

Urinary Incontinence – scope consultation 1 – 30 September 2004

Type	Stakeholder	Order no.	Section no.	Comments	Developer's response
SH	Airedale General Hospital				This organisation was approached but did not respond.
SH	Anglesey Local Health Board				This organisation was approached but did not respond.
SH	Association for Continence Advice (ACA)	1	3	Urinary incontinence can be a large drain on community health trusts resources – managing patients at home, in residential care and nursing care settings needing pads, catheters, sheaths, medication and other products. Carer time is also involved in assisting people with their toileting needs. Women in the population described within the scope document are the least drain upon these resources. The client group with functional, reflex, and neurological problems should also be addressed, probably more urgently than this group.	Thank you for your comments. Women across all healthcare settings will be considered in this guideline. Urinary incontinence (overactive bladder syndrome, stress or mixed incontinence) will be covered. Containment will also be considered by the guideline developers and has been incorporated into the scope.
SH	Association for Continence Advice (ACA)	2	3	The introduction of duloxetine, medication for stress urinary incontinence should be within the scope of this document.	Pharmacotherapy for stress urinary incontinence will be considered in the guideline and the scope now reflects this. Specific drugs will not be listed in the scope.
SH	Association for Continence Advice (ACA)	3	4.1.2	<p>Women with urinary incontinence which is not stress or urge, eg neurological, functional should be included.</p> <p>Men also have urinary incontinence, particularly urge. Most of the studies published for treatment of overactive bladder do not differentiate between men and women. Children also experience continence problems. Elderly women may have a mixture of symptoms. The aging bladder should be discussed.</p>	Incontinence in men, children, and in association with neurological disease is excluded. There will be no upper age limit for women included in this guideline. Inclusion of populations other than women is beyond the scope of this guideline. We recognise that incontinence is not a problem confined to women, but in order to cover the issues in the scope in a helpful way in sufficient depth and within the timeline, the guideline will be restricted to this population. However, NICE welcomes suggestions for future topics from stakeholders, healthcare professionals and the public, and would encourage you to put your views forward. From 1st December 2004 suggestions can be made via the NICE website (www.nice.org.uk).

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SH	Association for Continence Advice (ACA)	4	4.2	Competency of practitioners assessing pelvic floor function should be addressed.	We acknowledge that competency is an important issue in the management of women with incontinence. However, it is beyond the remit to look at competencies for all health professionals involved in their care. The competencies of surgeons performing operative procedures will be addressed as stated in the remit.
SH	Association for Continence Advice (ACA)	5	4.3	The role of Continence Services within primary and secondary care should not be overlooked.	NICE guidelines do not usually address service delivery, as these are best addressed locally where clinical practice recommendations overlap with service delivery.
SH	Association for Continence Advice (ACA)	6	6	The group should refer to the DoH publication 2000 Good Practice in Continence Services.	Thank you. The guideline developers will consider this publication alongside all other relevant evidence.
SH	Association for Continence Advice (ACA)	7	4.3 c, d	If surgery is being contemplated, which may require the patient to perform intermittent self catheterisation post-op their ability and willingness to do this should be assessed before surgery is offered.	Assessment of women prior to surgical treatment will be covered in the guideline.
SH	Association for Continence Advice (ACA)	8	4.3	It should be acknowledged that urinary incontinence is not life threatening. Those patients who prefer to do nothing should have their wishes respected, but with the understanding that the health service should not then be responsible for providing absorbent products instead. They should be given advice on coping and lifestyle management techniques.	The guidelines will always take patient preferences into account. The guideline will consider lifestyle and behavioural issues and these have been incorporated into the scope.
SH	Association for Continence Advice (ACA)	9	4.3 b	It should be recognised that waiting times for tests eg urodynamics may affect waiting times for consultant appointments. Continence advisors may also see patients in place of consultants.	Please refer to our above comments on service guidance.
SH	Association for Improvements in Maternity Services (AIMS)				This organisation was approached but did not respond.
SH	Association of British Health-Care Industries				This organisation was approached but did not respond.
SH	Association of British Neurologists /	3	4.3 g	Interventional procedure Guidance No 4 relates	Thank you for this suggestion, which will be

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	/Royal College of Physicians			to sacral nerve stimulation for urge incontinence. There is a potential problem that the experimental treatment of detrusor injection of botulinum toxin will not have achieved a licence by the time the guidelines are ready although it is emerging as the treatment of choice rather than sacral neuromodulation for severe UI.	considered by the Guideline Development Group. As stated in section 4.3 of the scope, NICE guidelines normally recommend use within licensed indications. Exceptionally, and only where the evidence clearly supports it, the guideline may recommend use of a pharmacological intervention beyond its licensed indications.
SH	Association of British Neurologists/Royal College of Physicians	1	General	Although we understand that the implicit aim of this work is to establish guidelines around surgery for stress incontinence and cover treatment of urgency incontinence in women, the inclusion of men in the scope, would greatly increase the value of the project to the NHS.	Inclusion of populations other than women is beyond the scope of this guideline. We recognise that incontinence is not a problem confined to women, but in order to cover the issues in the scope in a helpful way in sufficient depth and within the timeline, the guideline will be restricted to this population. However, NICE welcomes suggestions for future topics from stakeholders, healthcare professionals and the public, and would encourage you to put your views forward. From 1st December 2004 suggestions can be made via the NICE website (www.nice.org.uk).
SH	Association of British Neurologists/Royal College of Physicians	2	General	Neurological patients form a small proportion of all patients with incontinence but in them incontinence in combination with their other often mounting disabilities has a very negative effect on quality of life. Special attention to this group should be given even if men are not included in the scope. They illustrate the worst problems of incontinence. Ideally a patient with MS should be considered as part of the review panel. We are sure the MS Society could prove a suitable contact.	Incontinence in association with neurological disease is excluded from this guideline. Where appropriate in the guideline, cross-references will be made to the NICE guideline on Multiple Sclerosis, which covers bladder problems.
SH	Association of British Neurologists/Royal College of Physicians	3	3 b	"urgency" rather than "urge" is now the preferred term for this type of incontinence.	Thank you. The current International Continence Society definitions for incontinence and the overactive bladder syndrome have been incorporated into the scope.
SH	Association of the British Pharmaceuticals Industry (ABPI)	1	General	We have no comments to make on the scope and look forward to receiving the first draft in due course.	Thank you.

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SH	Astra Tech Ltd	1	4.3 Clinical management	The guideline should include advice on both short term and long-term management and treatment of urinary retention. Retention can be a complication following surgical treatment for stress urinary incontinence.	Assessment of women prior to surgical treatment will be covered in the guideline. Post-operative complications will be covered in the assessment of the literature on outcomes for surgical procedures.
SH	Bard Limited	1	General	Bard Ltd is the manufacturer of Contigen® the collagen-based urethral bulking agent your documentation refers to and is a market leader in this field with a wealth of clinical data. Bard Ltd also manufactures kits for tension free sling procedures: Uretex™ and Uretex®TO (transobturator) both with polypropylene mesh. In addition PelviLace™ is a similar procedural kit containing a biomaterial (Pelvicol™). All should be considered as part of your evaluation.	Thank you for your suggestions. Specific bulking agents will not be listed in the scope.
SH	Bard Limited (2)	2	1	Management of Urinary incontinence is too limited if only women, the scope should cover men as well.	Inclusion of populations other than women is beyond the scope of this guideline. We recognise that incontinence is not a problem confined to women, but in order to cover the issues in the scope in a helpful way in sufficient depth and within the timeline, the guideline will be restricted to this population. However, NICE welcomes suggestions for future topics from stakeholders, healthcare professionals and the public, and would encourage you to put your views forward. From 1st December 2004 suggestions can be made via the NICE website (www.nice.org.uk).
SH	Bard Limited (2)	3	2 a	Guidelines will provide recommendations for good practice – the document seems to cover treatment options but not good management which is essential for most patients long term.	The guideline will cover adult women along the care pathway, and will consider other healthcare interventions and containment.
SH	Bard Limited (2)	4	3 b	We agree the reference to 'treatment... will depend on the underlying cause'. Evaluation needs to be all encompassing with a care pathway objective as an outcome.	Please refer to the above comment.
SH	Bard Limited (2)	5	4.1	Should include men.	Please refer to the comments above regarding the population included in the guideline.

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SH	Bard Limited (2)	6		How will the elderly be covered? Why just stress and urge – mixed should be included.	The guideline will consider adult women; there will be no upper age limit. The guideline will consider women with overactive bladder, stress or mixed urinary incontinence, and the scope has been amended to reflect this.
SH	Bard Limited (2)	7	4.3	Clinical management covers treatment but not management ie catheterisation and the long term management of patients.	Containment will be covered in the guideline, and has been incorporated into the scope.
SH	Bard Limited (2)	8	4.3 e	Anaesthesia needs to be excluded.	Thank you. The section on 'interventions and clinical practice likely to reduce morbidity associated with the procedures – including those with anaesthesia' has been deleted as it is beyond the remit of the guideline.
SH	Bard Limited (2)	9	4.3 f	Will competencies be included for nurses as well as surgeons.	We acknowledge that competency is an important issue in the management of women with incontinence. However, it is beyond the remit to look at competencies for all health professionals involved in their care. The competencies of surgeons performing operative procedures will be addressed as stated in the remit.
SH	Bard Limited (2)	10	General	Will they guidelines be company neutral ie current TVT states Gynecare.	All relevant minimally invasive sling procedures will be considered generically.
SH	BES Rehab Ltd				This organisation was approached but did not respond.
SH	Birmingham Heartlands & Solihull NHS Trust				This organisation was approached but did not respond.
SH	Boehringer Ingelheim Ltd	1		See comments submitted jointly with Eli Lilly.	Thank you.
SH	Boston Scientific Limited				This organisation was approached but did not respond.
SH	Bradford Teaching Hospitals Trust				This organisation was approached but did not respond.
SH	British Association for Behavioural and Cognitive Psychotherapies (BABCP)				This organisation was approached but did not respond.
SH	British Association of Urological Surgeons (BAUS)	1	General	To be terminologically correct the Title and Remit should be " ... and Pelvic Organ Prolapse." This is important as the walls of the	The title remains as 'The management of urinary incontinence in women', as pelvic organ prolapse will not be considered beyond how it

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				<p>vagina may prolapse and require surgery without the uterus (womb) prolapsing. "... incontinence due to detrusor instability (overactive bladder muscle)", is now, by the new International Continence Society terminology (the internationally accepted terminology) "... <u>urge</u> incontinence due to detrusor <u>overactivity</u>".</p> <p>I chaired the 3rd International Consultation on Incontinence, held in collaboration with the WHO, six weeks ago. Our management algorithms will be available in the next 4–6 weeks. They are updated versions of those published in 1999 and 2002 and cover both urinary incontinence and pelvic organ prolapse. The 1999 algorithms were also published in the Lancet.</p>	<p>relates to the treatment of urinary incontinence and/or overactive bladder syndrome.</p> <p>Women with urinary incontinence (overactive bladder, stress or mixed incontinence) will be included in this guideline, and the scope has been amended accordingly.</p> <p>Thank you for this useful information. This will be considered by the guideline developers alongside all other relevant evidence.</p>
SH	British Association of Urological Surgeons (BAUS)	2	1	Suggest title: the management of urinary incontinence (delete "in women" see below).	The title remains as 'The management of urinary incontinence in women', as the guideline will not cover men (see response below).
SH	British Association of Urological Surgeons (BAUS)	3	2	Background section is a little misleading as one would assume that it would cover the problem (as in section 3) not just the process.	This section has been revised.
SH	British Association of Urological Surgeons (BAUS)	4	3	Clinical need: should also mention the rapid increase in prevalence with age and the implications of an ageing population. In addition, the huge social and economic costs of incontinence, particularly in the elderly, including in residential and nursing homes.	Thank you for these suggestions, which have been incorporated into the scope.
SH	British Association of Urological Surgeons (BAUS)	5	3 a	The definition of urge urinary incontinence needs to be updated to the current ICS definition 2002.	The current ICS definitions for incontinence have been incorporated into the scope.
SH	British Association of Urological Surgeons (BAUS)	6	3 c	Also include lifestyle interventions, for all types of incontinence and bladder training for urge incontinence. In the frail elderly it may be necessary to try to contain the incontinence rather than attempt to cure, by using pads,	Lifestyle and behavioural interventions, and containment will be considered in the guideline as you suggest, and the scope now reflects this.

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				appliances and catheters.	
SH	British Association of Urological Surgeons (BAUS)	7	3 e, f	Should probably be combined as there is little evidence for any difference in the mechanism by which incontinence is cured between "traditional slings" and "TVT and its look-alikes".	These are now referred to as conventional and minimally invasive sling procedures respectively in the scope.
SH	British Association of Urological Surgeons (BAUS)	8	3 e	Anterior repair should be handled separately.	This will be done in the full guideline. The scope gives examples of surgical procedures that will be covered.
SH	British Association of Urological Surgeons (BAUS)	9		As stated in section 3c most (female) incontinence is treated non-surgically as the prevalence figures (3a) and the relatively small numbers of surgical procedures show. It might be best to state that most sufferers require effective treatment in primary care. I would suggest reducing the sections d to g and having a section devoted to primary care interventions (also done in secondary and tertiary care) including lifestyle interventions, pelvic floor muscle training, bladder training and drug treatment.	Section 3 of the scope has been restructured, reflecting your comments.
SH	British Association of Urological Surgeons (BAUS)	10	4.1	<p>Incontinence is more prevalent in women, this is not the case in older patients, indeed overactive bladder and detrusor overactivity are probably more common in men over the age of 65. In an ageing population the burden of incontinence (social and economic) is borne equally by men and by women. Furthermore, from the practical point of view it will be difficult/impossible to disentangle women from the scientific evidence base that exists for the management of overactive bladder, as almost all reports refer to populations containing both men and women.</p> <p>Consideration should also be given to linking childhood incontinence to this work as in a proportion of children their problems continue into adulthood: this applies to both boys and girls. This is particularly true for congenital neurological conditions. Consideration should</p>	<p>We are aware that in some published studies data will include both men and women. Although we will consider this evidence alongside other relevant evidence, we will ensure that the applicability and extrapolation of the data are reflected in the guideline recommendations.</p> <p>Incontinence in men, children, and in association with neurological disease is excluded. Inclusion of populations other than women is beyond the scope of this guideline. We recognise that incontinence is not a problem confined to women, but in order to cover the issues in the scope in a helpful way in sufficient depth and within the timeline, the guideline will be restricted to this population. However, NICE welcomes suggestions for future topics from stakeholders, healthcare</p>

