



*National Institute for
Health and Clinical Excellence*

Issue date: October 2006

Urinary incontinence

**The management of urinary
incontinence in women**

NICE clinical guideline 40

Developed by the National Collaborating Centre for Women's and Children's Health

NICE clinical guideline 40

Urinary incontinence: the management of urinary incontinence in women

Ordering information

You can download the following documents from www.nice.org.uk/CG040

- The NICE guideline (this document) – all the recommendations.
- A quick reference guide – a summary of the recommendations for healthcare professionals.
- ‘Understanding NICE guidance’ – information for patients and carers.
- The full guideline – all the recommendations, details of how they were developed, and summaries of the evidence they were based on.

For printed copies of the quick reference guide or ‘Understanding NICE guidance’, phone the NHS Response Line on 0870 1555 455 and quote:

- N1128 (quick reference guide)
- N1129 (‘Understanding NICE guidance’).

This guidance is written in the following context

This guidance represents the view of the Institute, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. The guidance does not, however, override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

National Institute for Health and Clinical Excellence

MidCity Place
71 High Holborn
London
WC1V 6NA

www.nice.org.uk

© National Institute for Health and Clinical Excellence, October 2006. All rights reserved. This material may be freely reproduced for educational and not-for-profit purposes. No reproduction by or for commercial organisations, or for commercial purposes, is allowed without the express written permission of the Institute.

Urinary incontinence: the management of urinary incontinence in women

Contents

Introduction	4
Woman-centred care	5
Key priorities for implementation	6
1 Guidance	10
<i>1.1 Assessment and investigation</i>	<i>10</i>
<i>1.2 Conservative management</i>	<i>14</i>
<i>1.3 Surgical management</i>	<i>18</i>
2 Notes on the scope of the guidance	22
3 Implementation	23
4 Research recommendations	24
5 Other versions of this guideline	27
<i>5.1 Full guideline</i>	<i>27</i>
<i>5.2 Quick reference guide</i>	<i>27</i>
<i>5.3 ‘Understanding NICE guidance’</i>	<i>27</i>
6 Related NICE guidance	27
7 Updating the guideline	29
Appendix A: The Guideline Development Group	30
Appendix B: The Guideline Review Panel	32
Appendix C: The algorithms	33

Introduction

Urinary incontinence (UI) is a common condition that may affect women of all ages, with a wide range of severity and nature. Although rarely life-threatening, UI may seriously influence the physical, psychological and social wellbeing of affected individuals. The impact on the families and carers of women with UI may be profound, and the resource implications for the health service considerable.

UI is defined by the International Continence Society as ‘the complaint of any involuntary leakage of urine’. UI may occur as a result of a number of abnormalities of function of the lower urinary tract or as a result of other illnesses, which tend to cause leakage in different situations.

- Stress UI is involuntary urine leakage on effort or exertion or on sneezing or coughing.
- Urge UI is involuntary urine leakage accompanied or immediately preceded by urgency (a sudden compelling desire to urinate that is difficult to defer).
- Mixed UI is involuntary urine leakage associated with both urgency and exertion, effort, sneezing or coughing.

Overactive bladder syndrome (OAB) is defined as urgency that occurs with or without urge UI and usually with frequency and nocturia. OAB that occurs with urge UI is known as ‘OAB wet’. OAB that occurs without urge UI is known as ‘OAB dry’. These combinations of symptoms are suggestive of the urodynamic finding of detrusor overactivity, but can be the result of other forms of urethrovesical dysfunction.

This guideline focuses on the management of stress UI, OAB and urge UI, and mixed UI in women. It does not address transient or continuous UI or UI that is provoked by specific stimuli such as sexual intercourse, or laughing or giggling. Leakage in these situations may, however, be a manifestation of abnormalities of lower urinary tract function, such as detrusor overactivity or urodynamic stress incontinence, that are covered by the guideline.

Woman-centred care

This guideline offers best-practice advice on the care of women with UI.

Treatment and care should take into account women's individual needs and preferences. Women with UI should have the opportunity to make informed decisions about their care and treatment. If women do not have the capacity to make decisions, healthcare professionals should follow the Department of Health guidelines 'Reference guide to consent for examination or treatment' (2001) (available from www.dh.gov.uk). From April 2007 healthcare professionals will need to follow a code of practice accompanying the Mental Capacity Act (summary available from www.dca.gov.uk/menincap/bill-summary.htm).

Good communication between healthcare professionals and women is essential. It should be supported by the provision of evidence-based information offered in a form that is tailored to the needs of the individual woman. Treatment, care and the information women are given about it should be culturally appropriate. It should also be accessible to women who have additional needs, such as physical, sensory or learning disabilities, and to women who do not speak or read English.

Carers and relatives should also be provided with the information and support they need.

Key priorities for implementation

Italic text following a recommendation gives a short summary of the evidence supporting that recommendation, more detail is available in the full guideline (see section 5).

Assessment and investigation

- At the initial clinical assessment, the woman's urinary incontinence (UI) should be categorised as stress UI, mixed UI, or urge UI/overactive bladder syndrome (OAB). Initial treatment should be started on this basis. In mixed UI, treatment should be directed towards the predominant symptom.

Expert opinion concludes that symptomatic categorisation of UI based on reports from the woman and history taking is sufficiently reliable to inform initial, non-invasive treatment decisions. (See section 3.2 of the full guideline.)

- Bladder diaries should be used in the initial assessment of women with UI or OAB. Women should be encouraged to complete a minimum of 3 days of the diary covering variations in their usual activities, such as both working and leisure days.

Bladder diaries are a reliable method of quantifying urinary frequency and incontinence episodes. The Guideline Development Group (GDG) concluded that a 3-day period allows variation in day-to-day activities to be captured while securing reasonable compliance. (See section 3.9 of the full guideline.)

