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# Urinary incontinence in women The management of urinary incontinence in women

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**bpac<sup>nz</sup> guidelines** www.bpac.org.nz/guidelines



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## Introduction

The UK's National Institute for Health and Care Excellence (NICE) provides evidence-based guidance and advice to improve health and social care.

Clinical guidelines are recommendations by NICE on the most effective ways to diagnose, treat and care for people with specific conditions within the NHS and beyond. They are based on the best available evidence of clinical and cost effectiveness. While clinical guidelines help health professionals and others in their work, they do not replace their knowledge and skills.

Good clinical guidelines aim to improve the quality of healthcare and reduce inequalities and variation in practice. They can change the process of healthcare and improve outcomes for patients. Clinical guidelines:

- Help professionals and patients make decisions about the most appropriate treatment and care for specific clinical circumstances.
- Can be used to develop standards to assess the clinical practice of individual health professionals.
- Can support the education and training of health professionals and others.
- Can improve communication between patients and health professionals.

The Best Practice Advocacy Centre New Zealand (bpac<sup>nz</sup>) has an agreement with NICE to contextualise recently published NICE clinical guidelines for the New Zealand health care sector. The contextualisation process is described in detail on the bpac<sup>nz</sup> website. As part of this process, bpac<sup>nz</sup> will convene a Guideline Review and Contextualisation Group (GRCG) for each guideline. The GRCG will carefully consider the NICE guideline recommendations, taking into account the differences between the UK and New Zealand health care systems to produce a guideline that is relevant to those delivering and managing care in New Zealand.

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.

Urinary incontinence in neurological disease is outside the scope of this guideline but is covered in the NICE clinical guideline 148 – Urinary incontinence in neurological disease. This guideline has not been contextualised for New Zealand.

The guideline will assume that prescribers will use a medicine according to the New Zealand marketing authorisation (Medsafe) and the relevant sections of the New Zealand Medicines Act (1981).

## **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 by the New Zealand Code of Health and Disability Services Consumers' Rights. This contextualised guideline is written to reflect these rights.

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.

The Code of Health and Disability Services Consumers' Rights states that patients have rights as consumers of health and disability services provided by doctors and other health professionals in public and private services, for paid and unpaid services, within hospitals and within private practices. The code of rights is law under the Health and Disability Act 1994 (the HDC Act).

# Key priorities for implementation

The following recommendations have been identified by the GRCG as priorities for implementation.

## **Cultural considerations**

During any clinical assessment or management the clinician should be respectful of a
patient's cultural and ethnic background, specifically acknowledging that for Māori and
Pacific peoples all bodily waste (urine, menstrual blood, faeces) can be considered tapu. It
is important to keep things that are tapu, or restricted, separate from things that are noa,
or unrestricted. In many cases, these concepts align with good health and safety practice.

## 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.

## 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.

## **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.

### 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 containment strategy pending definitive treatment
  - an adjunct to ongoing therapy
  - long-term management of UI only after treatment options have wbeen explored.

## **Indwelling urethral catheters**

- 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.

## General principles when using overactive bladder (OAB) medicines

- Before OAB medicine 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.

## **Choosing OAB medicines**

• Offer oxybutynin (immediate release) to women with OAB or mixed UI.

If this is not effective or well-tolerated offer another option of tolterodine or solifenacin (subsidised with Special Authority approval).

## Surgical approaches for stress urinary incontinence (SUI)

• When offering a surgical procedure discuss with the woman the risks and benefits of the different treatment options for SUI (in the table 'Information to facilitate discussion of risks and benefits of treatments for women with stress urinary incontinence', Page 22).

### The multidisciplinary team (MDT)

• Offer invasive therapy (beyond botulinum toxin type A) for OAB and/or recurrent post surgical and complex cases of SUI symptoms only after an MDT review.

## Maintaining and measuring surgical expertise and standards for practice

• A national audit of continence surgery should be undertaken.

## 1. Recommendations

The following guidance is based on the best available evidence. The NICE full guideline (CG171)<sup>1</sup> gives details of the methods and the evidence used to develop the NICE guidance. The process and methods for contextualising the NICE guideline for the New Zealand health sector is available on the bpac<sup>nz</sup> website.<sup>2</sup>

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 the 'Strength of recommendations' section in this guideline (Page 33).

### **1.1** Assessment and investigation

1.1.1 During any clinical assessment or management the clinician should be respectful of a patient's cultural and ethnic background, specifically acknowledging that for Māori and Pacific peoples all bodily waste (urine, menstrual blood, faeces) can be considered tapu. It is important to keep things that are tapu, or restricted, separate from things that are noa, or unrestricted. In many cases, these concepts align with good health and safety practice.

#### History-taking and physical examination

- 1.1.2 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.
- 1.1.3 If stress incontinence is the predominant symptom in mixed UI, discuss with the woman the benefit of conservative management including OAB medicines before offering surgery.
- 1.1.4 During the clinical assessment seek to identify relevant predisposing and precipitating factors and other diagnoses that may require referral for additional investigation and treatment.

#### Assessment of pelvic floor muscles

1.1.5 Undertake routine digital assessment to confirm pelvic floor muscle contraction before the use of supervised pelvic floor muscle training for the treatment of UI.