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				<p>be given to including neurological urinary incontinence in men and women. Although in the young to middle aged the numbers of sufferers are small compared to non neurological patients, the prevalence of incontinence within the patient groups suffering from conditions like MS and spinal cord injury is high with appreciable social and economic costs. In the elderly, neurological conditions become much commoner (dementia, stroke and Parkinson's) with a very high prevalence of incontinence.</p> <p>In addition, nocturnal enuresis should be included as it is usually (in adults as opposed to children) part of the overactive bladder syndrome.</p>	<p>professionals and the public, and would encourage you to put your views forward. From 1st December 2004 suggestions can be made via the NICE website (www.nice.org.uk). Please also refer to the above comment regarding the inclusion of women with overactive bladder syndrome in this guideline.</p>
SH	British Association of Urological Surgeons (BAUS)	11	4.1.1	<p>We would strongly suggest that this should be rewritten as "children, women and men who have urinary incontinence". We would agree with the stakeholder meeting that 4.1.1.(b) be deleted as pelvic organ prolapse is not central to the issue of urinary incontinence although like faecal incontinence it may coexist.</p>	<p>Section 4.1.1 b has been deleted as you suggest.</p>
SH	British Association of Urological Surgeons (BAUS)	12	4.2 a	<p>This section could add that the guidelines should be used within the structure outlined by the DOH document on The Provision of Continence Services (2000). Suggest delete "with or without pelvic organ prolapse" (and in 4.3.6).</p>	<p>The DH document referred to will be considered by the guideline developers alongside other relevant evidence. 'With or without pelvic organ prolapse' has been deleted from both sections as you suggest, and is now referred to only in section 4.1.2.</p>
SH	British Association of Urological Surgeons (BAUS)	13	4.3 e	<p>Could be incorporated into 4.3.c which needs to consider lifestyle interventions.</p>	<p>Lifestyle and behavioural interventions have been incorporated into the scope and will be considered by the guideline developers.</p>
SH	British Association of Urological Surgeons (BAUS)	14	4.3 d	<p>Also needs to consider lifestyle interventions as well as bladder training.</p>	<p>Please refer to the above response.</p>
SH	British Association of Urological Surgeons (BAUS)	15	4.3 f	<p>This section should be expanded to cover competencies in initial patient assessment, specialist assessment (urodynamics) and surgical treatment, thus covering clinicians</p>	<p>We acknowledge that competency is an important issue in the management of women with incontinence. However, it is beyond the remit to look at competencies for all health</p>

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				other than surgeons (see DOH 2000 document).	professionals involved in their care. The competencies of surgeons performing operative procedures will be addressed as stated in the remit.
SH	British Association of Urological Surgeons (BAUS)	16	6	Could be expanded to "Related NICE and other governmental guidance" to include not only the 2000 document but also the document on outcome indicators.	We are aware of the 2000 DH publication, and the 1999 health outcome indicators for urinary incontinence, which will be considered by the guideline developers alongside all relevant information. Specific reference to them will not be made in the scope document.
SH	British Association of Urological Surgeons (BAUS)	17		As you know there are other procedures being considered by IPAC at present.	Thank you. The relevant interventional procedures being considered by IPAC have been listed in the scope. The guideline development group will consider these in their work.
SH	British Dietetic Association	18			This organisation was approached but did not respond.
SH	British Geriatrics Society/Royal College of Physicians	1	1	The guideline is a missed opportunity to include guidelines for the assessment and management of urinary incontinence in men.	Inclusion of populations other than women is beyond the scope of this guideline. We recognise that incontinence is not a problem confined to women, but in order to cover the issues in the scope in a helpful way in sufficient depth and within the timeline, the guideline will be restricted to this population. However, NICE welcomes suggestions for future topics from stakeholders, healthcare professionals and the public, and would encourage you to put your views forward. From 1st December 2004 suggestions can be made via the NICE website (www.nice.org.uk).
SH	British Geriatrics Society/Royal College of Physicians	2	General	The inclusion of a female urologist and physician with an interest in the subject would seem appropriate.	Urologists and general practitioners with the relevant background and expertise have been invited to join the guideline development group.
SH	British Geriatrics Society/Royal College of Physicians	3	1	There are conditions other than stress and urgency which lead to incontinence which should not be neglected.	The guideline will cover stress and mixed incontinence and the overactive bladder syndrome. The scope has been amended to reflect this.
SH	British Geriatrics Society/Royal College of Physicians	4	General	The guideline should address other bladder problems, such as urinary frequency and	Women with overactive bladder, wet or dry, will be included.

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				urgency which do not result in incontinence. 67% of women with overactive bladder syndrome remain "dry" but are significantly bothered by their condition.	
SH	British Geriatrics Society/Royal College of Physicians	5	General	The specific needs of the elderly in terms of a more holistic assessment should be addressed- this guideline should not just be a guideline for management of fit middle-aged women who require surgery.	An upper age limit will not be applied to the population considered in the guideline. A geriatrician with the relevant background and expertise has been invited to join the guideline development group to ensure this perspective is taken into account.
SH	British Geriatrics Society/Royal College of Physicians	6	General	The specific needs of institutionalised populations, where prevalence of the problem is high should be considered. This group receive containment by default in many cases.	Women in all healthcare settings will be considered. Containment will be considered by the guideline developers and this has been incorporated into the scope.
SH	British Geriatrics Society/Royal College of Physicians	7	4.3	The core competencies for Urodynamic assessment should be considered.	Competencies for urodynamic assessment will not be considered as this is beyond the remit of the guideline.
SH	British Geriatrics Society/Royal College of Physicians	8	4.3	The core competencies of specialist nurses, physiotherapists and physicians/surgeons should be considered.	We acknowledge that competency is an important issue in the management of women with incontinence. However, it is beyond the remit to look at competencies for all health professionals involved in their care. The competencies of surgeons performing operative procedures will be addressed as stated in the remit.
SH	British Geriatrics Society/Royal College of Physicians	9	4.3 e	It would seem appropriate that the guideline considers pre-operative assessment with regard to the incontinence procedure specifically.	Pre-operative assessment in terms of bladder assessment prior to surgery will be covered in the guideline.
SH	British Geriatrics Society/Royal College of Physicians	10	4.3 d	The guideline should include, non pharmacological measures for the management of incontinence (lifestyle and behavioural methods) and pelvic floor muscle therapy.	Lifestyle and behavioural interventions are now specified in the scope.
SH	British Geriatrics Society/Royal College of Physicians	11	4.3 e	The consideration of post operative problems associated with anaesthesia would seem to be outside the scope.	Thank you. The section on 'Interventions and clinical practice likely to reduce morbidity associated with the procedures – including those with anaesthesia' has been deleted as it is beyond the remit of the guideline.
SH	British Geriatrics Society/Royal College of Physicians	12	General	The effectiveness of toileting regimens for older, cognitively impaired individuals should be	The guideline will not address the specific needs of cognitively impaired adults, but will

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				considered within the scope.	cover behavioural interventions as stated above.
SH	British Geriatrics Society/Royal College of Physicians	13	General	Although including the management of children with incontinence it would seem that primary nocturnal enuresis would require a separate guideline.	Please see comments above regarding suggesting guideline topics to NICE.
SH	British Healthcare Trades Association				This organisation was approached but did not respond.
SH	British Menopause Society				This organisation was approached but did not respond.
SH	British National Formulary (BNF)				This organisation was approached but did not respond.
SH	British Psychological Society, The	1	4.3 a	... add in 'psychosocial' management. Up to one third of women with incontinence have clinical anxiety and/or depression and severe restrictions in Quality of Life (work, sexual relationships, social activities and exercise) are common. Psychological factors, such as shame, make a major contribution to delayed help seeking and poor quality of life.	Thank you for your comments. We consider that psychosocial management is covered within lifestyle and behavioural issues which have been incorporated into the scope.
SH	British Psychological Society, The	2	4.3 d	... add in and 'psychoeducational procedures' such as bladder re-training, fluid intake and stress reduction techniques. The evidence for bladder retraining (a commonly used treatment for urge incontinence) needs reviewing. Relapse rates are often high and they take up a lot of time and effort. There have been some studies showing the effectiveness of more comprehensive psychoeducational interventions including, behavioural, cognitive and stress reduction techniques. There is a similarity to effective treatments for Irritable Bowel Syndrome. Psychosocial factors can be triggers (e.g., sexual abuse), maintainers (anxiety, frequent toileting) or consequences (avoidance, depression) of incontinence. Failure to acknowledge this leads to unnecessary and	Lifestyle and behavioural interventions will be considered in the guideline and the scope now reflects this.

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				unhelpful surgical procedures being applied where good psychosocial and self-management interventions are needed.	
SH	British Society of Urogynaecologists	1	2 c	Would suggest including lifestyle changes as well as pelvic floor interventions. Evidence that weight loss and stopping smoking may reduce occurrence of USI. Fluid management and bladder drill are lifestyle changes for OAB.	Lifestyle and behavioural interventions will be considered in the guideline and the scope now reflects this.
SH	British Society of Urogynaecologists	2	2 c	No mention of new drug for USI: Duloxetine (Boehringer-Ingelheim-Lilly).	Pharmacotherapy for stress incontinence will be considered in the guideline and the scope now reflects this. Specific drugs will not be listed in the scope.
SH	British Society of Urogynaecologists	3	General	There is an excellent base of evidence in this area from the International Consultation on Incontinence (Monaco 2004) which will be published later this year, an evidence based book providing best practice in continence and prolapse. BSUG and ICS UK should be consulted at each stage.	Thank you for this useful information. The guideline developers will consider this evidence alongside all other relevant evidence. Further consultation with registered stakeholder organisations will occur when the first and final draft guidelines are produced.
SH	British Society of Urogynaecologists	4	General	The guidelines subcommittee also felt that there was an opportunity to assess/advise on the outcome measures used in continence surgery, the timing and nature of post-operative follow-up, evaluate questionnaires and quality of life tools. In addition, to advise on the management of post-operative complications e.g. failure, voiding dysfunction.	The role of tools for assessing outcome measures in day-to-day practice is limited from a clinical point of view. Whilst we recognise that these are important issues they are beyond the remit of the guideline. Post-operative complications will be considered where they are reported as an outcome in studies evaluating surgical procedures.
SH	Chartered Society of Physiotherapy	1	General	We welcome the development of this guideline, particularly as physiotherapists have a significant part to play in the management of this patient population. As such, we would be very keen to have a physiotherapist represented on the guideline development group.	Thank you. A physiotherapist with the relevant background and expertise has been invited to join the guideline development group.
SH	Chartered Society of Physiotherapy	2	General	The scope excludes men whereas the brief from the DH does not explicitly do this. We suggest that a specific comment is made	Men are excluded from this guideline, and the scope now makes this explicit.

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				regarding this exclusion.	
SH	Chartered Society of Physiotherapy	3	General	We would ask that other guidelines where urinary incontinence is a common symptom are referenced, for instance multiple sclerosis.	Cross-reference to the NICE Multiple Sclerosis guideline will be made where appropriate.
SH	Chartered Society of Physiotherapy	4	General	The scope does not incorporate any biopsychosocial aspects of the management of women with urinary incontinence.	We consider that these aspects are covered within lifestyle and behavioural issues, which are now incorporated into the scope.
SH	Chartered Society of Physiotherapy	5	3 c	The list of non-surgical approaches is very short, we suggest other interventions are included for instance biofeedback.	The scope refers to non-surgical treatments in the broad sense, and does not list all possible options. These will be considered by the guideline developers.
SH	Chartered Society of Physiotherapy	6	3 h	We suggest neuromuscular electrical stimulation for detrusor instability is included as a technique for the treatment of urge incontinence.	This has been included in section 3.
SH	Chartered Society of Physiotherapy	7	4.1	Concomitant faecal/flatal incontinence is not noted in the guideline and we suggest this is either specifically excluded or included.	The scope has been amended to specifically exclude anal (faecal/flatal) incontinence.
SH	Chartered Society of Physiotherapy	8	4.1.2	Patient populations with other co-morbidities eg neurological problems such as MS and stroke are not noted and we suggest these patient populations are either explicitly excluded or included.	Incontinence in association with neurological disease is excluded from this guideline, and the scope now states this.
SH	Chartered Society of Physiotherapy	9	4.3 a	We suggest that after diagnostic, medical and surgical 'and other healthcare interventions' is added.	Thank you for this suggestion, which has been incorporated into the scope.
SH	Chartered Society of Physiotherapy	10	6	The scope does not mention the guideline on post-natal care which is currently being developed and we would suggest that a link needs to be made to that guideline.	Reference to this guideline has been added to the scope.
SH	CIS'ters				This organisation was approached but did not respond.
SH	Clinimed Limited	1			This organisation was approached but did not respond.
SH	Colchester Primary Care Trust	1			This organisation was approached but did not respond.
SH	College of Occupational Therapists	1	General comment	Please can full references be given for the statements, facts and figures given – eg	Thank you. References used in the development of the scope are not cited in the

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				"urinary incontinence is defined as ...", "10 – 52 % of adult women have urinary incontinence". Etc.	scope document but are available from the National Collaborating Centre on request.
SH	College of Occupational Therapists	2	General	We understand the necessity to limit the scope of guidelines in order for them to be manageable. However, as there is a large number of patients who will be omitted from this guideline, it would be most helpful to know when and if other elements will be considered elsewhere.	Inclusion of populations other than women is beyond the scope of this guideline. We recognise that incontinence is not a problem confined to women, but in order to cover the issues in the scope in a helpful way in sufficient depth and within the timeline, the guideline will be restricted to this population. However, NICE welcomes suggestions for future topics from stakeholders, healthcare professionals and the public, and would encourage you to put your views forward. From 1st December 2004 suggestions can be made via the NICE website (www.nice.org.uk).
SH	College of Occupational Therapists	3	3 b	Please can information be provided as to how Quality of Life measure will be used? Will a standardised assessment be used?	Quality of life will be considered as an outcome in the evidence evaluated but we will not predefine which measures should be used to assess this.
SH	College of Occupational Therapists	4	3 d	'Subjective cure rate' – Please can you describe how this is actually measured?	Information on treatment outcomes has been deleted from section 3 of the scope.
SH	College of Occupational Therapists	5	General	Conservative management of incontinence is mentioned several times through the scope but this concentrates on pelvic floor muscle exercises – there are other forms of conservative management eg life style issues, use of assistive technology in home, work or education, use of products, etc.	Lifestyle and behavioural interventions will be considered in the guideline and the scope now reflects this.
SH	College of Occupational Therapists	6	4 (all section)	As above (General) the population group given within the scope is very limited. Can a guide be given as to when and how consideration will be given to men who experience stress and urge incontinence?	Men are excluded from this guideline, and the scope now explicitly states this.
SH	College of Occupational Therapists	7		Can clarification be given to when a young female person becomes an adult, to fit the criteria given in the scope?	In the context of this guideline, adulthood will be dealt with pragmatically to encompass the relevant literature. An age threshold for inclusion will not be defined.
SH	College of Occupational Therapists	8		It is very unclear if pelvic organ prolapse is to	We believe this issue is clarified in the revised

