Urinary incontinence in women (update) and pelvic organ prolapse in women: management

Consultation on draft scope

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1.	3	SH	Ferring UK	General	General	There needs to be an update on nocturia and the use of desmopressin: at the moment the guidance refers to the off-license use of desmopressin at higher doses. A new formulation of desmopressin is now licensed for nocturnal polyuria and is particularly suitable for use in the over 65s. This update is not included in the scope.	Thank you for your comment. The footnote on desmopressin will be updated in line with licensing.
2.	11	SH	Medtronic Ltd	General	General	The current NICE guideline and 2015 surveillance documents uses proprietary acronyms to refer to bladder treatment options based on electrical stimulation of nerves:: P-SNS for "percutaneous sacral nerve stimulation" T-SNS for "transcutaneous sacral nerve stimulation" P-PTNS for "percutaneous posterior tibial nerve stimulation" T-PTNS for "transcutaneous posterior tibial nerve stimulation" This terminology is rarely used in literature and common practice. SNS (sacral nerve stimulation) or SNM (sacral neuromodulation) are commonly used for percutaneous sacral nerve stimulation. Transcutaneous sacral nerve stimulation is differentiated by the name prefix "transcutaneous" (i.e. transcutaneous SNS). PTNS (posterior tibial nerve stimulation) is commonly used for percutaneous sacral nerve stimulation. Transcutaneous posterior tibial nerve stimulation is differentiated by the name prefix "transcutaneous" (i.e. transcutaneous PTNS). We feel that the acronyms used by NICE in the CG171 might generate confusion in the guideline users. The use of the common acronyms (SNS/SNM; PTNS) in combination with the name prefixes "percutaneous" or "transcutaneous" (e.g. transcutaneous SNS) might facilitate the translation of the guidelines into practice.	Thank you for your comment. We will consider the terminology in this section when preparing the guideline update.

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3.	12	SH	Medtronic Ltd	General	General	Some recent literature use PTNM (posterior tibial neuromodulation) instead of PTNS (posterior tibial nerve stimulation).	Thank you for your comment. We will consider the terminology in this section when preparing the guideline update.
4.	13	SH	RCGP	General	General	The scope seems wire-ranging and comprehensive	Thank you for your comment.
5.	27	SH	The Royal College of Midwives	General	General	The RCM agrees with the need to update this guideline (particularly following concerns about mesh surgery) and all the key areas that will be covered as outlined in the scope.	Thank you for your comment.
6.	29	SH	Cogentix Medical	General	General	The draft scope mentions on page 3, line 9 Management of overactive bladder neuromodulation with percutaneous posterior tibial nerve stimulation (P-PTNS) but doesn't mention if the updated guideline will cover percutaneous posterior tibial nerve stimulation or not.	Thank you for your comment. Existing guidance on neuromodulation (including percutaneous posterior tibial nerve stimulation) for overactive bladder will be retained.
7.	32	SH	Royal College of Nursing	General	General	The Royal College of Nursing welcomes the opportunity to review and comment on the draft scope to update the guideline for the management of urinary incontinence and pelvic organ prolapse in women. We invited members who care for women with this condition to review and comment on our behalf. The comments below reflect the views of our members.	Thank you for your comment.
8.	33	SH	Royal College of Nursing	General	General	The draft scope seems comprehensive.	Thank you for your comment.

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9.	43	SH	Royal College of Nursing	General	General	There does not seem to be anything on pelvic floor educators? Would be good to a review, are they relevant?	Thank you for your comment. The conservative management of pelvic organ prolapse is an area we will include in this guideline. Specific interventions and outcomes in this area will be defined in the review protocols by the guideline committee during guideline development. Recommendations relating to pelvic floor exercises for urinary incontinence will be retained from previous guidance (CG171).
10	53	SH	Astellas Pharma Ltd.	General	General	The associated risk of drugs with strong anticholinergic activity on the incidence of falls in this population, we recommend, should be carefully considered and patients deemed at risk offered a medication from an alternative class licensed for OAB, such as a ß3-agonist. Reducing a patient's anticholinergic load by altering their bladder medication may be simpler than for other conditions resulting in polypharmacy. There is evidence suggesting a higher prevalence of urinary incontinence in people over age 85 with dementia than in those without dementia (50 % vs. 18.3 % in men and 60.2 % vs. 35.8 % in women). The prevalence of urinary incontinence was also noted to increase with increasing severity of dementia. (Hellstrom et al. 1994).	Thank you for your comment and information on references. We plan to update the review on anticholinergic use for overactive bladder and the inclusion of evidence for those reviews will be led by criteria set out in the review protocols. Specific interventions, subgroups and outcomes will be defined in the review protocols by the guideline committee during development. As stated in section 3, specific consideration will be

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						Patients with dementia are frequently prescribed cholinesterase inhibitors as they intend to improve cognitive function or at least prevent cognitive decline. These patients are also more likely to subsequently be prescribed anticholinergics to treat urinary incontinence (Gill 2005). Consequently, the anticholinergics used to treat OAB may reduce the benefits of cholinesterase inhibitors, as they have a mechanism of action in direct opposition (Sink et al. 2008). Several investigators have reported that anticholinergics may be associated with an increased risk for sustained cognitive deficits, such as mild cognitive impairment or dementia. One biologically plausible mechanism for these findings is that cumulative use of these agents results in pathologic changes in the brain similar to those observed with Alzheimer's disease (Jessen et al 2010, Ancelin et al. 2006, Carriere et al. 2009). A study suggested a more rapid functional decline in higher functioning nursing home patients that were treated with a combination of anticholinergics and cholinesterase inhibitors, suggesting that a combination of these two drugs should be avoided or at least closely monitored (Sink et al. 2008). Another study provides the strongest evidence of the association between 10-year cumulative anticholinergic use and the risk for dementia in older adults. This observational study found an obvious dose-response	given to older women who may require alternative recommendations to younger women.

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						relationship between anticholinergic drug use and risk of developing dementia: the higher the usage, the greater the risk (Gray et al. 2015). Considering the evidence which suggests that the blood-brain barrier may be in poor condition in the elderly, we recommend the current guidance within CG171 be updated to recommend that all drugs for OAB that have a high anticholinergic load be avoided in the frail elderly patient.	
11	54	SH	Astellas Pharma Ltd.	General	General	**OAB therapy cycling** Patients suffering from OAB and UI are often treated with several courses of antimuscarinics. However, it is fairly common to observe patients returning to the clinic for the treatment of recurring symptoms after unadvised, voluntary discontinuation of medication. Results from several studies suggest that, for patients who remain incontinent after attempting an anticholinergic, cycling on additional anticholinergics may not provide any additional benefit. Further, it is also necessary to determine the duration of therapy that would be sufficient effectively to maintain symptom improvements. However, the point at which to discontinue any anticholinergic and the time during which sustained therapeutic efficacy remains after discontinuation have not yet been determined.	Thank you for your comment and information on references. We plan to update the review on anticholinergic use for overactive bladder and the inclusion of evidence for those reviews will be led by criteria set out in the review protocols. Specific interventions, comparisons and outcomes will be defined in the review protocols by the guideline committee during development.

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						A study from Basra showed that 35% of patients sought re-treatment 1 month after the discontinuation of antimuscarinic therapy. Another study (Chancellor *et al*. 2016) showed very high anticholinergic discontinuation rates (71 %), resulting in sub-optimal care. Further, results from another study showed that discontinuation of medication after treatment for 3 months with an antimuscarinic agent led to recurrent overactive bladder symptoms in most patients, resulting in a high re-treatment rate. Patients older than 55 years or with severe urgency may be more at risk for re-treatment (Myung-Soo et al. 2005). These results are similar with the findings of previous studies demonstrating poor adherence and persistence to anticholinergic treatments (Chancellor et al. 2014). These analyses suggested that antimuscarinic benefits had not yet been realised, thus leaving many patients without effective pharmacotherapy. Considering it is not common practice within other disease areas to cycle between agents within the same class of drug, and the lack of evidence to support the efficacious use of different agents from the same class of drug for OAB, these patients may be better served by a trial of non-anticholinergic therapies. Further, many physicians must decide when to stop prescribing these anticholinergics and when to expect recurrent symptoms without certain guidelines to abide by.	
12	55	SH	Astellas Pharma Ltd.	General	General	The current guidance (CG171) suggests taking account of total anticholinergic load prior to initiating a drug for overactive bladder. We propose this guidance to include a recommendation on alternative drugs	Thank you for your comment. We plan to review the evidence and guidance on anticholinergic use for overactive bladder. Specific

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						to consider if anticholinergic load is thought to be high or potentially problematic. The risks to women caused by long-term exposure to anticholinergic drugs with respect to cognitive function, the potential of falls, confusion, the association with the incidence of dementia, and mortality and recommendations of alternative treatments should be included in this guidance. And assessment of the effective use of medications for overactive bladder with higher persistence rates impact on other health and social care costs, for example reduced NHS consultations within both primary and secondary care should be made. In light of the evidence presented, we recommend that NICE include information / guidance on the high risk of antimuscarinic treatment not only in terms of lack of efficacy and persistence when antimuscarinic cycling, but also regarding the burden in patients with cognitive impairment. Therefore, alternative treatment recommendations moving to a different class earlier than current clinical practice should be made. Alternative treatments could potentially lead to reducing the burden on health, social and care costs.	interventions, subgroups and outcomes will be defined in in the review protocols by the guideline committee during development. Recommendations will also be made by the guideline committee who are informed by the clinical and cost effectiveness evidence presented to them, alongside their expertise. Registered stakeholders for the guideline will be invited to comment on the provisional guideline and recommendations.
13	56	SH	Astellas Pharma Ltd.	General	General	**Proposed composition of the Guideline Committee:**	Thank you for your comment. The scoping group considered these potential committee roles in

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						In line with the discussions which took place at the Scoping Workshop, we propose that the Guidelines Committee membership be extended to include: • Care-of-the-elderly physician could be a full member of the committee • Possibly include more than 2 lay members including one who has had successful stress urinary incontinence surgery, a member from the mesh injured community and a member who has responded to conservative methods of treatment • Community nurse, health visitor or continence advisor • Sexual counsellor, psychologist • Clinical scientist to assess urodynamics • Pathologist to talk about implants/grafts and aetiology	finalising the committee composition. A community continence adviser is included in the committee member list and it is agreed that ideally there should be a balance of lay member experience across the guideline topics. We agree that the role of care of the elderly physician should be a full member of the guideline committee and we have now advertised for this position.
14	57	SH	Astellas Pharma Ltd.	General	General	**References:** Ancelin ML, Artero S, Portet F, Dupuy AM, Touchon J, Ritchie K. Non-degenerative mild cognitive impairment in elderly people and use of anticholinergic drugs: longitudinal cohort study. BMJ. 2006; 332(7539):455-459. Basra R, Basra H, Khullar V, Kelleher C. Guys & St Thomas NHS Foundation Trust, 2. Imperial College Healthcare. Prescribing	Thank you for your comment. The guideline will explore the evidence base on risks to cognitive function for women taking anticholinergic drugs and make recommendations based on this evidence. Please note inclusion of evidence during guideline development will be led by criteria set out in the review protocols.

