NICE National Institute for Health and Care Excellence

Appendix B: Stakeholder consultation comments table

2019 surveillance of Lower urinary tract symptoms in men: management (2010)

Consultation dates: Thursday 25 July to Wednesday 7 August 2019

1. Do you agree with the proposal to not update the guideline?			
Stakeholder	**Overall response**	**Comments**	**NICE response**
Royal College of Nursing	No	We are very surprised that NICE are not updating this guideline as it was published 2010 and last updated in 2013. Since then, the management of the condition has changed. There is much more use of day case surgery and laser treatments for managing the condition which needs to be reflected in the guideline.	Thank you for your comment. Following stakeholder feedback, the 2019 surveillance review decision is to update the guideline section on surgical treatment of lower urinary tract symptoms. The information obtained through the surveillance review, including feedback from stakeholders through this consultation, will be passed onto developers for consideration during the update of the guideline.
Bladder and Bowel UK	Yes	Yes, agree with the proposal. The guideline is comprehensive and does not appear to need any additions or subtractions	Thank you for your comment.

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Ferring Pharmaceuticals	No	We propose that the guideline should be updated. As the treatment options have changed since the guidelines were last written, we propose they are updated to ensure health care professionals are aware of the low dose forms of desmopressin which may provide a safer option in adults and includes the over 65 population. In section 1.4.9 the guideline currently recommends 'offering oral desmopressin to men with nocturnal polyuria if other medical causes have been excluded and they have not benefited with other treatments.' The guideline also states that at the time of publication desmopressin did not have a UK marketing authorisation for this indication. Since 2015, there is now a UK licenced low dose form of desmopressin (oral lyophilisate) available. The 50 µg dose of desmopressin (oral lyophilisate) is licenced for men with nocturia due to idiopathic nocturnal polyuria in all adults, including the over 65's. Serum sodium monitoring is recommended only in the over 65's before initiating treatment, in the first week (4-8 days after initiation) and again at one month. Treatment should be discontinued if the serum sodium falls below the lower range (<135 mmol/L). Clinical efficacy of low dose desmopressin oral lyophilisate for men (50 µg) and women (25 µg) has been demonstrated in two phase III clinical trials1,2. In men, low dose desmopressin significantly reduced the frequency of nocturnal voids compared to placebo at 3 months (-1.25 voids vs -0.88 voids, treatment difference -0.37 voids, 95% CI: -0.57 to -0.17, p=0.0003). This was a clinically meaningful difference specifically in men with nocturia due to nocturnal polyuria3. Furthermore, low	Thank you for your comment. Following stakeholder feedback, the 2019 surveillance review decision is to update the guideline section on surgical treatment of lower urinary tract symptoms. The information obtained through the surveillance review, including feedback from stakeholders through this consultation, will be passed onto developers for consideration during the update of the guideline. The new evidence identified during this current surveillance review supports the guideline recommendation that oral desmopressin should be offered to men with nocturnal polyuria if other medical causes have been excluded and they have not benefited from other treatments. NICE advises to consult the summary of product characteristics for the contraindications and precautions and appropriate dose. A link to BNF (Desmopressin: indications and dose) will be add to recommendation 1.4.9 and the relevant foot note stating UK marketing authorisation of the drug will be amended. Thank you for highlighting references related to the guideline: Weiss et al. 2013 is included in the summary of the evidence in the current review and the finding supports current recommendation that oral desmopressin should be offered to men with nocturnal polyuria if other medical causes have been excluded and they have not benefited from other treatments. Sand et al. 2013 is not qualified for inclusion as the study population was comprised of only women. Weiss et al. 2018 is not included as the study population is consisted of men and women and (from reviewing the abstract) it is

