NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Guideline scope

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

This guideline will update the NICE guideline on urinary incontinence in women: management (CG171).

The guideline will be developed using the methods and processes outlined in Developing NICE guidelines: the manual.

1 Why the update is needed

New evidence that could affect recommendations was identified through the surveillance process. Topic experts, including those who helped to develop the existing guideline, advised NICE on whether areas should be updated or new areas added. Full details are set out in the surveillance review decision.

Surveillance of this guideline did not look at evidence on surgical approaches for stress urinary incontinence, in view of the pending NICE Interventional Procedures review and an interim report by the NHS England Mesh Working Group. The latter was published in December 2015, and 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 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.

NICE accepted these recommendations and commissioned an update of the existing urinary incontinence guideline to update guidance on complications arising from surgery for stress urinary incontinence and to include management of pelvic organ prolapse.

Why the guideline is needed

Key facts: urinary incontinence

Urinary incontinence is a common symptom that can affect women of all ages, with a wide spectrum of severity and nature. Although rarely life-threatening, incontinence may seriously affect the physical, psychological and social wellbeing of women and have an impact on their families and carers.

Key facts: pelvic organ prolapse

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, as well as 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.

Current practice

Urinary incontinence and pelvic organ prolapse are treated by lifestyle interventions, physiotherapy, medication, support pessaries and surgery.

Management of overactive bladder

- Overactive bladder is managed primarily by lifestyle interventions, in particular retraining, followed by antimuscarinic drug therapy or mirabegron if retraining is not helpful.
- Botulinum toxin A injections into the wall of the bladder and neuromodulation are options for women with overactive bladder in whom antimuscarinic drugs have not been effective or have not been tolerated. Neuromodulation includes percutaneous sacral nerve stimulation and percutaneous posterior tibial nerve stimulation.
- Surgery is also an option for treating overactive bladder if conservative management is unsuccessful. The most common surgical option for overactive bladder is clam cystoplasty, in which a segment of bowel is attached to the bladder.

Management of stress urinary incontinence

- Stress urinary incontinence is treated primarily by lifestyle measures such as weight loss and pelvic floor muscle training.
- If conservative treatments are not successful, surgical treatment can be considered. Surgical options include mid-urethral tapes, colposuspension, sling procedures and para-urethral bulking agents.

Management of pelvic organ prolapse

- Initial management of pelvic organ prolapse involves a comprehensive assessment of pelvic floor symptoms to include symptoms of prolapse, urinary, bowel and sexual function, as well as physical examination to determine the pelvic floor support of the anterior, central and posterior compartments.
- Lifestyle advice may be given about fluid management, heavy lifting, physical exercise and bowel evacuation.
- Physiotherapy, such as pelvic floor exercises, is widely offered to women for managing prolapse symptoms.
- Topical oestrogen in the form of vaginal pessaries or cream is offered to women with symptoms and signs of vaginal atrophy.

- Support pessaries are routinely used as an intervention to treat prolapse symptoms.
- Surgical management is offered to women who request this, or who decline to use pessaries, have an unsuccessful trial or decide to discontinue pessary use. There is a wide variety of surgical procedures, including:
  - native tissue pelvic floor repair
  - vaginal repair with mesh
  - vaginal hysterectomy
  - vaginal apical support procedures
  - abdominal (open and laparoscopic) vault and uterine support procedures with and without the use of mesh
  - in addition, colorectal surgery can repair posterior vaginal wall prolapse using a vaginal, transperineal or transanal route.

Concern about complications of surgical procedures using mesh

Synthetic mesh and mesh devices have been used for treating urinary incontinence and pelvic organ prolapse, to provide extra support when repairing tissues.

The NHS England Mesh Working Group recommended that NICE should review guidance on complications arising from surgery for stress urinary incontinence and pelvic organ prolapse. The Scottish Independent Review, the Medicines and Healthcare products Regulatory Agency (MHRA) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) have also produced interim reports on the safety of surgical meshes for treating incontinence and prolapse.

Policy, legislation, regulation and commissioning

Legislation, regulation and guidance

Professional bodies have produced the following relevant guidance:

- Post-hysterectomy vaginal vault prolapse (2015) RCOG Green-top guideline 46 (NICE accredited)

Commissioning

There are special commissioning arrangements for complex gynaecology, including recurrent prolapse and complex urogenital conditions:

- recurrent prolapse and urinary incontinence
- recurrent prolapse including laparoscopic surgery
- urogenital and anorectal conditions.

There is a voluntary system of registration and accreditation for units carrying out complex urogynaecology surgery, administered by the professional British Society of Urogynaecology:

- Standards for service provision in urogynaecology units: certification of units.

