

Urinary incontinence

The management of urinary incontinence in women

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Introduction

This guideline updates and replaces the previous NICE guidance on urinary incontinence in women: NICE clinical guideline 40 (published October 2006). The recommendations are labelled according to when they were originally published (see <u>About this guideline</u> for details).

Urinary incontinence (UI) is a common symptom that can affect women of all ages, with a wide range of severity and nature. While rarely life-threatening, incontinence 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.
- Urgency UI is involuntary urine leakage accompanied or immediately preceded by urgency (a sudden compelling desire to urinate that is difficult to delay).
- Mixed UI is involuntary urine leakage associated with both urgency and exertion, effort, sneezing or coughing.
- Overactive bladder (OAB) is defined as urgency that occurs with or without urgency UI and usually with frequency and nocturia. OAB that occurs with incontinence is known as 'OAB wet'. OAB that occurs without incontinence 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.

Since the publication of the 2006 guideline, new methods of managing urinary incontinence have become available on the NHS. Botulinum toxin A and sacral nerve stimulation are also now more commonly used for treating OAB symptoms. Synthetic tape procedures have become increasingly popular for the treatment of stress urinary incontinence, and there have been reported improvements in the effectiveness and advances in the types of procedure offered since 2006. Updated guidance is needed to reflect these changes. New recommendations for 2013 sit alongside the original recommendations from the 2006 guideline. It is important to emphasise that all of the 2006 recommendations are just as relevant and important now as they were when they were originally published.

Urinary incontinence in neurological disease is outside the scope of this guideline but is covered in <u>Urinary incontinence in neurological disease</u> (NICE clinical guideline 148).

The guideline will assume that prescribers will use a drug's summary of product characteristics to inform decisions made with individual patients.

This guideline recommends some drugs for indications for which they do not have a UK marketing authorisation at the date of publication, if there is good evidence to support that use. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. The patient (or those with authority to give consent on their behalf) should provide informed consent, which should be documented. See the General Medical Council's <u>Good</u> <u>practice in prescribing medicines – guidance for doctors</u> for further information. Where recommendations have been made for the use of drugs outside their licensed indications ('off-label use'), these drugs are marked with a footnote in the recommendations.

Patient-centred care

This guideline offers best practice advice on the care of women with urinary incontinence.

Patients and healthcare professionals have rights and responsibilities as set out in the <u>NHS</u> <u>Constitution for England</u> – all NICE guidance is written to reflect these. Treatment and care should take into account individual needs and preferences. Patients should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If the patient is under 16, their family or carers should also be given information and support to help the child or young person to make decisions about their treatment. Healthcare professionals should follow the <u>Department of Health's advice on consent</u>. If someone does not have capacity to make decisions, healthcare professionals should follow the <u>code of practice that accompanies the Mental Capacity Act</u> and the supplementary <u>code of</u> <u>practice on deprivation of liberty safeguards</u>. In Wales, healthcare professionals should follow <u>advice on consent from the Welsh Government</u>.

NICE has produced guidance on the components of good patient experience in adult NHS services. All healthcare professionals should follow the recommendations in <u>Patient experience</u> in adult NHS services.

Key priorities for implementation

The following recommendations have been identified as priorities for implementation.

History-taking and physical examination

• At the initial clinical assessment, categorise the woman's urinary incontinence (UI) as stress UI (SUI), mixed UI, or urgency UI/overactive bladder (OAB). Start initial treatment on this basis. In mixed UI, direct treatment towards the predominant symptom. **[2006]**

Assessment of pelvic floor muscles

• Undertake routine digital assessment to confirm pelvic floor muscle contraction before the use of supervised pelvic floor muscle training for the treatment of UI. [2006, amended 2013]

Bladder diaries

• Use bladder diaries in the initial assessment of women with UI or OAB. Encourage women to complete a minimum of 3 days of the diary covering variations in their usual activities, such as both working and leisure days. **[2006]**

Percutaneous posterior tibial nerve stimulation

- Do not offer percutaneous posterior tibial nerve stimulation for OAB unless:
 - there has been a multidisciplinary team (MDT) review, and
 - conservative management including OAB drug treatment has not worked adequately, and
 - the woman does not want botulinum toxin A^[1] or percutaneous sacral nerve stimulation. **[new 2013]**

Absorbent products, urinals and toileting aids

• Absorbent products, hand held urinals and toileting aids should not be considered as a treatment for UI. Use them 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. [2006]

General principles when using OAB drugs

- Before OAB drug treatment starts, discuss with women:
 - the likelihood of success and associated common adverse effects, and
 - the frequency and route of administration, and
 - that some adverse effects such as dry mouth and constipation may indicate that treatment is starting to have an effect, **and**
 - that they may not see the full benefits until they have been taking the treatment for 4 weeks. **[new 2013]**

Choosing OAB drugs

- Offer one of the following choices first to women with OAB or mixed UI:
 - oxybutynin (immediate release), or
 - tolterodine (immediate release), or
 - darifenacin (once daily preparation). [new 2013]
- If the first treatment for OAB or mixed UI is not effective or well-tolerated, offer another drug with the lowest acquisition cost^[2]. [new 2013]

The multidisciplinary team (MDT)

• Offer invasive therapy for OAB and/or SUI symptoms only after an MDT review. [new 2013]

Surgical approaches for SUI

• When offering a surgical procedure discuss with the woman the risks and benefits of the different treatment options for SUI using the information in <u>Information to facilitate discussion</u> of risks and benefits of treatments for women with stress urinary incontinence. **[new 2013]**

^[1] At the time of publication (September 2013), most Botulinum toxin type A preparations did not have a UK marketing authorisation for this indication. Evidence was only available for the licensed Botulinum toxin A (BOTOX, Allergan) preparation.

^[2] This could be any drug with the lowest acquisition cost from any of the drugs reviewed, including an untried drug from recommendation <u>1.7.7</u>. The evidence review considered the following drugs: darifenacin, fesoterodine, oxybutynin (immediate release), oxybutynin (extended release), oxybutynin (transdermal), oxybutynin (topical gel), propiverine, propiverine (extended release), solifenacin, tolterodine (immediate release), tolterodine (extended release), trospium and trospium (extended release). See chapter 6 of the <u>full guideline</u>.

1 Recommendations

The following guidance is based on the best available evidence. The <u>full guideline</u> gives details of the methods and the evidence used to develop the guidance.

The wording used in the recommendations in this guideline (for example words such as 'offer' and 'consider') denotes the certainty with which the recommendation is made (the strength of the recommendation). See <u>About this guideline</u> for details.

