

2002

2nd International Consultation on Incontinence

Organised by
International
Consultation on
Urological Diseases
(ICUD)

NGO in official
collaboration with
WHO

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International
Continence
Society
(ICS)

*In collaboration
with*

AUA

CAU

EAU

FIGO

SIU

UAA

and other medical
associations

Recommendations of the
International Scientific Committee :

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



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and *The Members of the Committees.*

INTRODUCTION

The 2nd International Consultation on Urinary Incontinence met from July 1-3, 2001 in Paris.

Organised by the International Continence Society (ICS) and the International Consultation on Urological Diseases (I.C.U.D.), NGO in official collaboration with the World Health Organisation (WHO), in order to *develop recommendations* for the diagnostic evaluation and treatment of *urinary incontinence, faecal incontinence and pelvic organ prolapse.*

The recommendations are evidence based on a *thorough review of the available literature* and the *global subjective opinion of recognised experts* serving on focused subcommittees. The individual *subcommittee 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 2002 will be *periodically re-evaluated* in the light of clinical experience and technological progress and research.

I. Definitions

The consultation agreed to use the new International Continence Society definitions (ICS) for lower urinary tract dysfunction (LUTD) including incontinence. These definitions will appear 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. Overactive Detrusor Function

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* and *neurogenic detrusor overactivity*.

Idiopathic Detrusor Overactivity is defined as overactivity when there is no defined cause.

Neurogenic Detrusor Overactivity is defined as overactivity due to a relevant neurological condition.

2. Urinary Incontinence

Urinary incontinence is *involuntary loss of urine* that is a social or hygienic problem.

Incontinence may be further defined according to the patient's symptoms:

- *Urge 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.
- *Nocturnal Enuresis* is any involuntary loss of urine occurring during sleep.
- *Post-micturition dribble* and *continuous urinary leakage* denotes other symptomatic forms of incontinence.

The symptoms and signs of incontinence do not give a definite diagnosis and the *cause* of inconti-

nence can only be absolutely determined by *urodynamic studies* (UDS). UDS allow the disease processes to be defined, for example *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

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II. Evaluation of Incontinence

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 in the evaluation of most patients. However, such tests may be helpful in selected patients who do not fulfil the criteria for the standard (usual) patients.

This section primarily discusses the Evaluation of *urinary incontinence* with or without *Pelvic Organ Prolapse* (POP). The evaluation of *Faecal Incontinence* is summarized in the Algorithm VIII in this document.

I. HIGHLY RECOMMENDED TESTS DURING INITIAL EVALUATION

The **main recommendations** for this consultation have been abstracted from the **extensive work** of the 25 sub-committees of the **2nd International Consultation on Incontinence (ICI)**. Each sub-committee has written a report that reviews and evaluates the published scientific work in each field of interest. 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, pelvic organ prolapse, neurogenic patients, the frail older person and faecal incontinence.

The **initial evaluation** should be done on every patient presenting with incontinence to a health care professional.

1. History and General Assessment

Management of a disease such as incontinence requires caregivers to **assess** the sufferer as a «**whole individual**». Many factors may influence a particular individual's symptoms, some may cause incontinence, and other factors will determine the success of treatment. General assessment has a number of **important components** :

- **Nature and duration** of genitourinary and lower alimentary tract symptoms.
- **Previous surgical procedures** (in particular as they affect the genitourinary tract).
- **Environmental issues**: these may include the social and cultural environment.
- **Patient mobility**: individuals who have compromised mobility may need to be managed differently
- **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.
- **Disease status**: coexisting diseases may have a profound effect on incontinence 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 the treatment is in fact causing or worsening the patient's condition.
- **Sexual function**: at present little information exists on the impact of incontinence: this aspect of the patients life should be assessed where appropriate (depending on age).

- **Bowel function** faecal incontinence is one of the subjects of this consultation and bowel function has considerable influence on urinary problems. Certain groups of urinary incontinent patients may have co-existing faecal incontinence, and/or constipation which may trouble them as much or even more than their urinary leakage.
- **Assess patients goals or expectations of treatment**
- **Assess patient's fitness** for possible *surgical procedures*

2. Assessment of Symptoms

A full history should be taken including:

- the **frequency** of incontinence
- the **perceived quantity** of leakage
- the **perceived impact** of leakage on every day life
- **Pelvic organ prolapse (POP)** symptoms

3. Physical Examination

There are a number of essential components in the examination of sufferers with incontinence and/or pelvic organ prolapse (POP).

- **Abdominal examination** after voiding in an effort to detect a palpable bladder.
- **Perineal examination** to assess sensation.
- **Rectal examination** to assess anal tone, pelvic floor function, the consistency of stool, and in the male, the prostate gland.
- **External genitalia** : including skin condition
- **Vaginal examination** to assess pelvic organ prolapse and with patient bearing down, pelvic floor function and oestrogen status.
- **Stress test for urinary incontinence** - patients with suspected stress incontinence should be asked to cough repeatedly and strain with a full bladder.

4. Urinalysis

As **urinary infection** is a readily detected and easily treatable cause of LUTS, urine testing is highly recommended. Testing may range from examination of urine in a **clear glass container**, through **dipstick** testing, to **urine microscopy**.

5. Tests before Further Investigation/ Treatment

a) Qualification of 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 is part of the initial assessment as the result is likely to influence management for example, in neurological patients.

PVR may be most accurately assessed by ultrasound. This will simultaneously provide information about bladder capacity and bladder wall changes, and can detect the presence of bladder stones, diverticula and a median prostate lobe. The invasive nature of any other means (i.e. catheterization) to determine residual urine, must be weighed against the benefits of the test.

Because of the marked intra-individual variability of residual urine volume, the test should be repeated to improve precision, if residual urine volume is significant at the first measurement.

II. RECOMMENDED DIAGNOSTIC 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 subcommittee reports.

1. Further Symptom and QoL Assessment

The use of a number of validated questionnaires is recommended for a more detailed assessment of the symptoms of incontinence and their impact on quality of life. The Consultation has developed a

validated *screening questionnaire for incontinence*, the *ICIQ-SF* (short form). This is particularly suitable for epidemiological studies and for use in initial assessment of incontinent individuals (Annex 2).

The Consultation is developing a modular questionnaire including the assessment of symptoms and impact on quality of life for use in assessing the effectiveness of treatments for incontinence.

2. Detailed Physical Examination

Certain aspects of physical examination, when indicated, need to be more detailed.

a) Neurological examination:

concentrating on the *sacral segments 2-4* (the nerve supply of bladder and urethra, rectum and anal canal). Also examine *lower limbs* and *observe gait*.

b) In Female patients

formal assessment is recommended when initial evaluation indicates the possibility of *oestrogen deficiency, urethral diverticulum, urinary fistula or pelvic organ prolapse*.

c) Pelvic organ prolapse

should be assessed using the *ICS classification* (POPQ) recommended in order to properly document the extent of prolapse. In clinical work it's use would be optional.

3. 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*.

4. Uroflowmetry and PVR

Uroflowmetry and the *measurement of postvoid residual urine (PVR)*. These tests are recommended as a screening test for symptoms suggestive of voiding dysfunction, or suspicious physical signs.

5. Urodynamic Testing

a) Urodynamic evaluation is recommended :

- prior to *invasive treatments*
- after *treatment failure*
- 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 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*

c) It is recommended that Routine Urodynamic Evaluation should consist of

- *filling cystometry* (with provocation, and tailored to the individual patient's requirements) together with
- *voiding cystometry*

6. Urinary Tract Imaging

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

a) Imaging of the lower urinary tract

is *recommended* in those with suspected lower tract or pelvic pathology.

b) Imaging of the upper urinary tract

is only *recommended* in *specific situations*. These include:

- neurogenic urinary incontinence e.g. myelodysplasia, spinal cord trauma,
- incontinence associated with significant postvoid residual,
- co-existing loin/kidney pain,
- severe pelvic organ prolapse, not being treated
- suspected extra-urethral urinary incontinence,
- children with incontinence where indicated

7. Endoscopy

Endoscopy is *recommended* :

- when initial testing suggest *other pathologies*, e.g. microscopic 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

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 :

- *static* and *stress 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 provocative routine urodynamics
- ambulatory urodynamics

2. Pad Testing

Pad testing is an optional test for the routine evaluation of 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* are optional in patients with incontinence and suspected peripheral lesions.

- concentric needle EMG
- sacral reflex responses to electrical stimulation of penis/clitoris

4. Further Urinary Tract Imaging

a) Cysto-urethrography

in complicated or recurrent incontinence.

b) Ultrasound, CT or MRI imaging

of the lower urinary tract and pelvic floor are optional and should have a specific indication.

c) Simultaneous LUT imaging and urodynamics,

are an optional test in complicated or recurrent incontinence. 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 is still optional. The further methods include myelography, CT and MRI.

6. Endoscopy,

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

IV. TESTS NOT RECOMMENDED FOR THE INITIAL OR FURTHER EVALUATION OF INCONTINENCE

- *Urinary tract imaging* is not recommended unless there are specific indications (see above).
- *Endoscopy of the urinary tract* is *not recommended unless there are specific indications (see above)*.
- *Gas cystometry* is not recommended as part of the urodynamic evaluation of incontinence.

III. Management Recommendations

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

- I. Children,
- II. Men,
- III. Women,
- IV. Pelvic Organ Prolapse
- V. Neurogenic Incontinence
- VI. Frail and Disabled Older Men
- VII. Frail and Disabled Older Women
- VIII. Faecal Incontinence

These algorithms are divided into two for groups I, II, III, IV : 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 Paris 2002, 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 in all continents, both in the developing and the developed world.

➔ *The specialised algorithms*

are intended for use by specialists in the management of incontinence problems. The specialised algorithms, as well as the initial management algorithms are based on evidence where possible and on the expert opinion of the 1000 healthcare professionals who took part in the Consultation.

◆ *Essential components of basic assessment*

Each algorithm contains a core of recommendations relating 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 risk. 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 the *order in which they should be instituted*. This order tends to list treatments in order of increasing invasiveness/complexity/cost.