2 Who the guideline is for

Women using services, their families and carers and the public will be able to use the guideline to find out more about what NICE recommends, and help them make decisions.

This guideline is for:

- healthcare professionals in:
  - gynaecology services
  - primary care
  - urology services
  - continence services
  - physiotherapy services
  - colorectal services
- service commissioners
- women using services, their families and carers and the public.

It may also be relevant for:

- staff in care homes
- private providers.

NICE guidelines cover health and care in England. Decisions on how they apply in other UK countries are made by ministers in the Welsh Government, Scottish Government and Northern Ireland Executive.

Equality considerations

NICE has carried out an equality impact assessment during scoping. The assessment:

- lists equality issues identified, and how they have been addressed
- explains why any groups are excluded from the scope.

The guideline will look at inequalities relating to age, physical disabilities and cognitive impairment.

3 What the updated guideline will cover

3.1 Who is the focus?

Groups that will be covered

- Women (aged 18 and over) with urinary incontinence.
- Women (aged 18 and over) with pelvic organ prolapse. (To be included in the update but not covered in the existing guideline.)
- Women (aged 18 and over) with complications associated with insertion of mesh for treating stress urinary incontinence or pelvic organ prolapse. (To be included in the update but not covered in the existing guideline.)

Specific consideration will be given to:

- older women
- women with physical disabilities
- women with cognitive impairment
- women considering future pregnancy.

3.2 Settings

Settings that will be covered

- All settings where NHS-funded healthcare is provided.
- Social care settings.

3.3 Activities, services or aspects of care

Key areas that will be covered in this update

We will look at evidence in the areas below when developing this update. We will consider making new recommendations or updating existing recommendations in these areas only.

1 Assessing stress urinary incontinence: urodynamic testing.
2 Alternative conservative management options for urinary incontinence: absorbent products.
3 Drugs for overactive bladder.
4 Invasive procedures for overactive bladder.
5 Surgical procedures for stress urinary incontinence.
6 Multidisciplinary team.
7 Assessing pelvic organ prolapse.
8 Managing pelvic organ prolapse.
9 Managing coexisting urinary incontinence and pelvic organ prolapse.
10 Assessing complications associated with mesh surgery for stress urinary incontinence or pelvic organ prolapse.
11 Managing complications associated with mesh surgery for stress urinary incontinence or pelvic organ prolapse.

Note that guideline recommendations for medicines will normally fall within licensed indications; exceptionally, and only if clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will assume that prescribers will use a medicine's summary of product characteristics to inform decisions made with individual patients.

Proposed outline for the guideline

The table below outlines all the areas that will be included in the guideline. It sets out what NICE plans to do for each area in this update.

Area in the guideline	What NICE plans to do
Assessment and investigation of UI: • history taking and physical examination • pelvic floor muscle assessment • urine testing • assessment of residual urine • referral • symptom scoring and quality-of-life assessment • bladder diaries • pad testing • other tests of urethral competence • cystoscopy • imaging	No evidence review: retain recommendations from existing guideline
Assessment and investigation of UI: information provision	No evidence review: no recommendations in existing guideline owing to lack of evidence
Assessment and investigation of UI: urodynamic testing	Review evidence: update existing recommendations as needed
Conservative management of UI: • lifestyle interventions • physical therapies • behavioural therapies • neurostimulation • alternative conservative management options – urinals and toileting aids – catheters – products to prevent leakage – complementary therapies – preventive use of conservative therapies • progress of treatment	No evidence review: retain recommendations from existing guideline
Conservative management of UI: • alternative conservative management options: pessaries	No evidence review: no recommendations in existing guideline owing to lack of evidence

• optimal sequence and timescales for conservative therapies	
Conservative management of UI: • alternative conservative management options for UI: absorbent products	Review evidence: update existing recommendations as needed
Pharmacological treatment for UI: desmopressin, duloxetine and oestrogens	No evidence review: retain recommendations from existing guideline
Pharmacological treatment for UI: diuretics	No evidence review: no recommendations in existing guideline owing to lack of evidence
Pharmacological treatment for UI: drugs for OAB	Review evidence: update existing recommendations as needed
Invasive procedures for OAB: • percutaneous sacral nerve stimulation • augmentation cystoplasty • urinary diversion	No evidence review: retain recommendations from existing guideline
Invasive procedures for OAB: • detrusor myectomy • vanilloid receptor agonists • sequence of surgical procedures for overactive bladder – economic evaluation	No evidence review: no recommendations in existing guideline owing to lack of evidence
Invasive procedures for OAB: botulinum toxin	Review evidence: update existing recommendations as needed
Surgical procedures for stress UI	Review evidence: update existing recommendations as needed
Multidisciplinary team	Review evidence: update existing recommendations as needed
Competence of surgeons performing operative procedures for UI in women	Remove: refer to professional body competence standards
Assessment and investigation of POP: assessment	Review evidence: update existing recommendations as needed
Conservative management of POP: • lifestyle interventions • other conservative management options	Review evidence: new area in the guideline
Pharmacological treatment for POP	Review evidence: new area in the guideline
Surgical procedures for POP	Review evidence: new area in the guideline
Managing coexisting UI and POP	Review evidence: new area in the guideline
Assessing complications associated with mesh surgery for stress UI or POP	Review evidence: new area in the guideline