1.1 Assessment and investigation

History-taking and physical examination

- 1.1.1 At the initial clinical assessment, categorise the woman's urinary incontinence (UI) as stress UI (SUI), mixed UI, or urgency UI/overactive bladder (OAB).
 Start initial treatment on this basis. In mixed UI, direct treatment towards the predominant symptom. [2006]
- 1.1.2 If stress incontinence is the predominant symptom in mixed UI, discuss with the woman the benefit of conservative management including OAB drugs before offering surgery. **[new 2013]**
- 1.1.3 During the clinical assessment seek to identify relevant predisposing and precipitating factors and other diagnoses that may require referral for additional investigation and treatment. **[2006]**

Assessment of pelvic floor muscles

1.1.4 Undertake routine digital assessment to confirm pelvic floor muscle contraction before the use of supervised pelvic floor muscle training for the treatment of UI.
 [2006, amended 2013]

Assessment of prolapse

1.1.5 Refer women with UI who have symptomatic prolapse that is visible at or below the vaginal introitus to a specialist. **[2006]**

Urine testing

- 1.1.6 Undertake a urine dipstick test in all women presenting with UI to detect the presence of blood, glucose, protein, leucocytes and nitrites in the urine. **[2006]**
- 1.1.7 If women have symptoms of urinary tract infection (UTI) and their urine tests positive for both leucocytes and nitrites send a midstream urine specimen for culture and analysis of antibiotic sensitivities. Prescribe an appropriate course of antibiotic treatment pending culture results. **[2006]**
- 1.1.8 If women have symptoms of UTI and their urine tests negative for either leucocytes or nitrites send a midstream urine specimen for culture and analysis of antibiotic sensitivities. Consider the prescription of antibiotics pending culture results. [2006]
- 1.1.9 If women do not have symptoms of UTI, but their urine tests positive for both leucocytes and nitrites, do not offer antibiotics without the results of midstream urine culture. **[2006]**
- 1.1.10 If a woman does not have symptoms of UTI and her urine tests negative for either leucocytes or nitrites do not send a urine sample for culture because she is unlikely to have UTI. **[2006]**

Assessment of residual urine

- 1.1.11 Measure post-void residual volume by bladder scan or catheterisation in women with symptoms suggestive of voiding dysfunction or recurrent UTI.
 [2006]
- 1.1.12 Use a bladder scan in preference to catheterisation on the grounds of acceptability and lower incidence of adverse events. [2006]
- 1.1.13 Refer women who are found to have a palpable bladder on bimanual or abdominal examination after voiding to a specialist. **[2006]**

Referral

- 1.1.14 Urgently refer women with UI who have any of the following^[3]:
 - microscopic haematuria in women aged 50 years and older
 - visible haematuria
 - recurrent or persisting UTI associated with haematuria in women aged 40 years and older
 - suspected malignant mass arising from the urinary tract. [2006]
- 1.1.15 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^[4]. [2006]

Symptom scoring and quality-of-life assessment

1.1.16 Use the following incontinence-specific quality-of-life scales when therapies are being evaluated: ICIQ, BFLUTS, I-QOL, SUIQQ, UISS, SEAPI-QMM, ISI and KHQ^[5]. **[2006]**

Bladder diaries

1.1.17 Use bladder diaries in the initial assessment of women with UI or OAB.
 Encourage women to complete a minimum of 3 days of the diary covering variations in their usual activities, such as both working and leisure days.
 [2006]

Pad testing

1.1.18 Do not use pad tests in the routine assessment of women with UI. [2006]

Urodynamic testing

- 1.1.19 Do not perform multi-channel cystometry, ambulatory urodynamics or videourodynamics before starting conservative management. [2006, amended 2013]
- 1.1.20 After undertaking a detailed clinical history and examination, perform multichannel filling and voiding cystometry before surgery in women who have:
 - symptoms of OAB leading to a clinical suspicion of detrusor overactivity, or
 - symptoms suggestive of voiding dysfunction or anterior compartment prolapse, or
 - had previous surgery for stress incontinence. [2006, amended 2013]
- 1.1.21 Do not perform multi-channel filling and voiding cystometry in the small group of women where pure SUI is diagnosed based on a detailed clinical history and examination. **[2006, amended 2013]**
- 1.1.22 Consider ambulatory urodynamics or videourodynamics if the diagnosis is unclear after conventional urodynamics. **[2006, amended 2013]**

Other tests of urethral competence

1.1.23 Do not use the Q-tip, Bonney, Marshall and Fluid-Bridge tests in the assessment of women with UI. **[2006]**

Cystoscopy

1.1.24 Do not use cystoscopy in the initial assessment of women with UI alone. [2006]

Imaging

1.1.25 Do not use imaging (MRI, CT, X-ray) for the routine assessment of women with UI. Do not use ultrasound other than for the assessment of residual urine volume. [2006]

1.2 Lifestyle interventions

Caffeine

1.2.1 Recommend a trial of caffeine reduction to women with OAB. [2006]

Fluid intake

1.2.2 Consider advising modification of high or low fluid intake in women with UI or OAB. **[2006]**

Weight

1.2.3 Advise women with UI or OAB who have a BMI greater than 30 to lose weight. [2006]

1.3 Physical therapies

Pelvic floor muscle training

- 1.3.1 Offer a trial of supervised pelvic floor muscle training of at least 3 months' duration as first-line treatment to women with stress or mixed UI. **[2006]**
- 1.3.2 Pelvic floor muscle training programmes should comprise at least 8 contractions performed 3 times per day. **[2006]**

- 1.3.3 Do not use perineometry or pelvic floor electromyography as biofeedback as a routine part of pelvic floor muscle training. **[2006]**
- 1.3.4 Continue an exercise programme if pelvic floor muscle training is beneficial. [2006]

Therapeutic stimulation

- 1.3.5 Do not routinely use electrical stimulation in the treatment of women with OAB.[2006]
- 1.3.6 Do not routinely use electrical stimulation in combination with pelvic floor muscle training. **[2006]**
- 1.3.7 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. **[2006]**

1.4 Behavioural therapies

Bladder training

1.4.1 Offer bladder training lasting for a minimum of 6 weeks as first-line treatment to women with urgency or mixed UI. **[2006]**

Multicomponent behavioural therapy

1.4.2 If women do not achieve satisfactory benefit from bladder training programmes, the combination of an OAB drug with bladder training should be considered if frequency is a troublesome symptom. **[2006]**

1.5 Neurostimulation

Within this guideline neurostimulation covers transcutaneous sacral nerve stimulation (surface electrodes placed above the sacrum), transcutaneous posterior tibial nerve stimulation (surface electrodes place above the posterior tibial nerve) and percutaneous posterior tibial nerve stimulation (needles inserted close to the posterior tibial nerve).

