National Institute for Health and Care Excellence

Menopause
Scope Consultation Table
24 May - 21 June 2013

Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
Abbott Healthcare Products Ltd			Question 1 Yes	Thank you for your comment
Abbott Healthcare Products Ltd			Question 2 4.3.1b Timing of treatment, monitoring, duration and withdrawal strategies, this area of prescribing could be clarified and give prescribers and pts confidence 4.3.1c Contribution of HRT to prevent long-term sequelae, this area of treatment divides opinion and guidance would provide clarity.	Thank you for your comment. These topics will be covered in the guideline.
Abbott Healthcare Products Ltd			Question 3 Hormone pharmaceutical treatments, these are mostly commonly used and have relatively large evidence base as treatment options for menopause related symptoms	Thank you for your comment. The use of HRT will be covered in the guideline.
Abbott Healthcare Products Ltd			Question 4 Yes	Thank you for your response to this question. Following stakeholder feedback the scoping group have retained the question in the final scope, with the addition of early onset dementia to the list of conditions prioritised.
Abbott Healthcare Products Ltd	1	4.3.1	The guidelines could provide an Please add to the list of issues guidance on women transitioning from, which may also support	Thank you for your comment,

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			any specific guidance relating to question 4.5.2.e	The differentiation between doses was not considered a priority for this clinical question. The evidence review will use the minimum recommended dose according to the SPC and BNF.
Abbott Healthcare Products Ltd	2	4.3.1	In reviewing different treatment options there is an opportunity to distinguish between the various types of oestrogen and progestogen, especially in light of the IMS recommendations / comments Please add to the list of issues guidance on women transitioning from on use of micronized progesterone or dydrogesterone	Thank you for your comment, The differentiation between different types of oestrogen and progesterone product was not considered a priority for this clinical question. The guideline will explore the class action of each type of drug instead.
Bayer Plc	1	4.3.2	**Clinical issues that will not be covered** f) Contraception during the menopause. Effective contraception is an important issue for this group of women. In 2011, 27.9% of conceptions in women aged 40 and over resulted in a legal abortion; this is higher than the proportions in women aged 30-34 and 35-39 at 12.8 and 16.0 respectively.[1] Whilst we appreciate that this area is sufficient to warrant a guideline in its own right, and therefore it cannot be addressed under the scope of the proposed guideline, we are concerned that its complete omission may lead to important issues which are integral to the holistic management of peri-menopausal and menopausal women being overlooked. For example, hormone replacement therapy (HRT) does not consistently suppress ovulation,[2] and therefore it is advised that it should not be relied upon as a contraceptive.[3] This is an important point for a guideline covering the use of treatments for symptomatic relief of the menopause.	Thank you for your comment Given the finite resources and time available to develop a guideline, a full review of contraception for women in the menopause was not considered to be a priority for the guideline. However, the topic of 'Information on contraception at the menopause' will form part of a new clinical question on information provision for these women. Whilst a separate evidence will not be done for contraception, this topic will be considered within the systematic review for advice that women should be given during the menopause

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			As a minimum, we suggest that a recommendation or cross reference should be included to ensure that the contraceptive needs of peri-menopausal women are considered in line with recommendations from nationally recognised guidelines such as those from the NICE accredited provider the Faculty of Sexual & Reproductive Healthcare, Clinical Guidance on Contraception for Women Aged Over 40 Years (July 2010).[3] **Proposed recommendation** Healthcare professionals should discuss the contraceptive needs of the woman as part of her management, and should be familiar with nationally recognised guidance on Contraception for Women aged over 40 Years from the NICE accredited provider the Faculty of Sexual & Reproductive Healthcare.[3] 1) Office for National Statistics (ONS). Conceptions in England and Wales, 2011 - Conceptions leading to abortion. 26 February 2013. Available at: http://www.ons.gov.uk/ons/rel/vsob1/conception-statistics--england-and-wales/2011/2011-conceptions-statistical-bulletin.html#tab-Conceptions-leading-to-abortion 2) Gebbie AE, Glasier A, Sweeting V. Incidence of ovulation in perimenopausal women before and during hormone replacement therapy. Contraception. 1995 Oct;52(4):221-2. 3) Faculty of Sexual & Reproductive Healthcare (FSRH) Clinical Effectiveness Unit. Clinical Guidance - Contraception for Women Aged Over 40 Years July 2010. ISSN 1755-103X. Available at: http://www.fsrh.org/pdfs/ContraceptionOver40July10.pdf	
British Menopause Society			Question 1 Yes	Thank you for your comment.
British Menopause Society			Question 2	Thank you for your comment.

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			The Key Clinical Issues (all are vital) a) Diagnosis and classification of menopause b) Optimal clinical management of menopause symptoms c) Contribution of HRT to long term sequelae d) Diagnosis and management of premature ovarian insufficiency	These topics will be covered in the guideline.
British Menopause Society			Question 3 Hormonal pharmaceutical treatments should be prioritised as these have the greatest impact on quality of life and prevention Non hormonal pharmaceutical and non pharmaceutical treatments are also important in those women in whom hormone therapy is contraindicated and in those wishing to avoid hormone therapy.	Thank you for your comment. These topics will be covered in the guideline.
British Menopause Society			Question 4 I would suggest adding stroke and dementia to this list	Thank you for your comment to this question. Following stakeholder feedback the scoping group have retained the question in the final scope, with the addition of early onset dementia to the list of conditions prioritised.
British Menopause Society	1	general	We are grateful to NICE that most of the comments made at the stakeholder meeting have been taken into consideration	Thank you for your supportive comment
British Menopause Society	2	3.1g	Suggest modification to …"symptoms can continue indefinitely"	Thank you for your comment, We have amended the text in scope in line with your comment.
British Menopause Society	3	3.2h	Suggest inclusion of following comment …. "Menopause societies and the endocrine society now believe that there is a	Thank you for your comment,

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			window of opportunity in the early menopause transition where treatment with HRT can result in cardiovascular benefit."	Whilst your suggested text may be correct, it cannot be included without completing our own evidence review. Therefore this text has not been added to the scope. This is a clinical area that will be reviewed in the full guideline and, if the GDG feel it is appropriate, will produce a recommendation accordingly.
British Menopause Society	4	4.1.2c	Groups not covered: Women and young people under 18 years - Will this not exclude young women with premature ovarian insufficiency?"	Thank you for your comment. This group has now been removed from the excluded populations list. The guideline will not, however, examine the diagnosis of the cause of primary amenorrhea, just the treatment of the menopausal symptoms.
British Menopause Society	5	4.3.1b	Suggest that we include review of evidence for DHEA	Thank you for your comment, DHEA was not prioritised as a short term treatment for menopausal symptoms because it was not considered to be a common treatment in the UK. Therefore it will not be covered within the guideline.
British Menopause Society	6	4.3.2b	There have been comments from a number of members that HRT in women with a personal or family history of breast cancer should be reconsidered. Although the previous NICE clinical guidelines on breast cancer have covered this issue it remains a controversial area which is managed inconsistently and needs further clarification.	Thank you for your comment, Breast cancer has not been excluded in its entirety. The exclusion of women who have (or are risk of) breast cancer is just for the review of systemic oestrogen-based hormonal treatment of menopausal symptoms. This decision was taken because there are existing NICE

