LUTS/BPS – scope consultation comments table (4 September – 29 October 2007)

Status	Organisation	Order no.	Section	Comments	Responses
SH	Addenbrookes Hospital, Cambridge University Hospital NHS Trust	1	3b	Suggest change last sentence from "..and may occasionally point to serious pathology of the urogenital tract " to " and may point to serious pathology of the urogenital tract ".	We agree and have amended this sentence as suggested.
SH	Age Concern England			This organisation was approached but did not respond.	
SH	Aintree University Hospitals NHS Foundation Trust			This organisation was approached but did not respond.	
SH	Allergan	1	General	Allergan currently has an on-going comprehensive formal clinical development program underway aiming to fully elucidate the role of botulinum toxin type-A as a treatment for the management of BPH. Key data from the clinical trials program will be presented during the lifetime of this guideline and we feel it is important to bring this to your attention. We would recommend that the therapy should only be used in the controlled clinical trials setting until the full potential has been identified via the formal clinical trials program.	Thank you for informing the developers of this treatment for the management of BPH. We will conduct an update search towards the end of the development period to include any emerging evidence after the initial search.
SH	Allergan	2	4.3 d	Under the section other pharmacotherapeutic agents; we feel it would be appropriate to name the specific agents which may be considered in the management of BPH when existing therapies have failed. As such botulinum toxin type-A, where there is emerging data should be named as a therapeutic option which may become available during the lifetime of this guideline but which at present should be restricted to use in the context of clinical trials.	The developers consider the list of pharmacological interventions to be appropriate. This guideline scope has not excluded the consideration of 2nd line treatments. We will conduct an update search towards the end of the development period to include any emerging evidence after the initial search.
SH	Allergan	3	4.3 d	As any use of botulinum toxin type-A for the management of BPH represents an unlicensed use of the class, it is important that its' use is considered against a background of the current literature. In consideration of reference to botulinum toxin type-A appropriately in this guideline, please find attached a recent literature review. Search engine: PUBMED Time period: 2005-2007 (Sept) Search terms: botulinum toxin type-A & prostate	Please note that guideline recommendations on prescribing will normally fall within licensed indications; exceptionally, and only where clearly supported by evidence, use outside a licensed indication may be recommended. Thank you for noting these references.

Status	Organisation	Order no.	Section	Comments	Responses
				Botulinum toxin for the treatment of lower urinary tract symptoms due to benign prostatic hyperplasia. *Antunes etal.,* Nat Clin Pract Urol 2007;4(3):155-60. **Botulinum-A toxin: An exciting new treatment option for prostatic disease** *Thomas CA etal.,* Int J Clin Pract 2006;60(Suppl 151):33-37. **The role of botulinum toxin in benign prostatic hyperplasia** *Goldstraw MAet al.,* BJU Int 2006; 98(6):1147-1148. **Botulinum: A toxin for the treatment of benign prostatic hyperplasia/lower urinary tract symptoms.** *Thomas CA etal.,* Curr Prostate Rep 2006;4(2):75-80. **The application of botulinum toxin in the prostate** *Chuang & Chancellor* J Urol 2006; 176(6):2375-82. **Evaluation of short term clinical effects and presumptive mechanism of botulinum toxin type A as a treatment modality of benign prostatic hyperplasia.** *Park et al.,* Med J 2006;47(5):706-14. **Sustained beneficial effects of intraprostatic botulinum toxin type A on lower urinary tract symptoms and quality of life in men with benign prostatic hyperplasia + Comment** *Chuang et al.,* BJU Int 2006;98(5):1033-7. **The use of botulinum toxin in men with benign prostatic hyperplasia** *Rusnack & Kaplan* Rev Urol 2005 Fall;7(4):234-6. **Other therapies for BPH patients: Desmopressin, anti-cholinergic, anti-inflammatory drugs, and botulinum toxin** *Azzouzi* World J Urol 2006;24(4):383-388. **Intraprostatic injection of botulinum toxin type A could relieve BPH symptoms** *Author Unknown* Nat Clin Pract Urol 2006 Jul;3(7):350. **Novel action of botulinum toxin on the stromal and epithelial components of the prostate gland** *Chuang* J Urol 2006 Mar;175(3):1158-63. **The initial experience of intraprostatic injection of botulinum toxin type A for benign prostatic hyperplasia: A comparative study of short-term effect with transurethral resection of prostate (KOR)** *Park et al.,* Korean J Urol 2005;46(11):1173-1179.	

Status	Organisation	Order no.	Section	Comments	Responses
				Botulinum toxin type A improves benign prostatic hyperplasia symptoms in patients with small prostates *Chuang et al.,* Urology 2005;66(4):775-779. **Intraprostatic Botox: An injection in patients with severe benign prostatic hyperplasia. A multicenter study** *Guercini et al.,* Eur Urol Suppl 2005 Mar;4(3):150 ABS-589. **Evaluation of short term clinical effects and presumptive mechanism of botulinum toxin type A as a treatment modality of benign prostatic hyperplasia** *Park et al.,* Abstr Internat Continence Soc (ICS) 2005;ABS-487. **Botulinum toxin type A imporves [improves] benign prostatic hyperplasia symptoms in patients with small prostates** *Chuang et al.,* Abstr Internat Continence Soc (ICS) 2005;ABS-204. **Intraprostatic botulin toxin injection in patients with severe benign prostatic hyperplasia: A multicenter feasibility study** *Guercini et al.,* J Urol 2005 Apr;173(4 Suppl):376 ABS-1387. **Prostate botulinum A toxin injection: An alternative treatment for benign prostatic obstruction in poor surgical candidates** *Kuo* Urology 2005 Apr;65(4):670-4.	
SH	American Medical Systems			This organisation was approached but did not respond.	
SH	Association for Clinical Biochemistry			This organisation was approached but did not respond.	
SH	Association for Continence Advice			This organisation was approached but did not respond.	
SH	Association of the British Pharmaceuticals Industry,(ABPI)			This organisation was approached but did not respond.	
SH	Astellas Pharma Ltd	1	General	Following the initial consultation on the SCOPE document for the management of LUTS associated with BPH, NICE have decided on broadening the remit of this document and developing guidelines for LUTS in general rather than LUTS specifically associated with BPH. We at Astellas fully support this change as we feel that this will assist clinicians in identifying the underlying cause of LUTS and enable them to treat the underlying pathology appropriately. Below are a few points taken from the previous SCOPE	Thank you for your comments. We have broadened the scope to cover adult men with a clinical working diagnosis of LUTS. We have amended the scope to reflect this and modified the title to "Management of male lower urinary tract symptoms".

