National Institute for Health and Clinical Excellence

Incontinence in neurological disease
Guideline Consultation Comments Table
8 March 2012 – 19 April 2012

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Airedale NHS Trust	1	Full	General		No comments have been made by the personnel dealing with this issue.	Thank you.
SH	Allergan Ltd UK	1	NICE	189	30	"Under the recommendations for augmentation cystoplasty, it is not clear where this treatment option would feature in the pathway in relation to other available treatment options	Thank you for your comment, we have added an algorithm to the introduction in the Full version of the guideline, and this addresses your concerns.
SH	Amdipharm PLC	1	Full	34	1	The current wording may induce the erroneous perception that botulinum toxin type A is a first-line treatment in adults. It should be stated that antimuscarinics with a licensed indication for neurogenic detrusor overactivity (NDO) present the first-line treatment.	Thank you for your comment, we think that the proviso "who are either unresponsive to..." is clear.
SH	Amdipharm PLC	2	Full	37	22	The class of antimuscarinics is not further differentiated with respect to the issue of licensed or non-licensed indications. It should be addressed that "newer" antimuscarinics, such as tolterodine, solifenacin, darifenacin, and fesoterodine, are not licensed for the treatment of neurogenic detrusor overactivity.	Thank you for your comment. A footnote has been added stating that not all antimuscarinics have a UK marketing authorisation for use in both adults and children.
SH	Amdipharm PLC	3	Full	42	32-35	It is not sufficiently addressed that in "newer" antimuscarinics no high quality clinical trials have been carried out. Moreover, the class of "newer" antimuscarinics is not defined. However, there is a strong clinical perception that	Thank you. This research recommendation has been amended in both versions of the guideline. The third line now reads " This is important because the more recently developed

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						"newer" antimuscarinics require much higher doses in neurogenic detrusor activity (NDO) compared to Overactive bladder (OAB) /Idiopathic detrusor overactivity (IDO), which would also have implications on the evaluation of daily treatment costs. Moreover, especially the so-called M_3-selective antimuscarinics might be considered as less suitable in NDO, both due to minor efficacy and higher constipation rates compared to non-selective antimuscarinics. Therefore, it may be misleading for the unexperienced reader to state for the population of patients with NDO that *"….the more recently developed medications …. claim (in the non-neurogenic population) to have fewer adverse effects."*	medications are of unknown efficacy, are more expensive and claim (in the non-neurogenic population) to have fewer adverse effects."
SH	Amdipharm PLC	4	Full	85	12	The references should include, according to the criteria given, the following paediatric study: *Grigoleit U. et al. Eur. Urol., 2006; 49:1114-1121.*	This paper was excluded because, the conditions under which reference standards as well as the time intervals between reference and during-treatment assessment, varied widely between patients.
SH	Amdipharm PLC	5	Full	111	14	It is stated that it is not possible "…..to recommend one treatment over another, in terms of side effects or effectiveness." Moreover: "Of course, where there is nothing to choose between the two, the lowest cost treatment should be provided." These statements neglect that at least for oxybutynin IR while, exerting comparable efficacy, a trend for inferior tolerability compared to other antimuscarinics has	The studies that were included in the clinical review did not identify any meaningful difference between the treatments. The studies identified were all very small studies and therefore side-effect event rates were low. The studies by *Madersbacher et al. 1995* and *Stroher et al. 2007,* were included in the review but found that the

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						been documented in studies focussing on neurogenic detrusor activity (NDO) (*Madersbacher H. et al. Br. J. Urol., 1995; 75:452-456, Stöhrer M. et al. European Urology, 2007; 51:235-242*). Our assumption is confirmed by a recent review of the use of antimuscarinics in the treatment of Overactive Bladder (*Kessler TM et al., PLoS ONE 2011; 6(2): e16718.doi:10.1371/journal.pone.0016718)*. Moreover, it is neglected that only oxybutynin, propiverine, and trospium, contrary to the "newer" antimuscarinics, are licensed for NDO.	confidence intervals for the adverse events, in both studies crossed the line of no effect considerably and can therefore not be considered a meaningful association. In the absence of specific and definitive data on tolerability in this population, the GDG felt that it was reasonable to provide general guidance rather than specific recommendations to clinicians. The use of licensed preparations will be addressed in an appropriate footnote stating that not all antimuscarinics have a UK marketing authorisation for use in both adults and children. .
SH	Amdipharm PLC	6	Full	161	14	It is unclear, why the model comparing cost-effectiveness of four strategies for the management of incontinence due to NLUTD does not include antimuscarinics.	This model looks at second line, treatments of NLUTD. Antimuscarinics are considered first line treatments so that only once a patient has failed to respond to antimuscarinics, for whatever reason, are they then considered for botulinum toxin treatment or augmentation cystoplasty.
SH	Amdipharm PLC	7	Full	117		*"The GDG agreed further research was required on the effects of the newer in*	The studies were heterogeneous, small in patient numbers and short

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						comparison with the older well established drugs." We fully agree with this statement. However, reflecting this statement given by the GDG, it is not understood, why the antimuscarinics are referenced unequivocally as one class, without differentiating that the evidence-based evaluation of individual compounds with respect to the indication of neurogenic detrusor activity (NDO) differs widely within the class.	in terms of follow up. There is no definitive study that singled out one or more specific agents as having powerful support for their use in NLUTD. However, taken as a group, and in the face of decades of clinical use, it would have been inappropriate not to recommend the use of any antimuscarinic drug. The GDG dealt with this dilemma by taking the pragmatic decision to treat antimuscarinic drugs as a generic group rather than isolated interventions.
SH	Amdipharm PLC	8	Full	General		Through out the draft the drugs classed as antimuscarinics in the context of neurogenic detrusor activity are not clearly defined. The group should be at least restricted to the internationally acknowledged compounds (*Andersson KE. et al. International Consultation on Incontinence, Paris July 5-8,2008, 4th edition, 2009, 631-699*). Thus atropine, propantheline, etc. would be ruled out. Moreover, the issue of licensed or non-licensed administration in the indication of NDO is not reflected in the draft Guideline. We assume that the GDG is aware of the fact that "newer" antimuscarinics (comprising tolterodine, solifenacin, darifenacin, and fesoterodine) are not licensed for the use in NDO, neither in adults nor in children. In contrast, other antimuscarinics (oxybutynin, propiverine, trospium) have been licensed for the	The glossary defines the drugs in a reasonable way: "An anticholinergic agent that specifically blocks the muscarinic form of the cholinergic receptor." Atropine and propantheline are therefore included appropriately. The use of licensed preparations has been addressed in an appropriate footnote.

