NICE National Institute for Health and Care Excellence

Appendix A: Stakeholder consultation comments table

2019 surveillance of Urinary incontinence in neurological disease: assessment and management (2012)

Consultation dates: 16 to 29 November 2018

Do you agree with the proposal not to update the guideline?			
Stakeholder	**Overall response**	**Comments**	**NICE response**
British Society of Urogynaecology	Yes	No comments provided	Thank you
Ferring Pharmaceuticals Ltd	No	No comments provided	Thank you
Multiple System Atrophy Trust	No	No comments provided	Thank you
Paediatric Continence Forum	No	"Key Priorities" on page 11: Although the main recommendations include Botox in children, they only mentions Botulinum Toxin for adults, which could be interpreted as in discouraging the use of Botulinum Toxin	Thank you for your comments. Botulinum Toxin The use of Botulinum Toxin in children is addressed in the main body of the guideline with recommendations advising on best use. Current recommendations state: 'Consider bladder wall injection

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		in children but there is plenty of evidence of its benefits children. Page 12 monitoring and surveillance Protocols Also need to consider long term follow up following bladder augmentation etc. See Long-term effectiveness and complication rates of bladder augmentation in patients with neurogenic bladder dysfunction. A systematic review: Hoen L, et. al . Neurourol Urodyn. 2017 Sep;36(7):1685-1702. doi: 10.1002/nau.23205. Epub 2017 Feb 7. Review 1.1.3 Physical examination: It is important also to check bowels and ensure appropriate management is in place and any underlying issues such as constipation treated appropriately. Good bowel management can help reduce bladder problems such as UTI etc. Para 1.1.11 is weak and is contradicted by 1.1.17. Both the International Children's Continence Society and British Association of Paediatric Urologists recommend that close surveillance for spina bifida patients should start early i.e. in neonatal period for open spina bifida - and be regular. British Association of Paediatric Urologists consensus statement on the management of the neuropathic bladder. Lee, B; et al. Journal of pediatric urology 12.2: 76-87. (Apr 2016)	with botulinum toxin type A for children and young people: with spinal cord disease and with urodynamic investigations showing impaired bladder storage and in whom antimuscarinic drugs have proved to be ineffective or poorly tolerated (1.3.11) 'Consider bladder wall injection with botulinum toxin type A for children and young people: with spinal cord disease and with symptoms of an overactive bladder and in whom antimuscarinic drugs have proved to be ineffective or poorly tolerated (1.3.9). <u>Monitoring and surveillance Protocols</u> Thank you for the reference. This study (Hoen et al. 2017) was identified and assessed through our surveillance process: a systematic review of 20 (n=511) relatively poor quality studies that showed bladder augmentation appears to be a highly effective procedure at protecting the upper urinary tract and improving quality of life. However, it is associated with moderately high morbidity in both the short and long term. The need for long-term follow up is recommended in the guideline: Recommendation 1.3.17: 'Offer patient life-long follow-up after augmentation cystoplasty because of the risk of long-term complications. Potential complications include metabolic effects, such as the development of vitamin B12 deficiency and the development of bladder cancer. <u>Physical examination</u> Bowel management is not within the remit of this guideline and reference has been made to NICE Faecal Incontinence guideline (CG49). <u>Recommendations 1.1.11 and 1.1.17</u>