- The use of multi-channel cystometry, ambulatory urodynamics or videourodynamics is not recommended before starting conservative treatment.
- For the small group of women with a clearly defined clinical diagnosis of pure stress UI, the use of multi-channel cystometry is not routinely recommended.
- Multi-channel filling and voiding cystometry is recommended in women before surgery for UI if:
 - there is clinical suspicion of detrusor overactivity, or

- there has been previous surgery for stress incontinence or anterior compartment prolapse, or
- there are symptoms suggestive of voiding dysfunction.

Ambulatory urodynamics or videourodynamics may also be considered in these circumstances.

It has not been shown that carrying out urodynamic investigations before initial treatment improves outcome. Complex reconstructive urological procedures were developed for use in specific urodynamic abnormalities. Hence, the GDG concluded that urodynamic investigations should be used to demonstrate the presence of specific abnormalities before undertaking these procedures. The GDG considered that urodynamic investigations are also of value if the clinical diagnosis is unclear prior to surgery or if initial surgical treatment has failed. (See section 3.11 of the full guideline.)

Conservative management

- A trial of supervised pelvic floor muscle training of at least 3 months' duration should be offered as first-line treatment to women with stress or mixed UI.

There is good evidence that daily pelvic floor muscle training continued for 3 months is a safe and effective treatment for stress and mixed UI. (See section 4.2 of the full guideline.)

- Bladder training lasting for a minimum of 6 weeks should be offered as first-line treatment to women with urge or mixed UI.

There is good evidence that bladder training is an effective treatment for urge or mixed UI, with fewer adverse effects and lower relapse rates than treatment with antimuscarinic drugs. (See section 4.3 of the full guideline.)

- Immediate release non-proprietary oxybutynin should be offered to women with OAB or mixed UI as first-line drug treatment if bladder training has been ineffective. If immediate release oxybutynin is not well tolerated, darifenacin, solifenacin, tolterodine, trospium, or an extended release or transdermal formulation of oxybutynin should be considered as

alternatives. Women should be counselled about the adverse effects of antimuscarinic drugs.

There is no evidence of a clinically important difference in efficacy between antimuscarinic drugs. However, immediate release non-proprietary oxybutynin is the most cost effective of the available options. (See section 4.4.1 of the full guideline.)

- Pelvic floor muscle training should be offered to women in their first pregnancy as a preventive strategy for UI.

There is evidence that pelvic floor muscle training used during a first pregnancy reduces the likelihood of postnatal UI. (See section 4.7 of the full guideline.)

Surgical management

- Sacral nerve stimulation is recommended for the treatment of UI due to detrusor overactivity in women who have not responded to conservative treatments. Women should be offered sacral nerve stimulation on the basis of their response to preliminary percutaneous nerve evaluation. Life-long follow-up is recommended.

The treatment options for women who have detrusor overactivity and have not responded to conservative therapy are all costly and associated with significant morbidity. There is a stronger body of evidence for the effectiveness of sacral nerve stimulation than for other procedures. Up to two-thirds of patients achieve continence or substantial improvement in symptoms after this treatment. (See section 5.1 of the full guideline.)

- Retropubic mid-urethral tape procedures using a 'bottom-up' approach with macroporous (type 1) polypropylene meshes are recommended as treatment options for stress UI where conservative management has failed. Open colposuspension and autologous rectus fascial sling are the recommended alternatives when clinically appropriate.

Many procedures have been described for the treatment of stress UI; although there is no strong evidence of superior effectiveness of any one, the best available data support the use of retropubic mid-urethral tape procedures, colposuspension

and autologous rectus fascial sling. Retropubic mid-urethral tape procedures consume fewer hospital resources and are associated with faster recovery than the other two procedures. (See section 5.2 of the full guideline.)

Competence of surgeons performing operative procedures for UI in women

- Surgery for UI should be undertaken only by surgeons who have received appropriate training in the management of UI and associated disorders or who work within a multidisciplinary team with this training, and who regularly carry out surgery for UI in women.

The expertise of the surgeon is one of the factors that influence surgical outcomes. The best outcomes are achieved when surgeons and/or their multidisciplinary team have specialist training and regular practice in continence surgery. (See section 6 of the full guideline.)

The following guidance is based on the best available evidence. The full guideline, [‘Urinary incontinence: the management of urinary incontinence in women’](#), gives details of the methods and evidence used to develop the guidance (see section 5 for details).

1 Guidance

1.1 Assessment and investigation

1.1.1 History-taking and physical examination

1.1.1.1 At the initial clinical assessment, the woman’s UI should be categorised as stress UI, mixed UI, or urge UI/OAB. Initial treatment should be started on this basis. In mixed UI, treatment should be directed towards the predominant symptom.

1.1.1.2 The clinical assessment should seek to identify relevant predisposing and precipitating factors and other diagnoses that may require referral for additional investigation and treatment.

1.1.2 Assessment of pelvic floor muscles

1.1.2.1 Routine digital assessment of pelvic floor muscle contraction should be undertaken before the use of supervised pelvic floor muscle training for the treatment of UI.

1.1.3 Assessment of prolapse

1.1.3.1 Women with UI who have symptomatic prolapse that is visible at or below the vaginal introitus should be referred to a specialist.

1.1.4 Urine testing

1.1.4.1 A urine dipstick test should be undertaken in all women presenting with UI to detect the presence of blood, glucose, protein, leucocytes and nitrites in the urine.

1.1.4.2 Women with symptoms of urinary tract infection (UTI) whose urine tests positive for both leucocytes and nitrites should have a

midstream urine specimen sent for culture and analysis of antibiotic sensitivities. An appropriate course of antibiotic treatment should be prescribed pending culture results.

