

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## QUALITY STANDARDS PROGRAMME

**Quality standard topic:** Lower urinary tract symptoms in males

**Output:** Briefing paper

### Introduction

This briefing paper presents a structured evidence review to help determine the suitability of recommendations from the key development sources, listed below, to be developed into a NICE quality standard. The draft quality statements and measures presented in this paper are based on published recommendations from the following key development sources:

[Lower urinary tract symptoms: The management of lower urinary tract symptoms in men](#). NICE clinical guideline 97 (2010).

### Structure of the briefing paper

The body of the paper presents supporting evidence for the draft quality standard reviewed against the three dimensions of quality: clinical effectiveness, patient experience and safety. Information is also provided on available cost-effectiveness evidence and current clinical practice for the proposed standard. Where possible, evidence from the clinical guideline is presented. When this is not available, other evidence sources have been used.

# 1 Initial assessment

## 1.1 NICE CG97 Recommendation 1.1.2 [KPI]

### 1.1.1 Relevant NICE clinical guideline recommendations and proposed quality statement

<b>Guideline recommendations</b>	1.1.2 At initial assessment, offer men with lower urinary tract symptoms (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).
<b>Proposed quality statement</b>	Men with lower urinary tract symptoms are offered a full physical examination at their initial assessment [including DRE].
<b>Draft quality measure</b>	<p><b>Structure:</b> Evidence of local arrangements to ensure men with lower urinary tract symptoms (LUTS) are offered a full physical examination at their initial assessment [including DRE].</p> <p><b>Process:</b> Proportion of men with lower urinary tract symptoms offered a full physical examination at their initial assessment [including DRE].</p> <p>Numerator – The number of men in the denominator who receive a full physical examination at their initial assessment [including DRE].</p> <p>Denominator – The number of men with LUTS.</p> <p><b>Outcome:</b></p> <p>Incidence of suspected LUTS in men</p> <p>Rates of diagnosis of LUTS in men</p>
<b>Definitions</b>	<p>Digital rectal examination (DRE)</p> <p>A routine test that is used to detect abnormalities of the prostate gland. The doctor or nurse inserts a gloved and lubricated finger (digit) into the patient's rectum, which lies just behind the prostate.</p>
<b>Discussion points for TEG</b>	

### **1.1.2 Clinical and cost-effectiveness evidence**

The diagnosis recommendations cover initial assessment and specialist assessment. Initial assessment refers to assessment carried out in any setting by a healthcare practitioner without specific training in the management of male LUTS. Specialist assessment refers to assessment carried out in any setting by a healthcare practitioner with specific training in the management of LUTS.

Recommendation 1.1.2 is based on GDG consensus and no clinical or economic studies were identified. The GDG agreed that diagnosis and effective management of symptoms was not possible without a history and examination. The GDG considered that a digital rectal examination (DRE) is good practice to identify abnormalities of the prostate and associated conditions which might affect bladder function.

### **1.1.3 Patient experience**

The GDG noted the short-term complications of embarrassment and transient discomfort of DRE.

### **1.1.4 Patient safety**

No patient safety evidence was identified (see full report from the patient safety function at the NHS Commissioning Board for broader themes).

### **1.1.5 Current practice**

Current practice in primary care for the assessment and management of LUTS appears to be variable. The NICE clinical guideline notes that there is uncertainty and variation in clinical practice on the diagnosis, monitoring and treatment of LUTS.

The GDG noted that DRE is not being done regularly and felt that it was important to raise awareness.

The National Audit of Continence Care<sup>1</sup> (2010) investigated the frequency of documentation for rectal examination within the different healthcare settings of acute (Hospital), Primary Care, Mental Health and Care Homes. The study population was split into under and over 65 years of age. It concluded that in both age groups, assessment for prostate size are documented most consistently in the hospital setting with 41% of the over 65s and 43% of the under 65s in comparison to only 13% of the over 65s and 0% in the under 65 age group being documented in care homes.