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		International Children's Continence Society's recommendations for initial diagnostic evaluation and follow-up in congenital neuropathic bladder and bowel dysfunction in children. Bauer, Stuart B; et al. Neurourology and urodynamics 31.5: 610-4. (Jun 2012) 1.3 Treatment of Bladder Storage Problems: There is now good evidence of the benefits of the use of the Beta 3 agonist Mirabegron for bladder storage problems. (I am aware that others have included relevant references with similar comments) 1.5 Treatment to improve bladder: Clean Intermittent Catheterisation (CIC) should be included in this section, and indeed in section 1.3 (Storage), because incomplete emptying impairs bladder storage. See Long-term bladder management by intermittent catheterisation in adults and children. Moore, K N; Fader, M; Getliffe, K; NLM. The Cochrane database of systematic reviews 4: CD006008. (Oct 17, 2007). (Unfortunately because CIC was rapidly and widely accepted as beneficial, there is a shortage of high quality RCTs) 1.11.4 Transfer from child to adult services Refer to NICE guidance re Transition published since this original CG https://www.nice.org.uk/guidance/ng43	Infants with spina bifida are all managed in highly specialised units where early and regular assessment should be standard practice. This is reflected in recommendation 1.9.5 which states: 'Consider urodynamic investigations as part of a surveillance regimen for people at high risk of urinary tract complications (for example, people with spina bifida, spinal cord injury or anorectal abnormalities)'. Both recommendations 1.1.11 and 1.1.17 draw attention to patients with spina bifida having a high of renal problems and requiring more intensive investigation. We do not believe there are contradiction between recommendations 1.1.11 and 1.1.17 Thank you for the reference. The papers (Lee et al. 2016; Baur et al. 2012) are consensus statement/guidance. Based on the surveillance process and methods, we focus on high quality evidence and do not generally consider opinion/consensus statement where it cannot be certain how the evidence has been collected or assessed. Treatment of Bladder Storage Problems NICE has produced evidence-based recommendations on mirabegron (Betmiga) for treating overactive bladder in adults. Mirabegron for treating symptoms of overactive bladder (TA290 2013). Treatment to improve bladder The highlighted study (Moore et al. 2017) was identified in our searches but was then excluded because the study population does not specifically include people with urinary incontinence due to neurological disease. Transfer from child to adult services

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		Finally, NIHR are funding Exeter University for: HTA project 17/20/02 Improving Continence for Children and young people with neurodisability. This is due for completion in 18 months, so we wonder whether review of this guidance might be postponed until summer/autumn 2020. NIHR website: https://www.journalslibrary.nihr.ac.uk/programmes/hta/172002/#/	A cross referral to NICE guideline NG43 (Transition from children's to adults' services for young people using health or social care services) will be made in recommendation 1.11.4 Thank you for highlighting the NIHR funded study. Ongoing studies that we identify, or receive notification about, will be assessed for the potential to impact on the guideline. We will track studies meeting this criterion and check for publication on a regular basis. If new evidence with an impact on recommendations is identified at any time, we may decide to update the guideline outside of the usual surveillance cycle.
Bladder and Bowel UK	Yes	No comments provided	Thank you
RCN		This is to inform you that the RCN have no comments to submit at this stage	Thank you
Royal College of Paediatrics and Child Health	No	The following recommendations should be updated: "Key Priorities" on page 11: Although the main recommendations include Botox in children, they only mention Botulinum Toxin for adults, which could be interpreted as in discouraging the use of Botulinum Toxin in children but there is plenty of evidence of its benefits for children. Page 12 monitoring and surveillance Protocols Also need to consider long term follow up following bladder augmentation etc. See Long-term effectiveness and complication rates of bladder augmentation in patients with neurogenic bladder dysfunction. A systematic review:	Thank you for your comments. Botulinum Toxin The use of Botulinum Toxin in children is addressed in the main body of the guideline with recommendations advising on best use. Current recommendations state: 'Consider bladder wall injection with botulinum toxin type A for children and young people: with spinal cord disease and with urodynamic investigations showing impaired bladder storage and in whom antimuscarinic drugs have proved to be ineffective or poorly tolerated (1.3.11) 'Consider bladder wall injection with botulinum toxin type A for children and young people: with spinal cord disease and with symptoms of an overactive bladder and in whom antimuscarinic drugs have proved to be ineffective or poorly tolerated (1.3.9).