1.1.4.3 Women with symptoms of UTI whose urine tests negative for either leucocytes or nitrites should have a midstream urine specimen sent for culture and analysis of antibiotic sensitivities. The healthcare professional should consider the prescription of antibiotics pending culture results.

1.1.4.4 Women who do not have symptoms of UTI, but whose urine tests positive for both leucocytes and nitrites, should not be offered antibiotics without the results of midstream urine culture.

1.1.4.5 Women who do not have symptoms of UTI and whose urine tests negative for either leucocytes or nitrites are unlikely to have UTI and should not have a urine sample sent for culture.

1.1.5 Assessment of residual urine

1.1.5.1 The measurement of post-void residual volume by bladder scan or catheterisation should be performed in women with symptoms suggestive of voiding dysfunction or recurrent UTI. A bladder scan should be used in preference to catheterisation on the grounds of acceptability and lower incidence of adverse events.

1.1.5.2 Women who are found to have a palpable bladder on bimanual or abdominal examination after voiding should be referred to a specialist.

1.1.6 Referral

1.1.6.1 Women with UI who have any of the following should receive an urgent referral¹:

- microscopic haematuria if aged 50 years and older
- visible haematuria
- recurrent or persisting UTI associated with haematuria if aged 40 years and older
- suspected malignant mass arising from the urinary tract.

1.1.6.2 In women with UI, further indications for consideration for referral to a specialist service include:

- persisting bladder or urethral pain
- clinically benign pelvic masses
- associated faecal incontinence
- suspected neurological disease
- symptoms of voiding difficulty
- suspected urogenital fistulae
- previous continence surgery
- previous pelvic cancer surgery
- previous pelvic radiation therapy.

1.1.7 Symptom scoring and quality-of-life assessment

1.1.7.1 The following incontinence-specific quality-of-life scales are recommended when therapies are being evaluated: ICIQ, BFLUTS, I-QOL, SUIQQ, UISS, SEAPI-QMM, ISI, and KHQ.²

1.1.8 Bladder diaries

1.1.8.1 Bladder diaries should be used in the initial assessment of women with UI or OAB. Women should be encouraged to complete a

¹ NICE's 'Referral guidelines for suspected cancer' (www.nice.org.uk/CG027) define urgent referral as the patient being seen within the national target for urgent referrals (currently 2 weeks).

² See full guidance for details.

minimum of 3 days of the diary covering variations in their usual activities, such as both working and leisure days.

1.1.9 Pad testing

1.1.9.1 Pad tests are not recommended in the routine assessment of women with UI.

1.1.10 Urodynamic testing

1.1.10.1 The use of multi-channel cystometry, ambulatory urodynamics or videourodynamics is not recommended before starting conservative treatment.

1.1.10.2 For the small group of women with a clearly defined clinical diagnosis of pure stress UI, the use of multi-channel cystometry is not routinely recommended.

1.1.10.3 Multi-channel filling and voiding cystometry is recommended in women before surgery for UI if:

- there is clinical suspicion of detrusor overactivity, or
- there has been previous surgery for stress incontinence or anterior compartment prolapse, or
- there are symptoms suggestive of voiding dysfunction.

Ambulatory urodynamics or videourodynamics may also be considered in these circumstances.

1.1.11 Other tests of urethral competence

1.1.11.1 The Q-tip, Bonney, Marshall, and Fluid-Bridge tests are not recommended in the assessment of women with UI.

1.1.12 Cystoscopy

1.1.12.1 Cystoscopy is not recommended in the initial assessment of women with UI alone.

1.1.13 Imaging

- 1.1.13.1 Imaging (magnetic resonance imaging, computed tomography, X-ray) is not recommended for the routine assessment of women with UI. Ultrasound is not recommended other than for the assessment of residual urine volume.

1.2 Conservative management

1.2.1 Lifestyle interventions

- 1.2.1.1 A trial of caffeine reduction is recommended for the treatment of women with OAB.
- 1.2.1.2 Consider advising modification of high or low fluid intake in women with UI or OAB.
- 1.2.1.3 Women with UI or OAB who have a body mass index greater than 30 should be advised to lose weight.

1.2.2 Physical therapies

- 1.2.2.1 A trial of supervised pelvic floor muscle training of at least 3 months' duration should be offered as first-line treatment to women with stress or mixed UI.
- 1.2.2.2 Pelvic floor muscle training programmes should comprise at least eight contractions performed three times per day.
- 1.2.2.3 If pelvic floor muscle training is beneficial, an exercise programme should be continued.
- 1.2.2.4 Perineometry or pelvic floor electromyography as biofeedback should not be used as a routine part of pelvic floor muscle training.
- 1.2.2.5 Electrical stimulation should not routinely be used in the treatment of women with OAB.

- 1.2.2.6 Electrical stimulation should not routinely be used in combination with pelvic floor muscle training.
- 1.2.2.7 Electrical stimulation and/or biofeedback should be considered in women who cannot actively contract pelvic floor muscles in order to aid motivation and adherence to therapy.

1.2.3 Behavioural therapies

- 1.2.3.1 Bladder training lasting for a minimum of 6 weeks should be offered as first-line treatment to women with urge or mixed UI.
- 1.2.3.2 If women do not achieve satisfactory benefit from bladder training programmes, the combination of an antimuscarinic agent with bladder training should be considered if frequency is a troublesome symptom.
- 1.2.3.3 In women with UI who also have cognitive impairment, prompted and timed voiding toileting programmes are recommended as strategies for reducing leakage episodes.

