National Institute for Health and Clinical Excellence

Incontinence in neurological disease: scope consultation

Scope Consultation Table

2 July 2010 – 30 July 2010

Type	Stakeholder	Order No	Section No	Theme	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Allergan	1	1	Subgroups/population	The title may not adequately reflect the inclusion of patients that suffer from lower urinary tract dysfunction due to causes other than neurological disease such as traumatic injury e.g. spinal cord injury	Thank you for your comment We have amended the scope to make it clear that we are including traumatic injury (See 4.1.1.a)
SH	Allergan	2	1.1	Subgroups/population	As per comment number 1	Thank you for your comment We have amended the scope to make it clear that we are including traumatic injury (See 4.1.1.a)
SH	Allergan	3	4.1.1 (a)	Subgroups/population	As per comment number 1 – Patients suffering from lower urinary tract dysfunction due to causes other than neurological disease such as traumatic injury e.g. spinal cord injury should also be included	We will be covering spinal cord injury and have amended the scope to make

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						this clear (4.1.1.a)
SH	Allergan	4	4.3.1 (c)	Botox	Allergan anticipates that BOTOX® will obtain a marketing authorisation in 2011 for the indication of treating urinary incontinence due to neurogenic detrusor overactivity and therefore may be licensed in this indication by the time this guideline is published.	We will be including botulinum toxin in the guideline, subject to confirmation from the manufacturers
SH	Allergan	5	4.3.1 (c)	Botox	Please note that BOTOX® is the only botulinum toxin type A with a clinical development programme for licensure and necessary supporting evidence base for the treatment of urinary incontinence due to neurogenic detrusor overactivity prior to the publication of this guidance. As per the recommendation of the MHRA and as reflected in the Summary Product Characteristics (SPC) for all botulinum toxin type A brands, the doses recommended for BOTOX® (Allergan) are not interchangeable for other preparations of botulinum toxin. The guideline should therefore reflect the available evidence for each brand of toxin.	Any recommendations on the use of botulinum toxin will be for licensed uses
SH	Association of British Neurologists	1	3.1 (a)	Other	This section is headed "Epidemiology" and ought to focus on the incidence of incontinence. The following statement hardly belongs here "*For example, kidney function can be lost as a result of abnormally high pressures within the bladder, from the effects of urinary tract infection and as a result of urinary tract stone disease*" as this affects only a small, albeit important, proportion of those with neurogenic lower urinary	Thank you. We have revised the scope to reflect the proportion of patients undergoing different interventions. We do not undertake epidemiological research as part of NICE

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					dysfunction. An appropriate analysis of the prevalence of incontinence would show that those with dementia, the frail elderly, and progressive neurological disease far outnumber those with spinal cord injury, spina bifida and very exceptional patients with MS who are the ones at risk of kidney damage. But I suspect from what is written later, renal complications will appear very much as a subsection. There is alot of data on prevalence of incontinence and this should be analysed together with the incidence of incontinence in each neurological condition. The figures about incontinence would appropriately inform the working group about where the emphasis of the document should lie.	guidelines
SH	Association of British Neurologists	2	4.3.1	Assessment and testing	There are very large numbers of health care professionals who manage incontinence without "*urodynamic studies (including cystometry, pressure/flow studies and video-urodynamics).*" I would have thought it would be better if " *Identification of criteria that should trigger referral for specialist assessment* " included urodynamics etc.	Noted - Thank you for your comment
SH	Association of British Neurologists	3	general	Role of surgery	I think the danger is that time and effort will be put into assessment of the efficacy of surgical urological interventions at the expense of focus on the true prevalence of incontinence in patients with progressive neurological disease who would never be considered for " *Surgical procedures to aid bladder emptying, for example external urethral sphincterotomy, urethral stents and sacral nerve stimulation (neuromodulation).*	Thank you for your comment. We have amended the scope.