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						treatment of NDO due to the successfully completed randomised controlled trials (*Madhuvrata P. et al., European Urology 2012, doi:10.1016/j.eururo.2012.02.036*).	
SH	Amdipharm PLC	9	Full	general		Because all antimuscarinics, even those without a licensed indication of neurogenic detrusor overactivity (NDO) are listed in the guideline, also propiverine ER 30 od. should be incorporated. Moreover, propiverine ER 45 mg od is an already licensed ER formulation for the treatment of NDO in the United Kingdom (PL15072/0010, 2009.11.30). However, the product is not available in the U.K. market yet. The respective study results (comparative study of propiverine IR 15 mg t.d.s and propiverine ER 45 mg .od.) are not yet published as a full paper, but available as abstract (*Stöhrer M. et al., Annual Meeting of the International Continence Society, San Francisco, USA, 2009; abstract 448*). The evaluation of the study outcome is provided in the MHRA Public Assessment Report (last update: Feb.2011).	The use of licensed preparations has been addressed in an appropriate footnote
SH	APOGEPHA Arzneimittel GmbH	1	Full	34	1	The current wording may induce the erroneous perception that botulinum toxin type A is a first-line treatment in adults. It should be stated that antimuscarinics with a licensed indication for neurogenic detrusor overactivity (NDO) present the first-line treatment.	The recommendations specify that botulinum toxin type A should only be considered for those people where antimuscarinics are ineffective or poorly tolerated.
SH	APOGEPHA	2	Full	37	22	The class of antimuscarinics is not further	The use of licensed or unlicensed

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	Arzneimittel GmbH					differentiated with respect to the issue of licensed or non-licensed indications. It should be addressed that "newer" antimuscarinics, such as tolterodine, solifenacin, darifenacin, and fesoterodine, are not licensed for the treatment of neurogenic detrusor overactivity.	preparations has been addressed in an appropriate footnote stating that: not all antimuscarinics have a UK marketing authorisation for use in both adults and children.
SH	APOGEPHA Arzneimittel GmbH	3	Full	42	32-35	It is not sufficiently addressed that in "newer" antimuscarinics no high quality clinical trials have been carried out. Moreover, the class of "newer" antimuscarinics is not defined. However, there is a strong clinical perception that "newer" antimuscarinics require much higher doses in neurogenic detrusor activity (NDO) compared to Overactive bladder (OAB) /Idiopathic detrusor overactivity (IDO), which would also have implications on the evaluation of daily treatment costs. Moreover, especially the so-called M_3-selective antimuscarinics might be considered as less suitable in NDO, both due to minor efficacy and higher constipation rates compared to non-selective antimuscarinics. Therefore, it may be misleading for the unexperienced reader to state for the population of patients with NDO that *"….the more recently developed medications …. claim (in the non-neurogenic population) to have fewer adverse effects."*	As no studies for the newer antimuscarinics were found it is not possible for the GDG to comment on the use of these other than note further research is required as stated in the LETR section. The use of licensed or unlicensed preparations has been addressed in an appropriate footnote stating that: Not all antimuscarinics have a UK marketing authorisation for use in both adults and children.
SH	APOGEPHA Arzneimittel GmbH	4	Full	85	12	The references should include, according to the criteria given, the following paediatric study: *Grigoleit U. et al. Eur. Urol., 2006;*	This study is listed in the excluded studies list. It was excluded from the clinical evidence review

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						49:1114-1121.	because ' the conditions under which reference standards as well as the time intervals between reference and during-treatment assessment, varied widely between patients'
SH	APOGEPHA Arzneimittel GmbH	5	Full	111	14	It is stated that it is not possible "…..to recommend one treatment over another, in terms of side effects or effectiveness." Moreover: "Of course, where there is nothing to choose between the two, the lowest cost treatment should be provided." These statements neglect that at least for oxybutynin IR while, exerting comparable efficacy, a trend for inferior tolerability compared to other antimuscarinics has been documented in studies focussing on neurogenic detrusor activity (NDO) (*Madersbacher H. et al. Br. J. Urol., 1995; 75:452-456, Stöhrer M. et al. European Urology, 2007; 51:235-242*). Our assumption is confirmed by a recent review of the use of antimuscarinics in the treatment of Overactive Bladder (*Kessler TM et al., PLoS ONE 2011; 6(2): e16718.doi:10.1371/journal.pone.0016718)*. Moreover, it is neglected that only oxybutynin, propiverine, and trospium, contrary to the "newer" antimuscarinics, are licensed for NDO.	The studies that were included in the clinical review did not identify any meaningful difference between the treatments. The studies identified were all very small studies and therefore side-effect event rates were low. The studies by *Madersbacher et al. 1995* and *Stroher et al. 2007,* were included in the review but found that the confidence intervals for the adverse events, in both studies crossed the line of no effect considerably and can therefore not be considered a meaningful association. In the absence of specific and definitive data on tolerability in this population, the GDG felt that it was reasonable to provide general guidance rather than specific recommendations to clinicians. The use of licensed preparations has been addressed in an appropriate footnote .
SH	APOGEPHA	6	Full	161	14	It is unclear, why the model comparing	This model looks at second line,

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	Arzneimittel GmbH					cost-effectiveness of four strategies for the management of incontinence due to NLUTD does not include antimuscarinics.	treatments of NLUTD. Antimuscarinics are considered first line treatments so that only once a patient has failed to respond to antimuscarinics, for whatever reason, are they then considered for botulinum toxin treatment or augmentation cystoplasty.
SH	APOGEPHA Arzneimittel GmbH	7	Full	117		*"The GDG agreed further research was required on the effects of the newer in comparison with the older well established drugs."* We fully agree with this statement. However, reflecting this statement given by the GDG, it is not understood, why the antimuscarinics are referenced unequivocally as one class, without differentiating that the evidence-based evaluation of individual compounds with respect to the indication of neurogenic detrusor activity (NDO) differs widely within the class.	The use of licensed and unlicensed preparations has been addressed in an appropriate footnote stating that: Not all antimuscarinics have a UK marketing authorisation for use in both adults and children.
SH	APOGEPHA Arzneimittel GmbH	8	Full	General		Through out the draft the drugs classed as antimuscarinics in the context of neurogenic detrusor activity are not clearly defined. The group should be at least restricted to the internationally acknowledged compounds (*Andersson KE. et al. International Consultation on Incontinence, Paris July 5-8,2008, 4th edition, 2009, 631-699*). Thus atropine, propantheline, etc. would be ruled out. Moreover, the issue of licensed or non-	The use of licensed and unlicensed preparationshas been addressed in an appropriate footnote stating that: Not all antimuscarinics have a UK marketing authorisation for use in both adults and children.

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						licensed administration in the indication of NDO is not reflected in the draft Guideline. We assume that the GDG is aware of the fact that "newer" antimuscarinics (comprising tolterodine, solifenacin, darifenacin, and fesoterodine) are not licensed for the use in NDO, neither in adults nor in children. In contrast, other antimuscarinics (oxybutynin, propiverine, trospium) have been licensed for the treatment of NDO due to the successfully completed randomised controlled trials (*Madhuvrata P. et al., European Urology 2012, doi:10.1016/j.eururo.2012.02.036*).	
SH	APOGEPHA Arzneimittel GmbH	9	Full	general		Because all antimuscarinics, even those without a licensed indication of neurogenic detrusor overactivity (NDO) are listed in the guideline, also propiverine ER 30 od. should be incorporated. Moreover, propiverine ER 45 mg od is an already licensed ER formulation for the treatment of NDO in the United Kingdom (PL15072/0010, 2009.11.30). However, the product is not available in the U.K. market yet. The respective study results (comparative study of propiverine IR 15 mg t.d.s and propiverine ER 45 mg .od.) are not yet published as a full paper, but available as abstract (*Stöhrer M. et al., Annual Meeting of the International Continence Society, San Francisco, USA, 2009; abstract 448*). The evaluation of the study outcome is provided in the MHRA Public Assessment Report (last update: Feb.2011).	The use of licensed and unlicensed preparations will be addressed in an appropriate footnote stating that: Not all antimuscarinics have a UK marketing authorisation for use in both adults and children.

