



# Urinary incontinence and pelvic organ prolapse in women: management

NICE guideline

Published: 2 April 2019

Last updated: 24 June 2019

www.nice.org.uk/guidance/ng123

# Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the <u>Yellow Card Scheme</u>.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

# **Contents**

Overview	5
Who is it for?	5
Recommendations	6
1.1 Organisation of specialist services	6
1.2 Collecting data on surgery and surgical complications	9
1.3 Assessing urinary incontinence	10
1.4 Non-surgical management of urinary incontinence	14
1.5 Surgical management of stress urinary incontinence	26
1.6 Assessing pelvic organ prolapse	29
1.7 Non-surgical management of pelvic organ prolapse	31
1.8 Surgical management of pelvic organ prolapse	33
1.9 Surgery for women with both stress urinary incontinence and pelvic organ prolapse	39
1.10 Assessing complications associated with mesh surgery	40
1.11 Managing complications associated with mesh surgery	47
Terms used in this guideline	51
Additional information	54
Recommendations for research	55
Key recommendations for research	55
Other recommendations for research	57
Rationale and impact	59
Organisation of specialist services	59
Collecting data on surgery and surgical complications	60
Urodynamic testing	61
Pelvic floor muscle training	61
Absorbent containment products	62
Medicines for overactive bladder	63
Botulinum toxin type A injection	64

	Surgical management of stress urinary incontinence	65
	Assessing pelvic organ prolapse	67
	Non-surgical management of pelvic organ prolapse	68
	Surgical management of pelvic organ prolapse	70
	Surgery for women with both stress urinary incontinence and pelvic organ prolapse	74
	Assessing complications associated with mesh surgery	74
	Managing complications associated with mesh surgery	75
C	Context	77
F	inding more information and resources	79
ι	Jpdate information	80

Urinary incontinence and pelvic organ prolapse in women: management (NG123)

This guideline replaces CG171 and IPG154.

This guideline is the basis of QS77.

## Overview

This guideline covers assessing and managing urinary incontinence and pelvic organ prolapse in women aged 18 and over. It also covers complications associated with mesh surgery for these conditions.

#### Who is it for?

- Healthcare professionals
- Service commissioners
- Women with urinary incontinence, pelvic organ prolapse, or complications associated with surgery for urinary incontinence or pelvic organ prolapse, their families and carers

## Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in <u>NICE's information on making decisions about your</u> care.

Making decisions using NICE guidelines explains how we use words to show the strength (or certainty) of our recommendations, and has information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

# 1.1 Organisation of specialist services

#### Local multidisciplinary teams

- 1.1.1 Local multidisciplinary teams (MDTs) for women with primary stress urinary incontinence, overactive bladder or primary prolapse should:
  - review the proposed treatment for all women offered invasive procedures for primary stress urinary incontinence, overactive bladder or primary prolapse
  - review the proposed management for women with primary stress urinary incontinence, overactive bladder or primary prolapse if input from a wider range of healthcare professionals is needed
  - work within an established clinical network that has access to a regional MDT.
     [2019]

Note: In 2018, NHS England consulted on specialised gynaecology surgery and complex urogynaecology conditions service specifications.

1.1.2 Local MDTs for women with primary stress urinary incontinence, overactive bladder or primary prolapse should include:

- 2 consultants with expertise in managing urinary incontinence in women and/or pelvic organ prolapse
- a urogynaecology, urology or continence specialist nurse
- a pelvic floor specialist physiotherapist

and may also include:

- a member of the care of the elderly team
- an occupational therapist
- a colorectal surgeon. [2019]
- 1.1.3 Members of the local MDT (listed in recommendation 1.1.2) should attend all local MDT meetings. **[2019]**

#### Regional multidisciplinary teams

- 1.1.4 Regional MDTs that deal with complex pelvic floor dysfunction and mesh-related problems should review the proposed treatment for women if:
  - they are having repeat continence surgery
  - they are having repeat, same-site prolapse surgery
  - their preferred treatment option is not available in the referring hospital
  - they have coexisting bowel problems that may need additional colorectal intervention
  - vaginal mesh for prolapse is a treatment option for them
  - they have mesh complications or unexplained symptoms after mesh surgery for urinary incontinence or prolapse
  - they are considering surgery and may wish to have children in the future.
     [2019]
- 1.1.5 Regional MDTs that deal with complex pelvic floor dysfunction and

#### mesh-related problems should include:

- a subspecialist in urogynaecology
- a urologist with expertise in female urology
- a urogynaecology, urology or continence specialist nurse
- a pelvic floor specialist physiotherapist
- a radiologist with expertise in pelvic floor imaging
- a colorectal surgeon with expertise in pelvic floor problems
- a pain specialist with expertise in managing pelvic pain

and may also include:

- a healthcare professional trained in bowel biofeedback and trans-anal irrigation
- a clinical psychologist
- a member of the care of the elderly team
- an occupational therapist
- a surgeon skilled at operating in the obturator region
- a plastic surgeon. [2019]
- 1.1.6 Regional MDTs that deal with complex pelvic floor dysfunction and mesh-related problems should have ready access to the following services:
  - psychology
  - psychosexual counselling
  - chronic pain management
  - bowel symptom management
  - neurology. [2019]

1.1.7 Members of the regional MDT (listed in recommendation 1.1.5) should attend regional MDT meetings when their specific expertise is needed.

[2019]

For a short explanation of why the committee made the 2019 recommendations and how they might affect practice, see the <u>rationale and impact section on organisation</u> of specialist services.

Full details of the evidence and the committee's discussion are in <u>evidence review F:</u> <u>effectiveness of multidisciplinary teams for the assessment and management of urinary incontinence or pelvic organ prolapse.</u>

# 1.2 Collecting data on surgery and surgical complications

- 1.2.1 Ask women having surgery for stress urinary incontinence or pelvic organ prolapse, or who have experienced complications related to these types of surgery, for their consent to enter the data listed in recommendation 1.2.2 in a national registry. Give each woman a copy of her data. [2019]
- 1.2.2 Providers must ensure that the following data are recorded in a national registry of surgery for urinary incontinence and pelvic organ prolapse in women:
  - the woman's NHS number
  - hospital and consultant identifiers
  - date and details of the procedure
  - for procedures involving mesh, the mesh material, manufacturer, product unique identification code and type of sutures used
  - for procedures involving colposuspension, the type of sutures used
  - for procedures involving bulking agent, the bulking material, manufacturer and product unique identification code

- date and details of any investigation for complications
- date and details of any surgical or non-surgical intervention for complications.
   [2019]
- 1.2.3 The national registry of surgery for urinary incontinence and pelvic organ prolapse in women must ensure that follow-up data are collected on key short- and long-term (at least 5 years) outcomes, including:
  - validated relevant outcome measures
  - adverse events including pain
  - suspected and confirmed mesh-related complications. [2019]
- 1.2.4 The national registry of surgery for urinary incontinence and pelvic organ prolapse in women should report annually and be quality assured. [2019]

For a short explanation of why the committee made the 2019 recommendations and how they might affect practice, see the <u>rationale and impact section on collecting</u> data on surgery and surgical complications.

Full details of the evidence and the committee's discussion are in <u>evidence review E:</u> <u>surgical and physical management of stress urinary incontinence</u> and <u>evidence review I: surgical management of pelvic organ prolapse.</u>

# 1.3 Assessing urinary incontinence

### History taking and physical examination

- 1.3.1 At the initial clinical assessment, categorise the woman's urinary incontinence as stress urinary incontinence, mixed urinary incontinence or urgency urinary incontinence/overactive bladder. Start initial treatment on this basis. In mixed urinary incontinence, direct treatment towards the predominant symptom. [2006]
- 1.3.2 If stress incontinence is the predominant symptom in mixed urinary incontinence, discuss with the woman the benefit of non-surgical

- management and medicines for overactive bladder before offering surgery. [2013, amended 2019]
- 1.3.3 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]

#### Assessing pelvic floor muscles

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

#### Urine testing

- 1.3.5 Undertake a urine dipstick test in all women presenting with urinary incontinence to detect the presence of blood, glucose, protein, leucocytes and nitrites in the urine. [2006]
- 1.3.6 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. See the <a href="NICE guideline on urinary tract infection (lower): antimicrobial prescribing">NICE guideline on urinary tract infection (lower): antimicrobial prescribing</a> for more information. [2006, amended 2019]
- 1.3.7 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]
- 1.3.8 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]
- 1.3.9 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]

#### Assessing residual urine

- 1.3.10 Measure post-void residual volume by bladder scan or catheterisation in women with symptoms suggestive of voiding dysfunction or recurrent UTI. [2006]
- 1.3.11 Use a bladder scan in preference to catheterisation on the grounds of acceptability and lower incidence of adverse events. [2006]

#### Symptom scoring and quality-of-life assessment

1.3.12 Use a validated urinary incontinence-specific symptom and quality-of-life questionnaire when therapies are being evaluated. [2006, amended 2019]

#### Bladder diaries

1.3.13 Use bladder diaries in the initial assessment of women with urinary incontinence or overactive bladder. 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

1.3.14 Do not use pad tests in the routine assessment of women with urinary incontinence. [2006]

#### Urodynamic testing

- 1.3.15 Do not perform multichannel filling and voiding cystometry before primary surgery if stress urinary incontinence or stress-predominant mixed urinary incontinence is diagnosed based on a detailed clinical history and demonstrated stress urinary incontinence at examination.
  [2019]
- 1.3.16 After undertaking a detailed clinical history and examination, perform multichannel filling and voiding cystometry before surgery for stress urinary incontinence in women who have any of the following:

- urge-predominant mixed urinary incontinence or urinary incontinence in which the type is unclear
- symptoms suggestive of voiding dysfunction
- anterior or apical prolapse
- a history of previous surgery for stress urinary incontinence. [2019]

For a short explanation of why the committee made the 2019 recommendations and how they might affect practice, see the <u>rationale and impact section on urodynamic testing</u>.

Full details of the evidence and the committee's discussion are in <u>evidence review A:</u> urodynamic assessment prior to primary surgery for stress urinary incontinence.

#### Other tests of urethral competence

1.3.17 Do not use the Q-tip, Bonney, Marshall and Fluid-Bridge tests in the assessment of women with urinary incontinence. [2006]

#### Cystoscopy

1.3.18 Do not use cystoscopy in the initial assessment of women with urinary incontinence alone. [2006]

#### **Imaging**

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

#### Indications for referral to a specialist service

1.3.20 In women with urinary incontinence, indications for consideration for referral to a specialist service include:

- persisting bladder or urethral pain
- palpable bladder on bimanual or abdominal examination after voiding
- 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. [2006]
- 1.3.21 Follow the <u>recommendations on referral for urinary tract cancer in the NICE guideline on suspected cancer</u>, for women with haematuria or recurrent or persistent unexplained UTI. [2006, amended 2019]

# 1.4 Non-surgical management of urinary incontinence

## Lifestyle interventions

- 1.4.1 Recommend a trial of caffeine reduction to women with overactive bladder. [2006]
- 1.4.2 Consider advising women with urinary incontinence or overactive bladder and a high or low fluid intake to modify their fluid intake. [2006]
- 1.4.3 Advise women with urinary incontinence or overactive bladder who have a BMI greater than 30 to lose weight. [2006]

#### Physical therapies

#### Pelvic floor muscle training

- 1.4.4 Offer a trial of supervised pelvic floor muscle training of at least3 months' duration as first-line treatment to women with stress or mixed urinary incontinence. [2019]
- 1.4.5 Pelvic floor muscle training programmes should comprise at least 8 contractions performed 3 times per day. **[2006]**
- 1.4.6 Do not use perineometry or pelvic floor electromyography as biofeedback as a routine part of pelvic floor muscle training. [2006]
- 1.4.7 Continue an exercise programme if pelvic floor muscle training is beneficial. [2006]

For a short explanation of why the committee made the 2019 recommendation and how it might affect practice, see the <u>rationale and impact section on pelvic floor</u> muscle training.