		Hoen L, et. al. Neurourol Urodyn. 2017 Sep;36(7):1685-1702. doi: 10.1002/nau.23205. Epub 2017 Feb 7. Review 1.1.3 Physical examination: It is important also to check bowels and ensure appropriate management is in place and any underlying issues such as constipation treated appropriately. Good bowel management can help reduce bladder problems such as UTI etc. 1.3 Treatment of Bladder Storage Problems: There is now good evidence of the benefits of the use of the Beta 3 agonist Mirabegron for bladder storage problems. 1.5 Treatment to improve bladder: Clean Intermittent Catheterisation (CIC) should be included in this section, and indeed in section 1.3 (Storage), because incomplete emptying impairs bladder storage. See Long-term bladder management by intermittent catheterisation in adults and children. Moore, K N; Fader, M; Getliffe, K; NLM. The Cochrane database of systematic reviews 4: CD006008. (Oct 17, 2007). (Unfortunately, CIC was rapidly and widely accepted as beneficial, there is a shortage of high quality RCTs) 1.11.4 Transfer from child to adult services Refer to NICE guidance re Transition published since this original CG https://www.nice.org.uk/guidance/ng43	Monitoring and surveillance Protocols Thank you for the reference. This study (Hoen et al. 2017) was identified and assessed through our surveillance process: a systematic review of 20 (n=511) relatively poor quality studies that showed bladder augmentation appears to be a highly effective procedure at protecting the upper urinary tract and improving quality of life. However, it is associated with moderately high morbidity in both the short and long term. The need for long-term follow up is recommended in the guideline: Recommendation 1.3.17: 'Offer patient life-long follow-up after augmentation cystoplasty because of the risk of long-term complications. Potential complications include metabolic effects, such as the development of vitamin B12 deficiency and the development of bladder cancer. Physical examination Bowel management is not within the remit of this guideline and reference has been made to NICE Faecal Incontinence guideline (CG49). Treatment of Bladder Storage Problems NICE has produced evidence-based recommendations on mirabegron (Betmiga) for treating overactive bladder in adults. Mirabegron for treating symptoms of overactive bladder (TA290 2013). Treatment to improve bladder The highlighted study (Moore et al. updated 2017) was identified in our searches but was then excluded because the study population does not specifically include people with urinary incontinence due to neurological disease.

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		Paragraph 1.1.11 is contradicted by 1.1.17. Both the International Children's Continence Society and British Association of Paediatric Urologists recommend close surveillance for spina bifida patients should be early i.e. in neonatal period for open spina bifida - and regular. British Association of Paediatric Urologists consensus statement on the management of the neuropathic bladder. Lee, B; et al. Journal of paediatric urology 12.2: 76-87. (Apr 2016) International Children's Continence Society's recommendations for initial diagnostic evaluation and follow-up in congenital neuropathic bladder and bowel dysfunction in children. Bauer, Stuart B; et al. Neurology and urodynamics 31.5: 610-4. (Jun 2012)	Transfer from child to adult services A cross referral to NICE guideline NG43 (Transition from children's to adults' services for young people using health or social care services) will be made in recommendation 1.11.4 Recommendations 1.1.11 and 1.1.17 Infants with spina bifida are all managed in highly specialised units where early and regular assessment should be standard practice. This is reflected in recommendation 1.9.5 which states: 'Consider urodynamic investigations as part of a surveillance regimen for people at high risk of urinary tract complications (for example, people with spina bifida, spinal cord injury or anorectal abnormalities)'. Both recommendations 1.1.11 and 1.1.17 draw attention to patients with spina bifida having a high of renal problems and requiring more intensive investigation. We do not believe there are contradiction between recommendations 1.1.11 and 1.1.17. Thank you for the reference. The papers (Lee et al. 2016 and Baur et al. 2012) are consensus statement/guideline. Based on the surveillance process and methods, we focus on high quality evidence and do not generally consider opinion/consensus statement where it cannot be certain how the evidence has been collected or assessed. Thank you for highlighting the NIHR funded study. Ongoing studies that we identify, or receive notification about, will be assessed for the potential to impact on the guideline. We will track studies meeting this criterion and check for publication on a regular basis. If new evidence with an impact on recommendations is identified at any time, we may decide to update the guideline outside of the

			usual surveillance cycle. This study will be tracked and the results assessed for impact on the guideline when published.

Do you have any comments on areas excluded from the scope of the guideline?			
Stakeholder	**Overall response**	**Comments**	**NICE response**
British Society of Urogynaecology	No	No comments provided	Thank you
Ferring Pharmaceuticals Ltd	Yes	One important aspect missing from the guideline is the management of nocturia, which can be common in patients with neurological disorders. Nocturia can be one of the symptoms of overactive bladder and may be addressed to some extent by the treatment options recommended in that section of the guidelines. However, nocturia is frequently of mixed aetiology and may not be due solely to OAB; nocturnal polyuria may play a significant role. It can be particularly bothersome, particularly in these patient groups and guidance on its management would be of value.	Thank you for your comment. NICE has published guideline on Bedwetting in under 19s (NICE clinical guideline CG111) which has recommendation on assessment, investigation/or referral when bedwetting is associated with neurological problems (recommendation 1.3.10). CG148 cross refers to CG111 for treatment of nocturnal enuresis.
Multiple System Atrophy Trust	Yes	People with Multiple System Atrophy often initially present with urological problems. Because the neurological cause isn't picked up they can remain in urology assessment rather than being referred to Neurology. We would want guidance which recommends "Refer to Neurology if bladder symptoms are associated with erectile dysfunction, early falls or balance issues." Guidance needs to say "Bladder surgery is not indicated with diagnosis of MSA"	Thank you for your comment. Management of comorbidities, general management of the underlying disorder, and management of associated faecal incontinence, sexual dysfunction or psychological problems are out of scope of this guideline. We found no evidence through intelligence gathering on InFlow Intraurethral pump for treatment of urinary incontinence due to neurological problem. This is not currently available in the UK.