		dose desmopressin improved the time to first void and sleep quality, compared with placebo at 3 months (118.8 mins vs 72.9 mins, treatment difference: 39 mins, 95% CI: 11.0 to 66.9, p=0.006). Low dose desmopressin has a favourably safety profile and has been specifically developed to address the risk of hyponatraemia, which is the most serious adverse reaction of desmopressin. Clinically significant (moderate to severe) hyponatraemia occurred in 2% of patients receiving low dose desmopressin in the phase III clinical trials1,2. References 1. Weiss, JP. et al. Efficacy and safety of low dose desmopressin orally disintegrating tablet in men with nocturia: results of a multicenter, randomized, double-blind, placebo controlled, parallel group study. The Journal of Urology 2013;190(3):965-972 2. Sand, PK. et al. Efficacy and safety of low dose desmopressin orally disintegrating tablet in women with nocturia: results of a multicenter, randomized, double-blind, placebo controlled, parallel group study. The Journal of Urology 2013a;190(3):958-964 3. Weiss, JP. et al. Low-dose Desmopressin Orally Disintegrating Tablet: Suggested Clinically Meaningful Benefit in Patients with Nocturia Due to Nocturnal Polyuria. Eur Urol Focus. 2018 Nov 20 2018 Nov 20. pii: S2405-4569(18)30333	not clear if nocturia in men caused by benign prostatic hyperplasia (the focus of this guideline).
Royal College of Physicians and Surgeons of Glasgow	No	Our reviewer disagreed, and felt that the guideline should be updated. There has been new evidence by way of publications on	Thank you for your comment. Following stakeholder feedback, the 2019 surveillance review decision is to update the guideline section on surgical treatment of lower urinary tract symptoms. The

		the outcome of several new procedures such as UroLiftÒ, RezumÒ , AquablationÒ and PAE (Prostate Artery Embolisation). These are not addressed at all in Section 1.5 of CG97, and the evidence base for using these procedures should be discussed and form part of the updated guidelines.	information obtained through the surveillance review, including feedback from stakeholders through this consultation, will be passed onto developers for consideration during the update of the guideline.
GlaxoSmithKline	No	GSK believes it would be helpful to update this guideline. In Section 1.4 Drug Treatment there is new safety evidence that is relevant and should be considered. This refers to Roehrborn CG et al. BJU Int. 2018; 121(4):647-658. (A prospective randomised placebo-controlled study of the impact of dutasteride/tamsulosin combination therapy on sexual function domains in sexually active men with lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH)). GSK would like to ask whether the study referred to above has been reviewed in the surveillance.	Thank you for your comment. A combination of an alpha blocker and a 5-alpha reductase inhibitor is recommended in the current guideline for men with bothersome moderate to severe LUTS however, no specific drug or dosage is mentioned. New evidence on alpha blocker combination therapy is in line with the current recommendations and no new evidence was identified which would change the recommendation. Roehrborn et al. 2018 was not considered for inclusion because treatment of LUTS was not the primary or secondary aims of this study. The study evaluated the efficacy and safety of once daily dutasteride 0.5 mg and tamsulosin 0.4 mg compared with placebo on sextual function in 489 men with LUTS. The study reported that the proportion of patients with any adverse effects (AEs), serious AEs, and drug-related AEs was significantly higher in the intervention group than in the placebo group. However, factors, such as age, co-medications, patients' and physician's perceptions, comorbidities and how information is collected (at baseline, during the trial and follow-up) may have affected the findings.

British Association of Urological Surgeons (BAUS)	No	multiple advances and studies on BPH since LUTS guidance, including combination therapies and minimally invasive surgical options. Upstream publication to advise on Urodynamics.	Thank you for your comment. The guideline was reviewed in 2012 and 2014. Following the 2014 surveillance review the guideline was updated around the use of phosophodiesterase-5 inhibitors. New evidence on combination therapies identified in the current surveillance review reinforces the current recommendations in NICE GC97 (see appendix A). Thank you for highlighting the on-going UPSTREAM trial. We will track this study to check for its publication. And developers will consider its findings during the proposed update of this guideline if the results are available. Following stakeholder feedback, the 2019 surveillance review decision is to update the guideline section on surgical treatment of lower urinary tract symptoms. The information obtained through the surveillance review, including feedback from stakeholders through this consultation, will be passed onto developers for consideration during the update of the guideline.