Full details of the evidence and the committee's discussion are in <u>evidence review H:</u> lifestyle and conservative management options for pelvic organ prolapse.

#### **Electrical stimulation**

- 1.4.8 Do not routinely use electrical stimulation in the treatment of women with overactive bladder. [2006]
- 1.4.9 Do not routinely use electrical stimulation in combination with pelvic floor muscle training. [2006]
- 1.4.10 Electrical stimulation and/or biofeedback should be considered for women who cannot actively contract pelvic floor muscles to aid motivation and adherence to therapy. [2006]

#### Behavioural therapies

- 1.4.11 Offer bladder training lasting for a minimum of 6 weeks as first-line treatment to women with urgency or mixed urinary incontinence. [2006]
- 1.4.12 If women do not achieve satisfactory benefit from bladder training programmes, the combination of an overactive bladder medicine with bladder training should be considered if frequency is a troublesome symptom. [2006]

#### Neurostimulation

- 1.4.13 Do not offer transcutaneous sacral nerve stimulation (surface electrodes placed above the sacrum, often known as transcutaneous electrical nerve stimulation [TENS]) to treat overactive bladder in women. [2013]
- 1.4.14 Do not offer transcutaneous posterior tibial nerve stimulation for overactive bladder. **[2013]**
- 1.4.15 Do not offer <u>percutaneous posterior tibial nerve stimulation</u> (needles inserted close to the posterior tibial nerve) for overactive bladder unless:
  - · there has been a local MDT review and
  - non-surgical management including overactive bladder medicine treatment has not worked adequately and
  - the woman does not want <u>botulinum toxin type A</u> or <u>percutaneous sacral nerve</u> <u>stimulation</u>. [2013, amended 2019]

In April 2019, most botulinum toxin type A preparations were off label for this indication. Evidence was only available for the licensed botulinum toxin type A preparation (BOTOX, Allergan).

#### Absorbent containment products, urinals and toileting aids

1.4.16 Do not offer absorbent containment products, hand-held urinals or toileting aids to treat urinary incontinence. Offer them only:

- as a coping strategy pending definitive treatment
- as an adjunct to ongoing therapy
- for long-term management of urinary incontinence only after treatment options have been explored. [2019]
- 1.4.17 Offer a review at least once a year to women who are using absorbent containment products for long-term management of urinary incontinence. The review should cover:
  - routine assessment of continence
  - assessment of skin integrity
  - changes to symptoms, comorbidities, lifestyle, mobility, medication, BMI, and social and environmental factors
  - the suitability of alternative treatment options
  - the efficacy of the absorbent containment product the woman is currently using and the quantities used. [2019]
- 1.4.18 Reviews for women who are using absorbent containment products for long-term management of urinary incontinence should be carried out by either:
  - a registered healthcare professional who is trained in assessing continence and making referrals to specialist services or
  - a non-registered healthcare worker, under the supervision of a registered healthcare professional who is trained in assessing continence and making referrals to specialist services.

See indications for referral to a specialist service in this guideline. [2019]

For a short explanation of why the committee made the 2019 recommendations and how they might affect practice, see the <u>rationale and impact section on absorbent</u> containment products.

Full details of the evidence and the committee's discussion are in <u>evidence review B</u>: treatment options for women using absorbent containment products.

#### **Catheters**

- 1.4.19 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 urinary incontinence may not result in continence.

  [2006]
- 1.4.20 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]
- 1.4.21 Give careful consideration to the impact of long-term indwelling urethral catheterisation. Discuss the practicalities, benefits and risks with the woman or, if appropriate, her carer. Indications for the use of long-term indwelling urethral catheters for women with urinary incontinence 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]
- 1.4.22 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

1.4.23 Do not use intravaginal and intraurethral devices for the routine management of urinary incontinence 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

1.4.24 Do not recommend complementary therapies for the treatment of urinary incontinence or overactive bladder. [2006]

#### Medicines for overactive bladder

- 1.4.25 Before starting treatment with a medicine for overactive bladder, explain to the woman:
  - the likelihood of the medicine being successful
  - the common adverse effects associated with the medicine
  - that some adverse effects of <u>anticholinergic medicines</u>, such as dry mouth and constipation, may indicate that the medicine is starting to have an effect
  - that she may not see substantial benefits until she has been taking the medicine for at least 4 weeks and that her symptoms may continue to improve over time
  - that the long-term effects of anticholinergic medicines for overactive bladder on cognitive function are uncertain. [2019]
- 1.4.26 When offering anticholinergic medicines to treat overactive bladder, take account of the woman's:
  - coexisting conditions (such as poor bladder emptying, cognitive impairment or dementia)

- current use of other medicines that affect total anticholinergic load
- risk of adverse effects, including cognitive impairment. [2019]
- 1.4.27 For women who have a diagnosis of dementia and for whom anticholinergic medicines are an option, follow the <u>recommendations on medicines that may cause cognitive impairment in the NICE guideline on dementia. [2019]</u>

#### Choosing medicine

- 1.4.28 Do not offer women flavoxate, propantheline or imipramine to treat urinary incontinence or overactive bladder. **[2013]**
- 1.4.29 Do not offer oxybutynin (immediate release) to older women who may be at higher risk of a sudden deterioration in their physical or mental health.[2013, amended 2019]
- 1.4.30 Offer the anticholinergic medicine with the lowest acquisition cost to treat overactive bladder or mixed urinary incontinence in women. [2019]
- 1.4.31 If the first medicine for overactive bladder or mixed urinary incontinence is not effective or well-tolerated, offer another medicine with a low acquisition cost (see <u>additional information</u>). [2013]
- 1.4.32 Offer a transdermal overactive bladder treatment to women unable to tolerate oral medicines. **[2013]**
- 1.4.33 For guidance on mirabegron, see the <u>NICE technology appraisal</u> guidance on mirabegron for treating symptoms of overactive bladder.
  [2013]
- 1.4.34 The use of desmopressin may be considered specifically to reduce nocturia in women with urinary incontinence or overactive bladder 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. [2013]
- 1.4.35 Do not use duloxetine as a first-line treatment for women with

predominant stress urinary incontinence. Do not routinely offer duloxetine as a second-line treatment for women with stress urinary incontinence, 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]

For guidance on safe prescribing of antidepressants (such as duloxetine) and managing withdrawal, see <a href="NICE's guideline on medicines associated">NICE's guideline on medicines associated</a> with dependence or withdrawal symptoms.

- 1.4.36 Do not offer systemic hormone replacement therapy to treat urinary incontinence. **[2006]**
- 1.4.37 Offer intravaginal oestrogens to treat overactive bladder symptoms in postmenopausal women with vaginal atrophy. [2006]

#### Reviewing medicine

- 1.4.38 Offer a face-to-face or telephone review 4 weeks after starting a new medicine for overactive bladder. Ask the woman if she is satisfied with the treatment and:
  - if improvement is optimal, continue treatment
  - if there is no or suboptimal improvement, or intolerable adverse effects, change
    the dose or try an alternative medicine for overactive bladder (see the
    recommendations for when the first medicine is not effective and offering a
    transdermal patch in the section on choosing medicines), and review again
    4 weeks later. [2013]
- 1.4.39 Offer a review before 4 weeks if the adverse events of a medicine for overactive bladder are intolerable. **[2013]**
- 1.4.40 Refer women who have tried taking medicine for overactive bladder, but for whom it has not been successful or tolerated, to secondary care to consider further treatment. [2013]
- 1.4.41 Offer a further face-to-face or telephone review if a medicine for

- overactive bladder or urinary incontinence stops working after an initial successful 4-week review. [2013]
- 1.4.42 Offer a review in primary care to women who remain on long-term medicine for overactive bladder or urinary incontinence every 12 months, or every 6 months if they are aged over 75. [2013, amended 2019]

For a short explanation of why the committee made the 2019 recommendations and how they might affect practice, see the <u>rationale and impact section on medicines for overactive bladder</u>.

Full details of the evidence and the committee's discussion are in <u>evidence review C:</u> the risks to cognitive function for women taking anticholinergic drugs for overactive bladder.

#### Invasive procedures for overactive bladder

- 1.4.43 For women with overactive bladder that has not responded to non-surgical management or treatment with medicine and who wish to discuss further treatment options:
  - offer urodynamic investigation to determine whether <u>detrusor overactivity</u> is causing her overactive bladder symptoms and
  - if detrusor overactivity is causing her overactive bladder symptoms, offer an
    invasive procedure in line with the <u>recommendation on bladder wall injection in
    the section on botulinum toxin type A</u> and the <u>recommendation in the section</u>
    on urinary diversionor
  - if there is no detrusor overactivity, seek advice on further management from the local MDT in line with the <u>recommendation on considering treatment with botulinum toxin type A in the section on botulinum toxin type A</u>. [2013, amended 2019]

#### **Botulinum toxin type A injection**

See <u>additional information</u> on prescribing botulinum toxin type A.

- 1.4.44 After a local MDT review, offer bladder wall injection with <u>botulinum toxin</u> type A to women with overactive bladder caused by detrusor overactivity that has not responded to non-surgical management, including pharmacological treatments. [2019]
- 1.4.45 Consider treatment with botulinum toxin type A after a local MDT review for women with symptoms of overactive bladder in whom urodynamic investigation has not demonstrated detrusor overactivity, if the symptoms have not responded to non-surgical management and the woman does not wish to have other invasive treatments. [2019]
- 1.4.46 After a local MDT review, discuss the benefits and risks of treatment with botulinum toxin type A with the woman and explain:
  - the likelihood of complete or partial symptom relief
  - the process of clean intermittent catheterisation, the risks, and how long it might need to be continued
  - the risk of adverse effects, including an increased risk of urinary tract infection
  - that there is not much evidence about how long the injections work for, how well they work in the long term and their long-term risks. [2019]
- 1.4.47 Start treatment with botulinum toxin type A only if the woman is willing, in the event of developing significant voiding dysfunction:
  - to perform clean intermittent catheterisation on a regular basis for as long as needed or
  - to accept a temporary indwelling catheter if she is unable to perform clean intermittent catheterisation. [2013, amended 2019]
- 1.4.48 Use 100 units as the initial dose of botulinum toxin type A to treat overactive bladder in women. **[2019]**

- 1.4.49 Offer a face-to-face or telephone review within 12 weeks of the first treatment with botulinum toxin type A to assess the response to treatment and adverse effects, and:
  - if there is good symptom relief, tell the woman how to self-refer for prompt specialist review if symptoms return, and offer repeat treatment as necessary
  - if there is inadequate symptom relief, consider increasing subsequent doses of botulinum toxin type A to 200 units and review within 12 weeks
  - if there was no effect, discuss with the local MDT. [2019]
- 1.4.50 If symptom relief has been adequate after injection of 100 units of botulinum toxin type A but has lasted for less than 6 months, consider increasing subsequent doses of botulinum toxin type A to 200 units and review within 12 weeks. [2019]
- 1.4.51 Do not offer botulinum toxin type B to women with overactive bladder. [2019]

For a short explanation of why the committee made the 2019 recommendations and how they might affect practice, see the <u>rationale and impact section on botulinum</u> toxin type A injection.

Full details of the evidence and the committee's discussion are in <u>evidence review D:</u> management of overactive bladder.