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Type	Stakeholder	Order no.	Section no.	Comments	Developer's response
				be included or not – sections 4.1.1 and 4.1.2 seem to contradict each other.	scope (4.1.2 a), which states that pelvic organ prolapse will be covered where it relates to the treatment of urinary incontinence and/or the overactive bladder syndrome, but not beyond this.
SH	College of Occupational Therapists	9	4.3	The scope gives a very limited view of management options – it seems to indicate that pelvic floor exercises are offered as first treatment option and then if they are not successful surgery is offered. There are many treatment modalities in between these two extremes (see comments in General section above).	The scope covers the broad interventions that will be considered in the guideline; that is, conservative techniques, pharmacotherapy and surgery. The guideline development group will further define the options and offer guidance on their use.
SH	Coloplast Limited				This organisation was approached but did not respond.
SH	Continence Foundation	1	General	We support the view expressed at the Stakeholders' meeting that, if at all possible, the Guideline should be extended to include men. A significant number of the treatments are the same in men as for women. If a separate guideline were to be proposed for men, it would need to cover some of the same ground, and take up the time of many of the same people.	Inclusion of populations other than women is beyond the scope of this guideline. We recognise that incontinence is not a problem confined to women, but in order to cover the issues in the scope in a helpful way in sufficient depth and within the timeline, the guideline will be restricted to this population. However, NICE welcomes suggestions for future topics from stakeholders, healthcare professionals and the public, and would encourage you to put your views forward. From 1st December 2004 suggestions can be made via the NICE website (www.nice.org.uk).
SH	Continence Foundation	2	3 a	We trust that the quoted estimate for the numbers of women with urinary incontinence will be improved on – the wide range is partly due to outdated studies, but also the lack of agreement on definitions, especially definitions of mild, moderate and severe incontinence and whether all of these should be included. If the Guideline used clear definitions, the statistics would be more reliable, and therefore of more use in planning for treatment.	The guideline will contain an expanded section on epidemiology, bearing in mind your comments.
SH	Continence Foundation	3	3 a	The Trustees of the Continence Foundation are	The guideline will cover stress and mixed

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				all agreed that the study should include urgency without loss of urine, because of patients who have combinations of symptoms e.g. stress incontinence with detrusor instability. There seemed to be a consensus at the recent ICS that Overactive Bladder Syndrome should be treated as a continuum. We also suggest including frequency (because frequency and urge go together). And retention should also not be ignored. Our GP Trustee summed up the full area that should be covered as "bladder storage problems".	incontinence and the overactive bladder syndrome. The scope has been amended to reflect this.
SH	Continence Foundation	4	3 b	We are pleased to see the references to improvement in quality of life and social functioning, since these are so important to patients. It would be useful if the Guideline could include reference to quality of life outcome scales, even if the GDG cannot agree on a single one to recommend.	Quality of life will be considered as an outcome in the evidence evaluated, but we will not predefine what measures should be used to evaluate this. We are aware that there are recommendations on which scales are validated for use in people with incontinence.
SH	Continence Foundation	5	3 c	Clinical question that now needs to be considered: the place of Duloxetine in the treatment pathway.	Thank you for this suggestion. Pharmacotherapy for stress incontinence will be considered in the guideline and the scope now reflects this. Specific drugs will not be listed in the scope.
SH	Continence Foundation	6	3 g	The bulking materials should include the copolymer manufactured by Q-Med.	The scope refers to non-surgical treatments in the broad sense, and does not list all possible options, which will be defined by the guideline developers.
SH	Continence Foundation	7	3 h	The list of antimuscarinic drugs is getting longer, with the potential for confusion regarding which one is most suitable for a particular patient: trospium chloride has been an option for some time, solifenacin has just been licensed and darafenacin may be available before this Guideline is completed. There will also be an oxybutinin patch by 2005. Clinical question: is it possible to make recommendations about the suitability of the various OAB drugs?	Thank you for the suggested question. The antimuscarinic group of drugs will be considered within this guideline.

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SH	Continenence Foundation	8	4.1.1	See general comment. We also support the view of [X] that neurogenic bladder should not be excluded.	Incontinence in association with neurological disease is excluded from this guideline, and the scope now states this.
SH	Continenence Foundation	9	4.3 f	We agree with the view expressed by ACA at the meeting that the competencies of nurses involved in diagnosis, investigation and/or treatment should be included. We would add the competencies of specialist physiotherapists.	We acknowledge that competency is an important issue in the management of women with incontinence. However, it is beyond the remit to look at competencies for all health professionals involved in their care. The competencies of surgeons performing operative procedures will be addressed as stated in the remit.
SH	Continenence Foundation	10	4.3 g	If pharmacological intervention beyond the licensed indications it to be included, that raises the question of including botulinum toxin injections in the bladder.	Thank you for this suggestion, which will be considered by the guideline development group. As stated in section 4.3 of the scope, NICE guidelines normally recommend used within licensed indications. Exceptionally, and only where the evidence clearly supports it, the guideline may recommend use of a pharmacological intervention beyond its licensed indications.
SH	Croydon Primary Care Trust	1	2 b	Clarity over NSF's and continence care.	This is a standard statement made in scope documents.
SH	Croydon Primary Care Trust	2	3 a	Define adult by age.	An age threshold for inclusion will not be defined, and there will be no upper age limit. In the context of this guideline, adulthood will be dealt with pragmatically to encompass the relevant literature.
SH	Croydon Primary Care Trust	3	General	In talking about urge it has recently be decided by The International Continenence Society to use the term urgency and urgency incontinence.	Thank you. The current International Continenence Society definitions for incontinence and the overactive bladder syndrome have been incorporated into the scope. Should these change during the development of the guideline, they will be adopted within it.
SH	Croydon Primary Care Trust	4	General	There is a feel within the document that it addresses well women with incontinence. Some of the proposals are not relevant for certain women. The document needs to address care for women with incontinence and learning disability, immobility, neurological disease,	The guideline will cover the management of stress and mixed incontinence, and the overactive bladder syndrome in women. The scope has been amended to reflect this. Incontinence in association with neurological disease is excluded.

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				mental illness, stroke etc.	
SH	Croydon Primary Care Trust	5	3 c	Need to include containment section and advice, bladder retraining, life style changes, fluid advice.	Lifestyle and behavioural interventions, and containment will be considered in the guideline as you suggest; the scope now reflects this.
SH	Croydon Primary Care Trust	6	3 h	Include caffeine restriction and injectables.	Lifestyle interventions have been incorporated into the scope and will be considered by the guideline developers.
SH	Croydon Primary Care Trust	7	4	Include pessaries.	Assuming that you refer to pessaries in relation to pelvic organ prolapse, the management of prolapse will not be considered beyond how it relates to the treatment of urinary incontinence and /or the overactive bladder syndrome.
SH	Croydon Primary Care Trust	8	4.1.1 a	Need to have clarity about those women who have urinary incontinence but also other health issues as identified above. Is this about well women or ill women or both or just one group.	Please refer to the above response regarding the population included.
SH	Croydon Primary Care Trust	9	4.1.2	Should this section include neuro conditions, terminally ill, cognitively impaired, severely ill.	The populations excluded from the guideline are specified in the revised scope.
SH	Croydon Primary Care Trust	10	4.3 a	Include health promotion, prevention, role of midwife, health visitor, opportunistic screening by GP's.	The scope defines the boundaries of the guideline and does not refer to the roles of health professionals. Conservative techniques, where used prophylactically, will be considered and the scope now reflects this. Screening is not included as it is beyond the remit of this guideline.
SH	Department of Health	1		Thank you for the opportunity to comment on the draft Scope of the above guideline. The attached table of comments reflects the views of the Department of Health.	Lifestyle and behavioural interventions will be considered in the guideline as you suggest, and the scope now reflects this.
SH	Dudley Group of Hospitals NHS Trust				This organisation was approached but did not respond.
SH	Eli Lilly and Company Ltd/Boehringer Ingelheim	1	General	We think that the format of the scope could be improved and made clearer (especially in sections 3 and 4.3) by having a more consistent approach to both Stress Urinary Incontinence (SUI) and Urge Urinary Incontinence (UUI) i.e. more aligned to Dr Paul Hilton's slides presented at the stakeholder meeting:	Thank you for these suggestions. Sections 3 and 4.3 of the scope have been restructured with consistency in mind. The guideline will cover stress and mixed incontinence and the overactive bladder syndrome; the scope now reflects this.

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				<p>SUI – Definition, UUI – Definition</p> <p>SUI – Treatments – lifestyle, exercises/training, medical (ie pharmacological) and surgical.</p> <p>UUI – Treatments – lifestyle, exercises/training, medical (ie pharmacological) and surgical.</p> <p>Relevant terms should be selected and used consistently throughout the document – the umbrella terms non-surgical/medical/training & exercises are not used consistently in the scope (see 3c, 3h, 4.3c & 4.3d).</p>	
SH	Eli Lilly and Company Ltd/Boehringer Ingelheim	2	General	There is no reference to pharmacological treatments for SUI throughout the document. (Duloxetine, Yentreve, is the first licensed treatment for moderate to severe SUI available in the UK).	Pharmacotherapy for stress urinary incontinence will be considered in the guideline and the scope now reflects this. Specific drugs will not be listed in the scope.
SH	Eli Lilly and Company Ltd/Boehringer Ingelheim	3	General and 4.1	We think that the scope (especially with regard to population) is well defined and will be a manageable workload. Further patient populations may make the guideline too big and unwieldy and hard to use in 'clinical practice'. Other populations should be the subject of further separate guidelines.	Noted with thanks.
SH	Eli Lilly and Company Ltd/Boehringer Ingelheim	4	3 c	This section more than likely refers to Stress Urinary Incontinence and it should state this. It should also make reference to 'pharmacological' treatment (eg duloxetine).	Distinction between the different types of incontinence is made where appropriate. Pharmacotherapy is now referred to in the scope.
SH	Eli Lilly and Company Ltd/Boehringer Ingelheim	5	4.3	We agree with the suggestion (raised at the stakeholder meeting) that 'lifestyle interventions' should be included.	Lifestyle and behavioural interventions will be considered in the guideline and the scope now reflects this.
SH	Eli Lilly and Company Ltd/Boehringer Ingelheim	6	6	This section may benefit from including the following reference: Department of Health (2000). Good Practice in Continence Services. London: Department of Health.	We are aware of the 2000 DH publication, which will be considered by the guideline developers alongside all relevant information. Specific reference to this document will not be made in the scope document, which refers specifically to other related NICE guidance.

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SH	Faculty of Public Health				This organisation was approached but did not respond.
SH	Ferring Pharmaceuticals Limited	1		<p>I attended the above meeting on 22nd September and found it quite informative. As urged by some of the presenters several times during the course of the presentations, I am writing to provide feedback concerning the guideline.</p> <p>Our feedback concerns the scope of the guideline. In agreement with many of the attending participants, we feel that the scope of the guideline is too narrow, as it only addresses continence issues concerning women. Children, men and the elderly have all been excluded from the guideline. There is no mention of any subgroups e.g. patients with Multiple Sclerosis or other patient groups with special needs. [X] mentioned nocturnal enuresis and how patients with this condition occupy a good deal of his daily practice time. [X] also mentioned nocturnal enuresis. The prevalence of this condition is of the order of half a million children in the UK, with approximately 1–2% of these continuing to experience nocturnal enuresis in adult life. These are not insignificant numbers and we feel that you should consider adding nocturnal enuresis to the scope of the guideline, particularly as it would complement the recently published Children's National Service Framework setting the standard for children's health and social services.</p>	<p>Incontinence in men and children, and incontinence associated with neurological disease, is excluded from this guideline. Elderly women will be included; no upper age limit will be applied. Inclusion of populations other than women is beyond the scope of this guideline. We recognise that incontinence is not a problem confined to women, but in order to cover the issues in the scope in a helpful way in sufficient depth and within the timeline, the guideline will be restricted to this population. However, NICE welcomes suggestions for future topics from stakeholders, healthcare professionals and the public, and would encourage you to put your views forward. From 1st December 2004 suggestions can be made via the NICE website (www.nice.org.uk). Cross-reference to other relevant guidelines will be made where appropriate e.g. the MS guideline.</p> <p>The guideline will cover stress and mixed incontinence and the overactive bladder syndrome in women. The scope has been amended to reflect this.</p>
SH	Fibroid Network Charity				This organisation was approached but did not respond.
SH	Galen Limited	1	3 h	The current wording suggests that only two antimuscarinics (oxybutynin and tolterodine) will be considered.	Thank you. The antimuscarinic group of drugs will be considered. Specific drugs are no longer listed in the scope to avoid confusion.
SH	Galen Limited	2		Galen Limited market tropsium chloride (as Regurin 20mg Tablets) in the UK. This is the	Please refer to the above response regarding antimuscarinic drugs.

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				third most widely prescribed antimuscarinic for the treatment of incontinence. We propose that the wording should be changed to “ ... medical treatment such as antimuscarinic drugs (for example oxybutynin, tolterodine and trospium chloride) ... ”	
SH	Galen Limited	3	4.1.1	<p>It is considered that the population to be studied should be widened to include men; it is not clear from the Government referral that the scope should be limited to women. We also propose that male and female elderly patients, and patients of all ages with neurological conditions, should be included as subgroups.</p> <p>Due to complicating medical and drug histories, potentially different responses to treatment and increased susceptibility of elderly patients to adverse events, it is considered that guidelines developed for the general population may not be easily transferable/applicable to the elderly population, who make up a large proportion of patients with urge incontinence.</p> <p>Similarly, patients with neurological conditions have particular needs, for example; restrictions in mobility, greater dependence on carers and possible impairment of cognitive function. Therefore, guidelines developed for the general population will not be easily transferable to this subgroup. It is important to identify the treatments that have been assessed and approved for use specifically for these patients.</p>	<p>Incontinence in men, and incontinence associated with neurological disease, is excluded from this guideline. Elderly women will be included; no upper age limit will be applied. Inclusion of populations other than women is beyond the scope of this guideline. We recognise that incontinence is not a problem confined to women, but in order to cover the issues in the scope in a helpful way in sufficient depth and within the timeline, the guideline will be restricted to this population. However, NICE welcomes suggestions for future topics from stakeholders, healthcare professionals and the public, and would encourage you to put your views forward. From 1 December 2004 suggestions can be made via the NICE website (www.nice.org.uk). We are aware that in some published studies data will include a mixed population. Although we will consider this evidence alongside other relevant evidence, we will ensure that the applicability and extrapolation of the data are reflected in the guideline recommendations.</p>
SH	Gloucestershire Hospitals NHS Trust	1		<p>There were 3 comments on the appendix.</p> <p>1. To widen the scope to males, children and the elderly would make the process and subsequent conclusions too complex and these groups are worthy of separate studies.</p>	<p>Thank you.</p> <p>1. The guideline will consider women only. Other populations have been explicitly excluded.</p>

