

## NICE Clinical Guideline: Menopause

### Stakeholder scoping workshop notes

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| <b>Scope</b>  |
| <b>Section 3.1 Epidemiology</b>   |
| <ul style="list-style-type: none"><li>• The phrase “natural biological” should be removed from the description of the menopause. Stakeholders argued that this is not entirely reflective, leaving “biological” would be more appropriate.</li><li>• The menopause should also be described as when eggs are no longer matured (or delivered); production of eggs is biologically incorrect when taken out of context.</li><li>• The description of “one or two eggs” being lost during each menstrual cycle is inaccurate, it is actually nearer 100. This should be amended.</li></ul>  |
| <b>Section 4.1 Population</b>   |
| <ul style="list-style-type: none"><li>• It was agreed that the included populations outlined should be retained within the consultation version of scope.</li><li>• Women who are breast feeding may experience temporary menopause-like symptoms due to hormone imbalance as well as amenorrhea. Once the woman stops breast feeding the menstrual cycle should recommence and therefore menopausal symptoms would disappear. This group should be excluded from the scope.</li><li>• It was suggested that women may have regular menstrual cycles during the early phases of the peri-menopause, often during “early menopause”. Excluding women with continuing menstrual cycles would be incorrect and may mean a group of women who would need treatment are missed. This group of women should not be excluded.</li><li>• Excluding young women who have not yet begun menstruating or have who have never menstruated would mean that women with primary amenorrhea are also excluded. This group of women, who have premature ovarian insufficiency (POI), should be included within the scope. These women will normally require long term hormonal (and non-hormonal) management and could arguably be the patient group where there is the greatest need for guidance.</li><li>• Excluding women with breast cancer (or women who have had breast cancer or are at a high risk of breast cancer) is inappropriate. These women would need alternative management due to hormonal therapy being contraindicated, and is therefore a group that is a high priority for guidance.</li><li>• It is speculated that women who have had breast cancer also experience more severe symptoms during the menopause. Furthermore, the chemotherapy to treat breast cancer often means women enter POI following treatment, or if their fertility returns after treatment they would be expected to experience an early menopause.</li><li>• Women who have a number of co-morbidities will need to be taken account of within sub-group analysis. Most notably those with</li></ul> |

diabetes, hypertension and those with a high BMI.

#### Equalities

- Socio-economic groups should be considered in the scope, there is a disparity in symptoms and treatment between groups. It was suggested that women in lower socio-economic groups have a higher incidence of POI. Whereas, women in higher socio-economic groups have more referrals for treatment and a greater access to hormone replacement therapy (HRT) treatment.
- Women in some ethnic groups do not wish to seek help for symptoms or have any treatments available to them due to their cultural perspective of the menopause. Indeed, in some groups it was suggested that menopause is rarely acknowledged or diagnosed.
- In women from eastern cultures, where isoflavones (specifically soy) are a significant part of the diet, it is hypothesised that incidence of menopause symptoms is reduced, and where there are symptoms these are less severe.
- Age of women should not be used a diagnostic tool for menopause, symptom changes are too variable. The use of age as a marker for treatment would be discriminatory.
- Menopause may be a concern for transgender people who are on hormonal treatments or have menopausal symptoms because of gender realignment.

#### Section 4.2 Healthcare setting

- No comments were made on the healthcare setting

#### Section 4.3 topics for review

##### ***The diagnosis and classification of the stages of menopause***

- The diagnosis of menopause was considered to be an important topic by stakeholders. The guidance for GPs is particularly poor, the diagnosis in primary care is variable and often women receive no treatment.
- If the STRAW+10 criteria (or a similar system) were verified within the guideline, the definitions throughout the guideline could be updated to correspond with those within that classification system.
- The ovarian reserve tests chosen were those also chosen in the fertility guideline. The stakeholders suggest that these outcomes for this review could be used but the extrapolation should be done with caution, and preferably not undertaken at all.