Status	Organisation	Order no.	Section	Comments	Responses
				document with respect to the above issue along with our comments. *In section 3, "Clinical need for the guideline", it is acknowledged that the pathophysiology of lower urinary tract symptoms (LUTS) is diverse and BPH is the most common cause of LUTS* *In section 4.1.1 it is clearly stated that this document is primarily for the treatment of men aged 18 years and above with a clinical working diagnosis of LUTS who might on clinical grounds be suspected to have benign prostatic hyperplasia (BPH) as a cause of benign prostatic enlargement (BPE).* *Furthermore, it is acknowledged that due to the non-*specific nature of many male LUTS, these guidelines will also provide guidance on the effective evidence-based management of male LUTS in general.	
SH	Astellas Pharma Ltd	2	General	Astellas Pharma Ltd. would like to emphasis the importance of elaborating the above issue in the guideline, as LUTS is not only associated with BPH but can be associated with a number of conditions; most importantly idiopathic OAB due to detrusor over activity, for which the treatment is not an alpha blocker but an anti-cholinergic. Hence it is important to be aware of this and be able to differentiate between these two conditions and other causes of LUTS, to manage patients effectively. Although, we do appreciate that the severity of LUTS is not directly proportional to the extent of enlargement of the prostate gland. However, at the same time patients suffering from LUTS due to BPH or BPE do usually have at least some enlargement of the prostate gland. It is important to perform a digital rectal examination (DRE) to appreciate and recognise this enlargement and this may require explaining in this document. The DRE will prevent patients suffering from LUTS due to idiopathic OAB, being prescribed an alpha blocker, and will facilitate them getting the appropriate treatment in the form of an anti-cholinergic.	The guideline is now covering adult men with a clinical working diagnosis of LUTS. We agree and have added 'digital rectal examination' (DRE) to the list of diagnostic assessments (section 4.3a).

Status	Organisation	Order no.	Section	Comments	Responses
SH	Astellas Pharma Ltd	3	4.3(d)	2) Section 4.3.(d) refers to the pharmacological interventions that will be considered as first and second line treatment for LUTS associated with BPH. Among these is the use of combination pharmacological therapy. Combination therapy for LUTS with an alpha adrenoceptor antagonist and a 5-alpha reductase inhibitor is established clinical practice. We would like to draw attention to the emerging concept of treating BPH patients with LUTS and associated OAB with the combination of an alpha adrenoceptor antagonist and an anti-cholinergic. A combination product on these lines has already been launched in India and hence, we feel that the scope document should cover this treatment option as well.	The guideline scope has included combination therapy. Evidence will be sought and considered by the GDG.
SH	Astellas Pharma Ltd	4	4.3	Finally, prostate specific antigen (PSA) is an important initial investigation for older men with LUTS and a marker for diagnosing and monitoring prostate cancer. A lot of the men diagnosed with prostate cancer initially present to their doctor with LUTS. Hence, it is important that despite there being a separate NICE guideline for prostate cancer, some mention should be given in this document on the level of PSA at which a GP should consider referral to the secondary care for TRUS prostate biopsies.	This may be considered if the guideline development group prioritise this question.
SH	Barnsley Hospital NHS Foundation Trust			This organisation was approached but did not respond.	
SH	Bedfordshire PCT			This organisation was approached but did not respond.	
SH	Boehringer Ingelheim Ltd	1	3	There is reluctance among men to seek medical evaluation. Only 5.6% of men with urinary symptoms consulted a doctor during the previous year for their urinary symptoms, whilst the majority remain with no treatment or no health professional advice (Simpson et al Br J Gen Pract 1994:44:499-502). Despite evidence that over 30% of men with LUTS felt that they needed help with their urinary symptoms, less than half actually sought help.(Taylor et al. BJU Int 2006;98:605-609) This behaviour suggests the possibility of low awareness that something can be done. Earlier diagnosis and intervention may help to improve outcomes and reduce morbidity and so should be encouraged.	Thank you for your comments. Evidence on diagnosis will be sought and considered by the GDG.

Status	Organisation	Order no.	Section	Comments	Responses
SH	Boehringer Ingelheim Ltd	2	3.d	We support the comments in this section that recognise that the use of pharmacological treatments in primary care may be associated with the considerable decline in surgical rates. In this regard we note the following figures: • Surgical rates have dropped by 16% over the last 5 years1 – (based on Data from England). In 2004 there were about 33,000 surgical operations for BPH in the UK at an estimated annual cost of £60m[1,2]. The present annual surgical rate is similar to that reported in 1990[1,3]. We also support the statement in this section that surgery can be associated with significant morbidity. We would provide the following information to support the value of early diagnosis of BPH and the risks associated with surgery: • Over 40% of those receiving BPH surgery present as emergencies[4]. 25% present with acute retention of urine, which carries a twofold risk of death and complications compared with prostatectomy for symptoms alone[4,5]. Operative risks are increased because the average age amongst those receiving surgery for BPH is relatively high at 70-74 years old[4]. Many also present with chronic urinary retention. Earlier detection and management of BPH may allow for the potential for successful conservative management and reducing the higher morbidity and even mortality associated with late presentation.	Thank you for your comments and relevant references.
SH	Boehringer Ingelheim Ltd	3	Refs	**References** 1.NHS Reference Costs produced by Department of Health at http://www.dh.gov.uk/PolicyAndGuidance/OrganisationPolicy/FinanceAndPlanning/NHSReferenceCosts/fs/en 2. Data on File. Boehringer Ingelheim. April 2006. 3. McNicholas TA. Management of Symptomatic BPH in the	Thank you for noting these references.

Status	Organisation	Order no.	Section	Comments	Responses
				UK: Who is treated and how? Eur Urol. 1999; 36(3):33-39. 4. Health Needs Assessment Series produced by Department of Public Health and Epidemiology at the University of Birmingham. Chapter on Benign Prostatic Hyperplasia at http://hcna.radcliffe-oxford.com/urinframe.html 5. Pickard RS, Emberton M and Neal DE. The management of men with acute urinary retention. Br J Urol 1998: 81; 712-20 6. Department of Health: Departmental Report 2005 at http://www.dh.gov.uk/PublicationsAndStatistics/Publications/AnnualReports/DHAnnualReportsArticle	
SH	Boehringer Ingelheim Ltd	4	4.2	The Department of Health's ***Choosing health through pharmacy*** initiative is clearly aimed at improving men's access to pharmacy. It promotes support for self-care for men and proposes that pharmacists can provide a more male-oriented service. (DH NHS 2005 choosing health through pharmacy) BPH management in pharmacy fits with the Department of Health's key aim for increasing accessibility of medicines and developing expert patients in long term conditions such as diabetes, asthma, heart disease etc.(DH NHS support for people with long term conditions 2006)	We are unable to look at service organisation issues within the remit of the guideline. However, we will be looking at effectiveness of treatments.
SH	Boehringer Ingelheim Ltd	5	4.2	The pharmacy environment is becoming more conducive to providing confidential consultation services like stop-smoking, sexual health including contraception and Chlamydia screening. Pharmacists are experienced in providing care for long term conditions such as asthma, diabetes, carrying out medical reviews, encouraging the effective use of medicines, etc. Hence, the role of the pharmacist would encourage a shared care approach in order to get men into primary care for a diagnosis as early as possible.	Thank you for your comment.
SH	Bolton Council			This organisation was approached but did not respond.	
SH	British Association of Urological Nurses			This organisation was approached but did not respond.	
SH	British Association of Urological Surgeons (BAUS)			This organisation was approached but did not respond.	
SH	British National Formulary (BNF)			BNF will not be taking part.	

