1 2	NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE
3	Guideline
4	Urinary incontinence and pelvic organ
5	prolapse in women: management
6	Draft for consultation, October 2018
7	
	This guideline covers assessing and managing urinary incontinence and pelvic
	organ prolapse in women aged 18 years and older. It also covers complications

Who is it for?

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

This guideline will update NICE guideline CG171 (published September 2013). NICE guideline CG171 updated NICE guideline CG40 (published October 2006).

We have reviewed the evidence in the following areas of the 2013 guideline:

- multidisciplinary teams
- urodynamic testing in urinary incontinence

associated with mesh surgery for these conditions.

- absorbent products for urinary incontinence
- medicines for overactive bladder
- botulinum toxin type A for overactive bladder
- surgical procedures for stress urinary incontinence.

We have also reviewed the evidence and added new recommendations in these areas:

- assessing and managing pelvic organ prolapse
- managing coexisting urinary incontinence and pelvic organ prolapse
- assessing and managing complications associated with mesh surgery for urinary incontinence or pelvic organ prolapse.

You are invited to comment on the new and updated recommendations. These are marked as **[2019]**.

We have not reviewed the evidence for the recommendations shaded in grey, and cannot accept comments on them. In some cases, we have made minor wording changes for clarification.

See <u>update information</u> for a full explanation of what is being updated.

This draft guideline contains:

- the draft recommendations
- recommendations for research
- the guideline context.

Information about how the guideline was developed is on the <u>guideline's page</u> on the NICE website. This includes the evidence reviews, the scope, and details of the committee and any declarations of interest.

Full details of the evidence and the committee's discussion on the 2019 recommendations are in the <u>evidence reviews</u>. Evidence for the 2013 recommendations is in the <u>full version</u> of the 2013 guideline.

For definitions of medical terms used in the guideline see <u>supplementary</u> <u>material B: glossary and abbreviations</u>.

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1 **Recommendations**

People have the right to be involved in discussions and make informed decisions about their care, as described in <u>your care</u>. <u>Making decisions using NICE guidelines</u> 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.

2 **1.1** *Multidisciplinary teams*

3	Local m	ultidisciplinary teams
4	1.1.1	Local multidisciplinary teams (MDTs) for women with primary stress
5		urinary incontinence (UI), overactive bladder (OAB) or primary prolapse
6		should:
7		 review the proposed treatment for all women offered invasive
8		procedures for primary stress UI, OAB or primary prolapse
9		 review the proposed management for women with primary stress UI,
10		OAB or primary prolapse if input from a wider range of professionals is
11		needed
12		 work within an established clinical network that has access to a
13		regional MDT ¹ . [2019]
14	1.1.2	Local MDTs for women with primary stress UI, OAB or primary prolapse
15		should include:
16		 2 urogynaecologists or urologists with expertise in female urology
17		 a urogynaecology, urology or continence specialist nurse
18		 a pelvic floor specialist physiotherapist
19		and may also include:

¹ NHS England is consulting on <u>specialised gynaecology surgery and complex urogynaecology</u> <u>conditions service specifications</u>. The consultation closes on 13 November 2018.

1		 a member of the care of the elderly team
2		an occupational therapist
3		• a colorectal surgeon. [2019]
1	Pagional	multidicainlinenzteeme
4	-	multidisciplinary teams
5	1.1.3	Regional MDTs that deal with complex pelvic floor dysfunction and
6		mesh-related problems should review the proposed treatment for women
7		if:
8		 they are having repeat continence surgery
9		 they are having repeat, same-site prolapse surgery
10		their preferred treatment option is not available in the referring hospital
11		 they have co-existing bowel problems that may need intervention
12		 vaginal mesh for prolapse is a treatment option for them
13		 they have mesh complications or unexplained symptoms after mesh
14		surgery for UI or prolapse. [2019]
15	1.1.4	Regional MDTs that deal with complex pelvic floor dysfunction and mesh-
16		related problems should include:
17		 a subspecialist in urogynaecology
18		 a urologist with expertise in female urology
19		 a urogynaecology, urology or continence specialist nurse
20		 a pelvic floor specialist physiotherapist
21		 a radiologist with expertise in pelvic floor imaging
22		 a colorectal surgeon with expertise in pelvic floor problems
23		a pain specialist
24		 a healthcare professional trained in biofeedback
25		and may also include:
26		 a member of the care of the elderly team
27		 an occupational therapist
28		• a plastic surgeon. [2019]

1 1.1.5 Regional MDTs that deal with complex pelvic floor dysfunction and mesh-2 related problems should have ready access to the following services: 3 psychology 4 psychosexual counselling 5 chronic pain management 6 bowel symptom management 7 neurology. [2019] 1.2 Collecting data on mesh surgery and mesh-related 8 complications 9 1.2.1 10 In women having mesh surgery for stress urinary incontinence or pelvic 11 organ prolapse, or who have mesh-related complications, seek consent to 12 enter the data listed in recommendation 1.2.2 in a national registry and 13 give them a copy of their data. 14 1.2.2 Ensure that the following data are collected in a national registry of 15 surgery involving mesh insertion to treat urinary incontinence (UI) or pelvic 16 organ prolapse (POP) in women: 17 all surgical procedures for urinary incontinence or pelvic organ prolapse 18 that involve the insertion of synthetic polypropylene mesh, including 19 date and details of the procedure 20 mesh material and type of sutures. 21 the woman's NHS number 22 hospital and consultant identifiers 23 follow-up information on key short- and long-term (at least 5 years) 24 outcomes, including: 25 symptom improvement or deterioration 26 objective measures of UI or POP 27 adverse events 28 suspected and confirmed mesh-related complications 29 date and details of any investigation for mesh-related complications

- date and details of any surgical or non-surgical intervention for mesh related complications. [2019]
- 1.2.3 The national registry of surgery involving mesh insertion to treat urinary
 incontinence or pelvic organ prolapse in women should report annually
 and be quality assured. [2019]
- 6 **1.3** Assessing urinary incontinence
- 7 History taking and physical examination
- 8 1.3.1 At the initial clinical assessment, categorise the woman's urinary
 9 incontinence (UI) as stress UI, mixed UI or urgency UI/overactive bladder
 10 (OAB). Start initial treatment on this basis. In mixed UI, direct treatment
 11 towards the predominant symptom. [2006]
- 12 1.3.2 If stress incontinence is the predominant symptom in mixed UI, discuss
 13 with the woman the benefit of non-surgical management and medicines
 14 for OAB 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]
- 18 Assessing pelvic floor muscles
- 19 1.3.4 Undertake routine digital assessment to confirm pelvic floor muscle
 20 contraction before the use of supervised pelvic floor muscle training for
 21 the treatment of UI. [2006, amended 2013]

22 Urine testing

- 1.3.5 Undertake a urine dipstick test in all women presenting with UI to detect
 the presence of blood, glucose, protein, leucocytes and nitrites in the
 urine. [2006]
- 1.3.6 If women have symptoms of urinary tract infection (UTI) and their urine
 tests positive for both leucocytes and nitrites, send a midstream urine

4		anagiman for gulture and analysis of antihistic consitivities. Dressribe an
1		specimen for culture and analysis of antibiotic sensitivities. Prescribe an
2		appropriate course of antibiotic treatment pending culture results ² . [2006]
3	1.3.7	If women have symptoms of UTI and their urine tests negative for either
4		leucocytes or nitrites, send a midstream urine specimen for culture and
5		analysis of antibiotic sensitivities. Consider the prescription of antibiotics
6		pending culture results. [2006]
7	1.3.8	If women do not have symptoms of UTI, but their urine tests positive for
8		both leucocytes and nitrites, do not offer antibiotics without the results of
9		•
9		midstream urine culture. [2006]
10	1.3.9	If a woman does not have symptoms of UTI and her urine tests negative
11		for either leucocytes or nitrites, do not send a urine sample for culture
12		because she is unlikely to have UTI. [2006]
13	Assessin	ig residual urine
14	1.3.10	Measure post-void residual volume by bladder scan or catheterisation in
15		women with symptoms suggestive of voiding dysfunction or recurrent UTI.
16		[2006]
17	1.3.11	Use a bladder scan in preference to catheterisation on the grounds of
18		acceptability and lower incidence of adverse events. [2006]
19	Sympton	n scoring and quality-of-life assessment
20	1.3.12	Use the following incontinence-specific quality-of-life scales when
21		therapies are being evaluated: ICIQ, BFLUTS, I-QOL, SUIQQ, UISS,
22		SEAPI-QMM, ISI and KHQ ³ . [2006]
23	Bladder o	diaries
24	1.3.13	Use bladder diaries in the initial assessment of women with UI or OAB.
25		Encourage women to complete a minimum of 3 days of the diary covering
-		

 ² NICE is developing guidance on <u>antimicrobial prescribing for lower urinary tract infections</u> (publication expected 12 October 2018).
 ³ See the 2013 <u>full guideline</u> for details.