Transcutaneous sacral nerve stimulation

1.5.1 Do not offer transcutaneous sacral nerve stimulation^[6] to treat OAB in women. [new 2013]

Transcutaneous posterior tibial nerve stimulation

- 1.5.2 Explain that there is insufficient evidence to recommend the use of transcutaneous posterior tibial nerve stimulation to treat OAB. **[new 2013]**
- 1.5.3 Do not offer transcutaneous posterior tibial nerve stimulation for OAB. [new 2013]

Percutaneous posterior tibial nerve stimulation

- 1.5.4 Do not offer percutaneous posterior tibial nerve stimulation for OAB unless:
 - there has been a multidisciplinary team (MDT) review, and
 - conservative management including OAB drug treatment has not worked adequately, and
 - the woman does not want botulinum toxin A^[7] or percutaneous sacral nerve stimulation. [new 2013]
- 1.5.5 Explain that there is insufficient evidence to recommend the use of percutaneous posterior tibial nerve stimulation to routinely treat OAB. [new 2013]

1.6 Alternative conservative management options

Absorbent products, urinals and toileting aids

- 1.6.1 Absorbent products, hand held urinals and toileting aids should not be considered as a treatment for UI. Use them 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.
 [2006]

Catheters

1.6.2 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 urgency UI may not result in continence. **[2006]**

Intermittent urethral catheters

1.6.3 Offer intermittent urethral catheterisation to women with urinary retention who can be taught to self-catheterise or who have a carer who can perform the technique. **[2006]**

Indwelling urethral catheters

- 1.6.4 Give careful consideration to the impact of long-term indwelling urethral catheterisation. Discuss the practicalities, benefits and risks 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 selfcatheterisation
 - 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. [2006]

Indwelling suprapubic catheters

1.6.5 Indwelling suprapubic catheters should be considered as an alternative to long-term urethral catheters. Be aware, and explain to women, that they may be associated with lower rates of symptomatic UTI, 'bypassing', and urethral complications than indwelling urethral catheters. **[2006]**

Products to prevent leakage

1.6.6 Do not use intravaginal and intraurethral devices for the routine management of UI in women. Do not advise women to consider such devices other than for occasional use when necessary to prevent leakage, for example during physical exercise. **[2006]**

Complementary therapies

1.6.7 Do not recommend complementary therapies for the treatment of UI or OAB. [2006]

Preventive use of conservative therapies

1.6.8 Offer pelvic floor muscle training to women in their first pregnancy as a preventive strategy for UI. **[2006]**

Women who choose not to have further treatment

- 1.6.9 If a woman chooses not to have further treatment for urinary incontinence:
 - offer her advice about managing urinary symptoms, and
 - explain that if she changes her mind at a later date she can book a review appointment to discuss past tests and interventions and reconsider her treatment options. [new 2013]

1.7 Pharmacological treatment

General principles when using OAB drugs

- 1.7.1 When offering antimuscarinic drugs to treat OAB always take account of:
 - the woman's coexisting conditions (for example, poor bladder emptying)
 - use of other existing medication affecting the total anticholinergic load
 - risk of adverse effects. [new 2013]
- 1.7.2 Before OAB drug treatment starts, discuss with women:
 - the likelihood of success and associated common adverse effects, and
 - the frequency and route of administration, and
 - that some adverse effects such as dry mouth and constipation may indicate that treatment is starting to have an effect, **and**
 - that they may not see the full benefits until they have been taking the treatment for 4 weeks. [new 2013]
- 1.7.3 Prescribe the lowest recommended dose when starting a new OAB drug treatment. [new 2013]
- 1.7.4 If a woman's OAB drug treatment is effective and well-tolerated, do not change the dose or drug. **[new 2013]**

Choosing OAB drugs

- 1.7.5 Do not use flavoxate, propantheline and imipramine for the treatment of UI or OAB in women. **[2006]**
- 1.7.6 Do not offer oxybutynin (immediate release) to frail older women^[i]. **[new 2013]**
- 1.7.7 Offer one of the following choices first to women with OAB or mixed UI:

- oxybutynin (immediate release), or
- tolterodine (immediate release), or
- darifenacin (once daily preparation). [new 2013]
- 1.7.8 If the first treatment for OAB or mixed UI is not effective or well-tolerated, offer another drug with the lowest acquisition cost^[9]. **[new 2013]**
- 1.7.9 Offer a transdermal OAB drug to women unable to tolerate oral medication. [new 2013]
- 1.7.10 For guidance on mirabegron for treating symptoms of overactive bladder, refer to <u>Mirabegron for treating symptoms of overactive bladder</u> (NICE technology appraisal guidance 290). **[new 2013]**

Reviewing OAB drug treatment

- 1.7.11 Offer a face-to-face or telephone review 4 weeks after the start of each new OAB drug treatment. Ask the woman if she is satisfied with the therapy:
 - If improvement is optimal, continue treatment.
 - If there is no or suboptimal improvement or intolerable adverse effects change the dose, or try an alternative OAB drug (see recommendations <u>1.7.8–1.7.9</u>), and review again 4 weeks later. [new 2013]
- 1.7.12 Offer review before 4 weeks if the adverse events of OAB drug treatment are intolerable. [new 2013]
- 1.7.13 Offer referral to secondary care if the woman does not want to try another drug, but would like to consider further treatment. **[new 2013]**
- 1.7.14 Offer a further face-to-face or telephone review if a woman's condition stops responding optimally to treatment after an initial successful 4-week review.[new 2013]

- 1.7.15 Review women who remain on long-term drug treatment for UI or OAB annually in primary care (or every 6 months for women over 75). **[new 2013]**
- 1.7.16 Offer referral to secondary care if OAB drug treatment is not successful. [new 2013]
- 1.7.17 If the woman wishes to discuss the options for further management (nontherapeutic interventions and invasive therapy) refer to the MDT and arrange urodynamic investigation to determine whether detrusor overactivity is present and responsible for her OAB symptoms:
 - If detrusor overactivity is present and responsible for the OAB symptoms offer invasive therapy (see recommendations in <u>section 1.9</u>).
 - If detrusor overactivity is present but the woman does not wish to have invasive therapy, offer advice as described in <u>recommendation 1.6.9</u>.
 - If detrusor overactivity is not present refer back to the MDT for further discussion concerning future management. [new 2013]