#### Percutaneous sacral nerve stimulation

- 1.4.52 Offer <u>percutaneous sacral nerve stimulation</u> to women after local or regional MDT review if their overactive bladder has not responded to non-surgical management including medicines and:
  - their symptoms have not responded to botulinum toxin type A or
  - they are not prepared to accept the risks of needing catheterisation associated with botulinum toxin type A. [2013, amended 2019]

- 1.4.53 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. [2013]
- 1.4.54 Tell women how to self-refer for prompt specialist review if symptoms return following a percutaneous sacral nerve stimulation procedure.[2013]

#### **Augmentation cystoplasty**

1.4.55 Restrict <u>augmentation cystoplasty</u> for the management of idiopathic detrusor overactivity to women whose condition has not responded to non-surgical 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**

1.4.56 <u>Urinary diversion</u> should be considered for a woman with overactive bladder only when non-surgical 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 lifelong follow-up. [2006, amended 2013]

In April 2019, most botulinum toxin type A preparations were off label for this indication. Evidence was only available for the licensed botulinum toxin type A preparation (BOTOX, Allergan).

# 1.5 Surgical management of stress urinary incontinence

There is public concern about the use of <u>mesh procedures</u>. For all of the procedures recommended in this section, including mesh procedures, there is evidence of benefit but limited evidence on the long-term adverse effects. In particular, the true prevalence of long-term complications is unknown.

- 1.5.1 If a woman is thinking about a surgical procedure for stress urinary incontinence, use the NICE patient decision aid on surgery for stress urinary incontinence to promote informed preference and shared decision making. Discussion with the woman should include:
  - the benefits and risks of all surgical treatment options for stress urinary incontinence that NICE recommends, whether or not they are available locally
  - the uncertainties about the long-term adverse effects for all procedures, particularly those involving the implantation of mesh materials
  - differences between procedures in the type of anaesthesia, expected length of hospital stay, surgical incisions and expected recovery period
  - any social or psychological factors that may affect the woman's decision.
     [2013, amended 2019]
- 1.5.2 If non-surgical management for stress urinary incontinence has failed, and the woman wishes to think about a surgical procedure, offer her the choice of:
  - colposuspension (open or laparoscopic) or
  - · an autologous rectus fascial sling.

Also include the option of a <u>retropubic mid-urethral mesh sling</u> in this choice but see the <u>recommendations in the section on mid-urethral mesh sling</u> <u>procedures</u> for additional guidance on the use of mid-urethral mesh sling procedures for stress urinary incontinence. [2019]

1.5.3 Consider <u>intramural bulking agents</u> to manage stress urinary incontinence if alternative surgical procedures are not suitable for or

acceptable to the woman. Explain to the woman that:

- these are permanent injectable materials
- repeat injections may be needed to achieve effectiveness
- limited evidence suggests that they are less effective than the surgical procedures listed in recommendation 1.5.2 and the effects wear off over time
- there is limited evidence on long-term effectiveness and adverse events.
   [2019]
- 1.5.4 If an intramural bulking agent is injected, give the woman written information about the bulking agent, including its name, manufacturer, date of injection, and the injecting surgeon's name and contact details.

  [2019]
- 1.5.5 If the woman's chosen procedure for stress urinary incontinence is not available from the consulting surgeon, refer her to an alternative surgeon.[2019]
- 1.5.6 Providers must ensure that data on surgical procedures for stress urinary incontinence are recorded in a national registry, as outlined in the <u>section</u> on collecting data on surgery and surgical complications in this guideline.

  [2019]

#### Mid-urethral mesh sling procedures

- 1.5.7 When offering a retropubic mid-urethral mesh sling, advise the woman that it is a permanent implant and complete removal might not be possible. [2019]
- 1.5.8 If a retropubic mid-urethral mesh sling is inserted, give the woman written information about the implant, including its name, manufacturer, date of insertion, and the implanting surgeon's name and contact details.
  [2019]
- 1.5.9 When planning a retropubic mid-urethral mesh sling procedure, surgeons should:

- use a device manufactured from type 1 macroporous polypropylene mesh
- consider using a retropubic mid-urethral mesh sling coloured for high visibility, for ease of insertion and revision. [2013, amended 2019]
- 1.5.10 Do not offer a transobturator approach unless there are specific clinical circumstances (for example, previous pelvic procedures) in which the retropubic approach should be avoided. [2019]
- 1.5.11 Do not use the 'top-down' retropubic mid-urethral mesh sling approach or single-incision sub-urethral short mesh sling insertion except as part of a clinical trial. [2019]

#### Artificial urinary sphincters

- 1.5.12 Do not offer women an artificial urinary sphincter to manage stress urinary incontinence unless previous surgery has failed. [2006, amended 2019]
- 1.5.13 For women who have had an artificial urinary sphincter inserted:
  - offer postoperative follow-up and
  - ensure access to review if needed. [2006, amended 2019]

#### Procedures that should not be offered

- 1.5.14 Do not offer women the following procedures to treat stress urinary incontinence:
  - anterior colporrhaphy
  - needle suspension
  - paravaginal defect repair
  - porcine dermis sling
  - the Marshall–Marchetti–Krantz procedure. [2019]

#### Follow-up after surgery

- 1.5.15 Offer a follow-up appointment within 6 months to all women who have had a surgical procedure to treat stress urinary incontinence. [2019]
- 1.5.16 For women who have had retropubic mid-urethral mesh sling surgery, the follow-up appointment should include a vaginal examination to check for exposure or extrusion of the mesh sling. [2019]
- 1.5.17 Providers should ensure that women who have had surgery for stress urinary incontinence have access to further referral if they have recurrent symptoms or suspected complications. See also <u>assessing complications</u> <u>associated with mesh surgery in this guideline</u>. [2019]
- 1.5.18 For women whose primary surgical procedure for stress urinary incontinence has failed (including women whose symptoms have returned):
  - seek advice on assessment and management from a regional MDT that deals with complex pelvic floor dysfunction or
  - offer the woman advice about managing urinary symptoms if she does not wish to have another surgical procedure, and explain that she can ask for a referral if she changes her mind. [2019]

For a short explanation of why the committee made the 2019 recommendations and how they might affect practice, see the <u>rationale and impact section on surgical</u> management of stress urinary incontinence.

Full details of the evidence and the committee's discussion are in <u>evidence review E:</u> <u>surgical and physical management of stress urinary incontinence</u>.

# 1.6 Assessing pelvic organ prolapse

1.6.1 For women presenting in primary care with symptoms or an incidental finding of vaginal prolapse:

- take a history to include symptoms of prolapse, urinary, bowel and sexual function
- do an examination to rule out a pelvic mass or other pathology and to document the presence of prolapse (see the <u>recommendations in the NICE</u> guideline on suspected cancer about ovarian cancer and bladder cancer)
- discuss the woman's treatment preferences with her, and refer if needed.
   [2019]
- 1.6.2 For women referred to secondary care for an unrelated condition who have incidental symptoms or an incidental finding of vaginal prolapse, consider referral to a clinician with expertise in prolapse. [2019]
- 1.6.3 For women who are referred for specialist evaluation of vaginal prolapse, perform an examination to:
  - assess and record the presence and degree of prolapse of the anterior, central and posterior vaginal compartments of the pelvic floor, using the POP-Q (Pelvic Organ Prolapse Quantification) system
  - assess the activity of the pelvic floor muscles
  - assess for vaginal atrophy
  - rule out a pelvic mass or other pathology. [2019]
- 1.6.4 For women with pelvic organ prolapse, consider using a validated pelvic floor symptom questionnaire to aid assessment and decision making.[2019]
- Do not routinely perform imaging to document the presence of vaginal prolapse if a prolapse is detected by physical examination. **[2019]**
- 1.6.6 If the woman has symptoms of prolapse that are not explained by findings from a physical examination, consider repeating the examination with the woman standing or squatting, or at a different time. [2019]
- 1.6.7 Consider investigating the following symptoms in women with pelvic organ prolapse:

- urinary symptoms that are bothersome and for which surgical intervention is an option
- symptoms of obstructed defaecation or faecal incontinence (see the recommendations for baseline assessment of faecal incontinence in the NICE guideline on faecal incontinence in adults)
- pain
- symptoms that are not explained by examination findings. [2019]

For a short explanation of why the committee made the 2019 recommendations and how they might affect practice, see the <u>rationale and impact section on assessing</u> pelvic organ prolapse.

Full details of the evidence and the committee's discussion are in <u>evidence review G:</u> assessing pelvic organ prolapse.

# 1.7 Non-surgical management of pelvic organ prolapse

- 1.7.1 Discuss management options with women who have pelvic organ prolapse, including no treatment, non-surgical treatment and surgical options, taking into account:
  - the woman's preferences
  - site of prolapse
  - lifestyle factors
  - comorbidities, including cognitive or physical impairments
  - age
  - · desire for childbearing
  - previous abdominal or pelvic floor surgery
  - benefits and risks of individual procedures. [2019]

#### Lifestyle modification

- 1.7.2 Consider giving advice on lifestyle to women with pelvic organ prolapse, including information on:
  - losing weight, if the woman has a BMI greater than 30 kg/m<sup>2</sup>
  - minimising heavy lifting
  - preventing or treating constipation. [2019]

#### Topical oestrogen

- 1.7.3 Consider vaginal oestrogen for women with pelvic organ prolapse and signs of vaginal atrophy. For managing urogenital atrophy, see the recommendations in managing short-term menopausal symptoms in the NICE guideline on menopause. [2019]
- 1.7.4 Consider an oestrogen-releasing ring for women with pelvic organ prolapse and signs of vaginal atrophy who have cognitive or physical impairments that might make vaginal oestrogen pessaries or creams difficult to use. [2019]

#### Pelvic floor muscle training

1.7.5 Consider a programme of supervised pelvic floor muscle training for at least 16 weeks as a first option for women with symptomatic POP-Q (Pelvic Organ Prolapse Quantification) stage 1 or stage 2 pelvic organ prolapse. If the programme is beneficial, advise women to continue pelvic floor muscle training afterwards. [2019]

#### **Pessaries**

- 1.7.6 Consider a vaginal pessary for women with symptomatic pelvic organ prolapse, alone or in conjunction with supervised pelvic floor muscle training. [2019]
- 1.7.7 Refer women who have chosen a pessary to a urogynaecology service if pessary care is not available locally. [2019]

#### 1.7.8 Before starting pessary treatment:

- consider treating vaginal atrophy with topical oestrogen
- explain that more than 1 pessary fitting may be needed to find a suitable pessary
- discuss the effect of different types of pessary on sexual intercourse
- describe complications including vaginal discharge, bleeding, difficulty removing pessary and pessary expulsion
- explain that the pessary should be removed at least once every 6 months to prevent serious pessary complications. [2019]
- 1.7.9 Offer women using pessaries an appointment in a pessary clinic every 6 months if they are at risk of complications, for example because of a physical or cognitive impairment that might make it difficult for them to manage their ongoing pessary care. [2019]

For a short explanation of why the committee made the 2019 recommendations and how they might affect practice, see the <u>rationale and impact section on non-surgical</u> management of pelvic organ prolapse.

Full details of the evidence and the committee's discussion are in <u>evidence review H:</u> lifestyle and conservative management options for pelvic organ prolapse.

# 1.8 Surgical management of pelvic organ prolapse

There is public concern about the use of <u>mesh procedures</u>. For all of the procedures recommended in this section, including mesh procedures, there is some evidence of benefit, but limited evidence on long-term effectiveness and adverse effects. In particular, the true prevalence of long-term complications is unknown.

