

## SCOPE

### 1 Guideline title

The management of male lower urinary tract symptoms (LUTS)

#### 1.1 Short title

Male lower urinary tract symptoms (LUTS)

Background

- a) The National Institute for Health and Clinical Excellence ('NICE' or 'the Institute') has commissioned the National Collaborating Centre for Acute Care to develop a clinical guideline on the management of male lower urinary tract symptoms (LUTS) for use in the NHS in England and Wales. This follows referral of the topic by the Department of Health (see appendix). The guideline will provide recommendations for good practice that are based on the best available evidence of clinical and cost effectiveness.
- b) The Institute's clinical guidelines support the implementation of National Service Frameworks (NSFs) in those aspects of care for which a Framework has been published. The statements in each NSF reflect the evidence that was used at the time the Framework was prepared. The clinical guidelines and technology appraisals published by the Institute after an NSF has been issued will have the effect of updating the Framework.
- c) NICE clinical guidelines support the role of healthcare professionals in providing care in partnership with patients, taking account of their individual needs and preferences, and ensuring that patients (and their carers and families, where appropriate) can make informed decisions about their care and treatment.

## **2 Clinical need for the guideline**

- a) Lower urinary tract symptoms (LUTS) are a collection of symptoms related to problems with the voiding, storage and post-micturition of urine. They generally arise as a result of abnormalities or inadequate functioning of the prostate, urethra, bladder or sphincters. The pathophysiology of LUTS are diverse. In men, benign prostate enlargement, which is secondary to benign prostatic hyperplasia and causes bladder outlet obstruction, is frequently considered to be the major cause of LUTS. However, many other conditions can cause LUTS, including detrusor muscle weakness or overactivity, prostatitis, urinary tract infection, malignancy and neurological disease. In acknowledgement of the non-specific nature of many male LUTS, this clinical guideline will advise on the effective evidence-based management of male LUTS in general, with a specific focus on LUTS associated with benign prostatic disease (presumed benign prostatic hyperplasia).
- b) LUTS in men are best categorised into voiding, storage or post-micturition symptoms to help define the source of the problem. Voiding symptoms (previously known as obstructive symptoms) include weak or intermittent urinary stream, straining, hesitancy, terminal dribbling and incomplete emptying. Storage symptoms (previously known as irritative symptoms, and currently often considered as a symptom complex known as 'overactive bladder') include urgency, frequency, urgency incontinence and nocturia. The major post-micturition symptom is dribbling, which is common and bothersome. Although LUTS do not usually cause severe illness, they can considerably reduce patients' quality of life, and may point to serious pathology of the urogenital tract.
- c) LUTS are a major burden for the ageing male population. Approximately 30% of men aged 50 and older have moderate to severe LUTS. This is a very large group potentially requiring treatment. Age is an important risk factor for LUTS and the

prevalence of LUTS increases as men get older. Other risk factors include hormonal status (presence of androgens), increased size of the prostate gland and bladder decompensation. Ethnicity may also be a risk factor: men of black origin seem to be more likely to need surgery for prostate enlargement than men of white origin. Men of Asian origin seem to be less likely than men of white origin to need surgery.

- d) Because prevalence increases with age, the figure above will continue to rise with increasing life expectancy and the resulting growth of the elderly population. This will place increasing demands on health service resources in the coming years. The past 25 years have seen an increase in the use of pharmacotherapy for LUTS, with a considerable decline in surgical rates. Nevertheless, in England, for the year 2003–2004, there were almost 30,000 endoscopic resections of the male bladder outlet, accounting for more than 138,000 bed days. Although transurethral resection of the prostate is often effective in reducing symptoms in men, it is associated with considerable morbidity and a significant overall annual cost. In addition, a significant proportion of men (25–30%) do not benefit from prostatectomy and have poor post-surgical outcome with no improvement of symptoms. Some failures can be attributed to poor surgical technique, whereas others may be due to incorrect diagnosis of the cause of LUTS. Therefore, to minimise the number of unnecessary operations, predicting the outcome of transurethral resection of the prostate is important.
- e) The British Association of Urological Surgeons primary care guidelines (2004) include recommendations on management and referral to secondary care. There are no specific recommendations on urodynamic studies. The European Association of Urology guidelines (2004) recommend the routine use of uroflowmetry before prostatectomy, and that pressure-flow studies should be used in certain circumstances (but not routinely). According to

expert opinion, most UK clinicians carry out uroflowmetry and, in appropriate patients in secondary care, pressure-flow studies are done before surgical intervention in units with access to the equipment. However, experts agree that there is wide variation in clinical practice in the UK. This is due to individual clinicians' belief in the value of urodynamic studies, and also due to staffing issues and access to the technology. There are many national and international guidelines concerned with the management of men with LUTS; however, these vary in quality.

- f) This NICE clinical guideline will address the variations in practice to allow equitable and appropriate treatment for all affected men. There may be cost savings in defining the appropriate use of suitable investigational modalities and existing pharmacotherapy, and by potentially preventing unnecessary surgical treatment and the costs of failed prostatectomy. However, costs incurred would include the cost of equipment, carrying out the tests and associated staff time. Uncertainty over the effectiveness of urodynamic studies makes it impossible to estimate resource impact.