#### Assessment of prolapse

1.1.6 Refer women with UI who have symptomatic prolapse that is visible at or below the vaginal introitus to a specialist.

#### Urine testing

1.1.7 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.

<sup>1.</sup> See; www.nice.org.uk/guidance/cg171

<sup>2.</sup> See: www.bpac.org.nz/guidelines/development-process.html

- 1.1.8 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.
- 1.1.9 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.
- 1.1.10 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.
- 1.1.11 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.

### Assessment of residual urine

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

## Referral

1.1.15 Urgently refer women with UI who have suspected malignant mass arising from the urinary tract.

Haematuria (macroscopic and microscopic) should be investigated urgently and referred according to local referral pathways.

- 1.1.16 In women with UI, further indications for consideration for referral to a specialist service include:
  - persisting bladder or urethral pain
  - recurrent or persisting UTI
  - 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<sup>3</sup>

3. For further indications for consideration for referral, see recommendations 1.1.5 and 1.1.13.

## Symptom scoring and quality-of-life assessment

1.1.17 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.<sup>4</sup>

## **Bladder diaries**

1.1.18 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.

### Pad testing

1.1.19 Do not use pad tests in the routine assessment of women with Ul.

#### Urodynamic testing

- 1.1.20 Do not perform multi-channel cystometry or videourodynamics before starting conservative management.
- 1.1.21 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.
- 1.1.22 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.
- 1.1.23 Consider videourodynamics if the diagnosis is unclear after multi-channel cystometry.

#### Other tests of urethral competence

1.1.24 Do not use the Q-tip, Bonney, Marshall and Fluid-Bridge tests in the assessment of women with UI.

#### Cystoscopy

1.1.25 Do not use cystoscopy in the initial assessment of women with UI alone.

#### Imaging

1.1.26 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.

<sup>4.</sup> See the NICE full guideline for details. Available from www.nice.org.uk/guidance/CG171

## 1.2 Lifestyle interventions

#### Caffeine

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

#### Fluid intake

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

#### Weight

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

## 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.
- 1.3.2 Pelvic floor muscle training programmes should comprise at least 8 contractions performed 3 times per day.
- 1.3.3 Do not use perineometry or pelvic floor electromyography as biofeedback as a routine part of pelvic floor muscle training.
- 1.3.4 Continue an exercise programme if pelvic floor muscle training is beneficial.

#### Therapeutic stimulation

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

## **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.

#### Multicomponent behavioural therapy

1.4.2 If women do not achieve satisfactory benefit from bladder training programmes or, in the case of some elderly women, anticipated to not achieve satisfactory benefit due to poor adherence to bladder training or pelvic floor muscle training, the combination of an OAB medicine with bladder training should be considered if frequency and urge UI are troublesome symptoms. 11

## 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 to treat OAB in women.

#### 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.
- 1.5.3 Do not offer transcutaneous posterior tibial nerve stimulation for OAB.

## 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 medicine treatment has not worked adequately, and
  - the woman does not want botulinum toxin type A<sup>5</sup> or percutaneous sacral nerve stimulation.
- 1.5.5 Explain that there is insufficient evidence to recommend the use of percutaneous posterior tibial nerve stimulation to routinely treat OAB.

## 1.6 Alternative conservative management options

## Absorbent products, urinals and toileting aids

- 1.6.1 Absorbent products,<sup>6</sup> 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.

#### 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

<sup>5.</sup> At the time of publication (May 2016), the Botulinum toxin type A with NZ Medsafe marketing authorisation for this indication is the BOTOX (Allergan) preparation.

<sup>6.</sup> District Health Board (DHB) provision of absorbent products is subject to the relevant Ministry of Health (MOH) service specification (The Community Health Care, Transitional and Support Services – Specialist Community Nursing Service – Continence Education and Consumables Services – Tier Level Three- Service Specification)

corrected. Healthcare professionals should be aware, and explain to women, that the use of indwelling catheters in urgency UI may not result in continence.

#### 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.

### 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.

### 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.

#### 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.

#### **Complementary therapies**

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

#### 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.

#### 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.

## **1.7 Pharmacological treatment**

#### General principles when using OAB medicines

- 1.7.1 When offering antimuscarinic medicines 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.
- 1.7.2 Before OAB medicine 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.
- 1.7.3 Prescribe the lowest recommended dose when starting a new OAB medicine treatment.
- 1.7.4 If a woman's OAB medicine treatment is effective and well-tolerated, do not change the dose or medicine.

#### **Choosing OAB medicines**

- 1.7.5 Offer oxybutynin (immediate release) to women with OAB or mixed UI.
- 1.7.6 Consider oxybutynin (immediate release) with caution for frail older women.<sup>7</sup>
- 1.7.7 If oxybutynin (immediate release) is not effective or well-tolerated, offer tolterodine or solifenacin (subsidised with Special Authority approval).
- 1.7.8 Transdermal oxybutynin or other transdermal OAB medicines can be offered to women unable to tolerate oral medication but are not currently subsidised in New Zealand.
- 1.7.9 Mirabegron is classified as a prescription medicine in New Zealand but there are currently no medicines containing mirabegron registered for use in New Zealand. For guidance on mirabegron for treating symptoms of overactive bladder, refer to Mirabegron for treating symptoms of overactive bladder (NICE technology appraisal guidance 290).<sup>8</sup>
- 1.7.10 Do not use propantheline, imipramine (or other tricyclic antidepressants) or flavoxate<sup>9</sup> for the treatment of UI or OAB in women.

