NATIONAL INSTITUTE FOR HEALTH AND   
CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION

SUMMARY REPORT

1. Quality standard title

Urinary incontinence in women

Date of Quality Standards Advisory Committee post-consultation meeting:   
9 October 2014

1. Introduction

The draft quality standard for urinary incontinence in women was made available on the NICE website for a 4-week public consultation period between 13 August and 10 September 2014. Registered stakeholders were notified by email and invited to submit consultation comments on the draft quality standard. General feedback on the quality standard and comments on individual quality statements were accepted.

Comments were received from 23 organisations, which included service providers, national organisations, professional bodies and others.

This report provides the Quality Standards Advisory Committee with a high-level summary of the consultation comments, prepared by the NICE quality standards team. It provides a basis for discussion by the Committee as part of the final meeting where the Committee will consider consultation comments. Where appropriate the quality standard will be refined with input from the Committee.

Consultation comments that may result in changes to the quality standard have been highlighted within this report. Comments suggesting changes that are outside of the process have not been included in this summary. The types of comments typically not included are those relating to source guidance recommendations and suggestions for non-accredited source guidance, requests to broaden statements out of scope, requests to include thresholds, targets, large volumes of supporting information, general comments on the role and purpose of quality standards and requests to change NICE templates. However, the Committee should read this summary alongside the full set of consultation comments, which are provided in appendices 1 and 2.

1. Questions for consultation

Stakeholders were invited to respond to the following general questions:

1. Does this draft quality standard accurately reflect the key areas for quality improvement?

2. If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures?

3. For each quality statement what do you think could be done to support improvement and help overcome barriers?

1. General comments

The following is a summary of general (non-statement-specific) comments on the quality standard.

* Several stakeholders suggested including anticholinergic medications in the introduction and removing diuretics as a listed pharmacological treatment.
* The importance of links between primary and secondary care when treating urinary incontinence was highlighted.
* A stakeholder felt the outcomes for women with UI should be expanded to include reducing hospitalisation, falls and pressure ulcer.
* Some stakeholders suggested changing the order of the statements to better reflect the chronology.
* A stakeholder suggested that the quality standard references the source of data on over active bladder (OAB) presented in the quality standard consultation document i.e. CG171 (2013) and other related guidance.
* A stakeholder suggested that the introduction better reflect that off-label medications should be used in accordance with the guideline recommendations. Healthcare professionals should obtain informed consent and follow relevant guidance take full responsibility of the decision.
* A stakeholder requested that the frailty status of the patient is noted as an important consideration in treatment selection and that tailored care should be emphasised in this sub-group when recommending treatment options.

### Consultation question 1

### Several stakeholders confirmed the quality standard accurately reflects the key areas for quality improvement and overall it was well received.

### Consultation question 2

* A stakeholder suggested the inclusion of some reference to birth mode and parity in the collection of data.

### Consultation question 3

Stakeholders made the following comments in relation to consultation question 3:

* A stakeholder suggested that the final set of statements and supporting metrics should be adapted and strengthened to enable commissioners to measure the performance of providers and design services which support women with urinary incontinence to move through a seamless and integrated care pathway.
* A stakeholder commented recent assessments of continence services have highlighted serious shortcomings in the provision of care based on individual need and variations in the quality of commissioning across the care pathway.
* A stakeholder suggested that the quality standard should be reassessed against the minimum standards for commissioning, drawn up by United Kingdom Continence Society.
* A stakeholder felt all statements require significant investment and reorganisation of services / pathways as changes to the way that services have been commissioned has resulted in a decrease in the number of specialist posts and continence services.
* A stakeholder commented that potential challenges in achieving these standards are 1) the need for inter-agency and inter provider collaboration against a background of complex commissioning arrangements 2) need to enhance staff awareness and training of incontinence issues across a wide range of healthcare professionals who may be involved in the care of this group of women 3) accommodating equality and diversity issues for those who may be unable or deterred from accessing mainstream services as a result of disability, cultural/religious issues.

1. Summary of consultation feedback by draft statement
   1. Draft statement 1

### Women with urinary incontinence have an initial assessment that includes bimanual assessment, recording of the type and duration of symptoms, and categorisation of the urinary incontinence.

### Consultation comments

Stakeholders made the following comments in relation to draft statement 1:

* Some stakeholders felt this statement was contrary to the guideline, stating there are no recommendations indicating that bimanual assessment is mandatory or appropriate for all women.
* Some stakeholders queried if the bimanual assessment is to be carried out in primary care as many healthcare professionals won’t have enough expertise to do it. A stakeholder suggested that all patients should be referred to a Continence Service and sees a specialist Nurse or Physiotherapist for their initial assessment.
* A stakeholder felt that categorisation based on expert opinion should be 5 point SUI, stress predominant mixed, mixed, urgency predominant mixed and UUI.
* A stakeholder felt that the definition of bimanual examination which appears on page 7 of the draft quality standard lacks clarity.
* A stakeholder commented that the guideline mentions abdominal examination in three sections and is one of three methods to assess post-void residual volume.
* Some stakeholders suggested using pelvic assessment/examination or abdominal and vaginal examination instead of bimanual or including a definition of bimanual.
* A stakeholder commented that young women not sexually-active should be excluded from the statement.
* A stakeholder suggested refining the draft metric into two separate metrics to better evaluate the quality of assessments leading to categorisation of UI.
* A stakeholder felt urine testing should be performed in the initial assessment.
* A stakeholder did not understand why assessment of pelvic floor muscle tone is included in a later statement and suggested is should be included in the initial assessment.
* A stakeholder suggested the inclusion of ‘onset’ in the statement.
* A stakeholder commented that on page 32 there is no reference to NICE Guidelines CG148 “Urinary Incontinence in Neurological Disease”.
* A stakeholder felt that at the initial assessment the impact on quality of life should be included as well as recording the type and duration of symptoms.

### Measurement

Stakeholders made the following comments:

* Stakeholders stated that bimanual VE assessment in general practice could be read-coded and thus auditable.

### Implementation

Stakeholders made the following comments:

* A stakeholder felt commissioners should ensure training available in bimanual examinations (See UKCS minimum standards document).
* A stakeholder commented that it is important to acknowledge that services should only be commissioned where there is evidence of a clear patient pathway which is in line with the NICE commissioning guide (2008).
* A stakeholder suggested that the QS recommends that services are commissioned where there is evidence of a clear patient pathway in line with the relevant budgets and service evaluations to aid commissioning groups and NHS England.
  1. Draft statement 2

Women with urinary incontinence are only offered containment products as a temporary coping strategy pending decisions about treatment, or in addition to ongoing treatment or as long-term management after all possible treatment options have been unsuccessful.

### Consultation comments

Stakeholders made the following comments in relation to draft statement 2:

* A stakeholder welcomed the emphasis within the draft quality statement that containment products should only be offered as a “temporary coping strategy”.
* A stakeholder commented that use of containment products pending definitive treatment should be incorporated into the statement.
* Stakeholders felt the statement on containment products should also emphasise the need for timely 4-week review in line with the NICE CG171 (2013).

### Measurement

Stakeholders made the following comments:

* A stakeholder commented that whilst it is possible to collect the data for the proposed quality measure, some continence products will be self-purchased and compromise their management plan. As well as recording prescriptions for containment products as a quality measure, recording whether patients are accessing these independently would be an additional measure.

### Implementation

Stakeholders made the following comments:

* To enable commissioners to evaluate whether this standard is being achieved locally, a stakeholder suggested separating the process measures to measure offer of temporary products and use when long term treatment is unsuccessful.
  1. Draft statement 3

### Women with urinary incontinence are not offered transcutaneous sacral nerve or transcutaneous posterior tibial nerve stimulation to treat overactive bladder.

### Consultation comments

Stakeholders made the following comments in relation to draft statement 3:

* Some stakeholders did not feel these treatments were being performed and the statement was not a key area for improvement.
* A stakeholder commented that this is sensible as offering these treatments is costly and women do not achieve the desired outcome.
* A stakeholder felt it may need to differentiate adequately between transcutaneous and percutaneous as this may be easily misread and misconstrued as PTNS/SNS, leading to the unintended consequence of reducing access to the clinically effective procedure of surgical Sacral Nerve Stimulation (SNS).
* A stakeholder felt that there should there be mention of the option to refer women with proven detrusor over activity for percutaneous sacral nerve stimulation (SNS) if they have exhausted all conservative and pharmacological treatments.
* A stakeholder felt there was a missed opportunity here to cement the importance of bladder diaries into the pathway and to link primary and secondary care as an integrated service.

### Measurement

Stakeholders made the following comments in relation to consultation question 2:

* A stakeholder commented that it should be possible to collect the data.

### Implementation

Stakeholders made the following comments in relation to consultation question 3:

* A stakeholder commented that access to percutaneous SNS could be improved if percutaneous SNS for refractory OAB in women was recognised within this guidance and also by an NHS England Commissioning Policy.
  1. Draft statement 4

Women with urinary incontinence have a multidisciplinary team review before they are offered surgery or other invasive treatment for overactive bladder or symptoms of stress urinary incontinence.

### Consultation comments

Stakeholders made the following comments in relation to draft statement 4:

* Several stakeholders agreed with the statement as the implications of invasive treatment/surgery are significant.
* A stakeholder stated that for stress incontinence the only effective treatments are pelvic floor exercises and surgery so if pelvic floor exercises are not beneficial, it is unclear how further discussion at an MDT is going to improve treatment. It was queried if the quality standard is saying that the opinion of a team should take higher precedence than evidence based medicine.
* Some stakeholders felt MDT discussion is required only in complex cases.
* A stakeholder felt that this recommendation had not been costed by NICE and would be expensive.
* A stakeholder felt the rationale suggested that a professional team's opinion takes priority over a woman's opinion.
* A stakeholder was unsure whether the multidisciplinary team needs to include both a urogynaecologist and a urologist with a sub-specialist interest in female urology.

### Measurement

Stakeholders made the following comments in relation to consultation question 2:

* A stakeholder felt this statement is impractical. That confirming review by a CNS or physio prior to SUI surgery and that 2 or 3 anticholinergics have been tried prior to BOTOX (or there be a CI to antichol) may be better. They advised the infrastructure is there and these can be built into the databases (e.g. BSUG) so felt this should be the standard rather than going through an MDT.
* Some stakeholders confirmed that this would be easy to collect on surgical databases.

### Implementation

Stakeholders made the following comments in relation to consultation question 3:

* Several stakeholders commented that the implication of this in terms of workload for MDT’s is huge with a significant potential cost to the NHS.
  1. Draft statement 5

### Women with urinary incontinence have a digital vaginal assessment to confirm correct pelvic floor muscle contraction before they are offered supervised pelvic floor muscle training.