1		variations in their usual activities, such as both working and leisure days.
2		[2006]
3	Pad testi	ng
4	1.3.14	Do not use pad tests in the routine assessment of women with UI. [2006]
5	Urodynaı	mic testing
6	1.3.15	Do not perform multichannel filling and voiding cystometry before primary
7		surgery if stress UI or stress-predominant mixed UI is diagnosed based on
8		a detailed clinical history and examination. [2019]
9	1.3.16	After undertaking a detailed clinical history and examination, perform
10		multichannel filling and voiding cystometry before surgery for stress UI in
11		women who have any of the following:
12		 urge-predominant mixed UI or UI in which the type is unclear
13		 symptoms suggestive of voiding dysfunction
14		anterior or apical prolapse
15		 a history of previous surgery for stress UI. [2019]
16	Other tes	ts of urethral competence
17	1.3.17	Do not use the Q-tip, Bonney, Marshall and Fluid-Bridge tests in the
18		assessment of women with UI. [2006]
19	Cystosco	ру
20	1.3.18	Do not use cystoscopy in the initial assessment of women with UI alone.
21		[2006]
22	Imaging	
23	1.3.19	Do not use imaging (MRI, CT, X-ray) for the routine assessment of
24		women with UI. Do not use ultrasound other than for the assessment of
25		residual urine volume. [2006]
26	Indicatio	ns for referral to a specialist service
27	1.3.20	In women with UI, indications for consideration for referral to a specialist
28		service include:

1		persisting bladder or urethral pain
2		palpable bladder on bimanual or abdominal examination after voiding
3		clinically benign pelvic masses
4		associated faecal incontinence
5		 suspected neurological disease
6		symptoms of voiding difficulty
7		 suspected urogenital fistulae
8		previous continence surgery
9		previous pelvic cancer surgery
10		previous pelvic radiation therapy. [2006]
11	1.3.21	For women aged over 45 who have haematuria, or a recurrent or
12		persistent unexplained UTI, follow the recommendations on referral for
13		bladder cancer in the NICE guideline on suspected cancer. [2006,
14		amended 2019]
15	1.4	Non-surgical management of urinary incontinence
16	Lifestyle	interventions
17	1.4.1	
18		Recommend a trial of caffeine reduction to women with overactive bladder (OAB). [2006]
18 19 20	1.4.2	
19		(OAB). [2006] Consider advising women with urinary incontinence (UI) or OAB and a
19 20 21	1.4.2 1.4.3	(OAB). [2006] Consider advising women with urinary incontinence (UI) or OAB and a high or low fluid intake to modify their fluid intake. [2006] Advise women with UI or OAB who have a BMI greater than 30 to lose
19 20 21 22	1.4.2 1.4.3	 (OAB). [2006] Consider advising women with urinary incontinence (UI) or OAB and a high or low fluid intake to modify their fluid intake. [2006] Advise women with UI or OAB who have a BMI greater than 30 to lose weight. [2006]
19 20 21 22 23	1.4.2 1.4.3 Physical	 (OAB). [2006] Consider advising women with urinary incontinence (UI) or OAB and a high or low fluid intake to modify their fluid intake. [2006] Advise women with UI or OAB who have a BMI greater than 30 to lose weight. [2006] therapies
19 20 21 22 23 24	1.4.2 1.4.3 Physical	<pre>(OAB). [2006] Consider advising women with urinary incontinence (UI) or OAB and a high or low fluid intake to modify their fluid intake. [2006] Advise women with UI or OAB who have a BMI greater than 30 to lose weight. [2006] therapies Offer a trial of supervised pelvic floor muscle training of at least 3 months'</pre>
19 20 21 22 23 24 25	1.4.2 1.4.3 Physical 1.4.4	 (OAB). [2006] Consider advising women with urinary incontinence (UI) or OAB and a high or low fluid intake to modify their fluid intake. [2006] Advise women with UI or OAB who have a BMI greater than 30 to lose weight. [2006] therapies Offer a trial of supervised pelvic floor muscle training of at least 3 months' duration as first-line treatment to women with stress or mixed UI. [2006]

1 2	1.4.6	Do not use perineometry or pelvic floor electromyography as biofeedback as a routine part of pelvic floor muscle training. [2006]
3 4	1.4.7	Continue an exercise programme if pelvic floor muscle training is beneficial. [2006]
5 6	1.4.8	Do not routinely use electrical stimulation in the treatment of women with OAB. [2006]
7 8	1.4.9	Do not routinely use electrical stimulation in combination with pelvic floor muscle training. [2006]
9 10 11	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]
12	Behaviou	ral therapies
13	1.4.11	Offer bladder training lasting for a minimum of 6 weeks as first-line
14		treatment to women with urgency or mixed UI. [2006]
15 16 17	1.4.12	If women do not achieve satisfactory benefit from bladder training programmes, the combination of an OAB medicine with bladder training should be considered if frequency is a troublesome symptom. [2006]
18	Neurostir	nulation
19 20 21	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 OAB in women. [2013]
22 23 24	1.4.14	Explain that there is insufficient evidence to recommend the use of transcutaneous posterior tibial nerve stimulation (surface electrodes placed above the posterior tibial nerve) to treat OAB. [2013]
25 26	1.4.15	Do not offer transcutaneous posterior tibial nerve stimulation for OAB. [2013]

1 2	1.4.16	Do not offer percutaneous posterior tibial nerve stimulation (needles inserted close to the posterior tibial nerve) for OAB unless:
2		
3 4 5 6 7		 there has been a local multidisciplinary team (MDT) review and non-surgical management including OAB medicine treatment has not worked adequately and the woman does not want botulinum toxin type A⁴ or percutaneous sacral nerve stimulation. [2013, amended 2019]
8 9 10	1.4.17	Explain that there is insufficient evidence to recommend the use of percutaneous posterior tibial nerve stimulation to routinely treat OAB .[2013]
11	Absorbei	nt containment products, urinals and toileting aids
12 13	1.4.18	Absorbent containment products, hand held urinals and toileting aids should not be considered as a treatment for UI. Use them only as:
14 15 16 17		 a coping strategy pending definitive treatment an adjunct to ongoing therapy long-term management of UI only after treatment options have been explored. [2006]
18 19 20	1.4.19	Offer a review at least once a year to women who are using absorbent containment products for long-term management of UI. The review should cover:
21 22		 routine assessment of continence assessment of skin integrity
23 24		 changes to symptoms, comorbidities, lifestyle, mobility, medication, BMI, and social and environmental factors
25		 the suitability of alternative treatment options
26		 the efficacy of the absorbent containment product the woman is
27		currently using and the quantities used

⁴ At the time of consultation (October 2018) most botulinum toxin type A preparations did not have a UK marketing authorisation for this indication. Evidence was only available for the licensed botulinum toxin type A preparation (Botox, Allergan).