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					• *Continent catheterisable abdominal conduits to allow transabdominal intermittent catheterisation of the bladder.* • *Urinary diversion procedures, including continent urinary diversion."* The right balance will be what determines the future value of this work.	
SH	Coloplast Ltd.	1	3.1 (e)	**Quality of life**	**Quality of Life –** Coloplast is concerned that this section states that *"Quality of Life is affected by the medical regime used to treat the urinary tract dysfunction; many patients have to cope with… the impact of catheterisation or the continuing use of pads or appliances."* It is important for the guidance to recognise that incontinence itself has a significant impact on the quality of life of a patient. Intervention through the use of a catheter, pad or other appliance in many instances gives a patient the ability to manage the function of their bladder effectively. Such interventions are greatly valued by patients who can continue to go to work, exercise or go on holiday. A patient's ability to seek and maintain employment reduces social isolation, helps prevent mental health issues and – more broadly - has a positive economic impact. Clinical intervention therefore creates potential public health savings. For example, with regards to bladder emptying dysfunction, we know that intermittent catheterisation is an effective way to manage the condition. Whilst more intensive clinical input is	Thank you for your comment. We have changed section 3.1.e of the scope to read 'medical interventions may not restore normal urinary function'

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					required initially to ensure the patient understands the purpose and process of using the device, in the long-term this intervention can lead to greater control over the condition and can also reduce issues around social isolation. In addition, it can reduce potential long-term complications associated with bladder dysfunction, such as renal failure, which can require further medical intervention and increase the cost of treatment. We propose that NICE removes from this section the negative association that is made with interventional therapy, as this can be the best way to manage incontinence and greatly increases a patient's quality of life if used properly with the advice of specialist practitioners. As a central aim, the guidance should strive to set out an assessment process for the various medical issues caused by a patient's neurological condition; each issue should then be treated using the appropriate clinical pathway.	
SH	Department of Health	1	general	Thanks	The Department of Health has no substantive comments to make, regarding this consultation	Thank you for your comment
SH	Faculty of Pain Medicine of the Royal College of Anaesthetists	1	4.1.1	Subgroups/population	Acute neurological disease such as cauda equina syndrome should be excluded.	Thank you for your comment. We will be including cauda equine syndrome
SH	Faculty of Pain Medicine of	2	4.3.1	Other	c. As there is a NICE guideline on neuromodulation for incontinence, we could refer to this guideline.	Thank you for your comment

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	the Royal College of Anaesthetists					The interventional procedure only applies to the non-neuropathic patient.
SH	Medtronic Limited	1	general	Thanks	Medtronic would like to thank the Institute for the opportunity to comment on a well thought out guideline	Thank you for your comment
SH	Medtronic Limited	2	2	Subgroups/population	Medtronic appreciate that there is a guideline in existence for lone faecal incontinence however, believe that the scope allows the inclusion of the double incontinent patient in this guideline. We would ask the institute to consider adding the subset of doubly incontinent patients that exist with neurological disease that are not covered in any other guideline.	Thank you for your comment This is not within our remit from DH
SH	Medtronic Limited	3	3.1. (f)	Other	Could the section make reference to the fact that the benefit of treatment will be determined by dividing the duration of benefit by the cost. In this way the playing field would be made more level for devices such as sacral nerve stimulators that have an upfront acquisition cost but a benefit period of up to 7 years?	The assessment of the economic implications of the assessed interventions will be undertaken in light with the NICE base case as discussed in section 4.5.
SH	Medtronic Limited	4	4.1.1	Subgroups/population	In relation to point 2 we would ask that the subset of the double incontinent are considered in the population scope	**This is not within our remit** See above
SH	Medtronic Limited	5	4.3.1 (c)	Botox	In the point for pharmacological treatment all agents except botulinum toxin are oral or transdermal. Botulinum toxin is administered with an endoscopic surgical procedure requiring the use of operating room facilities and the administration of the toxin via a	Thank you for your comment