##### ***The management of short term menopausal symptoms***

- The benefits and risks of HRT profile should include causal searches for some mental conditions, most notably Alzheimer's and dementia.
- Stakeholders suggested that the interventions that are used to treat short term menopausal symptoms should also include:
  - Selective oestrogen-receptor modulators (SERMs)
  - Serotonin–noradrenaline reuptake inhibitor (SNRI)
  - Bio-identical hormones
- A stakeholder suggested that of all the interventions that would come under “psychological support”, cognitive behavioural therapy (CBT) should be the prioritised option. CBT is the most supported intervention for treating mood symptoms in current clinical practice.

- Stakeholders reported that prescriptions are seldom offered to women in primary care. Any recommendations that would change this would have health economic implications. It was also noted that the cost of HRT particularly was comparatively low and any increase in cost of treatment would be expected to be offset with short and long term cost savings when treating severe symptoms.
- The dose, timing and combination of HRT prescriptions was considered a priority by stakeholders. When offered, HRT is often individualised and without structured guidance. Any guideline should recommend how HRT should be offered, how its use is monitored and when to refer to secondary care.
- Stakeholders emphasised that there is currently very little communication between primary and secondary care, it was acknowledged that many women who should be referred to secondary care are not because of poor network and multi-disciplined working.
- The prioritisation of short-term treatments was prioritised by stakeholders. It was expected the HRT would be the dominant treatment for most symptoms, however stakeholders also thought it would be useful to answer the following questions
  - What treatments are effective for specific (predominant) symptoms?
  - What treatments do not work?
  - What treatments are effective when HRT is not wanted or contraindicated?
- Stakeholders were in favour of a clinical question examining the correct discontinuation protocol of HRT. It was also suggested that this could be extended to other similar treatments (for example SSRIs)

#### ***The effect of HRT given for menopausal symptoms on long term sequelae of oestrogen depletion***

- The stakeholders agreed that review of long term HRT should be restricted to the prevention of osteoporosis and, possibly cardiovascular disease (CVD). HRT used as a treatment for osteoporosis would be too far outside of a scope for menopause and theoretically be covered elsewhere.
- Stakeholders noted that other guidelines should be used and cross-referenced to create a comprehensive pathway for post-menopausal women. This should bring together guidelines on breast cancer, CVD, fertility and treatment of osteoporosis.
- It was suggested that long-term lifestyle advice should be considered alongside long-term HRT. It was, however, noted that the evidence for such interventions would be sparse and any cause/effect findings would be subjective.
- While breast cancer is the most commonly known adverse event of HRT use, other cancers (for example ovarian) should also be considered within the guideline.
- Stakeholders also suggested that sarcopenia was now understood to be a long term sequela of oestrogen depletion and its prevention should therefore also be investigated
- Stakeholders noted that advice could also be given to women for the prevention of the sequela of oestrogen depletion during the earlier phases of the menopause without consideration of a short term cause. For example HRT and other interventions (vitamin D etc.) could be offered during the menopause to treat osteoporosis, without a short-term reason for prescriptions.

#### ***Premature ovarian insufficiency***

- Stakeholders commented that review questions on POI should apply to all forms of POI, including those presenting that are induced

by surgery (hysterectomy for example) and chemotherapy.

- The diagnosis of conditions that cause POI (for example Turner's syndrome) should be considered within the scope. Stakeholders noted that such conditions are often missed or misdiagnosed in primary care.
- The diagnostic value of menstrual cycles, symptoms and genetic profiling should be considered alongside ovarian reserve tests in women who are suspected of having POI, who are at risk of POI and women in the early stages of POI.
- Stakeholders also suggested that some surveillance may be appropriate in women at risk of POI. The cost and resource implications of such a policy was discussed – any guidance should take into account the epidemiology of POI and the difference in how often primary and secondary amenorrhea present in primary care.