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						antimuscarinics for overactive bladder; How many chances do we have to get it right? Br J Clin Pharmacol 80:2 209–220 Carrière I, Fourrier-Reglat A, Dartigues JF, et al. Drugs with anticholinergic properties, cognitive decline, and dementia in an elderly general population: the 3-City Study. Arch Intern Med. 2009;169(14):1317-1324 Chancellor M, Alon Yehoshua, Catherine Waweru, Denise Globe, I-Ning Cheng, Karen L. Campbell, Manher Joshi, Riya Pulicharam. Limitations of anticholinergic cycling in patients with overactive bladder (OAB) with urinary incontinence (UI): results from the CONsequences of Treatment Refractory Overactive bLadder (CONTROL) study. Int Urol Nephrol (2016) 48:1029–1036 Chancellor M, Royal Oak, MI; Riya Pulicharam, I-Ning Cheng, Torrance, CA; Karen Campbell, Catherine Corbell, Manher Joshi, Denise Globe, Irvine, CA. Anticholinergic cycling and treatment outcomes in overactive bladder in patients with urinary incontinence. The Journal of Urology. Vol. 191, No. 4S, Supplement, Sunday, May 18, 2014 Chiarelli PE, Mackenzie LA, Osmotherly PG Urinary incontinence is associated with an increase in falls: a systematic review. J Physiother. 2009; 55(2):89-95 DOI 10.1007/s11255-016-1277-0	

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						Gill SS, Mamdani M, Naglie G, et al. A prescribing cascade involving cholinesterase inhibitors and anticholinergic drugs. Arch Intern Med. 2005; 165:808–13	
15	58	SH	Astellas Pharma Ltd.	General	General	**References continued:** Gray S, Melissa L. Anderson, Sascha Dublin, Joseph T. Hanlon, Rebecca Hubbard, Rod Walker, Onchee Yu, Paul K. Crane, Eric B. Cumulative Use of Strong Anticholinergics and Incident Dementia. A Prospective Cohort Study. JAMA Intern Med. 2015;175(3):401-407. doi:10.1001/jamainternmed.2014.7663. Hellstrom L, Ekelund P, Milsom I, et al. The influence of dementia on the prevalence of urinary and faecal incontinence in 85-year-old men and women. Arch Gerontol Geriatr. 1994; 19:11–20 Jessen F, Kaduszkiewicz H, DaerrM, et al. Anticholinergic drug use and risk for dementia: target for dementia prevention. Eur Arch Psychiatry Clin Neurosci. 2010;260(suppl 2): S111-S115 NICE CG161 Myung-Soo Choo, Cheryn Song, Jin Hyun Kim, Jong-Bo Choi, Ji Youl Lerr, Byung Soo Chung and Kyu Sung Lee. Changes in Overactive Bladder Symptoms after Discontinuation of Successful 3-Month Treatment with an Antimuscarinic Agent: A Prospective Trial. The Journal of Urology. Vol. 174, 201–204, July 2005	Thank you for your comment. The guideline will explore the evidence base on risks to cognitive function for women taking anticholinergic drugs for overactive bladder and make recommendations based on this evidence. Please note inclusion of evidence during guideline development will be led by criteria set out in the review protocols.

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						Ruxton K, Woodman RJ, Mangoni AA. Drugs with anticholinergic effects and cognitive impairment, falls and all-cause mortality in older adults: A systematic review and meta-analysis. Br J Clin Pharmacol. 2015 Aug;80(2):209-20. doi: 10.1111/bcp.12617. Epub 2015 May 20 Salahudeen M, Duffull SB and Nishtala PS. Anticholinergic burden quantified by anticholinergic risk scales and adverse outcomes in older people: a systematic review. BMC Geriatrics (2015) 15:31 Sink KM, Thomas J, Xu H, et al. Dual use of bladder anticholinergics and cholinesterase inhibitors: long-term functional and cognitive outcomes. J Am Geriatr Soc. 2008; 56:847–53	
16	63	SH	Cochrane Incontinence Group	General	General	Although the previous guidelines CG171 conducted very extensive searching covering to the end of 2012 they did not incorporate the latest evidence from the relevant most up to date Cochrane reviews at that time (CG171 only cited information from the Cochrane reviews found for the previous 2006 version of the guidelines – the vast majority of the relevant Cochrane reviews had been updated at least once since these searches were performed). The Cochrane Incontinence Group is happy to supply up-to-date lists of all relevant Cochrane reviews to make sure that the most up to date Cochrane evidence is incorporated into the guidelines. We would be very happy to help the current evidence synthesis team in any way we can.	Thank you for your comment. We have made a note to identify those reviews when we conduct our literature searches, but the final inclusion of evidence will be led by criteria set out in the review protocols.

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						Our reviews cover containment and absorbent products, lifestyle, conservative, pharmacological and surgical management of UI. There is a Cochrane review looking at urodynamics.	
17	65	SH	Cochrane Incontinence Group	General	General	The Cochrane Incontinence Group along with the Cochrane Gynaecology and Fertility Group has reviews covering lifestyles, conservative management, pharmacological and surgical management of pelvic organ prolapse – many are up to date or are currently being updated. We are happy to provide the evidence synthesis team with a list of the relevant Cochrane reviews or any other help that they may require.	Thank you for your comment. We have made a note to identify those reviews when we conduct our literature searches, but the final inclusion of evidence will be led by criteria set out in the review protocols.
18	70	SH	Elective cesarean	General	General	**Which interventions or forms of practice might result in cost saving recommendations if included in the guideline?** 1. Communication of this guideline with all medical professionals and managers working in maternity care. In 2012, the NHSLA highlighted perineal trauma as one of the largest litigation areas for claims related to women, with allegations of negligence including failure to consider a caesarean (*NHS Litigation Authority Ten Years of Maternity Claims*). Four years ago, it reported 441 claims over 10 years, with an estimated total value of £31.2m, but given its latest 2016 report, and a recent award of £1.6m for obstetric anal sphincter injury, it's very likely this figure is already much, much higher. Even though NICE does not take litigation costs into account, the fact that	Thank you for your comment. We plan to disseminate the updated guideline to relevant stakeholders including women receiving care as well as healthcare professionals in settings that provide care to women. Recommendations on the mode of delivery have been covered by NICE clinical guidelines including intrapartum care (CG190) and caesarean section (CG132) and we will cross-refer to those where appropriate.

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						perineal trauma is "*one of the largest litigation areas for claims related to women*" highlights the financial impact on the NHS of treating all these cases. 2. Inform women about the risk of urinary incontinence and pelvic organ prolapse, especially where risk factors for increased risk during childbirth are evident. This is not to make women afraid or to encourage caesarean birth (most women plan to have a vaginal birth) but rather to reduce some of the psychological distress that can compound physical problems when a person is shocked and surprised by what has happened to them. It also opens up discussions about suggestions for how to try and reduce the risk of severe tearing during labour. Some women may choose to plan a caesarean, but others will not.	
19	71	SH	Elective cesarean	General	General	The organisation **electivecesarean.com** welcomes this new NICE guidance on the management of pelvic organ prolapse in women, and is grateful for the opportunity to comment on the Draft Scope. Thank you. My main overall concern about this guideline is one of fragmentation, and this is a concern I have with a number of related guidelines. A significant number of women experience urinary incontinence and/or pelvic organ prolapse as a direct result of vaginal birth, and especially where instruments are used. Nevertheless, neither 'birth' nor 'delivery' are referred to in the entire guideline.	Thank you for your comment. We will forward your comment to the NICE surveillance team for consideration in guideline updates as this issue may be addressed when the guidelines on faecal incontinence, intrapartum care and caesarean section are updated. In the final guideline, we aim to make clear reference to related NICE

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						Similarly, NICE guidance on faecal incontinence is a separate document, as are the guidelines on Intrapartum Care and Caesarean section. And despite the fact that they all overlap in very important ways, their separation (and lack of reference to one another in some cases) can create gaps in antenatal communication with women, and impact on their informed consent and informed decision-making. One of the most commonly reported reactions of women who experience pelvic organ prolapse is, "*No one told me this could happen.*" Notably, NICE's CG190 Intrapartum Care for healthy women and babies, for example, focuses primarily on 'where' women give birth rather than 'how' they give birth. This is just one example of how women are being provided with incomplete information with which to make an informed decision about their birth plan. More recently, this issue is being recognised: RCOG July 2014 Perineal tearing is a national issue we must address https://www.rcog.org.uk/en/blog/perineal-tearing-is-a-national-issue-we-must-address/ January 2017 The OASI Care Bundle https://www.rcog.org.uk/OASICareBundle (Aims to reduce overall OASI rates through an increase in the use of	guidance where appropriate and the updated NICE pathway from this guideline will also aim to improve ease of reference. There is also overlap with NICE CG37 post-natal care after birth.