### Consultation comments

Stakeholders made the following comments in relation to draft statement 5:

* A stakeholder queried where this would be done and what would happen if a patient could not contract as these patients will still need to be referred on.
* A stakeholder felt this was at odds with statement 4. They felt it meant all patients must undergo physio and go to an MDT, but won’t be referred if they can’t contract the pelvic floor.
* A stakeholder felt that this may be impractical as specialist physiotherapists in women’s health are not always easily available within the community.
* A stakeholder felt the rationale, which states that if a woman is unable to contract her pelvic floor muscles effectively then pelvic floor muscle training is unlikely to be beneficial, contradicts quality statement 6 which proposes that all women should be offered pelvic floor exercises.
* Stakeholders welcomed this standard because so many patients are offered just a leaflet and do not understand how to contract the pelvic floor.

### Implementation

Stakeholders made the following comments in relation to consultation question 3:

* A stakeholder felt that local data collection to assess adherence to this standard will be time consuming to collect and with no evidence of benefit.
* A stakeholder felt it should be possible to collect the data.
  1. Draft statement 6

### Women with symptoms of stress or mixed urinary incontinence are offered a trial of supervised pelvic floor muscle training of at least 3 months’ duration as first-line treatment.

### Consultation comments

Stakeholders made the following comments in relation to draft statement 6:

* A stakeholder queried whether patients with urgency predominant may need lifestyle and/or pharmacotherapy first.
* A stakeholder felt that if quality statement 5 is to remain then women with poor pelvic floor contraction should be excluded from statement 6.
* A stakeholder felt it was not clear from the statements whether supervised pelvic floor muscle training (Statement 6) or a minimum of 6 weeks bladder training (Statement 7) should be given as a first- line treatment.
* A stakeholder felt this was sensible but that the supervised treatment should take place with a suitably trained specialist nurse or physiotherapist.

### Measurement

Stakeholders made the following comments:

* A stakeholder felt it should be possible to collect the data.

### Implementation

Stakeholders made the following comments:

* A stakeholder commented that three months pelvic floor exercises will be difficult to cost and they felt it would help to identify the number of sessions within the three month period.
* A stakeholder felt the availability of supervised pelvic floor training may also be variable and one that commissioners need to address.
  1. Draft statement 7

Women with symptoms of urgency or mixed urinary incontinence should be offered bladder training for a minimum of 6 weeks as first-line treatment.

### Consultation comments

Stakeholders made the following comments in relation to draft statement 7:

* A stakeholder queried whether a review was suggested at 4 weeks for an anticholinergic?
* A stakeholder commented there is a missed opportunity to reinforce the role of a bladder diary here.
* A stakeholder commented this should also include a trial of anti-muscarinics / beta 3 agonists if bladder training fails.

### Implementation

Stakeholders made the following comments:

* A stakeholder felt a six weeks bladder drill will be difficult to cost, it would help to identify the number of sessions within the 6 week period for patients to be seen.
  1. Draft statement 8

### Women with urinary incontinence have indwelling urethral catheters for long-term treatment only if they have had a full assessment and discussion of the practicalities and potential urological complications.

### Consultation comments

Stakeholders made the following comments in relation to draft statement 8:

* A stakeholder felt this was not a key priority for quality improvement.
* A stakeholder felt this should be reworded as the complications of long term catheterisation may not just be urological e.g. possibly gynaecological.
* A stakeholder commented that full assessment and discussion is essential if the effects on a woman’s mental health and wellbeing of living with a catheter are to be minimised and it would be sensible to include regular review as best practice
* A stakeholder felt it would be helpful if there was a definition of what a “full assessment” would involve and who should undertake this, what the practicalities and potential urological complications are of a long-term indwelling urethral catheter
* A stakeholder felt that supporting patient literature will be essential to facilitate this.

1. Suggestions for additional statements

The following is a summary of stakeholder suggestions for additional statements.

* A stakeholder advised it would be appropriate to check the position of the colorectal community regarding abdominal mesh used for vault support before this guidance is issued.
* Several stakeholders felt a statement on bladder diaries and their importance should be included.
* A stakeholder commented that they would include more statements including the place of urodynamics, the use of medication and follow-ups.
* A stakeholder suggested a statement that highlights the need for psychological support, as well as physical treatments.
* A stakeholder suggested the following areas for additional statements: prevention strategies (e.g. lifestyle factors and antenatal pelvic floor exercises).
* Stakeholder suggested including an additional statement within the draft standard in relation to personalised care plans.
* A stakeholder proposed a statement on medication review at 4 to 6 weeks.
* A stakeholder suggested a statement on patient experience which 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 women with UI.
* A stakeholder suggested a statement on ‘follow up’ for the treatment and management of overactive bladder.
* Stakeholders suggested a statement on the pharmacological management of women with overactive bladder or mixed urinary incontinence should be either: oxybutynin (immediate release), tolterodine (immediate release), darifenacin (once daily preparation) and fesoterodine as outlined in CG171 (2013).