2. Do you have any comments on areas excluded from the scope of the guideline?

Stakeholder	Overall response	Comments	NICE response
Royal College of Nursing	No	No comments	Thank you for your comment.
Bladder and Bowel UK	Yes - agree	Agree there are no exclusions and that other related guidelines are available to cover any gaps that may exist in specialist practice	Thank you for your comment.

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Ferring Pharmaceuticals	Yes	YES: In section 1.4.9 the guideline currently recommends 'offering oral desmopressin to men with nocturnal polyuria if other medical causes have been excluded and they have not benefited with other treatments.' The guideline also states that at the time of publication desmopressin did not have a UK marketing authorisation for this indication. Since 2015, there is now a UK licenced low dose form of desmopressin (oral lyophilisate) available. The 50 µg dose of desmopressin (oral lyophilisate) is licenced for men with nocturia due to idiopathic nocturnal polyuria in all adults, including the over 65's. Serum sodium monitoring is recommended only in the over 65's before initiating treatment, in the first week (4-8 days after initiation) and again at one month. Treatment should be discontinued if the serum sodium falls below the lower range (<135 mmol/L).	New evidence supports the guideline recommendation that oral desmopressin should be offered to men with nocturnal polyuria if other medical causes have been excluded and they have not benefited from other treatments. NICE does not provide detailed information on administration of medicines but advises that the summary of product characteristics is consulted for the most up to date information contraindications and precautions and appropriate dose. A link to BNF (Desmopressin: indications and dose) will be added to recommendation 1.4.9. The foot note describing UK marketing authorisation of desmopressin will be updated to reflect the current licensing status.
Royal College of Physicians and Surgeons of Glasgow	No	Our reviewer disagreed, and felt that the guideline should be updated. There has been new evidence by way of publications on the outcome of several new procedures such as UroLiftÒ, RezumÒ , AquablationÒ and PAE (Prostate Artery Embolisation). These are not addressed at all in Section 1.5 of CG97, and the evidence base for using these procedures should be discussed and form part of the updated guidelines.	Thank you for your comment. Following stakeholder feedback, the 2019 surveillance review decision is to update the guideline section on surgical treatment of lower urinary tract symptoms. The information obtained through the surveillance review, including feedback from stakeholders through this consultation, will be passed onto developers for consideration during the update of the guideline.

GlaxoSmithKline	No	No comments	
British Association of Urological Surgeons (BAUS)	Yes	Should also have a section to advise GPs on PSA and DRE and LUTs	Thank you for your comment. The recommendations on initial assessment (1.1.1, 1.1.2, 1.1.5) provide advice on PSA and DRE.

3. Do you have any comments on equalities issues?

Stakeholder	Overall response	Comments	NICE response
Royal College of Nursing	No	No comments	Thank you.
Bladder and Bowel UK	No comments	No comments. All ok	Thank you.
Ferring Pharmaceuticals	Yes	YES: there needs to be equivalent guidelines with updated treatment options for women. The responses to Questions 1 and 2 need to be applied to equivalent guidelines with gender specific treatment for women.	Thank you for your comment. NICE has produced a guideline on Urinary incontinence and pelvic organ prolapse in women: management (NG123). In addition NICE has produced Clinical Knowledge Summaries on Incontinence - urinary, in women, and Urinary tract infection (lower) - women.
Royal College of Physicians and Surgeons of Glasgow	No	No equalities issues.	Thank you for your comment.

GlaxoSmithKline	No	No comments	Thank you.
British Association of Urological Surgeons (BAUS)	Yes	Female NICE guidance updated twice since initial publication in 2006.	Thank you for your comment. The LUTS guideline was reviewed in 2012 and 2014. Following the 2014 surveillance review, the guideline was updated after new evidence was identified around use of phosophodiesterase-5 inhibitors. Following stakeholder feedback, the 2019 surveillance review decision is to update the guideline section on surgical treatment of lower urinary tract symptoms. The information obtained through the surveillance review, including feedback from stakeholders through this consultation, will be passed onto developers for consideration during the update of the guideline.