#### **Reviewing OAB medicine treatment**

1.7.11 Offer a face-to-face or telephone review 4 weeks after the start of each new OAB

- 8. Available from: www.nice.org.uk/guidance/TA290
- 9. At the time of publication (May 2016), flavoxate had no marketing authorisation in New Zealand.

<sup>7.</sup> The NICE 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.

medicine 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 medicine (see recommendations 1.7.8–1.7.9), and review again 4 weeks later.
- 1.7.12 Offer review before 4 weeks if the adverse events of OAB medicine treatment are intolerable.
- 1.7.13 Offer referral to secondary care if the woman does not want to try another medicine, but would like to consider further treatment.
- 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.
- 1.7.15 Review women who remain on long-term medicine treatment for UI or OAB annually in primary care.
- 1.7.16 Offer referral to secondary care if OAB medicine treatment is not successful.
- 1.7.17 If the woman wishes to discuss the options for further management (nontherapeutic interventions and invasive therapy) refer to secondary care for urodynamic investigation to determine whether detrusor overactivity is present and responsible for her OAB symptoms and subsequent MDT review:
  - If detrusor overactivity is present and responsible for the OAB symptoms offer invasive therapy (see recommendations in section 1.9).
  - If detrusor overactivity is present but the woman does not wish to have invasive therapy, offer advice as described in recommendation 1.6.9.
  - If detrusor overactivity is not present refer back to the MDT for further discussion concerning future management.

#### Desmopressin

1.7.18 The use of desmopressin may be considered specifically to reduce nocturia<sup>10</sup> 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.

#### Duloxetine

1.7.19 Do not use duloxetine<sup>11</sup> 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.

<sup>10.</sup> At the time of publication (May 2016), desmopressin tablets had marketing authorisation for nocturia but was not subsidised for nocturia. Desmopressin spray does not have marketing authorisation for nocturia, and is only subsidised for primary nocturnal enuresis under Special Authority in New Zealand.

<sup>11.</sup> At the time of publication (May 2016), Duloxetine did not have current marketing authorisation for UI in New Zealand, and was not a subsidised medicine.

#### Oestrogens

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

### **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.

- 1.8.2 Offer invasive therapy (beyond botulinum toxin type A) for OAB and/or recurrent post surgical and complex cases of SUI symptoms only after an MDT review.
- 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 medicine therapy).
- 1.8.4 The MDT for urinary incontinence should include (if available):
  - a gynaecologist (ideally with sub-specialist interest in urogynaecology)
  - a urologist (ideally with a sub-specialist interest in female urology)
  - a specialist continence nurse
  - a physiotherapist with a special interest in pelvic floor health
  - 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.
- 1.8.5 Inform the woman of the outcome of the MDT review if it alters the provisional treatment plan.
- 1.8.6 All MDTs should work within an established regional clinical network, and be funded to ensure all women are offered the appropriate treatment options and high quality care.

## 1.9 Invasive procedures for OAB

#### Botulinum toxin type A<sup>5</sup>

1.9.1 Offer bladder wall injection with botulinum toxin type A to women with OAB caused by proven detrusor overactivity that has not responded to conservative management (including OAB medicine therapy).

- 1.9.2 Discuss the risks and benefits of treatment with botulinum toxin type A 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 longterm efficacy and risks
  - the risk of adverse effects, including an increased risk of urinary tract infection.
- 1.9.3 Start treatment with botulinum toxin type A only if women have been assessed and are able and willing to perform clean intermittent catheterisation on a regular basis for as long as needed.
- 1.9.4 Use **100** units when offering botulinum toxin type A.
- 1.9.5 Consider a higher dose of botulinum toxin type A if 100 units has not been effective.
- 1.9.6 If botulinum toxin type A treatment has no effect discuss with the MDT.
- 1.9.7 If botulinum toxin type A treatment is effective, offer follow-up at 6 months or sooner if symptoms return for repeat treatment without an MDT referral.
- 1.9.8 Tell women how to self-refer for prompt specialist review if symptoms return following a botulinum toxin type A procedure. Offer repeat treatment as necessary.
- 1.9.9 Do not offer botulinum toxin type B to women with proven detrusor overactivity.

## 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 medicines, and
  - they are unable to perform clean intermittent catheterisation.
- 1.9.11 Consider percutaneous sacral nerve stimulation after MDT review if a woman's OAB has not responded to conservative management (including medicines) and botulinum toxin type A.
- 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.
- 1.9.13 Tell women how to self-refer for prompt specialist review if symptoms return following a percutaneous sacral nerve stimulation procedure.

#### 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.

### **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 type A, percutaneous sacral nerve stimulation and augmentation cystoplasty are not appropriate or are unacceptable to her. Provide life-long follow-up.