- 1.8.1 Offer surgery for pelvic organ prolapse to women whose symptoms have not improved with or who have declined non-surgical treatment. [2019]
- 1.8.2 If a woman is thinking about a surgical procedure for pelvic organ

prolapse, use a decision aid (use the <u>NICE patient decision aids on</u> surgery for uterine prolapse and surgery for vaginal vault prolapse where they apply) to promote informed preference and shared decision making. Discussion with the woman should include:

- the different treatment options for pelvic organ prolapse, including no treatment or continued non-surgical management
- the benefits and risks of each surgical procedure, including changes in urinary, bowel and sexual function
- the risk of recurrent prolapse
- the uncertainties about the long-term adverse effects for all procedures, particularly those involving the implantation of mesh materials
- differences between procedures in the type of anaesthesia, expected length of hospital stay, surgical incisions and expected recovery period
- the role of intraoperative prolapse assessment in deciding the most appropriate surgical procedure. [2019]
- 1.8.3 Do not offer surgery to prevent incontinence in women having surgery for prolapse who do not have incontinence. **[2019]**
- 1.8.4 Explain to women considering surgery for anterior or apical prolapse who do not have incontinence that there is a risk of developing postoperative urinary incontinence and further treatment may be needed. [2019]
- 1.8.5 If the woman's chosen procedure for pelvic organ prolapse is not available from the consulting surgeon, refer her to an alternative surgeon.[2019]
- 1.8.6 If mesh is to be used in prolapse surgery:
  - explain to the woman about the type of mesh that will be used and whether or not it is permanent
  - ensure that details of the procedure and its subsequent short- and long-term outcomes are recorded in a national registry (see the <u>section on collecting data</u> on surgery and surgical complications in this guideline)

- give the woman written information about the implant, including its name, manufacturer, date of insertion, and the implanting surgeon's name and contact details. [2019]
- 1.8.7 Providers must ensure that data on surgical procedures for pelvic organ prolapse are recorded in a national registry, as outlined in the <u>section on collecting data on surgery and surgical complications in this guideline</u>.

  [2019]

#### Surgery for uterine prolapse

- 1.8.8 Discuss the options for treatment (see <u>recommendation 1.8.2 on using a decision aid</u>), including non-surgical options, hysterectomy and surgery that will preserve the uterus, with women who have uterine prolapse.

  [2019]
- 1.8.9 For women considering surgery for uterine prolapse:
  - discuss the possible complications and the lack of long-term evidence on the effectiveness of the procedures
  - use the <u>NICE patient decision aid on surgery for uterine prolapse</u> to discuss the benefits and risks of treatment, including non-surgical options. [2019]
- 1.8.10 For women with uterine prolapse who have no preference about preserving their uterus, offer a choice of:
  - vaginal hysterectomy, with or without <u>vaginal sacrospinous fixation</u> with sutures or
  - vaginal sacrospinous hysteropexy with sutures or
  - Manchester repair.

Also include the option of <u>sacro-hysteropexy</u> with mesh (abdominal or laparoscopic) in this choice but see recommendation 1.8.6 for specific guidance on the use of mesh in prolapse surgery. [2019]

1.8.11 For women with uterine prolapse who wish to preserve their uterus, offer a choice of:

- vaginal sacrospinous hysteropexy with sutures or
- Manchester repair, unless the woman may wish to have children in the future.

Also include the option of sacro-hysteropexy with mesh (abdominal or laparoscopic) in this choice but see recommendation 1.8.6 for specific guidance on the use of mesh in prolapse surgery. [2019]

- 1.8.12 If a synthetic polypropylene mesh is inserted, the details of the procedure and its subsequent short- and long-term outcomes must be collected in a national registry (see the <u>section on collecting data on surgery and surgical complications in this guideline</u>). [2019]
- 1.8.13 Ensure the proposed treatment is reviewed by a regional MDT (see the recommendation on MDTs reviewing proposed treatment in the section on regional multidisciplinary teams) if the woman wishes to have children in the future. [2019]

#### Surgery for vault prolapse

- 1.8.14 Discuss the options for treatment (see <u>recommendation 1.8.2 on using a decision aid</u>), including non-surgical and surgical options, with women who have vault prolapse. **[2019]**
- 1.8.15 For women considering surgery for vault prolapse:
  - discuss the possible complications and the lack of long-term evidence on the effectiveness of the procedures
  - use the <u>NICE patient decision aid on surgery for vaginal vault prolapse</u> to discuss the benefits and risks of treatment, including non-surgical options.
     [2019]
- 1.8.16 Offer women with vault prolapse a choice of:
  - vaginal sacrospinous fixation with sutures or

- <u>sacrocolpopexy</u> (abdominal or laparoscopic) with mesh.
  - See recommendation 1.8.6 for specific guidance on the use of mesh in prolapse surgery. [2019]
- 1.8.17 If a synthetic polypropylene mesh is inserted, the details of the procedure and its subsequent short- and long-term outcomes must be collected in a national registry (see the <u>section on collecting data on</u> surgery and surgical complications in this guideline). [2019]

#### Colpocleisis for vault or uterine prolapse

1.8.18 Consider <u>colpocleisis</u> for women with vault or uterine prolapse who do not intend to have penetrative vaginal sex and who have a physical condition that may put them at increased risk of operative and postoperative complications. [2019]

#### Surgery for anterior prolapse

- 1.8.19 Discuss the options for treatment (see <u>recommendation 1.8.2 on using a decision aid</u>), including non-surgical and surgical options, with women who have anterior prolapse. **[2019]**
- 1.8.20 Offer anterior repair without mesh to women with anterior vaginal wall prolapse. [2019]
- 1.8.21 Recommendation withdrawn in June 2019.
- 1.8.22 Recommendation withdrawn in June 2019.

June 2019: Recommendations 1.8.21 and 1.8.22, which related to the use of synthetic polypropylene or biological mesh insertion for women with recurrent anterior vaginal wall prolapse, have been withdrawn. Instead, please see <a href="NICE interventional">NICE interventional</a> procedures guidance 599 on transvaginal mesh repair of anterior or posterior vaginal wall prolapse, which says:

'1.1 Current evidence on the safety of transvaginal mesh repair of anterior or posterior vaginal wall prolapse shows there are serious but well-recognised safety concerns. Evidence of long-term efficacy is inadequate in quality and quantity. Therefore, this procedure should only be used in the context of research.

'1.2 All adverse events involving the medical devices (including the mesh) used in this procedure should be reported to the Medicines and Healthcare products Regulatory Agency.

'1.3 Further research should include details of patient selection, long-term outcomes including complications, type of mesh used and method of fixation, and quality of life.'

The replacement of the guideline recommendation with a cross-reference to IPG599 is to provide clarity regarding the relation of NG123 and IPG599 and to take account of a material change since publication in the availability of products CE-marked for the indication which was referred to in the guideline recommendations.

#### Surgery for posterior prolapse

1.8.23 Offer posterior vaginal repair without mesh to women with a posterior vaginal wall prolapse. **[2019]** 

#### Follow-up after surgery

- 1.8.24 Offer women a review 6 months after surgery for pelvic organ prolapse. Ensure that the review includes a vaginal examination and, if mesh was used, check for mesh exposure. [2019]
- 1.8.25 Providers should ensure that women who have had surgery for pelvic organ prolapse have access to further referral if they have recurrent

symptoms or suspected complications. Also see the <u>section on</u> assessing complications associated with mesh surgery in this guideline. [2019]

For a short explanation of why the committee made the 2019 recommendations and how they might affect practice, see the <u>rationale and impact section on surgical management of pelvic organ prolapse</u>.

Full details of the evidence and the committee's discussion are in <u>evidence review I:</u> surgical management of pelvic organ prolapse.

# 1.9 Surgery for women with both stress urinary incontinence and pelvic organ prolapse

- 1.9.1 Consider concurrent surgery for stress urinary incontinence and pelvic organ prolapse in women with anterior and/or apical prolapse and stress urinary incontinence. [2019]
- 1.9.2 When considering concurrent surgery for stress urinary incontinence and pelvic organ prolapse, discuss the options for treatment (see the recommendation on using the NICE decision aid in the section on surgical management of stress incontinence and in the section on surgical management of pelvic organ prolapse) and explain to the woman:
  - that there is uncertainty about whether the combined procedure is effective for treating stress urinary incontinence beyond 1 year, and that stress urinary incontinence might persist despite surgery
  - the risk of complications related to having surgery for stress urinary incontinence at the same time as prolapse surgery compared with the risk of complications related to having sequential surgery. [2019]

For a short explanation of why the committee made the 2019 recommendations and how they might affect practice, see the <u>rationale and impact section on surgery for</u> women with both stress urinary incontinence and pelvic organ prolapse.

Full details of the evidence and the committee's discussion are in <u>evidence review J:</u> surgical management of pelvic organ prolapse and stress urinary incontinence.

# 1.10 Assessing complications associated with mesh surgery

- 1.10.1 For women who report new-onset symptoms after having mesh surgery for urinary incontinence or pelvic organ prolapse, evaluate whether the symptoms might be caused by a mesh-related complication. These symptoms could include:
  - pain or sensory change in the back, abdomen, vagina, pelvis, leg, groin or perineum that is:
    - either unprovoked, or provoked by movement or sexual activity and
    - either generalised, or in the distribution of a specific nerve, such as the obturator nerve
  - vaginal problems including discharge, bleeding, painful sexual intercourse, or penile trauma or pain in sexual partners
  - urinary problems including recurrent infection, incontinence, retention, or difficulty or pain during voiding
  - bowel problems including difficulty or pain on defaecation, faecal incontinence, rectal bleeding or passage of mucus
  - symptoms of infection, either alone or in combination with any of the symptoms outlined above. [2019]
- 1.10.2 Refer women with a suspected mesh-related complication to a urogynaecologist, urologist or colorectal surgeon for specialist assessment. [2019]

- 1.10.3 For women who are referred for specialist evaluation of a suspected mesh complication:
  - take a history of all past surgical procedures for prolapse or incontinence using mesh, including the dates, type of mesh and site of mesh placement and the relationship of the symptoms to the surgical procedure(s)
  - consider using a validated pelvic floor symptom questionnaire and a pain questionnaire to aid assessment and decision making
  - perform a vaginal examination to:
    - assess whether mesh is palpable, exposed or extruded
    - localise pain and its anatomical relationship to mesh
  - consider performing a rectal examination, if indicated, to assess for the presence of mesh perforation or fistula
  - consider performing a neurological assessment to assess the distribution of pain, if present, sensory alteration or muscle weakness. [2019]
- 1.10.4 For women with a confirmed mesh-related complication or unexplained symptoms after a mesh procedure:
  - refer to a consultant at a regional centre specialising in the diagnosis and management of mesh-related complications or
  - if the woman has a vaginal exposure of mesh that is smaller than 1 cm<sup>2</sup> and no other symptoms, follow the <u>recommendations on discussing topical oestrogen</u> <u>cream treatment and a follow-up appointment for those having topical</u> oestrogen cream in the section on managing vaginal complications. [2019]
- 1.10.5 The responsible consultant should develop an individualised investigation plan for each woman with suspected or confirmed mesh-related complications, involving other members of the regional MDT if needed, and use table 1 in this guideline to inform decisions on possible investigations. [2019]
- 1.10.6 The responsible consultant must ensure that details of any confirmed mesh-related complications are:

- recorded in a national registry (see the <u>section on collecting data on surgery</u> and <u>surgical complications in this guideline</u>) and
- reported to the <u>Medicines and Healthcare products Regulatory Agency</u> (MHRA). [2019]

#### Table 1 Investigations for assessing suspected mesh-related complications

Investigation	Type of mesh	Indications	Benefits	Risks
Examination under anaesthesia	All types of mesh	Pain or suspected:  • vaginal or rectal exposure or extrusion  • sinus tract, urinary or bowel fistula	Allows diagnosis when not revealed by awake examination or when an awake, examination is not tolerated	Anaesthetic risk
Cystourethro-scopy	All types of mesh	Suspected:  urethral perforation  bladder perforation  fistula  calculus on suture or mesh material	<ul> <li>Allows         diagnosis by         direct         visualisation</li> <li>Aids         management         planning</li> </ul>	Anaesthetic risk and risk of urinary tract infection