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				guidelines which have addressed this topic and have made adequate recommendations in this area. These guidelines can be found at the following links: Familial breast cancer. NICE clinical guideline 164 (2013) Breast cancer (advanced). NICE clinical guideline 81 (2009) Early and locally advanced breast cancer. NICE clinical guideline 80 (2009).
British Menopause Society	7	4.3.2f	A number of members would like contraception in the menopause covered, particularly where it relates to choice of peri-menopause therapies in women needing contraception.	Thank you for your comment Given the finite resources and time available to develop a guideline, a full review of contraception for women in the menopause was not considered to be a priority for the guideline. However, the topic of 'Information on contraception at the menopause' will part of a new clinical question on for information provision for these women. Whilst a separate evidence will not be done for contraception, this topic will be considered within the systematic review for advice that women should be given during the menopause
British Menopause Society	8	4.4.1 & 4.5.2	Should we be applying a 5 year definition to short term outcomes/symptoms? Perhaps it is better not to define this, as the duration of symptoms is so variable.	Thank you for your comment, It was felt that the guideline should only address the management of the short term menopausal symptoms (and not the long term complications, such as

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				osteoporosis). For that reason a time limit has to be set. The choice of 5 years was on the basis that this should clearly cover appropriate treatment of all the short term symptoms.
British Menopause Society	9	4.5.3	Non hormonal options for managing vaginal symptoms should also be included e.g. lubricants & moisturisers	Thank you for your comment, The scoping group did not believe that lubricants and moisturisers were a treatment option in the same class as the other therapeutic interventions and not appropriate for comparison with the other agents listed in this section. It was thought that these were management options that could be considered in the lifestyle advice review.
British Menopause Society	10	4.5.4	It is important to consider the short and long term impact of POI in women who switch from COC to HRT, those who stop treatment before 51years and in those who cannot/do not want to use COC or HRT.	Thank you for your comment, It is expected that any data and guidance relating to this comment will come out in the clinical review of the oral contraceptive pill (OCP) vs. hormonal replacement therapy (HRT). Therefore no additional question has been added.
British Psychological Society			Question 1 The Society agrees with the areas in general but has some suggestions regarding emphasis and priorities. Within the draft scope there is a strong medical focus, i.e. discussion of "diagnosis" and "symptoms", , might suggest that menopause is an "illness" or a "disease", which it is not. It is a normal stage of women's lives. An initial short paragraph in the	Thank you for your comments. However, as women at the menopause present with complaints and seek professional help in a clinical setting (hence the need for the Guideline) it is felt that 1. The use of the term 'symptoms' is

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			remit section (2) could acknowledge this dilemma: 'For most women the menopause is experienced as a normal life transition; this clinical guidance focuses on their needs for evidence based information but also on the needs of those women who have problematic symptoms and who seek medical advice.' The clinical management section could then usefully include a section on provision of information and advice for women in general, as well as the section on treatment for those with problems. 4.3.2 We would recommend the inclusion of non hormonal interventions, including non-hormonal medications and psychological treatment, e.g. cognitive behaviour therapy (CBT) (Mann et al 2012; Duijts et al 2012) for this group of women who often have intense and distressing vasomotor symptoms and who tend to prefer non-medical approaches (Hunter et al 2004).	appropriate. 2. Being sure that the symptoms are due to the menopause is reasonable and the term 'diagnosis' is appropriate.
British Psychological Society			<u>Question 2</u> The Society believes that health related quality of life (HrQOL) and symptom management should be prioritised. HrQOL reflects patient reported outcomes and levels of functioning and is influenced by a range of psychosocial as well as biological factors (Ayers et al 2012). A broader biopsychosocial and multidisciplinary focus is needed to address symptom management and HrQOL; perception and appraisal of symptoms strongly influenced by psychosocial factors (Hunter & Mann 2010; Hunter & Chilcot 2013). The Society agrees that early menopause and primary premature ovarian insufficiency (POI) should be included, but some concern about the breadth of content, e.g. fertility strategies - ovum donation, cryopreservation, and expertise needed to address the complexity of this umbrella group of complex conditions. We believe that there is a need to have a better understanding	Thank you for your comments. The time and resources available for the development of the guideline are limited. Thus, the remit has to be finite also and concentrate on the most important topics and those where there is variation in practice currently.

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			of women's knowledge, preferences and beliefs about medical and non medical treatments across the menopausal transition, including risks and benefits. Similarly, research into GPs beliefs and practices regarding treatments offered is warranted.	
British Psychological Society			Question 3 We suggest that this section should include an initial section on consultation, including provision of balanced evidence based information about menopause and health taking a biopsychosocial perspective. Given that most women do not take HRT, non-pharmacological treatments should be prioritised. On the basis of uptake and preference, non-medical treatments should be have at least equivalent priority in the scoping as medical treatments, e.g. psychological interventions, e.g. CBT for hot flushes and night sweats, sleep, self esteem, anxiety and depressed mood (cross reference to NICE for anxiety and depression 'The guidance should cover lifestyle interventions, e.g. evidence-based interventions to improve exercise participation, effective weight control methods, because health related behaviours are associated with the experience of menopause (smoking, exercise) as well as long term conditions, such as cardiovascular disease, osteoporosis. To that end the new guidance should be linked to NICE Behaviour Change Guidance. The Society has concerns about terminology e.g. 'psychosocial' symptoms (perhaps change to psychological distress, see comments below), 'urogenital atrophy' and the implied focus on penetrative sex.	Thank you for your comments. 1. In response to your suggestion about Information Giving, we have added this as an additional topic. 2. It is anticipated that the review of all the interventions for treatment of symptoms of the menopause will allow the GDG to produce recommendations that are specific for specific symptoms. 3. In response to your comments we have changed 'psychosocial' to 'psychological'.
British Psychological Society			Question 4 The Society agrees with this in general. This question should include cognitive function and whether outcomes relate to timing of HRT use. The question is placed in the section that	Thank you for your response to this question. Following stakeholder feedback the scoping group have retained the question

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			focuses on possible long term benefits of HRT; we suggest that it is presented more neutrally i.e. secondary long term outcomes including positive and negative consequences.	in the final scope, with the addition of early onset dementia to the list of conditions prioritised.
British Psychological Society	1	1, 2.	The Society suggests that 'Menopause: definitions and management' might be more acceptable, being less medical.	Thank you for your comment, The original long title will be retained. The guideline will aim to cover the diagnosis of the menopause. It was felt that replacement of "diagnosis" with "defining the menopause" would not outline the content of the guideline to same extent.
British Psychological Society	2	3.1e	There is only limited consideration of ethnicity in the whole of the document. This deserves more expansion. More references to the cross cultural differences in experience of menopause and treatment preferences are needed. The guidance could usefully encourage sensitivity to the wide and diverse range of experience, values, lifestyles and preferences of women who might seek help relating to menopause.	Thank you for your comment. We have added additional text to the scope that goes into greater detail about the cultural and ethnicity differences in the management of the menopause. We would also like to draw your attention to the separate Equality Impact Assessment document, in which we detail how we will approach the identified equality considerations within the guideline.
British Psychological Society	3	3.1c	The Society suggests using 'psychological distress or psychological symptoms' rather than 'psychosocial symptoms'; psychosocial factors such as mood, socioeconomic status etc influence experience of the menopause.	Thank you for your comment, It was agreed that psychosocial is not appropriate; we have amended the scope to look at psychological symptoms instead.
British Psychological Society	4	3.1f and 4.3.1d	A clear explanation of the differences in the implications of premature menopause, POI and normal menopause for treatment and in relation to psychological health would be	Thank you for your comment, It was felt that the current text within the