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<sup>1</sup> Royal College of Physicians. National Audit of Continence Care 2010. <http://www.rcplondon.ac.uk/resources/national-audit-continence-care>

## Initial assessment – urinary frequency volume chart

### 2.1 NICE CG97 Recommendation 1.1.3 [KPI]

#### 2.1.1 Relevant NICE clinical guideline recommendations and proposed quality statement

<b>Guideline recommendations</b>	1.1.3 At initial assessment, ask men with bothersome lower urinary symptoms (LUTS) to complete a urinary frequency volume chart.
<b>Proposed quality statement</b>	Men with bothersome lower urinary tract symptoms [are asked to] complete a urinary frequency volume chart at their initial assessment.
<b>Draft quality measure</b>	<p><b>Structure:</b> Evidence of local arrangements to ensure men with bothersome lower urinary tract symptoms (LUTS) are asked to complete a urinary frequency volume chart.</p> <p><b>Process:</b> Proportion of men with bothersome LUTS who complete a urinary frequency volume chart.</p> <p>Numerator – The number of men in the denominator who complete a urinary frequency volume chart.</p> <p>Denominator – The number of men with bothersome LUTS.</p> <p><b>Outcome:</b></p>
<b>Definitions</b>	<p>Bothersome LUTS</p> <p>LUTS that are worrying, troublesome or have an impact on quality of life from the patient’s perspective.</p> <p>Urinary frequency volume chart</p> <p>A chart that records voided volumes and times of voiding (day and night) for at least 24 hours.</p>
<b>Discussion points for TEG</b>	<ul style="list-style-type: none"> <li>• Is there a time period within which the volume chart should be completed?</li> <li>• Is it necessary for the statement to focus on asking men to complete a chart?</li> </ul>

#### 2.1.2 Clinical and cost-effectiveness evidence

Recommendation 1.1.3 is based on GDG consensus and no clinical or economic studies were identified.

Voiding diaries are simple, non-invasive tools that are frequently part of the initial evaluation of patients complaining of LUTS, particularly those who have storage

symptoms such as increased urinary frequency and incontinence. These diaries give an indication of the voiding pattern, the severity of symptoms and they add objectivity to the history. Voiding diaries are also useful in identifying abnormalities of renal origin such as abnormal production of urine related to the circadian rhythm.

The GDG felt that completing a urinary frequency volume chart was important to build on information obtained from the medical history and will help the clinician to make an accurate diagnosis of the underlying cause of the symptoms.

### **2.1.3 Patient experience**

The GDG noted there are no side effects or harms associated with completing the chart but can be time consuming for the patients. The GDG noted that most patients find diaries acceptable for use over short periods.

### **2.1.4 Patient safety**

None identified.

### **2.1.5 Current practice**

The GDG identified a number of different diaries as defined by the International Continence Society (ICS), such as micturition Time Chart, Frequency/Volume Chart (FVC) and bladder diaries.

The National Audit of Continence Care (2010) concluded the documented use of any bladder diary in men occurred in around half of the notes audited; 53% of the under 65 years cases in primary care. A lower proportion of 30% of older men appear to have a documented use of bladder diary in clinical practice.

### 3 Initial assessment –lifestyle interventions

#### 3.1 NICE CG97 Recommendation 1.1.12

##### 3.1.1 Relevant NICE clinical guideline recommendations and proposed quality statement

<b>Guideline recommendations</b>	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.
<b>Proposed quality statement</b>	Men with lower urinary tract symptoms are offered advice on lifestyle interventions at their initial assessment.
<b>Draft quality measure</b>	<p><b>Structure:</b> Evidence of local arrangements to ensure men with lower urinary tract symptoms (LUTS) are offered advice on lifestyle interventions at their initial assessment.</p> <p><b>Process:</b> Proportion of men with LUTS who are offered advice on lifestyle interventions at their initial assessment.</p> <p>Numerator – The number of men in the denominator receiving advice on lifestyle interventions at their initial assessment.</p> <p>Denominator – The number of men with LUTS.</p> <p><b>Outcome:</b></p>
<b>Definitions</b>	
<b>Discussion points for TEG</b>	<ul style="list-style-type: none"> <li>• There is potential overlap with recommendation 1.1.12 and the published generic patient experience quality standard.</li> <li>• As written, the draft quality statement focuses only on the lifestyle intervention aspect at initial assessment.</li> <li>• The evidence for offering advice on lifestyle interventions specifically at initial assessment will need to be considered.</li> </ul>

### **3.1.2 Clinical and cost-effectiveness evidence**

Recommendation 1.1.12 is based on GDG consensus and no clinical or economic studies were identified. The GDG considered that giving reassurance and information is essential for men with non-bothersome symptoms who may be concerned of underlying causes.

The topic of advice on lifestyle interventions (fluid intake and types of fluids) is also addressed within the section of conservative management in the full guideline.

