National Institute for Health and Care Excellence

Lower Urinary Tract Symptoms in Men

Quality standard for LUTS in Men consultation comments table

No	ID	Stakeholder	Statement No	Comments	Responses
1	5	NHS Direct	General	NHS Direct welcome the quality standard and have no comments as part of the consultation	Thank you for your comment
2	3	Medtronic UK & Ireland	General	There is an inconsistent alignment with the clinical guideline CG 97 published in 2010 in some areas and we would request that the excellent provisions within this clinical guideline are transferred to the quality standard.	The Topic Expert Group (TEG) prioritised the areas of care they felt were most important for patients, based on the development sources listed such as CG97. The TEG prioritised areas of care where practice is variable, or where they felt based on their expert consensus that implementation could have a significant impact on patient care and improved outcomes, and where there is potential to generate measurable indicators. All suggestions for additional statements were discussed by the TEG who considered they were inappropriate for inclusion (for example, outside the scope of the quality standard), or already covered by existing statements. The quality standard contains key markers of clinical and cost effective care across a care pathway.

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3	6	Prostate Cancer UK	General	It is important that health-related quality of life and adverse effects are considered with an equal standing to the other clinical outcomes. Patient-reported outcomes should also be considered, to ensure that any agent or treatment is not only clinically effective but also improves outcomes of importance to this patient population.	Thank you for your comment. The Topic Expert Group (TEG) considered all suggested measures. Outcome measures are stated where the topic expert group felt they are appropriate, measurable and specifically attributable to the action stated in the statement.
4	8	British Association for Sexual Health and HIV (BASHH)	General	A number of interlinked conditions cause Lower Urinary Tract Symptoms (LUTS) in men in addition to prostatic enlargement. The 2010 guideline states that," the most common cause is benign prostate enlargement (BPE), which obstructs the bladder outlet. BPE happens when the number of cells in the prostate increases, a condition called benign prostatic hyperplasia. Other conditions that can cause LUTS include detrusor muscle weakness or overactivity, prostate inflammation (prostatitis), urinary tract infection, prostate cancer and neurological disease." However, there are two other common conditions which can cause these symptoms and these are the chronic pelvic pain syndrome (CPPS) and urethritis. The (CPPS) in men is an important and common condition which may present to genitourinary medicine (GUM). It has a lifetime prevalence of 2-14%.1 The terms CPPS and chronic prostatitis (CP) are often used interchangeably to describe a syndrome which causes perineal and genital pain, often in association with storage and voiding symptoms, which can be unrelenting and physically, as well as emotionally, exhausting.1-5 The median age of patients affected is early forties and the syndrome is usually of sudden onset.1,2,6,7 Patients with urethritis usually present with symptoms of discharge and/or dysuria and/or penile irritation and in our experience may also experience voiding symptoms such as frequency particularly if the dysuria is severe as can occur with gonorrhoea. However, we have reviewed the literature and can	Thank you for your comment.

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				find no original papers to support the statement that men with urethritis can also have voiding symptoms, so this is expert evidence only. Patients with urethritis although usually less than 30 yrs old can present over 50 yrs of age.8-12 There were over 80,000 cases of urethritis diagnosed in England in 2011 when gonococcal and chlamydial disease is also considered.	
5	12	Astellas Pharma Ltd	General	Astellas welcomes the development of a quality standard on LUTS in men as a high-priority area for quality improvement. LUTS can have a significant impact on quality of life[i] with the potential to negatively affect an individual's work productivity, their sleep and their mental wellbeing[ii]. More fundamentally, achieving good bladder control is a basic human need and is critical to maintaining both dignity and independence. These outcomes are at the heart of the NHS statutory duty to secure continuous improvements in the quality of services[iii] and to treat individuals with dignity and respect[iv]. However, evidence suggests that the diagnosis of both storage and voiding LUTS in men is low in relation to prevalence estimates and that despite the availability of proven, cost-effective interventions many men experiencing LUTS are unable to access appropriate treatment within primary care[v]. Recent assessments of continence services have also highlighted serious shortcomings in the provision of care based on individual need and variations in the quality of commissioning across the care pathway[vi,vii]. Age is a major risk factor for LUTS in men – hence as the population ages, early and effective management of symptoms will be critical in reducing morbidities and the need for high cost interventions that are associated with poor care[viii,ix]. The NICE quality standard has a critical role to play in driving	Thank you for your comment. The Topic Expert Group (TEG) considered all suggested measures. Outcome measures are stated where the topic expert group felt they are appropriate, measurable and specifically attributable to the action stated in the statement. We expect that the quality standard, alongside continuing implementation of the guideline will contribute to the important outcomes which you have highlighted.

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				quality improvement among health care professionals, at the provider level and throughout the commissioning cycle. To succeed, we recommend that the final set of statements and supporting metrics should be strengthened to help embed the approaches and interventions that will ultimately make the most difference in terms of patient outcomes, including: · Increased symptom awareness · Earlier symptom identification · Timely access to the best possible quality treatment and supportive care · A deliberate shift towards shared decision-making based on the individual goals of the patient · Driving up the quality of patient experience Our response focuses on the following sections of the draft quality standard: • Recognising the role of the QS in improving outcomes across the NHS Outcomes Framework (introduction) • Specific recommendations relating to quality statements 1-3, 5, 8 • The development of appropriate process and outcomes measures for quality statements 1-3, 5, 8 • Recommendations regarding additional quality statements: - Personalised management plans - Public awareness and patient identification - Patient experience	
6	12	Astellas Pharma Ltd	General	Continence problems are associated with significant social stigma – often people are too embarrassed to seek help and this has led to under-reporting of the conditions [xxii]. We recommend that NICE adopts additional quality statements that ensure commissioners and providers take appropriate steps to tackle under-reporting and under diagnosis of LUTS in men. This could be achieved in two ways:	Thank you for your comment. The Topic Expert Group (TEG) prioritised the areas of care where practice is variable, or where implementation could have a significant impact on patient care and improved outcomes, and where they represent key markers of clinical and cost effective care based on the development sources

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				· Through public awareness activity which helps men to understand the signs and symptoms of LUTS and when they should seek help · Through improved patient identification drawing on the 'every contact counts' approach so that symptoms are identified at the earliest opportunity by a qualified health professional .	listed. We acknowledge that it may be necessary to develop services in order to achieve the care described in the quality standard. However, it is not within the remit of the quality standard to describe all developments that may be required in order to deliver the quality statements and we hope that the quality standard will play an important role in raising awareness of LUTS alongside other initiatives. It is expected that decisions will be made locally to facilitate achievement of the quality statements.
7	12	Astellas Pharma Ltd	General	Astellas recommends that NICE includes an additional quality statement on patient experience, in order to support the delivery of improved outcomes under Domain Four of the NHS Outcomes Framework. The statement should seek to promote appropriate provision of information to support shared decision-making and patient-centred care, and should focus on the priorities for quality improvement for patients with LUTS. We support following process and outcome measures: Process measure: the proportion of men with LUTS who complete an experience/satisfaction survey Outcome measure: the proportion of men with LUTS who were satisfied with the treatment and care received (data source: experience surveys and real-time feedback)	Thank you for your comment. Within this Quality Standard, we include a reference to the published cross cutting NICE quality standard 15 (2012) on 'Patient experience in adult NHS services' which sets out the important areas including shared decision-making.
8	14	Pfizer Ltd	General	Pfizer would like to thank NICE for the opportunity to respond to the draft quality standard (QS) for lower urinary tract symptoms (LUTS) in men and we very much support its development. This is an important document to help ensure that any potential inappropriate variance in managing patients with LUTS is mitigated. In order to improve variance in patient	Thank for your comment.