Status	Organisation	Order no.	Section	Comments	Responses
SH	British Pain Society	1	General 3.b	The document should consider pain and discomfort as presenting symptoms of lower urinary tract dysfunction. Pain and discomfort may, or may not, be associated with voiding, storage or post-micturition symptoms. Sensory abnormalities, primarily, pain, discomfort and urge to void, are the commonest reasons for men under the age of 50 to present to a Urologist. In the past these sensory abnormalities were classified as interstitial cystitis and prostatitis. A better description would be prostate pain syndrome. Classification of lower urinary tract symptoms (LUTS) needs to include pain and discomfort. 1. Sand PK, Dmochowski R. Analysis of the standardisation of terminology of lower urinary tract function: report from the Standardisation Sub-committee of the International Continence Society. Neurourol Urodyn 2002; 21: 167-78. 2. Abrams P et al. A new classification is needed for pelvic pain syndromes - are existing terminologies of spurious diagnostic authority bad for patients? J Urol 2006; 175: 1989-90.	Thank you for your comments and references. The guideline development group will consider this point.
SH	British Pain Society	2	General	Both physical and psychological disability is associated with LUTS and may be severe. 1. Tripp DA et al. Catastrophizing and pain-contingent rest predict patient adjustment in men with chronic prostatitis/chronic pelvic pain syndrome. J Pain 2006; 7: 697–708. 2. Fall M et al. European Association of Urology guidelines on chronic pelvic pain. http://www.uroweb.org/fileadmin/user_upload/Guidelines/22_Chronic_Pelvic_Pain_2007.pdf	We will ensure the guideline development group considers this point. Thank you for noting these references.
SH	British Pain Society	3	4.3.b	Pain is frequently a major complaint in patients with LUTS. The science of the pain mechanisms and sensory abnormalities is well described and needs to be considered more widely by urologists. If a well defined cause for these symptoms has been excluded, a pain / symptom management approach can be undertaken, which prevents un-necessary re-investigation and invasive therapies. 1. Bielefeldt K, Gebhart GF. Visceral pain: basic mechanisms.	The scope has been broadened to include all men with LUTS. Pain would be considered in the initial assessment of LUTS. Thank you for noting these references.

Status	Organisation	Order no.	Section	Comments	Responses
				In: McMahon SB, Koltzenburg M, eds. Textbook of pain, 5th edn. New York: Churchill Livingstone, 2006: 721–36. 2. Baranowski AP, Abrams P, Fall M, eds. Urogenital pain in clinical practice. To be out December 2007.	
SH	British Pain Society	4	4.3.e	Appropriate peri-operative pain management is important, particularly for open prostatectomy. Chronic neuropathic pain is increasingly recognised as a complication of major pelvic surgery.	This is not explicitly excluded from the guideline. However, it may be considered if the guideline development group prioritise this.
SH	British Pain Society	5	4.3.g	Education of patients, carers and families is important. Education of medical practitioners is also important. 1. Diagnostic criteria, classification, and nomenclature for painful bladder syndrome/interstitial cystitis: an European Society for the Study of Interstitial Cystitis proposal. Baranowski AP et al. Eur Urol. In press.	Training of professionals is not within the remit of the guideline. However, we hope that this guideline will be educational to this group. We will be producing a professional and patient version of the guidance.
SH	British Pain Society	6	4.3.i	Once the sensory / pain syndrome has been identified, early referral to a pain clinic should be considered. Neuropathic analgesics, physiotherapy, nerve blocks and neuromodulation may all have a role in management. A multidisciplinary approach should be considered as the symptoms are sensory, psychological and sexual. 1. Rothrock NE et al. Coping strategies in patients with interstitial cystitis: relationships with quality of life and depression. J Urol 2003; 169: 233–6. 2. Raphael KG. Childhood abuse and pain in adulthood - more than a modest relationship? Clin J Pain 2005; 21: 371–3. 3. Sand PK, Dmochowski R. Analysis of the standardisation of terminology of lower urinary tract function: report from the Standardisation Sub-committee of the International Continence Society. Neurourol Urodyn 2002; 21: 167-78. 4. Fall M et al. European Association of Urology guidelines on chronic pelvic pain. http://www.uroweb.org/fileadmin/user_upload/Guidelines/22_Chronic_Pelvic_Pain_2007.pdf	This may be considered if the guideline development group prioritise it. Thank you for noting these references.

Status	Organisation	Order no.	Section	Comments	Responses
SH	Calderdale PCT			This organisation was approached but did not respond.	
SH	Chartered Physiotherapists Promoting Continence (CPPC)	1	general	No mention of plans to look at specific conservative management strategies associated with incontinence symptoms that may arise with BPH & post-TURP. Would recommend that Pelvic Floor Muscle rehabilitation in men is specifically included.	Thank you – evidence for non-pharmacological interventions will be sought and considered by the guideline development group (section 4.3c). We have added pelvic floor exercises as an example of behavioural and lifestyle changes in section 4.3(G).
SH	Commission for Social Care Inspection			This organisation was approached but did not respond.	
SH	Connecting for Health			This organisation was approached but did not respond.	
SH	Continence Foundation			This organisation was approached but did not respond.	
SH	Conwy LHB			This organisation was approached but did not respond.	
SH	Department of Health	1	General	In our view, the current use of urodynamics in general in this group of patients is variable. We feel that there is not a great deal of evidence to definitively say one way or the other whether urodynamics (either selectively or universal), improve outcome. In our opinion, the International Consultation on Incontinence (2004, published 2005) recommended measurement of urinary flow rate and post void residual in all of these patients, for whom surgical intervention was planned. Filling cystometry and pressure-flow studies were only recommended for those patients who had some incontinence with their LUTS, and for whom surgical intervention was planned. Could you please consider the inclusion of the following in your scope: • Would it be reasonable to assume that all who are planned to have surgery for LUTS/BPH would have measurement of urinary flow rate and post void residual? • Would it be reasonable to suspect that many urologists would expect to have filling cystometry and pressure-flow studies, if they are planning surgery (especially if the patient has incontinence)?	Thank you for your comments. Urodynamics are included within clinical management in the scope (section 4.3a). This will be considering the "appropriate use of pressure/flow urodynamics". The guideline development group will consider all these questions when prioritising the clinical questions.

Status	Organisation	Order no.	Section	Comments	Responses
				• Is there a need for any provision for filling cystometry and pressure-flow studies before initiating pharmacological therapy in some patients? (e.g. if detrusor over-activity is suspected, is it safe to involve the use of anticholinergic agents without knowing detrusor function during voiding)? • Does videourodynamics have any role in the initial treatment of this group of patients? • We feel that there are also the groups of patients with Parkinson's disease who need urodynamics, and the question of bladder outlet obstruction versus low pressure, low flow (the latter may present with identical symptoms, cannot be confidently identified on a flow test and have only a 50% chance of improvement of symptoms on treatment). In our view, it is answers to questions like these that would give an idea of the number and type of urodynamic tests that need to be carried out in this group of patients, and the implications for 18 weeks.	
SH	Department of Health	2	General	"If the remit is now lower urinary tract symptoms, it includes everything that could cause urinary symptoms. In our view, this will be a large project. From the physiological measurement perspective, we feel that it should include appropriate use of flow rate studies, residual urine measurements and the appropriate referral for urodynamic investigations (cystometry, videocystometry and ambulatory monitoring)".	Thank you for your comments. We agree that this is a large project. The guideline development group will need to prioritise the clinical questions covered within the guideline. All these points will be considered by the group.
SH	Department of Health, Social Security and Public Safety of Northern Ireland			This organisation was approached but did not respond.	
SH	Ferring Pharmaceuticals Ltd	1	3a	Primary nocturnal enuresis (PNE) would need to be covered by this scope as a specific topic. There are reports of PNE continuing into adulthood in anywhere between 0.5% and 2.3% of the adult population. In a paper published by the British Journal of Urology 2.3% of 8534 adult patients aged between	Thank you for your comments. The evidence retrieved on the subject will be considered by the guideline development group.

