopy and Lower Bowel imaging is Recommeded

- In faecal incontinence, except when there has been an acute sphicter injury, e.g during childbirth.
- With rectal prolapse, flexible sigmoidoscopy/colonoscopy to exclude other pathology.
- Other "alarm" symptoms, including rectal bleeding (see assessment chapter)

7. Small bowel follow-through or capsule endoscopy.

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

III. OPTIONAL DIAGNOSTIC TESTS

1. Additional Urodynamic Testing

➦ If a more detailed estimate of ***urethral function*** is required then the following ***urethral function tests*** are optional :

- ***urethral pressure profilometry***
- abdominal ***leak point pressures***
- ***video-urodynamics*** and or ***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. Either a short test (20 min to 1 hr) or a ***24 hr test*** is suggested.

3. Neurophysiological Testing

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 clitoris nerves.

4. Further Imaging

a) Techniques include cysto-urethrography, ultrasound, CT or MRI.

They may be indicated in :

- Suspected pelvic floor dysfunction
- Failed surgery
- Assessment of urethral mobility
- Recurrent posterior vaginal wall prolapse
- Follow-up of failed sling implant

b) Simultaneous LUT imaging and urodynamics,

are an optional test in complicated or recurrent incontinence in children and neurogenic patients. The imaging modality may be ultrasound or Xray.

5. Imaging of the Central Nervous System, including Spine

Even if simple imaging, for example spinal X-rays in patients with suspected neurological disease, is normal then further imaging can be considered. The further methods include myelography, CT and MRI.

6. Endoscopy

is an optional test in complicated or recurrent urinary incontinence (e.g. after failed stress incontinence surgery in women, or in post prostatectomy incontinence in men)

7. Gas cystometry

is not recommended as part of the urodynamic evaluation of incontinence measurement.

8. Pudendal nerve latency testing

is not recommended

9. Anorectal physiology testing

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

Electromyography is a useful investigative tool but is not needed for routine clinical evaluation.

3. Management Recommendations

The management recommendations are derived from the detailed work in the committee reports on management in ***children, men, women,*** the ***frail elderly, neurological*** patients ***pelvic organ prolapse, painful bladder syndrome,*** and ***faecal incontinence.*** The management of incontinence is presented in ***algorithm*** form with a***ccompanying notes.*** There are algorithms for

- **I. Children**
- **II. Men**
- **III. Women**
- **IV. Frail Older Men and Women**
- **V. Neurogenic Incontinence**
- **VI. Painful Bladder Syndrome**
- **VII. Pelvic Organ Prolapse**
- **VIII. Faecal Incontinence**

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

The management algorithms are designed to be used for patients whose predominant problem is incontinence. However there are many other patients in whom the algorithms may be useful such as those patients with urgency and frequency suggestive of ***detrusor overactivity*** but without incontinence.

It should be noted that these algorithms, dated January 2005, represent the ***"best opinion"*** 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.

➦ *The algorithms for initial management*

are intended for use by ***all*** or any health care workers including health care assistants, nurses, physiotherapists, 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 ***health care workers 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 ***level of evidence*** to the ***published work*** on the subject and devised ***grades of recommendation*** to inform patient management.

◆ Essential components of basic assessment

Each algorithm contains a core of recommendations in addition to a number of essential components of basic assessment (see I to III Diagnostic Tests, above).

- 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 desire for treatment. Today patient 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 worker will give an ***appropriate explanation of the patient's problem*** and the ***alternative lines of management, 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.

I. CHILDREN

A. INITIAL MANAGEMENT

1. Initial assessement should identify

➦ A group of children with ***complicated incontinence*** associated with:

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

Should have ***specialist management*** from the outset

Two other main groups of children should be identified by initial assessment:

➦***a) Nocturnal enuresis*** without other symptoms (mono-symptomatic).

➦***b) Daytime symptoms*** of frequency, urgency, urge incontinence with or without night-time wetting.

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***.

In children, ***history*** and ***general assessment*** requires particular attention not only taking a full incontinence history but also in assessing bowel function, the child's social environment and the child's general and behavioral development: each should be formally assessed and recorded.

Physical examination should aim to detect a palpable bladder, any abnormality of the external genitalia, signs of incontinence and evidence of bony abnormalities in the gluteo-sacral area (eg. sacral dimple) or feet. If possible the child should be observed voiding.

2. Treatment

Initial management should be instigated for those with «uncomplicated» nocturnal enuresis and/or daytime symptoms.

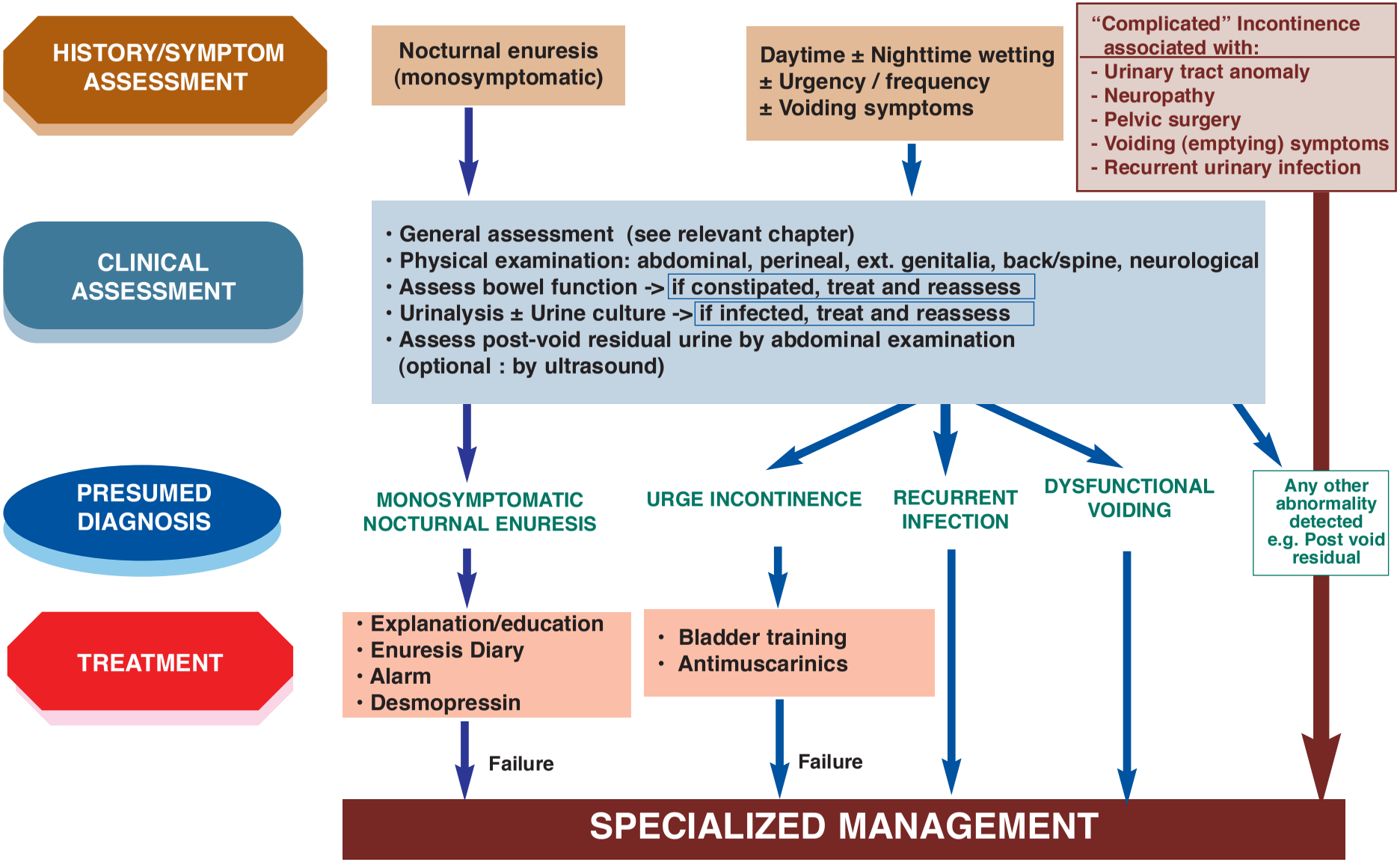
➦***a) Mono-symptomatic nocturnal enuresis*** should be treated initially with the ***enuresis alarm*** (Grade A). Other recommended treatments are ***behavioral modification***, diaries to record enuresis episodes, and ***anti-diuretic hormone analogues*** (Grade A).

➦***b) Daytime incontinence*** should be treated with bladder training (timed voiding) with or without antimuscarinic therapy (Grade B).

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.

Other conditions usually ***seen in adults may be seen in children***, for example stress urinary incontinence.

Initial Management of Urinary Incontinence in Children



I. CHILDREN

B. SPECIALIZED MANAGEMENT

The ***group*** of children with ***"complicated"*** incontinence should have specialist management from the outset.

Three other groups of incontinent children are considered under ***specialist management***:

- those that have ***failed basic management***
- children whose incontinence is due to, or associated with, ***urinary tract anomalies***
- children without urinary tract anomalies, but with ***recurrent infection*** and, proven or suspected, ***voiding dysfunction.***

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.***

Consideration should be given to the need for further ***renal imaging*** (nucleotide scanning, IVP) and /or ***lower urinary tract imaging*** and /or ***cysto-urethroscopy***. However, endoscopy is rarely indicated.

Urodynamic studies are ***highly recommended:***

- ***if invasive treatment*** is under consideration, for example, stress incontinence surgery, if there is sphincteric incompetence, or bladder augmentation if there is detrusor overactivity.
- If ***upper tract dilatation*** 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, for example, bio-feedback (with or without electromyography) for dysfunctional voiding.