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			helpful.	scope incorporates the extent of the current understanding of this area. One of the outcomes of the guideline will be to clarify the scope and make it clear that women with psychological problems in association with POI, early menopause and menopause require separate consideration.
British Psychological Society	5	3.1g	The term 'associated symptoms of the menopause' is rather vague; the main symptoms are vasomotor symptoms and 'urogenital symptoms'. 'Classic menopausal symptoms' could be changed to vasomotor symptoms. Psychological symptoms can occur but are not specific menopausal symptoms as they are likely to have a range of causes and are associated with (but not necessarily caused by) the menopause transition in approximately 10% of women (Mishra & Kuh, 2012). A solution is to state this, i.e. that some women have psychological symptoms but these are not a specific sign or symptom of menopause. Psychological symptoms can occur but are not specific menopausal symptoms as they are likely to have a range of causes and are associated with (but not necessarily caused by) the menopause transition in approximately 10% of women (Mishra & Kuh, 2012). However, it is noteworthy that 77% of the women experienced no change and 13% experienced improvement in psychological symptoms across the menopause transition.'	Thank you for your comment, We have removed the term "associated" from the scope. It was agreed that this is too vague. The symptoms listed are those that are known to be caused by the menopause. The guideline will explore each of the symptoms during the development of review question protocols acknowledging that not all the symptoms are exclusively caused by the menopause.
British Psychological Society	6	3.1h	The relative influence of age and lifestyle on long term conditions should be mentioned here.	Thank you for your comment, It is outside of the remit of the scope to give specific examples of other factors involved in the differing rates of osteoporosis and CVD. We have, however, added additional text to make it

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				clear that oestrogen depletion may be only partially responsible.
British Psychological Society	7	3.1i	The term climacteric syndrome is not generally used; The Society suggests 'Climacteric is a term used to refer to experience of the broader transition including hormonal, bodily and psychosocial changes experienced by women during midlife.'	Thank you for your comment, We agree with your comment and your suggested change has been incorporated into the final scope.
British Psychological Society	8	3.2a	Additional UK references for use of HRT before and after WHI are: Menon et al (2007) and Hunter et al (2012). The Society believes that it is important to understand more about what women know about HRT and why they take it. Psychological factors (stress and internal locus of control) have been found to predict intentions to use HRT in a clinical sample of postmenopausal women, as well as the benefits associated with taking it (Simpson, 2012). The experience of menopause varies considerably; some women have few symptoms, while those who take HRT or seek specialist advice tend to have more persistent symptoms and more psychological stress (Simpson & Thompson, 2009), hence a biopsychosocial and multidisciplinary approach is recommended.	Thank you for comment, In a guideline scope it is not standard practice to provide an exhaustive list of studies to support a statement. In this example the WHI and Million Women studies were specifically mentioned as they themselves have had a significant effect on HRT use. This has been made clear in the final scope. When the guideline begins development, all relevant studies will be considered and the recommendations and statements like this will be addressed according to the evidence they provide.
British Psychological Society	9	3.2b	This depends on many factors, including perception and severity of symptoms, cultural,.....we suggest adding perception and severity of symptoms,	Thank you for your comment, We agree with your comment and additional text has been added to this paragraph.
British Psychological Society	10	3.2c	The Society welcomes the suggestion to invite 50 year old women for a health review. Not all women will necessarily want treatment, but it could provide an opportunity to review health and well being at this age, and to provide information and	Thank you for your comment. This paragraph was added to scope to address the current clinical understanding

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			advice on lifestyle changes that could potentially prevent some long term conditions.	of and management options for the menopause. The health review was mentioned as it is a high profile policy within the area. The scope is not endorsing or recommending this health review. This may be an option that will be explored within the guideline.
British Psychological Society	11	3.2d	There is a need to provide evidence based information on complementary and alternative therapies (CAM).	Thank you for your comment, Two of the clinical questions will address the effectiveness of alternative therapies. The guideline will provide evidence based recommendations on their use.
British Psychological Society	12	4.1.1	The Society recommends a greater focus on meeting the needs of women of different backgrounds, ethnicity, race etc in the scope. This should include whether the needs of women who require information in a language other than English.	Thank you for your comments. Inequality of treatment is an important topic within all NICE guidelines. The separate Equality Impact Assessment Document expands on issues raised in the scope and explains how the equality issues are to be considered throughout the guideline's development.
British Psychological Society	13	3.2i	There is a need to have a better understanding of why GPs are so variable in their prescribing rates for HRT.	Thank you for your comment, We agreed with your comment. The guideline will explore this disparity and make recommendations to improve clinical practice
British Psychological Society	14	4.3	The clinical management section could usefully include a first section on provision of information and advice for women in	Thank you for your comment,

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			general (evidence based information, informed choice, monitoring, and evidence based lifestyle advice, on exercise (Gudmundsdottir et al., 2013; Choquette et al., 2013), diet (Reed et al., 2013) etc, as well as the main section on treatment for those with problems, since women may want information and not necessarily treatment.	It was agreed that information provision is important part of menopause management. An additional clinical question has been added to address this requirement.
British Psychological Society	15	4.31b	'We suggest using the term 'psychological' rather than psychosocial...; in relation to 'problems with sexual functioning'.	Thank you for your comment, It was agreed that psychosocial is not appropriate. We have amended the scope to look at psychological symptoms instead.
British Psychological Society	16	4.4.1a	This could also include a Women's Health Questionnaire (Hunter 2003); Hot flush rating scale to measure Hot flushes which includes Hot Flush Frequency and Problem rating (Hunter & Liao 1995): it is Problem rating or bother that is associated with HrQOL and help-seeking (Ayers et al 2012). Also include HrQOL measures (SF36) or levels of functioning, such as the Work and Social Adjustment Scale which is short and used in primary care services routinely.	Thank you for your comment, The Greene Climacteric Scale was given as an example. Other symptom scoring systems will also be considered in the development of the guideline, depending on the inclusion criteria agreed by the guideline development group.
British Psychological Society	17	4.4.1b	Psychological distress or symptoms'	Thank you for your comment, This amendment has been made.
British Psychological Society	18	4.5.1a	Menstrual changes plus hot flushes are the main signs of menopause; the other symptoms are not specific to menopause so would not be specific signs of menopause. We suggest removing low mood, palpitations, sleep disturbances and reduced libido as these would not be used to define menopause in the absence of menstrual changes or vasomotor symptoms.	Thank you for your comment, The scoping group agreed with your comment and have amended the clinical question accordingly.
British Psychological Society	19	4.5.2c	Add the impact of balanced, evidence based information and advice on menopause, health and QOL as an intervention in	Thank you for your comment,

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			itself (as for 4.3.1b). Psychological interventions (as for 4.3.1b)	The scoping group agreed with your comment and have amended the final scope to include a clinical question to provide evidence based information.
British Psychological Society	20	General	There is evidence that the menopause is generally viewed in a negative light, associated with negative changes in health, well being, body image and attractiveness and those negative beliefs that overly associate menopause with negative consequences can have a negative impact on women's experience of menopause (Ayers et al 2010). Similarly negative beliefs about menopause and about hot flushes and night sweats are in turn associated with more problematic symptoms (Rendall et al 2008). More needs to be done to promote the positive elements of menopause and to counter overly negative perspectives on this natural stage of life (Rubinstein & Foster, 2012).	Thank you for your comment, This paragraph has been added to scope to address the current clinical understanding of the menopause. The health review was mentioned as it is a high profile policy within the area. The scope is not endorsing or recommending this health review. This may be an option that can be explored on within the guideline, but not the scope. It was agreed that a fundamental part of the menopause management is the information that women receive. To reflect this requirement an additional clinical question on this topic has been added to the final scope. The evidence review for the additional clinical question will provide the GDG with opportunity to recommend what information should be offered to women.
Cornwall Menopause Referral Service			<u>Question 1</u> We feel that management should begin with information giving and discussion of lifestyle changes that may enable a woman to manage without intervention. This should include what should be advised about exercise, alcohol, smoking caffeine	Thank you for your comments. Information giving is a new topic that will be covered in the guideline. We shall only consider interventions for