Managing complications associated with mesh surgery for stress UI or POP	Review evidence: new area in the guideline
Abbreviations: MDT, multidisciplinary team; OAB, overactive bladder; POP, pelvic organ prolapse; UI, urinary incontinence.	

Recommendations in areas that are being retained from the existing guideline may be edited to ensure that they meet current editorial standards, and reflect the current policy and practice context.

Areas not covered by the guideline

These areas will not be covered by the guideline.

1 Information provision and consent for women considering surgical intervention for stress urinary incontinence or pelvic organ prolapse – this is being specifically addressed in reviews by NHS England and NHS Scotland.
2 Incontinence associated with neurological disease.
3 Rectal prolapse.
4 Fistula, except in relation to complications associated with mesh surgery.
5 Women who had surgical management of congenital anomalies of the lower genitourinary tract as children.
6 Faecal incontinence.
7 Urinary incontinence associated with pregnancy.
8 Causes of and risk factors for pelvic organ prolapse.
9 Causes of and risk factors for postoperative incontinence after prolapse surgery.
10 Assessing complications after non-mesh surgery for urinary incontinence and pelvic organ prolapse.
11 Managing complications after non-mesh surgery for urinary incontinence and pelvic organ prolapse.
12 Managing complications after mesh surgery that are not caused by mesh surgery.

Related NICE guidance

This guideline will not cover incontinence associated with neurological disease because it is already covered in NICE's guideline:

- Urinary incontinence in neurological disease: assessment and management (2012) NICE guideline CG148

NICE has published the following guidance that is closely related to this guideline:

- Single-incision short sling mesh insertion for stress urinary incontinence in women (2016) NICE interventional procedure guidance 566
- Multimorbidity: clinical assessment and management (2016) NICE guideline NG56
- Menopause: diagnosis and management (2015) NICE guideline NG23
- Older people with social care needs and multiple long-term conditions (2015) NICE guideline NG22
- Suspected cancer: recognition and referral (2015) NICE guideline NG12
- Falls in older people: assessing risk and prevention (2013) NICE guideline CG161
- Mirabegron for treating symptoms of overactive bladder (2013) NICE technology appraisal guidance 290
- Percutaneous posterior tibial nerve stimulation for overactive bladder syndrome (2010) NICE interventional procedure guidance 362
- Laparoscopic augmentation cystoplasty (including clam cystoplasty) (2009) NICE interventional procedure guidance 326
- Sacrocolpopexy with hysterectomy using mesh for uterine prolapse repair (2009) NICE interventional procedure guidance 284 (currently being updated; publication expected March 2017)
- Sacrocolpopexy using mesh for vaginal vault prolapse repair (2009) NICE interventional procedure guidance 283 (currently being updated; publication expected March 2017)

- Insertion of mesh uterine suspension sling (including sacrohysteropexy) for uterine prolapse repair (2009) NICE interventional procedure guidance 282 (currently being updated; publication expected June 2017)
- Infracoccygeal sacropexy using mesh for vaginal vault prolapse repair (2009) NICE interventional procedure guidance 281 (currently being updated; publication expected May 2017)
- Infracoccygeal sacropexy using mesh for uterine prolapse repair (2009) NICE interventional procedure guidance 280 (currently being updated; publication expected May 2017)
- Surgical repair of vaginal wall prolapse using mesh (2008) NICE interventional procedure guidance 267 (currently being updated; publication date to be confirmed)
- Faecal incontinence in adults: management (2007) NICE clinical guideline CG49
- Insertion of biological slings for stress urinary incontinence in women (2006) NICE interventional procedure guidance 154
- Intramural urethral bulking procedures for stress urinary incontinence in women (2005) NICE interventional procedure guidance 138
- Insertion of extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in women (2005) NICE interventional procedure guidance 133 (currently being updated; publication expected March 2017)
- Sacral nerve stimulation for urge incontinence and urgency-frequency (2004) NICE interventional procedure guidance 64

This update will include a network meta-analysis of interventional procedures guidance, including those with 'special arrangements' or 'only in research' recommendations. This will be outside NICE's usual processes, which allow guideline developers to consider only interventional procedures guidance with recommendations with normal arrangements.

