



Lower urinary tract symptoms in men: management

Clinical guideline

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This guideline replaces IPG256, IPG15, IPG224 and IPG120.

This guideline should be read in conjunction with IPG14 and IPG17.

Introduction

A recommendation on phosphodiesterase-5 inhibitors has been added to <u>section 1.4</u> on drug treatment. A research recommendation on phosphodiesterase-5 inhibitors has been added to <u>section 2.5</u>. The <u>addendum</u> contains details of the methods and evidence used to develop these recommendations.

Lower urinary tract symptoms (LUTS) comprise storage, voiding and post-micturition symptoms affecting the lower urinary tract. There are many possible causes of LUTS such as abnormalities or abnormal function of the prostate, urethra, bladder or sphincters. In men, the most common cause is benign prostate enlargement (BPE), which obstructs the bladder outlet. BPE happens when the number of cells in the prostate increases, a condition called benign prostatic hyperplasia. Other conditions that can cause LUTS include detrusor muscle weakness or overactivity, prostate inflammation (prostatitis), urinary tract infection, prostate cancer and neurological disease. This clinical guideline will advise on the effective evidence-based management of LUTS in men.

LUTS in men are best categorised into voiding, storage or post-micturition symptoms to help define the source of the problem. Voiding symptoms include weak or intermittent urinary stream, straining, hesitancy, terminal dribbling and incomplete emptying. Storage symptoms include urgency, frequency, urgency incontinence and nocturia. The major post-micturition symptom is post-micturition dribbling, which is common and bothersome. Although LUTS do not usually cause severe illness, they can considerably reduce men's quality of life, and may point to serious pathology of the urogenital tract.

LUTS are a major burden for the ageing male population. Age is an important risk factor for LUTS and the prevalence of LUTS increases as men get older. Bothersome LUTS can occur in up to 30% of men older than 65 years. This is a large group potentially requiring treatment.

Because uncertainty and variation exist in clinical practice, this guideline gives clear recommendations on diagnosing, monitoring and treating LUTS.

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

Recommendations about medicines

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

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

Patient-centred care

This guideline offers best practice advice on the care of men with lower urinary tract symptoms.

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

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

Key priorities for implementation

The following recommendations were identified as priorities for implementation in the 2010 guideline and have not been changed in the 2015 update.

Initial assessment

- At initial assessment, offer men with LUTS an assessment of their general medical history to identify possible causes of LUTS, and associated comorbidities. Review current medication, including herbal and over-the-counter medicines, to identify drugs that may be contributing to the problem. [2010]
- At initial assessment, offer men with LUTS a physical examination guided by urological symptoms and other medical conditions, an examination of the abdomen and external genitalia, and a digital rectal examination (DRE). [2010]
- At initial assessment, ask men with bothersome LUTS to complete a urinary frequency volume chart. [2010]
- Refer men for specialist assessment if they have LUTS complicated by recurrent or persistent urinary tract infection, retention, renal impairment that is suspected to be caused by lower urinary tract dysfunction, or suspected urological cancer. [2010]

Conservative management

- Offer men with storage LUTS (particularly urinary incontinence) temporary containment products (for example, pads or collecting devices) to achieve social continence until a diagnosis and management plan have been discussed. [2010]
- Offer men with storage LUTS suggestive of overactive bladder (OAB) supervised bladder training, advice on fluid intake, lifestyle advice and, if needed, containment products. [2010]

Surgery for voiding symptoms

 If offering surgery for managing voiding LUTS presumed secondary to BPE, offer monopolar or bipolar transurethral resection of the prostate (TURP), monopolar transurethral vaporisation of the prostate (TUVP) or holmium laser enucleation of the prostate (HoLEP). Perform HoLEP at a centre specialising in the technique, or with mentorship arrangements in place. [2010] • If offering surgery for managing voiding LUTS presumed secondary to BPE, do not offer minimally invasive treatments (including transurethral needle ablation [TUNA], transurethral microwave thermotherapy [TUMT], high-intensity focused ultrasound [HIFU], transurethral ethanol ablation of the prostate [TEAP] and laser coagulation) as an alternative to TURP, TUVP or HoLEP (see 1.5.2). [2010]

Providing information

- Make sure men with LUTS have access to care that can help with:
 - their emotional and physical conditions and
 - relevant physical, emotional, psychological, sexual and social issues. [2010]
- Provide men with storage LUTS (particularly incontinence) containment products at point of need, and advice about relevant support groups. [2010]

1 Recommendations

The following guidance is based on the best available evidence. The <u>full guideline</u> gives details of the methods and the evidence used to develop the 2010 recommendations. The <u>guideline</u> <u>addendum</u> gives details of the methods and the evidence used to develop the 2015 recommendations.

In this guidance, 'mild' refers to an International Prostate Symptom Score (IPSS) of 0–7, 'moderate' refers to an IPSS of 8–19 and 'severe' refers to an IPSS of 20–35.