Status	Organisation	Order no.	Section	Comments	Responses
				16-40 had PNE (*Yeung CK. British Journal of Urology International; 2004; 93(3)341-345*). It is commonly found that the incidence of bedwetting is higher in males than in female with the above paper stating 2.7% in males compared with 2.0% in females. There is a forthcoming guideline on PNE in children but this guideline would not cover the management of adults with this condition. It has been noted that bedwetting tends to be more prevalent in male children than female. Approximately 10% of child bedwetters continue wetting into adulthood (*Nappo et al British Journal of Urology International (2002), 90, 912–917: Nocturnal enuresis in the adolescent: a neglected problem*). It would be important to have adult bedwetting covered to some degree in a clinical guideline such as this.	
SH	Ferring Pharmaceuticals Ltd	2	General	Ferring are interested in the areas of BPH, PNE and also nocturia and we look forward to commenting on the draft guideline in the future.	Thank you for your comment.
SH	GlaxoSmithKline UK	1	**3b**	The document is focusing upon LUTS associated with BPH. It is indicated in this section that LUTS do not usually cause severe illness. However it would be useful to indicate in the scope that: ▪ progression of LUTS/BPH can lead to incapacitating sequelae such as acute urinary retention (AUR) and the need for BPH-related surgery [***Marks et al]*** ▪ LUTS can considerably reduce patients' quality of life, and may occasionally point to serious pathology of the urogenital tract. Reference: • ***Marks L, Roehrborn C, Andriole G . Prevention of Benign Prostatic Hyperplasia Disease J Urol Vol. 176, 1299-1306, October 2006).***	Thank you for your comments. We feel that these points are adequately addressed in this section. The section states that "they can considerably reduce patients' quality of life, and may point to serious pathology of the urogenital tract". Evidence retrieved on complications and quality of life will be considered by the GDG.
SH	GlaxoSmithKline UK	2	**4.1.1**	The scope of this document is to focus on men aged 18 years old or more. However published evidence to date suggests that LUTS as a result of BPH appears to be rare in men aged 40 years or less. It therefore may be useful to restrict the population to men aged 40 year or more.	We feel that it is appropriate to look at all men over the age of 18 as all causes of LUTS are now being considered in the guideline.

Status	Organisation	Order no.	Section	Comments	Responses
				References: ▪ ***Thorp A, Neal D. Benign prostatic hyperplasia. Lancet 2003;361:1359-67 Logie J, Clifford GM, Farmer RDT. Incidence, prevalence and management of lower urinary tract symptoms in men in the UK. Brit J Urol Int 2005;95:557-62.*** ▪ ***Sarma AV, Jacobson DJ, McCree ME et al. A population-based study of incidence and treatment of benigh prostatic hyperplasia among residents of Olmsted County, Minn: 1987 to 1997. J Urol 2005;173:2048-53.***	
SH	GlaxoSmithKline UK	3	**4.3 a):**	• Initial diagnostic assessments to identify the aetiology of LUTS are listed in this section. However, medical history, symptom score, urinalysis (including creatinine measurement), physical examination in general and more specifically using both digital rectal estimation (DRE) and transrectal ultrasound (TRUS) to determine prostate size are not included in this list. As these are standard as part of urological assessments we feel they should also be included in this section. ▪ We acknowledge the pending publication of the Prostate Cancer guidelines, but it may be worth also including in this section that the appropriate diagnostic and screening for prostrate cancer will be conducted as part of the symptomatic presentation of LUTS. This will require some assessment of PSA as mentioned in this section, but possibly also a sub-setting of the population as the need to screen will vary with age. • Please note there is a typo in this section, it should be CYSTOSCOPY not cytoscopy.	We have added DRE and symptom scoring to this section. However, this list of diagnostic tests is not meant to be exhaustive. We have amended the text to clarify this point. We have included PSA as one of the diagnostic tests. The GDG will prioritise additional diagnostic tests to be covered in the guideline. We will refer relevant men to the NICE clinical guideline on Prostate Cancer (due to be published February 2008). Thank you for pointing out the spelling mistake – we have corrected this.
SH	Health Commission Wales			This organisation was approached but did not respond.	
SH	Heart of England NHS Foundation Trust			This organisation was approached but did not respond.	

Status	Organisation	Order no.	Section	Comments	Responses
SH	Incontact (Action on Incontinence)	1	4.1.2	Will patients be excluded who have a co-morbidity of prostate cancer? It would be expected, as this is already under consideration.	Thank you for your comments. Patients with a co-morbidity of prostate cancer will be referred to the NICE clinical guideline on Prostate Cancer (due to be published February 2008).
SH	Incontact (Action on Incontinence)	2	4.3.a	We presume the scope means Cystoscopy. No mention of prostate sampling.	Thank you – we have amended this spelling mistake. The diagnostic tests included will be prioritised by the guideline development group.
SH	Incontact (Action on Incontinence)	3	4.3.c	No mention of fluid advice, F/V charts etc – please include. Reference to the Guideline of Oct 2006, will consideration be given to other conservative measures not already listed e.g pelvic floor exercises. There is plenty of evidence to support this.	The lists of diagnostic tests are examples and not meant to be exhaustive. Fluid advice and pelvic floor exercises are included under lifestyle and behavioural changes in section 4.3C.
SH	Incontact (Action on Incontinence)	4	4.3.h	Please include pads, sheaths etc in this section.	These will be considered by the guideline development group.
SH	Incontact (Action on Incontinence)	5	General	No mention of planning to look at the specific conservative management of incontinence symptoms associated with BPH and in particular post TURP. We note that you plan to reference the urinary incontinence guideline, but this only is specific to women. We would wish to recommend that conservative management in particular pelvic floor muscle rehabilitation of males is included.	The scope will consider non-pharmacological interventions including watchful waiting and lifestyle and behavioural changes. This will include pelvic floor exercises.
SH	Institute of biomedical Science			This organisation was approached but did not respond.	
SH	Leeds PCT			This organisation was approached but did not respond.	
SH	Leeds Teaching Hospitals Trust			This organisation was approached but did not respond.	
SH	London School of Hygiene and Tropical Medicine			This organisation was approached but did not respond.	
SH	Luton & Dunstable Hospital NHS Foundation Trust			This organisation was approached but did not respond.	
SH	Medicines and Healthcare Products Regulatory Agency (MHRA)			This organisation was approached but did not respond.	
SH	Medtronic Ltd	1	General	Medtronic feel this is a balanced and rational scope which includes all relevant technologies and treatment options for	Thank you for your comment.