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				management Pfizer have recommended some changes and additions to the QS	
9	16	British Association of Urological Surgeons	General	We would suggest there is one missing, between numbers 5 and 6, offering medical treatment(s) to men with bothersome LUTS	Thank you for your comment. The Topic Expert Group (TEG) prioritised the areas of care where practice is variable, or where implementation could have a significant impact on patient care and improved outcomes, and where they represent key markers of clinical and cost effective care based on the development sources listed.
10	16	British Association of Urological Surgeons	General	Throughout the document it promises a lot of patient information. Some of this exists but by no means all. Will NICE lead on this?	Thank you for your comment. The quality standard describes high-priority areas for quality improvement. The delivery of high quality care is signalled by good performance across the breadth of all statements and measures. NICE has produced a support document to help commissioners and others consider the commissioning implications and potential resource impact of this quality standard and patient information to explain to patients and carers what the quality standard means to them, both are available from www.nice.org.uk. This will be published alongside the quality standard. We would hope that the quality standard and the guideline would provide an impetus for others to develop such information which is outside the scope of this work.

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11	13	The Urology Trade Association	General	That statement is very broad in its approach and there are some areas where additional detail would be beneficial. As an example, the QS talks about men with LUTS undergoing assessment and digital rectal examination, but it does not specify who undertakes these procedures; it should say that it is undertaken by a 'competent practitioner'.	Thank for your comment. Quality standards do not typically contain statements on training and development, as this is an assumed aspect for those wishing to achieve the individual statements.
12	3	Medtronic UK & Ireland	General	Quality statement 6 is taken from CG recommendation 1.5.1; but there is no equivalent statement for CG recommendation 1.6.1. despite the NICE patient pathway including this recommendation: http://pathways.nice.org.uk/pathways/lower-urinary-tract-symptoms-in-men	Thank you for your comment. Final Quality Statement 6 uses the Clinical Guideline recommendation 1.5.1 as it is specific to 'surgery for voiding symptoms' which was prioritised as an area of quality improvement. The quality standard does not cover all aspects of the pathway. The rationale for this statement has been clarified in respect to recommendation 1.5.1.
13	3	Medtronic UK & Ireland	General	There is no quality statement for surgical options for storage symptoms; cystoplasty, BTX and SNS are recommended options for this in the CG.	The Topic Expert Group (TEG) prioritised the areas of care they felt were most important for patients, based on the development sources listed. The TEG prioritised areas of care where practice is variable, or where implementation could have a significant impact on patient care and improved outcomes, and where there is potential to generate measurable indicators. All suggestions for additional statements were discussed by the TEG who considered they were inappropriate for inclusion (for example, outside the scope of the quality standard), or already covered by existing statements. The quality standard contains key markers of clinical and cost effective care across a care pathway. It remains important that other

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					evidence-based guideline recommendations continue to be implemented.
14	3	Medtronic UK & Ireland	General	To further align with CG97 we propose to have storage symptom treatment options included in this QS i.e. a quality statement for surgery for voiding, and a separate quality statement for surgery for storage symptoms, to align it with the CG and patient pathway. Storage symptoms are debilitating and NICE spent time to map a patient pathway in CG97 and we feel that it should also be reflected in this QS	The Topic Expert Group (TEG) prioritised the areas of care they felt were most important for patients, based on the development sources listed. The TEG prioritised areas of care where practice is variable, or where implementation could have a significant impact on patient care and improved outcomes, and where there is potential to generate measurable indicators. The quality standard contains priority markers for quality improvement and it remains important that other evidence-based guideline recommendations continue to be implemented.
15	10	GlaxoSmithKline	General	A useful document, comprehensive and clear to read.	Thank you for your comment.
16	6	Prostate Cancer UK	Introduction	Prostate Cancer UK believes there needs to be clarity over what constitutes 'bothersome' symptoms. Are they the ones identified in the introduction? It would be helpful for patients and health professionals for the introduction to list (or refer to) all possible symptoms of LUTS as well as indicate which are considered "bothersome".	Thank you for your comment. 'Bothersome' symptoms was a term used in the source guideline. However, to add clarity on this, in the Introduction, we have now specified post-micturition symptoms as being bothersome and includes a definition within Quality Statement 2 of Bothersome LUTS as 'symptoms at presentation that are worrying, troublesome or have an impact on a man's quality of life. This may vary based on the individual man's circumstances. Those men who are seeking only reassurance about their LUTS are not covered by this quality statement'.

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17	9	Royal Pharmaceutical Society	Introduction	The Royal Pharmaceutical Society is concerned that the management of lower urinary tract symptoms by pharmacists as outlined in the NICE implementation brief Lower urinary tract symptoms: implementation briefing for pharmacists (November 2012) has not been factored into the statements. The provision of Tamsulosin to eligible adult patients for treatment of functional symptoms of benign prostatic hyperplasia (BPH) in men aged between 45 and 75 years together with the necessary advice and monitoring has been undertaken by community pharmacist since its availability as a pharmacy medicine in 2010; a scenario that is not reflected in the current quality statements. Pharmacist and the role they play within the community setting in managing lower urinary tract symptoms should be included in the audience of healthcare professionals identified for the draft quality statements.	Thank you for your comment. The Topic Expert Group (TEG) recognised this important role and we have now included the role of community and hospital pharmacists within the introductory text of this Quality Standard.
18	12	Astellas Pharma Ltd	Introduction	Astellas agrees that effective management of LUTS in men helps the NHS to deliver improvements in outcomes that are required under the NHS Outcomes Framework. However, at present, the outcomes for men with LUTS are too narrowly defined within the Quality Standard (page 2). In addition to Domain 2 (quality of life) and Domain 4 (patient experience), high quality care enables men to recover from episodes of ill-health (Domain 3) and contributes to their safety (Domain 5). For example, effective management of LUTS helps to: · Reduce acute hospitalisations due to urinary tract infection and prevent unnecessary catheterisation (Domain 3) · Lower the risk of falls and fractures among older men and reduce incidence of pressure ulcers related to incontinence (Domain 5) [xii],[xiii] It is therefore important that the quality standard is designed in a way that supports improvements in outcomes across all relevant domains (2-5) and this should be	Thank you for comment. In reviewing the Outcomes Frameworks and their technical specification manuals, it was decided that this standard was only directly specific to technical detail of the indicators provided in the NHS Outcomes Framework Domains 2 and 4.