The GDG noted the following:

- Advice on moderation of fluid intake is given by most services treating LUTS. There is much confusion over how much people should drink but there is some consensus that fluid intake should be based on body weight. However, patients (particularly those with storage LUTS) will often reduce their fluid intake excessively as a coping strategy, resulting in worsened symptoms and increased risk of infection.
- Advice on the modification of the type of fluids consumed is commonly provided to men with LUTS. Reduction in the intake of fluids containing alcohol, caffeine and artificial sweeteners together with avoidance of carbonated drinks is often advised by clinicians in the hope that this will reduce LUTS.

#### **Lifestyle interventions:**

The GDG noted that current evidence for lifestyle impact is of poor quality and a better understanding of different lifestyle elements (e.g. diet) and whether they are linked to causing LUTS or the progression of LUTS is needed.

### **3.1.3 Patient experience**

No patient experience information was identified.

### **3.1.4 Patient safety**

None identified.

### **3.1.5 Current practice**

The National Audit of Continence Care (2010) concluded overall, younger patients were much more likely to receive lifestyle and health advice than older patients.

### **3.1.6 Current indicators**

None identified.

## 4 Specialist assessment

### 4.1 NICE CG97 Recommendation 1.2.5

#### 4.1.1 Relevant NICE clinical guideline recommendations and proposed quality statement

<b>Guideline recommendations</b>	1.2.5 Offer men with LUTS who are having specialist assessment a measurement of flow rate and post void residual volume.
<b>Proposed quality statement</b>	Men with lower urinary tract symptoms undergoing specialist assessment are offered a measurement of flow rate and post void residual volume.
<b>Draft quality measure</b>	<p><b>Structure:</b> Evidence of local arrangements to ensure men with LUTS who are undergoing specialist assessment are offered a measurement of flow rate and post void residual volume.</p> <p><b>Process:</b> Proportion of men with LUTS who are undergoing specialist assessment are offered a measurement of flow rate and post void residual volume.</p> <p>Numerator – The number of men with LUTS who are undergoing specialist assessment who receive a measurement of flow rate and post void residual volume.</p> <p>Denominator – The number of men with LUTS undergoing specialist assessment.</p> <p><b>Outcome:</b></p>
<b>Definitions</b>	<p>Specialist assessment</p> <p>Specialist assessment refers to assessment carried out in any setting by a healthcare practitioner with specific training in the management of male lower urinary tract symptoms.</p>
<b>Discussion points for TEG</b>	

#### 4.1.2 Clinical and cost-effectiveness evidence

Recommendation 1.2.5 is based on evidence drawn from diagnostic studies evaluating the use of post void residual measurement in making a diagnosis in men with LUTS. The GDG considered that increasing the chance of an accurate diagnosis upon which to base management was the most important outcome when comparing test versus no test.

The evidence did not support its use at initial assessment.

The GDG felt that at specialised assessment, the benefit of correctly diagnosing obstruction was important for considering treatment options and that this test could be useful and cost effective, although evidence is limited.

The GDG considered that this test is important to be completed at specialised assessment as it adds information to other tests to give an overall diagnosis. All studies were performed at secondary care setting with high prevalence and so the GDG concluded that these should be used to inform recommendations for this setting.

#### **4.1.3 Patient experience**

The GDG noted that the ability of men with physical disability to perform these tests may need specific consideration.

#### **4.1.4 Patient safety**

No specific information identified.

#### **4.1.5 Current practice**

The National Audit of Continence Care (2010) concluded that at initial assessment, 51% the younger cohort of the under 65s within the acute hospital setting documented evidence of post void residual volume in comparison to 36% of the older cohort.

#### **4.1.6 Current indicators**

None identified.