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

2. Treatment

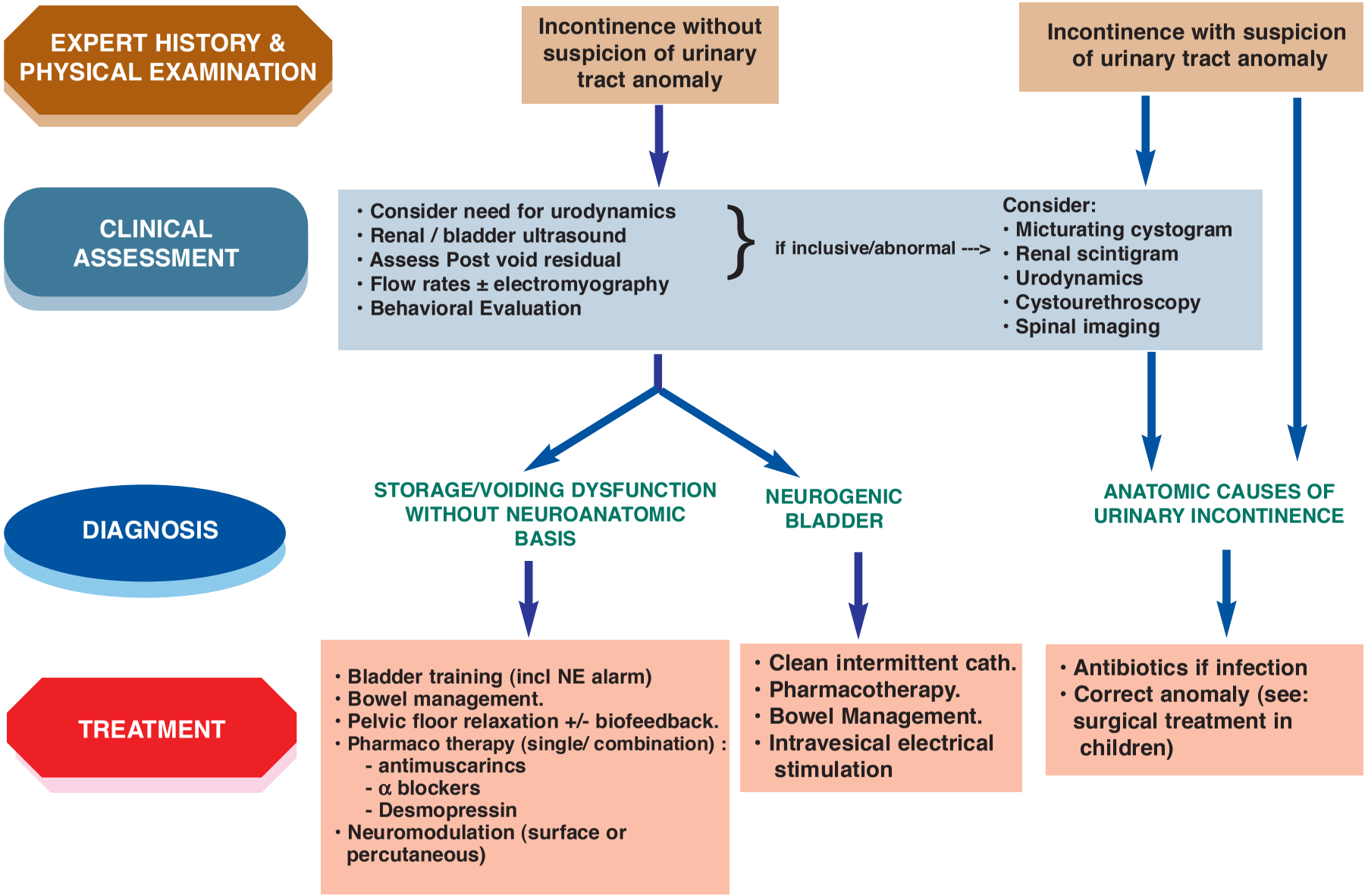
The treatment of incontinence associated with ***urinary tract anomalies is complex*** and cannot be dealt with in an algorithm (please see children's committee report).

Children with bowel dysfunction should be treated appropriately.

The treatment of stress and ***urge incontinence*** without voiding dysfunction is ***non-invasive*** and it is rare for invasive therapy to be considered: such children should only be dealt with by clinicians with expertise in incontinence and managing children.

When incontinence is associated with voiding dysfunction, which results in significant post-void residuals (>30% of total bladder capacity), then initial treatment should be directed at achieving better bladder emptying by ***biofeedback*** and ***intermittent catheterisation*** (Grade B/C): such therapy should be taught by those with special expertise in the care of children.

Specialized Management of Urinary Incontinence in Children



II. MEN

A. INITIAL MANAGEMENT

1. Initial Assessement should identify :

Men with "***complicated***" incontinence associated with ***haematuria, pain, recurrent infection***, or who are known to have, or who are thought to have ***poor bladder emptying*** for example due to bladder outlet obstruction, 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.

Initial assessment aims to ***identify 3 groups of men*** suitable for ***initial management***.

a) Those with ***post-micturition dribble alone***,

b) Those with symptoms of ***urgency*** with or without urge incontinence, together with frequency and nocturia (overactive bladder) and

c) Those with ***post-prostatectomy incontinence.***

2. Treatment

a) Post-micturition dribble requires ***no assessment*** and can usually be effectively treated by pelvic floor muscle training and manual compression of the bulbous urethra directly after micturition. (Grade A)

b) Urge incontinence and other overactive bladder symptoms should be treated by ***non-invasive*** means initially: (Grade C)

- Lifestyle interventions (grade C)
- pelvic floor muscle training (Grade C)
- bladder training (Grade C)
- antimuscarinic drugs if detrusor overactivity is suspected as the cause for overactive bladder symptoms. (Grade C)
- alpha adrenergic antagonists (a-blockers), can be considered if it is thought that there may also be bladder outlet obstruction. (Grade C)

c) Post prostatectomy stress incontinence should also be treated initially by pelvic floor muscle training (Grade A) augmented by lifestyle interventions (Grade B) or bladder training. (Grade C)

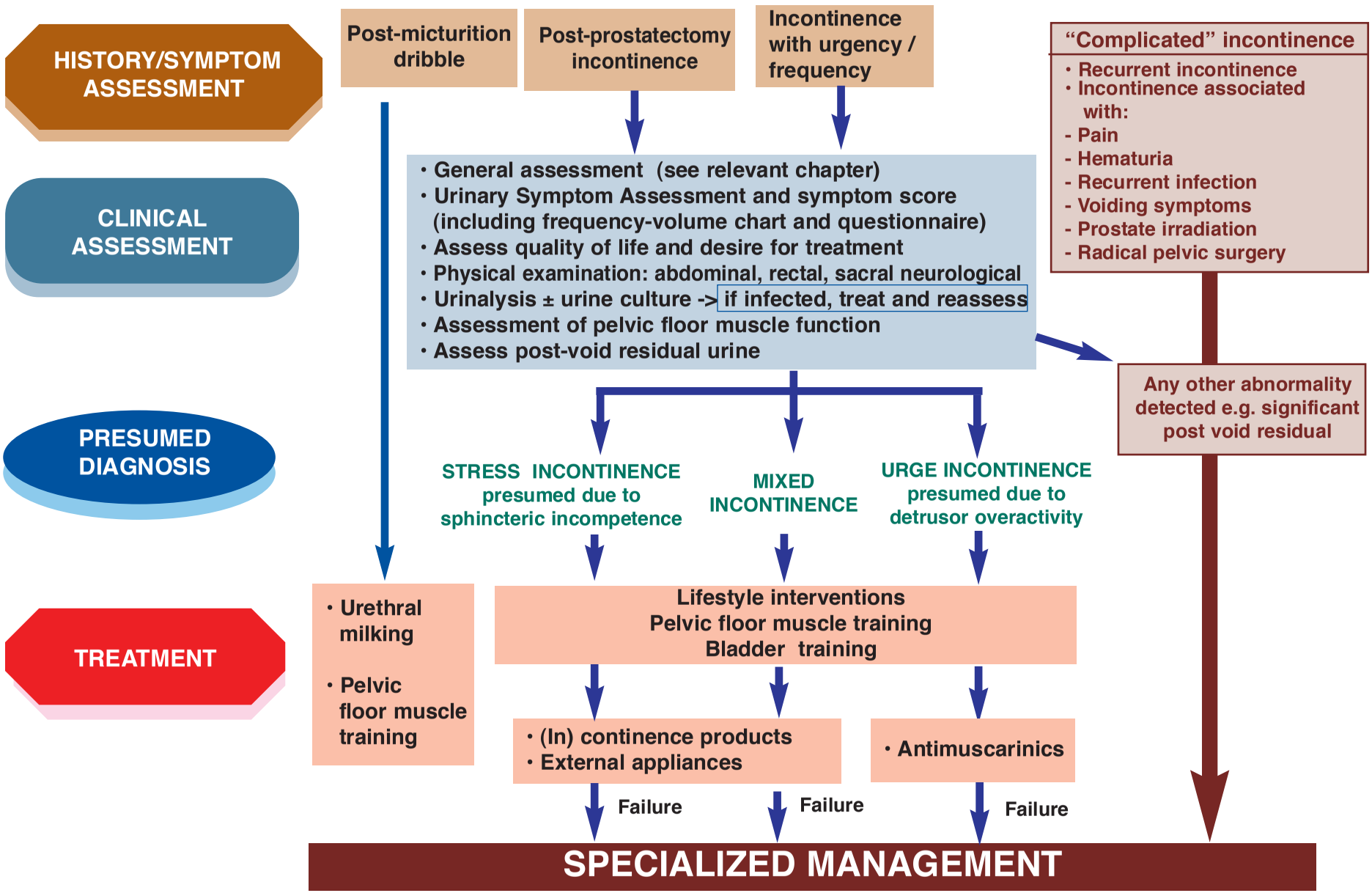
3. Outcome Assessment

➦ Should ***initial treatment*** be ***unsuccessful*** after a reasonable period of time (8-12 weeks), referral for a ***specialist's advice*** is highly recommended.

Note : It may be necessary for patients to use (in)***continence products*** whilst waiting for definitive treatment.

For ***frail older men*** with ***neurogenic dysfunction*** please see relevant algorythm and chapter

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. Assessement

➦ ***Patients referred directly to specialized management*** are likely to require additional testing, cytology, cystourethoscopy 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.

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).

➦ For the ***idiopathic detrusor overactivity***, (with intractible overactive bladder symptoms) the recommended therapies are bladder augmentation (Grade C), autoaugmentation (Grade D), neuromodulation and urinary diversion (Grade B).

➦ 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).