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				<p>2. The term 'prolapse of the womb' is unhelpful as different types of prolapse have varying effects on urinary symptoms.</p> <p>3. Ensure that the correct ICS terminology is used ie overactive bladder.</p>	<p>2. We state pelvic organ prolapse in the scope, and the guideline will consider this as stated in 4.1.2 a.</p> <p>3. The current ICS definitions have been incorporated into the guideline.</p>
SH	Good Hope NHS Trust				This organisation was approached but did not respond.
SH	Guy's & St Thomas' NHS Trust	1		<p>There are a few points I wish to raise:</p> <p>1) It really amazed me that guidelines are going to be drawn for females only. It struck me that people who decided on the scope, perceived this as exclusively a female problem which unfortunately is not the case. It would be waste of resources and time to concentrate on one sex and then set off after three years to draw more guidelines to cover males and then further three years for children!!</p> <p>2) Unfortunately management of incontinence involves several disciplines. Gynaecologists, Urogynaecologists and Urologists are the main specialists delivering surgical care alongwith their team members of continence advisers, physiotherapists etc who play a major role in the conservative and supportive treatment. As the problem has been perceived as of one sex, hence RCOG has been approached to take the lead in the formulation of guidelines. It would be very unfair to exclude urologists from this process who not only manage a large proportion of females but also are the only specialists looking after males with urinary incontinence.</p>	<p>Thank you.</p> <p>1) Inclusion of populations other than women is beyond the scope of this guideline. We recognise that incontinence is not a problem confined to women; but in order to cover the issues in the scope in a helpful way in sufficient depth and within the timeline, the guideline will be restricted to this population. However, NICE welcomes suggestions for future topics from stakeholders, healthcare professionals and the public, and would encourage you to put your views forward. From 1st December 2004 suggestions can be made via the NICE website (www.nice.org.uk).</p> <p>2) The guideline will be developed by a multidisciplinary group with technical support from the National Collaborating Centre for Women's and Children's Health. The following professional groups will be represented on the guideline development group: urology, gynaecology, elderly care, general practice, nursing and physiotherapy, as well as two patient/carer representatives.</p>

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				3) Management of urinary incontinence has not been at the top of priorities of either the health department or Trusts. While cancer has attracted lot of attention and guidelines have been issued regarding the time frame in which we see the patients and deliver the treatment, incontinence has largely been ignored and hence not enough resources have been put in to look after this patient population. I hope the committee will keep this fact in mind and give some idea of optimum standards trusts must meet to be compliant.	3) The guideline will make recommendations on the most cost-effective care of patients and include treatment options and patient preferences.
SH	Health Protection Agency				This organisation was approached but did not respond.
SH	Healthcare Commission				This organisation was approached but did not respond.
SH	Herefordshire Primary Care Trust				This organisation was approached but did not respond.
SH	Hertfordshire Partnership NHS Trust				This organisation was approached but did not respond.
SH	Hollister Ltd	1	General	Much debate at the meeting on the 22nd centred on broadening the scope of the document to include children, men, neurogenic subjects as well as the elderly. If the scope was changed from its current form we feel it would be vital that the consultation period be repeated.	Thank you. The scope has not changed with regard to the population included.
SH	Hollister Ltd	2	3 a	The definition of urinary incontinence is very simplistic and not consistent with the ICS standardisation committee's terminology: "Urinary Incontinence. This is defined as involuntary loss of urine which is objectively demonstrable and a social or hygienic problem. Loss of urine through channels other than the urethra is extraurethral incontinence."	The current International Continence Society definitions for incontinence and the overactive bladder syndrome have been incorporated into the scope. Should these change during the development of the guideline, they will be adopted within it.
SH	Hollister Ltd	3	3 a	What about mixed incontinence and overflow incontinence both suffered by women; is this not to be considered?	The guideline will cover stress and mixed incontinence and the overactive bladder syndrome in women. The scope has been

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					amended to reflect this.
SH	Hollister Ltd	4	3 c	Are patients who have had failed surgical procedures, where symptoms remain/deteriorate, to be considered?	Women will be included for the whole pathway of care, which will include first and subsequent procedures.
SH	Hollister Ltd	5	3 a	Female patients with voiding problems are not addressed; should this not be considered, along with appropriate treatment?	Please refer to the above comments regarding the population covered in this guideline.
SH	Hospital Infection Society				This organisation was approached but did not respond.
SH	Incontact (Action on Incontinence)	1	General	<p>First impression is that this document is very limited in scope. Why is it only for women? this is disappointing. Men should be included or have a specific guideline produced urgently.</p> <p>We recommend to NICE that this guideline ought to be developed relating to other populations, such as those listed below in point 4.1.2.</p> <p>Guidelines on adult urinary incontinence has to be a great step forward to ensure everyone has the same opportunities for obtaining good quality care throughout England and Wales.</p> <p>It would be a shame to limit it to SUI and urge incontinence. Scotland is at the end stage of such a wider guideline and it would make senses to consult and liaise with SIGN.</p>	<p>Thank you. Inclusion of populations other than women is beyond the scope of this guideline. We recognise that incontinence is not a problem confined to women, but in order to cover the issues in the scope in a helpful way in sufficient depth and within the timeline, the guideline will be restricted to this population. However, NICE welcomes suggestions for future topics from stakeholders, healthcare professionals and the public, and would encourage you to put your views forward. From 1st December 2004 suggestions can be made via the NICE website (www.nice.org.uk).</p> <p>We are aware of the SIGN guideline in development, which will be considered by the guideline developers alongside all other relevant evidence.</p>
SH	Incontact (Action on Incontinence)	2	3 c	Need to talk about other treatments i.e. fluid manipulation, bladder retraining, and biofeedback as well.	Lifestyle and behavioural interventions will be considered in the guideline and the scope now reflects this.
SH	Incontact (Action on Incontinence)	3	4.1.1	<p>First impression is that this document is very limited and the population chosen very narrow. Why is it only for Women? Men should be included.</p> <p>Clarify what age range will be scoped?</p>	An age threshold for inclusion will not be defined, and there will be no upper age limit. In the context of this guideline, adulthood will be dealt with pragmatically to encompass the relevant literature. Please refer to above response regarding the population included.
SH	Incontact (Action on Incontinence)	4	4.1.2	The scope needs to be extended to include urinary incontinence in the adult population.	Please refer to above response regarding the population included. Women with incontinence

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				This will entail Pathways for all people with bladder continence issues including – SUI, urge incontinence, mixed incontinence, neurological conditions such as MS, Parkinson's, Spina bifida etc. Spinal injuries should also be included with a separate statement for dealing with specific problems relating to Hypereflexia.	(overactive bladder, stress or mixed incontinence) will be covered in the guideline. Cross-reference to other relevant guidelines will be made where appropriate, e.g. the Multiple Sclerosis NICE guideline.
SH	Incontact (Action on Incontinence)	5	4.3 a	Should include the specialist nursing and physiotherapist management of women through all stages of their care.	The scope will not refer to professional roles. A representative with the relevant background and expertise from both professional groups has been invited to join the guideline development group.
SH	Incontact (Action on Incontinence)	6	4.3 b	This should read – Assessment, diagnosis and investigation. It is crucial that first line initial assessment is described. Good assessment is the key to correct pathways, for diagnosis and investigations. Early interventions are important for long-term health.	Thank you for this suggestion, which has been incorporated into the scope.
SH	Incontact (Action on Incontinence)	7	4.3 c	Nothing is mentioned about lifestyle choices and the promotion of healthy bladders. Will patients be dealt with from a holistic point of view and provided with support on the emotional issues that are very prominent in many people living with bladder incontinence? Lifestyle interventions are an important aspect. In relation to pelvic floor exercises details should include the length of time required before improvements are seen, duration of exercises and the need for adherence to daily routines for best results.	Lifestyle and behavioural interventions will be covered in the guideline and the scope now reflects this. Thank you for this suggestion, which will be considered by the guideline developers.
SH	Incontact (Action on Incontinence)	8	4.3 d	Very surgically dominated. Should read use of medical, specialist nursing/physiotherapy and surgical treatment options for overactive bladder symptoms. Must have standard of care in assessment and management for all health professionals' not just surgeons.	The guideline will advise on conservative techniques, pharmacotherapy and surgical options for stress or mixed urinary incontinence or overactive bladder. We acknowledge that competency is an important issue in the management of women with incontinence. However, it is beyond the remit to look at competencies for all health professionals

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					involved in their care. The competencies of surgeons performing operative procedures will be addressed as stated in the remit.
SH	Incontact (Action on Incontinence)	9	4.3 e	Exclude anaesthesia from remit – too wider scope.	Thank you. The section on 'Interventions and clinical practice likely to reduce morbidity associated with the procedures – including those with anaesthesia' has been deleted as it is beyond the remit of the guideline.
SH	Incontact (Action on Incontinence)	10	Appendix x	Detrusor instability no longer exists, this should read detrusor overactivity and the DoH and Welsh Assembly should really be looking at the overactive bladder. Symptoms for this will include frequency, urgency and nocturia as well as incontinence.	The guideline will cover stress and mixed incontinence and the overactive bladder syndrome. The scope has been amended to reflect this.
SH	Independent Healthcare Association				This organisation was approached but did not respond.
SH	Janssen-Cilag Ltd	1	4.1.1 Groups that will be covered	<p>We feel that men should be included in the population to be covered. The population is aging and urge incontinence is likely to become more prevalent as a result. Excluding men from this guideline will mean that health care professionals will not have the same degree of evidence-based guidance to manage a large group of the elderly population. We believe that this would be a great opportunity to offer guidance to healthcare professionals to alleviate the suffering of this group of men.</p> <p>The same applies to patients affected by neurological problems that lead to incontinence. Excluding men will mean that healthcare professionals will have less guidance on how to treat a large proportion of this group of patients.</p>	<p>Inclusion of populations other than women is beyond the scope of this guideline. We recognise that incontinence is not a problem confined to women, but in order to cover the issues in the scope in a helpful way in sufficient depth and within the timeline, the guideline will be restricted to this population. However, NICE welcomes suggestions for future topics from stakeholders, healthcare professionals and the public, and would encourage you to put your views forward. From 1st December 2004 suggestions can be made via the NICE website (www.nice.org.uk).</p> <p>Women with overactive bladder syndrome, stress or mixed incontinence will be included.</p>
SH	Johnson & Johnson Medical	1	4.3	We believe that primary and secondary prevention measures should be covered in the scope of the guideline. Where these are being addressed elsewhere then a clear cross-	Conservative techniques, where used prophylactically, will be considered and the scope now reflects this. Other relevant guidelines will be cross-referenced in the

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Type	Stakeholder	Order no.	Section no.	Comments	Developer's response
				reference between relevant guidelines should be made, eg, clinical guideline on Intrapartum care.	urinary incontinence guideline.
SH	Johnson & Johnson Medical	2	4.3 d and e	We agree that the guideline should cover the indications and appropriate use of relevant treatment options and the clinical practices most likely to reduce morbidity.	The guideline will cover the indications and appropriate use of the various treatment options. Clinical practice will be considered in so far as defining the competencies for surgeons.
SH	Johnson & Johnson Medical	3	4.3 c	We agree that the guideline should cover the surgical treatments that are effective and we would like to stress the importance at this stage of the need to demonstrate the long term effectiveness of an implant used in incontinence surgery. We request that the guideline bring clarity for health service providers on how effectiveness can be defined for mesh implants and on how "experimental" devices should be handled for maximum patient safety.	Thank you for the suggestions, which will be considered by the guideline development group.
SH	Johnson & Johnson Medical	4	4.3 f and Appendix	We agree that the guideline should cover the training requirements and competencies required for surgeons to perform primary and subsequent operations.	This remains in the scope.
SH	Johnson & Johnson Medical	5	General	We believe that the guideline should cover how new technology innovations should be approached during the term of the guideline until such time as the guideline is reviewed.	Thank you for this suggestion, which will be considered by the guideline development group.
SH	King George's Hospital NHS Trust				This organisation was approached but did not respond.
SH	Kingston Primary Care Trust				This organisation was approached but did not respond.
SH	Knowsley Primary Care Trust				This organisation was approached but did not respond.
SH	Leeds Teaching Hospitals NHS Trust				This organisation was approached but did not respond.
SH	Liverpool Women's Hospital NHS Trust				This organisation was approached but did not respond.
SH	Long-term Medical Conditions Alliance				This organisation was approached but did not respond.

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SH	Maternity Health Links				This organisation was approached but did not respond.
SH	Medicines and Healthcare Products Regulatory Agency (MHRA)				This organisation was approached but did not respond.
SH	Medtronic Limited	1	General	Clinical guidelines for urinary incontinence should be expanded to include men suffering from this condition. Both urge and urgency incontinence are common in men, and their prevalence increases with age. Given the aging population, the guidelines should not exclude such a big part of afflicted individuals as it may potentially lead to discrepancies in treatment offered to men versus women. Finally, most of the published scientific evidence is based on data for both men and women, which is likely to lead to difficulties in accurate literature reviews if the outcomes are to be focused on women only.	<p>Inclusion of populations other than women is beyond the scope of this guideline. We recognise that incontinence is not a problem confined to women, but in order to cover the issues in the scope in a helpful way in sufficient depth and within the timeline, the guideline will be restricted to this population. However, NICE welcomes suggestions for future topics from stakeholders, healthcare professionals and the public, and would encourage you to put your views forward. From 1st December 2004 suggestions can be made via the NICE website (www.nice.org.uk).</p> <p>We are aware that in some published studies data will include both men and women. Although we will consider this evidence alongside other relevant evidence, we will ensure that the applicability and extrapolation of the data are reflected in the guideline recommendations.</p>
SH	Medtronic Limited	2	3 b	The Urinary Incontinence category should also include Urgency-frequency – a form of voiding dysfunction characterised by the uncontrolled need to void many more times than is normal (more than 4–7 times per day). In fact, urinary urge incontinence and urgency-frequency are increasingly referred to as one condition: overactive bladder . Since incontinence due to overactive bladder muscle is explicitly mentioned in the DoH/WA referral for this guidance, both these categories should be addressed. Moreover, patients often “move” between urge incontinence and urgency-	The guideline will cover stress and mixed incontinence and the overactive bladder syndrome in women. The scope has been amended to reflect this.

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				frequency and it's not always easy to make a clear-cut distinction between these sub-categories of urinary incontinence. Finally, overflow urinary incontinence is also reported by patients suffering from Urinary Retention – where the bladder tends to fill excessively.	
SH	Medtronic Limited	3	3 c	Medical (drug) management of urinary incontinence is another treatment option currently available, in addition to conservative (e.g. biofeedback) and surgical treatments.	Pharmacotherapy is included as a treatment option in the scope.
SH	Medtronic Limited	4	3 h	Sacral Nerve Stimulation has also been demonstrated to be an effective treatment option for urgency-frequency and urinary retention (not just urge incontinence).	Noted. The place of this technique will be considered by the guideline developers.
SH	Medtronic Limited	5	3	Other/emerging surgical techniques: Implantation of periurethral balloon prosthetics (ACT brand products) for recurrent stress urinary incontinence (SUI) or intrinsic sphincter deficiency patients. This silicone elastomer prosthetic is designed to be adjusted post-operatively via injection into a subcutaneous port. Reported cure rates in recurrent SUI female patients range from 75–87% at 12 month with this post operatively adjustable system.	Thank you for your comments, which will be considered by the guideline development group. References to cure rates have been deleted from the background section.
SH	Medtronic Limited	6	4.1.1	Women suffering from symptoms Urgency-frequency and Urinary retention should also be covered by the guidelines, in addition to those with stress and urge incontinence.	Please see above comment regarding the population to be included.
SH	Medtronic Limited	7	4.3	The guidelines should also cover sacral nerve stimulation (presumably will be covered in the 'surgical treatments' group) as well as emerging techniques, such as periurethral balloon prosthetics (ACT brand products).	The place of sacral nerve stimulation and balloon bulking agents will be considered by the guideline developers.
SH	Medtronic Limited	8	6	Interventional Procedure Guidance (IPG) No 4 (2003): Sacral Nerve Stimulation for urge-incontinence and urgency-frequency has been replaced by IPG No 64 (2004): Sacral Nerve Stimulation for urge-incontinence and urgency-	The scope lists the updated interventional procedure guidance you refer to.