Status	Organisation	Order no.	Section	Comments	Responses
				symptomatic BPH.	
SH	National Patient Safety Agency			This organisation was approached but did not respond.	
SH	National Public Health Service - Wales			This organisation was approached but did not respond.	
SH	NHS Cancer Screening Programmes			This organisation was approached but did not respond.	
SH	NHS Clinical Knowledge Summaries service			This organisation was approached but did not respond.	
SH	NHS Direct	1	General	No comments from NHS Direct. Happy with scope.	Thank you.
SH	NHS Plus			This organisation was approached but did not respond.	
SH	NHS Quality Improvement Scotland			This organisation was approached but did not respond.	
SH	Norfolk & Waveney Prostate Cancer Support			This organisation was approached but did not respond.	
SH	North Tees PCT			This organisation was approached but did not respond.	
SH	Oldham PCT			This organisation was approached but did not respond.	
SH	PERIGON Healthcare Ltd			This organisation was approached but did not respond.	
SH	Pfizer Ltd	1	1 and 1.1	We request the guideline title be amended to remove reference to BPH. We have 3 reasons why the guideline title and focus should be "The management of male lower urinary tract symptoms": *1) Recent evidence suggests OAB is an important contributor to LUTS alone or in addition to BPH.* We agree male patients experiencing LUTS are likely to suffer from BPH; however, recent evidence confirms that these patients may solely or additionally suffer from OAB and other LUTS symptoms. (Rosenberg 2007) • One study showed that 43% of older men with LUTS suffer from detrusor overactivity not bladder outlet obstruction (Hyman 2001) • Another study shows only 50% of men with preoperative detrusor overactivity will have resolution after outlet	Thank you for your comments. We have amended the title to remove the reference to BPH. The title is "The management of male lower urinary tract symptoms". We agree that it is important to accurately diagnose the underlying causes of LUTS. The evidence on diagnosis will be sought and considered by the GDG.

Status	Organisation	Order no.	Section	Comments	Responses
				reduction surgery (van Venrooij 2002) • The majority of men under 50 years of age with LUTS do not have BPH (Kaplan 1996) *2) BPH is a histological diagnosis that does not capture overlapping symptoms of LUTS.* The term BPH can be misleading as it carries several interpretations that are now obsolete since standard terminology is available for LUTS (Chapple 2006). Epidemiological studies of male LUTS indicate the categorisation of urinary symptoms as BPH does not adequately capture the true nature of the complexity of the overlapping symptoms of storage, voiding and post-micturition. The EPIC study (Irwin 2006), performed in 2005 in 19,165 participants ≥18 years old from the UK, Canada, Germany, Italy and Sweden, highlighted the fact that rarely do urinary symptoms exist individually. EPIC found that among men with OAB (10.8% of all men), storage symptoms have a prevalence of 26.9%, voiding 29.7% and post-micturition 16.9%. There is also increased bother with increased symptoms and all must be considered when evaluating patients diagnosing their urinary symptoms. *3) Clear identification and separation of the underlying cause of symptoms is fundamental to the successful management of male LUTS.* Understanding and the appropriate management of LUTS attributable to OAB is critical to ensure accurate diagnosis and management of BPH. Without consideration of bladder or other causes as an underlying cause for symptoms, inappropriate pharmacotherapy or surgery may be undertaken.	
SH	Pfizer Ltd	2	General	There is inconsistency on the guideline title in the various documents and communications. It is important to not interchange terminology between BPH and LUTS as these have different clinical implications. As BPH is a sub-group of LUTS and the guideline scope is broader than just BPH, we suggest all documentation should refer to the title as male LUTS. In addition, to avoid confusion and aid synergies, a NICE clinical guideline for the management of male LUTS would be consistent with other NHS programmes such as the 18 week pathway www.18weeks.nhs.uk	During the consultation period we received an additional remit from the department of health on men with lower urinary tract symptoms. This was combined with this guideline on Benign Prostatic Hyperplasia to broaden the scope. We have amended the title to "The management of male lower urinary tract symptoms". Thank you for referencing this information source – we

Status	Organisation	Order no.	Section	Comments	Responses
					are aware of this initiative. However, the guideline will not be covering service organisation.
SH	Pfizer Ltd	3	3a	Post-micturition symptoms should be added to the first sentence.	We agree and have amended the scope accordingly.
SH	Pfizer Ltd	4	3a	Although benign prostate enlargement is frequently considered to be the major cause of LUTS, we request it is made clear that this may not always be the case and LUTS can be associated with OAB alone or in addition to BPH.	We feel that this is adequately addressed in section 3b, which refers to storage symptoms as a symptom complex known as overactive bladder.
SH	Pfizer Ltd	5	3d	We agree that failure of surgery may be due to incorrect diagnosis of the cause of LUTS. This is one of the reasons why the guideline needs to focus on the management of male LUTS and should not emphasise BPH alone.	We agree and the guideline has been amended to cover adult men with lower urinary tract symptoms.
SH	Pfizer Ltd	6	4.1.1a	The age group of 18 years and older is appropriate and this provides more reason why the emphasis on BPH should be removed from the guideline. The majority of men under 50 years of age with LUTS do not have BPH (Kaplan 1996).	We agree that the age group of 18 years and older is appropriate for the guideline.
SH	Pfizer Ltd	7	4.1.1a	Inclusion of OAB alone or OAB in addition to BPH as a specific group that will be covered is critical to providing a clinical guideline that is reflective of current terminology for LUTS and advances accurate diagnosis and appropriate treatment of LUTS with (or without) BPH.	We agree and have broadened the scope to cover all adult men who are 18 years or older with a clinical working diagnosis of LUTS. This will include men with LUTS due to overactive bladder.
SH	Pfizer Ltd	8	4.1.1a & 4.3b	Reference to “uncomplicated BPH” in 4.1.1a and “uncomplicated LUTS/BPH” in 4.3b is unclear and potentially misleading. Male LUTS has a varied, complex pathophysiology that may be multifactorial – the terminology “uncomplicated” is therefore unclear.	Thank you – we agree and have removed reference to “uncomplicated BPH” in these sections.
SH	Pfizer Ltd	9	4.3h	Advice on the appropriate evaluation and management of all men with LUTS is integral to the appropriate management of BPH. It is vital to classify LUTS appropriately and not emphasise BPH as the single most important factor. It is unclear how the clinical guideline will provide “general advice” on male LUTS if this were not made an integral part of the scope. The scope should be broadened to the management of male LUTS.	We agree and have broadened the scope to the management of male LUTS. The title has been modified to “the management of male lower urinary tract symptoms”.
SH	Pfizer Ltd	10	Refs	**REFERENCES** Chapple CR, Roehrborn CG. A shifted paradigm for the further understanding, evaluation, and treatment of lower urinary tract	Thank you for noting these references.