1.1 Initial assessment

Initial assessment refers to assessment carried out in any setting by a healthcare professional without specific training in managing LUTS in men.

- 1.1.1 At initial assessment, offer men with LUTS an assessment of their general medical history to identify possible causes of LUTS, and associated comorbidities. Review current medication, including herbal and over-the-counter medicines, to identify drugs that may be contributing to the problem. [2010]
- 1.1.2 At initial assessment, offer men with LUTS a physical examination guided by urological symptoms and other medical conditions, an examination of the abdomen and external genitalia, and a digital rectal examination (DRE). [2010]
- 1.1.3 At initial assessment, ask men with bothersome LUTS to complete a urinary frequency volume chart. [2010]
- 1.1.4 At initial assessment, offer men with LUTS a urine dipstick test to detect blood, glucose, protein, leucocytes and nitrites. [2010]
- 1.1.5 At initial assessment, offer men with LUTS information, advice and time to decide if they wish to have prostate specific antigen (PSA) testing if:
 - their LUTS are suggestive of bladder outlet obstruction secondary to BPE or
 - their prostate feels abnormal on DRE or
 - they are concerned about prostate cancer. [2010]

- 1.1.6 Manage suspected prostate cancer in men with LUTS in line with the NICE guidelines on prostate cancer and referral guidelines for suspected cancer.[2010]
- 1.1.7 At initial assessment, offer men with LUTS a serum creatinine test (plus estimated glomerular filtration rate [eGFR] calculation) only if you suspect renal impairment (for example, the man has a palpable bladder, nocturnal enuresis, recurrent urinary tract infections or a history of renal stones). [2010]
- 1.1.8 Do not routinely offer cystoscopy to men with uncomplicated LUTS (that is, without evidence of bladder abnormality) at initial assessment. [2010]
- 1.1.9 Do not routinely offer imaging of the upper urinary tract to men with uncomplicated LUTS at initial assessment. [2010]
- 1.1.10 Do not routinely offer flow-rate measurement to men with LUTS at initial assessment. [2010]
- 1.1.11 Do not routinely offer a post void residual volume measurement to men with LUTS at initial assessment. [2010]
- 1.1.12 At initial assessment, give reassurance, offer advice on lifestyle interventions (for example, fluid intake) and information on their condition to men whose LUTS are not bothersome or complicated. Offer review if symptoms change.

 [2010]
- 1.1.13 Offer men referral for specialist assessment if they have bothersome LUTS that have not responded to conservative management or drug treatment. [2010]
- 1.1.14 Refer men for specialist assessment if they have LUTS complicated by recurrent or persistent urinary tract infection, retention, renal impairment that is suspected to be caused by lower urinary tract dysfunction, or suspected urological cancer. [2010]
- 1.1.15 Offer men considering any treatment for LUTS an assessment of their baseline symptoms with a validated symptom score (for example, the IPSS) to allow assessment of subsequent symptom change. [2010]

1.2 Specialist assessment

Specialist assessment refers to assessment carried out in any setting by a healthcare professional with specific training in managing LUTS in men.

- 1.2.1 Offer men with LUTS having specialist assessment an assessment of their general medical history to identify possible causes of LUTS, and associated comorbidities. Review current medication, including herbal and over-the-counter medicines to identify drugs that may be contributing to the problem. [2010]
- 1.2.2 Offer men with LUTS having specialist assessment a physical examination guided by urological symptoms and other medical conditions, an examination of the abdomen and external genitalia, and a digital rectal examination (DRE).
 [2010]
- 1.2.3 At specialist assessment, ask men with LUTS to complete a urinary frequency volume chart. [2010]
- 1.2.4 At specialist assessment, offer men with LUTS information, advice and time to decide if they wish to have prostate specific antigen (PSA) testing if:
 - their LUTS are suggestive of bladder outlet obstruction secondary to BPE or
 - their prostate feels abnormal on DRE or
 - they are concerned about prostate cancer. [2010]
- 1.2.5 Offer men with LUTS who are having specialist assessment a measurement of flow rate and post void residual volume. [2010]
- 1.2.6 Offer cystoscopy to men with LUTS having specialist assessment only when clinically indicated, for example if there is a history of any of the following:
 - recurrent infection
 - sterile pyuria
 - haematuria

- profound symptoms
- pain. [2010]
- 1.2.7 Offer imaging of the upper urinary tract to men with LUTS having specialist assessment only when clinically indicated, for example if there is a history of any of the following:
 - chronic retention
 - haematuria
 - recurrent infection
 - sterile pyuria
 - profound symptoms
 - pain. [2010]
- 1.2.8 Consider offering multichannel cystometry to men with LUTS having specialist assessment if they are considering surgery. [2010]
- 1.2.9 Offer pad tests to men with LUTS having specialist assessment only if the degree of urinary incontinence needs to be measured. [2010]
- 1.3 Conservative management
- 1.3.1 Explain to men with post micturition dribble how to perform urethral milking.[2010]
- 1.3.2 Offer men with storage LUTS (particularly urinary incontinence) temporary containment products (for example, pads or collecting devices) to achieve social continence until a diagnosis and management plan have been discussed. [2010]
- 1.3.3 Offer a choice of containment products to manage storage LUTS (particularly urinary incontinence) based on individual circumstances and in consultation with the man. [2010]