1		long-term management strategies. [2019]
2 3	1.4.20	Reviews for women who are using absorbent containment products for long-term management of UI should be carried out by either:
4 5 7 8 9		 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]
10	Catheter	S
11 12 13 14 15 16 17 18 19	1.4.21	Bladder catheterisation (intermittent or indwelling urethral or suprapubic) should be considered for women in whom persistent urinary retention is causing incontinence, symptomatic infections, or renal dysfunction, and in whom this cannot otherwise be corrected. Healthcare professionals should be aware, and explain to women, that the use of indwelling catheters in urgency UI may not result in continence. [2006] 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]
20 21 22 23	1.4.23	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 UI include:
24 25 26 27 28		 chronic urinary retention in women who are unable to manage intermittent self-catheterisation skin wounds, pressure ulcers or irritations that are being contaminated by urine distress or disruption caused by bed and clothing changes

1 2		 where a woman expresses a preference for this form of management. [2006]
3 4 5 6	1.4.24	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]
7	Products	to prevent leakage
8 9 10 11	1.4.25	Do not use intravaginal and intraurethral devices for the routine management of UI in women. Do not advise women to consider such devices other than for occasional use when necessary to prevent leakage, for example during physical exercise. [2006]
12	Complem	ientary therapies
13 14	1.4.26	Do not recommend complementary therapies for the treatment of UI or OAB. [2006]
15	Medicine	S
16	1.4.27	Before starting treatment with a medicine for OAB, explain to the woman:
17 18 19 20 21 22 23 24 25 26	1 4 29	 the likelihood of the medicine being successful the common adverse effects associated with the medicine that some adverse effects of anticholinergic medicines, such as dry mouth and constipation, may indicate that the medicine is starting to have an effect that she may not see the full benefits until she has been taking the medicine for 4 weeks that the long-term effects of anticholinergic medicines for OAB on cognitive function are uncertain. [2019]
26 27	1.4.28	When offering anticholinergic medicines to treat OAB, take account of the woman's:
28 29		 coexisting conditions (such as poor bladder emptying, cognitive impairment or dementia)

1 2		 current use of other medicines that affect total anticholinergic load risk of adverse effects, including cognitive impairment. [2019]
3 4 5 6	1.4.29	For women who have a diagnosis of dementia and for whom anticholinergic medicines are an option, follow the recommendations on <u>medicines that may cause cognitive impairment</u> in the NICE guideline on dementia. [2019]
7	Choosing	medicine
8 9	1.4.30	Do not offer women flavoxate, propantheline or imipramine to treat UI or OAB. [2013]
10 11 12	1.4.31	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]
13 14	1.4.32	Offer the anticholinergic medicine with the lowest acquisition cost to treat OAB or mixed UI in women. [2019]
15 16	1.4.33	If the first medicine for OAB or mixed UI is not effective or well-tolerated, offer another medicine with a low acquisition cost ⁵ . [2013]
17 18	1.4.34	Offer a transdermal OAB treatment to women unable to tolerate oral medicines. [2013]
19 20	1.4.35	For guidance on mirabegron see <u>mirabegron for treating symptoms of</u> <u>overactive bladder</u> (NICE technology appraisal guidance 290). [2013]
21 22 23 24	1.4.36	The use of desmopressin may be considered specifically to reduce nocturia in women with UI or OAB who find it a troublesome symptom. Use particular caution in women with cystic fibrosis and avoid in those over 65 years with cardiovascular disease or hypertension. [2013]

⁵ 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.

1 2 3 4 5 6	1.4.37	Do not use duloxetine as a first-line treatment for women with predominant stress UI. Do not routinely offer duloxetine as a second-line treatment for women with stress UI, although it may be offered as second- line therapy if women prefer pharmacological to surgical treatment or are not suitable for surgical treatment. If duloxetine is prescribed, counsel women about its adverse effects. [2006]
7	1.4.38	Do not offer systemic hormone replacement therapy to treat UI. [2006]
8 9	1.4.39	Offer intravaginal oestrogens to treat OAB symptoms in postmenopausal women with vaginal atrophy. [2006]
10	Reviewin	g medicine
11 12 13	1.4.40	Offer a face-to-face or telephone review 4 weeks after starting a new medicine for OAB. Ask the woman if she is satisfied with the treatment and:
14 15 16 17 18		 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 OAB (see recommendations 1.4.33 and 1.4.34), and review again 4 weeks later. [2013]
19 20	1.4.41	Offer a review before 4 weeks if the adverse events of a medicine for OAB are intolerable. [2013]
21 22 23	1.4.42	Refer women who have tried taking medicine for OAB, but for whom it has not been successful or tolerated, to secondary care to consider further treatment. [2013]
24 25	1.4.43	Offer a further face-to-face or telephone review if a medicine for OAB or UI stops working after an initial successful 4-week review. [2013]
26 27 28	1.4.44	Offer a review in primary care to women who remain on long-term medicine for OAB or UI every 12 months, or every 6 months if they are aged over 75. [2019]

1	Invasive	procedures for overactive bladder
2	1.4.45	For women with OAB that has not responded to non-surgical
3		management or treatment with medicine and who wish to discuss further
4		treatment options:
-		
5		offer urodynamic investigation to determine whether detrusor
6		overactivity is causing her OAB symptoms and
7		 if detrusor overactivity is causing her OAB symptoms, offer an
8		invasive procedure in line with recommendations 1.4.46 to 1.4.59 in
9		this guideline
10		 if there is no detrusor overactivity, seek advice on further
11		management from the local MDT. [2013, amended 2019]
12	Botulinu	m toxin type A injection
13	1.4.46	After a local MDT review, offer bladder wall injection with botulinum toxin
14		type A ⁶ to women with OAB caused by detrusor overactivity that has not
15		responded to non-surgical management, including pharmacological
16		treatments. [2019]
17	1.4.47	Consider treatment with botulinum toxin type A ⁶ after a local MDT review
18		for women with symptoms of OAB in whom urodynamics has not
19		demonstrated detrusor overactivity, if the symptoms have not responded
20		to non-surgical management and the woman does not wish to have other
21		invasive treatments. [2019]
22	1.4.48	After a local MDT review, discuss the risks and benefits of treatment with
23		botulinum toxin type A ⁶ with women and explain:
24		 the likelihood of complete or partial symptom relief
25		 the process of clean intermittent catheterisation, the risks, and how
26		long it might need to be continued

⁶ At the time of consultation (October 2018) most botulinum toxin type A preparations did not have a UK marketing authorisation for this indication. Evidence was only available for the licensed botulinum toxin type A preparation (Botox, Allergan).

1		 the risk of adverse effects, including an increased risk of urinary tract
2		infection
3		 that there is not much evidence about how long the injections work for,
4		how well they work in the long term and their long-term risks. [2019]
5	1.4.49	Start treatment with botulinum toxin type A ⁷ only if the woman is willing, in
6		the event of developing significant voiding dysfunction:
7		 to perform clean intermittent catheterisation on a regular basis for as
8		long as needed or
9		 to accept a temporary indwelling catheter if she is unable to perform
10		clean intermittent catheterisation. [2013, amended 2019]
11	1.4.50	Use 100 units ^{7,8} as the initial dose of botulinum toxin type A to treat OAB
12		in women. [2019]
13	1.4.51	Offer a face-to-face or telephone review within 12 weeks of the first
14		treatment with botulinum toxin type A to assess the response to treatment
15		and adverse effects, and
16		 if there is good symptom relief, tell the woman how to self-refer for
17		prompt specialist review if symptoms return, and offer repeat treatment
18		as necessary
19		 if there is inadequate symptom relief, consider increasing subsequent
20		doses of botulinum toxin type A to 200 units ^{7,8} and review within
21		12 weeks
22		• if there was no effect, discuss with the local MDT. [2019]

⁷ At the time of consultation (October 2018) most botulinum toxin type A preparations did not have a UK marketing authorisation for this indication. Evidence was only available for the licensed botulinum toxin type A preparation (Botox, Allergan).