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

I. CHILDREN

A. INITIAL MANAGEMENT

1. Initial assessment 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

Complicated incontinence. 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.

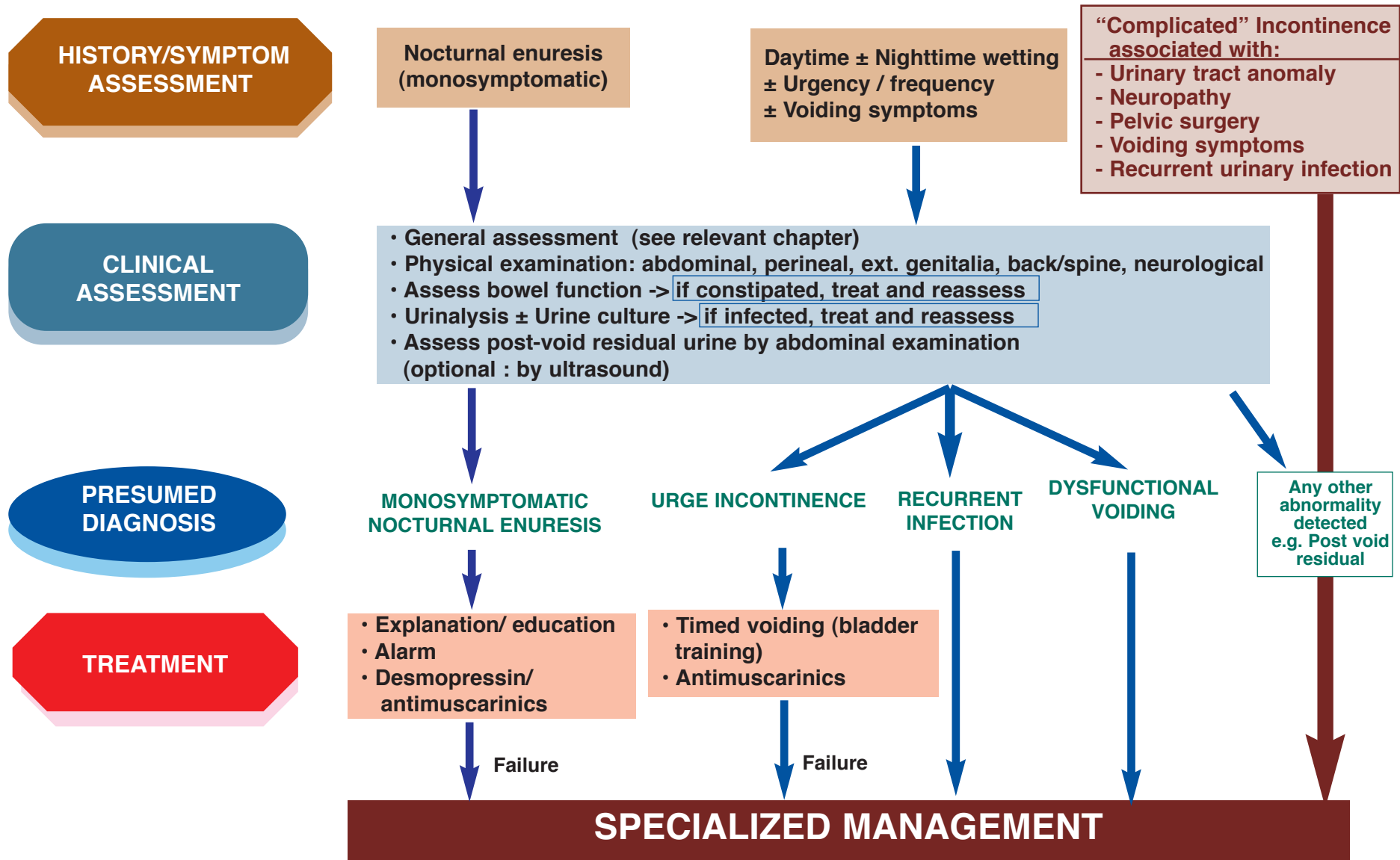
➔ a) *Mono-symptomatic nocturnal enuresis* should be treated initially with the *enuresis alarm*. Other recommended treatments are *behavioral modification*, for example "star charts", and *pharmacotherapy* including anti-diuretic hormone analogues and antimuscarinic drugs.

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

Should initial treatment be unsuccessful in a and b

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

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.

Urodynamic studies are not recommended if the child has normal renal upper tract imaging and is to be treated by non invasive means, for example, bio-feedback (with or without electromyography) for dysfunctional voiding.

2. Treatment

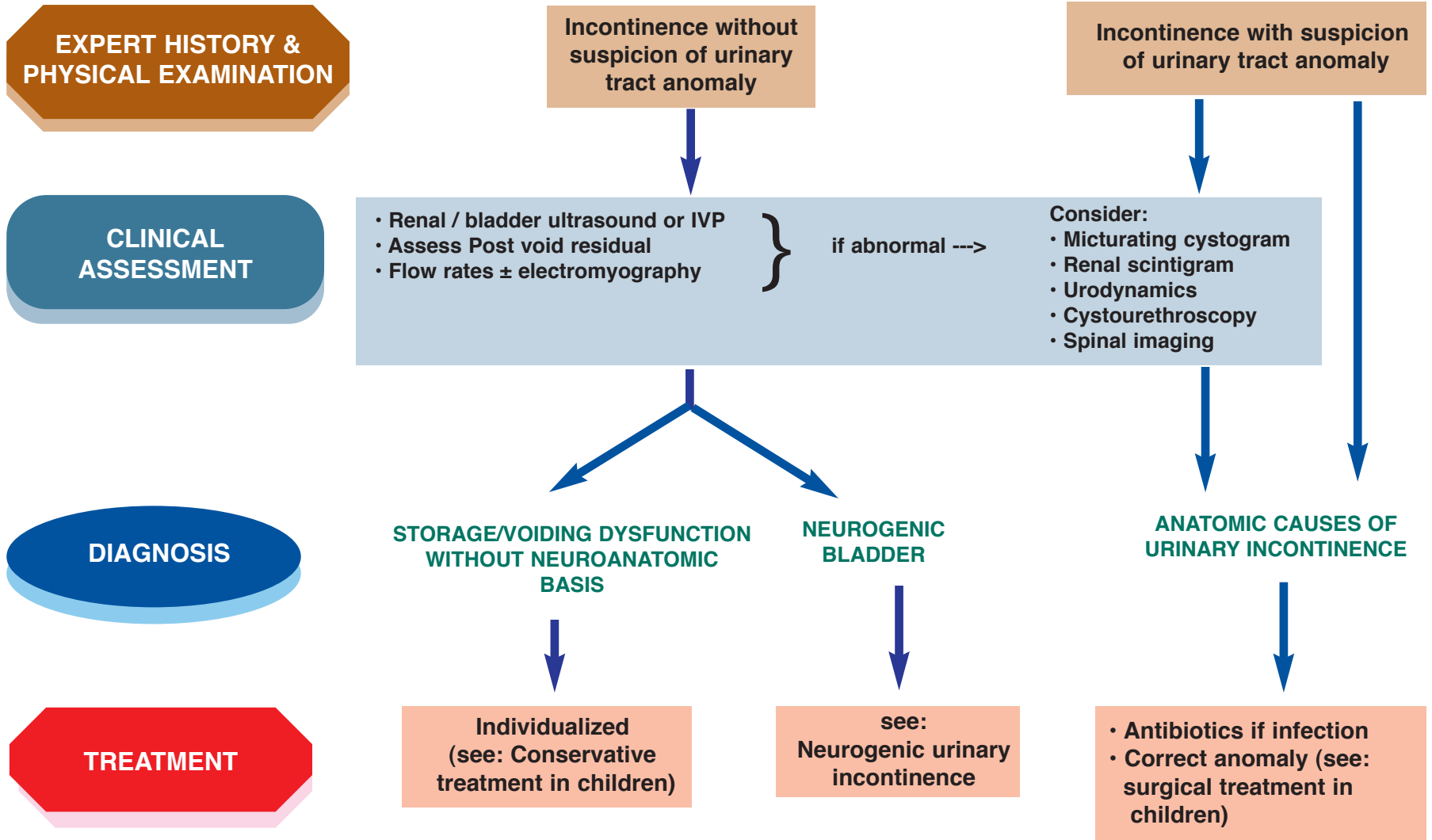
The treatment of incontinence associated with *urinary tract anomalies* is *complex* and cannot be dealt with in an algorithm (please see children's subcommittee reports).

Children with bowel dysfunction should be treated with increased fibre, adequate fluid intake and adding bulking laxatives if necessary.

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 pediatric urologists with a special interest in incontinence.

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 *intermittent catheterisation* : 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 Assessment 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* 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 exercises and manual compression of the bulbous urethra at the end of micturition.