Desmopressin

1.7.18 The use of desmopressin may be considered specifically to reduce nocturia^[10] in women with UI or OAB who find it a troublesome symptom. Use particular caution in women with cystic fibrosis and avoid in those over 65 years with cardiovascular disease or hypertension. **[2006, amended 2013]**

Duloxetine

1.7.19 Do not use duloxetine as a first-line treatment for women with predominant stress UI. Do not routinely offer duloxetine 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, counsel women about its adverse effects. **[2006]**

Oestrogens

- 1.7.20 Do not offer systemic hormone replacement therapy for the treatment of UI. [2006]
- 1.7.21 Offer intravaginal oestrogens for the treatment of OAB symptoms in postmenopausal women with vaginal atrophy. **[2006]**

1.8 The multidisciplinary team (MDT)

- 1.8.1 Inform any woman wishing to consider surgical treatment for UI about:
 - the benefits and risks of surgical and non-surgical options
 - their provisional treatment plan.

Include consideration of the woman's child-bearing wishes in the counselling. [2006, amended 2013]

- 1.8.2 Offer invasive therapy for OAB and/or SUI symptoms only after an MDT review. [new 2013]
- 1.8.3 When recommending optimal management the MDT should take into account:
 - the woman's preference
 - past management
 - comorbidities
 - treatment options (including further conservative management such as OAB drug therapy). [new 2013]
- 1.8.4 The MDT for urinary incontinence should include:
 - a urogynaecologist
 - a urologist with a sub-specialist interest in female urology

- a specialist nurse
- a specialist physiotherapist
- a colorectal surgeon with a sub-specialist interest in functional bowel problems, for women with coexisting bowel problems
- a member of the care of the elderly team and/or occupational therapist, for women with functional impairment. [new 2013]
- 1.8.5 Inform the woman of the outcome of the MDT review if it alters the provisional treatment plan. **[new 2013]**
- 1.8.6 All MDTs should work within an established regional clinical network to ensure all women are offered the appropriate treatment options and high quality care. [new 2013]

1.9 Invasive procedures for OAB

Botulinum toxin A

- 1.9.1 After an MDT review, offer bladder wall injection with botulinum toxin A^[7] to women with OAB caused by proven detrusor overactivity that has not responded to conservative management (including OAB drug therapy). [new 2013]
- 1.9.2 Discuss the risks and benefits of treatment with botulinum toxin A^[7] with women before seeking informed consent, covering:
 - the likelihood of being symptom free or having a large reduction in symptoms
 - the risk of clean intermittent catheterisation and the potential for it to be needed for variable lengths of time after the effect of the injections has worn off
 - the absence of evidence on duration of effect between treatments and the long-term efficacy and risks
 - the risk of adverse effects, including an increased risk of urinary tract infection. [new 2013]

- 1.9.3 Start treatment with botulinum toxin A^[7] only if women:
 - have been trained in clean intermittent catheterisation and have performed the technique successfully, **and**
 - are able and willing to perform clean intermittent catheterisation on a regular basis for as long as needed. [new 2013]
- 1.9.4 Use 200 units when offering botulinum toxin A^[7]. [new 2013]
- 1.9.5 Consider 100 units of botulinum toxin A^[7] for women who would prefer a dose with a lower chance of catheterisation and accept a reduced chance of success. [new 2013]
- 1.9.6 If the first botulinum toxin A^[7] treatment has no effect discuss with the MDT.
 [new 2013]
- 1.9.7 If botulinum toxin A^[7] treatment is effective, offer follow-up at 6 months or sooner if symptoms return for repeat treatment without an MDT referral. [new 2013]
- 1.9.8 Tell women how to self-refer for prompt specialist review if symptoms return following a botulinum toxin A^[7] procedure. Offer repeat treatment as necessary.
 [new 2013]
- 1.9.9 Do not offer botulinum toxin B to women with proven detrusor overactivity. [2006]

Percutaneous sacral nerve stimulation

- 1.9.10 Offer percutaneous sacral nerve stimulation to women after MDT review if:
 - their OAB has not responded to conservative management including drugs, and
 - they are unable to perform clean intermittent catheterisation. [new 2013]

- 1.9.11 Consider percutaneous sacral nerve stimulation after MDT review if a woman's OAB has not responded to conservative management (including drugs) and botulinum toxin A^[7]. **[new 2013]**
- 1.9.12 Discuss the long-term implications of percutaneous sacral nerve stimulation with women including:
 - the need for test stimulation and probability of the test's success
 - the risk of failure
 - the long-term commitment
 - the need for surgical revision
 - the adverse effects. [new 2013]
- 1.9.13 Tell women how to self-refer for prompt specialist review if symptoms return following a percutaneous sacral nerve stimulation procedure. **[new 2013]**

Augmentation cystoplasty

1.9.14 Restrict augmentation cystoplasty for the management of idiopathic detrusor overactivity to women whose condition has not responded to conservative management and who are willing and able to self-catheterise. Preoperative counselling for the woman or her carer should include common and serious complications: bowel disturbance, metabolic acidosis, mucus production and/or retention in the bladder, UTI and urinary retention. Discuss the small risk of malignancy occurring in the augmented bladder. Provide life-long follow-up. [2006, amended 2013]

Urinary diversion

1.9.15 Urinary diversion should be considered for a woman with OAB only when conservative management has failed, and if botulinum toxin A^[7], percutaneous sacral nerve stimulation and augmentation cystoplasty are not appropriate or are unacceptable to her. Provide life-long follow-up. **[2006, amended 2013]**

1.10 Surgical approaches for SUI

- 1.10.1 When offering a surgical procedure discuss with the woman the risks and benefits of the different treatment options for SUI using the information in Information to facilitate discussion of risks and benefits of treatments for women with stress urinary incontinence. [new 2013]
- 1.10.2 If conservative management for SUI has failed, offer:
 - synthetic mid-urethral tape (see recommendations <u>1.10.3–8</u>), or
 - open colposuspension (see also recommendation 1.10.9), or
 - autologous rectus fascial sling (see also recommendation <u>1.10.10</u>). [new 2013]