1.2.4 Drug therapies

- 1.2.4.1 Immediate release non-proprietary oxybutynin should be offered to women with OAB or mixed UI as first-line drug treatment if bladder training has been ineffective. If immediate release oxybutynin is not well tolerated, darifenacin, solifenacin, tolterodine, trospium, or an extended release or transdermal formulation of oxybutynin should be considered as alternatives. Women should be counselled about the adverse effects of antimuscarinic drugs.
- 1.2.4.2 An early treatment review should be undertaken following any change in antimuscarinic drug therapy.
- 1.2.4.3 Propiverine should be considered as an option to treat frequency of urination in women with OAB, but is not recommended for the treatment of UI.

- 1.2.4.4 Flavoxate, propantheline and imipramine should not be used for the treatment of UI or OAB in women.
- 1.2.4.5 The use of desmopressin may be considered specifically to reduce nocturia in women with UI or OAB who find it a troublesome symptom. However, the use of desmopressin for nocturia in women with idiopathic UI is outside the UK marketing authorisation for the product. Informed consent to treatment should be obtained and documented.
- 1.2.4.6 Duloxetine is not recommended as a first-line treatment for women with predominant stress UI. Duloxetine should not routinely be used as a second-line treatment for women with stress UI, although it may be offered as second-line therapy if women prefer pharmacological to surgical treatment or are not suitable for surgical treatment. If duloxetine is prescribed, women should be counselled about its adverse effects.
- 1.2.4.7 Systemic hormone replacement therapy is not recommended for the treatment of UI.
- 1.2.4.8 Intravaginal oestrogens are recommended for the treatment of OAB symptoms in postmenopausal women with vaginal atrophy.

1.2.5 Non-therapeutic interventions

- 1.2.5.1 Absorbent products, hand held urinals and toileting aids should not be considered as a treatment for UI. They should be used only as:
- a coping strategy pending definitive treatment
 - an adjunct to ongoing therapy
 - long-term management of UI only after treatment options have been explored.
- 1.2.5.2 Bladder catheterisation (intermittent or indwelling urethral or suprapubic) should be considered for women in whom persistent urinary retention is causing incontinence, symptomatic infections,

or renal dysfunction, and in whom this cannot otherwise be corrected. Healthcare professionals should be aware, and explain to women, that the use of indwelling catheters in urge UI may not result in continence.

1.2.5.3 Intermittent urethral catheterisation should be used for women with urinary retention who can be taught to self-catheterise or who have a carer who can perform the technique.

1.2.5.4 Careful consideration should be given to the impact of long-term indwelling urethral catheterisation. The practicalities, benefits and risks should be discussed with the patient or, if appropriate, her carer. Indications for the use of long-term indwelling urethral catheters for women with UI include:

- chronic urinary retention in women who are unable to manage intermittent self-catheterisation
- skin wounds, pressure ulcers or irritations that are being contaminated by urine
- distress or disruption caused by bed and clothing changes
- where a woman expresses a preference for this form of management.

1.2.5.5 Indwelling suprapubic catheters should be considered as an alternative to long-term urethral catheters. Healthcare professionals should be aware, and explain to women, that they may be associated with lower rates of symptomatic UTI, 'by-passing' and urethral complications than indwelling urethral catheters.

1.2.5.6 Intravaginal and intraurethral devices are not recommended for the routine management of UI in women. Women should not be advised to consider such devices other than for occasional use when necessary to prevent leakage, for example during physical exercise.

1.2.6 Complementary therapies

- 1.2.6.1 Complementary therapies are not recommended for the treatment of UI or OAB.

1.2.7 Preventive use of conservative therapies

- 1.2.7.1 Pelvic floor muscle training should be offered to women in their first pregnancy as a preventive strategy for UI.

1.3 *Surgical management*

1.3.1 Discussion of benefits and risks

- 1.3.1.1 Any woman wishing to consider surgical treatment for UI should be informed about the benefits and risks of surgical and non-surgical options. Counselling should include consideration of the woman's child-bearing wishes.

1.3.2 Procedures for OAB

- 1.3.2.1 Sacral nerve stimulation is recommended for the treatment of UI due to detrusor overactivity in women who have not responded to conservative treatments. Women should be offered sacral nerve stimulation on the basis of their response to preliminary percutaneous nerve evaluation. Life-long follow-up is recommended.
- 1.3.2.2 Augmentation cystoplasty for the management of idiopathic detrusor overactivity should be restricted to women who have not responded to conservative treatments and who are willing and able to self-catheterise. Preoperative counselling should include common and serious complications: bowel disturbance, metabolic acidosis, mucus production and/or retention in the bladder, UTI and urinary retention. The small risk of malignancy occurring in the augmented bladder should also be discussed. Life-long follow-up is recommended.

- 1.3.2.3 Urinary diversion should be considered for a woman with OAB only when conservative treatments have failed, and if sacral nerve stimulation and augmentation cystoplasty are not appropriate or are unacceptable to her. Life-long follow-up is recommended.
- 1.3.2.4 Bladder wall injection with botulinum toxin A should be used in the treatment of idiopathic detrusor overactivity only in women who have not responded to conservative treatments, and who are willing and able to self-catheterise. Women should be informed about the lack of long-term data. There should be special arrangements for audit or research. The use of botulinum toxin A for this indication is outside the UK marketing authorisation for the product. Informed consent to treatment should be obtained and documented.
- 1.3.2.5 Botulinum toxin B is not recommended for the treatment of women with idiopathic OAB.