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				reflected in the table on page 2 of the Quality Standard. In addition, incontinence is one of the main reasons why older people move into residential care (second only to dementia)[xiv]. As such, effective management of LUTS helps to contribute to Domain 2 of the Adult Social Care Outcomes Framework, delaying and reducing the need for care and support. Astellas considers improvements in the outcomes of men with LUTS to be the ultimate test of the success of the quality standard – both in relation to the content of the standard and how it is implemented. To support the process of evaluation, we propose a number of outcome measures (to supplement the draft process measures). These should be endorsed by NICE and adopted by commissioners to measure the performance of providers against the quality standard.	
19	11	Boehringer Ingelheim Limited	Introduction	Both the NHS Mandate, and NHS Outcomes Framework have overarching aims for "Enhancing Quality of Life for People with Long-Term Conditions". Boehringer Ingelheim welcomes the placement of this overarching indicator as a means for creating a framework for high quality care for men with LUTS. However, there are significant missed opportunities in the draft quality standards which fail to tackle some of the fundamental challenges faced by the NHS. The NHS Mandate states in its intent the desire to "empower and support the increasing number of people living with long-term conditions." By 2018, nearly 3 million people will be living with long term conditions. The NHS Outcomes Framework recognises the need for improvement in "ensuring people feel supported to manage their condition". Failure to do this will result in increasing numbers of men with bothersome symptoms, continuing to rely for long-term support on over-worked General Practitioners who have less and less time to deal with the increasing numbers of people with long-term conditions, placing local	Thank you for your comment.

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				Health Systems under greater pressure. Long term reliance on the GP following BPH diagnosis is not necessary and quality of care can be increased by closer pharmacist involvement. Additionally, as traditional GP appointments are likely to become harder to gain, left alone patients will continue to suffer in silence, without an appropriate diagnosis or treatment of LUTS. Within the proposed Quality Standards, it is therefore of paramount importance to utilise the professional skills of local pharmacists as part of the multi-disciplinary team in early involvement (first "port-of-call" in many cases), speedy referral where appropriate, and follow-on treatment and self-care for patients with LUTS. This would provide an additional pathway for patients with symptoms and would support the GP pathway as with other long-term conditions. NICE, through this Quality Standard, has a unique opportunity to help break the cultural and behavioural need for patients to visit their GP, as the root cause for lack of effective self-care, which will be essential for the survival and evolution of the health system.	
20	8	British Association for Sexual Health and HIV (BASHH)	QS1	We would suggest that in addition to draft quality statement 1: "Men with lower urinary tract symptoms (LUTS) are offered a full physical examination, including a digital rectal examination, as part of their initial assessment." Men should also be asked about pelvic pain including dysuria and urethral discharge. If present a sexual history should also be taken and a diagnosis of urethritis considered if they are at risk and the symptoms are of recent onset and a referral to a department of genitourinary medicine should be initiated. We believe this is an area where prospective information on the prevalence of LUTS in men with urethritis would be helpful.	The Topic Expert Group (TEG) reviewed your comment. They were however content with the current wording of this statement to reflect the underpinning recommendation.

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21	6	Prostate Cancer UK	QS1	Early prostate cancers often do not have any signs or symptoms. Both prostate cancer and lower urinary tract symptoms (LUTS) are common in older men. LUTS are likely to be caused by benign prostate disease, however if they are due to prostate cancer it has often reached an advanced and incurable stage[i]. It is therefore important for GPs to be aware of groups at high risk of prostate cancer and the tests which are available, as set out in the Prostate Cancer Risk Management Programme (PCRMP) guidelines[ii]. These should be included or referred to so that health professionals are aware how to determine between symptoms of possible prostate cancer and LUTS.	Thank you for your comment. The Topic Expert Group (TEG) prioritised the areas of care they felt were most important for patients, based on the development sources listed. There is a separate referral to develop a quality standard for prostate cancer in due course and we would value your contribution when we notify you of the stakeholder engagement exercise when this has been scheduled for development.
22	11	Boehringer Ingelheim Limited	QS1	Technically speaking this initial assessment may have to be split into stages...with the inclusion of a pharmacist as one of the potential entry points to the care pathway, which also include nurses, general practitioners and secondary care physicians.	Thank you for your comment. The content of this statement is guided by the underpinning recommendation. We have now included the important role of community and hospital pharmacists within the introductory text.
23	12	Astellas Pharma Ltd	QS1	Astellas supports the quality statements on initial assessment. We recommend that the statements could be strengthened by an explicit reference to the role of primary care in leading the initial assessment. NICE's national costing report on CG97 states that "improving the quality and consistency of LUTS management in primary care could lead to reductions in complications and their associated costs. Comprehensive initial assessment would help ensure that men with LUTS get the right treatment and that only correct referrals are made, relieving pressure on urologists in secondary care". In addition, urologists believe that around 41% of benign prostatic hyperplasia (BPH) referrals could be managed in primary care"[xv] We would recommend the inclusion of a process measure to reflect the expectation that assessments should	The Topic Expert Group (TEG) reviewed your comment. They were however content with the current wording of this statement. A definition of initial assessment is provided although this is not setting specific.

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				take place in primary care: the proportion of men with LUTS who receive an initial continence assessment in primary care	
24	1	Chartered Physiotherapists Promoting Continence & Association of Chartered Physiotherapists in Women's Health	QS1	Men with LUTS need a digital rectal examination to assess the prostate. They also need a digital anal examination to assess the grade of the pelvic floor muscles.	The Topic Expert Group (TEG) reviewed your comment. They were however content with the current wording of this statement.
25	1	Chartered Physiotherapists Promoting Continence & Association of Chartered Physiotherapists in Women's Health	QS1	Storage symptoms include stress urinary incontinence which is prevalent after prostatectomy	The Topic Expert Group (TEG) reviewed your comment. They were however content with the current wording of this statement.
26	4	The Association for Clinical Biochemistry and Laboratory Medicine	QS1	This is an important quality statement because it forms the basis of all the following statements, enables capturing of patients with multiple conditions where urinary symptoms may be an early presentation e.g. bladder or prostate malignancy, allowing early intervention and better outcomes.	Thank you for your comment.

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27	1	Chartered Physiotherapists Promoting Continence & Association of Chartered Physiotherapists in Women's Health	QS1	Men with urgency or urge incontinence should be shown urge suppression techniques.	The Topic Expert Group (TEG) reviewed your comment. They were however content with the current wording of this statement.
28	16	British Association of Urological Surgeons	QS2	Rationale – "They can also help…… urine passed each time" this is a bit woolly for nocturnal polyuria and where it states DO it really means OAB or OAB/DO	Thank you for your comment. In the final Quality Statement 2 rationale section, we now distinguish nocturnal polyuria (greater than a third of daily urine output during the night) from detrusor over activity (normal urine production but increased urinary frequency with urgency and small volumes of urine passed each time).
29	16	British Association of Urological Surgeons	QS2	Suggest that IPSS and F/V charts (both) should be used at the initial assessment to direct GPs towards what particular symptom needs to be addressed / treated.	The Topic Expert Group (TEG) reviewed your comment. They were however content with the current wording of this statement.
30	12	Astellas Pharma Ltd	QS2	Astellas supports the use of urinary frequency and volume charts as part of an initial assessment for men with bothersome LUTS. In addition to measuring frequency and urgency, it is also important to measure urgency in order to undertake a complete assessment of need and ensure that conditions such as urge OAB are not overlooked. To address this, we recommend that NICE includes the use of a bladder diary to evaluate urgency symptoms as part of the quality statement on initial assessment.	The Topic Expert Group (TEG) reviewed your comment. They were however content with the current wording of this statement.