Investigation	Type of mesh	Indications	Benefits	Risks
Sigmoidoscopy	Abdominally, laparo-scopically or vaginally placed mesh for pelvic organ prolapse	Suspected bowel perforation by mesh	<ul> <li>Allows         diagnosis by         direct         visualisation</li> <li>Aids         management         planning</li> </ul>	<ul> <li>Anaesthetic risk if carried out under anaesthesia</li> <li>Risk of bowel perforation</li> </ul>
Laparoscopy	Abdominally or laparo-scopically placed mesh for pelvic organ prolapse	<ul> <li>Pain</li> <li>Suspected bowel entrapment around mesh</li> <li>Suspected adhesions secondary to mesh placement</li> </ul>	Aids     management	<ul> <li>Anaesthetic risk</li> <li>Risks of laparoscopy, including bowel injury</li> </ul>

Investigation	Type of mesh	Indications	Benefits	Risks
MRI, protocolled and reported by a clinician with experience in interpreting mesh complications	All types of mesh	<ul> <li>Suspected mesh infection</li> <li>Anatomical mapping of suspected fistula</li> <li>Anatomical mapping and mesh localisation to guide further surgery</li> <li>Back pain following abdominal mesh placement with mesh attachment to sacral promontory</li> <li>Identification of discitis or osteomyelitis</li> </ul>	<ul> <li>Shows implanted material and complications nearby</li> <li>Shows location of mesh in relation to the vaginal wall and sacrum</li> </ul>	Generally regarded as safe, with a low risk of short- and long-term harms. Risk of contrast media injection

Investigation	Type of mesh	Indications	Benefits	Risks
Ultrasound scan (transperineal, transvaginal or translabial, or 3D), performed and reported by a clinician with experience in interpreting mesh complications	Vaginally placed mesh to treat incontinence	<ul> <li>Pain</li> <li>Voiding dysfunction</li> <li>Suspected infection</li> <li>Suspected urethral mesh perforation</li> <li>Anatomical mapping to guide excision surgery</li> </ul>	<ul> <li>Shows implanted material and local complications</li> <li>Identifies mid-urethral slings</li> <li>Shows location of mesh in relation to the vaginal wall and urethra</li> </ul>	Discomfort
СТ	All types of mesh, although CT is not commonly used to show implanted material	<ul><li>Suspected:</li><li>urinary tract injury</li><li>bowel injury</li><li>bowel obstruction</li></ul>	May be useful in assessing for urinary fistulae or bowel injury	Potential radiation-related harms and risk of contrast media injection

Investigation	Type of mesh	Indications	Benefits	Risks
Fluoroscopic studies (cystography or contrast enema). Perform with watersoluble contrast media Fluoroscopic studies and CT may be used according to local preference and expertise	All types of mesh	Suspected urinary or bowel fistula	Aids management planning	Potential radiation- related harms
Urinary flow studies and post-void residual volume assessment or cystometry	All types of mesh	<ul><li>Voiding dysfunction</li><li>Urinary incontinence</li></ul>	Aids management planning	Urinary tract infection and radiation risks if fluoroscopy is used
Neuro-physiology, including nerve conduction studies	All types of mesh	Suspected nerve injury	Allows diagnosis of impaired nerve function	Nerve conduction studies are difficult to perform and can induce more pain

Note: Individualised investigation plans may include, but are not limited to, 1 or more of these investigations.

For a short explanation of why the committee made the 2019 recommendations and how they might affect practice, see the <u>rationale and impact section on assessing</u> complications associated with mesh surgery.

Full details of the evidence and the committee's discussion are in <u>evidence review K:</u> assessing mesh complications after pelvic floor mesh surgery.

# 1.11 Managing complications associated with mesh surgery

#### General considerations before removing mesh

- 1.11.1 If a woman who has had a mesh procedure to treat urinary incontinence or pelvic organ prolapse is thinking about having the mesh removed, discuss the decision with her and with a regional MDT. [2019]
- 1.11.2 When discussing surgery to remove mesh, explain to the woman that:
  - there is limited evidence on the benefits of partial or complete removal compared with no mesh removal
  - surgery to remove mesh can have significant complications including organ injury, worsening pain, and urinary, bowel and sexual dysfunction
  - it is not certain that removing the mesh will relieve symptoms
  - it might not be possible to remove all of the mesh
  - removing only part of the mesh might be just as effective at improving symptoms as removing all of it
  - urinary incontinence or prolapse can recur after the mesh has been removed.
     [2019]

#### Managing vaginal complications

1.11.3 Discuss non-surgical treatment with topical oestrogen cream with

women who have a single area of vaginal mesh exposure that is smaller than 1 cm<sup>2</sup>. [2019]

- 1.11.4 Offer a follow-up appointment within 3 months to women with vaginal mesh exposure who choose treatment with topical oestrogen cream.

  [2019]
- 1.11.5 Consider partial or complete surgical removal of the vaginal portion of mesh for women:
  - who do not wish to have treatment with topical oestrogen or
  - if the area of vaginal mesh sling exposure is 1 cm<sup>2</sup> or larger or
  - if there is vaginal mesh extrusion or
  - if there has been no response to non-surgical treatment after a period of 3 months. [2019]
- 1.11.6 Offer imaging and further treatment to women who have signs of infection in addition to vaginal mesh exposure or extrusion. [2019]
- 1.11.7 Discuss with women who have vaginal complications after mesh sling surgery for stress urinary incontinence that:
  - complete removal of the vaginal portion of mesh sling is associated with a greater risk of recurrence of stress urinary incontinence than partial removal
  - partial removal is associated with a higher rate of further mesh sling extrusion
  - complete removal might not be possible. [2019]
- 1.11.8 Explain to women who have vaginal complications after vaginally placed mesh for pelvic organ prolapse that:
  - complete removal might not be possible
  - complete removal has a higher risk of urinary tract or bowel injury than partial removal
  - there may be a risk of recurrent prolapse. [2019]

- 1.11.9 Explain to women who have vaginal complications after abdominally placed mesh for pelvic organ prolapse that:
  - removal is associated with a risk of urinary tract and bowel injury
  - there is a risk of recurrent prolapse
  - they might need abdominal surgery to remove the mesh
  - complete removal might not be possible. [2019]
- 1.11.10 For women who have pain or painful sexual intercourse suspected to be related to previous mesh surgery:
  - if specialist assessment indicates a mesh-related complication, seek advice from a regional MDT
  - if assessment and investigation do not show a mesh abnormality such as vaginal extrusion or exposure, or an infection, consider non-surgical treatments such as pain management, vaginal oestrogen, dilators, counselling (including psychosexual counselling) and physiotherapy
  - if pain does not respond to initial management, seek advice from a regional MDT. [2019]

#### Managing urinary complications

- 1.11.11 Refer women who have mesh perforating the lower urinary tract to a centre for mesh complications for further assessment or management.

  [2019]
- 1.11.12 For women with urinary symptoms after mesh surgery for stress urinary incontinence or pelvic organ prolapse who are considering mesh removal surgery, explain that:
  - urinary symptoms might not improve and new symptoms might occur after complete or partial removal of the mesh
  - stress urinary incontinence might recur after mesh removal, and the risk of this happening is higher with complete than with partial mesh removal

- complete removal of the mesh might not be possible
- further treatment might be needed for mesh complications, or recurrent or persistent urinary symptoms
- there is a risk of adverse events such as urinary tract fistula. [2019]
- 1.11.13 Discuss division of mesh sling with women who have voiding difficulty after mesh sling surgery. [2019]
- 1.11.14 Refer women considering excision of mesh sling for persistent voiding dysfunction to a centre specialising in the diagnosis and management of mesh-related complications for assessment and management. [2019]
- 1.11.15 For women considering surgery to alleviate voiding symptoms caused by mesh surgery, explain that:
  - the risk of recurrent stress urinary incontinence is higher after mesh excision than mesh division
  - further surgery might be needed. [2019]

#### Managing bowel symptoms

- 1.11.16 For women who present with functional bowel disorders after mesh surgery for pelvic organ prolapse, follow the <u>recommendations in the NICE guideline on faecal incontinence in adults</u> for women with faecal incontinence or locally agreed protocols for women with obstructed defecation. [2019]
- 1.11.17 For women with bowel complications that are directly related to mesh placement, such as erosion, stricture or fistula, discuss treatment with a regional MDT that has expertise in complex pelvic floor dysfunction and mesh-related problems. Use this discussion to formulate an individualised treatment plan with the woman. [2019]
- 1.11.18 Explain to women with bowel complications directly related to mesh placement that:

- complete removal might not be possible
- bowel symptoms might persist or recur after mesh removal
- they might need a temporary or permanent stoma after mesh removal. [2019]

For a short explanation of why the committee made the 2019 recommendations and how they might affect practice, see the <u>rationale and impact section on managing complications associated with mesh surgery.</u>

Full details of the evidence and the committee's discussion are in <u>evidence review L:</u> management of mesh complications.

### Terms used in this guideline

This section defines some of the terms that are used in this guideline. For other definitions, see the <u>NICE glossary</u>.

#### Anticholinergic medicine

A type of medicine used to treat overactive bladder. It reduces the activity of the bladder muscle by blocking chemical messengers to the nerves that control muscle movements.

#### Augmentation cystoplasty

A procedure to treat overactive bladder. The bladder is made larger by adding a piece of tissue from the intestines to the bladder wall.

#### Autologous rectus fascial sling

A type of sling used to treat stress urinary incontinence. It is made out of tissue from the woman's abdomen. The sling supports the tube that carries urine out of the body (the urethra).

#### Botulinum toxin type A

A treatment used for overactive bladder. It is injected into the wall of the bladder.

#### Colpocleisis

An operation to treat pelvic organ prolapse by closing the vagina.

#### Colposuspension

A type of surgery used to treat stress urinary incontinence. The neck of the bladder is lifted up and stitched in this position.

#### **Detrusor overactivity**

Involuntary bladder contractions seen during a cystometry test. They can be the cause of overactive bladder symptoms.

#### Intramural bulking agents

Materials used to treat stress urinary incontinence. They are injected into the sides of the tube that carries urine out of the body (the urethra). This helps it remain closed so that urine is less likely to leak out.

#### Manchester repair

An operation used to treat uterine prolapse. The neck of the womb (the cervix) is shortened. It involves shortening the cervix (neck of the womb) and supporting the womb in its natural position.

#### Mesh procedure

An operation to insert plastic mesh to support tissues. Mesh procedures are used to treat stress urinary incontinence and pelvic organ prolapse in women.

#### Percutaneous sacral nerve stimulation

A procedure used to treat overactive bladder. A device is implanted in the back to stimulate the nerves at the base of the spine. These nerves affect the bladder and surrounding muscles.

#### Percutaneous posterior tibial nerve stimulation

A procedure used to treat overactive bladder. A mild electric current is passed through a fine needle to stimulate a nerve in the leg. This nerve controls bladder function.

#### Retropubic mid-urethral mesh sling

A type of sling used to treat stress urinary incontinence. A strip of plastic is placed behind the tube that carries urine out of the body (the urethra) to support it in a sling.

#### Sacrocolpopexy

A type of surgery used to treat vaginal vault prolapse. Plastic mesh is used to attach the vagina to a bone at the bottom of the spine.

#### Sacro-hysteropexy

An operation to treat uterine prolapse. Plastic mesh is used to attach the womb (the uterus) to a bone at the bottom of the spine.