- 1.3.4 Offer men with storage LUTS suggestive of overactive bladder (OAB) supervised bladder training, advice on fluid intake, lifestyle advice and, if needed, containment products. [2010]
- 1.3.5 Inform men with LUTS and proven bladder outlet obstruction that bladder training is less effective than surgery. [2010]
- 1.3.6 Offer supervised pelvic floor muscle training to men with stress urinary incontinence caused by prostatectomy. Advise them to continue the exercises for at least 3 months before considering other options. [2010]
- 1.3.7 Refer for specialist assessment men with stress urinary incontinence. [2010]
- 1.3.8 Do not offer penile clamps to men with storage LUTS (particularly urinary incontinence). [2010]
- 1.3.9 Offer external collecting devices (for example, sheath appliances, pubic pressure urinals) for managing storage LUTS (particularly urinary incontinence) in men before considering indwelling catheterisation (see 1.3.11). [2010]
- 1.3.10 Offer intermittent bladder catheterisation before indwelling urethral or suprapubic catheterisation to men with voiding LUTS that cannot be corrected by less invasive measures. [2010]
- 1.3.11 Consider offering long-term indwelling urethral catheterisation to men with LUTS:
 - for whom medical management has failed and surgery is not appropriate and
 - who are unable to manage intermittent self-catheterisation or
 - with skin wounds, pressure ulcers or irritation that are being contaminated by urine or
 - who are distressed by bed and clothing changes. [2010]
- 1.3.12 If offering long-term indwelling catheterisation, discuss the practicalities, benefits and risks with the man and, if appropriate, his carer. [2010]
- 1.3.13 Explain to men that indwelling catheters for urgency incontinence may not result in continence or the relief of recurrent infections. [2010]

1.3.14 Consider permanent use of containment products for men with storage LUTS (particularly urinary incontinence) only after assessment and exclusion of other methods of management. [2010]

1.4 Drug treatment

- 1.4.1 Offer drug treatment only to men with bothersome LUTS when conservative management options have been unsuccessful or are not appropriate. [2010]
- 1.4.2 Take into account comorbidities and current treatment when offering men drug treatment for LUTS. [2010]
- 1.4.3 Offer an alpha blocker (alfuzosin, doxazosin, tamsulosin or terazosin) to men with moderate to severe LUTS. [2010]
- 1.4.4 Offer an anticholinergic to men to manage the symptoms of OAB. [2010]
- 1.4.5 Offer a 5-alpha reductase inhibitor to men with LUTS who have prostates estimated to be larger than 30 g or a PSA level greater than 1.4 ng/ml, and who are considered to be at high risk of progression (for example, older men). [2010]
- 1.4.6 Consider offering a combination of an alpha blocker and a 5-alpha reductase inhibitor to men with bothersome moderate to severe LUTS and prostates estimated to be larger than 30 g or a PSA level greater than 1.4 ng/ml. [2010]
- 1.4.7 Consider offering an anticholinergic as well as an alpha blocker to men who still have storage symptoms after treatment with an alpha blocker alone. [2010]
- 1.4.8 Consider offering a late afternoon loop diuretic^[1] to men with nocturnal polyuria. [2010]
- 1.4.9 Consider offering oral desmopressin^[2] to men with nocturnal polyuria if other medical causes^[3] have been excluded and they have not benefited from other treatments. Measure serum sodium 3 days after the first dose. If serum sodium is reduced to below the normal range, stop desmopressin treatment. [2010]

1.4.10 Do not offer phosphodiesterase-5-inhibitors solely for the purpose of treating lower urinary tract symptoms in men, except as part of a randomised controlled trial. [new 2015]

Review

- 1.4.11 Discuss active surveillance (reassurance and lifestyle advice without immediate treatment and with regular follow-up) or active intervention (conservative management, drug treatment or surgery) for:
 - men with mild or moderate bothersome LUTS
 - men whose LUTS fail to respond to drug treatment. [2010]
- 1.4.12 Review men taking drug treatments to assess symptoms, the effect of the drugs on the patient's quality of life and to ask about any adverse effects from treatment. [2010]
- 1.4.13 Review men taking alpha blockers at 4–6 weeks and then every 6–12 months. [2010]
- 1.4.14 Review men taking 5-alpha reductase inhibitors at 3-6 months and then every 6-12 months. [2010]
- 1.4.15 Review men taking anticholinergics every 4–6 weeks until symptoms are stable, and then every 6–12 months. [2010]