NICE guidance that will be updated by this guideline

- Urinary incontinence in women: management (2013) NICE guideline CG171

NICE guidance about the experience of people using NHS services

NICE has produced the following guidance on the experience of people using the NHS. This guideline will not include additional recommendations on these topics unless there are specific issues related to urinary incontinence and pelvic organ prolapse in women:

- Medicines optimisation (2015) NICE guideline NG5
- Patient experience in adult NHS services (2012) NICE guideline CG138
- Medicines adherence (2009) NICE guideline CG76

3.4 Economic aspects

We will take economic aspects into account when making recommendations. For each review question (or key area in the scope) for which the evidence is being reviewed, we will develop an economic plan that states whether economic considerations are relevant, and if so whether this is an area that should be prioritised for economic modelling and analysis. We will review the economic evidence and carry out economic analyses, using an NHS and personal social services perspective, as appropriate.

3.5 Key issues and questions

While writing the scope for this updated guideline, we have identified the following key issues and key questions related to them.

1 Assessing stress urinary incontinence

  1.1 What is the value of urodynamic assessment in addition to clinical assessment before primary surgery for stress urinary incontinence?

2 Alternative conservative management options for urinary incontinence

  2.1 How often should alternative treatment options be reviewed for women who are using absorbent containment products?

3 Drugs for overactive bladder

  3.1 What are the risks to cognitive function for women taking anticholinergic drugs for overactive bladder?

4 Invasive procedures for overactive bladder

4.1 What is the value of urodynamic assessment before botulinum toxin type A treatment?

4.2 What is the most effective dose of botulinum toxin type A for treating overactive bladder?

5 Surgical procedures for stress urinary incontinence

5.1 What is the most effective surgical management of stress urinary incontinence, including mesh and non-mesh procedures?

6 Multidisciplinary team

6.1 What is the most effective way of coordinating services, for example for managing complications associated with mesh surgery?

7 Assessing pelvic organ prolapse

7.1 What is the most effective strategy for assessing pelvic organ prolapse?

8 Managing pelvic organ prolapse

8.1 What lifestyle interventions are effective for managing pelvic organ prolapse?

8.2 What is the effectiveness of topical oestrogen for managing pelvic organ prolapse with vaginal atrophy?

8.3 What are the most effective conservative management options (for example, pelvic floor exercises and pessaries) for pelvic organ prolapse?

8.4 What are the most effective surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse?

8.5 What is the role of surgery to prevent postoperative urinary incontinence in women having surgery for pelvic organ prolapse, including the sequence of interventions?

9 Managing coexisting urinary incontinence and pelvic organ prolapse

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

10 Assessing complications associated with mesh surgery for stress urinary incontinence or pelvic organ prolapse

10.1 What is the most effective strategy for assessing complications (for example, vaginal complications, sexual dysfunction, pain, urinary symptoms and bowel symptoms) after mesh surgery?

11 Managing complications associated with mesh surgery for stress urinary incontinence or pelvic organ prolapse

11.1 What are the most effective management options for vaginal complications (including exposure, extrusion and infection) after mesh surgery?

11.2 What are the most effective management options for sexual dysfunction after mesh surgery?

11.3 What are the most effective management options for pain after mesh surgery?

11.4 What are the most effective management options for urinary complications after mesh surgery?

11.5 What are the most effective management options for bowel symptoms after mesh surgery?

The key questions may be used to develop more detailed review questions, which guide the systematic review of the literature.

3.6 Main outcomes

The main outcomes that will be considered when searching for and assessing the evidence are:

1 clinical effectiveness (for example, cure rates and treatment-related adverse effects)
2 health-related quality of life
3 patient-reported outcome measures.

4 NICE quality standards and NICE Pathways

4.1 NICE quality standards

NICE quality standards that may need to be revised or updated when this guideline is published

- Urinary incontinence in women (2015) NICE quality standard 77

4.2 NICE Pathways

When this guideline is published, we will update the existing NICE pathway on urinary incontinence in women. NICE Pathways bring together everything NICE has said on a topic in an interactive flow chart.

5 Further information

This is the final scope, incorporating comments from registered stakeholders.

The guideline is expected to be published in February 2019.

You can follow progress of the guideline.

Our website has information about how NICE guidelines are developed.