1.3.3 Procedures for stress UI

- 1.3.3.1 Retropubic mid-urethral tape procedures using a 'bottom-up' approach with macroporous (type 1) polypropylene meshes are recommended as treatment options for stress UI if conservative management has failed. Open colposuspension and autologous rectus fascial sling are the recommended alternatives when clinically appropriate.
- 1.3.3.2 Synthetic slings using a retropubic 'top-down' or a transobturator foramen approach are recommended as alternative treatment options for stress UI if conservative management has failed, provided that women are made aware of the lack of long-term outcome data.
- 1.3.3.3 Synthetic slings using materials other than polypropylene that are not of a macroporous (type 1) construction are not recommended for the treatment of stress UI.

- 1.3.3.4 Intramural bulking agents (glutaraldehyde cross-linked collagen, silicone, carbon-coated zirconium beads, or hyaluronic acid/dextran co-polymer) should be considered for the management of stress UI if conservative management has failed. Women should be made aware that:
- repeat injections may be required to achieve efficacy
 - efficacy diminishes with time
 - efficacy is inferior to that of retropubic suspension or sling.
- 1.3.3.5 In view of the associated morbidity, the use of an artificial urinary sphincter should be considered for the management of stress UI in women only if previous surgery has failed. Life-long follow-up is recommended.
- 1.3.3.6 Laparoscopic colposuspension is not recommended as a routine procedure for the treatment of stress UI in women. The procedure should be performed only by an experienced laparoscopic surgeon working in a multidisciplinary team with expertise in the assessment and treatment of UI.
- 1.3.3.7 Anterior colporrhaphy, needle suspensions, paravaginal defect repair and the Marshall–Marchetti–Krantz procedure are not recommended for the treatment of stress UI.
- 1.3.3.8 Autologous fat and polytetrafluoroethylene used as intramural bulking agents are not recommended for the treatment of stress UI.

1.4 Competence of surgeons performing operative procedures for UI in women

- 1.4.1 Surgery for UI should be undertaken only by surgeons who have received appropriate training in the management of UI and associated disorders, or who work within a multidisciplinary team with this training, and who regularly carry out surgery for UI in women.

1.4.2 Training should be sufficient to develop the knowledge and generic skills documented below.

Knowledge should include the:

- specific indications for surgery
- required preparation for surgery, including preoperative investigations
- outcomes and complications of the proposed procedure
- anatomy relevant to the procedure
- steps involved in the procedure
- alternative management options
- likely postoperative progress.

Generic skills should include:

- the ability to explain procedures and possible outcomes to patients and family and to obtain informed consent
- the necessary hand–eye dexterity to complete the procedure safely and efficiently, with appropriate use of assistance
- the ability to communicate with and manage the operative team effectively
- the ability to prioritise interventions
- the ability to recognise when to ask for advice from others
- a commitment to multidisciplinary team working.

1.4.3 Training should include competence in cystourethroscopy.

1.4.4 Operative competence of surgeons undertaking surgical procedures to treat UI or OAB in women should be formally assessed by trainers through a structured process.

1.4.5 Surgeons who are already carrying out procedures for UI should be able to demonstrate that their training, experience and current practice equates to the standards laid out for newly trained surgeons.

- 1.4.6 Surgery for UI or OAB in women should be undertaken only by surgeons who carry out a sufficient case load to maintain their skills. An annual workload of at least 20 cases of each primary procedure for stress UI is recommended. Surgeons undertaking fewer than five cases of any procedure annually should do so only with the support of their clinical governance committee; otherwise referral pathways should be in place within clinical networks.
- 1.4.7 There should be a nominated clinical lead within each surgical unit with responsibility for continence and prolapse surgery. The clinical lead should work within the context of an integrated continence service.
- 1.4.8 A national audit of continence surgery should be undertaken.
- 1.4.9 Surgeons undertaking continence surgery should maintain careful audit data and submit their outcomes to national registries such as those held by the British Society of Urogynaecology (BSUG) and British Association of Urological Surgeons Section of Female and Reconstructive Urology (BAUS-SFRU).

2 Notes on the scope of the guidance

All NICE guidelines are developed in accordance with a scope that defines what the guideline will and will not cover. The scope of this guideline is available from www.nice.org.uk/CG040

This clinical guideline concerns the management of UI in adult women. It includes:

- stress UI
- OAB (with or without urge UI)
- mixed UI.

It has been developed with the aim of providing guidance on:

- initial and ongoing assessments and investigations
- appropriate use of conservative and surgical treatment options
- the competence required by surgeons performing the primary and subsequent operative procedures.

Areas outside the remit of the guideline include:

- the management and treatment of comorbidities, such as pelvic organ prolapse, except where they relate to the treatment of UI and/or OAB syndrome
- incontinence caused by neurological disease
- incontinence in men
- incontinence in children
- anal incontinence.

How this guideline was developed

NICE commissioned the National Collaborating Centre for Women's and Children's Health to develop this guideline. The Centre established a Guideline Development Group (see appendix A), which reviewed the evidence and developed the recommendations. An independent Guideline Review Panel oversaw the development of the guideline (see appendix B).

There is more information in the booklet: 'The guideline development process: an overview for stakeholders, the public and the NHS', which is available from www.nice.org.uk/guidelinesprocess or by telephoning 0870 1555 455 (quote reference N1113).

3 Implementation

The Healthcare Commission assesses the performance of NHS organisations in meeting core and developmental standards set by the Department of Health in 'Standards for better health' issued in July 2004. Implementation of clinical guidelines forms part of the developmental standard D2. Core standard C5

says that national agreed guidance should be taken into account when NHS organisations are planning and delivering care.

NICE has developed tools to help organisations implement this guidance (listed below). These are available on our website (www.nice.org.uk/CG040).

- Slides highlighting key messages for local discussion.
- Costing tools, including:
 - costing report to estimate the national savings and costs associated with implementation
 - costing template to estimate the local costs and savings involved.
- Implementation advice on how to put the guidance into practice and national initiatives that support this locally.
- Audit criteria to monitor local practice.