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				frequency.	
SH	Mid Staffordshire General Hospitals NHS Trust				This organisation was approached but did not respond.
SH	Multiple Sclerosis Society	1		Scope fine as far goes but disappointed no mention of neurol. disease/spinal injuries & impact on incontinence which requires different emphasis regards assessment & treatment to the problems mentioned in scoping document with surgery v. much exception rather than routine as implied in document. Would hope to see specific mention of Intermittent Self Catheterisation (ISC) in scoping document as this particularly useful technique/treatment for people with MS/Spinal injury. Also imp. guidelines include review of permanent catheters with regards appropriate use, care & management & ideally prevention/management of complications though may be beyond scope – sometimes only option for women with MS where other treatments failed & surgery not appropriate. Think it important that push to get at least neurological conditions/spinal injuries included if not specifically MS & should include a review of ISC & long term catheters/Supra Pubic catheters. There has been heated debate around NICE guidelines for MS advice regards management of urinary problems-ideal opportunity to clarify issues raised in debate.	Incontinence in association with neurological disease is excluded from this guideline, and the scope now states this. From 1st December 2004, topic suggestions for NICE guidelines can be made by stakeholders, healthcare professionals and the public via the NICE website (www.nice.org.uk). We would encourage you to put your views forward in this way. Containment will be considered within this guideline, and the scope now reflects this.
SH	National Childbirth Trust – 2nd contact	1	4.3	We suggest that the guideline include interventions or practices aimed at preventing urinary incontinence, including for example, searching for evidence of the effectiveness of antenatal, postnatal and continuing pelvic floor exercises, different birth positions, spontaneous vs directed pushing during second stage of labour. NICE should consider prevention of incontinence in the months after childbirth and in later years. As with many other conditions, if this condition could be prevented or reduced	Conservative techniques, where used prophylactically, will be considered in the guideline and the scope now reflects this. The intrapartum care guideline currently in development will cover bladder care during labour, and the postnatal guideline, also in development, covers the role of pelvic floor exercises in the postpartum period.

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				women would benefit and there would be a saving of NHS resources.	
SH	National Childbirth Trust – 2nd contact	2	General	Urinary retention (the inability of the bladder to empty) is another urinary disorder that may sometimes follow childbirth, and NICE may wish to consider the prevention and treatment of this condition at the same time.	The guideline will cover stress and mixed incontinence and the overactive bladder syndrome in women. The scope has been amended to reflect this. Urinary retention will not be covered in this guideline.
SH	National Council for Disabled People, Black, Minority and Ethnic Community (Equalities)				This organisation was approached but did not respond.
SH	National Patient Safety Agency				This organisation was approached but did not respond.
SH	National Public Health Service for Wales				This organisation was approached but did not respond.
SH	Newham PCT				This organisation was approached but did not respond.
SH	NHS Information Authority (PHSMI Programme)				This organisation was approached but did not respond.
SH	NHS Modernisation Agency, The				This organisation was approached but did not respond.
SH	NHS Quality Improvement Scotland				This organisation was approached but did not respond.
SH	North Essex Mental Health Partnership Trust				This organisation was approached but did not respond.
SH	North Tees and Hartlepool NHS Trust	1	General	Please indicate the role of physiotherapist.	The scope will not refer to professional roles. The guideline development group will include a physiotherapist with the relevant background and expertise, in order to ensure that this perspective is covered.
SH	North Tees and Hartlepool NHS Trust	2	General	Medical management of Stress Incontinence.	The title remains as the management of urinary incontinence in women, as the guideline will cover overactive bladder, stress and mixed incontinence.
SH	North Tees and Hartlepool NHS Trust	3	General	We would appreciate if prevention of incontinence with evaluation prevention strategies. Such as supervised pelvic floor education antenatal and postnatal.	Conservative techniques, where used prophylactically, will be considered and the scope now reflects this. The NICE postnatal care guideline currently in development covers the role of pelvic floor exercises in the postpartum period.

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SH	North Tyneside Primary Care Trust				This organisation was approached but did not respond.
SH	Northumberland Care Trust				This organisation was approached but did not respond.
SH	Nottingham City Hospital NHS Trust	1	General	Why is this confined to women? Many of the problems, and potential solutions, are common to both sexes. Might we end up with the bizarre circumstance of having a 'NICE-approved' treatment for, say, detrusor instability, in women, but not men? Given the way NICE advice is interpreted in the field, this might lead to treatments not being available of the grounds of sex!	Inclusion of populations other than women is beyond the scope of this guideline. We recognise that incontinence is not a problem confined to women, but in order to cover the issues in the scope in a helpful way in sufficient depth and within the timeline, the guideline will be restricted to this population. However, NICE welcomes suggestions for future topics from stakeholders, healthcare professionals and the public, and would encourage you to put your views forward. From 1st December 2004 suggestions can be made via the NICE website (www.nice.org.uk).
SH	Nottingham City Hospital NHS Trust	2	General	The document is thin on detrusor instability/overactive bladder, (and related issues such as bladder problems in neurological disease) and incomplete bladder emptying (IBE). Certainly in the older age population (who have the greatest prevalence of problems), detrusor instability is the biggest issue, followed by IBE rather than stress incontinence. As it stands, the guidance could really be renamed 'the management of SUI in middle aged women'. Given the relative neglect of the field, it would be disappointing to limit the scope to exclude the group with the greatest prevalence of problems. If possible, management of incontinence in dementia, and age-related nocturnal polyuria, should also be included as separate topics,	The guideline will cover stress and mixed incontinence and the overactive bladder syndrome in women. The scope has been amended to reflect this. An upper age limit will not be applied to women in the guideline.
SH	Nottingham City Hospital NHS Trust	3	4.3 g	Drug treatments for detrusor instability are disappointing, tolterodine at licenced dose included. Tolterodine 8mg (double licenced dose) is certainly more effective, at risk of a 25% incidence of IBE. We can quite easily	Thank you for this information. As stated in section 4.3 of the scope, NICE guidelines normally recommend use within licensed indications. Exceptionally, and only where the evidence clearly supports it, the guideline may

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				detect this by bladder scanning, so in patients who can tolerate it this is a useful addition to standard therapy. Also unlicensed combinations (eg imipramine plus tolterodine).	recommend use of a pharmacological intervention beyond its licensed indications.
SH	Nottingham City Hospital NHS Trust	4	4.3 g	Similarly, it would be useful to look at the role of desompressin in people over 65 (the limit to the licence).	Thank you for this suggestion, which will be considered by the guideline development group. Please also refer to the above response regarding recommendations for unlicensed use of pharmacotherapies.
SH	Nottingham City PCT	1	1	The PCT feels this scope should extend to cover men as well as women. Men also can suffer with stress and certainly urge, the institute will eventually have to write another VERY similar guideline for men, therefore repeating work already done.	Inclusion of populations other than women is beyond the scope of this guideline. We recognise that incontinence is not a problem confined to women, but in order to cover the issues in the scope in a helpful way in sufficient depth and within the timeline, the guideline will be restricted to this population. However, NICE welcomes suggestions for future topics from stakeholders, healthcare professionals and the public, and would encourage you to put your views forward. From 1st December 2004 suggestions can be made via the NICE website (www.nice.org.uk).
SH	Nottingham City PCT	2	3 a	Although stress and urge incontinence are the more common conditions, other types of incontinence should also be included. For example, prolapse in women may cause incomplete emptying and subsequent incontinence. By leaving this out the guideline will be incomplete. By excluding other types of incontinence, as with excluding men, the institute will find itself having to write another very similar guideline, thus repeating work already done, again.	The guideline will cover stress and mixed incontinence and the overactive bladder syndrome in women. The scope has been amended to reflect this. Pelvic organ prolapse will be considered where it relates to the treatment of urinary incontinence and/or the overactive bladder as stated in the scope.
SH	Nottingham City PCT	3	3 b	The guideline infers all diagnoses of urge incontinence should be backed up by urodynamic assessment - there will be cost implications to this re: availability of resources/equipment, suitably qualified staff to operate the equipment patient agreement to	The appropriate place of urodynamic assessment will be addressed in the guideline.

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				undergoing investigation. Usually urodynamic assessment would be used if the patient fails to respond to treatments offered, to then confirm diagnosis is correct.	
SH	Nottingham City PCT	4	3 c	Vaginal cones should be replaced with biofeedback. Vaginal cones are simply one method of biofeedback.	The term biofeedback remains in the scope, as a broad example of adjuncts to pelvic floor exercise.
SH	Nottingham City PCT	5	3 c	Electrical stimulation, using different frequency/hertz may also be given to help relieve frequency and urgency and this should be clearly stated.	Electrical stimulation has been incorporated into the scope.
SH	Nottingham City PCT	6	3 h	<p>Only 2 medications are mentioned which can be used to treat urgency – does this mean the range of medications available is to be limited or that research shows the drugs mentioned are more effective than the other available medications?</p> <p>Neuromuscular electrical stimulation can be used to treat urgency and urge incontinence, and is not a new treatment, (this is not the same as sacral nerve stimulation) this should be mentioned as a treatment for urge incontinence.</p>	<p>The antimuscarinic group of drugs will be considered. Specific drugs are no longer listed in the scope to avoid confusion.</p> <p>Neuromuscular electrical stimulation has been added to the scope as you suggest.</p>
SH	Nottingham City PCT	7	4.1.1	The PCT feels the guideline should cover not only man but also all different types of urinary incontinence, otherwise it will be incomplete. There is a danger of producing a guideline which will be appropriate only to well women with stress incontinence.	Please refer to above comments regarding the population and types of incontinence that will be covered.
	Nottingham City PCT	8	4.3 d	<p>The scope states the guideline will advise on appropriate use of medical and surgical treatment options for urge incontinence, conservative management should also be included here, as these have long term effective results, i.e. bladder training.</p> <p>Urge incontinence is the 'end stage' of an overactive bladder, the guideline should refer to overactive bladder rather than urge</p>	<p>Lifestyle and behavioural interventions will be considered in the guideline and the scope now reflects this.</p> <p>Please refer to above comments regarding the overactive bladder syndrome.</p>

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				incontinence. By stating urge incontinence, the guideline is restricted to those patients who have become incontinent, when we could have intervened sooner, WITH THE SAME TREATMENT, to prevent the problem progressing to incontinence. The guideline would not have to be any bigger, as the same treatments are offered to patients with overactive bladder as those who have progressed to urge incontinence.	
SH	Nottingham City PCT	9	4.3 e	When discussing appropriate use of procedures for stress incontinence, the guideline should clarify what treatment should be given prior to surgery being considered (ie, pelvic floor exercises, helped by biofeedback and electrical stimulation) and how long this treatment should be given before it is considered not to have worked.	Thank you for these suggestions, which will be considered by the guideline development group.
SH	Novartis Pharmaceuticals UK Ltd	1	General	<p>We are concerned that the remit of this Guideline is not concordant with the title of the draft scope. This may be because the remit itself is unclear.</p> <p>The first sentence of the remit may mean that the scope should cover only urinary incontinence that is associated with prolapse of the womb. However, it may instead mean that the scope should cover urinary incontinence and prolapse of the womb as quite separate conditions, albeit concomitant in some instances.</p> <p>The second sentence seems to suggest a much wider-reaching interpretation by including detrusor instability as well as stress incontinence.</p> <p>If the remit is intended to focus on urinary incontinence that is <i>caused</i> by prolapse of the</p>	We considered that to only include urinary incontinence in association with pelvic organ prolapse was too narrow a scope. The guideline will cover stress and mixed incontinence and the overactive bladder syndrome. The scope has been amended to reflect this. Pelvic organ prolapse will be covered where it relates to the treatment of urinary incontinence and/or the overactive bladder syndrome, but not beyond this.

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				<p>womb then the scope itself needs to reflect this by being more explicit in both title and content.</p> <p>If, however, the intended focus is to include a wider range of causes of incontinence, a number of comments arise, as detailed below. Our comments are based on an assumption that the intention of the scope is one of inclusion beyond concomitant prolapse of the womb.</p>	
SH	Novartis Pharmaceuticals UK Ltd	2	1 – Title	<p>We would suggest that the restriction of this scope to include only women is more exclusive than the remit intended and will be problematic to put into practice. Much of the data will not be limited to women only populations, thereby causing difficulties in interpretation. Moreover, to exclude men may lead to a group of patients who are effectively ignored in terms of access and funding to treatment.</p> <p>It might also be argued that those children who have urinary incontinence might also be similarly disadvantaged from being excluded. Quite where the cross-over occurs from child to adult is, of course, difficult to define.</p>	<p>Inclusion of populations other than women is beyond the scope of this guideline. We recognise that incontinence is not a problem confined to women, but in order to cover the issues in the scope in a helpful way in sufficient depth and within the timeline, the guideline will be restricted to this population. However, NICE welcomes suggestions for future topics from stakeholders, healthcare professionals and the public, and would encourage you to put your views forward. From 1 December 2004 suggestions can be made via the NICE website (www.nice.org.uk).</p> <p>An age threshold for inclusion will not be defined. In the context of this guideline, adulthood will be dealt with pragmatically to encompass the relevant literature.</p>
SH	Novartis Pharmaceuticals UK Ltd	3	3 a–g, h	<p>The need for this Guideline appears driven by stress incontinence, with only one section focusing on urge. This is also the case in section 4.3.</p>	<p>The guideline will cover stress and mixed incontinence and the overactive bladder syndrome. The scope has been amended to reflect this.</p>
SH	Novartis Pharmaceuticals UK Ltd	4	3 c	<p>This section makes no mention of the availability of pharmacological treatments. Instead, it suggests that the treatment pathway moves straight from exercises, cones and electrical stimulation to surgery.</p>	<p>Pharmacotherapy, lifestyle interventions and conservative techniques will be considered in the guideline, and are now listed in the scope.</p>
SH	Novartis Pharmaceuticals UK Ltd	5	4.1.1 a,	<p>We support the fact that incontinence</p>	<p>Please refer to the above comments regarding</p>

