National Institute for Health and Care Excellence

Clinical Guideline: Menopause diagnosis and management

Stakeholder Scoping Workshop

Wednesday 12th January 2022

Presentations

The group were welcomed to the meeting and informed about the purpose of the day. The Stakeholder Scoping Workshop is an opportunity for stakeholders to review the early draft scope and committee constituency and give their input into whether they are appropriate.

The group received presentations about NICE's work, the NGA Guideline Lead gave a presentation on the guideline development process and the role of the guideline committee. The Chair of the committee also presented the key elements of the draft scope and presented some general points for discussion.

Following questions, the stakeholder representatives were then divided into five breakout groups, which included a facilitator and a scribe. Each group had a structured discussion around the key issues.

Scope

General comments

The general impression of the scope was positive and the stakeholders thought that it covered most of the key elements that need updating in the current guideline.

Further points raised:

- What has been proposed in terms of updating is pragmatic and practical based on new evidence but it is important that this evidence placed into the context of clinical need.
- Important to consider integrated care / referrals between services or multidisciplinary teams
- Consideration of women with history of breast cancer
- Section on diagnosis of menopause may need updating or editing – clinical diagnosis first, blood test as adjunct (should not rule out menopause)
- Important to consider benefits of hormone replacement therapy (HRT) with regard to review of cardiovascular risk as a long-term outcome and bone health (including osteoporosis), as well as breast cancer mortality. There is evidence of benefit that is not sufficiently highlighted in the guideline. Focus of scope is on risk, rather than benefits. Needs to be balanced.
- There is a need to look at effectiveness for testosterone in menopause
- Over 60% population are overweight or obese; relevant to symptoms of menopause and future health risks; are these addressed? More needs to be done help women who are carrying excess weight; are women in menopause

offered weight management services; improving weight may improve efficacy of HRT?

- Importance of preventative health and empowerment of women, including information and education on symptoms for women at 40 years old; integration with public health services to support lifestyle changes.
- Overwhelming data on every aspect of long term health (ageing) that exercise is helpful; importance of exercise should be looked at in this guideline and how to implement this.
- NICE guidance needs to be relevant to people with symptoms, however, it should also provide information surrounding women who want advice on menopause.

Further discussion and suggestions for potential changes in the specific sections are documented below.

Who is the focus? (Section 3.1 of the draft scope)

Overall, stakeholders agreed with the population inclusion. However, some specific points were raised:

- Important to focus on women aged 40-45
- Women who go through temporary medical menopause should be considered
- Welcome specific consideration for women who have had breast cancer and familial risk of breast cancer, some further comments:
    - Women with triple negative breast cancer should be included
    - Younger women who developed breast cancer and went into premature menopause – integration of menopause care into oncology clinics needed
    - No need to stratify by different genotypes of breast cancer - breast cancer in itself does not change risk
    - Need to understand the difference between women with recurrent breast cancer and primary breast cancer
    - Women who have previously tried other therapies, important to avoid paternalistic approach, importance of shared care decision making and informed decision making with oncology team
- Agree not to update section on premature ovarian insufficiency. Noted that the European Society of Human Reproduction and Embryology (ESHRE) is planning to update guidance on premature ovarian insufficiency.

Key issues, draft review questions and update plan (Section 3.3 & 3.5 of the draft scope)

Draft review question 1.1 What is the effectiveness of cognitive behavioural therapy in managing vasomotor symptoms (hot flushes and night sweats) and psychological symptoms associated with the menopause?