# Appendix 1: Quality standard consultation comments table

| No | Stakeholder | Statement | Comment on | Comments |
| --- | --- | --- | --- | --- |
| 1 | Birmingham Women’s Hospital | General | Page 2 para 4 | Missed anticholinergic medications off the list of pharmacological agents |
| 2 | Birmingham Women’s Hospital | General | Q3 | I think there is a missed opportunity here to do 2 things cement bladder diaries and their importance and to link primary and secondary care as an integrated service. There also needs to be a clear statement about MDT’s and how this should be incorporated in job plans. There is an economic argument why putting so much through the MDT is not cost effective. At present most MDT’s are done around rather than as part of the job plan |
| 3 | King’s College Hospital | General | General | The document is well written and for the most part appropriate and achievable |
| 4 | Abertawe Bro Morgannwg University Health Board | General | General | As a whole very well organised and a pleasure to read. Thank you. |
| 5 | Astellas Pharma Limited | General | General | Astellas welcomes the development of the quality standard on urinary incontinence (UI) in women. Urinary incontinence can have a very negative impact on quality of life[[1]](#endnote-1) with the potential to affect an individual’s work productivity, sleep and mental wellbeing[[2]](#endnote-2). 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[[3]](#endnote-3) and to treat individuals with dignity and respect[[4]](#endnote-4).  However, recent assessments of continence services have highlighted serious shortcomings in the provision of care based on individual need and variations in the quality of commissioning across the care pathway[[5]](#endnote-5),[[6]](#endnote-6). Age is a major risk factor for urinary incontinence in women – so 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[[7]](#endnote-7),[[8]](#endnote-8).  The NICE quality standard has a critical role to play in driving 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 adapted and strengthened to enable commissioners to design services which support women with urinary incontinence to move through a seamless and integrated care pathway – one which ultimately embeds the approaches and interventions that will make the most difference in terms of patient outcomes:   * Increased symptom awareness * Earlier identification of symptoms * 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) * Ensuring that commissioners can design coordinated and overarching services which meet the needs of women with UI as well as men with LUTS, for whom a high quality service has many areas of overlap * Listing the full range of the class of treatments recommended by NICE within the introduction * Specific recommendations relating to quality statements 1 and 2 * Additional proposed statements relating to:   + Initial medication review at 4 weeks   + Personalised management plans   + Patient experience |
| 6 | Astellas Pharma Limited | General | Introduction | Astellas agrees that effective management of UI in women helps the NHS to deliver improvements in outcomes that are required under the NHS Outcomes Framework. However, at present, the outcomes for women with UI 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 women to recover from episodes of ill-health (Domain 3) and contributes to their safety (Domain 5). For example, effective management of UI 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 women and reduce incidence of pressure ulcers related to incontinence (Domain 5) ,  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 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). As such, effective management of UI 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 and experiences of care of women 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. Commissioners must be supported to measure the performance of providers against the quality standard to support a continuous process of evaluation and improvement. |
| 7 | Astellas Pharma Limited | General | Introduction: coordinated services | Astellas welcomes the emphasis on the need for commissioners to design person-centred and integrated services, and notes that the quality standard on lower urinary tract symptoms (LUTS) in men (QS45) is cited within the list of related NICE quality standards within the introductory text. Given the broad areas of overlap between high quality services for LUTS in men and UI in women, Astellas recommends that strengthened guidance should be provided within the introductory sections about an overarching pathway of care that meets the needs of both men with LUTS and women with UI. This will support commissioners to design high quality and effective services which improve not only outcomes but also experiences of care for patients.  Astellas recommends that, in order to effectively support commissioners to design high quality services for women with UI, the draft quality standard should be revised to follow a clear pathway of care: one which reflects the pathway outlined in CG171 as well as that set out for men with LUTS in QS45. We propose that the draft quality standard should be re-ordered, as below, with each statement adapted in relation to the specifics for stress and/or urge UI as set out in CG171:   * Initial assessment, physical examination and categorisation of UI (currently covered in part by statement 1) * Assessment of pelvic floor muscles and use of bladder diaries (currently covered in part by statements 5 and 1) * Advice on lifestyle and behaviour changes (currently covered in part by statements 6 and 7) * Use of temporary containment products (currently statement 2) * Treatments that should not be offered (currently statement 3) * Medication review of pharmacological review (not currently included in the draft standard) * Other, invasive and surgical treatment options, including the role of the MDT (currently statements 4 and 8)   Ultimately, by supporting commissioners to design high quality services in line with a clear pathway of care, the quality standard may help improve outcomes and experiences of care for women with OAB, whilst also ensuring that local services meet the holistic needs of men with LUTS and women with OAB. |
| 8 | Astellas Pharma Limited | General | Introduction: additional guidance on drug treatments | CG171 includes a number of recommendations (1.7.1 - 1.7.21) about the appropriate use of a range of agents to treat OAB (mirabegron, anticholinergics, oestrogens), nocturia (desmopressin) and stress UI (duloxetine).  Astellas notes however, that the list of pharmacological agents included within page 2 of the introductory text omits anticholinergics from its list. This is a significant omission given that NICE recommends this class of treatment as the first line of pharmacological treatment for overactive bladder in CG171 (recommendation 1.7.7). To ensure that the guidance reflects the full range of treatments reviewed by NICE, Astellas recommends that NICE revises the list of agents as follows: “Pharmacological treatment includes drugs such as mirabegron, [*insert: ‘anticholinergics’*], desmopressin, duloxetine and oestrogens”. |
| 9 | Femeda Limited | General | General | The topics covered in the 8 statements do not follow in a logical order or mirror the order in which topics are covered in the guideline. |
| 10 | The Primary Care Women’s Health Forum | General | Introduction | In the list of medications recommended for management of overactive bladder there is no mention of the anti-cholinergics, which is the main treatments used for this |
| 11 | The Primary Care Women’s Health Forum | General | General | These quality statements are limited to very few interventions and managements which are relevant to the guidance. This is an important quality standard and could include more statements including one about the place of urodynamics. There should be a QS about the use of medication and follow-ups |
| 12 | NHS Choices – Digital Assessment Service | General | General | We welcome this publication and have no comments on its content as part of the consultation |
| 13 | Bladder & Bowel Foundation | General | Q1 | The draft guidance does reflect the key areas for improvement. As it stands women find it very difficult to navigate their way through the myriad of existing ‘care pathways’. This is compounded by a lack of understanding from clinicians who often don’t know the correct local referral process which results in everyone being ‘referred to the Consultant’ This guidance will help to reinforce the fact that most continence referrals can be managed in the community by adequately trained staff. Investment will be needed so that staff can be developed to achieve specialist assessment skills and knowledge. Services will benefit from being promoted via patient groups and professional networks to help women access help. The B&BF helpline regularly tells women that their local service is a few miles from their house – most women state ‘I didn’t know where to get help’. |
| 14 | Bladder & Bowel Foundation | General | Q2 | Yes |
| 15 | Bladder & Bowel Foundation | General | Q3 | All statements require significant investment and reorganisation of services / pathways – changes to the way that services have been commissioned has resulted in a decrease in the number of specialist posts in this foield as well as some continence services ceasing to operate. Individuals struggling with incontinence may have other comorbidities e.g. Diabetes, Heart disease but they will always say that their Incontinence concerns them the most and has the most negative impact upon their quality of life. |
| 16 | Royal College of Obstetricians and Gynaecologists | General | Introduction | Page 2 of 36. Short paragraph on pharmacological treatment should include anticholinergics. Are diuretics really a treatment for incontinence? - diuretics are not mentioned in the guideline recommendations (section 1.7). |
| 17 | NHS England | General | General | No substantial comments |
| 18 | Department of Health | General | General | No substantial comments |
| 19 | British Association of Urological Surgeons, Section of Female, Neurological and Urodynamic Urology (BAUS SFNUU) | General | General | since these standards were drawn up , the UKCS has drawn up minimum standards for commissioning   starting in primary care and a look at these and reassessing these against the above standards and any potential new quality standards would not be a bad thing |
| 20 | Elective Cesarean | General | Introduction | Re: “The preventive use of physical and behavioural therapies and of lifestyle interventions is also included.”  A planned caesarean birth has often been derogatively described by some as a “lifestyle choice” or lifestyle intervention, and yet there is evidence that it actually has the preventative or prophylactic benefit of reducing the risk of pelvic floor related damage, including urinary incontinence. Where this birth plan is wanted or agreed to by women, there are positive psychological benefits too, but for the purposes of my organisation including it comments for this Quality Standard – and in the context of NICE’s role in looking at the cost-effectiveness of any interventions agreed to on the NHS – I would like to draw the quality standards team’s attention to the Health Economics section of the NICE CG132 guidance on Caesarean Sections:  One of the models included here looked at the cost of urinary incontinence as an outcome of different birth types, namely a Planned Vaginal Delivery and a Planned Caesarean Delivery. What the NICE GDG found was that when you simply compared the two birth plan types, the cost difference was £710, but this difference reduced to just £84 when urinary incontinence costs were factored in. Evidently, this is just one adverse outcome related to pelvic floor morbidity related to delivery mode (and of course some birth-related injuries only come to light long after the postnatal period), but it does demonstrate the estimated urinary incontinence cost per planned vaginal birth (£626).  As such, my organisation would like to suggest the inclusion of some reference to birth mode and parity in the collection of data as part of the Urinary Incontinence QS, as it is an ideal opportunity to gather this type of information from the women whose daily lives are being affected by urinary incontinence. |
| 21 | Elective Cesarean | General | General | Re: Questions for consultation - Does this draft quality standard accurately reflect the key areas for quality improvement?  One area of improvement might be to identify women whose urinary incontinence is as a direct result of birth-related pelvic floor injury/injuries. My organisation has been contacted by women who have experienced incontinence and/or prolapse symptoms following the birth of their first child and who would like to plan a caesarean birth in their subsequent pregnancy, but are refused this birth choice at their maternity hospital/unit. While it is not guaranteed that their symptoms will worsen in a subsequent vaginal delivery, it is certainly a possibility, and as such, their caesarean request is a valid one.    My organisation would like to see the inclusion of a question regarding the woman’s **parity** in this Quality Standard, and also the collection of data on **birth mode** – i.e. elective caesarean, emergency caesarean, spontaneous VD, instrumental VD. |
| 22 | Elective Cesarean | General | General | If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures?  See comments above regarding collection of data.  Parity and birth mode would be very useful data to capture. |
| 23 | Elective Cesarean | General | General | For each quality statement what do you think could be done to support improvement and help overcome barriers?  There can often be a fait accompli attitude towards women with urinary incontinence, and especially where their incontinence has occurred as a direct result of intrapartum morbidity.  It can be communicated as though urinary incontinence is an ‘expected’ or ‘accepted’ consequence of having a baby, and while some women are in absolute agreement with this, and can cope with handling their situation, there are others for whom the connection between their baby’s arrival and their loss of bladder control (especially if the urinary incontinence is just one problem – they may have other pelvic floor related problems too, such as prolapse or sexual health issues) is devastating.  My organisation has been contacted by women who are suffering severe depression as a result of incontinence problems, and professional women whose whole career has come to an end (also see Briefing Paper Appendix 3 on pg. 33 “*Women are often reluctant to seek treatment and are often told this is “normal” following childbirth. Social isolation, impacts on returning to work (Key area for quality improvement)*”)  A Statement or outcome that highlights the need for psychological support, as well as physical treatments, might be worth including (or incorporating into an existing Statement). This could help support improvements for some women.  In terms of ‘overcoming barriers’, it remains worth commenting here that the focus on arbitrarily reducing caesarean rates in hospitals, and refusing women’s maternal requests on the grounds of cost, is a barrier that women in this country often have to overcome. Women experiencing urinary incontinence should not be forced to have a vaginal delivery against their will. |
| 24 | British Society of Urogynaecology (BSUG) | General | General | The document is well written and for the most part appropriate and achievable |
| 25 | Pfizer Ltd | General | General | Pfizer suggest that NICE CG171 is referenced in the introduction section of the Quality Standard (QS) for urinary incontinence/over-active bladder (OAB). It is unclear currently which guideline had been used to inform the QS and we suggest that this would be useful in providing further information on the overview of urinary incontinence should the reader require it (NICE CG 171, 2013).  Pfizer request that NICE reference the source of data on OAB presented in the Quality Standard Consultation document i.e. CG171 (2013) and other related guidance. |