## 5 Conservative management - urethral milking

### 5.1 NICE CG97 Recommendation 1.3.1

#### 5.1.1 Relevant NICE clinical guideline recommendations and proposed quality statement

<b>Guideline recommendations</b>	1.3.1 Explain to men with post micturition dribble how to perform urethral milking.
<b>Proposed quality statement</b>	Men with post micturition dribble are informed on how to perform urethral milking.
<b>Draft quality measure</b>	<p><b>Structure:</b> Evidence of local arrangements to ensure men with lower urinary tract symptoms (LUTS) who have post micturition dribble are informed on how to perform urethral milking.</p> <p><b>Process:</b> Proportion of men with post micturition dribble who are informed on how to perform urethral milking.</p> <p>Numerator- The number of men in the denominator who receive information on how to perform urethral milking.</p> <p>Denominator – The number of men with LUTS who have post micturition dribble.</p> <p><b>Outcome:</b></p>
<b>Definitions</b>	<p>Post micturition dribble</p> <p>The term used when an individual describes the involuntary loss of urine immediately after he has finished passing urine, usually after leaving the toilet.</p> <p>Urethral milking</p> <p>This technique is also known as (post void milking), bulbar urethral elevation or bulbar urethral massage. This technique eliminates post micturition dribble (PMD) which is not associated with obstruction but may be caused by the urethra being emptied incompletely by the muscles surrounding it. To perform the technique the man places his fingers behind his scrotum after urinating and gently massage his bulbar urethra in a forwards and upwards direction. This releases the urine that is retained in the bulbar urethra and therefore eliminates the PMD.</p>
<b>Discussion points for TEG</b>	When should men be informed on this? At presentation, initial assessment or other point in the pathway?

### **5.1.2 Clinical and cost-effectiveness evidence**

Recommendation 1.3.1 is drawn from a single randomised controlled trial reporting the effect of post void milking on post-micturition dribbling (mean urine loss) in men who report LUTS. There is evidence that post void urethral milking is effective in men with post micturition dribble at 0 – 3 months follow up.

The GDG noted this was a very small study with limitations.

### **5.1.3 Patient experience**

No patient experience information was identified.

### **5.1.4 Patient safety**

None identified.

### **5.1.5 Current practice**

The National Audit of Continence Care (2010) concluded a low proportion of their study population required or had received urethral milking treatment with only 6% in the over 65s receiving this treatment in care homes and only 8% of the over 65s in the primary care setting.

The GDG concluded that it would be very easy to implement urethral milking as a technique if not already used in practice. There are leaflets available and many clinicians are aware of this technique. The technique is easy to learn and patients can usually master this technique in one session.

### **5.1.6 Current indicators**

None identified.

## 6 Conservative management for storage lower urinary tract symptoms

### 6.1 NICE CG97 Recommendation 1.3.2 [KPI] & 1.3.3

#### 6.1.1 Relevant NICE clinical guideline recommendations and proposed quality statement

<b>Guideline recommendations</b>	<p>1.3.2 Offer men with storage LUTS (particularly urinary incontinence) temporary containment products (for example, pads or collecting devices) based on individual circumstances and in consultation with the man to achieve social continence until a diagnosis and management plan have been discussed.</p> <p>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.</p>
<b>Proposed quality statement</b>	Men with storage LUTS are offered [a choice of] containment products following a discussion of the management plan.
<b>Draft quality measure</b>	<p><b>Structure:</b> Evidence of local arrangements to ensure men with storage LUTS are offered containment products following a discussion of the management plan.</p> <p><b>Process:</b> Proportion of men with storage LUTS are offered containment products following a discussion of the management plan.</p> <p>Numerator – The number of men in the denominator who receive containment products.</p> <p>Denominator – The number of men with storage LUTS [who have had a discussion of the management plan].</p> <p><b>Outcome:</b></p>
<b>Definitions</b>	<p>Storage LUTS</p> <p>Containment products</p> <p>Containment products designed to contain or divert the urine leaked during an episode of incontinence are widely used in men with LUTS involving incontinence. These include absorbent products (body worn pads, pants with integral pads, bed pads), external collection devices (sheath appliances, pubic pressure urinals), indwelling catheters and penile clamps.</p> <p>Permanent containment products</p>
<b>Discussion points for TEG</b>	<p>The concept of ‘choice’ is difficult to measure and ‘individual circumstances’. The draft statement as written is focussed on ensuring that products are offered only after a discussion of the management plan.</p> <p>Does this capture the intent of the recommendations?</p>

	<p>What is specifically meant by a temporary containment product?</p> <p>What is storage LUTS</p>
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### 6.1.2 Clinical and cost-effectiveness evidence

The GDG reviewed the evidence for the effect of one type of product (pads, pants, bed pants, penile sheaths appliances and penile clamps) versus no product or other conservative therapy on a range of relevant outcomes in men who report LUTS.

Only one RCT was identified which compared the effectiveness of penile clamps.

The GDG identified one economic study, a Health Technology Assessment (HTA) comparing different types of products for incontinence (inserts, diapers, pull-ups, T-shaped, washables). This was considered to have some usefulness in informing GDG decision making. The aim of this trial was to compare the performance and cost-effectiveness of the key absorbent product designs to guide selection and purchase.

