NICE National Institute for Health and Care Excellence

Prevention and non-surgical treatment of pelvic floor failure

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British Society of Urogynaecology	General		No comments - seems reasonable scope. The document seems somewhat unbalanced and against surgery! Although I agree that all conservative therapies should be offered, they do not always work that well. Good luck with your review	Thank you.
NHS England and NHS Improvement	General		Chronic pelvic pain syndromes can cover a large number of issues which are often unrelated to pelvic floor dysfunction, and I wonder how relevant they are to this guidance? (GW)	Thank you for your comment. We will focus only on pain associated with pelvic floor dysfunction on this guideline. Any other chronic pelvic pain syndromes unrelated to pelvic floor failure will be outside the scope of the guideline. We have revised the wording in the definition section to make it clear that only chronic pelvic pain associated with pelvic floor dysfunction is relevant.
NHS England and NHS Improvement	General		Current guidance details that individuals should continue with exercise if helpful but stop if not, this may not consider that whilst individuals are not improving with an exercise programme they may not be deteriorating further. (CAHPO)	Thank you for your comment. We cannot pre-empt what the recommendations for this topic will be. We agree that exercise is important, and the key area of this guideline is prevention. Within the outcomes in the scope we have specified 'adherence' and 'progression'; together we

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				believe these outcomes will take these issues into account.
NHS England and NHS Improvement	General	General	The role of elective Caesarean Delivery to prevent pelvic floor injury is not included in the scope. There is data on the role of mode of delivery in developing urinary incontinence, pelvic organ prolapse and fecal incontinence. The scope includes identifying groups of women at higher risk of pelvic floor dysfunction but omits the role of elective prelabour Caesarean in preventing this. (SC)	Thank you for your comment. One of the key areas that will be covered by this guideline is the 'identification of women at high risk of pelvic floor failure' and one of the associated draft review question is: 'What are the obstetric risk factors for pelvic floor dysfunction?' We would therefore anticipate that this question will include mode of birth, and thus the role of elective caesarean section will likely feature in the committee's deliberations on this topic.
NHS England and NHS Improvement	General	General	The draft scope makes no mention of or reference to highly relevant, referenced, specific recommendations in NHS Long Term Plan: https://www.longtermplan.nhs.uk/wp-content/uploads/2019/01/nhs-long-term-plan-june-2019.pdf	Thank you for your comment. We agree this is relevant and we have added a reference to this in the 'Policy, legislation, regulation and commissioning' section of the scope.

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			"3.17. ***We will improve access to postnatal physiotherapy to support women who need it to recover from birth.*** *About one in three women will experience urinary incontinence after childbirth85, one in ten faecal incontinence86, and one in twelve pelvic organ prolapse. Physiotherapy is by far the most cost-effective intervention for preventing and treating mild to moderate incontinence and prolapse87. We will ensure that women have access to multidisciplinary pelvic health clinics and pathways across England via referral. Clinics can also provide training and support for local clinicians working with women, such as GPs and midwives."* 85. Thom, D. & Rortveit, G. (2010) Prevalence of postpartum urinary incontinence: a systematic review. Acta Obstetricia et	

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			Gynecologica Scandinavica. 89 (12), 1511-22. Available from: https://doi.org/10.3109/00016349.2010.526188 86. Johannessen, H.H., Wibe, A., Stordahl, A., Sandvik, L., Backe, B. & Mørkved, S. (2013) Prevalence and predictors of anal incontinence during pregnancy and 1 year after delivery: a prospective cohort study. BJOG. 121 (3), 269-280. Available from: https://doi.org/10.1111/1471-0528.12438 87. Barber, M. (2016) Pelvic organ prolapse. BMJ. 354, i3853. Available from: https://doi.org/10.1136/bmj.i3853 (SC)	
NHS England and NHS Improvement	4	14-24	How do transgender patients fit into this? (GW)	Thank you for your comment. The issue of 'gender reassignment' has been highlighted in the 'equality considerations' section of the guideline and is outlined in greater detail in the 'Equality Impact Assessment' (EIA) form. In the EIA form we

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				describe how 'The guideline focusses on women's pelvic floor dysfunction and any complications associated with this. This would therefore be applicable to transgender men with female pelvic organs who may feel that this guideline may not apply to them or conversely would not be applicable to transgender women without female pelvic organs who may assume that the guideline would apply to them. To promote inclusivity related to trans people we have made the following addition to the 'who is the focus' section: 'For simplicity of language, this guideline uses the term 'women' throughout, but this should be taken to include those who do not identify as women but who have female pelvic organs.' This is aimed to highlighting the importance of this guideline to anyone with female pelvic