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31	4	The Association for Clinical Biochemistry and Laboratory Medicine	QS3	This quality statement is important because the majority of symptoms identified by the thorough examination detailed in quality statement 1 will be dealt with by the relatively straight forward lifestyle interventions.	Thank you for your comment.
32	9	Royal Pharmaceutical Society	QS3	Community pharmacies with their informal settings, longer opening hours, often central location and easy access continue to offer a viable and convenient option for members of the public seeking health advice. Many members of the public and patients see the pharmacist as a first port of call for advice, not just on their medicines but also on their underlying health problems. This is particularly true for men seeking advice on health issues. Pharmacists and support staff can and do offer advice on lifestyle interventions and temporary containment products such as pads as part of routine pharmacy counselling services. Additional support on the use of appliances including incontinence products is also available through pharmacy services such as the appliance use review which is available in England and we feel this should be reflected in these quality standards.	Thank you for your comment. We have now included the role of community and hospital pharmacists within the introductory text.
33	11	Boehringer Ingelheim Limited	QS3	Pharmacists are ideally placed to offer this advice on lifestyle interventions. The Quality Standard needs to be clear that Pharmacists are an integral part of the multi-disciplinary team and are regularly involved in supportive advice to both the well and unwell patient. This advice currently includes blood pressure monitoring, cholesterol checks and smoking cessation advice as well as medicines reviews	Thank you for your comment. We have now included the role of community and hospital pharmacists within the introductory text.

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34	12	Astellas Pharma Ltd	QS3	Astellas supports the quality statements on initial assessment. We recommend that the statements could be strengthened by an explicit reference to the role of primary care in leading the initial assessment. NICE's national costing report on CG97 states that "improving the quality and consistency of LUTS management in primary care could lead to reductions in complications and their associated costs. Comprehensive initial assessment would help ensure that men with LUTS get the right treatment and that only correct referrals are made, relieving pressure on urologists in secondary care". In addition, urologists believe that around 41% of benign prostatic hyperplasia (BPH) referrals could be managed in primary care"[xv] We would recommend the inclusion of a process measure to reflect the expectation that assessments should take place in primary care: the proportion of men with LUTS who receive an initial continence assessment in primary care	The Topic Expert Group (TEG) reviewed your comment. They were however content with the current wording of this statement.
35	12	Astellas Pharma Ltd	QS3	Quality statements that relate to specific interventions must be accompanied by appropriate outcome measures to ensure that the quality standard is focused on improving the outcomes that matter to patients. The metrics included in the quality standard should align with measures that are already being piloted in the NHS to ensure consistency and focus. The service specification for Any Qualified Provider includes a number of outcome measures that should be collected and monitored as part of local performance management [xix]. We recommend that as a minimum, the following outcome measures are incorporated into quality statements 3, 5, 6, 8: • The proportion of men whose symptom were controlled or alleviated following treatment/an intervention (data source: International Prostate Symptoms Score used in clinical audit and patient review) • The proportion of men who were satisfied with their care	Thank you for your comment. The Topic Expert Group (TEG) considered all suggested measures. Outcome measures are stated where the topic expert group felt they are appropriate, measurable and specifically attributable to the action stated in the statement.

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				(data source: local data collection, Patient Reported Experience Measures) • A reduction in avoidable secondary care attendance and admission (data source: individual patient record/local HES data) • A reduction in the proportion of men referred for surgical intervention (data source: individual patient record/local HES data) • A reduction in acute urinary retention (data source: individual patient record/local HES data)	
36		The Urology Trade Association	QS3	This statement discusses men receiving written advice; we think that it would be more appropriate to say that men should receive verbal advice backed up with written support documentation.	Thank you for your comment. The Topic Expert Group (TEG) were keen to state written advice in the final Quality Statement 3 and the expectation is that this would be reinforced by discussion.
37	1	Chartered Physiotherapists Promoting Continence & Association of Chartered Physiotherapists in Women's Health	QS4	URETHRAL MILKING IS OUTMODED. We now use a strong post-void pelvic floor contraction in an upwards direction to tighten bulbocavernosus and eliminate urine from the U-shaped urethra while still poised over the toilet.	The Topic Expert Group (TEG) reviewed your comment, however they were keen to keep this statement in as they did not view urethral milking as not an out-moded therapeutic technique. The group discussed this and concluded that it remains widely used and accepted throughout the urological community with good patient reported outcome.
38	6	Prostate Cancer UK	QS5	Prostate Cancer UK is concerned that men are only being offered temporary containment solutions. This may mean that the supply of pads or collecting devices will be limited and men will be faced with having to buy their own. Also, if some men decide they do not want surgery, these solutions should be made permanent for these men, which will allow patient choice.	The Topic Expert Group (TEG) reviewed your comment, however they still wanted to prioritise the quality issue of choice of containment products to be offered as soon as possible as being the key quality marker. This does not mean that men should only be offered temporary containment products. The rationale for this statement has been updated to

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					be consistent with the guideline recommends that their longer term use is a consideration where other treatments don't help or are unsuitable which also supports patient choice.
39	7	Royal College of Pathologists	QS5	In order to reduce the risk of developing a urinary tract infection, a urinary catheter should only be used when other containment products are not suitable. If a urinary catheter is required it should be used for as a short a time as possible.	Thank you for your comment. The Topic Expert Group (TEG) agreed with your view however as this not included in the underpinning Clinical Guideline 97 this was not included as a quality statement.
40	9	Royal Pharmaceutical Society	QS5	Community pharmacies with their informal settings, longer opening hours, often central location and easy access continue to offer a viable and convenient option for members of the public seeking health advice. Many members of the public and patients see the pharmacist as a first port of call for advice, not just on their medicines but also on their underlying health problems. This is particularly true for men seeking advice on health issues. Pharmacists and support staff can and do offer advice on lifestyle interventions and temporary containment products such as pads as part of routine pharmacy counselling services. Additional support on the use of appliances including incontinence products is also available through pharmacy services such as the appliance use review which is available in England and we feel this should be reflected in these quality standards.	Thank you for your comment. We have now included the role of community and hospital pharmacists within the introductory text.
41	12	Astellas Pharma Ltd	QS5	Astellas is concerned that the inclusion of a dedicated quality statement on choice of containment products positions containment as a marker of high quality care, when in fact, the starting point for care professionals should be to identify and treat the underlying condition and alleviate symptoms as far as possible. We acknowledge that the rationale for the statement seeks to establish the clinical context for the use of containment	The Topic Expert Group (TEG) reviewed your comment. They were however content with the current wording of this statement and that it reflects an important quality issues which needs to be highlighted.

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				products (primarily in the short term until a long term solution is reached). We also understand that concerns have been raised in the past about the rationing of continence products and the impact this has had on quality of life and personal care costs[xvi]. However, for the overwhelming majority of patients, other forms of conservative management (lifestyle changes or bladder training), as well as pharmacological or surgical interventions offer the best chance of improving individual outcomes and help to deliver greater value for money for the NHS[xvii]. We are concerned that guidance on the appropriate use of containment products is not accurately reflected in the summary statement. The content and positioning of the summary statement would also appear to misrepresent the role of containment products within high quality LUTS provision. This could have the unintended effect of encouraging services to prioritise choice of containment product over the development of a personalised treatment plan based on the desired outcomes of each individual patient.	
42	12	Astellas Pharma Ltd	QS5	• NICE includes additional detail in quality statement 5 to reflect the wording of CG97: Quality statement 5: Men with lower urinary tract symptoms who have urinary incontinence are offered a choice of temporary containment products to achieve social continence until a diagnosis and management plan have been discussed . Use of products should be reviewed at regular intervals in line with agreed treatment goals. It is notable that the quality statement on containment products does not include an outcome measure. Astellas calls for the inclusion of outcome measures in every statement that relates to a specific intervention, in order to evaluate the success of the intervention (statements 3, 5, 6, 8).	Thank you for your comment. The Topic Expert Group considered all suggested measure. Outcome measures are stated where the topic expert group felt they are appropriate, measurable and specifically attributable to the action stated in the statement.