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						standardised prevention practice) But serious gaps in information still remain. RCOG's July 2015 patient information leaflet on '*Choosing to have a Caesarean*' for example made no mention at all of the reduced risk of severe pelvic floor damage (pelvic organ prolapse, urinary incontinence and/or faecal incontinence for example). https://www.rcog.org.uk/globalassets/documents/patients/patient-information-leaflets/pregnancy/pi-choosing-to-have-a-c-section.pdf This is why it is so important that evidence-based NICE guidance works towards bringing all this information together, rather than keeping it all apart.	
20	87	SH	Elective Cesarean	General	General	These are some final points that I would ask the NICE guideline development group to please consider as it prepares its First Draft: England has a 12.8% instrumental delivery rate (7.2% forceps); 60% of women have a spontaneous vaginal delivery, and perineal laceration occurs in 41.6% of deliveries. Birth trauma charities report ***no contact*** from women following maternal request caesareans, and in a recent birth trauma study*, only 6% (n.47) of respondents had a planned caesarean (maternal/medical reasons not specified). *Women's descriptions of childbirth trauma relating to care provider actions and interactions. Reed et al. BMC Pregnancy and Childbirth (2017) 17:21	Thank you for your comment. We plan to disseminate the updated guideline to relevant stakeholders including women receiving care as well as health care professionals in settings that provide care to women. Recommendations on the mode of delivery are included in NICE clinical guidelines on intrapartum care (CG190) and caesarean section (CG132) and we

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						http://bmcpregnancychildbirth.biomedcentral.com/articles/10.1186/s12884-016-1197-0 In 2016, St Michael's Hospital in Bristol was ranked best maternity hospital in the UK. What's very positive is its low stillbirth and perinatal outcomes, and interestingly (opposite to the national average), it has more planned (13.66%) than emergency (9.96%) caesareans, and an induction rate of 30.8%. However, it also has a comparatively high instrumental delivery rate of 15.2%, and a total 8.4% forceps deliveries. In the Supreme Court judgment 'Montgomery v Lanarkshire Health Board [2015] UKSC 11', Lady Hale said: '*Whatever Dr McLellan may have had in mind, this does not look like a purely medical judgment. It looks like a judgment that vaginal delivery is in some way morally preferable to a caesarean section: so much so that it justifies depriving the pregnant woman of the information needed for her to make a free choice in the matter…* *A patient is entitled to take into account her own values, her own assessment of the comparative merits of giving birth in the "natural" and traditional way and of giving birth by caesarean section, whatever medical opinion may say, alongside the medical evaluation of the risks to herself and her baby…*	will cross-refer to those where appropriate.

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						The medical profession must respect her choice, unless she lacks the legal capacity to decide." The organisation **electivecesarean.com** maintains that maternity services could (and should) play a key role in signposting issues for women to look out for after they have given birth, and advising them to visit their GPs if x,y or z is occurring. Maternity services are also in the strongest position for noting any complications that occurred during labour that might precipitate the occurrence of urinary incontinence and/or pelvic organ prolapse, and should be more closely involved in the development of this guideline. There is an ethical responsibility to inform women about the risks and benefits of different birth plans, and there is increasing legal pressure to do so too. I hope that this guideline goes some way towards helping this become a reality. Thank you again for inviting comments from all organisations that represent patients.	
21	69	SH	Pelvic Obstetric and Gynaecological Physiotherapy	General	28	Lifestyle advice should be given	Thank you for your comment. Evidence will be reviewed and recommendations formulated by the guideline committee.

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22	74	SH	Elective cesarean	2	18-23	Re: Key Facts: "*The prevalence of pelvic organ prolapse is high; in primary care in the UK, 8.4% of women reported vaginal bulge or lump and on examination prolapse is present in up to 50% of women. One in 10 women will need at least one 20 surgical procedure, and the rate of re-operation is as high as 19%.*" There are some very important key facts that are missing from this section that I ask to be considered for inclusion. There are specific risk factors for prolapse in women, and while CG171 has listed '*Causes of and risk factors for pelvic organ prolapse*' as an area ***not*** to be covered in the guideline, I feel it is important that these are still cited as background, if nothing else. For example: "*Over 30% of women who deliver vaginally suffer trauma that is associated with future morbidity such as female pelvic organ prolapse, sexual dysfunction and anal incontinence…*" Skinner EM, Dietz HP. Psychological and somatic sequelae of traumatic vaginal delivery: A literature review. ANZJOG 2014 The "*reported rate of severe perineal tears in England tripled between 2000 and 2012 from 1.8% to 5.9%*". Edozien et al. Impact of third- and fourth-degree perineal tears at first birth on subsequent pregnancy outcomes: a cohort study. BJOG 2014	Thank you for your comment. The key facts portion of the scope is intended to be a brief introduction to the conditions covered and we recognise that it is not possible to the cover all background information. We will cross-refer to relevant guidelines on intrapartum care (CG190) and caesarean section (CG132) when appropriate, and will look at adding this topic in the introductory text in the guideline.

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						Some doctors say that: "*Pelvic floor and anal sphincter trauma should be key performance indicators of maternity services…*" Dietz, Pardy J, Murray H Pelvic floor and anal sphincter trauma should be key performance indicators of maternity services. Int Urogynecol J 2015	
23	73	SH	Elective cesarean	2	11-14	Re: Definition - "*Pelvic organ prolapse is defined as symptomatic descent of one or more of: the anterior vaginal wall, the posterior vaginal wall, the cervix or uterus, or the apex of the vagina (vault or cuff) after hysterectomy*." The way this is worded could be misinterpreted as though pelvic organ prolapse only occurs after hysterectomy, when it doesn't. Is it possible to reword this statement to ensure that a more complete definition is included? Namely, the fact that it can also occur after vaginal birth, and especially one where forceps were used. This is particularly important given the rising number of forceps deliveries (7.2%).	Thank you for your comment. We agree that this is potentially confusing and will remove the words 'after hysterectomy' from this sentence.
24	72	SH	Elective cesarean	2	9-10	Re: impact of urinary incontinence on "*physical, psychological and social wellbeing of women and have an impact on their families and carers.*" Wellbeing is a very important point, and I wonder could it be reiterated in the section on pelvic organ prolapse? I have been contacted by women whose careers and/or relationships have	Thank you for your comment. The key facts portion of the scope is intended to be a brief introduction to the conditions covered and we recognise that it is not possible to cover all background information.

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						ended, and their lifestyle completely impeded by pelvic floor damage, – including pelvic organ prolapse and faecal incontinence.	The committee may choose to include outcomes related to wellbeing and psychological health when considering pelvic organ prolapse review questions.
25	44	SH	C&G Medicare Ltd	2	10	It can also have a severe impact on their work life	Thank you for your comment. This section is a general, brief introduction to the topic.
26	14	SH	Association for Pelvic Organ Prolapse Support	2	15	vaginal bulge or sensation of something coming down, urinary incontinence, urine retention, fecal incontinence,	Thank you for your comment. This is a general, brief introduction to the topic: the original wording in the scope is more comprehensive and therefore will be retained. We have noted this list of symptoms.
27	15	SH	Association for Pelvic Organ Prolapse Support	2	16	~~sexual symptoms~~, pain with intimacy, loss of intimate sensation, rectal or vaginal pressure, inability to keep a tampon in, as well as pelvic and back pain. These symptoms affect	Thank you for your comment. This is a general, brief introduction to the topic: the original wording in the scope is more comprehensive and therefore will be retained. We have noted this list of symptoms.
28	45	SH	C&G Medicare Ltd	2	17	It can also have detrimental outcomes in her relationship with her partner	Thank you for your comment. The guideline committee will specify and discuss outcomes for each review question.

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29	61	SH	Cochrane Incontinence Group	3	1-31	Treatments missing eg for older cognitively impaired women: Toileting assistance programmes new Cochrane review due to be published this year, protocol available: Ostaszkiewicz J, Eustice S, Roe B, Thomas LH, French B, Islam T, O'Connell B, Cody JD. Toileting assistance programmes for the management of urinary incontinence in adults (Protocol). Cochrane Database of Systematic Reviews 2013, Issue 6. Art. No.: CD010589. DOI: 10.1002/14651858.CD010589. Available here: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD010589/full	Thank you for your comment and reference. We cannot provide a text book on all care that could apply to this population. Given that the results are not expected to be substantially different by bringing the studies together in the review with the addition of the ICONS trial, the scoping group agreed that other areas prioritised for an update would lead to larger changes in current clinical practice and/or resource use. Following this decision, we will log this issue for reconsideration at the next surveillance point, by when there may be more up to date high quality studies available. Please note that specific considerations in the guideline will be given to older women.
30	51	SH	Astellas Pharma Ltd.	3	1-13	The use of mirabegron in the current version of CG171 is referenced to the information provided in the TA290 (i.e. there is no specific recommendation of the use of mirabegron directly in the body of the	Thank you for your comment. We plan to review the guidance on the use of anticholinergic drugs for overactive bladder. Existing

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						CG171: refer to the sub-Section 1.7.10 of the Section 1.7: Pharmacological treatment of the guideline). We suggest the wording of the "Evidence-based recommendation" of the use of mirabegron in the TA290 be included, as follows: "1.1. *Mirabegron is recommended as an option for treating the symptoms of overactive bladder only for people in whom antimuscarinic drugs are contraindicated or clinically ineffective, or have unacceptable side effects.* *1.2 People currently receiving mirabegron that is not recommended for them in 1.1 should be able to continue treatment until they and their clinician consider it appropriate to stop*". In addition, we recommend clearer guidance emphasising that only one antimuscarinic overactive bladder (OAB) treatment be offered before considering an alternative treatment): "*1.7.5. Do not use flavoxate, propantheline and imipramine for the treatment of UI or OAB in women.* ***[2006]***	guidance in other areas of pharmacological management of overactive bladder will be retained including reference to TA 290.