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SH	Astellas pharma	1	Full	general		At this time we are happy with the content and have no further comments	Thank you.
SH	British Society of Gastroenterology	1	NICE	11	10	In requesting bowel symptoms be enquired of, it would help in the full version to clarify the 3 key questions to ascertain: 1. What drugs or physical manoeuvres, and how often, are used for bowel care? 2. How long does bowel care take? 3. Are there episodes of faecal incontinence	We are only covering urinary incontinence, please see faecal incontinence guideline.
SH	British Society of Gastroenterology	2	NICE	12	7	Rectal examination cannot determine "constipation" – it can identify faecal loading, or assess anal tone (both potentially important in some patients with urinary symptoms)	Thank you. The recommendation has been amended, 'constipation' has been changed to 'faecal loading'.
SH	British Society of Gastroenterology	3	NICE	17	Last line	It is important to recognise that anti-muscarinics may exacerbate or precipitate constipation, which in turn can impair bladder storage symptoms. It would be important to enquire about gut function after commencement of such drugs.	Thank you. Another bullet point has been added to the recommendation. It reads: 'antimuscarinic treatment may precipitate or exacerbate constipation.'
SH	Department of Health	1				I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.	Thank you.
SH	Medtronic UK Limited	1	Full			Thank you for the opportunity to comment on the draft guideline consultation on Incontinence in neurological disease. This draft guideline addresses an important area of incontinence and is to be commended. It appears, however, that sacral nerve stimulation, an accepted treatment option for this indication, has been excluded from the guideline, despite being included in the final scope.	Sacral nerve stimulation was given as an example of a treatment to improve bladder storage of urine that might be reviewed. However, the breadth of issues that the guideline was to cover (neonates to the elderly, the whole range of neurological disease that might affect LUT function) meant that the GDG needed to consider how best

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						The point at which sacral nerve stimulation has been omitted is unclear; it was within the remit of the final scope, yet it was not incorporated within the Review Questions developed from the PICO framework that were documented in the literature search phase (Appendices, section C). In alignment with the scope, sacral nerve stimulation would have been expected to be included in section C.3.2. 'Treatment: improving bladder storage', alongside alternative treatments such as Botulinum toxin A and augmentation cystoplasty. Sacral nerve stimulation is internationally recognised and accepted as a treatment for incontinence in neurological disease, recommended by both the International Consultation on Incontinence and the European Urology Association as a standard treatment for the specialised management of neurogenic urinary incontinence. [1,2] There is a growing evidence base on the safety and efficacy of sacral nerve stimulation across a range of neurological diseases including multiple sclerosis [3], spinal cord injury [4] and other areas [5-7], and this has recently been consolidated in a systematic review and meta-analysis study where the authors examined sacral nerve stimulation for neurogenic lower urinary tract dysfunction (LUTD) [8]. Notwithstanding the lack of large scale randomised controlled trials, a total of 26	to make use of the literature search resources that were available. A decision was made to exclude SNS from the formal literature review on the basis of the known sparsity of published data on its application to neurogenic incontinence. This was illustrated by the review that is cited as reference 8. NICE guidance cannot be exhaustive, but rather be a vehicle for providing advice on good practice based on the evidence available in the most important areas. Other surgical treatments that had to be omitted include the Finetech/Brindley sacral root stimulator, external urethral sphincterotomy and the use of urethral stents. The GDG's view was that the treatment has been in world-wide clinical use for over 15 years for other indications, and therefore the GDG concluded that the small number of reported neurogenic cases meant that the treatment had not established a place in clinical practice and it was felt that formal review of the treatment within the context of the NICE guidline could not be justified. It is hoped that the very limited data available will encourage

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						studies and 357 patients resulted in a pooled success rate of 92% for the permanent implantation of sacral nerve stimulation. The authors concluded that the existing evidence does indicate this therapy may be safe and effective for use in neurogenic lower urinary tract syndrome. Based on these results, the authors suggested that: *"After failed conservative treatment, SNM testing seems worthwhile in patients with neurogenic LUTD before more invasive treatments are considered"[8]* In addition to being a less invasive and reversible alternative to major surgery, sacral nerve stimulation could also potentially obviate the need for life-long indwelling catheterisation in patients with neurogenic urinary retention who are unable to perform intermittent self catheterisation. It is clear that further research, particularly randomised controlled trials, are needed to draw more firm conclusions on the safety and efficacy of sacral nerve stimulation. However, if sacral nerve stimulation therapy is to evolve in terms of best practice and research it is warranted that the current guideline acknowledges that this treatment option in the clinical pathway for incontinence. In conclusion, please could NICE clarify the reasoning and methodology behind the decision not to include sacral nerve	researchers to undertake the clinical trials that are required in order to inform those who are tasked to revisit this guideline in future years. .

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						stimulation in the consultation guideline, particularly when it was positioned within the final scope? We would like to request that sacral nerve stimulation is re-visited as a potential inclusion in this guideline, and if it is deemed unsuitable for inclusion in the final Clinical Guideline we would greatly appreciate any feedback as to the reasons why this may be the case. Thank you again for the opportunity to comment on this important guideline. We hope that you can take our points into consideration. **References** 1. Abrams P, Anderson KE, et al. Recommendations of the International Scientific Committee: Evaluation and treatment of urinary incontinence, pelvic organ prolapse and faecal incontinence. In: Abram P, Cardozo L, Khoury S, Wein A, eds. 3rd International Consultation on Incontinence. Plymouth: Health Publications, 2005;1589-1630 2. Thuroff J, Abrams P, et al. Guidelines on Urinary Incontinence. Arnhem, Netherlands: European Association of Urology, 2006 1-12	

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						3. Ruud Bosch & Groen. Treatment of refractory urge urinary incontinence with sacral spinal nerve stimulation in multiple sclerosis patients. The Lancet. 1996; 348: 717-19. 4. Sievert K, Amend B, Gakis G. et al. Early sacral neuromodulation prevents urinary incontinence after complete spinal cord injury. Ann Neurol. 2010; 67:74-84. 5. Chartier-Kastler E, Ruud Bosch J, Perrigot M. et al. Long-term results of sacral nerve stimulation(S3) for the treatment of neurogenic refractory urge incontinence related to detrusor hyperreflexia. J Urology. 2000; 164:1476-1480. 6. Hohenfellner M, Humke J, Hampel C. et al. Chronic sacral neuromodulation for treatment of neurogenic bladder dysfunction: long-term results with unilateral implants. Urology 2001; 58: 887-892 7. Wallace P, Lane F, Noblett K. Sacral nerve neuromodulation in patients with underlying neurological disease. Am J Obstet Gynecol. 2007; 197: 96 8. Kessler T, La Framboise D, Trelle S. et al. Sacral neuromodulation for neurogenic lower urinary tract dysfunction:	