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				organs regardless of which gender they may identify with. In the EIA form we also specify why 'men' were excluded from the scope: • mechanisms how, reasons why, and complications associated with pelvic floor dysfunction may differ in men as compared to women. • one of the reasons for the referral of this guideline is the avoidance of surgical treatment for women who had urinary incontinence or pelvic organ prolapse, which are two of the main complications of pelvic floor dysfunction.
NHS England and NHS Improvement	4	23	Specific reference has been made to women with Physical disabilities and cognitive impairment however women with respiratory disease maybe another key group for	Thank you for your comment. These two groups feature as part of specific considerations because it is likely these groups of people would need additional support with the different management options, for example

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			consideration and are mentioned later in the document (line 15 page 8) (CAHPO)	in undertaking pelvic floor exercises, or with understanding detailed instructions. We agree that respiratory disease is an important consideration; however, people with this condition are unlikely to need different support to other people with pelvic floor dysfunction. In one of the draft review questions we state we aim to determine which co-existing long term conditions are associated with a higher risk of pelvic floor dysfunction, although we cannot list all the conditions of interest in the question itself, we have revised this to: 'What co-existing long-term conditions (for example cystic fibrosis or chronic respiratory disorders) are associated with a higher risk of pelvic floor dysfunction?' We do not want to pre-empt the outcome of this review by adding any specific groups.
NHS England and NHS Improvement	4	26	Men being excluded from the Scope, whilst services for women can be limited men are often disadvantaged, we were unable to find	Thank you for your comment. Equality considerations related to gender have been

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			the EIA associated with this decision (CAHPO)	captured in the 'Equality Impact Assessment' (EIA) form. In the EIA form we state that men are excluded because: • mechanisms and reasons why men may develop pelvic floor dysfunction and the complications may differ. • one of the reasons for the referral of this guideline is the avoidance of surgical treatment for women who had urinary incontinence or pelvic organ prolapse which are two of the main complications of pelvic floor dysfunction. We would also highlight that stakeholders can contact NICE to propose potential topics for the development of new guidelines which are not currently covered by existing guidelines, such as pelvic floor dysfunction in men.
NHS England and NHS Improvement	9	18	Physiotherapy and pelvic floor muscle training is anticipated to be the first line management for individuals suffering dysfunction. It is	Thank you for your comment.

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			hoped that pelvic floor exercises will include consideration of the impact of pelvic floor exercise frequency, number of repetitions, technique, breathing control and along with functional progressive exercise programmes to optimise the outcomes of this intervention. (CAHPO)	The examples that are mentioned in this draft review question ('What is the effectiveness of physical devices (including support garments, pessaries and dilators) for improving symptoms of pelvic floor dysfunction?) are illustrative and are not meant to be comprehensive. We will raise this with the committee when the details (including the frequency and intensity) of this review are discussed and agreed during development of the guideline.
Royal College of General Practitioners	3	14	Consider including paediatric and adolescent services if children over 12 are to be included in the guideline	Thank you for your comment. In the section of the scope related to settings it states that that the guideline will cover 'all settings where NHS-funded or local-authority-funded healthcare is provided'. This would include paediatric and adolescent services.
Royal College of General Practitioners	4	15	The age covered by the guideline is stated as 12 and over yet the guideline also states that children are not covered (line 27 page 4). These 2 contradict each other, the group	Thank you for your comment. The convention adopted by the NICE style guide in relation to age is: • babies or infants: 1 year and under

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			should consider revising the statement or raising the age of inclusion to only adults.	• children: up to 12 years • young people: between 12 and 17 years. Therefore the two sections do not contradict each other.
Royal College of General Practitioners	8	12	Please consider adding constipation and its causes to the non obstetric risk factors of pelvic floor dysfunction	Thank you for your comment. The examples that are mentioned in this draft review question ('What are the non-obstetric risk factors (for example age, ethnicity and family history, diet [including caffeine and alcohol], weight, smoking, physical activity) for pelvic floor dysfunction?') are illustrative and are not meant to be comprehensive. We will raise this with the committee when the details of this review are discussed and agreed during development of the guideline.
Royal College of General Practitioners	8	15	Co-existing conditions are not limited to respiratory causes as in the document currently. The group should also consider including abdominal and pelvic conditions, polypharmacy with constipating agents e.g.	Thank you for your comment. The examples that are mentioned in this draft review question ('What co-existing long-term conditions (for example cystic fibrosis or respiratory disorders) are associated with a