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						1.7.6 Do not offer oxybutynin (immediate release) to frail older women[7]. ***[new 2013]*** *1.7.7 Offer one of the following choices first to women with OAB or mixed UI:* • ***Either*** *[Astellas* ***suggestion****] oxybutynin (immediate release),* ***or*** • *tolterodine (immediate release),* ***or*** • *darifenacin (once daily preparation).* ***[new 2013]*** 1.7.8. ***Mirabegron is recommended as an option for treating the symptoms of overactive bladder only for people in whom antimuscarinic drugs are contraindicated or clinically ineffective, or have unacceptable side effects.*** ***People currently receiving mirabegron that is not recommended for them in 1.1 should be able to continue treatment until they and their clinician consider it appropriate to stop".***	
31	75	SH	Elective cesarean	3	21-25	Re: *Management of pelvic organ prolapse.*	Thank you for your comment. Specific interventions and

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						Does this include any form of 3D or 4D imaging methods, and if not, is this a consideration for NHS examination and management of pelvic organ prolapse going forward? Will pelvic floor imagins be included/ discussed in the First Draft of the guideline?	outcomes will be defined in the review protocols by the guideline committee during development. We are planning to appoint a co-opted member of the committee who is a radiologist with a special interest in pelvic floor.
32	1	SH	Ramsay Health	3	3	Use of antimuscarinic drug therapy needs review in older age groups at risk of dementia.	Thank you for your comment. We plan to complete evidence reviews and update guidance on pharmacological treatments for urinary incontinence including anticholinergics. Specific interventions, outcomes and subgroups will be defined in the review protocol by the guideline committee during guideline development. One of the groups we have outlined in the scope to give specific considerations to is older women.
33	62	SH	Cochrane Incontinence Group	3	6	The term 'neuromodulation' when used by some clinicians is used to mean 'implanted' electrodes, you also mention 'percutaneous' on lines 8 and 9 but what about non-implanted electrodes ie transcutaneous electrical stimulation. There is a newly published Cochrane review covering this area:	Thank you for your comment. Limited evidence in this area was found when surveillance for the guideline was undertaken and the newly published Cochrane review

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						Stewart F, Gameiro LF, El Dib R, Gameiro MO, Kapoor A, Amaro JL. Electrical stimulation with non-implanted electrodes for overactive bladder in adults. Cochrane Database of Systematic Reviews 2016, Issue 12. Art. No.: CD010098. DOI: 10.1002/14651858.CD010098.pub4. Available at: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD010098.pub4/full	highlighted the need for more adequately powered trials. Therefore we have prioritised updating the pharmacological treatment of overactive bladder and retaining other existing guidance in this area.
34	16	SH	Association for Pelvic Organ Prolapse Support	3	12	overactive bladder is clam cystoplasty, in which a segment of bowel tissue is	Thank you for your comment. This is a brief introductory section, so we have retained the shorter form of words.
35	17	SH	Association for Pelvic Organ Prolapse Support	3	13	Attached to the bladder to increase bladder volume.	Thank you for your comment. This is a brief introductory section, so we have retained the shorter form of words.
36	48	SH	C&G Medicare Ltd	3	14	Management of UI can be successfully treated with the correct pessary. This can also delay or prevent the need for surgery.	Thank you for your comment. Due to limited new evidence in this area, we will retain existing guidance on the conservative management of UI. However, the conservative management of pelvic organ prolapse is a new area in the

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							guideline that will be reviewed. The specific interventions and outcomes for each review will be specified in the review protocols during guideline development.
37	9	SH	HQT Diagnostics	3	16	There is very good evidence that pelvic floor muscle strength can be improved by increasing the blood level of Vitamin D Suggest GP to measure 25(OH)D at first presentation and advise supplementation with Vitamin D3 to reach 100-150nmol/L Review after 3 months Evidence: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3691097/ http://www.vitamindwiki.com/Vitamin+D+and+urinary+incontinence+-+April+2010 http://journals.lww.com/greenjournal/Fulltext/2010/04000/Vitamin_D_and_Pelvic_Floor_Disorders_in_Women_.19.aspx https://www.ncbi.nlm.nih.gov/pubmed/25956283 http://www.grassrootshealth.net/media/download/scientists_call_to_dactio n_020113.pdf	Thank you for your comment and references. Inclusion of evidence is led by the criteria set out in the review protocols, where published randomised controlled trials are usually prioritised and comments / editorial pieces are excluded. The prevention of urinary incontinence and pelvic organ prolapse is beyond the remit of this guideline, hence, the population as per the anticipated protocol should be women over the age of 18 with urinary incontinence and/or pelvic organ prolapse. However, we will cross-refer to NICE guidance on vitamin D in the full guideline where appropriate. We will log this issue for reconsideration at the next surveillance point, by when there

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							may be more up to date high quality studies available.
38	46	SH	C&G Medicare Ltd	3	16	Stress incontinence has been successfully treated by using a pessary which supports the urethra and bladder neck into a natural anatomical position. Pessaries such as IncoStress can play an important part in retraining the pelvic floor.	Thank you for your comment. Due to limited new evidence in this area, we will retain existing guidance on the conservative management of urinary incontinence. However, the conservative management of pelvic organ prolapse is a new area in the guideline that will be reviewed. The specific interventions and outcomes for each review will be specified in the review protocols during guideline development.
39	4	SH	Speciality European Pharma Ltd	3	19	We are pleased to see that urethral bulking agents will be included in the Guideline scope. Having been out of scope in the 2013 update, there are very significant new data since the original guideline was published in 2006 to support the use of bulking agents as a primary surgical option for the surgical treatment of stress urinary incontinence. Furthermore the benefit: risk ratio of the various surgical treatments has also altered significantly during the course of the last 12 years. We also believe that it is important to differentiate between the 2 types of bulking agents: "particulates" and "non-particulates", as they achieve their bulking effect by very different means:	Thank you for your comment. Specific interventions and outcomes will be defined in the review protocols by the guideline committee during development.

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						For the particulate class of products, their bulking effect stems from the fibrosis formed around the microparticles as a result of their ability to I nduce a foreign body reaction (there is thus likely to be inherent variability and unpredictability in the eventual bulk that is formed) For the non-particulate class, their bulking effect is obtained only from the volume injected. Host cells enter the gel and form a lasting network of fine fibrous fibres, which anchor the gel in situ. The volume is secured by a constant exchange of water molecules between the gel and host extracellular matrix in a steady-state equilibrium. The differences between the classes in their composition and the way they achieve their bulking effect may translate into differences in the type and frequency of adverse events e.g. urinary retention, and in clinical effect.	
40	47	SH	C&G Medicare Ltd	3	25	Examination should be carried out both with the patient standing and in the supine position.	Thank you for your comment. Assessment of pelvic organ prolapse is an area being reviewed and updated. Recommendations will be made by the guideline committee who are informed by the clinical and cost effectiveness evidence presented to them, alongside their expertise. The section you refer to is intended to be a brief introduction to current practice and we recognise that it is

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							not possible to the cover all background information.
41	49	SH	C&G Medicare Ltd	4	1	It is paramount that all doctors and physiotherapists treating POP are fully trained in the correct use and fitting of pessaries.	Thank you for your comment. The conservative management of pelvic organ prolapse including the use of pessaries is a new area to be reviewed in this guideline. Recommendations will be made by the guideline committee who are informed by the clinical and cost evidence presented to them, alongside their expertise. Registered stakeholders for the guideline will be invited to comment on the provisional guideline and recommendations.
42	50	SH	C&G Medicare Ltd	4	1	The correct type of pessary can delay or prevent surgery.	Thank you for your comment. The conservative management of pelvic organ prolapse including the use of pessaries is a new area to be reviewed in this guideline. The specific interventions and outcomes included in this review will be defined in the review protocol during guideline development. Recommendations

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							will be made by the guideline committee who are informed by the clinical and cost evidence presented to them, alongside their expertise. Registered stakeholders for the guideline will be invited to comment on the provisional guideline and recommendations.
43	64	SH	Cochrane Incontinence Group	4	14	Members of the Cochrane Incontinence Group and other researchers at Newcastle University and University of Aberdeen are undertaking an evidence synthesis on: The Effectiveness and cost-effectiveness of Surgical Treatments for womEn with stRess urinary incontinence: an evidence synthesis (ESTER). *NHS NIHR Health Technology Assessment*, 2016. HTA Reference number: 15/09/06. (Craig D, Glazener CMA, Brazzelli M, MacLennan G, O'Connor J, Moloney E, et al.) Details available at: http://www.nets.nihr.ac.uk/projectsOld/hta/150906 Protocol available at: https://www.crd.york.ac.uk/prospero/display_record.asp?ID=CRD42016049339 This will include a comprehensive review of effectiveness, safety and cost-effectiveness and a network meta-analysis, economic modelling	Thank you for your comment. We have made a note to identify the review when we conduct our literature searches. The final inclusion of evidence will be led by criteria set out in the review protocols.

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						and detailed analysis of patient preferences. Estimated completion date: April 2018.	
44	76	SH	Elective Cesarean	5	16-28	Re: *Who the guideline is for*. It is important that this list includes 'maternity services', 'obstetricians' and 'midwives', as it contains information that is directly relevant to their work. I'm sure midwives and obstetricians would agree that it is their responsibility to fully understand the long-term implications of their actions and decisions during the antenatal and intrapartum care of women. As part of their training and education, midwives are not generally exposed to the long-term consequences of the vaginal births they attend. In 1999, an Australian parliamentary committee report cited a submission to its committee on the subject of patient demand, suggesting that "the adverse consequences of vaginal delivery, especially operative vaginal delivery, were not appreciated by midwives because they were often not apparent in the immediate postnatal period. This influenced midwives' views of the comparative benefits of vaginal as opposed to Caesarean delivery." The submission was made by Dr. Glen Barker, who reportedly said, "Most midwives are largely ignorant about prolapse and incontinence and their relation to childbirth because they do not deal with these problems in their professional lives. This colors their view of the childbirth process and leads them to see a 'natural delivery' with as little intervention (e.g. caesarean section) as possible as being the ideal."	Thank you for your comment. NICE Pathways provide links across guidance areas. The stakeholder list for this guideline includes the RCOG and other nurse and physician organisations: others are welcome to register on the web site. The causes of urinary incontinence and pelvic organ prolapse are excluded from the scope of this guideline, however we will look at including text in the introductory sections of the guideline.