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						systematic review and meta-analysis. European Urology. 2010; 58: 865-874	
NCC-WCH	NCC-WCH	1	Full	17	8	Please refer to the Urinary Incontinence in Women NICE guideline update in this section.	Thank you this has been added to the list of relevant guidance.
NCC-WCH	NCC-WCH	2	Full			We note that your draft guideline does not include a question and systematic review of neuromodulation, which is included in the Management of UI in Women update. We understand from discussions with you that neuromodulation is not suitable for this population. It would be helpful for readers of both UI guidelines if this issue could be more fully justified.	In the scope sacral nerve stimulation was given as an example of a treatment to improve bladder storage of urine that might be reviewed. However, the breadth of issues that the guideline was to cover (neonates to the elderly, the whole range of neurological disease that might affect LUT function) meant that the GDG needed to consider how best to make use of the literature search resources that were available. A decision was made to exclude SNS from the formal literature review on the basis of the known sparsity of published data on its application to neurogenic incontinence. At the time of writing the scope it was accepted practice to give examples of the sorts of interventions that the guideline may include, but this did not commit us to include everything mentioned in the scope.

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NCC-WCH	NCC-WCH	3	Full	115	6	There are recommendations in this draft guidance for the use of antimuscarinics in neurological patients with UI. It would be helpful to make reference to the need for selective or cautious use of certain antimuscarinic drugs (for example, the elderly, and/or those with a high antimuscarinic load overall in their medications) The UI update will make more precise recommendations about specific preparations based on clinical and cost-effectiveness. Could the neurological UI GDG consider whether it is appropriate to cross refer to the UI guidance for this recommendation? If it is not appropriate, could your guideline be clear about the reasons for this so that the readers of both do not see this as an inconsistency across NICE guidance.	Thank you. We should not cross refer as there is no evidence to support the contention that a drug that is good for idiopathic incontinence is good for neurogenic detrusor overactivity. We think the issue is adequately addressed in 8.2.2 evidence to recommendations.
NCC-WCH	NCC-WCH	4	Full	173	17	BoNT recommendations suggest that not all women will require self-catheterisation (CISC). The evidence for UI in Women suggests that it is rare for patients treated with BOTN to avoid catheterisation. The need for CISC may be less common in neurogenic detrusor overactivity treated with Botox. It would be helpful to have your view on whether CISC is only sometimes required for this (or all) UI populations to maintain clarity across guidelines.	Thank you for your comment. We agree that this should be emphasised and have amended the recommendation. It now reads as follows: "Before offering bladder wall injection with Botulinum toxin type A explain to the person and or their family members and carers that a catheterisation regimen is needed in most patients with neurogenic lower urinary tract dysfunction after treatment ,and ensure that they are able and willing to manage

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							such a regimen should urinary retention develop after the treatment"
NCC-WCH	NCC-WCH	5	Appendices	469	41	The health economic model compares cystoplasty, BoNT and best supportive care. The UI update has so far considered only cystoplasty as a third line treatment after drugs, BoTN and neuromodulation have failed since cystoplasty is such a drastic surgical option. The UI in Women GDG have heard neurologists justify the use of cystoplasty in women with neurogenic UI on the basis of the extreme severity of the incontinence. It would be helpful to have your GDG's view on why cystoplasty was included with the other interventions in this model to inform our own work and maintain consistency across guidelines.	Thank you for your comment. Cystoplasty is offered as an option as it is for the patient to make the decision as to whether they want to undergo a one-off surgical treatment that is very likely to render them dry or undergo a minimally invasive treatment that will need to be repeated at regular intervals and is less likely to achieve and maintain continence. It should be noted that cystoplasty is very reliable in the neuropathic population whereas results in the non-neuropath are less predictable. The advantages of one management approach over the other is not so clear-cut that the treatments should only be offered sequentially.
NCC-WCH	NCC-WCH	6	Full	189	5	"Please see cost-effectiveness analysis in section 7.3" – there does not seem to be a section 7.3	Thank you. 'In section 7.3' has been deleted as it is not relevant.
NCC-WCH	NCC-WCH	7	Full			The differences in treatment of neurogenic DOA and idiopathic DOA with the different treatments (retraining, drugs, Botox) may need to be highlighted in a separate section in both guidelines to avoid confusion.	Thank you for your comment.
SH	NHS Direct	1		General		NHS Direct welcome the guideline and have no comments on the contents.	Thank you.
SH	NHS Direct	2			page 5, first line of second	Typo "drug's" – I think this should be drugs.	Thank you. This has been amended.

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					paragraph		
SH	Parkinson's UK	1	NICE	8 & 12		If we suspect a patient has a UTI whether it be in clinic or as a telephone consultancy we would advice starting antibiotics and at the same time sending a urine sample to be tested and depending on the outcome of the sample we would advice continuing on the same antibiotic if appropriate or changing to a more suitable one and at the same time increasing their fluid intake.	Thank you for your comment. The recommendation has been amended and now reads: 1.1.6 If the dipstick test result and person's symptoms suggest an infection, arrange a urine bacterial culture and antibiotic sensitivity test before starting antibiotic treatment. Treatment need not be delayed but may be adapted when results are available.
SH	Parkinson's UK	2	NICE	6		Patients should be told about accredited sources of information such as Parkinson's UK helpline, or other accredited patient support organisations.	Thank you. Recommendations are based upon published trial evidence where this is available and we do not refer to other sources of information within the guideline. We do, however, produce another version of the guideline,. The 'Understanding NICE Guidance' which summarises the recommendations made in the guideline and is aimed at patients, their families and carers, and the wider public. This makes reference to other sources of information available.
SH	PromoCon	1	NICE	23		Under Monitoring and Surveillance there is no mention of long term monitoring of those individuals who have undergone	We would agree that long term follow up is advised but the argument about whether

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						bladder augmentation using section of bowel. There is evidence of potential risk of malignancy in such cases and as a result long term follow-up is usually advised	investigations are of much use is similar to that which applies to catheters. It is also a specialist procedure and so will be carried out by a team that will have a follow up policy. To go into follow up (e.g. vitamin b12 monitoring etc) is beyond the scope of the guideline.
SH	PromoCon	2	NICE	General		While this guidance is very much welcomed it appears to be very much surgically focused. It mentions the importance of an holistic approach to management but no recommendations have been made regarding ensuring appropriate bowel management to prevent/treat constipation and to resolve any faecal incontinence – both problems increase the risk of UTI's There is no recommendation regarding the introduction of clean intermittent catheterisation and points such the importance of commencing this early in infants born with spina bifida etc Also there is no mention of the use of appliances as part of management such as sheaths etc which can negate the use of pads	Thank you for your comment. Bowel management is not within the remit of this guideline and reference has been made to the Faecal Incontinence guideline (CG49). We agree that the management of ISC and sheaths are important and this is now reflected within the algorithms developed alongside the guideline. We consider that the use of ISC in infants does not need specific mention as such patients are all managed in highly specialised units. We believe that the point about ISC and sheaths is important in the sense that it is difficult to put the whole structure of the different aspects of management in context. The algorithms which have now been included in the guideline, address this.