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43	12	Astellas Pharma Ltd	QS5	Quality statements that relate to specific interventions must be accompanied by appropriate outcome measures to ensure that the quality standard is focused on improving the outcomes that matter to patients. The metrics included in the quality standard should align with measures that are already being piloted in the NHS to ensure consistency and focus. The service specification for Any Qualified Provider includes a number of outcome measures that should be collected and monitored as part of local performance management [xix]. We recommend that as a minimum, the following outcome measures are incorporated into quality statements 3, 5, 6, 8: • The proportion of men whose symptom were controlled or alleviated following treatment/an intervention (data source: International Prostate Symptoms Score used in clinical audit and patient review) • The proportion of men who were satisfied with their care (data source: local data collection, Patient Reported Experience Measures) • A reduction in avoidable secondary care attendance and admission (data source: individual patient record/local HES data) • A reduction in the proportion of men referred for surgical intervention (data source: individual patient record/local HES data) • A reduction in acute urinary retention (data source: individual patient record/local HES data)	Thank you for your comment. The Topic Expert Group considered all suggested measure. Outcome measures are stated where the topic expert group felt they are appropriate, measurable and specifically attributable to the action stated in the statement. The group also felt that the quality standard as a whole would contribute to a more overarching indicator on satisfaction with care and symptom control.

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44	13	The Urology Trade Association	QS5	This statement mandates that "men with lower urinary tract symptoms (LUTS) who have urinary incontinence are offered a choice of temporary containment products." However, the definition of temporary containment products does not include devices to assist intermittent voiding, though it does include indwelling catheters and sheaths. The definition of containment products in the draft is: "Containment products are designed to contain or divert the urine leaked during an episode of incontinence and are widely used in men with LUTS involving incontinence. Products include absorbent pads (pads worn next to the body, pants with integral pads, bed pads), external collection devices (sheath appliances, pubic pressure urinals), indwelling catheters and penile clamps." However, the current practice is less conservative than stated here when managing LUTS both in the short and long term. "Containment" should be changed to "management" – this implies an active, rather than passive, approach regarding the use of devices. This would mean that clean intermittent catheterisation could be considered as an option where it is appropriate. This is of particular relevance to those patients who choose not to go down a surgical treatment route and hence will need to consider how this issue can be managed proactively over the longer term	The Topic Expert Group (TEG) reviewed your comment and the rationale has been updated to clarify the intent of the statement.
45		The Urology Trade Association	QS5	This statement talks about access to temporary containment products. However, this statement ought to note that patients should have access to continence / urology services to support their clinical outcomes. It is also worth noting that product	The Topic Expert Group (TEG) reviewed your comment. They were however content with the current wording of this statement. The quality standards are based on the assumption that

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				usage may not be a temporary thing, particularly for those with spinal injuries, neurological conditions, and other long term conditions, and patients need to be reviewed to assess their ongoing continence support needs.	100% achievement may not always be possible or appropriate because of needs of clinical judgement, choice and safety.
46	14	Pfizer Ltd	QS5	The draft QS states that containment products “are not a cure and should not generally be a long-term solution, unless other treatments don’t help.” To ensure that containment products are not used as a long term solution, Pfizer recommend the QS specifies the maximum time patients should be on a containment product (eg pads) with-out being offered other appropriate treatments, such as medication. Pfizer also recommend the maximum time patients should be on a containment product with-out being offered other appropriate treatments is included as a quality measure	Thank you for your comment. In the final Quality Statement 4 within the definitions section we have stated ‘based on expert opinion from the Topic Expert Group (TEG) temporary containment products are used for a maximum of 3 months, by which time their use should be reviewed and a management plan should be in place'.
47	15	Urology User Group Coalition	QS5	The UUGC welcomes the note that a choice of products is offered as early as possible. The UUGC would like to note that specialist services are best-placed to advise on this given the range of products available and the sensitive nature of LUTS. A member of the UUGC has drawn our attention to anecdotal cases where men have resorted to using female sanitary products as the issue has not been discussed openly.	Thank you for your comment. We hope that the quality standard will help to highlight such variations in care. In the final Quality Statement 4, within the rationale section we mention 'It is important that a choice of suitable containment products is offered by a healthcare professional as early as possible even if there is no definite diagnosis and agreed plan on how to manage the symptoms'.
48	1	Chartered Physiotherapists Promoting Continence & Association of Chartered Physiotherapists in Women’s Health	QS5	Physiotherapy treatment with Pelvic floor muscle training and advice should be offered before containment pads. Containment pads can then be offered if necessary.	The Topic Expert Group (TEG) reviewed your comment and agreed that it does not cover all points on the pathway as set out in the guideline. They were however content with the current wording of this statement.

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49	15	Urology User Group Coalition	QS6	The quality statement around surgical options (statement 6 on pg15) , only includes surgery for voiding symptoms. SNS is not included in this category where it is an efficacious and less invasive option with a simple predictive test which gives an actual procedural NNT of 1. We request that SNS be given equal weight to surgery as a much less invasive option that has equal efficacy and a substantial evidence base.	The Topic Expert Group (TEG) prioritised the areas of care they felt were most important for patients, based on the development sources listed. The statement addressed the quality issue of ensuring that there is an appropriate offer of surgery to men with voiding symptoms where other treatments have not worked and this is consistent with the underpinning recommendation. The weighting of SNS would be addressed as part of guideline development rather than in the context of the quality standards.
50	8	British Association for Sexual Health and HIV (BASHH)	QS6	The management of the CPPS is clearly beyond the scope of the LUTS guideline and is generally recognised as being sub-optimal with new approaches to management being trialed.[1,3,4,6,7] However a recent systematic review of treatment for the CPPS has provided evidence that combination of antimicrobials and alpha blockers is of benefit in men with voiding symptoms as defined in the NIH CPSI score.[14] We note in the 2010 guidance that alpha blockers should be considered in the treatment of men with mild to moderate LUTS and the use of anti-microbials are not considered. Given that draft quality statement 6 states "Men with lower urinary tract symptoms (LUTS) and voiding symptoms which are severe or have not responded to drug treatment and conservative management options are offered surgery." NICE may want to consider mentioning the use of antibiotics in addition to alpha-blockers prior to recommending surgery in those men who have LUTS in association with the CPPS.	The Topic Expert Group (TEG) reviewed your comment. They were however content with the current wording of this statement which reflects the underpinning recommendation.
51	12	Astellas Pharma Ltd	QS6	Quality statements that relate to specific interventions must be accompanied by appropriate outcome measures to ensure that the quality standard is focused on improving the outcomes that	Thank you for your comment. The Topic Expert Group (TEG) considered all suggested measures. Outcome measures are stated where the topic