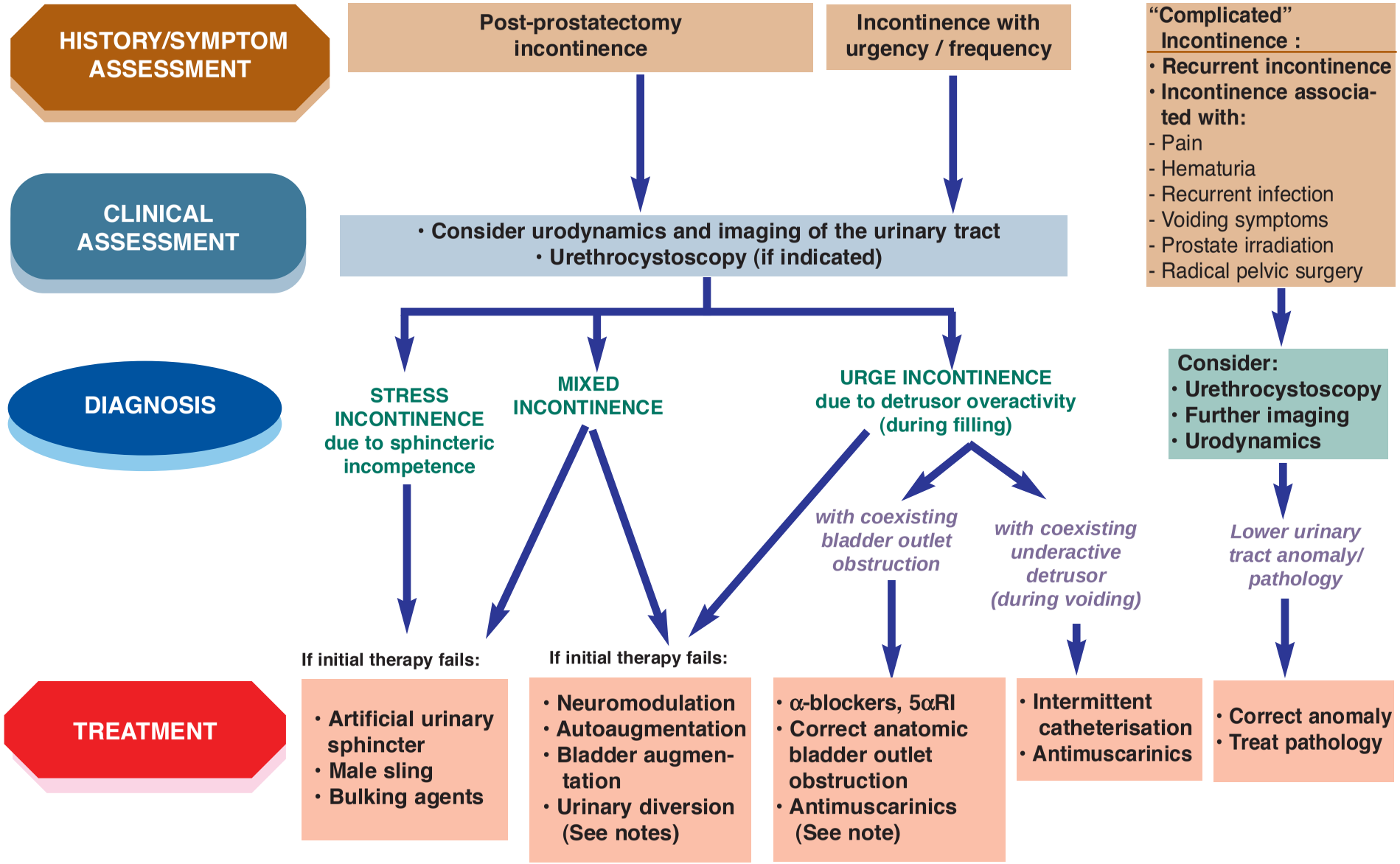
➦ If incontinence is associated with ***bladder outlet obstruction***, then consideration should be given to surgical treatment to relieve obstruction (Grade B/C). α-blockers or 5α reductase inhibitors would be an optional treatment (Grade C/D).

***Note*:** At the time of writing

➦ ***Botulinum toxin*** was showing ***promise*** in the treatment of symptomatic detrusor ***overactivity*** unresponsive to other therapies.

➦ Some evidence was emerging as to the safety of ***antimuscarinics*** for overactive bladder symptoms in ***men,*** chiefly in ***combination with an α-blocker.***

Specialized Management of Urinary Incontinence in Men



III. WOMEN

A. INITIAL MANAGEMENT

1. Initial assessment should identify :

• ***"Complicated" incontinence group.***

In certain parts of the developing world, exceptionally severe incontinence results from childbirth injury and ***urinary fistula***. These devastating injuries affect millions of women in sub-Saharan Africa. These women form a special group of women with ***special needs*** who must be identified at initial assessment, and require ***specialist management.***

Others include those who also have ***pain*** or ***haematuria, recurrent infections***, suspected or proven ***voiding problems, significant pelvic organ prolapse*** or who have persistent incontinence or recurrent incontinence after ***previous surgery***, such as ***pelvic irradiation***, ***radical pelvic surgery*** or ***previous surgery for incontinence***.

• ***Three other main groups*** of patients should be identified by initial assessment.

a) Women with ***stress incontinence*** on physical activity

b) Women with ***urgency***, ***frequency*** and ***urge incontinence*** (overactive bladder- OAB)

c) Those women with ***mixed*** urge and stress incontinence

In women, ***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 contraction, an important step prior to the teaching of pelvic floor muscle training.

2. Treatment

➦ ***Initial treatment*** should include lifestyle interventions, supervised pelvic floor muscle training, supervised bladder training, for women with stress urinary incontinence, urge urinary incontinence or mixed Urinary incontinence. (Grade A).

➦ ***Lifestyle interventions*** include weight reduction, smoking cessation, and dietary/fluid modification (including caffeine). (Grade A).

➦ 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).

➦ Conservative treatment may be augmented with appropiate ***drug therapy. Antimuscarinics*** for OAB, ***dual serotonin and noradrenalin reuptake inhibitors*** * for stress urinary incontinence (Grade A).

➦ Clinicians are likely to wish to ***treat the predominant symptom first*** in women with symptoms of ***mixed incontinence.*** (Grade C).

Some women with coexisting ***significant pelvic organ prolapse*** can be treated by ring pessary.

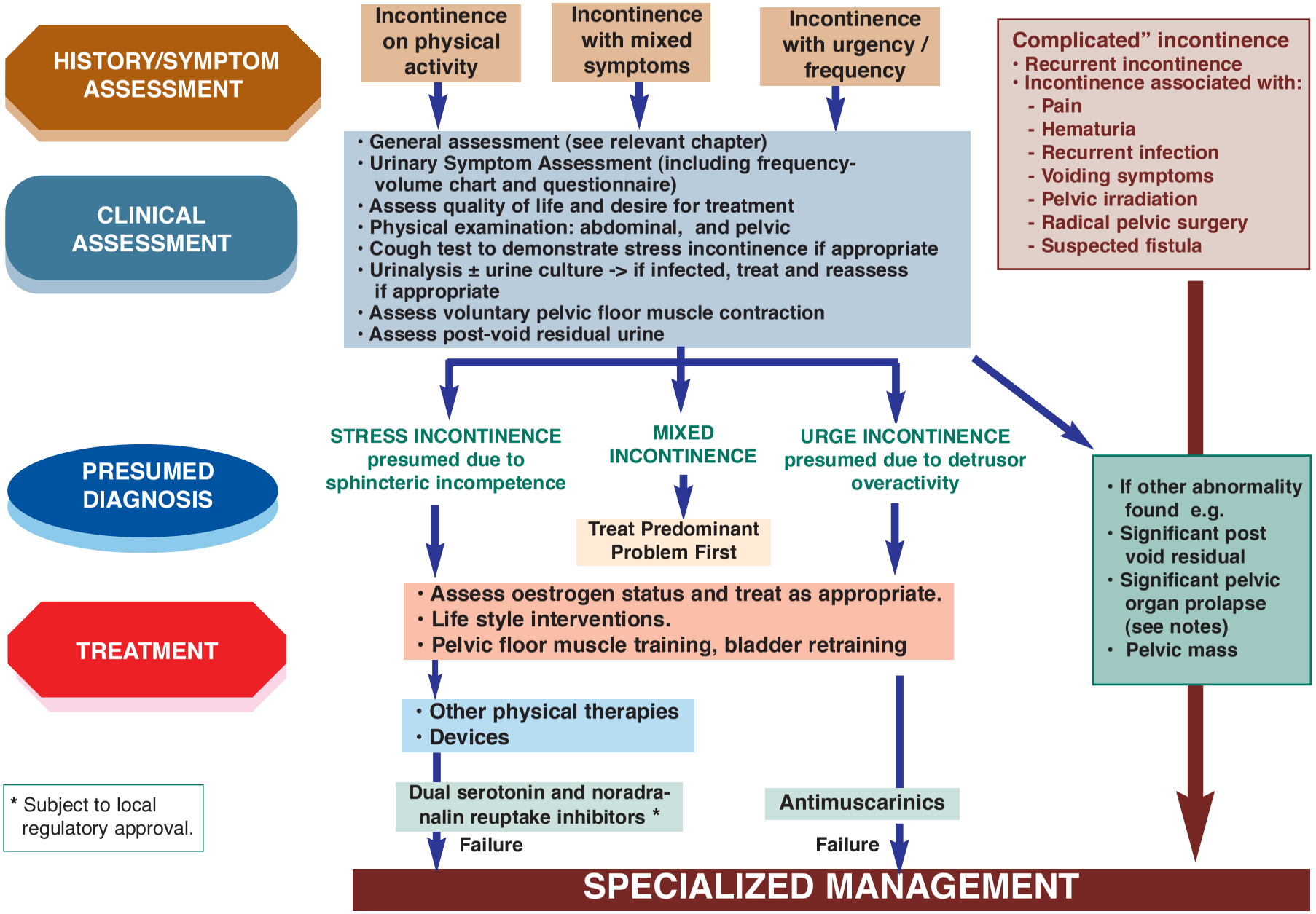
Initial treatment should be ***maintained for 8-12 weeks*** before reassessment and possible specialist referral for further management.

Note: It may be necessary for patients to use ***(in)continence products*** whilst waiting for definitive treatment.

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

** Subject to local regulatory approval.*

Initial Management of Urinary Incontinence in Women



III. WOMEN

B. SPECIALIZED MANAGEMENT

1. Assessement

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,*** because 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 ICS method should be used in research studies. Women with ***co-existing pelvic organ prolapse*** should have their prolapse treated as appropriate

➦ Women in developing countries with fistula due to ***childbirth injuries*** do not require urodynamic assessment and are best treated in specialist fistula units.