4 Research recommendations

The Guideline Development Group has made the following recommendations for research, based on its review of evidence, to improve NICE guidance and patient care in the future. The Guideline Development Group's full set of research recommendations is detailed in the full guideline (see section 5).

4.1 Multi-channel cystometry

Does carrying out multi-channel cystometry affect the outcome and cost-effectiveness of interventions for UI or OAB?

Why this is important

It has long been held that clinical assessment of patients with UI is unreliable; however, the widespread availability of invasive urodynamic testing, by multi-channel cystometry in particular, has led to an assumption of improved diagnostic value. Although many currently available treatments for UI and OAB have been evaluated in patients with known urodynamic background, it has never been shown for any treatment that carrying out urodynamic investigation improves outcome. Urodynamic investigation has its own associated cost and morbidity. Many units have significant waiting times for

investigation, and hence unnecessary use of investigations has significant resource implications.

4.2 Mid-urethral tape procedures compared with pelvic floor muscle training

What is the clinical and cost-effectiveness of mid-urethral tape procedures compared with pelvic floor muscle training in the first-line treatment of stress UI?

Why this is important

Although there are no useful comparative data on the effectiveness of pelvic floor muscle training and surgery in the treatment of stress UI, indirect comparison suggests that surgery is associated with higher cure rates but also substantially greater morbidity. Hence pelvic floor muscle training is used as first-line treatment. Information on long-term outcomes from pelvic floor muscle training is limited, although it appears that a significant number of women initially treated successfully by pelvic floor muscle training will ultimately undergo surgery. The development of newer minimal access procedures with shorter recovery periods than conventional surgery may make surgery a more acceptable option than previously. The clinical and cost-effectiveness of these procedures compared with pelvic floor muscle training has not yet been proven.

4.3 Pelvic floor muscle training

What is the optimum pelvic floor muscle training regimen for women with stress UI?

Why this is important

There is a large body of evidence to support the use of pelvic floor muscle training in the treatment of stress and mixed UI. A range of regimens has been employed, with variation in the number and frequency of exercises advocated, the duration of treatment, the method of delivery and the role of adjunctive therapies. Clarity as to the optimum regimen may improve the cost-effectiveness of this treatment.

4.4 Modifying lifestyle factors

What is the effectiveness of modifying lifestyle factors in reducing the prevalence and severity of UI and OAB?

Why this is important

Several studies have shown associations between various lifestyle factors and the prevalence or severity of UI and OAB. There is limited information on the effect of modifying these factors on urinary symptoms. Such interventions are in general free from adverse effects, and are cost neutral or cost saving. They therefore justify further evaluation.

4.5 Physical and behavioural therapies and lifestyle modifications

What is the effectiveness of physical and behavioural therapies and lifestyle modifications in the prevention of UI in women?

Why this is important

The impact of UI on individual women with the condition, their families and carers and on the NHS as a whole is huge. Prevention of UI would have advantages from all perspectives. There is limited information on the use of antenatal pelvic floor muscle training and some lifestyle modifications in the prevention of UI. There are, however, no data on the long-term outcomes of these and other conservative interventions used preventively. For example, although it has been shown that pelvic floor muscle training used in a first pregnancy may reduce the prevalence of UI postnatally, it is not known whether this has any influence following subsequent pregnancies.

4.6 Botulinum toxin A

What is the effectiveness of botulinum toxin A in the treatment of idiopathic detrusor overactivity?

Why this is important

There is a gap in our current management of idiopathic detrusor overactivity, between available conservative treatments of limited effectiveness and major

surgical options associated with a high level of morbidity. Botulinum toxin A has recently become available for the treatment of detrusor overactivity, and has rapidly been adopted in clinical practice to fill this gap. This has, however, occurred in advance of high-quality data on efficacy, safety and long-term outcomes.

5 Other versions of this guideline

5.1 Full guideline

The full guideline, 'Urinary incontinence: the management of urinary incontinence in women', contains details of the methods and evidence used to develop the guideline. It is published by the National Collaborating Centre for Women's and Children's Health and is available from www.ncc-wch.org.uk, our website (www.nice.org.uk/CG040fullguideline) and the National Library for Health (www.nlh.nhs.uk).

5.2 Quick reference guide

A quick reference guide for healthcare professionals is available from (www.nice.org/CG040quickrefguide).

For printed copies, phone the NHS Response Line on 0870 1555 455 (quote reference number N1128).

5.3 'Understanding NICE guidance'

Information for women with UI and their carers ('Understanding NICE guidance') is available from (www.nice.org.uk/CG040publicinfo).

For printed copies, phone the NHS Response Line on 0870 1555 455 (quote reference number N1129).

6 Related NICE guidance

Cancer service guidance

- Improving outcomes in urological cancers. *NICE cancer service guidance* (2002). Available from www.nice.org.uk/csguc

Clinical guidelines

- Routine postnatal care of women and their babies. *NICE clinical guideline* no. 37 (2006). Available from www.nice.org.uk/CG037
- Referral guidelines for suspected cancer. *NICE clinical guideline* no. 27 (2005). Available from www.nice.org.uk/CG027
- Infection control: prevention of healthcare-associated infection in primary and community care. *NICE clinical guideline* no. 2 (2003). Available from www.nice.org.uk/CG002

Interventional procedure guidance

- Insertion of biological slings for stress urinary incontinence in women. *NICE interventional procedure guidance* no. 154 (2006). Available from www.nice.org.uk/IPG154
- Insertion of extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in women. *NICE interventional procedure guidance* no. 133 (2005). Available from www.nice.org.uk/IPG133
- Intramural urethral bulking procedures for stress urinary incontinence in women. *NICE interventional procedure guidance* no. 138 (2005). Available from www.nice.org.uk/IPG138
- Sacral nerve stimulation for urge incontinence and urgency-frequency. *NICE interventional procedure guidance* no. 64 (2004). Available from www.nice.org.uk/IPG064
- Bone-anchored cystourethropexy. *NICE interventional procedure guidance* no.18 (2003). Available from www.nice.org.uk/IPG018

NICE is developing the following guidance (details available from www.nice.org.uk):

- The management of faecal incontinence in adults. *NICE clinical guideline*. (Publication expected June 2007.)