⁸ At the time of consultation (October 2018) the dose of 100 units of botulinum toxin type A has a UK marketing authorisation for overactive bladder. The dose of 200 units has a UK marketing authorisation for urinary incontinence due to neurogenic detrusor overactivity. Note that units of botulinum toxin type A are not interchangeable between preparations. If prescribing outside of the marketing authorisation, the prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's <u>Prescribing guidance</u>: prescribing unlicensed medicines for further information.

1 2 3 4	1.4.52	If symptom relief has been adequate after injection of 100 units ^{9,10} 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 ¹⁰ and review within 12 weeks. [2019]
5	1.4.53	Do not offer botulinum toxin type B to women with OAB. [2019]
6	Percutan	eous sacral nerve stimulation
7 8	1.4.54	Offer percutaneous sacral nerve stimulation to women after local or regional MDT review if:
9 10 11 12		 their OAB has not responded to non-surgical management including medicines and they are unable to perform clean intermittent catheterisation. [2013, amended 2019]
13 14 15	1.4.55	Consider percutaneous sacral nerve stimulation after local MDT review if a woman's OAB has not responded to non-surgical management (including medicines) and botulinum toxin type A ⁹ . [2013, amended 2019]
16 17	1.4.56	Discuss the long-term implications of percutaneous sacral nerve stimulation with women including:
18 19 20 21		 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

⁹ At the time of consultation (October 2018) most botulinum toxin type A preparations did not have a UK marketing authorisation for this indication. Evidence was only available for the licensed botulinum toxin type A preparation (Botox, Allergan).

¹⁰ At the time of consultation (October 2018) the dose of 100 units of botulinum toxin type A has a UK marketing authorisation for overactive bladder. The dose of 200 units has a UK marketing authorisation for urinary incontinence due to neurogenic detrusor overactivity. Note that units of botulinum toxin type A are not interchangeable between preparations. If prescribing outside of the marketing authorisation, the prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's <u>Prescribing guidance: prescribing unlicensed medicines</u> for further information.

1		the adverse effects. [2013]
I		
2 3 4	1.4.57	Tell women how to self-refer for prompt specialist review if symptoms return following a percutaneous sacral nerve stimulation procedure. [2013]
5	Augment	tation cystoplasty
6 7 9 10 11 12 13 14	1.4.58	Restrict augmentation cystoplasty 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]
15	Urinary o	liversion
16 17 18 19 20	1.4.59	Urinary diversion should be considered for a woman with OAB only when non-surgical management has failed, and if botulinum toxin type A ¹¹ , percutaneous sacral nerve stimulation and augmentation cystoplasty are not appropriate or are unacceptable to her. Provide life-long follow-up. [2006, amended 2013]
21	1.5	Surgical management of stress urinary incontinence
22 23 24 25	1.5.1	When offering a surgical procedure discuss with the woman the risks and benefits of the different treatment options for stress urinary incontinence (UI) ¹² . Include information about differences in type of anaesthesia, expected length of hospital stay, surgical incisions and expected recovery

26 period. [2013, amended 2019]

¹¹ At the time of consultation (October 2018) most botulinum toxin type A preparations did not have a UK marketing authorisation for this indication. Evidence was only available for the licensed botulinum toxin type A preparation (Botox, Allergan).

¹² NICE is developing shared decision aids on surgery for stress urinary incontinence and pelvic organ prolapse. They will be published with the final guideline in April 2019.

1 2	1.5.2	If non-surgical management for stress UI has failed, offer the woman a choice of:
3		 colposuspension (open or laparoscopic) or
4		 a retropubic mid-urethral mesh sling or
5		 an autologous rectus fascial sling. [2019]
6	1.5.3	When offering surgery for stress UI, advise the woman that there are long-
7		term complications associated with all procedures and uncertainty about
8		the proportion of women affected. [2019]
9	1.5.4	If the woman's chosen procedure is not available from the consulting
10		surgeon, refer her to an alternative surgeon. [2019]
11	Mid-uret	nral mesh sling procedures
12	1.5.5	When offering a retropubic mid-urethral mesh sling, advise the woman
13		that it is a permanent implant and complete removal might not be
14		possible. [2019]
15	1.5.6	If a retropubic mid-urethral mesh sling is inserted:
16		 give the woman written information on the implant including name,
17 18		manufacturer, date of insertion, and implanting surgeon's name and contact details;
19		• ensure that details of the procedure and its subsequent short- and long-
20		term outcomes are collected in a national registry (see <u>collecting data</u>
21		on mesh surgery and mesh-related complications in this guideline).
22		[2019]
23	1.5.7	When planning a retropubic mid-urethral mesh sling procedure, surgeons
24		should:
25		 use a device manufactured from type 1 macroporous polypropylene
26		mesh
27		 consider using a retropubic mid-urethral mesh sling coloured for high
28		visibility, for ease of insertion and revision. [2019]

- 11.5.8Do not offer a transobturator approach unless there are specific clinical2circumstances (for example, multiple previous abdominal procedures) in3which the retropubic approach should be avoided. [2019]
- 4 1.5.9 Do not use the 'top-down' retropubic mid-urethral mesh sling approach or
 5 single-incision sub-urethral short mesh sling insertion except as part of a
 6 clinical trial. [2019]

7 Other procedures

- 8 1.5.10 Do not offer women anterior colporrhaphy, needle suspensions,
 9 paravaginal defect repair or the Marshall–Marchetti–Krantz procedure to
 10 treat stress UI. [2019]
- 11 1.5.11 Do not offer women porcine dermis slings to treat stress UI. [2019]
- 12 1.5.12 Do not offer women intramural bulking agents to manage stress UI unless
 13 alternative surgical procedures are not suitable or acceptable. Explain to
 14 women that:
- repeat injections may be needed to achieve efficacy
- 16 efficacy is limited and diminishes with time. [2019]
- 17 1.5.13 Do not offer women an artificial urinary sphincter to manage stress UI
- unless previous surgery has failed. Offer lifelong follow-up to women who
 have an artificial urinary sphincter. [2019]

20 Follow-up after surgery

- 21 1.5.14 Offer a follow-up appointment within 6 months to all women who have had
 22 a surgical procedure to treat stress UI. For women who have had
- 23 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]
- 26 1.5.15 For women whose primary surgical procedure for stress UI has failed27 (including women whose symptoms have returned):

1		• seek advice on assessment and management from a regional MDT that
2		deals with complex pelvic floor dysfunction or
3		 if the woman does not wish to have another surgical procedure, offer
4		her advice about managing urinary symptoms and explain that if she
5		changes her mind at a later date she can book a review appointment to
6		discuss past tests and interventions and reconsider her treatment
7		options. [2019]
8	1.6	Assessing pelvic organ prolapse
9	1.6.1	For women presenting in primary care with symptoms or an incidental
10		finding of vaginal prolapse:
11		 take a history to include symptoms of prolapse, urinary, bowel and
12		sexual function
13		 do an examination to rule out a pelvic mass or other pathology and to
14		document the presence of prolapse (see the sections on ovarian
15		cancer and bladder cancer in the NICE guideline on suspected cancer)
16		 discuss the woman's treatment preferences with her, and refer if
17		needed. [2019]
18	1.6.2	For women referred to secondary care for an unrelated condition who
19		have incidental symptoms or an incidental finding of vaginal prolapse,
20		consider referral to a clinician with expertise in prolapse. [2019]
21	1.6.3	For women who are referred for specialist evaluation of vaginal prolapse,
22		perform an examination to:
23		assess and record the presence and degree of prolapse of the anterior,
24		central and posterior vaginal compartments of the pelvic floor, using the
25		POP-Q (Pelvic Organ Prolapse Quantification System)
26		 assess the activity of the pelvic floor muscles
27		 assess for vaginal atrophy
28		 rule out a pelvic mass or other pathology. [2019]