1.5 Surgery for voiding symptoms

- 1.5.1 For men with voiding symptoms, offer surgery only if voiding symptoms are severe or if drug treatment and conservative management options have been unsuccessful or are not appropriate. Discuss the alternatives to and outcomes from surgery. [2010]
- 1.5.2 If offering surgery for managing voiding LUTS presumed secondary to BPE, offer monopolar or bipolar transurethral resection of the prostate (TURP), monopolar transurethral vaporisation of the prostate (TUVP) or holmium laser enucleation of the prostate (HoLEP). Perform HoLEP at a centre specialising in the technique, or with mentorship arrangements in place. [2010]

- 1.5.3 Offer transurethral incision of the prostate (TUIP) as an alternative to other types of surgery (see 1.5.2) to men with a prostate estimated to be smaller than 30 g. [2010]
- 1.5.4 Only offer open prostatectomy as an alternative to TURP, TUVP or HoLEP (see 1.5.2) to men with prostates estimated to be larger than 80 g. [2010]
- 1.5.5 If offering surgery for managing voiding LUTS presumed secondary to BPE, do not offer minimally invasive treatments (including transurethral needle ablation [TUNA], transurethral microwave thermotherapy [TUMT], high-intensity focused ultrasound [HIFU], transurethral ethanol ablation of the prostate [TEAP] and laser coagulation) as an alternative to TURP, TUVP or HoLEP (see 1.5.2). [2010]
- 1.5.6 If offering surgery for managing voiding LUTS presumed secondary to BPE, only consider offering botulinum toxin injection into the prostate as part of a randomised controlled trial. [2010]
- 1.5.7 If offering surgery for managing voiding LUTS presumed secondary to BPE, only consider offering laser vaporisation techniques, bipolar TUVP or monopolar or bipolar transurethral vaporisation resection of the prostate (TUVRP) as part of a randomised controlled trial that compares these techniques with TURP. [2010]

1.6 Surgery for storage symptoms

- 1.6.1 If offering surgery for storage symptoms, consider offering only to men whose storage symptoms have not responded to conservative management and drug treatment. Discuss the alternatives of containment or surgery. Inform men being offered surgery that effectiveness, side effects and long-term risk are uncertain. [2010]
- 1.6.2 If considering offering surgery for storage LUTS, refer men to a urologist to discuss:
 - the surgical and non-surgical options appropriate for their circumstances and
 - the potential benefits and limitations of each option, particularly long-term results. [2010]

- 1.6.3 Consider offering cystoplasty to manage detrusor overactivity only to men whose symptoms have not responded to conservative management or drug treatment and who are willing and able to self-catheterise. Before offering cystoplasty, discuss serious complications (that is, bowel disturbance, metabolic acidosis, mucus production and/or mucus retention in the bladder, urinary tract infection and urinary retention). [2010]
- 1.6.4 Consider offering bladder wall injection with botulinum toxin to men with detrusor overactivity only if their symptoms have not responded to conservative management and drug treatments and the man is willing and able to self-catheterise. [2010]
- 1.6.5 Consider offering implanted sacral nerve stimulation to manage detrusor overactivity only to men whose symptoms have not responded to conservative management and drug treatments. [2010]
- 1.6.6 Do not offer myectomy to men to manage detrusor overactivity. [2010]
- 1.6.7 Consider offering intramural injectables, implanted adjustable compression devices and male slings to manage stress urinary incontinence only as part of a randomised controlled trial. [2010]
- 1.6.8 Consider offering urinary diversion to manage intractable urinary tract symptoms only to men whose symptoms have not responded to conservative management and drug treatments, and if cystoplasty or sacral nerve stimulation are not clinically appropriate or are unacceptable to the patient. [2010]
- 1.6.9 Consider offering implantation of an artificial sphincter to manage stress urinary incontinence only to men whose symptoms have not responded to conservative management and drug treatments. [2010]

1.7 Treating urinary retention

- 1.7.1 Immediately catheterise men with acute retention. [2010]
- 1.7.2 Offer an alpha blocker to men for managing acute urinary retention before removal of the catheter. [2010]

- 1.7.3 Consider offering self- or carer-administered intermittent urethral catheterisation before offering indwelling catheterisation for men with chronic urinary retention. [2010]
- 1.7.4 Carry out a serum creatinine test and imaging of the upper urinary tract in men with chronic urinary retention (residual volume greater than 1 litre or presence of a palpable/percussable bladder). [2010]
- 1.7.5 Catheterise men who have impaired renal function or hydronephrosis secondary to chronic urinary retention. [2010]
- 1.7.6 Consider offering intermittent or indwelling catheterisation before offering surgery in men with chronic urinary retention. [2010]
- 1.7.7 Consider offering surgery on the bladder outlet without prior catheterisation to men who have chronic urinary retention and other bothersome LUTS but no impairment of renal function or upper renal tract abnormality. [2010]
- 1.7.8 Consider offering intermittent self- or carer-administered catheterisation instead of surgery in men with chronic retention who you suspect have markedly impaired bladder function. [2010]
- 1.7.9 Continue or start long-term catheterisation in men with chronic retention for whom surgery is unsuitable. [2010]
- 1.7.10 Provide active surveillance (post void residual volume measurement, upper tract imaging and serum creatinine testing) to men with non-bothersome LUTS secondary to chronic retention who have not had their bladder drained. [2010]
- 1.8 Alternative and complementary therapies
- 1.8.1 Do not offer homeopathy, phytotherapy or acupuncture for treating LUTS in men. [2010]
- 1.9 Providing information
- 1.9.1 Ensure that, if appropriate, men's carers are informed and involved in managing their LUTS and can give feedback on treatments. [2010]