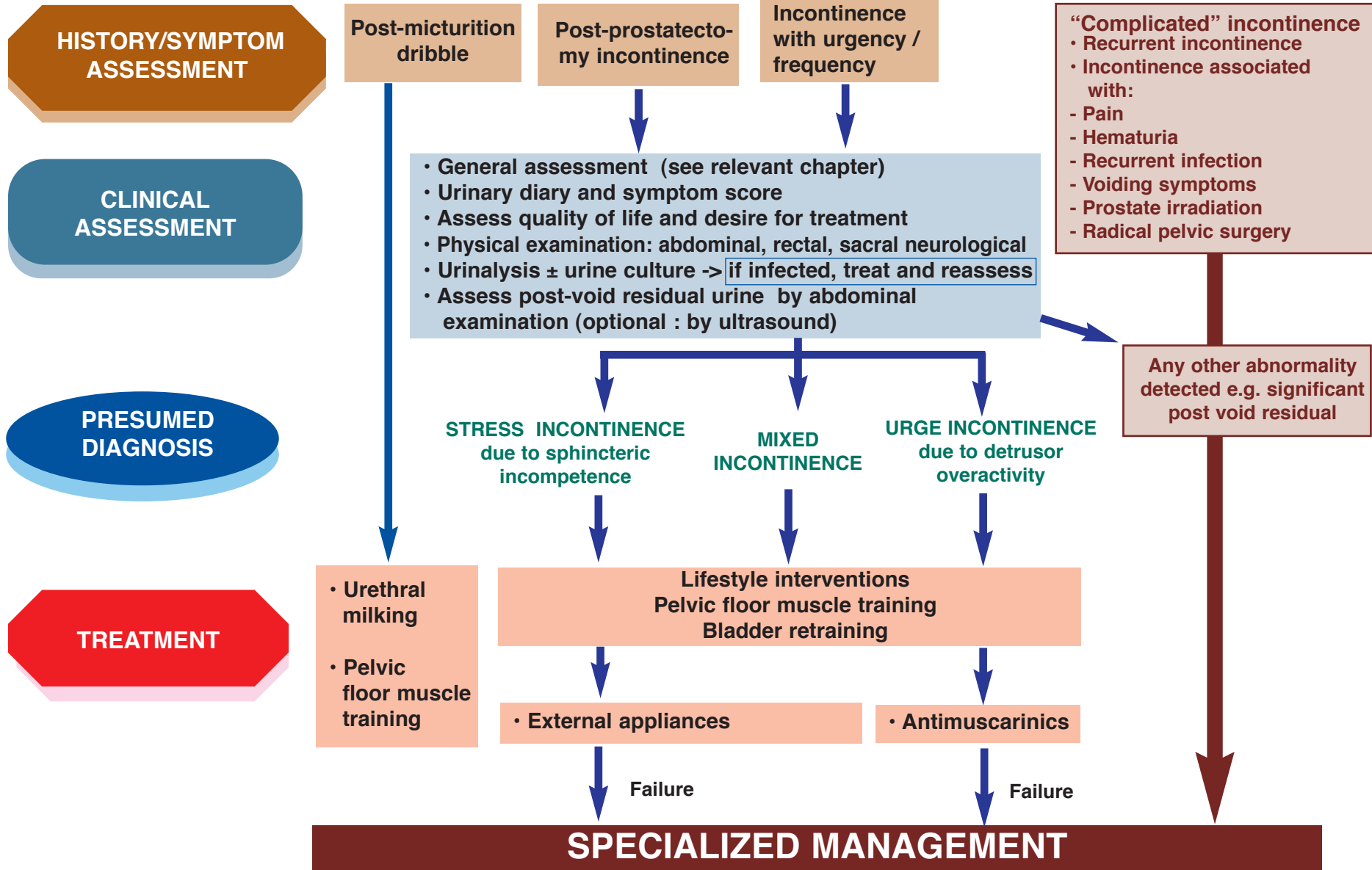
- b) *Urge incontinence* and other overactive bladder symptoms should be treated by *non-invasive* means initially :
 - pelvic floor exercises,
 - bladder training and
 - antimuscarinic drugs if detrusor overactivity is suspected as the cause for overactive bladder symptoms.
 - alpha adrenergic antagonists (α -blockers), should be considered if it thought that there may also be bladder outlet obstruction
- c) *Post prostatectomy stress incontinence* should also be treated initially by non- invasive means, by pelvic floor exercises.

Should initial treatment be unsuccessful

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

Initial Management of Urinary Incontinence in Men

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II. MEN

B. SPECIALIZED MANAGEMENT

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

1. Assessment

➔ *Patients 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 highly 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*.

➔ For the *idiopathic detrusor overactivity*, (overactive bladder) the recommended therapies are bladder augmentation, autoaugmentation, neuromodulation and urinary diversion.

➔ 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.

➔ If incontinence is associated with *bladder outlet obstruction*, then consideration should be given to surgical treatment to relieve obstruction. Alpha-blockers would be an optional treatment.

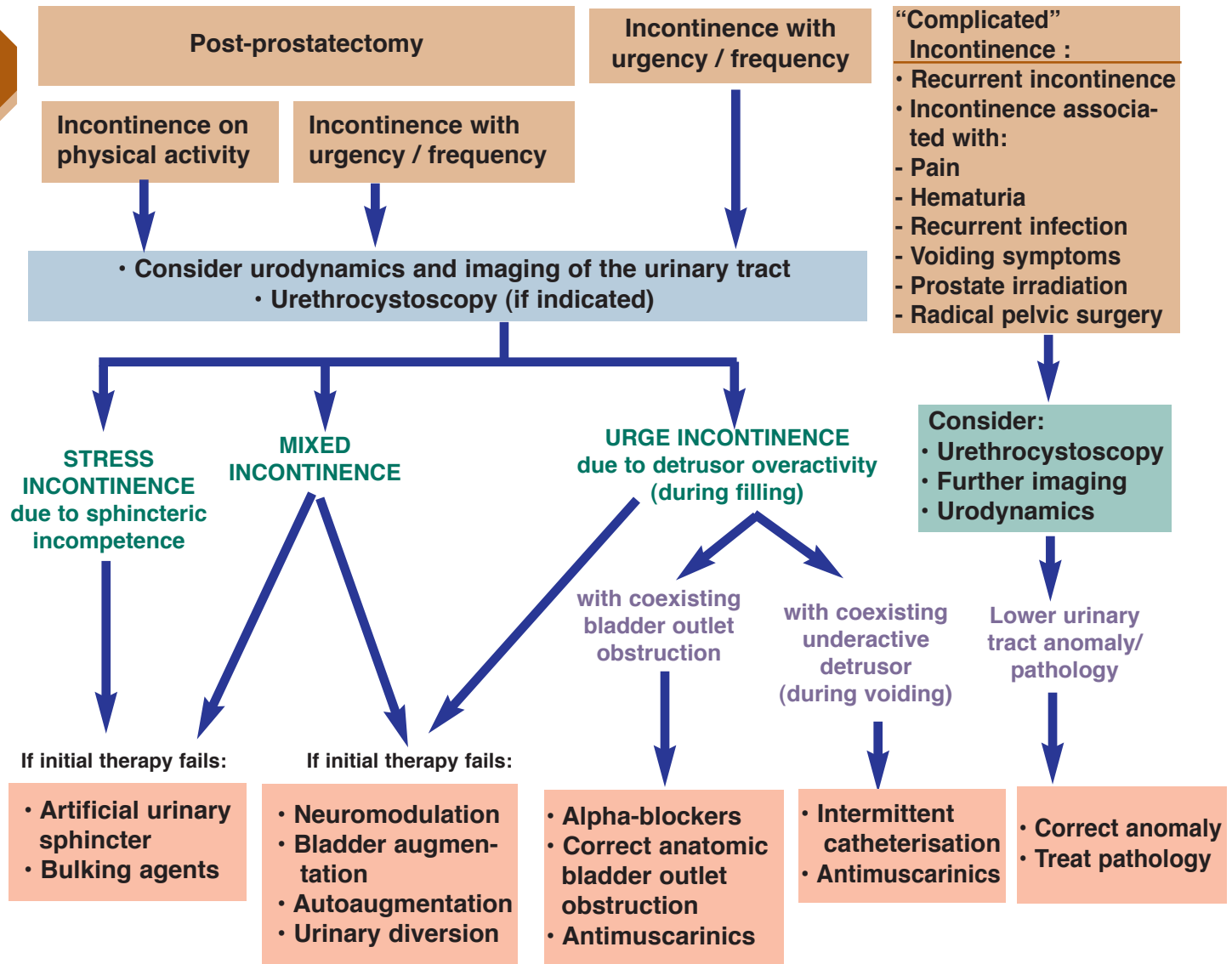
Specialized Management of Urinary Incontinence in Men

HISTORY/SYMPTOM ASSESSMENT

CLINICAL ASSESSMENT

DIAGNOSIS

TREATMENT



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.

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)
- 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 pelvic floor function, an essential step prior to the teaching of pelvic floor exercises. Vaginal examination is also an acceptable way to assess post-void residual urine if simple imaging methods are not available.

2. Treatment

➔ Initial treatment should include *life style interventions* in addition to therapies aimed at *specific types of incontinence*. Life style interventions include weight reduction, stopping smoking, and regulating food and fluid intake (including caffeine).

➔ *Oestrogen deficiency* and *urinary infection* should be treated at initial assessment and the patient reassessed after a suitable interval.

- a) *Presumed stress incontinence* should be treated by pelvic floor exercise and/or by devices such as intra-vaginal supporting tampons, intra-urethral plugs and meatal occlusion devices.
- b) *Presumed urge incontinence* should be treated by bladder retraining with or without antimuscarinic medication
- c) Women with symptoms of *both stress and urge leakage* should have their *predominant* symptom *treated initially*.

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

Initial Management of Urinary Incontinence in Women

HISTORY/SYMPTOM ASSESSMENT

CLINICAL ASSESSMENT

PRESUMED DIAGNOSIS

TREATMENT

Incontinence on physical activity

Incontinence with mixed symptoms

Incontinence with urgency / frequency

Complicated" incontinence

- Recurrent incontinence
- Incontinence associated with:
 - Pain
 - Hematuria
 - Recurrent infection
 - Voiding symptoms
 - Pelvic irradiation
 - Radical pelvic surgery
 - Suspected fistula

- General assessment (see relevant chapter)
- Urinary diary and symptom score
- Assess quality of life and desire for treatment
- Physical examination: abdominal, pelvic, sacral neurological & estrogen status -> **if atrophic, treat as necessary**
- Cough test to demonstrate stress incontinence
- Urinalysis ± urine culture -> **if infected, treat and reassess**
- Assess post-void residual urine by abdominal examination (optional : by ultrasound)

STRESS INCONTINENCE
due to sphincteric incompetence

MIXED INCONTINENCE

URGE INCONTINENCE
due to detrusor overactivity

Lifestyle interventions
Pelvic floor muscle training, Bladder retraining

- Other physical therapies
- Devices

- Antimuscarinics

Failure

Failure

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

SPECIALIZED MANAGEMENT

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*. 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. Urodynamics allow the precise diagnosis of the type of incontinence and therefore dictate the management plan.

➔ Women with *co-existing pelvic organ prolapse* should have their prolapse treated as appropriate

➔ Women in developing countries with *birth/pregnancy injuries* do not require urodynamic assessment and are best treated in specialist fistula units.