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, and bladder neck/sub-urethral sling operations. The correction of symptomatic pelvic organ prolapse may be desirable at the same time.

For patients with ***intrinsic sphincter*** deficiency and limited bladder neck mobility, sling procedures, injectable bulking agents and the artificial urinary sphincter can be considered.

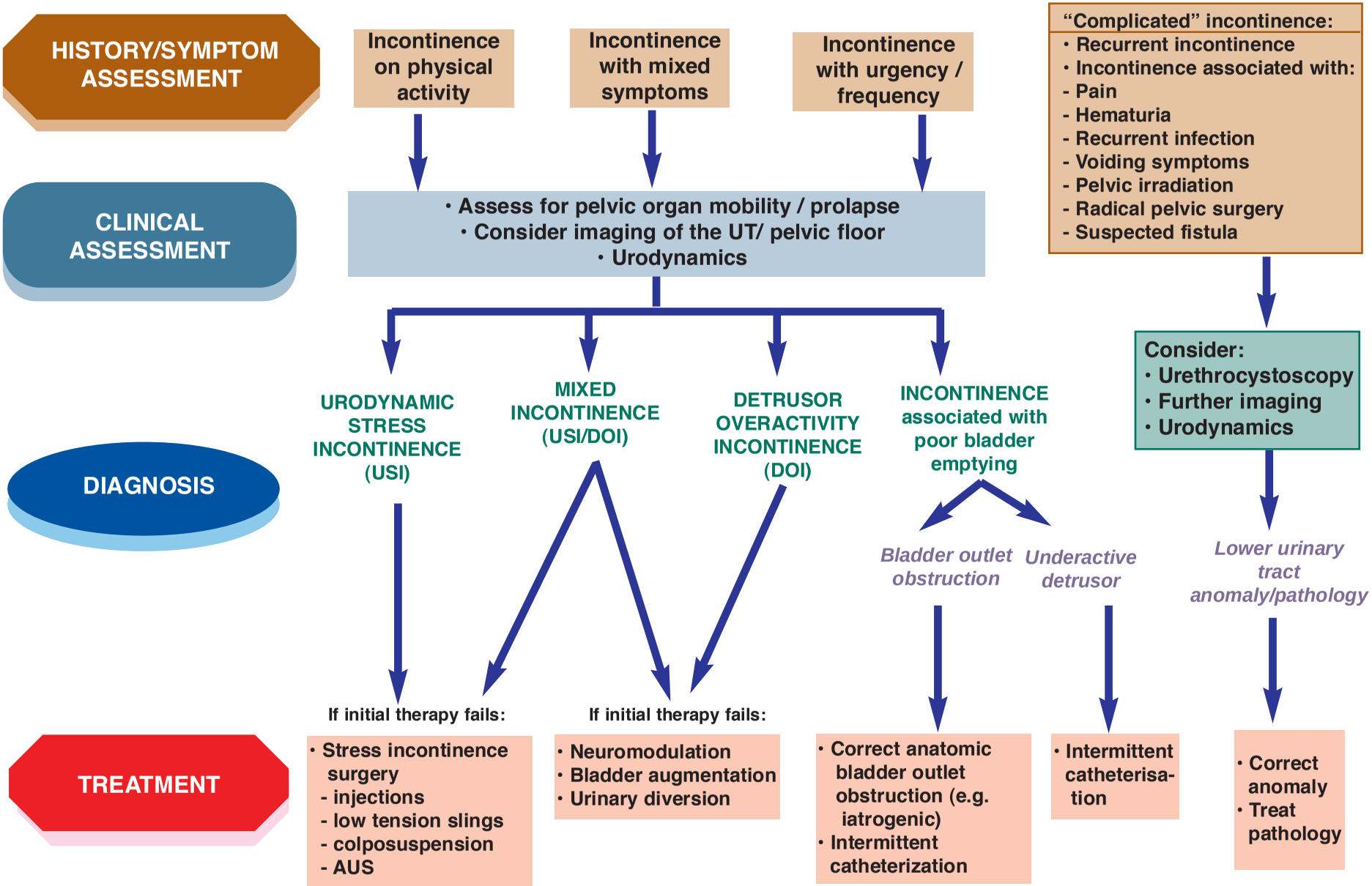
➦ ***Urge incontinence secondary to idiopathic detrusor overactivity*** (overactive bladder) may be treated by neuromodulation or bladder augmentation. Detrusor myectomy is an optional procedure (auto augmentation).

➦ 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.

Note: At the time of writing :

- Botulinum toxin was showing promise in the treatment of symptomatic detrusor overactivity unresponsive to other therapies.

Specialized Management of Urinary Incontinence in Women



IV. URINARY INCONTINENCE IN FRAIL OLDER MEN AND WOMEN

Older persons in general should receive a ***similar range of treatment options*** as younger persons. However, frail older persons ***present different problems*** and challenges compared with other fitter older patient populations. Implicit in the term "frail" is that such individuals may ***neither wish*** nor ***be fit enough*** to be considered for the full range of therapies likely to be offered to healthier or younger persons. The ***extent of investigation*** and ***management*** in frail older people should take into account the ***degree of bother*** to the patient and/or carer, their ***motivation*** and level ***of cooperation*** / compliance as well as the ***overall prognosis*** and ***life expectancy***. At the same time, management effective to meet their goals is possible for many frail persons [C].

I. HISTORY AND SYMPTOM ASSESSMENT

This algorithm applies to the evaluation of urinary incontinence in frail persons. Many of the same principles (especially assessment and treatment of potentially treatable or modifiable conditions and medications that may cause or worsen incontinence) also apply to faecal incontinence (FI) in frail elderly.

Clinical assessment

Treatable or ***potentially reversible*** conditions should be addressed first, followed by a ***physical examination*** targeted to ***comorbidity*** and ***functional assessment***. The "***DIAPPERS***" mnemonic covers some of these conditions. Bowel symptom history, rectal examination, and stool diary should be considered. While most cases of faecal incontinence are multifactoral, the primary goal of assessment is to distinguish overflow faecal incontinence, associated with constipation, from other causes.

While ***post-void residual urine*** (PVR) measurement is recommended because it could influence the choice of treatment, it is recognized that it is often is impractical to obtain a PVR, and in many cases may not change overall management. Impaired bladder emptying may occur in older men and women for various reasons including bladder ***outlet obstruction*** and ***detrusor underactivity.*** Treatment of coexisting conditions may reduce PVR, e.g. treatment of constipation and stopping drugs with antimuscarinic action. There is no specific "cut off" in this population, although PVR over 100 ml (men) and 200ml (women) are considered elevated, and a low PVR does not exclude outlet obstruction.

Clinical diagnosis

Mixed UI (stress UI and urge UI symptoms) is common in older women. A cough stress test is appropriate if the diagnosis is likely to influence treatment choice (e.g., consideration of surgery). Combined urge UI and high PVR (without obstruction), known as detrusor hyperactivity with impaired contractility (DHIC), also is common in the frail elderly.

II. INITIAL MANAGEMENT

Initial treatment should be individualised and influenced by the most likely clinical diagnosis. ***Conservative and behavioural*** therapy for UI and FI include lifestyle changes [C], bladder training in the more fit or alert patient [B], assisted voiding for more disabled patients [C] and prompted voiding for frailer and more cognitively impaired patients [B]. For select, cognitively intact frail persons, pelvic muscle exercises may be considered, but they have not been well studied in this population [C]. A cautious trial of ***anti-muscarinic drugs*** may be considered as an adjunct to conservative treatment of ***urge UI*** [C]. Similarly, ***α-blockers*** may be cautiously considered to assist bladder emptying in frail men with an ***elevated PVR*** [C], and topical oestrogens considered for women with vaginal/urethral atrophy [C]. With all ***drug treatment***, it is important to ***start with a low dose,*** and titrate upwards with regular review of efficacy and tolerability until desired effect or unwanted side effects occur. For ***constipation with overflow FI,*** bowel clear-out with combined suppositories/enemas and laxatives is recommended [C]. Loperamide can be used for FI in the absence of constipation [B].

III. SPECIALIZED MANAGEMENT

If after initial assessment a frail older person with UI is found to have ***other significant factors*** (e.g., pain, haematuria, rectal bleeding, persistent diarrhoea), then referral for ***specialist investigation*** should be considered.

Referral to specialists also may be appropriate for individuals who have not responded adequately to initial management and if further investigation/treatment is desirable which could improve continence and quality of life.