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				matter to patients. The metrics included in the quality standard should align with measures that are already being piloted in the NHS to ensure consistency and focus. The service specification for Any Qualified Provider includes a number of outcome measures that should be collected and monitored as part of local performance management [xix]. We recommend that as a minimum, the following outcome measures are incorporated into quality statements 3, 5, 6, 8: • The proportion of men whose symptom were controlled or alleviated following treatment/an intervention (data source: International Prostate Symptoms Score used in clinical audit and patient review) • The proportion of men who were satisfied with their care (data source: local data collection, Patient Reported Experience Measures) • A reduction in avoidable secondary care attendance and admission (data source: individual patient record/local HES data) • A reduction in the proportion of men referred for surgical intervention (data source: individual patient record/local HES data) • A reduction in acute urinary retention (data source: individual patient record/local HES data)	expert group felt they are appropriate, measurable and specifically attributable to the action stated in the statement.
52	9	Royal Pharmaceutical Society	QS8	Medicines Use Reviews (MURs) are already available nationwide as part of the community pharmacy contracts both in England and Wales. These reviews offered through pharmacies provide patients with an opportunity to meet with an accredited pharmacist in a convenient, easily accessible and acceptable location at an opportune time to discuss the medicines they have been prescribed thereby enabling a timely review of their medication. We feel this too should also be reflected in the quality standards.	The Topic Expert Group (TEG) reviewed your comment. They were however content with the current wording of this statement.

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53	11	Boehringer Ingelheim Limited	QS8	As per previous comments, the pharmacist is ideally placed as part of the multi-disciplinary team to conduct medicines reviews, leading to optimal treatments being prescribed by clinicians, and adhered to by patients.	Thank you for your comment. We have now included the role of community and hospital pharmacists within the introductory text.
54	14	Pfizer Ltd	QS8	The draft QS states that "It is important to ensure that men with LUTS taking drug treatments have a timely review of their symptoms, the effect of the drugs on their quality of life and adverse effects of treatment" Pfizer agree that QoL is an important measure of treatment success. OAB is a medical problem largely due to its negative impact on daily QOL. The subjective impact of the condition on psychosocial and physical well-being is an important aspect of caring for this group of patients. Failure to measure and achieve meaningful changes in quality of life may result in a poor rate of medication persistence ([xxv]). Pfizer therefore recommends that medication review includes the use of patient-reported outcome measures (PROs) as a means of assessing the success of treatment. The importance of PROs in clinical practice has been increasingly acknowledged; with diagnosis and treatment assessment for OAB now often combining the measurement of symptom bother and HRQoL outcomes with bladder diary variables such as UUI, frequency and urgency ([xxvi]).	Thank you for your comment. The Topic Expert Group (TEG) considered all suggested measures. Outcome measures are stated where the topic expert group felt they are appropriate, measurable and specifically attributable to the action stated in the statement.
55	12	Astellas Pharma Ltd	QS8	Quality statements that relate to specific interventions must be accompanied by appropriate outcome measures to ensure that the quality standard is focused on improving the outcomes that matter to patients. The metrics included in the quality standard should align with measures that are already being piloted in the NHS to ensure consistency and focus. The service specification for Any Qualified Provider includes a number of outcome measures that should be collected and monitored as part of local performance management [xix]. We recommend that as a	Thank you for your comment. The TEG considered all suggested measures. Outcome measures are stated where the topic expert group felt they are appropriate, measurable and specifically attributable to the action stated in the statement.

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				minimum, the following outcome measures are incorporated into quality statements 3, 5, 6, 8: • The proportion of men whose symptom were controlled or alleviated following treatment/an intervention (data source: International Prostate Symptoms Score used in clinical audit and patient review) • The proportion of men who were satisfied with their care (data source: local data collection, Patient Reported Experience Measures) • A reduction in avoidable secondary care attendance and admission (data source: individual patient record/local HES data) • A reduction in the proportion of men referred for surgical intervention (data source: individual patient record/local HES data) • A reduction in acute urinary retention (data source: individual patient record/local HES data)	
56	12	Astellas Pharma Ltd	QS8	Astellas welcomes the inclusion of quality statement 8 on medication review. Timely review of treatment enables patients and professionals to evaluate relevant outcomes of medication including impact on symptom control, side effects and quality of life. The review should be used to identify whether an alternative treatment could offer additional benefits – such as improved efficacy or tolerability. The draft statement includes the following classes of treatment: alpha blockers and 5-alpha reductase inhibitors and anticholinergics. In addition to these, the quality statement should cover treatment review for patients who have been prescribed a beta-3 agonist. It should also include patient review for patients who have been prescribed a combination of agents (such as an alpha-blocker with an anticholinergic).The statement should reflect the expectation that the review should	The Topic Expert Group (TEG) reviewed your comment. They were however content with the current wording of this statement and the rationale for this statement has been clarified.

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				be carried out in partnership with the patient, ensuring that they have the information they need to make decisions about their care. The statement should stipulate the key areas to be covered by the review: • symptom control (using IPSS) • adverse effects • patient satisfaction The quality standard should be reviewed and updated in a timely way to reflect developments in the treatment of LUTS in men in future. It should make clear that patients are entitled to a choice of clinically effective treatments. There should be the same expectation of choice and shared decision-making for medication as there is for other interventions, including the use of containment product where choice is included in the statement. In line with our comments on quality statement 5, guidance on pharmacological treatment should appear earlier in the quality standard. At present, medication is not referenced until the point at which a review is triggered (statement 8). However, evidence shows that men with LUTS are often unable to access treatments which could improve their quality of life , . For this reason, and in line with our comments on quality statement 5, we recommend that a new quality statement is included on a personal management plan (see our recommendation on p6-7). This would reflect the chronology of CG97 in which guidance on drug treatment follows conservative management. It would also reflect the expectation that men with LUTS should have prompt access to appropriate interventions including behavioural and lifestyle advice as well as pharmacological	

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				treatments in line with their clinical need. In addition to the outcome measures set out above, Astellas would also recommend that a further metric on treatment adherence is included in quality statement 8, 'the proportion of men with LUTS (OAB and BPH) who adhered to treatment at 6 months and at 12 months. Adherence to treatment may indicate treatment success or satisfaction with treatment and avoids the problems associated with discontinuation of treatment. It therefore provides a further metric to evaluate progress against the statement and improvements in outcomes of men with LUTS. In addition to the outcome measures set out above, Astellas would also recommend that a further metric on treatment adherence is included in quality statement 8, 'the proportion of men with LUTS (OAB and BPH) who adhered to treatment at 6 months and at 12 months. Adherence to treatment may indicate treatment success or satisfaction with treatment and avoids the problems associated with discontinuation of treatment. It therefore provides a further metric to evaluate progress against the statement and improvements in outcomes of men with LUTS.	
57	14	Pfizer Ltd	QS8	Draft quality measure c states the following: "Proportion of men with lower urinary tract symptoms taking anti-cholinergic who receive a timely medication review. Numerator – the number of men in the denominator who receive a medication review at 3-6 months and then every 6-12 months. Denominator-the number of men with lower urinary tract symptoms taking anti-cholinergic." In line with CG97(xxiii) Pfizer recommend that review should be at 4-6 weeks until stable, then every 6-12 months	The Topic Expert Group (TEG) reviewed your comment. They were however content with the current wording of this statement.