#### **Notable omissions**

- There is no specific review planned for communication and/or information provision. Stakeholders requested a review of the how information is given to women (specifically in primary care), the quality of the information and the education of the information providers
- Stakeholders suggested that some public health guidance in earlier life could affect the incidence and severity of menopausal symptoms. An extension of the guideline was suggested to examine the effect of these lifestyle factors (smoking and alcohol for example) and their effect upon menopause in later life. The extension of the guideline would go beyond the remit and should be covered in public health guidance.
- Contraception in women who are peri-menopausal should be reviewed. There are currently oestrogen pills that are designed for this group of women. Stakeholders noted that there is detailed guidance from the Faculty of Reproduction and Sexual Health.
- Stakeholders suggested that the use of a mandatory health check (as recommended by the British Menopause Society) should be considered. The difficulties of such an analysis were discussed, noting the lack of data that could show this policy's value in the UK population without it already being implemented and audited.

#### **Excluded topics**

- Stakeholders agreed with all the topics chosen to not be covered by the guideline.

#### **Section 4.4 Outcomes**

- Stakeholders noted that the short-term symptoms of menopause should be grouped in 5 specific groups:
  - Vasomotor symptoms
  - Musculoskeletal symptoms
  - Urogenital symptoms
  - Psychosocial symptoms
  - Altered sexual function
- A women's sexual function (libido) could be linked with urogenital symptoms. The treatment of the latter symptoms, therefore, may also affect sexual function in women.
- It was suggested that a woman's/patient's satisfaction should be included an outcome for short-term treatments.

- Stakeholders noted that metabolic syndrome was missing from the list of outcomes. This should be included if the metabolic effects of long-term HRT use are to be reviewed.

### **Definitions in menopause**

- Peri-menopause and post-menopause are both commonly used in clinical practice without an agreed evidence-based definition of either.
- It is thought that post-menopause describes the phase from one year after the last menstrual cycle in women. It was argued by stakeholders that this term is misleading as it implies that menopause is a temporary period. In actual fact, it may be appropriate to describe these women as menopausal as the effects of the “menopause” are not temporary. It was also noted that the “one year after” criteria of the post menopause is a retrospective not prospective diagnosis.
- ‘Premature ovarian insufficiency’ is the agreed term and should replace ‘premature ovarian failure’ and ‘premature menopause’. The use of “failure” is misleading. The diagnosis of premature ovarian insufficiency is defined as up to 12 months amenorrhoea in a woman who is under the age of 40y..
- Early menopause is a term used to describe women between the ages of 40 and 45y, with up to 12 months amenorrhoea. In clinical practice these women are treated in the same way as a woman with POI would be.

### **GDG composition**

#### **Included members**

- Stakeholders were, in the majority, content with the GDG membership list
- The consultant gynaecologist roles should have representation from both community and hospital based care. Each role would be able give a differing perspective. Furthermore, stakeholders suggested that a community gynaecologist could advise on the transition of care from a primary to secondary healthcare setting
- An epidemiologist wasn’t deemed essential to the GDG by stakeholders. Their expertise was shared by other roles on the group (particularly if the long term use of HRT is restricted to prevention and not treatment of secondary conditions like osteoporosis and CVD)

#### **Members that should be included**

- Specialised menopause clinics are still relatively rare. Therefore alongside a specialist nurse should be a practice nurse. Practice nurses are often care for women with menopausal symptoms in primary care, in many cases instead of a GP
- Pharmaceutical representation could offer an extra insight in the GDG. However, it was felt that conflicts of interest would prevent their inclusion.
- A psychologist was suggested, by stakeholders, as a potential expert advisor to the group. They did not feel that the current

membership would be able to fully explore mood changes without a psychologist involved.

- If primary amenorrhea was to be included then it would be appropriate to also have an adolescent endocrinologist on the group.
- There should be expertise on the GDG that would cover osteoporosis and CVD in older women; this role would probably be a health care of the elderly specialist or a physician with specialist expertise in either.