- Generally agreement of the relevance of this question

- Access to cognitive behavioural therapy (CBT) is a problem, long waiting times or lack of availability
- A stakeholder raised that if HRT is not given, CBT can be given, but would do nothing for cardiovascular/osteoporosis outcomes, however, another one raised that there is a need for a balance between HRT and CBT, they are not mutually exclusive
- Outcomes for this question should include vasomotor symptoms, psychological symptoms but also sleep disturbance – but can be more difficult to measure than hot flushes
- A mention of the impact on intimate relationships is missing.
- Format of CBT an important consideration (face to face, remote, individual, group)
- Many women feel not-validated if they are referred to an online CBT module – need to measure how women feel about CBT
- Is specific training on menopause needed for those delivering CBT?
- A stakeholder raised that other products aside from CBT to treat vasomotor symptoms have been developed since the last guideline (e.g. conjugated oestrogen product and oral Bijuva) and suggested that these could be investigated as well
- Other non-hormonal treatments are not mentioned e.g. SSRIs/SNRIs, in relation to psychological aspects

Draft review question 1.2 What the effectiveness of topical treatments (for example local oestrogen, ospemifene, prasterone, transvaginal laser therapy) in managing genitourinary symptoms associated with the menopause?

- A stakeholder raised that “genitourinary symptoms” is an Americanism and seems to treat menopause as a syndrome. In their view terminology should be corrected – urogenital atrophy is more accurate.
- Another stakeholder said that “urogenital atrophy” is used in practice. Many women do not know what the genitourinary symptoms are so may be useful to list the symptoms
- Another stakeholder raised that there is very little knowledge about urinary symptoms in general
- There are some mistakes in the wording of the question – ospimefene is not topical (it is oral)
- Different types of topical oestrogen should be looked at
- There tends to be a lot of hesitance from GPs in prescribing topical oestrogens
- Important to have a statement in the guideline saying is it safe to use vaginal oestrogen
- Need good advice on doses needed for treatments. This issue is massively under treated.

- The question needs to emphasise that this is in the long term post-menopause period (rather than at the transition & peri-menopause) & could be long term treatment some years into the menopause.
- Evidence for laser treatment is less encouraging. Also, treatment is not either/or, e.g. systemic HRT with additional laser treatment.
- Could also consider non-hormonal topical treatments, e.g. non-hormonal lubrication, as these are less well-known by the public

Draft review question 2.1 What are the effects of hormone replacement therapy for menopausal symptoms on the risk of developing breast cancer?

- Generally, agreement that this question is important to update.
- Breast cancer risk is major consideration for women starting HRT. Clear guidance on this needed.
- Important to consider what type of treatments used e.g. progesterone doses, types of progesterone delivery (patches, micronized etc.)
- The breast cancer part of the guideline is the most contentious. The MHRA update is quite controversial – at what level are we going to start including data that is non-randomised?
- Protocols should include how long people need to take HRT to see risks and benefits

Draft review question 2.2 What are the effects of hormone replacement therapy for menopausal symptoms on risk of developing endometrial cancer?

- Generally, agreement that this question is important to include.

Draft review question 2.3 What are the effects of hormone replacement therapy for menopausal symptoms on risk of developing ovarian cancer?

- Generally, agreement that this question is important to include.

Draft review question 2.4 What are the effects of hormone replacement therapy for menopausal symptoms on the risk of dementia?

- Generally, agreement that this question is important to update.
- There are some recent publications on dementia. Need to separate dementia from ‘brain fog’.
- A stakeholder said that this question should not be phrased as risk as the effect of HRT is beneficial.

Other comments in relation to HRT:

- Several stakeholders raised that it would be important to also update review question on cardiovascular disease risk. Further comments in relation to this:
    - Lots of confusion and no clear guidance around women 60 years or older.
    - A Cochrane review provides evidence in a more positive light than NG23 when stratified by age.
    - Women (who may be over 60 years) may present after struggling for years to access to HRT due to outdated evidence about risks
- Stakeholders discussed evidence around osteoporosis:
    - Osteoporosis has important impact on women – is there new evidence for physiotherapy exercise interventions?
    - Some stakeholders would like there to be a comment about the use of HRT for bone benefit
- Some stakeholders raised that the strength of NG23 is the balance of risks and benefits, the tone was right. The update questions seem to focus on risks.
- At the same time abnother stakeholder said that NG23 does not have sufficient information to balance bone benefits with cancer risks.
- A stakeholder raised the GPs may feel apprehensive towards HRT due to the way the guideline is presented. Guideline should be written in a way to let GPs confidently decide HRT is the right thing to do.
- Some stakeholders discussed the importance of terminology. For example, constantly using “risk” makes it seem that HRT is a bad thing. There is historical baggage from over-emphasising risks of HRT.
- A stakeholder raised that it is important to note that a bulk of evidence on HRT stems from a trial in which the population is different from the population of interest here (i.e. WHI trial included women 60 and above and who tended to be a lot more obese and older than people presenting with symptoms).
- The guidance on HRT is that it is used for symptom relief rather than long term management. However, some women may need >5 years of HRT or even a life time, so this should be considered in review questions.