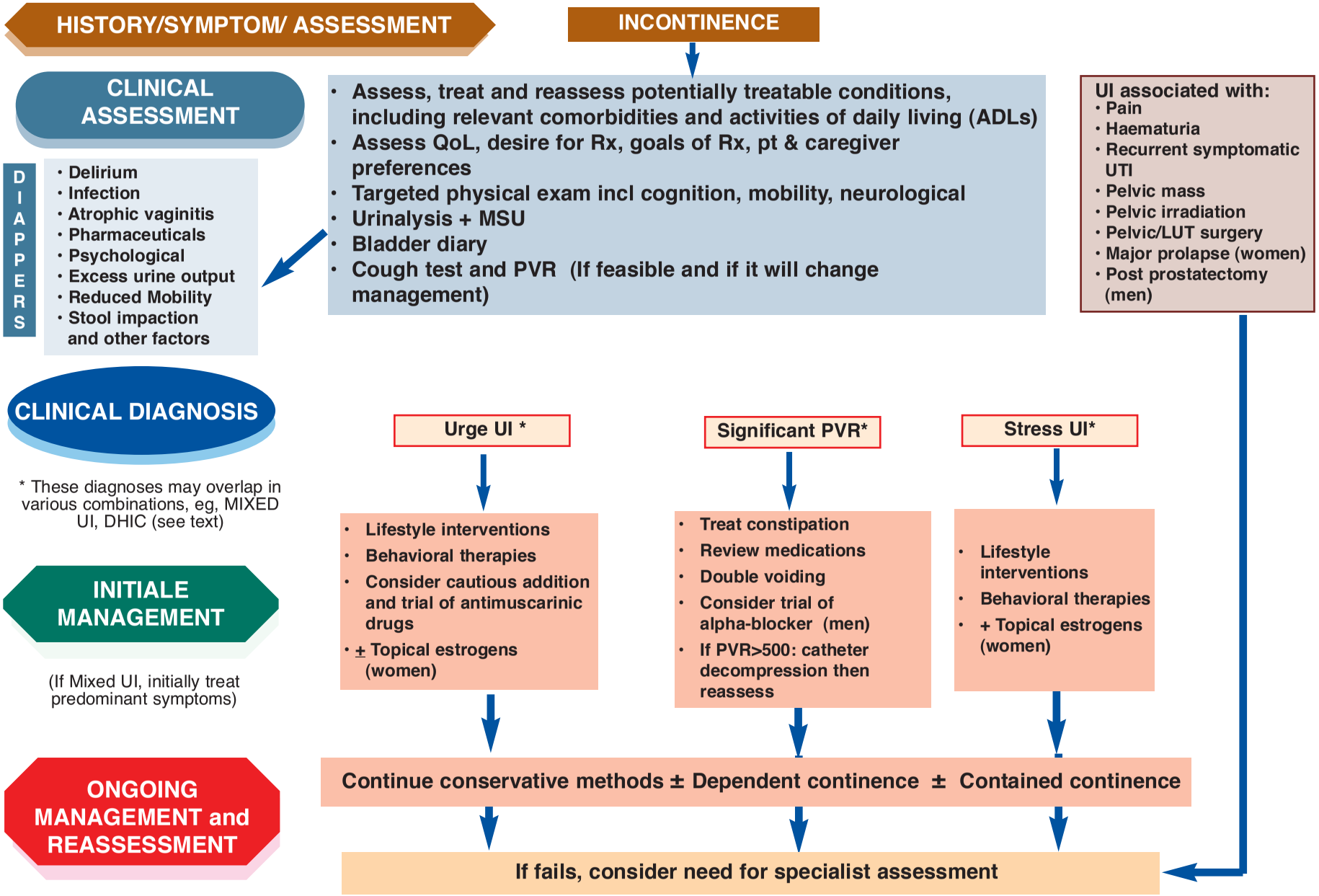
Age per se is not a contraindication to incontinence surgery [C], but before surgery:

- All modifiable comorbidity should be addressed [C];
- An adequate trial of conservative therapy should be followed by reassessment of the need for surgery [C];
- Urodynamic testing should be done because clinical diagnosis may be inaccurate [A]; and
- Preoperative assessment plus careful perioperative care is essential to minimise geriatric complications such as delirium, infection, dehydration and falls [A].

IV. ONGOING MANAGEMENT AND REASSESSMENT

If the patient cannot achieve ***Independent Continence*** (dry, not dependent on ongoing treatment) or ***Dependent Continence*** (dry with assistance, behavioral treatment, and/or medications) then "***Contained Incontinence***" (incontinence contained with use of appropriate aids and/or appliances) should be the treatment goal. Importantly, optimal care can usually be achieved by a combination of the above approaches [C].

MANAGEMENT OF URINARY INCONTINENCE IN FRAIL OLDER PERSONS



V. NEUROGENIC INCONTINENCE

A. INITIAL MANAGEMENT

1. Initial assessment

In assessing patients with incontinence due to neurogenic vesico-urethral dysfunction the management depends on an ***understanding of the likely mechanisms producing incontinence,*** which in turn depends on the ***site of the nervous system abnormality.*** Therefore, neurogenic incontinence patients can be divided as following:

Two groups of patients, (a) with peripheral nerve lesions (b) and the other with central lesions below the pons, should be managed by the specialist with a particular interest / training in neurological lower urinary tract dysfunction.

a) Peripheral lesions,

Including ***peripheral nerve lesions***, for example denervation that occurs after major pelvic surgery such as for cancer of the rectum or cervix. Also included are those lesions involving the ***lowest part of the spinal cord*** (conus/cauda equina lesions), eg. lumbar disc prolapse.

b) Central lesions below the pons

Suprasacral infrapontine spinal cord lesions, eg. traumatic spinal cord lesions, should be treated according to the results of urodynamic studies: the initial treatment should be maintained for 8-12 weeks, before reassessment and possible referral to the specialist.

c) Central lesions above the pons

Suprapontine central lesions include, for example, cerebro-vascular accident, stroke, Parkinson´s Disease and multiple sclerosis

➦ ***During initial assessment***

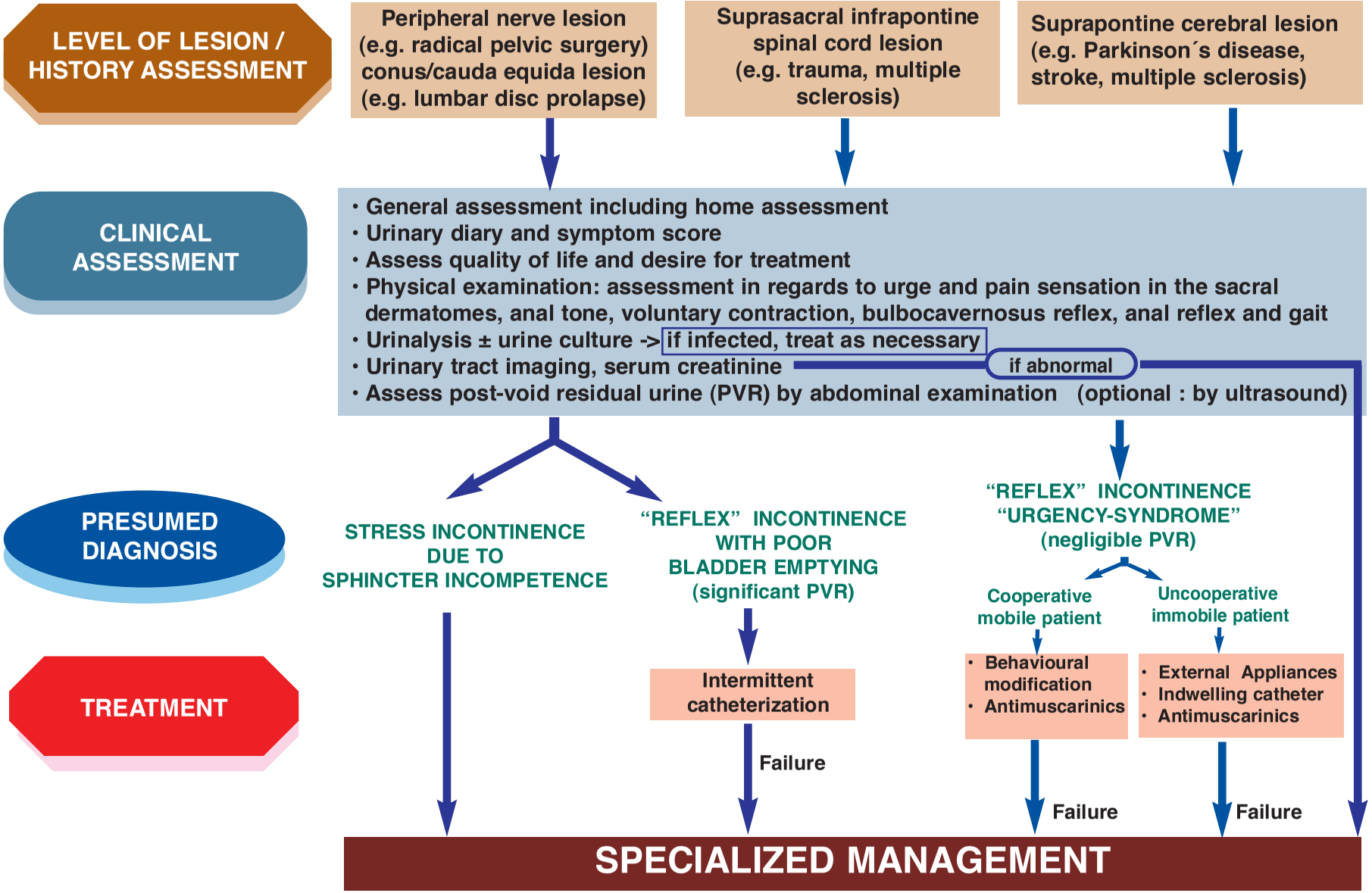
- ***physical examination*** is important in helping to distinguish these 3 groups and a ***simple neurological examination*** should be a routine.
- An estimate of ***post-void residual PVR*** is highly recommended (preferably by ultrasound). If a significant PVR is found, then upper tract imaging is required.

2. Treatment

Initial treatment is suitable for the large group of patients with incontinence due to suprapontine conditions like strokes. At initial assessment, these patients need to be assessed for their degree of ***mobility*** and their ***ability to cooperate,*** as these two factors will determine which therapies are possible.

The treatments recommended are: behavioral (including timed voiding) and ***bladder-relaxant drugs*** for presumed detrusor overactivity. ***Appliances*** or catheters may be needed in patients who are immobile or cannot cooperate.

Initial Management of Neurogenic Urinary Incontinence



V. NEUROGENIC INCONTINENCE

B. SPECIALIZED MANAGEMENT

1. Assessment

Most patients with ***peripheral lesion or central lesions below the pons*** require specialized assessment and management.

Urodynamic studies are highly recommended in these patients to establish both bladder and urethral function. ***Upper urinary tract imaging*** is needed in most patients and more detailed renal imaging or ***renal function studies*** will be desirable in some.

Urodynamics will define the filling function, with detrusor overactivity and neurogenic stress incontinence secondary to denervation being the most common abnormalities. During voiding, sphincter overactivity and detrusor underactivity are both likely to lead to persistent failure to empty.