- 1.9.2 Make sure men with LUTS have access to care that can help with:
 - their emotional and physical conditions and
 - relevant physical, emotional, psychological, sexual and social issues. [2010]
- 1.9.3 Provide men with storage LUTS (particularly incontinence) containment products at point of need, and advice about relevant support groups. [2010]

At the time of publication (June 2015), loop diuretics (for example, furosemide) did not have a UK marketing authorisation for this indication. Informed consent should be obtained and documented. 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 Good practice in prescribing and managing medicines and devices for further information.

At the time of publication (June 2015), desmopressin did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's <u>Good practice in prescribing and managing medicines and devices</u> for further information.

Medical conditions that can cause nocturnal polyuria symptoms include diabetes mellitus, diabetes insipidus, adrenal insufficiency, hypercalcaemia, liver failure, polyuric renal failure, chronic heart failure, obstructive apnoea, dependent oedema, pyelonephritis, chronic venous stasis, sickle cell anaemia. Medications that can cause nocturnal polyuria symptoms include calcium channel blockers, diuretics, and selective serotonin reuptake inhibitors (SSRIs).

2 Research recommendations

In 2010, the Guideline Development Group made the following recommendations for research, based on its review of evidence, to improve NICE guidance and patient care in the future. The Guideline Development Group's full set of research recommendations is detailed in the <u>full</u> guideline.

2.1 Multichannel cystometry

What is the clinical and cost effectiveness of multichannel cystometry in improving patient-related outcomes in men considering bladder outlet surgery? [2010]

Why this is important

This research would clarify whether this test could improve the outcome of surgery. By identifying which patients had bladder outlet obstruction, it could improve the chance of a good outcome from surgery. The study should be a randomised controlled trial comparing multichannel cystometry before surgery with no intervention in men waiting to have bladder outlet surgery.

2.2 Catheterisation

What are the clinical and cost effectiveness and associated adverse events of intermittent catheterisation compared with indwelling catheterisation (suprapubic or urethral) for men with voiding difficulty and chronic retention of urine? [2010]

Why this is important

The number of patients in this group is steadily increasing as the population ages and more radical prostatectomies are carried out. Current practice varies widely across the UK with no established standard of good practice. This research could establish the best approach to management in these men and so bring more effective, patient-focused treatment that is more cost effective. The study should be a randomised controlled trial comparing intermittent catheterisation, indwelling suprapubic and indwelling urethral catheterisation. Outcomes of interest would be quality of life, healthcare resource use and adverse events (including leakage, skin breakdown, infection, erosion and death).

2.3 Products for men with urinary incontinence

What are the clinical and cost effectiveness and associated adverse events of absorbent pads compared with sheath collectors for men with urinary incontinence? [2010]

Why this is important

The number of patients in this group is steadily increasing as more radical prostatectomies are carried out and the population ages. Current practice varies widely across the UK with no established standard of good practice. This research could establish the best approach to continence management in these men and so provide more effective, patient-focused treatment that is more cost effective. In current non-specialist practice, bladder training is often not considered, and adequate diagnosis and hence optimal treatment of bladder dysfunction is often not implemented. Evidence-based guidance on selecting the most suitable containment product and its subsequent management will increase the quality of life of patients, use skilled nurse/carer resources more efficiently and reduce the costs of waste of unsuitable or sub-optimal product use. The study should be a randomised controlled trial reporting symptom severity, quality of life, changes in measured leakage and occurrence of adverse events.

2.4 Male slings

In men with mild to moderate post prostatectomy urinary incontinence, what is the clinical and cost effectiveness of a male sling or an implanted adjustable compression device, when assessed by symptom severity, quality of life, changes in measured leakage and occurrence of adverse events? [2010]

Why this is important

Guidance is needed on the most suitable surgical options for this growing group of men who, until recently, have had no acceptable treatment option other than insertion of an artificial urinary sphincter. Many men consider insertion of an artificial sphincter to be too invasive and too prone to complication or failure, and therefore depend on containment alone for control of their urinary incontinence. A number of new interventions have been devised but it is uncertain which of these offers the best outcomes. This research could lead to clear recommendations and effective treatment for the majority of these men. A randomised controlled trial is recommended, comparing up to three current interventions: retrobulbar 'non-compressive' male sling, adjustable compression sling, and implanted adjustable compression device.