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					specialized cystoscope which is considerably more invasive than a pharmacological treatment administered *per os*. Moreover, patients who received Botulinum Neurotoxin bladder injections typically need also an oral antibiotic for some days as all endoscopic invasive procedures. Medtronic suggests that botulinum toxin is given a separate bullet point to make the distinction between its requirements for administration from other pharmacological treatments of medical management.	
SH	Medtronic Limited	6	4.4 (e)	Other	The PVR – post void residual volume is an important outcome measure of the success of bladder emptying interventions. Associated costs of high PVR should also be considered as adverse events management costs. Could the point "e" be amended to reflect this, for example: *"Symptoms relating to bladder emptying, for example poor urinary stream & post void residual volume."*	Thank you. The list is not meant to be exhaustive and the GDG will identify key symptoms
SH	MS Trust	1	general	Other	We do not have any specific comments on the scope but would like to ensure that the group is aware of the attached reference. www.jnnp.bmj.com/content/80/5/470.abstract?etoc	Thank you. This paper has been identified as part of the literature search to inform the scoping process
SH	NHS DIRECT	1	general	Thanks	NHS Direct welcome the guideline and have no comments on the content.	Thank you for your comment
NICE	NICE CCP Technical	1	3.1 (f)	Other	Not sure what 'management of treatment complications' refers to in this context. Are these complications associated with treatments for	We have rephrased this

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					incontinence? And what is meant by 'patient management'? Does this cover provision of treatments for incontinence in patients with a neurological condition?	section
NICE	NICE CCP Technical	2	3.2 (a)	Subgroups/population	Access to specialist services appears to be variable and referral seems to differ with the setting where the neurological condition is managed. For example, it seems probable that people with acute onset neurological conditions who are managed in secondary care are referred to another specialist service for management of urinary dysfunction in a timely and appropriate fashion. However, neurological conditions of intermittent onset or insidious deterioration are frequently managed in primary care, where there may be a greater potential for issues around accessing services. If access issues exist for specific groups should these be recognised specifically in the scope? Also, given the difference in treatment pathways would these groups be possible subgroups for any de novo analyses?	We have changed 4.3.1.b to read 'specialist assessment and/or management'. Access to services will also be highlighted in sections 4.3.1 d.e.f The GDG may wish to highlight populations that are disadvantaged in accessing services.
NICE	NICE CCP Technical	3		Subgroups/population	Do you need to differentiate between different groups of patients who may require different management approaches eg people with sudden onset of incontinence after injury compared with those with a slower onset progressive condition?	Thank you for your comment. This will be addressed during the evidence review
NICE	NICE CCP Technical	4	4.3.1 (a)	Assessment and testing	Is this assessment relevant to all settings or non-specialist only?	**Thank you for your comment** We will consider all settings

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NICE	NICE CCP Technical	5	4.3.1 (c)	Role of surgery	Bullet point 2. The footnote is a bit unclear. Explain that botulinum has not yet been the subject of a technology appraisal. Bullets points 3, 4, 7 and 9. Are the surgical procedures listed comprehensive? At the stakeholder workshop, many more procedures were suggested by participants and I am not certain what (if any) limits were decided on. Bullet point 4. Is 'incontinence' specific enough here? Other bullet points contain more specific statements such as 'bladder emptying' or 'bladder storage' etc.	1) NICE drafted the footnote for the scope. 2) The surgical procedures listed are those considered to be high priority. 3) We have specified this is due to sphincter weakness
NICE	NICE CCP Technical	6	4.4 (f)	Quality of life	Specify that this is quality of life of patient	All the outcomes are for patients
SH	Parkinson's UK	1	general	Subgroups/population	The scope must include co-morbidity that may affect bladder problems. Accurate diagnosis at a urology department is an essential part of effective management. Correct diagnosis and access to a specialist is essential and needs to be included.	Thank you for your comment. Given the resources available we are required to prioritise key areas where there is uncertainty/variation in practice. Therefore we would not normally include all co morbidities however we will address those that have a direct impact on the recommendations made within the guideline.
SH	Parkinson's UK	2	general	Other	The scope must include the importance of multi disciplinary working and the care pathway. This seems very geared towards different medical interventions	We agree. The composition of the GDG includes all