2. Treatment

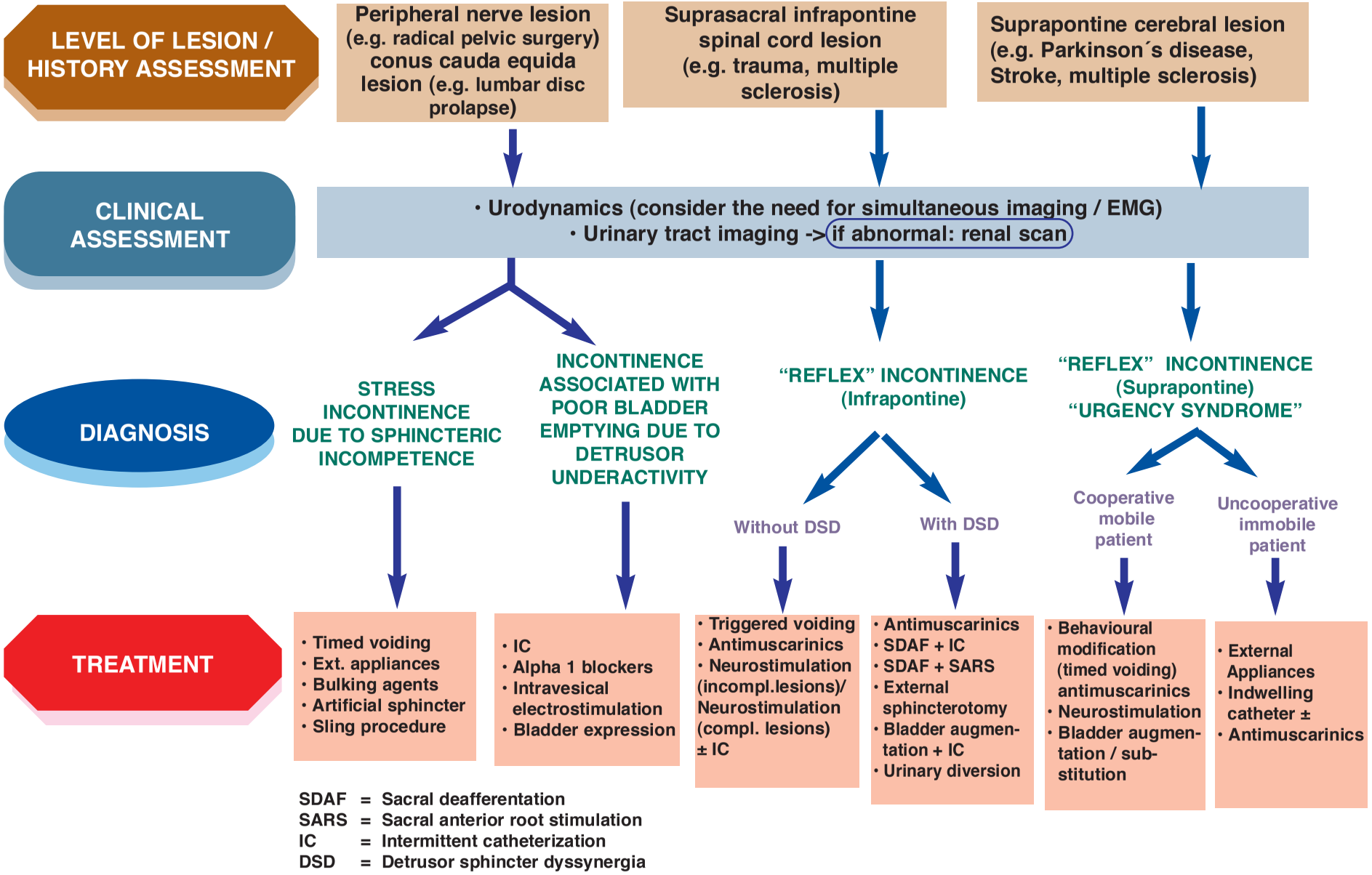
Management is straightforward in concept although the therapeutic options are extensive. The algorithm details the recommended options.

For ***sphincter incompetence*** the recommended options are the artificial urinary sphincter, sling procedures (in women) and injectables in selected patients.

Combinations of abnormalities are common e.g. in meningomyelocele. Incontinence may be due to a combination of detrusor overactivity and neurogenic stress incontinence because of sphincter underactivity. Residual urine may be caused by detrusor underactivity as well as functional sphincter obstruction in the same patient. Each element of vesicourethral dysfunction needs to be dealt with. However, it must be remembered that ***preservation of upper tract function is of paramount importance.***

For detailed discussion on treatment, please read the relevant chapter from the consultation.

Specialized Management of Neurogenic Urinary Incontinence



SDAF = Sacral deafferentation
SARS = Sacral anterior root stimulation
IC = Intermittent catheterization
DSD = Detrusor sphincter dyssynergia

VI. Painful Bladder Syndrome, Including IC (PBS/IC)

1. HISTORY / INITIAL ASSESSMENT

Men or women with bladder pain, with or without a sensation of urgency, often with urinary frequency and nocturia (especially if drinking a normal amount of fluids) and no abnormal gynecologic findings to explain the symptoms should be evaluated for PBS/IC. The initial assessment consists of a frequency/volume chart, focused physical exam, urinalysis, and urine culture. Cytology and cystoscopy are recommended if clinically indicated.

Patients with infection should be treated and reassessed. Those with recurrent urinary infection, abnormal urinary cytology, and haematuria are evaluated with appropriate imaging and endoscopic procedures, and only if findings are unable to explain the symptoms are they diagnosed with PBS/IC.

Grade of recommendation: C

2. INITIAL TREATMENT

Patient education, dietary manipulation, nonprescription analgesics, and pelvic floor relaxation techniques comprise the initial management of PBS/IC. When these fail, or symptoms are severe and conservative management unlikely to succeed, oral medication or intravesical treatment can be prescribed.
Grade of recommendation: C

3. 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 distention and possible bladder biopsy under anesthesia. Findings of bladder overactivity suggest a trial of antimuscarinic therapy. Findings of a Hunner's ulcer suggest therapy with transurethral fulguration or resection of the ulcer. Distention itself can have therapeutic benefit in up to one-third of patients, though benefits rarely persist for longer than a few months.

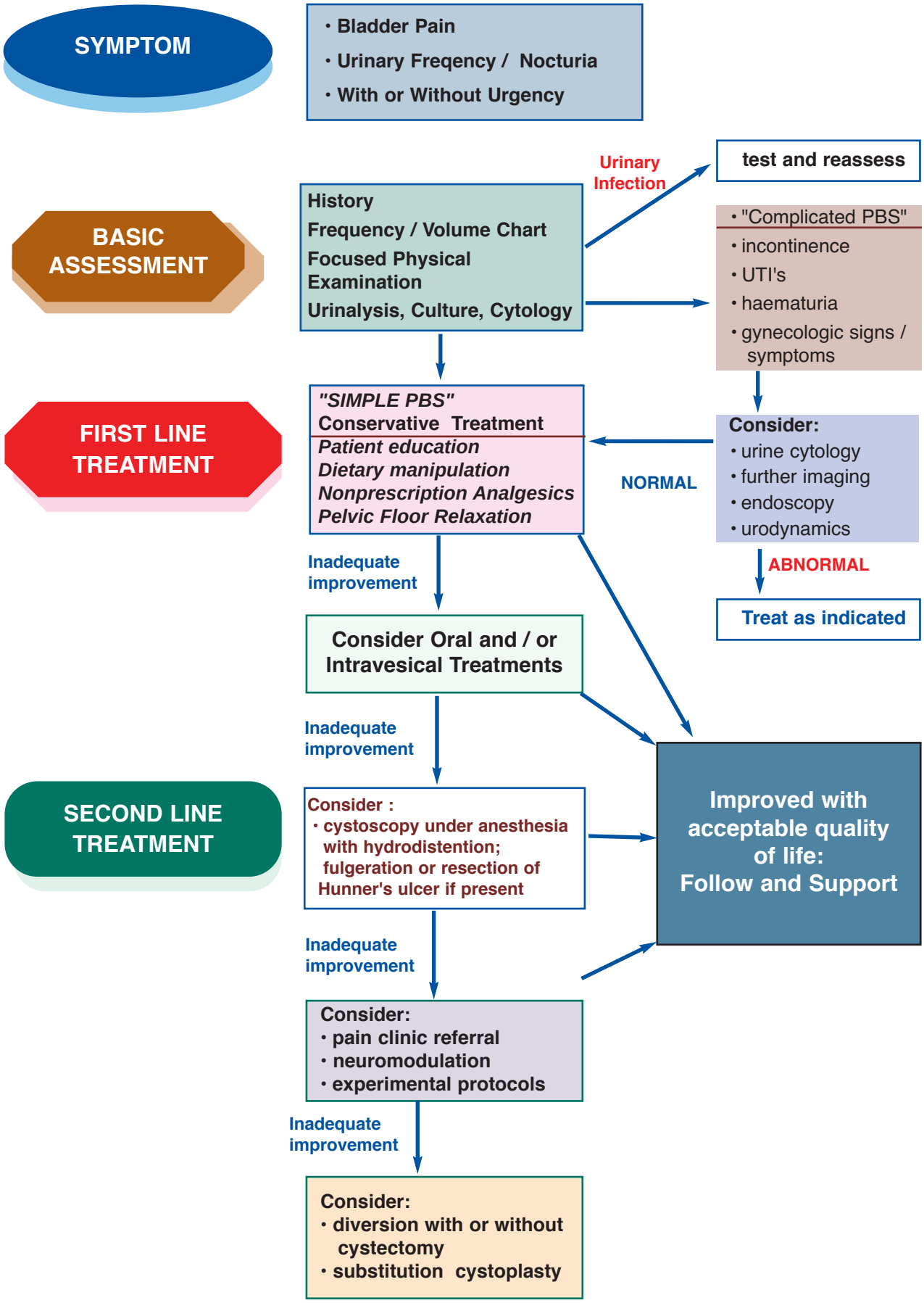
Grade of recommendation: C

4. REFRACTORY PBS/IC

Those patients with persistent, unacceptable symptoms despite oral and/or intravesical therapy are candidates for more aggressive modalities. These might include neuromodulation, pain clinic consultation, narcotic analgesia, and/or experimental treatment protocols. The last step in treatment is usually some type of surgical intervention aimed at increasing the functional capacity of the bladder or diverting the urine stream. Augmentation (substitution cystoplasty) and urinary diversion with or without cystectomy have been used as a last resort with good results in selected patients.

Grade of recommendation: C

PAINFUL BLADDER SYNDROME



VII. PELVIC ORGAN PROLAPSE

Introduction

Pelvic organ prolapse includes ***urogenital*** and ***rectal prolapse*** and may or may not be associated with ***urinary*** or ***faecal incontinence.*** In general, treatment for urogenital prolapse should be reserved for ***symptomatic patients.*** However, in select circumstances, ***asymptomatic POP*** may require treatment, especially rectal prolapse that can progress and cause faecal incontinence.

1. Assessment

Symptom enquiry will reveal a range of symptoms with varying components of prolapse and incontinence symptoms.

- Need for prolapse replacement to improve urinary symptoms, or if replacement leads to symptoms, such as incontinence, this is significant.
- Need for prolapse replacement in order to micturate or defaecate is important.