2. Treatment

➔ *If genuine stress incontinence is confirmed* then the treatment options that are recommended for patients with *some degree of bladder-neck and urethral mobility* include retropubic suspension procedures, and bladder neck/sub-urethral sling operations. Less invasive procedure may be offered to patients in specific circumstances, for example, needle suspensions in older, less fit, less energetic individuals. The correction of pelvic organ prolapse may be desirable at the same time.

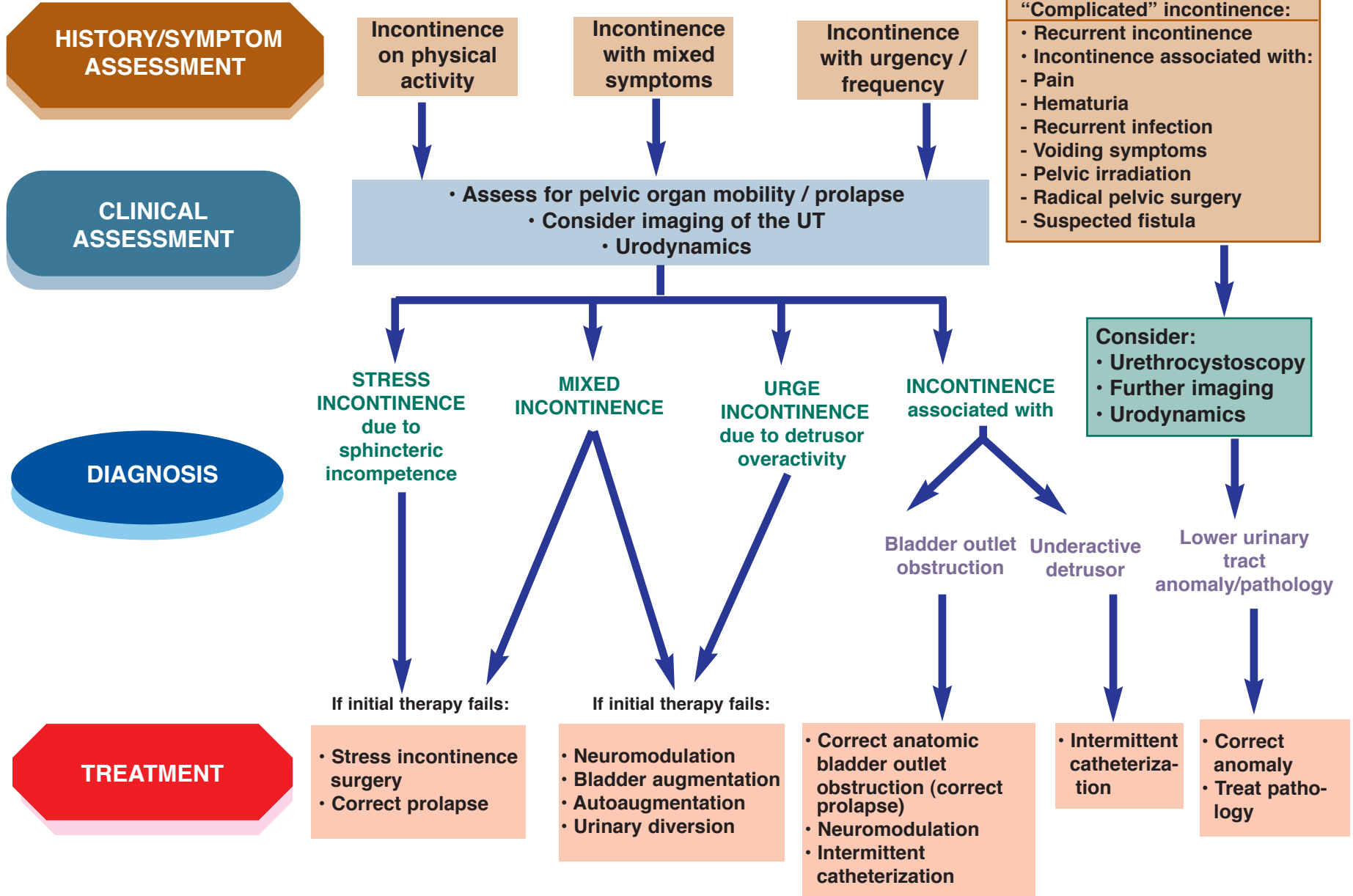
For patients with *intrinsic sphincter deficiency and limited bladder neck mobility*, sling procedures, injectable bulking agents and the artificial urinary sphincter are recommended.

➔ *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* (>30% of total bladder capacity) may have bladder *outlet obstruction* or *detrusor underactivity*. In women urethral dilatation is recommended to treat relative urethral narrowing. In most women with voiding dysfunction, the cause is detrusor underactivity, and intermittent catheterisation is recommended.

➔ Long-term low dose antibiotics are recommended if there are *persistent infections*.

Specialized Management of Urinary Incontinence in Women



IV. PELVIC ORGAN PROLAPSE

Introduction

Women may present with symptomatic pelvic organ prolapse (POP) with or without symptoms of urinary incontinence.

Evaluation for POP may be initiated by a carer or a health care worker.

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 *degree* of prolapse : examining the women standing and straining is desirable
- *Associated abnormalities* such as ulcerations or sores of 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 then the urethra may be distorted (kinked) leading to a significant PVR.

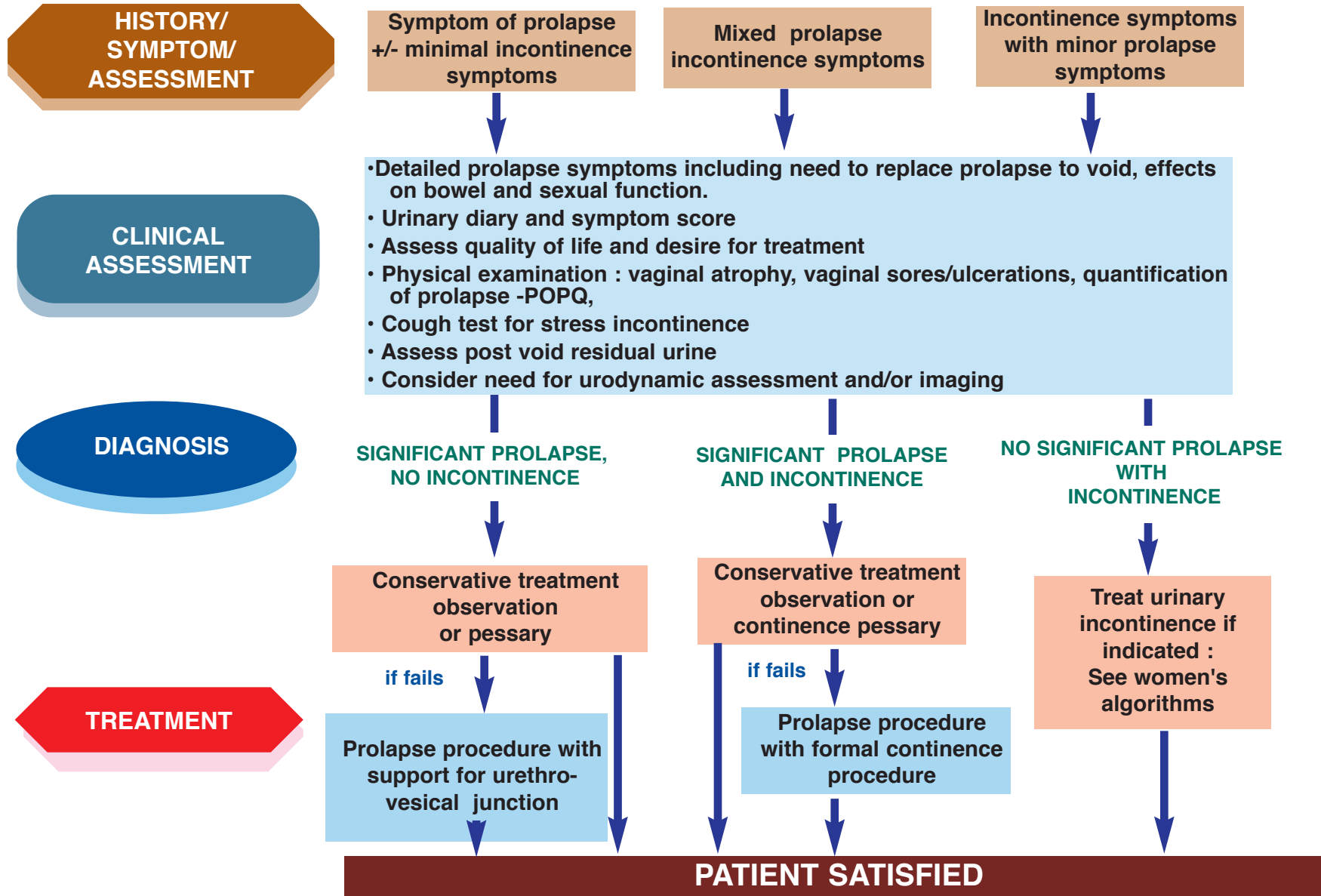
2. Treatment

In general it is considered wise to *treat only symptomatic prolapse*.

Treatment of asymptomatic prolapse may result in new urinary, bowel or sexual dysfunction symptoms.

- ➔ *Conservative treatment* is safe and satisfactory for certain patients.
- Periodic re-evaluation may be preferred.
- *Pessaries* may be used with caution in the presence of sore/ulcers but there must be regular follow-up.
- ➔ *Surgical treatments* aim to restore the normal anatomy as far as is possible. Readers should refer to the chapter for full details of techniques
- *Continence procedures* may be needed in conjunction with *prolapse procedures*, in these patients *urodynamic* studies are recommended prior to surgery, as they may be useful in selecting a specific procedure.