Status	Organisation	Order no.	Section	Comments	Responses
				symptoms in men: Focus on the bladder. *European Urology* 2006;49:651-9 Hyman MJ et al. Detrusor instability in men: correlation of lower urinary tract symptoms with urodynamic findings. *J Urol* 2001;166:550-3 Kaplan SA et al. Etiology of voiding dysfunction in men less than 50 years of age. *Urology* 1996;47:836-9 Rosenberg MT et al. A practical guide to the evaluation and treatment of male lower urinary tract symptoms in the primary care setting. *Int J Clin Pract* 2007; 61(9): 1535-1546 Van Venrooij GE et al. Correlations of urodynamic changes with changes in symptoms and well-being after transurethral resection of the prostate. *J Urol* 2002;168:605-9	
SH	Primary Care Pharmacists Association			This organisation was approached but did not respond.	
SH	PRIMIS+			This organisation was approached but did not respond.	
SH	PSA Prostate Cancer Support Association	1	General	We have been informed that the decision to add the 16th Wave LUTS remit ("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.") was taken at a late stage, and apparently after the 14th Wave LUTS/BPH Scope had been drafted. At best, the inclusion of the 16th Wave remit can be seen expressed in the Scope as only a rather inadequate afterthought. It is not clear from the Scope whether LUTS in general (as opposed to LUTS associated with BPH) will be covered only in respect of primary care, or throughout service provision. These distinctions matter from a patient's point of view, because what a man experiences is not BPH, but LUTS. To a patient, it does not matter whether LUTS are diagnosed and treated in primary care, or at other levels of provision, or whether they are associated with BPH or with other causes. As a result, it may appear that, whereas NICE has produced a	Thank you for your comments. The 16th wave remit for LUTS was referred after the scope was posted for consultation. We have now modified the scope appropriately to reflect this. The scope does cover primary, secondary and tertiary care settings (section 4.2). We will be considering all lower urinary tract symptoms in men, which will include incontinence. We will endeavour to answer your following queries regarding the scope now that it has been combined with the 16th wave remit for male LUTS.

Status	Organisation	Order no.	Section	Comments	Responses
				Clinical Guideline for the management of urinary incontinence in women (CG040), a corresponding guideline will not be produced for men. And, as commonly happens, health support for men may be inferior to health support for women. The following comments pick out the points on which it is not clear what additionality will be achieved when the 16th Wave remit is added to the 14th Wave remit.	
SH	PSA Prostate Cancer Support Association	2	1.1	Do we now mean LUTS, or LUTS/BPH?	Thank you for your comment we have now amended the short title to “LUTS”.
SH	PSA Prostate Cancer Support Association	3	3(a) and 4.1.1	"focus primarily on LUTS associated with BPH but … also … on … male LUTS in general". What criteria will be used to decide on the distinction between "primarily" and "also"? At the Stakeholders' meeting we were informed that only 50%-60% of male LUTS are associated with BPH.	The diagnosis of LUTS includes all pathophysiologies underlying LUTS. The guideline development group will prioritise the clinical questions and topics for review.
SH	PSA Prostate Cancer Support Association	4	4.3	"the management of LUTS/BPH in adult men" Should this be LUTS/BPH, or LUTS? Similar inconsistency in 4.3 (a), 4.3 (b), 4.3 (g), and 4.3 (h).	Thank you for noting this and we have amended these to ‘LUTS’ instead of “LUTS/BPH”.
SH	PSA Prostate Cancer Support Association	5	3(b) and 3(d)	Specific mention should be made of obstruction of the urethra/acute urinary retention, a not uncommon occurrence, in which pharmacological intervention is unlikely to be appropriate.	This may be considered if the guideline development group prioritises this subject.
SH	PSA Prostate Cancer Support Association	6	4.3 (a)	Why is DRE not mentioned in connection with the clinical management of BPH?	We have added this to the list of diagnostic tests to be considered. Please note that this list is not intended to be exhaustive.
SH	Q-Med UK Ltd			This organisation was approached but did not respond.	
SH	Royal College of General Practitioners			This organisation was approached but did not respond.	
SH	Royal College of Nursing	1	1 and 2	We note the guideline will now include Lower Urinary Tract Symptoms in men. Although the scope states in section 1 that the guidance will concentrate on the management of Lower Urinary Tract Symptoms (LUTS) in men associated with Benign Prostatic Hyperplasia (BPH), the background information in section 2 only refers to BPH. The information needs to be updated anb be consistent to avoid confusion.	Thank you for your comments. During the consultation period we received an additional remit from the department of health on “male lower urinary tract symptoms”. This was combined with this guideline on “Benign Prostatic Hyperplasia”. We have now modified the title and background section to reflect this update.

Status	Organisation	Order no.	Section	Comments	Responses
SH	Royal College of Nursing	2	3 (a)	As above - confusing says will concentrate on LUTS and BPH in one sentence then says it will consider other LUTS in next.	The guideline will look at the management of male lower urinary tract symptoms in general, but with a specific focus on LUTS associated with benign prostatic disease. This section has been amended to clarify this point.
SH	Royal College of Nursing	3	3 (d)	Will it include complex elderly and those with other chronic disease who have LUTs associated with BPH?	This guideline will include all men with lower urinary tract symptoms.
SH	Royal College of Nursing	4	4.1	The scope also does not discuss LUTS related to neurological dysfunction and whether these groups of men will be included or not.	The guideline will cover adult men with a clinical working diagnosis of LUTS. This will include men with LUTS related to neurological dysfunction.
SH	Royal College of Nursing	5	4.2	Health care setting will it outline how primary and secondary care will integrate this service in line with PBC and OHOCOS moving 5% urology out to community by 2008?	The NCC-AC is working to the remit received by NICE via the Department of Health. Service organisation is outside the remit of this guideline.
SH	Royal College of Nursing	6	4.3 (a)	Other tests urinalysis, U/E's, IPPS and other History Also note spelling mistake, should read 'cystoscopy'	Thank you for your comments and the spelling mistake has been corrected. This list of diagnostic tests is not meant to be exhaustive. We have amended the text to clarify this point.
SH	Royal College of Nursing	7	4.3 (e)	Under surgical interventions, the guideline needs to look at other forms of surgery such as Botox/SNM/Cystoplasties which are usually used for those with overactive bladders.	These interventions have not been excluded from the guideline and will be reviewed if the GDG prioritise this area.
SH	Royal College of Nursing	8	General	Robust assessment guidelines should be put in place to enable the majority of men to be able to be seen and assessed in primary care so that only those requiring further investigation/surgical intervention need to be seen in secondary care.	Thank you for your comments – we agree. Evidence on diagnosis will be sought and considered by the guideline development group.
SH	Royal College of Pathologists	1	1 and 2	The Title and Background to the Scoping document appear appropriate.	Thank you for your comment. During the consultation period we received an additional remit from the department of health on "the management of male lower urinary tract symptoms". The two remits were combined and subsequently the title has been amended to "The management of male lower urinary tract symptoms". However, the background information remains unchanged.