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			tricyclic antidepressants or opioid analgesics and those that impact on mobility.	higher risk of pelvic floor dysfunction?') are illustrative and are not meant to be comprehensive. We will discuss the range of co-existing conditions with the guideline committee when the details of this review are discussed and agreed during development of the guideline.
Royal College of General Practitioners	8	24	Can the group consider lifestyle modifications to address constipation including fluid intake, medication changes and laxatives where appropriate?	Thank you for your comment. The examples that are mentioned in this draft review question ('What are the non-obstetric risk factors (for example age, ethnicity and family history, diet [including caffeine and alcohol], weight, smoking, physical activity) for pelvic floor dysfunction?') are illustrative and are not meant to be comprehensive. We will discuss the range of potential lifestyle modifications that are likely relevant for all the included symptoms of pelvic floor dysfunction with the guideline committee when the details of this review are discussed and agreed during development of the guideline.

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Royal College of General Practitioners	9	5	When assessing for pelvic floor dysfunction please consider physical (e.g. post birth trauma, UTI, ovarian cancer etc.) and psychological (e.g sexual abuse) as differential diagnoses especially if this guideline includes children over 12 years old.	Thank you for your comment. The draft review question 'What assessments in primary care would identify whether the symptoms at presentation are caused by pelvic floor dysfunction?' is broad and would allow the committee to consider this. We will raise this with the committee when the details of this review are discussed and agreed during development of the guideline.
Royal College of General Practitioners	9	7	Can the group consider adding a question on the effectiveness of identifying constipation and treating it in pelvic floor dysfunction?	Thank you for your comment. It is intended that the whole section entitled 'Non-surgical management of symptoms associated with pelvic floor dysfunction (urinary incontinence, emptying disorders of the bladder, faecal incontinence, emptying disorders of the bowel, pelvic organ prolapse, sexual dysfunction and chronic pelvic pain syndromes)' would cover constipation as a subtype of emptying disorders of the bowel.

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				Constipation as a possible risk factor for pelvic floor dysfunction may also be covered in the review question 'What are the non-obstetric risk factors (for example age, ethnicity and family history, diet [including caffeine and alcohol], weight, smoking, physical activity) for pelvic floor dysfunction?'. The examples that are mentioned in this draft review question are illustrative and are not meant to be comprehensive. We will raise this with the committee when the details of this review are discussed and agreed during development of the guideline.
Royal College of General Practitioners	9	7.3	Please consider adding fluid management in addition to dietary food changes to the lifestyle modification section	Thank you for your comment. We anticipate that fluid management would be covered in the following review question: 'What dietary factors can increase or decrease symptoms of pelvic floor dysfunction?' The examples that are mentioned in this draft review question are illustrative and are not

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				meant to be comprehensive. However, particular types of fluid (caffeine and alcohol) are already added as examples in the non-obstetric risk factors question: 'What are the non-obstetric risk factors (for example age, ethnicity and family history, diet [including caffeine and alcohol], weight, smoking, physical activity) for pelvic floor dysfunction?' We will raise this with the committee when the details of this review are discussed and agreed during development of the guideline.
Royal College of General Practitioners	9	11	Behavioural interventions should include bladder retraining as an intervention in addition to toilet training	Thank you for your comment. The examples that are mentioned in this draft review question ('What is the effectiveness of behavioural approaches approaches (for example toilet training, seating, splinting) for improving symptoms of pelvic floor dysfunction?') are illustrative and are not meant to be comprehensive. We will raise this with the committee when the details of this review are

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				discussed and agreed during development of the guideline.
Royal College of General Practitioners	10	12	Can the group ensure they consider the impact on using topical vaginal oestrogen replacement in the pharmacological management of pelvic floor dysfunction in addition to other oral medication	Thank you for your comment. The details relating to which pharmacological management of pelvic floor dysfunction would be reviewed will be discussed with the committee during the development of the guideline. We will raise topical vaginal oestrogen replacement in the management of pelvic floor dysfunction with the committee when the details of this review are discussed and agreed during development of the guideline.
Royal College of Midwives	General		The draft scope appears to cover key issues with appropriate questions. RCM believes it will be a useful guideline for health professionals and women, supporting a life cycle approach in women's health by addressing prevention and strengthening women's engagement in improving their long-term well-being.	Thank you.