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						Parliament of Australia: Senate Community Affairs References Committee, *Rocking the Cradle: A Report into Childbirth Procedures* (Canberra: Senate Printing House, 1999) There are also a number of studies relating to the birth plan preferences of obstetricians, and whether obstetricians would agree to a maternal request caesarean, that demonstrate their being influenced by their own personal birth experience, with less And evidently, in RCOG's May 2015 joint meeting with the BSUG (*Childbirth and Pelvic Floor Trauma*), the college listed the following as '*Who should attend*': All Trainees and Consultants in Obstetrics, Gynaecology and Colorectal Surgery All Midwives and midwifery students Nurses and Physiotherapists with an interest in this field Staff Grades, Staff Doctors, Trust Doctors and Associate Specialists https://www.rcog.org.uk/globalassets/events/childbirth-and-pelvic-floor-trauma-programme.pdf It therefore seems incongruous that these same groups do not appear on the distribution list of this guideline scope. Again, the separation of related areas of healthcare in NICE guidelines, when the two are intrinsically linked, is something that would be great to see addressed. Is this something NICE is open to considering in the future?	

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45	18	SH	Association for Pelvic Organ Prolapse Support	5	3	including pelvic organ prolapse, recurrent prolapse and complex urogenital conditions: (APOPS stance is all POP procedures s/b performed by a specialist, including 1st time repairs, to reduce complication and failure rates, particularly with UI and POP mesh procedures of all types.)	Thank you for your comment. NICE clinical guidelines generally are focused on the majority of the population with the prevalent condition or major conditions not addressed before; it is not possible to address every aspect of a condition. The interventions, comparators, subgroups and outcomes will be outlined in each of the review protocols by the guideline committee during development.
46	67	SH	Pelvic Obstetric and Gynaecological Physiotherapy	6	General	***The may should read as should***	Thank you for your comment. Recommendations will be made by the guideline committee following a review of the evidence.
47	20	SH	Association for Pelvic Organ Prolapse Support	6	18-22	Specific consideration will be given to women with chronic UTI post pregnancy line: Consider adding women with chronic UTI	Thank you for your comment. We will consider adding women with chronic UTI as a subgroup in the relevant review protocols. The groups outlined in the scope for specific consideration were

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							prioritised as they may require additional recommendations throughout the areas covered by the guideline.
48	19	SH	Association for Pelvic Organ Prolapse Support	6	17	Mesh for treating stress urinary incontinence or pelvic organ prolapse: Consider adding, women with comorbid conditions which increase potential for POP, such as Ehlers Danlos, Marfan, neuromuscular diseases such as MS, which compound risk factor (we have significant following of women with EDS or double-jointed weak tissue issues).	Thank you for your comment. NICE clinical guidelines generally are focused on the majority of the population with the prevalent condition or major conditions not addressed before: it is not possible to address every aspect of a condition, and this guideline does not cover preventative measures for pelvic organ prolapse or urinary incontinence.
49	77	SH	Elective Cesarean	6	19	Re: *Specific consideration will be given to older women* What is the NICE definition of an 'older woman' in this context/ what is the age group referred to here? What is the reason for highlighting older women here more so than younger women? Again, my organisation has been contacted by young women whose lives have been devastated by incontinence and pelvic organ prolapse, including related sexual health problems, and they struggle with the	Thank you for your comment. The guideline will focus on women aged 18 and over, but additional recommendations may be needed for some groups such as older women, or women considering future pregnancy when, for example, some interventions may be contraindicated. The evidence review may lead to

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						impact on their careers and personal relationships. Most are enquiring about trying to find support for a future caesarean birth but there are many women who choose never to have another baby following severe pelvic floor trauma, and these younger women would not be covered by the guideline's '*women considering future pregnancy*' either.	recommendations that are categorised by age.
50	52	SH	Astellas Pharma Ltd.	6 13	21 22-23	**Cognitive impairment in patients on antimuscarinics** In section 3 .1 "Who is the focus?", women with cognitive impairment are included as part of the population to be considered. Further, in section 3.5. "Key issues and questions", point 3.1., a question regarding the risks to cognitive function associated with anticholinergic treatment is posed. NICE Guideline NG5 covers the safe and effective use of medicines in health and social care for people taking one or more medicines. It aims to ensure that medicines provide the greatest possible benefit to people by encouraging medicines reconciliation, medication review, and the use of patient decision aids when choosing medication. Urinary incontinence, including OAB, is considered a long term condition, therefore patients should be counselled on the longer term risks associated with exposure to OAB drugs with strong anticholinergic properties. Patients should be offered alternatives where possible, and their therapies should be reviewed in light of evidence relating to the risks of long-term exposure to drugs with strong anticholinergic properties.	Thank you for your comment and the information on references. Inclusion of evidence will be led by criteria set out in the review protocols. The specific interventions and their durations will be defined in those review protocols by the guideline committee during development. The updated guideline will cross-refer to NICE guidance NG5 on safe and effective use of medicines where appropriate.

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						Most of the anticholinergics used as a conservative treatment of OAB are often associated with the anticholinergic side effects, including but not limited to dry mouth, constipation and cognitive functions disorders (e.g. dementia, mild cognitive impairments, falls). While there is awareness that these drugs may cause short-term drowsiness or confusion, which is included in the prescribing information, there is no mention of long-term effects on cognition. We propose that the long-term effects of anticholinergic treatment should be taken into consideration and we would like NICE to consider including in the guideline a more in depth explanation of the risk association as well as what the alternative options are for these at-risk f patient. In addition, assessment of the effective use of medications specifically focusing on higher persistence rates could impact on other health and social care costs, for example reduced NHS consultations within both primary and secondary care should be made. We ask the guideline group to give significant attention to the high anticholinergic index of some of the OAB drugs when prescribed to elderly patients, patients with polypharmacy and on medicines with cumulative anticholinergic burden level 3 and over as defined by a variety of scoring scales reviewed by Salahudeen *et* a 2015. Patients with polypharmacy leading to high anticholinergic load may be at greater risk of cognitive impairment, falls and all-cause mortality in older	

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						adults (Ruxton et al.2015). NICE CG161, details that falls cost the NHS in excess of £2.3bn per year. Patients who suffer from urge urinary incontinence are at an elevated risk from falls according to a study by Chiarelli et al. (2009).	
51	2	SH	Ramsay Health	7	6	Guidelines should say in which order tests 'specifically urodynamic testing' should be carried out to avoid unnecessary expense and delayed surgery.	Thank you for your comment. This issue may be resolved as we will aim to find the value of urodynamic assessment in addition to clinical assessment before primary surgery for stress urinary incontinence. The specific comparisons and timings will be defined in the review protocols by the guideline committee during development.
52	28	SH	The Royal College of Midwives	8	General	However we are disappointed to note and unclear about why there are going to be 'no evidence reviews' on the following elements of the scope • Assessment and investigation of UI • Conservative management of UI	Thank you for your comment. We plan to complete evidence reviews on the assessment and investigation of UI related to urodynamic testing. We also plan on completing an evidence review on alternative conservative management for urinary incontinence, specifically how often alternative treatment options should be reviewed for women

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							using absorbent containment products. Surveillance prior to scoping did not identify new evidence warranting an update of additional areas within those two sections of the guideline.
53	59	SH	British Acupuncture Council	8	General	We note that the guideline will not review evidence or update existing recommendations for any aspect of conservative management of UI except for absorbent products. This is apparently because the surveillance review did not find any new evidence that would affect the existing management recommendations from the 2013 update. Looking at the surveillance review, in the section 'alternative conservative management options' there is a sub-section on complementary therapies (including acupuncture). This just includes 2 papers on herbs, nothing on acupuncture. The 2013 guideline is a partial update of the original 2006 guideline. It recommends against any CAM therapy, but this simply carries over the decisions of 2006. The evidence was not even reviewed for 2013 (though presumably there were surveillance reviews in the intervening years?). In the 2006 guideline, for acupuncture, 3 RCTs were unearthed (I'm ignoring the case series, as NICE does). They all had positive results against 'placebo' and NICE's summary admits they show evidence of short-term effectiveness - nevertheless they were found to be limited and of poor quality (not surprising given that two of them were from 1990 and 1991) - also they commented on the heterogeneity in the acupuncture	Thank you for your comment and references. Inclusion of evidence is led by the criteria set out in the review protocols, where published randomised controlled trials in English are usually prioritised. After much consideration, the scoping group agreed there was not enough robust evidence that would change current recommendations. The scoping group also noted that other topics prioritised for an update would lead to larger changes in current clinical practice and/or resource use. Following this decision, we will log this issue for reconsideration at the next surveillance point, by when there may be more up to date high quality studies available.