Other comments and suggestions

- There should be consideration to update the diagnosis section, e.g. testing in women 40 to 45 years, women presenting with non-standard symptoms (e.g. low mood).
- A stakeholder raised that prevention of menopausal symptoms is an important consideration – importance of information and education such as leaflets and about lifestyle changes in women at 40. Important to focus on lifestyle changes as adjunct to HRT i.e integration of public health services.

- Breast cancer ‘survivors’ may be missed from guideline. For them, lifestyle changes important as HRT not recommended but evidence is not clear, need more research. There are some trials showing no evidence of risk of recurrence of breast cancer with HRT.
- Several stakeholders mentioned that it would be good to look at the effectiveness of testosterone, with following further comments:
    - Access to testosterone is poor across the country.
    - A global consensus statement on testosterone has come out since NG23 and this could be referenced somehow.
- There is ongoing work in development e.g. on NK3 antagonists for hot flushes, that will be published in future.
- Some stakeholders suggested that review question on complementary therapies (e.g. sham acupuncture, yoga) should be updated because a meta-analysis has been published since last guideline.

Main outcomes (Section 3.6)

Overall, the stakeholders were satisfied with the main outcomes proposed. However further points were raised:

- Low mood (not clinical depression) - very important to make this distinction as being prescribed antidepressants has implications for travel insurance
- For women who develop low mood, the most appropriate treatment is HRT rather than antidepressants
- Suggest a change to psychological symptoms as an outcome – instead of “low mood” to include “mood related conditions”, which would cover anxiety and brain fog
- Treatment-related adverse events - clarify to include long-term risk and short-term events
- The cancer outcomes – mortality is just as important as incidence. Incidence can be a product of surveillance. No evidence of increase in mortality from HRT in women with breast cancer.
- Important to consider employment continuity and impact of menopause in the workplace
- Also to consider “lifestyle” choices and risks, e.g. obesity, smoking, alcohol, stress

Equalities considerations

The specific equalities issues discussed regarding menopause included:

- Postcode/geographical differences in access to specialist services is one of the biggest areas of inequality for the menopause population
- Consideration for transgender/non-binary people with menopause

- Risk of missing menopausal symptoms in women with learning disabilities
- Since COVID, a lot of support has moved to being remote, this is an inequality issue for some although great for some
- Low socioeconomic status and different ethnic backgrounds can influence people's perception of HRT
- There may be difficulty recognising menopausal symptoms for some ethnic minorities
- Inverse care law – those that need care the most, get least care so a more proactive active approach is needed from clinicians
- Inequalities in access to exercise, there may be barriers for certain ethnic minorities

Guideline Committee composition

Stakeholders made the following suggestions for the proposed members of the Guideline Committee:

- Cardiovascular epidemiologist
- A bone specialist
- An endometrial cancer specialist
- Pharmacists in primary care
- Clinical pharmacist (works with GPs and consultants)
- Public health specialist
- Local authority members/ integrated care service board members
- Psychologist with specialised knowledge on menopause
- Maybe a psychiatrist?
- Menopause specialist counsellor
- Endocrinologist (for cardiovascular health risk), many endocrinologists prescribe HRT, not just gynaecologists, especially if patients are young or with comorbidities
- Sleep specialist
- Specialist in sexual health and reproduction