## 1.10 Surgical approaches for SUI

- 1.10.1 In New Zealand, ranking patients for elective publicly funded surgical procedures for incontinence, and other gynaecology conditions, uses Clinical Priority Access Criteria (CPAC).<sup>12</sup> These criteria are based on a combination of:
  - Impact on life; whether a patient's incontinence compromises or causes her to avoid activities for some or all of the month
  - Effectiveness of the procedure in improving impact on life
  - Risk of complications /adverse effects of the surgical procedures.

The threshold CPAC score for surgery varies between DHBs throughout New Zealand. It is recommended that this be urgently addressed to ensure equitable access for surgery for all women in New Zealand, irrespective of their domicile.

- 1.10.2 When offering a surgical procedure discuss with the woman the risks and benefits of the different treatment options for SUI using the information (in the table 'Information to facilitate discussion of risks and benefits of treatments for women with stress urinary incontinence', Page 22).
- 1.10.3 If conservative management for SUI has failed, offer:
  - synthetic mid-urethral tape (see recommendations 1.10.4-9), or
  - open colposuspension (see also recommendation 1.10.10), or
  - autologous rectus fascial sling (see also recommendation 1.10.11).

#### Synthetic tapes

- 1.10.4 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<sup>13</sup>
  - only use a device that they have been trained to use (see recommendations in section 1.11)

- use a device manufactured from type 1 macroporous polypropylene tape
- consider using a tape coloured for high visibility, for ease of insertion and revision.
- 1.10.5 If women are offered a procedure involving the transobturator approach, make them aware of the lack of long-term outcome data.
- 1.10.6 Refer women to an alternative surgeon if their chosen procedure is not available from the consulting surgeon.
- 1.10.7 Use 'top-down' retropubic tape approach only as part of a clinical trial.
- 1.10.8 Refer to 'single-incision sub-urethral short tape insertion for stress urinary incontinence' (NICE interventional procedure guidance 262)<sup>14</sup> for guidance on single-incision procedures.
- 1.10.9 Offer a follow-up appointment (including vaginal examination to exclude erosion) within 6 months to all women who have had continence surgery.

#### Colposuspension

1.10.10 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.

#### **Biological slings**

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

#### Intramural bulking agents

- 1.10.12 Consider intramural bulking agents<sup>15</sup> (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.
- 1.10.13 Do not offer autologous fat and polytetrafluoroethylene as intramural bulking agents for the treatment of stress UI.

- 13. 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 NICE 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.
- 14. Available from: www.nice.org.uk/guidance/IPG262
- 15. At the time of publication (May 2016), Bulking agents were not listed in the Community or Hospital Pharmaceutical Schedules.

<sup>12.</sup> CPAC rankings are available from Ministry of Health website: www.health.govt.nz

#### Artificial urinary sphincter

1.10.14 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.

## Considerations following unsuccessful invasive SUI procedures or recurrence of symptoms

- 1.10.15 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 1.6.9 if the woman does not want continued invasive SUI procedures.

## **1.11** Maintaining and measuring surgical expertise and standards for practice

- 1.11.1 Surgery and invasive procedures 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.
- 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.
- 1.11.3 Training should include competence in cystourethroscopy.

- 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.
- 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.
- 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. For appropriately trained surgeons, in regional centres in particular, a lesser number of procedures may be acceptable, provided there are documented good clinical surgical outcomes. Surgeons undertaking fewer than 5 cases of any procedure annually should do so only with the support of their Clinical Director; otherwise referral pathways should be in place.
- 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.
- 1.11.8 A national audit of continence surgery should be undertaken.
- 1.11.9 Surgeons undertaking continence surgery should maintain careful audit data and submit their outcomes to registries such as the Urogynaecological Society of Australasia (UGSA) pelvic floor database or the Urological Society of Australia and New Zealand (USANZ) sling database.

Procedure Betronubic 'hottom_un'	7697					-		
	( t> tnenitno)	Perioperative events – tissue injury*		Continent >1 year	Erosion	Retention	noitɔnutɛyb gnibioV	De novo overactive bladder symptoms
	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% to 25% (4 studies)
			3 years	81% to 92% (5 studies)	0% (2 studies)	0% (1 study)	No studies	0% to 23% (2 studies)
			5 years	69 to 85% (4 studies)	0% to 1% (4 studies)	0% to 5% (2 studies)	0% to 1% (1 study)	0% to 18% (3 studies)
			7 years	70% to 85% (2 studies)	0% to 1% (2 studies)	No studies	No studies	17% (1 study)
			10 years	56% to 85% (2 studies)	No studies	No studies	No studies	17% (1 study)
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% (1 study)
			3 years	No studies	No studies	No studies	No studies	No studies
			5 years	No studies	No studies	No studies	No studies	No studies
			7 years	No studies	No studies	No studies	No studies	No studies
			10 years	No studies	No studies	No studies	No studies	No studies