#### Urinary diversion

A type of surgery used to treat stress urinary incontinence. It causes urine to flow through an opening in the abdomen into an external bag, instead of into the bladder.

#### Vaginal sacrospinous fixation

A type of surgery used to treat vaginal vault or uterine prolapse. The top of the vagina is stitched to a ligament in the pelvis. It is done through a cut on the inside of the vagina.

#### Vaginal sacrospinous hysteropexy

An operation used to treat uterine prolapse. The cervix is stitched to a ligament in the pelvis. It is done through a cut on the inside of the vagina.

#### Additional information

#### Recommendation 1.4.31

This could be any medicine with the lowest acquisition cost from any of the medicines reviewed in 2013. The evidence review considered the following medicines: 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 2013 full guideline.

#### Recommendations 1.4.44 to 1.4.50

In April 2019, only 1 preparation of botulinum toxin type A (BOTOX, Allergan) had a UK marketing authorisation for overactive bladder. The licensed dose was 100 units.

One preparation of botulinum toxin type A (BOTOX, Allergan) had a UK marketing authorisation for use at a dose of 200 units, for treating neurogenic detrusor overactivity with urinary incontinence due to subcervical spinal cord injury (traumatic or non-traumatic) or multiple sclerosis.

Note that units of botulinum toxin type A are not interchangeable between preparations. If prescribing outside the marketing authorisation ('off label'), see <a href="NICE's information on prescribing medicines">NICE's information on prescribing medicines</a>.

### Recommendations for research

The guideline committee has made the following recommendations for research.

## Key recommendations for research

#### 1 Anticholinergic medicines

What is the effectiveness and safety of anticholinergic medicines for overactive bladder in older women? [2019]

For a short explanation of why the committee made the recommendation for research, see the rationale on medicines for overactive bladder.

Full details of the evidence and the committee's discussion are in <u>evidence review C:</u> the risks to cognitive function for women taking anticholinergic drugs for overactive bladder.

## 2 Colpocleisis compared with sacrospinous fixation for pelvic organ prolapse

What is the effectiveness of colpocleisis compared with sacrospinous fixation for pelvic organ prolapse in elderly women? [2019]

For a short explanation of why the committee made the recommendation for research, see the rationale on surgical management of pelvic organ prolapse.

Full details of the evidence and the committee's discussion are in <u>evidence review I:</u> <u>surgical management of pelvic organ prolapse</u>.

#### 3 Assessing complications associated with mesh surgery

What is the effectiveness of ultrasound-guided visualisation compared with clinical assessment to identify complications after mesh surgery for stress urinary incontinence or pelvic organ prolapse in women? [2019]

For a short explanation of why the committee made the recommendation for research, see the rationale on assessing complications associated with mesh surgery.

Full details of the evidence and the committee's discussion are in <u>evidence review K:</u> assessing mesh complications after pelvic floor mesh surgery.

#### 4 Pessaries or surgery for pelvic organ prolapse

What are the long-term outcomes, including patient satisfaction, from the use of pessaries compared with surgery for pelvic organ prolapse in women? [2019]

For a short explanation of why the committee made the recommendation for research, see the <u>rationale on non-surgical management of pelvic organ prolapse</u>.

Full details of the evidence and the committee's discussion are in <u>evidence review H:</u> lifestyle and conservative management options for pelvic organ prolapse.

#### 5 Long-term risks of surgery with and without mesh

What are the long-term risks of mesh surgery compared with non-mesh surgery for stress urinary incontinence and pelvic organ prolapse in women? [2019]

For a short explanation of why the committee made the recommendation for research, see the <u>rationale on surgical management of stress urinary incontinence</u> and <u>surgical management</u> of pelvic organ prolapse.

Full details of the evidence and the committee's discussion are in:

- evidence review E: surgical and physical management of stress urinary incontinence
- evidence review I: surgical management of pelvic organ prolapse.

#### Other recommendations for research

## Long-term effectiveness of botulinum toxin type A for overactive bladder

What is the long-term effectiveness of bladder wall injection with botulinum toxin type A for overactive bladder in women? [2019]

For a short explanation of why the committee made the recommendation for research, see the rationale on botulinum toxin type A injection.

Full details of the evidence and the committee's discussion are in <u>evidence review D:</u> management of overactive bladder.

#### Surgery for stress urinary incontinence and pelvic organ prolapse

What is the most effective surgical management for women with both stress urinary incontinence and pelvic organ prolapse, including the sequence of interventions? [2019]

Urinary incontinence and pelvic organ prolapse in women: management (NG123)

For a short explanation of why the committee made the recommendation for research, see the <u>rationale on surgery for women with both stress urinary incontinence and</u> pelvic organ prolapse.

Full details of the evidence and the committee's discussion are in <u>evidence review J:</u> surgical management of pelvic organ prolapse and stress urinary incontinence.

#### Pain management after mesh surgery

What is the effectiveness of pain management for women who present with chronic pain 3 months after mesh surgery for stress urinary incontinence or pelvic organ prolapse? [2019]

For a short explanation of why the committee made the recommendation for research, see the rationale on managing complications associated with mesh surgery.

Full details of the evidence and the committee's discussion are in <u>evidence review L:</u> management of mesh complications.

## Rationale and impact

These sections briefly explain why the committee made the 2019 recommendations and how they might affect practice. They link to details of the evidence and a full description of the committee's discussion.

### Organisation of specialist services

Recommendations 1.1.1 to 1.1.7

#### Why the committee made the 2019 recommendations

The committee agreed, based on their experience, that women with stress urinary incontinence, overactive bladder or primary prolapse would benefit from the broad range of expertise provided by a local multidisciplinary team (MDT). They agreed that a local MDT working within a regional clinical network could refer women to other services within the network for treatments that are not available locally, thus providing a broader choice of treatments.

The committee thought that women with complications related to mesh surgery, or with complex pelvic floor problems, should have access to a specialist MDT working at the regional level. The regional MDT could provide expert assessment and ensure that women are offered all available treatment options.

The committee acknowledged that membership of local and regional MDTs needs to be flexible and will vary in line with local and regional arrangements.

#### How the recommendations might affect practice

The recommendations on the different levels of MDTs, their composition, and how they should work together might affect how local and regional MDTs are commissioned and how services are currently organised.

Return to recommendations

## Collecting data on surgery and surgical complications

Recommendations 1.2.1 to 1.2.4

#### Why the committee made the 2019 recommendations

The committee were concerned about the lack of reliable evidence on adverse events after surgery for urinary incontinence and pelvic organ prolapse, especially those that occur 2 years or more after surgery. They were also aware of the widespread public concern about the use of synthetic mesh to treat these conditions in women. The wording of the recommendations reflects the committee's strong support for the collection of data in a national registry of surgery for urinary incontinence and pelvic organ prolapse in women.

The committee agreed that it would be helpful to provide a broad indication of the types of information that should be included in the registry, rather than specifying this in detail. The data in the registry will be analysed in the future to provide more reliable evidence than is available currently on the use of the various procedures in England and Wales and their long-term effects. This could be used to inform future guidance. The recommendations support the findings of the Mesh Oversight Group Report on reporting procedures in a national database.

The committee also agreed to highlight the importance of obtaining consent from women to include their data in the registry, and giving women a copy of their own data.

#### How the recommendations might affect practice

The recommendations are likely to have an impact on healthcare professionals and providers who are not already doing this because additional time and resource will be needed to report data to the registry and because of the cost of maintaining the registry and analysing the data.

Return to recommendations

## Urodynamic testing

Recommendations 1.3.15 and 1.3.16

#### Why the committee made the 2019 recommendations

The evidence did not show any benefit from urodynamic testing to assess stress urinary incontinence or stress-predominant mixed urinary incontinence in women who have demonstrable stress urinary incontinence before primary surgery. The committee concluded that urodynamic testing is not necessary for most women in this situation.

However, based on their experience the committee agreed that urodynamic testing can be beneficial if the diagnosis is unclear or if the woman has symptoms of voiding dysfunction, anterior or apical prolapse, or a history of surgery for stress urinary incontinence.

#### How the recommendations might affect practice

The recommendations are likely to reduce variation in practice, which is largely caused by uncertainty about the clinical value of urodynamic testing before surgery. They are also expected to reduce the number of women having urodynamic testing before surgery, and avoid unnecessary use of a procedure that some women find unpleasant.

Return to recommendations

### Pelvic floor muscle training

Recommendation 1.4.4

#### Why the committee made the 2019 recommendation

Although there was some good evidence showing that surgery is more effective than pelvic floor muscle training to manage stress urinary incontinence, the committee also took into account the risks associated with surgery and the absence of side effects from pelvic floor muscle training. They noted that the 2006 guideline committee had recommended pelvic floor muscle training, and had looked at evidence on both stress urinary incontinence and mixed urinary incontinence. The 2019 committee looked at evidence on stress urinary incontinence alone. The evidence showed that pelvic floor

muscle training is just as effective as surgery for around half of women with stress urinary incontinence. The committee therefore decided to retain the 2006 recommendation for pelvic floor muscle training as a first-line treatment for stress urinary incontinence.

#### How the recommendation might affect practice

The 2019 recommendation is unchanged from 2006 and so should not lead to changes in clinical practice in most services. However, there might still be services in which pelvic floor muscle training is not routinely offered, so the recommendation might lead to a change in practice in those areas.

Return to recommendations

## Absorbent containment products

Recommendations 1.4.16 to 1.4.18

#### Why the committee made the 2019 recommendations

There was no evidence available on the use of absorbent containment products to manage urinary incontinence. In the committee's experience, these products are often used for long-term management, with no review of their ongoing suitability or discussion of other possible management options. The committee were particularly concerned about the effect that long-term use of these products can have on skin integrity if urine absorption is not adequate, noting that breakdown of vulval skin is uncomfortable and distressing. They agreed that a review of absorbent containment products should be done at least once a year to ensure that problems are identified more promptly and management can be tailored to women's changing clinical and lifestyle needs.

The committee noted that standard medical reviews often do not include absorbent containment product use, and therefore agreed that reviews of absorbent containment products should be conducted or overseen by a continence-trained healthcare professional. They thought this would ensure that reviews are consistent and thorough, and offer women a full range of management options, including referral to specialist services if needed.

#### How the recommendations might affect practice

The recommendations will result in an increase in reviews for women using absorbent containment products. This might reduce the overall use of these products and lead to more referrals for alternative treatment. Although short-term costs might rise, long-term costs can be expected to fall through reduction in the use of absorbent containment products.

Return to recommendations

#### Medicines for overactive bladder

Recommendations 1.4.25 to 1.4.27 and 1.4.30

#### Why the committee made the 2019 recommendations

The committee noted that there is very little evidence about how anticholinergic medicines prescribed for overactive bladder affect cognitive function in women. They were aware that some anticholinergic medicines have been associated with dementia and Alzheimer's disease. They also noted that large numbers of women are prescribed anticholinergic medicines, with some estimates suggesting that one-third of women aged over 65 have some degree of incontinence. Because the long-term effects of anticholinergic medicines are uncertain, the committee stressed the importance of a full discussion with the woman, taking account of the woman's total anticholinergic load and carrying out regular reviews. They also decided to make a research recommendation on anticholinergic medicines to inform future guidance.

The effectiveness of anticholinergic and other medicines for overactive bladder was not reviewed in this guideline update.

#### How the recommendations might affect practice

The recommendations might raise awareness of the potential adverse effects of anticholinergic medicines, especially on cognitive function, and result in women being able to make better informed choices about managing their overactive bladder. The recommendations should also ensure that healthcare professionals regularly review women who remain on long-term medication.