2.5 Phosphodiesterase-5-inhibitors

As part of the 2015 update, the Committee made an additional research recommendation on treating lower urinary tract symptoms in men.

What is the clinical and cost effectiveness of phosphodiesterase-5 inhibitors (PDE5Is) for treating lower urinary tract symptoms in men who do not have erectile dysfunction? [new 2015]

Why this is important

There is a gap in the evidence about the effectiveness of PDE5Is in men with LUTS who do not have erectile dysfunction. The current evidence includes men with LUTS and erectile dysfunction. Therefore the standing Committee decided that it was not appropriate to make a recommendation about the routine use of PDE5Is in clinical practice. More evidence is needed to enable a recommendation to be made on the use of PDE5Is in all men with LUTS, including those without erectile dysfunction. The study should be a randomised controlled trial comparing PDE5Is with usual care in men over 45 years with LUTS without erectile dysfunction. Outcomes should include IPSS symptom score, IPSS quality of life, maximal urinary flow, residual urine volume, postural hypotension, headaches and withdrawals due to adverse events.

See the <u>addendum</u> for more information.

3 Other information

3.1 Scope and how this guideline was developed

The <u>scope</u> for the 2010 guideline covers the recommendations labelled [2010]. The recommendation labelled [new 2015] has been produced during the update.

How this guideline was developed

The 2010 guideline was developed by the National Clinical Guideline Centre, which is based at the Royal College of Physicians. The Guideline Centre worked with a Guideline Development Group, comprising healthcare professionals (including consultants, GPs and nurses), patients and carers, and technical staff, which reviewed the evidence and drafted the recommendations. The recommendations were finalised after public consultation.

NICE's Clinical Guidelines Update Programme updated this guideline in 2015. This guideline was updated using a Standing Committee of healthcare professionals, methodologists and lay members from a range of disciplines and localities, as well as topic experts.

The methods and processes for developing NICE clinical guidelines can be found <u>here</u>.

3.2 Related NICE guidance

Details are correct at the time of publication (June 2015). Further information is available on the NICE website.

Published

General

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

Condition-specific

- Bladder cancer (2015) NICE guideline NG2
- Prostate cancer (2014) NICE guideline CG175
- <u>Urinary incontinence in women</u> (2013) NICE guideline CG171

- Mirabegron for treating symptoms of overactive bladder (2013) NICE technology appraisal guidance 290
- <u>Prostate artery embolisation for benign prostatic hyperplasia</u> (2013) NICE interventional procedures guidance 453
- <u>Urinary incontinence in neurological disease</u> (2012) NICE guideline CG148
- <u>Laparoscopic prostatectomy for benign prostatic obstruction</u> (2008) NICE interventional procedures guidance 275
- <u>Suburethral synthetic sling insertion for stress urinary incontinence in men</u> (2008) NICE interventional procedures guidance 256
- <u>Insertion of extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in men</u> (2007) NICE interventional procedures guidance 224
- Potassium-titanyl-phosphate (KTP) laser vaporisation of the prostate for benign prostatic obstruction (2005) NICE interventional procedures guidance 120
- Referral guidelines for suspected cancer (2005) NICE guideline CG27
- <u>Sacral nerve stimulation for urge incontinence and urgency-frequency</u> (2004) NICE interventional procedures guidance 64
- Holmium laser prostatectomy (2003) NICE interventional procedures guidance 17
- <u>Transurethral radiofrequency needle ablation of the prostate</u> (2003) NICE interventional procedures guidance 15
- <u>Transurethral electrovaporisation of the prostate</u> (2003) NICE interventional procedures guidance 14

Under development

NICE is developing the following guidance (details available from the <u>NICE website</u>):

- <u>Suspected cancer (update)</u>. NICE guideline update. Publication expected June 2015.
- The UroLift system for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia. NICE interventional procedures guidance. Publication expected September 2015.

4 Standing Committee and NICE staff

4.1 Standing Committee

Members of Standing Committee A and the topic experts for the 2015 update are listed on the NICE website.

For the composition of the previous Guideline Development Group, see the <u>full guideline</u>.

4.2 Clinical Guidelines Update Team

Philip Alderson

Clinical Adviser

Emma Banks

Co-ordinator

Sara Buckner

Technical Analyst

Paul Crosland

Health Economist

Nicole Elliott

Associate Director

Sarah Glover

Information Scientist

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Rebecca Parsons

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Charlotte Purves

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Toni Tan

Technical Adviser

4.3 NICE project team

Mark Baker

Clinical Lead

Christine Carson

Guideline Lead

James Hall

Editor

Bhash Naidoo

Technical Lead (Health Economics)

Beth Shaw

Technical Lead

Louise Shires

Guideline Commissioning Manager

Joy Carvill

Guideline Coordinator

Jessica Fielding

Public Involvement Adviser

4.4 Declarations of interests

The following members of the Standing Committee made declarations of interest. All other members of the Committee stated that they had no interests to declare.