| 26 | Pfizer Ltd | General | General | Pfizer recommend incorporating a statement indicating that OAB is often idiopathic in nature. Conventionally, urgency urinary incontinence is attributed to detrusor over-activity during bladder filling. This over-activity may be caused by bladder abnormalities (such as infections or lesions) or neurological disorders but more commonly, no cause is identified (classified as idiopathic OAB) (Nygaard, 2010). This point is currently not clear in the QS.    Pfizer request that NICE revise the definition of OAB to be stated as follows “Overactive bladder is defined as urgency with or without urgency incontinence and usually with frequency and nocturia and is often idiopathic. When it occurs with incontinence it is known as ‘OAB wet’; when it occurs without incontinence it is known as ‘OAB dry’. These combinations of symptoms suggest detrusor over-activity, but can result from other forms of urethrovesical dysfunction”. |
| 27 | Pfizer Ltd | General | General | Pfizer note that off-label drugs have been recommended as outlined in CG171 however, it is important to emphasise that such drugs should be recommended in accordance with the existing guidelines/guidance.  The NICE CG171 (sections 1.7.18, 1.7.19; 1.7. 20) indicates that the use of desmopressin, duloxetine and estrogens is in line with the treatment recommendations outlined in the guideline for each relevant intervention. However, the quality statements do not explicitly provide this information when listing pharmacological treatments for OAB.  Pfizer recommend that NICE emphasise that off-label medications are used in accordance with the guideline recommendations and also, healthcare professionals prescribing off-label interventions should follow relevant guidance taking full responsibility of the decision. Therefore, informed consent should be obtained and documented as per the General Medical Council’s Good practice in prescribing and managing medicines (2013). |
| 28 | Pfizer Ltd | General | General | It is important to explicitly report on the relevant pharmacological interventions as recommended in CG171 (2013) to ensure that there are no inconsistencies in the treatment and management of OAB in the QS. NICE CG171 (Section 1.7.1) outlines the general principles on when OAB drugs should be used, which takes in to consideration patients’ health status and lifestyle. The guideline states that oxybutynin, tolterodine or darifenacin should be used as first line therapy for women with OAB or mixed UI. Additionally, where a first line therapy is not well tolerated or ineffective, another antimuscarinic with a low acquisition cost should be offered including (not limited to) fesoterodine and solifenacin. Also, in women who are unable to tolerate oral medication, transdermal or topical gel treatment for OAB should be offered.  Pfizer request that NICE re-align the QS recommendation to include the use of pharmacological interventions such as oxybutinin, tolterodine, darifenacin and fesoterodine as outlined in CG171 (2013). |
| 29 | Pfizer Ltd | General | General | Pfizer note that the chronological order for the list of interventions starting with mirabegron has been used in the QS. However, this does not put in to perspective a clear treatment pathway on the use of pharmacological interventions in the treatment and management of OAB.  The NICE CG171 (Section 1.7.10) indicates that mirabegron is an alternative for treating the symptoms of overactive bladder in some patients. However, it should be initiated only in patients for whom antimuscarinic drugs are contraindicated or clinically ineffective, or have unacceptable side effects (NICE TA290). This is currently unclear in the QS and could lead to inconsistencies in patient management between the CG171 and the QS.  Pfizer request that NICE re-align the recommendation on the use of mirabegron as outlined in TA290, noting that mirabegron is only used after patients have unsuccessful been treated with the relevant antimuscarinics as outlined in NICE CG171 (2013). |
| 30 | Pfizer Ltd | General | General | When choosing OAB drugs it is important to consider that the treatment approach may need to be tailored for specific patient groups. NICE CG171 (2013) states that oxybutynin (immediate release) should not be offered to frail older women with OAB. Additionally, studies have shown that both men and women are equally affected by OAB however; older women are often affected with moderate and severe incontinence compared to their younger counterparts who tend to experience mild to moderate incontinence (Irwin et al. 2008 and Milsom et al. 2001).  Pfizer recommend that NICE note the frailty status of the patient as an important consideration in treatment selection and that tailored care should be emphasised in this sub-group when recommending treatment options. |
| 31 | Pfizer Ltd | General | General | Pfizer suggest including a statement, prior to paragraph (“When conservative...”); indicating that a multidisciplinary team (MDT) review is carried out before a recommendation for invasive therapy as an alternative therapy is given. This is in line with the NICE CG171 (Section 1.8) which states that invasive therapy for OAB and/or stress urinary incontinence (SUI) symptoms should only be recommended after an MDT review.  Pfizer suggest that NICE include a statement in the QS stating that MDT review is an important step in the treatment pathway prior to recommending surgical or invasive therapy in whom the conservative management and pharmacological treatment have not adequately treated the symptoms associated with overactive bladder or stress incontinence. |
| 32 | Pfizer Ltd | General | General | The current sequence of quality statements does not reflect the treatment pathway for OAB patients outlined in NICE CG171, for example invasive therapies should be used after conservative management and/or pharmacological interventions have failed. NICE CG171 outlines the treatment recommendation in chronological order of the OAB treatment pathway including assessment and investigation, lifestyle interventions, physical therapies, behavioural therapies, alternative conservative management options, pharmacological treatment, multidisciplinary team (MDT), neurostimulation, invasive procedures for OAB and surgical approaches for SUI as well as ensuring that regular reviews are carried out based on the risk/benefit ratio of success of each therapy.    The quality statements should be arranged in the order reflective of the clear treatment pathway of patients with OAB as outlined in the NICE CG171. Therefore, Pfizer would like to propose the following sequence for the Quality Statements.  **The following sequence is proposed in line with CG171 (2013)**  (a) **Statement 1** Assessment and investigation (History taking and physical examination including assessment of pelvic floor muscles)  (b) **Statement 2** Bladder diaries  (c) **Statement 3** Pelvic floor muscle training (where appropriate)  (d) **Statement 4** Absorbent products, urinals, toileting aids, catheters (used only as coping strategies pending definitive treatment)  (e) **Statement 5** Pharmacological interventions  (f) **Statement 6** Multidisciplinary team (MDT)  (g) **Statement 7** Invasive therapies for OAB  (h) **Statement 8** Surgery for SUI  Pfizer request that NICE re-arrange and align the sequence of quality statement to reflect the currently recommended pathway for the treatment and management of OAB as outlined in CG171. |
| 33 | UK Multiple Sclerosis Specialist Nurse Association | General | General | Page1 The introduction states that these standards do “not cover urinary incontinence in women with  neurological disease. For more information see the urinary incontinence in women topic overview” It is estimated that 75% of people living with MS have bladder problems and while this population is mixed (male and female) they will represent a significant number of the individuals who are frequent attenders at GP surgeries and Continence Clinics. This fragmentary approach to guidance in separating neurological incontinence from these quality standards is likely to disadvantage individuals with MS by making it more difficult for clinician trying to adhere to both Guidelines and these quality standards. |
| 34 | UK Multiple Sclerosis Specialist Nurse Association | General | General | Although the document explains that urinary incontinence should not be viewed as an inevitable consequence of ageing it does not mention any other particular considerations. As disruption of bladder function can be symptomatic of neurological damage it would be helpful to signpost the reader to NICE Guidelines CG148 “Urinary Incontinence in Neurological Disease” |
| 35 | Johnson & Johnson Medical Ltd | General | General | Johnson & Johnson Medical Ltd. support the development of the Urinary Incontinence Quality Standard with the aim of supporting the clinical community in delivering high quality, evidence-based care. In order to ensure their integration with, and indeed their impact on clinical practice, we would welcome further efforts aimed at monitoring and measuring their uptake across the broader NHS. |
| 36 | Faculty of Sexual and Reproductive Healthcare of the RCOG | General | General | The draft quality standard accurately reflects the key areas for improvement and has clearly been significantly influenced by the stakeholder engagement exercise.  If any additional quality statements were to be included suggested areas would be (1) prevention strategies (eg lifestyle factors and antenatal pelvic floor exercises) and (2) pharmacological treatment – this is a key stage in the management of OAB which if managed appropriately may avert the need for invasive/surgical procedures and there is evidence to suggest that compliance is poor which in turn limits the potential of this treatment modality.  Potential barriers/ challenges in achieving these standards are (1) the need for inter-agency and inter provider collaboration against a background of complex commissioning arrangements – this will need collaborative commissioning as well as co-ordination at provider level (2) need to enhance staff awareness and training of incontinence issues and management options across a wide range of healthcare professionals who may be involved in the care of this group of women (3) accommodating equality and diversity issues for those who may be unable or deterred from accessing mainstream services as a result of disability, cultural/religious issues (especially statements 1,5 and 6). |
| 37 | Faculty of Sexual and Reproductive Healthcare of the RCOG | General | General | The draft makes the inclusion criteria clear (ie women over 18 without neurological problems) however, it may be useful to add references to other documents dealing with excluded women. |
| 38 | Birmingham Women’s Hospital | 1 | P 7 | Does this relate to primary or secondary care (or both?) Who does the bimanual? Whilst this is a good idea and seems easy a lot of HCP’s may not be confident (particularly male GP’s who are seldom if ever asked to) |
| 39 | Birmingham Women’s Hospital | 1 | P8 | Commissioners ensure training available in bimanual examinations (See UKCS minimum standards document) |
| 40 | Birmingham Women’s Hospital | 1 | P9 | Categorisation based on expert opinion. This surely should be 5 point SUI, stress predom mixed, mixed, urgency predom mixed and UUI as this will direct which direction should be taken for most patients with mixed (Expert opinion!) |
| 41 | King’s College Hospital | 1 |  | Statement 1 recommends that Women with urinary incontinence have an initial assessment that includes bimanual assessment, in addition to recording of the type and duration of symptoms, and categorisation of the urinary incontinence.  If the initial assessment is to be carried out in the setting of primary care, a detailed bimanual examination may not be feasible/ beyond the level of expertise/experience required to make an informed judgement based on this examination |
| 42 | Abertawe Bro Morgannwg University Health Board | 1 | Line 167 | Useful to highlight here that for SSF the question of which suture to use is dealt with on line 345 |
| 43 | Royal College of General Practitioners | 1 |  | The QS standards to promote the care of women who suffer from this distressing condition is to be welcome but there will be challenges. Bimanual VE assessment in General practice could be read-coded and thus auditable however doing VE on women with physical disabilities in their own home will be difficult to implement in practice (use of chaperone etc). With recruitment and retention challenges in practice the same might also apply to women from particular ethnic backgrounds who would want a female practitioner. |
| 44 | Pelvic, Obstetric & Gynaecological Physiotherapy | 1 |  | ("Women with urinary incontinence have an initial assessment that includes bimanual assessment, recording of the type and duration of symptoms, and categorisation of the urinary incontinence.") is not consistent with the 2013 guideline. I cannot find any recommendation stating that a bimanual examination is an absolute requirement; neither does it appear in the care pathway algorithms. In addition, I feel that the descriptor of bimanual examination which appears on page 7 of the draft quality standard lacks clarity and could be interpreted in more than one way by healthcare professionals, service providers and commissioners.  The guideline mentions abdominal examination in para 3 of the physical examination section on page 52 ("can detect a significantly enlarged bladder or palpable pelvic mass"). It mentions it again in the introductory paragraph of section 4.4 on page 55 ("Women who present with symptoms of prolapsed and UI should have an abdominal examination to exclude other pathology") and in the introductory paragraph of section 4.6 on page 56 ("Abdominal examination can detect a significantly enlarged bladder, which may indicate the presence of chronic urinary retention"). The following paragraph at the top of page 57 lists abdominal palpation as one of three methods which can be used to assess post-void residual volume.  The only references I can find to bimanual examination are (i) para 4 of the physical examination section on page 52 ("Uterine enlargement may be determined by bimanual examination"); (ii) the introductory paragraph of section 4.4 on page 55 ("Bimanual examination will reveal any pelvic masses"); (iii) page 57 in the (assessment of residual urine) diagnostic accuracy section, the evidence of which is summarised lower down the page as "The sensitivity of bimanual examination to detect small post-void residual volumes is poor" and (iv) Recommendation 13 "Refer women who are found to have a palpable bladder on bimanual or abdominal examination."  Whilst clearly referenced in recommendation 13 of the guideline, I do not consider this to be an implicit recommendation that bimanual examination is a mandatory part of the assessment, particularly given the content referred to above, which appears in earlier in the document.    I feel it would be much more appropriate to state that the assessment must include a physical examination. If it is considered appropriate to be more specific it may be better to state 'abdominal and vaginal examination' or 'pelvic examination', as this is consistent with the language used in the guideline. 'Bimanual examination' as an essential component on the physical exam does not seem to be consistent with the language in the guideline.    The rationale (on page 7 of the draft quality standards document) states "Categorising urinary incontinence is important because different types of incontinence need different treatments. Some treatments are only offered after referral to a specialist. Initial assessment that includes bimanual assessment and recording of the nature and duration of symptoms allows categorisation of urinary incontinence and provision or referral for the correct treatment." The guideline, however, does not support the hypothesis that bimanual assessment is what helps to categorise the UI. This could be determined equally well by using the language of 'abdominal and vaginal examination' or 'pelvic examination' suggested above.    There appears to be a sudden jump from the guideline which talks about a range of assessment tools to specifically singling out bimanual examination as a ‘must be included’. My concern is that there is no clear definition of what a ‘bimanual examination means within the statement and this could be misinterpreted as the specific gynaecological examination technique which would mean that all women needing an incontinence assessment would have to see a gynaecologist or someone who had extra training in gynaecological bimanual examination. |