Management of Pelvic Organ Prolapse



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, one with peripheral nerve lesions (a) and the other with central lesions below the pons (b) 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 the 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 on a basis 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

LEVEL OF LESION / HISTORY ASSESSMENT

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

Suprasacral infrapontine
spinal cord lesion
(e.g. trauma, multiple
sclerosis)

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

CLINICAL ASSESSMENT

- General assessment including home assessment
- Urinary diary and symptom score
- Assess quality of life and desire for treatment
- Physical examination: assessment in regards to urge and pain sensation in the sacral dermatomes, anal tone, voluntary contraction, bulbocavernosus reflex, anal reflex and gait
- Urinalysis ± urine culture -> **if infected, treat as necessary**
- Urinary tract imaging, serum creatinine **if abnormal**
- Assess post-void residual urine (PVR) by abdominal examination (optional : by ultrasound)

PRESUMED DIAGNOSIS

STRESS INCONTINENCE
DUE TO
SPHINCTER INCOMPETENCE

“REFLEX” INCONTINENCE
WITH POOR
BLADDER EMPTYING
(significant PVR)

“REFLEX” INCONTINENCE
“URGE-SYNDROME”
(negligible PVR)

Cooperative
mobile patient

Uncooperative
immobile patient

TREATMENT

Intermittent
catheterization

• Behavioural
modification
• Bladder relaxant
drugs

• External Appliances
• Indwelling catheter
• Antimuscarinics

Failure

Failure

Failure

SPECIALIZED MANAGEMENT

V. NEUROGENIC INCONTINENCE

B. SPECIALIZED MANAGEMENT

1. Assessment

Most patients with *peripheral 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

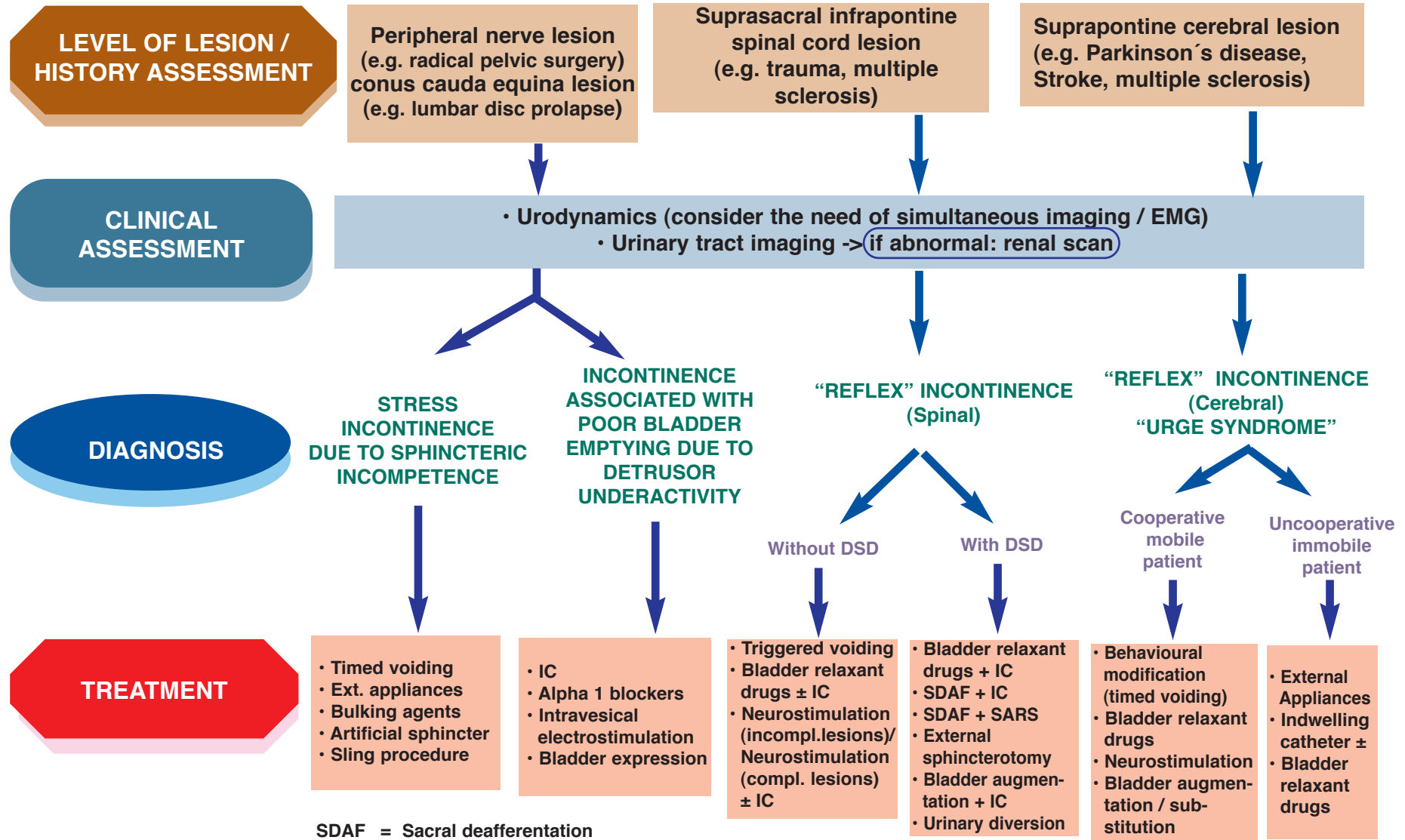
Management is straightforward in concept although the therapeutic options are extensive. The algorithm details the recommended options.

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 vesico-urethral dysfunction needs to be dealt with. However, it must be remembered that *preservation of upper tract function is of paramount importance*.

For detailed discussion please read the relevant chapters 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. Frail and/or Disabled Older Men

A. INITIAL MANAGEMENT

Frail older persons present different problems. Implicit in the terms “frail” is the realisation that such individuals may neither wish nor be fit enough to be considered for the full range of therapies likely to be offered to a fitter or younger incontinent individual.

However, every person should be given the opportunity to achieve continence, irrespective of their frailty or disability. This can be “*independent continence*”, “*dependent continence*” – dry with the assistance or reminder of a carer or “*social continence*” – dry with the use of appropriate aids and devices. Often dryness can be achieved by a combination of the above approaches.

1. Assessment

➔ During *initial assessment* the frail and/or disabled older person, besides a general continence assessment and a complete physical examination, needs to be assessed with specific inquiries into:

- Cognitive abilities
 - Mobility and environment including access to toilet
 - ADL (activities of daily living)
 - Level of support available to the incontinent person
 - Potentially reversible conditions that can cause or worsen incontinence in older people
 - Medication, particularly diuretics or drugs that cause sedation or confusion
- ➔ The *extent of investigation* and *management* in frail and/or disabled older people should take into account
- Degree of bother to the patient and/or carer
 - Patient motivation and level of cooperation
 - Patient’s comorbidities
 - Prognosis and life expectancy

➔ *Post-void residual urine* (PVR) should be assessed, preferably by ultrasound, or by in/out catheter, since it influences the choice of management. There is

no specific “cut off” for the different choices and the ranges listed below are provided as a broad guideline. It is often worthwhile to *repeat the PVR* since it can vary especially after reviewing drugs and treating constipation. A low PVR does not exclude outlet obstruction. Uroflowmetry may be helpful to rule out outlet obstruction but only if maximum flow is normal

2. Treatment

➔ *Conservative and behavioural therapy* includes pelvic floor muscle exercises, biofeedback, bladder training in the more fit or alert patient, assisted voiding for more disabled patients and prompted voiding for frailer and more cognitively impaired patients.

➔ *Bladder relaxant drugs* may be considered as an adjunct to these conservative treatments of detrusor overactivity, whilst *α-blockers* may be tried to assist bladder emptying. When they are being tried, it is important to dose titrate from a low dose, reviewing outcome and side effects regularly.

B. SPECIALISED MANAGEMENT

If after initial assessment the frail older person is found to have incontinence with other significant factors (eg pain, haematuria) then consideration should be given to further assessment and investigation by a specialist.

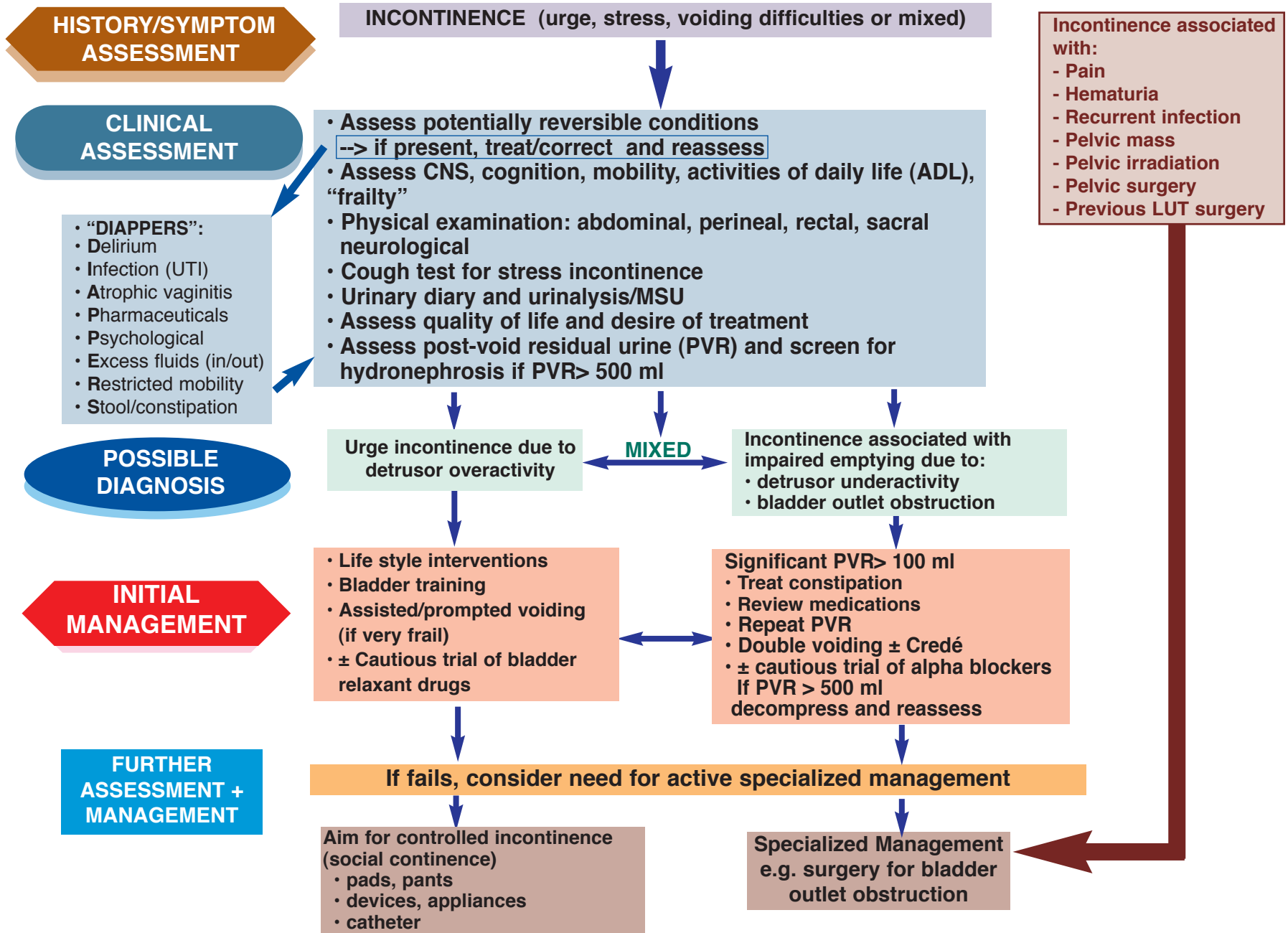
Referral for specialised management may also be applicable for individuals who have not responded adequately to simple conservative measures provided they are motivated and if such intervention and/or management might improve their continence management and quality of life.