Synthetic tapes

- 1.10.3 When offering a synthetic mid-urethral tape procedure, surgeons should:
 - use procedures and devices for which there is current high quality evidence of efficacy and safety^[11]
 - only use a device that they have been trained to use (see recommendations in section <u>1.11</u>)
 - use a device manufactured from type 1 macroporous polypropylene tape
 - consider using a tape coloured for high visibility, for ease of insertion and revision.
 [new 2013]
- 1.10.4 If women are offered a procedure involving the transobturator approach, make them aware of the lack of long-term outcome data. **[new 2013]**
- 1.10.5 Refer women to an alternative surgeon if their chosen procedure is not available from the consulting surgeon. **[new 2013]**
- 1.10.6 Use 'top-down' retropubic tape approach only as part of a clinical trial. **[new 2013]**

- 1.10.7 Refer to <u>single-incision sub-urethral short tape insertion for stress urinary</u> <u>incontinence</u> (NICE interventional procedure guidance 262) for guidance on single-incision procedures. **[new 2013]**
- 1.10.8 Offer a follow-up appointment (including vaginal examination to exclude erosion) within 6 months to all women who have had continence surgery. [new 2013]

Colposuspension

1.10.9 Do not offer laparoscopic colposuspension as a routine procedure for the treatment of stress UI in women. Only an experienced laparoscopic surgeon working in an MDT with expertise in the assessment and treatment of UI should perform the procedure. **[2006]**

Biological slings

1.10.10 Do not offer anterior colporrhaphy, needle suspensions, paravaginal defect repair and the Marshall–Marchetti–Krantz procedure for the treatment of stress UI. [2006]

Intramural bulking agents

- 1.10.11 Consider intramural bulking agents (silicone, carbon-coated zirconium beads or hyaluronic acid/dextran copolymer) for the management of stress UI if conservative management has failed. Women should be made aware that:
 - repeat injections may be needed to achieve efficacy
 - efficacy diminishes with time
 - efficacy is inferior to that of synthetic tapes or autologous rectus fascial slings.
 [2006, amended 2013]
- 1.10.12 Do not offer autologous fat and polytetrafluoroethylene used as intramural bulking agents for the treatment of stress UI. **[2006]**

Artificial urinary sphincter

1.10.13 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. **[2006]**

Considerations following unsuccessful invasive SUI procedures or recurrence of symptoms

- 1.10.14 Women whose primary surgical procedure for SUI has failed (including women whose symptoms have returned) should be:
 - referred to tertiary care for assessment (such as repeat urodynamic testing including additional tests such as imaging and urethral function studies) and discussion of treatment options by the MDT, or
 - offered advice as described in recommendation <u>1.6.9</u> if the woman does not want continued invasive SUI procedures. **[new 2013]**

1.11 Maintaining and measuring expertise and standards for practice

- 1.11.1 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 an MDT with this training, and who regularly carry out surgery for UI in women. [2006]
- 1.11.2 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 proposed procedure
 - anatomy relevant to procedure

- steps involved in 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 MDT working. [2006]
- 1.11.3 Training should include competence in cystourethroscopy. **[2006]**
- 1.11.4 Operative competence of surgeons undertaking surgical procedures to treat UI or OAB in women should be formally assessed by trainers through a structured process. [2006]
- 1.11.5 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. **[2006]**
- 1.11.6 Only surgeons who carry out a sufficient case load to maintain their skills should undertake surgery for UI or OAB in women. An annual workload of at least 20 cases of each primary procedure for stress UI is recommended. Surgeons undertaking fewer than 5 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. [2006]

- 1.11.7 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. **[2006]**
- 1.11.8 A national audit of continence surgery should be undertaken. [2006]
- 1.11.9 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).
 [2006]

Information to facilitate discussion of risks and benefits of treatments for women with stress urinary incontinence

Risks and benefits up to 1 year			Risks and benefits after 1 year						
Procedure	Continent <1 year	Perioperative events – tissue injury*		Continent >1 year	Erosion	Retention	Voiding dysfunction	De r ove blac sym	
Retropubic 'bottom-up'	67% to 90% (24 studies)	3% to 6% (29 studies)	2 years	74% to 95% (7 studies)	0% to 4% (4 studies)	0% to 13% (4 studies)	18% (1 study)	0% ⁻ (4 st	
			3 years	81% to 92% (5 studies)	0% (2 studies)	0% (1 study)	No studies	0% ⁻ (2 st	
			5 years	69 to 85% (4 studies)	0% to 1% (4 studies)	0% to 5% (2 studies)	0% to 1% (1 study)	0% ⁻ (3 st	
			7 years	70% to 85% (2 studies)	0% to 1% (2 studies)	No studies	No studies	17% stud	

			10 years	56% to 85% (2 studies)	No studies	No studies	No studies	17% stud
Trans- obturator 'outside-in	60% to 75% (10 studies)	3% to 12% (14 studies)	2 years	80% (1 study)	0% (1 study)	4% (1 study)	No studies	7% stud
			3 years	No studies	No studies	No studies	No studies	No s
			5 years	No studies	No studies	No studies	No studies	No s
			7 years	No studies	No studies	No studies	No studies	No s
			10 years	No studies	No studies	No studies	No studies	No s
Trans- obturator 'inside-out'	62% to 73% (19 studies)	1% to 3% (14 studies)	2 years	87% (1 study)	No studies	No studies	No studies	No s
			3 years	75% to 84% (2 studies)	1% (1 study)	No studies	No studies	No s
			5 years	69% to 89% (2 studies	1% (2 studies)	No studies	No studies	0% stud
			7 years	No studies	No studies	No studies	No studies	No s
			10 years	No studies	No studies	No studies	No studies	No s
Retropubic 'top down'	81% (2 studies)	3% to 7% (3 studies)	2 years	No studies	No studies	No studies	No studies	No s

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			3 years	No studies	No studies	No studies	No studies	No
			5 years	No studies	No studies	No studies	No studies	No :
			7 years	No studies	No studies	No studies	No studies	No :
			10 years	No studies	No studies	No studies	No studies	No :
Open colpo- suspension	53% to 94% (10 studies)	0% to 11% (6 studies)	2 years	70% to 86% (3 studies)	No studies	9% (1 study)	No studies	14% stuc
			3 years	89% (1 study)	No studies	No studies	No studies	No :
			5 years	78% to 79% (2 studies)	No studies	No studies	4% (1 study)	25% stuc
Autologous rectus fascial sling	93% (1 study)	No studies	5 years	No studies	3% (1 study)	No studies	No studies	16% stuc

* Tissue injury includes bladder perforation, vaginal wall perforation, urethral and bladder injury.

^[3]NICE's <u>Referral guidelines for suspected cancer</u> define urgent referral as the patient being seen within the national target for urgent referrals (currently 2 weeks).

^[4] For further indications for consideration for referral, see recommendations 1.1.5 and 1.1.13.