| 45 | Astellas Pharma Limited | 1 |  | As part of the initial assessment, Astellas supports the recording of type and duration of symptoms to enable the categorisation of the UI. Bladder diaries can help women with OAB and their healthcare professional understand the extent of symptoms as well as the impact of treatment, but evidence collected by the National Audit of Continence Care suggests that the bladder diaries are still used for, “at best, half of those [women] under investigation, regardless of age” . To support implementation, Astellas recommends that the draft statement is therefore strengthened, and further guidance is provided within the accompanying text, about how this can be achieved and measured, namely through the use of urinary frequency and volume charts (a bladder diary). To reflect recommendation 1.1.17 in CG171 , Astellas recommends that the draft statement is revised as follows:  “Women with urinary incontinence have an initial assessment that includes bimanual assessment, recording of the type and duration of symptoms [insert: through the use of a bladder diary for a minimum of 3 days], and categorisation of the urinary incontinence.”  In addition, Astellas is concerned that the proposed measure, as currently drafted, will not be meaningful enough to assess the quality of initial assessments and, more importantly, the accurate categorisation of UI. This is essential as it will underpin the care pathway that the patient receives as a result. As currently described, the measure combines three different processes into one overall measure: the number of women who receive bimanual assessments, recording of type and duration of symptoms, and categorisation of UI, expressed as a proportion of all women with UI . To better evaluate the quality of assessments leading to categorisation of UI, Astellas recommends refining the draft metric into two separate metrics, set out below:  1) Number of women with UI whose UI is categorised into stress UI, urge UI due to OAB, or mixed, expressed as a proportion of all women with UI  2) Number of women whose UI is categorised as either stress UI, urge UI due to OAB, or mixed following bimanual assessment and recording of the type and duration of symptoms, expressed as a proportion of women whose UI has been categorised |
| 46 | Femeda Limited | 1 |  | This statement has singled out a specific aspect of examination ‘bi-manual assessment’ to be included in an initial assessment. It is felt that this should not be singled out and that the statement should describe a ‘pelvic assessment’. The term bi-manual assessment is ambiguous and can mean different things to different healthcare professionals. If this statement stands as it is, it should at least include a definition of ‘bi-manual assessment’. |
| 47 | The Primary Care Women’s Health Forum | 1 | Measure | Urine testing should be performed in the initial assessment. Using urine dipstix conditions such as diabetes, UTI, haematuria should be excluded before a patient is referred for further treatment |
| 48 | The Primary Care Women’s Health Forum | 5 (should be 1) | statement | Bimanual examination is not always indicated for young not sexually-active women and this group should be excluded from the measure |
| 49 | Royal College of Nursing | 1 |  | Not all service providers currently undertake bimanual examination. Women are often referred into nurse led community services e.g. District nursing, where there would be significant training implications regarding this standard. Local pathways can facilitate initial assessment and treatment with referral onto specialist services competent in biannual examination if conditions do not improve. Expecting every woman with a continence problem to have a bimanual examination at initial assessment is clearly good practice but in the community setting may not be realistic. |
| 50 | Bladder & Bowel Foundation | 1 |  | This would be the gold standard of care and should be offered by all continence specialists; nurses, physiotherapists. Ideally all patients with urinary incontinence should be referred to a Continence Service and all should see a specialist Nurse or Physiotherapist for their initial assessment. Patients want to be seen by the right person at the right time in the right place and move forward to receive the right treatment for them. |
| 51 | Royal College of Obstetricians and Gynaecologists | 1 |  | No comments – key priority for implementation. Should be able to collect the data. |
| 52 | British Association of Urological Surgeons, Section of Female, Neurological and Urodynamic Urology (BAUS SFNUU) | 1 | Initial assessment | BAUS had stated that “Women with lower urinary tract symptoms (LUTS) should be offered a full physical examination, including a vaginal examination, as part of their initial assessment.”    The quality statement as written is too emphatic and uncompromising, whilst bimanual examination is an appropriate part of assessment for the majority of women with incontinence, we do not believe there is any robust evidence that demonstrates that its inclusion in the initial assessment is essential. It is an intrusive and, for some women, upsetting part of clinical examination and, in some cases, can be deferred in the clinical algorithm until an initial trial of conservative treatments has been undertaken. This is an area where clinical judgement and the views of the patient should be paramount, not the heavy-handed direction of a quality statement. PVR (in full please what does this mean) should be included.  We do not understand why assessment of pelvic floor muscle tone is included in a later statement and suggest is should be included here in the initial assessment. |
| 53 | Elective Cesarean | 1 |  | On page 7, both the ‘Process’ and ‘Numerator’ state:    “…the number in the denominator who receive an initial assessment including bimanual assessment, recording of type, ONSET and duration of symptoms, and categorisation of urinary incontinence.”  My organisation would like to suggest the inclusion of the word ONSET, in bold above.  Again, learning more about when a woman’s urinary incontinence began, together with information regarding her parity and birth mode, is worth considering for inclusion in this Quality Standard.  Also of relevance here is CG174 4.1.3 “Although women may develop urinary incontinence following vaginal birth, there is evidence that women may wait many years before presenting to a healthcare professional with urinary incontinence” |
| 54 | British Society of Urogynaecology (BSUG) | 1 | Initial assessment | Rationale. It states that initial assessment including bimanual examination allows categorisation of urinary incontinence. However, there is no evidence that a bimanual examination improves categorisation of incontinence. Stakeholders who recommended this in the briefing paper made the recommendation on the basis of excluding a pelvic mass. However, the sensitivity and specificity of a bimanual examination in diagnosis of pelvic masses is poor, particularly with an increasingly obese population. This assessment needs to be offered in primary care. |
| 55 | British Society of Urogynaecology (BSUG) | 1 |  | Does this relate to primary or secondary care (or both?) Who does the bimanual? Whilst this is a good idea and seems easy a lot of HCP’s may not be confident (particularly male GP’s ) seldom do these  Could Commissioners ensure training available in bimanual examinations (See UKCS minimum standards document)?  Categorisation based on expert opinion. This surely should be 5 point: SUI, stress predominant mixed, mixed, urgency predominant mixed and UUI as this will direct which direction should be taken for most patients with mixed |
| 56 | Pfizer Ltd | 1 | Initial assessment Statement ‘What the quality statement means ...”; Subheading – healthcare professionals | Pfizer note that ‘follow-up’ as emphasised in CG138 and CG171 is critical for treatment and management related aspects of OAB but is not included in these quality statements.  NICE CG138 (patient experience in adult NHS services) and NICE CG171 (2013) emphasise that ‘follow-up’ is an essential component in the treatment and care pathway of patients with OAB. The recommendations ensure that healthcare professionals take in to account care principles of treating patients as individuals, offering both psychological and emotional support, tailoring healthcare services for each patient, continuity of care and relationships as well as enabling patients to actively participate in their care.  Pfizer request that NICE include that ‘follow-up’ is an essential component in the treatment and management of OAB and therefore, this should be incorporated in each quality statement. |
| 57 | Pfizer Ltd | 1 | Initial assessment Statement ‘What the quality statement means ...”; Subheading commissioners | **I**t is important to acknowledge that services should only be commissioned where there is evidence of a clear patient pathway. This is in line with the NICE commissioning guide (2008) which stipulates how the commissioning of urinary continence services should be carried out based on specific service requirements.  This helps to determine local service levels and ensuring corporate and quality assurance in line with the treatment pathway. This information is currently lacking in the QS.  Pfizer request that NICE includes recommendations in the QS that services are commissioned where there is evidence of a clear patient pathway in line with the relevant budgets and service evaluations. Therefore, this should be incorporated within the QS to aid commissioning groups and NHS England. |
| 58 | UK Multiple Sclerosis Specialist Nurse Association | 1 |  | Page 7 “ Women with urinary incontinence have an initial assessment that  includes bimanual assessment, recording of the type and duration of symptoms, and  categorisation of the urinary incontinence.” There was no mention of screening for infection as part of the initial assessment. This is mentioned in NICE Guidelines CG148 “Urinary Incontinence in Neurological Disease” and is essential in establishing appropriate future management. |
| 59 | UK Multiple Sclerosis Specialist Nurse Association |  | Definitions and data sources for the quality measures | Page 32 There is no reference here to NICE Guidelines CG148 “Urinary Incontinence in Neurological Disease” |
| 60 | UK Multiple Sclerosis Specialist Nurse Association |  | Related NICE quality standards | Page 32 There is no reference here to NICE Guidelines CG148 “Urinary Incontinence in Neurological Disease” |
| 61 | Faculty of Sexual and Reproductive Healthcare of the RCOG | 1 |  | Initial assessment - Impact on quality of life should be included as well as recording the type and duration of symptoms |
| 62 | King’s College Hospital | 2 |  | Appropriate |
| 63 | Abertawe Bro Morgannwg University Health Board | 2 | 247-267 | Confusing section. Please can you consider rewording. NB the objective measures of success of better than Zero for Ba and Bp is setting the bar quite low. I prefer better than -1. The surgical ambition is separate to the patient subjective ambition |
| 64 | Royal College of General Practitioners | 2 |  | The availability of absorbent products through the NHS may be a challenge and one that commissioners need to consider. |
| 65 | Astellas Pharma Limited | 2 |  | Astellas welcomes the emphasis within the draft quality statement that containment products should only be offered as a “temporary coping strategy pending decisions about treatment, in additional to ongoing treatment, or as long-term management after all treatment options have been unsuccessful”. This rightly emphasises that containment products should be offered as soon as possible as part of the initial assessment of symptoms, but that 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 .  Astellas proposes that, to provide further guidance to commissioners when measuring implementation, a more detailed benchmark should be provided about when treatment decisions should be made. The LUTS in men quality standard suggests that a choice of temporary containment products should be offered “as part of the initial assessment”, “which may involve more than one consultation but normally no more than 3”. Astellas proposes that the same guidance should be included within this quality standard to drive consistency and ensure that personalised treatment plans are developed in a timely manner, in dialogue with the patient.  To enable commissioners to evaluate whether this standard is being achieved locally, Astellas proposes separating the process measures, as currently drafted, into two, as below:  1) Number of women with UI offered a choice of temporary containment products as part of their initial assessment (up to 3 consultations), as a temporary coping strategy pending decisions about treatment, expressed as a proportion of all women with UI prescribed containment products  2) Number of women with UI offered a choice of containment products in addition to long-term treatment or as long-term management after all treatment options have been unsuccessful, expressed as a proportion of all women with UI prescribed containment products |
| 66 | Bladder & Bowel Foundation | 2 |  | Patients understandably find it difficult when products are discontinued due to budget constraints. This statement encourages specialist staff responsible for supplying products to consider how long they may be needed for and also to begin the discussion with the patient at the beginning of their treatment plan. This would help to manage patient expectation and minimise disappointment. |
| 67 | Royal College of Obstetricians and Gynaecologists | 2 |  | This is a key priority for implementation in the guideline.  However, I think it will prove very difficult to determine whether the containment products are being used as a *temporary coping strategy.* |
| 68 | British Association of Urological Surgeons, Section of Female, Neurological and Urodynamic Urology (BAUS SFNUU) | 2 |  | Agreed |
| 69 | Pfizer Ltd | 2 | “Containment products” | Pfizer acknowledges the lack of sufficient evidence on pad-use as described in CG171 however; it is important to note that containment products such as pads are often recommended as coping strategies in patients pending definitive treatment.    Pfizer recommend that NICE emphasise that ‘pad-use’ pending definitive treatment is an important component in the treatment pathway and therefore, this information should be incorporated in to ‘Quality Statement 2’ in line with routine clinical practice. |
| 70 | Pfizer Ltd | 2 | “Containment products” | The statement on containment products should also emphasise the need for timely 4-week review in line with the NICE CG171 (2013), which has not been included in the QS. Pfizer are concerned that patients will remain on containment products longer than necessary without the incorporation of a review period in the QS.  The NICE CG171 (Section 1.6.1) indicates that absorbent products, urinals and toileting aids should not be considered as a treatment for UI however; they should only be used as a coping strategy pending definitive treatment or as an adjunct to ongoing therapy and long term management of UI only after alternative treatments have been explored (which incorporate routine monitoring or assessment of patients at timely 4-week intervals).  Pfizer suggest that NICE include a recommendation for routine assessment or follow-up at 4-week intervals in this quality statement to ensure that patients receive the relevant treatment and care. |