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						approaches (note: this is normal practice in traditional acupuncture). Hence not recommended. So the question in respect of the scope for the current update is what is the state of the evidence now? From the surveillance review one would imagine there are no new RCTs to consider since 2006 - but this is not the case. A cursory search of Pubmed turned up: Kim (2008), Aydogmus (2014), Yuan (2015), Zhang (2015), Solberg (2016), Xu (2016) and Wang (2016). All of these studies were published in English language journals. They all claim to be RCTs (I have not investigated the detail of this). They all appear to cover urinary incontinence conditions that are the subject of the guideline. They are all trials of needle acupuncture (and some are electroacupuncture). Wang (2016) describes the intervention as pudendal nerve stimulation but nevertheless uses acupuncture needles in locations designated at or very close to acupuncture points. These trials all have largely positive results for acupuncture - for stress UI, overactive bladder and mixed groups; in comparison with placebo, active mainline treatments or waiting list/no acupuncture. Only Yuan (2015) is a decent size (n=250); the rest are between 30 and 90 participants. Nevertheless a combined review of these seven plus the original 3 gives you 10 trials and over 700 patients, all with positive results (or equivalence to standard anti-muscarinic drug therapy). Does not this merit an updated review of this evidence?	
54	60	SH	British Acupunct	8	General	The surveillance review searched only up to June 2015, so would not have come across the 2016 papers. However, the most interesting of the studies, Yuan's, was first published online in Nov 2014. This looks to be a	Thank you for your comment and references. Inclusion of evidence is led by the criteria set out in the

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			ure Council			study of acceptable quality and reasonable size (n=240) so it's not clear why it has not been considered, or indeed why the body of evidence as a whole has not been presented. Given that there would have been double the number of studies available for the recent surveillance review as for the 2006 guideline it is surprising that this evidence has been swept under the carpet. In the pipeline are 3 large trials (n=300, 500, 500), the protocols of which appeared in English language journals in 2013 (Liu), 2014 (Liu) and 2015 (Su). Acupuncture is compared to sham in one, pelvic floor exercises in another and pelvic floor exercises + a standard drug in the third. The results will all be published in English. We think that it would be useful to bear in mind that these will be forthcoming, and could be incorporated in the guideline evidence if they appear in time. Given the huge demand for treatment for UI, the problems with existing interventions and the pressures that the NHS is operating under it would be hugely beneficial for it to be able to call upon a safe and effective alternative, operating holistically rather than focused narrowly on a single condition; also one delivered by skilled professionals (accredited by the PSA) without drawing on the existing overstretched NHS workforce. Extending the guideline scope to consider the acupuncture evidence would allow NICE the opportunity to address this proposition, rather than sticking with the usual restricted approaches. We suggest that acupuncture is put to the test in the context of a network meta-analysis: one suspects that it would do rather well.	review protocols, where published randomised controlled trials in English are usually prioritised. After much consideration, the scoping group agreed there was not enough robust evidence that would change current recommendations. The scoping group also noted that other topics prioritised for an update would lead to larger changes in current clinical practice and/or resource use. Following this decision, we will log this issue for reconsideration at the next surveillance point, by when there may be more up to date high quality studies available.

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55	68	SH	Pelvic Obstetric and Gynaecological Physiotherapy	8	General	***Pelvic floor exercises need to be included as a recommendation and not just reference to it being widely available***	Thank you for your comment. This is a general introduction to the topic. Recommendations will be made by the guideline committee following a review of the evidence.
56	78	SH	Elective Cesarean	8	Table Line1	Re: *Urinary incontinence 'history taking and physical examination'* Can you confirm that history taking and physical examination is to be included for management of pelvic organ prolapse? Will these notes include information from previous births regarding mode of delivery (e.g. forceps or ventouse use, length of labour, weight of baby)? This again highlights the importance of involving maternity services in the guideline, in order to ensure that birth records include all the information that would be useful if/when complications later arise. It also creates an important opportunity for communication with women during the postpartum period, which is key. Many women take years to pluck up the courage to speak to their GP about the problems they are having. They don't know what's normal and what's not (although the internet and social media groups are having a greater influence on this), and many are never warned about the potential repercussions of a	Thank you for your comment. History taking and physical examination of pelvic organ prolapse will be considered by the guideline committee in the area: Assessment. Specific assessments and outcomes will be further defined in review protocols by the guideline committee during development. Recommendations on the mode of delivery have been covered by NICE clinical guidelines on intrapartum care (CG190) and caesarean section (CG132) and we will cross-refer to those when appropriate.

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						traumatic vaginal delivery, and have no expectation that this might happen.	
57	34	SH	Royal College of Nursing	8	18	Suggest include the evidence to support the appropriate use of urodynamic as some clinical commissioning groups (CCGs) see this as first line assessment.	Thank you for your comment. The scope includes a review of the evidence on urodynamic testing prior to surgery for stress urinary incontinence and prior to botulinum toxin use. Recommendations will be made by the guideline committee who are informed by the clinical and cost evidence presented to them, alongside their expertise. Inclusion of evidence during the guideline development will be led by criteria set out in the review protocols.
58	35	SH	Royal College of Nursing	8	21	Neurostimualtion should not sit under conservative management.	Thank you for your comment. This section of the guideline is not being updated.
59	36	SH	Royal College of Nursing	8	33	Pessaries, would be a money saving management, rather than surgical option, should there be more research to support this option?	Thank you for your comment. The limited evidence, both clinical and economic, available in the previous guideline (2015) did not support the use of ring pessaries for the treatment of UI in women. There

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							was no new evidence identified in the NICE surveillance report nor in the scoping searches that would potentially result in the change of existing recommendations pertaining to the conservative management of UI.
60	37	SH	Royal College of Nursing	8	39	Suggest review of medication, due to potential increase of cost of medication when some companies become aware of their drugs being recommended by NICE.	Thank you for your comment. In the previous guideline, it was recommended not to use duloxetine as a first-line treatment for women with predominant stress UI and not to routinely offer duloxetine as a second-line treatment for women with stress UI, although it may be offered as second-line therapy if women prefer pharmacological to surgical treatment or are not suitable for surgical treatment. This recommendation was based on clinical and economic evidence. An economic model constructed for the purposes of the guideline suggested that pelvic floor muscle training (PFMT) was more cost

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							effective than duloxetine alone as first-line treatment. Given that the acquisition cost of duloxetine has potentially increased this would make duloxetine even less cost effective and the recommendation would remain unchanged. In the previous guideline (2015) there was insufficient evidence that desmopressin reduced incontinence in adult women and there was only a consider recommendation for nocturia. Likewise, there was a do not offer systemic hormone replacement therapy for the treatment of UI. So even if drug acquisition costs increased the recommendation pertaining to desmopressin and oestrogens will remain unchanged.
61	30	SH	Cogentix Medical	9	General	A row should be inserted between "Pharmacological treatment for UI: drugs for OAB" and "Invasive procedures for OAB". This should be named "Minimally invasive procedures for OAB". In the right cell "Review evidence: update existing evidence and treatment algorithm"	Thank you for your comment and references. Inclusion of evidence is led by the criteria set out in the review protocols, where published randomised controlled trials in English are usually prioritised.

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						There is inevitable evidence that percutaneous posterior tibial nerve stimulation is clinical effective, minimally invasive and from a patient's perspective the preferred treatment compared to more invasive surgical options, like botulinum toxin and sacral neuromodulation. Three new articles published after the 2-year surveillance 2015 of the Urinary Incontinence (2013) NICE CG171 emphasize the efficacy and patient's preference of percutaneous posterior tibial nerve stimulation: *1] Hashim H, Beusterien K, Bridges JF, Amos K, Cardozo L. Patient preferences for treating refractory overactive bladder in the UK. Int Urol Nephrol. 2015; 47(10):1619-27* *2] Kızılyel S, Karakeçi A, Ozan T, Ünüş İ, Barut O, Onur R. Role of percutaneous posterior tibial nerve stimulation either alone or combined with an anticholinergic agent in treating patients with overactive bladder. Turk J Urol. 2015; 41(4):208-14* *3] Scaldazza CV, Morosetti C, Giampieretti R, Lorenzetti R, Baroni M. Percutaneous tibial nerve stimulation versus electrical stimulation with pelvic floor muscle training for overactive bladder syndrome in women: results of a randomized controlled study. Int Braz J Urol. 2017;43(1):121-6 [Epub 2016 Nov 2].* In total there are 8 new publications (1 rct, 1 comparative study, 1 meta-analysis, 1 web survey, 1 case report, 1 cohort study, and 2 abstracts, on in total 4 cohorts that describe additional efficacy and patient preference of percutaneous posterior tibial nerve stimulation since the 2-year surveillance	Current recommendations allow percutaneous tibial nerve simulation for overactive bladder when certain conditions are met. After much consideration the scoping group agreed there was not enough robust evidence that would change current recommendations to extend beyond those areas. The scoping group also agreed that other topics prioritised for an update would lead to larger changes in current practice and/or resource use and could not be displaced for this topic. Following this decision, we will log this issue for reconsideration at the next surveillance point, by when there may be more up to date high quality studies available.