Age per se is not a contraindication to surgery for incontinence. However, in older people especially frail and/or disabled older people:

- *Modifiable reversible conditions* should be addressed prior to surgery
- Wherever possible, *adequate trial of conservative treatment* should be offered prior to surgery followed by reassessment of the need for surgery
- A *urodynamic assessment* should proceed surgery because clinical diagnosis may be inaccurate

Preoperative assessment plus perioperative care is essential to minimise postoperative geriatric complications such as delirium, infection, dehydration and falls.

Management of Urinary Incontinence in Frail and/or Disabled Older Men



VII. Frail and/or Disabled Older Women

A. INITIAL MANAGEMENT

Frail older persons present different problems. Implicit in the terms “frail” is the realisation that such individuals may neither wish nor be fit enough to be considered for the full range of therapies likely to be offered to a fitter or younger incontinent individual.

However, every person should be given the opportunity to achieve *continence*, irrespective of their frailty or disability. This can be “*independent continence*”, “*dependent continence*” – dry with the assistance or reminder of a carer or “*social continence*” – dry with the use of appropriate aids and devices. Often dryness can be achieved by a combination of the above approaches.

1. Assessment

➔ During *initial assessment* the frail and/or disabled older person, besides a general continence assessment and a complete physical examination, needs to be assessed with specific inquiries into:

- Cognitive abilities
 - Mobility and environment including access to toilet
 - ADL (activities of daily living)
 - Level of support available to the incontinent person
 - Potentially reversible conditions that can cause or worsen incontinence in older people
 - Medication, particularly diuretics or drugs that cause sedation or confusion
- ➔ *The extent of investigation and management* in frail and/or disabled older people should take into account:
- Degree of bother to the patient and/or carer
 - Patient motivation and level of cooperation
 - Patient’s comorbidities
 - Prognosis and life expectancy

It is highly recommended that *post-void residual urine (PVR)* is assessed preferably by ultrasound or by in/out catheter. Impaired bladder emptying may occur in older women because of pelvic organ prolapse, constipation, underactive detrusor, medications that impair bladder emptying, or postoperatively. The PVR therefore is a significant factor that should influence the choice of management. There is no specific “cut off” for the different choices and the ranges listed below are provided as a broad guideline.

Stress incontinence may coexist in older women with most other bladder conditions. It is appropriate to perform a cough stress test.

2. Treatment

It is sometimes worthwhile to *repeat the PVR* especially in the intermediate ranges listed or when medications could impact on it.

Conservative and behavioural therapy includes pelvic floor muscle exercises, biofeedback, bladder training in the more fit or alert patient, assisted voiding for more disabled patients and prompted voiding for frailer and more cognitively impaired patients.

Bladder relaxant drugs may be considered as an adjunct to these conservative treatments of detrusor overactivity. When they are being tried, it is important to dose titrate from a low dose, reviewing outcome and side effects regularly.

When PVR is high (eg greater than 500ml) the upper tracts should be screened to exclude hydronephrosis. However, treatment of coexisting conditions may reduce PVR, e.g treatment of constipation and stopping drugs with anticholinergic action.

In those patients where the various therapies fail, the patient can achieve “*dependent continence*” by assistance or prompting, and/or *social continence* with pads and/or appliances.

B . SPECIALISED MANAGEMENT

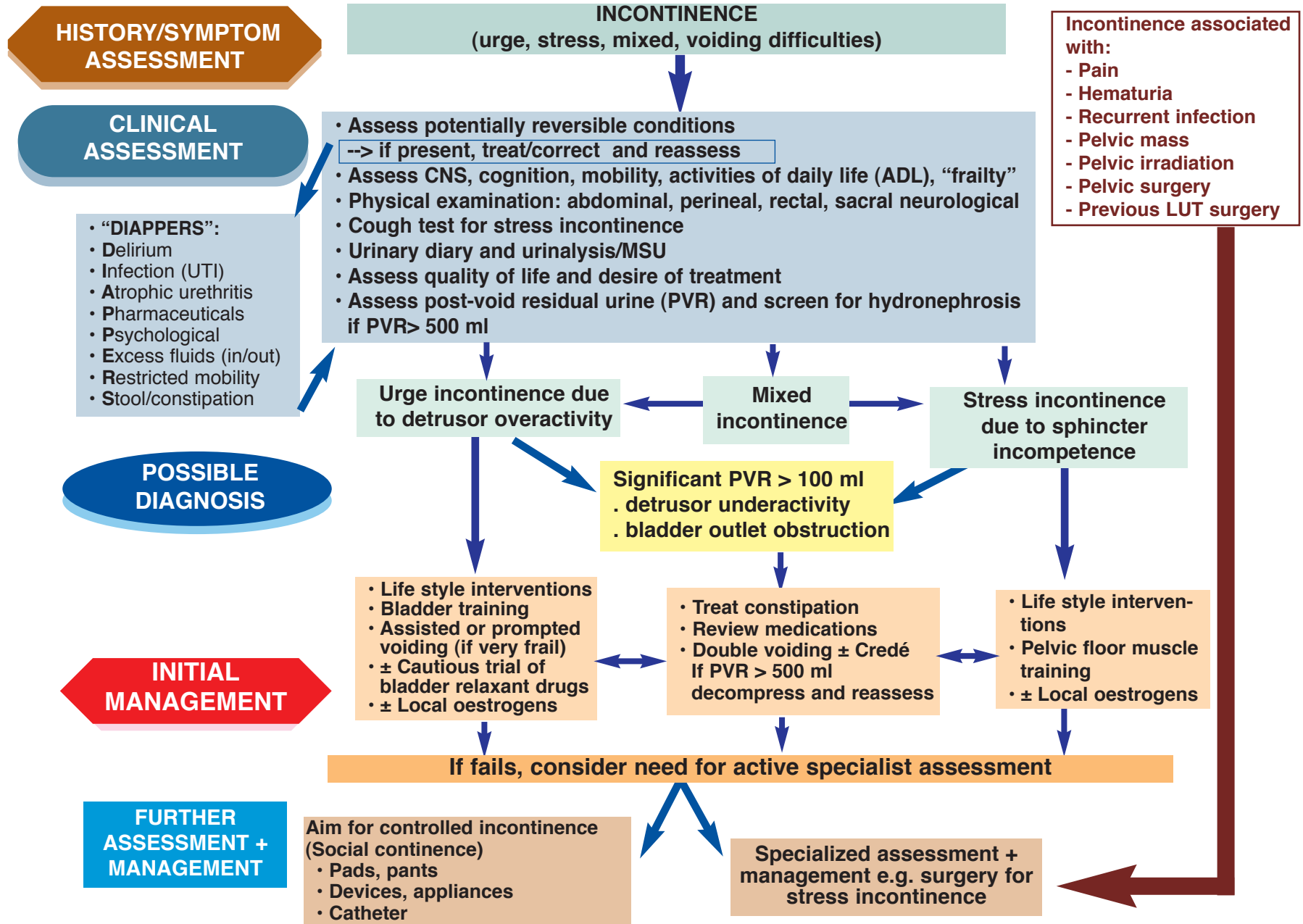
If after initial assessment the frail older person is found to have incontinence with other significant factors (eg pain, haematuria) then consideration should be given to further assessment and investigation by a specialist.

Referral for specialised management may also be applicable for individuals who have not responded adequately to simple conservative measures provided they are motivated and if such intervention and/or management might improve their continence management and quality of life. Age per se is not a contraindication to surgery for incontinence. However, in older people especially frail and/or disabled older people:

- *Modifiable reversible conditions* should be addressed prior to surgery
- Wherever possible, *adequate trial of conservative treatment* should be offered prior to surgery followed by reassessment of the need for surgery
- A *urodynamic assessment* should proceed surgery because clinical diagnosis may be inaccurate

Preoperative assessment plus perioperative care is essential to minimise postoperative geriatric complications such as delirium, infection, dehydration and falls.

Management of Urinary Incontinence in Frail and/or Disabled Older Women



VIII. Management of faecal incontinence in adults

1. Initial assessment

Patients present with a *variety of symptom complexes*.

Serious bowel pathology needs to be considered if the patient has a change in bowel habit or rectal bleeding.

History will include bowel symptoms, systemic disorders, local anorectal procedures, childbirth for women, medication, diet and effects of symptoms on life-style.

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 which is often a symptom of external anal sphincter dysfunction or intestinal hurry; and *passive loss of stool* may indicate internal anal sphincter dysfunction.