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			b	<p>associated with pelvic organ prolapse is seen as a separate issue (b). However, in section (a), the scope becomes even more restrictive by limiting incontinence to only stress and urge incontinence. We are concerned that there a number of conditions (e.g. multiple sclerosis, stroke, benign prostatic hypertrophy) where incontinence occurs as a secondary complication and which would not be covered by this Guideline. Moreover, since many such conditions are more commons in the elderly, it would appear that this group of patients will be excluded.</p> <p>Further, and as stated above for women v men, we wonder how much data is available in the specific urge or stress groups? It is likely that much of the existing evidence is gleaned from a number of patient populations making it difficult to draw clear conclusions.</p>	<p>the population to be included.</p> <p>We are aware that in some published studies data will include both men and women. Although we will consider this evidence alongside other relevant evidence, we will ensure that the applicability and extrapolation of the data are reflected in the guideline recommendations.</p>
SH	Novartis Pharmaceuticals UK Ltd	6	4.3 b	<p>We support the fact that diagnosis is to be part of this Guideline. We would also suggest that this should include some element of disease awareness since a number of people suffer from incontinence either without being fully aware of it, or without realising that treatments exist to deal with it. Even when people are aware, many prefer to employ coping mechanisms rather than seek medical advice, either due to embarrassment or lack of confidence in their GPs.</p>	<p>Thank you for your comments, which have been noted. Containment will be addressed in the guideline, and has been incorporated into the scope.</p>
SH	Parkinson's Disease Society	1	General	<p>Urinary incontinence is a common problem experienced by people with Parkinson's disease (Pd). Detrusor hyper reflexia leads to urinary frequency and urgency; the actual</p>	<p>Thank you.</p>

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				incontinence tends to follow in later Parkinsons. ¹ It is more likely to occur at the complex phase of the disease, although not all people with Parkinson's are affected by it, and those who are, may experience incontinence mildly or intermittently. ² It is also a side effect of the medication in some younger people,	
SH	Parkinson's Disease Society	2	General	The Parkinsons Disease Society believes that the scope of the guideline is too narrow and should include male urinary incontinence. Whereas stress incontinence is more prevalent in women, urge incontinence in men and women is a common side effect of Parkinson's, and for older men with Parkinson's, may be associated with prostatic outflow obstruction. ³ People with Parkinson's are also commonly affected by constipation and may also experience faecal incontinence and other bowel disorders. Whilst these issues are outside the scope of this Guideline, it should seek to ensure that it does not segregate the care and treatment of incontinence for people with Parkinson's.	Thank you for your comments. Inclusion of populations other than women is beyond the scope of this guideline. We recognise that incontinence is not a problem confined to women, but in order to cover the issues in the scope in a helpful way in sufficient depth and within the timeline, the guideline will be restricted to this population. Incontinence in association with neurological disease, and incontinence in men is specifically excluded from this guideline, and the scope now states this. A guideline for faecal incontinence has been commissioned by NICE. From 1st December 2004, topic suggestions for NICE guidelines can be made by stakeholders, healthcare professionals and the public via the NICE website (www.nice.org.uk). We would encourage you to put your views forward in this way.
SH	Parkinson's Disease Society	3	2 Background	The Guideline needs to complement and integrate with other national initiatives and clinical guidelines particularly the NSFs for Older People and Long Term Medical Conditions and the NICE Guidelines for Parkinson's, Dementia and Faecal Incontinence. These contain important frameworks for people with neurological conditions particularly Parkinson's, and	Other national initiatives and clinical guidelines will be considered by the guideline developers alongside all relevant evidence.

¹ Fowler C, Neurological disorders of micturation and their treatment, *Brain* 1999; 122(7), 1213-31.

² Norton, C. *Looking after your Bladder and Bowels in Parkinsonism*. Parkinsons Disease Society, 2002.

³ Fowler, 1999.

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				professionals and carers involved in their care and treatment, of which dealing with incontinence is a key component.	
SH	Parkinson's Disease Society	4	3 a Clinical need for the Guideline	It is crucial that this guideline addresses the specific issues and needs of neurological conditions, particularly Parkinson's. The guideline must encompass sufficient breadth and flexibility to support the highly personalised symptoms, medication and treatment package and associated social and medical needs of people with Parkinson's and those involved in the care and treatment of Parkinson's.	Thank you for the informative background information. Unfortunately as we state above, we will not cover the specific needs of patients with neurological conditions such as Parkinson's Disease, as this is outside the scope of this guideline.
SH	Parkinson's Disease Society	5		The guideline needs to encompass the specific needs of people with Parkinson's in all community and acute and specialised hospital settings – i.e. potentially complex and personalised drug treatments, the distinctive features of the condition caused by reduced dopamine levels such as mobility problems, rigidity, slowness of movement and bradykinesia, which may impair continence.	Thank you.
SH	Parkinson's Disease Society	6	3 b Causes of incontinence	Causes of incontinence in Parkinson's There are several possible causes of urinary symptoms in Parkinson's ⁴ . People with Parkinson's may experience both urge and stress incontinence, and therefore treatment may be problematic. <i>Urge incontinence</i> The damage to the basal ganglia which occurs	Thank you.

⁴ Fowler, 1999.

⁵ Galloway NT. Urethral sphincter abnormalities in Parkinsonism. *Br J Urol* 1983; 55: 691–93.

⁶ Fitzmaurice H, Fowler CJ, Rickards D, Kirby RS, Quinn NP, Marsden CD, et al. Micturition disturbance in Parkinson's. *Br J Urol* 1985; 57: 652–56.

⁷ Fitzmaurice et al., 1985; Christmas TJ, Kempster PA, Chapple CR, Frankel JP, Lees AJ, Stern GM, et al. Role of subcutaneous apomorphine in parkinsonian voiding dysfunction. *Lancet* 1988; 2: 1451–53.

⁸ Quinn N (editor). *'Parkinsonism', Balliere's Clinical Neurology*. Balliere Tindall, 1997.

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				<p>in Parkinson's, may have an inhibitory effect on the micturation reflex, and with cell loss in the substantia nigra, detrusor hyperreflexia develops. Therefore people with Parkinson's may experience urgency, frequency and sometimes urge incontinence.</p> <p><i>Urine retention</i> Parkinsonism can cause difficulty with starting to empty the bladder, either because of difficulty maintaining bladder contraction, the bladder fails to contract or because the sphincter does not relax or a combination of these factors. This causes residual urine build-up, which may lead to overflow incontinence and/or infection.</p> <p><i>Bradykinaesia</i> There may also be outflow obstruction in Parkinson's due to impaired relaxation or bradykinaesia of the urethral sphincter.⁵</p> <p><i>Effect of Parkinson's drug treatments</i> Levodopa, the main drug therapy for people with Parkinson's, has been found to worsen hyperreflexia⁶, although there is conflicting evidence on this point.⁷ Dopamine D1 and D2 receptors have been demonstrated in bladder biopsies but the long-term effect on these receptors of exposure to levodopa is unknown.</p> <p>A tendency to incomplete emptying can be made worse with anticholinergic drugs, such as benhexol or orphenadrine.</p>	

⁹ Norton C. *Nursing for Continence*. Beaconsfield Publishers, 1992.

¹⁰ Beck RO, Betts CD, Fowler CJ. Genitourinary dysfunction in multiple system atrophy: clinical features and treatment in 62 cases. *J Urol* 1994; 151: 1336–41.

¹¹ Beck et al., 1994.

¹² Sung JH, Mastro AR, Segal E. Pathology of Shy-Drager syndrome. *J Neuropathol Exp Neurol* 1979; 38: 353–68.

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				<p><i>Older People and Demensia</i> Parkinson's is more likely to be diagnosed in people over the age of 50.⁸ Therefore incontinence may occur through multiple pathology. Many elderly people with bladder or bowel problems also have other disorders to contend with, many of which will affect continence. Neurological disorders such as PD often impair ability to cope with the bladder function. A Parkinsonian tremor or a hemiparesis may make toileting slow or even impossible.⁹ Dementia often occurs in people with more advanced Parkinson's and may therefore lead to incontinence. The guideline therefore needs to address issues around ageing and neuro-damage.</p> <p>Parkinsonian syndromes <i>Multiple System Atrophy</i> The onset of urogenital symptoms in MSA may precede overt neurological involvement by some years - on average two years people to the appearance of more specific neurological symptoms¹⁰, It has been suggested that detrusor hyperreflexia is due to loss of parasympathetic drive on the detrusor following atrophy of cells in the intermediolateral cell columns¹¹. In addition anterior horn loss in Oluf's nucleus¹² results in denervation of the urethral sphincter so that the patient has a combination of bladder overactivity, together with incomplete emptying and a weak sphincter. Because of the motor neuron loss in Onuf's nucleus, changes of chronic re-innervation in the motor units of both sphincters may be demonstrated and sphincter electromyography may be contributory in making the diagnosis. However if this test is not available there are clinical urological criteria which may assist in</p>	

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				recognising patients with MSA – therefore a cautious approach to surgery is required. Bladder symptoms in other Parkinsonian syndromes are less prominent, and although they may occur as part of the patient's general disability, are rarely so severe or occur at a stage of the disease when a neurological pathogenesis is not evident so that urological surgery might be considered.	
SH	Parkinson's Disease Society	7	4.2 Health care setting	People with Parkinson's are cared for by a variety of health and social care professionals, including specialist nurses, therapists, GPs neurologists, geriatricians as well as continence advisors. The Guideline needs to compliment and support the daily care and treatment of Parkinson's disease as well as more specialised settings, and remain relevant to a variety of clinical and non-clinical audiences.	Thank you.
SH	Parkinson's Disease Society	8	4.3 a–g	The Guideline needs to be relevant to and support the practice of a wide variety of health and social care professionals (see above). It should seek to define and reinforce the competencies of the multi-disciplinary team of staff who work with Parkinson's, particularly the professional who co-ordinates the care of and/or acts as a central reference point for people with Parkinsons e.g. Parkinson's disease Nurse specialists and practice nurses.	We acknowledge that competency is an important issue in the management of women with incontinence. However, it is beyond the remit to look at competencies for all health professionals involved in their care. The competencies of surgeons performing operative procedures will be addressed as stated in the remit.
SH	Pfizer Limited	1	General	Pfizer welcomes the development of a national guideline on urinary incontinence and believes that it should encompass all types of incontinence as well as covering the entire incontinent population rather than being limited to females only.	Inclusion of populations other than women is beyond the scope of this guideline. We recognise that incontinence is not a problem confined to women, but in order to cover the issues in the scope in a helpful way in sufficient depth and within the timeline, the guideline will be restricted to this population. However, NICE welcomes suggestions for future topics from stakeholders, healthcare professionals and the public, and would encourage you to put your views forward. From 1st December 2004

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					suggestions can be made via the NICE website (www.nice.org.uk).
SH	Pfizer Limited	2	General	We believe that this guideline should encompass and reinforce the DH guidance <i>Good Practice in Continence Services</i> ¹³ that sets out the expectations of how continence should be managed and highlights the role of the Continence Nurse.	This guideline will not specifically address service delivery. The guideline developers will consider this publication alongside all other relevant evidence.
SH	Pfizer Limited	3	General	We also believe that the guideline should refer to the <i>NSF for Older People</i> ¹⁴ where incontinence features as an area to be managed properly in a structured way. There is an obvious link to Falls and Fracture reduction as well as single assessment.	The guideline developers will consider this publication alongside other relevant evidence.
SH	Pfizer Limited	4	General	The scope of the guideline is focused solely on women. We know that urge incontinence and overactive bladder is prevalent in all adults - not just women. If the guideline rules out 50% of this population, there is likely to be a need to review the guideline almost immediately to take into account the incidence and prevalence and management of males with urge incontinence.	Please refer to above comments regarding the population included.
SH	Pfizer Limited	5	3a	Clear differentiation between urge and stress incontinence is required throughout this document. Healthcare professionals need to make clear that these conditions as separate entities. The recommendations in the clinical guidelines will be dependent on this clear differentiation. There are a proportion of patients (approximately one third) with urinary incontinence who suffer from mixed incontinence (urge and stress together). We	The guideline will cover stress and mixed incontinence and the overactive bladder syndrome. The scope has been amended to reflect this.

¹³ *Good Practice in Continence Services*. Department of Health, 2000.

¹⁴ *National Service Framework for Older People*. Department of Health, 2001.

¹⁵ Stewart W, Van Rooyen J, Cundiff G, Abrams P, Herzog R, Corey R, Hunt T, Wein A. Prevalence and burden of overactive bladder in the United States. *World J Urol* 2002; 20(6): 327–36.

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				<p>believe that a clinical guideline on urinary incontinence also needs to cover this important group of patients and indicate how clinicians should manage them.</p> <p>In the absence of pathology, urge incontinence is part of a condition called 'overactive bladder syndrome (OAB).' There is no mention of this condition in this document. Overactive bladder represents the symptoms of urgency, with or without urge incontinence usually with frequency and nocturia. Urge incontinence therefore occurs as part of this condition, to discuss this in isolation is clinically inaccurate. The symptom of urgency (a strong compelling desire to void which is difficult to defer) may precede the incontinence and is the key symptom of overactive bladder.</p> <p>Overactive bladder is a prevalent condition estimated in large epidemiological studies to affect approximately 16% of the adult population in both Europe and USA¹⁵.</p>	<p>Thank you for the reference, which will be considered by the guideline developers alongside all other relevant evidence.</p>
SH	Pfizer Limited	6	3 b	<p>Urinary incontinence treatment pathways need to be divided in the 3 different types of incontinence (urge, mixed and stress). It is clinically inaccurate to pool them into 'urinary incontinence' as there are differing aetiologies and subsequent treatment pathways.</p> <p>Overactive bladder syndrome (urge incontinence) is a diagnosis that can be made by history, clinical examination and simple bedside tests in both primary and secondary care.</p>	<p>Please see above comments. Section 3 of the scope has been restructured reflecting your comments.</p> <p>The assessments and investigations to be considered will be defined by the guideline developers.</p>
SH	Pfizer Limited	7	3 c-h	<p>The scope of the guideline is weighted towards the management of stress urinary incontinence. There is an absence in the guideline looking at urge incontinence (and overactive bladder) and</p>	<p>The guideline will cover stress and mixed incontinence and the overactive bladder syndrome. The scope has been amended to reflect this, together with clarification of the</p>

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Type	Stakeholder	Order no.	Section no.	Comments	Developer's response
				the different management options (conservative, pharmacotherapy, bladder training and surgical procedures). We feel that this is a major omission in the draft scope.	management options that will be considered.
SH	Pfizer Limited	8	4.1.1 a	There should be differentiation of the different groups that are covered into urge, stress and mixed incontinence.	
SH	Princess Alexandra Hospital NHS Trust				This organisation was approached but did not respond.
SH	Q-Med (UK) Ltd				This organisation was approached but did not respond.
SH	RCOG/Harrogate Healthcare NHS Trust	1	3 g	(autologous fat, silicone (Macroplastique), collagen, polytetrafluoroethylene)	Thank you for the suggestion to add 'Macroplastique'. Examples of bulking agents have been deleted from the scope, as it is the role of the guideline developers to consider all options.
SH	RCOG/Harrogate Healthcare NHS Trust	2	3 g	Reported subjective cure rates for injectable bulking agents have varied widely from 33% to 70%. This may be related to their usage in complicated and recurrent incontinence problems.	Thank you for suggesting the second sentence. This has not been added to the scope as all references to cure rates have been deleted from the background section.
SH	RCOG/Harrogate Healthcare NHS Trust	2	3 d	The technique has been shown to be effective in primary stress urinary incontinence, with subjective cure rates in the region of 82% – 95% at 1 year.	References to cure rates have been deleted from the background section.
SH	Rotherham General Hospitals NHS Trust				This organisation was approached but did not respond.
SH	Rotherham Primary Care Trust				This organisation was approached but did not respond.
SH	Royal College of General Practitioners Wales	1	General	We are surprised to see that men are excluded from consideration. In the community setting, particularly in the elderly, male urinary incontinence can also create a significant burden for services and individuals and we feel some advice in this area would be valuable.	Inclusion of populations other than women is beyond the scope of this guideline. We recognise that incontinence is not a problem confined to women, but in order to cover the issues in the scope in a helpful way in sufficient depth and within the timeline, the guideline will be restricted to this population. However, NICE welcomes suggestions for future topics from stakeholders, healthcare professionals and the public, and would encourage you to put your