| 71 | Faculty of Sexual and Reproductive Healthcare of the RCOG | 2 |  | Containment products – whilst it is possible to collect the data for the proposed quality measure, not all use of continence products will be prescribed as these may constitute self – help that patients adopt and therefore compromise their management plan. As well as recording prescriptions for containment products as a quality measure, recording whether patients are accessing these independently would be an additional measure. Improvements in counselling and shared decision making between patient and practitioner should reduce this. |
| 72 | Birmingham Women’s Hospital | 3 |  | This seems very high. I am unsure of anyone who offers this so is it needed as it is in the NICE guidelines and isn’t common? |
| 73 | Birmingham Women’s Hospital | 3 | P 13 | I am a little unsure about this standard. There is a clear steer in the NICE guidelines about this. However in a day to day situation who is doing this? I did a literature search which shows very promising feasibility study from Glasgow Caledonian university. There are 3 other (small) RCT’s which in essence (not having seen this but having quite an extensive experience with PTNS) would suggest this is easier than PTNS and likely to be subject to a further (larger) RCT. This being the case the evidence base may well change in favour of the procedure and this document then be out of step with the evidence base. Given the other standards this on a practical level seems a little unnecessary? |
| 74 | King’s College Hospital | 3 |  | Agreed but may need to differentiate adequately between transcutaneous and percutaneous- as may be easily misread and misconstrued as PTNS/SNS |
| 75 | Medtronic Limited | 3 | Transcutaneous neurostimulation for overactive bladder | We agree with the sentiment inferred in Statement 3, however the ‘negative’ element - i.e. that transcutaneous sacral nerve and transcutaneous posterior tibial nerve stimulation is not recommended - could lead to the unintended consequence of reducing access to the clinically effective procedure of surgical Sacral Nerve Stimulation (SNS). SNS is recommended as a treatment option in CG 171 Section 1.9 Invasive procedures for OAB (refer to 1.9.10 Percutaneous Sacral Nerve Stimulation) and has an established clinical evidence base generated from over 20 years of clinical practice. Could we can therefore respectfully propose that the Quality Standard statement is repositioned to a more affirmative one which encourages clinically effective treatments and in doing so measurement of benefit/uptake is considered. For example:  ***Quality statement:***  ‘Women with UI should be offered Surgical Sacral Nerve Stimulation only after assessment by a MDT and in line with treatment options in CG 171’.  ***Rationale:***  Evidence for the use of Surgical SNS should not be used interchangeably with that of Transcutaneous SN or PTNS, the latter procedures having limited or no evidence to support its use within OAB.  All other points can remain unaltered. |
| 76 | Bladder & Bowel Foundation | 3 |  | This is sensible as offering these treatments is costly and women do not achieve the desired outcome – the number of treatments required increases the length of time to treat using these modalities leading to a significant delay in the patient achieving any further superior treatment.  However, should there be some mention of the option to refer women with proven detrusor over activity for percutaneous sacral nerve stimulation (SNS) if they have exhausted all conservative and pharmacological treatments.  Work by Klaus Matzel confirms the efficacy of percutaneous SNS in this patient group.  The Bladder & Bowel Foundation regularly receives calls from women who are finding it difficult to access percutaneous SNS for their bladder symptoms. These women have invariably been through all conservative and pharmalogical treatment and do not wish to have surgery yet. They read about percutaneous SNS and then cannot access it This could be improved if percutaneous SNS for refractory OAB in women was recognised within this guidance and also by an NHS England Commissioning Policy. |
| 77 | Royal College of Obstetricians and Gynaecologists | 3 |  | No comments – this is NOT a key priority but is important. Should be able to collect the data. |
| 78 | British Association of Urological Surgeons, Section of Female, Neurological and Urodynamic Urology (BAUS SFNUU) | 3 |  | Agreed - to be included as a quality standard but it is already part of the NICE guideline.  The big debate is whether this is therefore measured as a quality standard |
| 79 | British Society of Urogynaecology (BSUG) | 3 |  | Agreed but may need to differentiate adequately between transcutaneous and percutaneous  There is a missed opportunity here to do 2 things: cement bladder diaries and their importance into the pathway and to link primary and secondary care as an integrated service.  This seems very high. I am unsure of anyone who offers this so is it needed as it is in the NICE guidelines and isn’t common?  I am a little unsure about this standard. Whilst there is a clear steer in the NICE guidelines about this, who is doing this? A literature search shows a very promising feasibility study from Glasgow Caledonian university. There are 3 other (small) RCT’s which in essence (not having seen this but having quite an extensive experience with PTNS) would suggest this is easier than PTNS and likely to be subject to a further (larger) RCT. This being the case the evidence base may well change in favour of the procedure and this document then be out of step with the evidence base. Given the other standards this on a practical level seems a little unnecessary? |
| 80 | Faculty of Sexual and Reproductive Healthcare of the RCOG | 3 |  | No additional comments |
| 81 | Birmingham Women’s Hospital |  | Q2 P6 | Personally I think statement 4 is completely impractical. I know the drive is to ensure the conservative management is done prior to surgery but EVERY patient? From a cost effectiveness perspective confirming review by a CNS or physio prior to SUI surgery and that has tried 2 or 3 anticholinergics prior to BOTOX (or there be a CI to antichol) may be better. Certainly the infrastructure is there and these can be built into the databases (e.g. BSUG) so I would personally suggest this should be the standard rather than going through an MDT |
| 82 | Birmingham Women’s Hospital | 4 | P15 | This would be easy to collect on surgical databases, but just that other (pre-defined) criteria had been met. The implication of this in terms of workload for MDT’s is huge, all of which has to be costed and factored into otherwise busy jobs |
| 83 | King’s College Hospital | 4 |  | Absolutely agreed and should be emphasised |
| 84 | Abertawe Bro Morgannwg University Health Board | 4 | 341 | Another possibility is that the vaginal length was misjudged under anaesthesia and the anterior wall attachments are disrupted by approximating the vault to the ligament under tension. |
| 85 | BHR University Trust | 4 |  | General. NICE have not costed this recommendation. In addition to the time spent on discussing each case by a minimum of two consultants (one urologist and one gynaecologist), a physiotherapist and a highly trained nurse, there is the administrative support required. Potentially, the most costly aspect of this approach is the additional visits the woman would be required to make before a treatment plan can be confirmed. It is unreasonable of NICE to propose a quality standard with no research evidence to back it and no costings.  Rationale. It is stated that the multidisciplinary team will ensure that all other possible treatments have been considered before surgery. In the case of stress incontinence the only other evidence based treatment is pelvic floor exercises covered in quality statement 6. In the case of proven detrusor overactivity NICE recommends that the MDT should offer Botox injections. It is unclear of the role of the discussion when NICE has stated the conclusion they should reach. Is NICE saying that the opinion of a team should take higher precedence than evidence based medicine?  It is stated that the whole team approach can also help the decision of whether invasive treatment is suitable for the woman. This suggests that NICE feel that a professional team's opinion takes priority over a woman's opinion. |
| 86 | Bladder & Bowel Foundation | 4 |  | Yes this is essential – the implications of invasive treatment / surgery are huge and patients need to be prepared for this. Women also need post-operative MDT support. |
| 87 | Royal College of Obstetricians and Gynaecologists | 4 |  | Key priority for implementation. Should be able to collect the data.  We are not sure that the multidisciplinary team needs to include both a urogynaecologist and a urologist with a sub-specialist interest in female urology |
| 88 | British Society of Urogynaecology (BSUG) | 4 |  | For every patient undergoing surgery for stress incontinence or botox injections to be discussed at an MDT has not been costed. There is no evidence that the additional resources to set up and administer these meetings will translate into improved care. Clinical time may be better spent in one to one discussions with the woman ensuring that she is fully informed about the pros and cons of treatment. 'Local data collection' time would be better spent ensuring that quality statement 6 is covered than those women are discussed.  Absolutely agreed and the importance of MDTs should be emphasised  There is no evidence to support this statement. For stress incontinence the only effective treatments are pelvic floor exercises and surgery. If a woman has tried pelvic floor exercises it is unclear how further discussion at an MDT is going to improve treatment. If the MDT is a simple 'rubber stamping' exercise then it is a waste of time and resources. If it is not just a rubber stamping exercise but a real discussion, the risk is that the decisions made will be of the most dominant individual. It will be pushing the management of women away from an evidence based approach and toward an opinion based approach. It is unclear of the treatment pathway if the woman disagrees with the decision of the MDT, particularly women who decline pelvic floor exercises. In the briefing paper the stakeholders who supported this recommendation stated that a whole team review would ensure that consideration has been given to all available treatments (such as physiotherapy) rather than concentrating on surgical techniques. However, even in the best hands it is known that pelvic floor exercises will not help 50% of women and there is a risk of these women being denied effective treatment.  There also needs to be a clear statement about MDT’s and how this should be incorporated in job plans. There is an economic argument why putting so much through the MDT is not cost effective. At present most MDT’s are done around rather than as part of the job plan  How will a MDT discussion add any value to the decision making to straightforward cases of stress incontinence for TVT? The decision making should surely her doctor. I accept that if cases are complex then MDT will be helpful. Applying a standard for MDT for all cases will lead to unnecessary delay in treatment I would suggest this quality standard is revised (despite the NICE guidance) in line with what is realistic and of value.  This would be easy to collect on surgical databases, but just that other (pre-defined) criteria had been met. The implication of this in terms of workload for MDT’s is huge, all of which has to be costed and factored into otherwise busy jobs. Personally I think statement 4 is completely impractical. I know the drive is to ensure the conservative management is done prior to surgery but EVERY patient? From a cost effectiveness perspective confirming review by a CNS or physio prior to SUI surgery and that has tried 2 or 3 anticholinergics prior to BOTOX (or there be a CI to antichol) may be better. Certainly the infrastructure is there and these can be built into the databases (e.g. BSUG) so I would personally suggest this should be the standard rather than going through an MDT |
| 89 | British Association of Urological Surgeons, Section of Female, Neurological and Urodynamic Urology (BAUS SFNUU) | 4 |  | MDT discussion of all cases has major resource implications as, if put into practice, an MDT meeting would need to be held on a weekly basis with attendance from a Urogynaecologist, Urologist, Physiotherapist, Continence Nurse and other interested parties including colorectal surgeons.  This is a massive potential cost to the NHS.  This is not deliverable at the moment and there is limited evidence to support MDT discussion for all cases. Furthermore, the decisions that are being discussed are not complex in the large majority of cases.  These are straightforward clinical decisions that can be made with the support of the clear guidance which is already available.  The decisions are important but fall within the remit of a standard clinical consultation.  MDT discussions are unlikely to be of value in the large majority of cases but will lead to delays in the patient pathway.  There is, however, the need to support MDT working as part of the development of an Integrated Continence Service.  This should be recognised by NICE guidance – but not through the mandating of the discussion of a huge number of routine cases in a ludicrously bureaucratic way. All cases can only be discussed if the MDT is fully resourced and this is unlikely in the foreseeable future  There should be MDT discussion of cases that are complex or recurrent and surgery should only be undertaken by an appropriately trained clinician. Including a quality standard for an appropriately trained surgeon undertaking the surgery would be beneficial |
| 90 | Johnson & Johnson Medical Ltd | 4 |  | Johnson & Johnson Medical Ltd. empathise with all women suffering from Stress Urinary Incontinence (SUI), a condition which can be serious and debilitating. In keeping with the recommendations set forth in NICE’s Clinical Guideline 171 – Urinary Incontinence: The Management of Urinary Incontinence in Women – we would welcome greater alignment between Quality Statement #4 and the detailed guidance set forward in sections 1.8, 1.10, and 1.11 (“The multidisciplinary team”, “Surgical approaches for SUI”, and “Maintaining and measuring expertise and standards for practice”, respectively). |
| 91 | Faculty of Sexual and Reproductive Healthcare of the RCOG | 4 |  | No additional comments |
| 92 | Birmingham Women’s Hospital | 5 |  | Why? If they can’t do a contraction what will you do? These are patients who still need to be referred. The inference is that these patients then will be offered a different treatment or will be ineligible for PFMT/electrical stim? |
| 93 | Birmingham Women’s Hospital | 5 | P18 | This is slightly at odds with QS 4. So all have to have had physio and go to an MDT, but don’t refer if they can’t contract the PF. The algorithm then stops…So what do you do as you can’t operate as they haven’t been to physio or through the MDT? Are we now saying electrical stimulation isn’t useful or that we can’t train women. 30% will bear down and not contract. This potentially can create issues as there doesn’t appear to be a plan B |
| 94 | King’s College Hospital | 5 |  | I think that this may be impractical as specialist physiotherapists in women’s health are not always easily available within the community and supervised pelvic floor muscle training may be offered within the community rather than in a hospital setting so whilst this is desirable I don’t know that it is achievable |
| 95 | BHR University Trust | 5 |  | Rationale: States that if a woman is unable to contract her pelvic floor muscles effectively then pelvic floor muscle training is unlikely to be beneficial. This contradicts quality statement 6 which proposes that all women should be offered pelvic floor exercises. In addition, although that may be the feeling of the GDG, the evidence provided in section 4.3 of the full guideline does not support this view. In particular the test retest reliability is poor and there is level 3 evidence that digital assessment of the pelvic floor does not affect the outcome of pelvic floor exercises.  Process: Local data collection to assess adherence to this standard will be time consuming to collect. In view of the lack of evidence of benefit it is unclear why NICE feel the time and effort of collecting the data to be of benefit. |