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							The use of ISC in infants does not need specific mention in this relatively general guideline as such patients are all managed in highly specialised units.
SH	RCGP	1	NICE	General		These guidelines will be useful both to General Practice and the specialist services with implications for commissioning of incontinence services. The red flag symptoms were helpful and guidance on the prescribing of antibiotics also useful. There should also be reference to the GMC principles of good prescribing when considering off label prescribing.	Thank you for your comment, however following NICE methods we are unable to refer to non-NICE publications within our guidance however, on the issue of prescribing, this is currently being considered as part of NICE's guideline manual update.
SH	Robert Jones & Agnes Hunt Orthopaedic Hospital NHS Foundation Trust, Oswestry	1	**Full**	**280**	**7 - 15**	**We are concerned that the evidence cited is biased and based on a limited single study of 59 patients only (reference 229). This study is limited to identifying bladder cancers only.** **The quoted paper does not take into consideration the other pathologies that can develop within the vesical cavity including pre cancerous lesions, thick proteinaceous debris and or calculi that do not wash out through the catheters, that may not be identified radiologically and that can cause sepsis, significant morbidity including autonomic dysreflexia and increase disability.** **There are several studies however, some with several thousands of patients, that demonstrate some of the**	Thank you for your comments and suggestions. The evidence was searched for on the basis of looking for studies on surveillance regimes. The papers that are quoted all look at a different question, namely the incidence of bladder cancer in SCI patients. The quoted papers provide different estimates of the risk of bladder cancer – the validity of the estimates is reviewed by Subramanian et al BJUI 2004, 93, 739-743. Although there is probably an increased risk of developing a fatal bladder cancer in patients with SCI, the question is whether

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						reasons why routine cystoscopic surveillance is particularly important for patients with spinal cord injury managed with indwelling urethral or supra pubic catheters (references below). Indeed one of the references in support of cystoscopic surveillance suggests that this should be carried out on all patients with spinal cord injury irrespective of the method of bladder drainage (Kalisvart *et al*). **The following is a brief summary of literature (with references at the end) in support of regular cystoscopic surveillance in spinal cord injured patients.** The University of Tennessee [(1)] evaluated the risk factors for development of bladder tumors in SCI patients in a retrospective study. They reviewed all bladder tumors at 1 institution with matched controls for 7 years. There were 17 malignant and 2 benign tumors identified. There was statistically significant evidence for bladder stones and indwelling catheters as risk factors. Interestingly 4 biopsies although negative initially underwent repeat biopsies and cancers were found. El Masri and Fellows [(2)] studied a series of **6744** SCI patients with 25 diagnosed cancer bladder. They confirmed that the majority presented at younger age and there was a significantly higher incidence of	cystoscopy or any other test satisfies the accepted criteria for use in the context of screening for disease in a population. To illustrate this one can use the data from El Masri and Fellows. How many cystoscopies would need to be performed to detect 25 cancers in a population of 6,744 people? How many of the 25 would have been diagnosed earlier than they were? Would they have benefitted from an earlier diagnosis? What would the morbidity and cost of the thousands of cystoscopies have been? To answer the question as to whether routine cystoscopy is appropriate requires a prospective controlled trial of its use in a screening context. In the absence of such evidence, and in view of the very doubtful benefit of screening over prompt investigation of the symptomatic patient, the GDG took the view that the use of an invasive investigation that is known to be associated with some morbidity could not be recommended. The guideline recommendations strongly support the urgent referral and investigation of "red flag" symptoms that might suggest that

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						Squamous cell carcinoma (SCC). The interval between injury and diagnosis varied between 11 and 42 years with a mean of 23 years. They concluded that urine cytology is unreliable in presence of infection and haematuria being common in patients with neuropathic bladder due to infection or catheter trauma. Cord injury increased the risk of dying of bladder cancers by a factor of about 20. The diagnosis was delayed in the majority of the patients. Twenty out of the twenty five patients died within 2 years of diagnosis. They advocated vigilant investigation of urinary tract including Cystoscopy and biopsy. Kalisvaart [(3)] examined the characteristics of bladder cancers in a spinal cord injury (SCI) population. They included all SCI patients seen and diagnosed with bladder tumors between January 1983 and January 2007. There were 32 patients with bladder cancer identified out of **1319** patients seen. There were 46.9% squamous cell carcinoma (SCC), 31.3% transitional cell carcinoma (TCC), 9.4% adeno-carcinoma, and 12.5% mixed TCC and SCC. 42% of them were found on screening Cystoscopy. They concluded that Neurogenic bladder of spinal cord injury patients may be the risk factor for bladder cancer. Babjuk *et al* [(4)] demonstrated that the diagnosis of bladder cancer ultimately depends on cystoscopic examination of the bladder and histological evaluation of the	a bladder cancer has developed.

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						resected tissue. Chao et al [5] retrospectively reviewed traumatic SCI patients injured over 20 years or more to compare urinary tract preservation and incidence of urologic complications in patients with spontaneous voiding and indwelling catheters. There were 81 patients with long term injury but only 73 were regularly followed up. They included people on intermittent catheters and reflex voiding in spontaneous voider group (n=41), indwelling catheter group (n=32) comprised of urethral and suprapubic catheter. They analysed renal function, renal tract imaging and incidence of complications in both these groups. The renal function measure by creatinine clearance was similar in both groups. The catheterised group had higher prevalence of scarring and caliectasis which was statistically significant. There were 6 patients diagnosed with carcinoma bladder. who underwent radical cystectomy and diversion. Two of these were spontaneous voiders with Transitional Cell Carcinoma (TCC) and three were with indwelling catheters (1 TCC, 1 SCC and 1 Adenocarcinoma). They concluded that patients with SCI requiring indwelling catheter can be managed safely provided they undergo regular cystoscopy and urinary tract regular surveillance. Kamat et al [6] conducted an interesting health economic study to identify optimal	

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						bladder cancer surveillance and its cost. They assessed cost effectiveness of use of cytological evaluation in addition to Cystoscopy in 200 consecutive patients with a history of bladder cancer not invading the muscle undergoing surveillance for recurrence. They compared 5 surveillance and concluded that Cystoscopy alone remains the most cost-effective strategy to detect recurrence of bladder cancer not invading the muscle. The addition of urinary markers adds to cost, without improved detection of invasive disease. Navon et al [(7)] in California evaluated the effectiveness of annual cystoscopy in chronic SCI patients. They reviewed the medical records of all spinal cord injured patients with squamous cell cancer of the bladder between 1980 and 1996. They concluded that cystoscopy to screen for squamous cell cancer of the bladder in spinal cord injured patients with chronic or recurrent urinary tract infection results in an earlier stage at diagnosis and appears to convey a survival advantage. In-fact they went on to suggest that such a protocol should be strictly followed. Groah et al[8] in 2002 found 21 cases of bladder cancer in 3760 patients with SCI with a risk of 77/100,000 persons – year corresponding to an age and gender-adjusted standardized morbidity ratio	