The HTA study also included women and men with faecal incontinence although only one of the three RCTs included in the HTA assessment was included for the GDG review according to the male/female ratio of patients enrolled. In this study, patients living in the community setting were asked to rate their preference for one product. This study showed that there were significant and substantial differences between the designs of absorbent products and for moderate/heavy incontinence some designs are better for men than others. There was considerable individual variability in preferences and cost-effective management may best be achieved by allowing users to choose combinations of designs for different circumstances within a budget.

The GDG concluded (on the basis of the HTA) that the cost-effectiveness of products is uncertain and that the utility of containment products will vary by patient. In addition, given the considerable individual variability, the GDG concluded that a choice of products appear to be the most practical way to offer cost effective management of LUTS patients given the evidence available. These considerations support recommendation 1.3.3 above.

The GDG concluded that early implementation of continence support with appropriate products should be made available to all patients, taking into account personal preferences and clinical experience. The GDG agreed that pads or incontinence products should be offered as early as possible, even if a definite diagnosis has not yet been reached and a management plan formulated. These considerations support recommendation 1.3.2 above.

In relation to the permanent use of containment products, the GDG noted that products only help manage the incontinence. One the basis of limited evidence, the

GDG concluded that permanent could be 'considered' for men with storage LUTS only after assessment and exclusion of other methods of management. These considerations support recommendation 1.3.14.

This is a 'consider' recommendation reflecting the uncertainty in the evidence.

### **6.1.3 Patient experience**

The GDG noted men may have different preferences of product types and that product preference also depends on lifestyle and severity of the incontinence. A patient may also prefer different types of product for night time versus day time use and when going out compared to staying in.

For washable products, the GDG stated the privacy and practicalities of washing were concerns for men.

### **6.1.4 Patient safety**

None identified.

### **6.1.5 Current practice**

The NICE guideline notes that containment products designed to contain or divert the urine leaked during an episode of incontinence are widely used in men with LUTS involving incontinence. These include absorbent products (body worn pads, pants with integral pads, bed pads), external collection devices (sheath appliances, pubic pressure urinals), indwelling catheters and penile clamps.

The National Audit of Continence Care (2010) concluded that the proportionate use of disposable pads increases in the older cohort and across the sectors, with 19% of over 65s in care homes using these most frequently. Catheter use in primary care reflects what is known of community prevalence with only 7% over 65s and 4% of under 65s receiving this treatment.

Catheters used in hospitals is short term, for retention, rather than as management for incontinence which is reflected in the audit with 6% of over 65s and 9% of under 65s using intermittent catheterisation.

## 7 Conservative management for storage lower urinary tract symptoms

### 7.1 NICE CG97 Recommendation 1.3.14

#### 7.1.1 Relevant NICE clinical guideline recommendations and proposed

<b>Guideline recommendations</b>	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.
<b>Proposed quality statement</b>	Men with storage LUTS are [offered] permanent containment products following assessment and exclusion of other methods of management.
<b>Draft quality measure</b>	<p><b>Structure:</b> Evidence of local arrangements to ensure men with storage LUTS are offered permanent containment products following assessment and exclusion of other methods of management.</p> <p><b>Process:</b> Proportion of men with storage LUTS are offered permanent containment products following assessment and exclusion of other methods of management.</p> <p>Numerator – The number of men in the denominator who receive offered permanent containment products following assessment and exclusion of other methods of management.</p> <p>Denominator – The number of men with storage LUTS.</p> <p><b>Outcome:</b></p>
<b>Definitions</b>	<p>LUTS storage symptoms</p> <p>Permanent containment products</p>
<b>Discussion points for TEG</b>	

#### 7.1.2 Clinical and cost-effectiveness evidence

See related section 6 above for additional information.

In relation to the permanent use of containment products, the GDG noted that products only help manage the incontinence. On the basis of limited evidence, the GDG concluded that permanent containment products could be 'considered' for men with storage LUTS only after assessment and exclusion of other methods of management. These considerations support recommendation 1.3.14 which is a 'consider' recommendation reflecting the uncertainty in the evidence.

### **7.1.3 Patient experience**

See section 6 above.

### **7.1.4 Patient safety**

None identified.

### **7.1.5 Current practice**

No specific information was identified on permanent use of containment products.

See section 6 above.