1 2 3	1.6.4	For women with pelvic organ prolapse consider using a validated pelvic floor symptom questionnaire to aid assessment and decision-making. [2019]
4 5	1.6.5	Do not routinely perform imaging to document the presence of vaginal prolapse if a prolapse is detected by physical examination. [2019]
6 7 8	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 of day. [2019]
9 10	1.6.7	Consider investigating the following symptoms in women with pelvic organ prolapse:
11 12 13 14 15 16 17		 urinary symptoms that are bothersome and for which surgical intervention is an option symptoms of obstructed defaecation or faecal incontinence (the NICE guideline on faecal incontinence in adults has recommendations on baseline assessment of faecal incontinence) pain symptoms that are not explained by examination findings. [2019]
18	1.7	Managing pelvic organ prolapse
19 20 21	1.7.1	Discuss management options with women who have pelvic organ prolapse, including no treatment, non-surgical treatment and all surgical options, taking into account:
22		the woman's preferences
23		site of prolapse
24		benefits and risks of individual procedures
25 26		 comorbidities, including cognitive or physical impairments age
20 27		agedesire for childbearing
28		 previous abdominal or pelvic floor surgery
29		lifestyle factors. [2019]

1	Lifestyl	e modification
2	1.7.2	Consider giving advice on lifestyle to women with pelvic organ prolapse,
3		including information on:
4		 losing weight, if the woman is obese
5		 avoiding heavy lifting
6		 preventing constipation
7		 exercising and its effect on symptoms. [2019]
8	Topical	oestrogen
9	1.7.3	Consider vaginal oestrogen for women with pelvic organ prolapse and
10		signs of vaginal atrophy. For recommendations on managing urogenital
11		atrophy see managing short-term menopausal symptoms in the NICE
12		guideline on menopause. [2019]
13	1.7.4	Consider an oestrogen-releasing ring for women with pelvic organ
14		prolapse and signs of vaginal atrophy who have cognitive or physical
15		impairments that might make vaginal pessaries or creams difficult to use.
16		[2019]
17	Pelvic f	loor muscle training
18	1.7.5	Consider a programme of supervised pelvic floor muscle training for at
19		least 16 weeks as a first option for women with symptomatic POP-Q
20		(Pelvic Organ Prolapse Quantification System) stage 1 or stage 2 pelvic
21		organ prolapse. If the programme is beneficial, advise women to continue
22		pelvic floor muscle training afterwards. [2019]
23	Pessari	es
24	1.7.6	Consider a vaginal pessary for women with symptomatic pelvic organ
25		prolapse, alone or in conjunction with supervised pelvic floor muscle
26		training. [2019]
27	1.7.7	Refer women who have chosen a pessary to a urogynaecology service if
28		pessary care is not available locally. [2019]
29	1.7.8	Before starting pessary treatment:
	Urinary iı 2018)	ncontinence and pelvic organ prolapse in women NICE guideline DRAFT (October 25 of 45

1		 consider treating vaginal atrophy with topical oestrogen
2		 explain that more than one pessary fitting may be needed to find a
3		suitable pessary
4		 discuss the effect of a pessary on sexual intercourse
5		 describe common complications including vaginal discharge, bleeding
6		and pessary expulsion
7		 explain that the pessary should be removed at least once every
8		6 months. [2019]
9	Surgery	
10	1.7.9	Offer surgery for pelvic organ prolapse to women whose symptoms have
11		not improved with or who have declined non-surgical treatment. [2019]
12	1.7.10	Do not offer surgery to prevent incontinence in women having surgery for
13		prolapse who do not have incontinence. [2019]
14	1.7.11	Explain to women considering surgery for anterior or apical prolapse who
15		do not have incontinence that there is a risk of developing postoperative
16		urinary incontinence and further treatment may be needed. [2019]
17	1.7.12	If a woman has agreed to have a surgical procedure for pelvic organ
18		prolapse, before surgery discuss:
19		• the risks and benefits of each procedure, including changes in urinary,
20		bowel and sexual function
21		 the risks of recurrent prolapse
22		• the role of intraoperative prolapse assessment in finalising the choice of
23		surgical procedure ¹³ . [2019]
24		
25	1.7.13	If the woman's chosen procedure for pelvic organ prolapse is not available
26		from the consulting surgeon, refer her to an alternative surgeon. [2019]
27	1.7.14	If mesh is to be used in prolapse surgery, explain to the woman:

¹³ NICE is developing shared decision aids on surgery for stress urinary incontinence and pelvic organ prolapse. They will be published with the final guideline in April 2019.

1 2 3		 what type of mesh will be used and whether it is permanent. the uncertainty about long-term complications associated with mesh and about the proportion of women affected. [2019]
4	1.7.15	If mesh is to be used in prolapse surgery
5 6 7 8 9 10 11		 give the woman written information on the implant including name, manufacturer, date of insertion, and implanting surgeon's name and contact details ensure that details of the procedure and its subsequent short- and long-term outcomes are collected in a national registry (see <u>collecting data</u> on mesh surgery and mesh-related complications in this guideline). [2019]
12	Surgery	for uterine prolapse
13 14	1.7.16	Discuss the options for surgery with women who have uterine prolapse, including surgery that will preserve the uterus and hysterectomy. [2019]
15 16	1.7.17	For women with uterine prolapse who wish to preserve their uterus, offer a choice of:
17 18 19 20		 vaginal sacrospinous hysteropexy with sutures sacro-hysteropexy with mesh (abdominal or laparoscopic) Manchester repair, unless the woman is considering a future pregnancy or might become pregnant. [2019]
21 22	1.7.18	For women with uterine prolapse who have no preference about preserving their uterus, offer a choice of:
23 24 25 26		 vaginal hysterectomy, with or without sacrospinous fixation with sutures sacro-hysteropexy with mesh (abdominal or laparoscopic) vaginal sacrospinous hysteropexy with sutures Manchester repair. [2019]
27 28	1.7.19	If sacro-hysteropexy with mesh (abdominal or laparoscopic) is used, ensure that details of the procedure and its subsequent short- and long-

1 term outcomes are collected in a national registry (see collecting data on 2 mesh surgery and mesh-related complications in this guideline). [2019] 3 Surgery for vault prolapse 4 1.7.20 Offer women with vault prolapse a choice of: 5 sacrocolpopexy (abdominal or laparoscopic) with mesh 6 vaginal sacrospinous fixation with sutures. [2019] 7 1.7.21 If sacrocolpopexy (abdominal or laparoscopic) with mesh is used, ensure 8 that details of the procedure and its subsequent short- and long-term 9 outcomes are collected in a national registry (see collecting data on mesh 10 surgery and mesh-related complications in this guideline). [2019] 11 Colpocleisis for vault or uterine prolapse 12 1.7.22 Consider colpocleisis for women with vault or uterine prolapse who do not 13 intend to have penetrative vaginal sex and who have a physical condition 14 that may put them at increased risk of operative and postoperative 15 complications. [2019] 16 Surgery for anterior prolapse 17 1.7.23 Offer anterior repair without mesh to women with anterior vaginal wall 18 prolapse. [2019] 19 1.7.24 Consider synthetic polypropylene or biological mesh insertion for women 20 with recurrent anterior vaginal wall prolapse only after: 21 regional MDT review and 22 discussion with the woman about the risks of mesh insertion and if: 23 24 apical support is adequate or 25 • an abdominal approach is contraindicated. [2019] 26 If a synthetic polypropylene or biological mesh is inserted, ensure that 27 details of the procedure and its subsequent short- and long-term