| 96 | Pelvic, Obstetric & Gynaecological Physiotherapy | 5 |  | It would be appropriate for the rationale for quality statement 5 to state that 'Women with urinary incontinence are often given brief verbal advice and/or a leaflet in order to teach them how to contract their pelvic floor muscles. As a result, many women who are advised to commence pelvic floor muscle exercises will be unaware whether they are correctly/optimally contracting these muscles. Digital assessment establishes whether a woman is able to contract her pelvic floor muscles. If a woman is unable to contract these muscles correctly or optimally pelvic floor muscle training is unlikely to be beneficial.' This is similar to the rationale for statement 6 and consistent with the evidence |
| 97 | Royal College of Nursing | 5 |  | The RCN welcome this standard because our reviewer feels that so many patients are offered just a leaflet and do not understand how to contract the pelvic floor. |
| 98 | Bladder & Bowel Foundation | 5 |  | This is essential – many women cannot identify their pelvic floor muscles following a brief description either verbally or in written form. B&BF receive a huge number of calls reinforcing the fact that women simply aren’t sure if they are doing their pelvic floor exercises correctly. |
| 99 | Royal College of Obstetricians and Gynaecologists | 5 |  | No comments – key priority for implementation. Should be able to collect the data |
| 100 | British Society of Urogynaecology (BSUG) | 5 |  | I think that this may be impractical as specialist physiotherapists in women’s health are not always easily available within the community and supervised pelvic floor muscle training may be offered within the community rather than in a hospital setting so whilst this is desirable I don’t know that it is achievable.  Why? If they can’t do a contraction what will you do? These are patients who still need to be referred. The inference is that these patients then will be offered a different treatment or will be ineligible for PFMT/electrical stim?  This is slightly at odds with QS 4. So all have to have had physio and go to an MDT, but don’t refer if they can’t contract the PF. The algorithm then stops…So what do you do as you can’t operate as they haven’t been to physio or through the MDT? Are we now saying electrical stimulation isn’t useful or that we can’t train women? 30% will bear down and not contract. This potentially can create issues as there doesn’t appear to be a plan B |
| 101 | Faculty of Sexual and Reproductive Healthcare of the RCOG | 5 |  | No additional comments |
| 102 | Royal College of Nursing | 6 |  | Three months pelvic floor exercises will be difficult to cost, we feel it would help to identify the number of sessions within the three month period. One of our reviewers do 4 months sessions and see patients once per month |
| 103 | Birmingham Women’s Hospital | 6 |  | Stress predominant? Patients with urgency predominant may need lifestyle +/- pharmacotherapy first? |
| 104 | King’s College Hospital | 6 |  | Agreed |
| 105 | Royal College of General Practitioners | 6 |  | The availability of supervised pelvic floor training may also be variable and one that commissioners need to address. |
| 106 | BHR University Trust | 6 |  | Process: See notes above. If NICE are committed to quality statement 5 then they should exclude women with poor pelvic floor contraction. However, given the lack of evidence for quality statement 5, this would then discourage individuals from recording poor pelvic floor contraction if they felt a woman could benefit from pelvic floor exercises. |
| 107 | Pelvic, Obstetric & Gynaecological Physiotherapy | 6  7 |  | If you have mixed incontinence taking these two statements together it is unclear which treatment you would offer as ‘first-line’.  I also think that the order of the statements is illogical and not in keeping with the way topics are covered in the guideline. |
| 108 | Femeda Limited | 6  7 |  | There is confusion in the way that these statements are written. If a woman has mixed incontinence it is not clear whether a trial of supervised pelvic floor muscle training (Statement 6) or a minimum of 6 weeks bladder training (Statement 7) should be given as a first- line treatment. It is felt that the statements should include ‘mixed incontinence should be treated according to which element (Stress or Urgency incontinence) is the most bothersome symptom’. |
| 109 | Bladder & Bowel Foundation | 6 |  | This is sensible but will the supervised treatment should take place with a suitably trained specialist nurse or physiotherapist |
| 110 | Royal College of Obstetricians and Gynaecologists | 6 |  | No comments – this is NOT a key priority but is important. Should be able to collect the data. |
| 111 | British Association of Urological Surgeons, Section of Female, Neurological and Urodynamic Urology (BAUS SFNUU) | 6 |  | Agreed |
| 112 | British Society of Urogynaecology (BSUG) | 6 |  | Stress predominant? Patients with urgency predominant may need lifestyle +/- pharmacotherapy first? |
| 113 | Faculty of Sexual and Reproductive Healthcare of the RCOG | 6 |  | No additional comments |
| 114 | Birmingham Women’s Hospital | 7 |  | See point above. Isn’t review suggested at 4 weeks for an anticholinergic? |
| 115 | Birmingham Women’s Hospital | 7 | P24 | There is a missed opportunity to reinforce the roll of a bladder diary here |
| 116 | King’s College Hospital | 7 |  | Agreed |
| 117 | Abertawe Bro Morgannwg University Health Board | 7 | 537-9 | The principle should be “first do no harm”. Until there is strong evidence to support concomitant MUS it is prudent to avoid it. As written it gives license to put in mesh tapes when the data is sparse and confusing. Earlier on line 534 the term occult is used without definition. Clinicians vary in how they preoperatively assess the possibility of post vault support urinary incontinence. Section 4.2 very usefully deals with the role of urodynamics but not clinical assessment. The terms overt, occult and prophylactic could be clarified. I agree that if an MUS is used then its tension should be adjusted after the vault is fixed. The implication of the paragraph is that the tape should be tunnelled before the SSF-is that intentional? |
| 118 | Royal College of Nursing | 7 |  | Six weeks bladder drill will be difficult to cost, it would help to identify the number of sessions within the 6 week period for patients to be seen |
| 119 | Bladder & Bowel Foundation | 7 |  | As above |
| 120 | Royal College of Obstetricians and Gynaecologists | 7 |  | No comments – this is NOT a key priority but is important. Should be able to collect the data. |
| 121 | British Association of Urological Surgeons, Section of Female, Neurological and Urodynamic Urology (BAUS SFNUU) | 7 |  | should also include a trial of anti-muscarinics / beta 3 agonists if bladder training fail as quality standard |
| 122 | British Society of Urogynaecology (BSUG) | 7 |  | See point above. Isn’t review suggested at 4 weeks for an anticholinergic?  There is a missed opportunity to reinforce the roll of a bladder diary here |
| 123 | Faculty of Sexual and Reproductive Healthcare of the RCOG | 7 |  | No additional comments |
| 124 | King’s College Hospital | 8 |  | This should be reworded as the complications of long term catheterisation may not just be urological e.g. excoriation of the vulva is often a gynaecological or nursing issue |
| 125 | Abertawe Bro Morgannwg University Health Board | 8 | 597 | Statement of vaginal vault support strategy used or not at the time of hysterectomy-100% |
| 126 | Bladder & Bowel Foundation | 8 |  | Women are often devastated by the impact of living with a catheter. The implications and effect on their mental health and wellbeing should not be underestimated. Full assessment and discussion is essential if the effects are to be minimised and it would be sensible to include regular review as best practice. |
| 127 | Royal College of Obstetricians and Gynaecologists | 8 |  | This is NOT a key priority but is important.  It would be helpful if there was a section on ‘definition of terms used in this quality statement’ that included:   * What a “full assessment” would involve and who should undertake this assessment * What the practicalities and potential urological complications are of a long-term indwelling urethral catheter   Typo – section ‘Process’ – please change ‘… the long-term use indwelling urethral …’ to ‘… the long-term use of indwelling urethral …’ |
| 128 | Faculty of Sexual and Reproductive Healthcare of the RCOG | 8 |  | Supporting patient literature will be essential to facilitate this |
|  | Abertawe Bro Morgannwg University Health Board |  | Proposed additional statement: abdominal mesh | There is considerable disquiet in the colorectal community regarding abdominal mesh used for vault support. It would be appropriate to check their position before this guidance is issued. |
| 129 | Astellas Pharma Limited |  | Proposed additional indicator: personalised care plans | To support women with UI to make informed decisions about their care, Astellas recommends including an additional statement within the draft standard in relation to personalised care plans. Recommendation 1.8.1 states that the multidisciplinary teams should consider “provisional treatment plans” if conservative and pharmacological interventions fail to improve the patient’s outcomes. This quality standard can play an important role in ensuring that these plans are developed following a woman’s initial assessment, in dialogue with the patient to meet their treatment goals and preferences.  As such, Astellas proposes that NICE introduces an additional quality statement after quality statement 1, entitled ‘personalised management plan’. This would state that, “after initial assessment, all women with UI should receive a personalised treatment 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”. 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.  The proposed process measure 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.  Including this additional statement within the quality statement will underpin that the starting point for care professionals should be to identify and treat the underlying condition and alleviate symptoms as far as possible in line with the woman’s preferences. |
| 130 | Astellas Pharma Limited |  | Proposed additional statement: timely medication review of drug treatments | Astellas is concerned at the absence of a dedicated standard on the use, and regular review, of pharmacological agents for OAB within the draft quality standard. This is despite a core section of CG171 (1.7) focusing on pharmacological interventions, which can effectively alleviate symptoms of OAB and reduce the need for women with UI to proceed to invasive or surgical treatment. Moreover, 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. A review should be used to identify whether an alternative treatment could offer additional benefits – such as improved treatment efficacy or tolerability.  As such, Astellas recommends that NICE includes a new quality statement within this quality standard about timely medication reviews. This will bring the quality statement in line with: recommendations 1.7.11-1.7.17 in CG171; the pathway developed by NICE to accompany this guideline; and the quality standard on LUTS in men.  *Proposed Statement:* Women with OAB who are prescribed drug treatments to manage symptoms receive an initial medication review at 4 to 6 weeks, carried out in partnership with the patient, who should have the information they need to make decisions about their care.  *Proposed data source:* Local data collection  *Proposed measure*: Proportion of women with OAB prescribed OAB treatment who receive an initial medication review at 4 to 6 weeks  *Proposed numerator:* The number of women in the denominator who receive an initial medication review at 4 to 6 weeks  *Proposed denominator:* The number of women prescribed OAB treatment  As set out above in relation to the list of pharmacological agents listed on page 2 of the quality statement, Astellas recommends that any accompanying text for this quality statement must list the full range of class of pharmacological treatments referred to within NICE guidance, including anticholinergics.  Building on the process measure set out above, Astellas would also recommend that the following outcome metric is included to support the evaluation of outcomes in relation to pharmacological treatments: ‘*the proportion of women with OAB who persist with treatment at 6 months and at 12 months*’. Persistence with treatment may indicate treatment success or satisfaction 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 women with OAB, something which may be more meaningful to patients than the process measure of medication reviews alone. |
| 131 | Astellas Pharma Limited |  | Proposed additional statement: patient experience | 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 women with UI. We recommend the following process and outcome measures:  Process measure: the proportion of women with UI who complete an experience/satisfaction survey  Outcome measure: the proportion of women UI who were satisfied with the treatment and care received (data source: experience surveys and real-time feedback) |
| 13244 | Birmingham Women’s Hospital |  | Proposed additional statement: Blooder diaries | What about the role of bladder diaries? |
| 133 | Royal College of Obstetricians and Gynaecologists |  | Possible additional/alternative standards | • Women with urinary incontinence or overactive bladder should be encouraged to complete a bladder diary for a minimum of 3 days following their initial assessment  • The initial pharmacological management of women with overactive bladder or mixed urinary incontinence should be either: oxybutynin (immediate release), tolterodine (immediate release) or darifenacin (once daily preparation). |
| 134 | Pfizer Ltd |  | Section 1 : Introduction (Why is this quality standard is needed); Statement ‘the management of urinary incontinence ...” | Pfizer suggest that it important to incorporate a statement into the QS acknowledging the use of ‘bladder diaries’ as a management tool for urinary incontinence. Bladder diaries are often used when monitoring the effects of treatment. This should also cover various concepts of diary management including functional bladder capacity, each cycle of filling, diurnal and nocturnal cycles, leakage episodes, fluid intake, pad changes as well as total urine output.  The NICE CG171 (Section 1.1.17) recommends the use of bladder diaries in the initial assessment of women with UI or OAB. Therefore, women should be encouraged to complete at least three days of diary assessment covering their daily activities (both leisure and working days). This allows for patient informed decision making on their treatment and care pathway in partnership with the relevant healthcare professionals.  Pfizer suggest that NICE include the use of bladder diaries as part of the treatment of UI and OAB as outlined in the CG171 (2013). |
| 135 | Pfizer Ltd |  | General: “List of quality statements” | There has been no inclusion of pharmacological treatments as part of the list of quality statements. Pfizer suggest that a stand-alone quality statement on the use of pharmacological interventions for OAB should be included in the QS given that NICE CG171 indicates that pharmacological interventions in the treatment and management of OAB play a vital role in the care pathway. Therefore, general principles when using OAB drugs should apply based on a range of factors including (not limited to), risk of adverse effects, patients’ co-existing conditions, drug to drug interactions, frequency and route of administration and the likelihood of success.  Pfizer request that NICE include a stand-alone quality statement on pharmacological interventions is incorporated in to the QS. Additionally, the statement should include information on the use of antimuscarinic therapies prior to mirabegron or referral to secondary care as well as information on speciality options. |