^[5] See <u>full guideline</u> for details.

^[6] This is often known as transcutaneous electrical nerve stimulation (TENS).

^[7] At the time of publication (September 2013), most Botulinum toxin type A preparations did not have a UK marketing authorisation for this indication. Evidence was only available for the licensed Botulinum toxin A (BOTOX, Allergan) preparation.

^[a] The Guideline Development Group defined 'frail older women' as those with multiple comorbidities, functional impairments such as walking or dressing difficulties and any degree of cognitive impairment.

^[9] This could be any drug with the lowest acquisition cost from any of the drugs reviewed, including an untried drug from recommendation <u>1.7.7</u>. The evidence review considered the following drugs: darifenacin, fesoterodine, oxybutynin (immediate release), oxybutynin (extended release), oxybutynin (transdermal), oxybutynin (topical gel), propiverine, propiverine (extended release), solifenacin, tolterodine (immediate release), tolterodine (extended release), trospium and trospium (extended release). See chapter 6 of the <u>full guideline</u>.

^[w] At the time of publication (September 2013), desmopressin did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's <u>Good practice in prescribing and managing medicines and devices</u> for further information.

^[11] The guideline only recommends the use of tapes with proven efficacy based on robust RCT evidence. However, technological advances are frequent, therefore the choice of tape should include devices that are shown in future clinical trials to have equal or improved efficacy at equal or lower cost. At the time of publication (September 2013) the following met the Guideline Development Group criteria:

TVT or Advantage for a 'bottom-up' retropubic approach

TVT-O for an 'inside-out' transobturator approach

Monarc and obtryx halo for an 'outside-in' transobturator approach.

2 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.

2.1 Pelvic floor muscle training

How effective are different pelvic floor muscle training regimens in the management of women with overactive bladder (OAB) symptoms and to whom should it be offered?

Why this is important

For many women with urinary incontinence symptoms, management of their condition will take place predominantly in primary and community care. Pelvic floor muscle training may be their only experience of therapeutic intervention. It is not currently known whether different pelvic floor muscle training regimens have an impact on treatment outcomes. It is also not known whether other factors also have an impact on its effectiveness. These factors include the way that the training is offered, the technique that is taught, the intensity and frequency of training, and the length of time that pelvic floor muscle training is continued. Because pelvic floor muscle training is widely used in clinical practice, robust evaluation is needed to identify whether these or other factors have an important impact on patient-centred outcomes.

2.2 Neurostimulation

What is the comparative effectiveness and cost-effectiveness of transcutaneous stimulation of the sacral nerve roots, and transcutaneous and percutaneous posterior tibial nerve stimulation for the treatment of OAB?

Why this is important

Transcutaneous neurostimulation can be applied either over the sacrum or over the posterior tibial nerve to modulate the sacral nerve supply to the bladder. The treatment uses surface electrodes and the woman can carry it out in her own home. Percutaneous posterior tibial nerve stimulation involves the introduction of a needle in the region of the posterior tibial nerve near the

ankle, and at present is carried out in clinics in secondary care. Currently, it is offered widely as a conservative treatment for OAB without adequate evidence that it is effective. Although this is a relatively low cost treatment, both the equipment and staff time have a cost implication, and because it has been widely used in conservative management this has large resource consequences for the NHS. Robust evidence is needed to establish whether it is a cost-effective option relative to other conservative therapies for all women or for a selected group of patients who are unsuitable for or have unsuccessful botulinum toxin A, percutaneous sacral nerve stimulation or OAB drug treatment.

2.3 Botulinum toxin A

What is the long-term effectiveness, optimal dose and optimal frequency of repeat therapy of botulinum toxin A in women with OAB based on detrusor overactivity including risk of adverse events such as urinary infection and intermittent catheterisation?

Why is this important

There are currently no trials looking at long-term outcomes, quality of life, satisfaction, optimal dose, optimal frequency and long-term adverse effects of botulinum toxin A for women with OAB. Further research into these outcomes will have an impact on future updates of key recommendations within the guideline and would impact on how resources are used within urinary incontinence services. Effective treatment with botulinum toxin A may need repeated injections to remain effective but the frequency of these is not reported in the current evidence. Botulinum toxin A has the potential to cause incomplete bladder emptying resulting in the need for women to perform catheterisation indefinitely. This not only has financial implications but catheterisation and the morbidity associated with it will not always be acceptable to women. Additionally, there are currently no data on whether repeated botulinum toxin A injections alter bladder function.

2.4 Sequence of invasive OAB procedures

What is the effectiveness and optimum sequence of treatment with botulinum toxin A and percutaneous sacral nerve stimulation for the treatment of OAB after failed conservative (including drug) management?

Why is this important

It is not currently known which treatment option, either botulinum toxin A or percutaneous sacral nerve stimulation, is the most effective in the medium- and long-term for women with OAB in whom initial treatment, including OAB drugs, has failed. The initial outlay for percutaneous sacral nerve stimulation is high but when successful it appears to be effective. Botulinum toxin A also has a high failure rate but a lower outlay and it is not yet understood the cost threshold (in terms of treatment cycles or length of follow-up) at which botulinum toxin A is likely to be the less costeffective option compared with percutaneous sacral nerve stimulation. Currently, funding for percutaneous sacral nerve stimulation is on an individual basis because of its high cost, leading to geographical inequalities in access. A head-to-head longitudinal study of these 2 treatments would determine both which should be offered first and at what point in the treatment pathway. Such studies have not been done. This evidence could reduce inequalities in access to treatment. In subsequent NICE guidance, evidence would be available to inform recommendations on the treatment pathway and at which point in the treatment pathway for OAB each of these options should be offered. It would also provide more robust information to patients about the risk of adverse events and support women's choice about whether to proceed with treatment.

2.5 Predictors of tape failure

What are the effects of the following predictors on tape failure?