1		outcomes are collected in a national registry (see collecting data on mesh
2		surgery and mesh-related complications in this guideline). [2019]
3	Surgery	for posterior prolapse
4	1.7.25	Offer posterior vaginal repair without mesh to women with a posterior
5		vaginal wall prolapse. [2019]
6	Follow-	up after surgery
7	1.7.26	Offer women a review 6 months after surgery for prolapse. Ensure that
8		the review includes a vaginal examination and, if mesh was used, check
9		for mesh exposure. [2019]
10	1.8	Surgery for stress urinary incontinence and pelvic organ
11		prolapse
12	1.8.1	Consider concurrent surgery for stress urinary incontinence (UI) and
13		prolapse in women with anterior and/or apical prolapse and stress UI.
14		[2019]
15	1.8.2	When offering concurrent surgery for stress UI and prolapse explain to the
16		woman:
17		 that there is uncertainty about whether the combined procedure is
18		effective for treating stress UI beyond 1 year, and that stress UI might
19		persist despite surgery
20		 the risk of complications related to having surgery for stress UI at the
21		same time as prolapse surgery compared with the risk of complications
22		related to having sequential surgery. [2019]
23	1.9	Assessing complications associated with mesh surgery
24	1.9.1	For women who report new-onset symptoms after having mesh surgery
25		for urinary incontinence (UI) or pelvic organ prolapse, evaluate whether
26		the symptoms might be caused by a mesh-related complication. These
27		symptoms could include:

1		• pain or sensory change in the back, abdomen, vagina, pelvis, leg, groin
2		or perineum that is:
3		 either unprovoked, or provoked by movement or sexual activity and
4		 either generalised, or in the distribution of a specific nerve, such as
5		the obturator nerve
6		 vaginal problems including discharge, bleeding, painful sexual
7		intercourse, penile trauma or pain
8		 urinary problems including recurrent infection, incontinence, retention,
9		or difficulty or pain during voiding
10		 bowel problems including difficulty or pain on defaecation, faecal
11		incontinence, rectal bleeding or passage of mucus
12		 symptoms of infection, either alone or in combination with any of the
13		symptoms outlined above. [2019]
14	1.9.2	Refer women with a suspected mesh-related complication to a
15		urogynaecologist, urologist or colorectal surgeon for specialist
16		assessment. [2019]
17	1.9.3	For women who are referred for specialist evaluation of a suspected mesh
18		complication:
19		 take a history of all past surgical procedures for prolapse or
20		incontinence using mesh, including the dates, type of mesh and site of
21		mesh placement and the relationship of the symptoms to the surgical
22		procedure(s)
23		 consider using a validated pelvic floor symptom questionnaire and a
24		pain questionnaire to aid assessment and decision-making
25		 perform a vaginal examination to:
26		 assess whether mesh is palpable, exposed or extruded
27		 localise pain and its anatomical relationship to mesh
28		consider performing a rectal examination, if indicated, to assess for the
29		presence of mesh perforation or fistula

1 2 3		 consider performing a neurological assessment to assess the distribution of pain, if present, sensory alteration or muscle weakness. [2019]
4 5	1.9.4	For women with a confirmed mesh-related complication or unexplained symptoms after a mesh procedure:
6 7 8 9 10		 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 cm² and no other symptoms, follow <u>recommendation 1.10.3</u> in this guideline. [2019]
11 12 13 14	1.9.5	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 using <u>table 1</u> in this guideline.
15 16	1.9.6	The responsible consultant should ensure that details of any confirmed mesh-related complications are:
17 18 19 20		 collected in a national registry (see <u>collecting data on mesh surgery</u> <u>and mesh-related complications</u> in this guideline) and reported to the <u>Medicines and Healthcare Products Regulatory Agency</u>. [2019]
21		

Table 1 Investigations for assessing suspected mesh-related complications

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

Investigation	Type of mesh	Indications	Benefits and risks
Examination under anaesthesia	All types of mesh	 Pain, or suspected: vaginal or rectal exposure or extrusion sinus tract, urinary or bowel fistula 	Benefits Allows diagnosis when not revealed by awake examination or when an awake examination is not tolerated Risks Anaesthetic risk
Cystourethroscopy	All types of mesh	Suspected: • urethral perforation • bladder perforation • fistula • calculus on suture or mesh material	 Benefits allows diagnosis by direct visualisation aids management planning Risks Anaesthetic risk and risk of urinary tract infection
Sigmoidoscopy	Abdominally, laparoscopically or vaginally placed mesh for pelvic organ prolapse	Suspected bowel perforation by mesh	 Benefits allows diagnosis by direct visualisation aids management planning
			 Risks anaesthetic risk if carried out under anaesthetic risk of bowel perforation
Laparoscopy	Abdominally or laparoscopically placed mesh for pelvic organ prolapse	 Pain Suspected bowel entrapment around mesh Suspected adhesions secondary to 	 Benefits allows diagnosis by direct visualisation aids management planning

		mesh placement	Risks anaesthetic risk risks of laparoscopy, including bowel injury
MRI. protocolled and reported by a clinician with experience in interpreting mesh complications	All types of mesh	 Suspected mesh infection Anatomical mapping of suspected fistula Anatomical mapping and mesh localisation to guide further surgery Back pain following abdominal mesh placement with mesh attachment to sacral promontory Identification of discitis or osteomyelitis 	 Benefits show implanted material and complications nearby show location of mesh in relation to the vaginal wall and sacrum <i>Risks</i> Generally regarded as safe, with a low risk of short- and long-term harms
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	 Pain Voiding dysfunction Suspected infection Suspected urethral mesh perforation Anatomical mapping to guide excision surgery 	 Benefits show implanted material and local complications identify mid-urethral slings show location of mesh in relation to the vaginal wall and urethra Risks Discomfort
СТ	All types of mesh, although CT is not commonly used to show implanted material		<i>Benefits</i> May be useful in assessing for urinary fistulae or bowel injury

		Suspected: • urinary tract injury • bowel injury • bowel obstruction	<i>Risks</i> Potential radiation- related harms and risk of contrast media injection
Fluoroscopic studies (cystography or contrast enema)*	All types of mesh	Suspected urinary or bowel fistula	<i>Benefits</i> Aids management planning
*Perform with water- soluble contrast media. Fluoroscopic studies and CT may be used according to local preference and expertise.			<i>Risks</i> Potential radiation- related harms
Urinary flow studies and post-void residual volume assessment or cystometry	All types of mesh	 Voiding dysfunction Urinary incontinence 	<i>Benefits</i> Aids management planning
			<i>Risks</i> Urinary tract infection and radiation risks if fluoroscopy is used
Neurophysiology, including nerve conduction studies and quantitative sensory testing*	All types of mesh	Suspected nerve injury	<i>Benefits</i> Allows diagnosis of impaired nerve function
*Quantitative sensory testing is very specialised and not available in all centres			<i>Risks</i> Nerve conduction studies are difficult to perform and can induce more pain

1

2 **1.10** Managing complications associated with mesh surgery

3 General considerations before removing mesh

- 4
- 5 1.10.1 The decision to remove mesh for any indication should be made only after 6 a discussion with the woman and a regional MDT review. **[2019]**
- 7 1.10.2 When discussing surgery to remove mesh inserted to treat urinary
- 8 incontinence or pelvic organ prolapse, explain to the woman that:

1 2 3 4 5		 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
6 7 8		 symptoms as removing all of it urinary incontinence or prolapse can recur after the mesh has been removed. [2019]
9	Managin	g vaginal complications
10 11 12	1.10.3	Consider non-surgical treatment with topical oestrogen cream for women with a single area of vaginal mesh exposure or extrusion that is smaller than 1 cm ² . [2019]
13 14	1.10.4	Consider partial or complete surgical removal of the vaginal portion of mesh if:
15 16 17 18		 the area of vaginal mesh sling exposure or extrusion is 1 cm² or larger or there has been no response to non-surgical treatment after a period of 3 months. [2019]
19 20	1.10.5	Offer imaging and further treatment to women who have signs of infection in addition to vaginal mesh exposure or extrusion. [2019]
21 22	1.10.6	Explain to women who have vaginal complications after mesh sling surgery for stress UI that:
23 24 25 26 27		 complete removal of the vaginal portion of mesh sling is associated with a greater risk of recurrence of stress UI than partial removal partial removal is associated with a higher rate of further mesh sling extrusion complete removal might not be possible. [2019]
28 29	1.10.7	Explain to women who have vaginal complications after mesh surgery for pelvic organ prolapse that:

1 2 3 4		 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]
5 6	1.10.8	Explain to women who have vaginal complications after abdominally placed mesh that:
7 8 9 10		 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]
11	Managing	g pain and sexual dysfunction
12 13 14	1.10.9	 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
15 16 17 18 19 20 21		 advice from a regional MDT if assessment and investigation do not show a mesh abnormality such as vaginal extrusion or exposure, or an infection, offer non-surgical treatments such as pain management, vaginal oestrogen, dilators, psychosexual counselling and physiotherapy if pain does not respond to initial management, seek advice from a regional MDT. [2019]
22	Managing	g urinary complications
23 24 25	1.10.10	Refer women who have mesh perforating the lower urinary tract to a centre for mesh complications for further assessment or management. [2019]
26 27 28	1.10.11	For women with urinary symptoms after mesh surgery for stress UI or pelvic organ prolapse who are considering mesh removal surgery, explain that:

1		 urinary symptoms might not improve and new symptoms might occur
2		after complete or partial removal of the mesh
3		 stress UI might recur after mesh removal, and the risk of this
4		happening is higher with complete than with partial mesh removal
5		 complete removal of the mesh might not be possible
6		• further treatment might be needed for mesh complications, or recurrent
7		or persistent urinary symptoms
8		 there is a risk of adverse events such as urinary tract fistula. [2019]
9	1.10.12	Consider division of mesh sling for women with voiding dysfunction
10		caused by mesh sling surgery. [2019]
11	1.10.13	Refer women considering excision of mesh sling for persistent voiding
12		dysfunction to a centre specialising in the diagnosis and management of
13		mesh-related complications for assessment and management. [2019]
14	1.10.14	For women considering surgery to alleviate voiding symptoms caused by
15		mesh surgery, explain that:
16		 the risk of recurrent stress incontinence is higher after mesh excision
17		than mesh division
18		 further surgery might be needed. [2019]
19	Managin	ig bowel symptoms
20	1.10.15	For women who present with functional bowel disorders after mesh
21		surgery for pelvic organ prolapse, follow the recommendations in the
22		NICE guideline on <u>faecal incontinence in adults</u> for women with faecal
23		incontinence or locally agreed protocols for women with obstructed
24		defecation. [2019]
25	1.10.16	Discuss bowel complications in women that are directly related to mesh
26		placement, such as erosion, stricture, or fistula, with a regional MDT that
27		deals with complex pelvic floor dysfunction and mesh-related problems to
28		formulate an individualised treatment plan. [2019]

- 1.10.17 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]

7 **Recommendations for research**

8 The guideline committee has made the following recommendations for research.

9 Key recommendations for research

10 **1 Anticholinergic medicines**

- 11 What is the effectiveness and safety of anticholinergic medicines for overactive
- 12 bladder in older women?
- 13 To find out why the committee made this research recommendation see evidence
- 14 review C: risks to cognitive function for women taking anticholinergic drugs for
- 15 <u>overactive bladder</u>.

3

16 2 Colpocleisis compared with sacrospinous fixation for pelvic organ prolapse

- 17 What is the effectiveness of colpocleisis compared with sacrospinous fixation for
- 18 pelvic organ prolapse in elderly women?
- 19 To find out why the committee made this research recommendation see evidence
- 20 review I: surgical management of pelvic organ prolapse.

21 **3** Assessing complications associated with mesh surgery

- 22 What is the effectiveness of ultrasound-guided visualisation compared with clinical
- 23 assessment to identify complications after mesh surgery for stress urinary
- 24 incontinence or pelvic organ prolapse in women?
- 25 To find out why the committee made this research recommendation see evidence
- 26 review K: assessing mesh complications after pelvic floor mesh surgery.

1 4 Pessaries or surgery for pelvic organ prolapse

- 2 What is the long-term patient satisfaction with pessaries compared with surgery for
- 3 pelvic organ prolapse in women?
- 4 To find out why the committee made this research recommendation see evidence
- 5 review I: surgical management of pelvic organ prolapse.

6 **5 Long-term risks of surgery with and without mesh**

- 7 What are the long-term risks of mesh surgery compared with non-mesh surgery for
- 8 pelvic organ prolapse in women?
- 9 To find out why the committee made this research recommendation see evidence
- 10 review I: surgical management of pelvic organ prolapse.

11 Other recommendations for research

- 12 Long-term effectiveness of botulinum toxin type A for overactive bladder
- 13 What is the long-term effectiveness of bladder wall injection with botulinum toxin
- 14 type A for overactive bladder in women?

15 Lifestyle interventions for pelvic organ prolapse

- 16 Which lifestyle interventions improve the symptoms and prevent the progression of
- 17 pelvic organ prolapse in women?

18 Surgery for stress urinary incontinence and pelvic organ prolapse

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

21 Pain management after mesh surgery

- 22 What is the effectiveness of pain management for women who present with chronic
- 23 pain 3 months after mesh surgery for stress urinary incontinence or pelvic organ
- 24 prolapse?

25 **Context**

- 26 Urinary incontinence (UI) is a common symptom that can affect women of all ages,
- 27 with a wide range of severity and nature. Although it is rarely life-threatening, UI can

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1 be very detrimental to the physical, psychological and social wellbeing of the women 2 it affects. The impact on families and carers can also be profound, and the resource 3 implications for the health service are considerable. UI is defined by the International 4 Continence Society as 'the complaint of any involuntary leakage of urine'. UI can be 5 a result of functional abnormalities in the lower urinary tract or of illnesses. Stress UI 6 is involuntary urine leakage on effort or exertion or on sneezing or coughing. 7 Urgency UI is involuntary urine leakage accompanied or immediately preceded by 8 urgency (a sudden compelling desire to urinate that is difficult to delay). Mixed UI is 9 involuntary urine leakage associated with both urgency and exertion, effort, sneezing 10 or coughing. Overactive bladder (OAB) is defined as urgency that occurs with or 11 without urgency UI and usually with frequency and nocturia. OAB that occurs with 12 incontinence is known as 'OAB wet'. OAB that occurs without incontinence is known 13 as 'OAB dry'. These combinations of symptoms are suggestive of the urodynamic 14 finding of detrusor overactivity, but can be the result of other forms of urethrovesical dysfunction. 15

- Pelvic organ prolapse is defined as symptomatic descent of one 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 one 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 <u>NHS England Mesh Working Group report</u> 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
- 2 pelvic organ prolapse
- to review the current clinical guideline on urinary incontinence in women (CG171)
- to review evidence on complications arising from surgery for stress urinary
 incontinence and pelvic organ prolapse.
- 6 NICE accepted these recommendations and commissioned an update of the existing
- 7 urinary incontinence guideline to review the evidence on complications arising from
- 8 surgery for stress urinary incontinence and managing pelvic organ prolapse.

9 Finding more information and resources

- 10 To find out what NICE has said on topics related to this guideline, see our web
- 11 pages on <u>gynaecological conditions</u> and <u>urological conditions</u>.