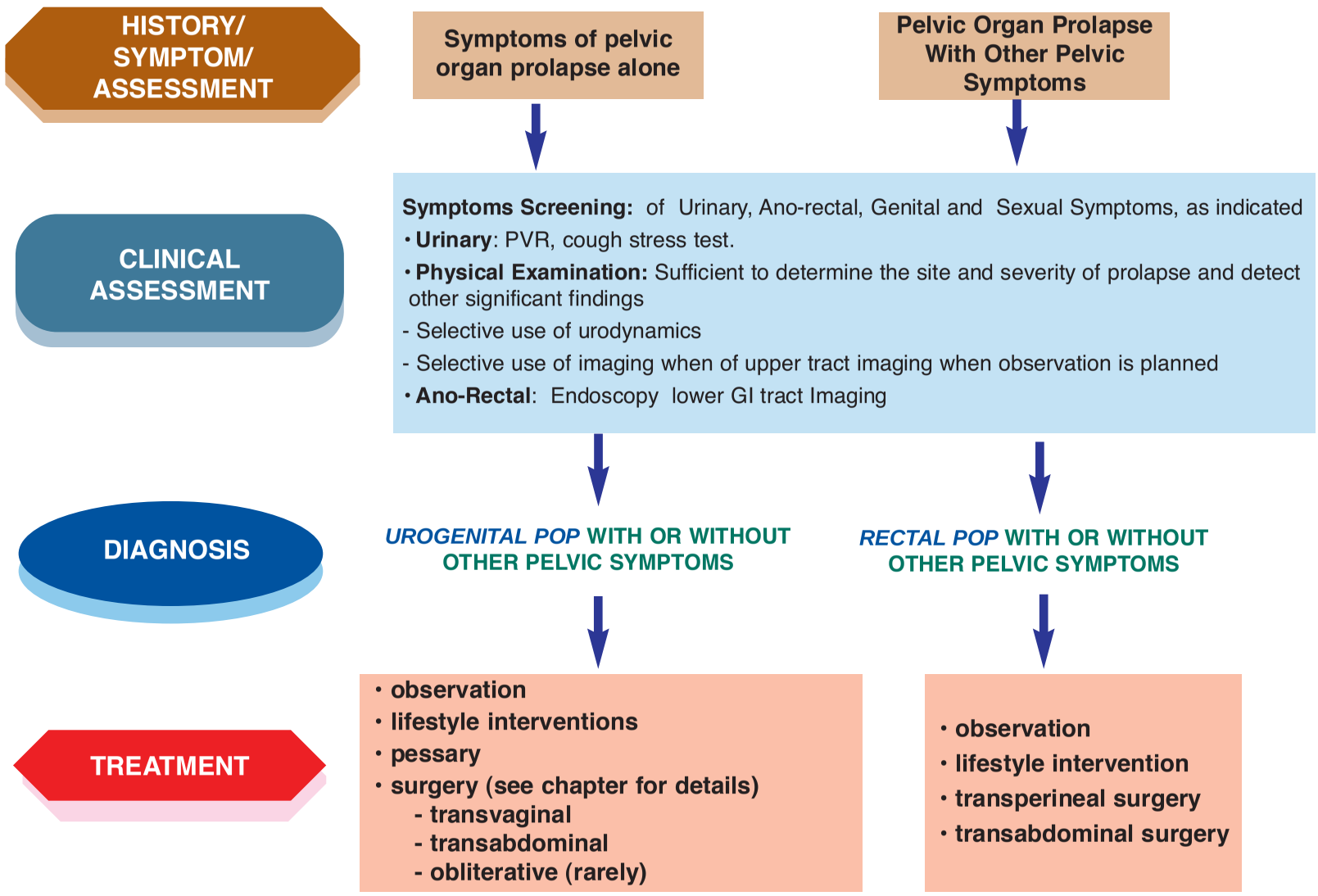
Physical examination should define :

- The ***type*** and ***stage*** of prolapse : examining the women standing and straining is desirable
- ***Associated abnormalities*** such as pelvic mass, or ulcerations or sores on exposed vaginal/cervical tissues, which may cause bleeding or copious discharge.
- ***Measurement of post void residual*** (PVR) is useful. If there is an anterior vaginal wall prolapse beyond the hymen, then the urethra may be distorted (kinked) leading to a significant PVR in which case imaging of the upper urinary tract is indicated particularly when conservative management is planned. ***Stress incontinence test,*** if positive, is meaningful unless the post void residual urine is large (eg >500ml)
- ***Rectal prolapse*** is best detected when the patient is straining whilst sitting on a toilet.

2. Treatment

- When ***observation*** of urogenital prolapse is medically safe and selected by the patient, ***PFMT*** may be effective in preventing prolapse from worsening (Grade C). In addition, ***conservative treatment*** (including lifestyle interventions, physical therapies and the use of pessaries) appears safe and is satisfactory for selected patients (grade D). When rings and pessaries are used for treatment, regular follow-up and care is necessary. Local oestrogen therapy may be helpful in preventing and treating vaginal ulceration.
- ***Reconstructive surgical treatment*** of urogenital pelvic organ prolapse should aim to restore normal anatomy as far as it is possible. The specific procedure (or group of procedures) should be selected after an assessment of concurrent pelvic symptoms, the necessity for concurrent pelvic surgery and the risk/benefit for the individual woman.
- ***Obliterative vaginal surgery*** is reserved for highly selected women who agree to permanent vaginal closure.
- ***Treatment of rectal prolapse*** is indicated in most cases to treat current and prevent development of faecal incontinence. Abdominal repairs provide the lowest recurrence rate, although perineal repairs may be warranted in patients with significant comorbidities.
- For the choice and details of surgical technique please see chapter text.

Management of Pelvic Organ Prolapse (POP, including rectal Prolapse)



VIII. Faecal Incontinence

1. Initial assessment

Patients present with a variety of symptom complexes.

- ***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: urge 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 urge and passive FI may be exacerbated in the presence of loose stool.

2. 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.

3. Investigations

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

4. Specialised management

➦***Patients*** with a ***clearly disrupted external anal sphincter*** as seen on anal ultrasound often benefit from surgical sphincter repair (Grade B).

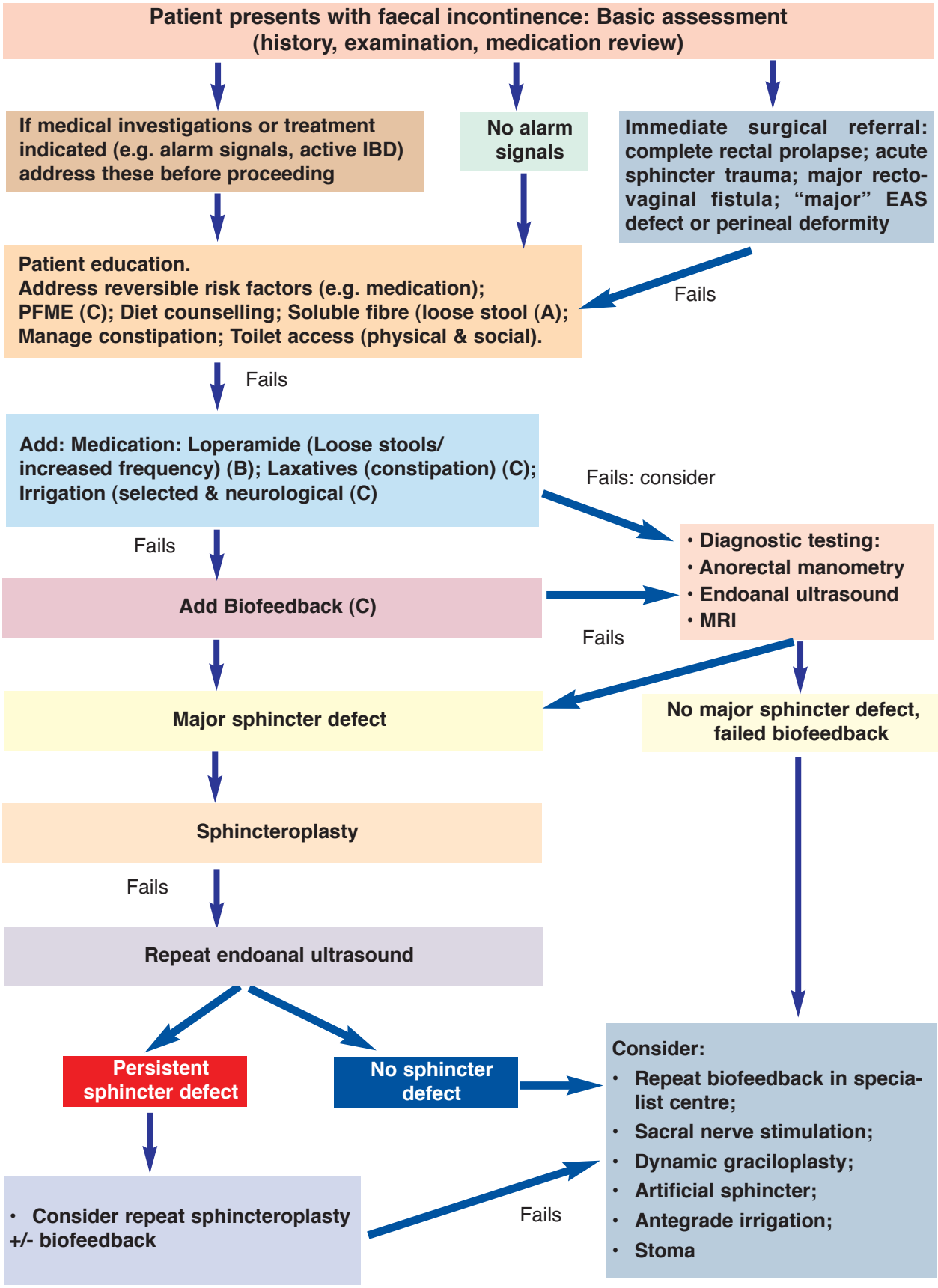
➦ ***"Biofeedback"*** therapy is usually a package of measures designed to enhance the patient's awareness of anorectal function, improve sphincter function and coordination and retrain the bowel habit (Grade C).