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58	11	Boehringer Ingelheim Limited	Consultation Question 1	Appropriate healthcare outcomes which involve the Pharmacist as part of the multi-disciplinary team are much more likely to lead to an enhancement of quality of life for people with long-term conditions. This enhancement in quality of life will be derived through ease of access to the care pathway, earlier access, long-term support and accessibility of the pharmacist and resulting medication reviews.	Thank you for your comment. We have now included the role of community and hospital pharmacists within the introductory text.
59	10	GlaxoSmithKline	Consultation Question 2	Is there a place in one of the quality statements for recommending the use of the IPSS questionnaire e.g. in Quality standard 2 or 7?	Thank you for your comment. The IPSS is now mentioned in statement 8 which categorises levels of symptom severity.
60	11	Boehringer Ingelheim Limited	Consultation Question 2	The standards do not adequately cover the whole patient care pathway. They have omitted the involvement of a key member of the MDT, the pharmacist. The pharmacist is in a unique position within the community in that they may be able to offer care at a time when convenient for the patient in a relaxed setting. The pharmacist is able to offer a symptom evaluation, lifestyle advice, monitor compliance and medication effects, whilst providing ease of access to the patient and reducing burden on GP appointments. This system is already partially in place for hypertension, and also for management of Dyspepsia (NICE Clinical guideline 17).	Thank you for your comment. We have now included the role of community and hospital pharmacists within the introductory text.
61	14	Pfizer Ltd	Consultation Question 2	While the Draft QS considers medication review, it does not look at when medication should be initiated. Pfizer therefore recommends that the QS include statements on appropriate medicines management. Specifically : Statements on the appropriate use of anti-cholinergic as defined by NICE CG97(xxiii) 1) in men with LUTs with OAB 2) as an additional therapy to alpha blockers in men who	Thank you for your comment. Final statement 6 is now focused on 'men with LUTS receiving a timely initial medication review'.

No	ID	Stakeholder	Statement No	Comments	Responses
				continue to have storage symptoms following alpha blocker therapy **Statement on the appropriate use of anti-cholinergics in men with LUTS with OAB** Proposed quality statement: Offer an anti-cholinergic to men suffering from bothersome OAB when conservative management options have been unsuccessful or are not appropriate. Rationale: The clinical development group for CG97(i) where of the opinion that the benefits of anti-cholinergics in carefully selected patients, where a large post voiding residual and significant obstruction as the predominant problem have been excluded, offset its costs. The national continence audit reports ( ) that antimuscarinic medications for OAB in men appear to be underutilised. The audit reports that in < 65s only of 34% (acute hospitals) and 14% (primary care) are recorded as being prescribed an anti-cholinergic for OAB. For over 65s the audit reports 24% (acute hospitals) and 6% (primary care) Proposed quality measure: Numerator: Proportion of men suffering from bothersome OAB despite conservative management treatment, or where such treatment is inappropriate, who have been offered and anti-cholinergic Denominator: Men suffering from bothersome OAB despite conservative management treatment, or where such treatment	

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				is inappropriate. **Statement on the appropriate use of anti-cholinergics as additional therapy to alpha blockers in men who continue to have storage symptoms following alpha blocker therapy** Proposed quality statement: Consider offering an anti-cholinergic as well as an alpha blocker to men who still have storage symptoms after treatment with an alpha blocker alone Rationale: Data collected from acute and specialist trusts and data collected from PCTs by the national audit of continence care shows that anti-cholinergics are being underused. Only 28% (acute hospital) and 25% (primary care) of >65 year old patients and 27% (acute hospital) and 17% (primary care) of <65 year old patients with persisting storage symptoms, despite treatment with alpha blockers, were reported as receiving an anti-cholinergic (ii). Quality measure: Numerator: proportion of men who still have storage symptoms after treatment with an alpha blocker alone who are offered an anticholinergic as well as an alpha blocker Denominator: men who still have storage symptoms after treatment with an alpha blocker alone	
62	15	Urology User Group Coalition	Consultation Question 2	The UUGC welcomes the focus on this area but believes that the draft QS needs to set out in more detail how men with lower urinary tract symptoms (LUTS) will receive a comparable service to women with LUTS – our members have drawn our attention to evidence that often men with LUTS are treated within women's health departments because there is either insufficient or no provision for men	Thank you for your comment. This Quality Standard will not cover women. A separate quality standard on 'Urinary incontinence in women' is to be developed.

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63	15	Urology User Group Coalition	Consultation Question 2	General practitioners need to be encouraged to refer men with LUTS to specialist services which can provide more specialist advice on treatment and management such as through bladder retraining and pelvic floor re-education, and where there is expert knowledge of the range of products available to manage LUTS.	Thank you for your comment.
64	15	Urology User Group Coalition	Consultation Question 2	Likewise, the clinical pathways from consultant to continence advisory service or specialist physiotherapist need to be improved, as there is often a lack of clinical understanding of LUTS.	Thank you for your comment.
65	10	GlaxoSmithKline	Consultation Question 3	All of these are very important; the 1st statement is most important. This may lend itself to some kind of audit (e.g. a simple measure of what proportion of male LUTS patients do in fact have a DRE offered/recorded as part of their initial assessment?) In addition Statement 8 (regarding that men with LUTS on drug treatment should receive timely review), is also important, e.g. review of patients can also provide an opportunity to repeat history/ DRE if necessary, assess any change in patient condition (e.g. disease progression/response to treatment etc), and also allow an opportunity for further investigation or to monitor PSA levels etc.	Thank you for your comment.
66	10	GlaxoSmithKline	Consultation Question 4	None of the measures look inappropriate.	Thank you for your comment.
67	11	Boehringer Ingelheim Limited	Section 2-Overview	Boehringer Ingelheim welcomes the recognition that services should be “commissioned from and coordinated across all relevant agencies encompassing the whole LUTS care pathway in men”. The Quality Standards need to be clear that this whole LUTS care pathway should include the multi-disciplinary team (MDT) which includes pharmacists in a person centred approach including ease of access	Thank for your comment. We have now included the role of community and hospital pharmacists within the introductory text of this standard.

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68	11	Boehringer Ingelheim Limited	Section 2-Overview	Boehringer Ingelheim supports the first Quality Statement on the initial assessment. However, a further statement is required which spans Quality Statement Number 1 and Quality Statement Number 2 'On confirmation of a confirmed diagnosis of BPH , the patient should be offered the option for management including lifestyle advice and provision of first line tamsulosin, if appropriate, by the extended healthcare team i.e. including the pharmacist. The pharmacist can provide support with lifestyle intervention, supply and compliance with tamsulosin and appropriate referral back to the General Practitioner. Evidence Source: NICE Guideline CG97 (see below) NICE Guideline CG 97: "LUTS are a major burden for the ageing male population. Age is an important risk factor for LUTS and the prevalence of LUTS increases as men get older. Bothersome LUTS can occur in up to 30% of men older than 65 years. This is a large group potentially requiring treatment. Because uncertainty and variation exist in clinical practice, this guideline gives clear recommendations on diagnosing, monitoring and treating LUTS. The guideline will assume that prescribers will use a drug's summary of product characteristics to inform decisions made with individual men." Tamsulosin hydrochloride was granted a Pharmacy (P) Licence by the MHRA on the 3rd December 2009 to treat Lower Urinary Tract Symptoms of a common condition called benign prostatic hyperplasia(BPH) This provides an option with ease of access, early access, long-	Thank you for your comment. The Topic Expert Group (TEG) prioritised the areas of care they felt were most important for patients, based on the development sources listed such as CG97. The TEG prioritised areas of care where practice is variable, or where implementation could have a significant impact on patient care and improved outcomes, and where there is potential to generate measurable indicators. All suggestions for additional statements were discussed by the TEG who considered they were inappropriate for inclusion (for example, outside the scope of the quality standard), or already covered by existing statements. The quality standard contains key markers of clinical and cost effective care across a care pathway.