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 studies
			3 years	75% to 84% (2 studies)	1% (1 study)	No studies	No studies	No studies
			5 years	69% to 89% (2 studies	1% (2 studies)	No studies	No studies	0% (1 study)
			7 years	No studies	No studies	No studies	No studies	No studies
			10 years	No studies	No studies	No studies	No studies	No studies
Retropubic 'top down'	81% (2 studies)	3% to 7% (3 studies)	2 years	No studies	No studies	No studies	No studies	No studies
			3 years	No studies	No studies	No studies	No studies	No studies
			5 years	No studies	No studies	No studies	No studies	No studies
			7 years	No studies	No studies	No studies	No studies	No studies
			10 years	No studies	No studies	No studies	No studies	No studies
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% (1 study)
			3 years	89% (1 study)	No studies	No studies	No studies	No studies
			5 years	78% to 79% (2 studies)	No studies	No studies	4% (1 study)	25% (1 study)
Autologous rectus fascial sling	93% (1 study)	No studies	5 years	No studies	3% (1 study)	No studies	No studies	16% (1 study)

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

## 2. Research recommendations

The Guideline Review and Contextualisation Group have recommended the following New Zealand-specific research priorities.

## 2.1 Epidemiology

A detailed prevalence study in New Zealand of UI and other symptoms of pelvic floor dysfunction (PFD), such as faecal incontinence and pelvic organ prolapse related to ethnicity and uptake of continence services is a high priority.

## 2.2 Surgery

There is an urgent need of a National Register and Audit of surgery and invasive procedures for UI and other types of PFD, in particular pelvic organ prolapse.

## 2.3 **Conservative treatment**

There is also a need of an audit of pelvic floor muscle and bladder retraining, both related to assessment (and in particular vaginal examination to assess voluntary pelvic floor muscle contractility and use of urinary diaries) and outcome of conservative treatment.

# 3. Other information

#### 3.1 Scope and how this guideline was developed

This bpac<sup>nz</sup> contextualised version of a NICE clinical guideline has been developed in accordance with a scope (available from www.bpac.org.nz/guidelines/2) that defines what the guideline will and will not cover.

#### How the NICE guideline was developed

NICE commissioned the National Collaborating Centre for Women's and Children's Health to develop the NICE guideline. The Centre established a Guideline Development Group (see Section 4.2), which reviewed the evidence and developed the recommendations.

The methods and processes for developing NICE clinical guidelines are described in 'Developing NICE guidelines: the manual'. See www.nice.org.uk/article/pmg20

## 3.2 Related NICE information

Further information on NICE Pathways for UI is available on the NICE website. See: pathways.nice.org.uk/pathways/urinary-incontinence-in-women

## 4. The Guideline Review and Contextualisation Group and the NICE Guideline Development Group

## 4.1 Guideline Review and Contextualisation Group

## Guideline Review and Contextualisation Group

The GRCG was composed of relevant healthcare professionals and bpac<sup>nz</sup> staff.

Don Wilson (Chair of GRCG)	Emeritus Professor of Obstetrics and Gynaecology, University of Otago, Consultant Urogynaecologist, Dunedin
Mark Weatherall	Consultant Geriatrician and President of the New Zealand Continence Association, Wellington
Tim Dawson	Consultant Urogynaecologist, Auckland
Lynn McBain	GP, Wellington
Sharon English (from 1 September 2015 following stakeholder feedback)	Consultant Urologist, Christchurch (Involved from first draft of guideline to publication)
Lucy Keedle	Continence Nurse Advisor, Palmerston North
Sharon Wilson	Physiotherapist (Pelvic, Women's and Men's Health), Nelson
Nigel Thompson	GP and Clinical Lead, Best Practice Advocacy Centre
Jared Graham	Project Manager, Best Practice Advocacy Centre

## 4.2 NICE 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

#### 4.3 NICE Guideline contextualisation quality assurance team

The NICE guideline contextualisation quality assurance team was responsible for quality assuring the guideline contextualisation process.

Phil Alderson	Clinical Adviser, NICE Centre for Clinical Practice
Christine Carson	Programme Director, NICE Centre for Clinical Practice
Andrew Gyton	Programme Manager, NICE Centre for Clinical Practice
Nichole Taske	Associate Director (Methodology), NICE Centre for Clinical Practice

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

The National Collaborating Centre for Women's and Children's Health was responsible for this guideline throughout its development. It was responsible for preparing information for the NICE GDG, for drafting the guideline and for responding to consultation comments.

## About this guideline

This bpac<sup>nz</sup> contextualised version of a NICE clinical guideline provides recommendations about the treatment and care of people with specific diseases and conditions in New Zealand.

NICE guidelines are developed in accordance with a scope that defines what the guideline will and will not cover. The bpac<sup>nz</sup> scope (available from www.bpac.org.nz/guidelines/2) outlines what the contextualised guideline will and will not cover.

This guideline was originally developed by the National Collaborating Centre for Women's and Children's Health in the United Kingdom, 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 within the UK.

The methods and processes for the bpac<sup>nz</sup> contextualisation of NICE clinical guidelines are described on the bpac<sup>nz</sup> website. The NICE guideline was developed using the process described in 'Developing NICE guidelines: the manual'. See www.nice.org.uk/article/pmg20

## **Update information**

The guideline bpac<sup>nz</sup> have contextualised was an updated guideline which replaced NICE clinical guideline 40 (published October 2006).