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Type	Stakeholder	Order no.	Section no.	Comments	Developer's response
					views forward. From 1st December 2004 suggestions can be made via the NICE website (www.nice.org.uk).
SH	Royal College of General Practitioners Wales	2	General	We feel that explicit consideration should be given to those in the community setting who have intractable problems with continence. They are often house bound and are seen and assessed by community nurses and may get a spectrum of help depending on local service provision. We feel that explicit advice about what constitutes a good continence service, what users and professionals can and cannot expect to have provided, and what are the elements of good care for such patients would be very valuable, as well as advice on what continence promoting products are most effective and cost-effective in this setting.	NICE guidelines do not usually address service delivery as this is best addressed locally. Containment will be covered in the guideline, and has been incorporated into the scope.
SH	Royal College of General Practitioners Wales	2	General	The guidance needs to reflect that the majority of people with continence problems are seen, assessed and cared-for solely in the primary care setting.	Thank you. A statement to that effect has been added to the scope. The guideline development group will have a primary care perspective by having representatives from the following professional groups: general practice, nursing and physiotherapy, as well as urology, gynaecology and elderly care, and from two patient/carer representatives.
SH	Royal College of Midwives	9	General	On 1st September 2004, the scope for the proposed NICE Urinary Incontinence guideline (closing date 30th September 2004), was posted on the NICE website at: http://www.nice.org.uk/pdf/UI_Consultation_scope.pdf The draft scope currently encompasses the diagnosis and investigation of urinary incontinence (stress and urge incontinence), treatment and surgical options, operative	There is interaction between the guideline developers for the ongoing guidelines you mention. With regard to Caesarian section and antenatal care, please see previous comments about putting forward suggestions for the updating of published guidelines. We are aware that the postnatal guideline will be looking at the role of pelvic floor exercises in the postpartum period. Thank you.

Type	Stakeholder	Order no.	Section no.	Comments	Developer's response
				<p>procedures and the competencies of surgeons and does not mention pregnancy and childbirth specifically, other than in the background information.</p> <p>The NICE Antenatal Care guideline made no reference to screening for or management of urinary incontinence (http://www.rcog.org.uk/resources/Public/Antenatal_Care.pdf http://www.rcog.org.uk/resources/Public/Antenatal_Care.pdf) and the NICE Postnatal Scope: (http://www.nice.org.uk/pdf/Scope_Post_Natal.pdf http://www.nice.org.uk/pdf/Scope_Post_Natal.pdf) whilst commenting on the "assessment of immediate physical needs of the mother ... " (4.3.2 i) and on the "ongoing and appropriate physical care of the mother ... " (4.3.2.ii) makes no specific reference to screening for or the management of urinary incontinence.</p> <p>Will there be liaison between the Postnatal Care and the Urinary Incontinence guidelines development groups, to ensure that one GDG does not assume that the other is addressing this important area of care?</p>	
SH	Royal College of Midwives (2)		3 c-h	Not commented on, as outside the knowledge and experience of RCM members.	Thank you.
SH	Royal College of Midwives (2)	1	General	The draft scope currently encompasses the diagnosis and investigation of urinary incontinence (stress and urge incontinence), treatment and surgical options, operative procedures and the competencies of surgeons. It does not mention pregnancy and childbirth specifically, other than in the background information. This was considered to be a significant omission.	Thank you for your comments.

Type	Stakeholder	Order no.	Section no.	Comments	Developer's response
				<p>RCM members feel strongly that the scope should adopt a more proactive and less one dimensional approach, by looking at ways that the risks of urinary incontinence could be prevented, minimised and/or managed during the preconconceptual, antenatal, intranatal and postnatal periods, as well as identified and treatment patterns activated.</p> <p>Some midwives have actually developed work in this area.</p> <p>Midwives considered that this scoping provides a crucial opportunity to achieve some consistency regarding midwifery management of bladder care during the woman's whole maternity episode. For example, some units use assessment tools to screen and refer women to an obstetric physiotherapist or dedicated woman's health physiotherapist. Some do routine palpation of the uterus following Caesarean section to effectively detect post partum urinary retention with the use of portable bladder scanners for diagnosis, but screening, diagnosis and management varies.</p>	<p>Conservative techniques, where used prophylactically, will be considered in the guideline and the scope has been amended to reflect this.</p> <p>The Intrapartum Care guideline will cover bladder care during labour. The postnatal care guideline, also in development, will cover the role of pelvic floor exercises in the postpartum period.</p>
SH	Royal College of Midwives (2)	2	General	<p>The NICE Antenatal Care guideline made no reference to screening for, prevention or minimising of, the health promotion in relation to or the management of urinary incontinence. It is crucial to highlight best practice in relation to sensitively and promptly identifying women who are suffering from urinary incontinence, so that early referral and treatment, can reduce the years of silent suffering and isolation that these women often endure. Pregnancy is a window of opportunity to work with women in identifying health problems, and exploring lifestyle choices and adaptations. It is therefore a time when problems with continence, which may have existed from a previous health problem, or after</p>	<p>The issue of screening will not be considered in the guideline as this is beyond the remit.</p> <p>Conservative techniques, where used prophylactically, will be considered in the guideline and the scope has been amended to reflect this.</p>

Type	Stakeholder	Order no.	Section no.	Comments	Developer's response
				<p>childbirth, can be addressed, and interventions commenced. Some women may view incontinence as an inevitable sequela of childbirth, and highlighting the importance of asking women about this should be emphasised. Whilst the evidence about the prevention and improvement of some symptoms by effective teaching and practising of Kegel (Pelvic floor exercises) is mixed, recommendations about their effectiveness or lack of effectiveness in pregnancy would be useful, as the NICE Antenatal care guideline, made no reference to them at all.</p> <p>If recommendations in relation to pregnancy are outside the remit of this guideline, can recommendations be made for the subsequent review of the Antenatal care guideline? http://www.rcog.org.uk/resources/Public/Antenatal_Care.pdf http://www.rcog.org.uk/resources/Public/Antenatal_Care.pdf</p>	<p>From 1 December 2004 there will be a facility on the NICE website for suggesting guideline topics. We suggest you put a proposal regarding the update of the antenatal care guideline forward in this way.</p>
SH	Royal College of Midwives (2)	3	General	<p>The scope of the NICE Intrapartum guideline currently makes only one reference to bladder care i.e. post epidural, however the RCM would support a careful review of the whole range of evidence to make recommendations related to minimising urinary dysfunction. The literature demonstrates evidence of the significant morbidity associated with urinary incontinence following childbirth, particularly in relation to vaginal and instrumental delivery and multiparity.</p> <p>The RCM would recommend that there be liaison between the two relevant NCCs and Guidelines Development Groups. http://www.nice.org.uk/pdf/Intrapartum_draft_sc</p>	<p>We note your comments. The Intrapartum Care guideline will cover bladder care during labour.</p> <p>The development of both guidelines is being led by the NCC–WCH.</p>

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Type	Stakeholder	Order no.	Section no.	Comments	Developer's response
				ope.pdf	
SH	Royal College of Midwives (2)	4	General	The NICE Caesarean section (CS) guidelines only make one specific recommendation to bladder care, i.e. 8.4. "Urinary catheter removal after CS", but note that further research is due to be published. The RCM consider that this rather a limited view. There must be some liaison between the two Guidelines Development Groups to inform the next CS review. http://www.nice.org.uk/page.aspx?o=114953	We suggest that you put this suggestion forward to NICE prior to the review of the Caesarian Section guideline.
SH	Royal College of Midwives (2)	5	General	The RCM expect that the NICE Postnatal Scope will result in the development of robust recommendations in relation to urinary dysfunction postnatally; i.e. " <i>assessment of immediate physical needs of the mother ...</i> " (4.3.2 i) and on the " <i>ongoing and appropriate physical care of the mother ...</i> " (4.3.2.ii) although it makes no specific reference to screening for or the management of urinary incontinence. Again there must be some liaison between the two Guidelines Development Groups. http://www.nice.org.uk/pdf/Scope_Post_Natal.pdf	There has been and will be liaison between the Postnatal guideline and urinary incontinence guideline developers.
SH	Royal College of Midwives (2)	6	General	The RCM would recommend strongly that there is liaison between the Urinary Incontinence guidelines development group and all other relevant maternity related GDGs i.e. Antenatal Care, Postnatal Care, Intrapartum and CS, to ensure that one GDG does not assume that the other is addressing this important area of care.	There is interaction between the guideline developers for the ongoing guidelines you mention. With regard to Caesarian section and antenatal care, please see above comments about making suggestions for the updating of the guidelines.
SH	Royal College of Midwives (2)	7	3 a	This is the only section which makes reference to pregnancy and childbirth.	Thank you.
SH	Royal College of Midwives (2)	8	3 b	This section introduces the concept of diagnosis and treatment, but makes no reference to screening. The RCM would	Screening will not be included as it beyond the remit of the guideline.

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Type	Stakeholder	Order no.	Section no.	Comments	Developer's response
				welcome a reference to screening and counselling from the pre-conceptual period, and through the maternity care, as women do develop, or already suffer from urinary incontinence during pregnancy, and or birth. Midwives are well placed to activate this work, and would strongly support this work in order to provide a sensitive, practice and high quality level of care to women.	
SH	Royal College of Nursing (RCN)	1	General	We consider the scope to be very surgically based with not enough about prevention/non invasive interventions.	Conservative techniques, used as treatments and prophylactically, will be considered in the guideline and the scope now reflects this.
SH	Royal College of Nursing (RCN)	2	4.1	Should the scope not also include men and children? If not, is a separate guideline planned for this group of patients?	Inclusion of populations other than women is beyond the scope of this guideline. We recognise that incontinence is not a problem confined to women, but in order to cover the issues in the scope in a helpful way in sufficient depth and within the timeline, the guideline will be restricted to this population. However, NICE welcomes suggestions for future topics from stakeholders, healthcare professionals and the public, and would encourage you to put your views forward. From 1st December 2004 suggestions can be made via the NICE website (www.nice.org.uk).
	Royal College of Nursing (RCN)	3	4.3 f	The guidelines should also include recommendations for training and education for all health professionals not just surgeons.	We acknowledge that competency is an important issue in the management of women with incontinence. However, it is beyond the remit to look at competencies for all health professionals involved in their care. The competencies of surgeons performing operative procedures will be addressed as stated in the remit.
SH	Royal College of Obstetricians and Gynaecologists	1	General	The RCOG would wish the focus of the guideline to remain on women. Our experience suggests that if the scope is too wide then the guideline becomes unwieldy and important areas are addressed superficially.	Thank you. The guideline will cover incontinence in women only.

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Type	Stakeholder	Order no.	Section no.	Comments	Developer's response
				The issue of including men and children was raised at the Stakeholders meeting. In our view, the best approach would be to develop guidelines specifically for these groups. A similar approach has already been taken in other areas, such as diabetes.	
SH	Royal College of Obstetricians and Gynaecologists	1	4.1.2 a	It is noted that pelvic organ prolapse will only be covered where it is related to urinary incontinence. We would support this but would strongly recommend a separate guideline in the area of pelvic organ prolapse and surgery.	From 1st December 2004 there will be a facility on the NICE website for suggesting guideline topics. We suggest you put a proposal forward in this way.
SH	Royal College of Obstetricians and Gynaecologists	2	4.3 f	The work on competencies should be carried out separately as it may well be beyond the expertise of the guideline development group members.	We realise that defining competencies is of a different nature to that of clinical recommendations. However, defining competencies for surgeons is required by the remit from the Department of Health, and therefore will remain in the scope.
SH	Royal College of Obstetricians and Gynaecologists (2)	3	4.1.1 a	The issue of inclusion of men has been addressed at the SH meeting. If separate advice is not to be issued, men should perhaps be taken into this guidance. Similarly the question of including children (no), patients with neurological disease (no) and the elderly (yes), needs careful consideration.	Inclusion of populations other than women is beyond the scope of this guideline. We recognise that incontinence is not a problem confined to women, however in order to cover the issues in the scope in a helpful way in sufficient depth and within the timeline, the guideline will be restricted to this population. Elderly women will be included. Incontinence in men, children, and in association with neurological disease is explicitly excluded.
SH	Royal College of Obstetricians and Gynaecologists (2)	4	4.1.1 a	The restriction to stress and urge incontinence is rather artificial. Other symptoms should also be included. For example nocturnal enuresis, post-micturition dribbling, overflow incontinence, and continuous leakage should be included.	The guideline will cover stress and mixed incontinence and the overactive bladder syndrome in women. The scope has been amended to reflect this.
SH	Royal College of Obstetricians and Gynaecologists (2)	5	4.1.1 a	Patients with urogenital fistula are a small but very specific group (150 per year in England & Wales). Nevertheless they are amongst the most severe cases, have considerable medico-legal consequences (being commonly iatrogenic), and require very specific management. To date there has been no	Being such a small group of patients, it would be inappropriate to justify their inclusion in the scope. The extent to which their management will be covered in the guideline will be determined by the guideline developers in the course of their work.