- Age per decade
- Lower maximum urethral closure pressure
- Secondary surgery versus primary surgery
- Higher maximal flow rate
- Concurrent pelvic organ prolapse surgery
- Nocturia versus no nocturia
- Urgency versus no urgency
- Pad weight (per 10 g)

- Previous urinary incontinence surgery versus no surgery
- Q-tip maximum straining less than 30 degrees, yes versus no
- Urge score (per 10 points)
- Urgency symptoms versus no urgency symptoms
- More than 20 procedures for each surgeon versus first 10 procedures for each surgeon
- General anaesthesia versus local anaesthesia
- BMI over 35 versus 30 or less
- Maximum urethral closure pressure of 31 or more versus 30 or less
- Primary surgery versus secondary surgery
- Preoperative anticholinergic medication use versus no use

Why is this important

The factors identified for this research question are thought anecdotally by surgeons to have an impact on the outcome of tape surgery but there is little robust evidence in the literature. Certain patient factors such as older age and increased weight are thought to produce a higher chance of recurrent symptoms. Similarly, the effect of previous incontinence surgery, concomitant prolapse surgery and the 'learning curve' of the surgeon are all thought to have adverse effects on outcome (including an increased chance of urgency incontinence). In addition there is little robust evidence regarding the effect of previous urgency incontinence, higher maximum flow rates, nocturia or preoperative use of anticholinergics on the occurrence of post-operative urgency and bladder overactivity. It would be useful to be able to individualise treatment by understanding these risks in more detail.

3 Other information

3.1 Scope and how this guideline was developed

NICE guidelines are developed in accordance with a <u>scope</u> that defines what the guideline will and will not cover.

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 <u>section 4</u>), which reviewed the evidence and developed the recommendations.

The methods and processes for developing NICE clinical guidelines are described in <u>The</u> guidelines manual.

3.2 Related NICE guidance

Details are correct at the time of publication of the guideline (September 2013). Further information is available on the <u>NICE website</u>.

General

- Patient experience in adult NHS services. NICE clinical guideline 138 (2012).
- Medicines adherence. NICE clinical guideline 76 (2009).

Condition-specific

- <u>Mirabegron for treating symptoms of overactive bladder</u>. NICE technology appraisal guidance 290 (2013).
- Urinary incontinence in neurological disease. NICE clinical guideline 148 (2012).
- Infection control. NICE clinical guideline 139 (2012).
- Lower urinary tract symptoms. NICE clinical guideline 97 (2010).

- <u>Percutaneous posterior tibial nerve stimulation for overactive bladder syndrome</u>. NICE interventional procedure guidance 362 (2010).
- <u>Laparoscopic augmentation cystoplasty (including clam cystoplasty</u>). NICE interventional procedure guidance 326 (2009).
- <u>Single-incision sub-urethral short tape insertion for stress urinary incontinence in women</u>.
 NICE interventional procedure guidance 262 (2008).
- Faecal incontinence. NICE clinical guideline 49 (2007).
- Insertion of biological slings for stress urinary incontinence. NICE interventional procedure guidance 154 (2006).
- Intramural urethral bulking procedures for stress urinary incontinence. NICE interventional procedure guidance 138 (2005).
- Insertion of extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in women. NICE interventional procedure guidance 133 (2005).
- <u>Sacral nerve stimulation for urge incontinence and urgency-frequency</u>. NICE interventional procedure guidance 64 (2004).

4 The Guideline Development Group, National Collaborating Centre and NICE project team

4.1 Guideline Development Group

Tony Smith (Chair) Consultant Urogynaecologist, Saint Mary's Hospital, Manchester

Paul Abrams Consultant Urological Surgeon, Southmead Hospital, Bristol

Elisabeth Adams Consultant Urogynaecologist, Liverpool Women's Hospital

Kate Anders Senior Nurse, King's College Hospital, London

Rosie Benneyworth GP, Taunton, Somerset

Stephanie Knight Principal Physiotherapist, Airedale General Hospital, Keighley

Cath Linney Patient member

Susie Orme Geriatrician, Barnsley Hospital NHS Trusts

June Rogers Patient member, PromoCon

Amanda Wells Continence Advisor

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

David Bevan Project Manager

Liz Bickerdike Research Assistant

Hannah Rose Douglas Associate Director, Health Economics

David James Clinical Co-director

Juliet Kenny Project Manager

Rosalind Lai Information Specialist

Hugh McGuire Senior Research Fellow

Nitara Prasannan Research Assistant

4.3 NICE project team

Nicole Elliott Associate Director

Sarah Dunsdon Guideline Commissioning Manager

Palida Teelucknavan

Guideline Coordinator

Judith Thornton

Technical Lead

Jasdeep Hayre

Health Economist

Jaimella Espley

Editor

Changes after publication

January 2015: Minor maintenance.

October 2014: Minor maintenance.

October 2013: A minor amend has been made to the botulinum toxin A footnote to accurately reflect the licence for the BOTOX, Allergan preparation.

About this guideline

NICE clinical guidelines are recommendations about the treatment and care of people with specific diseases and conditions in the NHS in England and Wales.

NICE guidelines are developed in accordance with a <u>scope</u> that defines what the guideline will and will not cover.

This guideline was developed by the National Collaborating Centre for Women's and Children's Health, which is based at the Royal College of Obstetricians and Gynaecologists. The Collaborating Centre worked with a Guideline Development Group, comprising healthcare professionals (including consultants, GPs and nurses), patients and carers, and technical staff, which reviewed the evidence and drafted the recommendations. The recommendations were finalised after public consultation.

The methods and processes for developing NICE clinical guidelines are described in <u>The</u> guidelines manual.

Update information

This guideline updates and replaces NICE clinical guideline 40 (published October 2006).

Recommendations are marked as [new 2013], [2013], [2006] or [2006, amended 2013]:

- [new 2013] indicates that the evidence has been reviewed and the recommendation has been updated or added.
- [2013] indicates that the evidence has been reviewed but no change has been made to the recommended action
- [2006] indicates that the evidence has not been updated and reviewed since 2006
- [2006, amended 2013] indicates that the evidence has not been updated and reviewed since 2006, but changes have been made to the recommendation wording that change the meaning (see below)

Recommendations from NICE clinical guideline 40 that have been amended

Some recommendations had had minor editorial changes to so they are written in the direct, active style or to improve clarity and implementation.

Recommendations listed in the table below are those where the evidence has not been reviewed but changes have been made to the recommendation wording that change the meaning.

Recommendation in NICE clinical guideline 40	Recommendation in current guideline	Reason for change
 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. (Recommendation [1.1.10.3] in 2006 guideline). 	 1.1.20 After undertaking a detailed clinical history and examination, perform multi-channel filling and voiding cystometry before surgery in women who have: symptoms of OAB leading to a clinical suspicion of detrusor overactivity, or symptoms suggestive of voiding dysfunction or anterior compartment prolapse, or had previous surgery for stress incontinence. [2006, amended 2013] 1.1.22 Consider ambulatory urodynamics or videourodynamics is unclear after conventional urodynamics. [2006, amended 2013] 	The criteria for multi- channel filling and voiding cystometry has been updated to improve clarity and implementation. The recommendation for ambulatory urodynamics has additional text to clarify that this procedure should take place following unclear outcomes from an initial urodynamic assessment.