## 8 Drug treatment

### 8.1 NICE CG97 Recommendation 1.4.7

#### 8.1.1 Relevant NICE clinical guideline recommendations and proposed quality statement

<b>Guideline recommendations</b>	1.4.3 Offer an alpha blocker (alfuzosin, doxazosin, tamsulosin or terazosin) to men with moderate to severe LUTS
<b>Proposed quality statement</b>	Men with moderate to severe LUTS are [offered] an alpha blocker
<b>Draft quality measure</b>	<p><b>Structure:</b> Evidence of local arrangements to ensure men with moderate to severe LUTS are offered an alpha blocker.</p> <p><b>Process:</b> Proportion of men with moderate to severe LUTS who are treated with an alpha blocker.</p> <p>Numerator – The number of men in the denominator who receive an alpha blocker.</p> <p>Denominator – The number of men with moderate to severe LUTS.</p> <p><b>Outcome:</b></p>
<b>Definitions</b>	Moderate to severe LUTS
<b>Discussion points for TEG</b>	

#### 8.1.2 Clinical and cost-effectiveness evidence

##### Alpha blockers

There is evidence from randomised controlled trials across a range of relevant outcomes (symptom scores, quality of life, adverse events) to support the use of alpha blockers for men with moderate to severe LUTS, as recommended in recommendation 1.4.3.

The GDG concluded that alpha blockers are cost-effective for men with moderate to severe symptoms.

### **Anticholinergic added on to alpha blockers in men who were still symptomatic after treated with alpha blockers.**

- Recommendation 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.

One randomised controlled trial which investigated the benefits of adding an anticholinergic to men with severe LUTS who did not achieve adequate control with alpha blockers. In the study this was defined as still symptomatic ((IPSS  $\geq 13$ , with IPSS (Storage $\geq 8$ )) to alpha blockers after at least 4 weeks of treatment for alpha blockers.

The study demonstrated statistically significant improvements among patients who had inadequate response to alpha blockers. However, improvements were very small and the benefits perceptible to patients were uncertain, that is, the change which can be recognised by a patient as being clinically significant. No economic evidence was found on combinations of anticholinergic and alpha blockers. It was the GDG opinion that generally the benefits of combination treatment would not be considered cost effective although concluded that when alpha blockers alone are not working, adding an anticholinergic could be justified.

In conclusion, the GDG reflected uncertainty in the reviewed evidence – recommendation 1.4.7 is a ‘consider’ recommendation.

#### **8.1.3 Patient experience**

Men with LUTS may opt for watchful waiting rather than medical (or surgical) treatment either if the symptoms are not bothersome or if they perceive that potential adverse events of treatment are greater than the benefits of treatment. This is particularly likely if they can be reassured that the likelihood of disease progression is low. This choice is often patient led.

#### **8.1.4 Patient safety**

None identified.

#### **8.1.5 Current practice**

Drug treatment is frequently initiated in primary care by general practitioners; particularly the use of alpha blockers and to a lesser extent 5-alpha reductase inhibitors.

The National Continence Audit (2010) identified that the use of alpha blockers in men with moderate to severe LUTS was lower than expected – for men over 65 the

documented use of an alpha blocker was 26% in primary care and 34% in secondary care.

#### **8.1.6 Current indicators**

None identified.

## 9 Surgery for voiding symptoms

### 9.1 NICE CG97 Recommendation 1.5.1

#### 9.1.1 Relevant NICE clinical guideline recommendations and proposed quality statement

<b>Guideline recommendations</b>	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.
<b>Proposed quality statement</b>	Men with lower urinary tract symptoms and voiding symptoms whose symptoms have not responded to treatment or conservative management options are offered surgery.
<b>Draft quality measure</b>	<p><b>Structure:</b> Evidence of local arrangements to ensure men with LUTS voiding symptoms are offered surgery if drug treatment and conservative management options have been unsuccessful or are not appropriate.</p> <p><b>Process:</b> Proportion of men with LUTS voiding symptoms are offered surgery if drug treatment and conservative management options have been unsuccessful or are not appropriate.</p> <p>Numerator – The number of men in the denominator who receive surgery if drug treatment and conservative management options have been unsuccessful or are not appropriate.</p> <p>Denominator – The number of men with LUTS voiding symptoms if drug treatment and conservative management options have been unsuccessful or are not appropriate.</p> <p><b>Outcome:</b></p>
<b>Definitions</b>	LUTS voiding symptoms
<b>Discussion points for TEG</b>	

#### 9.1.2 Clinical and cost-effectiveness evidence

The goals of treatment for men with bothersome voiding symptoms are to reduce the severity of symptoms together with the bother that they cause, to normalise the dynamics of the lower urinary tract and to resolve or prevent complications. Decisions about treatment options must balance likely benefits with the possible occurrence and severity of side effects. Transurethral resection of prostate (TURP)

has been the mainstay of treatment for symptomatic benign prostatic enlargement (BPE) for many years since it combines high effectiveness with a previously acceptable side effect profile.