➦ Products to manage ***severe faecal incontinence*** are ineffective in most cases. Severe faecal incontinence which ***fails to respond*** to management may lead to consideration of a ***novel surgical approach*** such as formation or implantation of a neosphincter, sacral nerve stimulation, or formation of a colostomy (Grade D).

5. Special patient groups

The main chapter (refer to the book) also gives algorithms for the management of third degree obstetric tears, soiling in children and faecal incontinence in older adults.

Management of Faecal Incontinence in Adults



4. RECOMMENDATIONS FOR CONTINENCE PROMOTION: PREVENTION, EDUCATION AND ORGANISATION

Continence promotion involves informing and educating both the public and health care professionals that incontinence (both urinary and bowel) is not inevitable or shameful, but is treatable or at least manageable. Progress has been made in the promotion of continence awareness through primary prevention, education of professionals and consumers, organization of the delivery of care, and public access to information on a worldwide basis. However, incontinence needs to be identified as a separate issue on the world health care agenda. All governments are encouraged to take an interest in and to support the development of continence services by actively developing policies and providing adequate funding. These should include a primary prevention strategy.

1. Primary Prevention

Primary prevention studies should not be limited to individual interventions, but also test the impact of population-based public health strategies **(Grade C)**

Pelvic floor muscle training (PFMT) should be a standard component of prenatal and postpartum care **(Grade B)**

Randomised controlled trials (RCTs) should be conducted to test the preventive effect of PFMT for men post-prostatectomy **(Grade B)**

Further investigation is warranted to assess the efficacy of PFMT and bladder training (BT) for primary prevention of urinary incontinence (UI) in older adults **(Grade B)**

2. Consumer and Professional Education

There is a need for rigorously evaluated continence education programmes which adhere to defined minimum standards for continence specialists, generalists and the public/consumer, utilizing web-based and distance learning techniques alongside traditional methods. (**Grade D**)

- Compulsory inclusion of incontinence in the basic curriculum (physicians, nurses, physiotherapists and allied health professionals). Incontinence should be identified, planned and preferably taught as a separate topic
- Specific education programmes adhering to approved standards should be reported to a recognized central body.
- Public education programmes should be independently evaluated

There is a need for research on the most effective means to educate the public and professional groups on continence issues. (**Grade D**)

- Translation of research into improved clinical practice and identification of methods by which this happens.
- Mechanisms for increasing professional motivation to acquire education and improve performance.
- Effectiveness and impact of consumer education initiatives

There is a need for collaboration at the national, international and practice level to ensure that efforts are not duplicated or in conflict. Information banks of continence education material should be shared. This could be facilitated by the ICS. (**Grade D**)

3. Organization

a) Delivery of Continence Care and Services

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 for funding, not to be linked to any one patient group (e.g. elderly or disabled), and not as an optional service. (**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 clinicians. Specialist consultation should generally be reserved for those patients where appropriate conservative options have failed, or for specified indications. (**Grade D**)

There is a need for research on outcomes, not just the process of service delivery. These outcomes must be patient-focused outcomes, evaluate the outcomes of all sufferers who present for care using validated audit tools/outcome measures and assess the values of services in the long-term by the undertaking of longitudinal studies. (**Grade D**)

There is a need for cost-effectiveness studies of the services currently provided. (**Grade D**)

b) National Organisation

There is a need for the formation of a worldwide resource centre, preferably through the ICS. The centre should update educational materials, verify best practice experiences or activities while ensuring efficient sharing and optimum utilisation of resources for promoting continence. This is especially important for countries where there is little development of services, education and awareness. A regular update via survey is useful for this purpose. **(Grade D)**

Continence organisations should establish long-term governmental, as well as, commercial collaboration, particularly in terms of continuing support and funding for mutual benefits. Agenda and funding priorities must be for the benefit of consumers and the general public. **(Grade D)**

It is critical that Continence organisations undergo independent evaluations. This evaluation process should include a measure of cost-effectiveness for each continence promotion activity or programme. **(Grade D)**

5. Recommendations for further basic science research

1. To place a greater emphasis on the integrated systems physiology and systems pharmacology of the lower urinary tract (LUT), lower gastrointestinal tract (LGIT) and genital tract (GT).

2. To generate and characterise good animal models to study the pathophysiology of the LUT, LGIT and GT

3. To identify targeted drug models, using human tissue from well-characterised patient groups and tissue from animal models.

4. To generate a greater understanding of structure-function relationships of all the tissues of the LUT, LGIT and GT

These should include:

- Smooth muscle function from: bladder dome, trigone, bladder neck and vesico-urethral junction; urethra; prostate; rectum and anus; and genital tract such as vaginal wall.
- Striated muscle of intraurethral sphincter, external anal sphincter and pelvic floor
- Tissue interactions, such as between epithelium and stroma.
- Their functional innervation.

5. There should be a greater promotion of basic research into LUT, LGIT and GT function through:

- Increased collaboration between basic, medical and surgical sciences
- Greater representation of medical and surgical scientists on research advisory boards of major funding agencies.
- Identification of multidisciplinary research strategies to investigate LUT, LGIT and GT pathophysiology
- Organisation of structured, multidisciplinary research meetings on topics relevant to understanding the pathophysiology of the LUT, LGIT and GT.
- The establishment of research centres of excellence.

6. Recommendations for further Research in Epidemiology

It is recommended that more sustained research is carried out on the measurement of urinary incontinence, its types and severity to further our understanding of the subject. Longitudinal study designs are needed to estimate incidence and remission of UI, describe the course of the condition, its different forms, and to investigate its risk factors and possible protective factors.

As there is little knowledge regarding the prevalence, incidence, and other epidemiological data in developing countries, it is recommended that research should be encouraged, and tailored to the cultural, economic and social environment of the population under study.

Crude prevalence studies (descriptive epidemiology) from USA and Europe are abundant, and further studies should be done only with recommended and validated questionnaires or in order to combine prevalence data in studies of co-factors and predictors for Urinary Incontinence (analytical epidemiology). Control for confounders, stratification, and multivariate techniques should be increasingly used because of the need for more advanced epidemiological analyses of risk factors and comorbidity. Strength of associations should be determined by relative risks and odds ratios, and confidence limits should be given.

There is a need for more epidemiological research in all areas of faecal incontinence and pelvic organ prolapse, covering prevalence, incidence, and risk factors. Uniform definitions of Faecal Incontinence and Pelvic Organ Prolapse should be used in studies, and there should be a move toward the standardisation of measurement instruments in community surveys that can be used worldwide.

7. Recommendations for 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 menopausel, 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) 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 considertion 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 Painful Bladder Syndromes (including Intersitial Cystitus):

- The patient population for PBS trials must be carefully defined. When appropriate, relaxed entry criteria should be used to reflect the full spectrum of the PBS patient population

- The primary endpoint of PBS 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.

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 50 250 275 200 150 BED 2.30 5.30 7.30 7.30 9.30 WC 11.00 3.00 6.00 9.30 11.45 12 270 250				1
17th	UP 260 210 230 150 220 250 50 BED 275 200 7.30 10.00 1.00 3.30 7.30 9.30 11 11 1.30 4.00				0
18th	UP 300 150 200 275 100 150 175 125 BED 400 7.00 9.00 11.15 2.15 4.15 6.30 8.00 10.30 11 4.30				6
19th	UP 250 300 310 75 200 50 250 BED 260 220 200 7.30 10.30 2.15 3.00 W 5.50 9.00 10.15 10.30 12.00 2.30 5.00				0
20th	UP 150 250 275 175 200 250 100 100 BED 350 7.30 10.30 2.00 4.30 7.15 9.45 11.00 0.45 1 5.00				0
21st	UP 200 100 175 75 200 220 300 BED 350 300 8 9.00 WC 11.00 11.45 2.30 5.30 7.30 10 (200) 3.30 6.00				1
22nd	UP 150 220 150 290 300 110 150 BED 350 7.30 9.30 11.00 2.15 5.00 7.00 WC 9.30 11 (200) 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					
GOT UP	7.15	200	0	–		800 – 2 cups coffee 400mls.
	7.30	100	+	–		
	11.30	275	++	W	wet pants	11.00 can coke
	12:00 noon					
	12.30	150	+	–		12.30 1 glass water – 250mls
	3.00	220	0	–		3.30
	3.45	–	–	W	sneezed 3 times	cup tea – 200ml
	5.30	175	0	–		
	6:00 pm					6.30
	7.45	200	–	–		glass water – 250mls.
	9.30	175	–	–		8.00 glass wine – 100 mls
BED	10.30	100	–	–		10.00 mug cocoa – 250 ml
	12:00 midnight					
	3.30	250	–	–		

Annex 2 : International Consultation on Incontinence Questionnaire (ICIQ) - ICIQ UI SF (Short-form)

ICIQ Introduction

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.

The first module to be developed was the ICIQ Short Form Questionnaire for urinary incontinence: the ICIQ-SF. The ICIQ-SF has now been fully validated and published1. Given the intention to produce an internationally applicable questionnaire, requests were made for translations of the ICIQ-SF at an early stage, for which the Advisory Board developed a protocol for the production of translations of its modules. The ICIQ-SF has been translated into 30 languages to date.

In addition to the ICIQ-SF, ten modules have been adopted which are direct (unchanged) derivations from already published questionnaires. (Table below)

WWW.ICIQ.net will be used to provide the validation status of the modules under development for urinary symptoms, bowel symptoms and vaginal symptoms.

Table 1. Fully validated ICIQ modules derived from previously developed questionnaires

ICIQ Modules	Derived from	For use in
ICIQ-MLUTS	ICS maleSF [4]	Men
ICIQ-MLUTS-LF	ICS male[2]	Men
ICIQ-FLUTS	BFLUTS SF [5]	Women
ICIQ-FLUTS-LF	BFLUTS [3]	Women
ICIQ-LUTSqol	KHQ [6]	Men and women
ICIQ-Nqol	N-QOL [7]	Men **and women**
ICIQ-OABqol	OABq [8]	Men and women
ICIQ-MLUTSsex	ICS male [2]	Men
ICIQ-FLUTSsex	BFLUTS [3]	Women
ICIQ-UIqol	I-QOL [9]	Men and women

**indicates a validated module*

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Annex 2 : International Consultation on Incontinence Questionnaire (ICIQ) - ICIQ UI SF (Short-form)

Initial number ☐☐ ☐☐ ☐☐☐

Today's date: DAY ☐☐ MONTH ☐☐ YEAR ☐☐

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.