2. Initial management

- ➔ Once local or systemic pathology has been excluded, initial management includes
 - patient information and education,
 - diet and fluid advice, establishing a regular bowel habit with complete rectal evacuation and
 - simple exercises to strengthen and enhance awareness of the anal sphincter.
- ➔ Anti-diarrhoeal medication can help if stools are loose.
- ➔ 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, measurement of pudendal nerve terminal motor latencies, 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*, especially if the function of the remaining muscle is good.
- ➔ *Those with sphincter disruption but poor function* may achieve lesser results and should normally try *conservative measures first*.
- “Biofeedback” therapy is usually a package of measures designed to enhance the patient’s awareness of anorectal function, improve sphincter function and retrain the bowel habit.
- Electrical stimulation may help in selected cases.
- ➔ 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*.

5. Special patient groups

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

Management of Faecal Incontinence

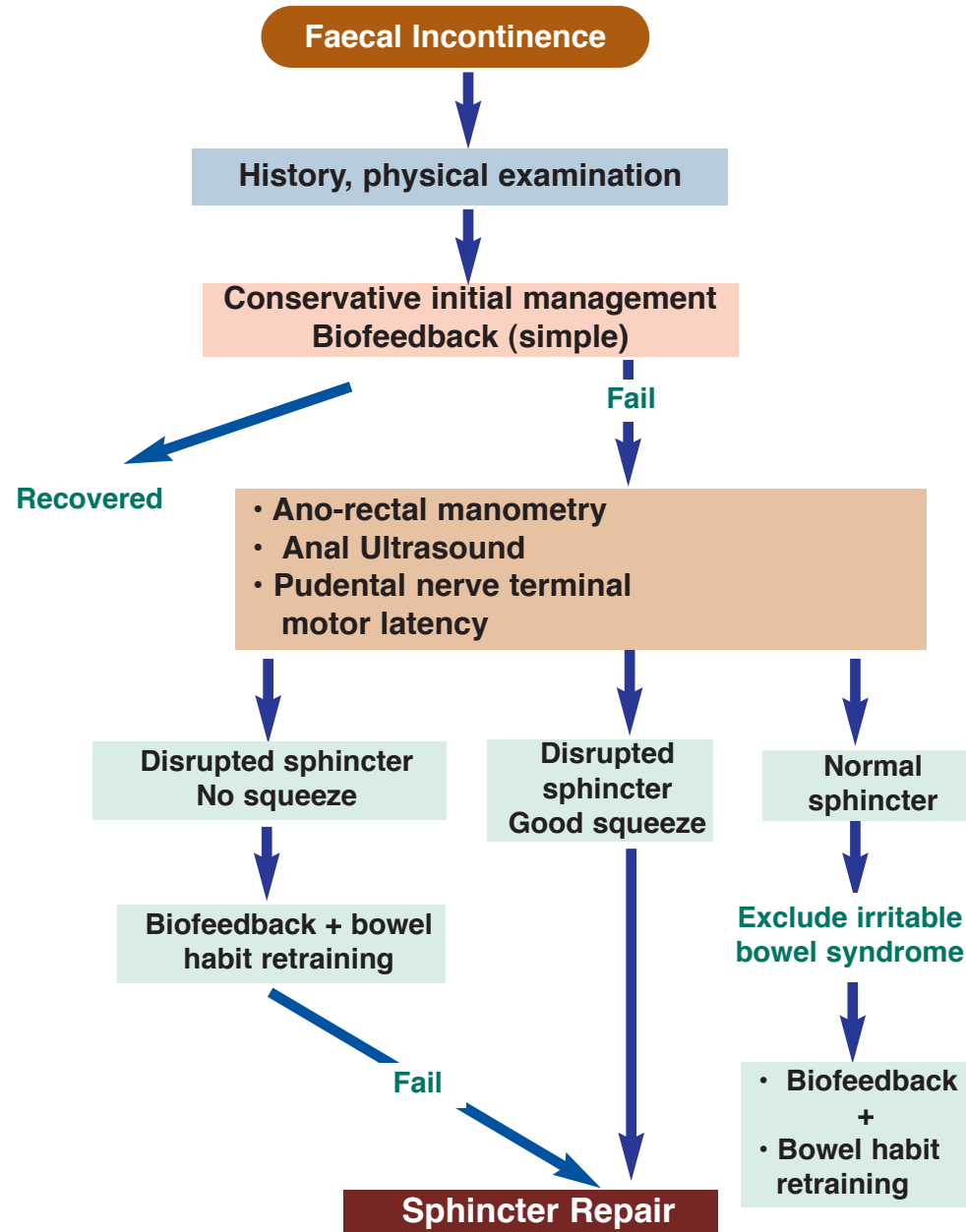
CLINICAL ASSESSMENT

INITIAL TREATMENT

FURTHER INVESTIGATIONS

DIAGNOSIS

SPECIALISED MANAGEMENT



IV. Recommendations for the Promotion, Education, and Organization for Continence Care

Progress has been made in the promotion of continence awareness, education of professionals and consumers, organization of the delivery of care and the delivery 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 planning policies and providing adequate funding. These should include a primary prevention strategy. For example, in developing countries with a high complication rate from childbirth, such prevention strategies could include ensuring that all births are attended by a qualified health care worker and also that there is access to secondary health care facilities for all in case of complications. The prevention strategy would include education in an attempt to prevent physically immature girls from becoming pregnant, as they have the highest incidence of complications.

The following are specific recommendations in three areas: promotion, education and organization

1. Promotion

Public awareness campaigns are essential in order to educate the public, break down taboos and to empower health-seeking behavior. The mass media, should wherever possible, be involved in raising public awareness. Continence promotion should be *health focused* and *use terminology*, which is understood by both the public and patient.

Public awareness campaigns could include *increasing the visibility of the problem*, advocate the need for research and evaluate the impact and efficacy of the program.

The Consultation supports the formation of a worldwide "Bladder Health" Day.

2. Education

The identification, assessment and management of incontinence must be a *compulsory subject* for all medical, nursing, and allied professional curricula and continuing education program. These programs should include basic principles of medical education that promotes change of knowledge, attitudes and behavior.

As professional education alone has not changed behavior, *other tools are needed to augment* or build on educational endeavors

3. Organization

The needs of service users (patients and carers) must be considered in planning continence services.

Continence services must be provided on a multi-disciplinary basis and provide a balance between community and specialist services.

Properly trained staff with the appropriate accreditation must deliver continence care.

Continence care should be based on *agreed consensus recommendations*.

a) Delivery of Continence Services

The *needs of service users* (patients and carers) must be considered in planning continence services.

Continence services must be provided on a *multi-disciplinary basis* and provide a balance between community and specialist services.

National and regional *service delivery models* need to be developed and tested.

Properly *trained professional staff* with the appropriate supervision must deliver continence care.

Continence care should be based on *agreed consensus recommendations*.

b) Worldwide Organization

Countries need to *increase collaboration* for use of scarce resources to further public awareness and education.

Organizations must undertake *market research* to better understand the needs of persons with incontinence; so as to *set their own agenda and priorities* rather than being led by the availability of funding.

Worldwide, countries are *educating the public* through self-help and support groups, telephone hotlines, Internet, brochures, and community outreach. These organizations, particularly the *Continence Promotion Committee (CPC)* of the *International Continence Society (ICS)* need to access marketing and public relation experts to broaden their efforts.

The CPC of ICS should be the *central co-coordinating body* to stimulate the collaboration of worldwide activity in the area of continence promotion.

V. Recommendations for Research

There are many goals of research—foremost to improve care of patients, but also to promote understanding of the disease process. We need a broad spectrum of information if we are to not only understand which treatments work but also how and why they work (or don't). The ultimate goal is to produce credible research. When research is inherently credible due to strong study design the impact is maximized. The clinical application of the research will be hastened and other investigators will be energized to use the information in their own quest for knowledge. Committee recommendations are reported as General recommendations for Incontinence Research, Recommendations for Specific Patient Groups, and Recommendations for Specific Types of Incontinence Therapy.

GENERAL RECOMMENDATIONS FOR CLINICAL RESEARCH IN INCONTINENCE

1. The first step of the planning phase involves reviewing previous and, if possible, ongoing work in the field. The work of the Cochrane Collaboration (www.cochrane.org) and its Cochrane Incontinence Group (www.otago.ac.nz/cure/) provide a tremendous asset to the potential investigator in defining the state of current knowledge and the key issues for further investigation.
2. Whenever possible, clinical research should be prospective, randomized, and multicenter. The randomized controlled trial (RCT) eliminates many of the biases that can corrupt research. While observational studies may be valuable in some areas, the bias that results from differential selection effects (both patient and clinician induced) cannot be eliminated, even by the use of advanced statistical methods. Multicenter trials involve a larger cross-section of the population and enhance the generalizability of the results.
3. Equivalence trials are underutilized. This design should be used to demonstrate that two treatments are similar in outcome or that there is no difference between treatment and controls. This can be of relevance when one treatment is significantly more cost-effective, offers a better quality of life, or is less toxic or time consuming for the patient when similar clinical outcome can be achieved. Failing to find a difference between two treatments is not the same as proving equivalence if this design is not used.
4. The study population should comprise a sample that is representative of the community overall—so that broad representativeness can be judged. This is as important for trials as for observational studies. Nevertheless, “the basic logic of clinical trials is comparative and not representative”.
5. The Consolidated Standards of Reporting Trials (CONSORT) statement provides guidelines for reporting the design, detailed methods, and results of RCTs.
6. Specific outcome measures are discussed in detail by individual Committees. In almost all situations, the outcome set should include a dimension representing the viewpoint of the patient (such as a questionnaire relating to symptoms and impact on quality of life) as well as an appropriate clinical outcome measure.
7. Secondary outcomes and subgroup analysis are subject to the dangers of multiple hypothesis testing. Such measures should be defined at the outset of the trial and should be used sparingly. Analyses of such outcomes are often best viewed as exploratory, i.e., as hypothesis-generating exercises for which independent confirmation is essential.
8. Inclusion and exclusion criteria should provide a relevant population to address the study question, and together define the heterogeneity or homogeneity of the study population. Broadening the inclusion criteria can make a study more generalizable and facilitate recruitment. Making the entry criteria too broad, however, may dilute the effect being sought in the most suitable patients. If the study population is defined too narrowly with many exclusion criteria, applicability of the results may be limited and subject recruitment may be difficult. The committee feels that clinical incontinence research is in great need of more large-scale RCTs in almost all areas. Broad entry criteria to include as many patients as possible are desirable.
9. The *target difference* is arguably the most important quantity that must be specified in calculating sample size. The target difference is defined as the minimum difference needed for clinical significance, a difference that would lead to a change in clinical management for the target group of patients. This must be specified in the planning phase of the research.
10. It is established practice that unless there are strong reasons to the contrary the primary analyses (for both primary and secondary outcomes) of an RCT should be on an intention-to-treat basis. It may be of interest to gauge the effect of treatment given full com-

pliance, so secondary analyses incorporating non-compliance and/or which treatment was actually received may be justified in addition to the primary analyses.