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			etc. This should come before treatments. We feel that there should be something about evidence of benefit (or lack of) from alternative therapies eg homeopathy, magnets We cannot understand why bio-identical hormone which are unlicensed are included and implants which were licensed and simply no longer marketed are not. Implants are still used within referral clinics but bio-identical hormones are not. Cognitive function should be included among long term sequelae on which the effect of HRT is examined We accept that there are guidelines regarding contraception in the over 40's but would ask that a mention is made both of when it is reasonable to infer that the woman cannot conceive and of any effect of HRT on fertility.	which there are RCT data. If they exist for homeopathy they will be reviewed. Bio-identical hormones and Implants will be reviewed if there are RCTs on their use in the short term treatment of menopausal symptoms and they have been licenced for use in the UK. This has now been added ('early onset dementia'). It has been agreed that the GDG will address providing information about contraception to women going through the menopause as a new topic in the scope.
Cornwall Menopause Referral Service			Question 2 The role of primary care in providing appropriate initial advice (see below) Diagnosis – as this is crucial Advice to patients – this may be enough and set the process off appropiately Evidence regarding and how to use prescribable treatments for colleagues.	Thank you for your comments. All the items you list are likely to be covered in a new question on information giving.
Cornwall Menopause Referral Service			Question 3 We need to disseminate the rationale for using that which we do prescribe – particularly in primary care and would prioritise	Thank you for your comments. We shall review all these drugs in the Guideline but the scope cannot prejudge

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			E+P – first line (including the difference between classes of progestogens) E – as first line after hysterectomy Tibolone – currently used as second line but its place is poorly understood Testosterone – used selectively (specialist initiated) and why SNRI – unlicensed but used frequently and often in inappropriate doses Gabapentin– unlicensed but used Clonidine –used but useless	the evidence and the conclusions of the GDG.
Cornwall Menopause Referral Service			<u>Question 4</u> We feel that psychosocial is not a helpful category and suggest that sleep disturbance, mood, concentration and memory and well being are addressed specifically as these are what women complain of.	Thank you for your response to this question. Following stakeholder feedback the scoping group have retained the question in the final scope, with the addition of early onset dementia to the list of conditions prioritised.
Cornwall Menopause Referral Service	1	4.2 a)	why is primary care in brackets? JD comments - surely this guidance should be aimed at primary care -as this is where patients first present if they have menopausal symptoms - if this is not aimed at primary care the limited secondary care provision will be swamped - or more likely - no GP's will bother to read the guidance and the ignorance of the last 10 years where Gp's have been afraid to prescribe HRT will worsen, the speciality will die out and millions of women will continue to suffer	Thank you for your comment, Implementation of the guideline is likely to have the greatest Impact in primary care. The brackets were there to emphasise this point. We agree that this was misleading and have removed this text.
Cornwall Menopause Referral Service	2	3.2.a)	Surely dates incorrect as published 2002 and 2003 respectively.?	Thank you for your comment, This correction has been made.
Department of Health			No comments.	Thank you for your comment.

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Faculty of Sexual and Reproductive Healthcare	1	General	We do not agree with NICE's decision not to cover contraception during the menopause. At the very least guidance should include: • The need for contraception in women with premature menopause because of potential fluctuation in ovarian function • The fact that the IUS is the only contraceptive proven to provide endometrial protection for women using estrogen HRT and that it must be replaced after 5 years. • Cross reference to FSRH guidance on Contraception for Women Over 40 Years for advice on when to stop contraception We can't see any mention of management of HRT side effects e.g. bleeding, which we think is important to cover.	Thank you for your comment Given the finite resources and time available to develop a guideline, a full review of contraception for women in the menopause was not considered to be a priority for the guideline. However, the topic of 'Information on contraception at the menopause' will form part of a new clinical question on information provision for these women. Whilst a separate evidence will not be done for contraception, this topic will be considered within the systematic review for advice that women should be given during the menopause
Faculty of Sexual and Reproductive Healthcare	2	4.5.4	The section on Diagnosis and Management of Premature Ovarian insufficiency should include other appropriate investigations e.g. thyroid function, Fragile X	Thank you for your comment. The investigation of Premature Ovarian Insufficiency (POI) was not considered to be a priority for the guideline. Specifically, the investigation of the cause of primary ovarian insufficiency has also been excluded from the scope as the conditions that cause primary POI were outside of the remit of the guideline.
Forum of Food and Health -Royal Society of Medicine			<u>Question 4</u> Yes	Thank you for your response to this question. Following stakeholder feedback the scoping group have retained the question

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				in the final scope, with the addition of early onset dementia to the list of conditions prioritised.
Forum of Food and Health -Royal Society of Medicine	1	4.5.3.j	Think there should be an addition of the condition SARCOPENIA as J Sarcopenia the loss of muscle mass is in many ways as dangerous for wellbeing as is osteoporosis in causeing fractures and debility > there is increasing evidence that Sarcopenia can be reduced and even avoided by appropriate strategies ,many of which are nutritional and lifestyle based	Thank you for your comment, Sarcopenia has been included in the review of long term chronic conditions associated with the menopause and HRT use.
Menopause UK Network (Daisy Network, Early Menopause, Hysterectomy Association, Menopause Matters UK)			Question 1 Overall we consider the draft scope to be comprehensive in its coverage of the key issues. The NICE guidelines on menopause represent a significant opportunity to improve treatment and care for women in menopause. The guidelines will benefit from being informed by the knowledge and insights of women affected by menopause, and we welcome this opportunity to comment on the draft scope. We support the inclusive approach taken to defining groups that will be covered by the guidelines, in particular women with premature ovarian insufficiency irrespective of cause. Many of the women who give and receive support through our organisations have entered menopause at a young age, and we are keen to ensure the guidelines result in a) improved diagnosis and management of menopause in younger women, including recognition of ovarian failure after hysterectomy, and b) clarity about the risks and benefits of HRT for younger women. We disagree with the exclusion of women at higher risk of breast cancer, women undergoing treatment for breast cancer, and women who have previously had breast cancer (at 4.3.2).	Thank you for your comment, Breast cancer has not been excluded in its entirety. The exclusion of women who have (or are risk of) breast cancer is just for the review of systemic oestrogen-based hormonal treatment of menopausal symptoms. This decision was taken because there are existing NICE guidelines which have addressed this topic and have made adequate recommendations in this area. These guidelines can be found at the following links: Familial breast cancer. NICE clinical guideline 164 (2013) Breast cancer (advanced). NICE clinical guideline 81 (2009) Early and locally advanced breast cancer. NICE clinical guideline 80 (2009).