## Stakeholders who submitted comments at consultation

* Abertawe Bro Morgannwg University Health Board
* Astellas Pharma Limited
* Barking, Havering and Redbridge (BHR) University Trust
* Birmingham Women’s Hospital
* Bladder & Bowel Foundation
* British Association of Urological Surgeons, Section of Female, Neurological and Urodynamic Urology (BAUS SFNUU)
* British Society of Urogynaecology (BSUG)
* Department of Health
* Elective Cesarean
* Faculty of Sexual and Reproductive Healthcare of the RCOG
* Femeda Limited
* Johnson & Johnson Medical Ltd
* King’s College Hospital
* Medtronic Limited
* NHS Choices – Digital Assessment Service
* NHS England
* Pelvic, Obstetric & Gynaecological Physiotherapy
* Pfizer Ltd
* Royal College of General Practitioners
* Royal College of Nursing
* Royal College of Obstetricians and Gynaecologists
* The Primary Care Women’s Health Forum
* UK Multiple Sclerosis Specialist Nurse Association

# Appendix 2: Quality standard consultation comments table (internal)

| ID | Internal NICE team | Statement No | Comments  Please insert each new comment in a new row. |
| --- | --- | --- | --- |
|  | NICE internal team | 1 | 1. Will it be clear whether the initial assessment needs to be done in primary or secondary care? 2. Shall we have the assessment details in the definition and not in the statement? |
|  | NICE internal team | 2 | The statement does not offer a pathway. Maybe it should finish in the first comma. |
|  | NICE internal team | 3 | The statement is clear. |
|  | NICE internal team | 4 | What are those invasive procedures? It is best if they are listed. |
|  | NICE internal team | 5 | It overlaps with statement 1. If it is done in primary care, somebody needs to make sure they are trained properly. |
|  | NICE internal team | 6 | The statement is clear |
|  | NICE internal team | 7 | The statement is clear |
|  | NICE internal team | 8 | The statement is clear |

1. Royal College of Physicians, *National Audit of Continence Care*, September 2010. Avalable online via <https://www.rcplondon.ac.uk/sites/default/files/full-organisational-and-clinical-report-nacc-2010.pdf> [↑](#endnote-ref-1)
2. 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. Available online via <http://www.ncbi.nlm.nih.gov/pubmed/18454794> [↑](#endnote-ref-2)
3. Department of Health, *Health and Social Care Act 2012: part 1, section 26 (14R),* 2012, available at <http://www.legislation.gov.uk/ukpga/2012/7/section/26/enacted> [↑](#endnote-ref-3)
4. Department of Health, *NHS Constitution,* March 2013, available at <https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/170656/NHS_Constitution.pdf> [↑](#endnote-ref-4)
5. Royal College of Physicians, *National Audit of Continence Care*, September 2010. Available online via <https://www.rcplondon.ac.uk/sites/default/files/full-organisational-and-clinical-report-nacc-2010.pdf> [↑](#endnote-ref-5)
6. P Abrams et al, *Commissioning for incontinence, lower urinary tract and bowel symptoms - an audit*, April 2012. Available online via <http://www.bui.ac.uk/PDFs/Commissioningforincontinencelowerurinarytractandbowelsymptoms-anaudit_2.pdf> [↑](#endnote-ref-6)
7. JS Brown et al., Comorbidities associated with overactive bladder, *The American Journal of Managed Care*. Jul; 6(11 Suppl): S574-9, 2000. Available online via <http://www.researchgate.net/publication/12146951_Comorbidities_associated_with_overactive_bladder> [↑](#endnote-ref-7)
8. Department of Health Social Care and Local Programme Partnerships, *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 online via <https://www.google.co.uk/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0CCkQFjAA&url=http%3A%2F%2Fwww.essexinsight.org.uk%2F(F(NuuaWf5zIrreqBSCAblByV2_rpCSm_VbBKLXYIubeJ5Dq4v1-ROVeU-b0R2BAb1cuBAZrhMGWaMdURRZWg-dh9dZVtQ2dLa6b0Rbk5EKahaVQ8xGnpFEgQBfpkjbqgAOjLNvFg2))%2Fget%2FShowResourceFile.aspx%3FResourceID%3D721&ei=36_9U77IFoXSaN3hgsgE&usg=AFQjCNGlb_HQMwLVHZ0diii8uVhachaZ-g&sig2=ACdyMXE2TyOefWpNUWNhAA> [↑](#endnote-ref-8)