## **Recommendations from NICE CG171 that have been contextualised**

Recommendations listed in the table below are those which changes have been made to the NICE clinical guideline to ensure they are appropriate for New Zealand.

from The n	nal recommendation Urinary Incontinence: nanagement of urinary ntinence in women (CG171)	Recommendation following contextualisation for this guideline		Rationale for contextualisation	
1.6.4	<ul> <li>Refer people using a suspected cancer pathway referral (for an appointment within 2 weeks) for bladder cancer if they are:</li> <li>aged 45 and over and have:</li> <li>unexplained visible haematuria without urinary tract infection or</li> <li>visible haematuria that persists or recurs after successful treatment of urinary tract infection, or aged 60 and over and have unexplained non-visible haematuria and either dysuria or a raised white cell count on a blood test.</li> </ul>	1.1.15	Urgently refer women with UI who have suspected malignant mass arising from the urinary tract. Haematuria (macroscopic and microscopic) should be investigated urgently and referred according to local referral pathways	This recommendation has been revised following high stakeholder concern at proposed wording based on the NICE Guideline 'Suspected cancer: recognition and referral' guideline (NG12; 2015). The GRCG has revised this recommendation to address the stakeholder comments received during consultation, and to reflect that local health pathway organisations, and DHBs, have existing health pathways in use throughout the country. Haematuria requires urgent investigation. Local pathways define the age restrictions and criteria for urgent referral for haematuria. 'Recurrent or persisting UTI' moved to 1.1.16	
1.1.19	Do not perform multi- channel cystometry, ambulatory urodynamics or videourodynamics before starting conservative management.	1.1.20	Do not perform multi- channel cystometry or videourodynamics before starting conservative management.	Ambulatory urodynamics is not performed in New Zealand, nor do the GRCG consider future use will be considered.	
1.1.22	Consider ambulatory urodynamics or videourodynamics if the diagnosis is unclear after conventional urodynamics.	1.1.23	Consider videourodynamics if the diagnosis is unclear after multi-channel cystometry.	In New Zealand, 'conventional' urodynamics is multi-channel cystometry, and so clarity is needed here to avoid confusion highlighted by stakeholder comments. Removal of Ambulatory urodynamics made as noted above.	
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.	1.4.2	If women do not achieve satisfactory benefit from bladder training programmes or, in the case of some elderly women anticipated to not achieve satisfactory benefit due to poor adherence to bladder training or pelvic floor muscle training, the combination of an OAB medicine with bladder training should be considered if frequency and urge UI are troublesome symptoms.	In NZ pay-per-service is a limiting factor, particularly in lower socioeconomic areas. The GRCG has acknowledged that a clinician may choose to initiate treatment with a combination of bladder training and OAB medicines in New Zealand to reduce cost to the patient.	

1.7.5	Do not use flavoxate, propantheline and imipramine for the treatment of UI or OAB in women.	1.7.10	Do not use propantheline, imipramine (or other tricyclic antidepressants) or flavoxate for the treatment of UI or OAB in women.	The GRCG felt prescribers were likely to consider other tricyclic antidepressants as these are able to be prescribed without restriction (although typically outside their marketing authorisation) in New Zealand and are subsidised , whereas the two alternative anticholinergic agents need special authority application, and other anticholinergic agents either do not have marketing authorisation or are not subsidised. Following stakeholder comments it
				was also agreed that the order of recommendations would best read from what was to be offered to what was not to be offered.
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	1.7.5	Offer oxybutynin (immediate release) to women with OAB or mixed UI.	In New Zealand tolterodine is only subsidised under special authority (otherwise the patient pays) if there is a 'documented intolerance of, or is non- responsive to oxybutynin'. Darifenacin does not have marketing authorisation in New Zealand and would have to be imported by a prescriber, and it would not be subsidised.
1.7.6	Do not offer oxybutynin (immediate release) to frail older women.	1.7.6	Consider oxybutynin with caution to frail older women.	See 1.7.9 below.
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 .	1.7.7	lf oxybutynin (immediate release) is not effective or well-tolerated, offer tolterodine or solifenacin (subsidised with Special Authority approval).	In New Zealand second-line agents (tolerodine and solifenacin) are available only on Special Authority (SA) if there is a 'documented intolerance of, or a patient is non-responsive to oxybutynin'
1.7.9	Offer a transdermal OAB drug to women unable to tolerate oral medication	1.7.8	Transdermal oxybutynin or other transdermal OAB medicines can be offered to women unable to tolerate oral medication but are not currently subsidised in New Zealand.	In New Zealand second-line agents (tolerodine and solifenacin) are available only on Special Authority (SA) if there is a 'documented intolerance of, or a patient is non-responsive to oxybutynin'
1.7.10	For guidance on mirabegron for treating symptoms of overactive bladder, refer to Mirabegron for treating symptoms of overactive bladder (NICE technology appraisal guidance 290	1.7.9	Mirabegron is classified as a prescription medicine in New Zealand but there are currently no medicines containing mirabegron registered for use in New Zealand. For guidance on mirabegron for treating symptoms of overactive bladder, refer to Mirabegron for treating symptoms of overactive bladder (NICE technology appraisal guidance 290).	Contextual difference as there are currently no medicines containing mirabegron registered in New Zealand