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			We recommend that the scope should be extended at 4.3.2 to include women at higher risk of breast cancer, women undergoing treatment for breast cancer, and women who have previously had breast cancer. Further comments on this are set out below.	
Menopause UK Network (Daisy Network, Early Menopause, Hysterectomy Association, Menopause Matters UK)			Question 2 We strongly support the inclusive approach to defining the population to be covered by the guidelines, and especially the inclusion of women in early menopause from any cause. We also strongly support the inclusion of women with or at higher risk of breast cancer . If decisions need to be made about which aspects of the guidelines to prioritise, we hope that the needs and concerns of women can provide a framework for assessing what the guidance should cover. Women want to know: • what treatments will help their symptoms and protect their health in the long term • whether treatments are safe, and if any risks outweigh benefits • when they should start treatment, and when and how they should stop. • When they see a health professional for help with menopause related symptoms or concerns, women want to know: • that their condition will be recognised, appropriately assessed and that appropriate advice or treatment will be offered • that they will be reviewed at appropriate intervals, and that they will be involved in decisions to initiate, change or stop	Thank you for your comment. We think the current version of the scope addresses these issues.

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			treatment • that it will be possible for them to be referred to specialist (secondary) care if needed.	
Menopause UK Network (Daisy Network, Early Menopause, Hysterectomy Association, Menopause Matters UK)			Question 3 The list of clinical issues and therapies is comprehensive. All are in use and it is difficult to see why any should be omitted if the guidelines are to provide comprehensive advice. We support the inclusion of non-pharmaceutical treatments, since these are widely used by women and authoritative advice about their usefulness would be of benefit.	Thank you for your comment.
Menopause UK Network (Daisy Network, Early Menopause, Hysterectomy Association, Menopause Matters UK)			Question 4 We support the prioritisation of the conditions listed in this section.	Thank you for your response to this question. Following stakeholder feedback the scoping group have retained the question in the final scope, with the addition of early onset dementia to the list of conditions prioritised.
Menopause UK Network (Daisy Network, Early Menopause, Hysterectomy Association, Menopause Matters UK)	1	4.3.2	**Breast cancer** We recommend that the scope should be extended at 4.3.2 to include women at higher risk of breast cancer, women undergoing treatment for breast cancer, and women who have previously had breast cancer, for the reasons set out below. The belief that HRT increases a woman's risk of breast cancer is widely held by women and healthcare professionals. Whilst in some cases this is true, the total number of women in this category is thought to be relatively small. So the pervasiveness of this concern has a disproportionate impact on women's decisions to seek treatment, and on professionals' assessments of the risks and benefits of HRT. The guidelines will only result in changed practice if they	Thank you for your comment, Breast cancer has not been excluded in its entirety. The exclusion of women who have (or are risk of) breast cancer is just for the review of systemic oestrogen-based hormonal treatment of menopausal symptoms. This decision was taken because there are existing NICE guidelines which have addressed this topic and have made adequate recommendations in this area. These guidelines can be found at the following links:

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			address the beliefs and concerns of women and health professionals, and are seen as a trusted and comprehensive source of information. To achieve this, the question that the guidelines most need to answer, and be seen to answer, is 'Does HRT increase the risk of breast cancer?". To remain silent on this point would seriously undermine the credibility and impact of the guidelines. Whilst it may be the case that the needs of women with previous breast cancer, or an increased genetic risk of breast cancer, are sufficiently well addressed by the existing NICE guideline on breast cancer, we recommend that the exclusion at 4.3.2 of women at higher risk of breast cancer, women undergoing treatment for breast cancer, and women who have previously had breast cancer, be softened. Firstly, we recommend that a commitment to include a summary of the existing guidance applying to these women, accompanied by prominent signposting to the appropriate guidance, be included in the scope and in the guidelines in due course. Secondly we recommend that where non-estrogen therapies for the management of menopausal symptoms, and non-systemic estrogen therapies (eg vaginal estrogen) are considered within the guidelines, their appropriateness should be evaluated for this group of women.	Familial breast cancer. NICE clinical guideline 164 (2013) Breast cancer (advanced). NICE clinical guideline 81 (2009) Early and locally advanced breast cancer. NICE clinical guideline 80 (2009).
Menopause UK Network (Daisy Network, Early Menopause, Hysterectomy Association, Menopause Matters UK)	2	4.4.1.b.	**Cognitive function** Cognitive symptoms, including forgetfulness, difficulty concentrating, and getting words muddled, are troubling symptoms that many women attribute to menopause, although there remains debate about the extent to which they may be explained by other changes such as sleep disturbance. The guidelines will be of benefit in assessing the evidence relating to cognitive symptoms, and the effectiveness of treatments in alleviating cognitive symptoms. We recommend the broadening of the scope to refer to 'cognitive and psychosocial symptoms' throughout, in relation to both symptom recognition	Thank you for your comment, The scoping group agreed with your comment and have amended the final scope to describe cognitive symptoms under the umbrella term "psychological symptoms"

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			and clinical management.	
Menopause UK Network (Daisy Network, Early Menopause, Hysterectomy Association, Menopause Matters UK)	3	3.1.g., 4.5.1.a.	**Urogenital symptoms** Problems such as urinary incontinence, pain during sex, irritation, atrophy of the genital tract and prolapse can have a significant impact on women's well being and their quality of life, including but not exclusively their sexual relationships. Women and healthcare professionals alike often do not make the link between these symptoms and hormonal changes, and they are sometimes described as the 'silent problems' of menopause. The inclusion of urogenital symptoms associated with menopause within the scoping document is therefore welcome, and should make an important contribution towards improving recognition and reporting of these symptoms, and the provision of appropriate treatment and support. We recommend that this would be enhanced by fully consistent terminology throughout the scoping document to refer to 'urogenital symptoms', covering the full spectrum of symptoms (see 3.1.g., 4.5.1.a.).	Thank you for your supportive comment, The terminology has been updated across the scope to be more consistent.
Menopause UK Network (Daisy Network, Early Menopause, Hysterectomy Association, Menopause Matters UK)	4	3.2.g.	**Inequalities** We welcome the recognition at 3.2.g. that there are significant inequalities in menopause care. Both age and socioeconomic status affect access to specialist treatment, and decisions about whether to seek treatment. Many women also report that prescribers apply arbitrary judgements as to whether or not to prescribe HRT and about the age at which to withdraw treatment with HRT, and that the decision to withdraw HRT is sometimes imposed on women against their wishes and with distressing consequences. Value judgments also seem evident in the growing number of women who describe, through our organisations, the problems they have with doctors who refuse to prescribe androgens as part of menopausal care. The attitude that women should welcome sexual decline as a natural part of the ageing process reflects gender stereotyping, which has no place in evidence-	Thank you for your comments. Inequality of treatment is an important topic within all NICE guidelines. The separate Equality Impact Assessment Document expands on issues raised in the scope and explains how the equality issues are to be considered throughout the guideline's development.