7 Updating the guideline

NICE clinical guidelines are updated as needed so that recommendations take into account important new information. We check for new evidence 2 and 4 years after publication, to decide whether all or part of the guideline should be updated. If important new evidence is published at other times, we may decide to do a more rapid update of some recommendations.

Appendix A: The Guideline Development Group

Elisabeth Adams

Subspecialist in Urogynaecology, Liverpool Women's NHS Foundation Trust

Alison Bardsley

Continence Advisor/Service Manager, Oxfordshire Continence Advisory Service

Linda Crumlin

Patient/carer representative, Leicestershire

Ian Currie

Consultant Gynaecologist (with an interest in urogynaecology),
Buckinghamshire Hospitals NHS Trust

Lynda Evans

Patient/carer representative, London

Jeanette Haslam

Women's Health Physiotherapist, Cumbria

Paul Hilton (Guideline Development Group leader)

Consultant Gynaecologist and Urogynaecologist, Newcastle upon Tyne
Hospitals NHS Trust

Margaret Jones

General Practitioner, Nottingham

Malcolm Lucas

Consultant Urological Surgeon, Swansea NHS Trust

Julian Spinks

General Practitioner, Strood, Kent

Joanne Townsend

Urogynaecology Nurse Specialist, University Hospitals of Leicester NHS Trust

Adrian Wagg

Consultant Geriatrician, University College London Hospitals NHS Foundation Trust

National Collaborating Centre for Women's and Children's Health

Martin Dougherty, Executive Director

Beti Wyn Evans, Research Fellow

Paul Jacklin, Senior Health Economist

Irene Kwan, Research Fellow

Debbie Pledge, Information Specialist

Samantha Vahidi, Work Programme Coordinator

Acknowledgements

Additional support was received from: Francoise Cluzeau, Wendy Riches, Rona McCandlish, Moira Mugglestone and colleagues at the National Collaborating Centre for Women's and Children's Health.

Appendix B: The Guideline Review Panel

The Guideline Review Panel is an independent panel that oversees the development of the guideline and takes responsibility for monitoring its quality. The Panel includes experts on guideline methodology, healthcare professionals and people with experience of the issues affecting patients and carers. The members of the Guideline Review Panel were as follows.

Mike Baldwin

Head of Health Technology Appraisals, Sanofi-Aventis

Jill Freer

Director of Patient Services, Rugby Primary Care Trust

Peter Robb (Chair)

Consultant ENT Surgeon, Epsom & St Helier University Hospitals and The Royal Surrey County NHS Trusts

John Seddon

Chairman, VOICES

Appendix C: The algorithms

Women with UI or OAB

Lifestyle interventions

Advise women with UI or OAB to:

- modify high or low fluid intake
- lose weight if their body mass index is over 30.

Initial assessment

Categorise UI as stress UI, urge UI/OAB or mixed UI. Start treatment on this basis.

- Identify factors that may require referral.
- Ask the woman to complete a bladder diary for at least 3 days, covering variations in usual activities (e.g. working and leisure days).
- Measure post-void residual urine in women with symptoms of voiding dysfunction or recurrent UTI. If available, use a bladder scan in preference to catheterisation.
- Use urine dipstick tests to detect blood, glucose, protein, leucocytes and nitrites.

Dipstick test results			
		Positive for leucocytes and nitrites	Negative for either leucocytes or nitrites
Urinary tract infection (UTI)	Symptoms	Send a mid-stream urine sample for culture and antibiotic sensitivity analysis. Prescribe appropriate antibiotics pending results.	Consider antibiotics pending results.
	No symptoms	Do not prescribe antibiotics unless there is a positive urine culture result.	UTI unlikely. Do not send a urine sample for culture.

The following are not recommended:

- urodynamics before conservative treatment
- ultrasound, except to assess residual urine volume
- routine use of pad tests or imaging (MRI, CT and X-ray)
- cystoscopy in the initial assessment of women with UI alone
- Q-tip, Bonney, Marshall and Fluid-Bridge tests.

MRI, magnetic resonance imaging;
CT, computed tomography

Stress UI

- See page 35.

OAB with or without UI

- See page 36.

Mixed UI

- Determine treatment according to whether stress or urge UI is the dominant symptom.
- See pages 35 and 36

Indications for referral

- Urgently refer women with any of the following:^a
 - microscopic haematuria if aged 50 years and older
 - visible haematuria
 - recurrent or persisting UTI associated with haematuria if aged 40 years and older
 - suspected pelvic mass arising from the urinary tract.
- Refer women with:
 - symptomatic prolapse visible at or below the vaginal introitus
 - palpable bladder on bimanual or physical examination after voiding.
- Consider referring women with:
 - persisting bladder or urethral pain
 - clinically benign pelvic masses
 - associated faecal incontinence
 - suspected neurological disease
 - voiding difficulty
 - suspected urogenital fistulae
 - previous continence surgery
 - previous pelvic cancer surgery
 - previous pelvic radiation therapy.

^a NICE's 'Referral guidelines for suspected cancer' (www.nice.org.uk/CG027) define urgent referral as the patient being seen within the national target for urgent referrals (currently 2 weeks).