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).	1.7.15	Review women who remain on long-term drug medicine treatment for UI or OAB annually in primary care	There is no contract with primary care practitioners to provide any form of regular review for patients of any age in New Zealand. Primary care in New Zealand is subsidised but is fee for service, so that recommendations for regular review will incur costs to the patient.
1.7.17	<ul> <li>If the woman wishes to discuss the options for further management (non-therapeutic 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:</li> <li>If detrusor overactivity is present and responsible for the OAB symptoms offer invasive therapy (see recommendations in section 1.9).</li> <li>If detrusor overactivity is present but the woman does not wish to have invasive therapy, offer advice as described in recommendation 1.6.9.</li> <li>If detrusor overactivity is not present refer back to the MDT for further discussion concerning future management.</li> </ul>	1.7.17	<ul> <li>If the woman wishes to discuss the options for further management (non- therapeutic interventions and invasive therapy) refer to secondary care for urodynamic investigation to determine whether detrusor overactivity is present and responsible for her OAB symptoms and subsequent MDT review:</li> <li>If detrusor overactivity is present and responsible for the OAB symptoms offer invasive therapy (see recommendations in section 1.9).</li> <li>If detrusor overactivity is present but the woman does not wish to have invasive therapy, offer advice as described in recommendation 1.6.9.</li> <li>If detrusor overactivity is not present refer back to the MDT for further discussion concerning future management.</li> </ul>	This reflects the different model of service and the current pathway used in New Zealand , and the role of the MDT [see 1.8.2] Not all regions will have MDT involvement as the continence service tends to be a stand-alone service.
1.8.2	Offer invasive therapy for OAB and/or SUI symptoms only after an MDT review	1.8.2	Offer invasive therapy (beyond botulinum toxin type A) for OAB and/or recurrent post surgical and complex cases of SUI only after an MDT review.	The GRCG considers that the use of botulinum toxin A for treatment of OAB, and the management of primary SUI is covered by local health pathways within New Zealand. The NICE GDG concluded that there was a requirement for the treatment plan to be validated by a group of qualified healthcare professionals who have not contributed to the prior treatment of the woman. Factors within New Zealand dictate that this requirement is not practical across all regions. This approach has been strongly supported through stakeholder comments received during consultation.

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1.8.4	<ul> <li>The MDT for urinary incontinence should include:</li> <li>a urogynaecologist</li> <li>a urologist with a sub- specialist interest in female urology</li> <li>a specialist nurse</li> <li>a specialist physiotherapist</li> <li>a colorectal surgeon with a sub-specialist interest in functional bowel problems, for women with coexisting bowel problems</li> <li>a member of the care of the elderly team and/or occupational therapist, for women with functional impairment.</li> </ul>	1.8.4	<ul> <li>The MDT for urinary incontinence should include (if available):</li> <li>a gynaecologist (ideally with sub-specialist interest in urogynaecology)</li> <li>a urologist (ideally with a sub-specialist interest in female urology)</li> <li>a specialist continence nurse</li> <li>a physiotherapist with a special interest in pelvic floor health</li> <li>a colorectal surgeon with a sub-specialist interest in functional bowel problems, for women with coexisting bowel problems</li> <li>a member of the care of the elderly team and/or occupational therapist, for women with functional impairment.</li> </ul>	This section must reflect the limited availability of each listed member. New Zealand has limited availability and the insertion of 'if available' to the recommendation has been made to reflect the New Zealand health system. Physiotherapist wording has been amended to reflect that at the time of publication the New Zealand Physiotherapy Board was developing a 3 tiered system of speciality. The highest tier had been established and a physiotherapist gaining this title can be called a 'Specialist pelvic floor Physiotherapist.' Other physiotherapists' can use the title 'Physiotherapist with special interest in pelvic floor health'. Both titles recognise training and expertise in treating urinary incontinence. The term 'continence' was inserted as within New Zealand a 'specialist nurse' may not have any training in continence.
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.	1.8.6	All MDTs should work within an established regional clinical network and be funded to ensure all women are offered the appropriate treatment options and high quality care	<i>This is to ensure that DHB's value this exercise and include attendance at MDT's in job descriptions for staff</i>
1.9.1	After an MDT review, offer bladder wall injection with botulinum toxin A to women with OAB caused by proven detrusor overactivity that has not responded to conservative management (including OAB medicine therapy).	1.9.1	Offer bladder wall injection with botulinum toxin type A to women with OAB caused by proven detrusor overactivity that has not responded to conservative management (including OAB medicine therapy).	The GRCG considers the use of botulinum toxin A for treatment of OAB, and the management of primary SUI is covered by local pathways within New Zealand. The NICE GDG concluded that there was a requirement for the treatment plan to be validated by a group of qualified healthcare professionals who had not contributed to the prior treatment of the woman. The GRCG involved in the contextualised guideline agreed that resource constraints regarding training for ISC in most centres in New Zealand meant the requirement for every case requiring botulinum toxin type A to be discussed at the MDT, or for explicit training in ISC prior to the use of botulinum toxin type A was not practical. The assessment of patients for use of botulinum toxin type A following local pathways was noted to work well and safely. This approach has been strongly supported through stakeholder comments received during consultation.