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			based healthcare. We recommend that the guideline development group should have regard to implicit value judgements associated with age and gender, and that the impact these attitudes may have on diagnosis and management should be recognised in 3.2.g. and should be the subject of specific recommendations in due course.	
Menopause UK Network (Daisy Network, Early Menopause, Hysterectomy Association, Menopause Matters UK)	5	4.3.1.b.	We strongly support the inclusion of duration of treatment under the key clinical issues to be considered. The question of when to start, and when to stop HRT is a difficult one for many women and especially those in early menopause.	Thank you for your supportive comment.
Merck Sharp & Dohme Limited			No comments.	Thank you for your comment.
National Osteoporosis Society			Question 1 The prioritised areas in the draft scope appear appropriate.	Thank you for your supportive comments.
National Osteoporosis Society			Question 2 Although treatment of osteoporosis, as a whole, is not covered (4.3.2) we are pleased to see the inclusion of the contribution of HRT to prevent long-term sequelae (especially osteoporosis and cardiovascular disease) and osteoporotic fractures as Long-term outcomes (4.4.2). If not all areas are to be covered we would stress the importance of considering bone health within this guideline.	Thank you for your supportive comments.
National Osteoporosis Society			Question 4 The conditions prioritised in section 4.5.3i appear appropriate	Thank you for your response to this question. Following stakeholder feedback the scoping group have retained the question in the final scope, with the addition of early onset dementia to the list of

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				conditions prioritised.
National Osteoporosis Society	1	General	The National Osteoporosis Society welcomes the development of a clinical guideline on *Menopause: diagnosis and management of menopause.*	Thank you for your comment
National Osteoporosis Society	2	General	We would like to make NICE aware of the National Osteoporosis Society Position Statement *Hormone Replacement Therapy for the Treatment and Prevention of Osteoporosis* http://www.nos.org.uk/document.doc?id=823 and that we feel HRT is an effective treatment for menopausal symptoms that also offers protection against fractures at both hip and spine. For the large proportion of women affected by osteoporosis, who are over the age of 60, HRT is not considered a suitable treatment for osteoporosis. However in the under 60 age group HRT still has a role to play in the management of osteoporosis.	Thank you for your comment, The scoping group agree with your comment. The review question on HRT and osteoporosis will explore the role of HRT in the prevention of osteoporosis, the treatment of a pre-existing condition will not be considered. The role of HRT will be considered within the remit of an extension the treatment of shorter term menopausal symptoms.
National Osteoporosis Society	3	4.5.3 h	We would suggest that this section is more clearly brought in line with 4.5.3f and 4.5.3g. Addressing the effectiveness of HRT on the development of osteoporosis (and including fracture) in postmenopausal women who have used short-term/long-term/not used HRT.	Thank you for your comment, The clinical question has been designed to look at the preventative properties of HRT in the development of osteoporosis. A clinical review for HRT being used in the treatment of pre-existing osteoporosis will not be done. The scoping group decided that other guidelines adequately covered the treatments offered. Therefore the two questions referenced will remain as currently written.
National Osteoporosis Society	4	5.1.1	It would also be appropriate to refer to Osteoporotic fractures - denosumab (TA204).	Thank you for your comment, This comment was agreed and the amendment has been made to the final

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				scope.
NHS Direct			Question 1 Yes	Thank you for your comment.
NHS Direct			Question 2 No opinion	Thank you for your comment.
NHS Direct			Question 3 No opinion	Thank you for your comment.
NHS Direct			Question 4 Yes	Thank you for your response to this question. Following stakeholder feedback the scoping group have retained the question in the final scope, with the addition of early onset dementia to the list of conditions prioritised.
NHS Direct	1	General	Review the scope – no comments on its content. Welcome the guidance.	Thank you for your comment.
Pfizer Ltd			Question 1 No, we believe that two key areas have been omitted from the scope. Firstly, many women will be transitioning from oral contraceptives and guidance for these patients is also required in the guideline. Secondly, "Hormonal treatment in women at risk of hereditary or familial breast cancer or are undergoing treatment for breast cancer or have previously had breast cancer." should not be excluded (section 4.3.2).	Thank you for your comment, Breast cancer has not been excluded in its entirety. The exclusion of women who have (or are risk of) breast cancer is just for the review of systemic oestrogen-based hormonal treatment of menopausal symptoms. This decision was taken because there are existing NICE guidelines which have addressed this topic and have made adequate recommendations in this area. These guidelines can be found at the following links:

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				Familial breast cancer. NICE clinical guideline 164 (2013) Breast cancer (advanced). NICE clinical guideline 81 (2009) Early and locally advanced breast cancer. NICE clinical guideline 80 (2009).
Pfizer Ltd			Question 3 Hormonal pharmaceutical treatments, in particular oestrogen combined with progestogen .	Thank you for your comment. The use of HRT will be covered in the guideline.
Pfizer Ltd	1	3.2 a	Please cite the information sources in full	Thank you for your comment, It is not the convention to reference sources of information in the scope for guidelines. We have, however, added more description about the general source of the statements and the statistics contained.
Pfizer Ltd	2	3.2 h	We suggest that the final sentence in section 3.2 h "However, the association between HRT and cardiovascular disease has subsequently been disputed" be amended to reflect the fact that there is some evidence disputing the link between HRT and cancer in a 10 year study (Schierbeck et al. (2012). Effect of hormone replacement therapy on cardiovascular events in recently postmenopausal women: randomised trial. BMJ 2012;345:e6409)	Thank you for your comment, The scoping group believed that the association with cancer and long term HRT use is established but the association between HRT and cardiovascular disease is less clear cut. In that respect the current statement is accurate. The uncertainty will be explored and the evidence reviewed in the guideline. From this conclusions will be drawn and recommendations made if the GDG deem it appropriate.

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Pfizer Ltd	3	3.2h	We suggest that the sentence "However, the association between HRT and cardiovascular disease has subsequently been disputed" be referenced e.g. Schierbeck et al. (2012). Effect of hormone replacement therapy on cardiovascular events in recently postmenopausal women: randomised trial. BMJ 2012;345:e6409.	Thank you for your comment, The scoping group believed that the association with cancer and long term HRT use is established to the extent that the current statement is accurate. This will be explored within the guideline, conclusions drawn and recommendations made if the GDG deem it appropriate.
Pfizer Ltd	4	4.1.1 a	We suggest that it is made clear that the post menopause phase will extend to end of life, not merely for the immediate period of symptomatic post-menopause. In addition osteoporosis treatment for these women may be chronic/long-lasting.	Thank you for your comment, The post menopause is known to extend for variable lengths of time (sometimes to the end of life). The guideline will only review treatment of symptoms of the menopause that occur in the five years (for example, hot flushes). Secondary conditions like CVD and osteoporosis will be addressed solely from the perspective of what preventative benefit there may be from that short term treatment especially HRT. The treatment of these long term complications is outside the remit of the guideline.
Pfizer Ltd	5	4.3.1	Please add to the list of issues guidance on women transitioning from oral contraceptives in the perimenopause period	Thank you for your comment, Given the finite resources available for this guideline we do not think it will be possible or worthwhile to compare different types of oestrogen or progesterone for the treatment of acute menopausal symptoms. Rather, the

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				review priority was considered to be the differences between the class action of the different types of intervention.
Pfizer Ltd	6	4.3.1. b	We would suggest that tissue selective estrogen complexes (TSECs) are added to the list of hormonal pharmaceutical treatments	Thank you for your comment Tissue-selective oestrogen complexes are not licensed for any indication within the UK and therefore we are not able to consider this treatment within the guideline.
Pfizer Ltd	7	4.5.2 c	We would suggest that tissue selective estrogen complexes (TSECs) are added to the list of hormonal pharmaceutical treatments	Thank you for your comment. Tissue-selective oestrogen complexes are not licensed for any indication within the UK and therefore we are not able to consider this treatment within the guideline.
Pfizer Ltd	8	4.3.2 c	Does the "Treatment of long-term sequelae of oestrogen depletion caused by menopause (especially osteoporosis and cardiovascular disease)" relate to fracture management or the prevention of recurrence? If it relates to the prevention of recurrence we believe "Treatment of long-term sequelae of oestrogen depletion caused by menopause (especially osteoporosis and cardiovascular disease)" should be this topic should be covered in the guideline as HRT is a treatment option.	Thank you for your comment, Prevention or amelioration or osteoporosis and CVD that might arise from short term treatment of menopausal symptoms will be the only topic reviewed. The data will be taken from epidemiological studies to determine the preventative effects of HRT. The treatment of long term conditions in later life with HRT is outside the remit of this guideline.