The conflicts of interest policy (2007) was followed until September 2014, when an <u>updated policy</u> was published.

Committee member	Interest declared	Type of interest	Decision taken
Damien Longson	Family member employee of NICE.	Personal family non-specific	Declare and participate
Damien Longson	Director of Research & Innovation, Manchester Mental Health & Social Care NHS Trust.	Personal non-specific financial	Declare and participate
Catherine Briggs	Husband is a consultant anaesthetist at the University Hospital of South Manchester.	Personal family non-specific	Declare and participate
Catherine Briggs	Member of the Royal College of Surgeons, the Royal College of General Practitioners, the Faculty of Sexual and Reproductive Health and the BMA.	Personal non-specific financial	Declare and participate
John Cape	Trustee of the Anna Freud Centre, a child and family mental health charity which applies for and receives grants from the Department of Health and the National Institute for Health Research.	Personal non-specific non-financial	Declare and participate
John Cape	Member of British Psychological Society & British Association for Behaviour & Cognitive Psychotherapists who seek to influence policy towards psychology & psychological therapies.	Personal non-specific non-financial	Declare and participate
John Cape	Clinical Services Lead half-day a week to Big Health, a digital health company that has one commercial product; an online CBT self-help programme for insomnia with online support.	Personal non-specific financial	Declare and participate
Alun Davies	Research grant funding: Commercial: Vascular Insights; Acergy Ltd; Firstkind; URGO laboratoires; Sapheon Inc (terminated 2013). All administered by Imperial College London as Sponsor and Prof Davies as CI.	Personal non-specific financial	Declare and participate

Alun Davies	Non-commercial: National Institute for Health Research, British Heart Foundation, Royal College of Surgeons, Circulation Foundation, European Venous Forum.	Personal non-specific financial	Declare and participate
Alun Davies	Non-commercial: Attendance at numerous national & international meetings as an invited guest to lecture where the organising groups receive funding from numerous sources including device and pharmaceutical manufacturers. Organising groups pay expenses and occasionally honoraria – the exact source of funding is often not known.	Personal non-specific financial	Declare and participate
Alun Davies	Non-commercial: Has received travel expenses to attend the Veith Meeting, New York, November 2013 to give lectures by Vascutek.	Personal non-specific financial	Declare and participate
Alison Eastwood	Member of an independent academic team at Centre for Review & Dissemination, University of York commissioned by NICE through NIHR to undertake technology assessment reviews.	Non-personal non-specific financial	Declare and participate
Sarah Fishburn	Organises workshops for physiotherapists treating pelvic girdle pain. Paid for this work.	Personal non-specific financial	Declare and participate
Sarah Fishburn	Receives payment and expenses from the Nursing and Midwifery Council as a lay panellist of the Fitness to Practise Investigating Committee.	Personal non-specific financial	Declare and participate
Sarah Fishburn	Lay reviewer with the Local Supervising Authority auditing supervision of midwives - receives payment and expenses for this work.	Personal non-specific financial	Declare and participate
Sarah Fishburn	Lay reviewer for the National Institute for Health Research; reviewed a number of research proposals being considered for funding. Paid for carrying out these reviews.	Personal non-specific financial	Declare and participate

Sarah Fishburn	Chair of the Pelvic Partnership, a support group for women with pregnancy-related pelvic girdle pain. This is a voluntary position.	Personal non-specific financial	Declare and participate
Sarah Fishburn	Trained as a chartered physiotherapist and qualified in 1988 but have not been in clinical practice since 1997. Remains a non-practicing member of the Chartered Society of Physiotherapy.	Personal non-specific financial	Declare and participate
Sarah Fishburn	Recently appointed by Mott MacDonald to carry out reviews as a lay reviewer on behalf to the Nursing and Midwifery Council of Local Supervising Authorities and Universities providing courses for nurses and midwives. This is paid work.	Personal non-specific financial	Declare and participate
Jim Gray	Deputy Editor, Journal of Hospital Infection (receive income for this work indirectly through primary employer).	Personal financial non-specific	Declare and participate
Jim Gray	Co-investigator in four major trials (3 HTA-funded; 1 British Council funded). Associate Editor, International Journal of Antimicrobial Agents. Associate Editor, Journal of Pediatric Infectious Diseases. Expert Advisor, British National Formulary for Children.	No-personal financial non-specific	Declare and participate
Jim Gray	My Department is in receipt of an Educational Grant from Pfizer Ltd to develop improved diagnosis of invasive fungal infections in immunocompromised children.	Non-personal financial non-specific	Declare and participate
Nuala Lucas (until December 2014)	Member Obstetric Anaesthetists' Association Executive Committee.	Personal non-specific non-financial	Declare and participate