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						(SMR) of 25.4 **(**95% confidence interval(CI),14.0-41.9**)** when compared with the general population . After controlling for age at injury, gender, level of completeness of the SCI, history of bladder calculi and smoking they found that those using solely indwelling catheters had a significantly greater risk of bladder cancer **(**relative risk (RR) = 4.9; 95% CI, 1.3-13.8**)** than those using non indwelling methods of drainage. They concluded that mortality caused by bladder cancer in individuals with SCCI is significantly greater than that of the USA population **(**SMR = 70.6; 95% CI 36.9-123.3**)** **References:** 1. **Risk factors for bladder tumors in spinal cord injury patients.** J Urol. 1996 Apr; 155(4):1248-50. Stonehill WH, Dmochowski RR, Patterson AL, Cox CE. Department of Urology, University of Tennessee, Memphis, Tennessee, USA. 2. **Bladder cancer after spinal cord injury.** Paraplegia. 1981;19(5):265-70. El-Masri WS, Fellows G. 3**. Bladder cancer in spinal cord injury patients.** Spinal Cord. 2010 Mar;48(3):257-61. Epub 2009 Sep 15. Kalisvaart JF, Katsumi HK, Ronningen LD,	

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						Hovey RM. SourceDepartment of Urology, University of California, Irvine, CA, USA. jonkalisvaart@gmail.edu 4. **Guidelines on Non-muscle-invasive Bladder Cancer (TaT1 and CIS)** M. Babjuk, W. Oosterlinck, R. Sylvester, E. Kaasinen, A. Böhle, J. Palou, M. Rouprêt European Association of Urology 2012 5. **Fate of upper urinary tracts in patients with indwelling catheters after spinal cord injury.** **Urology. 1993 Sep;42(3):259-62** Chao R, Clowers D, Mayo ME. SourceDepartment of Urology, University of Washington, Seattle 6. **Prospective trial to identify optimal bladder cancer surveillance protocol: reducing costs while maximizing sensitivity.** BJU Int. 2011 Oct;108(7):1119-23. doi: 10.1111/j.1464-410X.2010.10026.x. Epub 2011 Mar 22 Kamat AM, Karam JA, Grossman HB, Kader AK, Munsell M, Dinney CP. SourceDepartment of Urology, The University of Texas MD Anderson Cancer Center, Houston, TX 77030, USA. akamat@mdanderson.org 7. **Screening cystoscopy and survival of spinal cord injured patients with squamous cell cancer of the bladder.**	

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						J Urol. 1997 Jun;157(6):2109-11 Navon JD, Soliman H, Khonsari F, Ahlering T. Source Department of Surgery, University of California, Irvine Medical Center, Orange, USA 8. **Excess risk of bladder cancer in Spinal Cord Injury: Evidence for an association between Indwelling Catheter use and Bladder Cancer.** Archives Physical Med. And Rehab. Vol 83 March 2002 Groah SL, Weitzenkamp DA, Lammertse DP, Whiteneck GG, Lezotte DC, Hamman RF USA	
SH	Robert Jones & Agnes Hunt Orthopaedic Hospital NHS Foundation Trust, Oswestry	2	**FULL**	**40**	**28-29**	**We strongly disagree to the recommendation number 60 that routine cystoscopic surveillance is not required for patients with neurogenic bladder from a spinal cord injury. Current evidence does not support this recommendation.** **Although there is some evidence that all SCI patients would benefit from regular cystoscopy such evidence is not compelling. There is however irrefutably strong evidence to compel those who look after spinal cord injury patients with permanent Indwelling urethral or supra pubic catheters to carry out regular cystoscopic surveillance on an annual or alternate year basis depending on the cystoscopic findings.**	Thank you for your comments and suggestions. The evidence was searched for on the basis of looking for studies on surveillance regimes. The papers that are quoted all look at a different question, namely the incidence of bladder cancer in SCI patients. The quoted papers provide different estimates of the risk of bladder cancer – the validity of the estimates is reviewed by Subramanian et al BJUI 2004, 93, 739-743. Although there is probably an increased risk of developing a fatal bladder cancer in patients with

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						We would request the Panel to reconsider this recommendation taking into account the aforementioned evidence.	SCI, the question is whether cystoscopy or any other test satisfies the accepted criteria for use in the context of screening for disease in a population. To illustrate this one can use the data from El Masri and Fellows. How many cystoscopies would need to be performed to detect 25 cancers in a population of 6,744 people? How many of the 25 would have been diagnosed earlier than they were? Would they have benefitted from an earlier diagnosis? What would the morbidity and cost of the thousands of cystoscopies have been? To answer the question as to whether routine cystoscopy is appropriate requires a prospective controlled trial of its use in a screening context. In the absence of such evidence, and in view of the very doubtful benefit of screening over prompt investigation of the symptomatic patient, the GDG took the view that the use of an invasive investigation that is known to be associated with some morbidity could not be recommended. The guideline recommendations strongly support the urgent referral and investigation of "red flag"

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							symptoms that might suggest that a bladder cancer has developed.
SH	Robert Jones & Agnes Hunt Orthopaedic Hospital NHS Foundation Trust, Oswestry	3	**FULL**	**39**	**14 – 16**	**We do not agree with the recommendation number 46: "Do not offer alpha-blockers to patients with bladder emptying problems caused by neurological disease".** **Although alpha blockers may not significantly reduce the Leak point pressure in patients with neurogenic bladder from spinal cord injury; alpha blockers are very effective in reducing the autonomic symptoms that can be associated with detrusor sphincter dyssynergia.**	We did not find any evidence on which to base support for the use of alpha blockers to treat urinary symptoms. We did not loo k at the use of these, or any other drugs, in the treatment of autonomic dysreflexia which was outside the remit of the guideline.
SH	Royal College of Nursing	1	General	general	general	The Royal College of Nursing welcomes this guideline. It is comprehensive.	Thank you.
SH	Royal College of Nursing	2	NICE	11	1	How frequently should those with risk of renal impairment have upper tract screening?	Thank you for your comment. The GDG suggested annual or 2 yearly intervals for those at high risk of renal complications
SH	Royal College of Nursing	3	NICE	20	1.4.1	This section seems to imply that biofeedback and electrical stimulation are used routinely as a first line intervention when working on pelvic floor muscle function. It omits to mention that pelvic floor function and treatment can be assessed and improved without biofeedback in the first instance and this would be a first line	Thank you for your comment. We have amended the recommendation based on your suggestion: It now reads: Consider pelvic floor muscle training for people with: o Lower urinary tract dysfunction due to multiple sclerosis or stroke

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						intervention as recommended in the NICE Guideline CG40.	Or ○ Other neurological conditions where the potential to voluntarily contract the pelvic floor is preserved. • Select patients for this training after specialist pelvic floor assessment and consider combining treatment with biofeedback and/or electrical stimulation of the pelvic floor.
SH	Royal College of Nursing	4	NICE	21	1.6	Catheter valve - should patients have upper tract monitoring or urea and creatinne checked prior to using a catheter valve?	Thank you for your comment. The recommendation 1.6.3 in the section: catheter valve management reminds people that monitoring might be needed in some people who could have high pressure bladder storage. These individuals would be classed as high risk on the basis of their neurological diagnosis and/or urodynamic findings. The monitoring that is put in place is dealt with in the monitoring and surveillance section.

