NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

SCOPE

1 Guideline title

Urinary incontinence in neurological disease: management of lower urinary tract dysfunction in neurological disease

1.1 Short title

Lower urinary tract dysfunction in neurological disease

2 The remit

The Department of Health has asked NICE: ‘To produce a clinical guideline on the management of incontinence in neurological disease in all ages’.

3 Clinical need for the guideline

3.1 Epidemiology

a) The function of the urinary bladder is to store and expel urine in a coordinated and controlled manner. The central and peripheral nervous systems regulate this activity. A wide range of neurological conditions can affect the function of the lower urinary tract. The impact of this subsequent urinary dysfunction is variable, with some people experiencing symptoms that relate to impaired bladder storage, while bladder emptying will be a problem for others. Storage and voiding problems may also arise in combination. Neurological lower urinary tract dysfunction can have further important consequences. For example, kidney function can be lost as a result of abnormally high pressures within the bladder, from the effects of urinary tract infection and as a result of urinary tract stone disease.

b) Urinary symptoms resulting from neurological disease can occur because of damage to the brain, the suprasacral spinal cord, the sacral spinal cord (the conus medullaris) or the peripheral nervous system. Damage within each of these areas tends to produce characteristic patterns of bladder and sphincter dysfunction. The nature of the damage to the nervous system is also important. In children the neurological damage is often the result of congenital defects such as cerebral palsy, spina bifida (meningo-myelocoele) or sacral agenesis. It is important to distinguish between conditions that produce a fixed or stable injury to the nervous system (for example stroke, spinal cord injury and cauda equina compression) and those that produce progressive damage through inflammatory or degenerative processes. Progressive conditions include dementia, Parkinson's disease, multiple sclerosis and peripheral neuropathy.

c) One of the most distressing symptoms that arises from neurological lower urinary tract dysfunction is urinary incontinence. The prevalence of such incontinence in the population is not well understood and exact figures are difficult to obtain. The severity and nature of neurological incontinence is dependent on many factors, including the site, the extent and the development of the neurological lesion.

d) It is common for people to have multiple and varied symptoms. Storage symptoms include an increased frequency of urination (by day and/or night), urinary urgency and urinary incontinence. Problems with bladder emptying may lead to hesitancy, a slow urinary stream, the need to strain or urinary retention.

e) Urinary tract symptoms have a significant impact on quality of life; they can cause embarrassment, lead to social isolation and impair activities of daily living. They can also lead to impairments in renal function and reduce life expectancy. The secondary effects of neurological lower urinary tract dysfunction also have an impact on

quality of life; for example, the morbidity associated with recurrent urinary tract infections can be severe. Medical interventions do not necessarily restore normal urinary function. Quality of life is affected by the medical regime used to treat the urinary tract dysfunction; many patients have to cope with the side effects of medication, the impact of catheterisation or the continuing use of pads or appliances.

f) The economic impact of neurogenic urinary tract dysfunction is substantial. Significant expenditure is associated with patient assessment and follow-up, and dealing with complications of treatment. Improving patient care would lead to a better use of public resources and enhance the cost-effectiveness of service delivery. There are also major costs associated with the provision and usage of catheters and pads. Other costs arise through the use of drug treatments and surgical interventions. There is also a huge financial impact as a result of patient requirements for carer, nursing and medical support.

3.2 Current practice

a) A diverse range of interventions is used in the management of urinary incontinence and there is considerable variation in clinical practice. The condition can be managed in a variety of different settings ranging from the community to specialist surgical services. Access to supplies of aids and to specialist advice and services lacks uniformity. The integration between community, primary care and secondary/tertiary hospital services is of great importance and the effectiveness of these links is variable. The transition from paediatric to adult services requires particularly careful management.

b) There are a number of national and international guidelines on neurological lower urinary tract dysfunction. Some relate to specific neurological conditions, others to the range of relevant neurological

conditions. These guidelines are heavily reliant on consensus opinion rather than high-quality scientific evidence.

c) There are often several possible treatment strategies for neurological lower urinary tract dysfunction. A comprehensive review of benefits and risks of different management strategies in both the short and long term is needed to help patients and carers who are faced with a choice between different long-term treatment options.

4 The guideline

The guideline development process is described in detail on the NICE website (see section 6, 'Further information').

This scope defines what the 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.

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

4.1 Population

4.1.1 Groups that will be covered

a) Adults and children (from birth) with lower urinary tract dysfunction resulting from neurological disease and injury.

b) No subgroups of people have been identified as needing specific consideration.

4.1.2 Groups that will not be covered

a) No patient groups have been identified for exclusion.

4.2 Healthcare setting

a) All settings in which NHS care is received.

4.3 Clinical management

4.3.1 Key clinical issues that will be covered

a) Assessment of lower urinary tract function including:

- clinical history and examination
- simple functional tests (for example frequency and volume charts and pad testing)
- urodynamic studies (including cystometry, pressure/flow studies and video-urodynamics).

b) Identification of criteria that should trigger referral for specialist assessment.

c) Management of impaired voiding and storage of urine:

- Physical interventions to aid urinary storage, including behaviour and bladder training, pelvic floor muscle exercises and neuromuscular stimulation.
- Pharmacological therapies to aid urinary storage, for example: antimuscarinic agents and botulinum toxin.
- Surgical procedures to improving bladder storage capacity, for example augmentation cystoplasty and sacral nerve stimulation.
- Surgical procedures to treat incontinence resulting from sphincter weakness such as the use of urethral tapes, urethral slings, and the artificial urinary sphincter.
- Physical aids to bladder emptying for example:
  - intermittent catheterisation
  - indwelling urethral and suprapubic catheters
  - catheter valves.
- Drug therapy to improve bladder emptying, including alpha adrenergic antagonists.
- Urinary diversion procedures, including ileal conduit.
- Appliances and equipment to contain urinary incontinence.