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					and treatments, without giving enough emphasis to the importance of multi-disciplinary working. It is, of course, important to look at medical interventions and treatments, but for most services users their experience of the care pathway is most significant. For example, a home assessment after diagnosis at a urology department, might show that the home environment has obstacles preventing people getting to the toilet in time. It might not be incontinence at all but something that is linked to mobility.	disciplines involved in treating this patient group. Therefore multidisciplinary working will be reflected through this.
SH	Parkinson's UK	3	general	Other	The scope must include contra-indicated medication. When giving details of drug treatment, for people with Parkinson's it would be helpful to be specific about medication that should be avoided because of the detrimental impact they have on Parkinson's disease.	Contra-indications will be highlighted where appropriate.
SH	Parkinson's UK	4	3.1 (e)	Quality of life	We emphasise the need for quality of life to be taken into account. This has such a massive impact on every day activities and people's personal relationships as well as being something which may go untreated because of embarrassment.	Thank you. Quality of life has been specified as under the section 'main outcomes'
SH	Royal College of General Practitioners	1	general	Thanks	A good summary -I have no criticisms.	Thank you for your comment
SH	Royal College of Nursing	1	general	Thanks	The Royal College of Nursing welcomes proposals to develop this guideline.	Thank you for your comment
SH	Royal College of Nursing	2	general	Subgroups/population	This scope is vast and may be too ambitious. It might be more manageable if it was split into two separate guidelines, one aimed at adults and one covering children.	Thank you for your comment Our remit from DH is to cover

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						both adults and children
SH	Royal College of Nursing	3	general	Other	It might also help to develop the scope further if the target audience is more defined and specific - many people with urinary incontinence will not be dealt with by specialist neurologists or urologists, but by continence advisors, nurses, GPs and other practitioners in primary and general secondary care settings.	Thank you. The guideline development group will be comprised of a broad range of health professionals with an interested in the management of this condition and includes continence advisors, nurses and a GP
SH	Royal College of Nursing	4	general	Surgery	Perhaps the scope should focus on initial assessment and management and then identify criteria that should trigger referral for specialist management as well as assessment. This could mean that some of the interventions (e.g. some surgical interventions, which are not all necessarily specific to people with urinary incontinence relating to neurological disorders) could be considered separately by NICE as a technology appraisal and would reduce the workload of the NICE technical team and GDG in developing this guidance.	Thank you for your comment. We have amended the scope.
SH	Royal College of Nursing	5	3.1 (b)	Other	Urinary symptoms can also be exacerbated by non neurological causes such as BPH, restricted fluid intake, and in females' structural damage	Noted, Thank you for your comment.
SH	Royal College of Nursing	6	3.1 (b)	Other	Reduced ability to get to the toilet because of reduced mobility/spasticity	Noted, Thank you for your comment
SH	Royal College of Nursing	7	3.1	Other	Inadequate social care to toilet people at the correct times.	Noted, Thank you for your