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Royal College of Midwives	9	18-21	The pelvic floor muscles training in the scope questions covers Kegel exercises. RCM is aware there are several internal devices now on the market for pelvic floor some electronic, some not and non-medical. However, it is not clear how the devices function, some without associated Kegel exercises. As the commercial market is so vast how is the guideline going to address this. Would they be better excluded as not MHRA tested, though information for women is paramount as they are seen as a targeted marketing population.	Thank you for your comment. We agree this is important for women, and we anticipate this will be discussed with the guideline committee. However, it is usually the case that types of interventions are reviewed rather than specific commercial products. In addition, often there is limited published evidence on specific devices, making it difficult to determine their effects. We agree that person centred care, and information related to this is very important.
Royal College of Obstetricians and Gynaecologists	1	15	A needed guideline from the perspective of the abandonment of mesh and TVT procedures. Also encouraging more support within the community for patients with pelvic floor symptoms. However, the topic is VAST. Tackling urinary and bowel incontinence types, pelvic organ prolapse, chronic pain and sexual dysfunction are huge topics in their own right. There will	Thank you for your comment. As part of the guideline's output there will be a pathway and/or an algorithm which would divide the topic into sub-sections. We have also revised the definition section to clearly outline that we will only consider symptoms that are specifically caused by pelvic floor dysfunction.

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			have to be very clearly defined sub-sections to ensure health care professionals can follow the right course of advice.	
Royal College of Obstetricians and Gynaecologists	1	19	Does this include dyspareunia? Sexual dysfunction might include urinary or bowel symptoms during intercourse but could also include pain from prolapse.	Thank you for your comment. We include sexual dysfunction as one of the key symptoms of pelvic floor dysfunction, and will we include any form of this if specified in the identified literature.. Within each protocol we will include greater detail regarding subcategories of symptoms, and these will be discussed and agreed with the guideline committee during development
Royal College of Obstetricians and Gynaecologists	4	18	Separate women who are pregnant to women after pregnancy. Women who are pregnant are a complex group with more limited management options. I would like to see some recommendations on pessary usage in pregnancy.	Thank you for your comment. We have included 'women who are pregnant or women after pregnancy (including women with obstetric injury)' as specific groups that we will consider.

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Royal College of Obstetricians and Gynaecologists	4	**22**	Post-menopausal age group – ensure vaginal atrophy mentioned as a potential cause of urinary symptoms or sexual dysfunction	Thank you for your comment. We agree this is of interest, and it will be considered when the committee discusses and agrees the review protocols during development.
Royal College of Obstetricians and Gynaecologists	5	17	Ensure there is a clearly defined difference between the management of urinary symptoms and prolapse symptoms.	Thank you for your comment. The scope includes these as two different sets of symptoms, and they will be considered separately.
Royal College of Obstetricians and Gynaecologists	5	21	Include referral pathways for urodynamics and how to interpret them	Thank you for your comment One key area of the scope is the development of 'Community-based pelvic health pathways'. It is possible that referral may feature in this but the details of the pathway will be discussed and developed by the guideline committee, following the completion of the evidence review. Urodynamic testing is generally conducted in secondary care and may not feature in a community based pathway. Generally, women

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				will have urodynamic testing if conservative management has failed, and this is part of the pathway to surgery. As such, the role of urodynamic testing is included in the recently published guideline 'Urinary incontinence and pelvic organ prolapse in women: management'.
Royal College of Obstetricians and Gynaecologists	5	23	Lifestyle modifications: must include weight loss, cessation of smoking. It may be pertinent to mention in this section that it should be mentioned early in the assessment of symptoms to the patient that if she has co-morbidities such as raised BMI or smoking, then she will either struggle for consideration of surgery (if required) or surgery will be more likely to fail.	Thank you for your comment. We agree that smoking is important, and is included in the draft review question 'What are the non-obstetric risk factors (for example age, ethnicity and family history, diet [including caffeine and alcohol], weight, smoking, physical activity) for pelvic floor dysfunction?' We cannot predict outcomes of the review. However, if smoking is confirmed as a risk factor, this would allow the committee to cross refer to the Stop smoking interventions and services NICE guideline.