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SH	Royal College of Paediatrics and Child Health	1	Full	General		A very welcome and useful addition to NICE guidelines.	Thank you.
SH	Royal College of Paediatrics and Child Health	2	Full	General		Research recommendation: Monitoring of LUT function in severe cerebral palsy (GMFCS 4/5) from childhood into adulthood as this increasing group ages in order to classify their long-term risk category.	Thank you for your comment. This is a good suggestion, however we are not able to draft research recommendations for areas of research not looked at.
SH	Royal College of Paediatrics and Child Health	3	Full	36	16	A table of high risk and low risk conditions would be useful potentially to include "unknown risk" in addition.	The GDG felt that it was not possible to produce such a table but have indicated in the recommendations groups who might be considered as high or low risk.
SH	Royal College of Paediatrics and Child Health	4	Full	37	23	Define specialist continence assessment.	Thank you this has been amended and now reads: 'after assessment by a healthcare professional trained in the assessment of people with neurogenic lower urinary tract dysfunction'.
SH	Royal College of Paediatrics and Child Health	5	Full	40	19 and 25	When making recommendations for lifelong ultrasound surveillance/and consider surveillance with urodynamics, what frequency of surveillance was considered by the GDG?	The GDG agreed there was no good evidence but have suggested the frequency based on consensus.
SH	Royal College of	6	Full	117		Does the GDG feel able to make a	We did not feel able to get involved

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	Paediatrics and Child Health					recommendation between pre-emptive and wait-and-see approach in children with raised bladder storage pressures?	in such a specific area that will impact only on care in specialised units. It is an issue that might be best addressed by British Association of Paediatric Surgeons.
SH	Royal College of Paediatrics and Child Health	7	Full	118		Research recommendation: Does the use of early antimuscarinics for NLUTD affect cognitive development in children? Randomised multi-centre study in children with MMC/two groups; antimuscarinics vs botox A.	Thank you for your comment. This is an excellent suggestion. The existing research recommendations would implicitly support such a trial.
SH	Royal College of Paediatrics and Child Health	8	Full	292		The lack of an analysis looking at the benefit of catheterisation pre-empts the ability to recommend catheterisation and in particular early CIC in MMC/high risk children in which it is protective in the long-term. Is it accurate to inform parents of infants with high risk bladders that CIC is associated with increased risks of renal impairment? We inform them of the opposite.	Thank you for your comment the recommendation has been amended to: 'When discussing treatment options, tell the person that indwelling urethral catheters may be associated with higher risks of renal complications than other forms of bladder management.'
SH	SOLENT NHS TRUST	1	Full	10 12		Named individual not possible in all areas – this area is team transfer. Abdo and Genitalic examination not routine in this area, it would be put under the vaginal and rectal exam if clinically indicated, NOT a routine.	Thank you for your comment. We think it is possible to identify a lead clinician or nurse Abdominal and external genital examination should be routine i.e. only omitted for good reason.
SH	SOLENT NHS TRUST	2	Full	15 23		Perhaps a research link required for this or definition of 'low risk' – the wording may lead to ALL MS pts being eliminated from this. Individual case maybe identified rather	Thank you for your comment, this recommendation has been amended and now specifies: "most people with multiple

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						than condition. ? spelling – SCINTI rather than SCINTO – Scintigraphy.	sclerosis" We have also corrected the spelling of Scintigraphy in both versions of the guideline.
SH	Sue Ryder	1	Full	34	19-20	In addition to ensuring the smooth access and interaction of services at transition stage from paediatric to adult services, the same priorities and guidance need to be adhered to when transferring from one care provider to another. This will ensure a clear and structured care pathway. This should not be a unique recommendation to any particular age group.	Thank you for your comment. We agree, that this should not be a unique recommendation to a particular age group. However, our question was specifically addressing child to adult service and this was the area of literature reviewed. We are therefore only able to make recommendations on this. Recommendations related to continuity of care could be found in section 1.4 of the Patient experience guideline (CG138).
SH	Sue Ryder	2	Full	44	18-20	We agree that there is currently insufficient evidence about which bladder management strategies are best for patients, their family members and carers. The standard needs to recognise care that puts individuals first and this needs to be supported by validated research which is currently lacking. We therefore welcome the research recommendation that looks at the effect of different management strategies have on the quality of life for patients and their families.	Thank you.
SH	Sue Ryder	3	Full	69	16	We agree with the recommendations made for accessing appropriate information and advice, in particular access to information to participate in self management.	Thank you.

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SH	Sue Ryder	4	Full	83	39	We agree with the recommendation that there needs to be well trained staff in order to provide necessary training and education for patients and carers.	Thank you.
SH	Sue Ryder	5	Full	248	18	In addition cognitive ability, manual dexterity or the availability of a carer to assist must also be considered when putting together an individual's support plan.	We agree and this is now reflected in the LETR section.
SH	Sue Ryder	6	Full	269	8	Repetitive recommendation, this inhibits clarity and could make implementation more bureaucratic.	Thank you for your comment these recommendations address different issues and we do not consider them to be repetitive.
SH	Sue Ryder	7	Full	308	1	We echo the importance of, and support the need for this research recommendation. We would stress the lack of existing research to inform patient choice about appropriate methods for long term treatments and end of life care.	Agreed. However we didn't look at this area and therefore are unable to make a research recommendation.
SH	The Paediatric Continence Forum (PCF)	1	NICE	23		In light of research that suggests there may be a heightened risk of malignancy in those who have undergone bladder augmentation surgery, we would suggest that the Monitoring and Surveillance Protocols include following up with these patients over the long term.	Thank you for your suggestion. We have added the following recommendation to our guidance: Offer patients life-long follow up after augmentation cystoplasty in view of the risk of long-term complications. Potential risks include metabolic effects, such as the development of vitamin B12 deficiency, and the development of bladder cancer.
SH	The Paediatric	2	NICE	General		The PCF welcomes this guidance from	Thank you for your comment.

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	Continence Forum (PCF)					NICE, which deals particularly effectively with surgical matters. The draft guideline rightly notes the importance of a holistic approach and on this front we would suggest the following three additions for NICE's consideration: The guideline could benefit from including recommendations on bowel management to prevent and treat constipation and to resolve faecal incontinence. Both of these problems increase the risk of UTIs. The guideline could benefit from a recommendation on introducing clean intermittent catheterisation. It is especially important to start this early with infants born with spina bifida for instance. Finally the guideline could benefit from recommendations concerning the use of appliances such as sheaths as part of management. This can negate the need for pads.	Unfortunately, bowel management is not within the remit of this guideline, please refer to Faecal Incontinence guidance (CG49). Regarding the introduction of clean intermittent catheterisation, we agree that this important and this is now 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 patients are all managed in highly specialised units. The use of appliances such as sheaths as management, was not prioritised by the GDG as one of the clinical questions to include within the guideline.
SH	UK Clinical Pharmacy Association	1				We have no comments to make at this time.	Thank you.
SH	UK Multiple Sclerosis Specialist Nurse Association (UKMSSNA)	1	Full	General		This looks a pretty comprehensive document, it appears to cover all aspects and I feel it is self- explanatory and will provide good, clear guidelines for us to utilise.	Thank you.