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			(b)			comment
SH	Royal College of Nursing	8	3.1 (d)	Other	Frequency and urgency also associated with incomplete emptying	Noted, Thank you for your comment
SH	Royal College of Nursing	9	3.1 (e)	Other	Urinary incontinence can often cause carer breakdown.	Noted, Thank you for your comment
SH	Royal College of Nursing	10	3.1 (e)	Other	Urine infections commonly trigger relapses/exacerbation of existing symptoms e.g. spasticity, and can be silent in terms of urinary symptoms.	Noted, Thank you for your comment
SH	Royal College of Nursing	11	3.1 (e)	Other	Urinary symptoms often impact on the ability to stay in work/ inhibit performance at work.	Noted, Thank you for your comment
SH	Royal College of Nursing	12	3.1 (e)	Other	Economic impact on employer	The economic implication of assessed interventions will consider costs and resources used from an NHS and PPS (personal social service) perspective, as recommended by NICE.
SH	Royal College of Nursing	13	4.3.1 (a)	Assessment and testing	Simple tests e.g. post micturition bladder scan in the community/clinic setting.	Noted – thank you
SH	Royal College of Nursing	14	4.3.1 (a)	Other	Identification of constipation as exacerbating factor of urinary symptoms.	Noted – thank you.

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SH	Royal College of Nursing	15	4.3.1 (a)	Assessment and testing	Probably worth mentioning urinalysis and residual urine measurement as specific examples of simple functional tests to be investigated along with pad testing and frequency volume charts	Thank you for your suggestion. The list gives examples of functional tests and is not exhaustive. The GDG will consider the most appropriate functional tests which are to be considered.
SH	Royal College of Nursing	16	4.3.1 (c)	Additional intervention	Sativex reported as being beneficial to urinary symptoms. Now licensed in UK, though not prescribed by many PCTs	Thank you for your comment. Sativex is not licensed for urinary symptoms
SH	Royal College of Nursing	17	4.3.1 (c)	Other	Need to include lifestyle changes along with behavioural methods and bladder retraining as a "physical" intervention	Noted. Thank you for your comment
SH	Royal College of Nursing	18	4.3.1 (f)	Other	Information for employers and adaptations in the workplace	Our guidance is for NHS. It is not within our remit to make workplace recommendations.
SH	Royal College of Nursing	19	4.4 (e)	Other	Worth adding post-void residual urine/ urinary retention as a specific example of symptoms relating to poor bladder emptying	Thank you. The list is not meant to be exhaustive and the GDG will identify key symptoms
SH	Royal College of Nursing	20	general	Other	It might be useful if the guideline developers make reference to other related guidelines such as Childhood Constipation/ Management of UTIs etc that are relevant though outside the scope of this particular	Thank you. Please see section of the scope headed 'other related NICE guidance'

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					guideline.	We have also added 'Infection prevention and control' and 'Constipation in children and young people'.
SH	Royal College of Paediatrics and Child Health	1	4.1	Assessment and testing	The College would like clarification on whether the guideline will address the potential issue of under recognition of neurological lower tract dysfunction. This would be addressed in the definition of patient population. Is the evidence being gathered from the point when a patient is diagnosed with a neurological lower tract dysfunction, or is the guideline looking at evidence regarding the value of routinely 'screening' a number of patient groups (e.g. children with UTI, children with cerebral palsy, children presenting with incontinence, dyselimination syndrome, etc.) for potential lower tract dysfunction, using the history, examination, +/- investigations.	Given the time and resource allocated to produce the guideline we are unable to consider screening. However, this is partly covered in other NCE Guidance and we will cross refer to the infection prevention and control guideline where appropriate. We will be covering the diagnosis and assessment of children with incontinence due to neurological disorders
SH	Royal College of Physicians	1	general	Thanks	The RCP wishes to endorse the response submitted by the ABN to this draft scope consultation	Thank you for your comment
SH	Society of British Neurological Surgeons	1	general	Other	The surgical interventions used in the management of incontinence are not commonly available in all neurosurgery units. Their unavailability could disadvantage some patients.	Any surgical interventions found to be clinically and cost effective will be recommended and therefore should be offered by the NHS.

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SH	Spinal Injuries Association (SIA)	1	general	Thanks	SIA agrees with the draft scope in its entirety.	Thank you for your comment
SH	Welsh Assembly Government	1	general	Thanks	Thank you for giving the Welsh Assembly Government the opportunity to comment. Please note that we have no comment to submit at this stage.	Thank you for your comment