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Pfizer Ltd	9	4.3.2 c	Does the "Treatment of long-term sequelae of oestrogen depletion caused by menopause (especially osteoporosis and cardiovascular disease)" relate to cardiovascular disease management or secondary prevention? If it relates to secondary prevention we believe "Treatment of long-term sequelae of oestrogen depletion caused by menopause (especially osteoporosis and cardiovascular disease)" should be covered in the guideline.	Thank you for your comment, Prevention or amelioration or osteoporosis and CVD that might arise from short term treatment of menopausal symptoms will be the only topic reviewed. The data will be taken from epidemiological studies to determine the preventative effects of HRT. The treatment of long term conditions in later life with HRT is outside the remit of this guideline.
Royal College of General Practitioners			Question 1 Yes, except that I think breast cancer should have been included as this is a common diagnosis and women often have serious menopausal symptoms as a result of this. I realise that the non-endocrine treatments would be relevant, but I think it would have been really helpful to know the effects of hormonal treatments, especially topical oestrogen treatment for uro-genital atrophy.	Thank you for your comment, Breast cancer has not been excluded in its entirety. The exclusion of women who have (or are risk of) breast cancer is just for the review of systemic oestrogen-based hormonal treatment of menopausal symptoms. This decision was taken because there are existing NICE guidelines which have addressed this topic and have made adequate recommendations in this area. These guidelines can be found at the following links: Familial breast cancer. NICE clinical guideline 164 (2013) Breast cancer (advanced). NICE clinical guideline 81 (2009) Early and locally advanced breast cancer. NICE clinical guideline 80 (2009).

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Royal College of General Practitioners			Question 2 Natural menopause > iatrogenic menopause > premature ovarian insufficiency Why: most GP consultations will be about natural menopause	Thank you for your comments. All three types of menopause will be covered in the guideline,
Royal College of General Practitioners			Question 3 I think they are all important. Hormonal – because women will know and expect these to be discussed Non hormonal pharmaceutical Psychological If not sufficient resources, an overview of non-pharmaceutical treatment - also the area least likely to have robust evidence	Thank you for comments. All these interventions will be covered in the Guideline.
Royal College of General Practitioners			Question 4 Yes	Thank you for your response to this question. Following stakeholder feedback the scoping group have retained the question in the final scope, with the addition of early onset dementia to the list of conditions prioritised.
Royal College of General Practitioners	1	3.2 c	I think the group who have suggested the 50th birthday check should be named (I think it is the BMS). Also adopted by RCOG without any discussion with primary care. However it is still important to look at this and to do an economic evaluation of it. I am very sceptical about it and I think most of primary care would agree. (JS)	Thank you for your response, This paragraph has been added to the scope to address the current clinical understanding of the menopause. The health review was mentioned as it is a high profile policy within the area. The

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				scope is not endorsing or recommending such a health review. This may be an option that can be explored within the guideline, but not the scope.
Royal College of General Practitioners	2	3.2 f	US experience in this area is particularly irrelevant to the UK, because the structure of care is so different for gynaecological problems. I am sure there is UK information about this area (JS)	Thank you for your comment, The scoping group believe that many data from US sources can be extrapolated to the UK system. The guideline's evidence review will, however, consider this closely when assessments on the quality and relevance of the data are made.
Royal College of General Practitioners	3	3.2 i	Should be "of" after "provision" (JS)	Thank you for your comment, this change has been made.
Royal College of General Practitioners	4	4.3.1	It would be helpful to have some information and data about the natural history of the condition, before considering treatments i.e. put "no treatment" in as an option to consider short and long term effects (JS)	Thank you for your comment, It was agreed that information provision is important part of menopause management. An additional clinical question has been added to address this requirement. The natural history of the menopause would be explored within this review question.
Royal College of General Practitioners	5	4.3.2 b	I don't think breast cancer should be excluded (JS)	Thank you for your comment, Breast cancer has not been excluded in its entirety. The exclusion of women who have (or are risk of) breast cancer is just

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				for the review of systemic oestrogen-based hormonal treatment of menopausal symptoms. This decision was taken because there are existing NICE guidelines which have addressed this topic and have made adequate recommendations in this area. These guidelines can be found at the following links: Familial breast cancer. NICE clinical guideline 164 (2013) Breast cancer (advanced). NICE clinical guideline 81 (2009) Early and locally advanced breast cancer. NICE clinical guideline 80 (2009).
Royal College of General Practitioners	6	4.5.2	I think a section on initial assessment of the menopausal woman would be important – what examinations/tests should be done. In particular does every woman need a vaginal examination or not? (JS)	Thank you for your comment, The recommendations on what investigations to offer will come from the assessment of the listed diagnostic factors within the "diagnosis of the menopause" clinical questions.
Royal College of General Practitioners	7	4.2	"All settings in which NHS care is received or commissioned" Does NHS care in the statement above exclude private health insurance, private practitioners? In the new GP commissioning scenarios, how would this statement relate to 'any qualified provider'? (CA)	Thank you for your comment, The guideline will be relevant where treatment is offered by the NHS or on behalf of the NHS.
Royal College of General Practitioners	8	3.1g	The percentages would need a time frame eg 84% over 1 year. At presentation? (CA)	Thank you for your comment, We have amended the information referenced in your comment to be clearer

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				in the scope.
Royal College of General Practitioners	9	3.2a	Again, the percentages would need clarification, i.e. did 18% of women aged 45-64 consult the GP at least once during 1997 regarding their menopausal symptoms? (CA)	Thank you for your comment, We have amended the information referenced in your comment to be clearer in the scope.
Royal College of General Practitioners	10	3.2e	Could the percentages be explained better please? (CA)	Thank you for your comment, We have amended the information referenced in your comment to be clearer in the scope.
Royal College of General Practitioners	11	4.3.2	For areas not covered, could there be a pointer towards the most up-to-date resource that does cover that area? (CA)	Thank you for your comment, The clinical areas that are covered by other NICE guidelines will be signposted in the full guideline. The style of scope documents is not to reference other guidelines within the text, the related guidance are listed at the end of the document.
Royal College of Nursing			Question 1 Yes	Thank you for your comment
Royal College of Nursing			Question 2 Section 4.3.1 b, c and d 4.3.1 a) is diagnosis and classification – less important than management	Thank you for your comment
Royal College of Nursing			Question 3 All are important	Thank you for your comment

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Royal College of Nursing			Question 4 Not sure about Sarcopenia as a priority? Stroke might be included?	Thank you for your response to this question. Following stakeholder feedback the scoping group have retained the question in the final scope, with the addition of early onset dementia to the list of conditions prioritised.
Royal College of Nursing	1	General	The Royal College of Nursing welcomes proposals to develop this guideline. It is timely. The draft scope seems comprehensive.	Thank you for your comment
Royal College of Nursing	2	4.3.2.b	Women with menopausal symptoms who have had breast cancer are a difficult group, so some supporting evidence re hormone use would be good. It would be a shame to miss this group from the scope when they are a challenge clinically.	Thank you for your comment, Breast cancer has not been excluded in its entirety. The exclusion of women who have (or are risk of) breast cancer is just for the review of systemic oestrogen-based hormonal treatment of menopausal symptoms. This decision was taken because there are existing NICE guidelines which have addressed this topic and have made adequate recommendations in this area. These guidelines can be found at the following links: Familial breast cancer. NICE clinical guideline 164 (2013) Breast cancer (advanced). NICE clinical guideline 81 (2009) Early and locally advanced breast cancer. NICE clinical guideline 80 (2009).