Return to recommendations

## Botulinum toxin type A injection

Recommendations 1.4.44 to 1.4.51

#### Why the committee made the 2019 recommendations

The evidence on botulinum toxin type A injections for overactive bladder was limited, especially on the long-term effectiveness, dosage and frequency of injections, and the risks of adverse effects. The committee decided to make a <u>research recommendation on</u> the long-term effectiveness of botulinum toxin type A to inform future guidance.

The committee discussed starting doses and agreed that there was not enough evidence on the benefits and risks to recommend starting treatment with a higher dose than 100 units. The committee were aware from their own experience that there may be an increased risk of self-catheterisation with 200 units and that women usually wish to avoid this if possible. Although starting with the lower dose (100 units) may result in some women needing more injections, the committee agreed that there was not enough evidence to support starting at the higher dose.

Despite the limited evidence, the committee agreed that increasing the dose to 200 units might be effective for women who have not had a satisfactory response to 100 units. The committee also agreed that an increase in dose to 200 units should be considered for women who had a response to 100 units that lasted less than 6 months. These recommendations were based on the committee's clinical experience.

The committee discussed follow-up in clinical practice. They noted that the 2013 guideline recommended follow-up at 6 months, or sooner if symptoms return. However, based on their experience, the committee agreed that 6 months might be too late for some women, and recommended a telephone call or a clinic appointment within 12 weeks of their first injection.

#### How the recommendations might affect practice

The recommendations are expected to reduce variation in practice by giving clear guidance on the initial dose of botulinum toxin A for treating women with idiopathic

overactive bladder.

Changes in practice are unlikely because services are already in place to support botulinum toxin type A treatment. There will be a cost saving by having a starting dose of 100 units. There may also be savings because the recommendations no longer specify that women need training in self-catheterisation before treatment.

Return to recommendations

## Surgical management of stress urinary incontinence

Recommendations 1.5.1 to 1.5.18

#### Why the committee made the 2019 recommendations

The evidence showed that there were no important differences in the short- and mediumterm effectiveness of colposuspension, retropubic mid-urethral mesh slings and autologous rectus fascial slings, so the committee agreed that women should be offered a choice of these 3 procedures.

However, they emphasised that there is substantial uncertainty about the long-term complications associated with each procedure, and agreed that women should be made aware of this when choosing a procedure. They also made a <u>research recommendation on the long-term risks of surgery with and without mesh</u> to help inform future guidance.

The committee acknowledged the public concern about the risks of these procedures, especially those involving the insertion of mesh products. However, they agreed that women should not be denied effective surgical options. Instead, women should be fully informed and supported by their doctor to make the right decision about their treatment, taking into account the benefits and risks of all the options as well as any individual social or psychological factors that might affect their decision. The committee agreed that a patient decision aid could help women better understand the different surgical options and promote shared decision making.

The committee also noted variation in the amount of information and level of detail given to women before surgery and agreed that key information should be included in the

recommendations, with more detailed information provided in the patient decision aid. The committee noted the importance of giving women full information about the benefits and risks of these procedures.

#### Colposuspension

Evidence showed that open and laparoscopic colposuspension were equally effective procedures. Although there is a slightly increased risk of bladder injury with the laparoscopic approach, the committee thought this risk was not sufficient to exclude this option.

#### Retropubic mid-urethral mesh sling

The committee recommended the retropubic, rather than the transobturator, route because the evidence showed that retropubic mesh slings are more likely to cure incontinence in the short term and less likely to cause complications in the medium and short term. In addition, the committee agreed that the retropubic mesh slings are easier to remove if complications do occur. However, there is evidence of a greater risk of bladder injury and need for temporary catheterisation with a retropubic procedure.

#### Porcine slings

The committee agreed that porcine dermis slings should not be offered because they are less likely to result in a cure and more likely to lead to repeat surgery than a retropubic mesh sling.

#### Intramural bulking agents

The committee noted the lack of evidence on the long-term use of intramural bulking agents and uncertainty about the risks. However, in the committee's experience, some women, particularly those who are older or frail, find them beneficial. The committee agreed that intramural bulking agents should be considered if other surgery is unsuitable for, or unacceptable to, the woman. They emphasised that women who choose an intramural bulking agent should be fully advised of the risks, the lack of evidence for long-term effectiveness and adverse events, and that other surgical procedures may be more effective.

#### How the recommendations might affect practice

More thorough and detailed discussion with women before they have surgery for stress urinary incontinence is likely to moderately increase the time spent in consultations.

Synthetic mesh slings, colposuspension, autologous rectus fascial slings and intramural bulking agents are offered in current practice. However, all surgical options are not available at every hospital and women may require referral to another centre (regional centre) if they choose to have a procedure that is not available locally. Regional centres may require extra resources to meet this need. There might also be an increase in the number of colposuspensions and autologous rectus fascial sling procedures carried out.

Return to recommendations

### Assessing pelvic organ prolapse

Recommendations 1.6.1 to 1.6.7

#### Why the committee made the 2019 recommendations

The evidence indicated that self-reported symptoms can accurately identify pelvic organ prolapse, although the committee noted that prolapse is often an incidental finding. They agreed, based on the evidence and their clinical experience, that accurate assessment of suspected pelvic organ prolapse depends on a thorough clinical history and examination.

The committee thought that secondary care clinicians who suspect or identify vaginal prolapse could consider referral to a clinician with expertise in prolapse.

Evidence showed that the POP-Q (Pelvic Organ Prolapse Quantification) system produces an accurate assessment of pelvic organ prolapse, and the committee agreed that it provides an objective and standardised measure that will ensure consistency of assessment.

Based on their experience, the committee agreed that it is important to assess pelvic floor muscles and vaginal atrophy, and to rule out a pelvic mass or other pathology. They also agreed that a validated pelvic floor symptom questionnaire could aid assessment.

The committee noted evidence showing that imaging does not provide any additional

benefit in the assessment of vaginal prolapse diagnosed by physical examination. They agreed that imaging would delay management, and should not be routinely carried out in this situation.

Based on their experience, the committee agreed that symptoms of pelvic floor prolapse can become more prominent when the woman is straining or changes her position. They concluded that repeating the physical examination with the woman in a different position could be helpful if her symptoms are not explained by the physical examination. They also agreed, based on their experience, that other pelvic floor symptoms, including symptoms that remain unexplained after physical examination, should also be investigated.

#### How the recommendations might affect practice

The recommendations reflect current good practice, so the committee agreed there should be little change in practice.

Return to recommendations

### Non-surgical management of pelvic organ prolapse

Recommendations 1.7.1 to 1.7.9

#### Why the committee made the 2019 recommendations

Based on their experience, the committee agreed that there should be an initial discussion of the management options with women who have pelvic organ prolapse, including no treatment, non-surgical treatment and all surgical options.

#### Lifestyle modification

There was no evidence available on lifestyle modification to manage pelvic organ prolapse, so the committee used their knowledge and clinical experience to make this recommendation. They thought that advice on aspects of lifestyle that directly affect the pelvic organs is most useful for women with pelvic organ prolapse. The committee agreed that obesity, heavy lifting and constipation all exacerbate the symptoms of pelvic organ prolapse by increasing intra-abdominal pressure.

#### Topical oestrogen

There was no evidence available on topical oestrogen to manage pelvic organ prolapse. In the committee's experience, women with urogenital atrophy have more pronounced symptoms of pelvic organ prolapse. Treatment with a vaginal oestrogen reduces the effect of the atrophy and improves symptoms. The committee noted that vaginal oestrogen is available in a pessary, a cream or an oestrogen-releasing ring.

#### Pelvic floor muscle training

A small amount of evidence suggests that pelvic floor muscle training is beneficial for women with pelvic organ prolapse.

#### **Pessaries**

Limited evidence suggests that pessaries are an important alternative to surgical intervention for women with all stages of prolapse including advanced prolapse. The committee agreed that pessaries are an easily available option for women and that many women prefer them as an alternative to surgery. However, there is little evidence so the committee made a <u>research recommendation on pessaries or surgery for pelvic organ prolapse</u> to inform future practice.

The committee discussed the complications that can develop with pessary use and agreed that women should be advised of these, and of the importance of the pessary being removed at regular intervals. Serious complications such as pessary incarceration necessitating removal under anaesthetic, or the development of fistulae, can occur if pessaries are not changed regularly. The committee noted that women who have difficulty managing long-term pessary care because of physical or cognitive impairments are at higher risk of these complications. They therefore recommended regular appointments for these women.

#### How the recommendations might affect practice

#### Lifestyle modification

The recommendation generally reflects current practice, so the committee agreed there should be no major impact on practice.

#### Topical oestrogen

The committee concluded that these recommendations can be expected to increase the use of vaginal oestrogen, especially in primary care, and decrease the number of referrals for specialist advice and use of other interventions.

#### Pelvic floor muscle training

The recommendation is current practice in some services but not all, and the committee suspects that the recommendation may result in the need for some increase in resources.

#### **Pessaries**

The recommendations are current practice in some services and the committee does not expect it to result in significant resource increases.

Return to recommendations

## Surgical management of pelvic organ prolapse

Recommendations 1.8.1 to 1.8.25

#### Why the committee made the 2019 recommendations

#### Surgery for pelvic organ prolapse

The evidence on surgery for pelvic organ prolapse was limited, making it difficult for the committee to draw definite conclusions about the benefits and risks of the different types of surgery. In particular, they noted a lack of long-term evidence on the effectiveness of different types of mesh surgery. In view of this, the committee agreed that it is important to give women information on all the treatment options, including no treatment, physiotherapy, pessaries and the range of surgical options, so that they can decide which is their preferred treatment.

The committee emphasised that there is substantial uncertainty about the long-term success and complications associated with each procedure, and agreed that women should be made aware of this when choosing a procedure. They also made a <u>research</u>

recommendation on the long-term risks of surgery with and without mesh to help inform future guidance.

The committee acknowledged the public concern about the risks of procedures involving the insertion of mesh products. However, they agreed that women should not be denied effective surgical options. Instead, they should be fully informed and supported by their doctor to make the right decision about their treatment. They agreed that a patient decision aid could help women better understand the benefits and risks of the different treatment options and promote shared decision making.

The committee agreed informed choice is of great importance in making decisions about surgery, and that a woman should be provided with information on all her potential options for management. The committee were aware that multiple factors (for example, comorbidities and lifestyle) affect the choice of treatment, many of which were not captured by the evidence, and that these should be taken into account when discussing surgery with women.

The committee also noted variation in the amount of information and level of detail given to women before surgery and agreed that key information should be included in the recommendations, with more detailed information provided in the NICE patient decision aids. The committee noted the importance of providing full information about the benefits and risks of these procedures.

The committee noted that for some women, the full extent of prolapse in all compartments can only be evaluated during surgery. Therefore it is important to discuss with women the surgical plan if prolapse is found to be more severe than anticipated from clinic examination.

#### Surgery for uterine prolapse

The committee agreed that surgical options, including surgery that will preserve the uterus, should be discussed with the woman.

Based on their clinical experience, they agreed that women who wish to preserve their uterus should be offered a choice of 3 types of surgery. There was no evidence available that compared these 3 procedures.

For women who have no preference about preserving their uterus, the committee used

their clinical experience to agree that women should be offered a choice of 4 surgical options. There was a very small amount of evidence showing that vaginal hysterectomy might be slightly better than sacrospinous hysteropexy, but there was not enough evidence to justify a preference for any of the 4 options.

#### Surgery for vault prolapse

The committee noted that the evidence showed no difference in cure and quality of life between sacrocolpopexy and sacrospinous fixation. Based on the evidence and their clinical experience, the committee agreed that women with vault prolapse should be offered a choice of 2 types of surgery. The committee noted that sacrocolpopexy can be performed either as open surgery or laparoscopically.