12 Update information

13 October 2018

- 14 This guideline is an update of NICE guideline CG171 (published September 2013)
- 15 and will replace it. NICE guideline CG171 updated NICE guideline CG40 (published
- 16 October 2006).
- 17 We have reviewed the evidence on assessment and management for women with
- 18 urinary incontinence, pelvic organ prolapse and complications suspected to be
- 19 associated with mesh surgery.
- 20 Recommendations are marked **[2019]** if the evidence has been reviewed.

21 **Recommendations that have been deleted or changed**

- 22 We propose to delete some recommendations from the 2013 guideline. <u>Table 2</u> sets
- 23 out these recommendations and includes details of replacement recommendations.
- 24 If there is no replacement recommendation, an explanation for the proposed deletion
- is given.
- In recommendations shaded in grey and ending [2006, amended 2019] or [2013,
- amended 2019], we have made changes that could affect the intent without

- 1 reviewing the evidence. Yellow shading is used to highlight these changes, and
- 2 reasons for the changes are given in <u>table 3</u>.
- 3 In recommendations shaded in grey and ending [2006], [2006, amended 2013] or
- 4 [2013], we have not reviewed the evidence. In some cases minor changes have
- 5 been made for example, to update links, or bring the language and style up to date
- 6 without changing the intent of the recommendation. Minor changes are listed in
- 7 <u>table 4</u>.

8 Table 2 Recommendations that have been deleted

Decommendation in 2012 avridation	Comment	
Recommendation in 2013 guideline	Comment	
1.1.5 Refer women with UI who have symptomatic prolapse that is visible at or below the vaginal introitus to a specialist. [2006]	Replaced by new sections on assessing and managing pelvic organ prolapse.	
1.7.3 Prescribe the lowest recommended dose when starting a new OAB drug treatment. [new 2013]	This is covered in the NICE guideline on <u>medicines optimisation</u> and in the summaries of product characteristics for the individual medicines.	
1.7.4 If a woman's OAB drug treatment is effective and well-tolerated, do not change the dose or drug. [new 2013]	This is covered in the NICE guideline on <u>medicines optimisation</u> and in the summaries of product characteristics for the individual medicines.	
 1.7.7 Offer one of the following choices first to women with OAB or mixed UI: oxybutynin (immediate release), or tolterodine (immediate release), or darifenacin (once daily preparation). [new 2013] 	The cost of these medicines has changed since 2013 and the efficacy of all anticholinergics for overactive bladder is now similar.	

9

10 Table 3 Amended recommendation wording (change to intent) without an

11 evidence review

Recommendation in 2013 guideline	Recommendation in 2019 guideline	Reason for change
All recommendations that refer to 'conservative management'	All recommendations except those labelled [2019]	'Conservative management' has been changed to 'non-surgical management' for clarity and consistency with the 2019 recommendations.
1.1.14 This recommendation has been replaced by recommendations 1.6.4 and 1.6.5 in the NICE guideline on suspected cancer: recognition and referral.	1.3.21 For women aged over 45 who have haematuria, or a recurrent or persistent unexplained UTI, follow the recommendations on referral for <u>bladder cancer</u> in the NICE guideline on suspected cancer. [2006, amended 2019]	To clarify the cross- reference to the NICE guideline on suspected cancer.
 1.5.4 Do not offer percutaneous posterior tibial nerve stimulation for OAB unless: there has been a multidisciplinary team (MDT) review, and conservative management including OAB drug treatment has not worked adequately, and the woman does not want botulinum toxin A or percutaneous sacral nerve stimulation. [new 2013] 	 1.4.16 Do not offer percutaneous posterior tibial nerve stimulation (needles inserted close to the posterior tibial nerve) for OAB unless: there has been a local multidisciplinary team (MDT) review and non-surgical management including OAB medicine treatment has not worked adequately and the woman does not want botulinum toxin type A or percutaneous sacral nerve stimulation. [2013, amended 2019] 	'Local' has been added to differentiate this MDT from the regional MDT, as described in section 1.1.
1.7.6 Do not offer oxybutynin (immediate release) to frail older women. [new 2013]	1.4.31 Do not offer oxybutynin (immediate release) to older women who are at higher risk of a sudden deterioration in their physical or mental health. [2013, amended 2019]	The wording has been clarified to specify that it refers to cognitive as well as physical impairment

 1.7.17 If the woman wishes to discuss the options for further management (non-therapeutic interventions and invasive therapy) refer to the MDT and arrange urodynamic investigation to determine whether detrusor overactivity is present and responsible for her OAB symptoms: If detrusor overactivity is present and responsible for the OAB symptoms offer invasive therapy (see recommendations in section 1.9). If detrusor overactivity is present but the woman does not wish to have invasive therapy, offer advice as described in recommendation 1.6.9. 	 1.4.45 For women with OAB 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 detrusor overactivity is causing her OAB symptoms and if detrusor overactivity is causing her OAB symptoms, offer an invasive procedure in line with recommendations 1.4.46 to 1.4.59 in this guideline if there is no detrusor overactivity, seek advice on further management from the local MDT. [2013, amended 2019] 	Initial referral to the MDT has been removed because it is now covered in recommendation 1.1.1. 'Local' has been added to clarify that further advice should be sought from the local MDT and not the regional MDT.
• If detrusor overactivity is not present refer back to the MDT for further discussion concerning future management. [new 2013]		
 1.9.3 Start treatment with botulinum toxin A only if women: have been trained in clean intermittent catheterisation and have performed the technique successfully, and are able and willing to perform clean intermittent catheterisation on a regular basis for as long as needed. [new 2013] 	 1.4.49 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] 	Amended because the likelihood of needing catheterisation is lower with the dose of 100 units of botulinum toxin type A that is recommended in the 2019 guideline, and to remove restrictions on women being offered this treatment.

 1.9.10 Offer percutaneous sacral nerve stimulation to women after MDT review if: their OAB has not responded to conservative management including drugs, and they are unable to perform clean intermittent catheterisation. [new 2013] 	 1.4.54 Offer percutaneous sacral nerve stimulation to women after local or regional MDT review if: their OAB has not responded to non-surgical management including medicines and they are unable to perform clean intermittent catheterisation. [2013, amended 2019] 	'Local or regional' has been added to clarify that this refers to either the local or the regional MDT.
1.9.11 Consider percutaneous sacral nerve stimulation after MDT review if a woman's OAB has not responded to conservative management (including drugs) and botulinum toxin A. [new 2013]	1.4.55 Consider percutaneous sacral nerve stimulation after local MDT review if a woman's OAB has not responded to non- surgical management (including medicines) and botulinum toxin type A. [2013, amended 2019]	'Local' has been added to differentiate this MDT from the regional MDT, as described in section 1.1.
1.10.1 When offering a surgical procedure discuss with the woman the risks and benefits of the different treatment options for SUI using the information in <u>information to facilitate</u> <u>discussion of risks and</u> <u>benefits of treatments for</u> <u>women with stress urinary</u> <u>incontinence</u> . [new 2013]	1.5.1 When offering a surgical procedure discuss with the woman the risks and benefits of the different treatment options for stress urinary incontinence (UI). Include information about differences in type of anaesthesia, expected length of hospital stay, surgical incisions and expected recovery period. [2013, amended 2019]	The table of information referred to in the 2013 recommendation is to be replaced by shared decision aids on surgery for stress urinary incontinence and pelvic organ prolapse.

1 Table 4 Minor changes to recommendation wording (no change to intent)

Recommendation numbers in current guideline	Comment
All recommendations except those labelled [2019]	The term 'drug' has been replaced with 'medicine' (in line with current NICE style for recommendations in guidelines). Yellow highlighting has not been applied to these changes.
All recommendations except those labelled [2019]	Minor changes to language and style have been made (in line with current NICE style for recommendations in guidelines) where possible. Yellow highlighting has not been applied to these changes.

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