		We cannot see anywhere whether there have been any tests of efficacy of the product Vesiflo, although this is used and licensed elsewhere in the world. When might this become licensed? http://www.io.nihr.ac.uk/wp-content/uploads/migrated/InFlow-Intraurethral-pump-for-atonic-bladder.pdf	
Paediatric Continence Forum	Yes	There is a significant prevalence of symptomatic neurogenic bladder in people with Cerebral Palsy. Therefore they should be offered comprehensive bladder and bowel assessments. See Cerebral palsy, neurogenic bladder, and outcomes of lifetime care. Murphy KP[1], Boutin SA, Ide KR. Dev Med Child Neurol. 2012 Oct;54(10):945-50. doi: 10.1111/j.1469-8749.2012.04360.x. Epub 2012 Jul 13.	Thank you for your comment. Cerebral palsy was identified in the guideline as a neurological conditions that can affect lower urinary tract function (p6/47 recommendations; table 1) and is covered by this guideline. The identified article (Murphy et al. 2012) is a retrospective review of clinical records to determine the prevalence of symptomatic neurogenic bladder in people with cerebral palsy indicating that symptomatic neurogenic bladder is common in individuals with cerebral palsy. This will add information to the epidemiological data but has no impact on current recommendations.
Bladder and Bowel UK	Yes	Would it be considered appropriate in this document to reference to nocturia and nocturnal polyuria	Thank you for your comment. NICE has published guideline on Bedwetting in under 19s (NICE clinical guideline CG 111) which has recommendations on assessment, investigation/or referral when bedwetting is associated with neurological problems (recommendation 1.3.10). CG148 cross refers to CG111 for treatment of nocturnal enuresis.
RCN	Not answered	No comments provided	

Royal College of Paediatrics and Child Health	Yes	See above. Children with neurogenic bladder due to spina bifida – and requiring intermittent catheterisation. There is a significant prevalence of symptomatic neurogenic bladder in people with Cerebral Palsy. Therefore, they should be offered comprehensive bladder and bowel assessments. See Cerebral palsy, neurogenic bladder, and outcomes of lifetime care. Murphy KP1, Boutin SA, Ide KR. Dev Med Child Neurol. 2012 Oct;54(10):945-50. doi: 10.1111/j.1469-8749.2012.04360.x. Epub 2012 Jul 13.	Thank you for your comment. Cerebral palsy was identified in the guideline as a neurological conditions that can affect lower urinary tract function (p6/47 recommendations; table 1) and is covered by this guideline. The identified article (Murphy et al. 2012) is a retrospective review of clinical records to determine the prevalence of symptomatic neurogenic bladder in people with cerebral palsy indicating that symptomatic neurogenic bladder is common in individuals with cerebral palsy. This will add information to the epidemiological data but has no impact on current recommendations. Regarding the introduction of intermittent catheterisation, this is reflected within the algorithms developed alongside the guideline. However, we consider that the use of intermittent catheterisation in infants does not need specific mention as such infants are all managed in highly specialised units.

Do you have any comments on equalities issues?

Stakeholder	Overall response	Comments	NICE response
British Society of Urogynaecology	No	No comments provided	Thank you
Ferring Pharmaceuticals Ltd	No	No comments provided	Thank you
Multiple System Atrophy Trust	No	No comments provided	Thank you

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Paediatric Continence Forum	No	No comments provided	Thank you
Bladder and Bowel UK	No	No comments	Thank you
RCN	Not answered	No comments provided	
Royal College of Paediatrics and Child Health	No	No comments provided	Thank you