The population considered in this statement is men with bothersome LUTS predominantly voiding symptoms, who have failed to respond to conservative or pharmacological therapy. Some men will have undergone multichannel cystometry and will have been shown to have evidence of bladder outlet obstruction. These men are the most likely to benefit from surgery.

The GDG searched for RCT evidence comparing the effectiveness of different surgical interventions for lower urinary tract symptoms. The interventions they included including TUNA, laser, TUMT, TURP, TUIP, open prostatectomy, botulinum toxin, HoLEP, HIFU, TUVF and no treatment. The GDG noted that surgical interventions are associated with high costs and should be offered only if other treatments have failed.

### **9.1.3 Patient experience**

No patient experience information was identified.

### **9.1.4 Patient safety**

Two reports received to the NRLS which indicate that either inappropriate surgery was undertaken or there was an inappropriate delay in the surgery being offered.

### **9.1.5 Current practice**

Current practice in primary care for the assessment and management of LUTS appears to be variable. The NICE clinical guideline notes that there is uncertainty and variation in clinical practice on the diagnosis, monitoring and treatment of LUTS.

More recently, in the UK, men have tended to seek help earlier in the natural history of the disease and access to secondary health care has improved. This, together with more patients presenting with increasing co-morbidities present in the ageing population at risk, and the desire of health providers to contain costs, has fuelled the search for less morbid invasive treatments. These interventions can be sub-divided into surgical procedures that generally involve removal of prostate tissue requiring general or regional anaesthesia and minimally invasive options, which do not require general anaesthesia and can be carried out in a day case setting.

The availability of different techniques will differ from hospital to hospital depending on the training and experience of the urologists who work there. Decisions about surgical treatment will always be the result of an honest and balanced discussion

between surgeon and patient which must include information about the relative benefits and risks of each available procedure. It is particularly important that the surgeon is able to give information about outcomes in his/her own practice, not just evidence from the literature. Some patients may choose the most efficacious procedure, whilst others may be keen to trade efficacy for lower perioperative morbidity and shorter hospital stay.

The National Audit of Continence Care (2010) concluded TURP dominates the list of procedures when surgery for voiding symptoms in men is performed.

#### **9.1.6 Current indicators**

None identified.

## **Appendix A: Definition of patient safety**

The National Patient Safety Agency (NPSA) defines patient safety in the following terms:

Every day more than a million people are treated safely and successfully in the NHS, but the evidence tells us that in complex healthcare systems things will and do go wrong, no matter how dedicated and professional the staff. When things go wrong, patients are at risk of harm, and the effects are widespread and often devastating for patients, their families and the staff involved. Safety incidents also incur costs through litigation and extra treatment, and in 2009/10 the NHSLA paid out approximately £827,000,000 in litigation costs and damages. These incidents are often caused by poor system design rather than the error of individuals i.e. 'they are an accident waiting to happen'.

In short patient safety could be summarised as 'The identification and reduction of risk and harm associated with the care provided to patients' or 'Preventing patients from being harmed by their treatment'. Examples of this might be 'operating on or removing the wrong organ, ten times the dose of an opioid, giving a colonoscopy to the wrong patient with the same name as someone else in the waiting room etc.' These risks are unlikely to be identified through clinical trials or traditional evidence bases and so other evidence sources, such as the National Reporting and Learning System, need to be analysed to highlight the risks and improve system development. This does not however give an accurate picture of prevalence in that way that methods such as casenote review may do.

**On 1 June 2012 the key functions and expertise for patient safety developed by the National Patient Safety Agency (NPSA) transferred to the NHS Commissioning Board Special Health Authority.** For more information, please see [www.commissioningboard.nhs.uk](http://www.commissioningboard.nhs.uk) and [www.nrls.npsa.nhs.uk](http://www.nrls.npsa.nhs.uk).