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Royal College of Nursing	3	4.3.2.f	Contraception might be excluded but please can there be explicit links to current guidance within the context of the guidelines as it is an important topic.	Thank you for your comment Given the finite resources and time available to develop a guideline, a full review of contraception for women in the menopause was not considered to be a priority for the guideline. However, the topic of 'Information on contraception at the menopause' will part of a new clinical question on for information provision for these women. Whilst a separate evidence will not be done for contraception, this topic will be considered within the systematic review for advise that women should be given during the menopause
Sheffield Teaching Hospitals NHS Foundation Trust			Question 1 Yes	Thank you for your comment
Sheffield Teaching Hospitals NHS Foundation Trust			Question 3 Oestrogen and progestagen Oestrogen only Oestrogen and progesterone Tibolone Testosterone Bio identical hormones In order of frequency of prescription and most evidence	Thank you for your comment These interventions will be covered in the Guideline.
Sheffield Teaching Hospitals NHS Foundation Trust	1	4.3.2b	Exclude women at risk of hereditary or familial breast cancer- this is an area of uncertainty please clarify the meaning of "at risk"	Thank you for your comment, A definition of high risk will be taken from the recent Familial breast cancer. NICE clinical guideline 164 (2013), this will be

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Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				added in the introduction to the guideline.
Sheffield Teaching Hospitals NHS Foundation Trust	2	4.3.1	Include natural progesterone	Thank you for your comment, Your comment was agreed and the amendment has been made to final scope.
Sheffield Teaching Hospitals NHS Foundation Trust	3	4.5.2	Include natural progesterone	Thank you for your comment, Your comment was agreed and the amendment has been made to final scope.
Sheffield Teaching Hospitals NHS Foundation Trust	4	4.5.4	What do you mean by effectiveness ? Symptom control? Which symptoms/ long term prevention?	Thank you for your comment, Effectiveness is assessed by a combination of cost and clinical outcomes chosen by the GDG when the development of the guideline commences.
Worcestershire Acute Hospitals Trust			<u>Question 1</u> Yes	comment
Worcestershire Acute Hospitals Trust			<u>Question 2</u> Main outcomes	Thank you for your comment.
Worcestershire Acute Hospitals Trust			<u>Question 3</u> Treatment of Vasomotor symtoms, musculoskeletal & Uroginital atrophy.	Thank you for your comment. All these interventions will be covered in the guideline.
Worcestershire Acute Hospitals Trust			<u>Question 4</u> Yes	Thank you for your response to this question. Following stakeholder feedback the

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Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				scoping group have retained the question in the final scope, with the addition of early onset dementia to the list of conditions prioritised.
Worcestershire Acute Hospitals Trust	1	4	Most controversies exist in this area and therefore requires very detailed and careful review of the evidence.	Thank you for your comment. The clinical reviews will be undertaken in the most comprehensive manner, according to the NICE guidelines manual (2012).

Key – Questions to stakeholders:

Question 1	Do you agree with all the areas prioritised in the draft scope? If not, why?
Question 2	If we are not able to cover all the areas that stakeholders suggest, which areas do you feel should be prioritised and why?
Question 3	Which treatments (listed in 4.5.2c) should be prioritised and why?
Question 4	Do you agree with the conditions prioritised in 4.5.3i)?

These organisations were approached but did not respond:

Acre Pharma LTD
Action Cancer
Association of Anaesthetists of Great Britain and Ireland

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Association of British Insurers
Barnsley Hospital NHS Foundation Trust
Boots
Breast Cancer UK
Brighton and Sussex University Hospital NHS Trust
British Association of Skin Camouflage
British Medical Association
British Medical Journal
British National Formulary
British Nuclear Cardiology Society
Cambridge University Hospitals NHS Foundation Trust
Capsulation PPS
Care Quality Commission (CQC)
Chadderton Health Centre
Chartered Physiotherapists Promoting Continence
Clarity Informatics Ltd
Croydon Clinical Commissioning Group
Croydon Health Services NHS Trust
Department of Health, Social Services and Public Safety - Northern Ireland
Derbyshire Community Sexual Health Service
Diennet Ltd
Dr Loomba and Partner
Ealing Public Health
East and North Hertfordshire NHS Trust
East Kent Hospitals University NHS Foundation Trust
Economic and Social Research Council
Epilepsy Action
FBA and Brook
Five Boroughs Partnership NHS Trust
Gedeon Richter UK
Gedeon Richter Womens Health Division
Guy's and St Thomas' NHS Foundation Trust
Health Quality Improvement Partnership
Healthcare Improvement Scotland
Herts Valleys Clinical Commissioning Group

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Hockley Medical Practice
International Ovarian Tumor Analysis Trial
King's College Hospital NHS Foundation Trust
Liverpool Women's NHS Foundation Trust
London PMS and Menopause Centre
Luton and Dunstable Hospital NHS Trust
Medicines and Healthcare products Regulatory Agency
Menopause Exchange
Ministry of Defence
MSD Ltd
National Association of Primary Care
National Clinical Guideline Centre
National Collaborating Centre for Cancer
National Collaborating Centre for Mental Health
National Collaborating Centre for Women's and Children's Health
National Institute for Health Research Health Technology Assessment Programme
National Patient Safety Agency
National Treatment Agency for Substance Misuse
NHS Connecting for Health
NHS County Durham and Darlington
NHS England
NHS Greater Glasgow and Clyde
NHS Plus
NHS Sheffield
NHS Warwickshire North CCG
NICE technical lead
NICE TLOC GDG
North and East London Commissioning Support Unit
Northwick Park and St Mark's Hospitals
Nottingham City Council
Orion Pharma
Oxford Health NHS Foundation Trust
Pfizer
Poole Hospital NHS Trust

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Primary Care Pharmacists Association
Primary Care Womens Health Forum
Primrose Bank Medical Centre
Public Health Wales NHS Trust
Public Health Wales NHS Trust
Queen Elizabeth Hospital King's Lynn NHS Trust
Royal College of General Practitioners in Wales
Royal College of Midwives
Royal College of Obstetricians and Gynaecologists
Royal College of Paediatrics and Child Health
Royal College of Pathologists
Royal College of Physicians
Royal College of Psychiatrists
Royal College of Radiologists
Royal College of Surgeons of England
Royal Pharmaceutical Society
Royal Wolverhampton Hospitals NHS Trust
SAGE Publications Limited
Scottish Intercollegiate Guidelines Network
SimplyHormones
Social Care Institute for Excellence
Society for the Protection of Unborn Children
South Chadderton Health Centre
South London & Maudsley NHS Trust
South West Yorkshire Partnership NHS Foundation Trust
Southport and Ormskirk Hospital NHS Trust
Tayside Sexual and Reproductive Health
Teva UK
The Association for Clinical Biochemistry & Laboratory Medicine
The Patients Association
The Surrey Park Clinic
UCL/UCLH Institute for Women's Health
UK Clinical Pharmacy Association
United Kingdom Council for Psychotherapy
University Hospitals Birmingham

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Victoria Medical Centre
Welsh Government
Western Sussex Hospitals NHS Trust
Women’s Support Network
Women's Health Alliance
York Hospitals NHS Foundation Trust

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