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				We do not believe it is necessary to review the evidence on smoking cessation for management of pelvic floor dysfunction, as stopping smoking has well known and widespread health benefits.
Royal College of Obstetricians and Gynaecologists	5	28	Will this include – Pelvic Pain Clinics and local pudendal nerve injections for pudendal neuralgia – and where the latter should be carried out	Thank you for your comment. In the section of the scope related to settings it states that that the guideline will cover 'all settings where NHS-funded or local-authority-funded healthcare is provided'. This would include pelvic pain clinics. Details of the pelvic pain protocols will be discussed and agreed with the guideline committee, who will decide whether this should include 'pudendal nerve injections for pudendal neuralgia'.
Royal College of Obstetricians and Gynaecologists	5	29	Does there need to be a section on referral to secondary care and guidance associated?	Thank you for your comment. One key area of the scope is the development of 'Community-based pelvic health pathways'. It

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				is possible that referral may feature in this but the details of the pathway will be discussed and agreed with the guideline committee, following the completion of the evidence review.
Royal College of Obstetricians and Gynaecologists	8	13	They say "weight loss" as a non-obstetric risk factor for pelvic floor dysfunction. Do they mean weight GAIN or simply weight (as in increased BMIs)??	Thank you for your comment. We agree weight is likely to be a risk factor, and weight loss a potential management option. We have amended the review question to state 'weight' as suggested: ''What are the non-obstetric risk factors (for example age, ethnicity and family history, diet [including caffeine and alcohol], weight, smoking, physical activity) for pelvic floor dysfunction?'.
Royal College of Obstetricians and Gynaecologists	8	14	Will the effect of smoking cessation be considered?	Thank you for your comment. We agree that smoking is important, and is included in the draft review question 'What are the non-obstetric risk factors (for example age, ethnicity and family history, diet [including caffeine and alcohol], weight, smoking, physical

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				activity) for pelvic floor dysfunction?' We cannot predict outcomes of the review. However, if smoking is confirmed as a risk factor, this would allow the committee to cross refer to the Stop smoking interventions and services NICE guideline.
Royal College of Obstetricians and Gynaecologists	12	11/12	Are occupational factors also going to be assessed?	Thank you for your comment: We anticipate that this would be covered in the following review question: 'What is the effectiveness of modifying lifestyle factors (diet [including caffeine and alcohol], weight, smoking, physical activity) for preventing pelvic floor dysfunction? Physical activity could relate to occupational or non-occupational factors (for example lifting). We will raise this with the committee when the details of this review are discussed and agreed during development of the guideline.

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Velindre Cancer Centre	4	16	…women before and after cancer treatment other than surgery, i.e. pelvic radiotherapy and chemotherapy	Thank you for your comment. In the draft review question section we address the topic of 'co-existing long term conditions' as well as 'non-obstetric risk factors which could include cancer and/or chemotherapy as a condition/treatment that would increase the risk of having pelvic floor dysfunction. We will raise this with the committee when the details of this review are discussed and agreed during development of the guideline.
Velindre Cancer Centre	4	21	….whether it be natural menopause or induced menopause due to cancer treatment	Thank you for your comment. We prefer to keep this as 'women who are in perimenopause or postmenopause'" because there could be other situations where the 'menopause' is caused by external factors, for example cases of hysterectomy and oophorectomy (not associated with cancer). We think the definition as is, is more inclusive.
Velindre Cancer Centre	8	2	What are the gynae-oncology risk factors of pelvic floor dysfunction?	Thank you for your comment.

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				In the draft review question section we address the topic of risk factors. We have included three questions on risk factors, these include co-existing long term conditions, non-obstetric risk factors and obstetric risk factors. We will raise this with the committee when the details of these reviews are discussed and agreed during development of the guideline.
Velindre Cancer Centre	9	7	What is the effectiveness of smoking cessation for improving pelvic floor dysfunction?	Thank you for your comment. We agree that smoking is important, and is included in the draft review question 'What are the non-obstetric risk factors (for example age, ethnicity and family history, diet [including caffeine and alcohol], weight, smoking, physical activity) for pelvic floor dysfunction?' We cannot predict outcomes of the review. However, if smoking is confirmed as a risk factor, this would allow the committee to cross refer to the Stop

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				smoking interventions and services NICE guideline.
Velindre Cancer Centre	9	9	…and dilators	Thank you for your comment. We have added dilators to the examples as suggested: 'What is the effectiveness of physical devices (including support garments, pessaries and dilators) for improving symptoms of pelvic floor dysfunction?.