### **3 The guideline**

- a) The guideline development process is described in detail in two publications that are available from the NICE website (see 'Further information'). 'The guideline development process: an overview for stakeholders, the public and the NHS' describes how organisations can become involved in the development of a guideline. 'The guidelines manual' provides advice on the technical aspects of guideline development.
- b) This document is the scope. It defines exactly what this guideline will (and will not) examine, and what the guideline developers will consider. The scope is based on the referral from the Department of Health (see appendix).

- c) The areas that will be addressed by the guideline are described in the following sections.

### **3.1 *Population***

#### **3.1.1 *Groups that will be covered***

- a) Adult men (18 years or older) with a clinical working diagnosis of LUTS.
- b) Men who have a higher prevalence of LUTS or may be at higher risk including:
- older men
  - men who are of black origin.

#### **3.1.2 *Groups that will not be covered***

- a) Women.
- b) Men younger than 18 years.

### **3.2 *Healthcare setting***

- a) Primary, secondary and tertiary care settings.

### **3.3 *Clinical management***

- a) The clinical and cost effectiveness, and possibly morbidity, of intervention in the management of LUTS.
- b) Initial diagnostic assessments of LUTS, including:
- digital rectal examination (DRE)
  - symptom scores assessments
  - prostate-specific antigen
  - urinary flow rate
  - post-void residual
  - appropriate use of pressure/flow urodynamics
  - cystoscopy.

- c) Monitoring of chronic LUTS.
- d) Non-pharmacological interventions:
- active observation ('watchful waiting')
  - devices (such as catheters, pads and clamps).
  - lifestyle and behavioural changes (such as diet, bladder retraining and pelvic floor exercises).
- e) Pharmacological interventions as first- and/or second-line treatment:
- 5-alpha reductase inhibitors
  - alpha blockers
  - anticholinergics
  - other pharmacotherapeutic agents (such as phytotherapy and phosphodiesterase inhibitors)
  - combination therapy.
- f) Note that guideline recommendations 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 drug's summary of product characteristics to inform their decisions for individual patients.
- g) Surgical interventions or minimally invasive alternatives:
- transurethral electrovaporisation of the prostate
  - transurethral radiofrequency needle ablation of the prostate
  - all forms of laser therapy directed at the prostate, including enucleation and vaporisation
  - transurethral resection of the prostate, including newer forms of therapy such as bipolar excision
  - transurethral incision of the prostate
  - open prostatectomy.

- h) Combinations of the above interventions.
- i) Condition-specific information, support and communication needs of patients, carers and families with LUTS.
- j) General advice on the appropriate evaluation and management of LUTS in men.
- k) The Guideline Development Group will consider making recommendations on the principal complementary and alternative interventions or approaches to care relevant to male LUTS. This will include phytotherapy.
- l) The Guideline Development Group will take reasonable steps to identify ineffective interventions and approaches to care. If robust and credible recommendations for re-positioning the intervention for optimal use, or changing the approach to care to make more efficient use of resources can be made, they will be clearly stated. If the resources released are substantial, consideration will be given to listing such recommendations in the 'Key priorities for implementation' section of the guideline.

### **3.4 Status**

#### **3.4.1 Scope**

This is the final version of the scope.

The NICE has published the following related guidance:

- Urinary incontinence: the management of urinary incontinence in women. NICE clinical guideline 40 (2006)
- Referral guidelines for suspected cancer. NICE clinical guideline 27 (2005)
- Potassium-titanyl-phosphate (KTP) laser vaporisation of the prostate for benign prostatic obstruction. NICE interventional procedure guidance 120 (2005)

- Holmium laser prostatectomy. NICE interventional procedure guidance 17 (2003)
- Transurethral radiofrequency needle ablation of the prostate. NICE interventional procedure guidance 15 (2003)
- Transurethral electrovaporisation of the prostate. NICE interventional procedure guidance 14 (2003).

NICE is in the process of producing the following related guidance:

- Prostate cancer: diagnosis and treatment. NICE clinical guideline (publication expected February 2008).

### **3.4.2 Guideline**

The development of the guideline recommendations will begin on 12 December 2007.

## **4 Further information**

Information on the guideline development process is provided in:

- 'The guideline development process: an overview for stakeholders, the public and the NHS'
- 'The guidelines manual'.

These booklets are available as PDF files from the NICE website ([www.nice.org.uk/guidelinesmanual](http://www.nice.org.uk/guidelinesmanual)). Information on the progress of the guideline will also be available from the website.



## **Appendix: Referrals from the Department of Health**

The Department of Health asked the Institute:

‘To prepare a clinical guideline on the management of benign prostatic hyperplasia.’

‘To prepare a guideline on the assessment, investigation, management and onward referral of men with lower urinary tract symptoms (including male incontinence) within primary care.’