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 decisions made with individual patients.

d) Follow up protocols and management strategies to prevent and treat the complications of neurogenic lower urinary tract dysfunction and its management.

e) Managing the transition from child to adult services.

f) Information and support for patients and carers.

4.3.2 Clinical issues that will not be covered

a) General management of the underlying disorder.

b) Management of associated faecal incontinence, sexual dysfunction or psychological problems.

c) Management of comorbidities.

4.4 Main outcomes

There are many possible outcome measures that may be relevant to neurological lower urinary tract dysfunction. Among those we plan to consider are:

a) Frequency of voiding by day and night.

b) Number of incontinence episodes per week.

c) Severity of incontinence.

d) Urgency.

e) Symptoms relating to bladder emptying, for example poor urinary stream.

f) Quality of life.

g) Patients and carers' perception of symptoms.

h) Adverse events, including urinary tract infections, renal complications, bladder stones and unscheduled hospital admissions.

i) Treatment adherence.

j) Kidney function.

4.5 Economic aspects

Developers will take into account both clinical- and cost-effectiveness when making recommendations involving a choice between alternative interventions. A review of the economic evidence will be conducted and analyses will be carried out as appropriate. The preferred unit of effectiveness is the quality-adjusted life year (QALY), and the costs considered will usually be only from an NHS and personal social services (PSS) perspective. Further detail on the methods can be found in 'The guidelines manual' (see ‘Further information’).

4.6 Status

4.6.1 Scope

This is the final scope.

4.6.2 Timing

The development of the guideline recommendations will begin in October2010.

5 Related NICE guidance

5.1 Published guidance

5.1.1 NICE guidance to be updated

This guideline will update and replace part of the following NICE guidance (recommendations on bladder problems and urinary tract infections only):

- Multiple sclerosis. NICE clinical guideline 8 (2003). Available from www.nice.org.uk/guidance/CG8

5.1.2 Other related NICE guidance

- Constipation in children and young people. NICE clinical guideline 99 (2010). Available from www.nice.org.uk/guidance/CG99
- Male lower urinary tract symptoms. NICE clinical guideline 97 (2010). Available from www.nice.org.uk/guidance/CG97
- Lapararoscopic augmentation cystoplasty (including clam cystoplasty). NICE interventional procedure guidance 326 (2009). Available from www.nice.org.uk/guidance/IPG326
- Chronic kidney disease. NICE clinical guideline 73 (2008). Available from www.nice.org.uk/CG73
- Single-incision sub-urethral short tape insertion for stress urinary incontinence in women. NICE interventional procedure guidance 262 (2008). Available from www.nice.org.uk/guidance/IPG262
- Suburethral synthetic sling insertion for stress urinary incontinence in men. NICE interventional procedure guidance 256 (2008). Available from www.nice.org.uk/guidance/IPG256
- Insertion of extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in men. NICE interventional procedure guidance 224 (2007). Available from www.nice.org.uk/guidance/IPG224
- Urinary tract infection in children. NICE clinical guideline 54 (2007). Available from www.nice.org.uk/guidance/CG54

- Faecal incontinence. NICE clinical guideline 49 (2007). Available from www.nice.org.uk/guidance/CG49
- Dementia. NICE clinical guideline 42 (2006). Available from www.nice.org.uk/guidance/CG42
- Parkinson's disease. NICE clinical guideline 35 (2006). Available from www.nice.org.uk/guidance/CG35
- Urinary incontinence. NICE clinical guideline 40 (2006). Available from www.nice.org.uk/guidance/CG40
- Insertion of biological slings for stress urinary incontinence. NICE interventional procedure guidance 174 (2006). Available from www.nice.org.uk/guidance/IPG154
- Intramural urethral bulking procedures for stress urinary incontinence. NICE interventional procedures guidance 138 (2005). Available from www.nice.org.uk/guidance/IPG138
- Insertion of extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in women. NICE interventional procedure guidance 133 (2005). Available from www.nice.org.uk/guidance/IPG133
- Transobturator foramen procedures for stress urinary incontinence. NICE interventional procedure guidance 107 (2005). Available from www.nice.org/guidance/IPG107
- Sacral nerve stimulation for urge incontinence and urgency-frequency. NICE interventional procedure guidance 82 (2004). Available from www.nice.org.uk/guidance/IPG82
- Infection control, prevention of healthcare-associated infection in primary and community care. NICE clinical guideline 2 (2003). Available from www.nice.org.uk/guidance/CG2

5.2 Guidance under development

NICE is currently developing the following related guidance (details available from the NICE website):

- Nocturnal enuresis in children (bedwetting). NICE clinical guideline. Publication expected October 2010.
- Percutaneous posterior tibial nerve stimulation for overactive bladder syndrome. NICE interventional procedure guidance. Publication expected Autumn 2010.Infection control (update). NICE clinical guideline. Publication expected March 2012.
- Stroke rehabilitation. NICE clinical guideline. Publication expected April 2012.
- Spasticity in children. NICE clinical guideline. Publication expected June 2012.

6 Further information

Information on the guideline development process is provided in:

- 'How NICE clinical guidelines are developed: an overview for stakeholders the public and the NHS'
- 'The guidelines manual'.

These are available from the NICE website (www.nice.org.uk/GuidelinesManual). Information on the progress of the guideline will also be available from the NICE website (www.nice.org.uk).