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						2015 of the Urinary Incontinence (2013) NICE guideline CG171 have been published. This justifies an update review of the literature. In a separate document a literature review will be send.	
62	31	SH	Cogentix Medical	9	General	The draft scope mentions on page 3, line 9 Management of overactive bladder neuromodulation with percutaneous posterior tibial nerve stimulation but doesn't mention if the updated guideline if it will cover percutaneous posterior tibial nerve stimulation or not. Looking at cost-effectiveness Abeywickrama L *et al.* (*ICS Barcelona, 2013*) presented that long-term percutaneous posterior tibial nerve stimulation is more cost-effective compared to antimuscarinic treatment. Next to that there is evidence to place minimally invasive percutaneous posterior tibial nerve before the more invasive botulinum toxin and sacral neuromodulation treatments. An article by Martinson *et al.* (*Cost of neuromodulation therapies for overactive bladder: Percutaneous tibial nerve stimulation versus sacral nerve stimulation. J Urol 2013;189:210-6*) calculated percutaneous posterior tibial nerve stimulation to be more cost-effective than sacral neuromodulation. The Kings College (*Robinson et al. ICS-IUGA Toronto, 2010*) presented an economic analysis of the use of percutaneous tibial nerve stimulation and botulinum toxin. They conclude that the percutaneous tibial nerve stimulation is more cost-effective than botulinum toxin. The two comparisons of percutaneous posterior tibial nerve with more invasive botulinum toxin and sacral neuromodulation justify the placement of percutaneous posterior tibial nerve treatment before botulinum toxin and sacral neuromodulation in the treatment algorithm.	Thank you for your comment and references. Inclusion of evidence is led by the criteria set out in the review protocols, where published randomised controlled trials in English are usually prioritised. Current recommendations allow percutaneous tibial nerve simulation for overactive bladder when certain conditions are met. After much consideration the scoping group agreed there was not enough robust evidence that would change current recommendations to extend beyond those areas. The scoping group also agreed that other topics prioritised for an update would lead to larger changes in current practice and/or resource use and could not be displaced for this topic. Following this decision, we will log this issue for

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						Percutaneous posterior tibial nerve stimulation treatment, supported by Kings College in London is currently widely used in the UK and is common practice in more than 100 hospitals. Carers don't understand why NICE recommends offering percutaneous posterior tibial nerve stimulation only after botulinum toxin and sacral neuromodulation is offered. Patients choose for the minimally invasive percutaneous posterior tibial stimulation treatment. This is confirmed by the article by Hashim et al. (2015) that clearly indicate that patients with overactive bladder and are refractory to medication are willing to try other treatments with a preference of 57% for percutaneous posterior tibial nerve stimulation, 34% for sacral neuromodulation and 9% for Botox. Unfortunately, patients now sometimes have to travel for hours because the percutaneous posterior tibial nerve stimulation treatment is not offered in the hospital in their region. Looking at the European Urological Association and the American Urological association both place percutaneous posterior tibial nerve stimulation in the treatment algorithm before the more invasive sacral neuromodulation. A case report published by the North and Middlesex University hospital in London (Int Urogynecol J. 2015;26: 301-2) describe that in treating many patients (over 8000 since 2006), only few, and transient side effects are seen.	reconsideration at the next surveillance point, by when there may be more up to date high quality studies available.

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						We believe that there is enough evidence and support from the use in hospitals that a review of the treatment algorithm for Overactive Bladder in women should performed	
63	10	SH	Medtronic Ltd	9	1	Row 3 & 5: No evidence review is planned for percutaneous sacral nerve stimulation. We feel it worthwhile reconsidering this decision in light of new evidence published in 2015 and 2016, namely: • Siegel S, Noblett K, Mandel J et al. (2015) Results of a prospective, randomized, multicentre study evaluating sacral neuromodulation with InterStim therapy compared to standard medical therapy at 6-months in subjects with mild symptoms of overactive bladder. Neurourol Urodyn. 34(3):224-30 • Amundsen CL, Richter HE, Menefee SA et al. (2016) OnabotulinumtoxinA vs sacral neuromodulation on refractory urgency urinary incontinence in women: A randomized clinical trial. JAMA 316(13):1366-1374 We acknowledge that this evidence was published after the closure of the surveillance 2015 literature search. We also acknowledge that the evidence reports on efficacy, not on effectiveness of the respective treatments however, both publications present comparative evidence (clinical efficacy, health related quality of life, patient reported outcome measures, and safety). These publications may provide information on the following questions mentioned in the NICE 2-year surveillance 2015 decision matrix:	Thank you for your comment and references. Inclusion of evidence is led by the criteria set out in the review protocols, where published randomised controlled trials in English are usually prioritised. Current recommendations allow percutaneous sacral nerve simulation for OAB when certain conditions are met. After much consideration the scoping group agreed there was not enough robust evidence that would change current recommendations to extend beyond those areas. If sacral nerve simulation is more costly than conservative management and drugs, sacral nerve simulation would need to provide additional benefits to be considered cost-effective. Given that patient satisfaction is greater for botulinum toxin type A in the references

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						[171-26] In women with OAB, what is the effectiveness of neuromodulation (SNS or PTNS) compared with pharmacotherapy? [171-33] In women with OAB caused by detrusor overactivity, what is the comparative effectiveness of neuromodulation (SNS or PTNS), pharmacological interventions and Botulinum toxin A? [RR-13] Further RCT evidence is required for drugs, Botulinum toxin A and P-SNS in women with OAB due to idiopathic detrusor overactivity. In this context, we would also mention to the NICE guideline development group that there is additional evidence on mid- and long-term outcomes of percutaneous sacral nerve stimulation. These publication result from the single arm follow-up of the above mentioned RCT by Siegel et al.: • Noblett K, Siegel S, Mandel J et al. (2016) Results of a prospective, multicentre study evaluating quality of life, safety and efficacy of sacral neuromodulation at twelve months in subjects with symptoms of overactive bladder. Neurourol Urodyn. 35(29:246-51 • Siegel S, Noblett K, Mandel J et al. (2016) Three-year follow-up results of a prospective, multicentre study in overactive bladder subjects treated with sacral neuromodulation. Urology 94:57-63 • Noblett K, Benson K, Kreder K (2016) Detailed analysis of adverse events and surgical interventions in a large prospective trial of sacral neuromdulation therapy for overactive bladder patients. Neurourol Urodyn. Epub ahead of print.	supplied to us and the majority of clinical effectiveness measures are not statistically significant, it is unlikely the evidence would warrant a change to current recommendations. The scoping group also agreed that other topics prioritised for an update would lead to larger changes in current practice and/or resource use and could not be displaced for this topic. Following this decision, we will log this issue for reconsideration at the next surveillance point, by when there may be more up to date high quality studies that assess the clinical and cost effectiveness of sacral nerve simulation from a UK NHS perspective.
64	23	SH	Association for	10	18-19	Causes of and risk factors for postoperative incontinence after prolapse	Thank you for your comment. Specific interventions and

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			Pelvic Organ Prolapse Support			surgery. It is valuable for clinicians to recognize risk factors for post op incontinence, particularly with colpocleisis procedures and organ shift when POP is repaired.	outcomes will be defined in review protocols by the guideline committee during development.
65	21	SH	Association for Pelvic Organ Prolapse Support	10	15	Faecal incontinence. Please consider including this section, FI is an aspect that impacts many women with rectocele simultaneously with chronic constipation.	Thank you for your comment. The guideline will retain the focus on urinary incontinence and pelvic organ prolapse assessment and management. We cannot provide a text book on all care that could apply to this population. Your comment may be resolved when the guideline on faecal incontinence is updated. In the final guideline, we will cross-refer to NICE guidance on faecal incontinence (CG49) when appropriate. The NICE pathway will also improve ease of reference to other guidance.
66	79	SH	Elective Cesarean	10	15	Re: *Areas not covered – faecal incontinence* As above (concern about fragmentation of guidelines); this can be unhelpful in terms of health care communication and prevention. There is a danger that information contained within CG49 '*Faecal incontinence in adults*' may not be fully considered or communicated at the time when	Thank you for your comment. The guideline will retain the focus on urinary incontinence and pelvic organ prolapse assessment and management. We cannot provide a text book on all care that could

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						women are making decisions about their birth plans.	apply to this population. Your comment may be resolved when the guideline on faecal incontinence is updated. In the final guideline, we will cross-refer to NICE guidance on faecal incontinence (CG49) when appropriate. The NICE pathway will also improve ease of reference to other guidance.
67	22	SH	Association for Pelvic Organ Prolapse Support	10	17	Causes of and risk factors for pelvic organ prolapse. Please consider adding the section for causes and risk factors, it would make screening process easier for clinicians when communicating with patients, particularly at the diagnostic non-specialty level.	Thank you for your comment. The prevention of pelvic organ prolapse is outside the remit of this guideline. The assessment and management of pelvic organ prolapse has been prioritised.
68	80	SH	Elective Cesarean	10	17	Re: *Causes of and risk factors for pelvic organ prolapse* What is the reason for these not being covered in this guideline? Can you advise in which NICE guidance this important information ***is*** covered? Thank you.	Thank you for your comment. The prevention of pelvic organ prolapse is currently outside the remit of this guideline, the assessment and management of pelvic organ prolapse has been prioritised.
69	81	SH	Elective Cesarean	12	27-31	Re: *NICE guidance about the experience of people using NHS services - . This guideline will not include additional recommendations on these topics unless there are specific issues related to urinary incontinence and pelvic*	Thank you for your comment. The guideline will retain the focus on urinary incontinence and pelvic

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						organ prolapse in women. Looking at CG138 Patient experience in adult NHS services, I think there *are* specific issues related to urinary incontinence and pelvic organ prolapse in women, in that very often women are not informed about these risks when planning a vaginal birth. I understand that maternity care is different to other areas of healthcare within the NHS, but given the 2015 Montgomery v. Lanarkshire Health Board judgment, I think it would be prudent for NICE to address what is a very complex, controversial and litigious area of NHS care, and to consider including recommendations on these issues across all guidelines. The approach of many NHS maternity care services (see hospital trust websites for example) is that all women should be advised to plan for a spontaneous vaginal birth unless there are immediate clinical indications, and in practice, there can be a large degree of subjectivity and disagreement around what might be considered indications for even discussing an induction or planned caesarean (e.g. maternal age, estimated birth weight, gestation, family history of birth trauma and/or injury). The Birth Trauma Association has said that severe perineal trauma is one of the most common issues discussed by its members, and that the "*effects can be life changing and the impact on the NHS is underestimated.*"	organ prolapse assessment and management. We cannot provide a text book on all care that could apply to this population. Guidance in relation to maternity care can be found in other NICE clinical guidelines including intrapartum care (CG190) and caesarean section (CG132) and we may cross-refer to those guidelines when appropriate. The NICE pathway from this guideline will be updated to improve ease of reference between maternity care and patient experience.