]
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. (Recommendation [1.1.10.2] in 2006 guideline).	1.1.21 Do not perform multi- channel filling and voiding cystometry in the small group of women where pure SUI is diagnosed based on a detailed clinical history and examination. [2006, amended 2013]	Explanatory text was added to the recommendation on multichannel filling and voiding cystometry particularly because establishing a diagnosis of pure SUI requires a detailed clinical history and examination. This has been added to the recommendation to avoid women being offered surgical treatment for SUI without the identification of any symptoms of OAB.
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. (Recommendation [1.2.4.5] in 2006 guideline).	1.7.18 The use of desmopressin may be considered specifically to reduce nocturia ^[a] in women with UI or OAB who find it a troublesome symptom. Use particular caution in women with cystic fibrosis and avoid in those over 65 years with cardiovascular disease or hypertension. [2006, amended 2013]	The cautionary note for the use of desmopressin has been updated to reflect current clinical practice. The updated caution is taken from the current BNF indications for use.

r	1	
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. (Recommendation [1.3.2.2] in 2006 guideline).	1.9.14 Restrict augmentation cystoplasty for the management of idiopathic detrusor overactivity to women whose condition has not responded to conservative management and who are willing and able to self-catheterise. Preoperative counselling for the woman or her carer should include common and serious complications: bowel disturbance, metabolic acidosis, mucus production and/or retention in the bladder, UTI and urinary retention. Discuss the small risk of malignancy occurring in the augmented bladder. Provide life- long follow-up. [2006, amended 2013]	'for the woman or her carer' has been added to the recommendation. This update has been made to reflect the equality of treatment of some women who would be required to catheterise. 'Provide life-long follow-up' has been added to give a direct instruction and to match the recommendation for urinary diversion.
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. (Recommendation [1.3.2.3] in 2006 guideline).	1.9.15 Urinary diversion should be considered for a woman with OAB only when conservative management has failed, and if botulinum toxin A ^[1] , percutaneous sacral nerve stimulation and augmentation cystoplasty are not appropriate or are unacceptable to her. Provide life-long follow-up. [2006, amended 2013]	'Provide life-long follow-up' has been added to give a direct instruction and to match the recommendation for augmentation cystoplasty.

Intramural bulking agents1.10.11 Consider intramural bulking agents (silicone, carbon- coated zirconium beads or hyaluronic acid/dextran co- polymer) should be consideredI.10.11 Consider intramural bulking agents (silicone, carbon- coated zirconium beads or hyaluronic acid/dextran co- polymer) should be consideredGlutaraldehyde cross-linked collagen has been removed from thisfor the management of stress UI if conservative management has failed. Women should be made aware that:stress UI if conservative management has failed. Women should be made aware that:This update has been made because collagen is no longer used for this procedure in the UK.• repeat injections may be required to achieve efficacy • efficacy diminishes with time• efficacy diminishes with time • efficacy is inferior to that of synthetic tapes or autologous rectus fascial slings. [2006, amended 2013]Stress UI if e amended 2013](Recommendation [1.3.3.4] in 2006 quideling)[1.3.3.4] inStress UI			
	 (glutaraldehyde cross-linked collagen, silicone, carbon-coated zirconium beads, or hyaluronic acid/dextran copolymer) 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 	 bulking agents (silicone, carbon-coated zirconium beads or hyaluronic acid/dextran copolymer) for the management of stress UI if conservative management has failed. Women should be made aware that: repeat injections may be needed to achieve efficacy efficacy diminishes with time efficacy is inferior to that of synthetic tapes or autologous rectus fascial slings. [2006, 	cross-linked collagen has been removed from this recommendation. This update has been made because collagen is no longer used for this
^[3] At the time of publication (September 2013), desmopressin did not have a UK marketing	2006 guideline).		

^{III} At the time of publication (September 2013), desmopressin did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's <u>Good practice in prescribing and managing medicines and devices</u> for further information.

^[5] At the time of publication (September 2013), most Botulinum toxin type A preparations did not have a UK marketing authorisation for this indication. Evidence was only available for the licensed Botulinum toxin A (BOTOX, Allergan) preparation.

Strength of recommendations

Some recommendations can be made with more certainty than others. The Guideline Development Group makes a recommendation based on the trade-off between the benefits and harms of an intervention, taking into account the quality of the underpinning evidence. For some interventions, the Guideline Development Group is confident that, given the information it has looked at, most patients would choose the intervention. The wording used in the recommendations in this guideline denotes the certainty with which the recommendation is made (the strength of the recommendation).

For all recommendations, NICE expects that there is discussion with the patient about the risks and benefits of the interventions, and their values and preferences. This discussion aims to help them to reach a fully informed decision (see also <u>Patient-centred care</u>).

Interventions that must (or must not) be used

We usually use 'must' or 'must not' only if there is a legal duty to apply the recommendation. Occasionally we use 'must' (or 'must not') if the consequences of not following the recommendation could be extremely serious or potentially life threatening.

Interventions that should (or should not) be used – a 'strong' recommendation

We use 'offer' (and similar words such as 'refer' or 'advise') when we are confident that, for the vast majority of patients, an intervention will do more good than harm, and be cost effective. We use similar forms of words (for example, 'Do not offer...') when we are confident that an intervention will not be of benefit for most patients.

Interventions that could be used

We use 'consider' when we are confident that an intervention will do more good than harm for most patients, and be cost effective, but other options may be similarly cost effective. The choice of intervention, and whether or not to have the intervention at all, is more likely to depend on the patient's values and preferences than for a strong recommendation, and so the healthcare professional should spend more time considering and discussing the options with the patient.

Recommendation wording in guideline updates

NICE began using this approach to denote the strength of recommendations in guidelines that started development after publication of the 2009 version of 'The guidelines manual' (January 2009). This does not apply to any recommendations ending **[2006]** (see <u>Update information</u> above for details about how recommendations are labelled). In particular, for recommendations

labelled **[2006]** the word 'consider' may not necessarily be used to denote the strength of the recommendation.

Other versions of this guideline

The full guideline, <u>Urinary incontinence in women: the management of urinary incontinence in</u> <u>women</u>, 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.

The recommendations from this guideline have been incorporated into a NICE pathway.

We have produced information for the public about this guideline.

Implementation

Implementation tools and resources to help you put the guideline into practice are also available.

Your responsibility

This guidance represents the view of NICE, 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. However, the guidance does not 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, and informed by the summaries of product characteristics of any drugs.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

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