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Type	Stakeholder	Order no.	Section no.	Comments	Developer's response
				consistent rational referral process for such patients (most of which are handled by surgeons who deal with one case every 3 years). I feel strongly that they should be included.	
SH	Royal College of Obstetricians and Gynaecologists (2)	6	4.1.1 b	The handling of prolapse in the scope and referral document are substantially different. Whilst there is obviously some overlap, utero-vaginal prolapse is in itself just as large a clinical problem as incontinence. It commonly recurs after surgical management, and this may in part reflect ineffective primary treatment. It is numerically sufficiently large an entity for separate advice to be issued, although if this is not to be undertaken in the foreseeable future, serious consideration should be given to including it more formally in this guideline.	We considered that to include urinary incontinence only in association with pelvic organ prolapse was too narrow a scope. The guideline will cover pelvic organ prolapse where it relates to the treatment of urinary incontinence and/or the overactive bladder syndrome, but not beyond this.
SH	Royal College of Obstetricians and Gynaecologists (2)	7	4.3 f	The initiative to include surgical competence is welcomed, and reflects both professional and lay concerns. There is also considerable professional concern over the competence of all groups involved in the basic assessment and primary management of incontinence. Competence in urodynamic investigation is of particular importance, and whilst there will be no hard evidence on this issue, consensus statements would be welcomed.	We acknowledge that competency is an important issue in the management of women with incontinence. However, it is beyond the remit to look at competencies for all health professionals involved in their care. The competencies of surgeons performing operative procedures will be addressed as stated in the remit. Competencies for urodynamic assessment will not be considered as this is beyond the remit of the guideline.
SH	Royal College of Physicians of London	1		See comments submitted jointly with ABN. See comments submitted jointly with BGS.	Thank you.
SH	Royal College of Psychiatrists	1	3 Clinical Management	It is important that the guideline addresses the psychological sequelae of incontinence, such as stigma, the impact on self esteem, and autonomy, and the contribution towards depression. Psychological or psychiatric intervention may be necessary.	We consider that these aspects are covered within lifestyle and behavioural issues which are now incorporated into the scope.
SH	Royal National Orthopaedic Hospital NHS Trust				This organisation was approached but did not respond.
SH	Schwarz Pharma	1	Appendix	The proposed guideline does not sufficiently cover urinary incontinence. It does not fully	Thank you. The guideline will cover stress and mixed incontinence and the overactive bladder

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				cover overactive bladder with urge incontinence, which is a predominant issue especially for elderly women.	syndrome. The scope has been amended to reflect this.
SH	Schwarz Pharma	2	1.1	The guideline focuses too much on stress incontinence and does not sufficiently cover overactive bladder with urge incontinence. The latter is a special issue for elderly women. Why are men excluded?	Inclusion of populations other than women is beyond the scope of this guideline. We recognise that incontinence is not a problem confined to women, however in order to cover the issues in the scope in a helpful way in sufficient depth and within the timeline, the guideline will be restricted to this population.
SH	Schwarz Pharma	3	3 a	The epidemiological distribution described in the literature is estimated 30% stress incontinence, 30% overactive bladder with urge incontinence, and 40% mixed stress-urge incontinence.	Thank you. The full guideline will contain an expanded section on epidemiology.
SH	Schwarz Pharma	4	3 b	Reduction in the absolute number of incontinence episodes for evaluation of effectiveness of treatment. Please add volume/frequency charts = micturition diaries as a basic tool for diagnosis.	We agree that this is an outcome measure that should be considered by the guideline development group.
SH	Schwarz Pharma	5	3 c	This only applies to <u>stress</u> incontinence and not to all forms of urinary incontinence. A special chapter for overactive bladder with urge incontinence is missing.	Section 3 of the scope has been revised, with distinction between the different types of incontinence where appropriate.
SH	Schwarz Pharma	6	3 e	This does not sufficiently reflect the newer data on the outcomes of minimally invasive procedures.	All references to outcomes of interventions have been deleted from the scope. These will be considered by the guideline developers.
SH	Schwarz Pharma	7	3 h	There are now more approved drugs for overactive bladder than oxybutynin and tolterodine. It should be mentioned that more pharmacological treatments are expected to become available. What about different treatments for day and night incontinence?	Pharmacotherapy of incontinence will be considered by the guideline development group. Specific drugs, whether currently available or under development, are not listed in the scope to avoid confusion.
SH	Schwarz Pharma	8	4.1.1	Please add overactive bladder with urge incontinence. What about men and children?	Please refer to above comments.
SH	Schwarz Pharma	9	4.3 c	No mention of pharmacological intervention.	Please refer to above comments.
	Schwarz Pharma	10	4.3 d	Please add medical and non-medical treatment options for overactive bladder with urge	Pharmacotherapy, lifestyle and behavioural interventions will be considered by the guideline

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Type	Stakeholder	Order no.	Section no.	Comments	Developer's response
				incontinence.	development group. The scope has been amended to reflect this.
SH	Scottish Intercollegiate Guidelines Network (SIGN)	1	4.1.1 and 4.1.2	Missing inclusion/exclusion for nocturnal enuresis or detrusor-sphincter dyssynergia.	Nocturnal enuresis is a form of incontinence in adults so will not be excluded. Detrusor-sphincter dyssynergia will not be considered, as incontinence in association with neurological disease is excluded.
SH	Scottish Intercollegiate Guidelines Network (SIGN)	1	4.3 f	Competencies of surgeons – but no mention of the competencies required for primary care assessment or conservative treatment.	We acknowledge that competency is an important issue in the management of women with incontinence. However, it is beyond the remit to look at competencies for all health professionals involved in their care. The competencies of surgeons performing operative procedures will be addressed as stated in the remit.
SH	Sheffield South West Primary Care Trust				This organisation was approached but did not respond.
SH	Sheffield Teaching Hospitals NHS Trust				This organisation was approached but did not respond.
SH	South Birmingham Primary Care Trust				This organisation was approached but did not respond.
SH	South West Kent PCT	1		<p>I am a little puzzled by the groups covered, which seem very limited and appears to be focused on younger women with stress incontinence, who may be eligible for surgery. This cuts out many other categories: the elderly, children, not to say men.</p> <p>I appreciate that we have to start with where we are now in terms of people who have a bladder dysfunction. However it would seem to be important to put resources into health promotion and the prevention of conditions such as stress incontinence. Although pelvic floor damage may be inevitable sometimes in childbirth, there is evidence that teaching pelvic floor exercises to younger age groups can be very successful in preventing problems.</p>	<p>The guideline will cover stress and mixed incontinence and the overactive bladder syndrome in adult women; an upper age limit will not be applied.</p> <p>Men and children are specifically excluded. Inclusion of populations other than women is beyond the scope of this guideline. We recognise that incontinence is not a problem confined to women, however in order to cover the issues in the scope in a helpful way in sufficient depth and within the timeline, the guideline will be restricted to this population.</p> <p>Conservative techniques, where used prophylactically in the population included in this guideline, will be considered and the scope now reflects this.</p>

Type	Stakeholder	Order no.	Section no.	Comments	Developer's response
				<p>It seems odd to include women with urge incontinence, but not men – who can be just as affected by the condition</p> <p>As far as clinical management is concerned, why is it only 'competencies required by surgeons performing operative procedures' that are to be investigated? This would seem to confirm that the guidelines are intended to focus on the surgical aspects of stress incontinence. What about the competencies of someone like me – a Continence Advisor who treats women with stress incontinence? What about all the other health care professionals eg physiotherapies – are their competencies irrelevant?</p> <p>In spite of these comments, I very much welcome that NICE is focusing on the problems of urinary incontinence, a subject that tends to be treated by containment. Anything that advances the treatment of people with the condition can only be advantageous.</p>	<p>We acknowledge that competency is an important issue in the management of women with incontinence. However, it is beyond the remit to look at competencies for all health professionals involved in their care. The competencies of surgeons performing operative procedures will be addressed as stated in the remit.</p>
SH	Spinal Injuries Association				This organisation was approached but did not respond.
SH	Stroke Association, The				This organisation was approached but did not respond.
SH	Tameside and Glossop Acute Services NHS Trust				This organisation was approached but did not respond.
SH	The Royal Society of Medicine				This organisation was approached but did not respond.
SH	The Royal West Sussex Trust				This organisation was approached but did not respond.
SH	The Survivors Trust				This organisation was approached but did not respond.
SH	Tissue Viability Society (UK)				This organisation was approached but did not respond.
SH	Trafford Primary Care Trusts	1	3 b	Some reference should be made to specialist nurse assessment.	The scope will not refer to professional roles. A nurse with the relevant background and

Urinary incontinence guideline – comments received on draft scope, with developers responses

Type	Stakeholder	Order no.	Section no.	Comments	Developer's response
					expertise has been invited to join the guideline development group.
SH	Trafford Primary Care Trusts	2	General	Initial assessment (under strict criteria) should be undertaken in primary care, by specialist nurses and not secondary care. This would reduce the volume of consultant episodes and hospital waiting lists.	NICE guidelines do not usually address service delivery as this is best addressed locally. The appropriate use of assessments and investigations will be considered in the guideline.
SH	Trafford Primary Care Trusts	3	3 c	? more emphasis on non surgical options as first line treatments.	Pharmacotherapy, lifestyle and behavioural interventions will be considered by the guideline development group. The scope has been amended to reflect this.
SH	Trafford Primary Care Trusts	4	3 d, e, f, g	Levels of competency defined e.g minimal number of procedures undertaken per year, outcomes rates per surgeon.	Thank you for this suggestion, which will be considered along with other factors by the Guideline Development Group.
SH	Trafford Primary Care Trusts	5	3 h	One of the most misused drugs in this field. Protocols for assessment (including bladder scan), use, monitoring must be in place.	The appropriate use of drug treatments and assessments will be considered by the guideline developers.
SH	Trafford Primary Care Trusts	6	3 c, h	PFE, BR and drug therapy can be unsuccessful without direct patient support.	Please see above comments.
SH	UCB Pharma Ltd				This organisation was approached but did not respond.
SH	University College London Hospitals NHS Trust				This organisation was approached but did not respond.
SH	Vale of Aylesbury PCT				This organisation was approached but did not respond.
SH	Welsh Assembly Government (formerly National Assembly for Wales)	1		Thank you for giving the Welsh Assembly Government the opportunity to comment on the guideline. We are content with the document as drafted and have no further comments to make at this stage.	Thank you.
SH	West Cornwall PCT	1	4.2 a and 4.3 a	Will the guideline cover screening opportunities also, especially in primary care? There is suggestion that women present late as much as 15 yrs from the onset of symptoms. The primary care team, such as the practice nurse, have a valuable role in asking the right questions of women during routine procedures, such as smear testing, to ascertain if the woman is bothered by any urinary incontinence etc.	Screening will not be included as it beyond the remit of the guideline.

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SH	West Cornwall PCT	2	4.3 c, e	I am concerned about post-op complications, such as de novo detrusor instability and voiding dysfunction etc. Will the guideline make recommendations for care in terms of follow-up etc and best practice?	The guideline will cover the indications and appropriate use of the various treatment options, with consideration for best practice. Post-operative complications will be considered where they are reported as an outcome for surgical procedures.
SH	West Cornwall PCT	3	4.3 c	Will there be inclusion of recommendations of when to use duloxetine?	Pharmacotherapy for stress urinary incontinence has been incorporated into the scope; specific drugs are not listed within it. The guideline developers will consider the place of drug treatments.
SH	West Cornwall PCT	4	General	One of the users of the Continence Services User Group reported in her written story of her experiences that her journey from the point of presentation to a successful TVT involved 8 healthcare practitioners and private healthcare. A fundamental concern for the users is the time it takes to get prompt care and treatment and to be listened to. I hope that the guideline will include recommendations for patient journey time from presentation to treatment.	Thank you. NICE guidelines do not usually address service delivery as this is best addressed locally.
SH	West Cornwall PCT	5	4.3 b	Will the guideline draw on the International Continence Society best practice issues for urodynamics? I would like to see a recommendation that indicates maximum waiting times for this investigation as it is viewed as a secondary referral, therefore it can be a hidden waiting list, currently without high priority.	The ICS recommendations will be considered by the guideline developers alongside all other relevant evidence. With regard to waiting times, NICE guidelines do not usually address service delivery as this is best addressed locally where clinical practice recommendations overlap with service delivery.
SH	West Sussex Health and Social Care NHS Trust				This organisation was approached but did not respond.
SH	Wirral Hospital NHS Trust				This organisation was approached but did not respond.
SH	Women's Health Concern				This organisation was approached but did not respond.
SH	Yamanouchi Pharma Ltd	1	1	It is to be regretted that the scope only applies to females, though predominantly women suffer from stress incontinence, but men are afflicted with overactive bladder to a similar extent to	Inclusion of populations other than women is beyond the scope of this guideline. We recognise that incontinence is not a problem confined to women, but in order to cover the

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				women.	issues in the scope in a helpful way in sufficient depth and within the timeline, the guideline will be restricted to this population. However, NICE welcomes suggestions for future topics from stakeholders, healthcare professionals and the public, and would encourage you to put your views forward. From 1st December 2004 suggestions can be made via the NICE website (www.nice.org.uk).
SH	Yamanouchi Pharma Ltd	2	1 and 3 a	The process must consider the symptom syndrome encompassed within "over active bladder" since only 60% of subjects who would benefit from improved quality of care are actually incontinent.	The guideline will cover stress and mixed incontinence and the overactive bladder syndrome. The scope has been amended to reflect this.
SH	Yamanouchi Pharma Ltd	3	3 a	Urge incontinence and urgency are at least as great a clinical problem as stress incontinence.	See above comments.
SH	Yamanouchi Pharma Ltd	4	3 b	The use of 3 day voiding diaries is well documented as being "the" essential tool in evaluating patients. Studies that do not include this vital diagnostic measure should be considered of limited value.	Thank you. These comments will be considered by the Guideline Development Group.
SH	Yamanouchi Pharma Ltd	5	3 c	Physiotherapy and other non invasive measures including bladder re-training need to be carefully assessed and their likely value in a "care pathway" be evaluated.	Pharmacotherapy, lifestyle and behavioural interventions will be considered by the guideline development group.
SH	Yamanouchi Pharma Ltd	6	3 d	There are few adequate data on long term outcomes for female incontinence surgery, in particular the patient view of the outcome ± quality of life data.	These comments will be considered by the guideline developers.
SH	Yamanouchi Pharma Ltd	7	3 h	There are now additional licensed antimuscarinics for urge incontinence including solifenacin succinate for overactive bladder syndrome symptoms or other treatments for stress incontinence (e.g. duloxetine).	The antimuscarinic group of drugs will be considered, as will pharmacotherapy of stress urinary incontinence. Specific drugs are no longer listed in the scope to avoid confusion.
SH	Yamanouchi Pharma Ltd	8	4.1.1	Again it is a matter of regret that males are excluded from this consultation. Can this matter be referred back to parliament and the Welsh Assembly?	Please refer to the response above regarding the population included.
SH	Yamanouchi Pharma Ltd	9	4.2 a	Consideration should be given to the	The guideline will be developed by a

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				experience that has been gained from multi-disciplinary teams that manage patients with "bladder problems". The range of skills and their mix significantly improves the outcome for patients and can actually reduce inappropriate use of resources.	multidisciplinary group. The following professional groups will be represented on the guideline development group: urology, gynaecology, elderly care, general practice, nursing, and physiotherapy, as well as two patient/carer representatives.
SH	Yamanouchi Pharma Ltd	10	General	Consideration should be given to the composition of the guidelines development team and we would urge that a continence advisor be included as their experience in "real life" management of a case mix will ensure workable recommendations.	The guideline development group will include a continence nurse advisor with the relevant background and expertise, in order to ensure that this perspective is covered.
SH	Yamanouchi Pharma Ltd	11	4.3 e	When considering surgically related issues, anaesthesia should NOT be included as the risk factors involved from an anaesthetic point of view would prove very complex in such a patient population.	Thank you. The section on 'interventions and clinical practice likely to reduce morbidity associated with the procedures – including those with anaesthesia' has been deleted as it is beyond the remit of the guideline.
SH	Yamanouchi Pharma Ltd	12	General	Due emphasis must be given to patient related quality of life assessment of the outcomes of all interventions. This applies to drug therapies as well as surgery.	Thank you for you comments. Quality of life will be considered by the guideline developers with regard to all treatments or interventions.
SH	Yamanouchi Pharma Ltd	13	General	Urodynamics should not be a first line evaluation mandated for patients, since access is limited and the results of limited prognostic value. This particular test should be held in reserve for those who are intent upon surgical management of who fail non-invasive therapies.	The place of urodynamic and other objective assessments will be considered by the guideline developers.