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						https://www.rcog.org.uk/en/blog/perineal-tearing-is-a-national-issue-we-must-address/ Is NICE satisfied that this issue is sufficiently covered in CG138?	
70	82	SH	Elective Cesarean	13	4	Re: *Economic aspects* This is a very welcome inclusion in the urinary incontinence and pelvic organ prolapse guideline, and one that is supported by others too. For example: Economics of Incontinence, Hu et al 2002 https://www.ics.org/Publications/ICI_2/chapters/Chap14.pdf "*In order to facilitate economic studies regarding the cost of incontinence treatment, each country should gather data regarding the costs of the available treatments and investigations and publish average figures, which could be employed in economic studies. The actual cost of visits to each type of continence clinician should be obtained from the cost of doing business rather than relying on charges. Policy guidelines should be based not only on evidence-based medicine but also on cost-effectiveness.*" Economics of pelvic organ prolapse surgery, Cheon and Maher Int Urogynecol J (2013) 24:1873–1876 "*The annual economic costs of pelvic organ prolapse surgeries are significant… There is a paucity of good economic data relating to pelvic*	Thank you for your comment and references in support of economic burden associated with urinary incontinence and pelvic organ prolapse. This guideline will review the existing economic evidence pertaining to the economic costs of urinary incontinence and pelvic organ prolapse; existing economic evidence pertaining to the cost effectiveness of treatments for urinary incontinence and pelvic organ prolapse; and will also conduct economic analyses in high priority areas that will be decided in consultation with the guideline committee.

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						organ prolapse surgery." Birth Trauma Association 2014: "*Michelle Thornton, a consultant colorectal surgeon wrote a letter to the BMJ in 2006. She estimated repair costs at between £7,000 and £43,000 depending on treatment.*" https://www.rcog.org.uk/en/blog/perineal-tearing-is-a-national-issue-we-must-address/ In 2011, when NICE was developing its Caesarean section CG132, a comparison was being made between the cost of a planned caesarean birth and a planned vaginal birth; once urinary incontinence was factored in as an associated cost, the difference between the two planned modes fell to just £84. At the time, figures for faecal incontinence and pelvic organ prolapse were not included, and it would be very useful to have these figures.	
71	83	SH	Elective Cesarean	13	4	Another important point to raise on the issue of health economics is the way cost can be framed as a justifiable reason to withhold healthcare that may have very positive outcomes for women. For example, in August 2012, the RCOG, RCM and NCT recommended that CCGs set out a "*clear action plan*" to reduce caesarean rates to 20% and increase "*normal*" birth rates, which "***includes delivery by forceps** and ventouse*" and delivery "*without epidurals*". They said midwifery-led birth units should be the "*default option*" for pregnant women and "***Every potential [CS] that is enabled to be a normal birth saves £1200 in***	Thank you for your comment and references in support of the financial impact of urinary incontinence and pelvic organ prolapse. This guideline will review the existing economic evidence pertaining to the economic costs of urinary incontinence and pelvic organ prolapse; existing economic evidence pertaining to the cost

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						tariff price alone. [This] saves the NHS money." Weston N. Making sense of commissioning maternity services in England - some issues for Clinical Commissioning Groups to consider. 2012 RCOG In contrast, there is this opinion: Dietz HP, Campbell S. *Toward normal birth-but at what cost?* Am J Obstet Gynecol. 2016 Apr 27. "*…negative consequences of increasingly risky attempts at vaginal birth after cesarean delivery such as uterine rupture,* ***higher rates of pelvic floor and anal sphincter trauma due to rising forceps rates****, and a bias against elective cesarean delivery on maternal request.*" Updated information provided on the financial impact of urinary incontinence and pelvic organ prolapse – both for the NHS and for individual women – will help to inform this ongoing debate.	effectiveness of treatments for urinary incontinence and pelvic organ prolapse; and will also conduct new economic analyses in high priority areas that will be decided in consultation with the guideline committee.
72	84	SH	Elective Cesarean	13	12	Re: *Key issues and questions* Two question suggestions have been written above. Thank you.	Thank you for your comments and suggestions.
73	66	SH	Cochrane Incontinence Group	13	15	We have a Cochrane review covering: Urodynamic studies for management of urinary incontinence in children and adults. Cochrane Database of Systematic Reviews 2013, Issue 10. Art. No.: CD003195. DOI: 10.1002/14651858.CD003195.pub3. Available at:	Thank you for your comment. We have made a note to identify the review when we conduct our literature searches, but the final inclusion of evidence will be led by

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						http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD003195.pub3/full (Clement KD, Lapitan MCM, Omar MI, Glazener CMA)	criteria set out in the review protocols.
74	8	SH	Speciality European Pharma Ltd	13	22	Whilst there is an emerging relationship developing between the use of anticholinergics and its associated risks to dementia, there should be a distinction made between anticholinergics which are tertiary amines and those which are quaternary amines. Unlike tertiary amines, quaternary amines are hydrophilic with a reduced propensity to cross the blood brain barrier and less likely to be associated with CNS adverse effects such as dementia. It is important that this differentiation is made so as to avoid making inaccurate class wide statements.	Thank you for your comment. Specific subgroups and pharmacological interventions including any analysis by treatment class will be defined in review protocols by the guideline committee during development.
75	5	SH	Speciality European Pharma Ltd	13	30	We believe that the most effective surgical management of stress urinary incontinence is the wrong question, rather the most "appropriate" surgical management - for each individual patient, having established the patient's goals of treatment and attitude towards risk. (A sledgehammer is the most effective way to crack a nut, it doesn't necessarily mean it is the most appropriate way – either for the nut of the end consumer of the nut).	Thank you for your comment. We think that effective is the more appropriate term.
76	38	SH	Royal College of Nursing	13	18,19	Suggest annual review for patients on containment programme (pads) with option to be seen earlier if any changes in bladder problems.	Thank you for your comment. Recommendations will be made by the guideline committee who are informed by the clinical and cost evidence presented to them, alongside their expertise. Registered stakeholders for the guideline will be invited to comment

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							on the provisional guideline and recommendations.
77	39	SH	Royal College of Nursing	14	1	Suggest consider community continence teams - there are very few multi-disciplinary teams that include community continence teams. The continence team will manage long term chronic bladder problems and it would benefit the patient's journey to have a multidisciplinary team approach.	Thank you for your comment. Specific services will be defined in the review protocol for this area on how to co-ordinate services, by the guideline committee during development. A community continence advisor is a full member of the committee.
78	24	SH	Association for Pelvic Organ Prolapse Support	14	5	7.1 What is the most effective strategy for assessing pelvic organ prolapse? There would be considerable value in establishing a standing screen for POP protocol which would enable diagnostic clinicians to better recognize POP during routine pelvic exams when women have pronounced symptoms and supine position does not display accurate organ drop.	Thank you for your comment. NICE guidelines aim to standardise and improve the care received by women. Specific assessments will be defined in the review protocols by the guideline committee during development.
79	40	SH	Royal College of Nursing	14	7	Suggest include conservative treatment advice on weight management smoking cessation, moving and handling.	Thank you for your comment. Specific interventions will be defined in review protocols by the guideline committee during development.
80	41	SH	Royal College of Nursing	14	8	Topical oestrogen excellent for managing appropriate patients with vaginal atrophy in practice do not think it affects prolapse.	Thank you for your comment. The guideline will explore the evidence base on the use of topical

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							oestrogen and make appropriate recommendations based on this evidence.
81	42	SH	Royal College of Nursing	14	12	Pelvic floor exercises and pessaries work very well, not all women want to have surgery. Pessaries can be fitted in primary care but staff need to be trained and have refreshers, patients need to be advised that it is not an exact science and it may take 2-3 pessaries to achieve right fit.	Thank you for your comment. The conservative management of pelvic organ prolapse including the use of pessaries is a new area to be reviewed in this guideline. Recommendations will be made by the guideline committee who are informed by the clinical and cost evidence presented to them, alongside their expertise. Registered stakeholders for the guideline will be invited to comment on the provisional guideline and recommendations.
82	85	SH	Elective Cesarean	14	25 & 33	Re: *Sexual dysfunction after mesh surgery* Is it possible to include sexual dysfunction/function as a key issue or question more generally too (i.e. not only in relation to mesh surgery)? In which other guideline/s does NICE cover postpartum sexual dysfunction?	Thank you for your comment. We have considered this suggestion, however, we cannot provide a text book on all care that could apply to this population. We have prioritised surgical management of urinary incontinence and pelvic organ prolapse as well as management and assessment of complications

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							of mesh surgery to be included in this update.
83	86	SH	Elective Cesarean	15	18-20	Re: *NICE quality standards that may need to be revised or updated when this guideline is published.* Suggestions: QS105 Intrapartum Care (2015) QS32 Caesarean section (2013) Especially if the economics section here is fully updated.	Thank you for your comment on which quality standards might be updated when this guideline is published.
84	6	SH	Speciality European Pharma Ltd	15	12	When looking at "cure rates" It is important to determine the objectives for the outcome of treatment from the patient's perspective ref. What Do Women Want? Interpretation of the Concept of Cure, Robinson el al. Journal of Pelvic Medicine and Surgery: November/December 2003 – Volume 9 – Issue 6 – pp 273-277. This study suggests that there is a balance to be struck between "extent of cure" and "degree of invasiveness" of intervention and that this balance will be different for every patient. "Dry rates" are an important measure, and easy to compare between studies, however objective improvement as measured by, for example, reduction in leakage as measured by pad tests, and subjective improvement as measured by the patient's own determination of the improvement to their daily lives are equally valid measures of clinical effectiveness.	Thank you for your comment. Specific outcomes will be defined in review protocols by the guideline committee during development. Review protocols may include patient satisfaction and patient-reported outcomes as specified by the guideline committee, which includes service users.
85	7	SH	Speciality European	15	15	We are pleased that patient reported outcomes are to be a key component in the assessment of the evidence	Thank you for your comment. The list of outcomes included in the

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			Pharma Ltd				scope is not exhaustive and the most relevant outcomes will be agreed by the guideline committee separately in each review protocol.
86	25	SH	Association for Pelvic Organ Prolapse Support	15	15	patient-reported outcome measures.	Thank you for your comment. The list of outcomes included in the scope is not exhaustive and the outcomes will be agreed by the guideline committee separately in each review protocol.

No disclosure of any link to tobacco industry.

Registered stakeholders