Status	Organisation	Order no.	Section	Comments	Responses
SH	Royal College of Pathologists	2	3	Although men have been identified in the previous two sections, it would be worthwhile changing sentence 4 to read "In men, benign prostate enlargement……" but the remainder of this section appears appropriate.	We agree and have amended this sentence to clarify this point.
SH	Royal College of Pathologists	3	4	The "Populations" and "Healthcare" sections are appropriate. However, the section "Clinical Management" requires some clarification. Within this section, the use of prostate specific antigen (PSA) is identified. It is now recognised by expert prostate pathologists that, in some men, there are certain benign conditions associated with significantly elevated PSA, although these men do not have prostate cancer. Unfortunately, many pathologists are not adequately trained in prostate biopsy interpretation so that absence of cancer in the presence of a high PSA appears to be a common indicator for repeat biopsy. This is both unnecessary and harmful to patients in two respects: First, repeat investigations emphasize to patients that they are likely to have a malignancy that hasn't yet been "found". This is psychologically damaging and reinforces the feeling that these men are the "worried well". Second, there is a failure to appreciate the pathophysiological nature of the underlying disease such that biologically appropriate management strategies are not developed or applied.	Thank you for raising this issue. We will ensure the GDG consider these points when reviewing the evidence on PSA.
SH	Royal College of Pathologists	4	4.3 d	In this section, no mention is made of follow-up biopsy analysed by modern genetic techniques to identify the effectiveness of various drugs and other therapeutic agents that might have been administered to the individual patient. These can now be performed on a cost-effective basis and emphasized the personalised medicine strategy that should be being developed for each individual patient within the NHS.	This evidence will be considered if prioritised by the guideline development group.
SH	Royal College of Pathologists	5	General	No changes are recommended to subsequent sections of the Scoping document.	Thank you.
SH	Royal College of Pathologists	6	General	CONCLUSION: As an observation, there appears to be a serious lack of diagnostic pathology input to this document. Although LUTS is a clinical entity, it is the final common pathway of several different pathologies. To effectively manage individual patients presenting with LUTS, there is a need to base those	Thank you for your comment. The diagnosis of LUTS includes all pathophysiologies underlying LUTS. Appropriate diagnostic tests will be prioritised by the guideline development

Status	Organisation	Order no.	Section	Comments	Responses
				strategies, in a personalised manner, upon the firm biological foundation of the particular pathology causing the clinical symptoms in the individual man. Since many drugs commonly employed therapeutically (e.g. statins, anti-hypertension agents, ion channel blockers etc.) significantly modify the phenotype of many tissues, a comprehensive knowledge of the medications being taken by BPH patients would greatly assist an understanding of the pathogenesis and evolution of BPH – and hence of its appropriate management.	group.
SH	Royal College of Physicians of London			This organisation was approached but did not respond.	
SH	Royal College of Surgeons of England			This organisation was approached but did not respond.	
SH	Royal Society of Medicine			This organisation was approached but did not respond.	
SH	SACAR			This organisation was approached but did not respond.	
SH	Salford PCT			This organisation was approached but did not respond.	
SH	Schering-Plough Ltd			This organisation was approached but did not respond.	
SH	Scottish Intercollegiate Guidelines Network (SIGN)			This organisation was approached but did not respond.	
SH	Sedgefield PCT			This organisation was approached but did not respond.	
SH	Sheffield PCT			This organisation was approached but did not respond.	
SH	Sheffield Teaching Hospitals NHS Foundation Trust			This organisation was approached but did not respond.	
SH	Social Care Institute for Excellence (SCIE)			This organisation was approached but did not respond.	
SH	Society for Academic Primary Care			This organisation was approached but did not respond.	
SH	South East London Cardiac Network			This organisation was approached but did not respond.	
SH	The Afiya Trust			This organisation was approached but did not respond.	
SH	The Prostate Cancer Charity	1	4.3 d	These bullet points should include the point from 4.3 i. The GDG	Thank you for your comments.

Status	Organisation	Order no.	Section	Comments	Responses
				should do more than 'consider' the principal complementary interventions. They should assess them in the same way as the others. Men come across these remedies easily and frequently and need good support on whether or not to use them – and also to remind them to mention to their doctors if they do. Men themselves may judge them in the same way as drugs prescribed so the Guideline may as well do that too.	Evidence retrieved for complementary and alternative interventions will be assessed and reviewed (as will the pharmacological interventions).
SH	The Prostate Cancer Charity	2	4.3 g	This point is crucial, given the intolerable effects of badly controlled LUTS will have on the lives of all kinds of men.	Thank you for your comment.
SH	The Prostate Cancer Charity	3	4.3 g	Much of the condition specific information will have to take into consideration lay perceptions and understanding of prostate. The lay prostate 'messages' to which men are exposed can be quite peculiar and alarming, if not downright calamitous in tone. There are likely to be considerable unmet needs for information, due to the fear of the consequences of treatment for BPH and secondarily, the fear of prostate cancer.	Thank you – this comment is noted.
SH	The Prostate Cancer Charity	4	General	We welcome the frequent references to 'men' as opposed to the use of the word 'patients' and hope to see this reflected in the final Guideline.	Thank you for your comment and we agree that the guideline should reference 'men' or 'people' rather than using the term 'patient'.
SH	The Prostate Cancer Charity	5	General	The Scope does not seem to be wide enough at the 'entry'. The funnel into the guideline may be the wrong shape. It could address all men with LUTS in primary care – where they present - often to become cases of 'suspected BPH'. Then look at those with LUTS due to suspected BPH, at secondary care, siphoning off the 'other men' at that time. After all, there will be several cases of suspected LUTS/BPH who turn out to be nothing of the kind. There are probably huge numbers of men who do not perceive LUTS as either remediable or about which it is 'worth' bothering the GP, as they have such low expectations of the quality of life they can expect as older men. This should also be addressed as an education and information need.	We agree and have amended the scope to cover all adult men with lower urinary tract symptoms. Management will then cover LUTS in general but will a specific focus on LUTS due to benign prostatic disease. The guideline will consider evidence on patient views and education (section 4.3g).
SH	The Prostate Cancer Charity	6	General	The Scope should include some comment on early recognition and encouraging prompt presentation through education and health promotion. If there is no evidence on how to do it this will	Evidence retrieved on education will be considered. The guideline development group will prioritise research

Status	Organisation	Order no.	Section	Comments	Responses
				be a useful research recommendation at the end of the process. If there *is* evidence on how to encourage early presentation it would be of great use to have it 'out there'.	recommendations to be included with the guidance.
SH	The Prostate Cancer Charity	7	General	LUTS due to *anything* is a significant men's health issue so this guideline will be important in maintaining a standard of guideline creation that takes into account men's health seeking behaviours (or rather, lack of them, in many cases). If there is any chance of improving men's understanding of their health and what to do about it, it is important for this Guideline to support that.	The guideline development group supports improving men's health understanding and action taken to get early diagnosis. In section 4.3 (g) the scope gives consideration to condition-specific information, support and communication needs of patients, carers and families with LUTS.
SH	The Prostate Cancer Charity	8	General	There are prostate disorders self test kits on the market which we hope that the scope might also consider as part of the information and support part of the Guideline. We have a policy statement about them at the Charity – which is not in favour because of the danger that men will use them as a way of avoiding their doctor. If their LUTS are due to heart failure, for example, it does not help their health to have their concerns about prostate symptoms relieved [leaving aside whether or not this is in fact correct] – and leaving their heart failure or diabetes to persist untreated.	Thank you – your comment is noted and will be considered by the guideline development group.
SH	The Prostate Cancer Charity	9	General	It will be important to look at long term follow up and quality of life measures in LUTS management as part of the audit cycle of a LUTS support service.	Evidence retrieved on quality of life will be considered by the guideline development group. NICE is not responsible for implementing the guidance recommendations. However the implementation team at NICE will be supporting implementation of this guidance by producing a range of implementation support tools. Audit criteria will be developed by the NICE Audit team as part of the implementation strategy.
SH	The Prostate Cancer Charity	10	General	Avoiding age discriminatory evidence assessment will be important. Is it possible to assess cost effectiveness equitably where many of the men with this condition will be frail and elderly? This question arises from my ignorance of health economics rather than because I suspect it isn't possible to do!	Across the LUTS Guideline we do not intend to recommend different treatments for different age groups.