Stress UI

Stress UI

- First-line treatment for stress or mixed UI should be pelvic floor muscle training (PFMT) lasting at least 3 months.
 - Digitally assess pelvic floor muscle contraction before PFMT.
 - PFMT should consist of at least eight contractions, three times a day.
 - If PFMT is beneficial, continue an exercise programme.
 - During PFMT, do not routinely use:
 - ✧ electrical stimulation; consider it and/or biofeedback in women who cannot actively contract their pelvic floor muscles
 - ✧ biofeedback using perineometry or pelvic floor electromyography.
- Duloxetine:
 - should not be used as a first-line treatment for stress UI
 - should not routinely be used as a second-line treatment for stress UI
 - may be offered as an alternative to surgical treatment; counsel women about adverse effects.

Further assessment

- For the few women with pure stress UI multi-channel cystometry is not routinely necessary before primary surgery
- Use multi-channel filling and voiding cystometry before surgery for UI if:
 - there is clinical suspicion of detrusor overactivity, or
 - there has been previous surgery for stress UI or anterior compartment prolapse, or
 - there are symptoms of voiding dysfunction.
- Ambulatory urodynamics or videourodynamics may be considered before surgery for UI in the same circumstances as multi-channel filling and voiding cystometry.

Other treatments for UI or OAB

- Consider desmopressin to reduce troublesome nocturia.^b
- Consider propiverine to treat frequency of urination in OAB.
- The following are not recommended:
 - propiverine for the treatment of UI
 - flavoxate, imipramine and propantheline
 - systemic hormone-replacement therapy
 - complementary therapies.

Stress UI

- Discuss the risks and benefits of surgical and non-surgical options. Consider the woman's child-bearing wishes during the discussion.
- If conservative treatments have failed, consider:
 - retropubic mid-urethral tape procedures using a 'bottom-up' approach with macroporous (type 1) polypropylene meshes, open colposuspension or autologous rectus fascial sling
 - synthetic slings using a retropubic 'top-down' or a transobturator foramen approach. Explain the lack of long-term outcome data
 - intramural bulking agents (glutaraldehyde crosslinked collagen, silicone, carbon-coated zirconium beads, hyaluronic acid/dextran co-polymer). Explain that:
 - ✧ repeat injections may be needed
 - ✧ the effect decreases over time
 - ✧ the technique is less effective than retropubic suspension or sling.
 - an artificial urinary sphincter if previous surgery has failed.*
- The following are not recommended for stress UI:
 - routine use of laparoscopic colposuspension
 - synthetic slings using materials other than polypropylene that are not of a macroporous (type 1) construction
 - anterior colporrhaphy, needle suspensions, paravaginal defect repair and the Marshall–Marchetti–Krantz procedure
 - autologous fat and polytetrafluoroethylene as intramural bulking agents.

^b The use of desmopressin for idiopathic UI is outside its UK marketing authorisation. Informed consent to treatment should be obtained and documented.

* Provide life-long follow-up after this procedure.

OAB with or without urge UI

OAB with or without UI

- Recommend caffeine reduction.
- First-line treatment for urge or mixed UI should be bladder training lasting at least 6 weeks. If frequency remains troublesome, consider adding an antimuscarinic drug.
- If bladder training is ineffective, prescribe non-proprietary oxybutynin.
 - Counsel the woman about adverse effects of antimuscarinic drugs.
 - If oxybutynin is not tolerated, alternatives are darifenacin, solifenacin, tolterodine, trospium, or different oxybutynin formulations.
 - Carry out an early treatment review after any change in drug.
- In postmenopausal women with vaginal atrophy, offer intravaginal oestrogens for OAB symptoms.
- In women with UI who also have cognitive impairment, prompted and timed toileting programmes may help reduce leakage episodes.
- Do not routinely use electrical stimulation in OAB.



Further assessment

- Do not routinely use multi-channel cystometry before primary surgery for stress UI
- Use multi-channel filling and voiding cystometry before surgery for UI if:
 - there is clinical suspicion of detrusor overactivity, or
 - there has been previous surgery for stress UI or anterior compartment prolapse, or
 - there are symptoms of voiding dysfunction.
- Ambulatory urodynamics or videourodynamics may be considered before surgery for UI in the same circumstances as multi-channel filling and voiding cystometry.



Other treatments for UI or OAB

- Consider desmopressin to reduce troublesome nocturia.^b
- Consider propiverine to treat frequency of urination in OAB.
- The following are not recommended:
 - propiverine for the treatment of UI
 - flavoxate, imipramine and propantheline
 - systemic hormone-replacement therapy
 - complementary therapies.



OAB with or without UI

- Discuss the risks and benefits of surgical and non-surgical options. Consider the woman's child-bearing wishes during the discussion.
- If conservative treatments have failed, consider:
 - botulinum toxin A to treat idiopathic detrusor overactivity in those willing and able to self-catheterise; explain the lack of long-term data; special arrangements for audit or research should be in place^c
 - sacral nerve stimulation for UI due to detrusor overactivity; select patients on basis of response to preliminary peripheral nerve evaluation*
 - augmentation cystoplasty in those willing and able to self-catheterise; explain common and serious complications and the small risk of malignancy in the augmented bladder*
 - urinary diversion if sacral nerve stimulation and augmentation cystoplasty are not appropriate or unacceptable.*

^b The use of desmopressin for idiopathic UI is outside its UK marketing authorisation. Informed consent to treatment should be obtained and documented.

^c The use of botulinum toxin A for this indication is outside its UK marketing authorisation. Informed consent to treatment should be obtained and documented. Do not use botulinum toxin B.