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|  | | **Please read the checklist for submitting comments at the end of this form.** We cannot accept forms that are not filled in correctly or arrive after the deadline.  In addition to your comments below, we would like to hear your views on the below question:   1. Are there any cost saving interventions or examples of innovative approaches that should be considered for inclusion in this guideline?   [Developing NICE guidance: how to get involved](https://www.nice.org.uk/process/pmg22/chapter/introduction) has a list of possible areas for comment on the draft scope. | |
| Organisation name – Stakeholder or respondent  (if you are responding as an individual rather than a registered stakeholder please leave blank): | | **Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the UK** | |
| Disclosure  Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry. | | **None** | |
| Name of person completing form: | | **Ben Cottam** | |
| Type | | [for office use only] | |
| **Comment**  **No.** | Page  number  or **‘general’** for comments on the whole document | **Line**  **number**  or **‘general’** for comments on the whole document | Comments Insert each comment in a new row.  Do not paste other tables into this table, as your comments could get lost – type directly into this table. |
| Example | 003 | 055 | The draft scope currently excludes people who have already been diagnosed. We feel this group should be included because…. |
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| 1 | 001 | 20 onward | The draft scope and definition of menopause – should include peri-menopause and post-menopause, as some symptoms often do not reverse without treatment. This should be reflected by updated section 1.2 of the guidance and may include the STRAW classification system recognising the changes in symptoms from peri- menopause to post-. |
| 2 | 002 | Para 5 onward | There is no mention of who may or may not need what kind of treatments – explanation of range of symptoms would be useful and more detailed description of all symptoms. |
| 3 | 002 | Line 10 | Benefits including prevention or treatment of osteoporosis and prevention of cardiovascular and other disease arguably should be regulatory and outside of the scope of the document. The evidence needs to be reviewed for each treatment rather than overall assumption for all hormonal menopause interventions. |
| 4 | 001 | Line 13 onward | The guidance covers many aspects of menopause but does not cearly distinguish what is essentially troublesome and pathological. Loss of memory in aging is also a natural process – but extreme loss is pathological and arguably suicidal ideation (mood changes) or 10 plus VMS episodes a day is also pathological and needs appropriate pharmacological treatment. |
| 5 | 002 | Line 12-14 | Mild, moderate and severe definitions of VMS according to daily number of episodes and Genitourinary Syndrome of Menopause symptoms could be categorised as mild, moderate and severe, so treatments could be guided according to the regulatory label, some of which are classified by severity. |
| 6 | 004 | Line 8-10 | We do not support the revisions being limited to CBT and HRT on overall health outcomes. |
| 7 | 005 | In the table | 1.2 whilst peri-menopause is defined, no symptoms are discussed, which may be different from menopause itself – these symptoms include menorrhagia and often dysphoria and depression more frequently than in menopause. Patients should be counselled regarding pregnancy. In addition, there are hormonal treatments labelled for menorrhagia and dypsphoria that may be useful in this population and for menorrhagia there is NICE guidance which could be cross-referenced. |
| 8 | 005 | In the table | Section 1.4 we believe urogenital atrophy should be aligned with Genitourinary Syndrome of Menopause and possibly vulvar vaginal atrophy, as this latter term is still used in labelling for treatment, |
| 9 | 005 | In the table | Section 1.4 Whilst isoflavones and black cohosh have well establish use labels there is considerable uncertainty they are effective in VMS, yet the guidance gives little to distinguish from other more effective treatments. |
| 10 | 005 | In the table | Altered sexual function should be separated as dyspareunia from Hypoactive Sexual Desire Disorder (HSDD). Testosterone has been known for some years to be effective for HSDD and whilst Intrinsa testosterone patch demonstrated efficacy over placebo.Treatments for HSDD are available in US but for premenopausal women. The Intrinsa testosterone patch for HSDD was available but limited the indication to women with surgically induced menopause taking concomitant estrogen therapy. Perhaps should be dealt with in separate guidance as is menorrhagia, however. |
| 11 | 008 | Line 11 onwards | The risks of hormone replacement therapy should really be related to individual products. There is evidence, particularly for venous thrombosis, that different doses and combinations of oestrogens and progesterones and routes of administration (oral, patch, intravaginal, intrauterine etc) have different impacts on both clinical outcome and well established haematological surrogate markers. This was acknowledged in the Lancet article cited in the 2019 guidance update. The new oestrogen, estetrol (E4), as yet only approved for contraception, but in development for menopause, is a selective foetal oestrogen and has a very different pharmacological profile to E2. Grouping all products together will be very confusing for both prescriber and user. |
| 12 | 008 | Line 11 onwards | With regard to benefits – again these will also not apply to all hormonal treatments and routes of administration. Treatment should be separated from prevention with regard to benefit. Whilst there is some evidence for treatment for osteoporosis this is unlikely to be carried into the label of newer products, even those with hormonal basis for treatment. Prevention is difficult to demonstrate compared to risk and as with lipid lowering drugs should be demonstrated with interventional studies rather than the epidemiological data used for risk. A review of benefits is welcomed, but the implication that all treatments result in this should be avoided. |
| 13 | 008 | Line 11 onward | There is evidence from epidemiological and registry studies that hormonal replacement therapy has a benefit against progression in COVID to death, but no interventional studies have shown this. |
| 14 | 009 | Line 11 | Main long term outcomes – are very varied in terms of how robust the evidence might need to be collect and how ‘long term’ is defined. Some outcomes have been studied using scoring systems longitudinally, but many benefit outcomes will be difficult to separate individual treatments. Risks should be studied in conjunction with the big safety databases. |
| 15 | General |  | Information for specialist services needs to be reinforced throught the document. |

Add extra rows if needed

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| **Checklist for submitting comments**   * Use this comment form and submit it as a **Word document (not a PDF)**. * Complete the disclosure about links with, or funding from, the tobacco industry. * Include **page and line number (not section number)** of the text each comment is about. * Combine all comments from your organisation into 1 response. **We cannot accept more than 1 response from each organisation**. * Do not paste other tables into this table – type directly into the table. * Ensure each comment stands alone; do not cross-refer within one comment to another comment. * **Clearly mark any confidential information or other material that you do not wish to be made public. Also, ensure you state in your email to NICE that your submission includes confidential comments.** * **Do not name or identify any person or include medical information about yourself or another person** from which you or the person could be identified as all such data will be deleted or redacted. * Spell out any abbreviations you use * For copyright reasons, **do not include attachments** such as research articles, letters or leaflets. We return comments forms that have attachments without reading them. The stakeholder may resubmit the form without attachments, but it must be received by the deadline. * **We do not accept comments submitted after the deadline stated for close of consultation.**   **Note:** We reserve the right to summarise and edit comments received during consultations, or not to publish them at all, if we consider the comments are too long, or publication would be unlawful or otherwise inappropriate.  Comments received during our consultations are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the comments we received, and are not endorsed by NICE, its officers or advisory Committees.  **Data protection**  The information you submit on this form will be retained and used by NICE and its advisers for the purpose of developing its guidance and may be passed to other approved third parties. Please do not name or identify any individual patient or refer to their medical condition in your comments as all such data will be deleted or redacted. The information may appear on the NICE website in due course in which case all personal data will be removed in accordance with NICE policies.  By submitting your data via this form you are confirming that you have read and understood this statement.  For more information about how we process your data, please see our [privacy notice](https://www.nice.org.uk/privacy-notice). |