Status	Organisation	Order no.	Section	Comments	Responses
SH	UKHIFU Limited			This organisation was approached but did not respond.	
SH	University College London NHS Trust	1	General	The document needs to consider sensory abnormalities as these are the commonest reason for men under the age of 40 presenting to urologists	Thank you for your comments. All lower urinary tract symptoms will be considered and prioritised by the guideline development group at initial assessment.
SH	University College London NHS Trust	2	General	The main sensory abnormalities are the sensation of urge to void and pain / discomfort. In the past classified with terms such as interstitial cystitis and prostatitis. Abrams, P.; Cardozo, L.; Fall, M.; et al. The standardisation of terminology of lower urinary tract function: report from the Standardisation Sub-committee of the International Continence Society. Neurourol Urodyn. 2002, 21 (2), 167-78. Abrams, P.; Baranowski, A.; Berger, R.E.; et al. A new classification is needed for pelvic pain syndromes--are existing terminologies of spurious diagnostic authority bad for patients? J Urol. 2006, 175 (6), 1989-90.	Noted. Thank you for providing these references.
SH	University College London NHS Trust	3	General	The disability (physical and psychological) associated with these symptoms are as significant as those associated with many other conditions. Tripp DA, Nickel JC, Wang Y, et al. Catastrophizing and pain-contingent rest predict patient adjustment in men with chronic prostatitis/chronic pelvic pain syndrome. J Pain 2006;7:697–708.	Thank you – we have noted your comment.
SH	University College London NHS Trust	4	General	This is an area where the NIH, ICS, EAU and SIU have drawn up guidelines. These guidelines need to be rationalised and implemented in the UK. e.g., Kreiger, J.N.; Nyberg, L.; Nickel J.C. NIH consensus definition and classification of prostatitis. JAMA 1999, 282, 236-7. Hanno P, Baranowski AP, Fall M, et al. Painful Bladder Syndrome (including interstitial cystitis). Report from Committee 21 of the 3rd International Consultation on Incontinence -June 26-29, 2004. Monte Carlo, Monaco. Fall M, Baranowski AP, Fowler CJ, et al. EAU guidelines on chronic pelvic pain. Eur Urol 2004;46:681–9. Second edition in press.	We will review and appraise all existing guidelines on LUTS.

Status	Organisation	Order no.	Section	Comments	Responses
SH	University College London NHS Trust	5	General	The mechanisms are well understood and need to be considered more widely by urologists and gynaecologists. An appropriate differential diagnosis needs to be considered and managed. Once excluded a pain / symptom management approach should be undertaken. Bielefeldt K, Gebhart GF. Visceral pain: basic mechanisms. In: McMahon SB, Koltzenburg M, editors. Textbook of pain. ed. 5 New York: Churchill Livingstone; 2006 . p. 721–36. Urogenital pain in clinical practice, edited by Andrew P. Baranowski, Paul Abrams, Magnus Fall. To be out December 2007. Sharpe M, Mayou R, Walker J. Bodily symptoms: new approaches to classification. J Psychosom Res 2006;60: 353–6	This may be considered if the guideline development group prioritise this area.
SH	University College London NHS Trust	6	General	A multidisciplinary approach should be considered as the symptoms are sensory, psychological and sexual. Psychologists have a major role. e.g. Rothrock NE, Lutgendorf SK, Kreder KJ. Coping strategies in patients with interstitial cystitis: relationships with quality of life and depression. J Urol 2003;169:233–6. Nickel JC, Tripp D, Teal V, et al. Sexual function is a determinant of poor quality of life for women with treatment refractory interstitial cystitis. J Urol 2007;177:1832–6. And multiple other sources of evidence.	This may be considered if the guideline development group prioritise this area.
SH	University College London NHS Trust	7	General	Once the sensory / pain syndrome has been identified, early referral to a pain clinic should be considered. EAU and ICS guidelines above.	This may be considered if the guideline development group prioritise this area.
SH	University College London NHS Trust	8	General	Neuropathic analgesics should be considered. Multiple levels of evidence supports this approach. EAU and ICS guidelines above.	This may be considered if the guideline development group prioritise this area.
SH	University College London NHS Trust	9	General	Nerve blocks may have a role. EAU and ICS guidelines above.	This may be considered if the guideline development group prioritise this area.
SH	University College London NHS Trust	10	General	Education of the patient and medical specialities is of paramount importance. Diagnostic criteria, classification, and nomenclature for painful bladder syndrome/interstitial cystitis: an ESSIC proposal. Eur Urol. In press. Editorial for - Diagnostic Criteria, Classification, and Nomenclature for Painful Bladder Syndrome/Interstitial Cystitis: An ESSIC	This may be considered if the guideline development group prioritise this area.

Status	Organisation	Order no.	Section	Comments	Responses
				Proposal, Andrew P. Baranowski, Paul Abrams, Richard E. Berger, C.A. Tony Buffington, Amanda C. de C. Williams, Phil Hanno, John D. Loeser, J. Curtis Nickel, Ursula Wesselmann. Eur Urol. In press.	
SH	University College London NHS Trust	11	General	Neuromodulation may have a role. See NICE guidelines for faecal incontinence and guidelines for urinary retention.	This may be considered if the guideline development group prioritise this area.
SH	University College London NHS Trust	12	General	Physiotherapy management of trigger points and core muscles as well as EMG biofeedback may have a role. EAU guidelines to be published	This may be considered if the guideline development group prioritise this area.
SH	University College London NHS Trust	13	General	The relevance of sexual abuse and negative sexual encounters such as associated with rape and torture (for both the male and female) must be clarified. Where as these are not generally considered as causal, if present they must be managed. Raphael KG. Childhood abuse and pain in adulthood — more than a modest relationship? Clin J Pain 2005;21:371–3. Raphael KG, Widom CS, Lange G. Childhood victimization and pain in adulthood: a prospective investigation. Pain 2001;92:283–93. Anda RF, Felitti VJ, Bremner JD, et al. The enduring effects of abuse and related adverse experiences in childhood— a convergence of evidence from neurobiology and epidemiology. Eur Arch Psychiatry Clin Neurosci 2006;256:174–86	We feel that this area is outside of the remit of this guideline. The scope is very large and not all cases can be covered.
SH	University Hospital Aintree			This organisation was approached but did not respond.	
SH	University Hospital Birmingham NHS Foundation Trust			This organisation was approached but did not respond.	
SH	University Hospitals of Leicester NHS Trust			This organisation was approached but did not respond.	
SH	Welsh Assembly Government			This organisation was approached but did not respond.	
SH	Welsh Scientific Advisory Committee (WSAC)			This organisation was approached but did not respond.	
SH	West & East & North Hertfordshire PCTs			This organisation was approached but did not respond.	
SH	Whipps Cross University Hospital NHS Trust			This organisation was approached but did not respond.	
SH	Wiltshire PCT			This organisation was approached but did not respond.	

Status	Organisation	Order no.	Section	Comments	Responses
SH	Wirral University Teaching Hospital NHS Foundation Trust			This organisation was approached but did not respond.	
SH	York Hospital NHS Trust			This organisation was approached but did not respond.	