11. The CONSORT statement is specifically designed to provide standards for reporting RCTs. Adherence to these guidelines and the use of flow diagrams in particular is associated with improved quality in reporting of RCTs. Meta-analyses are themselves the subject of separate reporting guidelines, the QUORUM statement. Guidelines for reporting studies on diagnostic tests (the START document) will be published in 2001.
12. Recommendations for minimum data collection in clinical research are published in the proceedings of the NIH Terminology Workshop for Researchers in Female Pelvic Floor Disorders and by the International Continence Society (ICS) Standardization committee. A broad demographic description of the patient population is desirable; while few trials will be large enough to analyze the effect of these demographic factors on outcome, the potential use of meta-analysis makes a complete database valuable.
13. One or more validated symptom instruments should be chosen at the outset of a clinical trial to accurately define baseline symptoms and other areas in which the treatment may produce an effect. An ideal instrument would record all symptoms related to the lower urinary tract and relevant associated organ systems—gastrointestinal and sexual function are particularly important. An ideal instrument would record both the objective severity of the symptom and the impact or bother produced by the presence of the symptom. In addition to specific symptoms, the respondent's overall opinion of the condition should be included. Research in incontinence and LUTS should include both generic and condition-specific HRQOL instruments.
14. Clinicians' observations of anatomy, particularly female pelvic support, should be recorded using standardized, reproducible measurements. Pelvic muscle and voluntary sphincter function should be reported using a quantifiable scale. These measures should be repeated after intervention and correlated with primary clinical outcome measures.
15. Clinical trials of incontinence and LUTS should include bladder diaries as an essential baseline and outcome measure. The diary should include measured voided volume (for at least one day if a multi-day diary is employed).

16. Clinical trials of incontinence and LUTS should include a pad test as an essential baseline and outcome measure.
17. Most clinical studies should enroll subjects by carefully defined symptoms, not urodynamic tests (UDS). Blinded baseline UDS are highly desirable in order to determine their predictive value. In the ideal clinical study, urodynamic tests are performed at baseline and exit to correlate symptom changes with physiologic changes. In multicenter trials, urodynamic tests should be interpreted by a central reader to minimize bias.
18. Follow-up of incontinence treatment is suggested at 1 to 3 months and 12 months after treatment, and thereafter at yearly intervals for as long as possible.
19. Socioeconomic data can be an important outcome measure and should be collected whenever possible.

RECOMMENDATIONS FOR SPECIFIC PATIENT GROUPS

1. In males, if treatment could change prostate volume, measurements of volume should be performed before and after treatment. It may be appropriate to stratify patients by prostate volume. Whenever feasible, detrusor pressure-uroflow studies should be performed before and after treatment to document the presence and degree of change in bladder outlet obstruction.
2. Significantly more research is needed in the frail elderly population. This is a heterogeneous population requiring a detailed study design and careful description of baseline clinical data if results are to be interpretable. There is a need for validation of all instruments and procedures used in incontinence research for the population of frail elderly patients. "Clinically significant" outcome measures and relationships of outcome to socioeconomic costs are critically important to establishing the utility of treating urinary incontinence in this population.
3. We support increased clinical research in children. All investigators that work with children should be aware of the details of the document and particularly the issues surrounding informed consent. Long-term follow-up is of critical importance in the pediatric population in order to ascertain the effect of a treatment on normal growth and development. Research is needed to develop standardized outcome measures including validated, age-specific symptom and disease-specific quality of life outcome measures.
4. Detailed urodynamic studies are required for classi-

fication of neurogenic lower urinary tract disorders in research studies 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 in addition to symptom response.

RECOMMENDATIONS FOR SPECIFIC TYPES OF INCONTINENCE RESEARCH

1. Treatment protocols in behavioral and physiotherapy trials must be detailed to the degree that the work can easily be reproduced. More work is needed to separate the specific and non-specific effects of treatment
2. The United States Food and Drug Administration (FDA) had established detailed guidelines for studies on intra-urethral and vaginal devices and urethral bulking agents in the treatment of urinary incontinence. However, these treatments are not intrinsically similar and the guidelines should be refined such that recommendations are appropriate to the risk involved in the treatment.
3. In pharmacotherapy trials, investigators must be sensitive to the conflicts regarding the use of placebos in clinical trials. While placebos are often desirable from a scientific standpoint, every consideration should be given to making sure that the interests of the subjects are kept at the forefront in designing safe, ethical research.
4. Continuity in clinical direction from design through authorship is highly desirable. All authors should be able to accept responsibility for the published work and all potential conflicts of interest should be fully disclosed.
5. There is a great need for randomized clinical trials in surgical treatment of urinary incontinence. We recommend urodynamic testing in all subjects involved in surgical research. However, evidence does not exist to support recommendations for minimal testing or the use of specific tests. Research into the predictive value of pre-operative urodynamic studies would be most valuable.
6. Reports of successful treatment should be limited to subjects with a minimum of one year follow-up.

SUMMARY

In summary,

- All quality research, be it prospective or retrospective, clinical or preclinical, begins with detailed planning—establishing a clear and relevant hypothesis, developing a trial of appropriate magnitude to accept or reject the hypothesis, and defining methods of adequate sensitivity and specificity to produce credible data.
- Clinical research in incontinence must include a broad range of baseline and outcome measures including anatomic and physiologic variables, urodynamic testing, voiding diaries and pad tests, symptom assessment, and quality of life measures. Economic outcome assessment should be included whenever possible. In each area, data must be collected using structured, reproducible methodology. Symptom assessment and other instruments must be validated for the population being studied.
- The CONSORT statement should be adopted as criteria for publication of randomized clinical trials by researchers, reviewers, and editors.
- Baseline urodynamic assessment is required in the neurogenic population and recommended in surgical trials. However, baseline urodynamic studies are highly desirable in all types of incontinence research. There is a great need to critically examine the predictive value of urodynamic testing in order to refine our tools as well as the diagnosis and treatment of patients.
- The primary goal of clinical research is to improve the care of patients; the ultimate goal is to understand the nature of disease and how treatments actually work. We can make this progress by collecting comprehensive baseline and follow-up data, and correlating outcome to baseline characteristics and observed changes during treatment.

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*.
7. 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'**.

Fig 1 : FREQUENCY / VOLUME CHART - STANDARD VERSION - 7 DAYS

Name: _____

Date	7:00 am	Mid-day	Midnight	6:00am	Pads used

No. of drinks per day: _____

Fig. 2 : BLADDER DIARY Detailed version - one day

Name: _____ Date: _____

Urine passed Time/Amount	Urgency?	Leakage?	Comments ?	Drinks - time, type and amount
6:00 am				
12:00 noon				
6:00 pm				
12:00 midnight				

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 7.30 7.30 9.30	50 250 275 200 WC 11.00 3.00 6.00 9.30	150 BED 11.45 12 2.70 2.70	5.30 2.50	1
17th	UP 260 210 7.30 10.00	230 150 220 250 50 1.00 3.30 7.30 9.30 11	BED 11 275 1.30	200 4.00	0
18th	UP 300 150 200 7.00 9.00	275 100 150 175 125 11.15 2.15 4.15 6.30 8.00 10.20	BED 11 400 4.30		0
19th	UP 250 300 310 7.30 10.30	75 200 50 250 2.15 3.00 5.50 9.00 10.15	BED 10.30 260 12.00	220 2.30 200 5.00	0
20th	UP 150 250 7.30 10.30	275 175 200 250 100 2.00 4.30 7.15 9.45 11.00	100 BED 0.45 1 350 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	BED 10.20 350 3.30	300 6.00	1
22nd	UP 150 220 7.30 9.30	150 290 300 110 WC 11.00 2.15 5.00 7.00 9.30	BED 11 350 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				
<i>Got up</i> 7.15 200	0	-		8.00 - 2
7.30 100	+	-		cups coffee 400mls.
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	-		2.30
3.45 -	-	W sneezed 3 times		cup tea - 200ml
5.30 175	0	-		
6:00 pm				
7.45 200	-	-		6.30 glass water - 250mls.
9.30 175	-	-		8.00 glass wine - 100mls
<i>BED</i> 10.30 100	-	-		10.00 mg cocoa - 250ml
12:00 midnight				
3.30 250	-	-		

Annex 2 : ICIQ-SF

Initial number

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 | <input type="checkbox"/> | 0 |
| about once a week or less often | <input type="checkbox"/> | 1 |
| two or three times a week | <input type="checkbox"/> | 2 |
| about once a day | <input type="checkbox"/> | 3 |
| several times a day | <input type="checkbox"/> | 4 |
| all the time | <input type="checkbox"/> | 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 | <input type="checkbox"/> | 0 |
| a small amount | <input type="checkbox"/> | 2 |
| a moderate amount | <input type="checkbox"/> | 4 |
| a large amount | <input type="checkbox"/> | 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 | <input type="checkbox"/> |
| leaks before you can get to the toilet | <input type="checkbox"/> |
| leaks when you cough or sneeze | <input type="checkbox"/> |
| leaks when you are asleep | <input type="checkbox"/> |
| leaks when you are physically active/exercising | <input type="checkbox"/> |
| leaks when you have finished urinating and are dressed | <input type="checkbox"/> |
| leaks for no obvious reason | <input type="checkbox"/> |
| leaks all the time | <input type="checkbox"/> |

Thank you very much for answering these questions