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				term support, and patient convenience and care at the core of the statement. It also reduces the burden on the GP appointments system without any compromise in quality of care. Indeed it fits with the promotion of the multi-disciplinary team and how it can best work to provide appropriate care pathways for a variety of individuals.	
69	12	Astellas Pharma Ltd	Consultation Question 2	The quality standard needs to strike the right balance between enabling timely and appropriate access to containment products where there is a specific and usually short-term need, and ensuring that the first priority of the care professional is to identify and treat the condition and alleviate symptoms. To address this, Astellas recommends that: NICE introduces an additional quality statement after quality statement 2, entitled 'personalised management plan'. This would state that, after initial assessment, all men with LUTS, including urinary incontinence should receive a personalised management plan which covers diagnosis, self care, clinical management and a named professional to contact for further support. The plan should address lifestyle, behavioural and pharmacological interventions (set out in quality statement 8) which may be prescribed in combination in order to address both storage and voiding symptoms. The plan should be updated at appropriate intervals (for example, following further investigations) to provide an opportunity for the patient and their healthcare professional to identify and revisit treatment goals. Process measure: the additional statement could be measured in terms of the proportion of patients who have an agreed management plan in place, and the proportion of patients who have access to a named professional.	Thank you for your comment. In the final Quality Statement 4 on choice of containment products in the rationale section we state 'It is important that a choice of suitable containment products is offered by a healthcare professional as early as possible even if there is no definite diagnosis and agreed plan on how to manage the symptoms. Containment products only help manage the urinary incontinence – they are not a cure and should not generally be a long-term solution, unless other treatments don't help or are unsuitable. The Topic Expert Group (TEG) reviewed your comment regarding a personalised management plan. They were however content with the current wording of this statement.

No	ID	Stakeholder	Statement No	Comments	Responses
70	12	Astellas Pharma Ltd	References	Astellas Pharma Europe website, available at http://www.astellas.eu/therapy/urology/ Royal College of Physicians, National Audit of Continence Care, 2010 Coyne KS et al. The impact of overactive bladder, incontinence and other lower urinary tract symptoms on quality of life, work productivity, sexuality and emotional well-being in men and women: results from the EPIC study. BJU Int. 2008; 101(11):1388-95 Department of Health, Health and Social Care Act 2012: part 1, section 26 (14R), 2012 Department of Health, NHS Constitution, March 2013 Morant SV, Reilly K, Bloomfield G A and Chapple C., Diagnosis and treatment of lower urinary tract symptoms suggestive of overactive bladder and bladder outlet obstruction among men in general practice in the UK. International Journal of Clinical Practice. 62: 688–694, 2008 Royal College of Physicians, National Audit of Continence Care, September 2010 P Abrams et al, Commissioning for incontinence, lower urinary tract and bowel symptoms - an audit, April 2012 JS Brown et al., Cormorbidities associated with overactive bladder, The American Journal of Managed Care. Jul; 6(11 Suppl): S574-9, 2000 Health and Social Care Partnership, Prevention and early intervention: Continence services, detail taken from presentation from D Harari and National Audit of Clinical Care to Safe Care QIPP leads March 2011, available here http://www.hscpartnership.org.uk/resources/specialprojects/PEI_Learning_Pack_Continence_v9_270711.pdf accessed 21 February 2013 JS Brown et al., Cormorbidities associated with overactive bladder. The American Journal of Managed Care. Jul; 6(11	Thank for your comments.

No	ID	Stakeholder	Statement No	Comments	Responses
				Suppl): S574-9, 2000 Health and Social Care Partnership, Prevention and early intervention: Continence services, detail taken from presentation from D Harari and National Audit of Clinical Care to Safe Care QIPP leads March 2011, available here http://www.hscpartnership.org.uk/resources/specialprojects/PEI_Learning_Pack_Continence_v9_270711.pdf accessed 21 February 2013 Department of Health, Good practice in continence services, April 2000 NICE, National costing report: Lower urinary tract symptoms in men, 2010 Royal College of Physicians, National Audit of Continence Care, 2010 All-Party Parliamentary Group on Continence Care, 'Cost effective commissioning for continence care', 2011 NICE, CG97 – Lower urinary tract symptoms in men, 2010 Cheshire, Warrington and Wirral NHS Trust, Implementation Pack for Continence Services, May 2012 Morant SV, Reilly K, Bloomfield G A and Chapple C., Diagnosis and treatment of lower urinary tract symptoms suggestive of overactive bladder and bladder outlet obstruction among men in general practice in the UK. International Journal of Clinical Practice. 62: 688–694, 2008 Roger Kirby, Michael Kirby, John Fitzpatrick., Facilitating the medical management of benign prostatic hyperplasia in primary care. BJU International. 104: 751-757, 2009 NHS Choices, How to get NHS help for incontinence, available here: http://www.nhs.uk/Livewell/incontinence/Pages/Gettinghelp.aspx accessed 7 May 2013	

No	ID	Stakeholder	Statement No	Comments	Responses
71	8	British Association for Sexual Health and HIV (BASHH)	References	1. Street E, Wilson J, for the Clinical Effectivenss Group B. United Kingdom guideline for the management of prostatitis. http://www bashh org/guidelines 2008 Available from: http://www.bashh.org/guidelines 2. Shoskes DE. Chronic Prostatitis/Chronic pelvic pain syndrome. Humana Press; 2008. 3. Nickel JC, Shoskes DA. Phenotypic approach to the management of the chronic prostatitis/chronic pelvic pain syndrome. [Review]. BJU International 2010; 106(9):1252-1263. 4. Shoskes DA, Nickel JC, Kattan MW. Phenotypically Directed Multimodal Therapy for Chronic Prostatitis/Chronic Pelvic Pain Syndrome: A Prospective Study Using UPOINT. Urology 2010; 75(6):1249-1253. 5. Jonsson K, Hedelin H. Chronic abacterial prostatitis: Living with a troublesome disease affecting many aspects of life. Scandinavian Journal of Urology & Nephrology 2008; 42(6):545-550. 6. Schaeffer AJ. Clinical practice. Chronic prostatitis and the chronic pelvic pain syndrome. New England Journal of Medicine 2006; 355(16):1690-1698. 7. Murphy AB, Nadler RB. Pharmacotherapy strategies in chronic prostatitis/chronic pelvic pain syndrome management. [Review]. Expert Opinion on Pharmacotherapy 2010; 11(8):1255-1261. 8. Falk L, Fredlund H, Jensen JS. Symptomatic urethritis is more prevalent in men infected with Mycoplasma genitalium than with Chlamydia trachomatis. Sex Transm Infect 2004; 80(4):289-293. 9. Haddow LJ, Bunn A, Copas AJ, Gilson R, Prince M, Ridgway GL et al. Polymorph count for predicting non-gonococcal urethral infection: a model using Chlamydia trachomatis diagnosed by ligase chain reaction. Sex Transm Infect 2004; 80(3):198-200.	Thank you for your comments.

No	ID	Stakeholder	Statement No	Comments	Responses
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