Nuala Lucas (until December 2014)	Member NICE – Intra-partum Care GDG.	Personal non-specific non-financial	Declare and participate
Nuala Lucas (until December 2014)	Member, Editorial Board, International Journal of Obstetric Anesthesia.	Personal non-specific non-financial	Declare and participate
Kath Nuttall	None		No action
Tilly Pillay	None		No action
Nick Screaton	Attended Thorax meeting – travel expenses paid.	Non-specific personal financial	Declare and participate
Nick Screaton	Senior Editor British Journal of Radiology & Advisory Editor Clinical Radiology.	Non-specific personal financial	Declare and participate
Nick Screaton	Chair of East of England British Institute of Radiology.	Non-specific personal financial	Declare and participate
Nick Screaton	Director – Cambridge Clinical Imaging LTD.	Non-specific personal financial	Declare and participate
Lindsay Smith	None		No action
Philippa Williams	None		No action
Sophie Wilne	Recipient of NHS Innovation Challenge Award for clinical awareness campaign to reduce delays in diagnosis of brain tumours in children & young adults. Award will be used to develop the campaign.	Personal non-specific non-financial	Declare and participate

Sophie Wilne	Co-investigator for RFPB grant to undertake systematic reviews in childhood brain tumours.	Personal non-specific non-financial	Declare and participate
Sophie Wilne	Co-investigator for grant awards from charity to evaluate impact of brain tumour awareness campaign.	Personal non-specific non-financial	Declare and participate
Sophie Wilne	Funding for travel and accommodation from Novartis to attend a conference on the management of tuberous sclerosis.	Personal non-specific financial	Declare and participate
Topic-specific member (LUTS)	Interest declared	Type of interest	Decision
Jan Farrell	Elected onto the British Association of Urology Nurses (BAUN) Council 2015. Expenses paid.	Specific personal financial	Declare and participate
Jan Farrell	Travel scholarship to attend the European Society of Sexual Medicine (ESSM) Annual Conference 2015 from Takeda.	Non-specific personal financial	Declare and participate
Vikky Morris	Speaker fees from Astellas pharma for speaking at 2 one day events.	Non-specific personal financial	Declare and participate
Raj Persad	None		No action
John Taylor	None		No action

Changes after publication

October 2015: A footnote to recommendation 1.6.4 relating to botulinum toxin not having marketing authorisation for the use given in the recommendation has been deleted. Botulinum toxin does now have marketing authorisation for neurogenic detrusor activity because of spinal cord injury or multiple sclerosis, and for overactive bladder with symptoms of urinary incontinence, urgency and frequency.

About this guideline

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

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

The original guideline (published in 2010) was developed by the National Clinical Guideline Centre, which is based at the Royal College of Physicians. The Centre worked with a Guideline Development Group, comprising healthcare professionals (including consultants, GPs and nurses), patients and carers, and technical staff, which reviewed the evidence and drafted the recommendations.

NICE's Clinical Guidelines Update Programme updated this guideline in 2015. These guidelines are updated using a Standing Committee of healthcare professionals, methodologists and lay members from a range of disciplines and localities.

The recommendations were finalised after public consultation.

The methods and processes for developing NICE clinical guidelines are described in the guidelines manual.

NICE produces guidance, standards and information on commissioning and providing high-quality healthcare, social care, and public health services. We have agreements to provide certain NICE services to Wales, Scotland and Northern Ireland. Decisions on how NICE guidance and other products apply in those countries are made by ministers in the Welsh government, Scottish government, and Northern Ireland Executive. NICE guidance or other products may include references to organisations or people responsible for commissioning or providing care that may be relevant only to England.

Update information

A recommendation on phosphodiesterase-5 inhibitors has been added to section 1.4 on drug treatment. A research recommendation on phosphodiesterase-5 inhibitors has been added to section 2.5.

Recommendations are marked as [new 2015] or [2010]:

- [new 2015] indicates that the evidence has been reviewed and the recommendation has been added or updated.
- [2010] indicates that the evidence has not been reviewed since 2010.

Strength of recommendations

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

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

Interventions that must (or must not) be used

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

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

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

Interventions that could be used

We use 'consider' when we are confident that an intervention will do more good than harm for most patients, and be cost effective, but other options may be similarly cost effective. The choice of intervention, and whether or not to have the intervention at all, is more likely to depend on the

patient's values and preferences than for a strong recommendation, and so the healthcare professional should spend more time considering and discussing the options with the patient.

Recommendation wording in guideline updates

NICE began using this approach to denote the strength of recommendations in guidelines that started development after publication of the 2009 version of 'The guidelines manual' (January 2009).

Other versions of this guideline

The full guideline, <u>The management of lower urinary tract symptoms in men</u>, contains details of the methods and evidence used to develop the guideline. It is published by the National Clinical Guideline Centre.

The <u>addendum</u> to the full guideline contains details of the methods and evidence used to develop the updated recommendation (labelled 2015).

The recommendations from this guideline have been incorporated into a <u>NICE pathway</u>.

We have produced information for the public about this guideline.

Implementation

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

Your responsibility

This guidance represents the view of NICE, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer, and informed by the summaries of product characteristics of any drugs.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate

unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

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Accreditation