1.9.3	<ul> <li>Start treatment with botulinum toxin A only if women:</li> <li>have been trained in clean intermittent catheterisation and have performed the technique successfully, and</li> <li>have been assessed and are able and willing to perform clean intermittent catheterisation on a regular basis for as long as needed.</li> </ul>	1.9.3	Start treatment with botulinum toxin type A only if women have been assessed and are able and willing to perform clean intermittent catheterisation on a regular basis for as long as needed	Please see above comments
1.9.4	Use 200 units when offering botulinum toxin A	1.9.4	Use 100 units when offering botulinum toxin type A	In New Zealand the 100 units is the Medafe recommended dose With sensitivity to New Zealand's health funding, the initial 100 units, followed by the 200 units is reflected in this guideline.
1.9.5	Consider 100 units of botulinum toxin A for women who would prefer a dose with a lower chance of catheterisation and accept a reduced chance of success.	1.9.5	Consider a higher dose if 100 units has not been effective.	Please see above comments
1.9.6	If the first botulinum toxin type A treatment has no effect discuss with the MDT	1.9.6	If botulinum toxin type A treatment has no effect discuss with the MDT.	This reflects the lower initial starting dose used within New Zealand.
Insert 1.10.1	tion of recommendation (under )	1.10.1	<ul> <li>In New Zealand, ranking patients for elective publicly funded surgical procedures for incontinence, and other gynaecology conditions, uses</li> <li>Clinical Priority Access Criteria (CPAC). These criteria are based on a combination of: <ul> <li>Impact on life; whether a patient's incontinence compromises or causes her to avoid activities for some or all of the month.</li> <li>Effectiveness of the procedure in improving impact on life.</li> <li>Risk of complications / adverse effects of the surgical procedures.</li> </ul> </li> <li>The threshold CPAC score for surgery varies between DHBs throughout New Zealand. It is recommended that this be urgently addressed to ensure equitable access for surgery for all women in New Zealand, irrespective of their domicile.</li> </ul>	GRCG inserted recommendation to address the 'post-code lottery' due to variation across DHBs in New Zealand

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.	1.11.1	Surgery and invasive procedures 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.	This refers to invasive procedures for UI due to OAB and in particular the use of botulinum toxin type A i.e. should only be undertaken by appropriately trained surgeons in New Zealand as well as other surgical procedures.
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	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	There is little robust evidence related to numbers of procedures annually [after appropriate training]. This is addressed well in the NICE full guideline (10.3 Maintaining and measuring expertise and standards for practice, p297). Mention is made of a survey in the UK in 2001 in order to establish the most appropriate number of procedures to maintain competency. There was a differing opinion between general gynaecologists and urogynaecologists, which is also reflected within our own College in New Zealand [RANZCOG]. In this survey, the majority specialist view was 10–20 procedures per year [among general gynaecologists and urologists] while urogynaecologists and gynaecologists with a special interest stated 20–50 procedures per year. The GRCG is not aware of published evidence for these statements and in particular the relationship of numbers with clinical outcomes related to TVT. Although the GRCG endorsed the recommendation of an annual workload of at least 20 cases [which would be easily achieved in large centres in New Zealand] they added in comment regarding lesser numbers in regional centres but included "with documented good clinical outcomes, which is the bottom line related to surgery in any event.
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).	1.11.9	Surgeons undertaking continence surgery should maintain careful audit data and submit their outcomes to registries such as the Urogynaecological Society of Australasia (UGSA) pelvic floor database or the Urological Society of Australia and New Zealand (USANZ) sling database.	Contextual relevance specific to registries for New Zealand

## **Strength of recommendations**

Some recommendations can be made with more certainty than others. The original NICE Guideline Development Group made recommendations 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 Patient-centred care, Page 5). The bpac<sup>nz</sup> Guideline Review and Contextualisation Group have chosen to utilise the same conventions regarding wording for the strength of recommendations.

## Interventions that must (or must not) be used

We utilise the NICE wording of '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 utilise the NICE wording of '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 utilise the NICE wording of '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 their approach to denote the strength of recommendations in guidelines that started development after publication of a 2009 version of 'The guidelines manual' (January 2009). This does not apply to any recommendations ending [2006]. In particular, for recommendations labelled [2006] the word 'consider' may not necessarily be used to denote the strength of the recommendation.

## **UK versions of this guideline**

The full NICE guideline, Urinary incontinence in women: the management of urinary incontinence in women (see: www.nice.org.uk/guidance/cg171/evidence), contains details of the methods and evidence used to develop the guideline which has been contextualised. It was 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 (see: pathways. nice.org.uk/pathways/urinary-incontinence-in-women

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## Implementation

Bpac<sup>nz</sup> has developed supplementary material to help organisations implement this guidance. This can be accessed on the bpac<sup>nz</sup> website. See: www.bpac.org.nz/guidelines/2/tools.html

### Your responsibility

This guidance represents the view of bpac<sup>nz</sup> in contextualising the NICE clinical guideline Urinary Incontinence: The management of urinary incontinence in women (CG171), 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 medicines.

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An online version of this guideline is available from the bpac<sup>nz</sup> website: www.bpac.org.nz/guidelines/2

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