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SH	Urology User Group Coalition	1	NICE	23	1.9	Under Monitoring and Surveillance there is no mention of long term monitoring of those individuals who have undergone bladder augmentation using a section of bowel. There is evidence of potential risk of malignancy in such cases and as a result long term follow-up is usually advised. People undergoing bladder augmentation should be told of the increased risk of bladder cancer, formation of mucus bladder stones and the need for Intermittent Self Catheterisation or other mode of catheterisation. This will allow patients and others to cross reference to the sections on bladder stones and bladder cancer, and the need for lifelong renal monitoring.	Thank you for your comment. We have added a recommendation under the augmentation cystoplasty section that states: Offer patients 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. Further recommendations on providing information to patients on potential complications can be found in section 1.10 of the NICE guideline .
SH	Urology User Group Coalition	2	NICE	General		While this guidance is very much welcomed it appears to be largely surgically focused. It mentions the importance of a holistic approach to management but no recommendations have been made regarding ensuring appropriate bowel management to prevent/treat constipation and to resolve any faecal incontinence – both problems which increase the risk of UTI's. There is no recommendation regarding the introduction of clean intermittent catheterisation and points such the importance of commencing this early in infants born with conditions such spina	Thank you for your comment. Bowel management is not within the remit of this guideline and reference has been made to the Faecal Incontinence guideline (CG49). We agree that the management of ISC and sheaths are important and this is now reflected within the algorithms developed alongside the guideline. We consider that the use of intermittent catheterisation in infants does not need specific mention as such patients are all managed in highly

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						bifida. Also there is no mention of the use of appliances such as sheaths as part of management, which can negate the use of pads.	specialised units.
SH	Urology User Group Coalition	3	NICE	General		The guidance does not appear to be patient centred, but almost purely medically focused. People with neurological lower urinary dysfunction must be encouraged to make decisions and choices over their own treatment, and this should be reflected in the guidance. Most will need to manage the dysfunction for life.	Thank you for your comment. We think that this is addressed in the Access and Interaction with services section; cross reference has also been made to the Patient Experience Guideline which addresses the areas you raise. There is a lot of medical focus in the guideline because there are a lot of important messages that need to be widely disseminated to healthcare professionals in order to improve patient care.
SH	Urology User Group Coalition	4	NICE	General		Although we welcome the clinical guidance and most of the recommendations, the guidance seems somewhat disjointed in places. e.g. the section on catheter valves (1.6) seems out of context. Catheter valves may technically maintain normal bladder volumes in some patients but the evidence that they improve bladder emptying is lacking.	Thank you for your comment. The GDG believes that the overall structure of the guideline works for the presentation of evidence in what is, a complex field with many different facets. Noted, thank you for your view, however we have not meant to imply that catheter valves maintain normal bladder volumes or improve bladder emptying.

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SH	Urology User Group Coalition	5	Full	48		Recommendation 7 states "be aware that bacterial colonisation will be present in people using a catheter and so urine dipstick testing and bacterial culture may be unreliable for diagnosing active infection." However, this does not state what type of catheter. People who use intermittent catheters should not have bacterial colonisation. Anecdotally, we are aware of people who have used ISC for 20 years without colonisation. Others have had a deterioration in their normal status with a suprapubic/indwelling catheter and been told by a healthcare professional that they do not have a UTI, only bacteriauria, but when later treated with antibiotics the symptoms cleared and they were able to feel well again. This recommendation could mean that many people will go untreated for UTIs, with the resultant morbidity. There has been little research into preventing bacterial colonisation in people with long term indwelling catheters. It is just assumed it will occur.	Patients on intermittent catheterisation do in fact have bacterial colonisation. Numerous studies have shown that bacteria can be cultured from a high proportion of urine samples taken from individuals on self catheterisation. Unfortunately, the imprecision in the diagnostic tools that are available (clinical assessment, dip testing and urine culture) do mean that a degree of over and under treatment will continue to be present. There is good evidence that shows that bacterial colonisation of patients with in-dwelling catheters is inevitable. Reducing the conversion of such colonisation to active infection has been studied using antibiotics, silver catheters and other approaches.
SH	Urology User Group Coalition	6	Full	64		In the section on information and support there is no mention that patients should be given a choice about treatment options and use of products. Patients can only be put at the centre of their care if they have such a choice and are able to work in partnership with their clinicians to find the right products to meet their individual clinical and lifestyle	The GDG agrees with your comments on patient centred care and refers to the Patient Experience guideline which puts the patient firmly at the centre of their care and decision-making. We agree that the issue of access to a range of products is important

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						needs. This will enable participation in society, allowing **equality of opportunity.** It is vital that catheter and sheath users are given information about the different types of catheter and sheaths and drainage systems on the market. No one or two will be suitable for ISC, indwelling catheter/ suprapubic catheter or sheath users lifestyle and clinical needs. It is essential that users are allowed to try a range of products in their home and lifestyle settings to enable them to overcome individual impairments. Patients should be able to take advantage of innovation and products designed for use by patients, not by health care professionals, and be able to participate in society more easily. This is an example of **equality of opportunity** under the Equality Act. Too often people are limited to one or two products that an HCP thinks may suit them. It is vital that patients and their carers are given information about the range of prescribable continence and urology products on the Drug Tariff so that they are able to try different ones to meet lifestyle and clinical needs. Catheter design may influence whether a person successfully copes with intermittent self catheterisation. Design is also important in helping people use sheaths and indwelling or suprapubic catheters. The same principles also apply to people who	and the GDG have made an additional recommendation to emphasise this: Offer people with neurogenic urinary tract dysfunction, their family members and carers specific information and training. Ensure that people who are starting to use, or are using, a bladder management system that involves the use of catheters, appliances or pads: receive training, support and review from healthcare professionals who are trained to provide support in the relevant bladder management systems and are knowledgeable about the range of products available have access to a range of products that meet their needs have their products reviewed, at a maximum of 2 yearly intervals.

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						choose to manage long term incontinence by pad use. It is vital they are given a range of products to try in sufficient quantities to enable them to partake in society without loss of dignity or fear of embarrassment. Education of non specialist community health staff in the range of products available to manage incontinence is vital in ensuring that they can help patients make the best decisions.	
SH	Urology User Group Coalition	7	General			We are surprised there is no recommendation about long term follow up of people with neurological conditions with lower urinary tract dysfunction to ensure that they are continuing to use the best products for their needs. Many patients have been "lost" and continue to use catheters and sheaths/ drainage systems. They should have the opportunity to be followed up by a specialist continence advisor or urology nurse at least every 12 months so that their individual clinical and lifestyle needs can be reassessed and they can be updated on treatment choice.	We agree that the issue of access to a range of products is important and the GDG have made an additional recommendation to emphasise this. "Offer people with neurogenic urinary tract dysfunction, their family members and carers specific information and training. Ensure that people who are starting to use, or are using, a bladder management system that involves the use of catheters, appliances or pads: receive training, support and review from healthcare professionals who are trained to provide support in the relevant bladder management systems and are knowledgeable about the range of products available

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