#### Colpocleisis for vault or uterine prolapse

Based on their clinical experience, the committee agreed that colpocleisis should be considered a potential surgical option for managing symptoms of vault or uterine prolapse in some groups of women. There was no evidence comparing colpocleisis with other management options. However, the committee thought that colpocleisis should be considered for women who have no other surgical options or for whom the other procedures would carry a higher risk of a serious complication. They made a <a href="research recommendation on colpocleisis compared with sacrospinous fixation for pelvic organ prolapse">research recommendation on colpocleisis compared with sacrospinous fixation for pelvic organ prolapse</a> to help inform future guidance.

#### Surgery for anterior prolapse

The evidence suggested that mesh surgery has higher cure rates, fewer repeat surgeries for pelvic organ prolapse, and lower recurrence rates compared with anterior colporrhaphy. However, the committee were aware of the potential complications associated with mesh exposure and erosion, and that these may increase over time. This is particularly relevant for younger women having surgery, but there was no evidence specifically for these women. Based on the evidence of risks associated with mesh surgery, the committee agreed that anterior repair without mesh should be offered.

They agreed that mesh surgery could be considered, but only for recurrent prolapse in a very limited number of women for whom there is no alternative treatment. The committee noted that evidence supports the effectiveness of mesh placement for anterior prolapse. They discussed the balance between the risks associated with mesh surgery and the

potential harms of no treatment, which include persistent prolapse, problems with bladder emptying, ulceration of vaginal skin, recurrent urinary tract infections, pain and discomfort, sexual dysfunction, and problems with working and social life. The committee agreed that some women with recurrent prolapse after a non-mesh repair might be prepared to accept the risks associated with mesh surgery, and that these women should have the option to make an informed choice.

#### Surgery for posterior prolapse

There was no evidence showing that mesh surgery is better than non-mesh surgery for posterior prolapse, and mesh surgery is associated with an increased risk of complications. The committee therefore agreed that vaginal repair without mesh should be offered to women with posterior prolapse.

#### Follow-up after surgery

Based on their experience, the committee agreed that a review 6 months after any type of surgery for prolapse will help to establish the effectiveness and rate of short-term complications. In view of the concern regarding long-term complications, the committee considered that it was important that women should be referred for specialist advice if they experience recurrent symptoms or complications after 6 months.

#### How the recommendations might affect practice

More thorough and detailed discussion with women before they have surgery for pelvic organ prolapse is likely to moderately increase time spent in consultations. Sacrohysteropexy with mesh is not available at all centres so this might increase referrals between centres. However, because fewer women are choosing mesh surgery, the increase in this type of referral is likely to be negligible. Similarly, there could be a small increase in referrals for laparoscopic sacrocolpopexy and colpocleisis, but this is not expected to have a significant impact on practice.

Return to recommendations

## Surgery for women with both stress urinary incontinence and pelvic organ prolapse

Recommendations 1.9.1 and 1.9.2

#### Why the committee made the 2019 recommendations

The evidence did not show any clear benefits for concurrent surgery for stress urinary incontinence and pelvic organ prolapse, but the committee agreed that it should be considered in women with anterior and/or apical prolapse and stress urinary incontinence. They agreed that women should be told about the uncertainty of the benefits and risks of concurrent surgery compared with sequential surgery, to ensure that they are equipped to make an informed decision. The committee made a research recommendation on the most effective surgical management for women with both stress urinary incontinence and pelvic organ prolapse.

#### How the recommendations might affect practice

The committee expect these recommendations to reduce variations in care and improve the information women are given when choosing between sequential and concurrent surgery for stress urinary incontinence and pelvic organ prolapse.

Return to recommendations

## Assessing complications associated with mesh surgery

Recommendations 1.10.1 to 1.10.6

#### Why the committee made the 2019 recommendations

The committee noted, based on their experience, that there can be delays in the diagnosis of mesh-related complications. They therefore highlighted the importance of considering mesh as a possible cause of pain, vaginal problems, or urinary or bowel problems in women who have had mesh inserted.

The committee were unable to make generalised recommendations on assessing possible mesh-related complications because of the wide variety of procedures and implanted materials used, and the many different complications that might result from these. They therefore agreed that women with suspected mesh-related complications should be referred to a specialist centre unless they have an uncomplicated, small mesh exposure that can be treated with topical oestrogen.

There was little evidence available on the use of specific investigations to assess suspected mesh-related complications, so the committee decided to outline a range of possible investigations. They also made a <u>research recommendation on assessing</u> complications associated with mesh surgery to inform future guidance.

#### How the recommendations might affect practice

The recommendations reflect current good practice and the committee did not expect them to result in changes in practice.

Return to recommendations

## Managing complications associated with mesh surgery

Recommendations 1.11.1 to 1.11.18

#### Why the committee made the 2019 recommendations

The available evidence was very limited and so the committee made recommendations based on their experience. They noted that women often have multiple complications from mesh surgery and that these complications can be long lasting. They also noted that the success of mesh removal varies widely depending on the specific mesh-related complication. In addition, some women who have complete mesh removal will have further complications and recurrence of stress urinary incontinence, pelvic organ prolapse, or both. The committee therefore agreed that healthcare professionals should have a full discussion with women who are considering having partial or complete mesh removal. They also agreed that mesh should be removed only after a review by the regional MDT.

Based on their experience, the committee agreed that topical oestrogen is only likely to be

effective for small exposures of mesh and should be discussed with the woman as an option that could be tried before surgery is considered. They noted that some women who present with mesh exposure or extrusion with vaginal discharge may have a mesh infection, and imaging should be considered to assist in the diagnosis.

The committee acknowledged the impact that mesh perforation in the lower urinary tract has on women's quality of life, and agreed that women with this complication should be referred for further assessment. Similarly, women who have pain or painful sexual intercourse should be offered specialist assessment. The committee reiterated the need to tell women about the possible benefits and risks of mesh removal surgery. The committee also noted the lack of evidence in this area and made a recommendation for research on pain management after mesh surgery.

#### How the recommendations might affect practice

The committee thought that these recommendations will reduce delays in treatment for mesh-related complications, although they might increase the number of referrals.

Return to recommendations

### Context

Urinary incontinence is a common symptom that can affect women of all ages, with a wide range of severity and nature. Although it is rarely life-threatening, urinary incontinence can be very detrimental to the physical, psychological and social wellbeing of the women it affects. The impact on families and carers can also be profound, and the resource implications for the health service are considerable. Urinary incontinence is defined by the International Continence Society as 'the complaint of any involuntary leakage of urine'.

Urinary incontinence can be a result of functional abnormalities in the lower urinary tract or of illnesses. Stress urinary incontinence is involuntary urine leakage on effort, exertion, sneezing or coughing. Urgency urinary incontinence is involuntary urine leakage accompanied or immediately preceded by urgency (a sudden compelling desire to urinate that is difficult to delay). Mixed urinary incontinence 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 urinary incontinence 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.

Pelvic organ prolapse is defined as symptomatic descent of 1 or more of: the anterior vaginal wall, the posterior vaginal wall, the cervix or uterus, or the apex of the vagina (vault or cuff). Symptoms include a vaginal bulge or sensation of something coming down, urinary, bowel and sexual symptoms, and pelvic and back pain. These symptoms affect women's quality of life.

The prevalence of pelvic organ prolapse is high; in primary care in the UK, 8.4% of women reported vaginal bulge or lump, and on examination prolapse is present in up to 50% of women. One in 10 women will need at least 1 surgical procedure, and the rate of re-operation is as high as 19%. There is likely to be an increasing need for surgery for urinary incontinence and pelvic organ prolapse because of the ageing population.

The NHS England Mesh Working Group report published in December 2015 raised a number of concerns about the safety and efficacy of surgery for stress urinary incontinence and pelvic organ prolapse using mesh devices. The report made the following recommendations for NICE:

- to produce a clinical guideline that describes, holistically, care for women with pelvic organ prolapse
- to review the 2013 NICE guideline on urinary incontinence in women (CG171)
- to review evidence on complications arising from surgery for stress urinary incontinence and pelvic organ prolapse.

NICE accepted these recommendations and has reviewed the evidence on complications arising from surgery for stress urinary incontinence and managing pelvic organ prolapse and updated this guideline.

## Finding more information and resources

To find NICE guidance on related topics, including guidance in development, see the <u>NICE</u> topic pages on gynaecological conditions and urological conditions.

For full details of the evidence and the guideline committee's discussions, see the <u>evidence reviews</u>. You can also find information about <u>how the guideline was developed</u>, including details of the committee.

NICE has produced tools and resources to help you put this guideline into practice. For general help and advice on putting our guidelines into practice, see resources to help you put NICE guidance into practice.

## **Update information**

June 2019: Recommendations 1.8.21 and 1.8.22, which related to the use of synthetic polypropylene or biological mesh insertion for women with recurrent anterior vaginal wall prolapse, have been withdrawn. Instead, please see <a href="NICE interventional procedures">NICE interventional procedures</a> guidance 599 for recommendations on transvaginal mesh repair of anterior or posterior vaginal wall prolapse.

The replacement of the guideline recommendation with a cross-reference to IPG599 is to provide clarity regarding the relation of NG123 and IPG599 and to take account of a material change since publication in the availability of products CE-marked for the indication which was referred to in the guideline recommendations.

**April 2019:** We have reviewed the evidence and made new or updated recommendations on:

- organisation of specialist services
- collecting data on surgery and surgical complications
- urodynamic testing to assess urinary incontinence
- pelvic floor muscle training for urinary incontinence
- absorbent containment products for urinary incontinence
- medicines for overactive bladder
- botulinum toxin type A injection for overactive bladder
- surgical management of stress urinary incontinence
- assessing pelvic organ prolapse
- non-surgical management of pelvic organ prolapse
- surgical management of pelvic organ prolapse
- surgery for women with both stress urinary incontinence and pelvic organ prolapse
- assessing complications associated with mesh surgery

managing complications associated with mesh surgery.

These recommendations are marked [2019].

We have also made some changes without an evidence review:

- 'Conservative management' has been changed to 'non-surgical management' for clarity and consistency.
- A cross-reference to the <u>NICE guideline on suspected cancer</u> in the recommendation on referral for women aged over 45 with haematuria or a recurrent or persistent unexplained urinary tract infection (UTI) has been clarified.
- All references to the multidisciplinary team (MDT) have been specified as 'local' or 'regional' to make it clear which MDT is being referred to.
- The reference to 'frail older women' has been replaced by 'older women who are at higher risk of a sudden deterioration in their physical or mental health' to clarify that the recommendation includes women with cognitive as well as physical impairment.
- The recommendation that treatment with botulinum toxin type A be started only if the woman has been trained in clean intermittent catheterisation and performed it successfully has been amended because:
  - the likelihood of needing catheterisation is lower with the dose of 100 units of botulinum toxin type A recommended in the 2019 guideline and
  - to remove restrictions on women being offered this treatment.
- The table used to discuss treatment options for stress urinary incontinence has been removed. <a href="NICE's patient decision aid on surgery for stress urinary incontinence">NICE's patient decision aid on surgery for stress urinary incontinence</a> has been published.

These recommendations are marked [2006, amended 2019] or [2013, amended 2019].

Recommendations marked [2006], [2006, amended 2013] or [2006, amended 2019] last had an evidence review in 2006. Recommendations marked [2013] or [2013, amended 2019] last had an evidence review in 2013.

In some cases, minor changes have been made to the wording to bring the language and style up to date, without changing the meaning.

#### Minor changes since publication

**May 2022:** We added a link to NICE's guideline on medicines associated with dependence or withdrawal symptoms in section 1.4.

ISBN: 978-1-4731-3319-8

## Accreditation

